

Reference

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Acute and mid-term (six-week) effects of an ankle-foot-orthosis on biomechanical parameters, clinical outcomes and physical activity in knee osteoarthritis patients with varus malalignment

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Products

Agilium Freestep

Major Findings

With Agilium Freestep:

→ Immediately reduced medial knee loading with Agilium Freestep.

- Significant reduction of the first peak Knee Adduction Moment (KAM) by 41% ($p < 0.001$).
- Significant reduction in the KAM impulse by 19% ($p < 0.001$).
- Significant reduction in the Knee adduction angle (KAA) by 14% ($p < 0.001$).

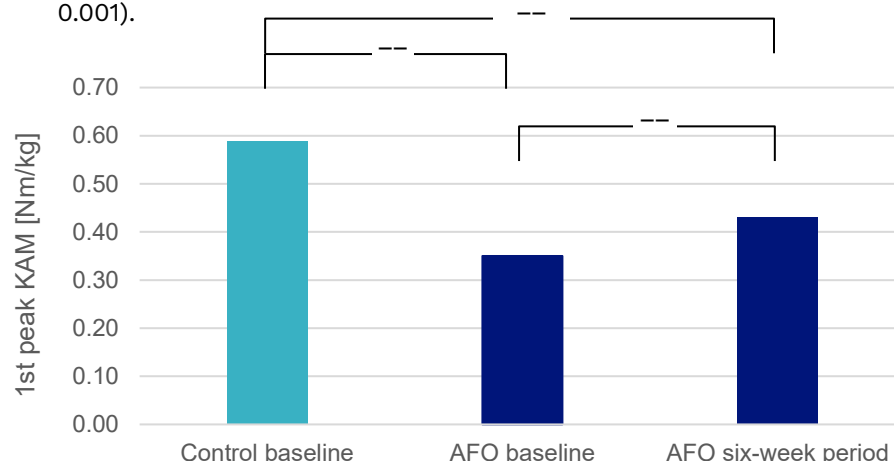


Figure 1: First peak of the Knee Adduction Moment (KAM) for walking without the Agilium Freestep, immediately after donning the Agilium Freestep, and after a six-week period of AFO use (--- indicates significant reduction, $p < 0.001$)

→ After six weeks of Agilium Freestep use, medial knee loading remained significantly lower compared to baseline without the Agilium Freestep.

- Significant reduction by 27% in the first peak KAM ($p < 0.001$).
- Significant reduction by 19% in the KAM impulse ($p < 0.001$).

→ Significantly increased knee flexion moment by 48% ($p < 0.001$) immediately after donning, and by 71% ($p < 0.001$) after six weeks of Agilium Freestep use.

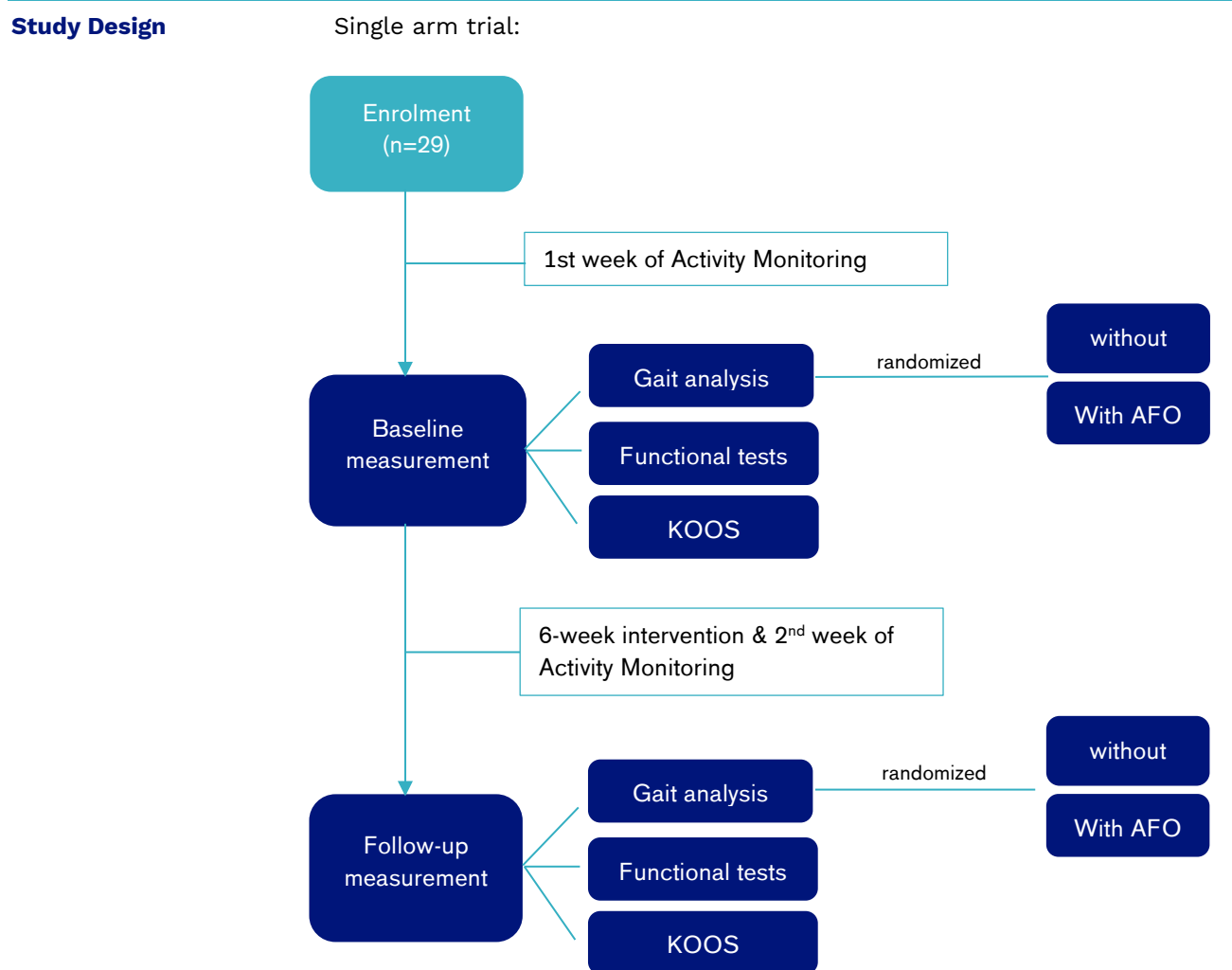
→ Physical function showed improvement after six weeks of Agilium Freestep use.

- Significantly faster fast-paced Walk Test ($p = 0.027$).
- Significantly faster Timed-Up-and-Go Test ($p = 0.013$).
- Significantly faster 15-Stair Climb Test ($p = 0.007$).

→ Patient-reported outcomes were significantly improved after the intervention period of six weeks.

- Knee Osteoarthritis Outcome Score (KOOS) subscales for pain, daily-life function, symptom and quality of life were significantly reduced ($p < 0.001$).
- Significantly lower sports scores were reported ($p = 0.002$).

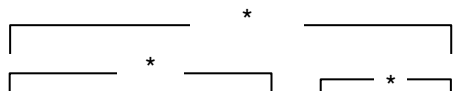
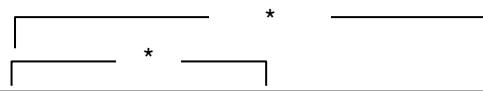
Population	Subjects:	29 (19 female, 10 males)
	Clinical condition:	diagnosed Knee osteoarthritis (KOA) according to the American College of Rheumatology guidelines and a knee varus malalignment (min. 2°)
	Previous injury:	15 yes, 14 no
	Affected side:	17 bilateral, 14 unilateral
	Mean age:	59.6 ± 9.9 years
	Mean body weight:	81.41 ± 19.06 kg



3D gait analysis was performed with patients walking at a self-selected speed while wearing their own footwear. Physical function was assessed using fast-paced Walk Test, Timed-Up-and-Go Test and 15-Stair Climb Test. Patient reported outcomes were evaluated using the Knee Osteoarthritis Outcome Score (KOOS). Physical activity during daily life was measured using a tri-axial accelerometer.

Results

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

Category	Outcomes	Control baseline vs. AFO baseline vs. AFO 6-week period			Sig. ^a
Biomechanics – Gait analysis	Gait speed [m/s]	Control baseline	AFO baseline	AFO post 6-week	0
		1.24 ± 0.22	1.23 ± 0.21	1.27 ± 0.18	
	1 st Peak knee adduction moment [Nm/kg]	The first peak of the knee adduction moment significantly decreased immediately after donning the Agilium Freestep and after a period of six weeks of use. Compared with AFO post-six weeks, values were significantly lower at AFO baseline (immediate effect). ^c			--
					
		Control baseline	AFO baseline	AFO post 6-week	
		0.59 ± 0.20	0.35 ± 0.16	0.43 ± 0.19	
	2 nd Peak knee adduction moment [Nm/kg]	0.41 ± 0.14	0.36 ± 0.14	0.38 ± 0.16	0
	Max knee flexion moment [Nm/kg]	The maximum knee flexion moment significantly increased immediately after donning the Agilium Freestep and after a period of six weeks of use.			++
					
		Control baseline	AFO baseline	AFO post 6-week	
	0.31 ± 0.25	0.46 ± 0.25	0.53 ± 0.27		
Knee adduction impulse [Nm/kg]	Knee adduction impulse [Nm/kg]	The maximum knee adduction impulse significantly decreased immediately after donng the Agilium Freestep and after a period of six weeks of use			--
					
		Control baseline	AFO baseline	AFO post 6-week	
		0.32 ± 0.11	0.26 ± 0.12	0.26 ± 0.13	
	1 st Peak knee adduction angle [°]	4.12 ± 4.23	3.54 ± 4.63	3.91 ± 6.27	0

Category	Outcomes	Control baseline vs. AFO baseline vs. AFO 6-week period			Sig. ^a
	1 st Peak knee flexion angle [°]	29.96 ± 5.02	30.89 ± 6.10	32.15 ± 10.82	0
	Stance phase duration	Compared with baseline, stance phase duration during walking in the control condition was significantly reduced by 2% after six weeks.			--
Functional tests	Fast-paced Walk Test	Baseline	Post-intervention		
		26.8 ± 4.7 s	26.1 ± 4.5 s		--
	Timed-Up-and-Go Test ^b	7.2 (2.3) s	7.1 (1.7) s		--
	15-Stair Climb ^b	14.2 (5.0)	13.9 (5.3)		--
Functional tests – physical activity of daily life	Amount of level, ascending & descending steps	No significant differences.			0
	Bicycling crank revolutions	No significant differences.			0
	Hours spend walking, bicycling, sitting or standing	No significant differences.			0
Clinical effects – KOOS subscales median score		Significant deteriorations in all listed KOOS subscales post-intervention:			
		Baseline	Post-intervention		
	Pain ^b	56 (21)	42 (32)		--
	Daily-life function ^b	68 (24)	47 (32)		--
	Symptoms	49 ± 18	37 ± 19		--
	Sports	31 ± 25	14 ± 27		--
	Quality-of-life	28 ± 17	14 ± 18		--

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

^b Data are presented as mean ± standard deviation for normally distributed variables and as median (interquartile range) for non-normally distributed variables.

^c The observed reduction in the first peak knee adduction moment of 41% is larger than typically reported in the literature, where reductions range between 15% and 25%.

*Significant difference between different time points/conditions

Author's Conclusion

“In conclusion, the AFO is an effective way to reduce the first KAM peak and KAM impulse in KOA patients with varus malalignment immediately and after six weeks. However, it also leads to increased maximal KFM at baseline and after six weeks. Furthermore, clinical outcomes did not improve (physical function and activity) or even deteriorated (pain and symptoms) and a significant amount of patients were not willing to complete the 6-week intervention period. Although the main surrogate measures for knee joint

loading appeared positively affected, it remains debatable whether KOA patients clinically benefit from the 6-week application of the device.” (Sliepen et al., 2018)

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