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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 (HV) 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 HV.

**Design** Systematic review with meta-analysis.

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

**Eligibility criteria for selecting studies** Interventional studies with content focus on HV orthosis design and any of the outcomes related to effectiveness for treating HV are included. The standardised 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, nine 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 HV angle (standardised mean difference: 0.50, 95% CI: 0.189 to 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 HV 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 characterised 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 among the general public, especially women, due to hereditary or improper footwear but also a significant burden on public healthcare 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 patients with HV 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 is constructed by using footprints or foot moulds 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 multifactorial, however, previous related studies have merely focused on the effectiveness of foot orthoses in patients with HV. This article conducts a systematic study to investigate the effectiveness of these orthoses, and quantitatively synthesises 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 1. The keywords include 'hallux valgus', 'orthosis', 'design', 'fabrication', 'construction', 'pressure', 'gait', 'alignment', 'pain' and 'walking speed'.

### Inclusion and exclusion criteria

The titles and abstracts were then reviewed by two 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 anonymise 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, randomisation, 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 standardised mean differences (SMDs) and 95% CIs were calculated. To calculate the SMDs, the means and SDs of preintervention and postintervention were used.[30] The mean difference was divided by the pooled SD.[31] The SMDs are calculated with the following formulas:

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

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

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 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

| 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 1** PICO question and a list of search strategy.

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

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 (V.1.6.13) to examine the trend of the results. Keywords with fewer than three occurrences were excluded, and general terms were filtered out so that the focus would be on more specific and informative terms.[35] Figure 2A visualises the results that among 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 nine studies are discussed in this systematic review. Figure 2B presents a PRISMA flow chart of the article selection process.

### Study characteristics

The nine studies selected for inclusion in this paper focused on various characteristics and included different demographics (table 1). Of the nine studies included, seven were randomised controlled trials,[36–42] 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)), function during daily activities (the American Orthopedic Foot and Ankle Score (AOFAS) and FAOS) and quality of life (FAOS). 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.

### 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 (nine papers). The individual study results for quality appraisal are shown in table 2. 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 summarised in figure 3. The main causes of potential bias were missing outcome data and outcome measurement error.

### Overview of results from meta-analyses

Figure 4 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, 95% CI: 0.075 to 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, 95% CI: 0.121 to 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, 95% CI: 0.143 to 1.325). Chadchavalpanichaya *et al*[36] developed a custom-moulded room temperature vulcanising (RTV) toe separator, which helps to correct the HVA by 2.1° in the HV group (SMD: 0.41, 95% CI: −0.012 to 0.827). The pooled estimation for orthoses with a toe separator was further investigated that the effect is medium (SMD: 0.50, 95% CI: 0.189 to 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, 95% CI: −0.038 to 1.127).[38] The pooled estimation for dynamic orthoses

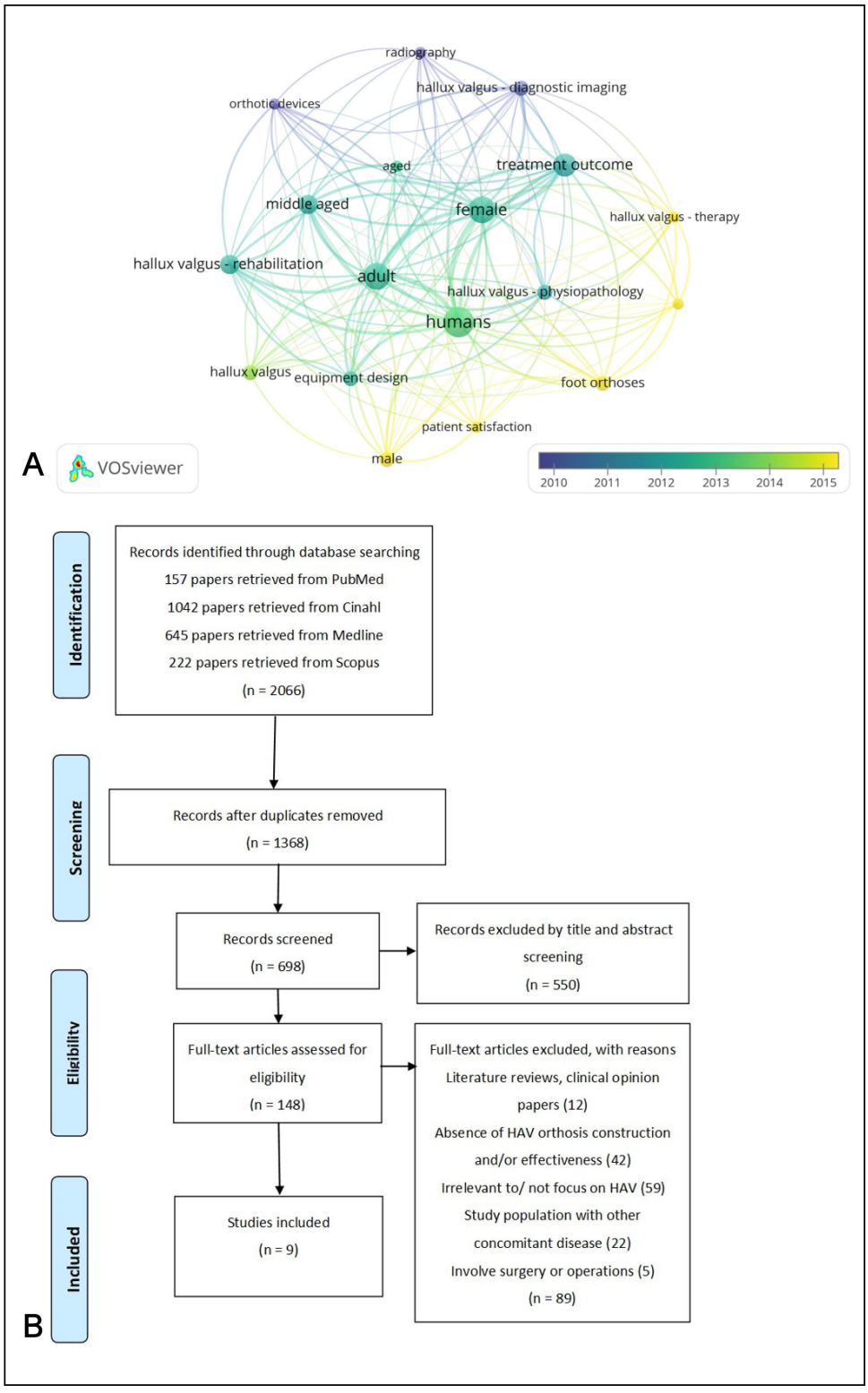



**Figure 2** (A) Visualisation of main keywords from 148 papers and (B) flowchart of study selection procedure. HAV, hallux valgus angle.

showed small effect in HVA correction (SMD: 0.27, 95% CI: −0.211 to 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, 95% CI: 0.319 to 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, 95% CI: −0.700 to 0.102) was achieved.

Two other studies investigated the impact of the foot orthosis on plantar pressure. Small effect for HV orthosis

**Table 1** Selected characteristics of studies included in analysis (nine unique studies)

| Authors(s)/country | Reference no. | Study aim | Method/device | Number of patients with HV | Age (mean±SD) | Orthosis | Orthosis material/ wearing duration | Result |
|---|---|---|---|---|---|---|---|---|
| Chadchavalpa nichaya *et al* 2018/Thailand | 36 | To investigate the effect of custom-moulded RTV silicone toe separator to reduce HVA. | Randomised controlled trial/ radiographic measurement and clinical assessment | 45 | HV group: 60.3±9.4 Control group: 60.8±10.8 | Custom-moulded 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 three different lengths. | Randomised controlled trial/ Tactilus Free Form Sensor System | 25 | Mean: 57 | Full-length orthosis<br>Sulcus-length orthosis<br>3/4-length orthosis | Not Reported/ 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 and maximum force. |
| Moulodi *et al* 2019/Iran | 38 | To compare the HVA, ROM, FAOS, pain and function in daily activities after the use of orthosis. | Randomised controlled trial/ clinical assessment | 24 | 22.79±1.44 | Static orthosis with toe separator<br>Dynamic orthosis | A bar and a single strap/1 month<br>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 analyse the effect of a dynamic orthosis on IMA and HVA. | Randomised controlled trial/ radiographic measurement and clinical assessment | 36 | HV group: 53.2±14.0 Control group: 48.5±12.9 | Dynamic orthosis | Not Reported/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 and HVA. | Randomised 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 and 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 and clinical assessment | 17 | 42.59±16.52 | Total contact orthosis with toe separator | Plastazote poron, microcell pull, plastazote and 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 and night-time orthosis on IMA, HVA and foot pain. | Randomised controlled trial/ radiographic measurement | 30 | 27±8.91 | Orthosis with toe separator<br>Nighttime orthosis | Polyfoam, polyethylene, plastazote toe separator/3 months<br>Polyfoam and a rigid polyethylene bar/3 months | IMA and HVA are reduced in both groups; however, the reduction is not significant; the orthosis with toe separator significantly reduces the pain intensity. |

Continued

Table 1 Continued

| Authors(s)/country | Reference no. | Study aim | Method/device | Number of patients with HV | Age (mean±SD) | Orthosis | Orthosis material/ wearing duration | Result |
|---|---|---|---|---|---|---|---|---|
| Torkki *et al* 2003/ Finland | 42 | To compare the effectiveness of surgical and orthotic treatment with patients on VAS. | Randomised controlled trial/ Not Reported | 69 | HV group: 49±10 Control group: 47±9 | Not Reported | Not Reported/12 months | Orthoses provide short-term symptomatic relief. |

FAOS, Foot and Ankle Outcome Score; HV, hallux valgus; HVA, hallux valgus angle; IMA, intermetatarsal angle; ROM, range of motion; RTV, room temperature vulcanising; VAS, Visual Analogue Scale.

in plantar pressure reduction was found (SMD: 0.41, 95% CI: 0.118 to 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, 95% CI: −0.090 to 1.354).

### Observation of key design features

#### Customised versus prefabricated

Among the orthoses that showed a significant reduction of the HVA after treatment among the patients with HV, 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 customised 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 versus dynamic

In terms of HVA reduction, the results are consistent with those of the patients with HV before and after the intervention. Both types of orthoses have a positive effect on treatment effectiveness, while 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 patients with HV, full-length is preferred, and arch support may be important to achieve therapeutic effects.

## DISCUSSION

This is the first study to systematically evaluate and synthesise 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 patients with HV.[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 patients with HV 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

**Table 2** Results of quality assessment of all included papers (nine unique studies)

| 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. Standardised 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. Standardised assessment of HV | 2 | 0 | 0 | 0 | 2 | 2 | 2 | 2 | 0 | 56 |
| Q25. Assessment period for case/control groups | 2 | – | – | – | 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. Generalisability of results to study population | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 |

Continued

**Table 2** Continued

| 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** | |
| Q31. Generalisability 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 | |

Entries in italics indicate 'Yes', bold indicates 'Partial', bold italic indicates 'No' or 'unable to determine', '–' indicates 'not applicable'; that is, items removed from scoring process and not included in % calculations.
HV, hallux valgus.

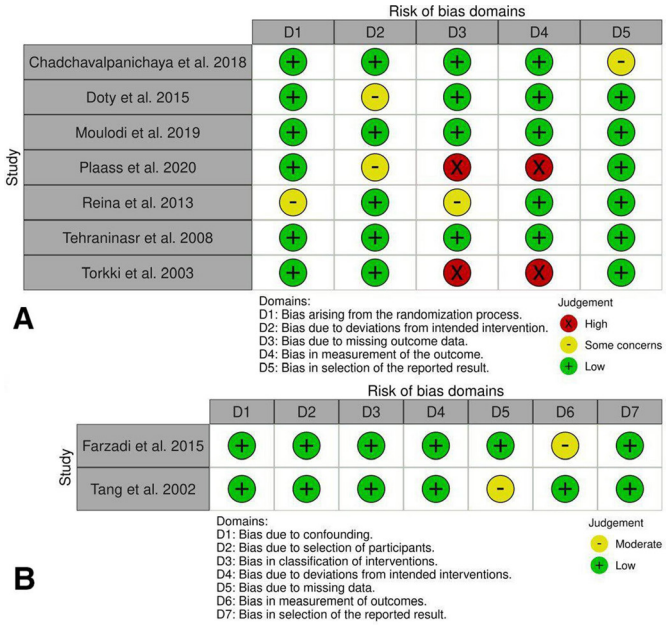
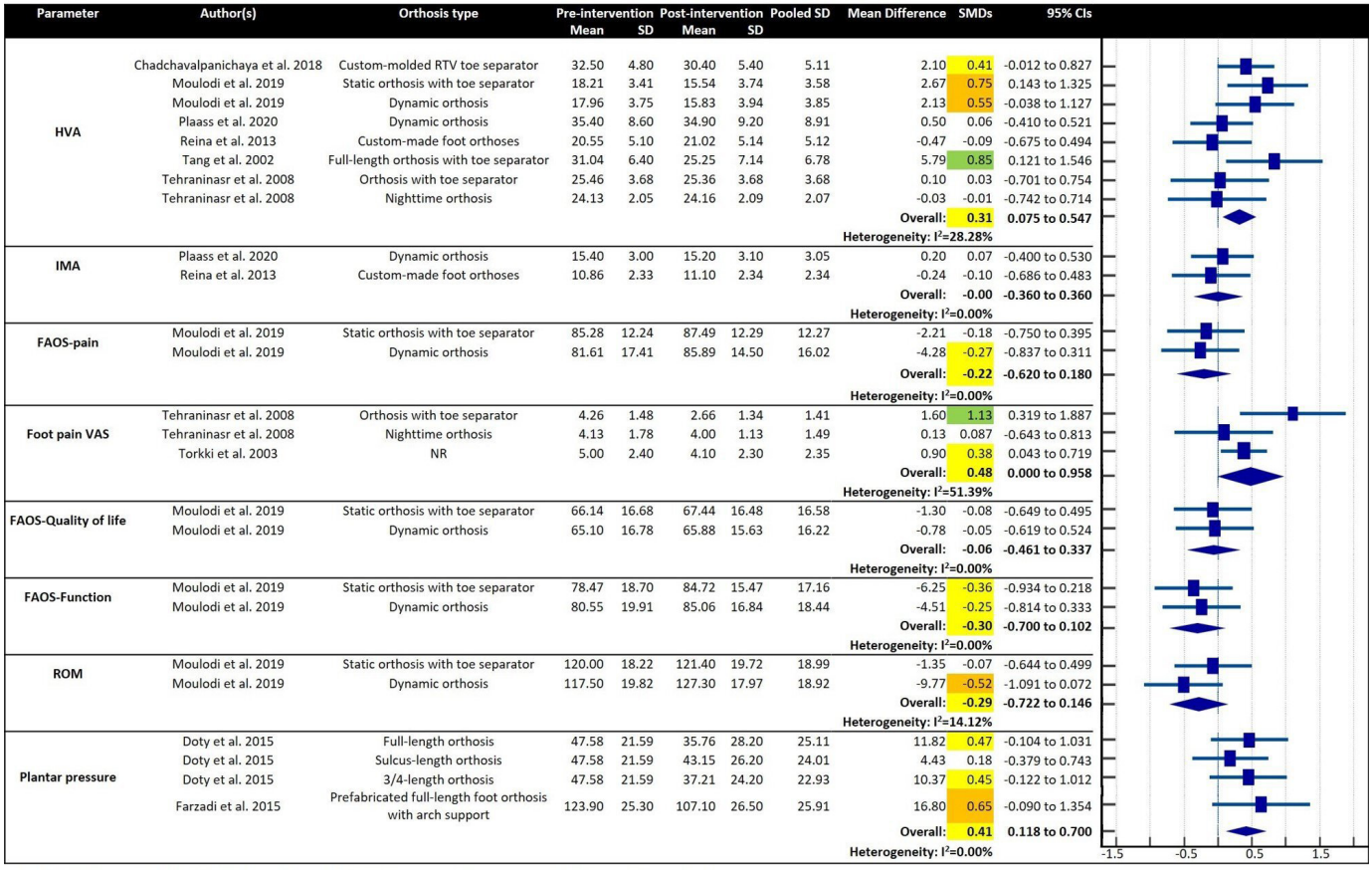



**Figure 3** Risk of bias in included studies. (A) Risk of bias for randomised studies. (B) Risk of bias for non-randomised studies.

collateral ligaments and bone subluxation.[41 43] However, due to the ease of use, fit and better appearance, users may be 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 maximising the total contact area of the foot with a full-length orthosis, the peak plantar pressure can be reduced by 30%–40%.[48 49] In addition, with adequate arch support, the anatomical alignment of the foot can be restored correctly.[41]

Both customised 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 with 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



| 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 |
| | Mouldodi 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 |
| | Mouldodi 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 | Mouldodi 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 |
| | Mouldodi 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 | Mouldodi 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 |
| | Mouldodi 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 | Mouldodi 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 |
| | Mouldodi 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 | Mouldodi 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 |
| | Mouldodi 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 4** Comparison of observations.[a]SMD ≥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. FAOS, Foot and Ankle Outcome Score; HVA, hallux valgus angle; IMA, intermetatarsal angle; ROM, range of motion; RTV, room temperature vulcanising; SMD, standardised mean difference; VAS, Visual Analogue Scale.

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 randomised controlled trials are compared and reported in this study and there is limited information on the materials of the orthotics studied. More randomised 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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