Systematic Review and Meta-Analysis

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# A systematic review and meta-analysis into the effect of lateral wedge arch support insoles for reducing knee joint load in patients with medial knee osteoarthritis

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**Abstract**

**Objective:** The aim of this study was to evaluate the immediate effects of lateral wedge arch support insoles (LWAS) on reducing the knee joint load in patients with medial knee osteoarthritis (OA) compared with an appropriate control.

**Methods:** Databases including Medline, EMBASE, Web of Science, Wiley Online Library, Cochrane library, and Google Scholar were searched with no limits on study date or language, from the earliest available date to October 31, 2016. The included studies had to have the aim of reducing knee load and have an appropriate control. The main measured values were the first and second peak external knee adduction moments (EKAM) and the knee adduction angular impulse (KAAI). The random-effects model was used for analyzing the eligible studies.

**Results:** Nine studies met the inclusion criteria with a total of 356 participants of whom 337 received LWAS treatment. The risk of methodological bias scores (quality index) ranged from 21 to 27 of 32. Treatment with LWAS resulted in statistically significant reductions in the first peak EKAM ($P=.005$), the second peak EKAM ($P=.01$), and the KAAI ($P=.03$). However, among trials in which the control treatment was control shoes, the LWAS showed no associations on the first peak EKAM ($P=.10$) or the KAAI ($P=.06$); among trials in which the control treatment was neutral insoles, the LWAS showed no associations on the second peak EKAM ($P=.21$) or the KAAI ($P=.23$). At the same time, the LWAS showed no statistically significant reduction on the first peak EKAM ($P=.39$) when compared with flat insoles.

**Conclusion:** Although meta-analysis outcomes of all studies indicated statistically significant associations between LWAS and reductions of the first peak EKAM, second peak EKAM and KAAI in people with medial knee OA while walking, different results existed in subgroups using various control conditions for comparison. These findings do not support the use of LWAS insoles for reducing knee load. An optimal LWAS treatment should provide the appropriate height of arch support and amount of lateral wedging. Further research should investigate the best combination of these 2 parameters to achieve efficacy without altered comfort.

**Abbreviations:** ACR = American College of Rheumatology, CIs = confidence intervals, EKAM = external knee adduction moment, HTO = high tibial osteotomy, KAAI = knee adduction angular impulse, LWAS = lateral wedge arch support insole, LWI = lateral wedge insole, OA = osteoarthritis, PRISMA = Preferred Reporting Items for Systematic Reviews and Meta-Analyses, RCT = randomized controlled trial, SD = standard deviation, SMDs = standard mean differences, VAS = visual analog scale, WOMAC = Western Ontario and McMaster Universities.

**Keywords:** gait, lateral wedge arch support insoles, meta-analysis, osteoarthritis

*Editor: Vijai Prakash Sharma.*

*F.X. and B.L. contributed equally to this study.*

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*This study received funding from National Natural Science Foundation of China (No. 81102607), Tianjin Health Bureau Science and Technology Foundation (No. 2014KY31) and Key Project of Tianjin Science and Technology (No. 13ZCZDSY01700).*

*The authors report no conflicts of interest.*

*Supplemental Digital Content is available for this article.*

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*Medicine (2017) 96:24(e7168)*

*Received: 9 February 2017 / Received in final form: 16 May 2017 / Accepted: 24 May 2017*

*http://dx.doi.org/10.1097/MD.0000000000007168*

## 1. Introduction

Knee osteoarthritis (OA) is a leading cause of knee pain and disability with substantial personal and economic burden in the elderly population and is one of the most common musculoskeletal disorders in the world.[1–4] Knee OA typically affects the medial tibiofemoral joint compartment[5,6] with a 10-fold propensity compared with the lateral compartment of the knee.[7] This discrepancy has been attributed to the higher loads[8] which the medial compartment carries, approximately 60% to 91% of the total knee load.[9–11] The unequal distribution of the transmitted load is because the line of force acting at the foot passes medially to the knee joint, producing the external knee adduction moment (EKAM).[12] As a commonly reported gait outcome measure in studies in the population with knee OA, the EKAM has consistently emerged as a valid surrogate to assess dynamic load on the medial compartment.[13–18] However, although limitations exist,[19,20] together with knee adduction angular impulse (KAAI), the first peak EKAM and second peak EKAM have been the main variables investigated in recent studies[20–22] owing to their relationship with medial contact force at the knee joint and OA progression.[13,19]

Unfortunately, there is currently no cure for this mechanically induced disease. Therefore, nonsurgical conservative management is of vital importance for this disease. Given that gait biomechanics have been associated with knee OA progression,[14–17] there has been much focus on modifying the gait biomechanical parameters mentioned previously with conservative interventions, such as varied orthotics directly influencing foot, ankle, and knee relationships with lower limb mechanics. Compared to surgical strategies such as high tibial osteotomy (HTO), unicompartmental knee replacement or total knee replacement aiming to alter static lower extremity alignment, orthotic treatment like knee braces or foot insoles can alter loading to the knee in the hope of reducing symptoms and disease progression.[23] The lateral wedge insole (LWI) is a wedge placed under the sole of the foot and angulated so that it is thicker at the lateral part than the medial edge, transferring loading from the medial to the lateral knee joint during weight bearing. Although different groups have promulgated different recommendations,[24–26] biomechanical studies have demonstrated an effect size in reduction of EKAM ranging from 4% to 12% with an LWI of at least 5 degrees.[20,27–35] However, the LWI can be uncomfortable for patients with knee OA[36] owing to the more pronated position.

The LWAS are lateral wedge insoles with added medial arch support (also called lateral wedge arch support insoles) aimed at minimizing the increase in the subtalar valgus angle to make patients more comfortable while maintaining their ability to reduce the EKAM during the late stance phase of gait. Recent studies have tested the effect on EKAM of adding an arch support to the LWI during gait but showed inconsistent findings.[21,23,29,37–46] Some authors found a reduction in the EKAM during the stance phase of gait using a lateral wedge and an arch support.[21,39–42,44–46] However, in some patients, no reductions[23,28] or smaller reductions[46] on the EKAM were observed. There is a lack of consensus on whether this kind of device should be recommended.

A recent meta-analysis evaluating the effect of LWI on biomechanical risk factors for knee OA progression reported small reductions, but the authors did not discuss the effect of the LWAS by distinguishing different types of interventions.[47] However, the LWAS played an important role and became more common in the conservative treatment of knee OA. The objective of this review was to assess the effects of LWAS on reductions of knee load in patients with knee OA by measuring biomechanical outcomes during gait analysis.

## 2. Materials and methods

### 2.1. Literature search

This review protocol has been published on the International Prospective Register of Systematic Reviews (PROSPERO, CRD 42017056749). The meta-analysis was programed on the basis of the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) Statement guidelines.[48] Several electronic databases were searched from the earliest available date to October 31, 2016, including Medline (via Pubmed), EMBASE (via OvidSP), Web of Science (via ISI Web of Knowledge), the Wiley Online Library, and Cochrane library. To cover any missing data, Google Scholar was also searched and screened with no limitation on study dates or any language restrictions. To improve the specificity and sensitivity of searching, we used Boolean logic operators "AND or OR" to combine the key words as a search strategy as follows: ("lateral wedge*" OR "medial arch*") AND osteoarthritis. In the Wiley Online Library and Google Scholar, we used the search strategy: "lateral wedge*" AND "medial arch*," AND osteoarthritis AND gait. Before initiating the screening, each database was searched by 2 independent researchers (F.X. and B.L.) to achieve agreement on the number of search hits achieved in each database.

### 2.2. Inclusion criteria

Studies considered eligible must have met certain criteria. First, study design: randomized controlled trials (RCTs), quasi-RCTs, and prospective cohort studies. For prospective studies, only baseline data inferring the immediate effects of LWAS were used. Second, population: adults with symptomatic diagnosed medial knee OA according to the clinical[49,50] and radiological[51] criteria. Third, intervention: LWAS, generally defined as an in-shoe orthotic device with an angle of inclination toward the lateral border of the foot with an added arch support at the medial side. Fourth, comparator: control shoe (standard or patient's own shoes) with a flat insole or neutral insole (with medial arch). Fifth, outcomes: the first or second peak EKAM or the KAAI, Sixth, test condition: walking stably on the ground.

### 2.3. Exclusion criteria

Studies considered ineligible contained one of the following features: allowing greater than a 1-month period of wear. (As mentioned in other studies, this is the longest time period where effects are not shown to decline with continued wear[27,52]); enrolling healthy participants; using footwear as a comparator, which is known independently to alter knee biomechanics; testing "variable stiffness" shoes whose features could vary across the test;[53,54] testing the condition of walking on a slope, upstairs, or downstairs.

### 2.4. Study inclusion

After importing the articles from the search of the aforementioned databases into the reference management software (Endnote X7), duplicate references were first removed. The eligibility criteria were applied to the title and abstract by 4 independent researchers (F.X., B.L., MJ.K., and JX.M.), with the retained articles cross-checked once more. Nineteen articles were retrieved in full-text and screened by reading the whole article; finally, 9 articles remained and formed the basis of this systematic review. Reference lists of previous related reviews were also screened and searched to prevent any missing data. Any differences of opinion between the 4 independent researchers were resolved by discussion initially; the opinion of the other researcher (Y.W.) was considered if consensus was not reached.

### 2.5. Quality assessment

Two independent reviewers (F.X. and B.L.) assessed each individual study using the Quality Index,[55] which contained 27 items relevant to a range of study designs and was still applicable to randomized studies. Each study was scored according to the scale with each item graded as yes (1 point), no (0 points), or unable to determine (0 points) to give a total score out of 32. The 27 items assessed not only the quality of reporting, internal validity (bias and confounding) and power but also the external validity.[55]

### 2.6. Data extraction

Two reviewers (F.X. and B.L.) independently extracted relevant data from the eligible literature including the title, publication year, first author and country, demographics of the patients, sample size, features of interventions, and descriptive (means, standardized differences) and inferential (*P* values and confidence intervals) statistical information. Once adequate data were reported, standardized mean differences (SMDs) were calculated as the mean difference of the biomechanical outcomes (peak EKAMs and KAAI) between interventions and control groups, divided by the pooled SD, with adjustment for small sample sizes (Hedges).[56] All data needed for calculations could be extracted directly from eligible articles. Corresponding authors of the included studies were contacted by E-mail if more information was required or needed to be confirmed.

### 2.7. Data synthesis and statistical methods

Review Manager Software for Windows (RevMan version 5.3., 2014) was used to perform the meta-analysis and present the results, using the inverse variance method.

Study heterogeneity was estimated through the $I^2$ statistic test, subsequent $\chi^2$, and Cochran *Q* test in accordance with the values of $I^2$ and *P*. Heterogeneity was interpreted by Guidelines from the Cochrane Collaboration, according to which, 25%, 50%, and 75% represent low, moderate, and high heterogeneity, respectively.[57] A fixed-effects model could be used if $I^2 < 50\%$ and $P > .1$. However, significant heterogeneity across studies was anticipated because of differences in comparators and the distribution of participant characteristics (i.e., severity of OA); therefore, a random-effects model was used to more conservatively estimate the pooled effect of the interventions.

For continuous outcomes, SMDs and 95% confidence intervals (95% CIs) were used to weigh the effect size. Effect sizes were interpreted as 0.2 (small), 0.5 (medium), and 0.8 (large).[58] To contextualise the effect sizes, the overall pooled estimates were back-transformed into original units using reference data from the largest study[44] (n = 70) with mean ± SD 0.39 ± 0.16 (Nm/kg) for the first peak EKAM, 0.33 ± 0.14 (Nm/kg) for the second peak EKAM, and 0.16 ± 0.07 (Nm/kg*s) for the KAAI.

If a neutral insole or flat insole was present, a subgroup analysis was also performed to assess the effects of these different comparators on altering the biomechanical differences, as their use previously has been shown to influence clinical outcomes.[47,59] Publication bias was assessed using funnel plots with Begg and Egger regression test using STATA (version 12).

## 3. Results

### 3.1. Search results

A total of 845 records were identified according to the search strategy and abstracts (Fig. 1). Two related articles not published in English (1 Korean and 1 Iraqi) were excluded because they did not meet our criteria. Nine studies were considered eligible, after reading the full text, and included in the final review. Reference lists of several review articles were searched with no additional studies found. Two authors of 3 studies provided some useful information about the researches and 2 related studies,[39,60] which confirmed parts of another larger research study were excluded eventually.

### 3.2. Study characteristics

Eventually, 9 eligible studies were enrolled. Eight studies had repeated-measures designs and 1 was a RCT.[45] Full-length insoles were used in 8 studies and 1 study included both heel and full-length insoles.[49] The inclination angles of insoles ranged from 3 degrees[43] to 11 degrees[37] and the most common angle was 5 degrees.[21,44,46,52] With regard to the medial arch support, 5 used a custom design based on patient comfort,[16,21,23,42,43] and 3 studies used prefabricated arch supports.[37,45,52] The

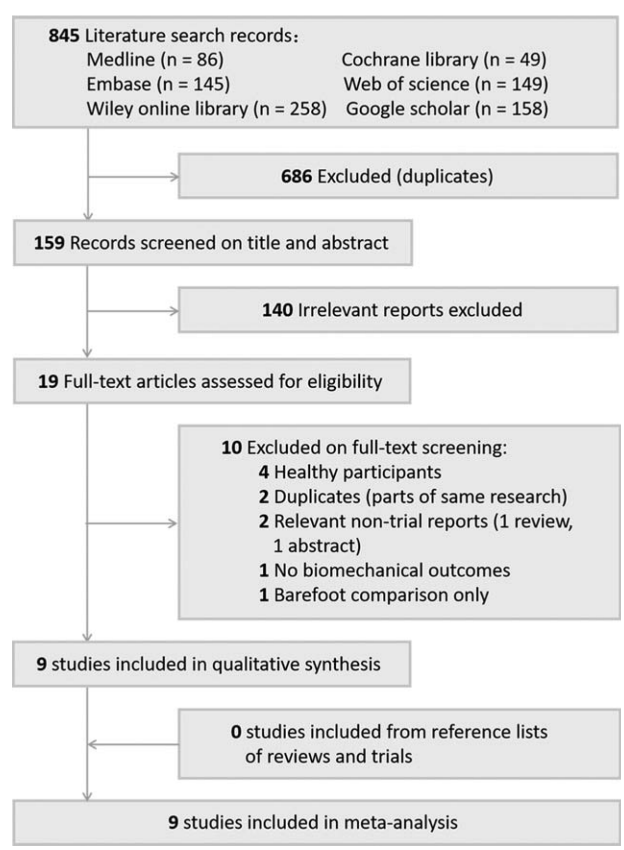


**Figure 1.** Review flow chart.

remaining study did not report these data.[44] Only 1 study used a flat insole as the comparison condition,[23] 3 studies used neutral insoles,[37,42,45] and 5 studies[16,21,43,44,52] used standardized footwear or patients' usual shoes. Only 2 studies reported the height of the arch support[37,42] and 3 studies reported the density of the lateral wedge[42,43,46] (Table 1).[16,21,23,37,42–45,52]

Totally, 337 participants were included. To represent the severity of knee pain, visual analogue scale (VAS) was used in 4 articles (mostly >3/10)[23,37,42,45] and the WOMAC (Western Ontario and McMaster Universities) OA index pain subscale was used in another 4 articles (mostly >30/100).[21,23,42,49] It is worth mentioning that, in different articles, pain level was recorded during level walking,[44,45] during moderate activities,[42] and on most days of the last week,[16] last 2 weeks,[21] or last 1 month.[23,37] Moreover, the Kellgren/Lawrence grade was used as radiographic assessment in most studies with a result as below: grade 2 or grade 3 in 4 articles[21,37,42,44], grade ≥2 in another 4 articles.[16,23,43,45] And criteria of the ACR (American College of Rheumatology) were used in 4 studies.[23,37,42,45] Three articles reported that the medial joint space was narrower than the lateral joint[21,42–45] and the varus knee alignment was also reported in several studies[23,37,42,43,49] (Table 2).[16,21,23,37,42–45,52]

### 3.3. Results of risk bias

The Quality Index scores of included studies ranged from 21 to 27 of 32 (Table 1). Agreement was finally reached by 2 reviewers (F.X. and B.L.). Only 1 study[42] described their interventions completely (item 4), whereas most studies failed to report the arch height and the density of the material used. Most studies also failed to report the sampling methods for recruitment (item 11) and the proportion of participants who agreed to participate from the initial recruitment (item 12). Few studies had adequate reports on these 2 items.[21,44] All studies failed to report whether assessors were masked during the analysis of primary outcome measures (item 15). And a few studies[16,42,45] reported that they performed an adequate allocation but did not report the sequence (item 24) (see Supplemental Table 1, http://links.lww.com/MD/B740, which demonstrates full scoring results).

### 3.4. Results of meta-analysis

**3.4.1. First peak EKAM.** Effect of LWAS on the first peak EKAM was reported in 9 studies. Among these studies, 5 used a shoe-only comparison, 2 used a neutral insole (with arch support), 1 used a flat insole (without arch support), and 1 used both the neutral insole and flat insole. Data synthesis included data from 15 comparisons (7 shoe-only comparisons, 7 neutral insole comparisons, and 1 flat insole comparison); however, some studies made multiple comparisons with different insole angles (Table 3).[16,21,23,37,42–45,52]

The overall pooled-effect estimate demonstrated that LWAS significantly reduced the first peak EKAM (SMD −0.22; 95% CI, −0.37 to −0.07; $P=.005$). This represents a small effect size and translates into an absolute change in the first peak EKAM of approximately −0.03 Nm/kg. Low statistical heterogeneity was found ($\chi^2=1.30$, $P=.97$, $I^2=0\%$) (Fig. 2).

Subgroup comparisons yielded different pooled effects. Among trials in which the control treatment was neutral insoles, the LWAS resulted in a statistically significant reduction on the first peak EKAM (SMD, −0.27; 95% CI, −0.51 to −0.04; $P=.02$; $I^2=0\%$; n=7). However, the LWAS showed no associations on the first peak EKAM compared to both the shoe-only condition (SMD, −0.17; 95% CI, −0.37 to 0.03; $P=.10$; $I^2=0\%$; n=7)

**Table 1**

**Characteristics of included researches.**

| Source | Country | QI | Intervention | Arch Height, mm | Density* | Control | Applied | Design |
|---|---|---|---|---|---|---|---|---|
| Abdallah and Radwan, 2011[37] | Egypt | 23 | 6° and 11° LWAS (full-length; prefabricated arch) | 10 | NM | Neutral insole + Standardized shoe | Bilateral/unilateral | RM |
| Barrios et al, 2013[45] | US | 23 | 8° LWAS (full-length; customized wedge; prefabricated arch) | NM | NM | Neutral insole + Walking shoes | Unilateral | RCT |
| Dessery et al, 2016[42] | Canada | 25 | 6° and 10° LWAS (full-length; customized arch) | 27.7 ± 3.3 | EVA; 75–80 | Neutral insole + Own shoes | Bilateral | RM |
| Fu et al, 2015[23] | Hong Kong | 22 | LWAS† (full-length; customized arch); VKB; LWI + SS; VKB + LWAS | NM | NM | Flat insole + Walking shoes | Bilateral | RM |
| Hatfield et al, 2015[16] | Canada | 27 | 5° LWAS (full-length; customized arch) | NM | EVA; 55 | Standardized shoe | Bilateral | RM |
| Jones et al, 2013[21] | UK | 24 | 5° LWAS (full-length) | NM | NM | Standardized shoe | Bilateral | RM |
| Jones et al, 2015[44] | UK | 25 | 5° LWAS (full-length); 5° LWI (full-length) | NM | NM | Standardized shoe | Bilateral | RM |
| Maly et al, 2002[52] | US | 23 | 5° LWAS (full-length); 5° LWI (heel; prefabricated) | NM | NM | Routine footwear | Bilateral | RM |
| Moyer et al, 2013[43] | Canada | 21 | 3°, 6°, and 9° LWAS (full-length; customized) | NM | EVA; 55 | Standardized shoe | Unilateral | RM |

EVA = ethylene vinyl acetate, LWAS = lateral wedge arch support insole, LWI = lateral wedge insole, NM = not mentioned, QI = Quality Index, RCT = randomised controlled trial, RM = repeated measure trials, SS = subtalar strap, VKB = valgus knee brace.

* Shore A Hardness.

† Angle of LWAS not mentioned.

**Table 2**

**Demographics of included studies.**

| Source | No. | Sex, M:F | Age, y | Height, m | Body mass, kg | BMI, kg/m$^2$ | Affected side | K/L grade for OA 1 | 2 | 3 | 4 |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Abdallah and Radwan, 2011[37] | 21 | 0:21 | 54.1 ± 7.4 | 1.57 ± 0.06 | 84.1 ± 8.7 | NM | NM | NM | NM | NM | NM |
| Barrios et al, 2013[45] | 38* | NM | 62.6 ± 7.4 | NM | NM | 33.6 ± 7.6 | Bilateral | 0 | 8 | 6 | 5 |
| Dessery et al, 2016[42] | 18 | 10:8 | 54.5 ± 8.6 | 1.70 ± 0.09 | 83.5 ± 9.8 | 28.9 ± 3.8 | NM | 0 | 15 | 3 | 0 |
| Fu et al, 2015[23] | 10 | 4:6 | 56 (51–65) | NM | NM | ≤40 | 9 bilateral 1 unilateral | NM | NM | NM | NM |
| Hatfield et al, 2015[16] | 26 | 4:22 | 64.0 ± 8.0 | 1.61 ± 0.98 | 70.6 ± 13.8 | 27.2 ± 4.2 | Part† | 0 | 16 | 10 | 0 |
| Jones et al, 2013[21] | 28 | 16:10 | 66.3 ± 8.2 | 1.75 ± 0.13 | 88.7 ± 15.1 | NM | NM | 0 | 10 | 18 | 0 |
| Jones et al, 2015[44] | 70 | 43:27 | 60.3 ± 9.6 | 1.69 ± 0.09 | 87.3 ± 18.5 | 30.5 ± 4.9 | NM | 0 | 17 | 25 | 0 |
| Maly et al 2002[52] | 12 | 9:3 | 60 ± 9.39 | NM | 99.1 ± 15.8 | 32.42 ± 5.03 | NM | NM | NM | NM | NM |
| Moyer et al, 2013[43] | 16 | 8:8 | 55 ± 7.0 | NM | NM | 32 ± 6.2 | Unilateral | 2 | 5 | 6 | 3 |

Values are indicated as mean ± SD unless indicated otherwise. BMI = body mass index, K/L = Kellgren/Lawrence, M:F = male:female, NM = not mentioned, OA = osteoarthritis.
* Total sample size was 38, with 19 in intervention group and 19 in control group.
† Bilateral OA included, but no details.

and the flat insole condition (SMD −0.39; 95% CI, −1.28 to 0.49; n = 1). Begg test (*P* = .921, see Supplemental Figure 1, http://links.lww.com/MD/B740, which shows the Begg funnel plot) and Egger test (SE = 0.63, *P* = .880, see Supplemental Figure 2, http://links.lww.com/MD/B740, which demonstrates the Egger publication bias plot) for funnel plot asymmetry were not statistically significant, indicating weak evidence of publication bias for the first peak EKAM.

**Table 3**

**Summary of comparisons in the analysis of parameters.**

| Source | Unit | Comparisons: Intervention | Control | SMD (95% CI) |
|---|---|---|---|---|
| First peak EKAM | | | | |
| Abdallah and Radwan, 2011 a[37] | Nm/kg | 6° LWAS (full-length; unilateral) | Neutral insole* | −0.39 (−1.00, 0.22) |
| Abdallah and Radwan, 2011 b[37] | Nm/kg | 11° LWAS (full-length; unilateral) | Neutral insole | −0.19 (−0.80, 0.42) |
| Abdallah and Radwan, 2011 c[37] | Nm/kg | 6° LWAS (full-length; bilateral) | Neutral insole | −0.18 (−0.79, 0.42) |
| Abdallah and Radwan, 2011 d[37] | Nm/kg | 11° LWAS (full-length; bilateral) | Neutral insole | −0.32 (−0.93, 0.29) |
| Barrios et al, 2012[45] | Nm/kg × m | 8° LWAS (full-length) | Neutral insole | −0.19 (−0.83, 0.44) |
| Dessery et al, 2016 a[42] | Nm/Bw × Ht | 6° LWAS (full-length) | Neutral insole | −0.42 (−1.08, 0.24) |
| Dessery et al, 2016 b[42] | Nm/Bw × Ht | 10° LWAS (full-length) | Neutral insole | −0.23 (−0.88, 0.43) |
| Dessery et al, 2016 c[42] | Nm/Bw × Ht | 6° LWAS (full-length) | Participant's own shoes | −0.15 (−0.81, 0.50) |
| Dessery et al, 2016 d[42] | Nm/Bw × Ht | 10° LWAS (full-length) | Participant's own shoes | 0.02 (−0.63, 0.68) |
| Fu et al, 2015[23] | Nm/kg | LWAS (full-length)† | Flat insole | −0.39 (−1.28, 0.49) |
| Hatfield et al, 2015[16] | Nm/kg | 5° LWAS (full-length) | Standardized shoe | −0.19 (−0.74, 0.35) |
| Jones et al, 2013[21] | Nm/kg | 5° LWAS (full-length) | Standardized shoe† | −0.55 (−1.08, −0.01) |
| Jones et al, 2015[44] | Nm/kg | 5° LWAS (full-length) | Standardized shoe† | −0.14 (−0.47, 0.19) |
| Maly et al, 2002[52] | Nm/kg | 5° LWAS (full-length) | Standardized shoe | 0.16 (−0.64, 0.96) |
| Moyer et al, 2013[43] | %BW × Ht | LWAS (full-length)‡ | Standardized shoe§ | −0.09 (−0.78, 0.60) |
| Second peak EKAM | | | | |
| Dessery et al, 2016 a[42] | Nm/Bw × Ht | 6° LWAS (full-length) | Neutral insole | −0.27 (−0.92, 0.39) |
| Dessery et al, 2016 b[42] | Nm/Bw × Ht | 10° LWAS (full-length) | Neutral insole | −0.33 [−0.99, 0.33) |
| Dessery et al, 2016 c[42] | Nm/Bw × Ht | 6° LWAS (full-length) | Participant's own shoes | −0.28 (−0.93, 0.38) |
| Dessery et al, 2016 d[42] | Nm/Bw × Ht | 10° LWAS (full-length) | Participant's own shoes | −0.34 (−1.00, 0.32) |
| Jones et al, 2013[21] | Nm/kg | 5° LWAS (full-length) | Standardized shoe | −0.49 (−1.02, 0.04) |
| Jones et al, 2015[44] | Nm/kg | 5° LWAS (full-length) | Standardized shoe | −0.14 (−0.47, 0.19) |
| Moyer et al, 2013[43] | %BW × Ht | LWAS (full-length)‡ | Standardized shoe | −0.22 (−0.92, 0.47) |
| KAAI | | | | |
| Barrios et al, 2012[45] | Nm × s/kg × m | 8° LWAS (full-length) | Neutral insole | −0.01 (−0.65, 0.62) |
| Dessery et al, 2016 a[42] | Nm × s/Bw × Ht | 6° LWAS (full-length) | Neutral insole | −0.35 (−1.01, 0.31) |
| Dessery et al, 2016 b[42] | Nm × s/Bw × Ht | 10° LWAS (full-length) | Neutral insole | −0.34 (−1.00, 0.32) |
| Dessery et al, 2016 c[42] | Nm × s/Bw × Ht | 6° LWAS (full-length) | Participant's own shoes | −0.18 (−0.83, 0.48) |
| Dessery et al, 2016 d[42] | Nm × s/Bw × Ht | 10° LWAS (full-length) | Participant's own shoes | −0.18 (−0.83, 0.48) |
| Hatfield et al, 2015[16] | Nm/kg × s | 5° LWAS (full-length) | Standardized shoe | −0.12 (−0.66, 0.43) |
| Jones et al, 2013[21] | Nm/kg × s | 5° LWAS (full-length) | Standardized shoe | −0.57 (−1.11, −0.04) |
| Jones et al, 2015[44] | Nm/kg × s | 5° LWAS (full-length) | Standardized shoe† | −0.14 (−0.47, 0.19) |
| Moyer et al, 2013[43] | %BW × Ht × s | LWAS (full-length)‡ | Standardized shoe§ | −0.02 (−0.71, 0.67) |

CI = confidence interval, EKAM = external knee adduction moment, KAAI = knee adduction angular impulse, LWAS = lateral wedge insole with medial arch support, SMD = standardized mean difference.
* Contoured foot insoles or foot insoles with arch support (prefabricated or custom).
† Angle of LWAS not mentioned.
‡ Mean effect of eight 9° LWAS, seven 6° LWAS, one 3° LWAS.

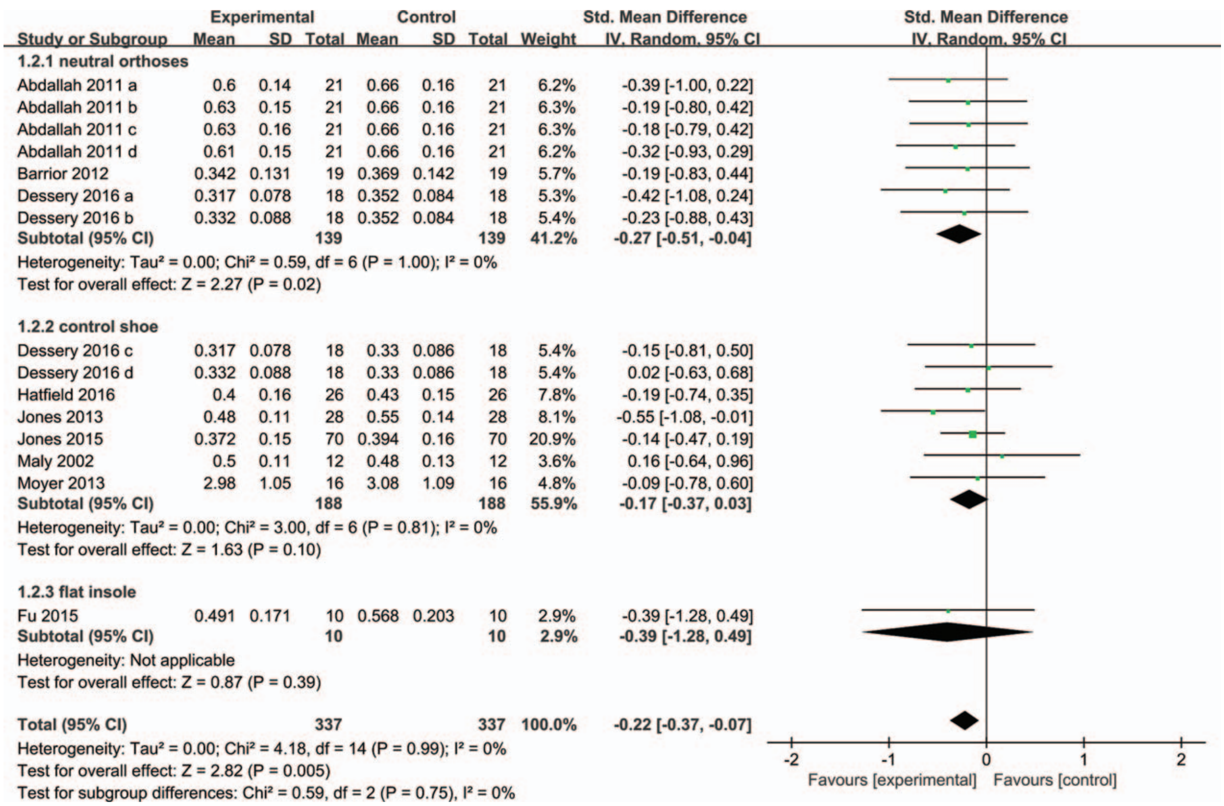


Figure 2. Forest plot of synthetic data for the first peak external knee adduction moment. The green squares indicate the effect size of every study. The transverse lines show the 95% CI. Black diamond represents the pooled estimate of every subgroup and the total effect. CI=confidence interval, SD=standardized errors.

*3.4.2. Second peak EKAM.* Effect of LWAS on the second peak EKAM was reported in 4 studies, among which 3 studies used a shoe-only comparison, 1 study reported both neutral insole comparison and shoe-only comparison. Data synthesis included data from a total of 7 comparisons (Table 3).

The overall pooled-effect estimate demonstrated that LWAS significantly reduced the second peak EKAM (SMD −0.26; 95% CI, −0.47 to −0.06; $P$=.01). This represents a small effect size and translates into an absolute change in the first peak EKAM of approximately −0.02 Nm/kg. Low statistical heterogeneity was found ($\chi^2$=1.30, $P$=.97, $I^2$=0%) (Fig. 3).

Subgroup comparisons also yielded different pooled effects. Among trials in which the control treatment was a shoe-only condition, the LWAS significantly reduced the second peak EKAM (SMD, −0.25; 95% CI, −0.48 to 0.17; $P$=.03; $I^2$=0%; n=5). However, the LWAS showed no associations on the second peak EKAM compared to the neutral insole condition (SMD, −0.30; 95% CI, −0.76 to 0.17; $P$=.21; $I^2$=0%; n=2). Begg test ($P$=.764, see Supplemental Figure 3, http://links.lww.com/MD/B740, which demonstrates the Begg funnel plot) and Egger test (SE=0.56, $P$=0.165, see Supplemental Figure 4, http://links.lww.com/MD/B740, which demonstrates the Egger publication bias plot) for funnel plot asymmetry were not statistically significant, indicating weak evidence of publication bias for the second peak EKAM.

### 3.5. KAAI

Six studies including 9 comparisons were reported for the effect of the LWAS on the KAAI: 4 studies with a shoe-only comparison, 1 study with a neutral insole comparison, and 1 study reported both neutral insole comparison and shoe-only comparison (Table 3).

The overall pooled estimate demonstrated a significant reduction in the KAAI using LWAS (SMD −0.21; 95% CI −0.39 to −0.02; $P$=.03). The pooled-effect size translated to an absolute change in the KAAI of approximately −0.02 Nm/kg$^*$s. Low statistical heterogeneity was found ($\chi^2$=3.04, $P$=.93, $I^2$=0%) (Fig. 4).

Subgroup comparisons also yielded different pooled effects. The LWAS showed no associations with KAAI compared to both the shoe-only condition (SMD, −0.20; 95% CI, −0.41 to 0.01; $P$=.06; $I^2$=0%; n=6) and the neutral insole condition (SMD −0.23; 95% CI, −0.61 to 0.15; $P$=.23; $I^2$=0%; n=3). Begg test ($P$=.602, see Supplemental Figure 5, http://links.lww.com/MD/B740, which demonstrates the Begg funnel plot) and Egger test (SE=0.87, $P$=0.779, see Supplemental Figure 6, http://links.lww.com/MD/B740, which demonstrates the Egger publication bias plot) for funnel plot asymmetry was not statistically significant, indicating weak evidence of publication bias for the KAAI.

## 4. Discussion

The LWAS played a positive role in conservative treatment for people with medial knee OA. Biomechanical parameters related with the medial compartment load of the knee joint including EKAMs and KAAI were reduced with the use of the LWAS without distinguishing between the comparators. However, it should be noted that the results were different when compared with the varied controlled conditions.

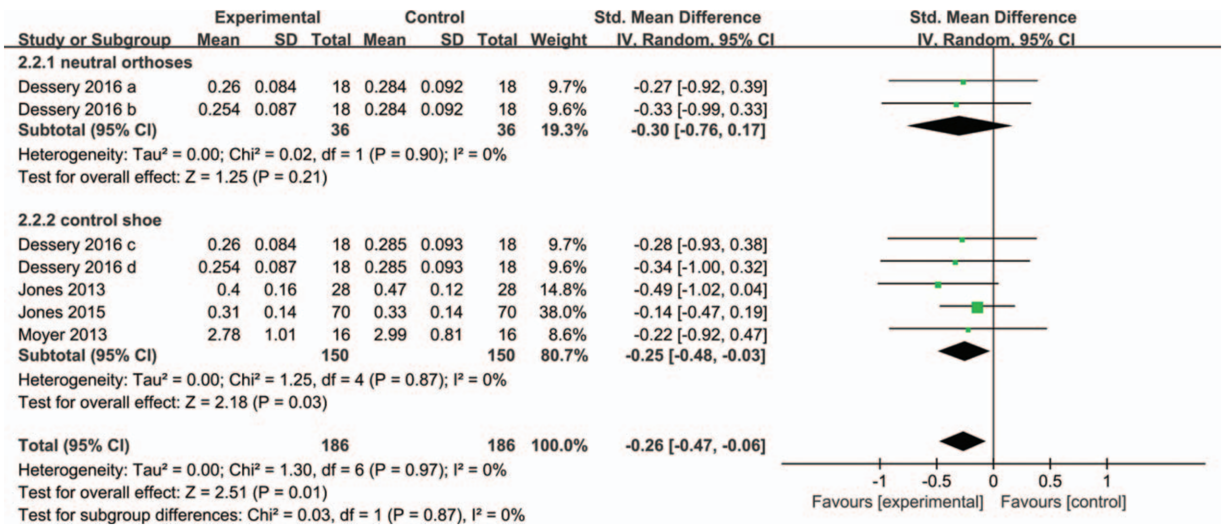


**Figure 3.** Forest plot of synthetic data for the second peak external knee adduction moment. The green squares indicate the effect size of every study. The transverse lines show the 95% CI. Black diamond represents the pooled estimate of every subgroup and the total effect. CI = confidence interval, SD = standardized errors.

To the best of our knowledge, no previous reviews quantitatively evaluated the effect of LWAS. A systematic review evaluated the literature for the effect of different orthotics or footwear on the peak EKAMs and drew the conclusion that LWI was associated with decreased peak EKAM in participants with medial knee OA. The authors also found that there was evidence for increased peak EKAMs with the use of arch supports or medial wedges, indicating increased joint loading at the knee, although medial arch supports have an effect on reducing the amount of foot pronation caused by the LWI.[61] However, this comprehensive review did not mention the effect of the LWAS in detail. The latest meta-analysis[47] regarding this topic did not focus on the different interventions, especially the condition with the medial arch support, to which an increasing number of investigators have recently paid attention. Therefore, our study is the most definitive analysis to clarify the effects of the LWAS alone on reducing knee load in people with knee OA.

The mechanism of the effects of the LWI for the medial osteoarthritic knee was first studied by Yasuda and Sasaki[62] and proved effective for conservative treatment of knee OA; they found that a higher degree of wedging may lead to higher reductions in the first peak EKAM. However, the LWI also has its limitations. Butler et al[63] suggested that the use of lateral wedges may increase rear foot eversion, which is traditionally considered to place individuals at risk of injury and Abdallah and Radwan[37] revealed significant negative correlations between the subtalar eversion and knee adduction moments. Recently, foot orthoses with arch supports have often been prescribed by clinicians to optimize patients' comfort[42] and medial arch support was also added to the LWI in many studies to increase

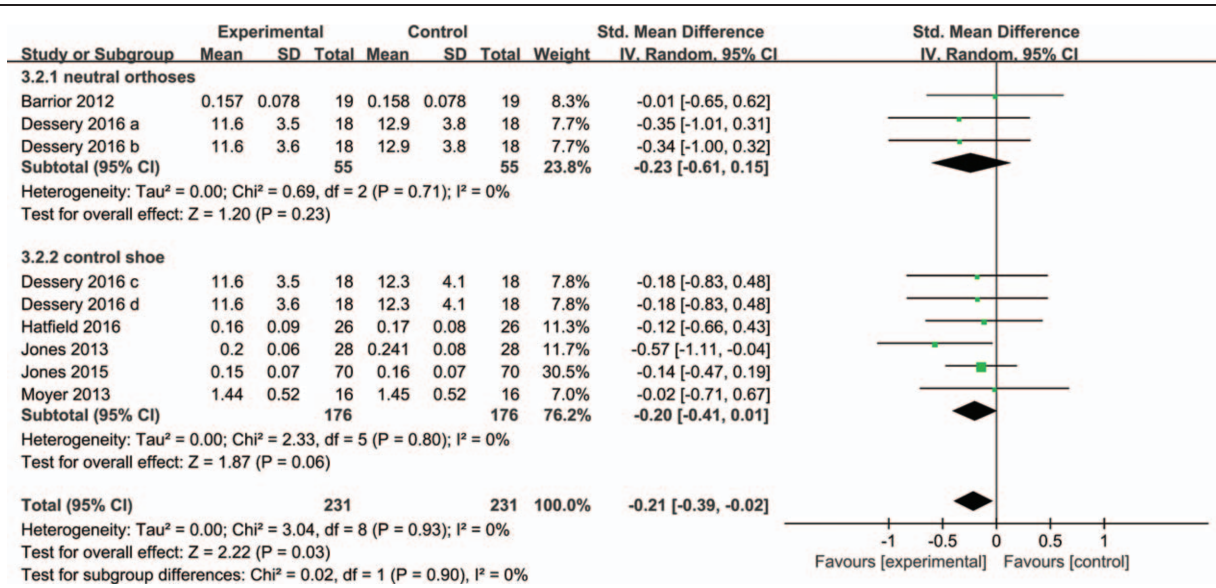


**Figure 4.** Forest plot of synthetic data for the knee adduction angular impulse. The green squares indicate the effect size of every study. The transverse lines show the 95% CI. Black diamond represents the pooled estimate of every subgroup and the total effect. CI = confidence interval, SD = standardized errors.

comfort; its effect on reducing the amount of foot pronation has been proved.[64] Hatfield et al[46] suggested that the ankle eversion angle peak and frontal plane excursion were significantly reduced in treatment with the lateral wedge plus arch support compared to the lateral wedge alone condition. However, it should be noted that a medially applied arch support might have interfered with the effect of LWI in producing foot pronation. A recent review has found laboratory-based evidence that the medial arch may be associated with increased EKAM, indicating increased joint loading at the knee.[61] Therefore, in the clinical setting, practitioners may face a dilemma when prescribing footwear for people with medial knee OA. In view of this condition, we decided to evaluate whether LWAS was effective in reducing knee loading in patients with medial knee OA compared with an appropriate control.

Besides the shoe-only condition, we also took the neutral insole and flat insole into consideration separately, for there is no consensus as to whether flat insoles are biomechanically inert.[47,59] The reported effects of the neutral insole are not consistent in recent studies.[38,65] Although meta-analysis pooling of all studies showed statistically significant associations between the use of LWAS and reductions of the first peak EKAM, second peak EKAM and KAAI during walking for people with medial knee OA, different results were observed when comparing with various control conditions. With regard to the first peak EKAM, the use of LWAS results in a small but statistically significant reduction when the control group is the neutral insole, whereas no significant difference existed in the shoe-only or flat insole condition. The neutral insole is described as a foot orthosis made with arch support[37,42] (prefabricated or custom) or contoured foot orthoses[45] in related studies, which have reported increasing EKAM in the early or late stance phase of the gait,[42,66] that is, less pronation along with larger EKAM caused by the neutral insole. This could explain why the reduction of the first peak EKAM seemed greater in this condition. In other words, the overall effect size is not as large as that found in the neutral group when considered in the shoe-only condition. The one and only article[23] including the flat insole comparison also suggested no significant reduction. Another explanation for the minimal reduction of the shoe-only group is the larger vertical ground reaction forces caused by the higher wedge inclination. As we know, knee external adduction moment is proportional to the combination of ground reaction force and its moment arm.[9] Because medial arch support tends to displace the center of pressure medially, the extent of the reduction of the knee lever arm by LWI zooms out. Furthermore, the vertical ground reaction force increases during walking with the use of a higher lateral wedge, which has also been discussed in a related article.[42] These 2 conditions may display a correlation with the inconspicuous reduction in the first peak EKAM.

Different results also appear in the subgroup analysis of the effects on the second peak EKAM. When compared with shoe-only conditions, the reductions caused by the LWAS were small but significant. However, contrary to our assumption, the neutral insole group showed insignificant reduction on the second peak EKAM, which was unexpected. According to Jones et al,[21] during mid and terminal stance, effect of the lateral wedge can be counteracted by multiple foot structures contacting with more ground and the articulations between them. Furthermore, the ground reaction force is likely to be strongly influenced by the fact that the body mass moves toward the contralateral limb before it making ground contact.[21] If so, the LWI should mainly affect the first peak EKAM with less influence on the second peak EKAM, which is inconsistent with our result (shoe-only condition). We call this characteristic the buffer effect hereafter. Although it is difficult to find a rational explanation for this result, we can ensure that it is the arch support, which caused this eccentric discrepancy. Initially, we only considered that the medial arch support may have opposite effects on the center position of pressure with the LWI, and ignored the fact that it made the LWI more comfortable (especially the custom ones). In view of the fact that appropriate medial arch support results in less tension or pressure than the flat insole on the medial and sole of the foot,[37,66] we speculate that the appropriate height of the medial arch support could weaken the buffer effect by fitting closely between foot arch and insole when used with the LWI simultaneously. Therefore, we find the LWAS has a significant effect on the second peak EKAM, although a insignificant effect on the first peak EKAM in the shoe-only group. At the same time, in the neutral insole group, such effect of the medial arch support is neutralized. The hypothesis above needs to be further studied, emphasizing the importance of coordination between the lateral wedge and medial arch. It is worth mentioning that we have not analyzed the participants' different responses and individual variations, which could be conspicuous as Hinman et al[38] observed. In addition, there are only 2 comparisons included in the neutral insole group for the second EKAM.

Differences also exist with regard to the KAAI, which has been proposed as a more useful measure to account for both the duration and magnitude of loading in knee OA. In both neutral insole and shoe-only conditions, the LWAS had no significant effect on KAAI. This result implied that the lateral wedge inclination is not large enough or the medial arch support is not appropriate. Few researchers have discussed how to combine these 2 parts.

As with any study, our review also has its limitations. First, our meta-analysis consists of 8 repeated measure studies and only 1 RCT. And most studies only test the instant effect of insoles. Long-term effect of LWAS needs to be studied. However, funnel plots revealed low publication bias supporting our inferences. Second, it should be mentioned that the measurement method and the walking speed of patients reported in the articles were not exactly the same and their roles in this research may need to be studied further. Third, inferring knee load with EKAM is also contentious since the contribution of muscle forces[47] and the external knee flexion moment to joint load are not considered. However, by studying outcomes related with disease progression,[14] clinical relevance was maintained in this review. Finally, only 2 articles reported the height of the arch support, which is a barrier for analyzing the combination of the LWI and the medial arch support. Although we searched the data in many ways and updated previous related reviews, only few trials were found. Because of the few comparisons included in some subgroups, the validity of our results might be threatened by the inability to extrapolate the findings to a larger population.

## 5. Conclusions

Considering the 9 trials together, this meta-analysis suggested a favorable effect of the LWAS insoles for reducing the biomechanical parameters (peak EKAMs and KAAI) related to knee load in patients with medial knee OA compared with a control. However, when we focused on the group of trials in which LWAS insoles were compared directly with shoe-only or flat insoles, we found no association with the first peak EKAM. We found no association with the second peak EKAM either, when comparing the LWAS with the neutral insole. No heterogeneity was found across all trial findings. These results suggest that compared with control interventions, the LWAS insoles were not more efficacious for reducing the knee load in patients with medial knee OA. An optimal LWAS should provide the appropriate arch support height and amount of lateral wedging. Further research should investigate the best combination of these 2 parameters to achieve appropriate benefit without altered comfort.

## Acknowledgment

The authors acknowledge all authors who provided information about their researches.

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