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Hallux Valgus Orthosis Characteristics and Effectiveness: A Systematic Review with Meta-analysis

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Abstract

Objective The design of orthoses for hallux valgus (HV) involves multiple complex factors, and therefore a systematic analysis of their properties is necessary. The objective of this systematic review and meta-analysis is to determine whether current foot orthoses are effective in treating HV, and to investigate the associated orthosis characteristics.

Design Systematic review with meta-analysis.

Data sources Electronic databases (PubMed, Scopus, Cinahl and Medline) are searched to February 2020.

Eligibility criteria for selecting studies Cross sectional studies with content focus on HV orthosis design and any of the outcomes related to effectiveness for treating HV are included.

Results In total, 2066 articles are identified. Among them, 9 are selected and quality rated, and data are extracted and closely examined. A meta-analysis is conducted where appropriate. The results show that a full-length orthosis with a toe separator has the best effect of correcting the hallux valgus angle (HVA), with a reduction of 5.79° (SMD 0.85, CI 0.13, 1.54). Orthoses with a toe separator can significantly reduce foot pain (SMD 1.13, CI 0.34, 1.87). Both full-length (SMD 0.47, CI -0.10, 1.03) and 3/4-length (SMD 0.45, CI- 0.12,1.01) orthoses can significantly reduce the plantar pressure in HV patients.

Conclusion The full-length orthoses design with a toe separator or an element that allows for the foot anatomic alignment is critical for reducing the HVA and relieving foot pain.

Strengths and limitations of this study

- This systematic review with meta-analysis represents, to the best of our knowledge, the most comprehensive examination of the evidence for the characteristics and effectiveness of orthosis in the treatment of hallux valgus.
- The results show that evidence is scarce and that very few studies have analyzed the characteristics and effectiveness of hallux valgus orthoses, and there is limited information on the materials of the orthotics studied.
- The results can highlight the design features and their relevance to HVA correction and pain relief.
- Future research should focus on the material properties of HV orthoses in order to provide effective solutions for the effective and optimal design of HV orthoses.

Introduction

Hallux valgus (HV) is a common foot deformity, estimated to affect 23% of adults and 35.7% of the elderly [1]. It is characterized by the hypermobility and pronation of the first metatarsal ray, which eventually lead to subluxation and pain of the first metatarsophalangeal joint [2]. The hallux valgus angle (HVA) is used as an indicator to objectively measure the degree of the deformity. An HVA ≥15° is a formal diagnosis of HV [3, 4]. The intermetatarsal angle (IMA) is another common measurement used to diagnose HV. An IMA <9° is considered to be a normal value, while 9-17° is mild to moderate, and ≥18° is severe [4]. HV is not only a prevalent and debilitating condition amongst the general public, especially women, due to hereditary or improper footwear but also a significant burden on public health care with the high demand for foot surgery [5], and its association with foot pain [6-9], which can inhibit the level of mobility and physical activity of those who suffer from the deformity [2]. This is especially devastating to athletes, who may acquire the condition due to prolonged periods of training. Previous research work has found that 9.3% of the Muay Thai kickboxers in their study suffer from HV [10-12]. Schöffl and Küpper [12] and Killian et al. [13] found that tight climbing shoes exert high pressure load on the forefoot which affects 53% of the long-term high-level climbers. Steinberg et al. [14] found that 40.0% dancers have bilateral HV and 7.3 % have unilateral HV. Contributors to the development of HV include the individual body structure, joint range of motion (ROM), anatomical abnormalities and extensive dance exercises that expose the spine and the lower limb joints to high loads and strains [14-16]. Former ballet dancers (73.7%) were also found to have a significantly higher HV incidence rate than the control group (2.6%) [15].

Extreme cases of HV require surgical intervention, but the recurrence rate is high. Surgical operations may reduce the subsequent mobility of the big toe, and the impact on athletes can be devastating [2]. Hence, studies have shown that treatment of HV in athletes should be as conservative as possible [10]**.** The complications related to HV surgical correction such as nerve damage also discourage surgery [17-21]. Therefore, non-surgical conservative treatments such as the use of foot orthoses have become a viable and popular option for HV patients to correct their foot deformity and relieve foot pain [17, 22]. As described by Charrette [23], HV orthoses act as a means of biomechanical support to reduce the pressure on the first metatarsal joint which would prevent further degeneration of mobility.

HV orthoses are available in a wide range of design features and materials. Ready-made and custom-made are the two main types of foot orthoses [24]. While the former are available online or in retail stores and made from standard patterns, the latter are constructed by using footprints or foot molds based on specifications of the clinician [25]. They may or may not have a toe separator, can have different lengths and made of different materials. The design of HV orthoses is multi-factorial, however, previous related studies have merely focused on the effectiveness of foot orthoses in HV patients. There has been very little work that systematically analyses the biomechanical parameters for the design of HV orthoses. The effects of different orthosis design features and material properties on foot support and control performance have not been fully reported in the field. A systematic review and meta-analysis should be carried out in a timely manner to determine available evidence on the outcomes of this conservative treatment through which practitioners can gain insights into how design decisions affect the performance of HV orthoses. This article conducts a systematic study to investigate the relationship between the elements and effectiveness of these orthoses, and quantitatively synthesizes the results based on the best available evidence. The results can provide reference for the clinical selection and future design trends of orthotics to achieve better treatment effects.

Methods

Search methods for identification of studies

Research articles published in peer-reviewed journals that describe the construction of HV orthoses and/or their effectiveness were searched on PubMed, Scopus, Cinahl and Medline for all years available up to February 2020. A highly sensitive search strategy was used and is reported in Table I. The keywords include "hallux valgus", "orthosis", "design", "fabrication", "construction", "pressure", "gait", "alignment", "pain" and "walking speed".

Table I List of search strategies

Search strategy
1. ("Hallux Valgus" AND (Design OR Fabrication OR Construction)) NOT (Implant OR Replacement)
2. ("Hallux Valgus" AND (Orthoses OR Orthosis) AND (Design OR Fabrication OR Construction)) NOT (Implant OR Replacement)
3. ("Hallux Valgus" AND (Orthoses OR Orthosis) AND Pressure) NOT (Implant OR Replacement)
4. ("Hallux Valgus" AND (Orthoses OR Orthosis) AND Gait) NOT (Implant OR Replacement)
5. ("Hallux Valgus" AND (Orthoses OR Orthosis) AND Alignment) NOT (Implant OR Replacement)
6. ("Hallux Valgus" AND (Orthoses OR Orthosis) AND Pain) NOT (Implant OR Replacement)
7. ("Hallux Valgus" AND (Orthoses OR Orthosis) AND "Walking speed") NOT (Implant OR Replacement)
8. ("Hallux Valgus" AND (Orthoses OR Orthosis) AND (Design OR Fabrication OR Construction) AND Pressure) NOT (Implant OR Replacement)
9. ("Hallux Valgus" AND (Orthoses OR Orthosis) AND (Design OR Fabrication OR Construction) AND Gait) NOT (Implant OR Replacement)
10. ("Hallux Valgus" AND (Orthoses OR Orthosis) AND (Design OR Fabrication OR Construction) AND Alignment) NOT (Implant OR Replacement)
11. ("Hallux Valgus" AND (Orthoses OR Orthosis) AND (Design OR Fabrication OR Construction) AND Pain) NOT (Implant OR Replacement)
12. ("Hallux Valgus" AND (Orthoses OR Orthosis) AND (Design OR Fabrication OR Construction) AND "Walking speed") NOT (Implant OR Replacement)

Inclusion and exclusion criteria

The titles and abstracts were then reviewed by 2 investigators. Full-text articles that assess HV orthosis designs or any of the outcomes related to the effectiveness of HV orthoses were then retrieved for detailed evaluation. The retrieved items were screened based on a two-stage selection process which subsequently considered the titles, abstracts, and full text. Assessment of the study eligibility was performed by one investigator.

Quality assessment and risk of bias

The included papers were assessed for methodological quality. The title, journal name, and author details were removed to anonymize the articles prior to the rating process. Quality rating was performed by using the Epidemiological Appraisal Instrument (EAI) [26-29], which has been validated for the assessment of observational studies. Thirty-one items from the original EAI were used, after removing those that are related to interventions, randomization, the follow-up period, or loss to follow-up that are not applicable to cross-sectional studies. Items were scored as “No” or “Unable to determine” (score = 0), “Partial” (score = 1), “Yes” (score = 2), or “Not Applicable” (item removed from scoring process) and an average score across all items was calculated for each study.

Data management

One investigator recorded the following details for all of the included papers: publication details (author, year, country, and study aim), sample characteristics (number of HV cases, number of control subjects, age and sex), study methodology (device, associated factors investigated, and orthosis wearing details) and result. The standardized mean differences (SMDs) and 95% confidence intervals (CIs) were calculated. To calculate the SMDs, the means and standard deviations (SDs) of pre-intervention and post-intervention [30], as well as the mean and SDs of the control and treatment groups were recorded [31]. The mean difference was divided by the pooled SD [32]. The SMDs are calculated with the following formulas:

1. $\text{SMDs}_{\text{intervention}} = \frac{\text{Mean of pre} - \text{intervention} - \text{Mean of post} - \text{intervention}}{\text{Pooled SD for the entire population}}$

2. $\text{SMDs}_{\text{group}} = \frac{\text{Mean of treatment group} - \text{Mean of control group}}{\text{Pooled SD for the entire population}}$

The interpretation of the SMDs was based on guidelines in previous studies: small effect ≥ 0.2, medium effect ≥ 0.5, and large effect ≥ 0.8 [29, 31, 33]**.** An SMD of "0" means that there is no difference in effect between the treatment and the control groups. SMDs that are "> 0" or "<0" indicate that one group is more efficacious than the other, and vice versa. SMDs are usually accompanied by 95% CIs to evaluate the reliability of the comparison [29, 31, 34].

Patient and Public Involvement statement

Patients and/or the public will not be involved in this study.

Results

Search results

The search strategy resulted in 2066 articles from PubMed, Scopus, Cinahl and Medline databases, with 1368 articles removed due to duplications. Then, the title and abstract of 698 articles were screened against the objective of the study, which resulted in the removal of 550 papers as they did not meet the requirements of the study design. The remaining 148 articles were assessed against the inclusion and exclusion criteria by examining the full text and were imported into the VOSviewer (version 1.6.13) to examine the trend of the results. Keywords with fewer than 3 occurrences were excluded, and general terms were filtered out so that the focus would be on more specific and informative terms [35]. Figure I(a) visualizes the results that amongst the 148 remaining articles, 18 keywords meet the threshold. The total link strength ranged from 26 to 71, with larger label denoting a higher total link strength. On average, the publication years of the articles ranged from 2010 to 2015, in which “male”, “patient satisfaction”, “foot orthoses” and “hallux valgus-therapy” are the latest research terms. After the assessment, another 89 articles were removed. The remaining 9 studies are discussed in this systematic review. Figure I(b) presents a PRISMA flow chart of the article selection process.

Figure I (a) Visualization of main keywords from 148 papers, and (b) Flowchart of study selection procedure

Study characteristics

The 9 studies selected for inclusion in this paper focused on various characteristics and included different demographics (Table II). The publication years of these papers range from 2002 to 2020. The studies evaluated the effects of 11 different types of HV orthoses on angle correction (IMA and HVA), plantar pressure, ROM, pain (Visual Analogue Scale (VAS) and Foot and Ankle Outcome Score (FAOS) -pain), function during daily activities (the American Orthopedic Foot and Ankle Score (AOFAS) and FAOS -function) and quality of life (Health-related quality of life index and FAOS -quality of life). The number of subjects who suffer from HV ranged from 16 to 69, with mild to moderate HV. Four of the studies involved control groups with 23 to 69 participants. Overall, the majority of the subjects are female.

Table II Selected characteristics of studies included in analysis (9 unique studies)

Authors(s)/ Country	Reference No.	Study aim	Method/ Device	N HV/ control	N male/ female	Age (Mean ± SD)	Orthosis	Orthosis material/ Wearing duration	Result
Chadchavalpanichaya et al. 2018/ Thailand	[36]	To investigate the effect of custom-molded room temperature vulcanizing (RTV) silicone toe separator to reduce HVA	Prospective randomized trial/ Radiographic measurement & clinical assessment	45/45	5/85	HV group: 60.3 ± 9.4 Control group: 60.8 ± 10.8	Custom-molded RTV toe separator	Silicone/ 12 months	Both groups have significant differences in mean HVA with a decrease of 3.3° ± 2.4° for the study group and increase of 1.9° ± 1.9° for the control group. Hallux pain of study group is reduced.
Doty et al. 2015/ USA	[37]	To compare the plantar pressure distribution in standard footwear and in the same footwear with orthoses of 3 different lengths	Case-control/ Tactilus Free Form® Sensor System	25/0	2/23	Mean: 57	Full-length orthosis Sulcus-length orthosis 3/4-length orthosis	NR/ Immediate	No significant changes in medial pressure with the addition of any orthosis compared with standard footwear alone
Farzadi et al. 2015/ Iran	[22]	To investigate the effect of orthosis with medial arch support on plantar pressure distribution	Quasi-experimental/ Pedar-X® in-shoe system	16/0	0/16	26.1 ± 5.7	Prefabricated arch support foot orthosis	5 mm thick polypropylene/ 1 month	The use of the foot orthosis leads to a decrease in peak pressure & maximum force
Moulodi et al. 2019/ Iran	[38]	To compare the HVA, ROM, FAOS, pain & function in daily activities after the use of orthosis	Case-control; clinical examination/ Goniometer	24/0	12/12	22.79 ± 1.44	Static orthosis with toe separator Dynamic orthosis	A bar & a single strap/ 1 month Firm plastic, straps & a free joint/ 1 month	Both orthoses can reduce HVA up to 2–3°; significant difference in ROM by using dynamic orthosis

Table II Continued

Author(s)/ Country	Reference No.	Study aim	Method/ Device	N HV/ control	N male/ female	Age (Mean ± SD)	Orthosis	Orthosis material/ Wearing duration	Result
Plaass et al. 2020/ Germany	[39]	To analyze the effect of a dynamic orthosis on IMA & HVA	Prospective randomized trial/ Radiographic measurement & clinical assessment	36/34	4/66	HV group: 53.2 ± 14.0 Control group: 48.5 ± 12.9	Dynamic orthosis	NR/ 3 months	Dynamic orthosis can provide pain relief in patients but showed no effect on HVA
Reina et al. 2013/ Spain	[40]	To determine if the use of custom-made foot orthotics prevents the advancement of IMA & HVA	Prospective trial using a repeated-measures design/ Radiographic measurement	23/23	0/54	HV group: 30.31 ± 9.27 Control group: 30.94 ± 14.06	Custom-made foot orthoses	3 mm thick polypropylene sheet & 3 mm thick polyethylene foam sheet/ 12 months	Custom-made orthoses appear to have no effect
Tang et al. 2002/ Taiwan	[41]	To assess the effects of a new foot-toe orthosis on HVA	Uncontrolled intervention study/ Radiographic measurement & clinical assessment	17/0	0/17	42.59 ± 16.52	Total contact orthosis with toe separator	Plastazote poron, microcell pull, plastazote & mineral oil–based polymer gel toe separator/ 3 months	The new total contact orthosis with fixed toe separator reduces HVA
Tehraninasr et al. 2008/ Iran	[42]	To compare the effects of wearing an orthosis with toe separator & nighttime orthosis on IMA, HVA & foot pain	Case control; x-ray examination/ Radiographic measurement	30/0	0/30	27 ± 8.91	Orthosis with toe separator	Polyfoam, polyethylene, plastazote toe separator/ 3 months	IMA & HVA are reduced in both groups; however, the reduction is not significant; the orthosis with toe separator significantly reduces the pain intensity
							Nighttime orthosis	Polyfoam & a rigid polyethylene bar/ 3 months	
Torkki et al. 2003/ Finland	[43]	To compare the effectiveness of surgical & orthotic treatment with patients on VAS & health-related quality of life index	Randomized controlled trial/ NR	69/69	8/61	HV group: 49 ± 10 Control group: 47 ± 9	NR	NR/ 12 months	Orthoses provide short-term symptomatic relief

Quality assessment and risk of bias

The inter-rater agreement on the EAI is 95% (14 disagreements out of 279 quality assessment items rated) across all included studies (9 papers). The individual study results for quality appraisal are shown in Table III. All of the studies defined the associated factors investigated and reported the sampling frame and statistical methods (9/9, 100%). Most studies clearly reported their aims and study design (8/9, 89%). More than half of the studies reported the inclusion criteria, sample characteristics, sample size calculations and statistical parameters (7/9, 78%; 6/9, 67%; 7/9, 78%; and 7/9, 78%, respectively). Few studies reported an attempt to blind the assessors towards the group allocation (1/4, 25%), although given the nature of HV deformities, blinding assessors is unlikely to be possible in most studies. No study fully considered confounding factors such as age and sex by using statistical adjustment techniques or comparing the case and control groups.

Reliability and validity were considered separately for both the HV assessment and measurement of the associated factors. Only a couple of the studies (2/9; 22%) provided a clear definition of HV by reporting angle values, another couple of studies (2/9; 22%) reported the reliability for the HV angle assessment, and only 11% (1/9) reported the validity of the HV assessment.

Table III Results of quality assessment of all included papers (9 unique studies) [a]

Author(s)	Chadchavalpanichaya et al. 2018	Doty et al. 2015	Farzadi et al. 2015	Moulodi et al. 2019	Plaass et al. 2020	Reina et al. 2013	Tang et al. 2002	Tehraninasr et al. 2008	Torkki et al. 2003	Studies scoring "Yes" (%)
Reference No.	[36]	[37]	[22]	[38]	[39]	[40]	[41]	[42]	[43]	
Q1. Reported study aim/objective clearly	Purple	Purple	Purple	Purple	Purple	Purple	Purple	Purple	Blue	**89**
Q2. Associated factors clearly defined	Purple	Purple	Purple	Purple	Purple	Purple	Purple	Purple	Purple	**100**
Q3. HV clearly defined	Blue	Purple	Blue	White	White	White	White	Purple	White	**22**
Q4. Reported study design	Purple	Purple	Purple	Purple	Purple	Purple	Purple	Blue	Purple	**89**
Q5. Reported sampling frame	Purple	Purple	Purple	Purple	Purple	Purple	Purple	Purple	Purple	**100**
Q6. Reported inclusion criteria	Purple	White	Purple	Purple	Purple	Purple	Purple	Purple	White	**78**
Q7. Reported participation rate	Purple	White	White	Purple	Blue	Purple	Blue	White	Purple	**44**
Q8. Reported sample characteristics	Purple	Purple	Blue	Blue	Purple	Purple	Purple	Blue	Purple	**67**
Q9. Reported statistical methods	Purple	Purple	Purple	Purple	Purple	Purple	Purple	Purple	Purple	**100**
Q10. Reported all basic data	White	White	White	White	White	White	Purple	White	White	**11**
Q11. Reported variability in data	Purple	White	Purple	Purple	Purple	Purple	White	Purple	Purple	**78**
Q12. Reported statistical parameters	Purple	Purple	Purple	Purple	Purple	Purple	Blue	Blue	Purple	**78**
Q13. Sample size calculations	Purple	Blue	Purple	Purple	Purple	Purple	Blue	Purple	Purple	**78**
Q14. Comparability of case/control groups	Purple	-	-	-	Purple	Purple	-	-	Purple	**100**
Q15. Adequate participation rate	Purple	Purple	Purple	Purple	Purple	Purple	Purple	Purple	Purple	**100**
Q16. Recruitment period for case/control groups	Purple	-	-	-	Purple	Purple	-	-	White	**75**
Q17. Non-responder characteristics described	White	White	White	White	White	White	White	White	White	**0**
Q18. Reliability of all associated factors	Purple	White	Blue	Purple	White	White	White	White	White	**22**

[a] Purple shading = "Yes", Blue shading = "Partial", White shading = "No" or "Unable to determine", "-" = "Not applicable"; that is, items removed from scoring process and not included in % calculations.

Table III Continued [a]

Author(s)	Chadchavalpanichaya et al. 2018	Doty et al. 2015	Farzadi et al. 2015	Moulodi et al. 2019	Plaass et al. 2020	Reina et al. 2013	Tang et al. 2002	Tehraninasr et al. 2008	Torkki et al. 2003	Studies scoring "Yes" (%)
Reference No.	[36]	[37]	[22]	[38]	[39]	[40]	[41]	[42]	[43]	
Q19. Validity of all associated factors				Yes						**11**
Q20. Standardized assessment of associated factors	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	**100**
Q21. Blinding of assessors	Yes	-	-	-	Partial		-	-		**25**
Q22. Reliability of HV assessment	Yes			Yes						**22**
Q23. Validity of HV assessment				Yes						**11**
Q24. Standardized assessment of HV	Yes				Yes	Yes	Yes	Yes		**56**
Q25. Assessment period for case/control groups	Yes	-	-	-	Yes	Yes	-	-	Yes	**100**
Q26. Collected data on HV severity/symptoms	Yes				Yes	Partial	Partial	Partial	Partial	**22**
Q27. Adjusted for covariates (sex and age)										**0**
Q28. Reported data for ≥ 3 levels of associated factors		Yes							Yes	**2**
Q29. Reported data for subgroups of subjects (e.g. by sex or age)										**0**
Q30. Generalizability of results to study population (participation rate)		Partial							Partial	**0**
Q31. Generalizability of results to other populations (random sampling)	Yes				Yes			Yes	Yes	**44**
Overall quality score (range 0 to 2)	**1.45**	**0.89**	**0.93**	**1.22**	**1.23**	**1.13**	**0.96**	**1.07**	**1.06**	

[a] Purple shading = "Yes", Blue shading = "Partial", White shading = "No" or "Unable to determine", "-" = "Not applicable"; that is, items removed from scoring process and not included in % calculations.

Overview of results from meta-analyses

Table IV provides the SMDs for individual studies in which 10 measurement factors before and after intervention in the HV group are compared. Six of the studies investigated the HVA. Tang et al. [41] stated that their full-length orthosis with a toe separator provides a significantly positive reduction of the HVA of 5.79° in the HV group (SMD 0.85, CI 0.13,1.54), which has the highest corrective effect among all the recorded orthoses. The static orthosis with a toe separator tested by Moulodi et al. [38] also showed a significant positive HVA correction of 2.67° in the HV group (SMD 0.75, CI 0.15,1.32). The dynamic orthosis tested also showed a significantly positive reduction of the HVA of 2.13° (SMD 0.55, CI -0.03,1.12) [38]. Chadchavalpanichaya et al. [36] developed a custom-molded RTV toe separator, which helps to correct the HVA by 2.1° in the HV group (SMD 0.41, CI -0.01,0.83). Two other studies, Plaass et al. [39] and Reina et al. [40], investigated the impact of the orthosis in terms of the IMA, but neither showed any significant results.

Three of the studies investigated the pain score with the use of two different types of rating scales. One of them, Tehraninasr et al. [42], showed that their orthosis with a toe separator can significantly reduce the pain level (SMD 1.13, CI 0.34,1.87). With the use of the VAS, Torkki et al. [43] also found that their orthosis can help to reduce pain (SMD 0.38, CI 0.04,0.72), however, they did not provide a description of the orthosis. The dynamic orthosis in Moulodi et al. [38] showed a positive impact on releasing pain (SMD -0.27, CI -0.83,0.31). The FAOS for pain is reduced by 4.28.

The quality of life and level of physical functioning before and after the application of an orthosis have also been compared. The orthosis in Torkki et al. [43] showed a positive effect based on the health-related quality of life index (SMD -0.31, CI -0.64,0.03), with an increase of the score by 2. The static orthosis with a toe separator and the dynamic orthosis tested by Moulodi et al. [38] showed a significantly positive FAOS for function with an increase of 6.25 and 4.51 points, respectively (static orthosis: SMD -0.36, CI -0.93,0.21; dynamic orthosis: SMD -0.25, CI -0.81,0.33).

The effects of foot orthoses on changes in the ROM have also been examined in the studies of concern. The dynamic orthosis tested by Moulodi et al. [38] showed a significant improvement in ROM with an increase of 9.77° (SMD- 0.52, CI -1.08,0.07). Two other studies investigated the impact of the foot orthosis on plantar pressure. Farzadi et al. [22] found that the prefabricated full-length arch support orthosis can significantly reduce the plantar pressure by 16.8 kPa (SMD 0.65, CI -0.08,1.34). Doty et al. [37] pointed out that the full-length and the 3/4-length orthoses result in a significant reduction of plantar pressure of 11.82 kPa and 10.37 kPa among HV patients, respectively (full-length orthosis: SMD 0.47, CI -0.10,1.03; 3/4-length orthosis: SMD 0.45, CI -0.12,1.01).

Table V provides the SMDs from five studies, which compare 4 measurement factors between the treatment and the control groups. The treatment group which was prescribed the custom-molded RTV silicone toe separator for 12 months showed a significant effect in reducing the HVA (SMD -0.46, CI -5,-0.23) [36]. The dynamic orthosis (halluxsan, Albrecht GmbH, Stephan-skirchen, Germany) worn by the treatment group can reduce both the HVA (SMD -0.22, CI -6.3,2.34) and IMA (SMD -0.22, CI -2.3,0.85) [39]. The customized orthosis developed by Reina et al. [40] also provided improvement in IMA (SMD -0.28, CI -1.8,0.67).

Observation of key design features

Customized vs. prefabricated

Among the orthoses that showed a significant reduction of the HVA after treatment amongst the HV patients, the orthoses developed by Chadchavalpanichaya et al. [36] and Tang et al. [41] are custom-made, while those in Moulodi et al. [38], Tehraninasr et al. [42], Torkki et al. [43], Doty et al. [37] and Farzadi et al. [22] are prefabricated. When comparing the treatment and control groups, the orthoses discussed by Chadchavalpanichaya et al. [36] and Reina et al. [40] are custom-made, while the orthosis in Plaass et al. [39] is prefabricated. This shows that the ability of an orthosis to reduce the severity of HV or its treatment effectiveness might not be related to whether it is customized or prefabricated. However, adjustment and fitting are still key factors, and patients are instructed to adjust the prefabricated orthosis to the best fitting position [39].

Static vs. dynamic

When comparing the treatment group and the control group, the use of both static and dynamic orthoses showed significant reductions of HV symptoms, and all of the static orthoses have a toe separator [36, 39]. In terms of HVA reduction, the results are consistent with those of the HV patients before and after the intervention. Both types of orthoses have a positive effect on treatment effectiveness, whilst all of the static orthoses that help to reduce the HVA are embedded with the feature of toe separator. Therefore, the toe separator seems to be the key element in correcting the misalignment of the big toe.

Considerations around orthosis length and arch support

In terms of the orthosis length, the full-length orthosis in Tang et al. [41] has a significant and exceptional corrective effect of HV in the HV group. The full-length orthoses in Farzadi et al. [22] and Doty et al. [37] can significantly reduce the plantar pressure. These results show that when considering the length of the orthosis for HV patients, full-length is preferred. Among these orthoses, only the orthosis tested by Farzadi et al. [22] provides arch support. It is anticipated that arch support may not be a mandatory design feature to achieve therapeutic effects.

Table IV Comparison of observations between pre- and post-interventions [a]

Parameter	Author(s)	Reference No.	Orthosis type	Pre-intervention			Post-intervention			Pooled SD	Mean Difference	SMDs	95% CIs	
				Mean	n	SD	Mean	n	SD				Lower	Upper
HVA	Chadchavalpanichaya et al. 2018	[36]	Custom-molded RTV toe separator	32.5	45	4.8	30.4	45	5.4	5.11	2.1	0.41	-0.01	0.83
	Moulodi et al. 2019	[38]	Static orthosis with toe separator	18.21	24	3.41	15.54	24	3.74	3.58	2.67	0.75	0.15	1.32
	Moulodi et al. 2019	[38]	Dynamic orthosis	17.96	24	3.75	15.83	24	3.94	3.85	2.13	0.55	-0.03	1.12
	Plaass et al. 2020	[39]	Dynamic orthosis	35.4	36	8.6	34.9	36	9.2	8.91	0.5	0.06	-0.41	0.52
	Reina et al. 2013	[40]	Custom-made foot orthoses	20.55	23	5.1	21.02	23	5.14	5.12	-0.47	-0.09	-0.67	0.49
	Tang et al. 2002	[41]	Full-length orthosis with toe separator	31.04	17	6.4	25.25	17	7.14	6.78	5.79	0.85	0.13	1.54
	Tehraninasr et al. 2008	[42]	Orthosis with toe separator	25.46	15	3.68	25.36	15	3.68	3.68	0.1	0.03	-0.69	0.74
	Tehraninasr et al. 2008	[42]	Nighttime orthosis	24.13	15	2.05	24.16	15	2.09	2.07	-0.03	-0.01	-0.73	0.702
IMA	Plaass et al. 2020	[39]	Dynamic orthosis	15.4	36	3	15.2	36	3.1	3.05	0.20	0.07	-0.40	0.53
	Reina et al. 2013	[40]	Custom-made foot orthoses	10.86	23	2.33	11.1	23	2.34	2.34	-0.24	-0.10	-0.68	0.48
FAOS-pain	Moulodi et al. 2019	[38]	Static orthosis with toe separator	85.28	24	12.24	87.49	24	12.29	12.27	-2.21	-0.18	-0.74	0.39
	Moulodi et al. 2019	[38]	Dynamic orthosis	81.61	24	17.41	85.89	24	14.5	16.02	-4.28	-0.27	-0.83	0.31
Foot pain VAS	Tehraninasr et al. 2008	[42]	Orthosis with toe separator	4.26	15	1.48	2.66	15	1.34	1.41	1.6	1.13	0.34	1.87
	Tehraninasr et al. 2008	[42]	Nighttime orthosis	4.13	15	1.78	4	15	1.13	1.49	0.13	0.087	-0.63	0.80
	Torkki et al. 2003	[43]	NR	50	69	24	41	69	23	23.51	9	0.38	0.04	0.72
Health-related quality of life index	Torkki et al. 2003	[43]	NR	91	69	6.9	93	69	6.1	6.51	-2.00	-0.31	-0.64	0.03

[a] SMDs ≥ 0.2 or ≤ -0.2 are highlighted in yellow; SMDs ≥ 0.5 or ≤ -0.5 are in orange, SMDs ≥ 0.8 or ≤ -0.8 are in green

Table IV Continued [a]

Parameter	Author(s)	Reference No.	Orthosis type	Pre-intervention Mean	n	SD	Post-intervention Mean	n	SD	Pooled SD	Mean Difference	SMDs	95% CIs Lower	Upper
FAOS-Quality of life	Moulodi et al. 2019	[38]	Static orthosis with toe separator	66.14	24	16.68	67.44	24	16.48	16.58	-1.30	-0.08	-0.64	0.49
	Moulodi et al. 2019	[38]	Dynamic orthosis	65.1	24	16.78	65.88	24	15.63	16.22	-0.78	-0.05	-0.61	0.52
FAOS-Function	Moulodi et al. 2019	[38]	Static orthosis with toe separator	78.47	24	18.7	84.72	24	15.47	17.16	-6.25	-0.36	-0.93	0.21
	Moulodi et al. 2019	[38]	Dynamic orthosis	80.55	24	19.91	85.06	24	16.84	18.44	-4.51	-0.25	-0.81	0.33
ROM	Moulodi et al. 2019	[38]	Static orthosis with toe separator	120	24	18.22	121.4	24	19.72	18.99	-1.35	-0.07	-0.64	0.50
	Moulodi et al. 2019	[38]	Dynamic orthosis	117.5	24	19.82	127.3	24	17.97	18.92	-9.77	-0.52	-1.08	0.07
Plantar pressure	Doty et al. 2015	[37]	Full-length orthosis	47.58	25	21.59	35.76	25	28.2	25.11	11.82	0.47	-0.10	1.03
	Doty et al. 2015	[37]	Sulcus-length orthosis	47.58	25	21.59	43.15	25	26.2	24.01	4.43	0.18	-0.37	0.74
	Doty et al. 2015	[37]	3/4-length orthosis	47.58	25	21.59	37.21	25	24.2	22.93	10.37	0.45	-0.12	1.01
	Farzadi et al. 2015	[22]	Prefabricated full-length foot orthosis with arch support	123.9	16	25.3	107.1	16	26.5	25.91	16.80	0.65	-0.08	1.34

[a] SMDs ≥ 0.2 or ≤ -0.2 are highlighted in yellow; SMDs ≥ 0.5 or ≤ -0.5 are in orange, SMDs ≥ 0.8 or ≤ -0.8 are in green

Table V Comparison of observations between treatment and control groups [a]

Parameter	Author(s)	Reference No.	Orthosis type	Pre-intervention			Post-intervention			Pooled SD	Mean Difference	SMDs	95% CIs	
				Mean	n	SD	Mean	n	SD				Lower	Upper
HVA	Chadchavalpanichaya et al. 2018	[36]	Custom-molded RTV toe separator	29.5	45	5.9	32.1	45	5.4	5.66	-2.60	-0.46	-5.00	-0.23
	Plaass et al. 2020	[39]	Dynamic orthosis	32.9	34	9	34.9	36	9.2	9.10	-2.00	-0.22	-6.30	2.34
	Reina et al. 2013	[40]	Custom-made foot orthoses	20.36	23	4.54	21.02	23	5.14	4.85	-0.66	-0.14	-3.50	2.22
	Tang et al. 2002	[41]	Full-length orthosis with toe separator	26.19	17	6.91	25.25	17	7.14	7.03	0.94	0.13	-4.00	5.85
IMA	Plaass et al. 2020	[39]	Dynamic orthosis	14.5	34	3.4	15.2	36	3.1	3.25	-0.70	-0.22	-2.30	0.85
	Reina et al. 2013	[40]	Custom-made foot orthoses	10.52	23	1.85	11.1	23	2.34	2.11	-0.58	-0.28	-1.80	0.67
Foot pain VAS	Torkki et al. 2003	[43]	NR	41	69	23	39	69	26	24.55	2.00	0.08	-6.30	10.26
Health-related quality of life index	Torkki et al. 2003	[43]	NR	93	69	6.1	93	69	6.6	6.36	0.00	0.00	-2.10	2.14

[a] SMDs ≥ 0.2 or ≤ -0.2 are highlighted in yellow; SMDs ≥ 0.5 or ≤ -0.5 are in orange, SMDs ≥ 0.8 or ≤ -0.8 are in green

Discussion

This is the first study to systematically evaluate and synthesize results from the extensive pool of literature that investigates the characteristics of HV orthoses and their effects on different factors. The data obtained from meta-analysis suggest that dynamic orthoses, and static orthoses with a toe separator help to reduce the HVA by approximately 2.1° to 5.79° among HV patients [36, 38, 41]. The studies also showed that the dynamic orthoses can reduce the contracture of the first metatarsophalangeal joint and better align the big toe through low torque and prolonged stretching [36, 44, 45]. In dynamic orthoses, the freedom of joint movement does not limit the ROM of the big toe, but help to maintain joint mobility and prevent joint stiffness, which seem to have a beneficial effect on the treatment of HV [38].

The results of this study show that both dynamic and static orthoses have a positive effect, and all static orthoses that help to reduce the HVA have a toe separator. Tehraninasr et al. [42] further pointed out that the toe separator can greatly alleviate pain by better aligning the big toe and relieving the overstretched collateral ligaments and bone subluxation [41, 42]. Generally, due to the ease of use, fit and better appearance, the users are more satisfied with dynamic than static orthoses [38].

The full-length orthosis developed by Tang et al. [41] has a significant and exceptional HVA correction effect for the HV group. The full-length orthoses tested by Farzadi et al. [22] and Doty et al. [37] help to reduce the plantar pressure significantly by 11.82 kPa to 16.8 kPa. Therefore, it can be suggested that forefoot pain has an evident relationship with plantar pressure in the metatarsalgia region [24, 46, 47]. The foot orthoses with an arch support developed by Farzadi et al. [22] reduces forefoot pain, which might be associated with better body load distribution by relieving the excessive pressure on the forefoot through metatarsal unloading. The finding indicates that when considering the length of the orthosis for HV patients, full-length is optimal. By maximizing the total contact area of the foot with a full-length orthosis, the peak plantar pressure can be reduced by 30% to 40% [48, 49].

Both customized and prefabricated orthoses can significantly reduce the symptoms of HV. Ring and Otter [50] compared the clinical efficacy of casted foot orthoses and prefabricated foot orthoses in the treatment of plantar heel pain in 67 patients, and found no significant difference in effectiveness between the bespoke or prefabricated orthoses. In addition, compared to the average cost of bespoke devices, the prefabricated orthoses are 38% less expensive per patient. They concluded that prefabricated orthoses can provide benefits that are equivalent to those of casted foot orthoses, but at considerably reduced costs. As shown in Table II, the material properties, thickness and rigidity of the three orthoses studied remain unknown. Thus, no conclusion can be made on the best material for HVA reduction. However, Chadchavalpanichaya et al. [36] found that an RTV silicone toe separator is comfortable to wear. Its compliance with treatment is higher than that of the nighttime HV strap [36]. The cost of a toe separator made of RTV silicone is only one-tenth of that of medical grade silicone, which can be considered as a clinical and cost-effective option [36].

Torkki et al. [18] pointed out that an orthosis can provide short-term symptomatic relief. However, the wearing duration of the three orthoses in their study ranges from 1 month to 1 year. This may show that orthoses with a toe separator help to reduce the HVA not only for a short period of time but also on a continuous basis. Moreover, the angle reduction did not increase with treatment duration, which may indicate that the treatment reaches its equilibrium result at a certain point of time.

Conclusion

Foot orthoses can be an acceptable treatment option to reduce HV deformity. This systematic review demonstrates a positive relationship between HVA reduction and pain level with orthoses that offer a toe separator. The length of the orthosis could also be a critical factor in HV treatment. Therefore, it is important to include these two elements in the conservative treatment of HV deformity, as well as the future development of HV orthoses. It is recommended that a full-length orthosis with a fixed toe separator or a dynamic orthosis is used to maintain the anatomic alignment of the big toe for those who suffer from HV. The results of this study provide patients, practitioners and physicians with important information to help them better understand the characteristics of various HV orthoses and their performance in reducing HV deformity, and contribute to decisions around optimal treatment for patients.

Strengths and limitations

As with any systematic review or meta-analysis, the strength of these results relies on the quality of the studies included. The limitations of this study include the scarcity of studies found on this topic in the literature, lack of consistency in the various study methods, and limited consideration of the reliability and validity of the HV assessments in the included studies. Only a few randomized controlled trials are compared and reported in this study and there is limited information on the materials of the orthotics studied. More randomized controlled trials related to HV orthoses are needed, and more research on the material properties of HV orthoses is also required, in order to offer an effective solution for effective and optimal designs of HV orthoses.

Contributors M-YK conceived and wrote this systematic review with meta-analysis. K-LY, JY and C-YT reviewed the protocol and provided extensive feedback. All authors approved the final manuscript.

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Figure legends

Figure I (a) Visualization of main keywords from 148 papers, and (b) Flowchart of study selection procedure

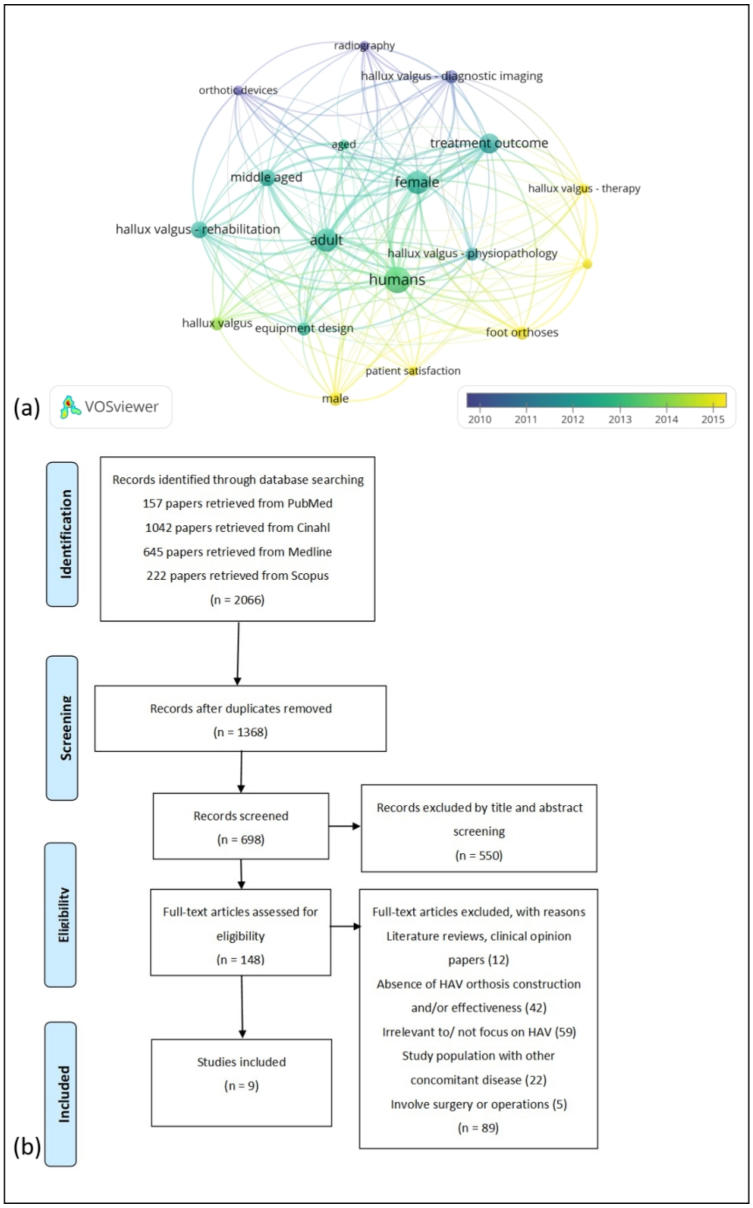

Figure I (a) Visualization of main keywords from 148 papers, and (b) Flowchart of study selection procedure

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PRISMA 2009 Checklist

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	1
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	2-3
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	4-5
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	6
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	7-8
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	7
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	7
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	8
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	9
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	9
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	8
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	8-9
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	9

PRISMA 2009 Checklist

Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	8
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	10-11
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	11-13
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	14-16
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	17-23
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	17-23
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	14-16
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	23-25
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	26
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	25-26
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	26-27

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Hallux Valgus Orthosis Characteristics and Effectiveness: A Systematic Review with Meta-analysis

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Hallux Valgus Orthosis Characteristics and Effectiveness: A Systematic Review with Meta-analysis

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Abstract

Objective The treatment effect of orthoses for hallux valgus is unclear with little interventional studies, the design involves multiple complex factors, and therefore a systematic analysis with meta-analysis is necessary. The objective of this systematic review and meta-analysis is to determine whether current foot orthoses are effective in treating hallux valgus.

Design Systematic review with meta-analysis.

Data sources Electronic databases (PubMed, Scopus, Cinahl and Medline) are searched to February 2020.

Eligibility criteria for selecting studies Interventional studies with content focus on hallux valgus orthosis design and any of the outcomes related to effectiveness for treating hallux valgus are included. The standardized mean differences are calculated. The risk of bias in included studies is assessed using the Cochrane Collaboration's risk of bias tools.

Results In total, 2066 articles are identified. Among them, 9 are selected and quality rated, and data are extracted and closely examined. A meta-analysis is conducted where appropriate. The major bias are missing outcome data and outcome measurement error. The results show that orthosis with a toe separator has the best effect of correcting the hallux valgus angle (SMD 0.50, CI 0.189,0.803).

Conclusion The orthoses design with a toe separator or an element that allows for the foot anatomic alignment is critical for reducing the hallux valgus angle and relieving foot pain. The results contribute to a better selection of treatment for patients.

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Strengths and limitations of this study

- This systematic review with meta-analysis represents, to the best of our knowledge, the most comprehensive examination of the evidence for the characteristics and effectiveness of orthosis in the treatment of hallux valgus.
- This study searched articles in large databases including SCOPUS, MEDLINE, PubMed, and Cinahl.
- The results highlight the key design features of orthosis and their relevance to hallux valgus angle correction and pain relief.
- This study provides evidence on the use of hallux valgus orthoses in angle correction and toe realignment.
- There is scarcity of studies on this topic and lack of consistency in the study methods.

Introduction

Hallux valgus (HV) is a common foot deformity, estimated to affect 23% of adults and 35.7% of the elderly [1]. It is characterized by the hypermobility and pronation of the first metatarsal ray, which eventually lead to subluxation and pain of the first metatarsophalangeal joint [2]. The hallux valgus angle (HVA) and intermetatarsal angle (IMA) are common indicators to objectively measure the degree of the deformity [3, 4]. HV is not only a prevalent and debilitating condition amongst the general public, especially women, due to hereditary or improper footwear but also a significant burden on public health care with the high demand for foot surgery [5], and its association with foot pain [6-9], which can inhibit the level of mobility and physical activity of those who suffer from the deformity [2]. This is especially devastating to athletes, who may acquire the condition due to prolonged periods of training. Previous research work has found that 9.3% of the Muay Thai kickboxers in their study suffer from HV [10-12]. Schöffl and Küpper [12] and Killian et al. [13] found that tight climbing shoes exert high pressure load on the forefoot which affects 53% of the long-term high-level climbers. Steinberg et al. [14] found that 40.0% dancers have bilateral HV and 7.3 % have unilateral HV. Contributors to the development of HV include the individual body structure, joint range of motion (ROM), anatomical abnormalities and extensive dance exercises that expose the spine and the lower limb joints to high loads and strains [14-16]. Former ballet dancers (73.7%) were also found to have a significantly higher HV incidence rate than the control group (2.6%) [15].

Extreme cases of HV require surgical intervention, but the recurrence rate is high. Surgical operations may reduce the subsequent mobility of the big toe, and the impact on athletes can be devastating [2]. Hence, studies have shown that treatment of HV in athletes should be as conservative as possible [10]**.** The complications related to HV surgical correction such as nerve damage also discourage surgery [17-21]. Therefore, non-surgical conservative treatments such as the use of foot orthoses have become a viable and popular option for HV patients to correct their foot deformity and relieve foot pain [17, 22]. As described by Charrette [23], HV orthoses act as a means of biomechanical support to reduce the pressure on the first metatarsal joint which would prevent further degeneration of mobility.

HV orthoses are available in a wide range of design features and materials. Ready-made and custom-made are the two main types of foot orthoses [24]. While the former is available online or in retail stores and made from standard patterns, the latter are constructed by using footprints or foot molds based on specifications of the clinician [25]. They may or may not have a toe separator, can have different lengths and made of different materials. The design of HV orthoses is multi-factorial, however, previous related studies have merely focused on the effectiveness of foot orthoses in HV patients. This article conducts a systematic study to investigate the effectiveness of these orthoses, and quantitatively synthesizes the results based on the best available evidence. The results can provide reference for the clinical selection and future design trends of orthotics to achieve better treatment effects.

Methods

Search methods for identification of studies

Research articles published in peer-reviewed journals that describe the construction of HV orthoses and/or their effectiveness were searched on PubMed, Scopus, Cinahl and Medline for all years available up to February 2020. The PICO questions designed on the basis of the study selection criteria and a highly sensitive search strategy are reported in Figure I. The keywords include “hallux valgus”, “orthosis”, “design”, “fabrication”, “construction”, “pressure”, “gait”, “alignment”, “pain” and “walking speed”.

Figure I PICO question and a list of search strategy

Inclusion and exclusion criteria

The titles and abstracts were then reviewed by 2 investigators. Full-text articles that assess HV orthosis designs or any of the outcomes related to the effectiveness of HV orthoses were then retrieved for detailed evaluation. The retrieved items were screened based on a two-stage selection process which subsequently considered the titles, abstracts, and full text. Assessment of the study eligibility was performed by one investigator.

Quality assessment and risk of bias

The included papers were assessed for methodological quality. The title, journal name, and author details were removed to anonymize the articles prior to the rating process. Quality rating was performed by using the Epidemiological Appraisal Instrument (EAI) [26-29], which has been validated for the assessment of observational studies. Thirty-one items from the original EAI were used, after removing those that are related to interventions, randomization, the follow-up period, or loss to follow-up that are not applicable to cross-sectional studies. Items were scored as “No” or “Unable to determine” (score = 0), “Partial” (score = 1), “Yes” (score = 2), or “Not Applicable” (item removed from scoring process) and an average score across all items was calculated for each study. Risk of bias was assessed with the use of Cochrane Collaboration tools.

Data management

One investigator recorded the following details for all of the included papers: publication details (author, year, country, and study aim), sample characteristics (number of HV cases, number of control subjects, age and sex), study methodology (device, associated factors investigated, and orthosis wearing details) and result. The standardized mean differences (SMDs) and 95% confidence intervals (CIs) were calculated. To calculate the SMDs, the means and standard deviations (SDs) of pre-intervention and post-intervention [30]. The mean difference was divided by the pooled SD [31]. The SMDs are calculated with the following formulas:

1. $$\text{SMDs}_{\text{intervention}} = \frac{Mean\ of\ pre-intervention\ -\ Mean\ of\ post-intervention}{Pooled\ SD\ for\ the\ entire\ population}$$

2. $$\text{SMDs}_{\text{group}} = \frac{Mean\ of\ treatment\ group\ -\ Mean\ of\ control\ group}{Pooled\ SD\ for\ the\ entire\ population}$$

The interpretation of the SMDs was based on guidelines in previous studies: small effect ≥ 0.2, medium effect ≥ 0.5, and large effect ≥ 0.8 [29, 32, 33]. An SMD of "0" means that there is no difference in effect between the groups. SMDs that are "> 0" or "<0" indicate that one group is more efficacious than the other, and vice versa. SMDs are usually accompanied by 95% CIs to evaluate the reliability of the comparison [29, 32, 34].

Patient and Public Involvement statement

Patients and/or the public will not be involved in this study.

Results

Search results

This review adhered to the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) Statement and has a registered protocol. The search strategy resulted in 2066 articles from PubMed, Scopus, Cinahl and Medline databases, with 1368 articles removed due to duplications. Then, the title and abstract of 698 articles were screened against the objective of the study, which resulted in the removal of 550 papers as they did not meet the requirements of the study design. The remaining 148 articles were assessed against the inclusion and exclusion criteria by examining the full text and were imported into the VOSviewer (version 1.6.13) to examine the trend of the results. Keywords with fewer than 3 occurrences were excluded, and general terms were filtered out so that the focus would be on more specific and informative terms [35]. Figure II (a) visualizes the results that amongst the 148 remaining articles, 18 keywords meet the threshold. The total link strength ranged from 26 to 71, with larger label denoting a higher total link strength. On average, the publication years of the articles ranged from 2010 to 2015, in which “male”, “patient satisfaction”, “foot orthoses” and “hallux valgus-therapy” are the latest research terms. After the assessment, another 89 articles were removed. The remaining 9 studies are discussed in this systematic review. Figure II (b) presents a PRISMA flow chart of the article selection process.

Figure II (a) Visualization of main keywords from 148 papers, and (b) Flowchart of study selection procedure

Study characteristics

The 9 studies selected for inclusion in this paper focused on various characteristics and included different demographics (Table I). Of the nine studies included, seven were randomized controlled trials [36-40, 41-42], and the others were uncontrolled intervention study [42] and quasi-experimental [22], respectively. The age of participants ranged from 22.79 ± 1.44 to 60.8 ± 10.8 years old. The publication years of these papers range from 2002 to 2020. The studies evaluated the effects of 11 different types of HV orthoses on angle correction (IMA and HVA), plantar pressure, ROM, pain (Visual Analogue Scale (VAS) and Foot and Ankle Outcome Score (FAOS) -pain), function during daily activities (the American Orthopedic Foot and Ankle Score (AOFAS) and FAOS -function) and quality of life (FAOS -quality of life). The number of subjects who suffer from HV ranged from 16 to 69, with mild to moderate HV. Four of the studies involved control groups with 23 to 69 participants. Overall, the majority of the subjects are female.

Table I Selected characteristics of studies included in analysis (9 unique studies)

Authors(s)/ Country	Reference No.	Study aim	Method/ Device	N HV	Age (Mean ± SD)	Orthosis	Orthosis material/ Wearing duration	Result
Chadchavalpa nichaya et al. 2018/ Thailand	[36]	To investigate the effect of custom-molded room temperature vulcanizing (RTV) silicone toe separator to reduce HVA	Randomized controlled trial/ Radiographic measurement & clinical assessment	45	HV group: 60.3 ± 9.4 Control group: 60.8 ± 10.8	Custom-molded RTV toe separator	Silicone/ 12 months	Both groups have significant differences in mean HVA with a decrease of 3.3° ± 2.4° for the study group and increase of 1.9° ± 1.9° for the control group. Hallux pain of study group is reduced.
Doty et al. 2015/ USA	[37]	To compare the plantar pressure distribution in standard footwear and in the same footwear with orthoses of 3 different lengths	Randomized controlled trial/ Tactilus Free Form® Sensor System	25	Mean: 57	Full-length orthosis Sulcus-length orthosis 3/4-length orthosis	NR/ Immediate	No significant changes in medial pressure with the addition of any orthosis compared with standard footwear alone
Farzadi et al. 2015/ Iran	[22]	To investigate the effect of orthosis with medial arch support on plantar pressure distribution	Quasi-experimental/ Pedar-X® in-shoe system	16	26.1 ± 5.7	Prefabricated arch support foot orthosis	5 mm thick polypropylene/ 1 month	The use of the foot orthosis leads to a decrease in peak pressure & maximum force
Moulodi et al. 2019/ Iran	[38]	To compare the HVA, ROM, FAOS, pain & function in daily activities after the use of orthosis	Randomized controlled trial/ clinical assessment	24	22.79 ± 1.44	Static orthosis with toe separator Dynamic orthosis	A bar & a single strap/ 1 month Firm plastic, straps & a free joint/ 1 month	Both orthoses can reduce HVA up to 3°; significant difference in ROM by using dynamic orthosis
Plaass et al. 2020/ Germany	[39]	To analyze the effect of a dynamic orthosis on IMA & HVA	Randomized controlled trial/ Radiographic measurement & clinical assessment	36	HV group: 53.2 ± 14.0 Control group: 48.5 ± 12.9	Dynamic orthosis	NR/ 3 months	Dynamic orthosis can provide pain relief in patients but showed no effect on HVA
Reina et al. 2013/ Spain	[40]	To determine if the use of custom-made foot orthotics prevents the advancement of IMA & HVA	Randomized controlled trial/ Radiographic measurement	23	HV group: 30.31 ± 9.27 Control group: 30.94 ± 14.06	Custom-made foot orthoses	3 mm thick polypropylene sheet & 3 mm thick polyethylene foam sheet/ 12 months	Custom-made orthoses appear to have no effect
Tang et al. 2002/ Taiwan	[43]	To assess the effects of a new foot-toe orthosis on HVA	Uncontrolled intervention study/ Radiographic measurement & clinical assessment	17	42.59 ± 16.52	Total contact orthosis with toe separator	Plastazote poron, microcell pull, plastazote & mineral oil–based polymer gel toe separator/ 3 months	The new total contact orthosis with fixed toe separator reduces HVA
Tehraninasr et al. 2008/ Iran	[41]	To compare the effects of wearing an orthosis with toe separator & nighttime orthosis on IMA, HVA & foot pain	Randomized controlled trial/ Radiographic measurement	30	27 ± 8.91	Orthosis with toe separator Nighttime orthosis	Polyfoam, polyethylene, plastazote toe separator/ 3 months Polyfoam & a rigid polyethylene bar/ 3 months	IMA & HVA are reduced in both groups; however, the reduction is not significant; the orthosis with toe separator significantly reduces the pain intensity
Torkki et al. 2003/ Finland	[42]	To compare the effectiveness of surgical & orthotic treatment with patients on VAS	Randomized controlled trial/ NR	69	HV group: 49 ± 10 Control group: 47 ± 9	NR	NR/ 12 months	Orthoses provide short-term symptomatic relief

Quality assessment and risk of bias

The inter-rater agreement on the EAI is 95% (14 disagreements out of 279 quality assessment items rated) across all included studies (9 papers). The individual study results for quality appraisal are shown in Table II. All of the studies defined the associated factors investigated and reported the sampling frame and statistical methods (9/9, 100%). Most studies clearly reported their aims and study design (8/9, 89%). More than half of the studies reported the inclusion criteria, sample characteristics, sample size calculations and statistical parameters (7/9, 78%; 6/9, 67%; 7/9, 78%; and 7/9, 78%, respectively). Few studies reported an attempt to blind the assessors towards the group allocation (1/4, 25%), although given the nature of HV deformities, blinding assessors is unlikely to be possible in most studies.

Reliability and validity were considered separately for both the HV assessment and measurement of the associated factors. Only a couple of the studies (2/9; 22%) provided a clear definition of HV by reporting angle values, another couple of studies (2/9; 22%) reported the reliability for the HV angle assessment, and only 11% (1/9) reported the validity of the HV assessment. The risk of bias of the included studies is summarized in Figure III. The main causes of potential bias were missing outcome data and outcome measurement error.

Table II Results of quality assessment of all included papers (9 unique studies) [a]

Author(s)	Chadchavalpanichaya et al. 2018	Doty et al. 2015	Farzadi et al. 2015	Moulodi et al. 2019	Plaass et al. 2020	Reina et al. 2013	Tang et al. 2002	Tehraninasr et al. 2008	Torkki et al. 2003	Studies scoring "Yes" (%)
Reference No.	[36]	[37]	[22]	[38]	[39]	[40]	[43]	[41]	[42]	
Q1. Reported study aim/objective clearly	2	2	2	2	2	2	2	2	1	**89**
Q2. Associated factors clearly defined	2	2	2	2	2	2	2	2	2	**100**
Q3. HV clearly defined	1	2	1	0	0	0	0	2	0	**22**
Q4. Reported study design	2	2	2	2	2	2	2	1	2	**89**
Q5. Reported sampling frame	2	2	2	2	2	2	2	2	2	**100**
Q6. Reported inclusion criteria	2	0	2	2	2	2	2	2	0	**78**
Q7. Reported participation rate	2	0	0	2	1	2	1	0	2	**44**
Q8. Reported sample characteristics	2	2	1	1	2	2	2	1	2	**67**
Q9. Reported statistical methods	2	2	2	2	2	2	2	2	2	**100**
Q10. Reported all basic data	0	0	0	0	0	0	2	0	0	**11**
Q11. Reported variability in data	2	0	2	2	2	2	0	2	2	**78**
Q12. Reported statistical parameters	2	2	2	2	2	2	1	1	2	**78**
Q13. Sample size calculations	2	1	2	2	2	2	1	2	2	**78**
Q14. Comparability of case/control groups	2	-	-	-	2	2	-	-	2	**100**
Q15. Adequate participation rate	2	2	2	2	2	2	2	2	2	**100**
Q16. Recruitment period for case/control groups	2	-	-	-	2	2	-	-	**0**	**75**
Q17. Non-responder characteristics described	0	0	0	0	0	0	0	0	0	**0**
Q18. Reliability of all associated factors	2	0	1	2	0	0	0	0	0	**22**
Q19. Validity of all associated factors	0	0	0	2	0	0	0	0	0	**11**
Q20. Standardized assessment of associated factors	2	2	2	2	2	2	**2**	**2**	**2**	**100**
Q21. Blinding of assessors	2	-	-	-	1	0	-	-	0	**25**
Q22. Reliability of HV assessment	2	0	0	2	0	0	0	0	0	**22**
Q23. Validity of HV assessment	0	0	0	2	0	0	0	0	0	**11**
Q24. Standardized assessment of HV	2	0	0	0	2	2	2	2	0	**56**
Q25. Assessment period for case/control groups	2	-	-	-	2	2	-	-		**100**
Q26. Collected data on HV severity/symptoms	2	0	0	0	2	1	1	1	1	**22**
Q27. Adjusted for covariates	0	0	0	0	0	0	0	0	0	**0**
Q28. Reported data for ≥ 3 levels of associated factors	0	2	0	0	0	0	0	0	2	**2**
Q29. Reported data for subgroups of subjects	0	0	0	0	0	0	0	0	0	**0**
Q30. Generalizability of results to study population	0	1	0	0	0	0	0	0	1	**0**
Q31. Generalizability of results to other populations	2	0	0	0	2	0	0	2	2	**44**
Overall quality score	**1.45**	**0.89**	**0.93**	**1.22**	**1.23**	**1.13**	**0.96**	**1.07**	**1.06**	

[a] Purple shading = “Yes”, Blue shading = “Partial”, White shading = “No” or “Unable to determine”, “-” = “Not applicable”; that is, items removed from scoring process and not included in % calculations.

Figure III Risk of bias in included studies (a) risk of bias for randomized studies, (b) risk of bias for non-randomized studies

Overview of results from meta-analyses

Figure IV provides the overall SMDs and SMDs for individual studies in the random-effects model in which eight measurement factors before and after intervention in the HV group are compared, with SMDs ≥ 0.2 or ≤ -0.2 highlighted in yellow; SMDs ≥ 0.5 or ≤ -0.5 in orange, and SMDs ≥ 0.8 or ≤ -0.8 in green. The primary function of HV orthosis is to correct the HVA, and a total of six studies investigated the effect of orthosis on the HVA correction. An overall effect for HV orthosis in correcting HVA was found to be 0.31 (0.075, 0.547). There was small heterogeneity between studies (I^2: 28.28%). Tang et al. [43] stated that their full-length orthosis with a toe separator provides a significantly positive reduction of the HVA of 5.79° in the HV group (SMD 0.85, CI 0.121,1.546), which has the highest corrective effect among all the recorded orthoses. The static orthosis with a toe separator tested by Moulodi et al. [38] also showed a significant positive HVA correction of 2.67° in the HV group (SMD 0.75, CI 0.143,1.325). Chadchavalpanichaya et al. [36] developed a custom-molded RTV toe separator, which helps to correct the HVA by 2.1° in the HV group (SMD 0.41, CI -0.012,0.827). The pooled estimation for orthoses with a toe separator was further investigated that the effect is medium with SMDs 0.50 (0.189,0.803), with I^2 statistics 14.52%. The dynamic orthosis tested also showed a significantly positive reduction of the HVA of 2.13° (SMD 0.55, CI -0.038,1.127) [38]. The pooled estimation for dynamic orthoses showed small effect in HVA correction with SMDs 0.27 (-0.211,0.751), I^2 42.29%.

Three of the studies investigated the pain score with the use of two different types of rating scales. One of them, Tehraninasr et al. [41], showed that their orthosis with a toe separator can significantly reduce the pain level (SMD 1.13, CI 0.319,1.887). The level of physical functioning before and after the application of an orthosis have also been compared. An overall effect of -0.30 (-0.700,0.102) was achieved.

Two other studies investigated the impact of the foot orthosis on plantar pressure. The overall SMDs in the random-effects model was found to be 0.41 (0.118, 0.700), indicating that there is small effect for HV orthosis in plantar pressure reduction. There was no significant heterogeneity between studies (I^2: 0.00%). It was found that the prefabricated full-length orthosis with an arch support [22] can significantly reduce the plantar pressure by 16.8 kPa (SMD 0.65, CI -0.090,1.354).

Observation of key design features

Customized vs. prefabricated

Among the orthoses that showed a significant reduction of the HVA after treatment amongst the HV patients, the orthoses developed by Chadchavalpanichaya et al. [36] and Tang et al. [43] are custom-made, while those in Moulodi et al. [38], Tehraninasr et al. [41], Torkki et al. [42], Doty et al. [37] and Farzadi et al. [22] are prefabricated. This shows that the ability of an orthosis to reduce the severity of HV or its treatment effectiveness might not be related to whether it is customized or prefabricated. However, adjustment and fitting are still key factors, and patients are instructed to adjust the prefabricated orthosis to the best fitting position [39].

Static vs. dynamic

In terms of HVA reduction, the results are consistent with those of the HV patients before and after the intervention. Both types of orthoses have a positive effect on treatment effectiveness, whilst all of the static orthoses that help to reduce the HVA are embedded with the feature of toe separator. Therefore, the toe separator seems to be the key element in correcting the misalignment of the big toe.

Considerations around orthosis length and arch support

In terms of the orthosis length, the full-length orthosis in Tang et al. [43] has a significant and exceptional corrective effect of HV in the HV group. The full-length orthoses with arch support in Farzadi et al. [22] can significantly reduce the plantar pressure. These results show that when considering the length of the orthosis for HV patients, full-length is preferred, and arch support may be important to achieve therapeutic effects.

Figure IV Comparison of observations

Discussion

This is the first study to systematically evaluate and synthesize results from the extensive pool of literature that investigates the characteristics of HV orthoses and their effects on different factors. The data obtained from meta-analysis suggest that dynamic orthoses, and static orthoses with a toe separator help to reduce the HVA by approximately 2.1° to 5.79° among HV patients [36, 38, 43]. The treatment effect of orthoses with a toe separator on HVA correction is larger than that of dynamic orthoses. The full-length orthosis with toe separator developed by Tang et al. [43] has a significant and exceptional HVA correction effect. The use of orthoses with a toe separator for moderate degree HV patients can reduce HVA and hallux pain without serious complications [36, 41]. The studies also showed that the toe separator can greatly alleviate pain by better aligning the big toe and relieving the overstretched collateral ligaments and bone subluxation [43, 41]. However, due to the ease of use, fit and better appearance, users may more satisfied with dynamic than static orthoses [38]. The dynamic orthoses can reduce the contracture of the first metatarsophalangeal joint and better align the big toe through low torque and prolonged stretching [36, 44, 45]. The freedom of joint movement does not limit the ROM of the big toe, but help to maintain joint mobility and prevent joint stiffness, which seem to have a beneficial effect on the treatment of HV [38].

The full-length orthoses with an arch support tested by Farzadi et al. [22] help to reduce the plantar pressure and forefoot pain significantly. It can be suggested that forefoot pain has an evident relationship with plantar pressure in the metatarsalgia region [24, 46, 47]. This might be associated with better body load distribution by relieving the excessive pressure on the forefoot through metatarsal unloading. By maximizing the total contact area of the foot with a full-length orthosis, the peak plantar pressure can be reduced by 30% to 40% [48, 49]. In addition, with adequate arch support, the anatomical alignment of the foot can be restored correctly [41].

Both customized and prefabricated orthoses can significantly reduce the symptoms of HV. Ring and Otter [50] compared the clinical efficacy of casted foot orthoses and prefabricated foot orthoses in the treatment of plantar heel pain in 67 patients, and found no significant difference in effectiveness between the bespoke or prefabricated orthoses. In addition, compared to the average cost of bespoke devices, the prefabricated orthoses are 38% less expensive per patient. They concluded that prefabricated orthoses could provide benefits that are equivalent to those of casted foot orthoses, but at considerably reduced costs. Since the material properties, thickness, and rigidity of the orthoses studied remain unknown. No conclusion can be made on the best material for HVA reduction. However, Chadchavalpanichaya et al. [36] found that an RTV silicone toe separator is comfortable to wear. Its compliance with treatment is higher than that of the nighttime HV strap [36]. The cost of a toe separator made of RTV silicone is only one-tenth of that of medical grade silicone, which can be considered as a clinical and cost-effective option [36].

Torkki et al. [18] pointed out that an orthosis can provide short-term symptomatic relief. However, the wearing duration of the three orthoses in their study ranges from 1 month to 1 year. This may show that orthoses with a toe separator help to reduce the HVA not only for a short period of time but also on a continuous basis. Moreover, the angle reduction did not increase with treatment duration, which may indicate that the treatment reaches its equilibrium result at a certain point of time.

Conclusion

Foot orthoses can be an acceptable treatment option to reduce HV deformity. This systematic review demonstrates a positive relationship between HVA reduction and pain level with orthoses that offer a toe separator. Therefore, it is important to include this element in the conservative treatment of HV deformity, as well as the future development of HV orthoses. It is recommended that a fixed toe separator or a dynamic orthosis is used to maintain the anatomic alignment of the big toe for those who suffer from HV. The results of this study provide patients, practitioners and physicians with important information to help them better understand the characteristics of various HV orthoses and their performance in reducing HV deformity, and contribute to decisions around optimal treatment for patients.

Strengths and limitations

As with any systematic review or meta-analysis, the strength of these results relies on the quality of the studies included. The limitations of this study include the scarcity of studies found on this topic in the literature, lack of consistency in the various study methods, subjects' conditions, and limited consideration of the reliability and validity of the HV assessments in the included studies. Only a few randomized controlled trials are compared and reported in this study and there is limited information on the materials of the orthotics studied. More randomized controlled trials related to HV orthoses are needed, and more research on the material properties of HV orthoses is also required, in order to offer an effective solution for effective and optimal designs of HV orthoses.

Contributors M-YK conceived and wrote this systematic review with meta-analysis. K-LY, JY and C-YT reviewed the protocol and provided extensive feedback. All authors approved the final manuscript.

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Patient consent Not required.

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Figure legends

Figure I PICO question and a list of search strategy

Figure II (a) Visualization of main keywords from 148 papers, and (b) Flowchart of study selection procedure

Figure III Risk of bias in included studies (a) risk of bias for randomized studies, (b) risk of bias for non-randomized studies

Figure IV Comparison of observations

PICO question

P	Population or Problem	Studies that included people with hallux valgus, and people without hallux valgus at baseline were included
I	Intervention	Randomized controlled trial, uncontrolled intervention study and quasi-experimental of the use of hallux valgus orthoses
C	Comparison or control	The comparison could be no hallux valgus orthotic treatment, or other orthotic designs
O	Outcome	Any effect of hallux valgus orthotic treatment

Search strategy

1. ("Hallux Valgus" AND (Design OR Fabrication OR Construction)) NOT (Implant OR Replacement)
2. ("Hallux Valgus" AND (Orthoses OR Orthosis) AND (Design OR Fabrication OR Construction)) NOT (Implant OR Replacement)
3. ("Hallux Valgus" AND (Orthoses OR Orthosis) AND Pressure) NOT (Implant OR Replacement)
4. ("Hallux Valgus" AND (Orthoses OR Orthosis) AND Gait) NOT (Implant OR Replacement)
5. ("Hallux Valgus" AND (Orthoses OR Orthosis) AND Alignment) NOT (Implant OR Replacement)
6. ("Hallux Valgus" AND (Orthoses OR Orthosis) AND Pain) NOT (Implant OR Replacement)
7. ("Hallux Valgus" AND (Orthoses OR Orthosis) AND "Walking speed") NOT (Implant OR Replacement)
8. ("Hallux Valgus" AND (Orthoses OR Orthosis) AND (Design OR Fabrication OR Construction) AND Pressure) NOT (Implant OR Replacement)
9. ("Hallux Valgus" AND (Orthoses OR Orthosis) AND (Design OR Fabrication OR Construction) AND Gait) NOT (Implant OR Replacement)
10. ("Hallux Valgus" AND (Orthoses OR Orthosis) AND (Design OR Fabrication OR Construction) AND Alignment) NOT (Implant OR Replacement)
11. ("Hallux Valgus" AND (Orthoses OR Orthosis) AND (Design OR Fabrication OR Construction) AND Pain) NOT (Implant OR Replacement)
12. ("Hallux Valgus" AND (Orthoses OR Orthosis) AND (Design OR Fabrication OR Construction) AND "Walking speed") NOT (Implant OR Replacement)

Figure I PICO question and a list of search strategy

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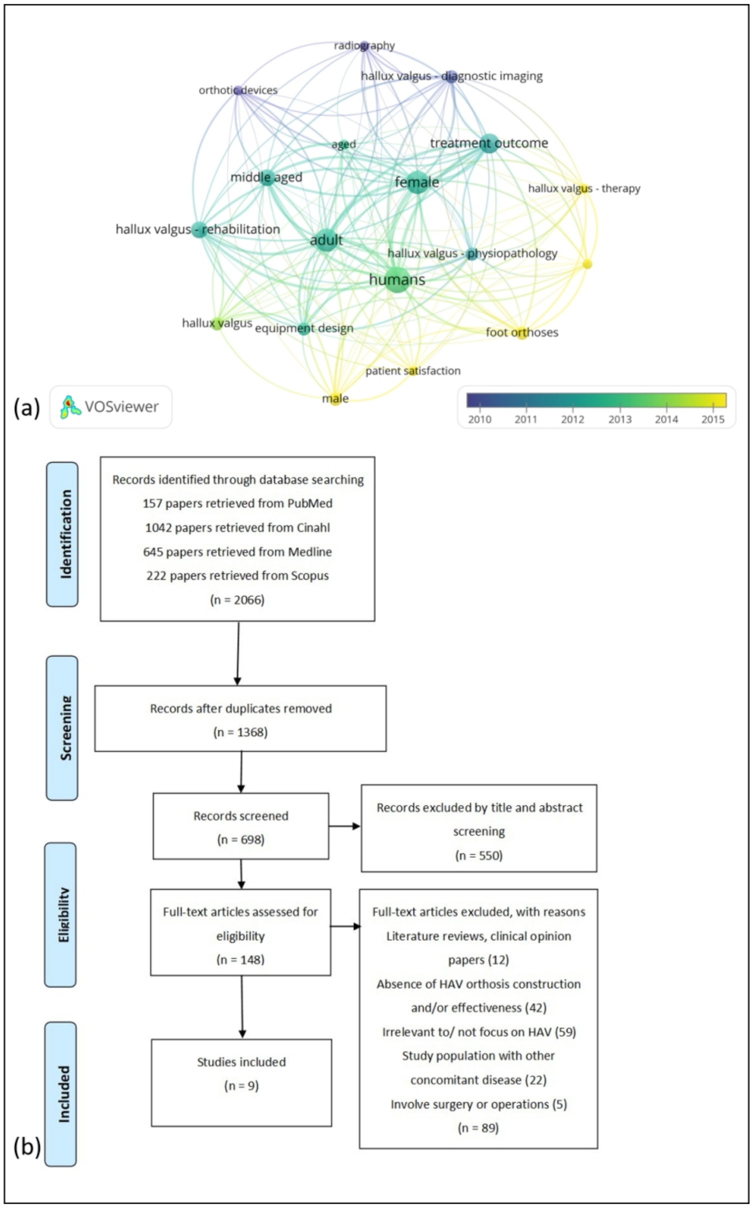

Figure II (a) Visualization of main keywords from 148 papers, and (b) Flowchart of study selection procedure

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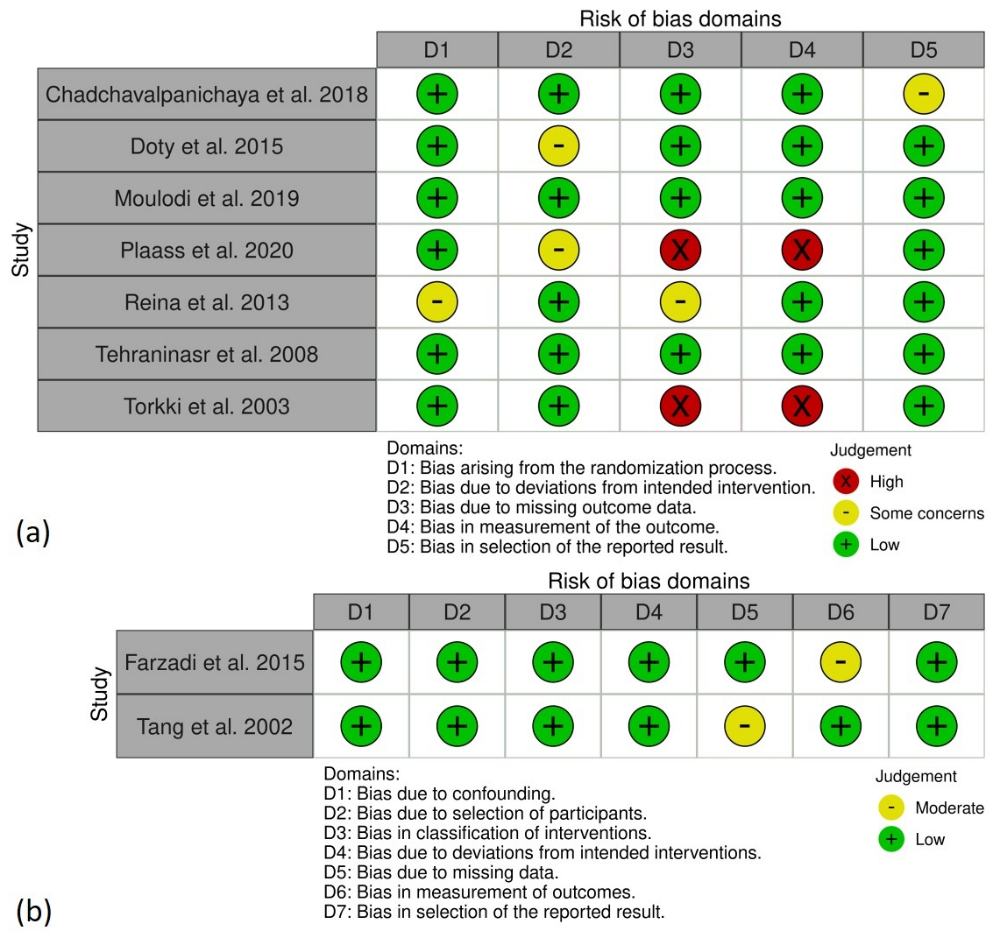

Figure III Risk of bias in included studies (a) risk of bias for randomized studies, (b) risk of bias for non-randomized studies

193x184mm (150 x 150 DPI)

Parameter	Author(s)	Orthosis type	Pre-intervention Mean	Pre-intervention SD	Post-intervention Mean	Post-intervention SD	Pooled SD	Mean Difference	SMDs	95% CIs
HVA	Chadchavalpanichaya et al. 2018	Custom-molded RTV toe separator	32.50	4.80	30.40	5.40	5.11	2.10	0.41	-0.012 to 0.827
	Moulodi et al. 2019	Static orthosis with toe separator	18.21	3.41	15.54	3.74	3.58	2.67	0.75	0.143 to 1.325
	Moulodi et al. 2019	Dynamic orthosis	17.96	3.75	15.83	3.94	3.85	2.13	0.55	-0.038 to 1.127
	Plaass et al. 2020	Dynamic orthosis	35.40	8.60	34.90	9.20	8.91	0.50	0.06	-0.410 to 0.521
	Reina et al. 2013	Custom-made foot orthoses	20.55	5.10	21.02	5.14	5.12	-0.47	-0.09	-0.675 to 0.494
	Tang et al. 2002	Full-length orthosis with toe separator	31.04	6.40	25.25	7.14	6.78	5.79	0.85	0.121 to 1.546
	Tehraninasr et al. 2008	Orthosis with toe separator	25.46	3.68	25.36	3.68	3.68	0.10	0.03	-0.701 to 0.754
	Tehraninasr et al. 2008	Nighttime orthosis	24.13	2.05	24.16	2.09	2.07	-0.03	-0.01	-0.742 to 0.714
								Overall:	**0.31**	**0.075 to 0.547**
								Heterogeneity: I^2=28.28%		
IMA	Plaass et al. 2020	Dynamic orthosis	15.40	3.00	15.20	3.10	3.05	0.20	0.07	-0.400 to 0.530
	Reina et al. 2013	Custom-made foot orthoses	10.86	2.33	11.10	2.34	2.34	-0.24	-0.10	-0.686 to 0.483
								Overall:	**-0.00**	**-0.360 to 0.360**
								Heterogeneity: I^2=0.00%		
FAOS-pain	Moulodi et al. 2019	Static orthosis with toe separator	85.28	12.24	87.49	12.29	12.27	-2.21	-0.18	-0.750 to 0.395
	Moulodi et al. 2019	Dynamic orthosis	81.61	17.41	85.89	14.50	16.02	-4.28	-0.27	-0.837 to 0.311
								Overall:	**-0.22**	**-0.620 to 0.180**
								Heterogeneity: I^2=0.00%		
Foot pain VAS	Tehraninasr et al. 2008	Orthosis with toe separator	4.26	1.48	2.66	1.34	1.41	1.60	1.13	0.319 to 1.887
	Tehraninasr et al. 2008	Nighttime orthosis	4.13	1.78	4.00	1.13	1.49	0.13	0.087	-0.643 to 0.813
	Torkki et al. 2003	NR	5.00	2.40	4.10	2.30	2.35	0.90	0.38	0.043 to 0.719
								Overall:	**0.48**	**0.000 to 0.958**
								Heterogeneity: I^2=51.39%		
FAOS-Quality of life	Moulodi et al. 2019	Static orthosis with toe separator	66.14	16.68	67.44	16.48	16.58	-1.30	-0.08	-0.649 to 0.495
	Moulodi et al. 2019	Dynamic orthosis	65.10	16.78	65.88	15.63	16.22	-0.78	-0.05	-0.619 to 0.524
								Overall:	**-0.06**	**-0.461 to 0.337**
								Heterogeneity: I^2=0.00%		
FAOS-Function	Moulodi et al. 2019	Static orthosis with toe separator	78.47	18.70	84.72	15.47	17.16	-6.25	-0.36	-0.934 to 0.218
	Moulodi et al. 2019	Dynamic orthosis	80.55	19.91	85.06	16.84	18.44	-4.51	-0.25	-0.814 to 0.333
								Overall:	**-0.30**	**-0.700 to 0.102**
								Heterogeneity: I^2=0.00%		
ROM	Moulodi et al. 2019	Static orthosis with toe separator	120.00	18.22	121.40	19.72	18.99	-1.35	-0.07	-0.644 to 0.499
	Moulodi et al. 2019	Dynamic orthosis	117.50	19.82	127.30	17.97	18.92	-9.77	-0.52	-1.091 to 0.072
								Overall:	**-0.29**	**-0.722 to 0.146**
								Heterogeneity: I^2=14.12%		
Plantar pressure	Doty et al. 2015	Full-length orthosis	47.58	21.59	35.76	28.20	25.11	11.82	0.47	-0.104 to 1.031
	Doty et al. 2015	Sulcus-length orthosis	47.58	21.59	43.15	26.20	24.01	4.43	0.18	-0.379 to 0.743
	Doty et al. 2015	3/4-length orthosis	47.58	21.59	37.21	24.20	22.93	10.37	0.45	-0.122 to 1.012
	Farzadi et al. 2015	Prefabricated full-length foot orthosis with arch support	123.90	25.30	107.10	26.50	25.91	16.80	0.65	-0.090 to 1.354
								Overall:	**0.41**	**0.118 to 0.700**
								Heterogeneity: I^2=0.00%		

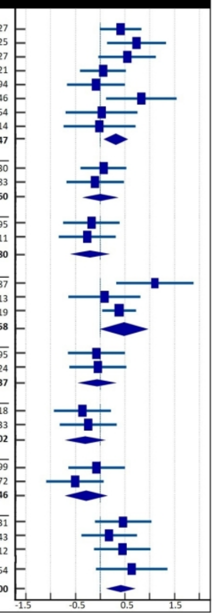

Figure IV Comparison of observations

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PRISMA 2020 for Abstracts Checklist

Section and Topic	Item #	Checklist item	Reported (Yes/No)
TITLE			
Title	1	Identify the report as a systematic review.	Yes
BACKGROUND			
Objectives	2	Provide an explicit statement of the main objective(s) or question(s) the review addresses.	Yes
METHODS			
Eligibility criteria	3	Specify the inclusion and exclusion criteria for the review.	Yes
Information sources	4	Specify the information sources (e.g. databases, registers) used to identify studies and the date when each was last searched.	Yes
Risk of bias	5	Specify the methods used to assess risk of bias in the included studies.	Yes
Synthesis of results	6	Specify the methods used to present and synthesise results.	Yes
RESULTS			
Included studies	7	Give the total number of included studies and participants and summarise relevant characteristics of studies.	Yes
Synthesis of results	8	Present results for main outcomes, preferably indicating the number of included studies and participants for each. If meta-analysis was done, report the summary estimate and confidence/credible interval. If comparing groups, indicate the direction of the effect (i.e. which group is favoured).	Yes
DISCUSSION			
Limitations of evidence	9	Provide a brief summary of the limitations of the evidence included in the review (e.g. study risk of bias, inconsistency and imprecision).	Yes
Interpretation	10	Provide a general interpretation of the results and important implications.	Yes
OTHER			
Funding	11	Specify the primary source of funding for the review.	Yes
Registration	12	Provide the register name and registration number.	No

From: Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. BMJ 2021;372:n71. doi: 10.1136/bmj.n71

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Hallux Valgus Orthosis Characteristics and Effectiveness: A Systematic Review with Meta-analysis

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Hallux Valgus Orthosis Characteristics and Effectiveness: A Systematic Review with Meta-analysis

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Abstract

Objective The treatment effect of orthoses for hallux valgus is unclear with little interventional studies, the design involves multiple complex factors, and therefore a systematic analysis with meta-analysis is necessary. The objective of this systematic review and meta-analysis is to determine whether current foot orthoses are effective in treating hallux valgus.

Design Systematic review with meta-analysis.

Data sources Electronic databases (PubMed, Scopus, Cinahl and Medline) are searched to February 2020.

Eligibility criteria for selecting studies Interventional studies with content focus on hallux valgus orthosis design and any of the outcomes related to effectiveness for treating hallux valgus are included. The standardized mean differences are calculated. The risk of bias in included studies is assessed using the Cochrane Collaboration's risk of bias tools.

Results In total, 2066 articles are identified. Among them, 9 are selected and quality rated, and data are extracted and closely examined. A meta-analysis is conducted where appropriate. The main causes of potential bias are missing outcome data and outcome measurement error. The results show that orthosis with a toe separator has the best effect of correcting the hallux valgus angle (SMD 0.50, CI 0.189,0.803).

Conclusion The orthoses design with a toe separator or an element that allows for the foot anatomic alignment is critical for reducing the hallux valgus angle and relieving foot pain. The results contribute to a better selection of treatment for patients.

PROSPERO registration number CRD42021260403

Strengths and limitations of this study

- This systematic review with meta-analysis represents, to the best of our knowledge, the most comprehensive examination of the evidence for the characteristics and effectiveness of orthosis in the treatment of hallux valgus.
- This study searched articles in large databases including SCOPUS, MEDLINE, PubMed, and Cinahl.
- The results highlight the key design features of orthosis and their relevance to hallux valgus angle correction and pain relief.
- This study provides evidence on the use of hallux valgus orthoses in angle correction and toe realignment.
- There is scarcity of studies on this topic and lack of consistency in the study methods.

Introduction

Hallux valgus (HV) is a common foot deformity, estimated to affect 23% of adults and 35.7% of the elderly [1]. It is characterized by the hypermobility and pronation of the first metatarsal ray, which eventually lead to subluxation and pain of the first metatarsophalangeal joint [2]. The hallux valgus angle (HVA) and intermetatarsal angle (IMA) are common indicators to objectively measure the degree of the deformity [3, 4]. HV is not only a prevalent and debilitating condition amongst the general public, especially women, due to hereditary or improper footwear but also a significant burden on public health care with the high demand for foot surgery [5], and its association with foot pain [6-9], which can inhibit the level of mobility and physical activity of those who suffer from the deformity [2]. This is especially devastating to athletes, who may acquire the condition due to prolonged periods of training. Previous research work has found that 9.3% of the Muay Thai kickboxers in their study suffer from HV [10-12]. Schöffl and Küpper [12] and Killian et al. [13] found that tight climbing shoes exert high pressure load on the forefoot which affects 53% of the long-term high-level climbers. Steinberg et al. [14] found that 40.0% dancers have bilateral HV and 7.3 % have unilateral HV. Contributors to the development of HV include the individual body structure, joint range of motion (ROM), anatomical abnormalities and extensive dance exercises that expose the spine and the lower limb joints to high loads and strains [14-16]. Former ballet dancers (73.7%) were also found to have a significantly higher HV incidence rate than the control group (2.6%) [15].

Extreme cases of HV require surgical intervention, but the recurrence rate is high. Surgical operations may reduce the subsequent mobility of the big toe, and the impact on athletes can be devastating [2]. Hence, studies have shown that treatment of HV in athletes should be as conservative as possible [10]**.** The complications related to HV surgical correction such as nerve damage also discourage surgery [17-21]. Therefore, non-surgical conservative treatments such as the use of foot orthoses have become a viable and popular option for HV patients to correct their foot deformity and relieve foot pain [17, 22]. As described by Charrette [23], HV orthoses act as a means of biomechanical support to reduce the pressure on the first metatarsal joint which would prevent further degeneration of mobility.

HV orthoses are available in a wide range of design features and materials. Ready-made and custom-made are the two main types of foot orthoses [24]. While the former is available online or in retail stores and made from standard patterns, the latter are constructed by using footprints or foot molds based on specifications of the clinician [25]. They may or may not have a toe separator, can have different lengths and made of different materials. The design of HV orthoses is multi-factorial, however, previous related studies have merely focused on the effectiveness of foot orthoses in HV patients. This article conducts a systematic study to investigate the effectiveness of these orthoses, and quantitatively synthesizes the results based on the best available evidence. The results can provide reference for the clinical selection and future design trends of orthotics to achieve better treatment effects.

Methods

Search methods for identification of studies

Research articles published in peer-reviewed journals that describe the construction of HV orthoses and/or their effectiveness were searched on PubMed, Scopus, Cinahl and Medline for all years available up to February 2020. The PICO questions designed on the basis of the study selection criteria and a highly sensitive search strategy are reported in Figure I. The keywords include “hallux valgus”, “orthosis”, “design”, “fabrication”, “construction”, “pressure”, “gait”, “alignment”, “pain” and “walking speed”.

Figure I PICO question and a list of search strategy

Inclusion and exclusion criteria

The titles and abstracts were then reviewed by 2 investigators. Full-text articles that assess HV orthosis designs or any of the outcomes related to the effectiveness of HV orthoses were then retrieved for detailed evaluation. The retrieved items were screened based on a two-stage selection process which subsequently considered the titles, abstracts, and full text. Assessment of the study eligibility was performed by one investigator.

Quality assessment and risk of bias

The included papers were assessed for methodological quality. The title, journal name, and author details were removed to anonymize the articles prior to the rating process. Quality rating was performed by using the Epidemiological Appraisal Instrument (EAI) [26-29], which has been validated for the assessment of observational studies. Thirty-one items from the original EAI were used, after removing those that are related to interventions, randomization, the follow-up period, or loss to follow-up that are not applicable to cross-sectional studies. Items were scored as “No” or “Unable to determine” (score = 0), “Partial” (score = 1), “Yes” (score = 2), or “Not Applicable” (item removed from scoring process) and an average score across all items was calculated for each study. Risk of bias was assessed with the use of Cochrane Collaboration tools.

Data management

One investigator recorded the following details for all of the included papers: publication details (author, year, country, and study aim), sample characteristics (number of HV cases, number of control subjects, age and sex), study methodology (device, associated factors investigated, and orthosis wearing details) and result. The standardized mean differences (SMDs) and 95% confidence intervals (CIs) were calculated. To calculate the SMDs, the means and standard deviations (SDs) of pre-intervention and post-intervention [30]. The mean difference was divided by the pooled SD [31]. The SMDs are calculated with the following formulas:

1. $\text{SMDs}_{\text{intervention}} = \frac{Mean\ of\ pre-intervention\ -\ Mean\ of\ post-intervention}{Pooled\ SD\ for\ the\ entire\ population}$

2. $\text{SMDs}_{\text{group}} = \frac{Mean\ of\ treatment\ group\ -\ Mean\ of\ control\ group}{Pooled\ SD\ for\ the\ entire\ population}$

The interpretation of the SMDs was based on guidelines in previous studies: small effect ≥ 0.2, medium effect ≥ 0.5, and large effect ≥ 0.8 [29, 32, 33]**.** An SMD of "0" means that there is no difference in effect between the groups. SMDs that are "> 0" or "<0" indicate that one group is more efficacious than the other, and vice versa. SMDs are usually accompanied by 95% CIs to evaluate the reliability of the comparison [29, 32, 34]. The total variation observed across studies that is due to heterogeneity is denoted as I^2. A heterogeneity value of 0%–40% is considered “low heterogeneity”; 30%–60% is “moderate heterogeneity”; 50%–90% is “substantial heterogeneity”; and 75%–100% is “considerable heterogeneity”.

Patient and Public Involvement statement

Patients and/or the public will not be involved in this study.

Results

Search results

This review adheres to the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) Statement and has a registered protocol. The search strategy resulted in 2066 articles from PubMed, Scopus, Cinahl and Medline databases, with 1368 articles removed due to duplications. Then, the title and abstract of 698 articles were screened against the objective of the study, which resulted in the removal of 550 papers as they did not meet the requirements of the study design. The remaining 148 articles were assessed against the inclusion and exclusion criteria by examining the full text and were imported into the VOSviewer (version 1.6.13) to examine the trend of the results. Keywords with fewer than 3 occurrences were excluded, and general terms were filtered out so that the focus would be on more specific and informative terms [35]. Figure II (a) visualizes the results that amongst the 148 remaining articles, 18 keywords meet the threshold. The total link strength ranged from 26 to 71, with larger label denoting a higher total link strength. On average, the publication years of the articles ranged from 2010 to 2015, in which “male”, “patient satisfaction”, “foot orthoses” and “hallux valgus-therapy” are the latest research terms. After the assessment, another 89 articles were removed. The remaining 9 studies are discussed in this systematic review. Figure II (b) presents a PRISMA flow chart of the article selection process.

Figure II (a) Visualization of main keywords from 148 papers, and (b) Flowchart of study selection procedure

Study characteristics

The 9 studies selected for inclusion in this paper focused on various characteristics and included different demographics (Table I). Of the nine studies included, seven were randomized controlled trials [36-40, 41-42], and the others were uncontrolled intervention study [42] and quasi-experimental [22], respectively. The age of participants ranged from 22.79 ± 1.44 to 60.8 ± 10.8 years old. The publication years of these papers range from 2002 to 2020. The studies evaluated the effects of 11 different types of HV orthoses on angle correction (IMA and HVA), plantar pressure, ROM, pain (Visual Analogue Scale (VAS) and Foot and Ankle Outcome Score (FAOS) -pain), function during daily activities (the American Orthopedic Foot and Ankle Score (AOFAS) and FAOS -function) and quality of life (FAOS -quality of life). The number of subjects who suffer from HV ranged from 16 to 69, with mild to moderate HV. Four of the studies involved control groups with 23 to 69 participants. Overall, the majority of the subjects are female.

Table I Selected characteristics of studies included in analysis (9 unique studies)

Authors(s)/ Country	Reference No.	Study aim	Method/ Device	N HV	Age (Mean ± SD)	Orthosis	Orthosis material/ Wearing duration	Result
Chadchavalpanichaya et al. 2018/ Thailand	[36]	To investigate the effect of custom-molded room temperature vulcanizing (RTV) silicone toe separator to reduce HVA	Randomized controlled trial/ Radiographic measurement & clinical assessment	45	HV group: 60.3 ± 9.4 Control group: 60.8 ± 10.8	Custom-molded RTV toe separator	Silicone/ 12 months	Both groups have significant differences in mean HVA with a decrease of 3.3° ± 2.4° for the study group and increase of 1.9° ± 1.9° for the control group. Hallux pain of study group is reduced.
Doty et al. 2015/ USA	[37]	To compare the plantar pressure distribution in standard footwear and in the same footwear with orthoses of 3 different lengths	Randomized controlled trial/ Tactilus Free Form® Sensor System	25	Mean: 57	Full-length orthosis	NR/ Immediate	No significant changes in medial pressure with the addition of any orthosis compared with standard footwear alone
						Sulcus-length orthosis		
						3/4-length orthosis		
Farzadi et al. 2015/ Iran	[22]	To investigate the effect of orthosis with medial arch support on plantar pressure distribution	Quasi-experimental / Pedar-X® in-shoe system	16	26.1 ± 5.7	Prefabricated arch support foot orthosis	5 mm thick polypropylene/ 1 month	The use of the foot orthosis leads to a decrease in peak pressure & maximum force
Moulodi et al. 2019/ Iran	[38]	To compare the HVA, ROM, FAOS, pain & function in daily activities after the use of orthosis	Randomized controlled trial/ clinical assessment	24	22.79 ± 1.44	Static orthosis with toe separator	A bar & a single strap/ 1 month	Both orthoses can reduce HVA up to 3°; significant difference in ROM by using dynamic orthosis
						Dynamic orthosis	Firm plastic, straps & a free joint/ 1 month	
Plaass et al. 2020/ Germany	[39]	To analyze the effect of a dynamic orthosis on IMA & HVA	Randomized controlled trial/ Radiographic measurement & clinical assessment	36	HV group: 53.2 ± 14.0 Control group: 48.5 ± 12.9	Dynamic orthosis	NR/ 3 months	Dynamic orthosis can provide pain relief in patients but showed no effect on HVA
Reina et al. 2013/ Spain	[40]	To determine if the use of custom-made foot orthotics prevents the advancement of IMA & HVA	Randomized controlled trial/ Radiographic measurement	23	HV group: 30.31 ± 9.27 Control group: 30.94 ± 14.06	Custom-made foot orthoses	3 mm thick polypropylene sheet & 3 mm thick polyethylene foam sheet/ 12 months	Custom-made orthoses appear to have no effect
Tang et al. 2002/ Taiwan	[43]	To assess the effects of a new foot-toe orthosis on HVA	Uncontrolled intervention study/ Radiographic measurement & clinical assessment	17	42.59 ± 16.52	Total contact orthosis with toe separator	Plastazote poron, microcell pull, plastazote & mineral oil–based polymer gel toe separator/ 3 months	The new total contact orthosis with fixed toe separator reduces HVA
Tehraninasr et al. 2008/ Iran	[41]	To compare the effects of wearing an orthosis with toe separator & nighttime orthosis on IMA, HVA & foot pain	Randomized controlled trial/ Radiographic measurement	30	27 ± 8.91	Orthosis with toe separator	Polyfoam, polyethylene, plastazote toe separator/ 3 months	IMA & HVA are reduced in both groups; however, the reduction is not significant; the orthosis with toe separator significantly reduces the pain intensity
						Nighttime orthosis	Polyfoam & a rigid polyethylene bar/ 3 months	
Torkki et al. 2003/ Finland	[42]	To compare the effectiveness of surgical & orthotic treatment with patients on VAS	Randomized controlled trial/ NR	69	HV group: 49 ± 10 Control group: 47 ± 9	NR	NR/ 12 months	Orthoses provide short-term symptomatic relief

Quality assessment and risk of bias

The inter-rater agreement on the EAI is 95% (14 disagreements out of 279 quality assessment items rated) across all included studies (9 papers). The individual study results for quality appraisal are shown in Table II. All of the studies defined the associated factors investigated and reported the sampling frame and statistical methods (9/9, 100%). Most studies clearly reported their aims and study design (8/9, 89%). More than half of the studies reported the inclusion criteria, sample characteristics, sample size calculations and statistical parameters (7/9, 78%; 6/9, 67%; 7/9, 78%; and 7/9, 78%, respectively). Few studies reported an attempt to blind the assessors towards the group allocation (1/4, 25%), although given the nature of HV deformities, blinding assessors is unlikely to be possible in most studies.

Reliability and validity were considered separately for both the HV assessment and measurement of the associated factors. Only a couple of the studies (2/9; 22%) provided a clear definition of HV by reporting angle values, another couple of studies (2/9; 22%) reported the reliability for the HV angle assessment, and only 11% (1/9) reported the validity of the HV assessment. The risk of bias of the included studies is summarized in Figure III. The main causes of potential bias were missing outcome data and outcome measurement error.

Table II Results of quality assessment of all included papers (9 unique studies) [a]

Author(s)	Chadchaval panichaya et al. 2018	Doty et al. 2015	Farzadi et al. 2015	Mouldodi et al. 2019	Plaass et al. 2020	Reina et al. 2013	Tang et al. 2002	Tehraninasr et al. 2008	Torkki et al. 2003	Studies scoring "Yes" (%)
Reference No.	[36]	[37]	[22]	[38]	[39]	[40]	[43]	[41]	[42]	
Q1. Reported study aim/objective clearly	2	2	2	2	2	2	2	2	1	**89**
Q2. Associated factors clearly defined	2	2	2	2	2	2	2	2	2	**100**
Q3. HV clearly defined	1	2	1	0	0	0	0	2	0	**22**
Q4. Reported study design	2	2	2	2	2	2	2	1	2	**89**
Q5. Reported sampling frame	2	2	2	2	2	2	2	2	2	**100**
Q6. Reported inclusion criteria	2	0	2	2	2	2	2	2	0	**78**
Q7. Reported participation rate	2	0	0	2	1	2	1	0	2	**44**
Q8. Reported sample characteristics	2	2	1	1	2	2	2	1	2	**67**
Q9. Reported statistical methods	2	2	2	2	2	2	2	2	2	**100**
Q10. Reported all basic data	0	0	0	0	0	0	2	0	0	**11**
Q11. Reported variability in data	2	0	2	2	2	2	0	2	2	**78**
Q12. Reported statistical parameters	2	2	2	2	2	2	1	1	2	**78**
Q13. Sample size calculations	2	1	2	2	2	2	1	2	2	**78**
Q14. Comparability of case/control groups	2	-	-	-	2	2	-	-	2	**100**
Q15. Adequate participation rate	2	2	2	2	2	2	2	2	2	**100**
Q16. Recruitment period for case/control groups	2	-	-	-	2	2	-	-	**0**	**75**
Q17. Non-responder characteristics described	0	0	0	0	0	0	0	0	0	**0**
Q18. Reliability of all associated factors	2	0	1	2	0	0	0	0	0	**22**
Q19. Validity of all associated factors	0	0	0	2	0	0	0	0	0	**11**
Q20. Standardized assessment of associated factors	2	2	2	2	2	2	**2**	**2**	**2**	**100**
Q21. Blinding of assessors	2	-	-	-	1	0	-	-	0	**25**
Q22. Reliability of HV assessment	2	0	0	2	0	0	0	0	0	**22**
Q23. Validity of HV assessment	0	0	0	2	0	0	0	0	0	**11**
Q24. Standardized assessment of HV	2	0	0	0	2	2	2	2	0	**56**
Q25. Assessment period for case/control groups	2	-	-	-	2	2	-	-		**100**
Q26. Collected data on HV severity/symptoms	2	0	0	0	2	1	1	1	1	**22**
Q27. Adjusted for covariates	0	0	0	0	0	0	0	0	0	**0**
Q28. Reported data for ≥ 3 levels of associated factors	0	2	0	0	0	0	0	0	2	**2**
Q29. Reported data for subgroups of subjects	0	0	0	0	0	0	0	0	0	**0**
Q30. Generalizability of results to study population	0	1	0	0	0	0	0	0	1	**0**
Q31. Generalizability of results to other populations	2	0	0	0	2	0	0	2	2	**44**
Overall quality score	**1.45**	**0.89**	**0.93**	**1.22**	**1.23**	**1.13**	**0.96**	**1.07**	**1.06**	

[a] Purple shading = "Yes", Blue shading = "Partial", White shading = "No" or "Unable to determine", "-" = "Not applicable"; that is, items removed from scoring process and not included in % calculations.

Figure III Risk of bias in included studies (a) risk of bias for randomized studies, (b) risk of bias for non-randomized studies

Overview of results from meta-analyses

Figure IV provides the overall SMDs and SMDs for individual studies in which eight measurement factors before and after intervention in the HV group are compared. The primary function of HV orthosis is to correct the HVA, and a total of six studies investigated the effect of orthosis on the HVA correction. A small effect for HV orthosis in correcting HVA was found (SMD 0.31, CI 0.075, 0.547) with I^2 28.28%. Tang et al. [43] stated that their full-length orthosis with a toe separator provides a significantly positive reduction of the HVA of 5.79° in the HV group (SMD 0.85, CI 0.121,1.546), which has the highest corrective effect among all the recorded orthoses. The static orthosis with a toe separator tested by Moulodi et al. [38] also showed a significant positive HVA correction of 2.67° in the HV group (SMD 0.75, CI 0.143,1.325). Chadchavalpanichaya et al. [36] developed a custom-molded RTV toe separator, which helps to correct the HVA by 2.1° in the HV group (SMD 0.41, CI -0.012,0.827). The pooled estimation for orthoses with a toe separator was further investigated that the effect is medium (SMD 0.50, CI 0.189,0.803) with I^2 14.52%. The dynamic orthosis tested also showed a significantly positive reduction of the HVA of 2.13° (SMD 0.55, CI -0.038,1.127) [38]. The pooled estimation for dynamic orthoses showed small effect in HVA correction (SMD 0.27, CI -0.211,0.751) with I^2 42.29%.

Three of the studies investigated the pain score with the use of two different types of rating scales. One of them, Tehraninasr et al. [41], showed that their orthosis with a toe separator can significantly reduce the pain level (SMD 1.13, CI 0.319,1.887). The level of physical functioning before and after the application of an orthosis have also been compared. A small effect (SMD -0.30, CI -0.700,0.102) was achieved.

Two other studies investigated the impact of the foot orthosis on plantar pressure. Small effect for HV orthosis in plantar pressure reduction was found (SMD 0.41, CI 0.118, 0.700) with I^2 0.00%. It was found that the prefabricated full-length orthosis with an arch support [22] can significantly reduce the plantar pressure by 16.8 kPa (SMD 0.65, CI -0.090,1.354).

Observation of key design features

Customized vs. prefabricated

Among the orthoses that showed a significant reduction of the HVA after treatment amongst the HV patients, the orthoses developed by Chadchavalpanichaya et al. [36] and Tang et al. [43] are custom-made, while those in Moulodi et al. [38], Tehraninasr et al. [41], Torkki et al. [42], Doty et al. [37] and Farzadi et al. [22] are prefabricated. This shows that the ability of an orthosis to reduce the severity of HV or its treatment effectiveness might not be related to whether it is customized or prefabricated. However, adjustment and fitting are still key factors, and patients are instructed to adjust the prefabricated orthosis to the best fitting position [39].

Static vs. dynamic

In terms of HVA reduction, the results are consistent with those of the HV patients before and after the intervention. Both types of orthoses have a positive effect on treatment effectiveness, whilst all of the static orthoses that help to reduce the HVA are embedded with the feature of toe separator. Therefore, the toe separator seems to be the key element in correcting the misalignment of the big toe.

Considerations around orthosis length and arch support

In terms of the orthosis length, the full-length orthosis in Tang et al. [43] has a significant and exceptional corrective effect of HV in the HV group. The full-length orthoses with arch support in Farzadi et al. [22] can significantly reduce the plantar pressure. These results show that when considering the length of the orthosis for HV patients, full-length is preferred, and arch support may be important to achieve therapeutic effects.

Figure IV Comparison of observations [a]

Discussion

This is the first study to systematically evaluate and synthesize results from the extensive pool of literature that investigates the characteristics of HV orthoses and their effects on different factors. The data obtained from meta-analysis suggest that dynamic orthoses, and static orthoses with a toe separator help to reduce the HVA by approximately 2.1° to 5.79° among HV patients [36, 38, 43]. The treatment effect of orthoses with a toe separator on HVA correction is larger than that of dynamic orthoses. The full-length orthosis with toe separator developed by Tang et al. [43] has a significant and exceptional HVA correction effect. The use of orthoses with a toe separator for moderate degree HV patients can reduce HVA and hallux pain without serious complications [36, 41]. The studies also showed that the toe separator can greatly alleviate pain by better aligning the big toe and relieving the overstretched collateral ligaments and bone subluxation [43, 41]. However, due to the ease of use, fit and better appearance, users may more satisfied with dynamic than static orthoses [38]. The dynamic orthoses can reduce the contracture of the first metatarsophalangeal joint and better align the big toe through low torque and prolonged stretching [36, 44, 45]. The freedom of joint movement does not limit the ROM of the big toe, but help to maintain joint mobility and prevent joint stiffness, which seem to have a beneficial effect on the treatment of HV [38].

The full-length orthoses with an arch support tested by Farzadi et al. [22] help to reduce the plantar pressure and forefoot pain significantly. It can be suggested that forefoot pain has an evident relationship with plantar pressure in the metatarsalgia region [24, 46, 47]. This might be associated with better body load distribution by relieving the excessive pressure on the forefoot through metatarsal unloading. By maximizing the total contact area of the foot with a full-length orthosis, the peak plantar pressure can be reduced by 30% to 40% [48, 49]. In addition, with adequate arch support, the anatomical alignment of the foot can be restored correctly [41].

Both customized and prefabricated orthoses can significantly reduce the symptoms of HV. Ring and Otter [50] compared the clinical efficacy of casted foot orthoses and prefabricated foot orthoses in the treatment of plantar heel pain in 67 patients, and found no significant difference in effectiveness between the bespoke or prefabricated orthoses. In addition, compared to the average cost of bespoke devices, the prefabricated orthoses are 38% less expensive per patient. They concluded that prefabricated orthoses could provide benefits that are equivalent to those of casted foot orthoses, but at considerably reduced costs. Since the material properties, thickness, and rigidity of the orthoses studied remain unknown. No conclusion can be made on the best material for HVA reduction. However, Chadchavalpanichaya et al. [36] found that an RTV silicone toe separator is comfortable to wear. Its compliance with treatment is higher than that of the nighttime HV strap [36]. The cost of a toe separator made of RTV silicone is only one-tenth of that of medical grade silicone, which can be considered as a clinical and cost-effective option [36].

Torkki et al. [18] pointed out that an orthosis can provide short-term symptomatic relief. However, the wearing duration of the three orthoses in their study ranges from 1 month to 1 year. This may show that orthoses with a toe separator help to reduce the HVA not only for a short period of time but also on a continuous basis. Moreover, the angle reduction did not increase with treatment duration, which may indicate that the treatment reaches its equilibrium result at a certain point of time.

Conclusion

Foot orthoses can be an acceptable treatment option to reduce HV deformity. This systematic review demonstrates a positive relationship between HVA reduction and pain level with orthoses that offer a toe separator. Therefore, it is important to include this element in the conservative treatment of HV deformity, as well as the future development of HV orthoses. It is recommended that a fixed toe separator or a dynamic orthosis is used to maintain the anatomic alignment of the big toe for those who suffer from HV. The results of this study provide patients, practitioners and physicians with important information to help them better understand the characteristics of various HV orthoses and their performance in reducing HV deformity, and contribute to decisions around optimal treatment for patients.

Strengths and limitations

As with any systematic review or meta-analysis, the strength of these results relies on the quality of the studies included. The limitations of this study include the scarcity of studies found on this topic in the literature, lack of consistency in the various study methods, subjects' conditions, and limited consideration of the reliability and validity of the HV assessments in the included studies. Only a few randomized controlled trials are compared and reported in this study and there is limited information on the materials of the orthotics studied. More randomized controlled trials related to HV orthoses are needed, and more research on the material properties of HV orthoses is also required, in order to offer an effective solution for effective and optimal designs of HV orthoses.

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Figure legends

Figure I PICO question and a list of search strategy

Figure II (a) Visualization of main keywords from 148 papers, and (b) Flowchart of study selection procedure

Figure III Risk of bias in included studies (a) risk of bias for randomized studies, (b) risk of bias for non-randomized studies

Figure IV Comparison of observations [a]

PICO question

P	Population or Problem	Studies that included people with hallux valgus, and people without hallux valgus at baseline were included
I	Intervention	Randomized controlled trial, uncontrolled intervention study and quasi-experimental of the use of hallux valgus orthoses
C	Comparison or control	The comparison could be no hallux valgus orthotic treatment, or other orthotic designs
O	Outcome	Any effect of hallux valgus orthotic treatment

Search strategy

1. ("Hallux Valgus" AND (Design OR Fabrication OR Construction)) NOT (Implant OR Replacement)
2. ("Hallux Valgus" AND (Orthoses OR Orthosis) AND (Design OR Fabrication OR Construction)) NOT (Implant OR Replacement)
3. ("Hallux Valgus" AND (Orthoses OR Orthosis) AND Pressure) NOT (Implant OR Replacement)
4. ("Hallux Valgus" AND (Orthoses OR Orthosis) AND Gait) NOT (Implant OR Replacement)
5. ("Hallux Valgus" AND (Orthoses OR Orthosis) AND Alignment) NOT (Implant OR Replacement)
6. ("Hallux Valgus" AND (Orthoses OR Orthosis) AND Pain) NOT (Implant OR Replacement)
7. ("Hallux Valgus" AND (Orthoses OR Orthosis) AND "Walking speed") NOT (Implant OR Replacement)
8. ("Hallux Valgus" AND (Orthoses OR Orthosis) AND (Design OR Fabrication OR Construction) AND Pressure) NOT (Implant OR Replacement)
9. ("Hallux Valgus" AND (Orthoses OR Orthosis) AND (Design OR Fabrication OR Construction) AND Gait) NOT (Implant OR Replacement)
10. ("Hallux Valgus" AND (Orthoses OR Orthosis) AND (Design OR Fabrication OR Construction) AND Alignment) NOT (Implant OR Replacement)
11. ("Hallux Valgus" AND (Orthoses OR Orthosis) AND (Design OR Fabrication OR Construction) AND Pain) NOT (Implant OR Replacement)
12. ("Hallux Valgus" AND (Orthoses OR Orthosis) AND (Design OR Fabrication OR Construction) AND "Walking speed") NOT (Implant OR Replacement)

Figure I PICO question and a list of search strategy

242x90mm (150 x 150 DPI)

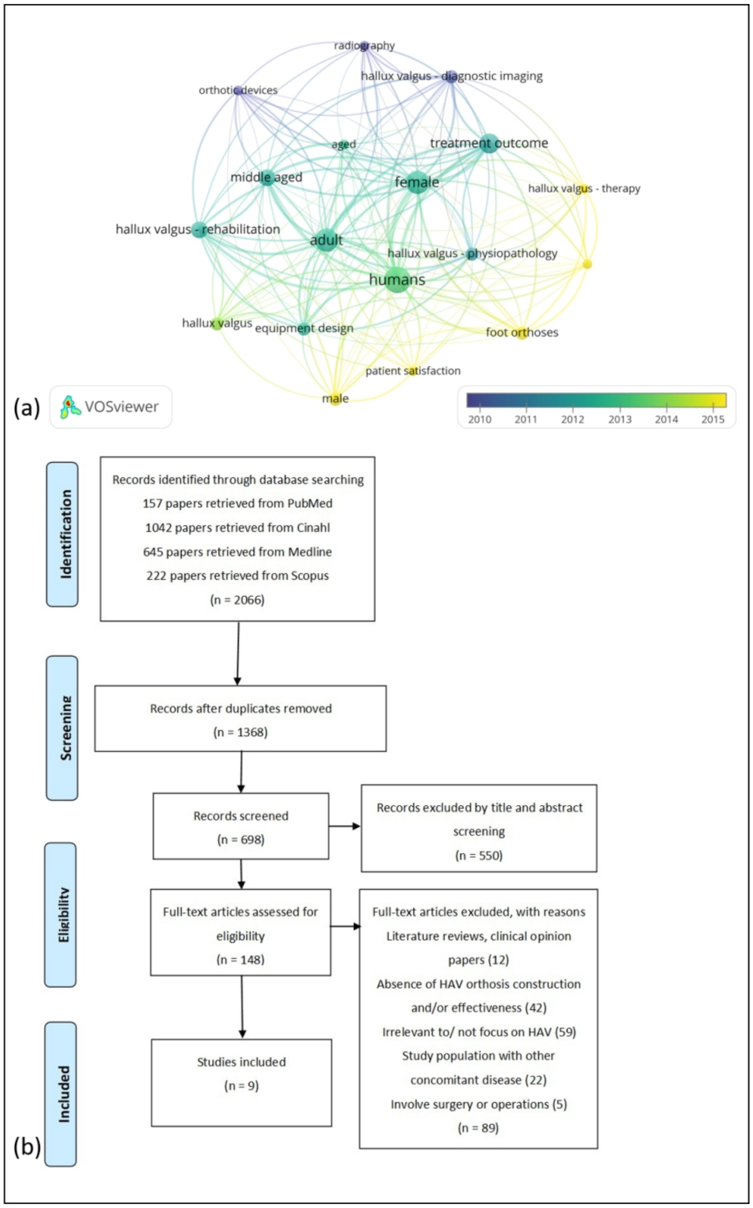


Figure II (a) Visualization of main keywords from 148 papers, and (b) Flowchart of study selection procedure

184x296mm (300 x 300 DPI)

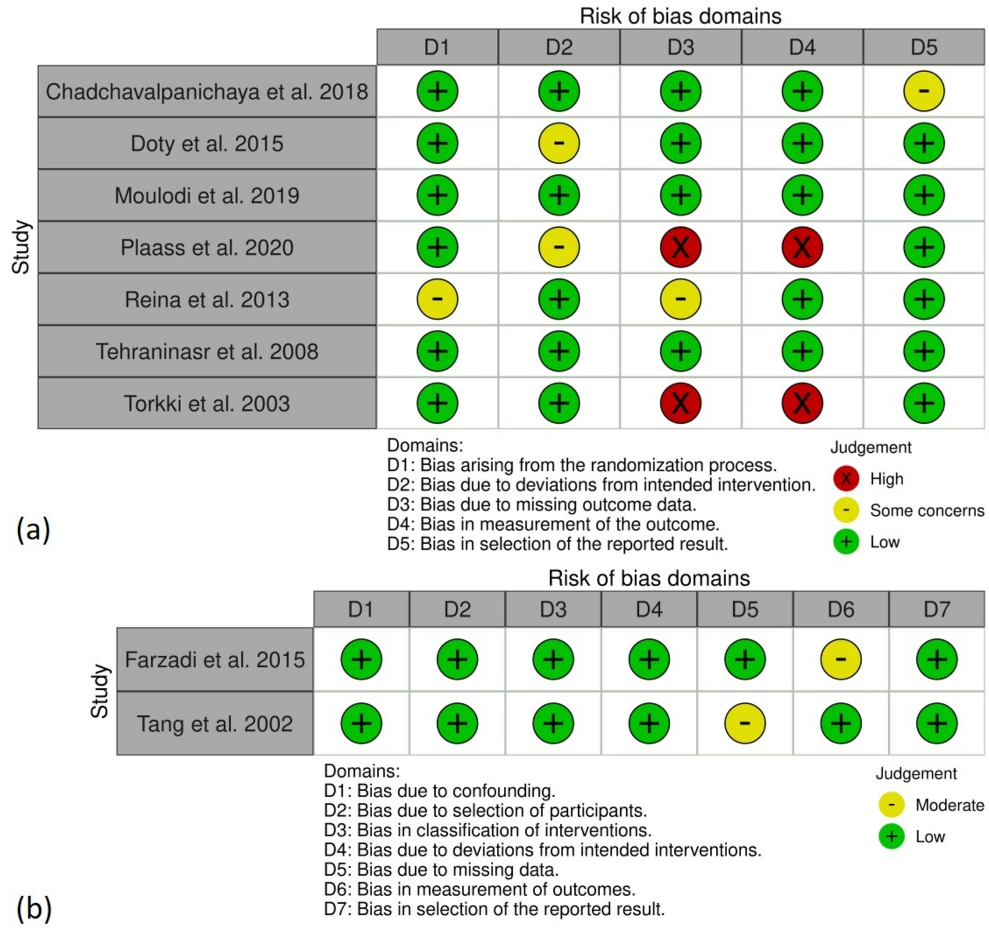
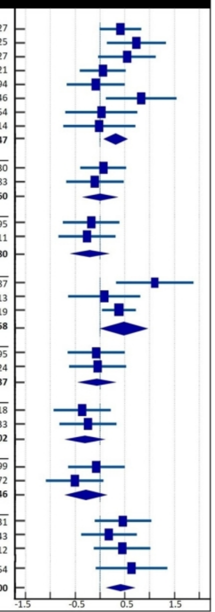


Figure III Risk of bias in included studies (a) risk of bias for randomized studies, (b) risk of bias for non-randomized studies

193x184mm (150 x 150 DPI)

Parameter	Author(s)	Orthosis type	Pre-intervention Mean	Pre-intervention SD	Post-intervention Mean	Post-intervention SD	Pooled SD	Mean Difference	SMDs	95% CIs
HVA	Chadchavalpanichaya et al. 2018	Custom-molded RTV toe separator	32.50	4.80	30.40	5.40	5.11	2.10	0.41	-0.012 to 0.827
	Moulodi et al. 2019	Static orthosis with toe separator	18.21	3.41	15.54	3.74	3.58	2.67	0.75	0.143 to 1.325
	Moulodi et al. 2019	Dynamic orthosis	17.96	3.75	15.83	3.94	3.85	2.13	0.55	-0.038 to 1.127
	Plaass et al. 2020	Dynamic orthosis	35.40	8.60	34.90	9.20	8.91	0.50	0.06	-0.410 to 0.521
	Reina et al. 2013	Custom-made foot orthoses	20.55	5.10	21.02	5.14	5.12	-0.47	-0.09	-0.675 to 0.494
	Tang et al. 2002	Full-length orthosis with toe separator	31.04	6.40	25.25	7.14	6.78	5.79	0.85	0.121 to 1.546
	Tehraninasr et al. 2008	Orthosis with toe separator	25.46	3.68	25.36	3.68	3.68	0.10	0.03	-0.701 to 0.754
	Tehraninasr et al. 2008	Nighttime orthosis	24.13	2.05	24.16	2.09	2.07	-0.03	-0.01	-0.742 to 0.714
								Overall:	**0.31**	**0.075 to 0.547**
								Heterogeneity: I^2=28.28%		
IMA	Plaass et al. 2020	Dynamic orthosis	15.40	3.00	15.20	3.10	3.05	0.20	0.07	-0.400 to 0.530
	Reina et al. 2013	Custom-made foot orthoses	10.86	2.33	11.10	2.34	2.34	-0.24	-0.10	-0.686 to 0.483
								Overall:	**-0.00**	**-0.360 to 0.360**
								Heterogeneity: I^2=0.00%		
FAOS-pain	Moulodi et al. 2019	Static orthosis with toe separator	85.28	12.24	87.49	12.29	12.27	-2.21	-0.18	-0.750 to 0.395
	Moulodi et al. 2019	Dynamic orthosis	81.61	17.41	85.89	14.50	16.02	-4.28	-0.27	-0.837 to 0.311
								Overall:	**-0.22**	**-0.620 to 0.180**
								Heterogeneity: I^2=0.00%		
Foot pain VAS	Tehraninasr et al. 2008	Orthosis with toe separator	4.26	1.48	2.66	1.34	1.41	1.60	1.13	0.319 to 1.887
	Tehraninasr et al. 2008	Nighttime orthosis	4.13	1.78	4.00	1.13	1.49	0.13	0.087	-0.643 to 0.813
	Torkki et al. 2003	NR	5.00	2.40	4.10	2.30	2.35	0.90	0.38	0.043 to 0.719
								Overall:	**0.48**	**0.000 to 0.958**
								Heterogeneity: I^2=51.39%		
FAOS-Quality of life	Moulodi et al. 2019	Static orthosis with toe separator	66.14	16.68	67.44	16.48	16.58	-1.30	-0.08	-0.649 to 0.495
	Moulodi et al. 2019	Dynamic orthosis	65.10	16.78	65.88	15.63	16.22	-0.78	-0.05	-0.619 to 0.524
								Overall:	**-0.06**	**-0.461 to 0.337**
								Heterogeneity: I^2=0.00%		
FAOS-Function	Moulodi et al. 2019	Static orthosis with toe separator	78.47	18.70	84.72	15.47	17.16	-6.25	-0.36	-0.934 to 0.218
	Moulodi et al. 2019	Dynamic orthosis	80.55	19.91	85.06	16.84	18.44	-4.51	-0.25	-0.814 to 0.333
								Overall:	**-0.30**	**-0.700 to 0.102**
								Heterogeneity: I^2=0.00%		
ROM	Moulodi et al. 2019	Static orthosis with toe separator	120.00	18.22	121.40	19.72	18.99	-1.35	-0.07	-0.644 to 0.499
	Moulodi et al. 2019	Dynamic orthosis	117.50	19.82	127.30	17.97	18.92	-9.77	-0.52	-1.091 to 0.072
								Overall:	**-0.29**	**-0.722 to 0.146**
								Heterogeneity: I^2=14.12%		
Plantar pressure	Doty et al. 2015	Full-length orthosis	47.58	21.59	35.76	28.20	25.11	11.82	0.47	-0.104 to 1.031
	Doty et al. 2015	Sulcus-length orthosis	47.58	21.59	43.15	26.20	24.01	4.43	0.18	-0.379 to 0.743
	Doty et al. 2015	3/4-length orthosis	47.58	21.59	37.21	24.20	22.93	10.37	0.45	-0.122 to 1.012
	Farzadi et al. 2015	Prefabricated full-length foot orthosis with arch support	123.90	25.30	107.10	26.50	25.91	16.80	0.65	-0.090 to 1.354
								Overall:	**0.41**	**0.118 to 0.700**
								Heterogeneity: I^2=0.00%		



[a] SMDs ≥ 0.2 or ≤ -0.2 highlighted in yellow; SMDs ≥ 0.5 or ≤ -0.5 in orange, and SMDs ≥ 0.8 or ≤ -0.8 in green

Figure IV Comparison of observations ^a

338x222mm (150 x 150 DPI)

PRISMA 2020 Checklist

Section and Topic	Item #	Checklist item	Location where item is reported
TITLE			
Title	1	Identify the report as a systematic review.	1
ABSTRACT			
Abstract	2	See the PRISMA 2020 for Abstracts checklist.	2
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of existing knowledge.	4-5
Objectives	4	Provide an explicit statement of the objective(s) or question(s) the review addresses.	4-5
METHODS			
Eligibility criteria	5	Specify the inclusion and exclusion criteria for the review and how studies were grouped for the syntheses.	6
Information sources	6	Specify all databases, registers, websites, organisations, reference lists and other sources searched or consulted to identify studies. Specify the date when each source was last searched or consulted.	6
Search strategy	7	Present the full search strategies for all databases, registers and websites, including any filters and limits used.	6
Selection process	8	Specify the methods used to decide whether a study met the inclusion criteria of the review, including how many reviewers screened each record and each report retrieved, whether they worked independently, and if applicable, details of automation tools used in the process.	6
Data collection process	9	Specify the methods used to collect data from reports, including how many reviewers collected data from each report, whether they worked independently, any processes for obtaining or confirming data from study investigators, and if applicable, details of automation tools used in the process.	6-7
Data items	10a	List and define all outcomes for which data were sought. Specify whether all results that were compatible with each outcome domain in each study were sought (e.g. for all measures, time points, analyses), and if not, the methods used to decide which results to collect.	6-7
	10b	List and define all other variables for which data were sought (e.g. participant and intervention characteristics, funding sources). Describe any assumptions made about any missing or unclear information.	6-7
Study risk of bias assessment	11	Specify the methods used to assess risk of bias in the included studies, including details of the tool(s) used, how many reviewers assessed each study and whether they worked independently, and if applicable, details of automation tools used in the process.	7
Effect measures	12	Specify for each outcome the effect measure(s) (e.g. risk ratio, mean difference) used in the synthesis or presentation of results.	7
Synthesis methods	13a	Describe the processes used to decide which studies were eligible for each synthesis (e.g. tabulating the study intervention characteristics and comparing against the planned groups for each synthesis (item #5)).	6
	13b	Describe any methods required to prepare the data for presentation or synthesis, such as handling of missing summary statistics, or data conversions.	7
	13c	Describe any methods used to tabulate or visually display results of individual studies and syntheses.	7
	13d	Describe any methods used to synthesize results and provide a rationale for the choice(s). If meta-analysis was performed, describe the model(s), method(s) to identify the presence and extent of statistical heterogeneity, and software package(s) used.	7
	13e	Describe any methods used to explore possible causes of heterogeneity among study results (e.g. subgroup analysis, meta-regression).	7
	13f	Describe any sensitivity analyses conducted to assess robustness of the synthesized results.	7
Reporting bias assessment	14	Describe any methods used to assess risk of bias due to missing results in a synthesis (arising from reporting biases).	6-7
Certainty assessment	15	Describe any methods used to assess certainty (or confidence) in the body of evidence for an outcome.	7

PRISMA 2020 Checklist

Section and Topic	Item #	Checklist item	Location where item is reported
assessment			
RESULTS			
Study selection	16a	Describe the results of the search and selection process, from the number of records identified in the search to the number of studies included in the review, ideally using a flow diagram.	Figure II
	16b	Cite studies that might appear to meet the inclusion criteria, but which were excluded, and explain why they were excluded.	Figure II
Study characteristics	17	Cite each included study and present its characteristics.	Table I
Risk of bias in studies	18	Present assessments of risk of bias for each included study.	Figure III
Results of individual studies	19	For all outcomes, present, for each study: (a) summary statistics for each group (where appropriate) and (b) an effect estimate and its precision (e.g. confidence/credible interval), ideally using structured tables or plots.	Figure IV
Results of syntheses	20a	For each synthesis, briefly summarise the characteristics and risk of bias among contributing studies.	13-14
	20b	Present results of all statistical syntheses conducted. If meta-analysis was done, present for each the summary estimate and its precision (e.g. confidence/credible interval) and measures of statistical heterogeneity. If comparing groups, describe the direction of the effect.	Figure IV
	20c	Present results of all investigations of possible causes of heterogeneity among study results.	13-14
	20d	Present results of all sensitivity analyses conducted to assess the robustness of the synthesized results.	13-14
Reporting biases	21	Present assessments of risk of bias due to missing results (arising from reporting biases) for each synthesis assessed.	11
Certainty of evidence	22	Present assessments of certainty (or confidence) in the body of evidence for each outcome assessed.	13-14
DISCUSSION			
Discussion	23a	Provide a general interpretation of the results in the context of other evidence.	15-16
	23b	Discuss any limitations of the evidence included in the review.	17
	23c	Discuss any limitations of the review processes used.	17
	23d	Discuss implications of the results for practice, policy, and future research.	17
OTHER INFORMATION			
Registration and protocol	24a	Provide registration information for the review, including register name and registration number, or state that the review was not registered.	2
	24b	Indicate where the review protocol can be accessed, or state that a protocol was not prepared.	2
	24c	Describe and explain any amendments to information provided at registration or in the protocol.	2
Support	25	Describe sources of financial or non-financial support for the review, and the role of the funders or sponsors in the review.	17
Competing interests	26	Declare any competing interests of review authors.	17
Availability of data, code and other materials	27	Report which of the following are publicly available and where they can be found: template data collection forms; data extracted from included studies; data used for all analyses; analytic code; any other materials used in the review.	18

From: Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. BMJ 2021;372:n71. doi:

PRISMA 2020 Checklist

10.1136/bmj.n71

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