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Impact of in shoe and barefoot placed frontal wedges on plantar loading: A systematic review

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A R T I C L E I N F O

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A B S T R A C T

Purpose: The main aim of this review is to report the effect of different types of in-shoe and barefoot wedges on the distribution of the plantar loading of the human foot. We hypothesise that frontal plane wedges modify this parameter.

Methods: A systematic review was performed, using the PubMed, CINAHL, Prospero and Scopus databases, consulted from their date of first publication to May 2020. Only observational (cross-over studies), randomised controlled trials (RCTs) and quasi-experimental studies addressing the effects of in-shoe and barefoot frontal plane wedges on plantar loading were included. All articles were subjected to quality assessment, using the Newcastle-Ottawa scale for the observational (cross-over) studies, TREND for quasi-experimental studies and the Cochrane Collaboration's tool for the RCTs.

Results: Eleven papers were included in the final review. Four were cross-over studies, other four were quasi-experimental studies and three were RCTs. These eleven studies included 320 patients, with ages ranging from 20 to 60 years. Regarding the risk of bias, most of the observational studies and RCTs had a moderate level of quality. Conclusions: The results suggest that lateral wedges are more effective, producing a lateral shift of the centre of pressure and increasing the pressure. Regarding the impact on the peak impact force there seems to be less consensus among the published data.

1. Introduction

Foot orthoses (FOs) are commonly used in treating injuries of the foot, ankle and lower extremity [1], to optimise foot mechanics and function and to provide cushioning and off- loading of foot structures. [2].

A wide range of FOs are currently employed in clinical practice and research. They typically form part of a multidimensional treatment perspective but are almost always considered a fundamental aspect of footwear advice [3].

The design of FOs is normally focused on three dimensions: (i) selecting the necessary geometric features; (ii) selecting the necessary materials, taking into account their mechanical properties; (iii) selecting the desired visual properties [4]. With respect to the former, specific modifications or add-on components, such as metatarsal pads or metatarsal domes, are often applied in custom or non-customised FOs to achieve the required clinical endpoint. Another commonly applied geometric feature in foot orthotic practice encompasses frontal plane wedges. These may be applied in various ways [2], including medial and lateral wedges placed on the outsole of the shoe (shoe wedges) [1] or wedges placed directly on the FO (wedged FOs) [5]. Alternatively, a variable stiffness shoe with a stiffer medial or lateral midsole may be used, although this option is generally considered a non-validated surrogate for aforementioned frontal plane wedges [6].

In addition to the regional location, frontal plane wedges may also present differences in their anterior/posterior length, taking forms such as medial rearfoot wedge insole, medial forefoot wedge insole, lateral rearfoot wedge insole, lateral forefoot wedge insole or full-length wedge

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insole [7–9].

The effectiveness of these wedges in decreasing pain and in enhancing foot and knee function has been summarized in various systematic reviews [10–21]. The principal biomechanical purpose of frontal plane wedges is to alter the external moments across several joints of the foot and lower limb, by modifying the location of ground reaction forces during specific subphases of the stance phase. In the literature, two contradictory hypotheses have been proposed regarding the alteration of ground reaction forces. According to the first, a medially-placed (or varus) wedge increases the peak pressure under the medial aspect of the (rear)foot, while a lateral (or valgus) wedge does so under the lateral aspect. The alternative hypothesis is that medially-placed wedges tilt the foot laterally and shift the peak pressure to the lateral aspect of the (rear) foot. [22].

Four systematic reviews have examined the effect of frontal plane wedges on the kinematics and kinetics of the foot and lower limb [23–26], but only one has considered the effects of frontal plane wedges on plantar pressure and on the displacement of the centre of plantar pressure (COP) [27]. However, the latter review focused exclusively on participants with 'normal' feet and flexible flat feet.

Plantar pressure technology is a compelling option, as it is readily accessible in clinical and research practice [28]. Moreover, pressure distribution assessments at the shoe-ground, foot-orthotic or foot-shoe interface have been used as a non-validated surrogate measure in estimating foot joint kinetics [29].

In this perspective, COP displacement is often used as a biomechanical measure, since it provides a monoplanar perspective of the displacement of the ground reaction forces at the plantar surface. Nevertheless, to our knowledge, no prior review has been conducted of the plantar pressure redistribution properties of frontal plane wedges. Therefore, the aim of the present review is to summarise the literature on the effects of different types of frontal plane wedged conditions on plantar pressure distribution.

Our main hypothesis is that medially placed wedges produce a medial shift of the gait line, the latter being the displacement point of application of the ground reaction force throughout the stance phase of walking. [30,31], and an increase in vertical loading of the medially located regions of interest. The second hypothesis of this review was that the peak impact force is altered following the utilisation of frontal plane wedges.

2. Methods

This review is registered at the international prospective register of systematic reviews (PROSPERO CDR 42020210082).

2.1. Design

This review was performed in accordance with the preferred reporting items for systematic reviews and meta-analyses (PRISMA) statement [32].

2.2. Search strategy

After establishing the aim of this review and checking that no previous studies in this area had been performed, one of the authors (MMR) conducted the literature search. The databases searched were PubMed, Cumulative Index to Nursing and Allied Health Literature (CINAHL), Scopus and Prospero. As described in Appendix 1, a systematic search strategy was applied, from the date of first publication until May 2020.

2.3. Eligibility criteria

The PICO (P = Patients, I = Intervention C = Comparator O = Outcome) framework was applied in order to frame and develop the literature search and inclusion strategy in the current systematic review.

2.3.1. Type of studies

The papers considered were all observational (cross-over) studies, randomised controlled trials (RCTs) and quasi-experimental studies addressing the effect of frontal plane wedges (FPW) on plantar pressure distribution. There were no restrictions related to the year of publication. Only full-text original research reports published in English or Spanish were included. Case series, abstracts, editorials, reviews and other types of designs were excluded.

2.3.2. Type of participants

The participants in these studies had to be adults (≥18 years), with or without pathologies. However, studies that included participants who had undergone surgery were excluded. No restrictions were applied with respect to participants' gender or ethnicity.

2.3.3. Type of intervention and comparison

All types of frontal plane wedged conditions were included in the analysis, customised or not, with or without a medial arch support, and with or without other FO features such as metatarsal domes. Therefore, these types included valgus or varus wedge, lateral wedge, medial wedge, forefoot wedge or rearfoot wedge, regardless of the material used and method of production.

Studies were eligible if they included a frontal plane wedge insole, either inside the shoe or without a shoe (attached by adhesive strips in case of barefoot conditions, for example). Articles that analysed only frontal plane wedges (without insole) placed on the sole inside the shoe were also included. However, articles that studied frontal plane wedges integrated in the out-sole of a shoe or that examined variable stiffness shoes were excluded.

2.3.4. Definition of intervention

- **Lateral/ Valgus wedge:** A triangular shaped element placed with his inclined plane oriented in the frontal plane. The highest/thickest point is located at the lateral side of the foot and the lowest side of the inclined plane is located on the medial side of the foot.
- **Medial/Varus Wedge:** Opposite of valgus/lateral wedge
- **Wedge or a posting:** synonyms of each other.
- **Lateral wedge insole:** An insole with an integrated lateral wedge along the entire length of the foot. When the wedge encompasses only the heel than it is called a lateral heel wedge insole.

2.4. Types of wedge

Studies in which so-called dose-response analysis was targeted (e.g., those including different degrees of wedges) or those comparing wedged conditions with a flat insole or with no insole were also included. Articles that studied wedges used in conjunction with other elements, such as a knee brace, were included only when the results relating to the wedged conditions could be extracted independently.

2.4.1. Type of outcome

Studies that used a pressure platform and/or a force platform and/or an in-shoe pressure system were eligible for inclusion in the present review if at least one of the following outcomes was assessed: COP data (gait line) and/or vertical force (e.g., peak force, mean force, force-time integral) and/or pressure data (e.g., peak pressure, mean pressure, pressure-time integral) and/or surface data (e.g., contact area) and/or time related variables (e.g., initial contact, final contact, contact duration, time to peak force or peak pressure) of specific regions of interest. Only the results for the vertical component captured by a force plate were included in this review.

2.5. Study selection

The following procedure was used to select studies for analysis. One of the researchers carried out the initial literature review and then evaluated the results in conjunction with another researcher, in accordance with the above-described inclusion criteria. In the event of any disagreement, a third author was consulted. It was also planned, if necessary, to email the original authors to obtain further information regarding the published findings, but in practice this measure was not required.

2.6. Data extraction

After this search process, one author (MMR) screened the citations and abstracts obtained to identify all eligible articles. The full-text version of every paper meeting the inclusion criteria was then obtained and analysed by two researchers (MMR and ABOA).

From each study, the following data were extracted: author, date, country, type of study (RCT or cross-sectional), population (gender and age), outcome, measurement tool, intervention, follow-up and subdivision of foot.

Due to the heterogeneity of populations, types of follow-up and outcomes included in these studies, no meta-analysis was performed.

2.7. Quality assessment of the studies included

Two researchers (AOA and MMR) independently assessed the risk of bias in the studies included, using the Newcastle-Ottawa scale [33] for observational (cross-over) studies, the Cochrane Collaboration's tool for RCTs [34] and the TREND (Transparent Reporting of Evaluations with Nonrandomised Designs) checklist for quasi-experimental studies [35].

The Newcastle-Ottawa scale is based on seven items grouped into four blocks: (1) methods for selecting study participants (selection bias), one item; (2) methods to control confounding (performance bias), two items; (3) statistical methods (detection bias), two items; (4) methods for measuring the outcome variables (information bias), two items.

Each of these items is scored on a scale ranging from 0 (high risk of bias) to 3 (low risk of bias), and the recommended interpretation of each score is provided. The maximum score that can be obtained with this scale is 21 points.

For studies with an RCT design, the Cochrane Collaboration's tool was used.

This instrument has seven domains: random sequence generation, allocation concealment (selection bias), blinding of participants and research personnel (performance bias), selective reporting (reporting bias) and other types of bias. Each domain is evaluated as low bias, unclear bias or high bias.

Finally, for the quasi-experimental studies, the TREND (Transparent Reporting of Evaluations with Nonrandomised Designs) checklist was used. This checklist contains 22 points evaluating the following sections of the article considered: Title and abstract, Introduction (or Background) Methods (participants, intervention, objectives, outcomes, sample size, assignment method, blinding, unit of analysis, statistical methods), Results (participant flow, recruitment, baseline data, baseline equivalence, numbers analysed, outcome and estimation, ancillary

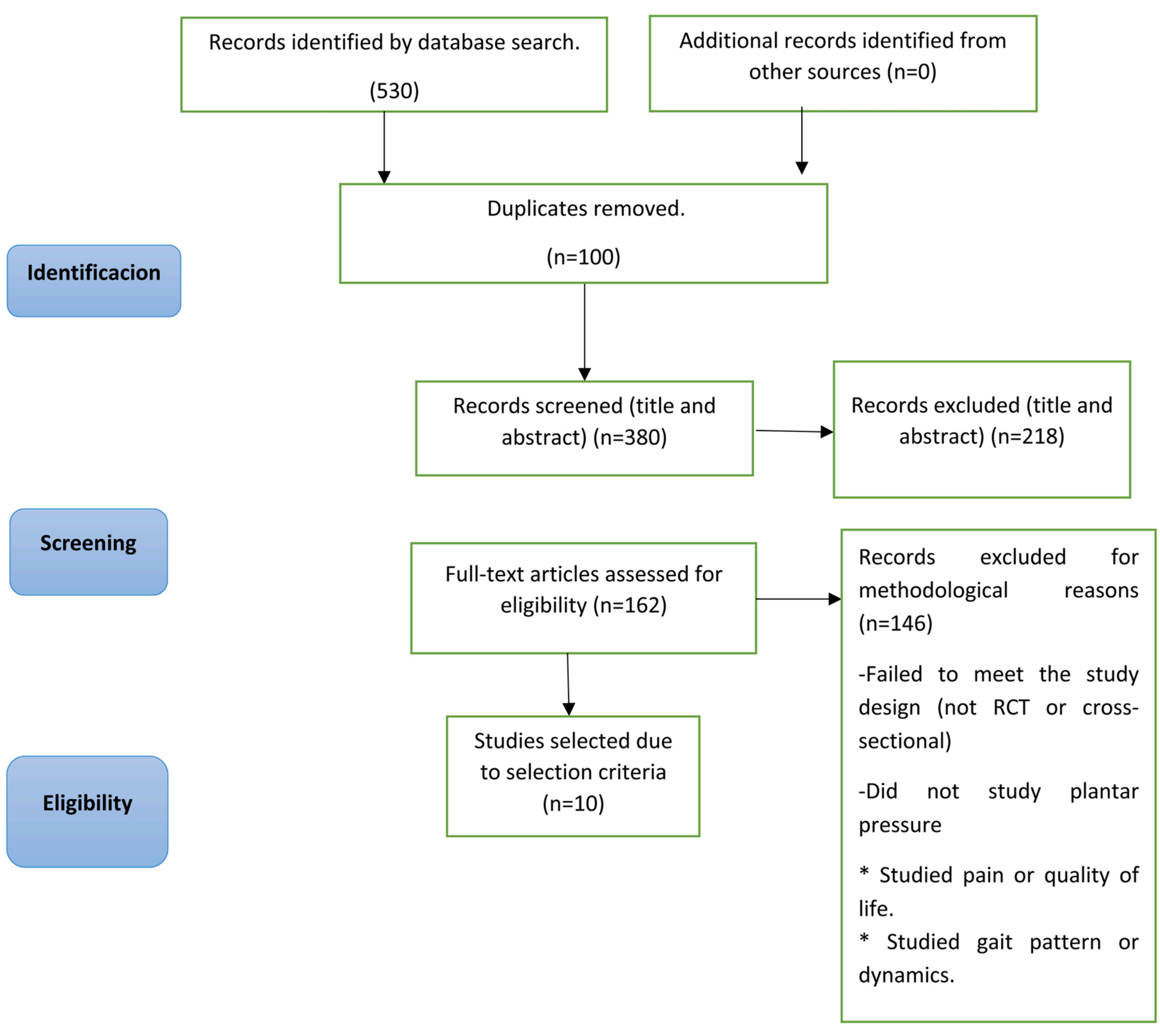

Fig. 1. PRISMA flow diagram for the studies reviewed ([36]).

analyses, adverse events) and Discussion (interpretation, generalisability, overall evidence).

3. Results

The initial search obtained 530 studies, but 100 were duplicates and so a net 430 studies were included (Fig. 1). The first screening of these papers was focused on the title, abstract and key words. This process led to a further 50 studies being excluded. Of the remaining 380, only 162 were full-text and hence eligible for inclusion. Finally, after applying the detailed selection criteria, eleven met all the requirements and were analysed.

3.1. Study characteristics

Three of the eleven papers were RCTs, four were cross-over studies and four were quasi-experimental. These eleven studies encompassed a total of 320 participants, with an age range of 20–62 years. The majority of the study participants were male (63.44 %).

The RCTs included a total of 127 participants, 30 of whom were male and 97 gender not stated. The participants' mean age was 34 years. The principal outcome measures were COP data and pressure data, and the lateral wedge was the condition most commonly studied (Tables 1 and 4).

The quasi-experimental studies included a total of 94 participants, of whom 26 were male. For the remaining 68 participants, the gender was not stated. The participants' ages ranged from 46 to 64 years (Tables 2 and 5).

The cross-over studies included a total of 128 participants (57.03% of whom were male), with a mean age of 48.3 years. The main outcome measure was COP and vertical ground reaction (peak impact force) force and the intervention most commonly employed was the lateral wedge insole (Tables 3,4,5 and 6).

Table 1
RCTs: PIC characteristics.

Principal author	Population	Intervention	Comparator
Jin, H. 2019 [37]	30 males Mean age: 21 years	Customised 3D-printed single-sided lateral wedge insole (CLWI) (6°) *Made of polyvinyl acetate. *Designed and manufactured using the Bodyarch® 3D-printing system	*Control condition Basic insole
Hinman, R.S. 2011 [38]	73 participants Mean age: 50 years	Lateral wedge insole (5°) *Standardised non-customised lateral wedge insoles made of high-density ethyl vinyl acetate. *Full-length insole.	*Control condition Insole with and without 5° lateral wedge
Telfer, S. 2013 [39]	12 participants with pronated feet and 12 controls.	¾ length semi-rigid Designed using Orthomodel software. Manufactured using a 3D printing system	*Different degrees of wedging – 6° Lateral posting – 4° Lateral posting – 2° Lateral posting – 0° Neutral posting – 2° Medial posting – 4° Medial posting – 6° Medial posting – 8° Medial posting – 10° Medial posting.

Table 2
Quasi-experimental studies: PIC characteristics.

Principal author	Population	Intervention	Comparator
Leitch, K.M. 2010[28]	26 participants 9 male, 17 female Mean age: 46 years	Lateral heel wedge *Made from ethylene–vinyl acetate (EVA) foam. *Lateral heel wedge	– Different degrees of wedging – No wedge – 4° wedge – 8° wedge
Russell, E.M. 2012[40]	14 obese women Mean age: 26 years 14 with normal weight Mean age: 29 years	Lateral wedge insole (8°) *Made of ethyl vinyl acetate material. *Full length.	*Control condition No insole
Guldemond, N.A. 2006[41]	17 male participants Mean age: 64 years	Custom-made full-length 5° varus and valgus 'posts' or 'wedges' made of cork *With arch support *Component insole	*Basic insole
Van Gheluwe, B. 2004[22]	23 participants	*Forefoot varus/valgus wedge *Rearfoot varus/valgus wedge *Made of dense ethylene vinyl acetate material.	*Different degrees of wedging Forefoot wedging: – 3° valgus – Flat (0°) – 3° valgus – 6° varus. Rearfoot wedging: – 4° valgus – Flat (0°) – 4° varus – 8° varus

3.2. Risk of bias

The best cross-over studies scored 17 of 21 possible points on the Newcastle-Ottawa scale, while the worst scored 12 and the overall mean score was 15 points. The two domains that scored most highly were statistical methods and methods for measuring outcome variables, and the area of weakest reporting was the method used to control for confounding factors.

(Table 7).

Among the RCTs, the best study presented six areas with low risk of bias, while the worst had three low-risk and three high-risk areas. Overall, the areas in which the best qualitative score were obtained were: Random sequence generation (selection bias), Incomplete outcome data (attrition data) and Selective reporting (reporting bias). The poorest area was Blinding of participants and personnel, for which two of the three studies presented high risk. However, all three RCTs were classified, overall, as low risk (Fig. 2).

In the case of the quasi-experimental studies, the quality of the studies is more difficult to determine, since the scores obtained with the TREND checklist vary widely.

In this respect, the best areas overall were: Title and abstract (only one study failed to meet this requirement), Objective and outcomes (i.e., specific objectives and hypotheses, clearly-defined primary and secondary outcome measures, method used to collect data, and information on validated instruments such as their psychometric and biometric properties) and Unit of analysis and statistical methods. Most of the

Table 3
Cross-over studies: PIC characteristics.

Principal author	Population	Intervention	Comparator
Kakihana, W. 2004[42]	**Experiment 1.** 5 healthy men (mean age: 25.2 years) and 5 healthy women (mean age: 24.8 years) **Experiment 2.** 5 healthy men (mean age: 27.6 years) and five healthy women (mean age: 22.8 years)	Lateral wedge insole * Made of ethylene vinyl acetate (EVA 8200) * Full length insole	Different degrees of wedging – No wedge – Low wedge with a 3º lateral angle – High wedge with a 6º lateral angle.
Kakihana. W, Torii S 2005[43]	50 male university athletes (25 with an unstable lateral ankle and 25 healthy controls) Mean age: 20.8 years	Lateral wedge insole (6° lateral angle) *Made of ethylene vinyl acetate (EVA 8200) *Full length insole	Control wedge – Foot orthosis with 0º lateral angle)
Zhang, M. 2012[44]	32 participants (13 male, 19 female) with unilateral early-stage medial knee osteoarthritis Mean age: 67.06 years	Lateral wedge (5º lateral angle) *Customised *Full length lateral wedge * Without arch support	*Standard shoes (control condition) *Standard shoes and lateral wedge *Standard shoes and unload knee bracing
Kakihana, W. 2005[45]	26 elderly women (13 healthy participants, 13 with osteoarthritis) Mean age: 64 years	Lateral wedge insole (6° lateral angle) *Made of ethylene vinyl acetate (EVA 8200) *Full length insole	*Control wedge (0º)

articles met all of these requirements.

On the other hand, certain weak points were common to all the articles, especially the time frame considered, and the measures taken to optimise compliance or adherence. Other poor results were obtained in the Results section, in areas such as analysis, description of deviation from the original study protocol, recruitment and adverse events (Table 8). None of the studies fully met these requirements. Finally, the Discussion and the Implications of the study findings were also inadequate (see Annex 2).

4. Discussion

The main aim of this review was to summarize the effects of different types of frontal plane wedges on plantar loading, and specifically on the centre of pressure (COP), vertical ground reaction force and the distribution of the loading beneath the human foot. We hypothesized that the use of wedges modifies significantly these parameters.

Regarding the COP, our results reveal a clear trend: the lateral wedge insole provokes a lateral displacement of the COP, while medial wedges seem to cause a medial shift of the COP.

However, in relation to the peak impact force, there is no clear consensus among authors [37,38,42,43,45]. some report an increase in the peak impact force and others a decrease. One study obtained inconsistent results [41].

The use of FOs is shown to alter plantar pressure distribution. The lateral wedge insole and the can increase lateral foot pressure, while the medial wedge increases medial foot pressure [22,28].

Our review findings are based on RCTs, quasi-experimental and cross-over studies of the effects of frontal plane wedges on plantar loading. Among the many types of wedges that can be used, the articles analysed mainly focus on lateral/ valgus wedges, medial/varus wedges [22,37,38,40,42,45] and lateral and medial rearfoot, midfoot and forefoot postings [39].

Similar measuring instruments were used in all articles. Data on peak impact force and COP location were mainly obtained by means of a force platform [28,38,40,42–45]. Some authors studied both COP and pressure, doing so with a combination of force plate and pressure plate [37,41], although one used the Pedar-X system for this purpose [39].

We were unable to perform a meta-analysis due to the considerable differences found, both among the interventions performed and in the data reported. The follow-up procedures employed were also heterogeneous (some studies presented the immediate results, while others observed the outcome at two weeks); indeed, most do not even mention this question, and so no clear pattern can be determined.

The clearest trend reported is that the lateral wedge insole causes a lateral displacement of the COP [28,37,38,40,42–45]. This type of frontal plane wedge has been studied in different types of patients presenting a variety of conditions: some were healthy [37], others had ankle instability [45] or knee osteoarthritis [28,37,38,44,45] and one study examined patients with obesity [40]. Nevertheless, all these authors drew the same conclusion, namely that unlike valgus wedges,

Table 4
RCT studies.

Rct studies							
Author	Patients	Intervention	Comparator	Outcome	Measurement tool	Subdivision of foot	Follow up
Jin, H. 2019 [37]	30 healthy male participants Mean age: 21 years	*Customised 3D-printed single-sided lateral wedge insole	*Traditional single insert *Flat insoles	COP Vertical ground reaction force	Pressure plate with a piezoelectric force sensor	COP: distance from the longitudinal axis of the foot. Positive values indicate a lateral shift.	–
Hinman, R.S. 2011 [38]	73 participants (45 female, 28 male) with medial compartment knee osteoarthritis. Mean age: 50 years	Lateral wedge insole	With and without 5º lateral wedge	COP Ground reaction force	Two 0R6–6–2000 force plates	Distance from to the line of the foot (calcaneus to 2nd metatarsal)	Study immediate effects
Telfer, S. 2012 [39]	12 participants with pronated feet and 12 controls	FO: ¾ length semi rigid device designed with OrthoModel 3Dsoftware. Nine FOs per participant with rearfoot post angle ranging from 6º lateral to 10º medial posting, in 2º increments, designed with CAD software.	Neutrally posted training shoes	Plantar pressure	Pedar- X system	Medial rearfoot, lateral rearfoot, midfoot, 1st ray and lateral forefoot	

Table 5
Quasi-experimental studies.

Quasi-experimental studies							
Author	Patients	Intervention	Comparator	Outcome	Measurement tool	Subdivision of foot	Follow up
Leitch, K.M. 2010[28]	26 participants: 9 male and 17 female 12 adults with osteoarthritis on the medial compartment of the tibiofemoral joint 14 healthy adults with no symptoms affecting the lower extremity. Mean age: 46 years	Lateral heel wedge	*No wedge *4° wedge *8° wedge	COP Lateral heel pressure	Force plate In-shoe plantar pressure measurement system	The heel was defined as approximately the rear 30% of the foot and was divided into two quadrants.	Two separate occasions in the same week.
Russell, E.M. 2012[40]	14 obese women. Mean age: 26 years 14 normal-weight women. Mean age: 29 years	Lateral wedge insole	No insole	COP	Force platform	First and fifth metatarsal heads and distal toe.	–
Guldemond, N.A. 2006[41]	17 male diabetic patients with flexible, non-deformed neuropathic feet and elevated bare foot plantar pressure. Mean age: 64 years	Different combinations of a metatarsal dome, varus and valgus wedges and arch supports with different heights were added to a fitted basic insole	Basic insole	Plantar pressure Peak Pressure Pressure time integral	Pedar insole-system Pressure platform	The lateral, (fourth and fifth toes and lateral foot area), central (second and third toe and heel) and first ray.	
Van Gheluwe, B. 2004[22]	23 healthy participants Mean age: 22.2 years	Forefoot wedging: – 3° valgus – Flat (0°) – 3° valgus – 6° varus. – Rearfoot wedging: – 4° valgus – Flat (0°) – 4° varus – 8° varus	Between them	COP Peak and average pressure Maximal loading rate Peak time	Footscan pressure insole system (RSScan, Olen, Belgium) was used to record and measure plantar pressures.	The measurement sites on the Footscan insole are the five metatarsal heads and the medial and lateral heel. The position of the COP was quantified by measuring the distance from the COP to the lateral border of the Footscan insole at five different moments.	–

Table 6
Cross-over studies.

Cross-over studies						
Author	Patients	Intervention	Comparator	Outcome	Measurement tool	Subdivision of foot
Kakihana W. 2004[42]	**Experiment 1.** 10 healthy adults (five men (Mean age: 25.2 years) and five women Mean age: 24.8 years) **Experiment 2.** 5 men (Mean age: 27.6 years) five women (Mean age: 22.8 years)	Lateral wedge	-No wedge -A low wedge with a 3-degree lateral angle -A high wedge with a 6-degree lateral angle.	COP Vertical Ground reaction force	Force platform	–
Kakihana. W. Torii S 2005,[43]	50 male university athletes (25 with an unstable lateral ankle and 25 healthy controls) Mean age: 20.8 years	Lateral wedge insole	Control wedge (foot orthosis with 0° lateral angle)	COP Vertical ground reaction force	8 force platforms	COP during stance phase expressed as a percentage of the bare foot.
Kakihana. W. 2005[45]	26 elderly women (13 healthy and 13 with osteoarthritis) Mean age: 64 years	Lateral wedge	Control wedge (0°)	COP Vertical ground reaction force	8 force platforms	Lateral and medial malleoli, lateral and medial calcaneal tubercles, head of talus, and 1st and 5th metatarsal heads.
Zhang, M. 2012[44]	32 participants (13 male and 19 female) Mean age: 67.06 years.	Lateral wedge	Standard shoes and lateral wedge Standard shoes and unload knee bracing	COP	Walkway with two force platforms	Heel, lateral malleolus, medial malleolus, 1st and 5th metatarsal landmarks and toe cap.

frontal plane wedges provoke a medial displacement of the COP [22]. Two articles did not assess this parameter [39,41].

In future research, it would be useful to investigate the effect of wedges within a specific population, as this outcome is subject to the patient's biomechanical and physical characteristics.

Our analysis shows there is no clear consensus regarding the effect produced by wedges on the peak of impact force (vertical ground reaction force). Although the data we consider refer to only one type of wedge (the lateral wedge insole), certain aspects may account for the differences in the findings reported. For example, some studies used an insole attached to the subject's bare feet with adhesive tape [42,43,45]. In other cases, the patients wore socks but not shoes [37] and inserted the insole in their own shoes [38]. Each of these differences could have significantly affected the results obtained.

Regarding the subdivisions of the foot, major differences were also apparent among the studies reviewed. Some focused their attention on the lateral and medial part of the calcaneus, and the first and fifth metatarsal heads [37,38,41].

Table 7
Risk of bias, cross-over studies.

Domain of evaluation	Selection of participants (i.e., Selection bias)	Control of confounding factors (i.e., Performance bias)		Statistical methods (i.e., Detection bias)		Measurement of outcome variables (i. e., Information bias)		
	Is the source population (cases, controls, cohorts) appropriate and representative of the population of interest?	*Is the sample size adequate and is there sufficient power to detect a meaningful difference in the outcome of interest?*	*Did the study identify and adjust for any variables or confounders that may influence the outcome?*	*Did the study use appropriate statistical analysis methods relative to the outcome of interest?*	*Is there little missing data and did the study handle it accordingly?*	*Is the methodology of the outcome measurement explicitly stated and is it appropriate?*	*Is there an objective assessment of the outcome of interest?*	
Zhang M. et al. 2012	**3**	**1**	**1**	**3**	**3**	**3**	**3**	17
Kakihana W Torii S et al. 2005	**3**	**1**	**0**	**3**	**3**	**3**	**3**	16
Kakihana W. et al. 2005	**2**	**1**	**0**	**3**	**3**	**3**	**3**	15
Kakihana W. et al. 2004	**0**	**0**	**0**	**3**	**3**	**3**	**3**	12

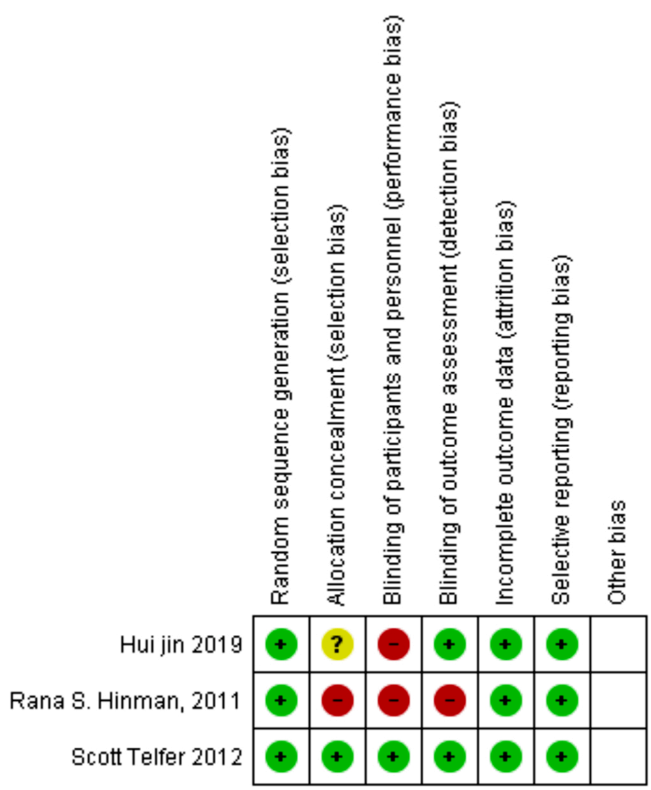

Fig. 2. Risk of bias summary.

However, a very different subdivision was made in other cases [22,39,41]. Thus, Guldemond et al. [41] divided the foot into lateral, central and medial forefoot and the big toe;.

Telfer et al. [39] considered four regions, the medial rearfoot, midfoot, first ray and lateral forefoot. Lastly, Van Gheluwe & Dananberg [22] took as a reference the five metatarsal heads and the medial and lateral heel.

The considerable heterogeneity in the design of FOs may be a factor in the varying degrees of effect observed for the wedges in the frontal plane. In this respect, two main groups can be distinguished: studies in which a personalised insole was adapted to the patient's foot, and those using standardised insoles (i.e., an insole to which the element to be studied was attached, or the direct use of a wedge without an insole).

Both Jin et al. [37] and Telfer et al. [39] used a 3D technology system to manufacture their FOs. In the former case, a Bodyarch 3D printing system was used, creating FOs of different thicknesses according to the patient's characteristics and the pressure distribution in the particular circumstance. In this study, the wedges used had an inclination of 6°.

Telfer et al. also used a 3D system, but in this case the patients were allowed a period of adaptation to the FOs, and this factor may have influenced the results obtained. These authors, moreover, analysed various wedge inclinations, ranging from 6° with the lateral wedge to 10° with the medial wedge (increasing the inclination by 2° in each test). This approach differed greatly from that of the former study, in which a single inclination, of 6°, was studied.

Guldemond et al. [41] also used customised FOs, but in this study a mould was created with phenolic foam and the FO was subsequently produced from diverse components.

The other studies all used standardised FOs [22,28,38,40,42–45].

The studies by Russell et al. [40] and Leitch et al. [28] examined the use of a flat insole and wedges made with EVA. The first of these studies used wedges with 8° inclination and the second one, wedges with 4° and 8° inclination.

Kakihana et al. [45], Kakihana et al. [43] and Kakihana et al. [42], too, studied flat insoles made of EVA. In these studies, the insole filled the entire length of the shoe and the wedges extended from the back of the heel to the forefoot. These insoles were attached to the shoe with Velcro or double-sided tape. The degree of inclination varied from 3° to 6°.

Hinman et al. [38] used a similar design, with flat insoles running the entire length of the shoe. These insoles were standardised and not adapted specifically to the patient's foot. The degree of wedge inclination was 5°.

Van Gheluwe and Dananberg [22] studied lateral and medial wedges, using a flat insole in which different types of wedges were inserted. These wedges were not specifically adapted to the patient.

In a comparative study, it is important to use the same FO design in every case, because a FO that is perfectly adapted to the patient's foot will not have the same characteristics or produce the same effect as a flat insole. Moreover, the initial pressure distribution will differ between the two designs. A further challenge is that in the articles studied, various degrees of inclination were used, which makes it difficult to draw clear conclusions on their effectiveness.

Regarding the risk of bias, our review shows that most of the cross-over studies considered presented only moderate quality [42,44,45]. The weaknesses most commonly present concerned "Methods for selecting study participants" and "Methods to control confounding". Some studies had only a small sample of patients [42,43] and others

Table 8
Results. of the review.

		Results		
	Type of frontal plane wedge	COP	Vertical ground reaction force	Pressure datas
Leitch, K.M. 2010[28]	Lateral heel wedge	**COP shifted laterally** *Difference in two days: (95% CI) ***COP x-direction (mm) (anteroposterior) Total displacement of the COP in the stance phase*** **No wedge** **Day 1 Day 2 DF** **No wedge** 51.38 51.86 − 0.29 **4º wedge:** 52.09 52.99 − 0.78 **8º wedge:** 52.68 52.97 − 0.38 * ***COP y- direction (mm) (mediolateral) Total displacement of the COP in stance phase*** **Day 1 Day 2 DF** **No wedge** 64.1 61.7 1.21 **4º wedge:** 64.04 63.24 0.68 **8º wedge:** 65.22 64.98 0.1 * A lateral and anterior shift was observed in the COP, together with an increase in LHP with the 8º heel wedge, compared to no wedge.	Not applicable	**Increase lateral heel pressure.** *Difference (DF) in two days: (95% CI) **No wedge Day 1 Day 2 DF (kPa)** 124.26 129.08 **-4.82** **4º wedge:** 135.76 143.70 **-7.94** **8º wedge:** 144.93 151.14 **-6.21**
Kakihana W. 2004[42]	Lateral wedge	**COP shifted laterally** **No data reported.**	**No differences in the peak of impact force (N)** **No wedge:** 664 ± 12 **Low wedge with 3º**: 674 ± 14 **High wedge with 6º**: 654 ± 13	
Kakihana, W. Torii S 2005[43]	Lateral wedge	**COP shifted laterally during stance phase.** **No data reported**	**Reduction in the peak of impact force during terminal stance (VGRF) (N/Kg)** **No wedge**: 9.88 N/kg. **Lateral wedge:** 9.76 N/kg **(P < 0.001)** for the more affected side 0.3% reduction for the healthy controls and a 1.4% reduction for the athletes with unstable lateral ankles	
Jin, H. 2019[37]	Lateral wedge	**COP shifted laterally** The side wedge insole increased the lateral displacement of the COP.	Vertical GRF **of the experimental group was higher** than in the control group at the two time points (immediately after wearing insole and after wearing insole for 20 min) **(P < 0.05)***	Not applicable
Hinman, R.S. 2011[38]	Lateral wedge	**COP shifted laterally.** **No wedge**: − 5.6 (4.3) mm **Wedges:** − 9.1 (4.6) mm **Mean differences:** − 3.4 (−2.8, −4.1) mm **Changes:** − 60.7% **P value**: < 0.001	**More vertical frontal plane ground reaction force vector** GRF magnitude (N) (95% CI) **No wedges**: 840.5 (174.5) **Wedges:** 837.0 (174.7) **Mean difference:** − 3.5 (−10.6, 3.7) **Change**; − 0.4% **P value** 0.34	Not applicable
Kakihana, W. 2005[45]	Lateral wedge	**COP shifted laterally during stance phase** **No data reported.**	**No obvious difference in peak of impact force.** N (0º lateral wedge) W (6º lateral wedge) **N W** **Healthy Elders** 7.52 7.49 **OA Patients** 7.58 7.62	Not applicable
Russell, E.M. 2012[40]	Lateral wedge	**The peak medial position of the COP shifted laterally across the stance phase of walking.** **Control** **No insole Insole** 2.98 cm 2.82 cm **Obese** 2.94 cm 2.65 cm	Not applicable	Not applicable
Zhang, M. 2012[44]	Lateral wedge	**COP shifted laterally (more laterally directed COP in stance phase)** **No wedge**: 0.018 m **Lateral wedge insole:** 0.026 m **Between 1 and 2:** 44.4% **P value** 0.000 *	**No significant results.** **No wedge**: 1.197 ± 0.03 **Lateral wedge insole**: 1.191 ± 0.02 **P value** = 0.739	Not applicable
Van Gheluwe, B. 2004[22]	Varus /Valgus wedge	**Trajectory of COP in stance phase** (at first heel contact, at maximal heel load, when the heel and forefoot are equally loaded, at maximal forefoot load, and at toe-off)	Not applicable	**Valgus wedges increase lateral pressure data** **.** **Varus wedges increase medial**

(continued on next page)

Table 8 (*continued*)

	Type of frontal plane wedge	Results COP	Vertical ground reaction force	Pressure datas
		COP shifted laterally with valgus wedge **COP shifted medially with varus wedge** Only heel contact with 6° varus and 4° valgus rearfoot wedge produce a significant COP shift for both feet		**pressure data** **The results were significant.** Varus wedges produce higher medial peak pressure. However, between 3° and 6° varus wedges the differences were not significant. On the rearfoot all wedge conditions differed significantly except between 4° and 8° varus for the lateral heel.
Guldemond, N.A. 2006[41]	Varus / Valgus wedge	Not applicable	Not applicable	**Inconsistent results** SAS (standard arch support) EAS (extra arch support) **Lateral forefoot** **Peak P.** Basic. SAS EAS Varus (KPa) 135 141 133 Valgus (KPa). 132 134 130 **Central forefoot** **Peak P.** Basic SAS EAS Varus (kPa) 206 188 154 Valgus (kPa) 206 186 162 **Medial Forefoot** **Peak P.** Basic SAS EAS Varus (kPa) 182 211 178 Valgus (kPa) 226 217 191 **Big toe peak P.** Basic SAS EAS Varus (kPa) 182 170 146 Valgus (kPa) 170 170 171
Telfer, S. 2012[39]	Lateral / Medial rearfoot, midfoot and forefoot posting	No results	No results	**Significant and linear dose-response effect of FOs on plantar pressure variables at the rearfoot, midfoot and forefoot.** **Mean lateral rearfoot** Control: 0.29 Group: 0.385 Difference: - 0.58% Linear $p = 0.001$ * **Peak midfoot** Control: 0.287 Group: 0.521 Difference: - 2.48% Linear $p < 0.001$.* **Mean midfoot** Control: 0.361 Group: 0.536 Difference: − 1.59% Linear $p < 0.001$ **Peak lateral forefoot** Control:0.448 Group: 0.632 Difference: 0.74% Linear $p < 0.001$ * **Mean lateral forefoot** Control: 0.256 Group 0.619 Difference: 0.71% Linear $p < 0.001$ *

failed to specify where the sample had been drawn from. It is important to highlight these deficiencies in the studies considered, since they may have significant repercussions for the research findings presented.

Most of the RCTs also presented only moderate quality with respect to protection against bias [37,38,40,41,44]. The weak point in these cases was the inadequate blinding performed, of the patients and of the evaluator. If both the patients and the researcher know in advance what type of intervention is going to be performed, this knowledge may bias the research findings obtained. In consequence, these results may be influenced by subjectivity and cannot be considered valid. For this reason, it is essential to blind everyone involved in the investigation.

Another possible source of bias is the failure to specify the randomisation method applied. This question is important, as it reveals whether the randomisation has been performed properly and therefore whether the study results are valid in this respect. Inadequate (or the absence of) randomisation can lead to the study being affected by selection bias. Appropriate randomisation enables the researcher to assess the effects observed knowing that they were actually caused by the treatment and that confounding factors have been excluded.

Future research in this field should consider larger sample sizes, with a clearly-defined age range for participants and focusing on a single disease or biomechanical pathology. In addition, a prolonged follow-up should be performed, since the effect of frontal plane wedges or FOs may differ according to the time frame considered.

One of the problems encountered in the present review is that most of the papers examined did not specify the study design employed. In some cases, the patient groups were randomised, but the overall experimental structure was not that of an RCT. Furthermore, in many cases the methodological quality of the studies described was not very satisfactory, while many articles did not properly differentiate the sections or did not provide all the necessary information.

4.1. Strengths and weaknesses

The present systematic review presents numerous strengths. To our knowledge, it is the first of its type to study the effect of wedges on foot plantar loading, comparing and studying all types of wedges in all types of patient, without restricting the focus to any specific group. Furthermore, specific review tools are applied to analyse the risk of bias. Moreover, this review is very complete, thanks to the literature search performed of four medical databases.

Nevertheless, it is also subject to certain limitations. Firstly, despite the broad search conducted, the number of studies included in the review is rather small. This is especially so with respect to the cross-over studies considered. Moreover, the studies reviewed present many potential sources of bias. Finally, the study data reported and analysed are fairly heterogeneous (in areas such as the age of patients and the length of the follow-up period), which made it impossible to conduct a meta-analysis and hampered the overall assessment. Finally, the language restriction imposed (only studies published in English or Spanish were analysed) reduced the number of articles included in the sample.

5. Conclusions

There is considerable body of evidence suggesting that frontal plane wedges cause a redistribution of the plantar pressure (Lateral wedges produce an increase in lateral heel pressure and medial wedge an increase in medial heel pressure). Lateral or valgus wedges produces a lateral shift of the gait line and varus or medial wedges produce a medial shift of this biomechanical feature.

These frontal plane wedges may cause distinct force and pressure increases in different areas of the foot.

Future studies should take into account how the centre of pressure changes depending on the pressure distribution in the foot.

With respect to peak impact force (vertical ground reaction force) the published results are contradictory, and no clear conclusions can be drawn.

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Declaration of Competing Interest

All the authors declare that they have no conflict of interest derived from the outcomes of this study.

Appendix A. Supporting information

Supplementary data associated with this article can be found in the online version at doi:10.1016/j.gaitpost.2022.07.233.

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