

# CONSERVATIVE TREATMENT OF KNEE PROBLEMS

## Effects of a semi-flexible knee orthosis on pain perception, physical activity, and functional abilities of patients suffering from medial osteoarthritis of the knee

Stetter, B.J.; Fiedler, J.; Arndt, M.; Stein, T.; Sell, S., Institute of Sport and Sport Science, Karlsruhe Institute of Technology (KIT) [1]

### INTRODUCTION

Osteoarthritis of the knee (KOA) causes pain, physical restrictions, and a loss of function that can prevent patients participating in domestic, professional, or social activities, thus reducing quality of life (QoL) [2,3,4]. Studies have also shown that KOA is associated with impaired joint proprioception [5,6].

Early treatment is key and it highlights the need for effective conservative treatment measures, such as appropriate physical activity and the use of orthopedic aids (e.g. a relieving knee orthosis) because surgery should be reserved for those who do not respond satisfactorily to less invasive methods [2]. However, please note that most previous studies refer to either rigid orthoses or supports providing neuromuscular stabilization, which have been in use for longer [7]. Subsequently, there is a lack of research relating to the effectiveness of semi-rigid knee orthoses when treating medial KOA [7,8].

The objective of this study was to examine the effects of a new semi-flexible knee orthosis on pain perception, physical activity, and functional abilities.

### METHOD

- Clinical study / prospective, one-arm, controlled
- Six weeks of monitoring
- Data collection using questionnaires (KOOS, Lequesne Score), visual analog scale (VAS), activity sensor (movisens®), and 6-min walking test (6-MWT)
- Patients: n = 24 (10 women, 14 men), 61.4 ± 7.3 years, BMI: 26.4 ± 4.1 kg / m<sup>2</sup>
- Moderate, unilateral, medial osteoarthritis of the knee
- Kellgren Lawrence (KL) Score: KL 2 = 6 / KL 3 = 12 / KL 4 = 6
- Support wearing duration: on average at least 5 hours per day for six weeks
- Measurement, Week 0 without a support: Baseline
- Measurement, Week 6 with the support: Long-term effect

Pain levels, physical activity, and functional abilities were examined in 24 patients suffering from symptomatic medial osteoarthritis of the knee. The study protocol followed a pre-test/post-test design. Data was collected one week before the start (pre-test, Week 0, no orthosis) and during the sixth week of treatment using the orthosis (post-test, Week 6, with the orthosis). The overall test period was 7 weeks.

Patients were asked to wear the orthosis during all everyday activities for at least 5 hours per day. Activities also included medical exercises and sports. The recommendation was to take off the orthosis for extended periods of sitting, such as office work.

### RESULTS

The wearing duration objectively recorded using an integrated sensor in the orthosis was 5.13 ± 2.95 h/day on average.

The data evaluated for the osteoarthritis patients showed that pain levels in all measurement situations in Week 6 was significantly lower than before treatment started (Week 0).

Pain at night (-43.2%), pain when walking (-45.8%), pain when taking the stairs (-41.4%), and pain when sitting (-48.1%) significantly reduced while the knee orthosis was worn. (Fig. 1)

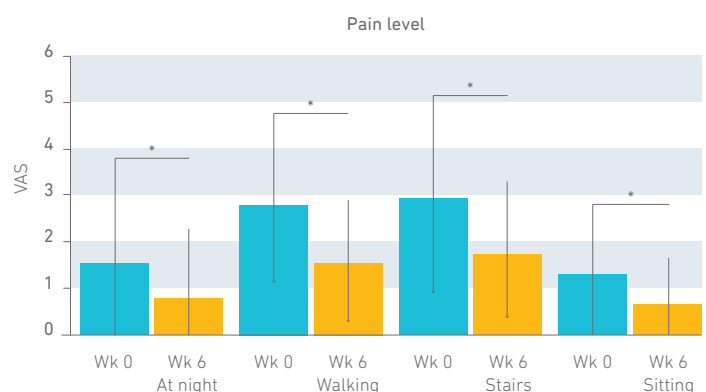


Fig. 1: Pain perception during different situations; Wk 0 = without orthosis and Wk 6 = with orthosis



Physical activity measured when using the GenuTrain OA during Week 6 showed an average increase of 20.2 minutes with intensive physical activity (+50.6%), while there were no significant changes during mild to moderate physical activity. (Fig. 2)

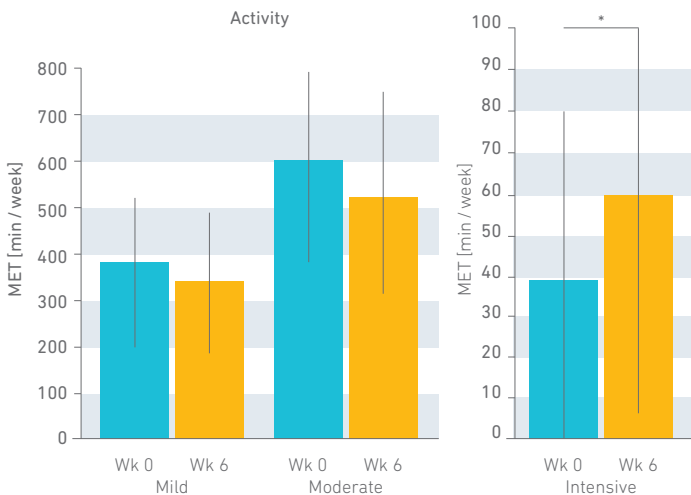


Fig. 2: Activity specified in Metabolic Equivalent (MET) minutes per week, categorized by mild, moderate, and intensive activity; Mild: MET < 3; Moderate: MET 3-6; Intensive: MET > 6  
1 MET: 1 kcal/kg\*h or 4.184 \* kJ/kg\*h and 1 MET x 16.8 = 1 watt

When the orthosis was used (Week 6), the distance covered during the 6-minute walking test increased by 5% compared to before treatment with the orthosis (Week 0). (Fig. 3).

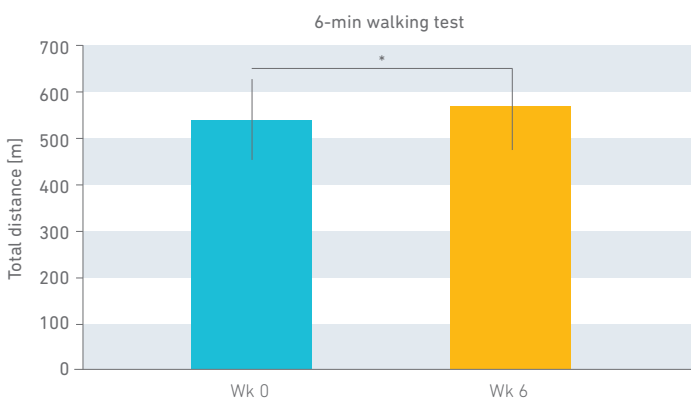


Fig. 3: Functional ability; 6-min walking test specified in meters

Patients also reported feeling less restricted during everyday activities (+4%) and sporting activities (+16%) as well as noticing improved quality of life (+13.4%). (Fig. 4)

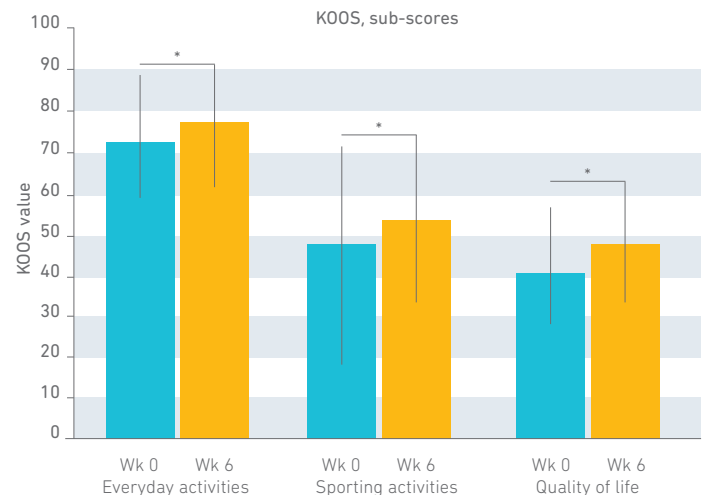


Fig. 4: KOOS value scale: 0 = extreme restrictions, 100 = no restrictions Roos & Lohmander, 2003 [9]

After six weeks of using the orthosis, patients rated their condition-related restrictions reduced by 1.3 points according to the Lequesne Index. This corresponds to an improvement from a moderate to a mild handicap. (Fig. 5)

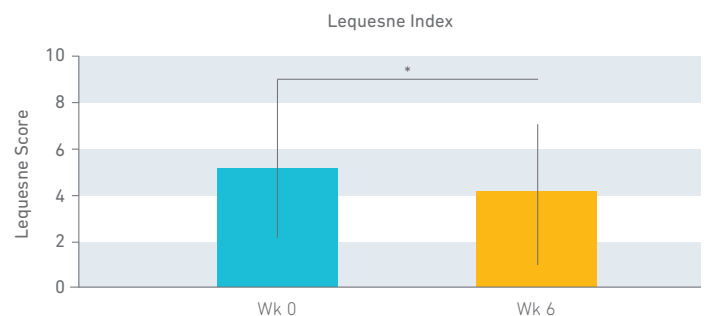


Fig. 5: Everyday activities rated according to the Lequesne questionnaire; Lequesne value range 0 = no handicap; 1-4 = mild handicap; 5-7 = moderate handicap; 8-10 = serious handicap; 11-13 = very serious handicap; >14 = extremely serious handicap



## DISCUSSION

Results show that the orthosis contributes to lower pain intensity during walking and taking the stairs as well as during sitting and at night, even when the orthosis is no longer worn. This also corresponds to results from a previous study conducted by Dries et al. where the majority of 381 patients examined also demonstrated significant pain reduction when wearing a semi-rigid knee orthosis [10].

The positive effects of pain reduction in cases of medial KOA could be that those affected may be encouraged and enabled to increasingly take part in everyday situations which they may have otherwise avoided because of their pain. This will, in turn, lead to further physical, psychological, and social benefits, thus contributing to an improved overall quality of life [2,4], as substantiated by the results from this study.

After six weeks of using the orthosis, patients showed improved functional abilities\* reflected, for example, in an increased distance during the 6-MWT. An increase in high-intensity physical activity was also noted, while there was no significant change in mild and moderate activity. It is worth pointing out that the increase in intensive physical activity took place in parallel with the reduction in pain. This means that, owing to the use of the orthosis, patients suffering from medial KOA have a wider choice when it comes to everyday and sporting activities, which may have a positive effect on their general quality of life and could support the management of their condition [4,11].

Further improvements were measured with the KOOS for everyday (KOOS ADL) and sporting (KOOS SL) activities as well as with the Lequesne Index. Previous studies into the treatment of patients suffering from osteoarthritis of the knee using hard-frame orthoses, also known as Unloaders, showed similar improvements in functional abilities\*, the KOOS, and the Lequesne Index, but the results differed in absolute values. This may be based on, for example, a longer follow-up time (sometimes up to several months) and more pronounced symptoms in the examined patients at the beginning of the study [12,13].

To sum up, the study results demonstrate that pain reduction, improvement of function, and improved quality of life can be achieved by wearing a semi-flexible knee orthosis during conservative treatment of active patients suffering from medial KOA.

\*\*Functional abilities:

The sum of all abilities and skills of a person when handling proposed tasks. This primarily refers to the ability to handle everyday requirements in the household, family, workplace, and leisure as well as during the study's functional test.

### CONCLUSION: GenuTrain® OA

- reduces pain by 48.1 %
- increases intense physical activity by 50.6 %
- increases mobility by 5 %
- increases quality of life by 13.4 %

**Sources:** [1] Stetter, B.J.; Fiedler, J.; Arndt, M.; Stein, T.; Sell, S. Impact of a Semi-Rigid Knee Orthotic Intervention on Pain, Physical Activity, and Functional Capacity in Patients with Medial Knee Osteoarthritis. *J. Clin. Med.* 2024, 13, 1535. <https://doi.org/10.3390/jcm13061535> [2] Hunter, D.J.; Bierma-Zeinstra, S. Osteoarthritis. *Lancet* 2019, 393, 1745–1759. [3] Long, H.B.; Liu, Q.; Yin, H.Y.; Wang, K.; Diao, N.C.; Zhang, Y.Q.; Lin, J.H.; Guo, A. Prevalence Trends of Site-Specific Osteoarthritis, From 1990 to 2019: Findings From the Global Burden of Disease Study 2019. *Arthritis Rheumatol.* 2022, 74, 1172–1183. [4] Salaffi, F.; Carotti, M.; Stancati, A.; Grassi, W. Health-related quality of life in older adults with symptomatic hip and knee osteoarthritis: A comparison with matched healthy controls. *Aging Clin. Exp. Res.* 2005, 17, 255–263. [5] Barrett, D.S.; Cobb, A.G.; Bentley, G. Joint Proprioception in Normal, Osteoarthritic and Replaced Knees. *J. Bone Jt. Surg. Br.* 1991, 73, 53–56. [6] Bennell, K.L.; Hinman, R.S.; Metcalf, B.R.; Crossley, K.M.; Buchbinder, R.; Smith, M.; McColl, G. Relationship of knee joint proprioception to pain and disability in individuals with knee osteoarthritis. *J. Orthop. Res.* 2003, 21, 792–797. [7] Dzidotor, G.K.; Moorhead, J.B.; Ude, C.C.; Ogueri, K.S.; Ghosh, D.; Laurencin, C.T. Functions and Effectiveness of Unloader, Patellofemoral, and Knee Sleeve Orthoses: A Review. *Regen. Eng. Transl. Med.* 2023. [8] Cudejko, T.; van der Esch, M.; van der Leeden, M.; Roorda, L.D.; Parad, J.; Bennell, K.L.; Lund, H.; Dekker, J. Effect of Soft Braces on Pain and Physical Function in Patients With Knee Osteoarthritis: Systematic Review With Meta-Analyses. *Arch. Phys. Med. Rehabil.* 2018, 99, 153–163. [9] Roos, E.M.; Lohmander, L.S. The Knee injury and Osteoarthritis Outcome Score (KOOS): From joint injury to osteoarthritis. *Health Qual. Life Outcomes* 2003, 1, 64. [10] Dries, T.; van der Windt, J.W.; Akkerman, W.; Kluijtmans, M.; Janssen, R.P.A. Effects of a Semi-Rigid Knee Brace on Mobility and Pain in People with Knee Osteoarthritis. *J. Rehabil. Med. Clin. Commun.* 2022, 5, 2483. [11] Farr, J.N.; Going, S.B.; Lohman, T.G.; Rankin, L.; Kasle, S.; Cornett, M.; Cussler, E. Physical activity levels in patients with early knee osteoarthritis measured by accelerometry. *Arthritis Rheum. Arthr.* 2008, 59, 1229–1236. [12] Thoumie, P.; Marty, M.; Avouac, B.; Pallez, A.; Vaumousse, A.; Pipet, L.P.T.; Monroche, A.; Graveleau, N.; Bonnin, A.; Amor, C.B.; et al. Effect of unloading brace treatment on pain and function in patients with symptomatic knee osteoarthritis: The ROTOR randomized clinical trial. *Sci. Rep.* 2018, 8, 10519. [CrossRef] [13] Hjartarson, H.F.; Toksvig-Larsen, S. The clinical effect of an unloader brace on patients with osteoarthritis of the knee, a randomized placebo controlled trial with one year follow up. *BMC Musculoskelet. Dis.* 2018, 19, 341.