

Reference

Menger B, Kannenberg A, Petersen W, Zantop T, Rembitzki I, Stinus, H.

Department of Orthopaedic and Trauma Surgery, School of Medicine, University of Goettingen, Goettingen, Germany.

Effects of a novel foot–ankle orthosis in the non-operative treatment of unicompartmental knee osteoarthritis

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doi: 10.1007/s00402-016-2500-2.

Products

Agilium Freestep

Major Findings

With Agilium Freestep compared to no orthosis:

→ **The Western Ontario and McMaster Universities Arthritis Index (WOMAC) total score and all subscores improved significantly within one year during Agilium Freestep use:**

Results of 12-month follow-up:

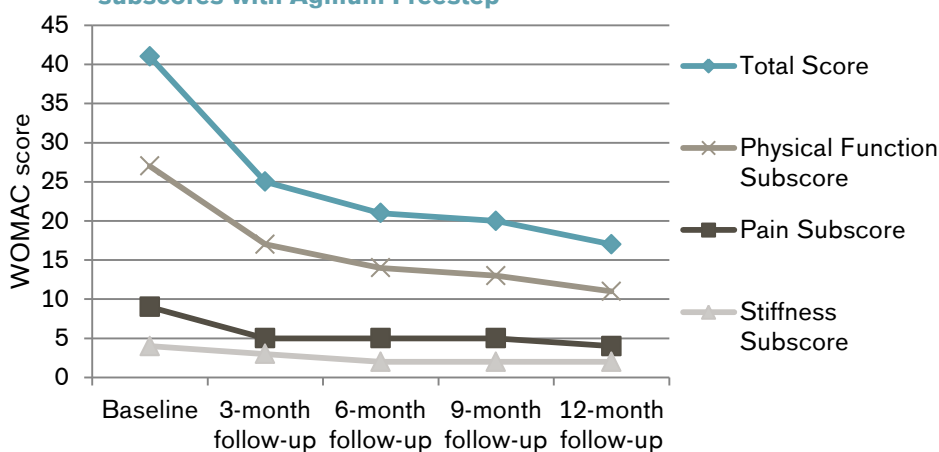
Total score: -59,4%

- Pain subscore: -59.3%
- Stiffness subscore: -55.8%
- Physical Function subscore: -59.9%

→ **With Agilium Freestep, knee pain was significantly reduced after six (-24.5%) and twelve months (-30.6%).**

→ **The restriction of activities of daily living (ADL) and sport-related activity decreased over time with Agilium Freestep.**

Significant improvement of WOMAC total score and subscores with Agilium Freestep

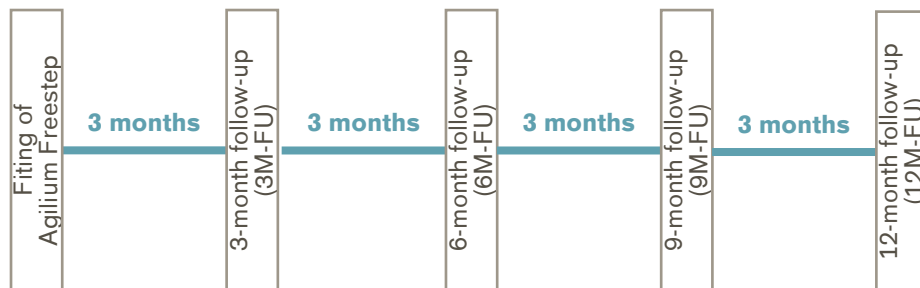


Population

Subjects: 25 knee OA patients (15 male, 10 female)
Drop-outs: 2
Mean age: 60.5 ± 11.7 yrs
Affected side: Left knee = 15 patients; Right knee = 10 patients
Affected compartment: Medial = 21 patients; Lateral = 4 patients
OA grade classification: Kellgren-Lawrence:
Grade I (8); Grade II (14); Grade III (3)
Leg axis: Neutral = 10 patients; Varus deviation = 11 patients;
Valgus deviation = 4 patients

Study Design

Prospective cohort study:



Recorded orthosis use over twelve months:

1 patient: < 4 hours; 17 patients: 4-8 hours; 5 patients: > 8 hours

Results

Functions and Activities						Participation
Biomechanics – Static measures	Biomechanics – Gait analysis	X-Ray	EMG	Functional tests	Clinical effects	Satisfaction

Category	Outcomes	Results for Agilium Freestep				
		Baseline vs 3M-FU	Baseline vs 6M-FU	Baseline vs 9M-FU	Baseline vs 12M-FU	
Clinical effects	WOMAC (Western Ontario and McMaster Universities Osteoarthritis Index)	Total score	-38.6% ++	-49.1% ++	-50.6% ++	-59.4% ++
		Pain subscore	-49.5% ++	-49.5% ++	-49.5% ++	-59.3% ++
		Stiffness subscore	-25.6% ++	-48.8% ++	-46.5% ++	-55.8% ++
		Physical Function subscore	-36.9% ++	-49.3% ++	-51.8% ++	-59.9% ++
Knee Pain (VAS)	Knee pain was significantly reduced with Agilium Freestep at 6- and 12-month follow-up:	Baseline vs 3M-FU	Baseline vs 6M-FU	Baseline vs 9M-FU	Baseline vs 12M-FU	
		-18.4% +	-24.5% ++	-22.4% +	-30.6% ++	
Restriction (ADL & sport-related activity)	ADL and sport-related activity restriction decreased over time with Agilium Freestep. (<i>Measured by four-item Lickert Scale</i>)					

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

Author's Conclusion

"In conclusion, the results of our study suggest that the AFO evaluated here is effective at significantly reducing the pain and stiffness and improving the physical function of patients with mild to moderate unicompartmental osteoarthritis of the knee. The clinical benefits of this AFO appear to be similar to those demonstrated in clinical trials of knee unloader braces, although our study suggests that overall patient compliance with AFOs may be superior to unloader braces. However, additional prospective randomized studies are needed to further characterize this AFO in the treatment of unicompartmental OA." (Menger et al. 2016)

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