

Agilium Freestep

Clinical Effects & Satisfaction

Major Findings

With Agilium Freestep:

→ **Knee pain could be significantly reduced:**

- **by 51% after two weeks** (Schmalz et al. 2011)
- **by 24.5% (after 6 months) and 30.6% (after 12 months).** (Menger et al. 2016)

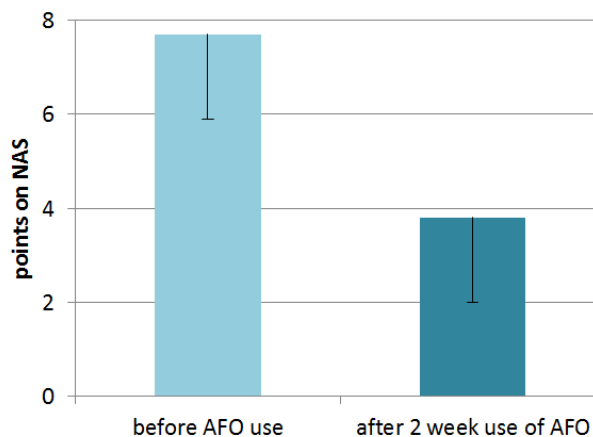
→ **WOMAC total score and all subscores improved significantly within one year during Agilium Freestep use** (Menger et al. 2016)

Results of 12-month follow-up:

Total score: -59,4%

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

Knee pain on numeric analog scale (NAS, 0...10)



Knee pain on NAS for patients with knee OA before and after 2-week use of Agilium Freestep [Schmalz et al. 2011]

Clinical Relevance

Osteoarthritis (OA) is a degenerative joint disease and the leading cause of pain and disability in elderly people worldwide (Hinman et al. 2005). The prevalence of OA increases with age (O'Reilly et al. 1998). Symptomatic knee OA affects 10% of persons over age 55 (Peat et al. 2001) and 12% of persons older than 60 years (Felson et al. 2009).

Patients suffer from pain, stiffness, decreased range of joint motion and a sensation of instability and buckling of the affected knee. These problems may limit the ability to rise from a chair, stand comfortably, walk or climb stairs (Felson et al. 2009, Kaufman et al. 2001).

The results of this observational study with Agilium Freestep are similar to the positive clinical experience with knee braces for the treatment of knee OA (Draper et al. 2000, Finger & Paulos 2002, Hillström et al. 2000).

The pain reduction in the daily use of Agilium Freestep can be classified as meaningful and should improve the prognosis for increasing capacity in the leisure and professional environments.

Furthermore, comfort and handling were rated invariably positive. With regard to these important subjective criteria, the Agilium Freestep seems to be a viable alternative to conventional knee braces, which are sometimes marked by low compliance. (Schmalz et al. 2011) It is concluded, that there is high likelihood for improved compliance with the Agilium Freestep (Schmalz et al. 2011).

The Agilium Freestep is used in unicompartmental OA. It is an AFO (ankle-foot-orthosis) that reduces the pain during activities of daily living and shows a high patient satisfaction.

Summary

Four biomechanical studies have evaluated the effectiveness of the Agilium Freestep:

Schmalz et al. (2006) observed a significant reduction of the knee lever arm of the ground reaction force (GRF) in the frontal plane and a significantly decreased knee adduction moment with Agilium Freestep in combination with shoe wedges.

Schmalz et al. (2011) investigated the Agilium Freestep without shoe wedges. Also here, a significant reduction of the knee lever arm of the GRF in the frontal plane and a significantly decreased knee adduction moment with Agilium Freestep could be shown.

Fantini-Pagani et al. (2013) conducted their study with subjects that showed a tendency towards a knee varus alignment. The former results could be confirmed. Significant reductions were seen in the knee lever arm and the knee adduction moment.

First clinical results show that pain was reduced by up to 51% after wearing Agilium Freestep for two weeks and that the patient satisfaction is high (Schmalz et al. 2011).

Menger et al. (2016) proved the influence of Agilium Freestep on the knee pain over a time period of one year. The pain was significantly reduced after six (-24.5%) and twelve months (-30.6%) when using the orthosis. Another part of this study was the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC). The total score and all three subscores were improved within one year by nearly 60%.

Thus, Agilium Freestep can alter the load distribution within the knee joint and thereby offload the affected knee compartment. The use of this AFO represents an alternative for conservative treatment of knee OA.

References of summarized studies

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Other References

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