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# Foot Orthotics for Painful Medial Compartment Knee Osteoarthritis? What is the Current Consensus

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## Abstract

This work revisits the evidence base concerning the efficacy of laterally wedged foot orthotics for improving the symptomology associated with painful disabling osteoarthritis of the knee medial compartment. To this end, all relevant peer reviewed publications on this topic published in the English language from 1980 onwards were retrieved and examined. In addition, related biomechanical publications were reviewed. Results showed there is a reasonably robust scientific basis for applying wedged insoles in attempts to reduce osteoarthritic pain at the knee medial compartment, but a lack of clinical consensus prevails regarding either their short term efficacy and/or their long term efficacy. Further research to substantiate their efficacy in well-designed clinical trials using validated biochemical, kinematic and kinetic outcome measures, customized inserts, and narrowing the inclusion criteria to those mild to moderate knee osteoarthritis cases with definitive radiographic solitary medical compartment lesions and varus deformities, who are not receiving other confounding treatments is strongly recommended.

**Keywords:** Medial compartment knee osteoarthritis; Pain; Orthotics; Varus deformity; Wedged insoles

## Introduction

Osteoarthritis (OA), a highly prevalent and disabling joint disease of uncertain origin involving progressive disruption of the structure and function of one or more freely moving synovial joints [1,2] commonly affects the knee joint, causing unrelenting joint pain, instability, and deformity, muscle weakness, muscle fatigue, joint swelling and chronic inflammation [3,4]. Several studies have shown the medial compartment of the osteoarthritic knee to be especially problematic in this regard [5] and that among other possible causative factors, is a pre-existing varus malalignment deformity of the ipsilateral lower leg, which can produce abnormal force concentrations across the knee medial compartment [6].

As a result, efforts to attenuate the progression of medial compartmental knee osteoarthritis have focused historically on reducing the excess stress placed on the knee medial compartment, especially that attributable to an abnormally aligned varus deformity of the lower leg using a variety of mechanical [7,8] and surgical measures [9]. Others have advocated for foot orthotics within the shoe [10-12] or knee bracing [13-16].

However, bracing may not be ideally suited for the morbidly obese osteoarthritis case, nor for those presenting with a peripheral vascular disease, neuropathy of the lower leg, any skin disease or an inability to apply a brace due to other physical challenges, and laterally wedged orthoses may yield similar if not more superior overall effects [17]. Surgery too may not be indicated for a variety of reasons, or may be more effective when combined with orthotic approaches [12]. By contrast, the specific benefits of utilizing foot orthotics for managing medial compartment knee osteoarthritis include, but are not limited to, their potential to selectively stabilize or restrict motion in one or more joints, their potential to minimize body forces due to weight, their potential to correct or reduce limb mal positioning, and their potential to reduce medial knee joint compartment overload [6]. However, regardless of a reasonably sound basis for applying lateral wedge orthotics to ameliorate medial knee osteoarthritis, and research that has persisted for more than 40 years [18] the current evidence base detailing this approach continues to paint an ambiguous picture that is not sufficiently robust to render this mode of intervention universally desirable.

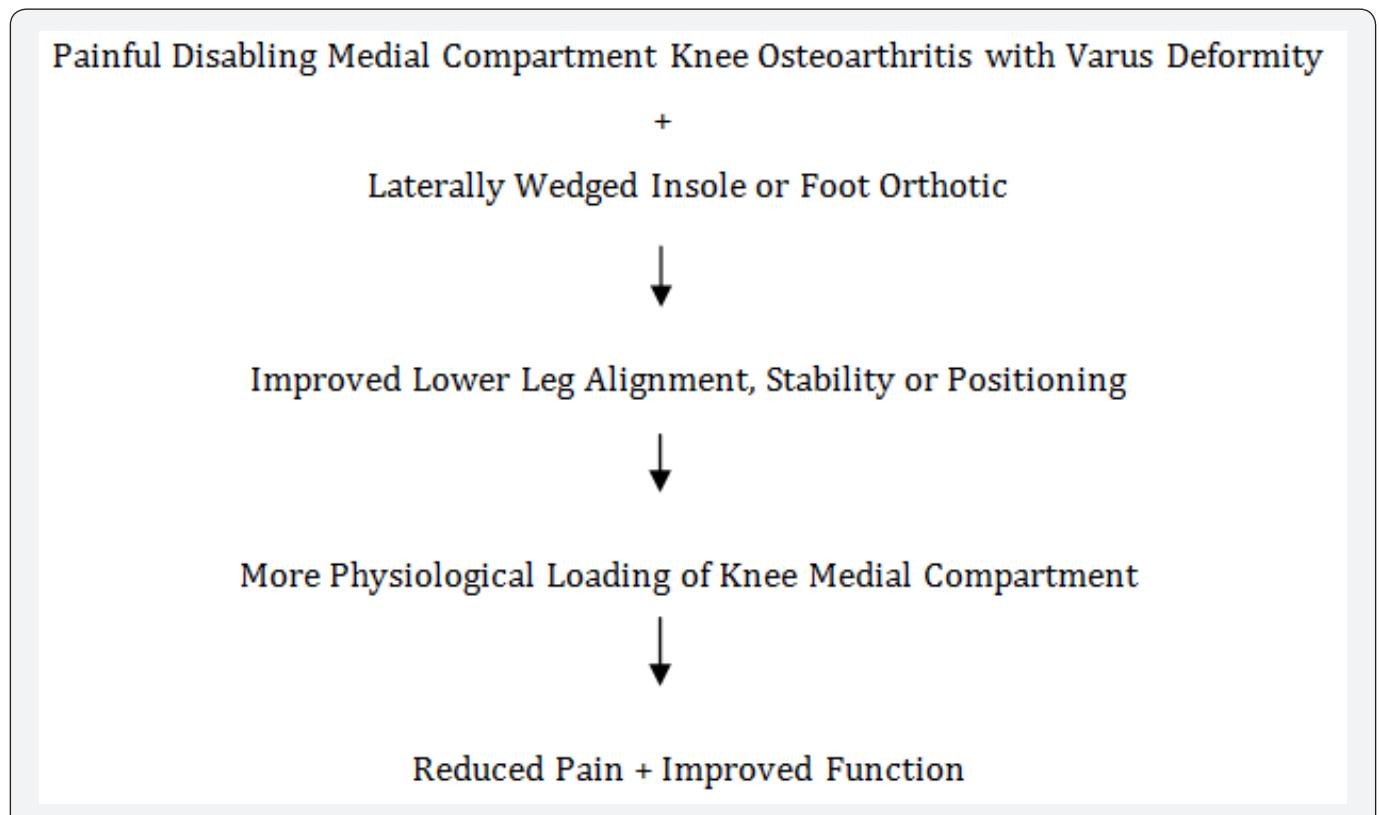
Arguments that more research is needed, made in 2009 [19] continue to persist despite considerable effort to address this issue [20].

Criticisms of the prevailing failure to carry out conclusive research are increasing however. Indeed, as indicated by Gokel et al. [21] it does seem that if laterally wedged insoles are thoughtfully applied in a sustained manner, considerable structural as well as symptomatic benefits might be forthcoming for the individual affected by medial compartment knee osteoarthritis.

Given the immense pain and ensuing disability that can accompany medial compartmental knee osteoarthritis, plus the fact not all cases will require or benefit from surgery, it would appear to be matter of some significance to both patients, and to health care providers to firmly establish whether or not laterally wedged insoles or foot wedges are potentially efficacious for reducing pain and improving function in this condition. As well, even if this form of therapy is not efficacious for all medial compartment knee osteoarthritis patients, the fact that subpopulations may exist that can benefit significantly from the application of lateral wedge insoles [22] has been raised and warrants further exploration. Moreover, unlike pain and anti-inflammatory medications, which are increasingly being shown to place patients at risk for vascular conditions and others, and

may create dependencies over time, a sizeable number of knee osteoarthritis cases have been found to experience significant improvements in their condition following orthotic application without any unwarranted side effects. In addition, this positive post-orthotic application effect does not appear to decline with continuous use [23] and could thus be both effective as well as cost effective as an intervention for the many individuals with this condition who are elderly and may not have adequate resources for securing more costly long term treatments. In this regard, the present objectives were:

- i. To review all pertinent clinical studies that have specifically examined the efficacy of laterally wedged insole orthotic devices as a treatment strategy for medial compartment knee osteoarthritis available in the English language.
- ii. To outline results of these studies, and some of their characteristics.
- iii. To point out limitations in the realm of the current research base on the use of laterally wedged insoles and medial knee osteoarthritis.
- iv. Provide recommendations for future research. The framework guiding this line of research was based on the hypothetical associations depicted below in Figure 1.



**Figure 1:** Possible outcome of applying a customized laterally shaped wedged insole or foot orthotic in cases with mild to moderate knee medial compartment osteoarthritis and an accompanying tibia varus alignment deformity.

## Methods

Retrieved from a computerized PUBMED, SCIENCE CITATION INDEX, SCOPUS, AND WEB OF SCIENCE database search plus a manual search of bibliographies of original and review articles and appropriate internet resources, articles extending from 1976-April 30, 2017 were considered. Keywords used were: osteoarthritis, and laterally shaped wedges, or orthotics. To be included articles had to be published as full length reports in English or have an English abstract. No restrictions were placed on study design, as some very important cross sectional studies provide very insightful basic information about the mechanics of such an approach. Others have conducted randomized clinical studies with or without a historical control group and blinding, others have reported results of prospective or cross-over studies of a single group or more than one group, but none of this is in our view sufficient for a high level meta analysis. Indeed, a scan of the available data readily revealed that several clinical studies were not necessarily constituted by samples with clearly defined osteoarthritic lesions of the knee medial compartment, or uni-compartment lesions versus lesions for example of the patella femoral joint, nor adequate sample sizes, and very few researchers selected samples with clear varus alignment deformities to study.

As well, no uniform orthotic approach was adopted across studies, regardless of design, even though the premise of a reduction of medial compartment stress is contingent on the need for this, as well as the magnitude of the slope of the wedge. Given the widely divergent clinical samples studied, possible confounding issues due to the presence of osteoarthritis in other joints, pain levels that are already low due to medication or steroid use of both, their differing research questions and premises, methodologies and durations, and the fact this realm of non pharmacologic strategies has been so readily subjected to systematic meta-analyses with no definitive conclusion, a descriptive report rather than an aggregated approach was adopted to glean the status of this body of research.

## Results

### Early studies

Studies on the present topic, which began in the mid 1970s [24] can generally be categorized as either basic or experimental studies, or clinical or intervention studies of human subjects. In terms of applying a suitable rationale for employing a wedged insole to reduce the stresses at the osteoarthritis varus knee, the key assumption is that by altering the angle of the foot at the ankle, excess pressure being placed on the knee medial compartment during weight bearing activities, will be reduced, because it will be shifted laterally, and this will minimize further joint damage and possibly pain. This belief that the angle at the foot has some bearing on the mechanics of the knee joint in the presence of a varus deformity of the lower leg initially examined by Yasuda & Sasaki [25] has continued until the present time.

Basically, this group specifically examined whether the application of a laterally shaped wedged insole would impact:

- I. The line through the center of gravity, such that it would run through the lateral side of the sole.
- II. The femoro-tibial angle, such that it would be displaced in the valgus direction.
- III. The calcaneus, which would be similarly displaced.
- IV. The inclination of the weight bearing lower limb favourably.

Since their results, which applied radiography supported these assumptions, their idea that a 5° laterally wedged insole might prove effective for treating painful medial compartment knee osteoarthritis set the stage for further study. This biomechanical study was not a clinical study, however, and no effect on pain was assessed, nor was a functional analysis forthcoming, but it was in line with early findings by Tomatsuri et al. [18]. That group had studied the potential efficacy of using a 5° laterally wedged foot orthosis for treating painful medial compartment knee osteoarthritis, noting satisfactory subjective reports of pain relief when applied to individuals with symptomatic osteoarthritic varus knees.

In a further related study [26] Sasaki and Yasuda did examine the subjective pain reports experienced by 40 persons with medial compartment knee osteoarthritis who received analgesics only, and 67 persons who received analgesics in conjunction with the use of a customised wedged insole, albeit no apparent attempt at randomization was evident. They further examined the outcomes of pain and walking ability using three types of orthoses: a sponge rubber material inserted into a normal shoe; a shoe-type insole consisting of the same sponge rubber material and covered partly with a polypropylene mesh and a magic band (used without shoes indoors); and a sponge rubber material covered with leather. In all three cases, the insole, 7-12 mm in height, tilted the calcaneus 5° laterally. Results showed almost 65 percent of those prescribed the wedged insoles discontinued their use within one year, with about a third citing pain disappearance as the primary reason for this action. Fifty percent of subjects, who reported their orthotic was "effective", also reported decreased knee pain and increased walking ability. Those patients treated with the laterally wedged insoles generally showed greater clinical improvements than those treated with analgesics alone. Only three cases complained pain that had occurred at another limb site.

When the impact of the wedged insole was considered according to radiological stage, significant improvements in pain, as well as walking ability were observed for those cases with radiographic disease stages I-III, but not for those in stage IV. These results correlated well with the degree of satisfaction reported by subjects at the conclusion of the study. That is, 77

percent of those in disease stages I-III who used the orthoses were satisfied, while only 40 percent of those in disease stage IV reported satisfaction. No subject demonstrated improvements in their radiological findings consequent to using the inserts, however, only one advanced in severity. It is possible that the failure to stress the importance of adherence to the orthotic intervention regimen obviated the attainment of further more long lasting improvements over the 1-5 year study period. There were also very few cases in the stage IV disease category, and that may have limited the level of significance demonstrated.

In an analogous study by Wolfe & Brueckmann [27] the authors examined the outcomes among 55 individuals with knee osteoarthritis and either valgus or varus malalignment deformities who wore medial or lateral heel wedges in the shoes of their affected side, or both sides, if both knees were affected. The other simultaneously applied treatment was constituted by anti-inflammatory medication. At the end of one week, when the patients still on medication were asked to report whether their joint pain was either absent or lessened, most reported that using the wedges resulted in pain relief and they were more able to be active than before. The 20 percent that discontinued their medication still experienced pain relief. Sixty nine percent said if they stopped wearing the wedges, their pain levels increased. The authors noted that those individuals with mild angulation deformities of the lower leg responded more readily to the wedged insoles than those with more extensive angulation deformities. It was further found that 27 percent reported they had unlimited walking ability with no pain, and 9 percent could walk more than a mile with no pain. These findings were not without limitations, but were certainly promising, given that the actual density of the insole material, their inclination, and type of placement in a shoe may be further adapted to improve upon these findings as outlined by Crenshaw et al. [28]. The results seemed related to actual physiological changes as verified by standing radiographs that show the application of lateral wedged insoles can change the angle of force through the knee joint in a favourable way.

In a more extensive prospective study of 62 individuals with knee osteoarthritis, mean age 57 years, 49 patients were examined radiographically and by means of a pain and activity questionnaire after receiving treatments with 5-10° lateral heel wedges and analgesics, and 13 were similarly examined after receiving treatments with analgesics alone. On average, after 9.6 years, Tohyama et al. [29] found 37.1 percent of the knees treated with orthotics and analgesics showed advancing disease, whereas 52.9 percent of the knees treated with analgesics alone showed advancing disease, even though there was an equally significant increase in the femoro-tibial angle in both groups. This suggested that even though lateral heel wedge inserts might not prevent the long-term progression of joint mal alignment, their application might still delay the onset of disability for a variety of other reasons. Unfortunately the researchers did not

document the outcomes of those not followed, and adherence to the regimens was not clear. There is evidence however, that one can expect kinetic as well as kinematic changes with the use of lateral wedges, and that orthotics manufactured from multiple layers of functional materials can improve balance and proprioception, and can lower fatigue experienced during activity [30]. There is also evidence of a favourable reduction in knee adduction moments in response to lateral wedge insoles, [31] and decreases in the laterally directed ground reaction force during the contact phase of gait, implying a possible increased attenuation of joint impact in response to a wedged insole [32].

Indeed, in a follow-up study, Keating et al. [33] specifically observed that even individuals with severe osteoarthritis were able to improve their clinical presentation after using laterally wedged insoles. Most noteworthy in that study was that 38 percent of the 85 cases with medial compartment knee osteoarthritis showed pain improvements commensurate with those of joint replacement surgery for this condition. Fifty percent improved to a moderate degree, including some with radiographic evidence of a complete loss of joint space and bone erosions. Although all participants were on anti-inflammatory medications, unless contraindicated, these results were attributed to related improvements in the structural alignment of the subject's lower leg in that subjects walked with increased valgus at the subtalar joint and a widened step width as assessed in a gait laboratory. Importantly, those who experienced early pain relief tended to use the wedges for an extended period.

However, according to Yasunaga [34] who recorded the effect of laterally-wedged insoles on the lateral thrust of the knee, these may tend to produce much lower restraining effects than high tibia osteotomy when weight bearing activities such as descending stairs and slopes are considered. Nevertheless, if one considers that most daily activities occur on level ground, their data did show that the application of a laterally-elevated wedged-insole reduced the magnitude of the first peak of the lateral acceleration forces falling on the knee during weight bearing, which may be considered more protective than not. It could also be argued that osteotomy surgery is expensive and favourable results cannot be guaranteed, while the use of insoles with sub talar strapping can effectively yield therapeutic outcomes commensurate with those of high tibial osteotomy [35]. Although this latter view was not wholly supported by Maillefert et al. [36] who compared the effects of wearing laterally wedged insoles and neutrally wedged insoles among cases with knee osteoarthritis, medication intake was reduced in the experimental group at six months, but not in the control group. Compliance also favoured the experimental group. It is possible more definitive clinical benefits could be forthcoming by using urethane derivative insoles, by carefully customising the wedges based on a dynamic rather than on a static evaluation, or by using a customized arch support [37-39] or an elastic sub talar strap as outlined by Kuroyanagi et al. [40] and

Toda et al. [41] even though Reilly et al. [42] concluded lateral wedges produce no change in the normal course of knee medial compartment osteoarthritis [43].

Indeed, Kerrigan et al. [44] who tested whether a laterally-wedged insole inclined at either 5° or 10° and applied to cases with clinical and radiographic knee osteoarthritis found favourable results in terms of reductions of knee varus torques during walking when cases using the wedges were compared to those using no insole or a non-wedged control insole of the same material and thickness. This potential for reducing joint forces when subjects walked was more marked however, for the 10° wedge than the 5° wedge, even though the 5° wedge seemed more comfortable to wear. This finding appeared consistent with that of Kakihana et al. [45] for cases without medial knee osteoarthritis, and in an uncontrolled study for pain relief by Rubin et al. [46] as well as by Jones et al. [47], Ogata et al. [48] and Maly et al. [49] however, concluded that there was no evidence to support the impact of lateral wedged insoles in favour of the knee adduction theory when examining cases with medial knee osteoarthritis, a conclusion also reached by Duivendoorden et al. [50] in a retrospective analysis of 80 patients with knee osteoarthritis of the medial compartment subjected to an orthosis or a brace for six months, and Weinhandl et al. [51] who reported that laterally angled wedges increased the vertical ground reaction force at the instant of peak knee abduction moments in osteoarthritis cases. However, here again contrary findings in similar studies are those of Butler et al. [52] & Russell & Hamill [53].

Shimada et al. [54] noted that generalizations concerning the efficacy of the laterally-wedged insole are thus challenging to formulate, and this ambiguity may reflect the extent to which the disease severity varies across samples of medial osteoarthritis of the knee, as observed by Kuroyanagi et al. [40]. Another factor bearing on the observed outcome of employing an inserted lateral wedge to influence lower limb mechanics is footwear type [55]. Variations in wedge application methods, failure to control for competing interventions, and the use of clinical criteria instead of radiographic criteria in many studies, are other factors precluding the ability to arrive at any consensus among reported studies. In addition, some of the anticipated benefits of a wedge are possible benefits derived from the study of healthy subjects, rather than those with medial compartment osteoarthritis Nestor et al. [32].

Indeed, it is unsurprising therefore, that Reilly et al. [42] was unable to discern any consensus about the utility of treating medial compartment knee osteoarthritis with laterally inclined wedged inserts despite 19 years of research and more than twelve attempts in recent years to synthesize or reconcile studies on this topic.

### Contemporary studies

As discussed above, the apparent shortcomings, biases, or poor design factors that have been evidenced in the early body

of related research on the present topic, seem to continue to prevail in more recent attempts to establish the efficacy of lateral wedges in cases of knee osteoarthritis. For example, some studies continue to examine the use of wedges alongside competing interventions, and the failure to examine the intervention using a non-treatment control group to establish efficacy continues to prevail [56,57].

Others examine insole variants other than the laterally angled wedge, such as the effect of ankle foot orthoses on knee joint mechanics, [31] two-piece foot orthoses, [5] and heeled footwear with lateral wedges [55], 8-12mm elevated insoles with subtalar strapping, [58] and wedged insoles with arch support [59]. The results of these and other data also diverge even when the same approach is used. For example, laterally shaped wedges are said to impact changes in the femoro tibial angle in a dose dependent way, but according to Kutner et al. [60] lateral wedges might be too limited to have any meaningful clinical effect on knee medial compartment loading.

Yet, Skou et al. [61] who examined the use of customized insoles on pain among other factors in a sample of 51 medial knee osteoarthritis cases found pain appeared to be significantly reduced. As well, Barrios et al. [62] found lateral foot wedges beneficial for reducing knee adduction moments over time suggesting the treatment is more advantageous than not.

Positive results were also observed by Rafiae & Karimi [63] among cases with medial compartment knee osteoarthritis randomized to use various kinds of lateral wedge insoles, regardless of extent of wedge, although the progression of osteoarthritis in the 7mm group was less evident according to the researchers than that of the group using 3 mm wedges. Earlier, Segal et al. [64] did find that wedge use improved pain and daily activity levels to the same extent as wedges plus concurrent ankle support. Subjects were 14 adults with medial knee joint osteoarthritis. But, as with almost all studies in this realm, the actual benefit of the wedged insole intervention could not be ascertained, because no non-treatment control group was examined.

### Aspects of confusion in the reported literature

The distinction of whether laterally inclined wedges relieve pain or whether they improve joint biomechanics seems to be one issue complicating synthesis of the study methods and outcomes published in the realm of the present topic. Jones et al. [65] for example examined the effect of different types of insoles or shoe modifications on medial joint loading in cases with knee osteoarthritis of the knee medial compartment and assessed pain and comfort during walking. Compared with the control shoe, lateral wedge insoles reduced knee extension adduction moments of the affected compartment, regardless of whether a typical or supported wedge was used, but knee pain was less positively affected. The results of this Level 1 randomised clinical trial conducted in a single visit was supported by Alshawabka et

al. [66]. who found cases with medial knee osteoarthritis exhibit reduced peak knee adduction moments during stair ascent and descent, and may explain the favourable pathomechanics associated with the application of a lateral foot wedge over a one year period for cases with symptomatic knee osteoarthritis [62,67].

Separating the unique effect of applying laterally wedged insoles on osteoarthritis biomechanics and pain remains challenging however, for example Arazpour [68] found laterally wedged insoles produced outcomes commensurate with unloader knee orthoses for reducing pain, but this group failed to employ a non-treatment control group. Similarly, De Campos et al. [69] who conducted a prospective randomized trial of 58 cases with knee osteoarthritis, examined the use of a lateral wedge with subtalar strapping, and compared this approach to a neutral insole with similar strapping, thereby concluding the lateral wedge was effective, but no more effective than the neutral insole. The duration of use here was broad, and patient-derived, the idea that the neutral insole was a placebo can be challenged, and only subjective assessments were employed. In contrast, Hatef et al. [70] who conducted a double blind parallel treatment trial of 118 knee osteoarthritis patients found the use of a laterally elevated wedged insole was more effective than neutrally wedged insoles for pain relief in cases with knee osteoarthritis. In addition, regardless of the degree of lateral wedging used, Yilmaz et al. [71] found these did shift the load carrying line at the knee more effectively among a sample of 20 medial knee osteoarthritis subjects than when an insole was not used.

Dessery et al. [38] too appear to support a role for applying a wedged insole for reducing knee osteoarthritis disability. This group analyzed outcomes for 18 patients affected by medial

knee osteoarthritis, in terms of pain and comfort scores, frontal plane kinematics and kinetics of the ankle, knee, and hip under four conditions. They found lower-extremity gait kinetics were characterized by a significant decrease in the second peak knee adduction moment in laterally the wedged insole conditions. No significant difference in knee adduction moment was observed between differently angled laterally wedged insole conditions. In contrast, a significant increase in the knee adduction moment during the loading response was observed in the customized foot orthoses without the lateral wedge insert. They concluded customized foot orthoses with a medial arch support may only be suitable for the management of medial knee osteoarthritis when a lateral wedge is included. But a medial arch support alone may increase knee loading, which could potentially be detrimental to these patients.

#### **Additional factors affecting application of laterally wedged insoles**

Results of studies mentioned above may vary for other reasons, including the quality of the insert employed, the use of uni versus bilateral inserts, and the degree of wedging. Hsieh et al. [72] for example, found that knee osteoarthritis participants of a prospective double-blinded randomized study assessed at 1,2, and 3 month periods had better outcomes when soft insoles, rather than rigid were used. Similarly, Abdullah & Abdullah [59] who examined the effect of unilateral and bilateral laterally wedged insole usage with arch supports in 33 cases of women with medial knee osteoarthritis, found loading rates decreased significantly in unilateral 11° versus bilateral 6° insoles. Yet, even 5° lateral wedge and arch supports appeared to produce favourable immediate as well as medium term effects on pain and physical function as assessed prospectively among 40 patients with knee osteoarthritis, mean age 61years [73].

**Table 1:** Snapshot of diverse study designs and outcomes conducted in last five years dealing with the application of laterally wedged foot insoles for adults with medial compartment knee osteoarthritis [OA].

Authors	Type of Study	Sample	Outcome Measures	Conclusions
Alshawabka et al. [66]	Within-subjects comparison of lateral wedge for 2 activities	8 knee OA cases	Kinematic and kinetic measures	Lateral wedge reduced medial compartment loading during stair ascent and descent
Barrios et al. [62]	Prospective 2 group controlled study	19 knee OA patients who received active treatment; 19 who received neutral insoles	Gait analysis	Knee adduction moments increased over 12 months only in the control group
De Campos et al. [69]	Prospective randomized trial of wedge with lateral strapping or neutral insole with strapping for 5-10hr per day for 24 wk	58 knee OA cases	Visual analogue pain scale	Pain improved to the same degree in both groups
Dessery et al. [5]	Within subjects comparison of 1+2-piece foot adjustable orthoses versus no orthoses	17 knee OA cases	Gait analysis	1 or 2 piece orthoses have very modest benefits on gait velocity, knee flexion moment, comfort and first peak of knee adduction moment

Fantini Pagani et al. [31]	Controlled laboratory study	14 healthy male subjects with varus alignment	Kinetic and kinematic analysis	An ankle foot orthosis reduces the knee adduction moment during gait
Fu et al. [74]	Prospective cohort study with sequential interventions	10 knee OA cases	Gait analysis	Results support the use of orthotic treatment for early medial compartment knee OA
Hatef et al. [70]	Double blind parallel treatment study	118 cases with knee OA, 57 assigned to experimental group using 5 degree wedge vs 61 cases using neutral insoles	Edinburgh functional scale, medication intake	Laterally elevated wedges were more effective than neutrally wedged insoles in relief of knee OA
Hinman et al. [22]	Within subject comparisons of wedge use versus no wedge	73 knee OA cases	Kinetics during gait	Lateral wedges reduce peak knee adduction moment and knee adduction angular impulse
Hsieh et al. [73]	Pretest posttest design	40 knee cases	Pain and function	Custom molded insoles provide medium term and immediate relief and functional benefits
Hsu et al. [75]	Prospective 6 week single group pretest posttest study	10 bilateral knee OA cases	Gait analysis	After long term use of the insoles pain+ function improved, and knee moments decreased
Jones et al. [47]	Within subjects comparison of different insoles or shoe modifications	70 knee OA cases	Gait analysis	Compared with control shoes, insoles or barefoot walking reduced medial knee loads, but only barefoot walking reduced knee flexion moment
Kutzner et al. [60 ]	Within-subjects of 2 types of laterally wedged shoes, a laterally directed insole, and no wedge conditions	6 subjects	Instrumented knee implants	Medial force reductions with wedged shoes during gait were small, the larger 10mm wedge yielded better force reductions than 5 mm wedges or insole
Menger et al. [76]	Observational study over 12 months	23 knee OA cases	WOMAC total score, pain, activity restriction, complication rate	A novel foot-ankle orthosis is effective at reducing pain and stiffness as well as function in mild to moderate knee OA
Rafiae et al. [63]	Randomized study comparing 3 and 7mm lateral wedge insoles	36 knee OA cases	Quality of life, pain	Both wedge sizes improved the clinical condition, but this was larger for the 7mm group
Skou et al. [61]	Prospective study	51 consecutive knee OA cases	Pain, function, quality of life	Pain and function improved with custom made lateral wedges in older adults with mild to severe medial knee OA
Yilmaz et al. [71]	Within subjects comparison of 5 and 10 degree wedges	20 knee OA with bilateral joint disease	Postural alignment in standing, load displacement	Both wedges were effective in moving the unilateral lower extremity load carrying line laterally

Treatment mode and the interpretation of findings may be another variable leading to confusion as to the magnitude of any outcome demonstrated. Bennell et al. [67] for example reported no added impact was notable when laterally shaped wedged insoles were compared to control inserts, but more control subjects exhibited progressive medial compartment damage, and the hourly usage of the wedges per day was one third less for the experimental group than the control group. Over the same time period, Fu et al. [74] in contrast, found cases with medial knee osteoarthritis receiving orthotic treatment consisting of a lateral wedged insole with arch support were able to reduce their pain to a greater extent than either wedges alone or valgus knee braces. Moreover, gait analysis of sequentially treated patients showed significant peak and mean knee adduction moments in all orthotic groups compared with a flat insole. The finding was supported by earlier work by Hsu et al. [75]. This group noted that the use of a laterally wedged insole not only impacted the pain and function of persons with bilateral medial osteoarthritis positively, but usage also decreased the knee abductor moment. However, this finding was somewhat confusing given that the possible benefits of a wedged insole have been attributed to reductions in peak knee adduction moments and these may depend solely on lever arm influences [76,77]. See Table 1 for a snapshot of related studies conducted over the past five years.

### Discussion

Although Gelis et al. [78] & Penny et al. [79] among others concluded that there is a paucity of evidence favouring the application of lateral wedges for reducing pain and improving function in people with medial compartment knee osteoarthritis, a fair number of clinical studies examining the efficacy of wedged foot orthotics for the treatment of this condition show their application can reduce pain, [80] even when compared to a non treated control group, [81] and may effectively reduce peak knee adduction moments, [47,82] joint stiffness, and drug dosage [83]. They can also reduce physical dysfunction, improve proprioception and balance, and Kellgren/Lawrence grading, are deemed safe to apply, [45] and do not affect ankle or hip joint structure adversely [84].

However, regardless of outcome, the majority of these efficacy studies were not well-designed, with few considering the use of any true placebo control non treatment group. Moreover, even when studies were quite well designed, the diverse samples studied, the limited numbers of cases receiving customized inserts, as opposed to generically constructed uniformly angulated inserts, along with many different intervention modes, materials, and dosages, [83] arguably renders any firm conclusion challenging at best. Meta analyses, of which there are at least twelve recent submissions on this topic, do not always review similar studies, and even if they do, do not consistently yield the same conclusions.

Serious flaws in this body of research such as:

- a. The failure to clearly establish the radiographic presence of the disease.
- b. The questionable use of bilateral wedged insoles in cases with unilateral disease and possibly only a single wedge in the presence of bilateral disease.
- c. Basic studies that are often conducted solely on healthy samples, rather than cases with knee osteoarthritis.
- d. Limited follow-up periods among other factors render the process of synthesis not only impossible, but questionable at best. Unsurprisingly, therefore, Baerts et al. [85] found the present research results to be ambiguous, despite claims of a beneficial effect of lateral wedges on pain and function, which seems to be due to the ability of the wedged insole to diminish focal loading on the medial joint surface of the knee by changing the angle of the joint surface [27,33] and which can be demonstrated empirically [18,25,28].

This is because for every positive finding, there is a similar contrary finding. For example, in reference to the aforementioned statement, Jones et al. [86] reported pain could decrease following a brief application of a lateral wedge, regardless of any biomechanical effect, while Weinhandl et al. [52] found results suggesting laterally wedged insoles are ineffective at reducing tibiofemoral joint loading, and indeed may increase joint loading.

In addition to this aforementioned confusion regarding the relationship between medial knee loads and pain when wearing a laterally wedged insole, the finding that the wedge insole and its application does not result in a disease regression or decrease medication usage compared to neutral insoles based largely on only two high quality studies [14] must be challenged, in light of the fact favourable biomechanical changes do seem to occur in the symptomatic osteoarthritic knee in response to lateral wedging [85] and failure to include historical controls in such studies in order to demonstrate whether this absence of any observable disease regression is actually positive in this progressively disabling disease. Being unsure of the extent of the placebo effect in this context, also raises uncertainty about claims that there is no tangible support for the use of lateral wedges [87-89] because new evidence prevails indicating neutral insoles are not as efficacious as lateral wedges, although they are better than having no treatment at all [79].

The widespread use of attempting to conduct systematic reviews or meta analyses to establish the efficacy of laterally wedged insoles in cases of medial knee osteoarthritis, is also questionable. Consider the limited sample sizes of almost all available studies on this topic that may affect power of a study, their variable inclusion criteria, inconsistent study time frames, along with quite varied modes of application. The use

of potentially insensitive outcome measures not necessarily designed nor applied appropriately to capture important clinically relevant physiological changes, even if these are occurring, [36] and occur impressively at one month for up to one year may pose further challenges [90].

As well, very few studies have examined the efficacy of employing customized laterally wedged insoles, rather than generic wedges as pointed out by Lewinson & Stefanyshyn [20] main effects studied are largely subjective, blinding practices are unclear, and inclusion criteria in clinical studies often fail to consider the important impact of disease severity, the presence of osteoarthritis of other joints, and the extent of any varus deformity. In addition, few have examined comparable study dosages, over an extended time frame among similar samples, and most did not mention subjects undergoing a washout period prior to any such study or instructions to subjects to refrain from other treatments prior to or during any study, and to avoid excess impact loading.

The rationale for their use in cases where there is no clinically important malalignment factor must render this data base questionable at best, as medial compartment lesions can arise from sources other than joint overload. In addition, static rather than dynamic measures have been used to establish effects of laterally wedged insoles on the knee medial compartment in osteoarthritis, [58] even though static alignment may not be altered by lateral wedges [22] and even if this is altered, does not predict dynamic loading readily. Comfort issues, as well as inappropriate wedge angulations may further explain failure to attenuate knee loads during activity, as May worsening knee pain [91,92] but careful comparison studies are very limited.

Other barriers to deriving a clear picture of the strengths and weaknesses of the concept of applying lateral wedges in knee osteoarthritis are arbitrary treatment durations and dosages, the applying wedges of different lengths, heights, and material properties, [86,84] and mode of wedge manufacture [93]. Others include failure to assess actual adherence to treatment recommendations, possible concurrent kinetic chain impairments, [93] and different methods for defining the presence of medial compartment knee osteoarthritis [94]. Also, a high percentage of studies in this realm have commonly failed to assess pain and function with commensurate approaches, older adults are not as frequently examined as younger adults, even though the disease affects older people more severely and at a higher rate, while others have only assessed knee medial compartment forces, but not pain, or studied healthy subjects [95].

Another factor that adds confusion to arriving at a sound conclusion is that the act of placing either a wedged insole or a neutral insole in one or both shoes which may have distinctly different mechanical effects is rarely discussed as a determinant

of outcomes or treatment approaches in the context of any current systematic review even though the importance of wedge design and its impact on femorotibial angle, [58] pain and life quality [63] as well as on knee loading has been stressed [95,96]. In those studies where bilateral wedges were applied [90,95] there is clearly no clear evidence to support the use of the same size wedge from side to side if it is the lever arm effect that is the paramount active outcome determinant [83].

Yet a broader issue is the fact orthotic applications may have no effect or weak effects on the external knee adduction moment in neutral knees, [57] thus perhaps only those knee medial compartment osteoarthritis cases with clinically observable varus angulation deformities should be included in future studies. Other confounding factors include but are not limited to the failure to report or exclude the use of co-interventions, the presence of knee or ankle joint instability, [33] the extent of alignment symmetry in bilateral cases, [75] contraindications for wedge insoles, obesity and osteoporosis issues, the concurrent use of pain medications or steroid injections, along with the nature of the patient's daily activities. The presence of subtalar strapping alone as a control strategy should also be examined given that this approach may reduce excessive tensile forces placed upon the lateral collateral ligament, and possibly pain of ligamentous origin, regardless of whether a wedge is used or not [13,25,58].

Perhaps too, as with surgical procedures, a laterally wedged insole might provide more beneficial outcomes if applied in more advanced cases of medial compartment knee osteoarthritis than those presently studied to see if these are specifically designed, whether they can overcorrect for any prevailing joint malalignment. Crafted in light of the precise magnitude of the prevailing osteoarthritic varus deformity, as would be the case for surgical procedures, may produce more successful pain reduction as well as degeneration impacts than generically available wedged insoles. Alternately, the early application of appropriate shoe orthoses based on a dynamic, rather than a static biomechanical evaluation, along with appropriate neuromuscular training, might greatly improve current outcomes as suggested by findings of Brighton [97].

To overcome having patients who experience pain relief early on, discard the modality,[26] improving patient education regarding the importance of adherence to this form of intervention, even if pain is ameliorated, would produce better long term structural changes [23]. Conversely, if more pain is forth coming, re examination might be warranted to uncover the reasons for this, such as increased invertor moments at the ankle, or failure to strengthen ankle invertors in cases with bilateral medial knee osteoarthritis [78].

The type of material used to produce the wedged insole, and degree of inclination, which may produce differential effects

on shock absorption, comfort, and the willingness to use a wedged insole for a prolonged period [14] clearly merits further exploration in the research realm plus careful thought in the clinical realm. In addition, the application duration needed to demonstrate important clinical outcomes should be studied as indicated by Malvankar et al. [90] trials should be of high quality with adequate long term follow up periods and applications, clear radiographically defined lesions and degree of axial leg alignment deviation should be documented, and careful personal diaries to record activity type, duration, and ease of use over time are likely to prove valuable. Also advocated are validated biomechanical, as well as radiographic and biochemical outcome measures, acknowledging the importance of the time factor in measuring progress, plus the importance of comparable comparison groups.

While this will require an enormous investment in time and money, it is the present authors' view that given the inordinate social and economic costs associated with medial compartment knee osteoarthritis and the detrimental side effects that can occur consequent to excessive medication and/or some forms of knee joint surgery, such efforts will prove to be of substantive benefit to clinicians, and their patients. This is especially so in light of the possible utility of orthotic therapy for a given patient from the earliest point in time, which might well produce results commensurate with those of osteotomy or arthroplasty surgery [35].

### Conclusion

Despite 40 years of research, the present data base provides no clear evidence or convincing data for or against the use of the laterally wedged insole for treating adults diagnosed as having medial compartment knee osteoarthritis. However, even if laterally wedged orthoses are only as efficacious as neutral insoles, [86] their application may still afford a considerable cushioning protection against the sequelae of abnormal loading of the knee medial compartment [50] and unrelenting progression of the disease due to daily micro traumatic impact loads, as well as important quality of life improvements [32] and should be studied further. As well, pain, the most important complaint of patients can be reduced during bed rest, pain after getting up, pain after standing up from a seated position and walking distance with the use of subtalar strapped laterally wedged insoles, and this improvement exceeds that of cases using traditional insoles when applied to osteoarthritis cases with varus knees and this must be acknowledged [97-101]. Compared to neutral devices, wedged insoles may also aid in maintaining frontal plane mechanics over a 12 month period in patients with medial knee osteoarthritis more effectively than neutral devices [62]. Yet clinical benefits differentiating those attributable to laterally wedged insoles must clearly be more comprehensively examined against inert control strategies or regular footwear in well-defined samples. As well, assessments of their immediate,

as well as their long-term effects, must go beyond the sole use of subjective evaluations and static alignment tests as cogently argued by Hsu et al. [75] and Lewison & Stefanyszyn [91] in order to interpret ambiguous findings, such as those reported by Hatfield et al. [102]. Examining the impact of different materials on long term insole use, studying muscle activity relative to their use, and their ability to promote comfort and work performance is advocated as well [59].

At present, however, despite some promising basic and applied clinical study outcomes and observations, the lack of uniformity in the current results discussed above in the context of pain, function and disease progression, is likely to continue if more careful thought is not forthcoming to address a multitude of overlapping issues including:

- i. Testing and blinding issues [14,57].
- ii. Research design and methodological quality issues [14,21,76,78,86,98,102,101-103].
- iii. Nature of disease severity and duration [54,61,63,86].
- iv. Numbers of affected joints/joint sites [97].
- v. Age and body weight of samples [99].
- vi. Gender mix of sample and sample size [21].
- vii. Mode of intervention [37,58,59,101].
- viii. Mode and validity of outcome evaluations [21,87,99].
- ix. Underlying cause of condition [99].
- x. Extent of prevailing muscle strength, proprioception, balance, pain, and inflammation [78].
- xi. Extent of tibia varus [21,63].
- xii. Presence of a leg length discrepancy from side to side.
- xiii. Overall health status.
- xiv. Use of concurrent therapies or competing interventions [76].
- xv. Extent of compliance and follow-up period [14,52,85,86].
- xvi. Extent of extent of baseline external knee adduction moments [11,87,104,105].
- xvii. Influence of gait speed, gait biomechanics, testing duration, footwear types [52,65,88,104].
- xviii. Order and extent of testing in multiple strategy case studies.
- xix. Extent of medication usage, adherence to recommendations, and daily activities.
- xx. Materials examined and their varying dimensions, comfort, and structural features.

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