

EFFECTIVENESS AND USER EXPERIENCES OF AN UNLOADING KNEE BRACE

MEDIAL KNEE OSTEOARTHRITIS – RESULTS OF A MIXED-METHODS RCT

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INTRODUCTION

Knee osteoarthritis is one of the most common degenerative joint diseases and primarily affects the medial compartment of the knee. It leads to pain and functional limitations and may, in the long term, necessitate surgical interventions such as total knee arthroplasty. Conservative treatment approaches such as physiotherapy, injections, and orthoses aim to reduce loading on the affected structures and maintain quality of life.

Unloading knee braces such as the SecuTec® OA act biomechanically by altering load distribution at the knee and reducing stress on the medial compartment. The aim of this randomized, mixed-methods study was to evaluate the brace's effectiveness on pain perception, joint function, and activities of daily living, as well as on subjective user experiences.

METHODS

- Study design: Single-centre randomized controlled trial with a mixed-methods design (evidence level: 1b)
- Population: n = 55 (f = 26, m = 29) patients with radiographically confirmed medial knee osteoarthritis (Kellgren & Lawrence grade 2–3), age 40–75 years, varus malalignment
- Intervention: Fitting of an individually adjustable SecuTec OA valgus brace (after 6 months: n = 23)
- Wear time: Gradually increased to an average of 6.6 hours / day
- Control group: Usual care, but without a brace (after 6 months: n = 23)

There was no significant difference between groups regarding additional treatments (physiotherapy, etc.).

Assessments: Pain (VAS at rest and after the 6-minute walk test), WOMAC score, SF-12 Health Survey, walking distance per day, analgesic use, complications. In addition, qualitative interviews (n = 11) addressing comfort, suitability for daily use, aesthetics, and overall satisfaction.

RESULTS

Analysis of the quantitative data showed that use of the SecuTec OA brace after six months led to a significant reduction in load-induced knee pain. In the 6-minute walk test, pain intensity on the visual analogue scale (VAS) was significantly lower by an average of 2.13 cm compared with the control group (95% CI -3.57 to -0.69). This

difference exceeded the Minimum Clinically Important Difference (MCID) defined in the literature, indicating a clinically relevant reduction in pain.

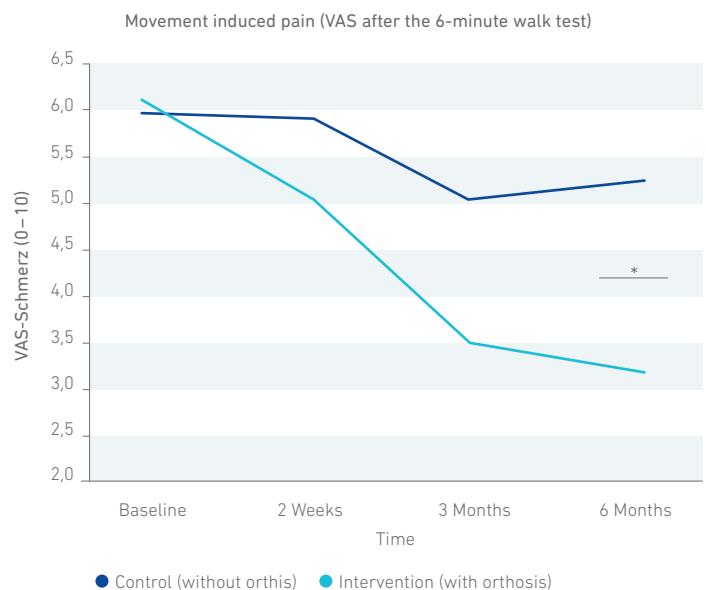


Fig.1: Pain reduction based on a 10-point VAS (Visual Analog Scale, 0–10 cm; 0 = no pain, 10 = worst imaginable pain) measured at four time points after a 6MWT (6-Minute Walking Test). Intervention = patients with brace, control group = patients without brace.

In contrast, no significant difference between the groups was found for pain at rest. Likewise, there were no significant between-group differences in walking distance, general health-related quality of life (SF-12), or other osteoarthritis-related symptoms (WOMAC total scores).

Another relevant finding was the markedly lower analgesic consumption in the intervention group. While a comparable number of patients in both groups took pain medication, the mean total number of tablets taken over six months was 21 tablets in the brace group, whereas the control group took an average of 54 tablets over the same period. This difference is both statistically significant and clinically meaningful, suggesting that wearing the brace may potentially contribute to a reduced need for pain medication.

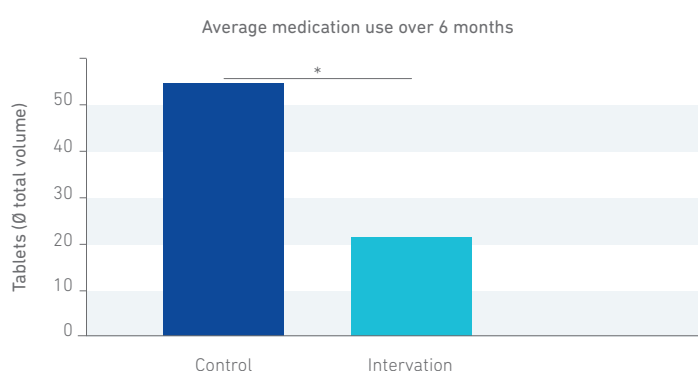


Fig. 2: Average analgesic consumption (total number of tablets) over 6 months. Control = patients without a brace, Intervention = patients with a brace.

DISCUSSION

The results confirm that the SecuTec OA brace can effectively contribute to pain reduction during weight-bearing activities. In addition, there appears to be potential to reduce analgesic requirements. Other functional parameters did not show significant improvements, which may partly be due to the small sample size and a possible type II error (i.e., failing to detect an effect that is actually present).

The qualitative findings complement this picture: despite limited measurable improvements, many patients reported relevant practical benefits in everyday life, improved quality of life, and a perceived increase in stability and daily activity. This underscores the importance of mixed-methods approaches to incorporate subjective patient experiences into effectiveness evaluations.

Overall, the brace represents a relevant conservative treatment option, particularly for patients with moderate medial knee osteoarthritis who wish to delay surgery. Notably, patients with more advanced osteoarthritis (Kellgren & Lawrence grade 3) and severe symptoms more often reported skeptical or negative experiences with the brace than patients with mild to moderate osteoarthritis (Kellgren & Lawrence grade 2). Future research should include larger, multicentre studies with longer follow-up and identify patient profiles that benefit the most.

With regard to adverse events, patients reported skin irritation such as pressure marks, redness, or itching during the first three weeks. However, these complaints were mostly transient and decreased markedly over time or resolved in the following weeks. Initial fit issues, such as slipping or the brace feeling too tight, could be addressed in most patients through corrective adjustments.

The qualitative interviews showed that individual experiences varied considerably. About half of the respondents reported a clear reduction in everyday pain, especially when climbing stairs or walking for longer periods. In addition, several patients described improved joint stability and a greater sense of security during daily activities. Activities such as gardening or carrying heavy loads were also facilitated by the brace. At the same time, some patients reported limitations in activities involving strong knee flexion, particularly kneeling, getting into a car, or cycling.

Handling of the brace was largely rated as straightforward, although some patients found putting it on and taking it off difficult. Psychological aspects such as embarrassment played a minor role; most respondents stated that they did not experience wearing the brace as stigmatizing. Overall, satisfaction predominated: the majority of patients expressed an intention to continue using the brace beyond the study period.

CONCLUSION

- The SecuTec OA, an unloading knee brace, provides a demonstrable benefit in reducing pain during weight-bearing activities.
- SecuTec OA may potentially reduce the need for analgesics.
- SecuTec OA provides patients with improved stability and increased activity in everyday life.
- SecuTec OA represents a relevant conservative treatment option, particularly for patients with moderate medial knee osteoarthritis who wish to delay surgery.