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Reduction of clinical signs associated with metatarsalgia in women with three-dimensional element of discharge in biomechanical socks, a preliminary report of a randomized clinical trial

Reducción del cuadro clínico asociado con la metatarsalgia en mujeres con un elemento tridimensional de descarga en calcetines biomecánicos, un informe preliminar de un ensayo clínico aleatorio

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Keywords:

Shocks biomechanics, metatarsal discharge, pain, disability, foot function index.

Abstract

Objective: Although it is known that socks with biomechanical elements reduce plantar pressures, it is unknown whether this would have a beneficial effect on patients with metatarsalgia. Therefore, the objective of this study was to evaluate the clinical scale in female patients with metatarsalgia after one month of using metatarsal relief socks.

Patients and methods: The sample consisted of 32 women over 55 years old with metatarsalgia. Two groups were randomly formed: one of 16 participants (experimental group) who would wear the Podoks Metatarsal® sock with integrated offloading for one month, and another of 16 participants (control group) who would wear a sock with the same fibers and characteristics but without integrated offloading. All participants completed the Foot Function Index questionnaire before and after 30 days of use.

Results: After the month of wearing the socks, patients who used the experimental sock showed better scores on the pain scale of the Foot Function Index, with the Podoks® group having an average of 29.8 ± 15.16 and the control group 38.3 ± 19.77 (p = 0.032). The differences in the overall scale were identified in the pain and disability subscales, where patients who wore the experimental socks showed lower values in these subscales (p = 0.023 and p = 0.042 respectively).

Conclusions: The use of socks with offloading elements shows a reduction in pain associated with metatarsalgia, as well as an improvement in perceived disability by the patient. Thus, socks with biomechanical elements could be part of the podiatrist's therapeutic arsenal, either as a treatment element in initial stages or as an adjunct in more severe deformities.

Palabras clave:

Calcetines, biomecánica, descarga metatarsal, dolor, discapacidad, foot function index.

Resumen

Objetivo: Aunque se conoce que calcetines con elementos biomecánicos reducen las presiones plantares, se desconoce si esto tiene un efecto beneficioso en pacientes con metatarsalgia. Por ello, el objetivo de este estudio fue valorar la escala clínica en pacientes mujeres con metatarsalgia tras un mes de uso de calcetines de alivio metatarsal.

Pacientes y métodos: La muestra se compuso de 32 mujeres mayores de 55 años con metatarsalgia. Se realizaron dos grupos al azar, uno de 16 participantes (grupo experimental), que llevaría el calcetín Podoks Metatarsal® con descarga integrada durante un mes y otro de 16 participantes (grupo control), que llevaría un calcetín de iguales fibras y características, pero sin descarga integrada. Se realizó a todos los participantes el cuestionario Foot Function Index previo, y tras 30 días de uso.

Resultados: Tras el mes de uso de los calcetines, las pacientes que usaron el calcetín experimental presentaron una mejor puntuación en la escala de dolor del Foot Function Index, presentando el grupo Podoks® una media de 29.8 ± 15.16 y el grupo control 38.3 ± 19.77 ($p = 0.032$). Las diferencias en la escala global se identifican en los apartados de dolor y discapacidad donde las pacientes que llevaron los calcetines experimentales presentaron valores más bajos en dichas subescalas ($p = 0.023$ y $p = 0.042$, respectivamente).

Conclusiones: El uso de calcetines con elementos de descarga muestra una reducción del dolor asociada a la metatarsalgia, y también una mejora en la discapacidad percibida por la paciente. Así, los calcetines con elementos biomecánicos podrían formar parte del arsenal terapéutico del podólogo, como un elemento de tratamiento en estadios iniciales o bien como coadyuvante en deformidades más severas.

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Introduction

The therapeutic plan for certain conditions in the adult population usually includes the implementation of moderate physical activity, aiming to prevent cardiovascular risk derived from a sedentary lifestyle[1]. Additionally, the World Health Organization recommends physical exercise not only for its cardio-healthy effects but also to improve muscle tone and balance to prevent falls[2], enhance bone health, and maintain proper functional status and mental health. However, this activity may be hindered by pain resulting from certain musculoskeletal injuries of low or moderate importance[3]. One of these injuries is metatarsalgia, which is one of the most common reasons for consultation in foot disease. It consists of sharp or chronic pain in the plantar area of the forefoot, at the level of one or several central metatarsals and their respective metatarsophalangeal joints[4]. Additionally, this plantar pain is accompanied by digital deformities and dislocations in the metatarsophalangeal joints, which aggravates the clinical picture of the patients suffering from it[5]. This progressive deformity promotes excess plantar pressure, leading to the appearance of hyperkeratosis or corns that increase the pre-existing pain[6]. All these signs and symptoms are more common in women, particularly in those older than 55 or 60[7], and can deteriorate walking function and increase the risk of falls, with the terrible consequences this can have in postmenopausal age[8]. This issue causes patients to perceive a decrease in their quality of life, and they find the chronic pain associated with metatarsalgia a limiting factor for ambulation and, therefore, for maintaining an active lifestyle[8].

Although in a normal and balanced foot, the load is greater on the central metatarsals, the progressive deformity of the central metatarsophalangeal joints, whether in primary, secondary, or iatrogenic metatarsalgias, results in a significant increase in plantar pressure values in the forefoot, commonly known as metatarsal overload[9]. Thus, the following scenario is presented: *a)* Plantar pain, experienced as an unpleasant emotional experience associated with the perception of tissue damage[10], *b)* More prevalent, up to 83%, in patients aged 55 or older[11], *c)* More prevalent in women[12], *d)* A sustained hyperpressure in the central forefoot area, and *e)* A decrease in physical activity due to this issue[13]. However, this model can be reversed with treatment that restores the primary damage and allows for regular aerobic exercise, which would continue to benefit the improvement of chronic pain effects of musculoskeletal origin[14].

A common conservative method for managing metatarsalgia is to implement treatment through unloading plantar orthotics, which aim to stabilize the foot's pathomechanics and provide selective unloading of the affected metatarsal heads[15], being effective in reducing plantar pressure in the forefoot area and relieving associated pain[16]. However, these orthotics must be adjusted or modified and may not always integrate efficiently into footwear. Another provisional treatment in this case is the application of metatarsal pads[17], which are applied in a U-shape covering the entire metatarsal area except for the overloaded and painful sector, which would remain at a slightly elevated level and therefore with less involvement in walking[18]. On one hand, they are quite effective in reducing pain and improving the patient's clinical condition[19], in addition to being very cost-effective, while they have the disadvantage of having to be replaced very frequently, every 3-5 days, so their effectiveness is understood to be short-term[20]. As an alternative, removable alignment and unloading devices have emerged, which would function to stabilize and unload the affected metatarsophalangeal joint and do not require frequent changes, as they are washable and reusable elements[21]. However, these treatments depend on adherence to a cumbersome plan, as they must be replaced often, require adjustments or periodic reviews, or hinder adaptation to the patient's usual footwear.

Recently, the possibility has arisen to integrate certain 3D plantar elements, such as orthopedic pieces, into an element that forms part of the individual's usual clothing, such as socks. These biomechanical socks have shown a preliminary positive effect in reducing dynamic plantar pressures under the second and third metatarsal heads[22], although their medium- or long-term effect has not yet been tested. This project is based on the hypothesis that socks with metatarsal unloading elements would have a positive impact on reducing pain associated with metatarsalgia. We believe that the effective usage hours of treatments would increase since the socks are part of the patients' usual attire. Furthermore, associated costs would decrease due to not requiring frequent replacement of removable pads, stabilizing devices, or periodic reviews to adapt plantar orthotics. Therefore, the objective of this study was to evaluate the clinical impact of this device in female patients with metatarsalgia after one month of using metatarsal relief socks compared to a control group with socks without unloading elements.

Patients and methods

We conducted a randomized clinical trial with a sample that consisted of 32 participants, all women, aged between 55 and 71 years (mean age 61.6 ± 4.9 years), with a mean weight of 72.5 ± 9.7 kg and a mean height of 1.6 ± 0.07 m, who voluntarily collaborated and provided their informed consent to participate in this study.

Inclusion and exclusion criteria

The inclusion criteria for participating in this study were as follows: *a)* female sex; *b)* age ≥ 55 years, as metatarsalgia is more prevalent from this age; *c)* moderate to severe pain in the plantar area of the forefoot; *d)* hyperkeratosis in the region of the central metatarsal heads; *e)* presence of predislocation syndrome in the second or third metatarsophalangeal joint. Subjects were excluded if they: a) presented cognitive impairment that prevents the proper development of the study; *b)* had undergone previous osteoarticular surgical procedures on the feet; *c)* had a diagnosis of rheumatoid arthritis, psoriatic arthritis, or other rheumatic diseases affecting the metatarsophalangeal joints of the foot; *d)* presented symptoms compatible with Morton's neuroma; *e)* regularly used walking aid devices; *f)* were undergoing treatment with plantar orthotics; or *g)* refused to use the designated socks or plantar supports during the follow-up period.

Study Protocol

We conducted a a brief collection of anthropometric data (sex, age, height in cm, weight in kg, and shoe size, EU size) for each participant. We conducted a physical examination of the patient to

confirm that they indeed had mechanical metatarsalgia (confirmed after conducting anamnestic data collection, palpation, and standard complementary examinations in podiatric practice), and they completed the pain questionnaire and The Foot Function Index (FFI). If the FFI result reflects a high value, the general symptoms the participant presents in their foot will be more severe than if they present a low value in the FFI[23]. This article evaluated the overall score as well as the individual subscales that compose it (pain, disability, and limitation).

Group Allocation

Participants with a diagnosis of metatarsalgia will be randomly divided into 2 groups, Group A (experimental) and Group B (control). The macro for Excel, AleatorMetod.xls (www4.ujaen.es/~mramos/EPIP/AleatorMetod.xls), was used for this. The obtained randomization will be applied according to the order of patient appointments in the podiatric care center, so that the first patient appointed will be assigned the number 1, and so on. Before knowing this numerical assignment, the patients will freely choose the date and time to attend the center, from those offered by the research staff.

1. Experimental group of 16 participants who will wear Podoks® metatarsal unloading socks. These are made from Coolmax Eco® (50 % polyester, 35 % polyamide, and 15 % elastane) and contain a biomechanical element, shaped as a U-shaped unloading on the second and third metatarsal heads (Figure 1).
2. Control group of 16 participants (socks of the same design, thickness, and fibers as the experimental sock but without the unloading element).

The researcher responsible for collecting functional data was blinded to the delivery of the socks, which was the responsibility of the lead author. Two pairs of socks were given to each participant so that they could wear them for as long as possible. Participants were advised to put on the delivered socks each morning and wear them throughout the day. After the 30-day period, participants were to return so that the blinded researcher could collect the final Foot Function Index questionnaire without knowing to which group the participant belonged.

Figura 1. Podoks shocks with metatarsal offloading. Left: General view; Right: Detail of the unloading element.

Statistical Analysis

For the statistical analysis, a Student's t-test for independent samples was performed. Statistical analyses of the results were conducted using SPSS version 29.0 (Campus UEX license). A significance level of 5 % ($p < 0.05$) was established.

Results

Score of the FFI prior to the Intervention

The mean Foot Function Index (FFI) score in the overall group was 54.82 ± 19.99. Regarding the different scales: 1) pain had a pre-score of 61.80 ± 21.40, 2) the pre-disability scale was 58.35 ± 21.55, and 3) the limitation scale had a mean of 24.36 ± 11.44 (Table I).

Comparing the FFI score according to the group to which the participants belonged (experimental or control), a mean of 53.77 ± 19.15 was observed in the experimental group and 55.76 ± 20.01 in the control group, showing no significant difference ($p = 0.713$).

Score of the FFI after the intervention

Upon comparing the overall FFI score prior to the intervention and after the 1-month follow-up, a significant reduction between both values was reported (54.82 ± 19.99 pre vs. 35.55 ± 16.38 post, $p = 0.013$). In relation to the different items by groups, the control group had a higher score (38.3 ± 19.77) vs. the experimental one (29.8 ± 15.16), with the difference being statistically significant ($p = 0.032$, Table II).

Table I. Pre-FFI with subscales.

	N	Mean	Standard Deviation
FFI Global Pre	32	54.82	19.99
Pain Scale Pre	32	61.80	21.40
Disability Scale Pre	32	58.35	21.55
Limitation Scale Pre	32	24.36	11.44

FFI. Foot Function Index.

Table II. Post-FFI per group (whether experimental or control).

Group	N	Mean	SD	*p*
FFI Post	Experimental	12	29.8	15.16
	Control	12	38.3	19.77

FFI. Foot Function Index.

Table III. Post-Subscales per group (whether experimental or control).

Group	N	Mean	Standard Deviation	*p*
Pain Scale Post	Experimental	12	38.6	19.2
	Control	12	49.4	22.8
Disability Scale Post	Experimental	12	29.5	12.7
	Control	12	40.9	18.6
Limitation Scale Post	Experimental	12	13.0	8.1
	Control	12	15.4	9.5

Compared to the subscales of the FFI after the 1-month follow-up, in the post-pain scale, we obtained a mean of 38.6 ± 19.2 in the experimental group vs 49.4 ± 22.8 in the control group, with this difference being statistically significant (p = 0.023, Table III). A lower score was also found in the experimental group vs the control group in the disability subscale (29.5 ± 22.8 vs. 40.9 ± 18.6 respectively, p = 0.042, Table III). No differences were ever found in the limitation subscale (p = 0.313, Table III).

Discussion

This project investigated pain in the plantar region of the foot, which is very common in women aged 55 and older. This pain also prevents physical exercise, thus limiting the activity that a person can do and negatively influencing their overall physical health. Our patients, regardless of group, started from a clinical situation of an FFI with a moderate score (54 points), with a score of 100 being indicative of the greatest possible deterioration. Participants in both groups started from a similar clinical situation, since their pre-FFI values were similar (53 in the experimental group vs 55 in the control).

After the intervention (30 days of intensive use of the socks), an improvement in clinical status was observed in the overall sample, with a reduction of 19 points in the FFI. However, this reduction was not homogeneous in both groups, as the control group improved by 16 points, compared to 25 points in the experimental group.

This improvement from the initial moment could be attributed to the intensive use of the socks. We observed that the control group achieved an improvement in foot function, probably due to the recommendation to use socks with front cushioning (even without the discharge element). In most patients, prior to the study, very thin tights, pinky socks, or socks of very reduced thickness (approximately 1 mm) were being used. The significant improvement in the scale was achieved with the experimental socks (with metatarsal discharge plate), showing lower values vs the control group, especially in the pain and disability scales (Table III). Thus, the selective cushioning, in U-shape, helps the second and third metatarsal heads remain at a higher plane, thereby reducing their interaction with the shoe sole. This reduction in pressure and friction decreases the total load supported, leading to a reduction in pain. Althought his U-shaped element is similar to those used in provisional discharges[24], it is maintained durably in the sock. Other models of socks with biomechanical elements have also shown a slight reduction in pain associated with plantar fasciitis after a short period of use of 15 days[25].

Although 83 % of patients aged 65 suffer from plantar pain with a negative impact on quality of life, this problem has not received sufficient attention in the literature. It seems that the increase in pain due to progressive foot deformation should be accepted as a sign of aging and not warrant the development of new treatments. However, the establishment of an extremely simple treatment such as a sock[26] has shown preliminary effects of reducing plantar pressure[22], related to the onset of pain, and a reduction in friction in the forefoot[27], which is related to the onset of keratopathies. Thus, in a simple way, under the control of the patient themselves, without constant medical monitoring and without side effects, a highly beneficial effect could be achieved.

Moreover, metatarsal discharge socks are compatible with the use of plantar supports, which, to date, is the recommended treatment for managing metatarsalgia. In early stages, socks could be the first-line therapy, while more advanced stages could be combined with the use of plantar orthoses. Our patients had metatarsalgia in early stages, having not previously undergone orthotic treatment for their condition. It was also observed that the experimental group significantly reduced their FFI score, showing symptomatic improvement and in the ability to perform daily living tasks.

This new proposal will lead to knowledge transfer to society and the medical textile industry to develop new three-dimensional orthopedic elements integrated into socks. Furthermore, this will represent a breakthrough in the prevention and management of metatarsalgia, which will have a direct impact on the quality of life of patients who suffer from it.

However, our study has several limitations that should be considered when interpreting the results. The first is that we have a limited sample, so we would need a larger sample to infer the effect achieved on other population groups. Another limitation is that follow-up is only for 30 days. Longer follow-up could provide interesting data to assess the long-term treatment with biomechanical socks for metatarsalgia.

In conclusion, the use of shocks with discharge elements has shown a reduction in the symptoms associated with metatarsalgia, especially in pain relief. This could be the starting point for incorporating socks with biomechanical elements into the therapeutic arsenal of podiatrists, as a treatment element in early stages or as an adjunct in more severe deformities.

Ethics declaration

The present study was performed under the approval of the bioethics and biosafety committee of University of Extremadura, Spain (ID: 151//2023).

Conflicts of interest

Fixtoe Device SL, the manufacturer of the Podoks® socks, provided the experimental and control socks to the authors. The lead author (AMN) acts as a scientific advisor in the development of socks for the company, with an economic link between the company and this author.

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None.

Authors' contributions

Conception and design of the study: AMN, PVMM.
Creation, drafting, and preparation of the draft: RSR.
Final review: AMN, PVMM.

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