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# Agilium Reactive


Quality for life

## Clinical Study Summaries

This document summarizes clinical studies conducted with the Agilium Reactive. The included studies were identified by a literature search made on PubMed and within the journal Medizinisch Orthopädische Technik.

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## Table of content:


1 Overview table ..... p 3

2 Summaries of categories ..... p 4-8

Clinical effects ..... p 5

Satisfaction ..... p 7

3 Summaries of individual studies ..... p 9-12

Liebau et al. 2017 ..... p 10

4 Copyright ..... p 13

# 1 Overview table

The summaries are organized in three levels depending on the detail of information. The overview table (Level 1) lists all the relevant publications dealing with a particular product (topic) as well as researched categories (e.g. gait analysis, clinical effects, satisfaction, etc.). By clicking on underlined categories, a summary of all the literature dealing with that category will open (Level 2).

For those interested to learn more about individual studies, a summary of the study can be obtained by clicking on the relevant reference (Level 3).

| Reference | | Category | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | Functions and Activities | | | | | | Participation |
| Author | Year | Biomechanics – Static measures | Biomechanics – Gait analysis | X-Ray | EMG | Functional tests | Clinical effects | Satisfaction |
| Liebau | 2017 | | | | | | x | x |
| Total number: 1 | | 0 | 0 | 0 | 0 | 0 | 1 | 1 |

# 2 Summaries of categories

On the following pages you find the summary of categories researched in several studies (e.g. gait analysis, clinical effects, satisfaction, etc.). At the end of the summary you will find a list of reference studies contributing to the content of the particular summary.

# Clinical effects

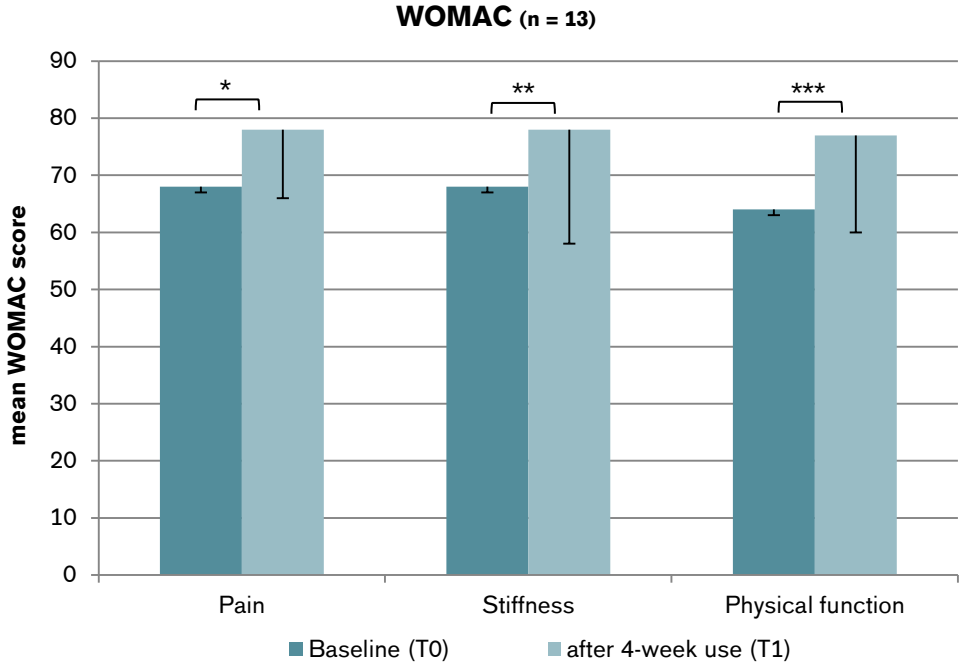
**Major Findings**

With Agilium Reactive:

**→ All WOMAC sub-scores improved significantly after 4-week use of Agilium Reactive** (Liebau et al. 2017)

- Pain sub-score: + 19%
- Stiffness sub-score: + 28%
- Physical function sub-score: + 30%

## Significant improvement of all WOMAC sub-scores with Agilium Reactive after 4 weeks




* = significant less pain with Agilium Reactive after 4-week use (p = 0.003)
** = significant less stiffness with Agilium Reactive after 4-week use (p = 0.043)
*** = significant improved physical function with Agilium Reactive after 4-week use (p = 0.001)
(Liebau et al., 2017)

**Clinical Relevance**

Knee osteoarthritis (OA) is one of the most common joint disorders. Approximately 6% of the population aged 30 years or older and 12% of the population aged 65 years or older suffer from knee OA (Maleki et al. 2016, Raja & Dewan 2011). OA of the medial knee compartment is most prevalent due to the load distribution in normal walking. Here, 60%–80% of load is distributed over the medial compartment of the knee joint because of the external varus (or adduction) moment acting on the knee joint. (Krohn 2005, Maleki et al. 2016)

Knee OA causes considerable pain, immobility, disability, a sensation of instability and buckling of the affected knee, a reduced quality of life, and negative changes in kinetic and kinematic parameters. These problems may limit the ability to rise from a chair, stand comfortably, walk or climb stairs. In response to pain, patients change

their gait pattern and these adaptations may result in further progression of OA. Treatments for knee OA are designed to alleviate pain by attempting to correct mechanical malalignment. (Chuang et al. 2007, Felson et al. 2009, Kaufman et al. 2001, Maleki et al. 2016, Simic et al. 2011)

The WOMAC (Western Ontario and McMaster Universities Arthritis Index) is self-administered and assesses the patient's opinion about their knee and associated problems. Pain, stiffness and mobility are assessed to gain insights into the level of independence of the patient. A decreased pain level as well as an increased grade of mobility is crucial to reach a satisfying level of quality of life. Activities of daily living (ADLs) include self-care activities as functional mobility, dressing, eating and personal hygiene as well as activities to live independently in a community.

## Summary

All three WOMAC sub-scores (pain, stiffness and physical function) could be significantly improved after 4-week use of Agilium Reactive. The improvements amount for 19% in the pain score, for 28% in the stiffness score and for 30% in the physical function score. (Liebau et al. 2017)

## References of summarized studies


Liebau, C., Petersen, W., Rembitzki, I.V. (2017). Eine klinische Studie zur Wirksamkeit einer medialen Entlastungsorthese (Agilium Reactive®) bei Patienten mit unikompartimenteller Gonarthrose. A clinical study on the effectiveness of a medial unloader brace (Agilium Reactive®) in patients with unicompartimental knee OA. *MOT: Medizinisch Orthopädische Technik*, 1: 32-36.


## Other References


Chuang, S.-H., Huang, M.-H., Chen, T.-W., Weng, M. C., Liu, C. W., Chen, C. H. (2007). Effect of knee sleeve on static and dynamic balance in patients with knee osteoarthritis. *The Kaohsiung Journal of Medical Sciences,* 23(8):405–411. DOI: http://dx.doi.org/10.1016/S0257-5655(07)70004-4

Felson, D. T. (2009). Developments in the clinical understanding of osteoarthritis. *Arthritis Research & Therapy,* 11(1): 203-2013. DOI: 10.1186/ar2531.

Kaufman, K. R., Hughes, C., Morrey, B. F., Morrey, M., An, K. N. (2001). Gait characteristics of patients with knee osteoarthritis. *Journal of biomechanics,* 34(7): 907–915.

Krohn K. (2005). Footwear alterations and bracing as treatments for knee osteoarthritis. *Curr Opin Rheumatol,* 17(5): 653–656.

Maleki, M., Arazpour, M., Joghtaei, M., Hutchins, S. W., Aboutorabi, A., Pouyan, A. (2016). The effect of knee orthoses on gait parameters in medial knee compartment osteoarthritis: A literature review. *POI: Prosthetics and Orthotics International*, 40(2):193-201. DOI: 10.1177/0309364614547411

Raja, K. & Dewan, N. (2011). Efficacy of knee braces and foot orthoses in conservative management of knee osteoarthritis: a systematic review. *Am J Phys Med Rehabil,* 90(3):247–262.

Simic, M., Hinman, R. S., Wrigley, T.V., Bennell, K. L., Hunt, M. A. (2011). Gait modification strategies for altering medial knee joint load: a systematic review. *Arthritis Care & Research,* 63(3):405–426.


↑ Back to overview table

# Satisfaction

**Major Findings**

With Agilium Reactive:

How do you assess the handling of the orthosis?

**→ easy:** **46%**
**→ learnable:** **54%**

Do you feel restricted by the orthosis?

**→ no:** **31%**
**→ slight:** **54%**
**→ moderate:** **15%**

Is it uncomfortable to wear the orthosis?

**→ no:** **46%**
**→ slightly:** **39%**
**→ moderate:** **15%**

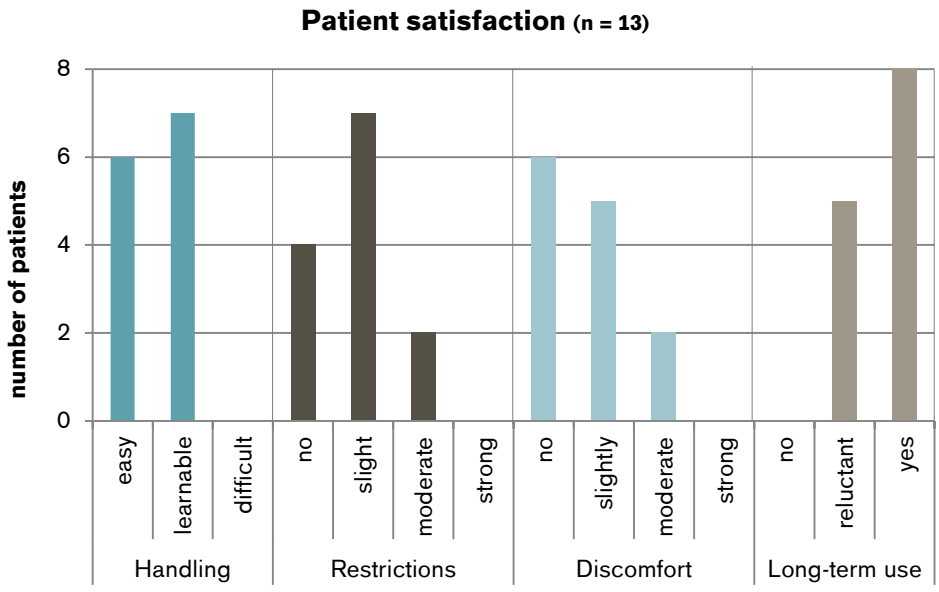
Would you wear the orthosis over a longer period of time?

**→ yes:** **62%**
**→ reluctant:** **38%**

Would you recommend the orthosis?

**→ yes:** **100%**

## Agilium Reactive showed a high patient satisfaction




(Liebau et al. 2017)

**Clinical Relevance**

Satisfaction can be measured to determine the general well-being of a person and the fulfillment of his expectations to the medical device. The evaluation of this very meaningful parameter is important to investigate as it has a direct impact on the patients' well-being and compliance. It is influenced by additional categories and can therefore be seen as a summary of possible pain reduction and better performance of ADLs.

Satisfaction is also correlated with the usage of the medical device. Studies on the non-use of devices suggest, on average, a third of all provided devices are not used (Scherer 2002). Possible causes involve a lack of consumer involvement, inadequate performance of the product, failure of the product to improve function, and difficulty in operating the product (Batavia & Hammer 1990, Wielandt & Strong 2000). Obtaining user perspectives and satisfaction is therefore fundamental.

**Summary**

The majority of patients were satisfied with the Agilium Reactive. The handling is rated as easy or learnable. No strong restrictions were perceived. About 85% felt no restrictions or only slightly restrictions by the orthosis. Nearly the half of patients rated the orthosis as comfortable and 39% said that the orthosis is slightly uncomfortable. The majority would use the orthosis for a longer period of time and no one precluded the long-term use a priori. More importantly all patients would recommend the Agilium Reactive. (Liebau et al. 2017)

**References of summarized studies**

Liebau, C., Petersen, W., Rembitzki, I.V. (2017). Eine klinische Studie zur Wirksamkeit einer medialen Entlastungsorthese (Agilium Reactive®) bei Patienten mit unikompartimenteller Gonarthrose. A clinical study on the effectiveness of a medial unloader brace (Agilium Reactive®) in patients with unicompartimental knee OA. *MOT: Medizinisch Orthopädische Technik*, 1: 32-36.

**Other References**

Batavia, A. I., & Hammer, G. S. (1990). Toward the development of consumer-based criteria for the evaluation of assistive devices. *Journal of rehabilitation research and development*, 27(4):425-436.

Scherer, M. J. (2002). The change in emphasis from people to person: introduction to the special issue on Assistive Technology. *Disability and rehabilitation*, 24(1-3):1-4.

Wielandt, T., & Strong, J. (2000). Compliance with prescribed adaptive equipment: a literature review. *The British Journal of Occupational Therapy*, 63(2):65-75.

↑ Back to overview table

# 3 Summaries of individual studies

On the following pages you find summaries of studies that researched Agilium Reactive. You find detailed information about the study design, methods applied, results and major findings of the study. At the end of each summary you also can read the original study authors' conclusions.

**Reference**

Liebau, C., Petersen, W., Rembitzki, I.V.

# A clinical study on the effectiveness of a medial unloader brace (Agilium Reactive®) in patients with unicompartimental knee OA.

Eine klinische Studie zur Wirksamkeit einer medialen Entlastungsorthese (Agilium Reactive®) bei Patienten mit unikompartimenteller Gonarthrose

MOT: Medizinisch Orthopädische Technik 2017; 1: 32-36.

**Products**

**Agilium Reactive**

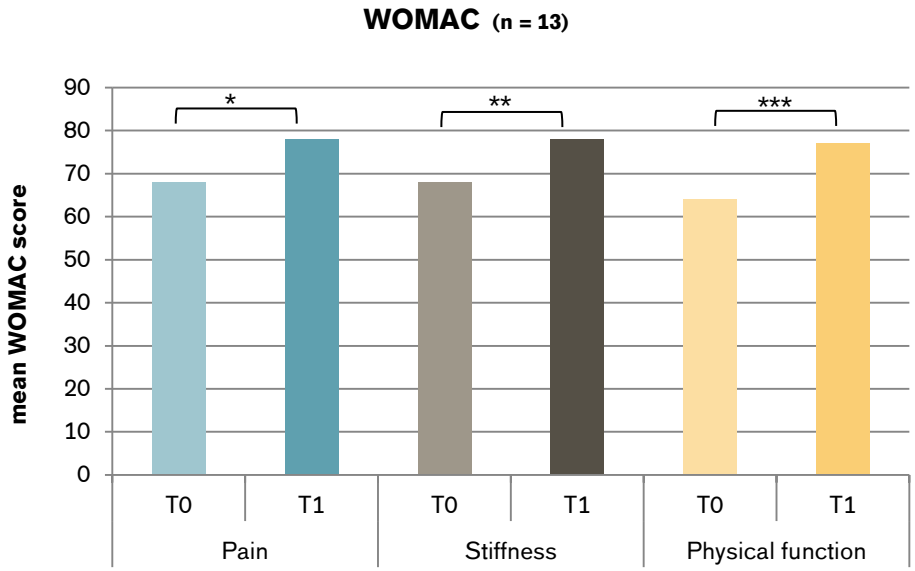
**Major Findings**

With Agilium Reactive:

WOMAC score

**→ Significant improvements in all WOMAC sub-scores**

**Agilium Reactive showed significant improvements in all WOMAC sub-scores**




T0= baseline; T1= after 4-week use of Agilium Reactive
Significant improvements: *p = 0.003; **p = 0.043; ***p = 0.001

Patient satisfaction and compliance

**→ No or slight restrictions due to orthosis**

**→ No or slight discomfort while wearing the orthosis**

**→ Easy or learnable handling of the orthosis**

**→ Orthosis can be worn over long-time period**

**→ Orthosis is recommended by the patients**

## Population

| | |
|---|---|
| Subjects: | 13 patients (6 male, 7 female) |
| Mean age: | 61.2 ± 15.9 years (range 41-91 years) |
| Affected side: | left (4 patients); right (7 patients); both (2 patients) |
| OA classification: | - grade I: 2 patients<br>- grade II: 2 patients<br>- grade III: 5 patients<br>- grade IV: 4 patients |
| Inclusion criteria: | - unicompartimental medial knee OA (Kellgren-Lawrence grade I-IV)<br>- genu varum<br>- older than 40 years |
| Exclusion criteria: | - unicompartimental lateral knee OA |

## Study Design

Prospective before-and-after study with 4-week follow-up (with Agilium Reactive):


## Results

Functions and Activities | Participation

Biomechanics – Static measures | Biomechanics – Gait analysis | X-Ray | EMG | Functional tests | Clinical effects | Satisfaction

| Category | Outcomes | Results for Agilium Reactive | | | | Sig.* |
|---|---|---|---|---|---|---|
| Clinical effects | **WOMAC score** | **Baseline vs. 4-week follow-up** | | | | |
| | Pain sub-score | + 19% (from 68 to 78 points) | | | | ++ |
| | Stiffness sub-score | + 28% (from 68 to 78 points) | | | | ++ |
| | Physical function sub-score | + 30% (from 64 to 77 points) | | | | ++ |
| Satisfaction | | no | slight | moderate | strong | |
| | Restrictions | 31% | 54% | 15% | 0% | n.a. |
| | Discomfort | 46% | 39% | 15% | 0% | n.a. |
| | Handling | easy: 46% | learnable: 54% | difficult: 0% | | n.a. |
| | Long-term use | yes: 62% | reluctant: 38% | no: 0% | | n.a. |
| | Recommendation | yes: 100% | | | | n.a. |

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

**Author's Conclusion**

In summary, the presented results demonstrate the clinical evidence to justify the use of the Agilium Reactive® in patients with genu varum and medial knee OA.

"Zusammenfassend zeigen die vorgestellten Ergebnisse klinische Evidenz vor, um den Einsatz der Agilium Reactive® bei Patienten mit Genu varum und medialer Gonarthrose zu rechtfertigen." (Liebau et al. 2017)

↑ Back to overview table