Reference

Wolf Petersen[1], Andree Ellermann[2], Jörg Henning[3], Stefan Nehrer[4], Ingo Volker Rembitzki[5], Jürgen Fritz[6], Christoph Becher[7], Alfio Albasini[8], Wolfgang Zinser[9], Volker Laute[10], Klaus Ruhnau[11], Hartmut Stinus[12], Christian Liebau[13]

Non-operative treatment of unicompartmental osteoarthritis of the knee: a prospective randomized trial with two different braces — ankle–foot orthosis versus knee unloader brace

Archives of Orthopedic and Trauma Surgery, 139(2), February 2019. DOI: 10.1007/s00402-018-3040-8.

Products

Agilium Freestep

Major Findings

With Agilium Freestep compared to Unloader One (conventional knee brace):

→ Significantly less bruises in the Agilium Freestep group (23,5%) in contrast to the Unloader One group (66,7%) (p<0.001)

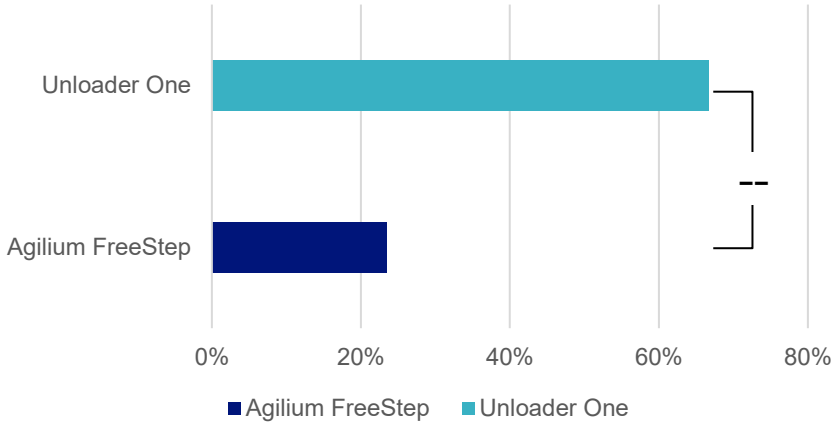


Figure 1: shows percentage of patients reporting bruises in each treatment group (**––** indicates significant difference)

→ Significant improvements for both groups

- Walking pain: Significantly decreased walking pain over a period of 8 weeks and 6 months for both Unloader One and Agilium Freestep compared to baseline.
- Pain at sports: Significantly decreased walking pain over a period of 8 weeks and 6 months for both Unloader One and Agilium Freestep.
- Koos subscales: Significant improvement of all five KOOS subscales (Symptoms, Pain, Activities of Daily Living, Sports/Function, Quality of Life) over time in both treatment groups ($p < 0.001$).

→ Non-inferiority of the Agilium Freestep orthosis was demonstrated compared to Unloader One

- Walking pain: no significant difference between the two groups.
- Pain at sports: no significant difference between the two groups

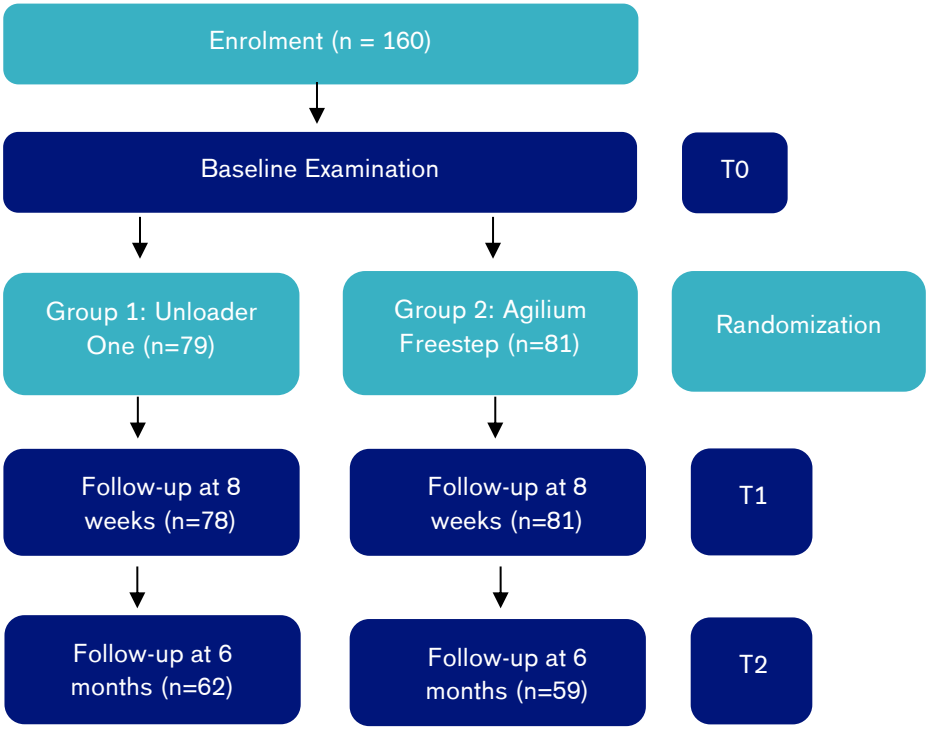
Population

Subjects:	Total: 160 (71 females, 89 males)
Clinical condition:	Medial knee osteoarthritis grade 1 or higher based on Kellgren-Lawrence scale *
Affected side:	68 left, 87 right, 1 bilateral
Mean age:	57.3 years ± 10.1
Body Mass Index (BMI):	28.6 kg/m² ± 5.6

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

Study Design

Multicentric, prospective randomized trial:



The study was conducted as a non-inferiority comparison between the Agilium Freestep and Unloader One orthoses. At baseline (T0), all participants underwent a clinical examination and completed standardized questionnaires assessing pain and knee function before orthosis application. Follow-up assessments (T1, T2) were conducted using the same questionnaires. The primary outcome was pain at rest, during walking, and during sports, assessed using a numerical analogue scale (NAS; 0–100, with higher scores indicating greater pain). Secondary outcomes included knee function measured by the Knee Injury and Osteoarthritis Outcome Score (KOOS) comprising the subscales symptoms, pain, activities of daily living, sport and recreation, and knee-related quality of life. Dropouts occurred during follow-up for various reasons, including discontinuation without a stated reason, and time constraints.

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. Unloader One	Sig.*[a]
Clinical effects – primary outcome pain	Pain at rest	In the Unloader One group, pain at rest improved significantly from T0 to T2 ($p = 0.026$). No significant between-group differences were observed at any time point, nor for absolute or percentage changes (all $p \geq 0.05$).	0
	Walking pain	Walking pain improved significantly in both groups from T0 to T1 ($p < 0.001$) and from T0 to T2 ($p = 0.004$ / $p < 0.001$). No significant changes were observed between T1 and T2 ($p \geq 0.05$). There were no significant between-group differences at any time point (T0, T1, T2) or in absolute or percentage changes (all $p \geq 0.05$). Non-inferiority of the Agilium Freestep for walking pain was demonstrated for both T1–T0 and T2–T0 comparisons.	0
	Pain at sports	Both groups showed a significant improvement from T0 to T2 (Unloader One: $p = 0.017$; Agilium Freestep: $p = 0.011$). In the Agilium Freestep group, a significant improvement was also observed between T0 and T1 ($p = 0.001$). No significant between-group differences were found for absolute or percentage changes between any time points ($p \geq 0.05$). For pain during sports, non-inferiority of the Agilium Freestep orthosis was demonstrated for both the T0–T1 ($p < 0.001$) and T0–T2 ($p = 0.095$) comparisons.	0
Clinical effects – secondary outcome KOOS subscales	Symptoms	Increased in both treatment groups over all the follow up time points.	0
	Pain	Improvement of 8.3 points was achieved in the Unloader One group in comparison to an improvement of 11.1 points in the Agilium Freestep group.	0
	Activity	No significant group difference at T0, T1, and T2 ($p \geq 0.05$). Both groups showed a significant improvement between T0 and T1 ($p < 0.001$) and between T0 und T2 ($p < 0.001$). Between time points T1 and T2, a significant improvement was observed in the Unloader One group ($p = 0.044$).	0
	Sport	The Unloader One group showed a significant improvement between T1 and T2 as well as between T0 and T2 ($p = 0.021$ and $p = 0.042$). No significant group difference was observed in T0, T1, or T2 in terms of absolute or percent differences ($p \geq 0.05$).	0
	Quality of life	Quality of life improved twice as much in the Agilium Freestep group (median score increase of 12.5 points) in comparison to the Unloader One group (median score increase of 6.25 points). No significant group differences at T0, T1, and T2 were detected.	0
Clinical effects	Additional interventions	No significant differences between the two groups at any time point. The number of patients who used additional bandages after 6 months was significantly higher in the Agilium Freestep group than in the Unloader One group ($p = 0.001$).	0

Category	Outcomes	Results for Agilium Freestep vs. Unloader One	Sig.*[a]
	Adverse effects	Significantly less reported bruises in the Agilium Freestep group (23.5%) compared with the Unloader One group (66.7%) ($p<0.001$).	––
Satisfaction	Compliance	At T1 and T2, there was no significant group difference in weekly or daily brace use.	0

*Significance column refers exclusively to between-group differences in the direct comparison of Agilium Freestep and Unloader One.
[a] no difference (0), positive trend (+), negative trend (–), significant (++/––), not applicable (n.a.)

Author's Conclusion

"In conclusion, the present prospective randomized clinical trial shows that an ankle foot orthosis is as effective as a conventional knee brace for the improvement of pain and function in patients with unicompartmental osteoarthritis." (Petersen et al., 2018)

Author's Affiliation

[1] Klinik für Orthopädie und Unfallchirurgie, Martin Luther Krankenhaus, Grunewald, Caspar Theyß Strasse 27-31, 14193 Berlin, Germany

[2] Arcus Sportklinik, Rastatter Straße 17, 75179 Pforzheim, Germany

[3] Krankenhaus Lahnhöhe, Zentr. für konserv. Orthopädie, Am Kurpark 1, 56112 Lahnstein, Germany

[4] Donau Universität Krems, Dr. Karl Dorrek Straße 30, 3500 Krems, Austria

[5] Deutsche Sporthochschule Köln, Cologne, Germany

[6] Orthopädisch Chirurgisches Centrum Tübingen, Wilhelmstr. 134, 72074 Tübingen, Germany

[7] Orthopädische Klinik der MH Hannover, Anna-von-Borries-Straße 1-7, 30625 Hannover-Kleefeld, Germany

[8] FISIOTERAPIA Albasini and Müller, Viale Giuseppe Motta 15, 6500 Bellinzona, Switzerland

[9] St. Vinzenz Hospital-Dinslaken, Dr. Otto-Seidel Str. 31, 46535 Dinslaken, Germany

[10] Gelenk und Wirbelsäulenzentrum, Kieler Str. 1, 12163 Berlin, Germany

[11] Gemeinschaftspraxis Rosenthal and Schubert, Viktoriastr. 66-70, 44787 Bochum, Germany

[12] Orthopaedicum Northeim, Sturmbäume 3, 37154 Northeim, Germany

[13] Asklepios Harzklinik Fritz-König-Stift, Ilsenburger Straße 95, 38667 Bad Harzburg, Germany