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REVIEW ARTICLE (META-ANALYSIS)

Shoe Lifts for Leg Length Discrepancy in Adults With Common Painful Musculoskeletal Conditions: A Systematic Review of the Literature

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Abstract

Objective: To determine whether shoe lifts effectively treat leg length discrepancy (LLD)—associated morbidities in adults with common painful musculoskeletal conditions.

Data Sources: Trip database, Cochrane Central Register of Controlled Trials database, PubMed database, Physiotherapy Evidence Database, and National Guideline Clearinghouse database. The search was performed in September 2017, was limited to English only, and had no time constraints.

Study Selection: Two reviewers independently determined study eligibility. Inclusion criteria were (1) participants ≥18 years old with musculoskeletal-related complaints and LLD; (2) a shoe lift intervention was used; and (3) the study reported on pain, function, range of motion, patient satisfaction, quality of life, or adverse events. Randomized controlled trials (RCTs) and controlled intervention, cohort, before-and-after, case series, and case report studies were included. Three-hundred and nineteen articles were screened, and 9 guidelines were reviewed.

Data Extraction: We extracted data pertaining to participant demographic characteristics, study setting, recruitment, randomization, method of LLD measurement, shoe lift characteristics, treatment duration, and outcome measures. We included 10 studies, including 1 RCT.

Data Synthesis: LLD was associated with low back pain, scoliosis, and osteoarthritis of the hip and knee. Description of LLD correction strategy was often inadequate. Study quality was very low or poor. In non-RCT studies reporting on the proportion of participants who improved with a shoe lift, 88%±3% of 349 participants treated had partial or complete pain relief (effect size range, 66.7%−100%). All 22 RCT participants receiving treatment experienced pain relief (mean pain reduction, 27±9mm on a 150-mm visual analog scale). Two of 9 guidelines recommended shoe lift use based on consensus and were of moderate-to-high quality.

Conclusions: There is low-quality evidence that shoe lifts reduce pain and improve function in patients with LLD and common painful musculoskeletal conditions. High-quality research evaluating a threshold LLD to correct and a strategy to do so is necessary. Developing an appropriate comparison group to test clinically relevant outcome measures would make a valuable contribution in this regard.

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Musculoskeletal conditions, including osteoarthritis (OA) and mechanical low back pain (LBP), are by far the most common causes of pain and reduced function in developed countries.[1] Leg length discrepancy (LLD), also known as leg length inequality, is a condition in which paired lower limbs are noticeably unequal in length.[2] LLD can be a source of pain, poor function, and disability[2] because of biomechanical, postural, and functional changes in the lower extremity, pelvis, and spine.[1-6] Numerous investigations have explored potential relations between musculoskeletal conditions and LLD.[2] Knee and hip OA in both the longer and shorter limbs (the longer being more frequent), mechanical LBP, and scoliosis are associated with LLD.[1-6] LLD may also arise in patients with joint contractures, or as a complication of joint arthroplasty, resulting in reduced postoperative satisfaction.[7-9]

The most common causes for LLD fall into 1 of 2 categories: (1) anatomic (fracture or trauma to the immature epiphyseal

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growth plate, degenerative disorders, posthip or knee arthroplasty, or idiopathic developmental abnormalities), and (2) functional (joint contractures, adaptive shortening of soft tissues, ligamentous laxity, axial malalignment, or abnormal foot mechanics).[3] A third category, environmental, has been proposed and is related to repeated exposure to uneven ground (eg, consistently running on one side of a crowned road) but may be less commonly seen in the clinical setting.[3,10] LLD may also arise as part of physiologic growth.[11] Further classification may be based on the magnitude of the discrepancy: mild (<30mm), moderate (30−60mm), or severe (>60mm).[3,12-14] LLD affects up to 90% of the general population, and 59% have an LLD of ≥5mm.[13,15]

Treatment of LLD has generally been managed by considering the magnitude of the discrepancy and symptom severity.[3] A shoe lift is one of the most common interventions for LLD and has many advantages, including being noninvasive, inexpensive, easily applied, and potentially removed if no longer desired.[16] Shoe lifts can correct LLD in patients with LBP, hip OA, or knee OA to relieve pain and improve functional outcome.[5,6,17,18] More definitive surgical treatment may also be considered, but this is usually not recommended if the discrepancy is <25mm[16] because of potential surgery-associated morbidities and limited benefit.[19]

The objective of this systematic review was to critically appraise the literature and evidence for the use of shoe lifts for the treatment of LLD in adults with musculoskeletal conditions, including those previously noted. We defined a shoe lift as a shoe modification which raises the entire foot and excluded interventions such as shoe wedges and heel lifts, which only raise specific parts of the foot. We sought evidence to answer 3 fundamental questions to help guide clinical treatment of LLD: (1) Which common painful musculoskeletal conditions associated with LLD show benefit from LLD correction with a shoe lift?; (2) What magnitude of LLD should be corrected and by what proportion (LLD correction strategy)?; and (3) Which clinical outcomes are improved by LLD treatment with a shoe lift?

Clinical practice guidelines are developed to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances.[20] Hence, in addition to the primary studies, we also searched clinical practice guidelines to help answer our clinical questions.

Methods

Data sources and selection of literature

We identified relevant trials by searching the following databases: Trip, Cochrane Central Register of Controlled Trials, PubMed (National Center for Biotechnology Information, U.S. National Library of Medicine, National Institutes of Health), and Physiotherapy Evidence Database. We also searched for potentially relevant articles through the reference lists provided in the included studies. The search was performed in September 2017 and was limited to English only with no time constraints. The search terms used were *shoe lifts*, *shoe*, *leg length inequality*, *limb length inequality*, *limb length discrepancy*, and *leg length discrepancy*. The database search strategies can be found in supplemental appendix S1 (available online only at http://www.archives-pmr.org/). We also searched the National Guideline Clearinghouse database for evidence-based clinical practice guidelines. To minimize the likelihood of omitting a relevant guideline, we manually searched each guideline in the National Guideline Clearinghouse database under the specialty areas of orthopedic surgery, rheumatology, and physical medicine and rehabilitation. Our protocol was established and documented within our research institute prior to initiating the review and was not altered during the course of the review, but it was not registered or publicly available prior to publication.

Because of the paucity of evidence discovered during a preliminary scoping review, we decided to include a broader range of primary study designs including randomized controlled trials (RCTs), controlled intervention studies, before-and-after studies, cohort studies, case series, and case reports.

Selection criteria

A literature search was performed based on the following inclusion criteria: (1) adult participants (≥18y of age) with musculoskeletal symptoms/complaints and LLD; (2) a shoe lifting device was used to raise the whole foot; and (3) findings reported on at least one of the following outcomes: pain, function, range of motion (ROM), patient satisfaction, quality of life, or adverse event. Outcome measure selection and definition was based on those listed in the Western Ontario and McMaster Universities Osteoarthritis Index, a commonly used rheumatologic evaluation scale,[21,22] and the Knee injury and Osteoarthritis Outcome Score, a commonly used orthopedic evaluation scale.[23] Studies reporting only on participants with neurologic or neuromuscular disease and/or healthy volunteers were excluded.

To focus on the specific effect of shoe lifts and avoid confounding effects from biomechanical correction that shoe lifts do not provide, we excluded interventions which did not raise the entire foot (eg, medial or lateral wedges, metatarsal wedges, variable or constant stiffness shoes), other orthotic devices, and barefoot technology. Studies reporting on heel lifts for the treatment of LLD were also excluded because LLD correction with a heel lift was not considered identical to that of a shoe lift (eg, heel lifts lack forefoot height correction which alters ground reaction force moments across the joints,[24] are often used for conditions such as Achilles tendinosis which would not usually be treated with a shoe lift,[25] and have a theoretic risk of plantar-flexion contracture if used for long periods[26]).

Article titles and abstracts were independently screened by 2 review authors (E.T.G. and B.B.G.). Both reviewers independently screened full texts of potentially relevant studies. Differences in opinion were discussed between the 2 reviewers, and decisions were reached by consensus. The risk of bias and quality of the included studies were assessed independently by the same reviewers. Disagreements were resolved by consensus.

List of abbreviations:

GRADE	**Grading of Recommendation, Assessment, Development and Evaluation**
LBP	**low back pain**
LLD	**leg length discrepancy**
OA	**osteoarthritis**
RCT	**randomized controlled trial**
ROM	**range of motion**
THA	**total hip arthroplasty**
VAS	**visual analog scale**

We reviewed guidelines relevant to LLD and musculoskeletal conditions, evaluating the most recent version of included guidelines. Based on this search, we reviewed 9 guidelines: the American College of Rheumatology OA guidelines,[27] Osteoarthritis Research Society International guidelines,[28,29] European League Against Rheumatism OA guidelines,[30] the National Institute for Health and Care Excellence guidance,[31] the Toward Optimized Practice program's *Guideline for the Evidence-Informed Primary Care Management of Low Back Pain*,[32] the American College of Occupational and Environmental Medicine guidelines,[33,34] and the *Prescription Custom Foot Orthoses Practice Guidelines* of the American College of Foot and Ankle Orthopedics and Medicine.[35]

Data extraction and quality assessment

The Cochrane risk of bias tool was used to assess RCTs for risk of bias. This tool assesses 5 domains (selection, performance, detection, attrition, and reporting bias).[36] Because this tool should not be used to evaluate non-RCTs,[36] we assessed non-RCT study quality using the National Institutes of Health quality assessment tool for controlled intervention studies, before-and-after studies, cohort studies, and case series studies.[36,37] For case reports, only applicable criteria from the National Institutes of Health case series assessment tool were considered. Poor study quality is associated with high risk of bias.[36,38]

The following data were extracted from each study to describe study characteristics, assess risk of bias or study quality, and assess effects of shoe lifts: characteristics of the participants, setting, recruitment, randomization, method of LLD measurement, type of shoe lift, amount of correction, duration of correction, outcome measures, and results.

We assessed the quality and reporting of guidelines with the Appraisal of Guidelines for Research and Evaluation. The Appraisal of Guidelines for Research and Evaluation addresses the issue of variability in the quality of practice guidelines.[39] We also assessed the overall quality of the evidence for each outcome with the Grading of Recommendation, Assessment, Development and Evaluation (GRADE) approach.[40] The GRADE approach specifies 4 levels of quality: high, moderate, low, and very low (supplemental table S1). Quality of a body of evidence involves consideration of 5 factors: limitation in the design or execution, inconsistency of results, indirectness of evidence, imprecision, and publication bias. We analyzed RCTs separately from nonrandomized studies; therefore, there is a separate GRADE summary of findings for non-RCTs.

Although we did not register our protocol, we otherwise adhered to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses statement for systematic reviews.[41]

Data synthesis and analysis

Data were not pooled because of study design and outcome measure heterogeneity. We present a summary of available results for the included studies. For dichotomous outcomes, we report the percentage improvement. For continuous outcomes, we analyzed mean differences with SD. We report the range of effect sizes across studies for each outcome. We analyzed non-RCTs separately from RCTs.

Results

Selection of studies and study characteristics

We identified 401 articles through database searching and 4 additional articles through citation searching. We excluded 86 duplicate articles. We screened 319 articles. After reviewing the titles and abstracts, 297 citations were excluded for not meeting the eligibility criteria. We excluded a total of 12 studies after full-text review. Eight studies were excluded based on their participants' characteristics (6 studies included healthy subjects and 2 studies included participants <18y of age). A study by Brady et al[3] was excluded because the study design did not meet criteria. Three studies described a different type of intervention.[7,9,42] We excluded a study by Bhave et al[9] that identified functional problems and treatment solutions using a customized multitreatment regimen after total hip arthroplasty (THA) or total knee arthroplasty. A shoe lift was introduced to only 4 of 118 participants, and the effect of the shoe lift intervention could not be separated from other interventions in the regimen. We excluded another study by Bhave et al[43] involving participants with postoperative soft tissue—related functional problems 3 months after THA. Five of the 78 participants received shoe lifts for LLD as part of a multi-intervention regimen, and the effect could not be separated from the other interventions. Figure 1[44-52] depicts the review process.

We identified 11 publications for inclusion that met our eligibility criteria: 1 RCT,[4] 1 controlled intervention study,[53] 2 before-and-after studies,[17,54] 1 noncomparative cohort,[55] 3 case series,[56-58] and 3 case reports.[59-61] Two of the case reports presented results for the same participant and were considered to be a single study.[60,61] Ten studies were therefore included. Their characteristics are summarized in table 1. The sample size ranged from 1 to 290. Age range was described in 7 studies. Three studies described both men and women using a shoe lift. Two case reports described only female cases. Six studies did not provide a clear description of the number of men and women using a shoe lift. LLD was measured in all participants ranging from 0 to 45mm. Study characteristics are summarized in table 1.

We reviewed 9 guidelines relevant to LLD and musculoskeletal conditions. We identified 2 clinical practice guidelines that recommended the use of shoe lifts for LLD in low back disorders[34] and hip and groin disorders.[33] We found 1 guideline that recommended shoe modification for OA.[35] The recommendations from all 3 guidelines were based on consensus.

Risk of bias and study quality assessment

For the non-RCTs, study populations were poorly defined[17,53-55,58] without justification for the sample size.[17,54,55] Interventions were often heterogenous or vaguely described,[17,53-56,58] with a lack of well-defined, valid, reliable outcome measures implemented consistently across all participants.[54-56,58] Often no statistical analysis was described or used.[54-56,58] Overall, non-RCT quality was graded as poor for all included studies, indicating a high risk of bias. Table 2 summarizes the sources and risks of bias for each study.

For the RCT,[4] internal validity was affected by selection bias because of inadequate random sequence generation for participant allocation and lack of concealment of allocation once participants were assigned to a group. There was risk of performance bias because of lack of blinding of participants and risk of detection

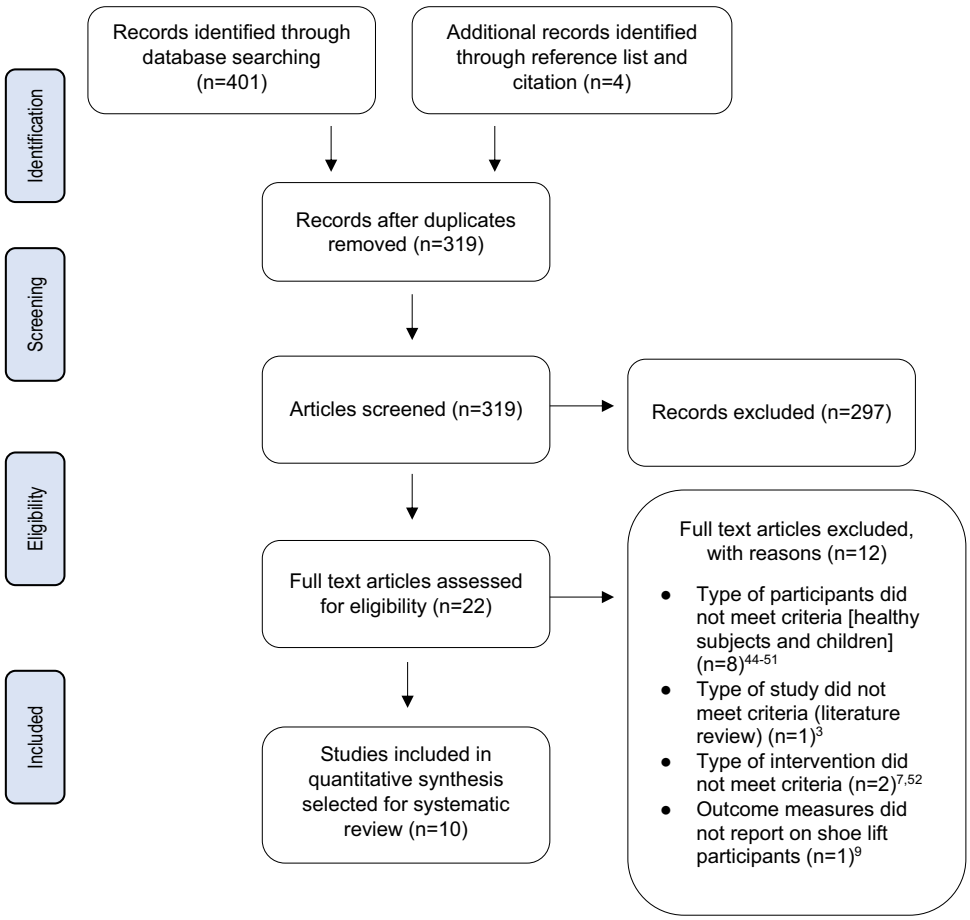

Fig 1 Preferred Reporting Items for Systematic Reviews and Meta-Analyses flow diagram of search results.

bias because of lack of blinding of outcome assessors. Overall, the risk of bias was high. Table 2 summarizes the sources and risks of bias for the RCT.

Painful conditions associated with LLD that benefit from correction with a shoe lift

LLD in participants with LBP was described in 7 studies.[4,17,54-58] One study reported participants with an orthopedic injury to the ankle, foot, or leg.[53] Another study reported participants after THA,[17] and 3 studies reported participants with hip symptoms.[55,58,59] Only 1 single-subject study discussed knee pain.[58] Delacerda,[60] Delacerda,[61] and colleagues reported a case of a participant who suffered damage to the distal epiphyseal plate of the right tibia at an early age, resulting in a shorter right leg. Helliwell[56] reported participants having LBP, pain in the sciatic nerve distribution (unilateral and bilateral), scoliosis, pelvic tilt, and painful restriction of the lumbar spine. For all the conditions identified, participants treated with a shoe lift showed improvement in at least 1 clinical outcome (effect of shoe lift on clinical outcome is subsequently discussed).

LLD correction strategy

The amount of LLD correction provided by a shoe lift varied among the included studies. Shoe lift characteristics, LLD correction strategies, and corresponding results are described in table 3. The shoe lift construction material was described in 3 studies and included elastic smooth plastic material, Nickelplast sheet, crepe sheet, and/or cork and plastic.[4,17,60]

The correction strategy to lift the leg was inadequately described in most of the studies and not at all in 5 studies.[53,56,58-60] The included studies used different strategies for adjustment of the lift height. Giles and Taylor[54] used a shoe raise equal to the magnitude of LLD, and manipulation therapy was introduced in combination with the shoe raise. Friberg[55] used lifts that were a few millimeters less than the measured LLD. Defrin et al[4] used lifts equal to the LLD minus 10%. Gofton[57] provided lifts that fully corrected the participants' LLD (9−10mm). Golightly,[17] Defrin,[4] Friberg,[55] and colleagues gradually adjusted lift height over 7 to 10 days, every 2 to 3 days, or stepwise, respectively. In the Nellensteijn et al study,[59] the participant was prescribed a 40-mm shoe lift.

Effect of shoe lift on clinical outcome

Pain

Eight non-RCTs showed a reduction in pain for participants with LLD and LBP, hip pain, knee pain, or orthopedic conditions (injury to the ankle, foot, or leg). All studies but 1 study[53] reported the proportion of participants who experienced pain relief. Of these studies, 384 received shoe lifts and 342 (86%±3%)

Table 1 Characteristics of included studies

Study, Type of Design	Study Population	No. of Patients Treated With Shoe Lifts	LLD Measurement Method	LLD Range and Joint(s) Assessed	Pain	Function/ Disability	ROM	Other Outcome
Defrin et al,[4] RCT	LBP	22 (mean age, 43.4±11.8y)	Anatomic (ultrasound)	LLD (≤10mm) and LBP	✓	✓	NA	NA
Delacerda and Wickoff[60] and Delacerda and McCrory,[61] case report*	Damage to distal epiphyseal plate of right tibia	1 (30 women)	Anatomic (standing blocks)	LLD (28.6mm)	NA	NA	NA	Oxygen consumption and kinematic energy analysis
Friberg[55] (noncomparative cohort)	LBP, unilateral hip symptoms	290	Anatomic (radiograph)	LLD (<5mm, >5mm, >10mm, >15mm) and LBP	✓	NA	NA	NA
Giles and Taylor,[54] before and after†	LBP and scoliosis	15† (age range, 19 to >50y)	Anatomic (radiograph)	LLD (≥9mm) and LBP	✓	NA	✓	NA
Gofton,[57] case series	LBP	10 (6 men/4 women; age range, 36–59y)	Clinical method (not described) and anatomic radiograph	LLD (≥10mm) and LBP	✓	NA	NA	NA
Golightly et al,[17] before and after	Chronic LBP	12 (6 men/6 women; age range, 19–62y)	Anatomic (bony landmarks and radiograph)	LLD (6.4–22mm) and LBP	✓±	✓±	NA	NA
Helliwell,[56] case series	LBP, sciatica, scoliosis	18	Anatomic (bony landmarks for all; radiograph for 15)	LLD (≥20mm) and LBP	✓	NA	NA	NA
Kipp et al,[53] controlled intervention	Orthopedic injury to the ankle, foot, or leg treated with a walking boot	17 (mean age, 43.4±13.8)	Thickness of boot sole	NA	✓	✓	✓	Muscle strength
Nellensteijn et al,[59] case report	THA	1 (woman, 85y of age)	Anatomic (standing blocks)	LLD (45mm) and LBP	✓	NA	NA	NA
Rothenberg,[58] case series	LBP, hip and knee discomfort	12	Anatomic (radiograph)	LLD (6–38mm) and LBP, hip pain, or knee pain	✓	NA	NA	NA

Abbreviations: ✓, beneficial effect (improvement); ✓±, 66.7% improved and 33.3% no change; NA, not assessed.

* Delacerda and Wikoff[60] is a companion case report of Delacerda and McCrory[61] with different outcomes measured in each: oxygen consumption in Delacerda[61] and kinematic analysis in Delacerda.[60]

† Five participants received both shoe lifts and manipulation therapy.

Table 2 Results of methodologic assessment (risk of bias)

Study	Assessment Tool Used	Source of Bias	Overall Risk of Bias
Defrin et al[4]	Cochrane risk of bias tool	Inadequate random sequence generation (selection bias) No allocation concealment (selection bias) No blinding of participants and personnel (performance bias) No blinding of outcome assessment (detection bias)	High
Delacerda and Wickoff[60] and Delacerda and McCrory[61]	NIH quality assessment tool (case series, criteria 1, 5, 6, 9)	Subject selection (selection bias) No allocation concealment (selection bias) No blinding of participants and personnel (performance bias) No blinding of outcome assessment (detection bias)	High
Friberg[55]	NIH quality assessment tool (cohort)	No random sequence generation (selection bias) No blinding of participants and personnel (performance bias) No blinding of outcome assessment (detection bias) Lack of control	High
Giles and Taylor[54]	NIH quality assessment tool (before and after)	No random sequence generation (selection bias) No allocation concealment (selection bias) No blinding of participants and personnel (performance bias) No blinding of outcome assessment (detection bias)	High
Gofton[57]	NIH quality assessment tool (case series)	Subject selection (selection bias) No allocation concealment (selection bias) No blinding of participants and personnel (performance bias) No blinding of outcome assessment (detection bias) No result (reporting and attrition bias) Lack of control	High
Golightly et al[17]	NIH quality assessment tool (before and after)	Patient preference of treatment (selection bias) No blinding of participants and personnel (performance bias) No blinding of outcome assessment (detection bias)	High
Helliwell[56]	NIH quality assessment tool (case series)	Subject selection (selection bias) No allocation concealment (selection bias) No blinding of participants and personnel (performance bias) No blinding of outcome assessment (detection bias)	High
Kipp et al[53]	NIH quality assessment tool (controlled intervention studies)	Inadequate random sequence generation (selection bias) No allocation concealment (selection bias) No blinding of participants and personnel (performance bias) No blinding of outcome assessment (detection bias)	High
Nellensteijn et al[59]	NIH quality assessment tool (case series, criteria 1, 5, 6, 9)	Subject selection (selection bias) No allocation concealment (selection bias) No blinding of participants and personnel (performance bias) No blinding of outcome assessment (detection bias)	High
Rothenberg[58]	NIH quality assessment tool (case series)	Subject selection (selection bias) No allocation concealment (selection bias) No blinding of participants and personnel (performance bias) No blinding of outcome assessment (detection bias) Lack of control	High

Abbreviation: NIH, National Institutes of Health.

Table 3 Characteristics of shoe lift, correction strategy, and outcomes

Study, Type of Design	Characteristics of the Shoe Lift	Strategy and Amount of Correction	Result
Defrin et al,[4] RCT	Shoe insert was made of elastic smooth plastic material of 2-mm thickness.	The height was adjusted gradually (2mm each) every 2d until desirable height was achieved. The correction of LLD was equal to the LLD minus 10%.	The mean duration ± SD of wearing the shoe insert was 10±2wk. VAS scores for pain measurement decreased significantly after wearing the shoe lift, to a level of 20±16 ($P<.001$), 5 patients obtained complete relief of pain. Shoe inserts significantly reduced both LBP intensity and disability score. Sixteen patients had substantial pain reduction, ranging between 33% and 72% (mean, 48.5%). One patient did not have pain relief. Follow-up period: 10wk (mean).
Delacerda and Wickoff[60] and Delacerda and McCrory,[61] case report	A lift constructed of cork and plastic.	No description.	The use of a lift approximately equalized the time durations for the phases of a gait cycle and reduced the total kinetic energy of the gait cycle. Follow-up period: outcomes measured immediately after LLD correction.
Friberg,[55] noncomparative cohort	No description.	The sole was raised with an insert in the shoe for LLD up to 10mm and an external elevation for an LLD of >10mm. Lift elevation was a few millimeters less than the measured LLD. For marked LLD, the lift was implanted in steps, never exceeding the height of the sole by >5mm.	Ninety-six patients out of 128 had been symptom free of LBP, and 20 had symptoms alleviated after using shoe lift. Twelve patients found no relief. Sixty-one patients out of 83 had been symptom free of sciatica, and 13 had symptoms alleviated after using shoe lift. Ten patients found no relief. Fifty-six patients out of 79 with hip symptoms were symptom free, and 12 had symptoms alleviated after using shoe lift. Eleven patients found no relief. Follow-up period: 6mo.
Giles and Taylor,[54] before and after	No description.	The raise of the heel was equal to the difference in leg length, and the raise of the sole was 5mm less. Patients with >9mm LLD received shoe raise therapy and if LBP persisted for 1mo, they received lumbosacral manipulation.	Reduction in scoliosis with the use of a shoe raise and lumbosacral manipulation in 4mo after treatment. Some patients stated that they no longer experienced LBP as long as they wore their shoe raise. Follow-up period: 24mo.
Golightly et al,[17] before and after	Heel lift and inserts were constructed from sheets of Nickelplast. External shoe lift was constructed from crepe sheets.	Magnitude of each subject initial lift correction was 3.18mm, which was increased every 7–10d. The correction did not exceed 9.54mm. Lift height was a mean 7.7mm, and lift correction was a mean 61.3%.	The mean number of days ± SD between pre and postlift testing was 28±13.3. Nine of 12 patients demonstrated improvement in pain and function outcome measures. One third or less of the subjects demonstrated no change in the outcome measures. Follow-up period: 1mo.
Gofton,[57] case series	No description.	A lift was placed on heel or both heel and sole when the heel raise alone was not tolerated.	No description. Follow-up period: 3–11y.

(*continued on next page*)

Table 3 (*continued*)

Study, Type of Design	Characteristics of the Shoe Lift	Strategy and Amount of Correction	Result
Helliwell,[56] case series	No description.	No description.	Eight out of 18 patients were pain-free after the use of shoe lift. Five patients had substantial improvement. Three patients had moderate improvement. Two patients had no improvement. Follow-up period: at least 3mo.
Kipp et al,[53] controlled intervention	Evenup.	No description.	The mean number of hours ± SD subjects wore the walking boot was 334±265 for the Evenup group. Subjects in the intervention group also wore the Evenup a mean of 201±126h. LEFS, OSW, NPRS, and AROM improved significantly in all participants ($P=.0001$).
Nellensteijn et al,[59] case report	No description.	The patient was prescribed a 40-mm heel lift.	After 6wk, the pain had disappeared completely. Follow-up period: 6wk.
Rothenberg,[58] case report	No description.	No description. Mostly a lift of 9–10mm was used.	Six patients had complete LBP relief after using shoe lift. Two patients had partial LBP relief after using shoe lift. Three patients had no response to shoe lift. One patient was noncomplaint. Follow-up period: not described

Abbreviations: AROM, active ROM; LEFS, Lower Extremity Functional Scale; NPRS, numerical pain rating scale; OSW, Oswestry Low Back Pain Disability Questionnaire.

improved. The effect size ranged from 66.7% to 100%. It is uncertain if this improvement would have been observed without the shoe lifts because there was no comparator group that did not receive shoe lifts in the 8 non-RCTs.

A visual analog scale (VAS) for pain was used by Golightly,[17] Defrin,[4] and colleagues. Golightly[17] reported that 75% (n=9) of participants with LLD experienced relief of LBP after intervention with lift therapy with a mean pain reduction of 31±14mm for general pain and 26±13 for standing pain after 1 month of treatment. Defrin[4] (the only RCT) used a 150-mm VAS and reported that 22.7% (5/22) of participants experienced complete pain relief, 72.7% (16/22) had substantial pain reduction, and 4.5% (1/22) had a small pain reduction. The mean pain reduction was 27±9mm in the treatment group compared with an increase of 4±5mm in the control group. They concluded that their shoe lift was effective for LBP because the subjects did not return to receive alternative treatment in the year after the study; however, this was not verified, and other possible reasons for loss to follow-up (eg, participant frustration because of lack of benefit) were not explored. Kipp et al[53] did not report the total number of participants who experienced pain relief with the Evenup[a], but did show a mean pain reduction of 61±29mm using a numerical pain rating scale (a segmented variation of the VAS), but this was not significantly different from the control group (no Evenup; mean reduction, 59±26mm). Table 3 summarizes these findings.

The remaining studies did not provide a clear pain measurement tool description. For example, Giles and Taylor[54] reported that symptoms for subjects with LBP and LLD generally improved and some participants stated that they no longer had LBP as long as they wore their shoe lift. Friberg[55] reported that after correction of the LLD, 75% (n=96) of participants with LBP, 70% (n=56) of the participants with hip symptoms, and 73.4% (n=61) of participants with sciatica were symptom-free. Gofton[57] reported that using a shoe lift can stop a persistent recurrent symptom complex of low back discomfort. Although there was lack of a control group in all studies reporting the proportion of patients showing pain reduction except the RCT,[4] the percentage of patients who improved after treatment with a shoe lift was similar when comparing the non-RCT and RCT results. The overall quality of evidence for the treatment of pain using a shoe lift was considered very low using GRADE (tables 4 and 5).

Function/disability

The use of shoe lifts was found to improve function in participants with LLD and back pain, after THA, or after orthopedic injury to the ankle, foot, or leg in 3 studies.[4,17,53] In the controlled intervention study, function was measured using 2 scales: the Lower Extremity Functional Scale (consisting of 20 items scored from 0 [unable] to 4 [no difficulty], with a maximum of 80 points possible), and a Modified Oswestry Low Back Pain Disability Questionnaire (consisting of 10 questions, scored from 0 to 5, with a maximum of 50 points possible). Both scales showed improvement of functional status for treatment and comparator groups ($P=.001$); however, there was no significant difference found between the groups.[53] In the before-and-after study, functional evaluation included a disability questionnaire modeled from version 2 of the Oswestry Disability Index, consisting of 10 questions that closely reflected the difficulties encountered by persons with LBP during daily activities (eg, sitting, standing, walking, sleeping).[17] Participants had less disability after the intervention ($P=.001$). For the RCT, there was a mean functional improvement of 1.1±2.1

Table 4 GRADE evidence summary for nonrandomized studies

Outcomes	Effects of Shoe Lifts for LLD	No. of Participants (Studies)	Quality of Evidence (GRADE)	What it Means
Pain	Nine studies showed partial or complete pain relief ranging from 66.7% to 100%	381 (9 studies)	⊕◯◯◯ Very low*,†	We are uncertain whether shoe lifts improve pain in adults with LLD
Function/disability	Three studies showed improvement in function/disability ranging from 75% to 100%	34 (3 studies)	⊕◯◯◯ Very low*,†	We are uncertain whether shoe lifts improve function/disability in adults with LLD
ROM	Two studies showed improvement in ROM (lumbar spine and hip)	20 (2 studies)	⊕◯◯◯ Very low*,†	We are uncertain whether shoe lifts improve ROM in adults with LLD

NOTE. Patient or population: adults with LLD and musculoskeletal conditions. Setting: general population or patients seen at a clinic. Intervention: shoe lifts. GRADE Working Group grades of evidence include (1) high quality: we are very confident that the true effect lies close to that of the estimate of the effect; (2) moderate quality: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different; (3) low quality: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect; and (4) very low quality: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect. ⊕◯◯◯, visual representation of the quality rating.

* Downgraded for high risk of bias and study design (with no control groups).

† Downgraded for imprecision of results (less than optimal sample size).

points compared with the control group who experienced a functional decline of 0.3±1.1 points on the Roland-Morris Disability Questionnaire, a self-reported 24-point scale for participants with LBP evaluating a number of factors, including back movement and positioning, dressing, and mobility.[4] The overall quality of the evidence for improvement in function using a shoe lift was very low using GRADE (see tables 4 and 5).

Range of motion

Two studies measured ROM.[53,54] Kipp et al[53] measured ankle ROM using a 30 cm goniometer. Dorsiflexion, plantar flexion, inversion, and eversion improved in all participants ($P=.001$), but no differences were found between groups.[53] Giles and Taylor[54] measured straight leg raising and ROM of the lumbar spine using a Leighton flexometer and spine and hip flexion using a perspex calibrated device. This study showed that shoe lifts improved ROM. The overall quality of evidence for ROM was very low using GRADE (see table 4).

Patient satisfaction

No studies evaluated patient satisfaction.

Quality of life

No studies evaluated quality of life.

Adverse events

No serious adverse events were reported in any of the included studies; however, methods for tracking and reporting such events were not described in any study. Defrin et al[4] noted that one disadvantage of using a shoe insert to correct LLD is that it

Table 5 GRADE evidence summary for RCT

Outcomes	Anticipated Absolute Effects ± SD		No. of Participants (Studies)	Quality of Evidence (GRADE)	What it Means
	Risk With Control	Risk With Shoe Lifts			
Pain VAS from 0 to 150mm (lower score means better) Follow-up: 5–12wk	Mean reduction in pain scores in the control group was 4±5mm	Mean reduction in pain scores in the intervention group was 27±9mm	33 (1 RCT)	⊕◯◯◯ Very low*,†	We are uncertain whether shoe lifts improve pain in adults with LLD
Disability RMDQ score from 0 to 24 (lower score means better) Follow-up: 5–12wk	Mean change in disability scores in the control group was 0.3±1.1	Mean improvement in disability scores in the intervention group was 1.1±2.1	33 (1 RCT)	⊕◯◯◯ Very low*,†	We are uncertain whether shoe lifts improve disability in adults with LLD

NOTE. Patient or population: adults with LLD and LBP. Setting: outpatient physical therapy clinic. Intervention: shoe lifts. Comparison: control group (did not receive shoe lift). The risk in the intervention group is based on the assumed risk in the comparison group and the relative effect of the intervention. GRADE Working Group grades of evidence include (1) high quality: we are very confident that the true effect lies close to that of the estimate of the effect; (2) moderate quality: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different; (3) low quality: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect; and (4) very low quality: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect. ⊕◯◯◯, visual representation of the quality rating.

Abbreviation: RMDQ, Roland-Morris Disability Questionnaire.

* Downgraded 2 levels for high risk of bias: no random sequence generation, no allocation concealment, and no blinding.

† Downgraded for imprecision of results (less than optimal sample size).

Table 6 Quality assessment of guidelines which mention shoe lifts or shoe modifications

AGREE II Domain	ACOEM Guidelines (LBP)	ACOEM Guidelines (Hip and Groin)	ACFAOM Guidelines
Domain 1: scope and purpose (items 1–3)	21	21	18
Domain 2: stakeholder involvement (items 4–6)	19	19	14
Domain 3: rigor of development (items 7–14)	56	56	42
Domain 4: clarity of presentation (items 15–17)	17	17	18
Domain 5: applicability (items 18–21)	12	12	10
Domain 6: editorial independence (items 22–23)	14	14	8
Overall assessment (items 24–25)	5/recommended	5/recommended	4/recommended
Score	144/168	144/168	114/168

Abbreviations: ACFAOM, American College of Foot and Ankle Orthopedics and Medicine; ACOEM, American College of Occupational and Environmental Medicine; AGREE II, Appraisal of Guidelines for Research and Evaluation.

requires space in the shoe and therefore may be less comfortable with sandals.

Clinical guidelines and practice recommendations

Six of the 9 musculoskeletal guidelines made no reference to the use of shoe lifts or surgery for the treatment of LLD. The 2 guidelines that considered shoe lifts each recommended their use for symptomatic participants with LLD.[33,34] The third guideline recommended that shoe modification be considered for the treatment of LLD.[35] All the recommendations were consensus-based. Two guidelines recommended the use of shoe lifts for people with LBP and LLD of >2cm.[33,34] The other guideline discussed participant foot and ankle OA,[35] but did not specify an LLD magnitude that should be treated. One of the included clinical guidelines commented that shoe lifts have few adverse effects, but no supporting data were cited.[33] The 3 guidelines were of moderate-to-high quality (table 6 and supplemental table S2).

Discussion

In this review, we evaluated the evidence to help answer fundamental questions related to the treatment of LLD associated with commonly encountered painful musculoskeletal conditions: (1) Which common painful musculoskeletal conditions associated with LLD benefit from LLD correction with a shoe lift?; (2) What magnitude of LLD should be corrected and by what proportion?; and (3) Which clinical outcomes are improved by LLD treatment with a shoe lift?

Our search identified 10 studies meeting eligibility criteria. We found studies reporting on participants with LLD and LBP, OA of the hip or knee, scoliosis, orthopedic injury to the ankle, foot, or leg, and damage to the distal epiphyseal plate of the right tibia. In the included studies, shoe lifts were described as being effective for participants with hip, knee, and back pain.

Shoe lift therapy studies are conflicted in their description of the magnitude of LLD that should be considered normative, and which should be considered for treatment. There is also disagreement about shoe lifts being the optimal treatment for LLD of >20-mm magnitude.[18] At this magnitude, some suggest surgical correction may be appropriate, but this is not widely agreed on.[2] Anecdotally, 0.5-in, 10-mm, or 20-mm differences in leg length would be considered normative, not requiring correction[62,63]; however, at least 4 of our included studies treated LLD <10mm when associated with a painful musculoskeletal condition, with all noting a treatment benefit[4,17,55,58] (see table 1). Two of the included clinical guidelines suggested a magnitude that should be corrected, that being >2cm.[33,34] It has been proposed that individuals with a high functional level of activity may benefit from these lower-magnitude corrections[2]; however, this could not be confirmed by the data in the included studies because the participants' level of activity was not always described.[4,17,55,58]

There was little consistency regarding the proportion of LLD to correct. This was guided using percentage of the LLD (ranging from about 60% to 90%), or magnitude (often a few millimeters less than the measured LLD), and was done gradually by some or all at once by others (see table 3 for details). We were therefore unable to determine an evidence-based approach to the appropriate magnitude of correction or the period over which an LLD should be corrected. None of the included clinical guidelines addressed this issue. Anecdotally, a recently acquired LLD (eg, posttrauma) may be fully corrected rapidly to avoid LLD-related pain, whereas chronic cases may benefit from partial correction because of adaptation to unequal limb lengths. Various approaches to correcting such chronic LLDs exist, including correcting up to about two-thirds of the LLD, 75% of the LLD, or within 1cm of the LLD.[26,63]

A variety of outcomes were assessed using various measurement tools in different patient populations, making comparison among studies difficult. Pain was assessed in all but 1 study.[59] After treatment, pain was reported to be improved for either most or all of the participants, regardless of the magnitude of LLD (range, 0–45mm). In the included clinical guidelines, shoe lifts were recommended for the treatment of pain, but none of them recommended a specific outcome measurement tool. Function and disability outcomes were assessed in 3 studies.[4,17,53] Again, each study reported positive results. For both outcomes however, the overall quality of evidence was very low, and we have little confidence in the effect estimate. No studies reported on patient satisfaction or quality of life, which are considered to be essential outcome measures for evaluating orthotic devices.[64] These outcomes should likely be considered for inclusion in future studies.

Many of the studies included in this review are a decade old or older. Much of the recent literature regarding the management of common painful musculoskeletal conditions has focused on advanced, interventional treatments (eg, image-guided injections, mesenchymal stem cell therapy), each at high cost with risk of adverse outcomes.[44,65,66] Shoe lifts on the other hand are inexpensive, noninvasive, and reversible. Additionally, there is likely minimal risk associated with prescribing a shoe lift

because none of the studies included in this review articulate concerns regarding adverse events from this treatment (although methods for tracking such events were not described in any study). This is supported by expert opinion in one of the included clinical guidelines which described shoe lifts as having few adverse effects.[33]

How then should clinicians proceed given the available evidence? Although the quality of evidence supporting shoe lifts for the correction of LLD in patients with symptoms related to common musculoskeletal conditions is generally low, the included studies predominantly demonstrate improvement in measured outcomes. Two clinical guidelines have also endorsed the use of shoe lifts for LBP, hip pain, and foot or ankle OA.[33-35] Based on the available data, we agree that shoe lifts should be considered when treating patients with LLD and musculoskeletal-related pain. High-quality, controlled clinical studies are required to determine the optimal treatment approach and evaluation. The development of an appropriate comparison group that allows blinding of participants and/or evaluators would be helpful in this regard. Such comparators could include a shoe modification with little to no treatment effect, or for larger LLDs, a direct comparison with surgical intervention while taking care to maintain evaluator blinding.

Review limitations

Limitations include a low number of studies meeting inclusion criteria, heterogeneity of the participant populations, and a scarcity of high-quality trials. Studies of LLD to date have predominantly had small sample sizes, were uncontrolled, and likely suffered from the introduction of bias. We found low-quality studies suggesting the effectiveness of shoe lifts on pain and functional outcomes in patients with musculoskeletal conditions. Most (90%) of the studies had <50 participants, possibly resulting in imprecision of the reported outcomes. Because all studies suffer from selection, detection, and performance bias, the results could be influenced by knowledge of the intervention and possibly by the selection of participants on the basis of likelihood of response. Because of the very low quality of the included studies, it must be stated that there is uncertainty as to whether shoe lifts are effective.

Conclusions

We sought evidence to answer fundamental questions for guiding clinical treatment of LLD for common painful musculoskeletal conditions. In the setting of mechanical LBP and hip and knee OA, correction of LLD using a shoe lift may reduce pain, improve function, and increase ROM; however, these benefits remain uncertain because of very low-quality evidence. We were unable to make evidence-based conclusions regarding the magnitude or proportion of LLD that should be corrected. More rigorous, high-quality studies evaluating which LLD-associated conditions benefit from shoe lift correction, shoe lift correction strategy, and relevant patient outcomes are required to guide clinical treatment. An appropriate comparison group would be helpful in this regard.

Suppliers

a. Evenup; ProCare.

Keyword

Leg length inequality; Rehabilitation; Review, systematic

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Supplemental Appendix S1 Search strategies (performed September 25, 2017)

Cochrane Central Register of Controlled Trials		
Search strategy		Results
#1	Shoe lifts: ti, ab, kw (word variations have been searched)	16
#2	Adult	456,981
#3	#1 and #2	14

Physiotherapy Evidence Database	
Search terms	Results
Shoe lifts	0
Shoe	103
Leg length discrepancy	6
Leg length inequality	0
Limb length discrepancy	3
Limb length inequality	1
Total	113

Trip Database	
Search terms	Results
Shoe lifts	246

PubMed		
Search strategy		Results
#1	shoes[MeSH Terms]	5591
#2	shoes	7730
#3	shoe	9758
#4	#1 or #2 or #3	9758
#5	lifting[MeSH Terms]	2321
#6	lifting	14,430
#7	lift	22,443
#8	#5 or #6 or #7	22,443
#9	#4 AND #8	137
#10	leg length inequality[MeSH Terms]	2810
#11	leg	145,918
#12	length	583,569
#13	inequality	422,057
#14	#11 AND #12 AND #13	3078
#15	leg length inequality	2948
#16	discrepancy	37,730
#17	#11 AND #12 AND #16	1538
#18	leg length discrepancy	3676
#19	leg length discrepancy[MeSH Terms]	2810
#20	#10 or #14 or #15 or #17 or #18	3806
#21	#9 AND #20	28

Abbreviation: MeSH, Medical Subject Headings.

Supplemental Table S1 Grading of the quality of the evidence

Quality Level	Definition
High	We are very confident that the true effect lies close to that of the estimate of the effect
Moderate	We are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different
Low	Our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect
Very low	We have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect

NOTE. We used the GRADE approach to assess the quality of the evidence.[34] There are 4 categories: high, moderate, low, and very low. Factors that may decrease the quality level of a body of evidence (down 1 or 2 levels) include: (1) limitations in the design and implementation of available studies suggesting high likelihood of bias, (2) indirectness of evidence (indirect population, intervention, control, and outcomes), (3) unexplained heterogeneity or inconsistency of results (including problems with subgroup analyses), (4) imprecision of results (wide confidence intervals), and (5) high probability of publication bias.

Supplemental Table S2 Quality assessment of guidelines which mention shoe lifts or shoe modifications using AGREE II

AGREE II Domain	Items	ACOEM Guidelines (LBP)	ACOEM Guidelines (Hip and Groin)	ACFAOM Guidelines
Domain 1: scope and purpose	1. The overall objective(s) of the guideline is (are) specifically described.	7	7	6
	2. The health question(s) covered by the guideline is (are) specifically described.	7	7	5
	3. The population (patients, public, etc) to whom the guideline is meant to apply is specifically described.	7	7	7
Domain 2: stakeholder involvement	4. The guideline development group includes individuals from all the relevant professional groups.	6	6	4
	5. The views and preferences of the target population (patients, public, etc) have been sought.	6	6	3
	6. The target users of the guideline are clearly defined.	7	7	7
Domain 3: rigor of development	7. Systematic methods were used to search for evidence.	7	7	7
	8. The criteria for selecting the evidence are clearly described.	7	7	6
	9. The strengths and limitations of the body of evidence are clearly described.	7	7	5
	10. The methods for formulating the recommendations are clearly described.	7	7	6
	11. The health benefits, side effects, and risks have been considered in formulating the recommendations.	7	7	5
	12. There is an explicit link between the recommendations and the supporting evidence.	7	7	5
	13. The guideline has been externally reviewed by experts prior to its publication.	7	7	3
	14. A procedure for updating the guideline is provided.	7	7	5
Domain 4: clarity of presentation	15. The recommendations are specific and unambiguous.	6	6	6
	16. The different options for management of the condition or health issue are clearly presented.	5	5	6
	17. Key recommendations are easily identifiable.	6	6	6
Domain 5: applicability	18. The guideline describes facilitators and barriers to its application.	0	0	0
	19. The guideline provides advice and/or tools on how the recommendations can be put into practice.	4	4	3
	20. The potential resource implications of applying the recommendations have been considered.	4	4	3
	21. The guideline presents monitoring and/or auditing criteria.	4	4	4
Domain 6: editorial independence	22. The views of the funding body have not influenced the content of the guideline.	7	7	4
	23. Competing interests of guideline development group members have been recorded and addressed.	7	7	4
Overall assessment	24. Rate the overall quality of this guideline.	5	5	4
	25. I would recommend this guideline for use.	Yes	Yes	Yes
Score		144/168	144/168	114/168

Abbreviations: ACFAOM, American College of Foot and Ankle Orthopedics and Medicine; ACOEM, American College of Occupational and Environmental Medicine; AGREE II, Appraisal of Guidelines for Research and Evaluation.