

Reference

Elsa Mauricio¹, Maik Sliepen², Dieter Rosenbaum²

Acute effects of different orthotic interventions on knee loading parameters in knee osteoarthritis patients with varus malalignment

The Knee, 25(5), October 2018. DOI: 10.1016/j.knee.2018.06.017.

Products

Agilium Freestep

Major Findings

With ankle-foot orthosis (AFO; Agilium Freestep) compared to unloader brace, laterally wedged shoes, or no intervention:

→ **Significant decrease in first peak knee adduction moment (KAM) by 9% with the Agilium Freestep and by 27% with the wedged shoes**

→ **Significant correlation between first KAM peak at baseline (control condition) and the reduction of KAM when using the interventions ($p < 0.001$)**

- Indicating that with a higher baseline KAM, a more pronounced KAM reduction can be expected when using the interventions.

→ **Decrease in the second KAM peak with all interventions compared to control condition without interventions**

- By 8% with the Agilium Freestep
- By 3% with the unloader brace
- Significant decrease by 10% with the wedged shoes

→ **Significant decrease in KAM impulse with all interventions compared to control condition without interventions**

- By 18% with the Agilium Freestep
- By 7% with the unloader brace
- By 8% with the wedged shoes

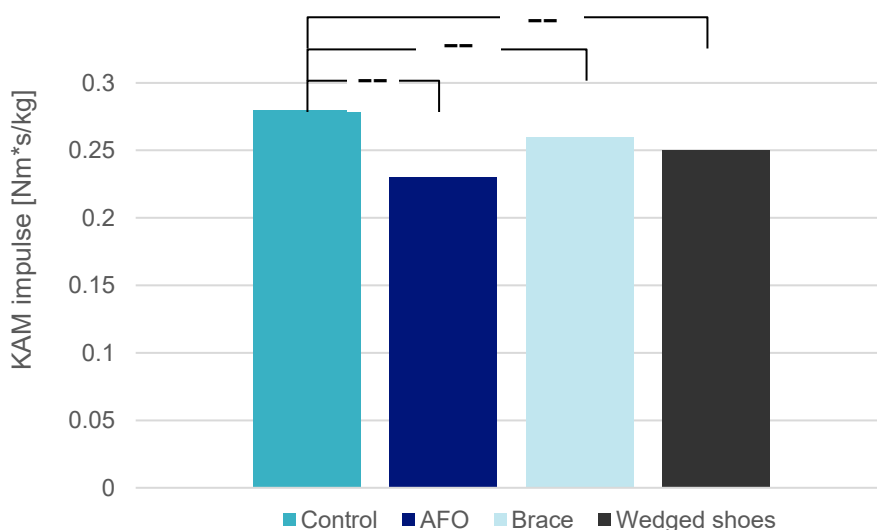


Figure 1: Knee adduction moment (KAM) impulse compared between the control condition and the three interventions (--- indicates significant reduction)

→ **Significant increase in knee flexion moment by 26% with Agilium Freestep compared to control condition without interventions**

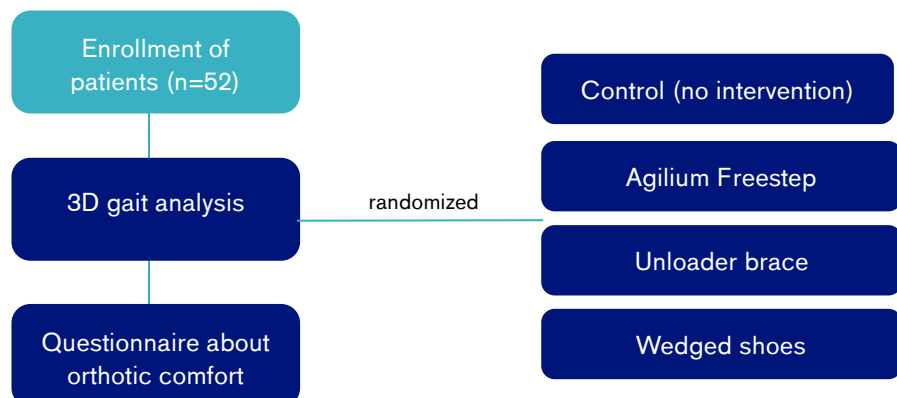
→ **Most patients (47/52) rated the Agilium Freestep to be the most comfortable intervention out of the three interventions**

Population

Subjects:	52 (30 female, 22 males)
Mean age:	59 ± 10 years
Body mass index:	27.5 ± 4.9 kg/m ²
Clinical condition:	Knee osteoarthritis (KOA) according to the American College of Rheumatology guidelines, varus malalignment ≥ 2°
Affected side:	34 bilateral, 18 unilateral
Previous knee injury:	28 yes, 24 no
Knee Osteoarthritis Outcome Score (KOOS):	to assess patients' opinion about their knee and associated problems; scale 1-100, 100 representing no knee problems
Pain:	53.3 ± 23.3
Symptoms:	49.2 ± 17.8
Activities of daily living:	60.0 ± 24.1
Sports:	31.2 ± 24.5
Quality of life:	28.4 ± 16.5

Study Design

Randomized acute intervention study:



If patients were diagnosed with bilateral KOA, the devices were applied to the more symptomatic knee. The patients walked with a comfortable self-selected speed. Immediately after the gait analysis patients were asked to rate the comfort of each device from 1 (most comfortable) to 5 (uncomfortable).

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 Control vs. AFO vs. Brace vs. Wedged Shoes				Sig. ^a
Biomechanics – Gait analysis – Spatiotemporal parameters	Gait velocity [m/s] IQR	Control	AFO	Brace	Wedged Shoes	--
		1.29 (0.27)	1.26 (0.26)^c	1.26 (0.21)^c	1.25 (0.25)^c	
		Patients walked with a significantly slower gait velocity when wearing the three interventions.				
	Step length [m]	0.68 ± 0.12	0.68 ± 0.09	0.68 ± 0.10	0.64 ± 0.11^c	--
		Step length was significantly reduced when patients walked with wedged shoes.				
	Stance phase [%]	63.39 ± 3.33	63.57 ± 3.98	63.84 ± 3.10	62.78 ± 2.61	0
	Swing phase [%]	36.55 ± 3.38	36.17 ± 4.36	36.06 ± 3.30	37.06 ± 2.47	0
	Double support phase [%]	13.76 ± 3.11	13.69 ± 3.88	13.88 ± 1.99	12.30 ± 2.93^c	--
		Double support phase was significantly reduced when patients walked with wedged shoes.				
	Single support phase [%]	35.70 ± 2.84	35.79 ± 2.90	35.79 ± 2.20	37.01 ± 2.72^c	++
		Single support phase was significantly increased when patients walked with wedged shoes.				
	Step width [m]	0.12 ± 0.03	0.13 ± 0.04^c	0.13 ± 0.04^c	0.11 ± 0.02	++
		Step width was significantly increased when patients walked with AFO or brace.				
Biomechanics – Gait analysis – Ground reaction force	GRF Max ₁ , vertical [BW]	1.11 ± 0.13	1.10 ± 0.11	1.10 ± 0.10	1.09 ± 0.11	0
	GRF Min vertical [BW]	0.75 ± 0.09	0.75 ± 0.10	0.77 ± 0.09^c	0.76 ± 0.12	++
		The minimum of the vertical ground reaction force component was significantly increased when patients walked with the brace.				
	GRF Max ₂ vertical [BW]	1.04 ± 0.10	1.05 ± 0.12	1.06 ± 0.10^c	1.07 ± 0.14	++
		The 2 nd maximum of the vertical ground reaction force component was significantly increased when patients walked with the brace.				
Biomechanics – Gait analysis – Knee moments	Peak ₁ KAM [Nm/kg]	0.55 ± 0.34	0.50 ± 0.29^c	0.53 ± 0.22	0.44 ± 0.34^c	--
		The 1 st peak of the knee adduction moment was significantly reduced when patients walked with the AFO or wedged shoes.				

Category	Outcomes	Results for Control vs. AFO vs. Brace vs. Wedged Shoes				Sig. ^a
	Peak ₂ KAM [Nm/kg]	0.38 ± 0.16	0.36 ± 0.22	0.38 ± 0.16	0.34 ± 0.18^c	--
		The 2 nd peak of the knee adduction moment was significantly reduced when patients walked with wedged shoes.				
	Peak KFM [Nm/kg]	0.36 ± 0.32	0.47 ± 0.37^c	0.39 ± 0.28	0.37 ± 0.35	++
		The peak of the knee flexion moment was significantly increased when patients walked with the AFO.				
	KAM impulse [Nm*s/kg]	0.28 ± 0.16	0.23 ± 0.11^c	0.26 ± 0.14^c	0.25 ± 0.12^c	--
		The knee adduction moment impulse was significantly reduced when patients walked with all three interventions.				
Satisfaction	Orthotic comfort*	AFO	Brace	Wedged Shoes		++
		2.2 ± 0.7	3.0 ± 0.9	3.2 ± 1.1		
		The AFO was rated as the most comfortable of the three interventions. Its median comfort score was significantly lower than those of the brace and the wedged shoes. The brace was rated as the second most comfortable intervention and had a significantly lower score than the wedged shoes.				

^a no difference (0), positive trend (+), negative trend (–), significant (++/--), not applicable (n.a.)

^b Significant difference between ‘Control’ and ‘AFO’, ‘Control’ and ‘Brace’, and ‘Control’ and ‘Wedged Shoes’

* Comfort on a scale of 1 to 5; 1 = most comfortable, 5 = least comfortable

Abbreviations: GRF: Ground Reaction Force; BW: Body Weight; KAM: Knee Adduction Moment; KFM: Knee Flexion Moment

Author’s Conclusion

“The novel AFO and the wedged shoes reduced the first peak KAM impulse more effectively compared to the conventional unloader one brace. As the AFO was rated the most comfortable of the three interventions, it seems to be a comfortable and effective way to reduce these parameters in KOA patients with varus alignment. However, the effect of an increased KFM on KOA remains unclear and requires further investigation. In our study, the three orthopaedic devices revealed a better reduction on the first peak KAM in patients who had a higher KAM at baseline. Therefore, we suggest that future studies should examine the relationship between KAM on baseline and KAM reduction with different orthotic interventions or in a population with a more severe stage of OA. At the same time, future studies should examine the mid- and long-term outcome of these orthotic interventions since the effects might be different after prolonged use.” (Mauricio et al., 2018)

Author’s Affiliation

¹Funktionsbereich Bewegungsanalytik, IEMM, Universitätsklinikum Münster, Albert-Schweitzer Campus 1, Gebäude D3, 48129 Münster, Germany.

²Funktionsbereich Bewegungsanalytik, IEMM, Universitätsklinikum Münster, Albert-Schweitzer Campus 1, Gebäude D3, 48129 Münster, Germany.

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