## **CRITICALLY APPRAISED TOPIC**

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## EFFECT OF LATERAL IN-SHOE WEDGE ON REDUCING PAIN IN MEDIAL KNEE OSTEOARTHRITIS

**Clinical Question:** Is the use of a lateral in-shoe heel wedge effective in reducing pain associated with medial knee osteoarthritis?

**Patient (P):** Participants age 40-75 years old, radiographic diagnosis of medial OA<sup>2,3</sup>, Kellgren-Lawrence grade 1 or above<sup>1,4,7</sup>, presence of medial tibiofemoral joint osteophytes<sup>6</sup>

**Intervention (I):** Full length 5 degree lateral wedged insoles<sup>3,6,7</sup>, 6 degree lateral wedged insole<sup>1</sup>, 5 degree lateral wedged insole and then up to 15 degree lateral wedge insole<sup>2</sup>, variations of lateral wedged insoles with knee braces and subtalar straps<sup>4</sup>

**Comparison** (C): Flat insoles<sup>3</sup>, no insoles<sup>6,7</sup>, neutral insoles<sup>2</sup>, baseline condition of subject pre-treatment<sup>1,4</sup>

**Outcome (O):** The Western Ontario and McMaster Universities Arthritis Index (WOMAC)<sup>1-4,6,7</sup>, Visual Analog Scale for pain (VAS)<sup>1,4,7</sup>, medial tibial cartilage volume<sup>3</sup>, sagittal knee ROM<sup>1</sup>, walking speed<sup>1</sup>, step length<sup>1</sup>, 6 minute walk test<sup>2</sup>, timed stair negotiation test<sup>2</sup>, knee adduction moment (KAM)<sup>1,4,6</sup>, Ritchie index score - rest, walking, standing<sup>7</sup>

**Background:** Osteoarthritis is the most common type of arthritis. It is estimated that 10% of adults older than 55 suffer from knee osteoarthritis(OA).<sup>5</sup> Surgical interventions are often used in severe forms of OA, but they are costly and involve risk. <sup>2,6</sup> Therefore, less-costly, conservative options are often preferred, especially in cases of mild or moderate OA. <sup>2,6</sup> In-shoe lateral heel wedges are one such option for the treatment of knee OA that may improve a patient's quality of life via pain relief.

**Search Strategy:** 

Databases Searched: <u>www.pubmed.gov</u>, <u>www.oandp.org</u>

**Search Terms:** lateral wedge, osteoarthritis, pain, medial knee pain, in-shoe **Inclusion/Exclusion Criteria:** 2008-present. English. Excluded if study examined: external wedges, medial wedges, lateral knee pain, or did not measure pain.

**Synthesis of Results**: Although one study found that lateral wedge insoles vs flat insoles provided no additional benefit in alleviating symptoms or slowing disease progression<sup>3</sup>, five additional studies showed improvement with use of a lateral wedge. Immediate reduction in WOMAC scores and KAM were found in one study, as well as improvements in pain and physical function after three months<sup>6</sup>. VAS scores, knee ROM, walking speed, and step length improved when walking with a lateral wedge inlay<sup>1</sup>. WOMAC scores and KAM were significantly reduced when using lateral wedges.<sup>2</sup> When lateral wedges were used in conjunction with arch supports, the WOMAC, VAS, and KAM were all significantly reduced<sup>4</sup>. Using lateral wedges improved VAS scores at rest/standing and WOMAC pain/function and total versus baseline<sup>6</sup>.

**Clinical Message:** The use of lateral wedge in-shoe insoles can be an effective conservative treatment for relieving pain associated with mild or moderate medial knee OA. The majority of the evidence focuses on short-term immediate effects (up to 3 months, with only one study following up after one year). However, more research must be conducted regarding long-term use of lateral wedge in-soles to determine if pain relief is maintained.

## **References:**

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	Fu, 2015 <sup>4</sup>	Bennell, 2011 <sup>3</sup>	Hinman, 2008 <sup>6</sup>	Arazpour, 2012 <sup>1</sup>	Barrios, 2009 <sup>2</sup>	Koca, 2009 <sup>7</sup>
Population	10 participants (19 knees), >50 years old, isolated medial knee OA, main symptom: pain, varus knee alignment, OA of Kellgren- Lawrence grade 2 or above over medial compartment	179 participants, > 50 years old, radiographic diagnosis of mild to moderately severe medial knee OA, pain over medial knee compartment, pain <= 3/10	40 participants, >= 50 years old, presence of medial tibiofemoral joint osteophytes, average pain >3 on 11 point scale, knee pain when walking 2 blocks	24 participants, mean age 59 years old, medial compartment knee OA, Kellgren/ Lawrence grade of 1 or 2	66 participants (but only 45 completed 1 year follow up), 40- 75 years old, radiographically diagnosed with medial knee OA, knee pain while walking at least 3/10 on VAS	37 participants, medial knee OA, Lawrence- Kellgren 2 or 3, convenience sample
Study Design	Non-randomized prospective cohort study with cross-over design	Double blind, randomized controlled trial with stratification	Randomized trial, single- subject design	Quasi- experimental design	Prospective controlled trial, block randomization	Randomized controlled study
Intervention	Unilateral flat insole, lateral- wedged in sole, lateral-wedged in sole with subtalar strap, lateral-wedged in sole with arch support, valgus knee brace, valgus knee brace with lateral-wedged insole with arch support on affected side	Unilateral full length 5 degree lateral wedged insoles on affected side	Bilateral insoles 5 degree wedged along entire lateral length of foot	Unilateral laterally wedged insole (6 degrees) or custom unloader knee orthosis on affected side	Unilateral full- length lateral wedge insole (5 degree) on affected side. After 5 degree addition, 3 or 5 degrees added also (up to 15 degrees total) until pain reduction at initial fitting on affected side	Unilateral 5 degree lateral wedge on affected side
Comparison	All participants wore all intervention types. Pre- treatment and post-treatment	Control: flat insoles. Participants receive one or other	Usual footwear without the insoles	Compared to baseline condition and across groups	Control group with neutral orthosis (70 durometer crepe with full-length micropuff cover)	Control group had no insole
Methodology	3D gait analysis before and during use of each orthotic treatment (use each intervention for 4 weeks)	Measures completed at week 0 and week 52	3D gait analysis before insoles and immediately after insole insertion. Pain measures collected at baseline and after 3 months	Patients put into one of 2 groups, fitted with intervention, wear for 6 weeks, then reevaluate biomechanics	Complete outcome measures after fitting, at 1 month, and continuous 3 month follow ups, and 1 year	All subjects received therapy, outcome measures at fitting, 1 and 3 months

Outcomes	WOMAC, VAS mean knee adduction moment (KAM), peak knee adduction moment	WOMAC, medial tibial cartilage volume, physical activity	WOMAC, external KAM, static alignment	VAS, max external applied KAM, sagittal plane knee motion (ROM), walking speed, step length	WOMAC, 6 minute walk test, timed stair negotiation test	WOMAC, VAS, Ritchie index score – rest, walking, standing
Key Findings	<ul> <li>Lateral wedge group: WOMAC score and KAM significantly reduced</li> <li>Lateral wedge + arch support: WOMAC, VAS, KAM significantly reduced</li> </ul>	• Lateral wedge insoles vs flat control provide no additional benefit in alleviating symptoms or slowing disease progression over 12 months	<ul> <li>Laterally wedged insoles result in immediate reduction in walking pain (WOMAC) and KAM (no change in static alignment)</li> <li>After 3 months improvements in pain/ physical function</li> </ul>	<ul> <li>Pain significantly reduced and knee ROM improved when walking with lateral wedge inlay</li> <li>Improvement in KAM, knee ROM, walking speed, step length</li> </ul>	<ul> <li>Statistically significant improvement for pain (WOMAC), stiffness, physical function, 6 min walk test, stair test compared to baseline for both groups</li> <li>Significant interaction that favors lateral wedge group for 6 minute walk test (not observed in control group)</li> </ul>	<ul> <li>Wedge group improved VAS at rest/standing and WOMAC pain/function and total versus baseline, Control no difference</li> <li>3<sup>rd</sup> month: Wedge group improved in all measures of VAS and WOMAC except stiffness versus baseline, Control showed no improvement</li> </ul>
Study Limitations	Small sample size, selection bias, short follow-up period, orthotic compliance unknown, sequential non- randomized application of orthoses	Different MRI used for some patients, sample doesn't represent population, non- standardized footwear	Possible placebo effect, radiographic measure does not account for dynamic alignment, non- standardized footwear	Subjects not blinded to treatments	Each subject had different amount of wedging	Subjects not blinded to treatment