Reference

Mahsa Kavyani Boroujeni [1], Mohammad Taghi Karimi [2, 3], Masoud Rafiaei [1], Hossein Akbari Aghdam [4, 5]

The effect of Agilium Freestep ankle–foot orthosis on the kinetic and kinematic parameters of gait in patients with knee osteoarthritis

The Knee. Vol. 60, January 2026. DOI: 10.1016/j.knee.2026.104353.

Products

Agilium Freestep

Major Findings

With Agilium Freestep compared to no orthosis:

→ Significantly decreased stride length by 3.5% immediately after wearing Agilium Freestep (p=0.02)

→ Significantly decreased second peak of vertical ground reaction force (GRF) by 28.3% when wearing Agilium Freestep (p=0.02)

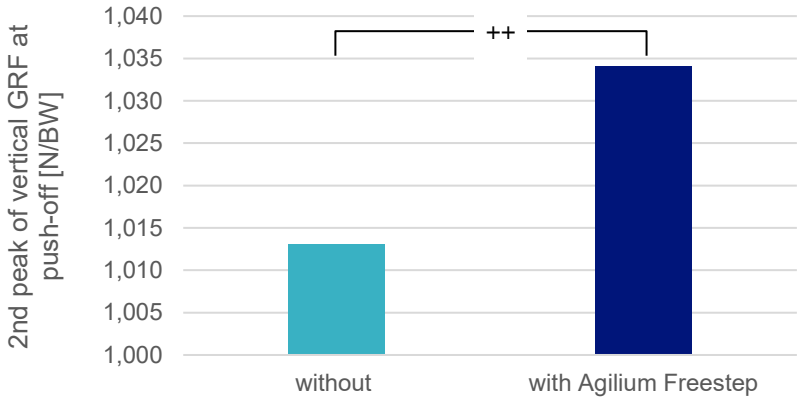


Figure 1: shows second peak of the vertical component of ground reaction force (GRF; at push off) comparing walking with Agilium Freestep to walking without it. (++ indicates significant difference)

→ Significantly increased peak of mediolateral ground reaction force (GRF) by 2% when wearing Agilium Freestep (p=0.001)

→ No significant difference for the vertical component of the mean peak knee joint contact force (p=0.920 for 1st peak and p=0.164 for the 2nd peak). The magnitude of the forces determined here does not correlate with values reported in the literature.

→ Study limitations:

- Small sample size limits statistical power and generalizability.
- Only mild-to-moderate OA patients were included.
- Only immediate effects were assessed.
- No control group was implemented.
- Potential type I error, as no correction for multiple comparisons was applied.

Population

Subjects:	10 (all female)
Clinical condition:	Medial knee osteoarthritis grade 2-3 based on Kellgren-Lawrence scale *
Affected side:	10 right
Mean age:	≥ 50 years

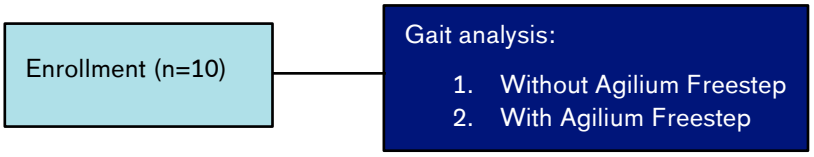
Other orthotic interventions: none

*Kellgren-Lawrence scale = classifies the severity of osteoarthritis (OA) based on characteristic changes seen in joint X-rays.

Grade	0	1	2	3	4
Name	No OA	Doubtful OA	Mild OA	Moderate OA	Severe OA

Study Design

Single-arm trial:



Patients were asked to walk at a self-selected comfortable walking speed. An open-source software (OpenSim) for biomechanical modelling and simulating musculoskeletal systems was used to measure knee joint kinematics, moments and estimate knee joint contact forces. The perception of pain was not investigated.

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. without	Sig.[a,b]
Biomechanics – Gait analysis	Stride length [m]	Significantly decreased stride length when wearing Agilium Freestep compared to without it. **Without**: 1.101m ± 0.095m; **With Agilium Freestep**: 1.141m ± 0.103m	--
	Stride time [s]	No significant differences.	0
	Speed [m/s]	Decreased walking speed, when wearing Agilium Freestep compared to without it, but the difference was not significant. **Without**: 0.760m/s ± 0.163m/s; **With Agilium Freestep**: 0.815m/s ± 0.145m/s	–
	Cadence [steps/min]	No significant differences.	0

Category	Outcomes	Results for Agilium Freestep vs. without	Sig.[a,b]
	Fz (mediolateral) [N/BW(normalized to body weight)]	Significantly increased mediolateral ground reaction force component when wearing Agilium Freestep compared to with-out it. **Without**: 0.0540 ± 0.017 — **With Agilium Freestep**: 0.0421 ± 0.0102	++
	Fx1 (anteroposterior while breaking during loading response) [N/BW]	No significant differences.	0
	Fx2 (anteroposterior while progression during pre-swing phase) [N/BW]	No significant differences.	0
	Fy1 (vertical during loading response) [N/BW]	No significant differences.	0
	Fy2 (vertical at push-off) [N/BW]	Significantly decreased vertical component at push off when wearing Agilium Freestep compared to without it. **Without**: 1.013 ± 0.030 — **With Agilium Freestep**: 1.034 ± 0.035	−−
	Mean peak knee joint contact force (JCF)	No significant differences.	
	JCFz (medilateral) [N/BW]	Decreased medilateral mean peak knee joint contact force, when wearing Agilium Freestep compared to without it, but the difference was not significant. **Without**: 1.243 ± 0.811 — **With Agilium Freestep**: 1.804 ± 0.657	−
	JCFx (anteroposterior) [N/BW]	No significant differences.	0
	JCFy (vertical) [N/BW]	No significant differences.	0
	Sagittal knee moment [NM/kg]	No significant differences.	0
Clinical effects	Range of motion of knee and ankle joint [°]	No significant differences.	0

[a] no difference (0), positive trend (+), negative trend (–), significant (++/––), not applicable (n.a.)
[b] significance set at $p<0.05$; trends set at $0.1>p>0.05$

Author's Conclusion

"Based on the results of this study, Agilium Freestep AFO has no significant effect on knee joint contact force. Further research with larger sample sizes is recommended to clarify and confirm these preliminary findings. However, therapists can consider recommending this AFO for osteoarthritic knee patients to potentially decrease knee joint loading, especially for those who cannot tolerate knee orthoses." (Boroujeni et al., 2026)

Author's Affiliation

[1]Musculoskeletal Research Center, Isfahan University of Medical Sciences, Isfahan, Iran

[2]Orthotics and Prosthetics Department, Rehabilitation Faculty of Shiraz University of Medical Sciences, Shiraz, Iran

[3]Orthopedic and Rehabilitation Research Center, Shiraz University of Medical Sciences, Shiraz, Iran

[4]Department of Orthotics and Prosthetics, Isfahan University of Medical Sciences, Isfahan, Iran

[5]Department of Orthopedic Surgery, School of Medicine, Isfahan University of Medical Sciences, Isfahan, Iran