

How Effective are Lateral Wedge Orthotics in Treating Medial Compartment Osteoarthritis of the Knee? A Systematic Review of the Recent Literature

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Abstract: Lateral wedges were originally proposed to manage medial compartment osteoarthritis of the knee but recent reviews suggest that lateral wedges do not affect disease progression. We performed a systematic review to analyse the recent literature and define how effective, if at all, lateral wedges are in the management of medial compartment osteoarthritis of the knee. The inclusion criteria were defined as any study published within the last decade, using a sample size of at least twenty patients, and investigating the effect of insoles or wedges on either unilateral or bilateral knee varus osteoarthritis. The standardised keyword term ‘lateral*wedge*OR insole*OR orthotic* OR medial compartment OR varus OR osteoarthritis* OR knee*’ was used. We identified 10 studies that fitted our inclusion criteria. Although there is not enough evidence in the literature to prove that lateral wedge orthotics are an effective treatment for varus osteoarthritis of the knee, there is some evidence to suggest that they do have some symptomatic effect. Patients with early osteoarthritis and higher BMI may benefit to a greater extent than those with a greater extent of degenerative changes and lower BMI. The literature is unclear as to what the optimal duration for the use of lateral wedges is, but does support the prolonged use of the wedges as the benefits at one month are maintained at one year. Future studies should be randomised controlled trials with a large sample size with long follow-up, and use objective clinical, biomechanical and radiological outcome measures.

Keywords: Osteoarthritis, varus, knee, lateral wedge, orthotic.

INTRODUCTION

Patients with medial compartment osteoarthritis of the knee typically feature genu varum on weight-bearing [1]. This malalignment shifts the mechanical axis medially at the level of the knee joint, increasing the stresses on the medial compartment of the knee and potentially exacerbating knee osteoarthritis [1]. In the 1980’s, Sasaki and Yasuda first reported the potential of laterally wedged insoles in the shoe to manage medial knee osteoarthritis [2]. They demonstrated that the insole statically aligned the knee in a more anatomical position, helping reduce the excessive loading of the medial joint surface and leading to symptomatic pain relief [2]. However since then studies have shown inconsistent results in the effectiveness of lateral wedges.

Two recent reviews have concluded that lateral wedges do not affect disease progression. A review carried out by Hinman *et al.*, (2009) stated that although non-experimental studies showed that lateral wedges improved symptoms, clinical studies did not corroborate this [3]. A review by Reilly *et al.*, (2006) reported that radiographs did not show

that lateral wedges altered the normal course of medial knee osteoarthritis [4]. The aim of this systematic review is to define how effective lateral wedges are by reviewing the recent literature.

METHODS

Inclusion criteria were defined as any study published from May 2001 to May 2011 that investigated the effects of insoles or wedges on either unilateral or bilateral knee varus osteoarthritis with a sample of at least 20 patients. Reviews and case reports were excluded. Studies that did not specifically investigate the effects on knee varus osteoarthritis or did not have any clinical or radiological outcome measure were also excluded. The standardised keyword term “lateral*wedge*OR insole* OR orthotic* OR medial compartment OR varus OR osteoarthritis* OR knee*” was searched in the databases AMED, BioMed Central, CINAHL Library, BIOSIS Previews, CINAHL Plus, Cochrane Library, EMBASE, Journals@OVID, PubMed, SCOPUS, UCL Library catalogue and Web of Science. The abstracts of 93 studies were then screened to see if they mentioned the use of insoles or wedges as treatment for varus osteoarthritis of the knee. Fourteen studies were found to be relevant however this was reduced to 10 studies after a review of the full text.

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RESULTS

The details of the 10 studies included in our review [5-14] are detailed in Table 1.

Pham *et al.*, (2004) compared the clinical effects of laterally wedged insoles and neutrally wedged control insoles in patients with medial knee osteoarthritis [5]. They conducted a 24 month prospective randomised controlled study using 156 patients with a mean age 65 years. They found that at final two year follow-up, there was no statistically significant difference between the two groups with regards to the percentages of patients with self-reported improvement, WOMAC scores and mean joint space narrowing. The number of days with non-steroidal anti-inflammatory drugs (NSAIDs) intake was however significantly lower in the group with laterally wedged insoles than in the neutrally wedged group ($p=0.003$). They reported a greater compliance with the lateral wedges ($p=0.023$).

Butler *et al.*, (2006) performed a biomechanical randomised clinical control trial investigated the effect of lateral wedges on the hind foot and hip biomechanics [6]. Using gait analyses, they found that lateral wedges resulted

in hind foot eversion in 93% of patients, whilst having no effect on their hip adduction. A non-randomised control cross-over study by Kakihana *et al.*, (2007) however found that six degree lateral wedges failed to reduce the knee joint varus moment in 18% of patients, and increased the knee joint varus moment in 16% [7]. Shimada *et al.*, (2006) carried out a case control study using gait analysis and found that lateral wedges had beneficial kinetic and kinematic effects in patients with early medial compartment osteoarthritis [8]. Similar results were noted in another study [9] where patients wore either lateral wedges or neutral insoles for six weeks, with a four week wash out period before a cross-over. The pain scale in patients with milder osteoarthritis and patients with a BMI over thirty improved the most.

We identified three studies that investigated the optimal duration that lateral wedges should be worn. Toda *et al.*, (2005) conducted a study where participants had to wear insoles with subtalar strappings for varying durations over two weeks, and found that the greatest improvement was seen in patients who wore the insoles for eight hours a day [10]. These results were not confirmed by Hinman *et al.*,

Table 1. Details of the 10 Studies Identified Including Type of Study, Number of Subjects and Numbers Lost to Follow-Up, Duration of Follow-Up and Outcome Measures Used

Study	Type of Study	Number of Subjects	Number of Subjects Lost to Follow-Up	Follow-Up	Outcome Measures Used
Pham <i>et al.</i> (2004) [5]	Prospective double-blind randomised control trial	156	50	2 years	Patients' overall assessment of disease activity (5 grade scale), WOMAC index subscales and need for concomitant treatments.
Butler <i>et al.</i> (2009) [6]	Prospective single-blind randomised control trial	30	N/A	N/A	Gait analysis study with kinematic and force measurements to determine the hind foot, knee and hip moment.
Kakihana <i>et al.</i> (2007) [7]	Prospective non randomised, cross-over study	70	N/A	N/A	Gait analyses to determine the knee and subtalar joint moments, and centre of pressure. Blinded radiological assessment with Kellgren and Lawrence grading.
Shimada <i>et al.</i> (2006) [8]	Prospective case-control study	65	N/A	N/A	Gait analyses study that measured peak external adduction moment at the knee during the stance phase of gait and the first acceleration peak after heel strike at the lateral side of the femoral condyles. Kellgren and Lawrence grading system for radiographic assessment of osteoarthritis.
Baker <i>et al.</i> (2007) [9]	Prospective double-blind randomised crossover trial	90	4	16 weeks	WOMAC pain and disability scale, the overall knee pain with a 50 feet walk and any medication for knee pain taken.
Toda <i>et al.</i> (2005) [10]	Prospective randomised control trial	81	0	2 weeks	Femorotibial angle on blinded weight-bearing radiographs, and the remission scores of the Lequesne index.
Hinman <i>et al.</i> (2009) [11]	Prospective randomised control trial	20	0	1 month	Gait analyses study measuring knee adduction moments and adduction angular impulse.
Barrios <i>et al.</i> (2009) [12]	Prospective single-blinded block randomised control trial	66	10	1 year	WOMAC index, six minute walk distance and pain change, and chair negotiation time and pain change.
Toda <i>et al.</i> (2008) [13]	Prospective single-blinded block randomised control trial	227	20	12 weeks	Pain using the Lequesne index and the Visual analogue score (VAS), and last assessment of material wear of the insole.
Toda <i>et al.</i> (2001) [14]	Prospective randomised control trial	90	0	8 weeks	Femorotibial angle and talar tilt angle using weight-bearing radiographs, and VAS.

(2009) who investigated the biomechanical effects of lateral wedges after one month in 20 patients [11]. They found that, irrespective of the duration of daily use, the insoles demonstrated a reduction in adduction moment parameters at one month. Barrio *et al.*, (2009) analysed the Western Ontario and McMaster universities (WOMAC) score, six minute walk test and stair negotiation test at baseline, after one month and after one year of using individualised orthotics [12]. Significant improvements in pain, stiffness and physical function was noted at one month follow-up and at one year follow-up compared to baseline ($p < 0.001$), but no change was seen between the first month and one year assessments.

In 2008 Toda *et al.*, found that lateral wedges with and without shoes showed significant improvements in pain measured using the Lequesne index and the Visual analogue score (VAS) [13]. In a previous clinical randomised control trial, Toda *et al.*, (2001) had established that the best orthotic for the management of medial compartment osteoarthritis was lateral wedges with subtalar strappings rather than the conventional insole [14]. Results showed that only patients who wore the subtalar strappings had a significant improvement in the VAS. These insoles may not however be clinically effective as they were associated with adverse effects such as popliteal pain [14].

DISCUSSION

Although two recent reviews have concluded that lateral wedges do not affect disease progression, a recent randomised controlled trial has shown a reduced NSAID intake and a better compliance compared with the control group [5]. The recent literature shows, using gait analyses studies, that lateral wedges reduce the varus malalignment of the knee by everting the hind foot, and do not affect the hip joint [6]. This would suggest that lateral wedges should not be used in patients with hind foot pathologies. Evidence also suggests that not all patients have a reduction in their knee joint varus moment [7], and patients with early osteoarthritis and higher BMI may benefit to a greater extent than those with a greater extent of degenerative changes and lower BMI [8,9]. The literature is unclear as to what the optimal duration for the use of lateral wedges is [10,11], but does support the prolonged use of the wedges as the benefits at one month are maintained at one year [12]. Although the literature suggests that lateral wedges with subtalar strappings are better than conventional insoles for medial compartment knee osteoarthritis, patients using the strappings experienced adverse effects such as popliteal pain and blisters [14] that in the clinical setting would adversely affect compliance.

The recent literature on the use of lateral wedges for medial compartment knee osteoarthritis is insufficient to draw any substantial conclusions from. The studies have some heterogeneity in the results that could be explained by confounding factors that were not controlled. Some studies used NSAIDs as an adjunctive therapy, confounding the results [5, 14]. Objective outcome measures such as the WOMAC score was only used in three studies [5, 9, 12], and the VAS in two [13, 14]. Although radiographs were used in

four studies [7, 8, 10, 14], the correlation between the efficacy of the wedges and radiographic severity of the osteoarthritis was only assessed in one study [14]. In addition, the study samples were small and the follow-ups short. Only one study had control wedges [14], and failed to confirm that they were made of the same material or similar confirm material wear.

CONCLUSION

In conclusion, although there is not enough evidence in the literature to prove that lateral wedge orthotics are an effective treatment for varus osteoarthritis of the knee, there is some evidence to suggest that they do have some symptomatic effect. The literature suggests that orthotics may have a place in the management of patients with early medial compartment osteoarthritis. There are however many confounding factors that hinder the reliability of these pooled results. Future studies should be randomised controlled trials with a large sample size with long follow-up, and use objective clinical, biomechanical and radiological outcome measures.

CONFLICT OF INTEREST

The authors confirm that this article content has no conflict of interest.

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