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Lateral Wedge Insoles as a Conservative Treatment for Pain in Patients With Medial Knee Osteoarthritis:

A Meta-analysis

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Abstract

IMPORTANCE—There is no consensus regarding the efficacy of lateral wedge insoles as a treatment for pain in medial knee osteoarthritis.

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OBJECTIVE—To evaluate whether lateral wedge insoles reduce pain in patients with medial knee osteoarthritis compared with an appropriate control.

DATA SOURCES—Databases searched include the Cochrane Central Register of Controlled Trials, EMBASE, AMED, MEDLINE, CINAHL Plus, ScienceDirect, SCOPUS, Web of Science, and BIOSIS from inception to May 2013, with no limits on study date or language. The metaRegister of Controlled Trials and the NHS Evidence website were also searched.

STUDY SELECTION—Included were randomized trials comparing shoe-based treatments (lateral heel wedge insoles or shoes with variable stiffness soles) aimed at reducing medial knee load, with a neutral or no wedge control condition in patients with painful medial knee osteoarthritis. Studies must have included patient-reported pain as an outcome.

DATA EXTRACTION AND SYNTHESIS—Trial data were extracted independently by 2 researchers using a standardized form. Risk of bias was assessed using the Cochrane Risk of Bias tool by 2 observers. Eligible studies were pooled using a random-effects approach.

MAIN OUTCOME AND MEASURES—Change in self-reported knee pain at follow-up.

RESULTS—Twelve trials met inclusion criteria with a total of 885 participants of whom 502 received lateral wedge treatment. The pooled standardized mean difference (SMD) suggested a favorable association with lateral wedges compared with control (SMD, −0.47; 95% CI, −0.80 to −0.14); however, substantial heterogeneity was present (I^2 = 82.7%). This effect size represents an effect of −2.12 points on the 20-point Western Ontario and McMaster Universities Arthritis Index (WOMAC) pain scale. Larger trials with a lower risk of bias suggested a null association. Meta-regression analyses showed that higher effect sizes (unstandardized β, 1.07 [95% CI, 0.28 to 1.87] for trials using a no treatment control) were seen in trials using a no wedge treatment control group (n = 4 trials; SMD, −1.20 [95% CI, −2.09 to −0.30]) and lower effect sizes (unstandardized β, 0.26 [95% CI, 0.002 to 0.52] for each bias category deemed low risk) when the study method was deemed at low risk of bias. Among trials in which the control treatment was a neutral insole (n = 7), lateral wedges showed no association (SMD, −0.03 [95% CI, −0.18 to 0.12] on WOMAC; this represents an effect of −0.12 points), and results showed little heterogeneity (I^2 = 7.1%).

CONCLUSIONS AND RELEVANCE—Although meta-analytic pooling of all studies showed a statistically significant association between use of lateral wedges and lower pain in medial knee osteoarthritis, restriction of studies to those using a neutral insole comparator did not show a significant or clinically important association. These findings do not support the use of lateral wedges for this indication.

Osteoarthritis of the knee is a common painful chronic disease whose prevalence is increasing and for which there are few efficacious treatment options.[1] The increase in rates of knee replacement for osteoarthritis has made the identification of effective nonsurgical treatments a high priority. Medial osteoarthritis is one of the most common subtypes of knee osteoarthritis.

One type of treatment for medial knee osteoarthritis involves reducing medial loading to ease the physical stress applied to that compartment of the joint.[2,3] The wedge is placed under the sole of the foot and angulated so that it is thicker over the lateral than the medial edge, transferring loading during weight bearing from the medial to the lateral knee

compartment. Studies have documented a modest 5% to 6% reduction in the external knee adduction moment, a measure of medial (vs lateral) loading.[4–7] As a consequence of this medial unloading, painful knee symptoms should be reduced. However, studies examining knee pain following treatment have shown inconsistent findings, some suggesting a larger amount of pain decreases when using wedged insoles,[8–10] and others (including a recent randomized clinical trial [RCT][11]) suggesting that they produce little pain reduction compared with a control treatment.

In reviewing those studies, different groups have promulgated different recommendations. For example, in recent osteoarthritis treatment guidelines,[12] the American College of Rheumatology did not recommend lateral wedge insoles as a treatment for medial knee osteoarthritis. On the other hand, the Osteoarthritis Research Society international treatment guidelines state, “Lateral wedged insoles can be of symptomatic benefit for some patients with medial tibio-femoral compartment [osteoarthritis] OA.”[13] In the United Kingdom, the National Institute for Health and Care Excellence noted “limited data for the effectiveness of insoles in reducing the symptoms of knee osteoarthritis” but stated “…in the absence of well-designed trial data and given the low cost of the intervention, the [guideline development group] GDG felt that attention to footware with shock-absorbing properties was worth consideration.”[14]

The objective of this review was to assess the efficacy of lateral wedge treatments (shoes and insoles designed to reduce medial knee compartment loading) in reducing knee pain in patients with medial knee osteoarthritis. To our knowledge, there has not been a comprehensive meta-analysis examining this issue.

Methods

Literature Search

The Cochrane Central Register of Controlled Trials, EMBASE, AMED, MEDLINE, CINAHL Plus, ScienceDirect, SCOPUS, Web of Science, and BIOSIS databases were searched from the earliest available date to May 2013. There were no limits on study dates or any language restrictions. Search keywords comprised of synonyms of knee osteoarthritis and orthotic devices (full details of terms used appear in eMethods in the Supplement).

Reference lists of relevant articles were manually searched, and expert guidance sought to locate trials not included in clinical trial registers, and potential unpublished trials. The NHS Evidence website was used to check for any potential gray literature regarding wedge insole trials. The metaRegister of Controlled Trials also was searched using the keywords insole or *insert and osteoarth** to look for relevant registered trials that may have data, but did not have any published papers.

Relatively few RCTs using lateral wedges were labeled with keywords or titles that appropriately depicted them as such to a specific search filter. Thus, no specific filter for RCTs was used during database searches; reviewers instead manually excluded nonrandomized designs at the screening stage. This was to maximize the chances of including all relevant RCTs in this review.

Study Selection

This review considered RCTs investigating the use of all kinds of lateral wedge treatments (shoes, insoles, or both, designed to reduce medial knee loading) as treatment for painful symptoms in patients with medial knee osteoarthritis. Treatment could have included ankle support or strapping that was either off-the-shelf or custom-fitted. The wedge needed to be of 5° to 15° of angulation, which is a level shown in previous studies[15] to reduce external knee adduction moment; a shoe followed the same principle (eg, soft medial; hard lateral sole) and had been shown to reduce the knee adduction moment.[16,17]

The trials must have included (1) an intervention group that received treatment, and (2) a control condition in which either an appropriate placebo treatment was applied (ie, a neutral or flat insole or shoe) or no treatment. Trials in which a treatment was applied alongside concomitant therapy were deemed acceptable as long as the same treatments were also applied in the control condition (eg, wedged insole plus 500 mg of paracetamol vs neutral insole plus 500 mg of paracetamol). Studies with active comparators (eg, braces or drug therapies) that were not applied to the treatment condition were not included unless these studies also had a treatment group with an appropriate control.

The study samples must have included adult patients (aged >18 years) with predominantly medial compartment knee osteoarthritis only. Knee osteoarthritis needed to be confirmed either clinically, radiologically, or using some established existing criterion such as the American College of Rheumatology criteria for osteoarthritis.[18] Patients should have had no exposure to similar treatments prior to the study unless an adequate washout period was described.

Outcome Measures

The primary outcome in this review was self-reported pain. This was prespecified before review commencement. Reviewers accepted any form of pain scale reported on the hierarchy of pain-related outcomes described by Jüni et al.[19] When articles provided more than 1 pain outcome, the highest-listed outcome in the hierarchy was considered in our review. When multiple time points were reported either in 1 particular report of a study or over the course of several articles from the same study, the longest follow-up period on treatment was considered in our review. We performed sensitivity analyses focusing on trials that provided Western Ontario and McMaster Universities Arthritis Index (WOMAC) data and relying on other hierarchy-based outcomes when WOMAC was not reported.

Quality Assessment

Two authors (M.J.P. and D.T.F.) independently assessed study quality using the Cochrane Risk of Bias tool.[20] After discussions to resolve disagreements, a consensus score was arrived at for each element of quality in each trial.

Data Collection

Two reviewers (M.J.P. and N.M.) independently extracted and cross-checked data from all English-language articles. One Japanese-language article was reviewed and had the data extracted by 2 reviewers (N.A.S. and K.T-N.) fluent in Japanese.

Statistical Analysis

Standardized mean differences (SMDs) were calculated as the mean difference in pain change produced by the intervention and the control divided by the pooled standard deviation, with adjustment for small samples (Hedges g).[21] When these data were not directly reported in the article, they were calculated from other available data when possible (eg, from 95% confidence intervals or *P* values from *t* tests). Several studies included in the review provided means and standard deviations at baseline and follow-up, but did not report the within-subject change standard deviation, which was required for the meta-analysis. Initially, corresponding authors were contacted to obtain the unreported data. In the few cases in which a response was not available, we pursued an imputation approach. In these cases, mean difference standard deviations ($SD_{(follow\text{-}up\text{-}baseline)}$) were estimated by combining the standard deviations reported at baseline and follow-up with the weighted mean correlation (Cor) between baseline and follow-up visits reported by other reports, thus weighted by the sample size of each trial:

$$SD_{(follow-up-baseline)} = \sqrt{SD^2_{baseline} + SD^2_{follow-up} - (2 \times Cor_{(baseline,follow-up)} \times SD_{baseline} \times SD_{follow-up})}$$

Given that 4 studies required this imputed standard deviation, sensitivity analyses were performed to assess the robustness of the method used to impute. A total of 3 sensitivity analyses were performed: 1 using the highest-reported correlation between baseline and follow-up to calculate the standard deviations, 1 using the lowest-reported correlation, and 1 excluding any trials with imputed standard deviations. Standardized mean differences can be difficult to interpret in a clinical context. Using Jinks et al[22] as an estimate of a typical osteoarthritis patient population with a mean (SD) WOMAC pain subscale score of 6.57 (4.52) on a scale of 0 to 20 (0 = no pain and 20 = highest pain score), we translated the SMDs observed into a mean difference in WOMAC scores in a typical population of patients.

Study heterogeneity was assessed by using the I^2 statistic and subsequent χ^2 test. As we anticipated heterogeneity in SMDs due to differences in study characteristics, random-effects meta-analysis was used to combine the study results. Meta-regression was performed to investigate if study characteristics could explain the heterogeneity observed. Among the variables tested as predictors of study heterogeneity were likelihood of study bias, treatment duration, type of control used (no treatment or a neutral wedge), year of publication, and patient characteristics.

The risk of small study effects was assessed through visual inspection of contour-enhanced funnel plots,[23] followed by an Egger regression test[24] (the slope interpretation form outlined by Sterne et al[25]) to formally test for small study effects. If the regression slope significantly deviated from the vertical slope, this suggests small study bias.

All statistical analysis were performed using Stata statistical software version 11.2 (StataCorp). All statistical tests performed were 2-sided and considered a *P* value of less than .05 or a 95% confidence interval that excluded a null result as statistically significant.

Results

After using the outlined literature search strategy and removing duplicates, 884 articles were found. Of these, 717 were excluded (Figure 1). More than half of these (417 articles) were reports of surgical trials or studies of other unrelated orthoses, 108 were lateral wedge studies using healthy participants, only reporting kinetic or kinematic outcomes, or had 2 active treatment conditions with no adequate control group. A further 192 articles were not trials (ie, systematic and narrative reviews, clinical guidance documents, commentaries, letters, and press releases). This left 167 articles assessed in more detail for eligibility. Of these, 13 met the inclusion criteria. One study did not report sufficient data to be included and the authors of the study did not respond to repeated contacts.[26]

Twelve trials were included and the summary characteristics appear in Table 1 and Table 2. Additional information on trial groups not included in the final analysis are provided in eTables 1 and 2 in the Supplement. Of the 12 trials, 11 used a lateral wedge insole as treatment and 1 used a variable-stiffness shoe designed to produce the same treatment effect as a lateral wedge insole.[16,17] Two trials[39,41] included additional conditions in which a wedge was directly strapped to the feet of participants with subtalar strapping. In these studies, we used the insert without strapping condition because it was comparable with the other lateral wedge implementations. Regarding controls, 7 studies used a neutral (flat) control wedge,* 4 used no treatment (ie, an empty shoe),[8,27,36,39] and 1 used a subtalar strap as a control (the strap was also included in the active treatment).[40] Treatment duration ranged from 2 weeks to 2 years. Three of the 12 studies involved the application of concomitant therapy alongside the treatment and the control.[8,27,36] Data from a total of 885 participants were extracted of whom 502 received lateral wedge treatment.

No trials were deemed low risk of bias in all domains of the Cochrane Risk of Bias tool (provided in eFigure 1 in the Supplement). Perceived likely unblinding of participants and personnel was the most frequent deficiency in trials, particularly for trials with no control treatment.

Considering all 12 trials, the overall effect estimate was a SMD in pain between interventions of −0.47 (95%CI, −0.80 to −0.14), a moderately significant effect of a lateral wedge on pain reduction. This translated into a WOMAC pain effect of −2.12 points on the 0 to 20 scale. However, effects were highly heterogeneous across studies (I^2 = 82.7%, χ^2_{11} = 63.71, P<.001). The effect estimates from the sensitivity analyses showed little change.

A meta-regression examined factors underlying the heterogeneity. Among factors examined, there was no association of the treatment effect size with treatment duration (unstandardized β, 0.01; 95% CI, −0.01 to 0.02), number of bias categories rated high risk (unstandardized β, −0.11; 95% CI, −0.52 to 0.30) or unclear risk (unstandardized β, −0.33; 95% CI, −0.68 to 0.02), and appearance on a clinical trial register (unstandardized β, 0.63; 95% CI, −0.39 to 1.66) (Table 3). There was an association between treatment effect size and number of bias categories rated low risk (unstandardized β, 0.26; 95% CI, 0 to 0.52). A significant

*References 2, 11, 17, 28–35, 37, 38, 41–43

difference in treatment effect was found between the type of control condition used (either a neutral wedge or nothing) (unstandardized β, 1.07; 95% CI, 0.28 to 1.87) with a lesser treatment effect seen in trials in which the control condition was a neutral wedge.

When trials were grouped according to the control group treatment (Figure 2), we found that compared with neutral inserts, lateral wedges had no association with knee pain (SMD, −0.03; 95% CI, −0.18 to 0.12) and heterogeneity was much lower across trial findings (I^2 = 7.1%, χ^2_6 = 6.46, P = .37). The neutral control subgroup SMD of −0.03 represents a decrease of −0.12 points on the WOMAC pain subscale more than a control group wearing a neutral wedge during the same period.

We then tested for asymmetry in our funnel plot (eFigure 2 in the Supplement) to investigate if small studies reported greater treatment effect sizes than larger studies (ie, small study effects). The Egger test result was positive with the smaller studies (those with increased standard error) finding greater differences in pain reduction in favor of the lateral wedge condition (slope, −5.11 [95% CI, −7.97 to −2.25]; *P* = .003). The contours of the figure suggested that the largest studies were null, but the smaller studies were a mixture of null and statistically significant, with all of the significant studies showing favorable associations with treatment and none showing the opposite effect. Because small study effects can be caused by different types of patients in small studies, or by more intensive and effective treatments in these small studies, we examined the smaller studies and found little difference in the interventions or in the patients enrolled. However, when we separately evaluated the Egger test in the different control subgroups (nothing vs neutral insole), the slopes were no longer statistically significant; however, the smaller numbers of studies reduced our ability to detect deviations in slope (slope for nothing as control subgroup, −14.72 [95% CI, −62.24 to 32.79]; *P* = .31; slope for neutral insole as control subgroup, −2.23 [95% CI, −5.13 to 0.67]; *P* = .11).

Discussion

Overall, the meta-analysis including 12 trials showed a large degree of heterogeneity and small study bias. However, among trials comparing wedge insoles with neutral insoles, there were no significant or clinically important effects of laterally wedged insoles on knee pain.

This is not the first systematic review of lateral wedge insoles reducing pain in knee osteoarthritis; however, to our knowledge, it is the first comprehensive meta-analysis of this issue. Five reviews have been published.[44–48] Four of these[44–47] were systematic reviews that did not include a meta-analysis. In a review mixing pain and gait outcomes, Malvankar et al[45] used trials that were nonrandomized, and the literature search took place before the publication of a recent, large-scale RCT.[11] Brouwer et al[44] and Raja and Dewan[46] both considered braces and orthoses as treatment for knee osteoarthritis. The review by Raja and Dewan[46] included trials that had no control group and mixed pain and gait outcomes. In contrast, Reilly et al[47] and Brouwer et al[44] considered RCTs separately and the findings outlined in the present meta-analysis are in agreement with their reported main findings, particularly when looking at RCTs only. The only meta-analysis we found is a recently published review of physiotherapy treatments, which included orthotic (wedge) treatment.[48]

It found only 2 of the studies that we reviewed and must be considered incomplete in its treatment of lateral wedge insoles. The present analysis, therefore, adds to and updates existing reviews, and provides the first comprehensive meta-analysis.

Several points can be drawn from this analysis. Considering only analyses that are low in heterogeneity, it appears that compared with neutral inserts, lateral wedges are associated with only a slight, nonsignificant pain reduction compared with control (SMD of 0.03, representing a decrease of −0.12 points on the WOMAC pain subscale, which is a clinically trivial reduction).

Variation in the magnitude of effect sizes has previously been noted by other authors in studies investigating lateral wedge insoles.[44,49] To this end, our meta-analysis also sought to investigate possible explanations for the observed heterogeneity in effect sizes. This analysis found 3 potential factors associated with observed treatment effects: the quality of the trial reporting, the quality of the study design (by inference, with particular emphasis on adequate randomization and blinding), and the type of control condition used as a comparison with the wedge.

We found small study effects, which could have a number of potential causes.[50,51] However, in this case, they appear to be explained primarily by the type of control group. When we grouped our studies according to type of control group, the small study biases decreased to a nonsignificant effect (although this restriction also decreased the sample size used to perform the test, effectively reducing the power to detect small study effects).

We found that trials that used no intervention as a control condition reported larger treatment effects than those which opted to use a neutral (flat) wedge. One possible explanation for this finding is that neutral wedges have an effect on patients' self-reported pain, and are therefore not a truly inert control. Alternatively, the change in pain caused by the lateral wedge may be due to a placebo effect. Pain, being a self-reported, subjective outcome, is particularly susceptible to these effects, and such influences have been documented in reviews of osteoarthritis literature.[52,53] This finding is difficult to confirm without specific 3-group trials that contain an intervention, placebo intervention, and no intervention, which has been recommended in a previous review.[54]

It is also possible that lateral wedges are no more efficacious than neutral inserts for pain reduction because their effect on medial loading of the knee does not affect pain. First, lateral wedges cause only 5% to 6% reductions in the external adduction moment across the knee, and this may be insufficient to reduce pain. Second, other factors such as the sagittal moment and muscle co-contraction may contribute importantly to medial knee loading so that reducing the adduction moment alone may be insufficient to reduce knee pain.

There are several limitations to our study. First, our meta-analysis captured only a small number of RCTs; however, for controlled trials using neutral inserts as controls, the 95% confidence intervals around our estimate of a null effect excluded a substantial clinical benefit (upper bound, −0.18 SMD, representing a reduction of 0.81 points on the 20-point WOMAC). We could have taken advantage of nonrandomized or even uncontrolled studies to acquire more data on this intervention but chose to limit our work to RCTs. Different

trials used different pain surveys as outcomes and this could have created some of the heterogeneity we found among trials. Lastly, whereas the meta-regression investigating relationships with wedge angulation proved null, the trials we summarized tested mostly wedges of around 5° to 6° and this analysis included few trials, giving lower power to detect a difference. Greater wedge angulations may have more favorable effects, although at least 1 of our trials did use more angulation and reported null results. More angulation is often less tolerable for patients.

In conclusion, considering the 12 trials together, this meta-analysis suggested a favorable association of lateral wedge insoles in reducing pain in patients with medial knee osteoarthritis compared with a control. However, when we focused on the group of trials in which lateral wedges were compared directly with neutral insoles, we found no association with pain and also little heterogeneity across trial findings. These results suggest that compared with control interventions, lateral wedges are not efficacious for the treatment of knee pain in persons with medial knee osteoarthritis.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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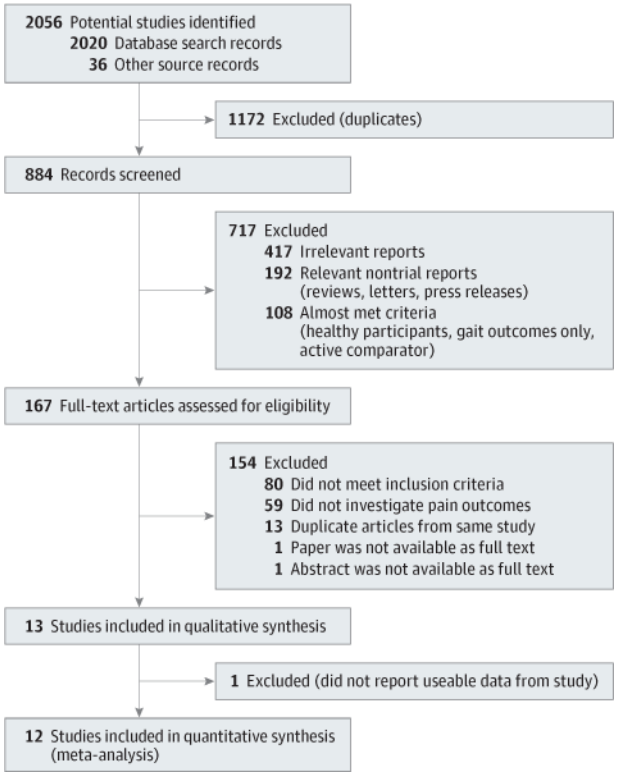

Figure 1.
Review Flow Diagram

Source	Duration of Study	SMD (95% CI)	Weight, %
No wedge treatment given (control group)			
Toda,[39] 2002	2 wk	-0.30 (-0.96 to 0.36)	7.51
Akinbo and Iko,[27] 2007	6 wk	-1.53 (-2.17 to -0.90)	7.68
Koca et al,[36] 2009	3 mo	-0.58 (-1.24 to 0.08)	7.52
Sattari and Ashraf,[8] 2011	9 mo	-2.47 (-3.31 to -1.63)	6.32
Subtotal		-1.20 (-2.09 to -0.30)	29.03
Test for heterogeneity: I^2 = 85.0%, P<.001			
Neutral insole given (control group)			
Maillefert et al,[37] 2001 and Pham et al,[38] 2004	2 y	0.06 (-0.26 to 0.37)	9.81
Wallace,[42] 2006 and Wallace et al,[43] 2007	12 wk	-0.64 (-1.31 to 0.03)	7.43
Baker et al,[28,29] 2005 and 2007	6 wk	-0.16 (-0.46 to 0.14)	9.89
Toda and Tsukimura,[41] 2008	12 wk	-0.02 (-0.46 to 0.42)	9.06
Barrios et al,[30-33] 2006, 2009, 2010, and 2013	1 y	-0.11 (-0.60 to 0.37)	8.74
Erhart-Hledik et al,[2] 2012 and Erhart et al,[17] 2010	1 y	-0.06 (-0.59 to 0.48)	8.38
Bennell et al,[11,34,35] 2007, 2010, and 2011	1 y	0.18 (-0.10 to 0.45)	10.01
Subtotal		-0.03 (-0.18 to 0.12)	63.32
Test for heterogeneity: I^2 = 7.1%, P = .37			
Subtalar strapping given (control group)			
Toda et al,[40] 2005	2 wk	-0.94 (-1.58 to -0.30)	7.65
Overall		-0.47 (-0.80 to -0.14)	100
Test for heterogeneity: I^2 = 82.7%, P<.001			

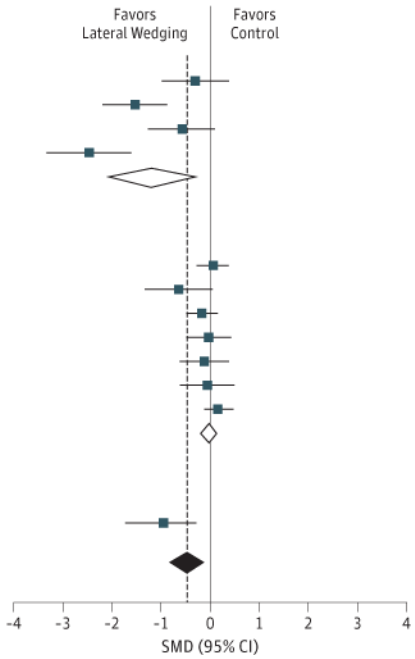

Figure 2. Forest Plot of Effect Size for Heel Wedge Interventions

Weights are from a random-effects analysis. SMD indicates standardized mean difference.

Table 1

Characteristics of Included Studies

Source	Country	Intervention	How Applied Laterally	Treatment Dosage	Treatment Duration	Funding Source
Akinbo and Iko,[27] 2007	Nigeria	Both groups: own shoes (implied) + thermal therapy + soft tissue knee massage Treatment group: + LWI (macrorubber material, 8 mm) Control group: + no treatment	Unclear	Instructed to apply the wedge religiously	6 wk	Not stated
Baker et al,[28,29] 2005 and 2007	United States	Both groups: own shoes (implied) Treatment group: + LWI (5°, NickelPlast) Control group: + neutral insole (NickelPlast)	Applied to affected knee only[a]	Retrospectively asked patients for adherence, worn for 7–8 h/d in all conditions	6 wk	National Institutes of Health
Barrios et al,[30–33] 2006, 2009, 2010, and 2013	United States	Both groups: New Balance MW811 or WW811 walking shoes Treatment group: + individually prescribed LWI on affected limb (5°–15°) + neutral wedge on contralateral limb Control group: + bilateral neutral wedge	Unilateral to most symptomatic limb	Once the orthoses and shoes could be comfortably worn for 1 d, encouraged to wear as much as possible to maximize the treatment effect	1y	National Center for Research Resources
Bennell et al,[11,34,35] 2007, 2010, and 2011	Australia	Both groups: own shoes (implied) Treatment group: + LWI (ethyl vinyl acetate, 5°) Control group: + neutral insole (low-density ethyl vinyl acetate)	Bilateral	Asked to wear the insoles full time in their shoes	1y	National Health and Medical Research Council and Australian Research Council
Erhart-Hledik et al,[2] 2012 and Erhart et al,[17] 2010	United States	Treatment group: Nike variable stiffness shoe Control group: Athletic shoe with a similar appearance, with constant stiffness sole	Bilateral	Retrospectively asked patients for adherence; worn for 6.4–7.9 h/d in both groups	1y	US Department of Veterans Affairs
Koca et al,[36] 2009	Turkey	Both groups: own shoes + 1500 mg/d of paracetamol + strengthening exercises Treatment group: + LWI (5°) Control group: + no treatment	Unclear	All day long	3 mo	Not stated
Maillefert et al,[37] 2001 and Pham et al,[38] 2004	France	Both groups: own shoes Treatment group: + LWI (custom-fitted, Ledos material, various heights) Control group: + neutral insole (custom-fitted, Ledos material, various heights)	Bilateral	Retrospectively checked adherence at 6 mo[b]	2y	Programme Hospitalier de Recherche Clinique, French Health Ministry
Sattari and Ashraf,[8] 2011	Iran	Both groups: activity modification + heating agents + exercises + analgesics	Unclear	Whenever patients wore shoes	9mo	Not stated

Source	Country	Intervention	How Applied Laterally	Treatment Dosage	Treatment Duration	Funding Source
		Treatment group: + LWI (¼ in; approximately 6°) Treatment group: + LWI (¼ in; approximately 6°) Control group: + no treatment				
Toda,[39] 2002	Japan	Both groups: NSAID Treatment group: + LWI (height not described) Control group: + no treatment	Unclear	Unclear	6 wk	National health insurance
Toda et al,[40] 2005	Japan	Both groups: subtalar strapping + own shoes Treatment group: + LWI (urethane, 11.2°) worn for 5–10 h/d Control group: + no treatment	Unclear	5–10 h/d (medium group) used in analysis	2 wk	National health insurance
Toda and Tsukimura,[41] 2008	Japan	Both groups: own shoes Treatment group: + LWI (sponge rubber, 5°) Control group: + neutral wedge (odor repellant)	Unclear	5–10 h/d whenever wearing shoes	12 wk	National health insurance
Wallace,[42] 2006 and Wallace et al,[43] 2007	United States	Both groups: own shoes Treatment group: + LWI (custom-fitted ¾ length, ethyl vinyl acetate + foam, 7°) Control group: + neutral insole (ethyl vinyl acetate + foam)	Bilateral	Retrospectively recorded[c]	12 wk	American College of Sports Medicine and International Society of Biomechanics

Abbreviations: LWI, lateral wedge insole; NSAID, nonsteroidal anti-inflammatory drug.

[a] For unilateral pain: wedge plus neutral insole; bilateral pain: wedge times 2.

[b] In the treatment group, 87.8% reported permanently wearing insoles; control group, 74.3%.

[c] The mean (SD) adherence was 10.3 (3.2) hours/day in the treatment group and 9.1 (2.3) hours/day in the control group.

Table 2

Demographics of Included Studies

Source	No.	ITT Analysis Used?	No. (%) of Women[a]	Mean (SD)[a]		No. (%) With K-L Grades ≥3	Outcome	Time Point
				Age, y	Body Mass Index[b]			
Akinbo and Iko,[27] 2007	50	No; no dropouts included	Treatment: 14(56) Control: 14(56)	Treatment: 54.42 (2.66) Control: 52.50(2.61)	Treatment: 28.87 (1.53) Control: 27.40 (1.00)	Treatment: 20(100) Control: 20 (100)	WOMAC pain subscale (Likertscale)	6 wk
Baker et al,[28,29] 2005 and 2007	86	Yes; complete case analysis	Neutral to wedge: 27 (66) Wedge to neutral: 24 (53)	Neutral to wedge: 67.8 (9.9) Wedge to neutral: 68.2 (8.7)	Neutral to wedge: 32.9 (6.4) Wedge to neutral: 33.0 (4.8)	Neutral to wedge: 38 (93) Wedge to neutral: 42 (93)	WOMAC pain subscale (500-point version)	6 wk
Barrios et al,[30–33] 2006, 2009, 2010, and 2013	66	Yes; last observation carried forward	Treatment: 18 (58) Control: 19 (54)	Treatment: 62.6 (7.4) Control: 62.8 (9.6)	Treatment: 34.2 (7.2) Control: 31.9 (6.9)	Treatment: 20 (61) Control: 19 (57)	WOMAC pain subscale (500-point version)	1y
Bennell et al,[11,34,35] 2007, 2010, and 2011	200	Yes; complete case analysis (imputation)	Treatment: 62 (60) Control: 56 (58)	Treatment: 63.6 (8.1) Control: 65 (7.9)	Treatment: 28.1 (4.2) Control: 30.4 (5.6)	Treatment: 28 (90) Control: 19 (73)	Global pain scale (11-point Likert scale)	1y
Erhart-Hledik et al,[2] 2012 and Erhart et al,[17] 2010	55	Yes; complete case analysis	Treatment: 14 (41) Control: 15 (58)	Treatment: 61.4 (9.2) Control: 62.1 (9.9)	Treatment: 27.6 (4.5) Control: 27.4 (5.4)	Not stated	WOMAC pain subscale (20-point version)	1y
Koca et al,[36] 2009	37	No; no dropouts included	Overall: 37 (100)	Treatment: 55.36 (11.50) Control: 54.83 (9.27)	Treatment: 31.33 (3.44) Control: 29.64 (4.79)	Treatment: 15 (79) Control: 14 (78)	Pain on walking VAS (100 mm)	3 mo
Maillefert et al,[37] 2001 and Pham et al,[38] 2004	156	Yes; last observation carried forward	Treatment: 54 (66) Control: 61 (82)	Treatment: 64.0 (10.8) Control: 65.6 (9.9)	Treatment: 29.0 (5.6) Control: 28.5 (5.3)	Treatment: 43 (52) Control: 40 (54)	WOMAC pain subscale (VAS)	2y
Sattari and Ashraf,[8] 2011	40[c]	No; dropouts replaced	Overall: 38/60 (63)	Overall: 48 (3 treatment groups, no spread reported)	Not stated	Treatment: 20 (100) Control: 20 (100)	Pain on walking (VAS)	9 mo
Toda,[39] 2002	36[c]	No; no dropouts included	Treatment: 20 (100) Control: 16 (100)[c]	Treatment: 65.2 (9.5) Control: 60.1 (6.6)	Treatment: 28.1 (3.5) Control: 28.1 (1.8)	Treatment: 8 (40) Control: 2 (12.5)	Lequesne Index	6 wk
Toda et al,[40] 2005	42[c]	No; no dropouts included	Medium treatment: 20 (100) Control: 22 (100)[c]	Medium treatment: 64.1 (12.3) Control: 62.0 (9.8)	Short treatment: 24.5 (4.0) Medium treatment: 23.8 (3.2) Long treatment: 24.2 (2.3) Control: 25.5 (4.3)	Medium treatment: 3 (15) Control: 3 (14)	Lequesne Index	2 wk

Source	No.	ITT Analysis Used?	No. (%) of Women[a]	Mean (SD)[a]		No. (%) With K-L Grades ≥3	Outcome	Time Point
				Age, y	Body Mass Index[b]			
Toda and Tsukimura,[41] 2008	81[c]	Yes; last observation carried forward	Inserted insole with shoes: 38 (88) Control: 32 (84)[c]	Inserted insole with shoes: 66.1 (8.6) Control: 64.6 (9.8)	Inserted insole with shoes: 24.7 (2.9) Control: 24.6 (3.1)	Inserted insole with shoes: 16 (30) Control: 15 (39)	Lequesne Index	12 wk
Wallace,[42] 2006 and Wallace et al,[43] 2007	36	Yes; complete case analysis	Treatment: 8 (44) Control: 8 (44)	Treatment: 60.8 (9.8) Control: 61.0 (9.2)	Treatment: 28.7 (3.7) Control: 27.9 (4.2)	Treatment: 17 (94) Control: 17 (94)	WOMAC pain subscale (Likert scale)	12 wk

Abbreviations: ITT, intention to treat; K-L, Kellgren-Lawrence radiographic scale; VAS, visual analog scale; WOMAC, Western Ontario and McMaster Universities Arthritis Index.

[a] Unless otherwise indicated.

[b] Calculated as weight in kilograms divided by height in meters squared.

[c] Participants from irrelevant treatment groups were excluded.

Table 3

Meta Regression Analysis of Factors Potentially Related to Heterogeneity[a]

	Unstandardized β (95% CI)	*P* Value
Duration of intervention (in weeks)	0.01 (−0.01 to 0.02)	.31
No. of bias categories rated		
High risk	−0.11 (−0.52 to 0.30)	.57
Low risk	0.26 (0 to 0.52)	.05
Unclear risk	−0.33 (−0.68 to 0.02)	.06
Does the study appear on a recognized trial register?	0.63 (−0.39 to 1.66)	.20
Year of study commencement	−0.04 (−0.20 to 0.12)	.58
Study sample size	0.01 (0 to 0.01)	.07
Type of control condition used (nothing vs neutral wedge; n = 11)[b]	1.07 (0.28 to 1.87)	.01
Did the study have an imputed standard deviation?	−0.88 (−1.75 to −0.01)	.05
Wedge angulation (consistently applied to all participants; n = 8)[c]	−0.16 (−0.50 to 0.19)	.31
Proportion of study sample that was female	0.09 (−2.52 to 2.70)	.94
Mean age of study sample	0.11 (0.06 to 0.16)	<.001
Mean body mass index of study sample (n = 11)[d]	0.04 (−0.09 to 0.17)	.53

[a] Each item was regressed in a univariate fashion against effect size.

[b] For this meta-regression, Toda et al[40] was excluded because it was neither a neutral wedge nor a no treatment control.

[c] Four of the 12 trials either did not report wedge angulation or used various angles of wedge on different participants, and were therefore not included in this meta-regression.

[d] The study by Sattari and Ashraf[8] did not report mean body mass index of the sample and was not included in this meta-regression.