Reference

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

Varus knee limits pain relief effects of laterally wedged insoles and ankle-foot orthoses in medial knee osteoarthritis

Journal of Rehabilitation Medicine (2022), 54, 1129.

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Products

Agilium Freestep

Major Findings

With Agilium Freestep, an ankle-foot orthosis (AFO), compared to laterally wedged insoles (LWI):

→ Both aids reduced pain significantly compared to baseline

→ Greater varus malalignment (higher mechanical axis deviation (MAD)) was significantly correlated with less pain reduction for both aids

→ A cut-off value of 14-15mm MAD (i.e. >3° knee varus) was identified to predict pain response

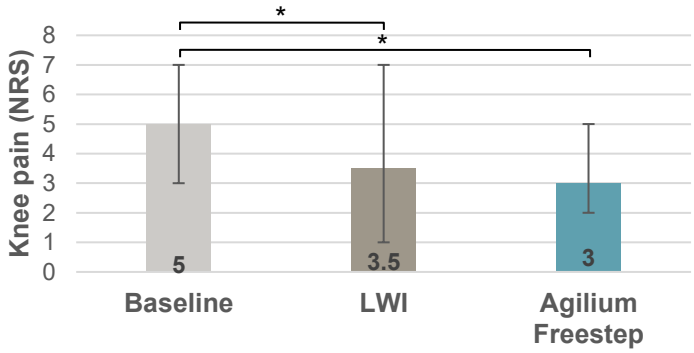


Figure 1: Median (quartiles) of knee pain in the last seven days.
NRS: numerical rating scale (0 – no pain, 10 – worst pain)

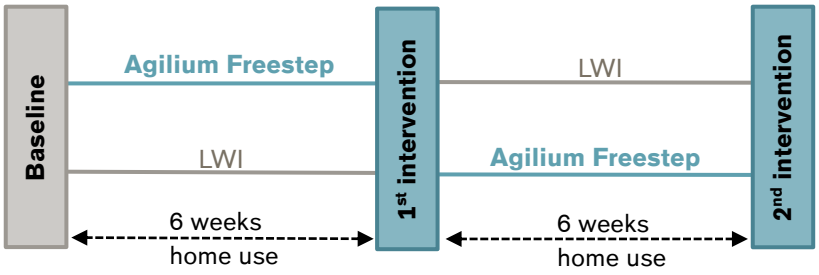
Population

Subjects:	28 (16 male, 12 female)
Underlying condition:	symptomatic medial knee osteoarthritis stage 1-3*
Previous orthosis:	none
Mean age:	58.3 ± 8.0 years
Mean height:	173 ± 10 cm
Mean weight:	90.4 ± 14.0 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

Secondary [1] analysis of a randomized, monocentric, clinically prospective cross-over study:



In the original study patients were randomly divided into two groups. Each patient received either a lateral wedged insole (LWI) or an ankle-foot orthosis (AFO; Agilium Freestep). After the first six-week 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).

This is a secondary analysis of the study specifically investigates the influence of limb alignment (mechanical axis deviation, MAD) on pain reduction - a relationship not previously explored in the primary study. It uses radiographic data (MAD) to correlate with pain outcomes from a questionnaire.

[1] Schwarze M, Bartsch LP, Block J, Alimusaj M, Jaber A, Schiltenwolf M, et al. A comparison between laterally wedged insoles and ankle-foot orthoses for the treatment of medial osteoarthritis of the knee: a randomized cross-over trial. Clin Rehabil 2021; 10.1177/0269215521993636:269215521993636

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 for Agilium Freestep vs. LWI	Sig.*
Clinical effects	**Knee pain at examination dates** [0 – no pain, 10 – worst pain]	Knee pain was reduced after both interventions.	n.a.

Examination date	Knee pain [Median (quartiles)]
Baseline	5 (3; 7)
After LWI** use	3.5 (1; 7)
After Agilium Freestep** use	3 (2; 5)

	Change of knee pain (Δ pain)	Knee pain is significantly reduced by both aids, but no significant difference between aids was found.	

Examination dates	Knee pain [Median (quartiles)]	
LWI – baseline	–0.5 (–3; +1)	++
Agilium Freestep – baseline	–1.5 (–3; +1)	++
LWI vs Agilium Freestep	n.a.	0

Category	Outcomes	Results for Agilium Freestep vs. LWI		Sig.*
	Correlations	**Mechanical axis deviation vs.**	Tibiofemoral angle	++
			Knee pain after LWI	0
			Knee pain after AFO	++
			Knee pain change LWI	++
			Knee pain change AFO	++
			Knee pain baseline	0
		Tibiofemoral angle vs.	Knee pain after LWI	0
			Knee pain after AFO	++
			Knee pain change LWI	++
			Knee pain change AFO	++
			Knee pain baseline	0
		Knee pain after LWI vs.	Knee pain baseline	++
		Knee pain after AFO vs.	Knee pain baseline	++
	Responders and non-responders to LWI and Agilium Freestep	Responders and non-responders to LWI and Agilium Freestep with calculated cut-off values for the mechanical axis deviation (MAD)		n.a.

	LWI	Agilium Freestep
Responders (n)	14	16
Non-responders (n)	14	12
Cut-off MAD (mm)	14.25	14.75
Sensitivity (%)	85.7	87.5
1 – specificity (%)	28.6	25.0

*no difference (0), positive trend (+), negative trend (–), significant (++/––), not applicable (n.a.)
significance set at $p<0.05$; trends set at $0.1>p>0.05$
**LWI- laterally wedged insole, Agilium Freestep: ankle-foot orthosis (AFO)

Author's Conclusion

"Both laterally wedged insoles and ankle-foot orthoses can be used successfully to reduce pain in medial osteoarthritis of the knee. The success of the therapy can be predicted with a sensitivity >80% by the mechanical axis deviation on full weight-bearing long-standing radiographs." (Bartsch et al., 2022)

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