

Can Foot Orthoses Impose Different Gait Features Based on Geometrical Design in Healthy Subjects? A Systematic Review and Meta-analysis

Abstract

Objective: Foot orthoses (FOs) are popular treatment to alleviate several abnormalities of lower extremity. FO designs might alter lower extremity biomechanics differently, but the association is not yet known. This review aimed to evaluate how different FO designs, namely FO with medial posting, lateral posting, arch support, or arch & heel support, change lower limb kinematics and kinetics during walking.

Literature Survey: Electronic database search were conducted from inception to March 2019, and 25 papers passed the inclusion criteria. Two independent reviewers checked the quality using a modified Downs and Black checklist ($73.7\pm 5.5\%$) and a biomechanical quality checklist ($71.4\pm 17.1\%$). Effect sizes for differences between with- and without- FO walking were calculated, and meta-analysis was performed whenever at least two studies reported the same variable.

Results: Medial posting reduced peak ankle eversion moment. Lateral posting brought about higher peak ankle dorsiflexion and peak ankle eversion for kinematics, as well as higher peak ankle abduction moment, lower peak knee adduction moment, and higher peak mediolateral ground reaction force (GRF) for kinetics. FOs with either arch support or arch & heel support tended to decrease vertical ground reaction force, but it was not significant.

Conclusion: The findings of this review reveal that medial or lateral posting work efficiently to change foot and knee kinematics and kinetics. However, the impact force is just slightly decreased by arch-supported and heel supported FOs. Due to the small number of available studies, and heterogeneity in meta-analysis findings, further research with more standardized biomechanical approach are required.

Keywords: foot orthosis, posting, arch support, arch & heel support, meta-analysis, gait analysis

Introduction

Foot orthosis (FO) has been suggested as an intervening tool to control the transmission of ground reaction force (GRF) to bony structures and soft tissues [1, 2]. The foot, as the in-contact segment, adapts primarily to FO effect by producing, attenuating or re-orienting motion [1]. The compensatory mechanisms are then generated by knee and hip, as non-contact segments, to response for inter-joint coordination and support movement propulsion [3]. Therefore, FO can be used to prevent and relieve not only foot injuries, but also knee and hip musculoskeletal disorders [4]. FOs might behave differently in terms of their contribution to control three-dimensional joint kinematics and kinetics based on their specific designs. Various designs of FO are available in the market, whereas a few studies evaluated their design impact on biomechanical outputs. Furthermore, there is no database to introduce classification of designs for common FOs based on their biomechanical effects.

Several studies have confirmed the synergic effect between musculoskeletal disorders and abnormal foot motion during walking [3, 5-7]. For example, in individuals with lateral ankle sprain, greater range of motion for subtalar joint has been observed, predisposing them to ankle osteoarthritis [8]. Generally, excessive foot motion due to flatfoot or pronated foot might lead to foot, knee and hip problems including joint and tendon damage in inflammatory conditions such as rheumatoid arthritis [9], anterior knee pain, tendinopathy and knee arthritis symptoms [10], and higher vulnerability of elderly individuals to hip osteoarthritis due to intersegmental coupling [11, 12]. In addition, plantar fasciitis can be prolonged due to higher first metatarsophalangeal joint dorsiflexion [13]. On the other hand, patients with medial knee osteoarthritis suffer from higher knee adduction moment and more medial knee contact force. To compensate, they might alter foot progression angle, by more lateral foot contacts, to reduce the lever arm between GRF and knee joint center in frontal plane. Such strategy could help them to reduce knee adduction moment as well as medial contact force [14, 15], and avoid pain [5]. Based on these evidences, a proper FO design can be an efficient candidate to deal with different musculoskeletal problems by controlling the foot posture.

Various modifications have been implemented in the design of FO to deal with several pathologies. When there is a need to incline the foot medially, a medial posting would be added to FO design. The medial posting might incline the rearfoot, forefoot, or full-length of the foot [9, 14]. On the

other hand, lateral postings are designed to incline the foot laterally either on rearfoot, forefoot, or all foot length [9, 16]. Adding arch support pads or designing a contour shape of FO that follows the arch shape can prevent the collapse of medial arch and provide stability and balance [15, 17]. FOs with heel cup have a concave shape at the heel region in order to absorb the shock of ground reaction force, maintain the foot alignment [18, 19]. Therefore, it is important to understand the biomechanical effect of each FO design in order to suggest proper FO to patients.

While some studies have suggested specific designs of FO to prevent or improve lower extremity injuries, controversies and variabilities exist between studies regarding their biomechanical performance. As the effect of walking with medial posting, studies found it both efficient [2, 9] and without significant effect [20, 21] to reduce rearfoot eversion and foot pronation. Increase in knee adduction moment with this orthosis has then been confirmed [2] or questioned [14]. Although lateral posting was shown to response for reduction in knee adduction moment [5, 15, 22-24], some contrary results were reported as well [2, 9, 25]. Inconsistencies also exists in higher [3, 21, 22] or lower [9, 14, 26] ankle eversion and ankle eversion moment with this posting. No evidence has yet been found as the effect of FO with medial arch support on either foot kinematics or GRF [10, 15, 19]. Similarly, there still remains ambiguity as to whether heel cup insoles are efficient to absorb the shock of impact force during walking [18, 19].

To our view, the necessity and benefit of a meta-analysis in this area fall into two main aspects. *(i)* As long as any individual study verifies a significant effect of a specific FO design, and this effect remains consistent between studies with similar FO, the applicability of that design could offer a guide reference for podiatrists and clinicians. The importance of providing such reference is highlighted when the clinicians do not have any database to detect which FO design could modify joint loading in order to help individuals walking more efficient and less painful. *(ii)* On the other hand, inconsistent findings between studies or lack of evidence in individual studies could be inferred to methodological weaknesses. Detecting and introducing such weaknesses could provide hints for further studies to pursue higher methodological and biomechanical standards and reduce the sources of error.

Although computer aided design and manufacturing technology have facilitated the production of customized FOs [9], the biomechanical effect of different designs of FO is still unknown. Some previous reviews have assessed the effect of FO on kinematics, kinetics and impact forces [27, 28],

but none of them evaluated how these effects change depending on FO geometrical design. The aim of this study was primarily to find previous literature for different designs of FO and categorize them based on FO design. Then a meta-analysis was performed to find any changes in kinematics and kinetics of lower extremity during walking with each design of FO compared to walking either with shoes or barefoot. We focused deliberately on healthy subjects to avoid the ambiguity on whether changes were due to the effect of FO design or a compensation for pathology.

Methods

Search strategy

Three main groups of keywords describing “foot orthosis”, “design and geometrical modifications” and “biomechanical and locomotion metrics” were devised. Each group was a combination of several related MeSH terms and keywords. An electronic search was then performed in five databases namely Scopus, EMBASE, Medline, PubMed, and Cochrane library from their oldest available date to March 2019. The search string took advantage of the Boolean Operator “AND” to combine the three main groups, and “OR” to provide a comprehensive set of terms for each group (**Supplementary materials: Groups of keywords**). A double-screening method was used to detect the eligibility of studies by “MH” and “GD”. The full text was reviewed for papers with lack of sufficient information in their title and abstract. Any disagreement between assessors was solved by argument and consensus.

Selection criteria

Eligible articles had to be peer-reviewed *in-vivo* studies (except pilot studies), written in English, based on gait analysis approach during walking either on treadmill or along walkway, and focusing on healthy adults with no history of lower extremity injury. Then, the publications evaluating the effect of FO material or production approach (casting, molding, etc.), or evaluation with high-heel shoes were excluded. The eligible articles were additionally narrowed to ones that considered the four most-common FO designs. These groups were medial posting, lateral posting, arch support, and arch & heel support. FO with medial posting was considered as FO inclining the foot medially with either rearfoot posting or a full-length wedge. Lateral posting was composed of the FO design that inclined the lateral foot region with either rearfoot posting or full-length wedge. FOs with arch

support used contour shape or pad in order to maintain the medial longitudinal arch. FOs with arch & heel support added a heel cup to arch-supported FO. FOs with total contact insert were included in the arch & heel support group. The articles with other types of FO or a combination of mentioned groups were excluded. Finally, eligible papers were limited to ones addressing kinematics and kinetics of lower extremity as well as GRF.

Methodological quality

The quality of included studies was assessed by two independent reviewers, MH and GD, using modified Downs & Black checklist for non-randomized trials [29]. This checklist included eight items for reporting, two for external validity, four for internal validity (bias), three for internal validity (confounding), and one for power, as used in previous reviews (Supplementary materials: Table S Error! **No text of specified style in document..I**) [30, 31]. Each item was answered as 0 (“no”), 1 (“yes”) or UD (“unable to determine”). Item 5 asking about principal confounders was the only item answered 0 (“no”), 1 (“partially”), 2 (“yes”), and UD (“unable to determine”). The confounders were regarded as walking speed, foot orthosis material, proof of healthy foot, and shoe model to answer this item. Here, the quality of each study was reported as a percentage of maximum possible score. A paper was classified as high quality for score $\geq 75\%$, moderate quality for $60\% \leq \text{score} < 75\%$, and low quality for score $< 60\%$ [31]. Inter-rated agreement for quality assessment was estimated by κ level of agreement [32] for each question ranging from 0 to 1. The agreement was reported as slight $0.00 < \kappa \leq 0.20$, fair $0.21 < \kappa \leq 0.40$, moderate $0.41 < \kappa \leq 0.60$, substantial $0.61 < \kappa \leq 0.80$, and almost perfect $0.81 < \kappa \leq 1.00$ [33].

In addition, the quality of biomechanical measurement was estimated based on markerset and walking condition. The questions of this section were also answered as 1, 0, unable to determine (UD), and not applicable (NA). Placing markers on skin (1) or shoes (0), considering foot as multi-segment (1) or single segment (0), and using more than (1) or equal to (0) three markers on each segment were scored in markerset section. Studies which did not evaluate foot kinematics/kinetics got NA in the first two questions of this section. In addition, this section was not relevant for studies evaluating only GRF. The quality of walking condition was determined based on four parameters: walking with shoes (1) or barefoot (0); walking along walkway (1) or on treadmill (0); the number of cycles with more than or equal to 5 cycles (1), otherwise (0); monitoring and controlling the speed of walking (1), otherwise (0). Those experimental aspects are known to affect the quality of

outcome measures [34-39] and also the gait pattern [40-43]. The score was expressed in percentage and the biomechanical quality was classified similar to the methodological quality.

Data extraction and reporting

Several methodological details of studies including population (sample size, sex, and age), experimental protocol, foot model, foot orthosis (design and material), shoe model, and outcome measures were extracted. In addition, peak values [mean \pm SD] of kinematics and kinetics in sagittal, frontal, and transverse planes for foot, knee and hip as well as vertical and mediolateral GRF were extracted as dependent variables. The authors who did not report the numerical values of mentioned outcomes were contacted [9, 23, 44-46]. We reported foot results as one segment, since only six studies used multi-segment foot models [3, 9, 10, 15, 16, 46, 47]. The extracted data were reported in any corresponding four groups of foot orthosis.

To extract and report data the following aspects were considered: the nearest value to normal walking speed [48] was selected for studies with different speeds [3, 45]; the more commonly-used wedging inclination was selected for studies with multiple wedging inclinations [9, 14, 16, 24, 44, 49, 50]; for peak knee flexion moment and peak knee adduction moment the higher peak value was selected [5, 9, 16, 23, 47]; one reference frame was selected in studies which reported kinematics in different frames [10, 47]; when the data were collected in different sessions, the results of first session were extracted [25]. The synthesis of this review followed the PRISMA guideline for reporting systematic reviews and meta-analysis.

Statistical analysis

RevMan (version 5.3, Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration, 2014) was used to perform meta-analysis for variables reported by at least two studies in each group of foot orthosis. Forest plots enabled us to inspect the effect of foot orthosis on dependent variables by calculating effect size (ES) using standardized mean difference in a randomized effect model. In addition, they could reflect 95% confidence interval (95% CI), overall effect (p value), and heterogeneity index (I^2). Pooled ES were regarded as trivial ($ES \leq 0.2$), small ($0.2 < ES \leq 0.5$), moderate ($0.5 < ES \leq 0.8$), and large ($ES > 0.8$) [51]. When 95% CI crossed zero ($p > 0.05$), no significant differences could be inferred from meta-analysis. The level of inconsistency between included studies was estimated as low, moderate, and high with thresholds of 25%, 50%, and 75%

for I^2 [52]. Wherever a significant difference was observed for peak joint rotations, the mean difference (net difference in degree between with- and without- orthosis) was also calculated. Mean differences were easier than ESs to be interpreted clinically.

Results

Search results

Our literature search yielded 4756 articles, from which 1628 were removed as duplicates (*i.e.* 3128 articles). Initial screening based on title and abstract retrieved 386 relevant articles. There, the full texts of articles were reviewed to further check the inclusion criteria and details of orthosis design, where 361 papers were excluded. A final screening was performed with focus on reported outcome measures, which handled 25 papers for further processing (Figure Error! **No text of specified style in document..1**).

As this review looked for the effect of each orthosis design, classification of included studies was done based on the design. Through this classification one study with medial posting [50], sixteen studies with lateral posting [2, 3, 5, 8, 16, 22-26, 44-47, 49, 53], four studies with both medial and lateral posting [2, 9, 14, 21], one study with lateral posting and arch support [15], and one study with arch support and arch & heel support [19], and three studies with arch & heel support [10, 17, 18] were detected. Details of studies are available in Table Error! **No text of specified style in document..1**.

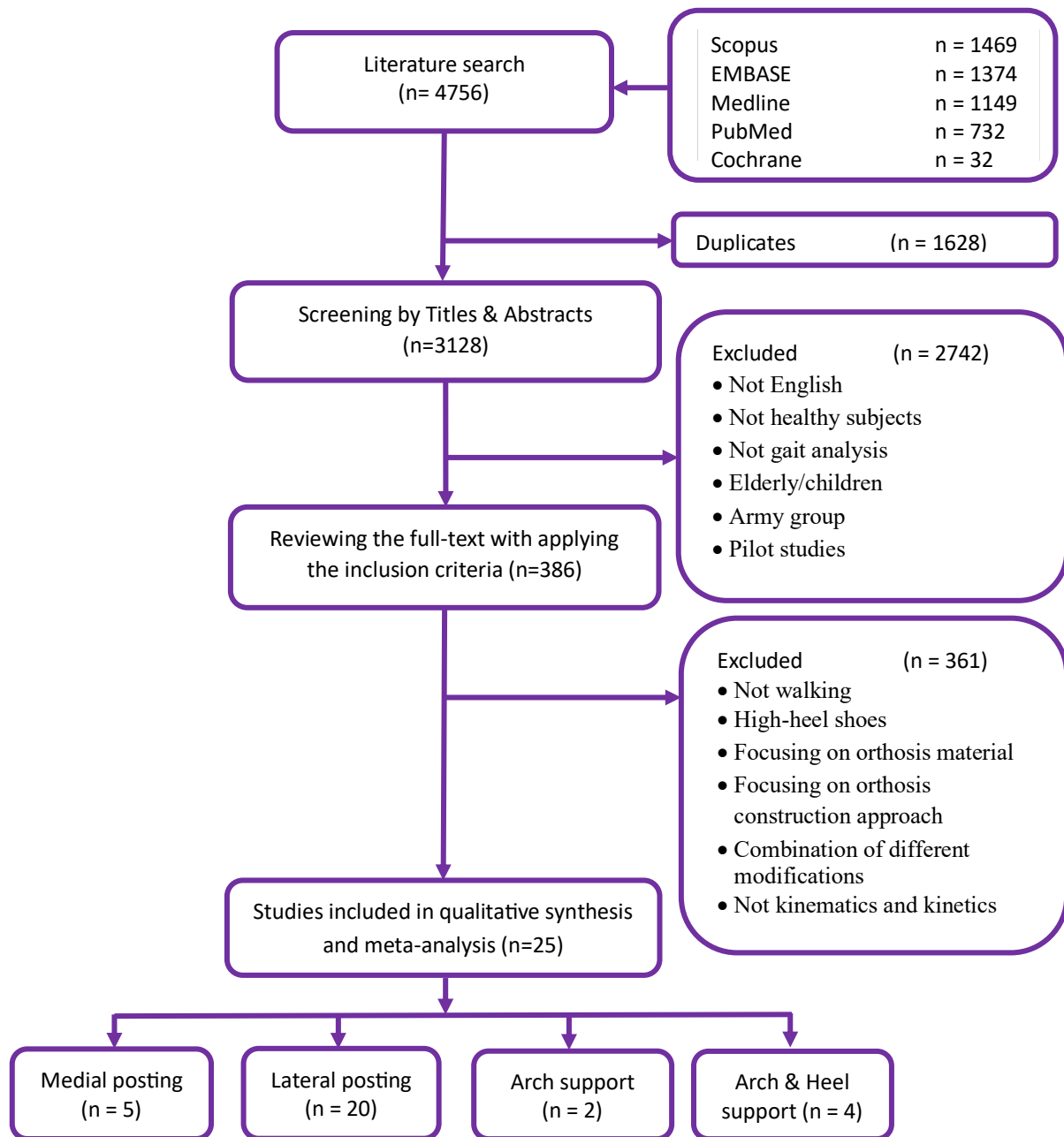


Figure Error! No text of specified style in document..1 : Flow diagram of search strategy and study selection

Subjects' characteristics

The total number of participants for all included studies in the group of medial posting was 75 subjects (27 female and 48 male), with an average age of 28 ± 7 years old, height 176 ± 7 cm, and weight 70 ± 12 kg. In lateral posting group, a total number of 376 subjects (157 females, 184 males,

35 not mentioned), with age 27 ± 7 years old, height 170 ± 11 cm, and weight 66 ± 14 kg were included. Studies with arch support included 30 subjects (19 females, 11 males), with averages of age 26 years old, height 164 cm, and weight 55 kg. Since one of two studies in this group did not report standard deviations, the subject characteristics are reported just by average value. The arch & heel support group included 71 subjects (41 females, 30 males), age of 28 ± 8 years old, height 167 ± 11 cm, and weight 61 ± 14 kg.

Studies' quality

The quality assessment showed a range from 68.4% to 84.2%. Moderate quality was achieved for 18 studies, while 7 other studies [3, 9, 15, 16, 24, 26, 53] were classified as high quality (Table **Error! No text of specified style in document..2**). Overall, items about reporting got good scores by most of studies. The score for external validity items, however, were not met in most of studies. Only four studies [3, 9, 44, 53] reported the source of population and the criteria of selecting subjects. Out of the 25 papers, 2 studies [3, 53] stated the proportion of participants asked to attend and agreed. One paper [9] wrote about blinding for data processing in internal validity (bias). One paper [21] mentioned the time interval during which participants were recruited in internal validity (confounding) section. Finally, in power section five papers [15, 16, 24, 26, 53] declared the criteria for sample size. The κ level of agreement was substantial to almost perfect for scoring each individual item (Table **Error! No text of specified style in document..2**). A complete agreement was achieved for all items except for item 5 about explaining the principal confounders ($\kappa = 0.74$), item 10 related to reporting actual probability values ($\kappa = 0.83$), item 11 ($\kappa = 0.96$) and item 22 ($\kappa = 0.96$) asking about the population selection.

In terms of biomechanical quality (Table **Error! No text of specified style in document..3**) the scores ranged between 40% and 100% with nine high, eight moderate and eight low quality studies. Out of the 25 included papers, 6 studies placed the markers directly on skin [3, 5, 9, 10, 15, 21], 4 studies used multi-segment foot models for analysis [3, 9, 10, 15], 13 studies used marker redundancy (≥ 3 markers/segment) [3, 5, 8-10, 15, 22-26, 44-47], 19 studies asked the subjects to walk with shoes [2, 3, 5, 9, 14, 16-19, 22-26, 44, 45, 49, 50, 53], 22 on a walkway [2, 5, 8, 9, 14-19, 21-26, 44, 46, 47, 49, 50, 53], 20 collected more than or equal to 5 cycles [2, 3, 5, 9, 10, 14, 15, 18, 21-26, 44-47, 49, 50], and 18 studies monitored the walking speed [2, 3, 8-10, 14-19, 22-24, 26, 45, 46, 50].

Table Error! No text of specified style in document..1. Summary of included studies

Study	Participants	Experimental protocol		Case condition: foot orthosis	Control condition: shod/bare	Outcome measures
		Task	Foot model			
Medial posting						
Burston et al. [50]	n= 15 (8 F, 7M) age= 30.1 ± 10.0 y	Walking along walkway at self-selected speed 5 trials/ condition	>4 markers On shoes	5° medial wedge added to full-length Slimflex™ insoles Material: EVA	Individuals' training shoes	<u>kinematics</u> [°]: knee flexion <u>kinetics</u> [Nm]: knee flexion moment
Fukuchi et al. [14]	n = 21 (21 M) age = 25 ± 3.4 y W=73.3 ± 9.1 kg H=178.1 ± 6.7 cm	walking along walkway at range of 1.4 m/s ≥5 trials/ condition	1 segment 3 markers on shoes	6° medial wedge added to insole, full-length material: EVA	standard neutral shoes (Aegis 2.0, Adidas international); with no extra insole barefoot	<u>kinetics</u> [Nm]: ankle inversion moment, knee abduction moment
Huerta et al. [21]	n = 12 (6 F, 6 M) age = 24.6 ± 5.6 y W=62.8 ± 13.7 kg	walking along 20 m walkway at self-selected speed 10-12 trials/ condition	1 segment 3 markers on skin	7° medial wedge, rearfoot, 14 cm long and 4 cm width adhered to heel with double-sided tape material: high-density EVA		<u>kinematics</u> [°]: ankle abduction, internal tibia rotation <u>kinetics</u> [Nm/kg]: ankle inversion moment
Nester et al. [2]	n =15 (7 F, 8 M) age = [19-41] y	walking at a controlled cadence of 108 step/min 10 trials/ condition	1 segment 3 markers on shoes	10° medial wedge, extending from heel to 1 st metatarsal placed under 3 mm orthosis material: high-density EVA	individual shoes	<u>kinematics</u> [°]: Internal tibia rotation relative to foot (pronation), External tibia rotation relative to foot (supination)
Telfer et al. [9]	n = 12 (6 F, 6 M) age = 31.7 ± 10 y W=72.8 ± 12.3 kg H= 173 ± 7 cm	walking along walkway at controlled speed within 5% of individual pre-determined self-selected speed ≥7 strikes/ condition	2 segments 13 markers on skin	6° medial rearfoot posting, 3D foot surface scan and 3D printed, ¾ foot length material: semi-rigid, Polylactide	standard shoe, neutrally posted	<u>kinematics</u> [°]: rearfoot eversion, forefoot abduction, internal tibia rotation <u>kinetics</u> [%BW*height]: ankle eversion moment, knee adduction moment
Lateral posting						
Fischer et al. [16]	N= 19 (7 F, 12 M) Age = 24 ± 3 y	Walking along 10 m walkway 3 trials/condition	3 segments Marker clusters On foot	5° lateral wedge attached under comfort insole material: High density EVA with durometer 60	Neutral frontal plane stability shoes (gel-beyond, Asics, JP)	<u>kinetics</u> [%BW*height]: knee adduction moment

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Study	Participants	Experimental protocol		Case condition: foot orthosis	Control condition: shod/bare	Outcome measures
		Task	Foot model			
Forghany et al. [44]	n = 8 (8 M) age = 33.5 ± 4.5 y W= 71.4 ± 10.6 kg H=170 ± 6 cm	walking along 10 m walkway at self-selected speed; 10 trials/ condition	1 segment 4 markers on shoes	5° lateral heel and sole wedge attached to flat insole material: high density vinyl acetate wedge, EVA flat insole	standard shoe	<u>kinematics</u> [°]: ankle eversion
Fukuchi et al. [14]	n = 21 (21 M) age = 25 ± 3.4 y W= 73.0 ± 9.1 kg H= 178.1 ± 6.7 cm	walking along walkway at range of 1.4 m/s ≥5 trials/ condition	1 segment 3 markers on shoes	6° lateral wedge added to insole, full-length material: EVA	standard neutral shoes (Aegis 2.0, Adidas international); with no extra insole	<u>kinetics</u> [Nm]: ankle inversion moment, knee abduction moment
Hornestam et al. [3]	n = 20 (14 F, 6 M) age = 23.7 ± 3.4 years W= 64.2 ± 12.1 kg H= 168 ± 6 cm	walking on treadmill (ProAction G635) at 5 km/h 30 trials/ condition	Rearfoot segment, 7 markers on skin	15° medially inclined insole, full-length material: high density EVA	standard neutral shoe (Crusader 4, Mizuno Inc); with flat insole made of high density EVA	<u>kinematics</u> [°]: rearfoot eversion
Huerta et al. [21]	n = 12 (6 F, 6 M) age = 24.6 ± 5.6 y W= 62.8 ± 13.7 kg	walking along 20 m walkway at self-selected speed 10-12 trials/ condition	1 segment 3 markers on skin	7° lateral wedge, rearfoot, 14 cm long and 4 cm width adhered to heel with double-sided tape material: high-density EVA	barefoot	<u>kinematics</u> [°]: ankle abduction, internal tibia rotation <u>kinetics</u> [Nm/kg]: ankle inversion moment
Jones et al. [22]	n = 15 (5 F, 10 M) age = 30.5 ± 8.6 y W= 66.9 ± 13.3 kg H= 169 ± 7 cm	walking along walkway at self-selected speed 10 trials/ condition	1 segment 6 markers on shoes	5° lateral wedge, full-length material: 70 shore A hardness	standard shoes (ECCO Zen)	<u>kinematics</u> [°]: subtalar joint eversion, knee flexion, knee varus <u>kinetics</u> [Nm/kg]: ankle/subtalar joint eversion moment, knee flexion moment, knee adduction moment

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Study	Participants	Experimental protocol		Case condition: foot orthosis	Control condition: shod/bare	Outcome measures
		Task	Foot model			
Kakahana et al. [8]	n = 25 (25 M) age = 20.7 ± 1.2 y W= 77.1 ± 13.1 kg H= 175.2 ± 4.8 cm	walking along 7 m walkway at self-selected cadence (95.8±4.0 step/min)	1 segment 7 markers on skin	6° lateral wedge insole, full-length material: EVA 8200	barefoot with 0° lateral wedge insole, flat insole, full-length, (material EVA 8200)	<u>GRF</u> [N/kg]: vertical GRF, mediolateral GRF
Kang et al. [53]	n = 48 (24 F, 24 M) age = 23.5 ± 2.5 y W= 70.5 ± 21.5 kg H=170 ± 19 cm	walking along 6 m walkway at self-selected speed 3 trials/ condition	1 segment 3 markers on skin	5° lateral wedge insole, full-length	conventional shoes (flat, thin insoles)	<u>kinetics</u> [Nm/kg]: knee adduction moment
Kluge et al. [45]	n = 22 (19 F, 3 M) age = 22.3 ± 2.2 y W= 62.1 ± 9.1 kg H= 166 + 8 cm	walking on instrumented treadmill at 1.3 m/s 1 minute/ condition	1 segment 6 markers on shoes	4-5° lateral wedge insole (placed under control insole), height of 4 mm, full-length material: cork	standard shoe model (Green Silence, Brooks) with unwedged insole and individualized arch support (igli insoles, medi)	<u>kinematics</u> [°]: ankle eversion <u>kinetics</u> [Nm/kg]: knee adduction moment <u>GRF</u> [N/BW]: vertical GRF, mediolateral GRF
Leitch et al. [49]	n = 14 (10 F, 4 M) age = 44 ± 8 y W=70.4 ± 13.3 kg H= 168 ± 9 cm	walking along 8 m walkway at self-selected normal speed ≥5 trials/ condition	1 segment 3 markers	4° lateral wedge (placed under the control insole) material: EVA, 55 shore A durometer	standardized neutral shoe (New Balance 882) with no wedge insole	<u>kinetics</u> [%BW*height]: knee adduction moment
Molgaard et al. [23]	n = 12 (4 F, 8 M) age = 31.9 y, range [22-50] y W= 73.5 kg H=175 cm, range [157-196] cm	walking along 10 m walkway at self-selected comfortable speed within ±5% 6 trials/ condition	1 segment 6 markers on shoes	10° lateral wedge insole, full-length model: Rehband, Technogel-Pes Velour	neutral running shoes (Nike Air Pegasus)	<u>kinetics</u> [%BW*height]: ankle abduction moment, knee flexion moment, knee adduction moment

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Study	Participants	Experimental protocol		Case condition: foot orthosis	Control condition: shod/bare	Outcome measures
		Task	Foot model			
Nakajima et al. [15]	n = 20 (9 F, 11 M) age = 28.4 ± 6.1 y W=59.8 ± 10.9 kg H=167.2 ± 9.4 cm	walking along 7 m walkway at self-selected speed with controlling cadence 5 trials/ condition	rearfoot segment on skin	6° lateral wedge insole, full-length material: EVA 8200	barefoot with 5-mm thick flat insole	<u>kinematics</u> [°]: knee valgus <u>kinetics</u> [%BW*height]: subtalar abduction moment, knee adduction moment
Nester et al. [2]	n =15 (7 F, 8 M) age = [19-41] y	walking at a controlled cadence of 108 step/min 10 trials/ condition	1 segment 3 markers on shoes	10° lateral wedge (placed under 3mm base with cushioning material), full-length material: high-density EVA	individual shoes	<u>kinematics</u> [°]: ankle plantarflexion, ankle dorsiflexion, rearfoot abduction, Internal tibia rotation relative to foot (pronation), External tibia rotation relative to foot (supination) <u>kinetics</u> [Nm/kg]: ankle abduction moment
Russell et al. [26]	n = 14 (14 F) age = 26.1 ± 6.9 y W=60.1 ± 6.5 kg H= 164 ± 7 cm	walking along walkway at 1.24 m/s 10 trials/ condition	1 segment 8 markers, on shoes	8° lateral wedge insole, full-length material: EVA	same standard shoe model (New Balance RC 550)	<u>kinematics</u> [°]: ankle plantarflexion, ankle dorsiflexion, ankle eversion, knee flexion, knee adduction
Sawada et al. [46]	n = 15 age = 22.5 ± 1.5 y W= 58.5 ± 10.1 kg H= 165 ± 10 cm	walking along 10 m walkway at self-selected speed 5 trials/ condition	3 segments Oxford foot model [54] on skin	5.3° lateral wedge insole (approximately) with base height equal to 5 th metatarsal, ¾ foot length material: high-intensity silicon rubber	barefoot	<u>kinetics</u> [Nm/kg]: knee adduction moment
Telfer et al. [9]	n = 12 (6 F, 6 M) age = 31.7 ± 10 y W=72.8 ± 12.3 kg H= 173 ± 7 cm	walking along walkway at controlled speed ≥7 trials/ condition	2 segments 13 markers on skin	6° lateral rearfoot posting, 3D foot surface scan and 3D printed, ¾ foot length material: semi-rigid, Polylactide	standard shoe, neutrally posted	<u>kinematics</u> [°]: rearfoot eversion, forefoot abduction, internal tibia rotation <u>kinetics</u> [%BW*height]: ankle eversion moment, knee adduction moment

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Study	Participants	Experimental protocol		Case condition: foot orthosis	Control condition: shod/bare	Outcome measures
		Task	Foot model			
Tipnis et al. [24]	n = 25 (13 F, 12 M) Age = 23.1 ± 2.3 y W= 60.9 ± 9.4 kg H= 166 ± 6 cm	walking along 23 m walkway at 1.46 m/s 5 trials/ condition	1 segment 5 markers on shoes	6° lateral wedge (Der-Tex Corp, Saco) adhered to full length orthosis (KLM lab Inc) material: crepe (70) and covered with micro-puff	standard shoe (Nike Air Pegasus) with 0° lateral wedge	<u>kinematics</u> [°]: knee flexion <u>kinetics</u> [Nm/BW*height]: knee adduction moment
Tokunaga et al. [5]	n = 20 age = 23.1 ± 3.5 y W= 64.9 ± 12.6 kg H= 172 ± 7 cm	walking along 10 m walkway at comfortable speed 5 trials/ condition	1 segment 5 markers on skin	7° lateral wedge insole fixed to the sole, full-length material: EVA	flat insole, thickness 5mm, from EVA	<u>kinetics</u> [Nm/kg]: ankle abduction moment, knee adduction moment <u>GRF</u> [N/kg]: vertical GRF, mediolateral GRF
Weinhandl et al. [25]	n = 10 (10 F) age = 21.8 ± 0.6 y W= 60.1 ± 4.63 kg H= 165 ± 5 cm	walking along 15 m walkway at self-selected speed 5 trials/ condition	1 segment 4-marker cluster on shoes	9° lateral wedge insole, along the rear lateral aspect of the insole material: EVA, 55 shore A durometer	individual athletic shoe with the shoe insole	<u>kinetics</u> [Nm/kg]: knee abduction moment <u>GRF</u> [N/kg]: vertical GRF, mediolateral GRF
Yamaguchi et al. [47]	n = 29 (9 F, 20 M) age = 28 ± 4 y W= 59 ± 10 kg H= 166 ± 9 cm	walking along 8 m walkway at self-selected speed 5 trials/ condition	rearfoot segment 5 markers on skin	6° lateral wedge, full length	barefoot with flat insole, 5 mm thickness	<u>kinetics</u> [Nm/BW*height]: knee adduction moment
Arch support						
Nakajima et al. [15]	n = 20 (9 F, 11 M) age = 28.4 ± 6.1 y W=59.8 ± 10.9 kg H=167.2 ± 9.4 cm	walking along 7 m walkway at self-selected speed with controlling cadence 5 trials/ condition	rearfoot segment on skin	flat insole with customized arch support, full-length material: EVA 8200	barefoot with 5 mm thickness flat insole	<u>kinematics</u> [°]: knee valgus <u>kinetics</u> [%BW*height]: subtalar abduction moment, knee adduction moment
Yung-Hui et al. [19]	n = 10 (10 F) age = 23 y, range [20-28] y W= 50 kg, range [47-53] kg H= 160 cm, range [156- 162] cm	walking on treadmill at 1.3 m/s 3 trials/ condition	NA	custom-made total contact insole with arch-support material: semi-rigid multi-form molded (AliMed Inc)	commercially available flat shoes, 1 cm thickness	<u>GRF</u> [%BW]: vertical GRF

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Study	Participants	Experimental protocol		Case condition: foot orthosis	Control condition: shod/bare	Outcome measures
		Task	Foot model			
Arch & heel support						
Creaby et al. [18]	n = 22 (11 F, 11 M) age = 27 ± 5.6 y W= 66.2 ± 10.2 kg H= 170 ± 7 cm	walking along 10 m walkway at 1.20 m/s 5 trials/ condition	1 segment Plug-in-Gait markerset [55]	full-length insole with heel cup (Superfeet Blue, Superfeet Worldwide Inc) material: medium density foam footbed (A 45) with polypropylene shell	standard shoes (Nike Pegasus)	<u>GRF</u> [%BW]: vertical GRF
Hong et al. [17]	N=20 (20 F) Age= 25.4 ± 3.8 y W= 50.5 ± 4.2 kg H= 157.8 ± 5.0 cm	Walking along a walkway at 1.3 m/s 3 cycles/condition	No markerset	Customized total contact insert orthosis Material: semi-rigid, multiform molded material, hardness 35 shore A, density 0.17 g/cm ³	Standard shoes with flat sole (1.0 cm)	<u>GRF</u> [%BW]: vertical GRF, anteroposterior force, mediolateral force
Wahmkow et al. [10]	n =19 (19 M) age = 36 ± 11 y W= 79 ± 10 kg H= 180 ± 5 cm	walking on treadmill at 5 km/h 1 minute/ condition	3 segments Oxford foot model [54] on skin	medial arch support (height 30 mm) with a concave-shaped heel wearing with standardized silicon slippers, full-length material: polyurethane foam (shore 25; with an EVA core, shore 55)	barefoot	<u>kinematics</u> [°]: rearfoot eversion, internal tibia rotation
Yung-Hui et al. [19]	n = 10 (10 F) age = 23 y, range [20-28] W= 50 kg, range [47-53] kg H= 160 cm, range [156- 162] cm	walking on treadmill at 1.3 m/s 3 trials/ condition	NA	custom-made total contact insole with heel cup	commercially available flat shoes, 1 cm thickness	<u>GRF</u> [%BW]: vertical GRF

This table is arrayed based on the orthosis design. The papers which have more than one orthosis design are listed as duplicates with an update in the details of orthosis [9, 14, 15, 19, 21]; Some articles have more than one orthosis within the same group, but with different inclinations or heights. In such cases, the table just mentions the included design in our meta-analysis [9, 10, 14, 24, 44, 49]. The peak values of all outcome measures have been extracted for this systematic review and meta-analysis. Gray color shows the studies repeated in different categories.

F: female, M: male, y: years old, SD: standard deviation, EVA: ethylene vinyl acetate, GRF: ground reaction force, BW: body weight.

Table Error! No text of specified style in document..2. Methodological quality assessment

Study	Reporting								External validity		Internal validity (bias)				Internal validity (confounding)			Power	Score	
	Q1	Q2	Q3	Q4	Q5 ^a	Q6	Q7	Q10	Q11	Q12	Q15	Q16	Q18	Q20	Q21	Q22	Q25	Q27 ^b	QS (%)	QC
Burston <i>et al.</i> [50]	1	1	1	1	2	1	1	1	UD	UD	UD	1	1	1	1	UD	1	UD	73.7	MQ
Creaby <i>et al.</i> [18]	1	1	1	1	2	1	1	1	UD	UD	UD	1	1	1	1	UD	1	UD	73.7	MQ
Fischer <i>et al.</i> [16]	1	1	1	1	2	1	1	1	UD	UD	UD	1	1	1	1	UD	1	1	78.9	HQ
Forghany <i>et al.</i> [44]	1	1	1	1	1	1	1	0	1	UD	UD	1	1	1	1	UD	1	0	68.4	MQ
Fukuchi <i>et al.</i> [14]	1	1	1	1	2	1	1	1	UD	UD	UD	1	1	1	1	UD	1	UD	73.7	MQ
Hong <i>et al.</i> [17]	1	1	1	1	2	1	1	0	UD	UD	UD	1	1	1	1	UD	1	UD	68.4	MQ
Hornestam <i>et al.</i> [3]	1	1	1	1	2	1	1	1	1	1	UD	1	1	1	1	UD	1	UD	84.2	HQ
Huerta <i>et al.</i> [21]	1	1	1	1	1	1	0	1	UD	UD	UD	1	1	1	1	1	1	UD	68.4	MQ
Jones <i>et al.</i> [22]	1	1	1	1	1	1	1	1	UD	UD	UD	1	1	1	1	UD	1	UD	73.7	MQ
Kakahana <i>et al.</i> [8]	1	1	1	1	2	1	1	1	UD	UD	UD	1	1	1	1	UD	1	UD	73.7	MQ
Kang <i>et al.</i> [53]	1	1	1	1	1	1	1	1	1	1	UD	1	1	1	1	UD	1	1	84.2	HQ
Kluge <i>et al.</i> [45]	1	1	1	1	2	1	1	1	UD	UD	UD	1	1	1	1	UD	1	UD	73.7	MQ
Leitch <i>et al.</i> [49]	1	1	1	1	1	1	1	1	UD	UD	UD	1	1	1	1	UD	1	UD	68.4	MQ
Molgaard <i>et al.</i> [23]	1	1	1	1	2	1	1	1	UD	UD	UD	1	1	1	1	UD	1	UD	73.7	MQ
Nakajima <i>et al.</i> [15]	1	1	1	1	2	1	1	1	UD	UD	UD	1	1	1	1	UD	1	1	78.9	HQ

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Study	Reporting								External validity		Internal validity (bias)				Internal validity (confounding)			Power	Score	
	Q1	Q2	Q3	Q4	Q5 ^a	Q6	Q7	Q10	Q11	Q12	Q15	Q16	Q18	Q20	Q21	Q22	Q25	Q27 ^b	QS (%)	QC
Nakajima et al. [15]	1	1	1	1	2	1	1	1	UD	UD	UD	1	1	1	1	UD	1	1	78.9	HQ
Nester et al. [2]	1	1	1	1	1	1	1	1	UD	UD	UD	1	1	1	1	UD	1	UD	68.4	MQ
Russell et al. [26]	1	1	1	1	2	1	1	1	UD	UD	UD	1	1	1	1	UD	1	1	78.9	HQ
Sawada et al. [46]	1	1	1	1	2	1	1	1	UD	UD	UD	1	1	1	1	UD	1	UD	73.7	MQ
Telfer et al. [9]	1	1	1	1	2	1	1	1	1	UD	1	1	1	1	1	UD	1	UD	84.2	HQ
Tipnis et al. [24]	1	1	1	1	2	1	1	1	UD	UD	UD	1	1	1	1	UD	1	1	78.9	HQ
Tokunaga et al. [5]	1	1	1	1	1	1	1	1	UD	UD	UD	1	1	1	1	UD	1	UD	68.4	MQ
Wahmkow et al. [10]	1	1	1	1	2	1	1	0	UD	UD	UD	1	1	1	1	UD	1	UD	68.4	MQ
Weinhandl et al. [25]	1	1	1	1	1	1	1	1	UD	UD	UD	1	1	1	1	UD	1	UD	68.4	MQ
Yamaguchi et al. [47]	1	1	1	1	1	1	1	1	UD	UD	UD	1	1	1	1	UD	1	UD	68.4	MQ
Yung-Hui et al. [19]	1	1	1	1	2	1	1	0	UD	UD	UD	1	1	1	1	UD	1	UD	68.4	MQ
																			73.7 (5.5)	MQ
κ level of agreement	1	1	1	1	0.74	1	1	0.8 3	0.96	1	1	1	1	1	1	0.96	1	1	0.97	

Quality assessment of included studies using modified Downs & Black checklist; Q1: clear aim, Q2: clarity of reporting outcomes, Q3: clarity of patients' characteristics, Q4: describing interventions, Q5: explaining principal confounders, Q6: description of main findings, Q7: estimation and report of random variability, Q10: reporting actual probability values, Q11: asked participants well represent the whole population, Q12: the prepared participants well represent the whole recruited participants, Q15: blinding of who measure outcomes, Q16: clarity of probable data dredging, Q18: appropriate statistical tests, Q20: accuracy of outcome measures, Q21: recruiting cases and controls from same population, Q22: recruiting cases and controls over the same time interval, Q25: adequate adjustments for confounding in the analysis, Q27: sufficient statistical power. QS: quality score [0%-100%], 1: yes, 2: no, UD: unable to determine, QC: quality classification categorized as HQ: high quality (QS≥75%), MQ: moderate quality (60% ≤ QS < 75%), LQ: low quality (QS < 60%). ^a The score for this question is 0: no, 1: partially, and 2: yes similar Downs & Black checklist; ^b The score for this question was modified as 0,1, UD to facilitate comparison.

Table Error! No text of specified style in document..3 : Biomechanical quality assessment

Study	Markerset			Walking condition				Score	
	Placement	Segment	Redundancy	Barefoot/ Shoes	Treadmill/ Walkway	Cycles	Speed	QS (%)	Quality classification
Burston <i>et al.</i> [50]	NA	NA	1	1	1	1	1	100	HQ
Creaby <i>et al.</i> [18]	NA	NA	NA	1	1	1	1	100	HQ
Fischer <i>et al.</i> [16]	NA	NA	1	1	1	0	1	80	HQ
Forghany <i>et al.</i> [44]	0	0	1	1	1	1	0	57.1	LQ
Fukuchi <i>et al.</i> [14]	0	0	0	1	1	1	1	57.1	LQ
Hong <i>et al.</i> [17]	NA	NA	NA	1	1	0	1	75	HQ
Hornestam <i>et al.</i> [3]	1	1	1	1	0	1	1	85.7	HQ
Huerta <i>et al.</i> [21]	1	0	0	0	1	1	0	42.9	LQ
Jones <i>et al.</i> [22]	0	0	1	1	1	1	1	71.4	MQ
Kakahana <i>et al.</i> [8]	NA	NA	NA	0	1	UD	1	50.0	LQ
Kang <i>et al.</i> [53]	NA	NA	0	1	1	0	0	40.0	LQ
Kluge <i>et al.</i> [45]	0	0	1	1	0	1	1	57.1	LQ
Leitch <i>et al.</i> [49]	NA	NA	0	1	1	1	0	60.0	MQ
Molgaard <i>et al.</i> [23]	0	0	1	1	1	1	1	71.4	MQ
Nakajima <i>et al.</i> [15]	1	1	UD	0	1	1	1	71.4	MQ
Nakajima <i>et al.</i> [15]	1	1	UD	0	1	1	1	71.4	MQ
Nester <i>et al.</i> [2]	0	0	0	1	1	1	1	57.1	LQ
Russell <i>et al.</i> [26]	0	0	1	1	1	1	1	71.4	MQ
Sawada <i>et al.</i> [46]	NA	NA	1	0	1	1	1	80.0	HQ
Telfer <i>et al.</i> [9]	1	1	1	1	1	1	1	100	HQ
Tipnis <i>et al.</i> [24]	NA	NA	1	1	1	1	1	100	HQ
Tokunaga <i>et al.</i> [5]	1	0	1	1	1	1	0	71.4	MQ
Wahmkow <i>et al.</i> [10]	1	1	1	0	0	1	1	71.4	MQ
Weinhandl <i>et al.</i> [25]	NA	NA	1	1	1	1	0	80	HQ
Yamaguchi <i>et al.</i> [47]	NA	NA	1	0	1	1	0	60.0	MQ
Yung-Hui <i>et al.</i> [19]	NA	NA	NA	1	1	0	1	75	HQ
								71.4 ± 17.1	MQ

Biomechanical quality assessment of studies: Foot markerset: placement: on skin (1) or on shoes (0); segment: multi-segment/ rearfoot segment (1) or one segment (0); redundancy: >3 markers (1) or 3 markers (0); Walking quality: shoes (1) or barefoot (0); walkway (1) or treadmill (0); ≥ 5 cycles (1) or < 5 cycles (0); speed monitored (1) or not monitored (0). T: treadmill, W: walkway, UD: unable to determine, NA: not applicable. For studies which did not calculate the foot kinematics or kinetics, the first two questions were not relevant. The placement of marker of foot does not affect the knee kinematics/kinetics or ground reaction force. For studies which report the ground reaction force, the first three questions were not relevant. The quality of studies was calculated by excluding the NAs from the scoring.

Medial posting

Regarding kinematics, one single study showed a decrease in peak ankle eversion with a mean difference -2.2° , (large ES -1.58 ; 95% CI -2.51 to -0.64 , $p = 0.001$) when wearing FO with medial posting [9] (Table Error! No text of specified style in document..4 and Table Error! No text of specified style in document..5). Single studies looked at peak ankle abduction [21], forefoot adduction [9], external shank rotation relative to rearfoot (inversion) [2], as well as peak knee flexion and knee flexion moment [50] without finding any significant differences between control and orthosis conditions. Similarly, our meta-analysis exhibited no significant difference for peak foot rotation angle (internal tibia rotation relative to rearfoot, or rearfoot eversion) reported by three studies [2, 9, 21] (Figure Error! No text of specified style in document..2).

Table Error! No text of specified style in document..4: Summary of statistical analysis for parameters explored in a single study

Outcome measure	Included study, quality [methodological, biomechanical], sample size (n)	<i>p</i> value	Effect size (95% CI)
Medial posting			
Peak ankle eversion	Telfer <i>et al.</i> [9], [HQ, HQ], n = 12	0.001*	-1.58 [-2.51 to -0.64]
Peak ankle abduction	Huerta <i>et al.</i> [21], [MQ, LQ], n = 12	0.39	-0.35 [-1.16 to 0.46]
Peak forefoot adduction	Telfer <i>et al.</i> [9], [HQ, HQ], n = 12	0.14	-0.62 [-1.44 to 0.21]
Peak external shank rotation relative to foot	Nester <i>et al.</i> [2], [MQ, LQ], n=15	0.54	0.22 [-0.49 to 0.94]
Peak knee flexion	Burston <i>et al.</i> [50], [MQ, HQ], n=15	0.69	-0.15 [-0.86 to 0.57]
Peak knee flexion moment	Burston <i>et al.</i> [50], [MQ, HQ], n=15	0.74	-0.12 [-0.84 to 0.59]
Lateral posting			
Peak forefoot adduction	Telfer <i>et al.</i> [9], [HQ, HQ], n = 12	0.83	-0.09 [-0.89 to 0.71]
Peak external shank rotation relative to foot	Nester <i>et al.</i> [2], [MQ, LQ], n=15	0.10	-0.61 [-1.34, 0.13]
Peak hip flexion	Russell <i>et al.</i> [26], [MQ, MQ], n = 14	0.85	-0.07 [-0.81 to 0.67]
Peak hip extension	Russell <i>et al.</i> [26], [MQ, MQ], n = 14	1.00	0.00 [-0.74 to 0.74]

Peak hip adduction	Russell <i>et al.</i> [26], [MQ, MQ], n = 14	0.66	0.17 [-0.58 to 0.91]
Peak knee extension moment	Molgaard <i>et al.</i> [23], [MQ, LQ], n = 13	0.09	0.70 [-0.10 to 1.49]

Table Error! No text of specified style in document..4 (continued)

Outcome measure	Included study, quality [methodological, biomechanical], sample size (n)	<i>p</i> value	Effect size (95% CI)
Arch support			
Peak knee adduction	Nakajima <i>et al.</i> [15], [HQ, MQ], n=20	0.008*	-0.88 [-1.53 to -0.23]
Peak ankle abduction moment	Nakajima <i>et al.</i> [15], [HQ, MQ], n = 20	0.72	0.11 [-0.51 to 0.74]
Peak knee adduction moment	Nakajima <i>et al.</i> [15], [HQ, MQ], n = 20	0.26	-0.36 [-0.99 to 0.27]
Arch & heel support			
Peak ankle eversion	Wahmkow <i>et al.</i> [10], [MQ, MQ], n = 19	0.14	-0.49 [-1.13 to 0.16]
Peak internal tibia rotation	Wahmkow <i>et al.</i> [10], [MQ, MQ], n = 19	0.61	0.17 [-0.47 to 0.80]
Anteroposterior ground reaction force	Hong <i>et al.</i> [17], [MQ, HQ], n = 20	0.56	-0.18 [-0.80 to 0.44]
Mediolateral ground reaction force	Hong <i>et al.</i> [17], [MQ, HQ], n = 20	0.58	0.17 [-0.45 to 0.80]

Effect size is standardized mean difference. A positive value shows “increase”, and negative value shows “decrease” for that parameter during wearing orthosis compared to no orthosis. HQ: high quality; MQ: moderate quality; LQ: low quality; GRF: ground reaction force. Where significant effect of wearing foot orthosis was found for single studies, it is shown with (*).

Table Error! No text of specified style in document..5: Mean effect of walking with foot orthosis on joint rotations

Outcome measure	Included studies, quality [methodological, biomechanical], and sample size (n)	<i>p</i> value	Mean difference (95% CI) [°]
Medial posting			
Peak ankle eversion	Telfer <i>et al.</i> [9], [HQ, HQ], n = 12	<0.0001	-2.15° [-3.20, -1.1]
Lateral posting			
Peak ankle dorsiflexion	Nester <i>et al.</i> [56], [MQ, LQ], n = 15; Russell <i>et al.</i> [26], [MQ, MQ], n = 14	0.005	2.04° [0.60, 3.47]
Arch support			
Peak knee adduction	Nakajima <i>et al.</i> [15], [HQ, MQ], n = 20	0.005	-1.36° [-2.30 to -0.42]

The mean differences are only reported for significant effect of foot orthosis on kinematics. A positive value for mean difference shows “increase”, and negative value shows “decrease” for that parameter during walking with orthosis compared to without orthosis. HQ: high quality; MQ: moderate quality; LQ: low quality.

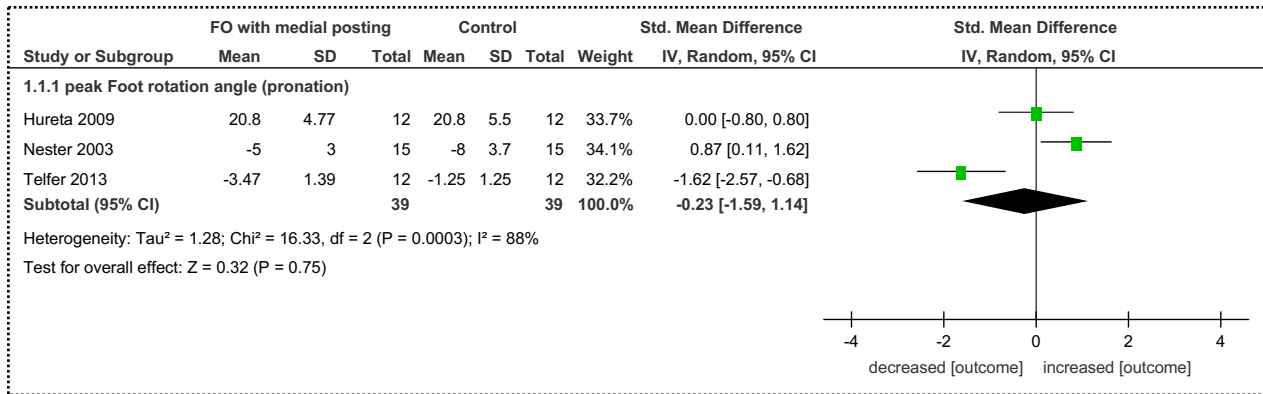


Figure Error! No text of specified style in document..2 : Forest plot indicating the effect of foot orthosis with medial posting on lower extremity kinematics. The subtotal effect for each parameter and the total effect were calculated as standardized mean difference (95% CI). SD: standard deviation, std: standardized, CI: confidence interval, IV: inverse variance.

As for kinetics, three studies reported peak ankle eversion moment [9, 14, 21] and two compared peak knee adduction moment [9, 14]. Meta-analysis showed significant decrease in peak ankle eversion moment with medial posting (large ES -1.18; 95% CI -2.12 to -0.24, $p=0.01$, moderate heterogeneity $I^2 = 75\%$). However, no significant effect for peak knee adduction moment was observed (95% CI cross zero, $p > 0.05$; Figure Error! No text of specified style in document..3).

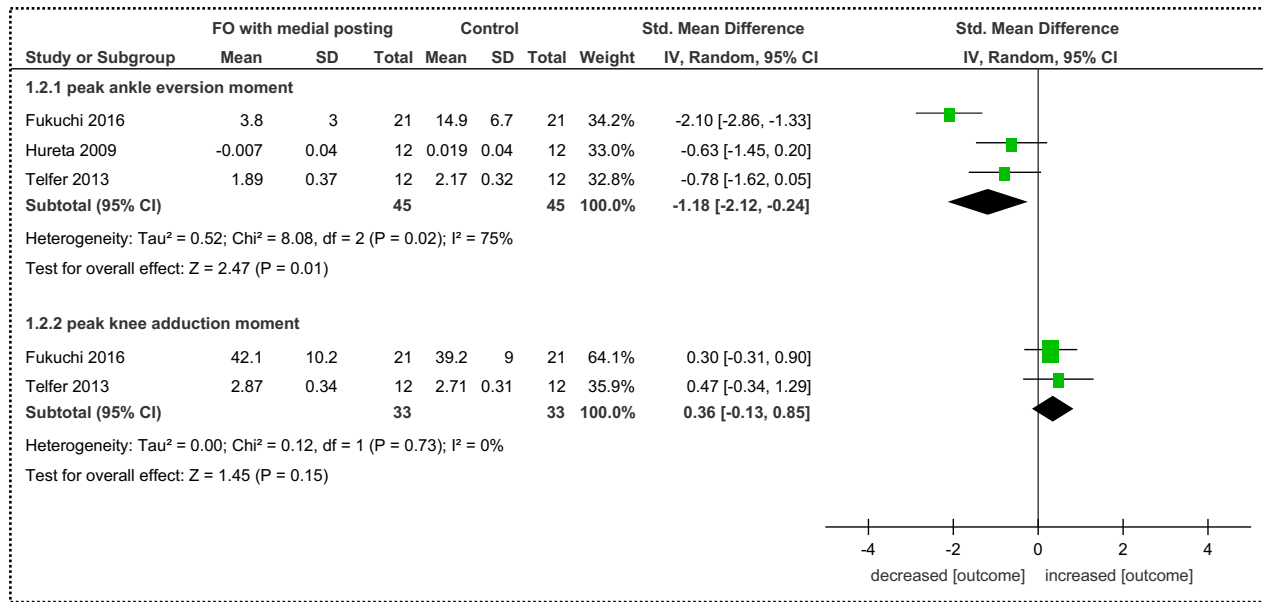


Figure Error! No text of specified style in document..3 : Forest plot indicating the effect of foot orthosis with medial posting on lower extremity joint moments.

Lateral posting

For kinematics, the results of our meta-analysis showed a mean of 2.0° significant increase in peak ankle dorsiflexion during walking with- compared to without- orthosis (moderate ES 0.69; 95% CI 0.15 to 1.22, $p = 0.01$, minimal heterogeneity $I^2 = 0\%$) [2, 26]. In addition, 0.3° higher peak ankle eversion (small ES 0.34; 95% CI -0.51 to 1.19, $p = 0.43$, high heterogeneity $I^2 = 88\%$), 1.8° higher peak ankle plantarflexion (small ES 0.43; 95% CI -0.09 to 0.96, $p = 0.11$, minimal heterogeneity $I^2 = 0\%$), 1.7° lower peak ankle abduction (small ES -0.37; 95% CI -0.91 to 0.17, $p = 0.18$, minimal heterogeneity $I^2 = 0\%$), was achieved for differences in foot kinematics as an effect of walking with orthosis (Figure Error! No text of specified style in document..4). However, these differences were not statistically significant due to insignificant results in individual studies and controversial effects between studies. In terms of knee kinematics, four studies reported peak knee flexion [22, 24, 26, 45], four studies peak knee adduction [22, 24, 26, 45], and two studies peak internal tibia rotation [9, 21]. However, our meta-analysis revealed no significant differences between control and orthosis conditions especially due to the fact that individual studies reported no significant effect (Figure Error! No text of specified style in document..4). In addition, single studies compared peak external shank rotation relative to foot

(inversion) [2], as well as peak hip flexion, extension and adduction [26] without reaching any significant differences between walking with- and without- orthosis (Table Error! No text of specified style in document..4).

In terms of kinetics, walking with laterally posted led to significant increase in peak ankle abduction moment (large ES 1.70; 95% CI 0.83 to 2.57, $p = 0.0001$, high heterogeneity $I^2 = 78\%$), as reported in four studies [2, 5, 15, 23]. Meta-analysis on 14 studies [5, 9, 14-16, 22-25, 45-47, 49, 53] showed a decrease in peak knee adduction moment (moderate ES -0.55; 95% CI -0.85 to -0.24, $p = 0.0005$, moderate heterogeneity $I^2 = 69\%$), and on four studies [5, 8, 25, 45] indicated an increase in mediolateral GRF (small ES 0.44; 95% CI 0.02 to 0.87, $p = 0.04$, low heterogeneity $I^2 = 40\%$; Figure Error! No text of specified style in document..5). In addition, meta-analysis was performed on four studies [9, 14, 21, 22] looking at the peak ankle eversion moment, two studies [22, 23] at the peak knee flexion moment, and four studies [5, 8, 25, 45] at the peak vertical GRF (Figure Error! No text of specified style in document..5). However, no significant effect of using FO with lateral posting was reported there. A single study [23] reported peak knee adduction moment, without finding any significant effect of walking with lateral posting.

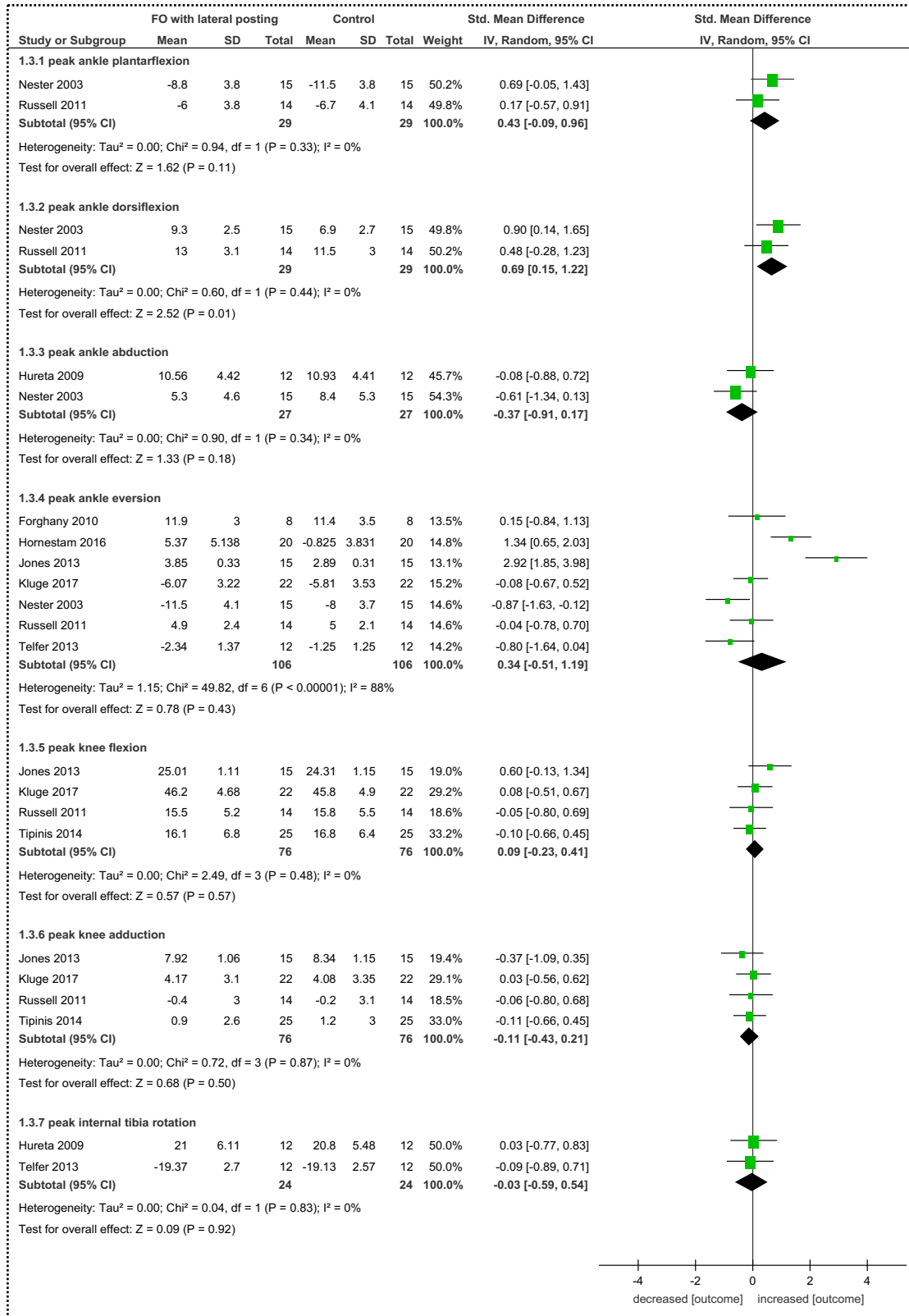


Figure Error! No text of specified style in document..4 : Forest plot indicating the effect of foot orthosis with lateral posting on lower extremity kinematics.

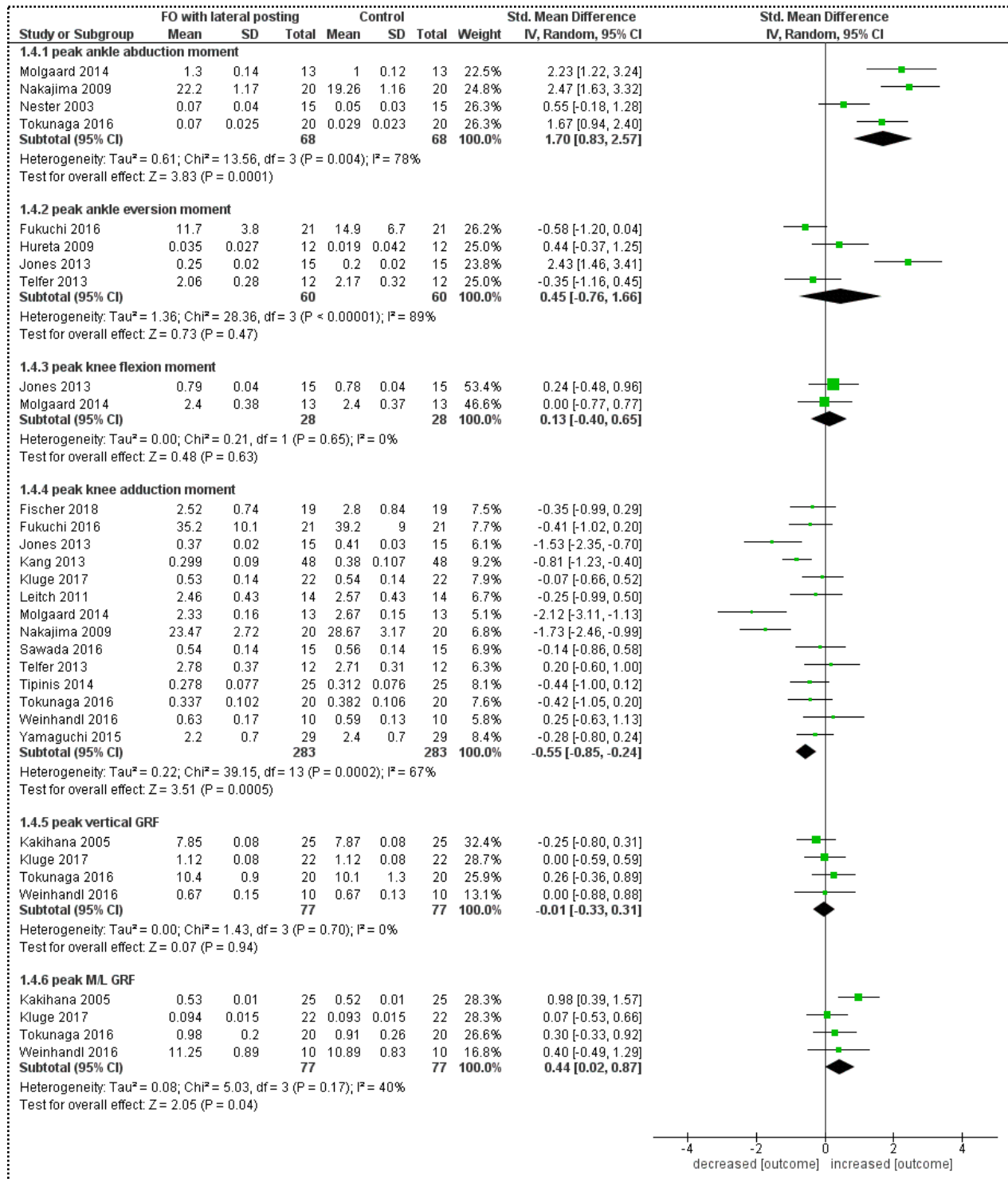


Figure Error! No text of specified style in document..5 : Forest plot indicating the effect of foot orthosis with lateral posting on lower extremity joint moments and ground reaction force. The subtotal effect for each parameter and the total effect were calculated as standardized mean difference (95% CI). SD: standard deviation, std: standardized, CI: confidence interval, IV: inverse variance.

Arch support

One study [15] indicated a significant decrease of -1.36° in peak knee adduction (large ES -0.88 ; 95% CI -1.53 to -0.23 , $p = 0.008$) when walking with arch-supported FO (Table Error! **No text of specified style in document..4**). Regarding joint moments, one single study [15] showed that FO with arch support did not make any significant difference in either peak ankle abduction moment or peak knee adduction moment. Meta-analysis was only possible on peak vertical GRF reported by two studies [15, 19], where no significant effect of walking with arch-supported orthosis was found (trivial ES -0.08 ; 95% CI -0.59 to 0.43 , $p=0.42$, minimal heterogeneity $I^2 = 0\%$; Figure Error! **No text of specified style in document..6**).

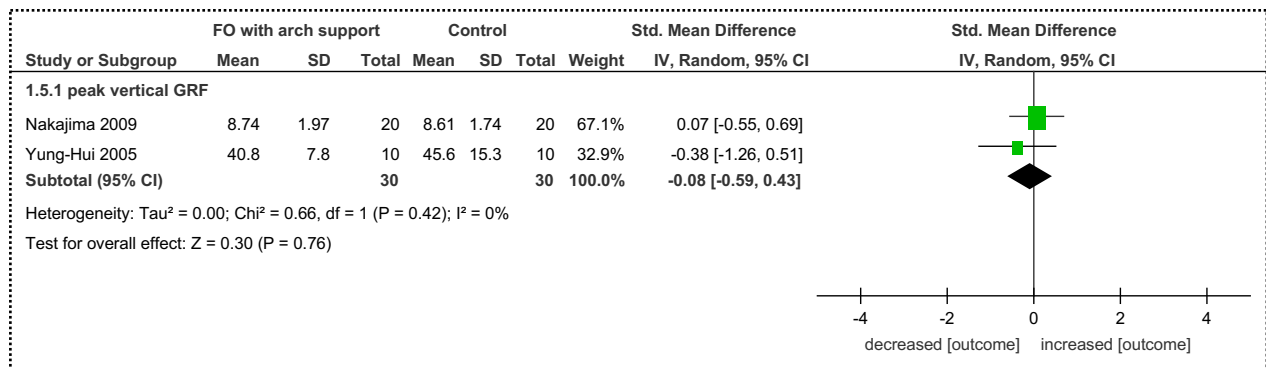


Figure Error! **No text of specified style in document..6** : Forest plot indicating the effect of foot orthosis with arch support on ground reaction force. The effect was calculated as standardized mean difference (95% CI). SD: standard deviation, std: standardized, CI: confidence interval, IV: inverse variance.

Arch & Heel support

No significant difference was observed in peak ankle eversion and peak internal tibia rotation during walking with- and without- arch & heel supported FO as reported by Wahmkow *et al.* [10]. No single study reported either kinematic or kinetic parameters for this design of FO. Meta-analysis evaluation for peak vertical GRF showed no significant effect of walking with heel supported FO (trivial ES -0.20 ; 95% CI -0.58 to 0.19 , $p = 0.54$, minimal heterogeneity $I^2 = 0\%$; Figure Error! **No text of specified style in document..7**) [17-19].

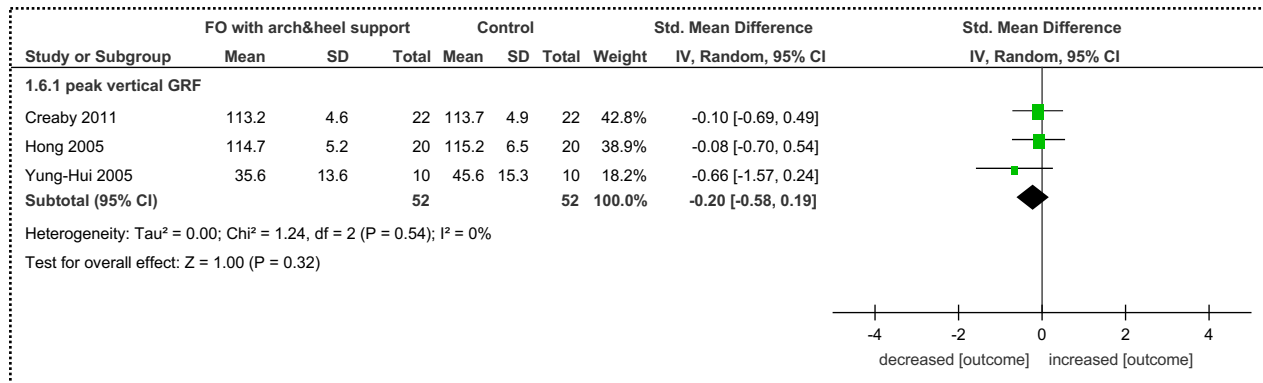


Figure Error! No text of specified style in document..7 : Forest plot indicating the effect of foot orthosis with arch & heel support on ground reaction force. The effect was calculated as standardized mean difference (95% CI). SD: standard deviation, std: standardized, CI: confidence interval, IV: inverse variance

Discussion

Until now it was unclear how segment movement or inter-segment coordination are affected by various FO designs. Four categories of FO designs, namely FO with medial posting, lateral posting, arch support and arch & heel support, were selected as the available and common geometrical modifications to control lower extremity movements and absorb shock. Although the final optimal FO might be a combination of these designs, we basically aimed to detect their separate effects. Based on this systematic review and meta-analysis, postings either medially or laterally appear to function effectively to control the foot posture, lower extremity kinematics and moment arms. Arch supports could modify foot positioning partially as well as how the foot interacts with GRF. Heel supports have been reported to attenuate the impact of ground force and rate of loading. It can also be added that the control of GRF by arch supported FO goes toward the propulsion and stability of walking, while heel supported FO conducts the shock absorption rule.

Medial posting

FO with medial posting exhibited decrease in ankle eversion moment and slight increase in knee adduction moment. These effects have been referred to less everted position of foot, and the medial shift of center of pressure (CoP) imposed by this FO design [14]. Foot pronation is necessary during contact phase to provide foot flexibility and absorb the GRF impact [3, 9]. However, the foot needs to supinate and provide enough arch height for efficient propulsion. Otherwise,

excessive pronation, observed in flatfoot, over-pronated foot or plantar fasciitis, would impose higher load on musculoskeletal system, since the foot is unstable and the rigid lever required at toe off cannot be provided [57]. Our results showed that medial posting can be effective for reducing the pronation components, ankle eversion and ankle eversion moment, in this group of people. There, these individuals could have more support during midstance and propulsion. This FO design could actually behave as a supportive structure to decrease stress on tissues and avoid muscle fatigue [21, 58]. However, some studies reached a weak relationship between controlling the motion of pronated foot and reducing the rate of injury [59]. Medial posting has also been effective for lateral knee osteoarthritis and patellofemoral pain syndrome by reducing the lateral knee loading and pain [60, 61], which could be confirmed by our meta-analysis findings.

Lateral posting

Compared to medial posting, lateral posting showed a reverse effect for ankle eversion and knee adduction moment, as expected due to its mediolateral reverse inclination [8, 45]. There were more studies using FO with lateral posting compared to other categories during walking for healthy subjects. Therefore, more gait measures were available in this category for meta-analysis. Further observations were increase in peak ankle dorsiflexion, peak ankle abduction moment and peak mediolateral GRF during walking with- orthosis compared to without-orthosis. To our observation, the main application of this FO design for improving gait pattern in patients with medial knee osteoarthritis [15], has made it a quite popular target in research. Its efficiency to reduce knee adduction moment, medial knee contact force and loading has been stated in several studies [8, 15, 22], and confirmed by our meta-analysis. For patients with peroneal tendon problems, lateral ankle sprain, and supination injuries, the lateral posting can be a mechanical support to control the excessive motion of subtalar joint [8]. In fact, FO with lateral posting could assist heel bone to a pronated position by higher ankle eversion and higher ankle dorsiflexion, verified by our review findings [8, 62]. In addition, high arch in cavus foot is associated with a stiff and rigid foot, which transfer higher energy to tibia and femur, and increase their vulnerability to stress fracture [57]. Our meta-analysis showed that decreasing the arch height by lateral posting could decrease the loading on the frontal plane of knee. FO with lateral posting has also been thought to improve balance and gait and correct foot varus deformity for patients with stroke [44]. Irrespective of mechanical efficiency provided by lateral posting, some studies reported that they

might neither reduce pain [23] nor improve comfort [24]. Meta-analysis was not possible for the effect of lateral posting on hip loading, and the only available study did not report any changes. This effect needs to be considered in future studies.

Arch support

Meta-analysis about FO with arch support was just possible on vertical GRF without finding any significant effect. Medial arch support has been prescribed for low arch feet to avoid excessive pronation, anterior knee pain and arthritis symptoms. Through using this FO design, the medial arch is supported against depression during weight-bearing and the ground reaction impact force is reduced [10]. It was also shown to decrease the tension in plantar aponeurosis [1, 19]. FO with arch support has been reported to improve fit, balance and mechanical transfer of ground force to foot, and reduce pain [45, 63-67]. However, careful attention should be paid on their positioning to avoid bias in knee alignment [45]. Previous research did not show consistent results for the mechanical performance of arch supports. Franz *et al.* [64] stated that arch-supported FO could increase the toe-out angle, decrease the moment arm of knee, and relieve knee pain. Mulford *et al.* [66] also confirmed the effectiveness of arch- supported FO in improving balance and pain in elderly subjects. However, Nakajima *et al.* [15] showed similar knee adduction moment and subtalar joint adduction moment for FO with arch support and flat insoles. To our observation, arch supported FO has been evaluated for balance and stability rather than modifying kinematics and kinetics. Therefore, further studies are required to response for the efficiency of FOs with arch support to alter foot kinematics.

Arch & Heel support

Heel cups are usually suggested to attenuate the force at the initial foot contact. At this moment, high impact force is induced on the foot, which is further transmitted to knee and hip. The long term effect of high impact forces and the rate of loading could be cartilage damage, overuse injuries, and knee osteoarthritis [18, 65]. Adding heel cup to arch supported FO can provide foot support in both rearfoot and medial arch which play an important role in balance and propulsion. Most of FOs with heel cup have been examined during running, where they have been reported to efficiently reduce the impact force [68, 69]. During walking, lower extremity kinematics and kinetics were assessed by three studies focusing on FO with arch and heel support. Yung-Hui *et*

al. [19] reported efficient attenuation of impact force and higher comfort with arch & heel supported FOs. However, Creaby *et al.* [18] found flat material insole more efficient in reducing the peak impact forces between ground, foot, and knee compared to FO with arch & heel support. They inferred that while FO with heel cup could be quite effective for subjects with low intrinsic shock-absorbing capacity [70, 71], flat material insoles work better for young individuals during walking. In addition, Hong *et al.* [17] did not find any significant effect of this FO on ground reaction force. Therefore, due to limited studies as well as controversial effects of heel cup in shock absorption during walking, more studies are required in this field.

Clinical considerations

It is quite important to see whether our findings on the association between FO designs and their corresponding biomechanical effects are meaningful with clinical perspective. Based on previous literature findings even small orientation changes, *i.e.* 1° to 2° , in the interaction between foot and ground could be effective to either reduce or overcome lower extremity pathologies [72-74]. It has also been mentioned that small changes in knee adduction angle could alter knee joint contact forces and stress distribution within the cartilage [75, 76]. Referring to these evidences, 2.15° decrease in peak ankle eversion with medial posting, 2.04° increase in peak ankle dorsiflexion with lateral posting, and 1.36° in peak knee adduction with arch supported FO, found in the present meta-analysis, could be clinically meaningful. Small non-significant difference was found for peak ankle eversion during walking with laterally posted FO which was due to inconsistent findings of included studies. Different methodological approach for kinematic analysis, differences in the FO design and material, and different populations can be stated as the source of inconsistencies. Using multi-segment foot models as well as standardizing and customizing FO design are suggested to be implemented in future studies to reach more reliable results.

A further clinically important point is to perceive the negative aspects of each FO design, and look for the possible solutions. Regardless of whether medial and lateral postings are used for modifying foot abnormality [9] or knee problems [8], they are susceptible to alter the kinematics and kinetics of ankle and knee simultaneously [8, 9, 22]. Rodrigues *et al.* [61] reported that medial wedging for the treatment of valgus knee osteoarthritis might impose changes in talus and talocalcaneal kinematics at the same time. Therefore, modifying one abnormality might happen in cost of inducing another pathology if this important point is ignored in treatments with FO. Some solutions

have been suggested to overcome this problem: using appropriate dose of posting or controlling unfavorable movements with adding extra supports. A few studies evaluated the dose-effect of posting in terms of biomechanical changes and comfort [9, 14, 24]. Tipnis *et al.* [24] showed a systematic decrease in knee adduction moment with increasing the dose of lateral posting, but comfort level worsened for higher doses of wedging ($> 6^\circ$). Telfer *et al.* [9] reported a linear relationship between dose of posting and mechanics of rearfoot and knee. Fukuchi *et al.* [14] found higher positive correlation between CoP and ankle joint moment compared to knee joint moment. This might indicate that although lower dose of posting can be effective for ankle instabilities, it might not be capable to improve knee mechanics, and consequently overcome knee problems. In terms of extra supports, some studies suggested to add ankle support to control the movement of talus when posting was aimed to treat knee osteoarthritis [61, 77]. In addition, Nakajima *et al.* [15] revealed that adding arch support to lateral posting for patients with osteoarthritis increase comfort and clinical efficiency. It was thought that an arch support could modulate the subtalar joint over-abduction imposed by lateral wedge. Based on these findings, we believe that optimal FO could be reached if specific pathological and individual needs in terms of dose of posting and support as well as combining different categories of FO designs are taken into account.

Methodological considerations

Although we did not focus on the material of FO, it has been reported that FOs made of materials of different rigidities impose changes on foot support and control effects [1]. Therefore, it is suggested that further research assess FOs with different materials as well as how the deformation of FO changes during walking as a function of FO rigidity. In addition, the medial and lateral posting categories included orthoses with rearfoot postings or full-length wedges. The rearfoot postings could just control foot contact to midstance not to late stance [62]. Higher and longer pronation, *i.e.* rearfoot eversion, forefoot abduction and forefoot plantarflexion, is just partially controlled by rearfoot posting. Therefore, it is important to suggest full-length posting when abnormalities are observed in forefoot motion or late stance phase. Otherwise, over-pronation might stress hip joint to response for inter-joint coordination, and provide a potential for hip pathology [11]. We believe that our findings in healthy subjects could provide a quite helpful database to suggest different FO designs based on the biomechanical needs to treat different pathologies. However, this should not be ignored that the compensatory mechanisms employed by

patients might interact with FO biomechanical effect. As a result, the effect of similar FO design might be different in healthy individuals *versus* patients. For example, as an effect of medial posting, Telfer *et al.* [9] reported a decrease in forefoot adduction for healthy individuals in contrast to an increase for flatfoot individuals. To come up with this issue, it is important to verify the effect of FO design on any specific pathology before its clinical use.

Several inconsistencies for experimental measurement were observed between the included studies. While some studies asked subjects to walk barefoot, others used either standardized shoes or subject comfortable shoes. Discussing on which method could be more effective regarding FO measurements is beyond the goals of this review. However, synthesizing the results of all these conditions in this review might have imposed bias and heterogeneity in our results. The interaction between foot, FO, shoes and ground would be different among these conditions which effect on kinematics and kinetics [45, 78]. In addition, the kinematic analysis was based on the position of reflective markers in all included studies. However, they were not similar in terms of attaching the markers on skin or shoes, regarding foot as multiple segment, and attaching redundant markers on each segment. These variables would effect on the accuracy of foot kinematics due to more or less compensation for soft tissue artefacts [38, 79]. Walking on treadmill or along walkway as well as the walking speed should be added as other non-identical factors. For example, Hornestam *et al.* [3] reported that healthy subjects exhibited a decrease in pronation during higher speed of walking with lateral wedges.

Some heterogeneous as well as unexpected results existed in the context of this meta-analysis which could be addressed to various methodological and biomechanical approaches. Fukuchi *et al.* [14] showed a decrease in peak ankle eversion moment as an effect of walking with both medial and lateral posting. The high decrease of this gait parameter for FO with medial posting in this study led to high heterogeneity index in meta-analysis results. This high difference might be inferred to its low biomechanical quality in terms of selected foot model. Indeed, this study considered foot as single segment, and placed just three reflective markers on shoes to record foot kinematics. In addition, lateral posting, due to the effect of its geometry on foot positioning, was expected to increase ankle eversion moment. However, three out of four studies did not fulfill such an expectation: (i) Telfer *et al.* [9] reported decrease in peak ankle eversion and peak ankle eversion moment. This can be related to the contoured shape of their customized orthosis, which

prevents the deformation of medial longitudinal arch; (ii) Fukuchi *et al.* [14] mentioned that the increase in ankle eversion moment was only possible with higher degrees of wedges, and we may hypothesize that it might be partly related to its low biomechanical quality; (iii) Huerta *et al.* [21] explained that peak ankle eversion moment occurs at initial contact, where the point of lateral heel contact cannot be deteriorated by lateral wedge. In this study, Helen Hayes marker set [55] was used for recording kinematics, the subjects walked barefoot, and the speed of walking was not monitored. All of these parameters could also have led to such unexpected finding. No systematic effect was found for changes in internal tibia rotation for any of medial/lateral posting or arch support. Previous studies referred this observation to high inter-individual variability in this gait measure depending on foot type [9, 10, 80]. Decrease in peak knee adduction moment during walking with lateral posting was confirmed by all studies, with different effect sizes, except by Telfer *et al.* [9] and Weinhandl *et al.* [25]. This controversial result was probably related to the contoured geometry of FO by Telfer *et al.* [9], and to not controlling gait speed as well as no change in the range of motion for ankle due to putting markers on the shoes by Weinhandl *et al.* [25]. In the category of FO with arch & heel support, high variability in the response of individuals to insoles prohibited us to find any effect in our meta-analysis. Creaby *et al.* [18] stated that heel cup insoles might just be effective for some individuals and suggested to separate individuals with-effect and without-effect for future studies.

As it can be seen through this review, different methodological approach has given rise to controversial and heterogeneous outcomes, where it makes it hard to provide a comprehensive database for clinical use. We believe that further studies could be more qualified in terms of designing more thoughtful and standardized protocols as well as measurement approach.

Conclusion

Our meta-analysis found evidence for decrease in peak ankle eversion moment with medial posting. Increase in peak ankle dorsiflexion, peak ankle eversion, peak ankle abduction moment, and peak mediolateral GRF, as well as decrease in peak knee adduction moment were the effects of walking with lateral posting. No significant evidence was found for FO with arch support or arch & heel support through our meta-analysis. The heterogeneity between the findings of included studies and the limited number of available studies were the deterrent effects for finding more evidence in different categories. Although the mechanical and clinical approach to reach the

optimal FO design remains to be more elucidated, this meta-analysis is the first comprehensive study to examine the interplay between FO design and gait kinematics and kinetics in healthy individuals. We think that heterogeneity between studies could reduce with introducing standard multi-segment foot models for kinematic analysis and making use of additive manufacturing technology to design customized foot orthosis based on individual needs.

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Supplementary materials

Groups of keywords

Group #1: related to “foot orthosis”

[MeSH terms: "Foot Orthoses"

OR

Keywords (title, abstract, and keywords): insole OR "shoe insert" OR "foot orthosis" OR "foot orthotics" OR "foot orthoses"]

AND

Group #2: related to “design and geometrical modifications”

[MeSH terms: "Computer-Aided Design" OR "Evidence-Based Facility Design"

OR

Keywords (title, abstract, and keywords): Wedge* OR post OR posting OR posted OR heel* lift* OR flange* OR heel* spur* cut* OR metatars* cut* OR plantar* fascial* groov* OR navicul* shell* OR heel* cup* OR flat* OR arch* support* OR offload* OR heel* skive* OR cushion* OR slip* resist* OR Design* OR structure* OR model* OR geometr*]

AND

Group #3: related to “biomechanical and locomotion metrics”

[MeSH terms: "Locomotion" OR "Biomechanical Phenomena" OR "Mechanics" OR "Mechanical Phenomena" OR "Electromyography"

OR

Keywords (title, abstract, and keywords): Motion OR movement OR locomot* OR kinematic* OR kinetic* OR pressur* OR dynamic* OR load* OR biomech* mechanic* OR shock* absorb* OR shock* attenuat* OR friction* OR moment* OR angle* OR rotation* OR force* OR angular* impuls* OR EMG OR electromyograph* OR muscle* activity* OR torque* OR energy*]

Table S Error! No text of specified style in document..I: Methodological quality assessment, modified Downs and Black checklist

Category	#Question in downs & black checklist	Question	Hints for assigning scores
Reporting	1	Is the hypothesis/aim/objective of the study clearly described?	“1” if yes, “0” if no
	2	Are the main outcomes to be measured clearly described in the Introduction or Methods section?	“1” for papers describing outcomes before result section. Otherwise “no”
	3	Are the characteristics of the patients included in the study clearly described?	“1” for describing age, sex, and health of lower extremity, otherwise “no”
	4	Are the interventions of interest clearly described? Treatments and placebo (where relevant) that are to be compared should be clearly described [footwear design]	“1” if foot orthosis design (treatment) and the awareness/blinding of wearing orthosis (placebo) have been described, otherwise “no”
	5	Are the distributions of principal confounders in each group of subjects to be compared clearly described?	Principal confounders: walking speed, foot orthosis material and design, the proof of healthy foot, shoe model. “2” if all of the principal confounders are clarified, “1” if some of the are clarified, otherwise “0”
	6	Are the main findings of the study clearly described?	“1” if outcome data have been reported for major findings and analyses, otherwise “no”
	7	Does the study provide estimates of the random variability in the data for the main outcomes?	“1” if reporting standard deviation, standard error or confidence interval for results, otherwise “0”
	10	Have actual probability values been reported (e.g. 0.035 rather than <0.05) for the main outcomes except where the probability value is less than 0.001?	“1” if yes, otherwise “0”

Table S Error! No text of specified style in document..I (continued)

Category	#Question in downs & black checklist	Question	Hints for assigning scores
External Validity	11	Were the subjects asked to participate in the study representative of the entire population from which they were recruited? where a list of all members of the relevant population	“1” if the study described the source population, and the approach of selecting participants, otherwise “0”
	12	Were those subjects who were prepared to participate representative of the entire population from which they were recruited?	“1” if the proportion of participants asked to attend, and agreed should be stated, otherwise “0”
Internal Validity (Bias)	15	Was an attempt made to blind those measuring the main outcomes of the intervention?	“1” if there was blinding for data processing, otherwise “0”
	16	If any of the results of the study were based on “data dredging”, was this made clear?	“1” if there is not any report of unplanned analysis and results, otherwise “0”
	18	Were the statistical tests used to assess the main outcomes appropriate?	“1” if proper statistical tests had been used, otherwise “0”
	20	Were the main outcome measures used accurate (valid and reliable)?	“1” if any clue has been given for the validity and reliability of outcome measures, otherwise “0”
Internal Validity- confounding (selection bias)	21	Were the patients in different intervention groups (trials and cohort studies) or were the cases and controls (case control studies) recruited from the same population?	“1” If the groups were matched for age, sex, and level of daily activities, otherwise “0”
	22	Were study subjects in different intervention groups (trials and cohort studies) or were the cases and controls (case-control studies) recruited over the same period of time?	“1” If all the participants were recruited over a mentioned and limited period of time, otherwise “0”

Table S Error! No text of specified style in document..I (continued)

Category	#Question in downs & black checklist	Question	Hints for assigning scores
Internal Validity- confounding (selection bias)	25	Was there adequate adjustment for confounding in the analyses from which the main findings were drawn?	“1” if walking speed and shoe model was not significantly different between participants, otherwise “0”
Power	27	Did the study have sufficient power to detect a clinically important effect where the probability value for a difference being due to chance is less than 5%?	“1” if the number of participants were selected based on any power or sample size calculation, otherwise “0”