

STUDY PUBLICATION OF SELECTED RESULTS

EVALUATION OF EFFECT AND THERAPEUTIC SAFETY OF THE GenuTrain OA[®] KNEE ORTHOSIS

BACKGROUND

The joint most frequently affected by osteoarthritis is the knee (gonarthrosis). The condition becomes more prevalent with age, it affects patients' quality of life and their ability to cope with everyday tasks. It also generates high costs for the healthcare system (1).

The goal of the study was to determine the effectiveness of the relieving GenuTrain OA knee orthosis, which has been designed to treat osteoarthritis of the knee, measured using parameters such as perception of pain and stability as well as mobility, from being provided with the medical product to the next appointment. Additionally, data was collected relating to compliance, wearing characteristics, handling, and fit of the orthosis. The data recorded by the physician was used to make possible assumptions about medical treatment goals and to what extent they were achieved.

STUDY DESIGN

Non-interventional, clinical study; case series, one-arm (evidence level 3)

METHODOLOGY

Sample:	n = 113 patients; Age: 64.4 ± 11 years Gender: 41 percent male; 59 percent female
Test orthosis:	GenuTrain [®] OA (Bauerfeind AG)
Treatment duration:	On average 5.4 calendar weeks (± 1.4 calendar weeks)
Timing of being provided with the orthosis:	Non-surgical 81 percent After surgery 16 percent Before surgery 3 percent
Test method:	Data collection using a questionnaire
Investigation period:	Initial diagnosis at T1 and data collection during the second appointment T2
Data assessment:	Inductive statistics: paired t-test
Inclusion criteria:	Medial or lateral osteoarthritis of the knee
Exclusion criteria:	Patients who are mentally and/or physically unable to guarantee the safe use of the orthosis

TREATMENT GOALS AND THEIR ACHIEVEMENT AS IDENTIFIED BY THE PHYSICIAN

Data was collected in eight different practices. The most important treatment goals as identified by physicians were, in decreasing order, pain reduction (93 percent), knee joint relief (67 percent), knee joint stabilization (55 percent), and the restoration of normal patient mobility (29 percent). Achievement of the goal was rated as good (rating 2.20 to 1.87) after an average of five weeks (5.4 / +/- 1.4 calendar weeks) of treatment. (Fig. 1)

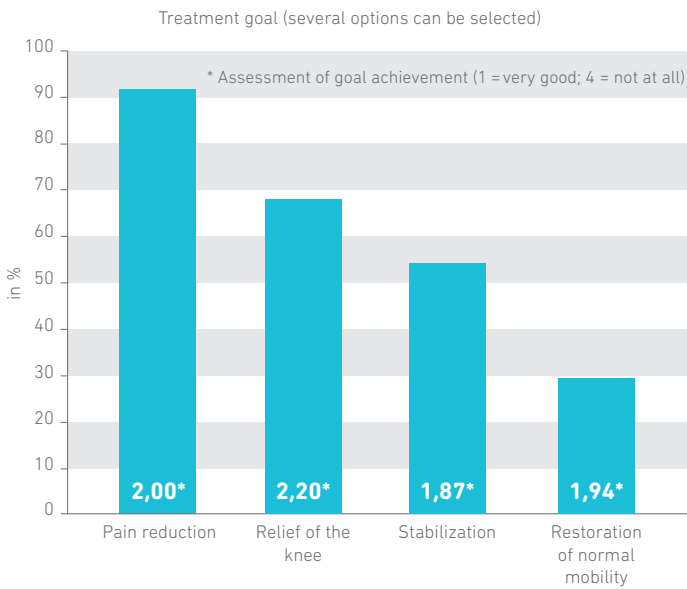


Fig. 1: Treatment goal and its achievement as a result of being provided with the GenuTrain OA

COMPLIANCE

A quarter (25.2 percent) of patients wore the orthosis for more than 8 hours every day. The majority (38.3 percent) reported that they wore the orthosis for 5 to 8 hours every day. 23.4 percent wore the orthosis for 3 to 4 hours, and 13.1 percent for 1 to 2 hours every day (Fig. 2).

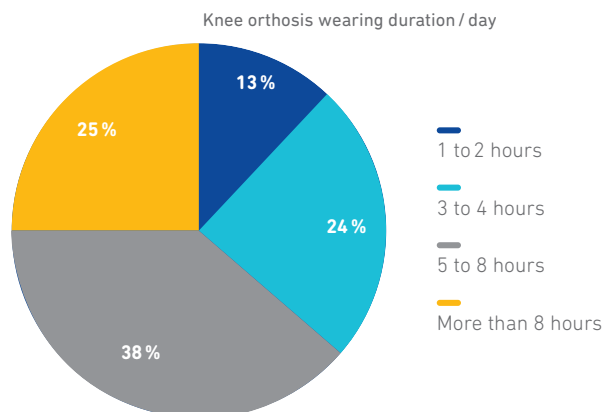


Fig. 2: Proportional distribution of the wearing duration of the orthosis; n = 107

SUPPORT AND STABILITY PROVIDED BY THE ORTHOSIS

Patients rated on a scale of 1 to 6 (1 = very good, 6 = none at all) whether the orthosis supported treatment and provided stability. On average, patients gave a rating of 2.2. This means the support provided by the orthosis was good (n = 107).



STABILITY, MOBILITY, AND PAIN PERCEPTION

During treatment, pain reduced to 3.4 as a result of using the orthosis, compared with 7 before treatment, measured using a 10-point VAS. The feeling of stability in the knee increased from 3.8 to 7.3 as a result of wearing the orthosis. Patient mobility increased to 6.9 during treatment, compared with 3.2 before treatment. This also manifested in the pain-free walking distance that increased from 3.2 to 6.9 on a 10-point scale (1 = short, 10 = long). All changes are statistically significant and clinically relevant (Fig. 3).

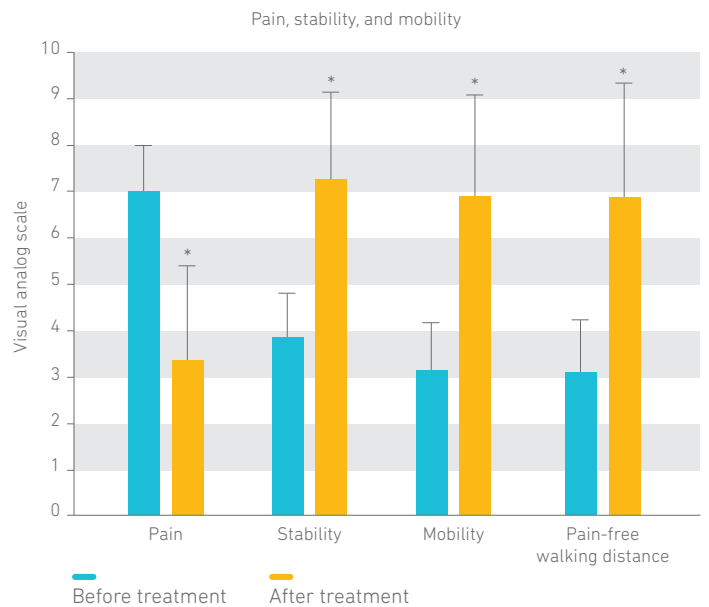


Fig. 3: Pain, stability, mobility, and pain-free walking distance before treatment with the orthosis and after treatment with the orthosis (an average of 5.4 weeks), specified using a visual analog scale. Showing averages with standard deviation; * p < 0.001 (paired t-test)

CONSUMPTION/REDUCTION OF PAIN MEDICATION

44 percent of patients indicated that they were taking pain medication at least once a week (n = 112). When asked whether consumption of pain medication could be reduced as a result of wearing the orthosis, 77 percent of patients said "Yes" (n = 75).

PATIENT SATISFACTION

Handling or putting on the orthosis was described by 92 percent of patients as very easy, easy, or without difficulty. The fit was rated as excellent or good by 79 percent of patients. The majority of participants (73 percent) also rated the non-slip characteristics as excellent or good (Fig. 4).

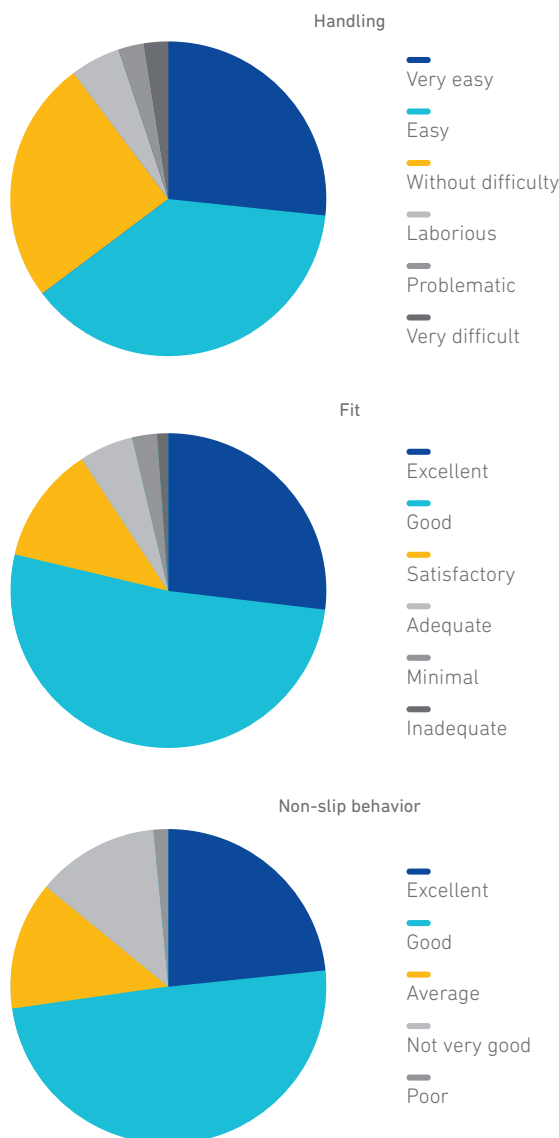


Fig. 4: Patient assessment of handling, fit, and non-slip characteristic of the orthosis

Wearing comfort, for which specifically skin-friendliness, breathability, and weight were asked about, was rated by patients on average with good (2.2) (1 = very good, 6 = poor).

When asked when they were wearing the orthosis, 50 percent of patients reported that they wore the orthosis during their leisure time, 43 percent the entire day, 41 percent during work, 19 percent during exercise, and nobody at night (multiple selection possible).

27 percent of those asked were able to carry out everyday activities without restrictions when wearing the orthosis. The majority (47 percent) was able to carry out everyday activities easily. 21 percent indicated that they were restricted during everyday activities, and 3 percent were severely restricted. One patient (0.9 percent) reported that he or she was not able to carry out everyday activities when wearing the orthosis.

With reference to care of the orthosis, 61 percent of patients rated it as easy, 36 percent as average, and 2 percent as difficult.

Using a 10-point scale, patients were also asked to what extent they expected the orthosis to be slim and that it can be worn beneath clothing (0 = unimportant, 10 = very important). The average was 7.2 ± 2.97 , meaning this is an important criterion for patients. Overall, when patients weighed up all "Pros" and "Cons", there was a clear indication that they were happy with the orthosis (average: 2.1; n = 110).

HOW SATISFIED ARE PATIENTS WITH THE GenuTrain® OA



DISCUSSION

In order to reduce knee strain, hard-frame orthoses are often used as part of non-surgical treatment. For this orthosis design, previous studies have shown pain reduction, mechanical joint relief, as well as improved function in those affected (2, 3). The low level of wearing comfort, however, poses a problem because it leads to insufficient patient compliance (4).

As part of an observational study, this study was able to show that the GenuTrain OA combines both: it provides stabilization, reduces pain by means of targeted relief, and increases patient mobility. At the same time, its wearing comfort, great fit, non-slip characteristics, and easy handling ensure a high level of compliance. This, in turn, increases the effectiveness of the orthosis and therefore patient satisfaction.

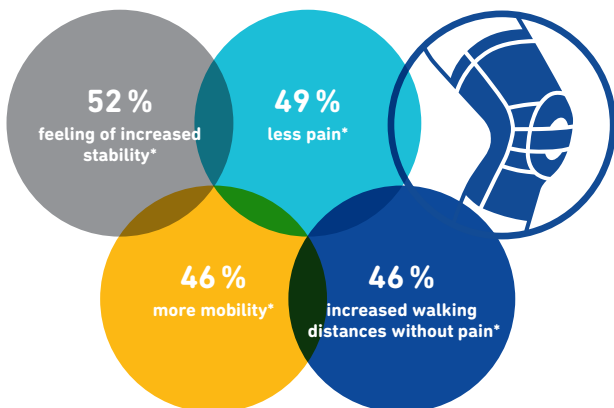
CONCLUSION

- +** In patients suffering from osteoarthritis of the knee, the GenuTrain OA leads to a significant and clinically relevant reduction of pain as well as increased stabilization and mobility.
- +** Thanks to its wearing comfort, the GenuTrain OA results in a high level of compliance, which helps with the clinical effect of the orthosis.
- +** Overall, the majority of patients (74 percent) was happy or very happy with the orthosis, and the treating physician rated the achievement of the treatment goals as good.

SOURCES

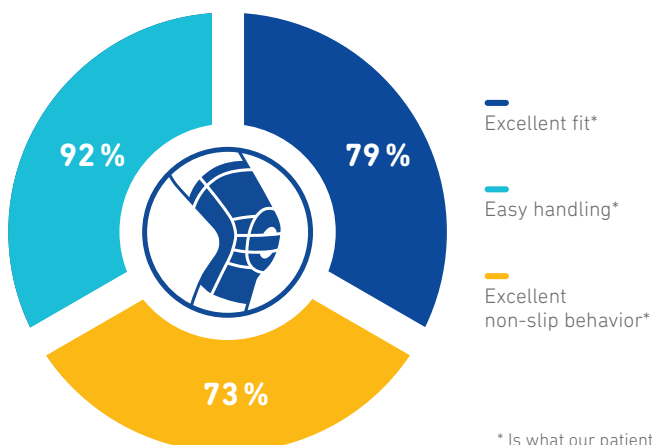
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- [2] Gohal C, Shanmugaraj A, Tate P, Horner NS, Bedi A, Adili A, et al. Effectiveness of Valgus Offloading Knee Braces in the Treatment of Medial Compartment Knee Osteoarthritis: A Systematic Review. Sports health. 2018;10(6):500-14.
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Stability, mobility, pain perception, and walking distance



* Compared with not wearing an orthosis

Patient satisfaction



* Is what our patients say