Reference

Schwarze, Martin[1]; Bartsch, Leonie P.[1]; Block, Julia[1]; Alimusaj, Merkur[1]; Jaber, Ayham[1]; Schiltenwolf, Marcus[1]; Wolf, Selbastian I.[1]

A comparison between laterally wedged insoles and ankle-foot orthoses for the treatment of medial osteoarthritis of the knee: A randomized cross-over trial

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Products

Agilium Freestep 2.0

Major Findings

With Ankle-foot orthosis (AFO; Agilium Freestep 2.0) compared to laterally wedged insoles (LWI):

→ **Significantly reduced knee pain (measured by numeric rating scale) with both LWI (-1 pt, p=0.008) and AFO (-1.5 pts, p=0.004) compared to baseline, with no significant difference between the devices.**

→ **Significantly improved health-related quality of life (EQ-5D-5L) with both LWI (+0.06, p=0.001) and AFO (+0.04, p=0.002), with no significant difference between the devices.**

→ **Significantly reduced external Knee Adduction Moment (eKAM) with both AFO and LWI compared to baseline, indicating a reduction in medial knee load.**

- The reduction was significantly greater at the 1st peak with AFO (18%, p<0.001) than with LWI (6%, p=0.02)(AFO vs. LWI: p=0.001).

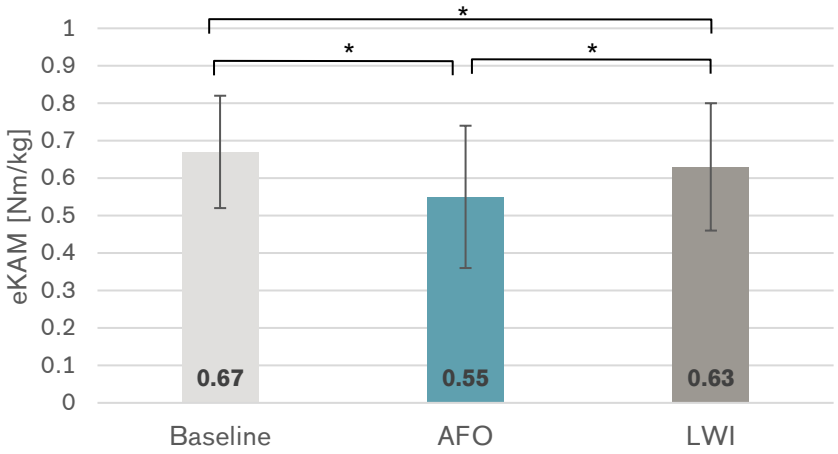


Figure 1. Mean first peak external knee adduction moment (eKAM) at baseline, and after 6-week intervention with AFO, and LWI.

* indicate statistically significant differences ($p < 0.05$).

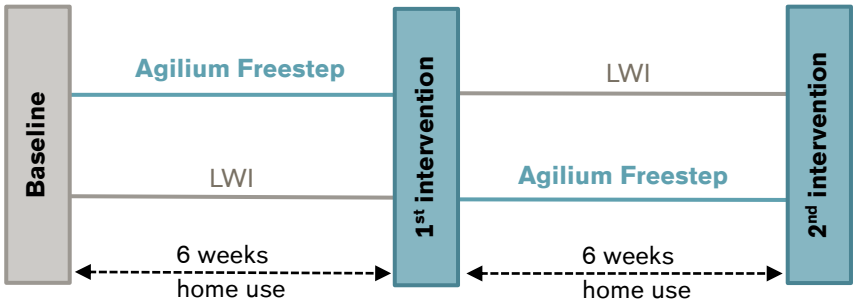
Population

Subjects:	39 patients (20 male, 19 female)
Underlying condition:	symptomatic medial knee osteoarthritis stage 1-3*
Previous orthosis:	none
Mean age:	58.9 ± 8.4 years
Mean height:	172 ± 10 cm
Mean weight:	87.6 ± 15.1 kg

*According to Kellgren and Lawrence: classification of osteoarthritis from 0 to 4 with 0: none, 1: doubtful, 2: minimal, 3: moderate, and 4: severe osteoarthritis

Study Design

Single-centre, block-randomized, cross-over controlled trial:



Patients were randomly assigned to one of two groups. Each patient received either a lateral wedged insole (LWI) or an ankle-foot orthosis (AFO; Agilium Freestep 2.0). After six-week home-use phase patients switched to the alternate intervention for another six weeks.

The patients underwent three assessments: at baseline, after six weeks (1st intervention) and after twelve weeks (2nd intervention). The primary outcome was the change in the knee adduction moment measured by instrumented 3D gait analysis. Secondary outcomes included patient reported measures (e.g. EQ-5D-5L, Oxford Knee Score (OKS), pain rating, as well as additional biomechanical gait parameters.

Results

Functions and Activities						Participation	Environment
Biomechanics – Static Measurement	Biomechanics – Gait analysis	X-Rays	EMG	Functional tests	Clinical effects	Satisfaction	Health Economics

Category	Outcomes	Results [a]	Sig. [b]
Biomechanics – Gait analysis	Speed [m/s]	No significant differences.	0
	GRF total 2nd peak [N/kg]	Trend to reduction with LWI (–0.9%, p=0.07), but not AFO (–0.9%, p=0.61):	–
	Knee Adduction Moment, 1st peak 0-30% GC (KAM) [Nm/kg]	Significant reduction of 1st peak KAM (load on knee) with both interventions; greater reduction with AFO (–17.9%, p < 0.001) than with LWI (–6.0%, p = 0.02):	––

Baseline	AFO	LWI
1.30 ± 0.15	1.30 ± 0.16	1.31 ± 0.16

Baseline	AFO	LWI
10.7 ± 0.7	10.6 ± 0.7	10.6 ± 0.8

		Baseline	AFO	LWI	
		0.67 ± 0.15	0.55 ± 0.19	0.63 ± 0.17	
	KAM, 2nd peak 30–60% GC [Nm/kg]	Significant reduction with LWI (–4.7%, p=0.03), but not AFO (–2.3%, p=0.24):			––
		Baseline	AFO	LWI	
		0.43 ± 0.13	0.42 ± 0.14	0.41 ± 0.13	
	Knee Flexion Moment peak (KFM) [Nm/kg]	Significant increase with AFO (+8.9%, p=0.05), but not LWI (+7.1%, p=0.13):			++
		Baseline	AFO	LWI	
		0.56 ± 0.23	0.61 ± 0.21	0.60 ± 0.23	
	Knee Adduction Angular Impulse (KAAI) [Nm·s/kg]	Significant reduction with both AFO (–10.9%, p<0.001) and LWI (–4.7%, p=0.05); AFO vs. LWI (p=0.02):			––
		Baseline	AFO	LWI	
		21.1 ± 4.8	18.8 ± 5.9	20.1 ± 5.9	
Functional Tests	Walking speed, stride length	No clinically relevant changes with either intervention: Speed ~1.30 m/s at baseline, AFO and LWI (all p > 0.5)			0
Clinical effects	Oxford Knee Score (knee pain and knee-related function in daily life)	Significant improvement with both LWI (+2.6%, p=0.003) and AFO (+7.9%, p=0.001):			++
		Baseline	AFO	LWI	
		38 [32–41]	41 [34–43]	39 [35–43]	
	AKS Knee Score (clinician-assessed score that evaluates the medical and functional condition of the knee joint)	Significant improvement with both LWI (+16.7%, p=0.01) and AFO (+21.2%, p=0.004):			++
		Baseline	AFO	LWI	
		66 [51–71]	80 [61–86]	77 [61–86]	
	AKS Function Score (patient's ability to perform functional activities)	Trend for LWI (+2.3%, p=0.07); but not AFO (+2.3%, p=0.19):			+
		Baseline	AFO	LWI	
		88 [70–100]	AFO 90 [80–100]	90 [75–100]	
	Knee Pain (NRS)	Significant pain reduction with both LWI (–40%, p=0.008) and AFO (–40%, p=0.004):			––
		Baseline	AFO	LWI	
		5 [3–7]	3 [2–5]	3 [1–5]	
Satisfaction / QoL	EQ-5D Index	Significant improvement with both LWI (+3.5%, p=0.001) and AFO (+4.7%, p=0.002):			++
		Baseline	AFO	LWI	
		0.85 [0.68–0.90]	0.89 [0.78–0.94]	0.88 [0.82–0.94]	

[a] Results displayed as mean ± SD or median [IQR]

[b] no difference (0), positive trend (+), negative trend (–), significant (++/––), not applicable (n.a.)

IRQ = Interquartile Range

Author's Conclusion

"In summary, this study shows that lateral wedge insoles and ankle-foot orthoses do not differ in their clinical improvements after six weeks of use. Biomechanically, the ankle-foot orthosis causes a significantly larger reduction of medial knee load than the lateral wedge insole. As this biomechanical difference was not reflected in patient-reported outcomes, the link between biomechanical and clinical changes produced by the aids remains unclear. A clinically relevant improvement of pain and functional outcomes cannot be generally assumed for all patients. This makes uncritical use of the devices questionable. Nevertheless, since the majority of patients experienced a pain reduction with both aids, we consider a therapy attempt justified in mild to moderate knee osteoarthritis.

The heterogeneous response to both devices highlights a need for research to determine patient characteristics that better predict which patients fully harness the benefits of the biomechanical changes. Regarding the promising biomechanical effects of the ankle-foot orthosis, insights on the long-term influence on disease progression would prove to be valuable." (Schwarze et al. 2021)

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