Foot orthoses for flexible flatfeet in children and adults: a systematic review and meta-analysis of patient-reported outcome measures

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Abstract

Background: This systematic review and meta-analysis provides an overview of the effectiveness of orthoses for flexible flatfeet in terms of patient-reported outcome measures (PROMs) in children and adults.

Methods: Electronic databases were searched for studies comparing PROMs at baseline and follow-up in an orthoses versus control group. Methodological quality of the studies was assessed and a meta-analysis was performed if there were multiple studies with the same PROM.

Results: Four randomized controlled trials (RCTs) in children (N=353) and four RCTs and one prospective study in adults (N=268) were included. There was considerable heterogeneity between studies. A meta-analysis demonstrated that pain reduction between baseline and follow-up was significantly larger in the orthoses (N=167) than in the control groups in adults (N=157; p=0.05).

Conclusion: Due to heterogeneity in study designs we cannot conclude that foot orthoses are useful for flexible flatfoot in children and adults. However, based on the meta-analysis orthoses might be useful in decreasing pain in adults.

Introduction

Flatfoot is a usually asymptomatic condition that can be influenced by multiple congenital and acquired factors [1]. The etiology differs between children and adults. Normal development of the foot in children is associated with physiological flatfoot [2]. Most babies are flatfooted and the arch elevates spontaneously in the first decade [3]. All youth ages have a wide range of normal arch heights [4]. Flatfeet are identified as present in 54% of 3-year-olds and 26% of 6-year-olds [5]. It is estimated that 10–60% of children with flexible flatfeet have functional impairment [6]. Prevalence in older adults has been reported to reach 19% [7].

There are two types of flatfeet: flexible and rigid. In contrast with flexible flatfeet, the rigid type is less common. Rigid flatfeet account for less than 1% of the population [5], are characterized by a lowered arch both weightbearing and non-weightbearing [8], and foot orthoses probably have little effect because of the limited range of motion.

Foot orthoses are frequently prescribed in daily practice for symptomatic flexible flatfeet. Although studies suggest that orthoses for asymptomatic flexible flatfeet are not necessary [5], 10% of American children with flatfeet are treated with orthotics, while only 1–2% are symptomatic [5]. About 50% of all adults with symptomatic flexible flatfeet are treated with foot orthoses [9]. However, the literature on the effect of foot orthoses for symptomatic flatfeet is controversial, likely due to the high heterogeneity between studies [9–11].

It is important to establish the effectiveness of orthoses because the large number of orthosis prescriptions worldwide has a major impact on healthcare costs. Moreover, evidence of a potential positive or negative effect of orthoses on flatfeet can be used in the orthopedic clinic as an argument to improve treatment of patients with flatfeet.

In previous systematic reviews, kinematic and radiological measurements were mainly used as outcome measures [11–13]. Some reviews included studies without a control group or patients without symptoms or without follow-up [14]. One systematic review included stage 1 adult-acquired flatfoot, which is a precursor to visible changes in foot alignment [15]. In order to obtain valid evidence on the clinical effectiveness of orthoses from a patient perspective and subsequently improve evidence-based medicine in routine orthopedic practice for both children and adults with symptomatic flatfeet, a systematic overview of studies reporting patient-reported outcome measures (PROMs) that includes an appropriate control group is warranted.

This systematic review and meta-analysis provides an overview of the effect of orthoses for symptomatic flexible flatfeet in terms of PROMs in children and adults.

Methods

We adhered to the standard guidelines of Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) [16].

Inclusion and exclusion criteria

Studies were included in this systematic review if the study (1) compared adults or children with flexible flatfeet with orthoses with a control group with sham soles or no orthoses; (2) evaluated PROMs at baseline and after treatment with a follow-up of at least two weeks; (3) had full text available; (4) was published in English, Dutch or German. Studies concerning patients with neuromuscular or systemic diseases were excluded. Comments, editorials, case reports, reviews, letters, guidelines and protocols were also excluded.

Information sources

Electronic databases (EMBASE, Medline (OvidSP), Web-of-Science, Scopus, CINAHL, Cochrane, Pubmed) were systematically searched for relevant studies since their inception up to February 2021. In addition, reference lists of included articles were screened for eligible studies that were not found in the electronic databases. Article titles, keywords, and abstracts were searched for the following keywords and their synonyms: flatfoot AND orthoses. All search strategies in the databases are specified in Supplementary data 1.

Study selection

One reviewer (NO) examined article titles and abstracts for eligibility. Full texts of potential studies were screened by the same reviewer to determine final eligibility for inclusion in this review and meta-analysis (Fig. 1). Uncertainty concerning inclusion of studies was solved in a single consensus meeting with a second reviewer (CP).

Quality assessment

Two authors (NO and CP) independently assessed the methodological quality of each included study using the Revised Cochrane risk-of-bias tool (RoB 2) for randomized trials and the Risk Of Bias In Non-Randomized Studies - of Interventions (ROBINS-I) for prospective cohort studies [17, 18]. All quality criteria domains were rated as “low risk”, “some concerns”, or “high risk” by answering the corresponding questions and following the algorithm for judgment (Fig. 2). Disagreements were solved by consensus. In case of persistent disagreement, a third reviewer was consulted (IN).

Data extraction and presentation

One author (NO) extracted the data of the included studies. Information was collected on study design, study population, measuring method for pes planus, types of orthoses, PROMs, follow-up period, and results. Meta-analyses using a random-effects model was performed if there were multiple articles – or subgroups within articles – in which the same PROM was used. Outcome data of children and adult articles were not combined in the meta-analysis because of the difference in etiology of flexible symptomatic flatfeet.

When standard deviations were not provided in the article, the range split by four was used as standard deviation. The I^2 statistic was calculated to determine the percentage of variation across studies that is due to heterogeneity rather than chance. Data analysis was performed with Review Manager (Revman) version 5.4.1.

Results

Study inclusion

The initial search identified 4629 potentially relevant studies. After removing duplicates, titles and abstracts of 2579 articles were screened (Fig. 1). A total of nine studies met all eligibility criteria: four RCTs in children and four RCTs and one prospective study in adults (Table 1) [19–27].

Table 1
Overview of study characteristics.

	First author, year published	Design	Overall risk of bias †	N (% male)	Mean age in years ± SD	Included patients (% flexible)	Measurement method for pes planus	Brand or type of orthoses versus control group (N)	Outcome measurement *	FU	Conclusion of authors
Children	Asgaonkar 2012 [19]	RCT	High	60 (50%)	I: 9.4 ± 2.7 C: 9.3 ± 2.4	Flatfoot (100%)	Staheli arch index Instep footprint	I: Valgus pad, rubber (30) C: No orthoses (30)	Pain (VAS)	1Y	Significant less pain established in orthoses group compared control gro (p < .05)
	Hsieh 2018 [27]	RCT	Low	52 (54%)	I: 6.9 ± 0.6 C: 6.2 ± 0.4	Symptomatic flatfoot (100%)	Beighton > 4 NDT ≥ 6mm FPI-6 > 6 X-ray angles	I: Thermoplastic insoles with medial arch support High-density EVA (26) C: No orthoses (26)	Physical function Questionnaires: PODCI and HRQoL	3M	Significant improvem in pain/comf and physic health (p < .05) in interventio group compared control gro
	Sinha 2013 [22]	RCT	High	81 (59%)	I: 8.3 ± 4.3 C: 8.3 ± 4.4	Symptomatic flatfoot (100%)	Pain Fatigue Gait disturbances	I: Medial arch orthoses (55) C: No orthoses (26)	AOFAS score	> 2Y	Significant improvem in AOFAS scores between interventio and contro group, benefitting the interventio group (p < .05)
	Whitford 2007 [24]	RCT	Low	160 (53%)	I: 9.5 ± 1.5 I: 9.8 ± 1.3 C: 9.5 ± 1.4	Excess pronation (100%)	RCSP > 4 NDT	I: Custom orthoses (52) I: Ready-made orthoses (54) C: No orthoses (54)	Pain yes/no Self Perception Profile for Children	1Y	No significant differences between groups in self-perception and pain
Adults	Andreasen 2013 [20]	RCT	High	70 (19%)	43.0 ± 3.0	Flatfoot and chronic pain conditions in the foot (100%)	Calcaneal valgus > 6° Overload-related pain under knee	I: Medial arch and calcaneus support, EVA (20) I: Exercise program (19) I: Orthoses + exercise program (17) C: Folder with exercises (14)	Pain during walking, running, resting (VAS)	1Y	No significant differences in pain between orthoses groups compared non-orthos groups
	Esterman 2005 [23]	RCT	High	47 (94%)	21.6 ± 3.9	Air Force recruits with flatfeet (100%)	Arch index = footprint B/(A + B + C)	I: Flexible/semi-rigid orthoses, AOL, with rearfoot varus wedge (25) C: No orthoses (22)	Pain yes/no General foot health, injury Quality of life Physical health	8W	No significant differences between study grou for pain, injury, foot health, and quality of l

First author, year published	Design	Overall risk of bias †	N (% male)	Mean age in years ± SD	Included patients (% flexible)	Measurement method for pes planus	Brand or type of orthoses versus control group (N)	Outcome measurement *	FU	Conclusion of authors
Shih 2011 [21]	RCT	High	24 (75%)	I: 31.3 ± 8.3 C: 34.4 ± 9.8	Flatfoot in runners with pain over anterior knee or foot region during running (100%)	Navicular Drop Test Non-weightbearing rearfoot varus > 5° or weightbearing calcaneal valgus > 5°	I: Wedged foot orthoses, EVA (12) C: Sham orthoses (12)	Pain (VAS) after 60-minute treadmill test	2W	Significant less pain i the immediate and short-term effec on inciden of pain between groups (p < .05)
Taspinar 2017 [26]	PS	Some concerns	60 (25%)	50.5 ± 9.0	Bilateral flatfoot, identical type (97%)	Navicular Drop Test X-ray: CP < 20	I: Medial arch support (20) I: Thomas heel, external support (20) C: Exercise program (20)	Foot pain index Foot function index SF36-PCS	3M	All groups improved pain, foot function index, and quality of l (p < .05); n significant difference between groups
Yurt 2019 [25]	RCT	Low	67 (42%)	I: 21.7 ± 2.9 I: 23.1 ± 5.5 C: 21.1 ± 2.0	Foot pain for at least one month due to flatfoot (100%)	MFPI ≥ 6 Tibiocalcaneal angle > 5°	I: CAD-CAM orthoses and exercise (22) I: Conventional orthoses and exercise (22) C: Sham orthoses and exercise (23)	Pain (VAS) Foot function index SF-36 Satisfaction	8W	Pain intensity a physical health significant improved i CAD-CAM and conventio orthoses compared sham grou (p < .05)

* Only PROMs are described with corresponding conclusions in this table.

† Overall risk of bias assessment (high, low, some concerns) according to the RoB 2 and ROBINS I quality assessment tools presented in Fig. 2.

Abbreviations: AAFD = adult-acquired flatfoot deformity, AFO = molded angle-foot orthosis, AOFAS = American Orthopaedic Foot and Ankle Society, AOL = Australian orthotics laboratory, C = control group, CAD-CAM = computer-aided design/computer-aided manufacturing, CSE = central stabilizer element (customized orthoses), EVA = ethylene-vinyl acetate, FHSQ = foot health status questionnaire, FU = follow-up, HRQoL = health-related quality of life, I = intervention group, (M)FPI = (modified) foot posture index, M = months, N = number of patients, NA = not available, NDT = navicular drop test, PCI = physiologi cost index, PODCI = pediatric outcomes data collection instrument for pain/comfort and happiness, PS = prospective study, PTTI = posterior tibial tendon insufficiency, QA = quality assessment, RCSP = resting calcaneal stance position, RCT = randomized controlled trial, SD = standard deviation, SF-36 = Short-Fo Health Survey, UCBL = orthosis type of University from California Biomechanics Laboratory (aims to limit motion of subtalar joint), VAS = Visual Analogue Scale, W = week, Y = year

Risk of bias in studies

Three RCTs were classified as low risk of bias, five RCTs as high risk of bias. The only prospective study was qualified as “some concerns” (Fig. 2). The methodological shortcomings of the RCTs mainly concerned domain 4 (measurement of the outcome). Domain 1 (randomization process) was scored best with six studies as “low risk” and two studies as “some concerns”, followed by domain 2 (deviations from the intended interventions) and domain 5 (selection of the reported results), where six studies scored “low risk” and two studies were judged as “some concerns”.

Study characteristics

The sample size of the included studies on the effectiveness of orthoses for flatfeet in children ranged from 52 to 160. Studies on the effectiveness in adults had sample sizes of 24 to 70 participants. Mean age of children and adults per study ranged from 6.2 to 9.5 years (weighted mean 8.8) and 21.1 to 50.5 years (weighted mean 34.8), respectively. Patient recruitment varied widely between the child studies (Table 1). One study recruited children in primary and secondary school [19], one in a rehabilitation outpatient clinic [27], another in an orthopedic outpatient clinic [22], and the last child study recruited among the general population via media and pamphlets [24]. Only one of these studies assessed patient compliance. Compliance with the treatment protocol was reported to be nearly 100% and was similar between the intervention and the control group [24]. Four adult studies recruited patients in outpatient rehabilitation clinics [21, 23, 25, 26] and one study recruited patients in an outpatient orthopedic clinic [20]. The study populations included in the adult studies varied: three studies included the general patient population with symptomatic flexible flatfeet [20, 25, 26], the other two included only Air Force recruits [23] or runners [21]. Most studies specifically included patients with symptomatic flatfeet (Table 1). Only one of the adult studies measured patient compliance and reported that only half of the subjects in the orthoses group wore their orthosis most of the time or always [23]. Methods of measuring flatfeet varied between studies; most researchers used arch indexes, the Navicular Drop Test or the (Modified) Foot Posture Index as diagnostic method. The follow-up in the studies with children ranged from three months [27] to over two years [22], and in the studies with adults from three weeks [21] to one year [20].

None of the child studies used sham soles as control group, whereas two out of five adult studies did [21, 25]. No other studies had insoles as control group. The nine studies had in total eleven intervention groups with orthoses, since there were two adult studies with both prefabricated orthoses and customized orthoses groups [24, 25]. These were all medial wedged internal orthoses. One child study and one adult study had an intervention group that used prefabricated orthoses [24, 25]. Three child studies and two adult studies had an intervention group that used custom-made orthoses [20, 22, 24, 25, 27], of which one adult study used Computer Aided Design-Computer Aided Manufacturing (CAD-CAM) to design the orthoses [25]. One child study and three adult studies did not specify whether the orthosis were prefabricated or customized [19, 21, 23, 26]. Materials for orthoses were thermoplastic [22–24, 26], ethylene-vinyl acetates (EVA) [20, 21, 25, 27], and rubber [19].

Only one study controlled the analysis of orthoses' effectiveness for physiotherapy as a potential confounder by splitting both the orthoses group and the no-orthoses group into a physiotherapy and no-physiotherapy group [20].

Patient-reported outcome measures in children

Effectiveness of orthoses was mainly measured in terms of pain reduction. In one RCT it was shown that the orthoses group experienced significantly less pain, expressed as VAS score reduction over a follow-up period of one year, compared to no orthoses ($p < 0.05$) [19]. Step length, physical cost index (PCI), stride length, cadence, and velocity were also measured in addition to pain. An improvement in walking efficiency was seen based on these parameters.

In another RCT, that used the American Orthopaedic Foot and Ankle Score (AOFAS) for patients' forefoot, midfoot, and hindfoot as outcome measure, the orthoses group also had significantly less pain during two years follow-up in all foot areas (all $p < 0.01$), whereas the no-orthoses control group only showed significantly reduced pain in the forefoot [22]. A significant difference between pain reduction in the orthoses and control groups was reported for the midfoot and forefoot ($p < 0.05$). Multiple angles were measured on X-ray. A correlation between the calcaneal pitch angle and the lateral talocalcaneal angle with the AOFAS hindfoot score was found.

When motor proficiency, presence of pain (yes/no), exercise efficiency (measured as maximal oxygen uptake by VO_2 max), and self-perception were used as primary outcome measures in a study with customized, prefabricated orthoses and no-orthoses control groups, no difference between these groups was observed after three months and after one year follow-up [24]. In this RCT, the authors used the Self Perception Profile for Children because of the suggestion that foot orthoses might be embarrassing for children.

In the fourth RCT, physical activity (10-m normal and fast walking, stair ascent, stair descent, and chair rising), physical function, and psychometric properties (Pediatric Outcome Data Collection Instrument for evaluating pain/comfort and happiness and Pediatric Quality of Life Inventory) were evaluated at baseline and at 3 months follow-up. The intervention group showed significant improvement in all outcomes compared to the no-orthoses group ($p < 0.05$) [27].

Patient-reported outcome measures in adults

Four RCTs and one prospective study in adults were included in this systematic review. Three studies used visual analogue scale (VAS) scores as outcome measure. One RCT included patients with excessive pronation and chronic foot pain (mean duration of pain = 7.2 years) [20]. Participants were randomized into an orthoses group, an exercise program group, an orthoses with exercise program group, and a control group, which received a folder with exercises. Pain intensity was assessed during resting, walking, and running. There was significant pain reduction during walking within all four groups between baseline and at 4 and 12 months follow-up. No significant differences could be found between the groups [20].

Another RCT examined the immediate and short-term effects of foot orthoses during a 60-minute running test in pronated-foot runners with overuse knee or foot pain during running [21]. VAS score decreased significantly in the orthoses group after a 2-week treatment ($p < 0.01$) but did not decrease in the sham sole group.

An 8-week follow-up study with three groups – CAD-CAM, conventional, and sham soles – also reported significantly less pain using VAS in both orthoses groups after treatment compared to the sham soles group ($p < 0.05$) [25]. All groups scored significantly higher on physical health (SF-36). The mental health domain of the SF-36 did not show a significant difference between the groups. The Foot Function Index (FFI) showed significantly better outcomes for the conventional orthoses group ($p < 0.001$) compared to the sham sole group.

The study population of the fourth RCT consisted of Air Force recruits. In this study population there was no significant difference in "lower limb pain in the previous 24 hours", nor in the questionnaires General Foot Health (GFHQ), Quality of life (WHOQOL), or Physical health (WHOQOL) between the orthoses and the no-orthoses groups [23].

The only prospective study included found a significant improvement in the orthoses group, external shoe modification group, and pes planus exercise group after treatment of three months in terms of foot pain, FFI, and quality of life ($p < 0.05$). There were no differences between the groups [26].

Meta-Analysis: Visual Analogue Scale

Because of the heterogeneity in outcome measures used in the included studies, we could only perform a meta-analysis of the three adult RCTs that used VAS scores as outcome measure (Fig. 3). Analyses were stratified for the conditions in which VAS scores were measured: resting, walking, and running. Pain reduction between baseline and follow-up in the orthoses groups was significantly larger than in the control groups when resting (9.46, 95% CI [16.50, 2.42], $p < 0.001$) and when walking (6.26, 95% CI [8.93, 3.61], $p < 0.001$). Pain reduction was not significantly different between the orthoses and control groups during running (2.96, 95% CI [5.33, 11.24], $p = 0.48$). The I^2s indicated considerable heterogeneity in the resting ($I^2 = 88\%$) and running ($I^2 = 78\%$) categories. Overall, a significant difference in pain reduction was found between the orthoses groups and the control groups (4.76, 95% CI [9.46, 0.06], $p = 0.05$).

Discussion

The aim of this systematic review was to provide an overview of the effectiveness of orthoses for symptomatic flexible flatfeet in terms of patient-reported outcome measures compared to no orthoses or sham soles in children and adults.

Three of the four included RCTs in children with no orthoses as control group found that improvements in PROMs were significantly higher in the orthoses than in the control groups [19, 21, 22]. The only study not to specifically include symptomatic participants did not find any differences between the groups [24]. Of the five included adult studies, two RCTs compared orthoses with sham soles and reported significantly higher PROM improvement in the orthoses group compared to the control group [21, 25]. The only prospective study, in which participants could choose between two different types of orthoses or an exercise program, noted improvement in all PROMs in all groups, with no significant differences observed between groups [26]. The remaining two adult RCTs also reported no significant difference between the intervention and control groups [20, 23]. The difference in effectiveness of orthoses reported by the included studies could not be explained by differences in study design, population, follow-up, or any of the other parameters presented in the studies. It is therefore difficult to draw any firm conclusions. However, the meta-analysis showed that the overall decrease in VAS score at follow-up compared to baseline was significantly higher in the orthoses group than the no-orthoses or sham sole group in adults.

This systematic review evaluated differences in PROMs between orthoses and control groups to assess effectiveness of orthoses from a patient perspective. Besides the nine studies included in this review, six prospective studies in children [28–33], one RCT [34], nine prospective [35–43] studies, and one retrospective study [44] in adults were identified which also described effectiveness of orthoses in terms of PROMs. However, these studies did not meet several of our inclusion criteria, i.e. the presence of a control group with no orthoses or sham soles and follow-up measurements. When control groups were present, they consisted of patients without symptomatic flexible flatfeet, with other orthoses, or with tape. In the orthoses groups of these studies, improvements in PROMs over time were seen in five child studies and eight adult studies. These results should however be interpreted with caution, since three studies in our systematic review showed significant improvements in PROMs in control groups as well, without significant differences between the orthoses and control groups [20, 24, 26].

Although child and adult flatfeet differ in etiology, all ages are included in this review because of the wide overlap in diagnosing flatfeet, type of symptoms, method of measurement, and treatment (Table 1).

The main limitation of this review was the heterogeneity between included studies, which involved differences in patient characteristics, PROMs, conditions in which the PROM was measured, length of follow-up, and orthoses used, as well as the choice for sham sole or no soles as control group. The use of sham soles as a comparison group is questionable. The aim of using a sham sole in the control group is to decrease the psychological effect of the idea of being treated. However, it is important to be aware that a sham sole could have a positive influence on stability and thereby on PROMs.

There are 40 definitions of flexible flatfeet in children [45]. As there is no universally accepted definition of flatfoot, studies investigating the effect of orthoses on flatfeet have conducted multiple diagnostic measurements based on physical examination and radiographs, which causes further heterogeneity [2, 9–11, 14, 46].

Only one RCT reported compliance and found that just half of the participants in the intervention group wore the orthoses most of the time or always, with lack of comfort as primary reason for not wearing them [23]. Besides compliance, activity and/or supported physiotherapy are also known to affect the PROMS of orthoses usage. Only one study controlled for physiotherapy as confounder with two extra groups [20].

For future studies, it is recommended to give extra consideration to subject characteristics, the control group used, and whether there is physiotherapy involved. Randomized controlled trials on the effectiveness of orthoses for flatfeet could likewise benefit from the use of a universal PROM tool. A promising possibility may be the use of Patient Reported Outcomes Measurement Information System (PROMIS) to provide evidence-based medicine in orthopedic clinics [47]. PROMIS offers a standardized tool to measure PROMs and allows for comparison of health outcomes across different disease states and populations regardless of age, culture, or disabilities.

Based on the results of this systematic review we cannot conclude that foot orthoses are useful for flexible flatfoot in children and adults. However, the meta-analysis showed a significant decrease in pain in the adult orthoses group after treatment compared to the no-orthoses and sham orthoses groups.

Declarations

- Ethics approval and consent to participate: not applicable.
- Consent for publication: Not applicable.
- Availability of data and materials: The datasets used and/or analysed during the current study available from the corresponding author on reasonable request.
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Figures

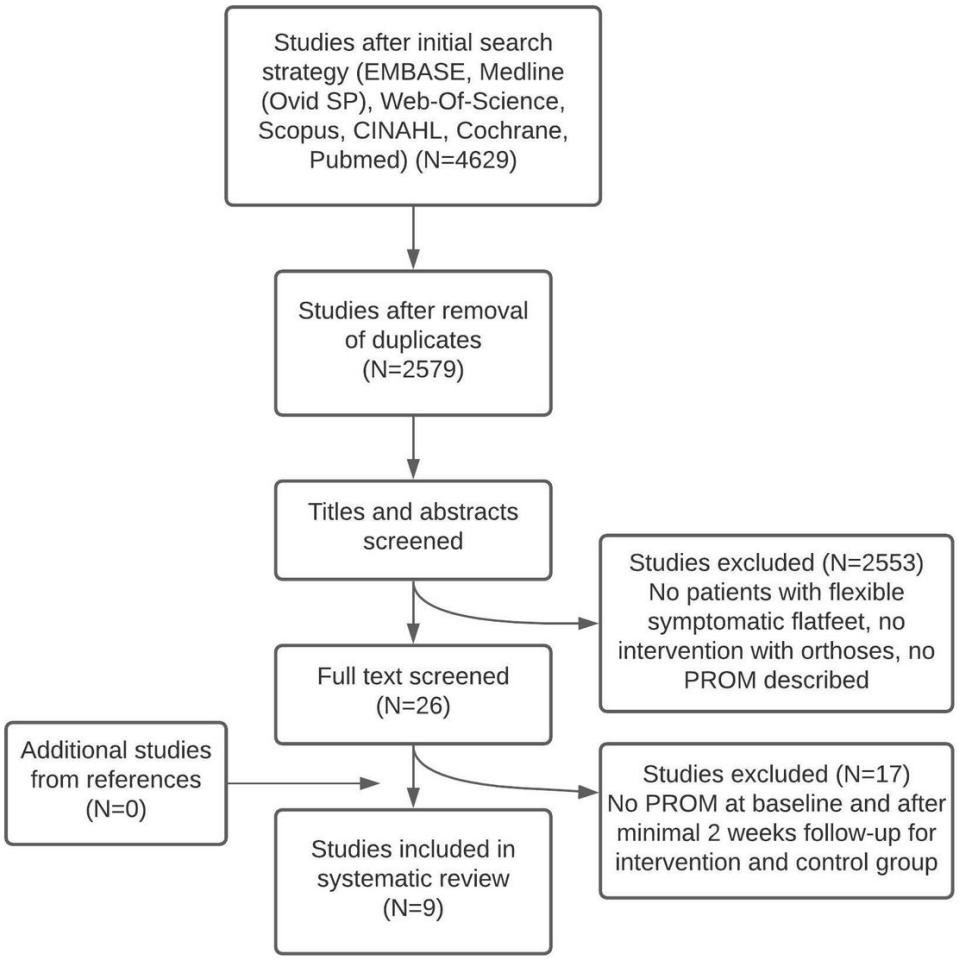

Figure 1

Study selection. Nine studies were included in the systematic review, four of them on children and five on adults.

Figure 2

Quality assessment domains. RCTs are evaluated with the Cochrane RoB tool and the prospective study is evaluated with the Cochrane ROureureBINS-I tool.

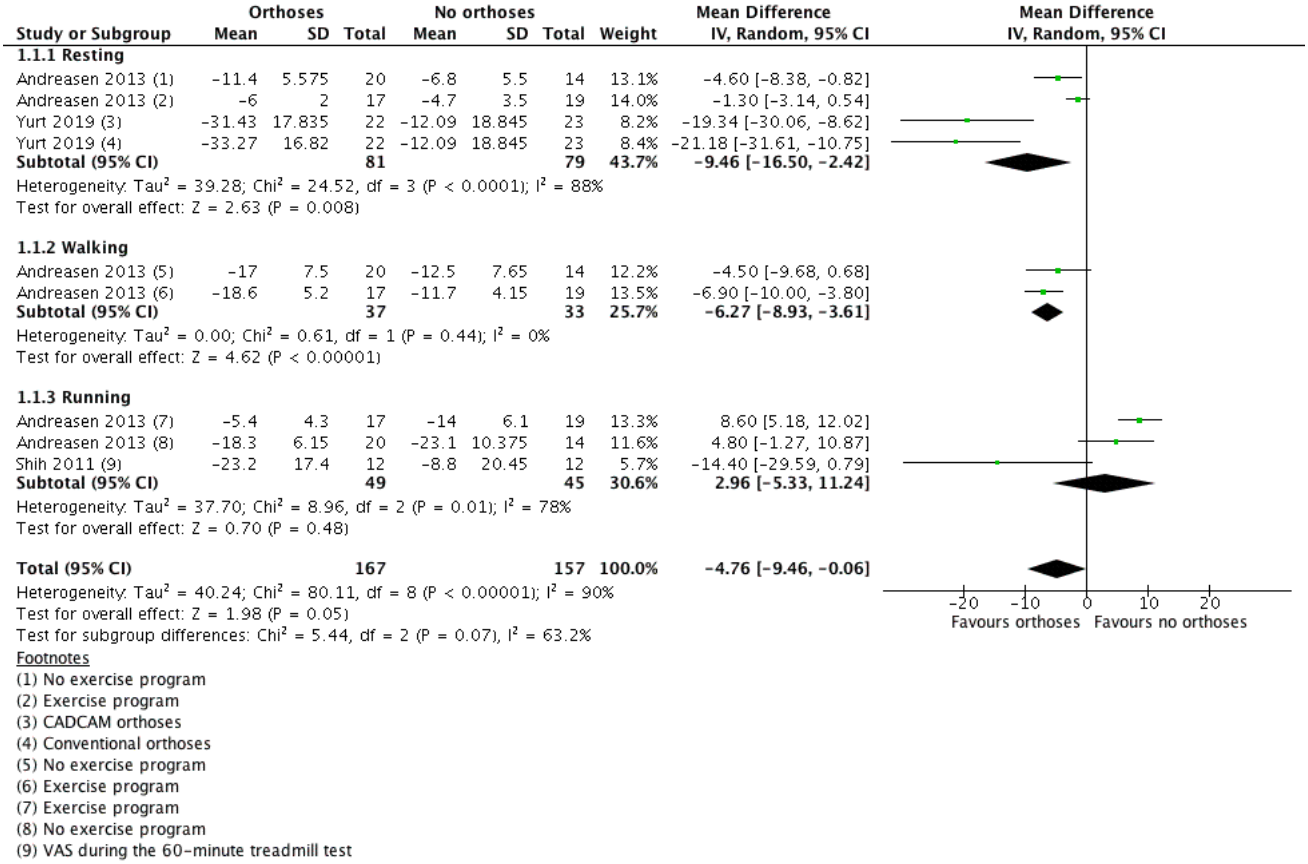

Figure 3

Meta-Analysis of difference in VAS at baseline and after treatment, for orthoses group and no orthoses/sham soles group. Pain reduction between baseline and follow-up in the orthoses groups was significantly larger than in the control groups during resting and walking as well as between all groups. No significant difference was seen in the running subgroup.

Supplementary Files

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- Supplementarydata1.docx