Title

Effectiveness of custom-made foot orthoses for treating forefoot pain: a systematic review.

Abstract:

Purpose: Pain in and around the metatarsal heads, the metatarsal phalangeal joints and the surrounding soft tissues is called metatarsalgia. Non-operative treatment of metatarsalgia includes foot orthoses. Foot orthoses may be classified as standard or custom-made. A systematic review was carried out to determine whether custom-made foot orthoses are effective for treating forefoot pain.

Methods: The Medline, Cinahl, The Cochrane Library and PEDro databases were searched for relevant articles reporting patients undergoing treatment for forefoot pain by means of custom-made foot orthoses. Two reviewers independently reviewed all titles and abstracts, and extracted the available data. The study eligibility criteria were: randomized controlled clinical trials, that included participants with forefoot pain treated with custom-made foot orthoses, and that reported levels of forefoot pain after the use of orthoses. The data consisted of patient demographics, pathologies related to forefoot pain, type of foot orthoses used, follow-up period and clinical outcomes.

Results: Nine studies were selected which had a total of 487 participants. The pathologies evaluated were rheumatoid arthritis, hallux abductus valgus and isolated and secondary metatarsalgia. The use of custom-made foot orthoses was the intervention that exerted the most significant reduction of the level of pain in the forefoot in most of the studies.

Conclusions: the use of custom-made foot orthoses improved the level of forefoot pain in rheumatoid arthritis, hallux abductus valgus and secondary metatarsalgia as it increases sole pressures.

Keywords (MESH): Pain; foot; forefoot; foot orthoses.

Introduction

Foot pain is defined as the unpleasant emotional experience associated with the perception of damage in the tissues under the heel.[1] Its prevalence is very high: Benvenuti et al. reported a prevalence of 83% in a survey of 459 subjects 65 years or older.[2] It entails limitations of daily life activities, and the inability and deterioration of the physical aspects related to quality of life.[1]

Metatarsalgia is described as a pain in and around the metatarsal heads, the metatarsal phalangeal joints and the surrounding soft tissues.[3] It is calculated that at least 80% of people suffer from it at some time in their life.[4] It is predominant in women, with 88.5% of cases.[5] Primary metatarsalgia is idiopathic and mainly due to degenerative changes and age. Secondary metatarsalgia is associated with metabolism, neurological and post-surgery events, inflammatory arthropathy, traumatisms, tumours, infections or compensation of rearfoot deformities. The pain can be connected with the forefoot's relative pressure. The isolated problem is called primary or pressure metatarsalgia.[3, 6]

Many patients can be treated successfully via foot orthoses.[6] Cushioning in the metatarsal zone, forefoot padding, molded insoles and metatarsal bars are mainly used for forefoot pain.[3] Foot orthoses are a form of mechanical treatment which is widespread as conservative care for a type of pain which mainly takes place when walking or running.[1] A foot orthosis is an external orthotic device which, applied to the plantar surface of the foot, is able to modify the foot function, posture and/or structure. It can therefore be used for different purposes.[7, 8]

There are many types of foot orthoses available: standard, custom-made, modifiable or with components. Custom-made orthoses are defined as those with a form which can be extracted from the footwear and that are molded or manufactured using footprints or foot casts, and made in accordance with a clinician's specifications.[1] Standard or non-rectifiable prefabricated orthoses are made from a standard pattern. Their size varies according to that of the footwear.[7]

Many studies have been carried out to test the effectiveness of custom-made foot orthoses in people who had metatarsalgia. Different authors have checked that this treatment was efficient in diverse types of metatarsalgia [3], from secondary to rheumatoid arthritis (RA) [9–12], associated with Hallux Valgus (HAV)[1, 13], and related to flat feet in childhood.[14] Other authors have concluded that this type of treatment was not efficient in painful HAV.[13, 15]

In this work, a systematic review of studies which were focused on the effectiveness of treating forefoot pain via custom-made foot orthoses was carried out, with the aim of determining the existing evidence about the results of this kind of treatment.

The research or PICO question was defined, focused on both the clinical intervention objective and the population of interest of this study: *"Are custom-made foot orthoses effective in people with forefoot pain or a painful forefoot pathology?"*. Then, the necessary search strategy was developed.

Methods

Identification, eligibility criteria and selection of studies:

This systematic review was registered in PROSPERO. The title chosen was "Effectiveness of custom-made foot orthoses for the treatment of forefoot pain", and the registration number assigned "42016038899". The following databases were searched: MEDLINE, CINAHL, The Cochrane Library and PEDro.

The searches were conducted in October 2016, after designing the strategies to be used in the different databases selected and after carrying out a series of pilot tests to check the correct execution of the process in each of them. The search strategy used can be consulted in appendix 1.

The identification of the random clinical tests in MEDLINE was first performed using the Cochrane search strategy for PubMed, which maximises sensitivity ("*Cochrane Highly Sensitive Search Strategy: sensitivity-maximizing version*").[16] However, due to the high number of references recovered, we decided to use the version which maximises sensitivity and precision ("*Cochrane Highly Sensitive Search Strategy: sensitivity- and precision-maximizing version*").[16] In CINAHL, only the filter of "controlled random tests" was applied. In The Cochrane Library, the "Trials" filter was selected. Lastly, in PEDro, four drop-downs of the thirteen sections available for doing the search were selected, using the Boolean search "AND" among them.

Neither the year of publication nor the language of the documents was limited in any of the documents. With PubMed, CINAHL and The Cochrane Library databases, whenever possible, the descriptors corresponding to the terms of interest were used, as well as the free terms. In all of them the advanced search tool to construct the strategy was employed.

The inclusion criteria were: randomised controlled clinical trials (RCCTs), with participants of any age, sex, race or ethnicity, any kind of job position and physical or sports lifestyle, regardless of medical history and current health issues, who showed pain in the forefoot, disregarding the etiology underlying the pain and the characteristics of the symptoms (location, type and duration). Any kind of comparison between interventions was valid, as long as one of them consisted in the prescription, manufacture and application of custom-made foot orthoses, regardless of the way in which the shoe lasts, measurements or references were taken for their fabrication, the types of material used, and the procedure of manufacture and adaptation of the orthoses to the foot and footwear of the participants of the studies. The use of another complementary pharmacological, orthotic and/or physical treatment was not a reason for exclusion, although this was taken into account in the analysis of the data. The type of results that the studies were required to report was the level of pain in the forefoot after the use of the foot orthoses. Studies that, in addition to this, reported another type of result, such as the level of functional capacity,

quality of life or satisfaction of the patient after the use of the foot orthoses, were not excluded.

Assessment of characteristics of studies:

The selection process was carried out by two independent reviewers (IAM and MRB). Each of them evaluated that the reports compiled fulfilled the inclusion criteria defined in the systematic review, or were excluded for being evidently irrelevant. To do so, the title and abstract of each of the documents were read. Each reviewer independently evaluated the main characteristics of the studies described in them, pointing out if these coincided or not with the eligibility criteria:

- Study type: whether it was, was not clear or was not, a random clinical study, a quasiexperimental, cohort, control-case, descriptive study, or whether it was a different type of study.

- Participants: whether they fulfilled the inclusion criteria or not, or whether this was not clear.

- Interventions: whether the type of intervention or interventions carried out fulfilled or not the inclusion criteria, or whether this was not clear.

- Comparisons: whether the type of comparison or comparisons carried out fulfilled or not the inclusion criteria, or whether this was not clear.

- Outcomes: whether the type of result or results measured fulfilled or not the inclusion criteria, or whether this was not clear.

After this first selection, the complete reports were sought, this time using a sole reviewer, as finally only studies in scientific journals were selected. In both evaluations, the non-fulfillment of a single criterion of eligibility was enough reason to exclude the study. This way, after the first

negative item appeared, each reviewer could exclude the study without the need to continue valuing the rest of it.

Reasons for exclusion were those studies which did not surpass the eligibility criteria described and/or whose level of methodological quality was doubtful. The risk of bias assessment in the studies was carried out using the tool Review Manager (RevMan) of The Cochrane Library, v.5.3. Likewise, any study selected could have been omitted from the review if, during the data extraction, information had been found which justified its exclusion, such as, in the end, not fulfilling the inclusion criteria defined, or if there were suspicions about the methodological quality used, among others. Studies in which the participants did not have forefoot pain were excluded, as well as those which did not use custom-made foot orthoses, or used them as a preventative or post-surgical compensatory treatment without there being forefoot pain. After obtaining them, a complete reading was carried out, again independently, of the documents selected by each of the previous reviewers. In the complete reading we valued anew their eligibility according to the strict fulfillment of the inclusion criteria originally described, which was necessary for the study to be finally selected for review.

Data extraction:

Due to the high number of references dealt with, to facilitate the first selection process, an Excel sheet was designed as a data collection form in which, via a codification of the items (criteria) to evaluate, the inclusion or non-inclusion of the report and the reason for its exclusion were registered. Each reviewer handled his/her own sheet.

Having carried out the first evaluation of the reports, their results were pooled and the inclusion or exclusion of the incompatible documents was discussed. That is to say, those which had been selected by only one of the reviewers, without the need of requiring the opinion of a third evaluator to decide on the definitive inclusion or exclusion of them in the following review phase.

For the second evaluation of reports, a Word format data collection form was designed to note the general information referring to the study, both its identification (ID study or report) and its main characteristics (type of participants, interventions, results, etc.), again focused on the fulfillment of the eligibility criteria described in the review.

This evaluation was based on the complete reading of the documents selected in the first sift. Their inclusion or eventual exclusion from the review was once more discussed by the two initial reviewers, but, on this occasion, the intervention of a third reviewer (PVMM) was necessary to decide the final inclusion or exclusion of some of the documents due to the lack of agreement between the first two reviewers.

Lastly, a sole reviewer (IAM) carried out the complete extraction of the data of the documents eventually selected in the second evaluation. To do so, a continuation of the Word format data collection initial form was designed.

The Word forms were based on the translation and adaptation of the existing model designed by The Cochrane Collaboration for RCTs.[16]

Results

The different stages of the selection process of the studies finally included in the review are shown in Figure 1, for which a flow diagram was used, based on the one established by the PRISMA declaration.[16–18] The design of the PICO question was based on the study selection criteria [16, 19, 20] (table 1). A summary of the data extracted corresponding to the most important characteristics of the main sections of each study is shown in Table 2. The risk of bias in the studies included is shown Figures 2 and 3.

Of the nine studies included, eight were parallel RCTs [3, 6, 9–11, 13–15] and the other was a cross-over RCT [12]. The whole follow-up period range among all the studies oscillated between 1 month and 4 years. The total number of *participants* in all the studies was 487 (84 men and 403 women). The age ranged from 8.3 ± 4.4 to 72.0 ± 2.03 years old. Only one study solely included children [14]; the rest were conducted on adults. Custom-made foot orthoses were used as *intervention* for the treatment of forefoot pain in people with rheumatoid arthritis (RA) [9–12], osteoarthritis [12], hallux abducto valgus (HAV) [13, 15] and metatarsalgia [3, 6, 14]. In the case of metatarsalgia, two of the studies valued isolated metatarsalgia [3, 6], although one of them also included metatarsalgia associated with HAV, or after first radius surgery [6]. The other studied secondary flat foot metatarsalgia in children [14]. There were seven types of *comparisons* used with custom-based sole orthoses: standard foot orthoses [6, 11], wide fitting footwear[3, 9, 11, 13] silicone digital orthoses [12], night splints [13], surgery [15], pain relievers [14] and nothing [15]. Different *outcomes* were evaluated in each study. In all of them pain was valued, but so were other variables, such as foot function [9, 11, 12], gait [10, 12], therapeutic adherence [6, 9], sole pressures [3, 6, 12], disability [12, 15], foot angles [13, 14], illness perception and improvement shown [6, 11] and satisfaction with the treatment and quality of life [15], among the most outstanding, as can be noted in the previous table. Depending on the study, diverse measurement or evaluation instruments or tools were used to evaluate the results. Regarding pain, the Visual Analog Scale (VAS) [6, 9–11, 13, 15], the sub-section for pain valuation of the Foot Function Index or "FFI" questionnaire [12], and the AOFAS scale [14] were used in most of the studies, and a questionnaire designed exclusively for its use in one of them [3].

To better show the analysis of the different studies in the review, these were grouped according to the characteristics of the participants, specifically based on the similarity of the pathology or health problem present in the forefoot into three groups: a group of participants

with rheumatoid forefoot pain, a group of participants with secondary forefoot pain with HAV, and a group of participants with isolated or secondary metatarsalgia.

Regarding rheumatoid forefoot pain, in 2000, Chalmers et al. [9] compared the effects of semi-rigid and soft sole orthoses in physiological footwear and only the use of footwear on patients with forefoot pain and RA. Twenty-four patients participated for 12 weeks and a cross-over study was carried out. The semi-rigid orthoses were an effective treatment for metatarsalgia. The use of only footwear or soft orthoses did not bring about a decrease of the symptomatology. A *p* value of 0.006 was described when this was compared with the use of custom-made orthoses manufactured with soft materials and the use of wide footwear with good contention alone. Also, it was shown that the effect produced on the difference of the pain level between the beginning and the end of the study was very high in those patients who had the intervention of semi-rigid orthoses ($p = 0.0004$).

In 2014, Bongi et al. [12] carried out a study on the effectiveness of two protocols that combined polypropylene soles with silicon orthoses for the toes in 24 women with RA and osteoarthritis. They concluded that the use of foot orthoses and silicones is efficient in forefoot pain. This was significantly reduced after the use of a semi-rigid foot orthosis, again made with a thermoplastic material as the main element ($p < 0.001$).

In 2004, Mejjad et al. [10] carried out a study to assess the efficiency of orthoses in 16 patients with RA and painful forefeet. The sole orthoses increased the level of comfort by reducing pain, but not sufficiently to correct the gait. The use of a custom-made foot orthosis manufactured from a semi-flexible material (in this case a foam) significantly reduced the level of forefoot pain when walking ($p = 0.008$).

The weakest results were those of Cho et al.'s study in 2009 [11]. They carried out a controlled clinical trial to determine the effect of custom-made semi-rigid orthoses and a standard orthosis

combined with specialised footwear in 42 women with RA during 6 months. In both groups the pain decreased and the foot function increased, although no significant differences were found between the two treatments. Likewise, no significant differences were found when the type of foot orthosis was compared to determine which reduced pain forefoot the most - whether it was the custom-made semi-rigid or the soft standard. However, when the average values corresponding to the decrease of pain were noted according to the intervention applied, it could be seen that the score obtained in the VAS scale was lower for the standard orthosis (31.3 ± 17.0), which meant that the participants expressed less pain, although the score was similar to that obtained for the custom-made orthoses (32.5 ± 24.2). It was also seen that the score range was again greater with the standard orthosis (-19.2 ± 16.7) than with the custom-made ones (-12.2 ± 26.9), thus the former achieved a more significant effect.

Regarding the forefoot pain secondary to HAV, contrary to the previous group, the intervention with the best statistical results of the studies corresponded to one that did not use a custom-made foot orthosis. In 2003, Torkki et al. [15] carried out a study of the effectiveness of surgery, foot orthoses and observation without therapeutic intervention in an RCT of painful HAV. After 12 months, the decrease of the intensity of pain was greater in the surgery group. After 2 years of follow-up, a reduction of the level of forefoot pain was similar in all the groups. Many of the results were shown to be positive in all the groups; in fact, they were mostly similar. Nevertheless, satisfaction with the treatment was greater in those who underwent surgery, and the problems derived from aesthetic appearance and those related to the footwear stemming from the pathology decreased considerably more in this group than in the rest, especially during the first year of treatment, as has been commented. The results of the valuation of quality of life were very similar in all the groups, although they were slightly better in the surgery and orthosis groups.[15]

In 2008, Tehraninars et al. studied the effect of foot orthoses with a digital separator and a night splint in patients with painful HAV. After three months, the deformity decreased in both groups, although not significantly. The orthosis with a separator significantly decreased the pain intensity. The study showed significant differences between the two groups ($p < 0.05$), with better results being obtained in the orthosis group than in the night splint group. The foot orthosis was semi-rigid. The materials used to make it were thermoplastic (polyethylene) for the orthosis body and a polyethylene foam on it which covered the upper surface.[13]

With respect to the group of patients with isolated metatarsalgia, the results obtained in the studies were positive in relation to the use of custom-made foot orthoses, but certain matters were appraised as always. In 2013, Sinha et al. [14] valued the effect of foot orthoses in 81 children with flat feet. There was a check-up every 3 weeks. In the treatment group the correction of the flat foot and the forefoot, midfoot and rearfoot pain level improved. To this effect, the administration of pain relievers in another intervention group was used as a comparison. In the two groups, the results were statistically very significant ($p < 0.001$), with the two interventions reducing pain alike in the participants.

In 1998, Postema et al. [3] analysed the effectiveness of sole orthoses in 42 patients with metatarsalgia using standard and custom-made orthoses, with or without metatarsal bar insoles. Although they focused especially on the analysis of the plantar pressures, they also evaluated the change in the pain level with each of the interventions applied, noting statistically significant differences between the use of a custom-made sole orthosis and a standard one ($p < 0.001$) in those patients who expressed forefoot pain during the study. This was irrespective of whether the shoe used had a rocker or not. Furthermore, the participants who felt pain preferred to use a custom-made orthosis over a standard one ($p = 0.001$).

Lastly, in the study of Kelly & Winson [6], the use of a “semi-custom-made” foot orthosis was indicated, although for the review it was considered that it was custom-made, as the layout of

the elements that it was made of was individualised to be adapted to each of the participants who used it. Polyethylene foam was used to make it (although its stiffness and density is unknown) and a retrocapital unloading was added to it (to decrease the pressure of the central metatarsals at the distal level), along with a posted orthosis at the rearfoot level, which was placed according to the orthopedist´s judgment. The report only showed descriptive values for the data related to the evaluation of the pain levels. It indicated that the reduction was greater in the participants who used a custom-made orthosis (a decrease of 15.4 ± 16.0 points in the VAS scale) instead of a standard one (a decrease of 13.6 ± 23.3). The plantar pressures were also evaluated; a greater reduction at the forefoot level with respect to the rearfoot level was noted in both intervention groups (custom-made and standard orthoses), with that in the group that used custom-made orthoses being more significant ($p < 0.001$).

Discussion

The aim of this systematic review was to answer the question of whether the use of custom-made plantar orthoses in patients with forefoot pain was effective. This objective arose from the fact that forefoot pain is the most frequent reason why patients go to the Orthopaedics Unit of the Clinical Area of Podiatry at the University of Seville (Spain). Due to the scarcity of studies found about this topic in the literature, the realisation of a systematic review was proposed, with the aim of gathering as much information as possible with a high level of evidence, related to this health issue. Nine studies met the inclusion criteria and, therefore, they were included in the review for analysis. Due to the apparent heterogeneity observed among them regarding the characteristics of the participants, the interventions performed, and the use of different instruments for the evaluation of the results, it was decided to carry out the qualitative synthesis of the results.

296 It was observed that the studies included could be grouped into 3 groups according to the
297 characteristics of the participants: those with rheumatoid forefoot pain, those with forefoot pain
298 secondary to HAV, and those with isolated metatarsalgia or secondary to another pathology.

299 Within the group of participants with rheumatoid forefoot pain, the results concerning the
300 level of pain with the greatest statistical significance were those described in the studies by
301 Bongi [12], Chalmers [9]and Mejjad [10]. The first two noted the positive effect of the use of a
302 custom-made, semi-rigid sole orthosis fabricated mainly with thermoplastic materials.
303 According to the results of these studies, it may be stated that the use of a custom-
304 made foot orthosis in patients with rheumatoid forefoot pain can significantly reduce
305 the painful symptomology located in the forefoot. Also, for the custom-made foot
306 orthosis to be effective this must be semi-rigid and at the same time have a high
307 cushioning capacity of the main material of the orthosis itself, or via the use of other
308 elements and/or materials. It is worth mentioning that the use of a digital orthosis as a
309 complementary treatment to the custom-made foot orthoses could help reduce the
310 level of forefoot pain even more in people with this type of pathologies when its use is
311 considered necessary.

312 Regarding forefoot pain with HAV, although the efficacy of surgery in the short term for this
313 health problem is still shown in Torkki et al's study [15], we must evaluate the intervention of
314 interest for the review. On this occasion, only the main material used to manufacture the foot
315 orthosis is known; neither its characteristics, nor whether it also had some kind of element
316 and/or material integrated into it, has been specified. Although the results obtained with the
317 orthoses were slightly better than those achieved with the control group, both behaved in a
318 similar manner. This could be due to the lack of cushioning provided by the orthoses if it was
319 exclusively made of polypropylene, a rigid thermoplastic that, in spite of being more flexible and
320 elastic than others, has a strong stiffness. This is why, in spite of generating some kind of indirect

effect on the forefoot, which would decrease the pain level by controlling other structures that are different but related to it (the reduction of the plantar pressures, for example, or simply a placebo effect), it is considered that the participants' forefeet of this intervention group were exposed to practically the same conditions as the control group. Thereby, this would justify such similar results between the two groups. Another question arose at the end of the study, when, after a first evaluation in favour of surgery, at the last moment the three groups showed equivalent results. The swift visible improvement at first by the group that had surgery can be understood logically as being due to the cause that produced the pain having been completely eliminated. However, the lack of later orthotic compensation and, especially, of a cushioning support in the forefoot exposed it again to the same situation as was previously described. This is why, perhaps, if a different design for the foot orthosis had been chosen, one more focused on alleviating the forefoot symptomology, the results of this intervention would have been more relevant.[15]

From the study by Tehraninars et al [13], it can be highlighted that an integrator element in the foot orthosis acts in the same way as would an exclusively interdigital orthosis. Therefore, in this group of participants two interventions at once would be valued and not one, and the results would correspond to the sum of them and not just to the use of the foot orthosis. Based on this fact, it may be said that the use of both interventions at the same time improves the level of forefoot pain in people with HAV, or that the use of an interdigital separator is considered a good option to complement the treatment with the foot orthosis. This is because, in spite of not having been valued independently, the effectiveness of the foot orthosis very probably helps to decrease the forefoot pain level due to its characteristics [13].

In the third group, the good results obtained by Sinha et al [14] with the orthoses were probably due to the functional control and the sustaining of the structures achieved. Also, although administering pain relievers also attained significant changes in the pain levels, it is advisable to

346 value the fact of opting for the action that is least harmful for health when the benefit is the
347 same. Consequently, the use of foot orthoses instead of pain killers would be a good long-term
348 choice [14]. Notwithstanding, given the participants' characteristics and the clear identification
349 of the pathology that caused the pain, it is difficult to extrapolate and compare the results of
350 Sinha et al.'s study with the rest of the studies, both for the analysis group and the review group.
351 The foot orthosis used was rigid. The type of thermoplastic it was made of is unknown. The aim
352 was to limit the movement of the subtalar and midfoot articulation.

353 Postema et al [3] showed the relationship between the increase of plantar pressures and
354 metatarsalgia. This is why the effectiveness of foot orthoses is justified if these achieve the
355 redistribution of plantar pressures and the alleviation of the peaks where the maximum values
356 are attained. On the other hand, the type of custom-made orthosis and the materials used in
357 this study are unknown, although their elements and measures are described. Due to this, we
358 know that the aims were to control the movement at the forefoot level by its medial part and
359 to unload the central metatarsals in order to alleviate plantar pressure in this area. This
360 information, along with the significant data obtained in the study regarding the decrease of pain
361 and plantar pressures in the forefoot ($p < 0.000$ for the 2^{nd}. and 3^{rd}. metatarsals, and $p = 0.03$
362 for the 4^{th}. and 5^{th}. metatarsals), shows the relationship between plantar pressure and
363 metatarsalgia. The relation between metatarsalgia and the presence of peaks of plantar
364 pressures at the forefoot level is evident, as sustained by Postema [3], and Kelly and Wilson [6].
365 This is why the authors of the present review support the idea that the use of custom-made foot
366 orthoses that achieve better distribution of body loads to alleviate the excess of pressure in the
367 forefoot via elements of metatarsal unloading and control of structures, probably decreases
368 forefoot pain.

369 This study has certain limitations. One of them was the lack of specification when describing the
370 main outcome at the forefoot in some studies. This reason was decisive for the exclusion of

some of them from the review. Other studies also had to be excluded due to the absence of a final evaluation of this result. The absence of an explicit description of the interventions carried out in the studies also posed a limitation when detailing their characteristics in the case of results that achieved positive effects. Moreover, the use of different tools or measurement instruments of the results among the studies included was the reason why the comparison and synthesis of those obtained about pain had to be performed qualitatively.

This review opens the possibility of continuing with the research, for example, by extending the literature search designed to other parts of the foot, or focusing it on one or several specific pathologies. Nonetheless, we think that a logical open line is to carry out a quantitative synthesis of the data (meta-analysis). One of the limitations found was the use of different measurements of results to evaluate the same variables among the studies. This is why an attempt will be made to locate some kind of tool or instrument to convert the measurement units of the results that helps increase homogeneity. It will thus be possible to make comparisons between the different interventions with statistical methods that show the real size of the effect. More clinical trials (RCT) should be done related to pathologies that cause forefoot pain and its treatment via the use of sole orthoses, as the scientific evidence found is scant.

Conclusions

The use of custom-made foot orthoses improved the level of forefoot pain in different pathologies or health problems, such as rheumatoid forefoot pain, hallux abductus valgus and secondary metatarsalgia due to the increase of sole pressures. Semi-rigid custom-made foot orthoses that cushion the foot have been effective in people with rheumatoid forefoot pain, or forefoot pain associated to HAV. The use of a digital orthosis along with a custom-made foot orthosis in these patients can help decrease forefoot pain even more.

Custom-made foot orthoses that facilitate the redistribution of pressures in the metatarsal zone and control foot structures have been effective in people with secondary metatarsalgia due to an increase of the sole pressure in the forefoot.

Conflict of Interest

IMAM, MRB, and PVMM declare that they have no conflict of interest.

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