Foot Orthotics with Morton's Extension doesn't Affects the Forces inside First Metatarsophalangeal Joint in Osteoarthritis Pathology.

Ruben Sanchez-Gomez (rusanc02@ucm.es)
Universidad Complutense de Madrid https://orcid.org/0000-0001-7071-9860

Juan Manuel Lopez-Alcorocho
Clínica Cemtro: Clinica Cemtro

Carlos Romero-Morales
Universidad Europea de Madrid Campus de Villaviciosa de Odón: Universidad Europea de Madrid SLU

Alvaro Gomez-Carrion
Universidad Complutense de Madrid Escuela Universitaria de Enfermeria Fisioterapia y Podologia

Ignacio Zaragoza-García
Complutense University of Madrid: Universidad Complutense de Madrid

Carlos Martinez-Sebastian
Complutense University of Madrid: Universidad Complutense de Madrid

Ismael Ortuño-Soriano
Complutense University of Madrid: Universidad Complutense de Madrid

Blanca De la Cruz-Torres
Universidad de Sevilla

Research

Keywords: Hallux rigidus, metatarsal bones, metatarsophalangeal joint, algometer

Posted Date: June 8th, 2021

DOI: https://doi.org/10.21203/rs.3.rs-570394/v1

Abstract

Study design

Case-control study

Background

Rigid Morton's extension (ME) are a kind of orthotics that have been used as conservative treatments of hallux rigidus (HR) named osteoarthritis, but only their effects on first metatarsophalangeal joint (MPJ) mobility and position in healthy subjects have been studied, but not on its applied forces neither in HR subjects.

Objectives

This study sought to understand how ME orthotics with three different thicknesses could influence the kinetic first MPJ, measured dorsally using the Jack maneuver and comparing subjects with normal first MPJ mobility versus those with HR. We aimed to clarify whether tension values were different between healthy and HR subjects.

Methods

Fifty-eight healthy subjects were selected, of which 30 were included in the case group according to HR criteria, and 28 were included in the control group. A digital algometer was used to assess the pulled tension values (kgf) of the first MPJ during the Jack maneuver (2-mm, 4-mm, and 8-mm ME thicknesses) versus the first MPJ in the weight-bearing resting position (WRP).

Results

The pulled tension values were reliable (ICC > 0.963). There were no statistically significant differences between the pulled tension values for the different WRP and ME conditions in the case ($p = 0.969$) or control ($p = 0.718$) groups.

Conclusions

Different ME thicknesses had no influence on the pulled tension applied during the simulated dorsiflexion Jack maneuver.

Clinical Relevance

This research aims to highlight the importance of the force effects of ME when treating hallux rigidus conservatively. Our results indicate that the tension values of the first MPJ during Jack maneuver had no significant pulling force effects on ME in healthy and hallux rigidus subjects, which suggests that its prescription can be made without danger of joint overload.

Introduction

Osteoarthritis of the first metatarsophalangeal joint (MPJ) is a pathological condition referred to as Cotterill,[3] hallux flexus, hallux equinus, or hallux rigidus (HR).[37] HR is the most common presentation of osteoarthritis in the foot, with an incidence of ~2.5% in people older than 50 years of age.[8] The main symptoms are pain with an active or passive load under manual dorsal and plantar mobilization of the first MPJ or during the heel off-phase of the gait cycle or pain related to impingement of the medial branch of the superficial peroneal nerve from the dorsal osteophyte, as well as cartilage destruction and restricted joint mobility.[2] HR could disturb the normal gait cycle and thus affect other structures of the body, such as the lower back and hip.[7] If this pathological status is not addressed, surgery will eventually be required to improve the symptoms and restore mobility.[5]

Although most literature reviews have shown that non-surgery interventions cannot stop the degeneration progress of HR in the first MPJ,[11] non-surgical management of symptomatic HR has been suggested as an early-stage (0-2) palliative solution[41]. Non-steroidal anti-inflammatory drugs, ultrasound therapy, shoe modifications, hallux strapping, and rigid insoles have been identified as the best options to reduce clinical pain[4,15,41,42], with a 60% success rate[16]. These rigid insoles [with a modification on the first ray, which was also described as Morton's Extension (ME)[7,16]] have been used in orthopaedics to treat restrictive pathologies like symptomatic HR. MEs are rectangular pieces of semi-rigid material (of varying thicknesses) that are placed under the insoles around the first MPJ. Morton[13] was the first author to argue for first-ray alteration as an aetiology of overload disease under the second metatarsal bone, but it was Ebisui[13] and Kelso[21] who detected the relationship between the first-ray dorsiflexed position in the sagittal plane and the first MPJ's restrictive dorsiflexion motion and Dananberg[6] who related its biomechanical consequences.

The Windlass mechanism has been described as a spring system formed by a cable that is attached to a fat plantar pad and calcaneus bone on one end and the proximal phalanx of the hallux base and the first metatarsal head on the other. This cable is the plantar aponeurosis and – under normal conditions – stabilises the medial arch of the foot during the gait cycle. The Windlass mechanism also rises and shortens the medial arch through the first MPJ's dorsiflexion during the heel off-phase of the gait cycle[18]. When the first MPJ's mobility is restricted by soft tissue structures or bone alterations[26,35], this Windlass mechanism is altered, thereby affecting the normal propulsion of the body. One of these bone alterations is metatarsus primus elevatus[24,31], where the first metatarsal bone takes an elevated position in the sagittal plane relative to the second metatarsal bone and to the floor. In this way, simulated restriction of the first MPJ's dorsiflexion with a 4- or 8-mm acrylic platform under the first ray (e.g., a ME) was already demonstrated, using a classical goniometer, in healthy participants[36]. However, it remains unclear if the first metatarsal bone's action, which leads to ME-induced metatarsus primus elevatus, would have the same reducing effects in subjects with the first MPJ restriction pathology. Also, mobility assessment of the first MPJ is not the only approach to assess the biomechanical function of the foot; kinetic parameters can also be useful[22]. Given this, the Jack's test describes a passive, static, weight-bearing resting position (WRP) to assess the mobility of the first MPJ, thereby simulating the push-off phase of the gait cycle executing a simulated Windlass mechanism[18], pulling the hallux in the dorsal direction passively with the subject in a WRP until the movement stops[10,19]. However, the pull tension necessary to perform this test under different ME specifications has not been studied. A lot of pathologies of the locomotive system don't show any mobility and/or visual restrictions, cause biomechanical forces moments don't always have kinematics behaviour but also kinetics effects[9]. By these reasons authors think that tension values can represent better than mobility values what occurs inside the joint.

Therefore, the purpose of this research was to know the effects of three different ME insoles on the pulled tension values that were required to perform simulated dorsiflexion of the first MPJ, executing validated[38] Jack's test, in subjects with normal and restricted ranges of motion of the first MPJ (i.e., HR). Also, this study sought to compare the tension values of healthy and HR subjects during the Jack's test without any orthotic element. Knowing these force-inside-joint alterations, the orthotics could be recommended to avoid overload inside the joint. The hypothesis was that there was difference in tension values between subjects with HR and those with normal dorsiflexion mobility of the first MPJ during the Jack's test with or without any of the ME insoles.

Methods

*Study design*A case-control study was carried out between January 2021 and March 2021, following the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) requirements[44]. This research was approved by the Institutional Review Board of a private hospital affiliated with the authors in October 2020; the device used in the present research is non-dangerous and non-invasive. All legal permissions were obtained. Informed consent and data protection act forms were signed by each participant. The standards of the Helsinki declaration regarding human experimentation were respected. *Participants*The research case group associated with HR consisted of participants who met the following inclusion criteria: 1) restricted first MPJ-assisted dorsal mobility, according to a validated active range of motion with the subject in a non-weight-bearing test, below 75°[40]; 2) restricted non-weight-bearing-assisted plantarflexion of the first MPJ under 35°[40]; 3) pain during active and passive plantarflexion and dorsiflexion of the first MPJ[28]; 4) no trauma or injury in the lower limbs and feet; 5) normal range of motion in the subtalar joint (30°), midtarsal joint (15° along the longitudinal axis), and ankle joint (at least 20° of dorsiflexion with the knee fully extended); and 6) age between 30 and 60 years old. Subjects were excluded if they were under the effects of any drugs or had any hypermobility condition (e.g., ligamentous hyperlaxity). The control group consisted of healthy, age-matched subjects.

Measurement procedures, instruments, and variables

To set the first metatarsal bone in the dorsiflexion position, flat insoles with ME thicknesses of 2, 4, and 8 mm[36] were made, in 45° shore-A hardness, of ethylene-vinyl acetate (EVA) (Fig. 1), adjusted to the size of the subjects' feet and incorporated randomly to the right foot for each measurement and for each subject. The ME was a rectangular piece of EVA that was also placed inside of the insoles under the area of the first MPJ. Three measurements were made for each condition to determine consistency. To avoid any imbalance, the same flat insole in the contralateral foot was placed.

To assess the effects of the four WRPs and three ME thicknesses on the first MPJ, a digital algometer (FPX® 25, Wagner Instruments®, Greenwich CT, USA) with a rigid strip anchored to the iron hook's extremity was used. This device had a 10 × 0.01 kgf (kilogram-force) capacity/graduation and an accuracy of 0.3% of the full scale. Previous studies have reported good reliability and validity for this device (intra-rater reliability: 0.895, 95%CI = 0.846–0.928; SEM = 2.36, MDC = 6.55)[20]. In the static WRP, the proximal phalanx of the hallux was pulled to its maximal dorsal position until foot showed supination movement on rearfoot Helbing´s sign[30,33], by an experienced clinician (RS-G), transmitting the tension needed to perform the Jack´s test[19] through the rigid strip anchored to the algometer (Fig. 2).

Sample size

The sample size was calculated using software from the Epidemiology Unit of Biostatistics (www.fisterra.com) to detect differences in the kgf applied to the first MPJ during the Jack's test between the case and control groups and between the different MEs. Previous measures in healthy subjects have shown that the mean strength with the 8-mm insole was 3.2 ± 0.7 kgf (mean ± SD) (personal observations). In another similar study, ten healthy subjects were recruited[36]. According to these data, we needed to include at least 46 subjects (23 in the control group and 23 in the case group) to detect a difference in the mean strength of 0.7 kgf using Student's t-test for independent samples with 80% power, in a bilateral contrast, and $\alpha = 0.05$. Taking into account that some subjects could be lost to follow-up, we established a final sample of 60 subjects (30 per group).

Statistical methods

To validate the reliability across the measurement trials, the intra-class correlation coefficients (ICCs)[25] were evaluated according to the specifications of Landis and Koch: coefficients less than 0.20 represent a slight agreement, between 0.20 and 0.40 fair reliability, between 0.41 and 0.60 moderate reliability, between 0.61 and 0.80 substantial reliability, and between 0.81 and 1.00 almost perfect reliability. Coefficients of 0.90 or larger reflect sufficient reliability given that reliability coefficients exceeding 0.90 increase the likelihood that a measure is also reasonably valid[32].

All the continuous data were studied for normality using the Kolmogorov-Smirnov test; normal distributions were noted for p-values > 0.05. Independent Student's t-tests were used to determine if there were significant differences between the case and control groups under the WRP and three continuous variables used in the study. Similarly, ANOVA was used to test if there were significant differences in the applied tension values between the different conditions. Tukey's test was used for post-hoc comparisons. The Spearman rank correlation coefficient was used to determine the correlation between the thickness of the ME insoles and the effect on the pulled applied tension. We present each descriptive summary as mean ± SD. For all the analyses, we considered p-values < 0.05 (within a 95% confidence interval) as statistically significant. We analysed the data using SPSS software, version 19.0 (SPSS Science, Chicago, IL, USA).

Results

A total of 58 subjects (34 females and 24 males) participated in the study; 28 subjects were recruited to the control group and 30 subjects were included in the case group (Fig. 3).

Representation of participants' recruitment

IMPJ = first metatarsophalangeal joint; n = population

The sociodemographic characteristics of the case and control groups are shown in Table 1. The homogeneity of the four measured physical characteristics [weight, height, foot size, and body mass index (BMI)] guaranteed the applicability of the results to the sample. The distribution was normal ($p > 0.05$).

The reliability of the variables followed perfect ICC criteria and ranged from 0.963 to 0.989 (Table 2). According to our obtained values (Table 2), the control group required almost 1 kgf less effort than the case group to move the MPJ dorsally under the 4-mm ME [4.122 ± 0.162 kgf in the case group vs. 3.325 ± 0.139 kgf in the control group under WRP ($p < 0.001$); 4.211 ± 0.116 kgf in the case group vs. 3.538 ± 0.123 kgf in the control group under a 4-mm ME ($p < 0.001$)]. The differences were smaller for the 2-mm ME: 4.139 ± 0.142 kgf in the case group vs. 3.421 ± 0.133 kgf in the control group ($p < 0.001$) (Fig. 4). Nevertheless, in the case group, the WRP and the different ME insoles had similar pulled tension values, which ranged from 4.122 ± 0.16 kgf in the WRP to 4.211 ± 0.116 kgf in the 4-mm ME condition (not statistically significantly different, $p > 0.05$); the differences were smaller with the 2- and 8-mm MEs (4.139 ± 0.142 kgf with a 2-mm ME and 4.179 ± 0.126 kgf with an 8-mm ME) (Table 2). For the controls, the WRP and different ME insole conditions showed similar pulled tension values, which ranged from 3.325 ± 0.139 kgf in the WRP to 3.538 ± 0.123 kgf with the 4-mm-thick ME; the 8-mm-thick ME (3.465 ± 0.134 kgf) and 2-mm-thick ME (3.421 ± 0.133kgf) values were quite similar (Table 2) ($p > 0.05$). These data are shown in Figure 4, where it is possible to see the differences in tension values between the groups.

Spearman's Rho correlations between the ME thickness and the amount of pulled joint tension were not statistically significant for either group (case, $p = 0.715$; control, $p = 0.481$) (Fig. 5).

Discussion

Rigid MEs have been used as a conservative treatment for the first stages of HR[41] and their effects over the first ray have been studied with respect to the ME position[36], but not their forces applied or developed with it. This research presents, with a similar piece to ME, highly valid data over an excellent homogeneous sample and reaches useful conclusions that are relevant to clinical practice.

First MPJ is a rolling joint regulated by rotational equilibrium theory described before[23] in which kinetic and kinematics forces are present in the different phases of the human gait. Taking into account that this study is not about the first MPJ's mobility or position but instead about pulled, our results do not agree with those of some other studies, in which the authors argued that the dorsal first MPJ's mobility was influenced by the position of the first ray[13,21,36].

The hypothesis proposed at the beginning of the present study could not be confirmed according to our results because there was no statistically significant difference between the applied pulled tension in the Jack's test for the case or control groups, regardless of the ME thickness. Also, the differences that were detected were very small. In our study, the pulling force applied on the first MPJ during the measurements did not show any proportional correlation with the ME thickness, as opposed to the results of Roukis et al.[36], who showed a 19.3% incremental restriction on the first MPJ's mobility in proportion with 4-mm first-ray simulated dorsiflexion. Our surprising results could mean that following reach the joint stop movement through ME´s thickness, the pulling force needed to perform the Jack´s test was the same, regardless of external ME´s restrictions. The total amount of dorsal mobility of the first ray in WRP reported by previous studies was set at 4.9mm[17], which is higher than that achieved in the ankle dorsiflexion position; this is due to the increased tension on the plantar aponeurosis related to the Windlass mechanism[12,18] as it has been shown previously by the intrinsic correlation between first MPJ and the triceps surae[27,39]. The ME thicknesses used in our experiment were 2, 4, and 8 mm; in our results, the 4-mm ME orthotic produced the greatest tension effort on the first MPJ, which could be compared with the mobility results of Grady[17], but without any statistical significance. This is likely due to "artificial dorsal-opening" of the first MPJ through the ME´s effects under the first ray, and therefore this orthotic solution could be used to avoid pain inside the joint, pushing away the phalanx and metatarsal dorsal surfaces during the push-off phase, but this ME had no effects on the kinetic data, as shown in our research, because the exerted tension was enough to produce the needed dorsiflexion of the first MPJ. Further dynamic research is now needed to clarify if the present data could be applied to functional gait and if our kinetics results would be similar to the results of examining the kinematics variables under similar conditions.

Nevertheless, according to our data, we could hypothesize that the case group had more difficulty achieving peak mobility in the Jack's test, as shown by the greater force values applied, than in the control group, regardless of the ME's thickness. As expected, this is in accordance with the field's current knowledge about the mobility of the first MPJ[6,14,36]. Grebing et al.[17] detected a decrease of the first-ray simulated dorsiflexion when comparing healthy versus first MPJ arthrodesis subjects, which explains the increase we observed in pulled force in the HR group, compared to the healthy control group.

There are controlling orthoses for hyper-pronated feet[29], and these have been shown to restore the mobility of first MPJs with restricted dynamic mobility (named functional hallux limitus) at the 5-month follow-up. It is also possible to improve this mobility in real time using cut-out orthoses[1]; nevertheless, the objective of the present research was to assess the tension values of the ME on a totally restricted first MPJ, not just dynamic-functional restriction. Moreover, Reina et al.[34] showed no statistical difference in the X-Ray IMA and HAV-angle values between custom-made foot orthoses and no orthoses in subjects with HAV, indicating that kinematics data are not always related to kinetics values, which is in line with our results.

Limitations

The present device had a 10 × 0.01 kgf capacity/graduation and an accuracy of 0.3% of the full scale; furthermore, the small effect size throughout the results showed between the WRP and MEs inside each control and case group are in line with another comparative kinetic and kinematics study with small effect sizes between the case and control groups[43]. Therefore, the reported values should be considered with caution.

This is a novel force-kinetic study related to pulled tension and did not focus on the first MPJ's mobility or position; therefore, further investigations are needed to be able to make comparisons with these results. Also, further dynamics measurements will be required to verify the ME effects discovered in the present simulated research. In addition, future research with X-Ray assessments to correlate the elevation of first metatarsal bone with ME with ME and how it changes forces of dorsiflexion, could be interesting. There is no reliable method for determining the final position of the proximal phalanx of the hallux during the Jack manoeuvre. Future research will be needed to clarify this issue and improve the Windlass mechanism test.

Conclusion

The orthopaedic use of rigid ME as a palliative treatment for HR has been studied regarding mobility, but not force-kinetic effects. In the present study, we showed that with the use of similar MEs, the tension values detected during the simulated toe-off phase of the gait cycle (i.e., the Jack's test) in healthy individuals and subjects with HR had no correlation with the ME's thickness. Although we were able to confirm that performing the Jack's test in individuals with HR required higher kgf tension values than in healthy individuals, our data showed that the prescription of ME orthoses didn't affect to tension forces inside the first MPJ and its prescription can be made carefree of joint damage.

Abbreviations

EVA: ethylene-vinyl acetate

HR: hallux rigidus

ICC: Intra-class correlation coefficient

Kgf: kilogram-force

MDC: minimum detectable change

ME: Rigid Morton's extension

MPJ: metatarsophalangeal joint

SEM: standard error of measurement

WRP: weight-bearing resting position

Declarations

"All authors contributed equally in the preparation of this manuscript."

Declaration of funding and funding roles

None.

Conflict of Interest.

None.

Declarations section

Ethics approval and consent to participate

CEIC Hospital Universitario Ntra. Sra. de Valme

RAMON MORILLO VERDUGO

Secretario del CEIC Hospital Universitario Ntra. Sra. de Valme

Hospital Nuestra Senora de Valme P*.prii 1 de I

Ctra. de Cadiz, km. 548,9 Sevilla 41014 Sevilla Espana

Tel. 955 01 50 90 Fax. Correo electranico vicente.viruel@juntadeandalucia.es

CERTIFICA

10. Que el CEIC Hospital Universitario Ntra. Sra. de Valme en su reunion del dia 27/10/2020, acta REUNION 9/20 ha evaluado la propuesta del promotor referida al estudio:

Titulo: efectos de la extensión de Morton en la primera articulación metatarsofalángica

COdigo Promotor: Plantilla vaciados **Coo:lig° Interno:** 21161-N-20

Promotor: Investigador

Fecha Entrada: 20/10/2020

C.P. Extensión- C.I. 21161-N-20

10. Considera que

- El estudio se plantea siguiendo los requisitos de la Ley 14/2007, de 3 de julio, de Investigacion Biomedica y su realization es
- Se cumplen los requisitos necesarios de idoneidad del protocolo en relation con los objetivos del estudio y estan justificados los riesgos y molestias previsibles para el
- Son adecuados tanto el procedimiento para obtener el consentimiento informado coma la connpensaciOn prevista para los sujetos por clarios que pudieran derivarse de su participation en el

El alcance de las compensaciones economicas previstas no interfiere con el respeto a los postulados eticos. La

capacidad de los Investigadores y los medios disponibles son apropiados para Ilevar a cabo el estudio.

Por lo que este CEIC emite un **DICTAMEN FAVORABLE.**

Este CEIC acepta que dicho estudio sea realizado en los siguientes CEIC/Centros por los Investigadores:

CEIC Hospital Universitario Ntra. Sra. de Valme BLANCA DE LA CRUZ TORRES

(ftsioterapia)Universidadde Sevilla

Lo que firma en Sevilla, a 27 de octubre de 2020 Fdo:

Informe Dictamen Favorable Proyecto Investigacion Biomedica

27 de octubre de 2020

Consent for publication

All authors give thier consent for publication the present paper.

Regarding to subjects data or something relative to the their privacy, **is not applicable on the present manuscritp**

Availability of data and material

All sources data and worn material to develop the present research are available under editors and reviewers requirements. Please contact author for data requests.

Competing interests

At the end of the text, under a subheading "Conflict of interest statement" all authors must disclose any financial and personal relationships with other people or organisations that could inappropriately influence (bias) their work. Examples of potential conflicts of interest include employment, consultancies, stock ownership, honoraria, paid expert testimony, patent applications/registrations, and grants or other funding. **The authors declare that they have no competing interests**

Funding

All sources of funding should be declared as an acknowledgement at the end of the text. Authors should declare the role of study sponsors, if any, in the study design, in the collection, analysis and interpretation of data; in the writing of the manuscript; and in the decision to submit the manuscript for publication. If the study sponsors had no such involvement, the authors should state this. **The authors declare that they have no funding source.**

Authors' contributions

1a. Substantial contributions to study conception and design

Rubén Sánchez-Gómez

Carlos Romero Morales

1b. Substantial contributions to acquisition of data

Rubén Sánchez-Gómez

Juan Manuel López-Alcorocho

Carlos Romero Morales

Álvaro Gómez Carrión

Ignacio Zaragoza García

Carlos Martínez Sebastián

Ismael Ortuño Soriano

Blanca de la Cruz Torres

1c. Substantial contributions to analysis and interpretation of data

Juan Manuel Lopez Alcorocho

Blanca de la Cruz Torres

2. Drafting the article or revising it critically for important intellectual content

Ismael Ortuño Soriano

Rubén Sánchez-Gómez

Ignacio Zaragoza García

3. Final approval of the version of the article to be published

Álvaro Gómez Carrión

Ignacio Zaragoza García

Carlos Martínez Sebastián

Acknowledgements

All contributors who do not meet the criteria for authorship as defined above should be listed in an acknowledgements section. Examples of those who might be acknowledged include a person who provided purely technical help, writing assistance, or a department chair who provided only general support. Such contributors must give their consent to being named. Authors should disclose whether they had any writing assistance and identify the entity that paid for this assistance. **The authors declare that there are no acknowledgement of other contributors**

Author Signature Date Author Signature Date

Rubén Sánchez-Gómez, PhD, MsC, DP 24-5-21

Juan Manuel López-Alcorocho, PhD 24-5-21

Carlos Romero Morales, PhD, DF 24-5-21

Carlos Martínez Sebastián DP 24-5-21

Alvaro Gómez Carrión DP 24-5-21

Ismael Ortuño Soriano PhD 24-5-21

Blanca de la Cruz Torres 24-5-21

Ignacio Zaragoza García 24-5-21

References

1. Becerro de Bengoa Vallejo R, Gomez RS, Losa Iglesias ME. Clinical improvement in functional hallux limitus using a cut-out orthosis. *Prosthet Orthot Int*. 2016;40(2):215-223. doi:10.1177/0309364614550262.
2. Caravelli S, Mosca M, Massimi S, et al. A comprehensive and narrative review of historical aspects and management of low-grade hallux rigidus: conservative and surgical possibilities. *Musculoskelet Surg*. February 2018. doi:10.1007/s12306-018-0530-3.
3. Cotterill JM. Stiffness of the Great Toe in Adolescents. *Br Med J*. 1887;1(1378):1158.

4. Coughlin MJ, Shurnas PS. Hallux rigidus: demographics, etiology, and radiographic assessment. *Foot ankle Int*. 2003;24(10):731-743.
5. Coughlin MJ, Shurnas PS. Hallux Rigidus. *J Bone Jt Surg*. 2004;86(Pt 2):119-130. doi:10.2106/00004623-200409001-00003.
6. Dananberg HJ. Functional hallux limitus and its relationship to gait efficiency. *J Am Podiatr Med Assoc*. 1986;76(11):648-652. doi:10.7547/87507315-76-11-648.
7. Dananberg HJ. Gait style as an etiology to chronic postural pain. Part I. Functional hallux limitus. *J Am Podiatr Med Assoc*. 1993;83(8):433-441. doi:10.7547/87507315-83-8-433.
8. Deland JT, Williams BR. Surgical management of hallux rigidus. *J Am Acad Orthop Surg*. 2012;20(6):347-358. doi:10.5435/JAAOS-20-06-347.
9. Desmyttere G, Hajizadeh M, Bleau J, Begon M. Effect of foot orthosis design on lower limb joint kinematics and kinetics during walking in flexible pes planovalgus: A systematic review and meta-analysis. *Clin Biomech*. 2018;59:117-129. doi:10.1016/j.clinbiomech.2018.09.018.
10. Downey M. Tarsal coalitions. A surgical classification. *J Am Podiatr Med Assoc*. 1991;81(4):187-197. doi:10.7547/87507315-81-4-187.
11. Drago JJ, Oloff L, Jacobs AM. A comprehensive review of hallux limitus. *J Foot Surg*. 23(3):213-220.
12. Durrant MN, Siepert KK. Role of soft tissue structures as an etiology of hallux limitus. *J Am Podiatr Med Assoc*. 1993;83(4):173-180. doi:10.7547/87507315-83-4-173.
13. Ebisui JM. The first ray axis and the first metatarsophalangeal joint: an anatomical and pathomechanical study. *J Am Podiatry Assoc*. 1968;58(4):160-168. doi:10.7547/87507315-58-4-160.
14. Van Gheluwe B, Dananberg HJ, Hagman F, Vanstaen K. Effects of hallux limitus on plantar foot pressure and foot kinematics during walking. *J Am Podiatr Med Assoc*. 96(5):428-436.
15. Gould N. Hallux rigidus: cheilotomy or implant? *Foot Ankle*. 1981;1(6):315-320.
16. Grady JF, Axe TM, Zager EJ, Sheldon LA. A retrospective analysis of 772 patients with hallux limitus. *J Am Podiatr Med Assoc*. 2002;92(2):102-108.
17. Grebing BR, Coughlin MJ. The effect of ankle position on the exam for first ray mobility. *Foot Ankle Int*. 2004;25(7):467-475. doi:10.1177/107110070402500705.
18. Hicks J. The mechanics of the foot. II. The plantar aponeurosis and the arch. *J Anat*. 1954;88(1):25-30.
19. Jack E. Naviculo-cuneiform fusion in the treatment of flat foot. *J Bone Joint Surg Br*. 1953;35-B(1):75-82.
20. Kelly-Martin R, Doughty L, Garkavi M, Wasserman JB. Reliability of modified adheremeter and digital pressure algometer in measuring normal abdominal tissue and C-section scars. *J Bodyw Mov Ther*. 2018;22(4):972-979. doi:10.1016/j.jbmt.2018.02.017.
21. Kelso SF, Richie DH, Cohen IR, Weed JH, Root M. Direction and range of motion of the first ray. *J Am Podiatry Assoc*. 1982;72(12):600-605. doi:10.7547/87507315-72-12-600.
22. Kim HK, Mirjalili SA, Fernandez J. Gait kinetics, kinematics, spatiotemporal and foot plantar pressure alteration in response to long-distance running: Systematic review. *Hum Mov Sci*. 2018;57:342-356. doi:10.1016/j.humov.2017.09.012.
23. Kirby KA. Subtalar joint axis location and rotational equilibrium theory of foot function. *J Am Podiatr Med Assoc*. 2001;91(9):465-487. doi:10.7547/87507315-91-9-465.
24. Lambrinudi C. Metatarsus Primus Elevatus. *Proc R Soc Med*. 1938;31(11):1273.

25. Landis JR, Koch GG. The measurement of observer agreement for categorical data. *Biometrics*. 1977;33(1):159-174.
26. Lyritis G. Developmental disorders of the proximal epiphysis of the hallux. *Skeletal Radiol*. 1983;10(4):250-254.
27. Maceira E, Monteagudo M. Functional hallux rigidus and the Achilles-calcaneus-plantar system. *Foot Ankle Clin*. 2014;19(4):669-699. doi:10.1016/j.fcl.2014.08.006.
28. Mann RA, Coughlin MJ, DuVries HL. Hallux rigidus: A review of the literature and a method of treatment. *Clin Orthop Relat Res*. (142):57-63.
29. Munuera P V, Domínguez G, Palomo IC, Lafuente G. Effects of rearfoot-controlling orthotic treatment on dorsiflexion of the hallux in feet with abnormal subtalar pronation: a preliminary report. *J Am Podiatr Med Assoc*. 96(4):283-289.
30. Noakes H, Payne C. The reliability of the manual supination resistance test. *J Am Podiatr Med Assoc*. 2003;93(1-6):185-189. doi:10.7547/87507315-93-3-185.
31. Ohara K, Tanaka Y, Taniguchi A, Kurokawa H, Kumai T, Yamada H. Is metatarsus primus elevatus truly observed in hallux rigidus? Radiographic study using mapping methods. *J Orthop Sci*. September 2018. doi:10.1016/j.jos.2018.09.005.
32. Portney L, Watkins M. *Foundations of Clinical Research: Applications to Practice,*. Vol 47. 3rd ed. (Hall PP, ed.). Upper Saddle River, NJ: Prentice Hall Health, 2009; 2002. doi:10.1016/s0039-6257(02)00362-4.
33. Redmond AC, Crosbie J, Ouvrier RA. Development and validation of a novel rating system for scoring standing foot posture: The Foot Posture Index. *Clin Biomech*. 2006;21(1):89-98. doi:10.1016/j.clinbiomech.2005.08.002.
34. Reina M, Lafuente G, Munuera P V. Effect of custom-made foot orthoses in female hallux valgus after one-year follow up. *Prosthet Orthot Int*. 2013;37(2):113-119. doi:10.1177/0309364612447097.
35. Root ML, Orien WP WH. *Normal and Abnormal Function of the Foot*. Vol II. (Corp CB, ed.). Los Angeles: Clinical Biomechanics Corp. (1977); 1977.
36. Roukis TS, Scherer PR, Anderson CF. Position of the first ray and motion of the first metatarsophalangeal joint. *J Am Podiatr Med Assoc*. 1996;86(11):538-546. doi:10.7547/87507315-86-11-538.
37. Rzonca E, Levitz S, Lue B. Hallux equinus. The stages of hallux limitus and hallux rigidus. *J Am Podiatry Assoc*. 1984;74(8):390-393. doi:10.7547/87507315-74-8-390.
38. Sánchez-Gómez R, Becerro-de-Bengoa-Vallejo R, Losa-Iglesias ME, et al. Reliability Study of Diagnostic Tests for Functional Hallux Limitus. *Foot Ankle Int*. 2020;41(4):457-462. doi:10.1177/1071100719901116.
39. Sánchez-Gómez R, Romero-Morales C, Gómez-Carrión Á, et al. Effects of novel inverted rocker orthoses for first metatarsophalangeal joint on gastrocnemius muscle electromyographic activity during running: A cross-sectional pilot study. *Sensors (Switzerland)*. 2020;20(11):1-12. doi:10.3390/s20113205.
40. Shereff MJ, Bejjani FJ, Kummer FJ. Kinematics of the first metatarsophalangeal joint. *J Bone Joint Surg Am*. 1986;68(3):392-398.
41. Shurnas PS. Hallux Rigidus: Etiology, Biomechanics, and Nonoperative Treatment. *Foot Ankle Clin*. 2009;14(1):1-8. doi:10.1016/j.fcl.2008.11.001.
42. Smith RW, Katchis SD, Ayson LC. Outcomes in hallux rigidus patients treated nonoperatively: a long-term follow-up study. *Foot ankle Int*. 2000;21(11):906-913.

43. Sung PS, Zipple JT, Andraka JM, Danial P. The kinetic and kinematic stability measures in healthy adult subjects with and without flat foot. *Foot*. 2017;30:21-26. doi:10.1016/j.foot.2017.01.010.
44. Vandenbroucke JP, von Elm E, Altman DG, et al. Strengthening the Reporting of Observational Studies in Epidemiology (STROBE): Explanation and elaboration. *Int J Surg*. 2014;12(12):1500-1524. doi:10.1016/j.ijsu.2014.07.014.

Tables

Table 1. Descriptive socio-demographics data of cases and control healthy group subjects.

	Total population N=58	CASES GROUP HR participants n=30	CONTROL GROUP healthy participants n=28	
Variable	**mean ± SD** **(95% CI)**	**mean ± SD** **(95% CI)**	**mean ± SD** **(95% CI)**	***p* value**
Age (years)	40.62±1.12 (40.98-40.33)	42.53±5.72 (44.57-40.48)	38.57±1.12 (38.98-38.15)	0.9
Weight (kg)	67.44±9.98 (70-64.87)	66.6±9.37 (69.95-63.24)	68.35±10.7 (72.31-64.38)	<0.001
Height (cm)	167.77±10.01 (170.34-165.19)	167.53±7.72 (170.29-164.76)	164±12.14 (168.49-159.5)	<0.001
Foot Size (Es)	40.2±1.9 (40.50-39.89)	38.2±2.10 (38.95-37.44)	40.3±0.35 (40.42-40.17)	<0.001
BMI (kg/m2)	21.48±1.47 (21.85-21.1)	20.2±1.74 (20.82-19.57)	22.95±2.58 (23.90-21.99)	<0.001

Abbreviations: N= sample size; CASES GROUP= participants with hallux rigidus; CONTROL GROUP = healthy participants, without hallux rigidus; SD= Standard Deviation; CI= Confidence Interval; *p* value= level of significance; $p < 0.05$ (with a 95% confidence interval) was considered statistically significant; Es = number according European mode size; BMI = body mass index.

Table 2. Mean values and reliability of pulled tension for measurements of first MPJ under each Morton´s Extensions insoles thickness between cases and control groups.

	CASES GROUP n=30			CONTROL GROUP n=28		
Thickness ME **Variable**	**mean** (kgf) **± SD** **(95% CI)**		**ICC 95% IC** **(Li-Ls)**	**mean** (kgf) **± SD** **(95% CI)**	**ICC 95% IC** **(Li-Ls)**	***p* value**
I MPJ **Weightbearing resting position**	4.122±0.162	(3.79-4.45)	0.989 (0.98-0.994)	3.325±0.139 (3.03-3.61)	0.971 (0.948-0.98)	<0.001
ME 2mm	4.139±0.142	(3.84-4.43)	0.97 (0.94-0.985)	3.421±0.133 (3.14-3.69)	0.963 (0.928-0.982)	<0.001
ME 4mm	4.211±0.116	(3.97-4.45)	0.969 (0.943-0.984)	3.538±0.123 (3.28-3.79)	0.94 (0.88-0.97)	<0.001
ME 8mm	4.179±0.126 4.43)	(3.92-	0.972 (0.939-0.987)	3.465±0.134 (3.18-3.74)	0.971 (0.94-0.986)	<0.001
***p* value**	0.969		-	0.718	-	-

Abbreviations: CASES GROUP = participants with hallux rigidus; CONTROL GROUP= healthy participants, without hallux rigidus; SD= Standard Deviation; CI= Confidence Interval; ICC= Intraclass Correlation Coefficient; Li, inferior limit; Ls, Superior limit; IMPJ= first metatarsophalangeal joint; Weightbearing resting position= without insoles; ME= Morton´s Extension insoles; mm=millimeters; *p* value= level of significance; $p < 0.05$ (with a 95% confidence interval) was considered statistically significant.

Figures

Figure 1

Flat insoles with Morton Extension of 2, 4 and 8mm

Figure 2

Digital algometer pulling hallux with Morton Extension flat insole

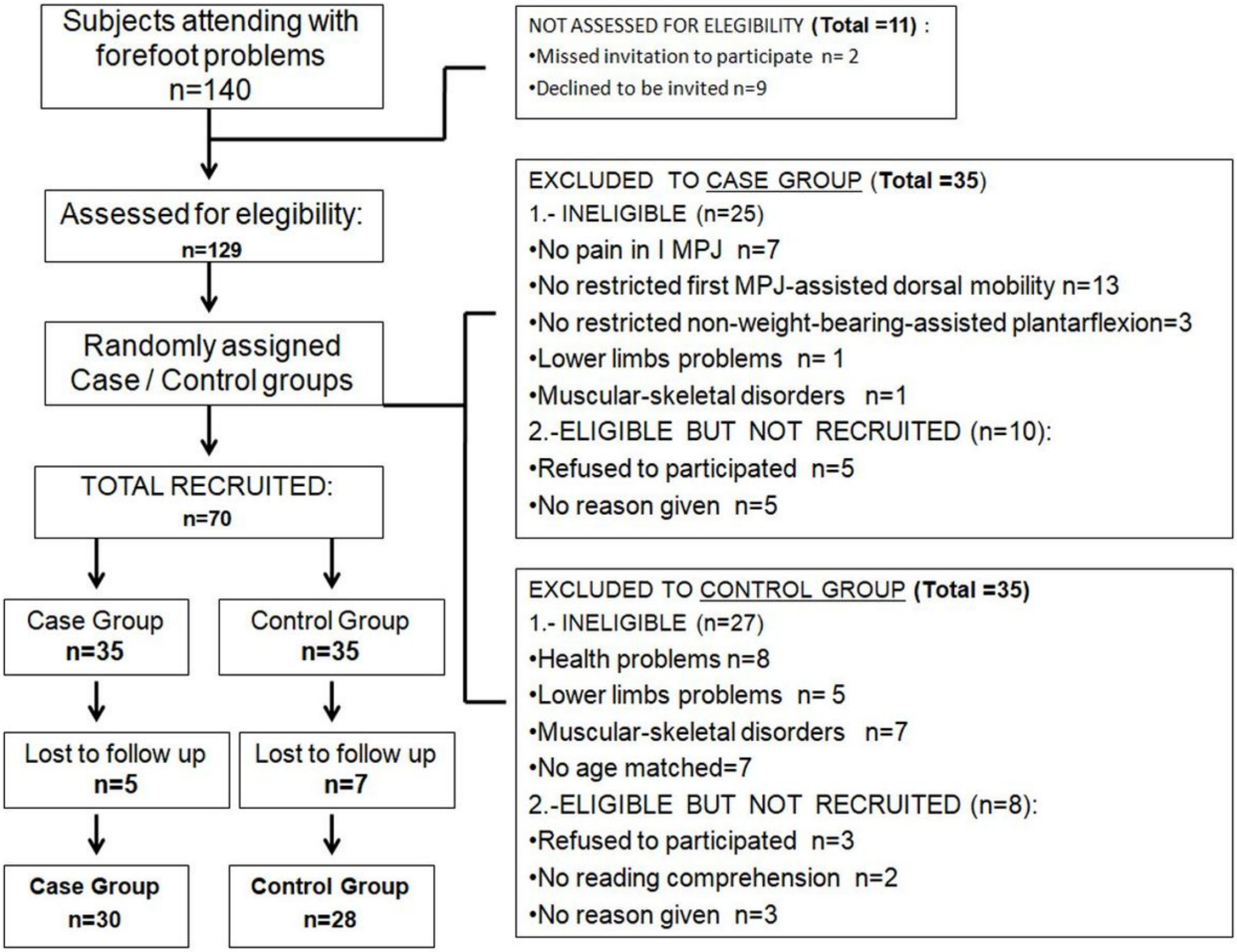

Figure 3

Flow chart Representation of participants' recruitment IMPJ = first metatarsophalangeal joint; n = population

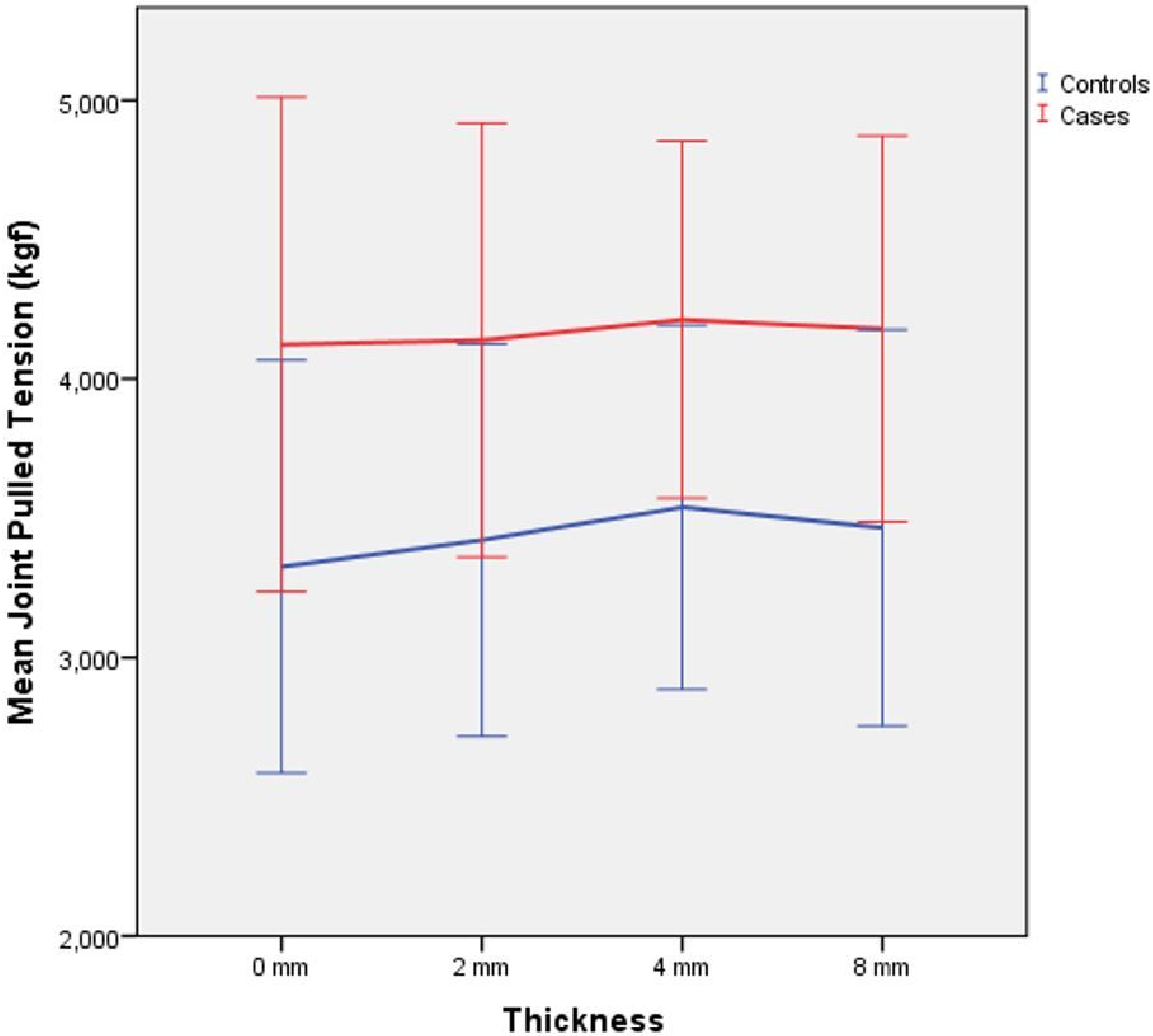

Figure 4

Difference in pulled joint tension applied (kgf) between the cases group and the control group. Mean + SD data between cases (red lines) and controls (blue lines) groups. It is showed the clear difference in highest´s values of cases (hallux rigidus) group

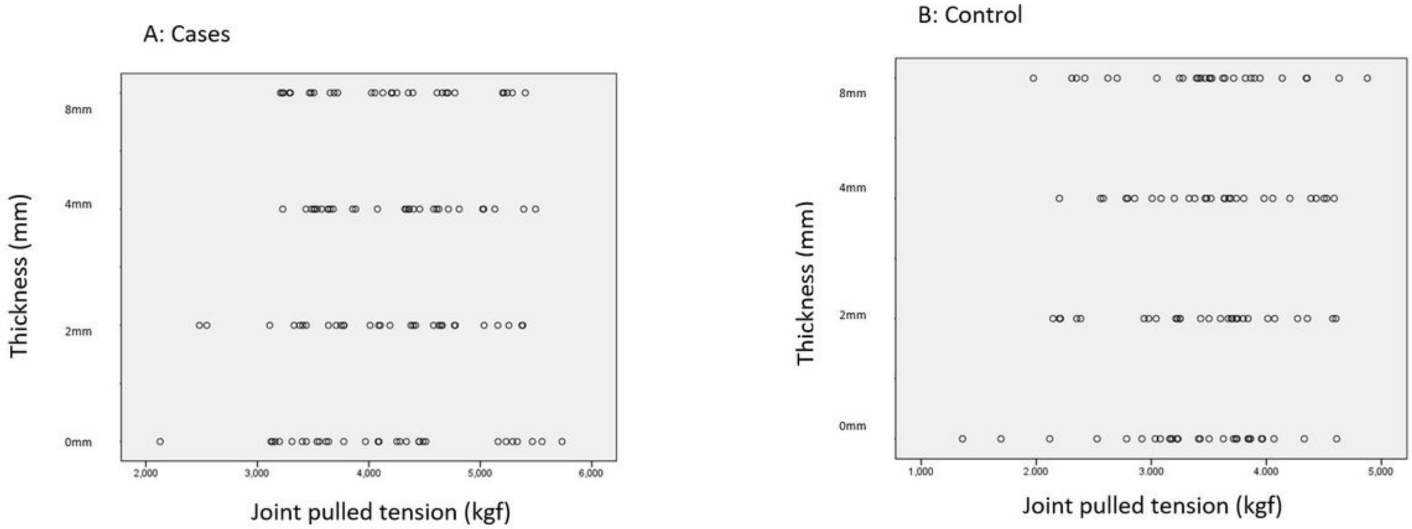

Figure 5

The correlation between Morton Extension´s insoles thickness (mm) and pulled joint tension applied (kgf). A= Cases group; hallux rigidus participants. B= control group; healthy participants. Spearman's Rho= level of significance; $p < 0.05$ (with a 95% confidence interval) was considered statistically significant; Kgf= kilogram force.

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- AuthorAgreementForm.doc
- CE.pdf
- authorcontributions.docx
- conflictinterestdisclosure.doc