Management of osteoarthritis

Agilium line – Clinically proven advantages

Quality for life

Information for physicians
Osteoarthritis management according to the guidelines

Biomechanical interventions are recommended by the Osteoarthritis Research Society International (OARSI) for all morbidity criteria. Conservative biomechanical interventions should be used, in particular for unicompartmental osteoarthritis of the knee. OARSI recommends surgical treatment only after several conservative treatment forms are ineffective. [9]

### Recommended treatments

**Core treatments**  
Suitable for all patients

- Land-based exercise
- Weight management
- Strength training

- Water-based exercise
- Self-management and education

**Recommended treatments**  
Appropriate for the following types of osteoarthritis:

**Osteoarthritis of the knee alone – no comorbidities**

- Biomechanical procedures
- Intra-articular corticosteroids
- Topical NSAIDs
- Walking cane
- Oral COX-2 inhibitors (selective NSAIDs)
- Capsaicin
- Oral non-selective NSAIDs
- Duloxetine
- Acetaminophen (Paracetamol)

**Knee-only osteoarthritis – with comorbidities**

- Biomechanical procedures
- Walking cane
- Intra-articular corticosteroids
- Topical NSAIDs

**Multi-joint osteoarthritis – no comorbidities**

- Oral COX-2 inhibitors (selective NSAIDs)
- Intra-articular corticosteroids
- Oral non-selective NSAIDs
- Duloxetine
- Biomechanical procedures
- Acetaminophen (Paracetamol)

**Multi-joint osteoarthritis – with comorbidities**

- Balneotherapy
- Biomechanical procedures
- Intra-articular corticosteroids
- Oral COX-2 inhibitors (selective NSAIDs)
- Duloxetine

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For patellofemoral osteoarthritis

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As a consequence of demographic developments, osteoarthritis of the knee is becoming the most common non-traumatic cause of knee disorders. The main symptom of osteoarthritis of the knee is pain.

Unicompartmental osteoarthritis of the knee is usually manifested in the medial knee compartment; the lateral knee compartment is less often involved. The patellofemoral joint may also be affected. [1-3]

Significance of the leg axis

The mechanical axis of the lower limb does not pass through the centre of the knee joint, but is shifted about 1° in medial direction. For this reason, the medial knee compartment bears 60%–70% of the weight put on the knee. This physiological imbalance can be a predisposing factor for osteoarthritis of the medial knee. The direction of the external forces and the orientation of the limbs when walking generate an adduction moment at the knee. This moment is determined by the ground reaction force vector and the distance to the centre of the knee. This distance corresponds to the lever arm. A longer lever arm results in a larger adduction moment. This parameter is measured as a surrogate for pressure in the medial knee joint. The pressure load on the medial knee compartment is increased by 70% to 90% with a varus position of 4°–6° in the leg axis. A increase in the knee adduction moment of just 20% considerably increases the risk of progression of osteoarthritis.

One goal of biomechanical measures in conservative treatment is to reduce the knee adduction moment and thus halt or slow progression. [3-5]
Significance of patellar alignment

The force in the patellofemoral joint is approx. 0.5 times body weight when walking normally, when climbing stairs, it increases to 3.3 times body weight and during knee flexion (approx. 130° flexion) it is 7.8 times body weight. These high forces are generated by the lever arm and transmission of force to the quadriceps muscle.

Studies have shown that faulty loading due to malalignment of the patella can contribute directly to the development of osteoarthritis of the patellofemoral joint. [6–8]
The application site and site of action are not identical in the Agilium Freestep foot-ankle brace. The advantage of this mechanism of action is that the external application of force and thus the effect is highly reliable due to the stationary position. The Agilium Freestep spans the ankle joints in the frontal plane. This, combined with the lateral counter-support from the brace results in a shift of the ground reaction force (GRF) vector from medial to lateral and to a reduction of the varus angle at the knee joint. Furthermore, the limitation of eversion has an effect on tibia rotation. As a result, the knee adduction moment, which is measured as a surrogate for pressure, is reduced. Clinical and biomechanical studies show significant and clinically relevant effects. [11–14]
The Agilium Freestep spans the ankle joints in the frontal plane. This allows the defined application of force in the proximal-lateral region of the lower leg. The lateral shift of the ground reaction force vector shortens the lever arm in the knee. This in turn reduces the varus effect of the external knee moment. The integrated adjustment mechanism allows the direction and size of the acting force to be influenced.

The knee angle in the frontal plane can be significantly reduced by the Agilium Freestep, indicated by a switch from the varus to the valgus position. [11]

The knee lever arm, i.e. the distance from the centre of the knee to the ground reaction force vector, is shortened significantly with the Agilium Freestep. [11, 14]

The vertical component of the ground reaction force is shifted up to 13 mm laterally in the frontal plane with the Agilium Freestep. [13]
Reduced knee adduction moment

The progression of medial osteoarthritis of the knee is observed more frequently in patients with increased knee adduction moments. [22] A high adduction moment indicates high pressure in the medial compartment.

The knee adduction moment (KAM) is significantly reduced with the Agilium Freestep.

- In patients, this reduction is 22% [13]
- In healthy subjects, the reduction is 11%-20% [11, 13, 18]

![Mean maximum knee adduction moment (KAM) when walking](image)

** = significant (p ≤ 0.01) change between the conditions with/without Agilium Freestep for the healthy subjects and osteoarthritis of the knee patients [13]

![Reduction of the adduction moment during the gait cycle](image)

The Agilium Freestep reduces the frontal adduction moment in the first peak of the gait cycle by 11%-22%. [19]
Influence of pes planovalgus insoles on the effect of Agilium Freestep

In medical practice, the diagnosis of osteoarthritis of the knee is often associated with a foot deformity. Accordingly, insoles and braces are often prescribed simultaneously. Whether and to what extent insoles influence the effect of the Agilium Freestep brace for osteoarthritis of the knee was investigated in the following biomechanical study. Healthy subjects were fitted with a combination of the Agilium Freestep and a pes planovalgus insole. Result: The knee load is clearly reduced with the Agilium Freestep alone (-20%) and in combination with a pes planovalgus insole (-23%) to a comparable extent. [15]

Change in the knee adduction moment
• With Agilium Freestep -20%
• With Agilium Freestep + insole -23%
• With insole +1%

<table>
<thead>
<tr>
<th>Subject</th>
<th>Agilium Freestep</th>
<th>Insole</th>
<th>Insole + Agilium Freestep</th>
<th>Lateral wedge</th>
<th>Insole + lateral wedge</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>-31.0%</td>
<td>-11.0%</td>
<td>-32.2%</td>
<td>-18.2%</td>
<td>-14.0%</td>
</tr>
<tr>
<td>2</td>
<td>-11.1%</td>
<td>+1.8%</td>
<td>-30.3%</td>
<td>-17.2%</td>
<td>-10.1%</td>
</tr>
<tr>
<td>3</td>
<td>-31.7%</td>
<td>+11.7%</td>
<td>-22.1%</td>
<td>-6.7%</td>
<td>+0.2%</td>
</tr>
<tr>
<td>4</td>
<td>-8.1%</td>
<td>+0.8%</td>
<td>-18.2%</td>
<td>-3.3%</td>
<td>-0.2%</td>
</tr>
<tr>
<td>5</td>
<td>-21.0%</td>
<td>+2.2%</td>
<td>-20.4%</td>
<td>-18.7%</td>
<td>-2.1%</td>
</tr>
<tr>
<td>6</td>
<td>-23.1%</td>
<td>+10.8%</td>
<td>-23.5%</td>
<td>+7.1%</td>
<td>+10.1%</td>
</tr>
<tr>
<td>7</td>
<td>-17.9%</td>
<td>-5.3%</td>
<td>-20.3%</td>
<td>-17.3%</td>
<td>-15.6%</td>
</tr>
<tr>
<td>8</td>
<td>-22.4%</td>
<td>+2.4%</td>
<td>-21.9%</td>
<td>-14.6%</td>
<td>-8.9%</td>
</tr>
<tr>
<td>9</td>
<td>-6.5%</td>
<td>+4.7%</td>
<td>-12.0%</td>
<td>+3.7%</td>
<td>+6.4%</td>
</tr>
<tr>
<td>10</td>
<td>-21.9%</td>
<td>-4.4%</td>
<td>-27.6%</td>
<td>-9.9%</td>
<td>-1.1%</td>
</tr>
<tr>
<td>MV</td>
<td>-18.7% (±8.4%)</td>
<td>+1.4% (±7.0%)</td>
<td>-22.9% (±6.0%)</td>
<td>-9.5% (±8.5%)</td>
<td>-3.5% (±8.5%)</td>
</tr>
</tbody>
</table>

The combination of the Agilium Freestep with a pes planovalgus insole is possible and can be recommended, as the knee-relieving effect is increased. [15]
Pain reduction

Pain caused by osteoarthritic processes result in patients avoiding painful movements or activities.

The subjective pain assessment on the numerical analogue scale (NAS 0-10) was significantly reduced with the Agilium Freestep.

- By up to 51% after a two-week intervention (from 7.7 ±1.8 to 3.8 ±1.8 points, p < 0.01) [13]
- By 25% after 6 months and by 31% after 12 months of average daily use [12]

Changes in the pain assessment using the NAS from the inclusion examination to the various follow-up examinations with the Agilium Freestep. * p < 0.03; ** p < 0.04 [12]
Improved knee function

Patients with osteoarthritis of the knee suffer regularly from stiffness, reduced range of motion and a perception of instability. These problems have a direct effect on coping with everyday routine and leisure time. Movements such as sitting down and getting up from a chair and standing, walking and using stairs comfortably are challenges for patients.

The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) is a self-assessment questionnaire that makes it possible to evaluate the most important and relevant consequences of osteoarthritis of the hip and knee joints.

The overall WOMAC score and all sub-categories improved significantly after 12 months of using the Agilium Freestep. [12]

- WOMAC overall score - 59.4%
- WOMAC pain - 59.3%
- WOMAC stiffness - 55.8%
- WOMAC body function - 59.9%

Significant improvement of the WOMAC score with Agilium Freestep
Less impairment in daily routine

The perceived impairment due to knee problems was assessed by patients with osteoarthritis of the knee. During the intervention period, the perceived impairment – both in everyday routine and in sports and leisure activities – was reduced.\cite{12}
The Agilium Reactive knee brace uses the three-point principle in the frontal plane and can apply an external varus or valgus force to the knee joint. This makes it possible for it to shift the functional mechanical axis from the medial to the lateral compartment or vice versa.

The knee adduction moment in patients with genu varum and medial osteoarthritis of the knee can be reduced significantly (up to 32%) with a valgus correction brace. Since an increase in the knee adduction moment of only approx. 20% increases the risk of progression of osteoarthritis of the knee, the effect of this brace is clinically relevant. [1, 2, 7, 10]
Pain reduction

The WOMAC (Western Ontario and McMaster Universities Arthritis Index) is a self-assessment questionnaire for patients that makes it possible to assess the consequences of osteoarthritis. It includes questions on the intensity of pain, knee stiffness, and activity. The questions are rated on a scale of 0-100. The higher the rating, the better the patient is doing. The WOMAC score was assessed before treatment and after 4 weeks of treatment with the Agilium Reactive.

Clear improvement was found on all three scales after treatment with the Agilium Reactive. [20]

- With respect to pain, an improvement of 19% can be achieved
- Stiffness is improved by 28%
- Body function is improved by 30% over the baseline situation

WOMAC scales for pain, stiffness, and activity before treatment and after 4 weeks of treatment with the Agilium Reactive. * Shows significant improvement: Pain p=0.003; Stiffness p=0.043; Body function p=0.001 [20]
The patients rated the Agilium Reactive with the questions about the subjective assessment. All 13 patients would recommend the brace to others. The 13 patients also rated the handling of the brace and wearer comfort positively. The following figures show the distribution of the responses to these questions.\cite{20}

### Quality of life and overall satisfaction

The patients rated the Agilium Reactive with the questions about the subjective assessment. All 13 patients would recommend the brace to others. The 13 patients also rated the handling of the brace and wearer comfort positively. The following figures show the distribution of the responses to these questions.\cite{20}
The Agilium Patella brace applies a medialisng force to the patella via a dynamic re-alignment mechanism for knee flexion angles between 0° and 30°, i.e. precisely in the range in which the patella is not stabilised by the patellar groove.

At flexion angles over 30°, the patella is still tracked, but the corrective tension is progressively reduced. Here too, biomechanical causes are significant factors for the progression of the osteoarthritis in the patellofemoral joint. The pressure in the patellofemoral joint is more evenly distributed when the patella is re-aligned in the patellar groove by a brace. [16–17]
Dynamic re-alignment

All subluxations and dislocations of the patella are lateral, i.e. when switching from extension to flexion, the patella leaves the patellar groove and moves to the outside of the leg. [24]

Ex vivo study

With the Agilium Patella, direct biomechanical effects to improve patella tracking can be achieved. The patella can be medialised by 1.9 mm or 40%. [21]

Reduced lateralisation with the Agilium Patella

The lateralisation of the patella was analysed using video fluoroscopy; ** significant group difference with p < 0.05. [5]
Magnetic resonance imaging (MRI)

Patellofemoral MRI parameters typical for the disorder were examined in standing patients with and without a brace with knees completely extended and in controlled flexion of 15° and 30°. With a brace, there was significant improvement of all parameters examined. Up to 15.6% medialisation was achieved. [16]

Effectiveness of the Agilium Patella in magnetic resonance imaging (MRI) under weight bearing

<table>
<thead>
<tr>
<th>Index</th>
<th>0° flexion</th>
<th>15° flexion</th>
<th>30° flexion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insall-Salvati index</td>
<td>p &lt; 0.001</td>
<td>p &lt; 0.001</td>
<td>p &lt; 0.001</td>
</tr>
<tr>
<td>Caton-Deschamps index</td>
<td>p &lt; 0.001</td>
<td>p &lt; 0.001</td>
<td>p &lt; 0.001</td>
</tr>
<tr>
<td>Patellotrochlear index</td>
<td>p &lt; 0.001</td>
<td>p &lt; 0.001</td>
<td>p &lt; 0.001</td>
</tr>
<tr>
<td>Bisect offset</td>
<td>p &lt; 0.001</td>
<td>p &lt; 0.001</td>
<td>p &lt; 0.001</td>
</tr>
<tr>
<td>Patellar tilt</td>
<td>p &lt; 0.001</td>
<td>p &lt; 0.001</td>
<td>p &lt; 0.001</td>
</tr>
<tr>
<td>TT-TG distance</td>
<td>n. sign.</td>
<td>p &lt; 0.001</td>
<td>p &lt; 0.001</td>
</tr>
</tbody>
</table>

Improvements measured with the Agilium Patella in the patellofemoral MRI parameters typical for the disorder. [16]
Pain relief

Using the numerical analogue scale (NAS), patients can subjectively indicate the intensity of their pain on a scale from 0 (no pain) to 100 (the worst pain imaginable). The result of this pain assessment helps to check and evaluate an intervention.

Pain assessment after 54 weeks

Pain assessment after a one-year intervention; ** significant differences with $p < 0.001$. [7]
Pain assessment

After 6 and 12 weeks
In a comparative study with patients who had physiotherapy and those who had additional treatment with an Agilium Patella brace, the patients with a brace were found to have a significant reduction of pain in the categories "Using stairs" and "Sports". [22]

- 38% reduction for "Using stairs" after a 6-week intervention
- 39% reduction for "Using stairs" after a 12-week intervention
- 33% reduction for "Sports" after 12 weeks
- A trend towards pain reduction was also found in the categories
  - "Resting pain" after 12 weeks (-20%)
  - "Sitting" after 6 and 12 weeks (-14% and -21%)
  - "Walking" after 6 and 12 weeks (-14% and -37%)
  - "Sports" after 6 weeks (-24%)

After 54 weeks
In the comparison of the examinations at the beginning of the study (T0) and after 54 weeks, significant improvement was found for both groups in 4 of 5 categories. No difference was found between the groups. [22]

- 88% reduction for "Resting pain"
- 60% reduction for "Sitting"
- 68% reduction for "Using stairs"
- 69% reduction for "Sports"
Agilium Patella

Improved knee function

Instruments such as the KOOS (knee injury and osteoarthritis outcome score) or Kujala score are used to measure and assess pain caused by the patient’s damaged knee. Among other things, they measure the factors pain, mobility, and activity, which have a big effect on patients’ quality of life.

Kujala

After 6 and 12 weeks
In the comparison of patients who had physiotherapy with those who were also treated with the Patella Pro, the patients with the brace had significant (p<0.05) improvement of 5% at both examinations. [22]

After 54 weeks
In the comparison of the examinations at the beginning of the study (T0) and after 54 weeks, significant improvement of 28% was found for both groups. A group difference of 5% was found for the brace group. [22]
KOOS

**After 6 and 12 weeks**
In the comparison of patients who had physiotherapy with those who were also treated with the Agilium Patella, the patients with the brace had significant improvement in all sub-categories. [22]

- 16% and 11% improvement in the sub-category "Symptoms"
- 15% and 19% improvement in the sub-category "Pain"
- 11% and 8% improvement in the sub-category "ADLs"
- 10% and 20% improvement in the sub-category "Sports"

**After 54 weeks**
In the comparison of the examinations at the beginning of the study (T0) and after 54 weeks, significant improvement was found for both groups in all sub-categories. A group difference was found only for the sub-category "ADLs". [22]

- 38% improvement in the sub-category "Symptoms"
- 41% improvement in the sub-category "Pain"
- 25% improvement in the sub-category "ADLs" (p>0.05)
- 61% improvement in the sub-category "Sports"
- 86% improvement in the sub-category "Quality of life"

### KOOS scores, mean values

<table>
<thead>
<tr>
<th></th>
<th>Physiotherapy + Agilium Patella</th>
<th>Physiotherapy only</th>
</tr>
</thead>
<tbody>
<tr>
<td>6 weeks</td>
<td><strong>80</strong></td>
<td></td>
</tr>
<tr>
<td>12 weeks</td>
<td><strong>85</strong></td>
<td>70</td>
</tr>
<tr>
<td>6 weeks</td>
<td>80</td>
<td>75</td>
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<tr>
<td>12 weeks</td>
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<tr>
<td>6 weeks</td>
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<tr>
<td>12 weeks</td>
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<tr>
<td>6 weeks</td>
<td>90</td>
<td><strong>95</strong></td>
</tr>
<tr>
<td>12 weeks</td>
<td><strong>100</strong></td>
<td><strong>100</strong></td>
</tr>
</tbody>
</table>

**Significant improvement in all KOOS sub-categories at the examinations after 6 and 12 weeks with Agilium Patella; * significant group differences with p < 0.05; ** significant group differences with p < 0.001**. [22]
References
