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

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An update to the previously published work by Bondre and Hall<sup>1</sup>

**Clinical Question:** Is the use of an isolated lateral in-shoe heel wedge effective in reducing pain associated with medial knee osteoarthritis (OA)?

**Patient (P):** Participants weighted average age 62.8 years old (y/o) with range of 45-80 y/o, radiographic evidence of medial knee OA<sup>2,3</sup>, symptomatic medial knee OA<sup>4-6</sup>, and Kellgren-Lawrence grade (KL) 2-4.<sup>24,5,7</sup>

**Intervention (I):** 8° lateral wedge insole (LWI) at heel tapered to  $0^{\circ7}$ , variety of LWIs ranging from 2-10°<sup>4</sup>, 5° LWIs<sup>2,6,8</sup>, 6° LWIs<sup>5</sup>, 10° tapered LWI.<sup>3</sup>

**Comparison (C):** Neutral insoles<sup>2-8</sup>, Foot orthoses (FOs) with medial longitudinal arch support and lateral wedges (MLA-LWI)<sup>2,6</sup>, Biaxial AFO with free motion lateral joint and limited eversion posterior joint.<sup>7</sup>

**Outcome (O):** The Western Ontario and McMaster Universities Arthritis Index (WOMAC)<sup>5-7</sup>, Visual Analog Scale for pain (VAS)<sup>3-5</sup>, knee adduction moment (KAM)<sup>2,4,7,8</sup>, Knee Injury and Osteoarthritis Outcome Score (KOOS)<sup>4,8</sup>, Likert Scale Comfort Score<sup>6,8</sup>, Gait Analysis<sup>2,7</sup>, Timed Stair Climb<sup>4,6</sup>, Self-reported Logbook and Comfort Scores<sup>4,6</sup>, Foot Function Index (FFI)<sup>6</sup>, Medial Meniscus Extrusion.<sup>3</sup>

**Background:** OA is one of the most common degenerative joint diseases, causing pain and stiffness in the affected joints.<sup>5</sup> OA of the knee affects approximately 10% of people over the age of 55, inciting responses such as pain, reduced activity, and instability.<sup>7</sup> Conservative methods of intervention are necessary as there is no cure for OA, and total knee arthroplasty (TKA) procedures are reserved for severe presentations.<sup>2,6</sup> LWIs placed inside the shoes are one treatment option that may reduce pain related to mild to moderate medial knee OA.

### Search Strategy:

Databases Searched: www.pubmed.gov, www.oandp.org, www.ebsco.com

Search Terms: lateral wedge, in-shoe, in shoe, osteoarthritis, pain, medial knee pain Inclusion/Exclusion Criteria: 2016-present. English. Excluded if study examined: external wedges, medial wedges, lateral knee pain, or did not measure pain.

## Synthesis of Results:

The findings of the seven studies were mixed as to whether an isolated LWI is effective in reducing pain associated with medial knee OA. Three studies found that use of isolated unilateral LWIs led to statistically significant reduction in pain as measured by the WOMAC,<sup>7</sup> VAS,<sup>3</sup> and an 11-point numerical rating scale.<sup>8</sup> A fourth study<sup>6</sup> found that use of isolated bilateral LWIs resulted in minimal clinically important difference (MCID) in the WOMAC pain score for 54% of users; however, overall, the change in WOMAC was not statistically significant. Three additional studies found that LWIs had no impact on pain, as measured by the VAS<sup>4,5</sup>, WOMAC<sup>5</sup>, or an 11-point numerical rating scale.<sup>2</sup> Multiple studies also reported the impact of LWI use on KAM; two reported a reduction in KAM<sup>2,7</sup> with LWI use, while one reported no change.<sup>4</sup> Two studies<sup>3,8</sup> explored methods of prescreening participants for responsiveness to LWI treatment; while these studies did not demonstrate clinically significant efficacy of prescreening, investigators may continue to explore this possibility. Studies<sup>2,6</sup> also compared LWIs to MLA-LWIs. Both found superior results with the addition of MLA support including an improved participant-reported comfort<sup>2</sup>, higher incidence of pain reduction<sup>6</sup>, and higher participant preference.<sup>6</sup>

### **Clinical Message:**

Recent literature suggests that the use of in-shoe LWIs is likely insufficient for pain relief associated with mild to moderate medial knee OA. This is in contrast to the original CAT addressing this question, which found that LWIs could offer a conservative, low-cost, and effective treatment for such pain.<sup>1</sup> However, evidence published since 2016 suggests that more nuanced, robust, and customized care may be in order. Use of prescreening to determine which patients will respond positively to LWI treatment may warrant further exploration. Additionally, comparisons to MLA-LWIs suggest that these may be a more broadly effective, and still conservative, treatment to reduce pain. A focused appraisal of the literature on MLA-LWIs for treatment of medial knee OA is needed to confirm this.

### **References:**

- 1. Bondre N, Hall M. Effect of lateral in-shoe wedge on reducing pain in medial knee osteoarthritis. AAOP. 2015.
- 2. Hatfield GL, Cochrane CK, Takacs J, et al. Knee and ankle biomechanics with lateral wedges with and without a custom arch support in those with medial knee osteoarthritis and flat feet. *J Orthop Res.* 2016;34(9):1597-1605.
- 3. Ishii Y, Ishikawa M, Nakashima Y, et al. Dynamic response of medial meniscus extrusion to the lateral wedge insole is correlated with immediate pain reduction in knee osteoarthritis patients: real-time ultrasonographic study. *J Med Ultrason* (2001). 2022;49(4):731-738.
- 4. Ferreira V, Machado L, Vilaça A, Xará-Leite F, Roriz P. Effects of tailored lateral wedge insoles on medial knee osteoarthritis based on biomechanical analysis: 12-week randomized controlled trial. *Clin Rehabil.* 2021;35(9):1235-1246.
- 5. Hsu W-C, Chou L-W, Chiu H-Y, Hsieh C-W, Hu W-P. A Study on the Effects of Lateral-Wedge Insoles on Plantar-Pressure Pattern for Medial Knee Osteoarthritis Using the Wearable Sensing Insole. *Sensors*. 2023;23(1).
- 6. Hunt MA, Takacs J, Krowchuk NM, Hatfield GL, Hinman RS, Chang R. Lateral wedges with and without custom arch support for people with medial knee osteoarthritis and pronated feet: an exploratory randomized crossover study. *J Foot Ankle Res.* 2017;10:20.
- Barati K, Ebrahimi Takamjani I, Shamsoddini A, Ejraei Dolatabad H. A comparison of the biomechanical and clinical effects of a biaxial ankle-foot orthosis and lateral wedge insole in individuals with medial knee osteoarthritis. *Disabil Rehabil*. 2022;44(26):8501-8508.
- 8. Felson DT, Parkes M, Carter S, et al. The Efficacy of a Lateral Wedge Insole for Painful Medial Knee Osteoarthritis After Prescreening: A Randomized Clinical Trial. *American College of Rheumatology*. 2019;71:908-915.

	Barati, 2022 <sup>7</sup>	Felson, 2019 <sup>8</sup>	Ferreira, 2021 <sup>4</sup>	Hsu, 2023 <sup>5</sup>	Hatfield, 2016 <sup>2</sup>	Hunt, 2017 <sup>6</sup>	Ishii, 2022 <sup>3</sup>
Population	n = 31	n = 62	n = 38	n = 23	n = 26	n = 26	n = 25
	<i>Demographics</i> Age = 52.2 y/o Sex = 25 F	Demographics Age = 64.2 y/o Sex = 23 F	<i>Demographics</i> Age = 61.7 y/o Sex = 23 F	<i>Demographics</i> Age = 69.1 y/o Sex = 17 F	<i>Demographics</i> Age = 64.0 y/o Sex = 22 F	<i>Demographics</i> Age = 64.0 y/o Sex = 22 F	<i>Demographics</i> Age = 69.9 y/o Sex = 11 F
	<i>Inclusion</i> KL2 or KL3; BMI 18.5-25; 45-60 y/o	Inclusion Overall knee pain $\geq 4/10$ in the past wk; KL $\geq 2$ ; 40-85 y/o; patellofemoral OA less severe than medial knee OA and < KL 3	<i>Inclusion</i> Medial knee OA; KL2 or KL3; 45- 80 y/o; genuvarum; VAS ≥ 3 for knee pain	<i>Inclusion</i> Medial knee pain; KL ≥ 2; age ≥ 55 y/o	<i>Inclusion</i> Symptomatic, radiographically diagnosed OA; KL≥2; FPI ≥ 4+	Inclusion Knee pain $\geq 3/10 \geq$ 6 mo; medial osteophytes; narrowed medial joint; FPI $\geq 4+$	Inclusion Medial knee pain ≥ 1 mo; ability to walk w/o AD; independent in ADLs
	<i>Exclusion</i> History of: lateral knee OA, disease impacting gait, intraarticular knee injections w/i 6 mo, knee surgery, orthotic use	<i>Exclusion</i> BMI > 35; Inability to walk w/o AD; History of: fibromyalgia, diabetic neuropathic pain, RA or other LE inflammatory joint disease, knee injection w/i 3 mo, knee realignment surgery or arthroplasty, knee arthroscopy w/i 6 mo	<i>Exclusion</i> BMI > 35; History of: lateral knee OA, patellofemoral OA, systemic arthritis, other diagnosis affecting LE function, corticosteroid injections w/i 6 wk, knee surgery w/i 6 mo	<i>Exclusion</i> Inability to walk w/o AD; suspected local or systemic infection; History of: central nervous system disease, RA or other LE inflammatory joint disease, severe trauma or fracture in LE, surgery in LE	Exclusion Pain with walking ≤ 3/10 over last wk; inability to walk w/o AD; inability to use orthoses; History of: diagnosis affecting LE function, oral corticosteroid w/i 4 wk, knee injection or surgery w/i 6 mo	<i>Exclusion</i> Current or previous orthotic use; History of: diagnosis affecting LE function, knee joint replacement, tibial osteotomy, knee injection or surgery w/i 6 mo, oral corticosteroid w/i 4 wk	<i>Exclusion</i> History of: "severe" OA, traumatic injury, neuromuscular disease, corticosteroid injections, knee surgery
Study Design	Randomized crossover	Randomized crossover	Randomized control trial	Randomized control trial	Randomized crossover	Exploratory, w/i subjects, randomized	Crossover
						crossover	

	Barati, 2022 <sup>7</sup>	Felson, 2019 <sup>8</sup>	Ferreira, 2021 <sup>4</sup>	Hsu, 2023 <sup>5</sup>	Hatfield, 2016 <sup>2</sup>	Hunt, 2017 <sup>6</sup>	Ishii, 2022 <sup>3</sup>
Intervention	Unilateral LWI	Unilateral LWI	Unilateral LWI	Bilateral LWIs	Bilateral LWIs	Bilateral LWIs	Unilateral LWI
	Specifications 8-degree wedge at heel, tapered to 0 degrees at toe tips; PVC; full length	<i>Specifications</i> 5-degree wedge; 70 Shore A density	Specifications 2, 4, 6, 8, or 10- degree wedge; unspecified material; full length	<i>Specifications</i> 6-degree wedge; polyurethane; full length	Specifications 5-degree wedge; polypropylene base, EVA wedge, neoprene cover; sulcus length	Specifications 5-degree wedge; polypropylene base, EVA wedge, neoprene cover; sulcus length	<i>Specifications</i> 10-mm wedge; silicone; full length
Comparison	Biaxial AFO	Neutral insole	Neutral insoles	Neutral insoles	Bilateral MLA- LWI and no insoles	Bilateral MLA- LWI	No insoles and a control group of healthy individuals
	Specifications Free motion lateral joint and limited eversion posterior joint	Specifications 70 Shore A density	Specifications Full length	<i>Specifications</i> Polyurethane; full length	Specifications 5-degree wedge; polypropylene base, EVA wedge, neoprene cover; sulcus length	Specifications 5-degree wedge; polypropylene base, EVA wedge, neoprene cover; sulcus length	
Methodology	Self-report measures and 3D gait analysis completed at 0 and 2 wk for each intervention, with 2 wk washout period between	3D gait analysis to prescreen subjects for KAM reduction ≥ 2% from neutral insole to LWI. For eligible subjects, self-report measures and MRI completed at 0 and 8 wk for each intervention, with 8 wk washout period between	Self-report and physical function measures and 3D gait analysis completed at 0 and 12 wk	Self-report measures and plantar pressure measurement completed at 0 and 20 wk	Self-report measures and 3D gait analysis testing only at 0 wk	Self-report and physical function measures completed at 0 wk and 2 mo for each intervention, with 2 mo washout period between	Video motion analysis, ultrasonography and self-report measure only at 0 wk
Outcomes	WOMAC, walking speed, KAM	KAM (prescreen only), pain scale (11-point Likert scale), KOOS, BML volume per MRI	VAS, KOOS, 30 second sit-to-stand, 40 m fast-paced walk test, 12-step stair climb test, usage logbook, self-report	WOMAC, VAS, plantar pressure moments	Immediate pain and comfort scales, walking speed, KAM, frontal plane ground moment arm at knee, ankle	WOMAC, FFI, timed stair climb test, usage logbook, self- report comfort and change of symptoms scales	VAS, MME, ΔMME

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			comfort/ improvement scales, KAM		eversion moment and ROM	(5-point Likert scales)	
Key Findings	Both the biaxial AFO and LWI significantly reduced the WOMAC pain and function scores compared to baseline. The magnitude of pain reduction from baseline did not significantly differ between interventions. Both the biaxial AFO and LWI significantly reduced first and second peak KAM compared to baseline. Moreso using the AFO.	LWI use was associated with lower pain scores in the last week and in participants' nominated most painful activity compared to neutral insoles with statistical significance. No statistically significant difference in KOOS scores between conditions. Pain improvement at MCID reported in 28% of participants with LWI and 22% of participants with neutral insoles. No effect on medial BML volume.	No statistically significant difference or MCID in using LWI vs. neutral insoles as it pertains to pain intensity, biomechanics, KOOS, and physical function test.	LWI had no statistically significant changes on WOMAC pain and function scores or VAS.	No statistically significant difference in pain between the conditions. No statistically significant difference in comfort between LWI and no insole. MLA-LWI were significantly more comfortable than no insole. LWI reduced the external KAM peak and impulse by 8% compared to the control.	MLA-LWI led to improvements in all OMs, while LWI alone led to no significant improvements compared to baseline. However, there were no significant differences in outcomes between conditions except for the stair climb. MCID improvement for WOMAC pain was seen in 54% of LWI and 64% of MLA-LWI compared to baseline. 77% of participants preferred MLA- LWI over LWI.	LWI reduced the VAS pain scores compared to no insoles with statistical significance. With LWI, 40% of participants, deemed "responders," had MCID improvement of VAS score With LWI, all participants with knee OA had a statistically significant decrease in maximum MME and $\Delta$ MME during walking compared to no insoles. Decrease in $\Delta$ MME was greater in responders than in non- responders with statistical significance.

	Barati, 2022 <sup>7</sup>	Felson, 2019 <sup>8</sup>	Ferreira, 2021 <sup>4</sup>	Hsu, 2023 <sup>5</sup>	Hatfield, 2016 <sup>2</sup>	Hunt, 2017 <sup>6</sup>	Ishii, 2022 <sup>3</sup>
Study Limitations	Limited to participants with KL 2 and KL 3	Limited to participants with KL >= 2	Limited to participants with KL 2 and KL 3	Limited to participants with KL >= 2	Limited to participants with KL 2 and KL 3	Limited to participants with KL 2 and KL 3	Limited to participants with KL 2 and KL 3
	Participants were majority female	No standard footwear	No standard footwear	No standard footwear	No standard footwear	No standard footwear	No standard footwear
	No control of activity level	No control of activity level during home use	Participants were majority female	Participants were majority female	Participants were majority female	Participants were majority female	No participant blinding
during Self-re time No par investi blindir	Self-reported wear time	Adherence to advised wear time not reported Moderate number (7) of reported	No control of activity level during home use Self-reported wear time	No control of activity level during daily use Adherence to advised wear time not reported	No participant or investigator blinding No acclimation period prior to data collection	No control of activity level during home use	No acclimation period prior to data collection
	No participant or investigator					Self-reported wear time	Unclear if order of test conditions was randomized
	adverse events	blinding	Footwear not standardized		No participant blinding		
			No standard angle for LWI			High number (16) of reported adverse events	

Additional abbreviations used in the table: within (w/i), without (w/o), months (mo), lower extremity (LE), weeks (wk), assistive device (AD), rheumatoid arthritis (RA), activities of daily living (ADLs), polyvinyl chloride (PVC), ethylene-vinyl acetate (EVA), Foot Posture Index (FPI), minimal clinically important difference (MCID), bone marrow lesion (BML), medial meniscus extrusion (MME), difference between maximum and minimum MME ( $\Delta$ MME)