

Agilium Freestep

Reimbursement Reference Guide



Quality for life

Agilium Freestep Features and Benefits

Reduced Symptoms

Agilium Freestep has been shown to reduce pain and stiffness, while at the same time increasing function. This is similar to results found with off-loading knee orthoses.

Suspension

Agilium Freestep has a foot plate that inserts into the patient's shoe, which in effect suspends the device. Unlike with a knee orthoses, the user does not have to worry about it slipping or falling off.

Abnormal Thigh/Calf Size

Off-loading knee braces can be both bulky and heavy, particularly when made for larger patients. The advantage of the Agilium Freestep compared to an off-loading knee orthosis is that the Agilium uses ground reaction force (GRF) to off-load the affected knee compartment. GRF increases with the weight of the patient, thus resulting in a greater offloading effect in larger/heavier patients, without adding to the weight/bulkiness of the device.

Compliant Design

Agilium Freestep has a lightweight, slim comfortable design, is much less conspicuous than a knee brace, and does not extend over the knee cap, so the knee is unencumbered. Patients may be more compliant as a result.



May be Easier to Tolerate

The Agilium has been found to be as effective as a knee brace; however, it doesn't come with the typical adverse effects found with knee braces. The Agilium uses ground reaction force (GRF) to off-load the affected knee compartment. The GRF is transmitted inside the body, by controlling the subtalar joint, which provides 94% of the off-loading effect. Knee braces, on the other hand, have to create the offloading force/moment, which also creates the adverse effects resulting in discontinuation.

Agilium Freestep OA Solution

How does Agilium Freestep work in knee osteoarthritis?

The basic idea for developing Agilium Freestep was the research finding that the effect of using lateral shoe wedges and wedged insoles to treat medial knee osteoarthritis (OA) may be compromised by a hypermobile subtalar joint that may absorb the created rear-foot pronation moment, preventing it from counteracting the external varus/adduction moment at the knee [1-5]. Therefore, a limitation of the range of motion of the subtalar joint with an ankle-foot orthosis (AFO) seems to be a logical method to unload an affected knee compartment [1-4]. Agilium Freestep shifts the center of pressure (CoP) as the application point of the ground reaction force (GRF) under the foot 7-10 mm lateral (for OA of the medial knee compartment, see figure) or medial (for OA of the lateral knee compartment). In addition, it controls the subtalar joint and employs a calf upright to ensure proper force transmission to the knee joint. As a result, the lever arm of the GRF, and thus the external varus/adduction moment acting on the knee, is reduced. The biomechanical mechanism of Agilium Freestep has been verified in three studies [5-7] that found an unloading effect on the knee compartments of 10-12%, which is comparable to that of knee unloader braces [4-6, 8].

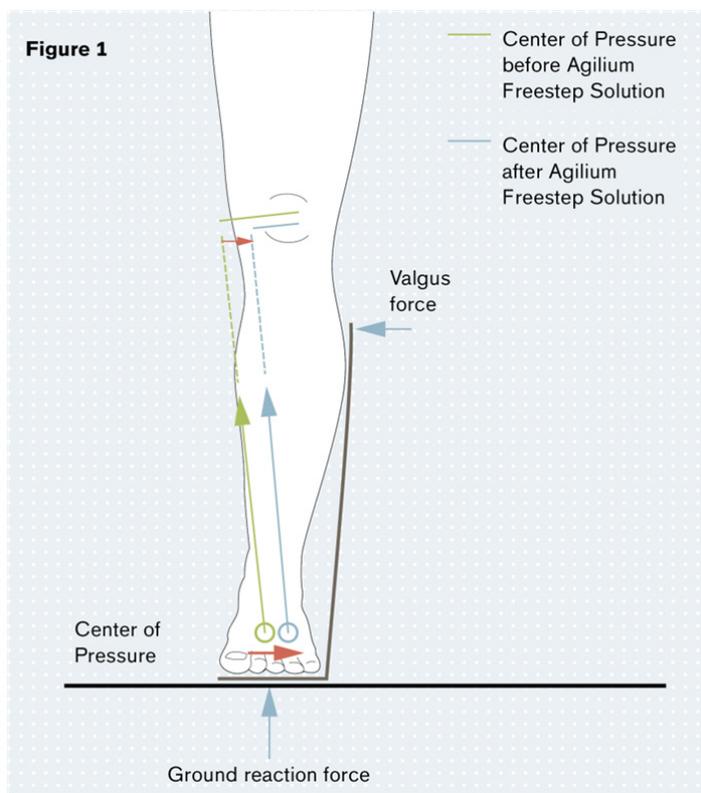


Figure: Mechanisms of action and effect of the Agilium Freestep AFO in medial knee OA.

Agilium Freestep OA Solution

Clinical effects and benefits of Agilium Freestep

An observational study with 25 patients with medial (83%) or lateral (17%) compartment knee osteoarthritis was conducted by two orthopedic surgeons in cooperation with the University Hospital of Göttingen, Germany, to investigate the clinical effects and benefits of Agilium Freestep in a real-life outpatient clinical setting.

According to the OA classification of Kellgren & Lawrence as extracted from the medical records, 33% of patients had grade 1 OA, 55% had grade 2 OA, and 12% of patients suffered from grade 3 OA. 78% of subjects had used a knee sleeve or soft knee brace prior to this study, 56% were using non-steroid anti-inflammatory drugs (NSAID) as on-demand pain medication. The outcome measure used in this study was the Western Ontario & McMasters Universities Osteoarthritis Score (WOMAC). Patients were assessed at baseline and every 3 months over a total follow-up period of 12 months with Agilium Freestep. The statistical analysis was done with the Student's t-test for paired samples in WinStat for Microsoft¹ Excel [9].

Results

- With Agilium Freestep, the total WOMAC score as well as the subscores for pain, stiffness, and physical function were significantly improved in all follow-up visits compared to the baseline scores (9).
- The mean total WOMAC score improved 38.6% ($p < .03$) in the first 3 months and reached a maximum 59.4% improvement ($p < .001$) after 12 months of Agilium Freestep use.
- The mean WOMAC pain score improved 49.5% ($p < .02$) in the first 3 months and reached a maximum 58.5% improvement ($p < .004$) after 12 months.
- The mean WOMAC stiffness score improved 25.6% ($p < .03$) in the first 3 months and reached a maximum 55.8% improvement ($p < .0003$) after 12 months.
- The mean WOMAC physical function score improved 36.8% ($p < .03$) in the first 3 months and reached a maximum 59.8% improvement ($p < .0002$) after 12 months of Agilium Freestep use.

Discussion

The improvements in the WOMAC total score and its Pain, Stiffness, and Physical Function domains achieved by using Agilium Freestep have the same magnitude as the improvements seen in the three knee unloader studies that also used the WOMAC as the primary outcome measure [10-12]. Although the present study had no control group of patients using a knee sleeve or soft orthosis, the fact that 78% of patients had used such devices prior to enrollment in this study suggests that Agilium Freestep may also be more effective in reducing pain and stiffness as well as improving physical function than simple knee sleeves or soft orthoses. In summary, the literature and the results of this study suggest that the biomechanical and clinical effects of the Agilium Freestep AFO in mild to moderate knee osteoarthritis are absolutely comparable to those known for knee unloader braces.

A potential advantage of the AFO over knee unloaders may be that the compliance rate in this study was very high, especially in light of the high attrition rate in knee unloader studies found and criticized by a recent Cochrane Review [13]. Discontinuation of knee unloader use is quite common in clinical practice

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and may be as high as 55% [12]. Main reasons are lack of effectiveness, bondage forces around the knee, and limitations in the choice of leg clothing. The latter two reasons for attrition may be diminished by using an AFO.

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