

SUMMARY OF SELECTED RESULTS

INTERNATIONAL OBSERVATIONAL STUDY ON THE EFFECTIVENESS OF THE GENUTRAIN IN THE CONSERVATIVE TREATMENT OF SPORTS INJURIES

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ABSTRACT

Every year, around 4.5 sports injuries are treated in outpatient and inpatient healthcare facilities in the European Union. 40% of these are caused by the world's most popular sport: football. Ball sports in general pose a higher risk of injuries due to the rapid and abrupt changes in direction involved. Around 61% to 90% of all football injuries affect the lower extremities. Along with the ankle, the knee joint is one of the body parts most commonly affected by such injuries¹. In particular, tears of the anterior cruciate ligament (ACL) are one of the most severe of all sports injuries². The regimes used for the conservative treatment of knee injuries can include e.g. supports and orthoses, physical therapy, or painkillers. The GenuTrain stabilizes the knee joint, alleviates pain and discomfort and facilitates quicker mobilization³. How do patients perceive this after a sports injury? Answering this question was the aim of the observational study.

STUDY DESIGN

prospective, transnational, multicenter observational study

METHODS

Sample:	The study centers were recruited from various international Bauerfeind companies. Medical specialists in the fields of orthopedics, surgery, trauma surgery, and sports medicine from nine countries were involved. 620 patient cases were treated using the GenuTrain.
Product:	GenuTrain knee support (Bauerfeind AG)
Data collection:	July 2015 – March 2016 Documentation form filled in by physician and patient Measurement of patient's range of motion using the neutral-zero method ⁴
Assessment dates:	T0*: Time before injury T1*: Initial examination (prescribing of aid, or shortly after aid is dispensed to the patient) T2*: during recovery T3*: Final examination (recovery is foreseeable) * The intervals between these dates were defined by the examiner based on the indication and the expected regeneration time.
Evaluation of data:	Descriptive statistics for the time points T0, T1, T2, T3 a) based on the overall data b) Investigation of effectiveness based on treatment regime clusters: product without additional prescription, product and physiotherapy, product and painkillers, mix (product, physiotherapy, painkillers)
Inclusion criteria:	<ul style="list-style-type: none">• Patients with a sports injury: Instability (functional instability/"non-coper;" instability due to anatomical deficits e.g. ligament insufficiency, ligament rupture), joint pain with restriction of movement due to inappropriate or excessive mechanical stress (e.g. tendomyopathy, injuries to the capsular ligament, bruising, compression injuries, sprains), inflammation (e.g. tendinitis)• ≥ 29 prescriptions• Documentation of at least two of the three visits following primary treatment

¹ Kianmarz, Y. (2016): Konditionelle Leistungsdiagnostik zur Prävention von Verletzungen im Fußball. Logos Verlag Berlin GmbH. Universität Hamburg.

² Klein, Ch., Bloch, H., Luig, P. (2016): Richtig testen, richtig trainieren. Sportphysio 2016; 04(04): 159-166

³ <https://www.bauerfeind.de/de/produkte/bandagen/knie-huefte-oberschenkel/genustrain.html>

⁴ Neutral-zero measurement: standardized orthopedic evaluation and documentation index for joint mobility

RESULTS

The demographic data of the patients treated with the GenuTrain showed the following:

Table 1: Demographic data

Prescriptions	620
Age	47.6 ± 19.7 years
Men	335
Women	274
Missing	11
Countries	Germany, Austria, Poland, Canada, the Middle East, Singapore, Switzerland, Hungary, Italy

In these nine countries (see Table 1), the GenuTrain was most frequently prescribed for joint pain (74.9%). A further 13.4% of all patients included in the study exhibited symptoms of joint inflammation. 11.6% of patients suffered from instability of the knee joint.

Table 2: Patient symptoms

Symptoms	Knee pain (74.9%) Inflammation in the knee joint (13.4%) Instability of the knee (11.6%)
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Prior to injury, more than half of the patients practiced recreational sport (63.9%). 36.1% of patients were not taking part in any sports activities prior to their injury. The study results revealed a trend toward improvement of the flexion and extension in the knee joint:

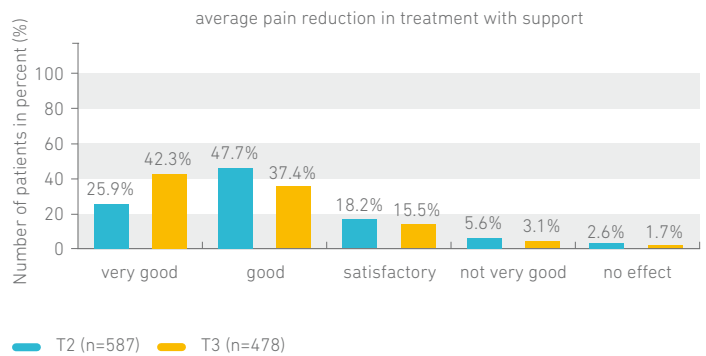
Table 3: Range of motion of the knee joint according to the neutral-zero measurement

ROM			
Flexion	T1 (n=614)	T2 (n=588)	T3 (n=476)
mean	117.2	123.7	127
SD	23.5	20.5	23.7

ROM			
Extension	T1 (n=132)	T2 (n=118)	T3 (n=66)
mean	1.3	1.3	2.3
SD	2.8	2.7	3.7

In addition to the range of motion of the knee joint, the patients' individual perceptions of pain were also examined over the course of treatment. 73.9% of patients reported "good" to "very good" pain relief when wearing the support in addition to other treatment measures. At the time of foreseeable recovery, this figure had increased by a further 6% (79.7% (T3)).

Fig. 1: Assessment of patients' pain relief when wearing the support (T2, T3) Overall data
(options: very good, good, satisfactory, not very good, no effect)

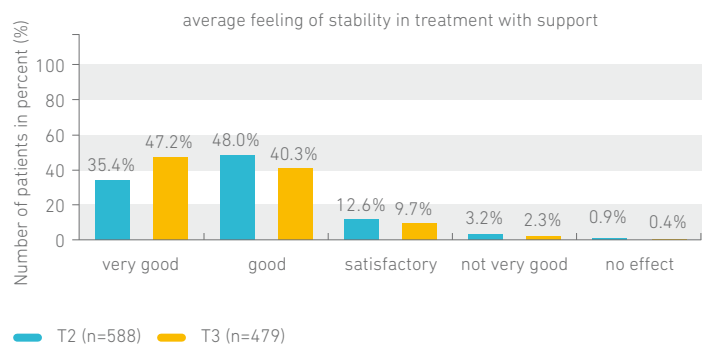


The consumption of painkillers was also closely linked to pain relief.

At the start of treatment (T1), 63.8% of patients needed pain medication occasionally to up to three times a day. During treatment this figure remained virtually unchanged (61.4% (T2)). By the end of treatment, a different picture had emerged. Only 38.1% of patients were still taking painkillers; while more than half no longer required them (61.9% (T3)).

Patients were also asked about their feeling of stability at the various points of the study. During treatment (T2), 83.4% of patients reported good to very good stability when wearing the support. At the end of treatment (T3), this rating was given by 87.5% of patients.

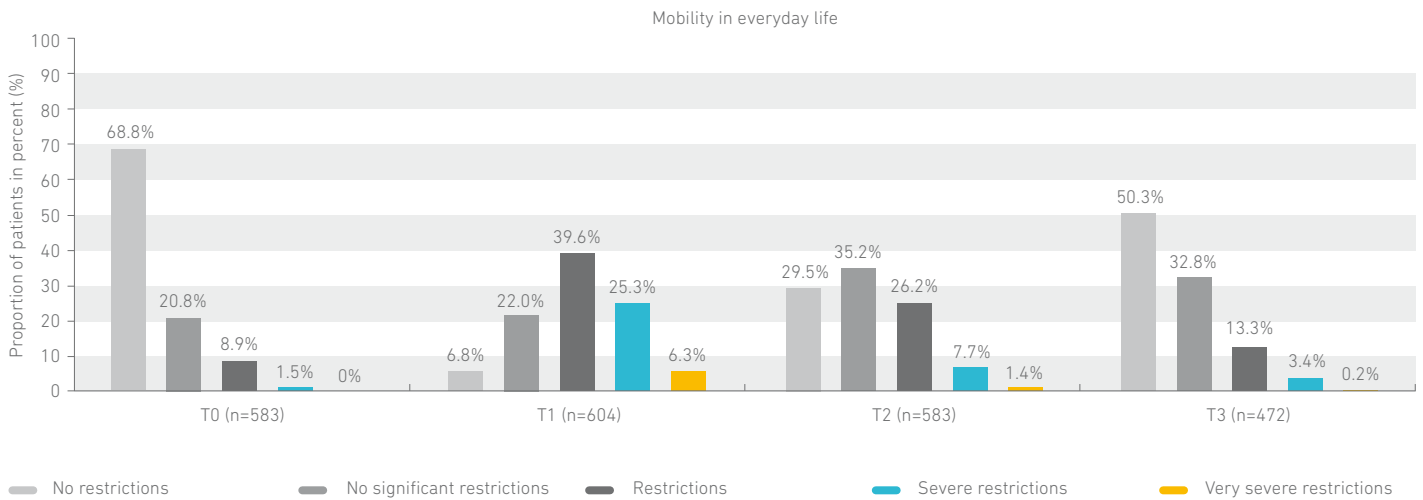
Fig. 2: Assessment of patients' stability when wearing the support (T2, T3)



During treatment, patients were also asked to rate their feeling of stability. At the time of injury (T1), 71.2% of patients experienced restrictions in their movement to varying degrees. Over the course of treatment (T2), this figure decreased to 35.3%. More than half of the patients (64.7%) were already no longer experiencing restrictions at this point in time, or had regained full mobility in their daily lives. At the time of foreseeable recovery, this figure increased further. By the end of treatment, 83% of patients had regained full mobility in their daily lives or were experiencing no restrictions.

Fig. 3: Evaluation of mobility in everyday life (T1, T2, T3)

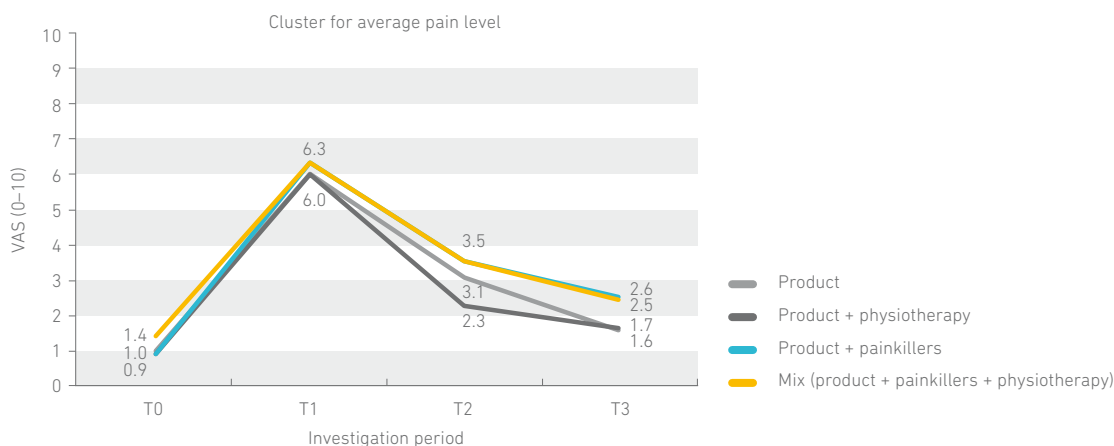
Overall data



Following evaluation of the patient results from various treatment regimes for the above-mentioned symptoms relating to the knee joint area, the next step involved examining how the patients perceived the use of the individual treatment regimes over the course of treatment. This was divided into two separate aspects – the patient’s pain level and their feeling of stability. The following results were found with regard to the pain level:

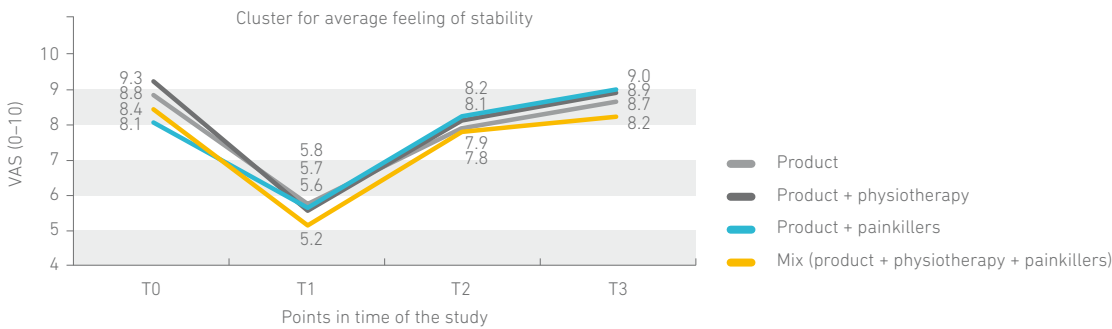
For a virtually identical starting level of pain at the time of injury (T1), patients experienced the most significant reduction in pain during treatment through a combination of physiotherapy and the GenuTrain (T3, VAS: 1.6). Sole use of the GenuTrain for the same symptoms after a sports injury gave similar results. Patients experienced a lower reduction in pain when prescribed additional painkillers alongside the knee support and when receiving the mixed treatment regime (VAS: 2.5; 2.6).

Fig. 4: Pain level T0–T3 – clustered by treatment regime (product, product and physiotherapy, product and painkillers, mix (product, physiotherapy and painkillers))



With regard to the feeling of stability, an examination of the individual treatment regimes reveals the following picture: During treatment (T2) and at the end of treatment (T3), patients reported virtually the same effectiveness in terms of their stability for the different treatment measures. All the prescribed treatment regimes were able to achieve a pretrauma feeling of stability in the knee joint by the end of treatment (T3).

Fig. 5: Feeling of stability T0–T3 – clustered by treatment regime (product, product and physiotherapy, product and painkillers, mix (product, physiotherapy and painkillers))



In addition, patients rated the use of the GenuTrain with a high level of wearing comfort (8 out of 10 points) in the course of treatment (T2) and at the point of foreseeable recovery (T3). In the course of treatment (T2), 87.7% of patients rated the knee support as easy to very easy to handle. By the end of treatment (T3), 91.2% of patients were of this opinion.

SUMMARY & DISCUSSION

The international observational study showed that prescribing the GenuTrain as a first priority in response to knee joint pain following a sports injury can lead to a subjective increase in the patient's feeling of stability and can reduce their pain levels. Another study conducted by Bauerfeind AG was able to objectively measure the increase in stability. Sell et al. used active and passive tests to show that the GenuTrain significantly improves proprioception in cases of chronic inflammatory knee joint complaints, thus increasing joint stability⁵. A study by "Gollhofer et al." also demonstrated neuromuscular joint stabilization in a gait analysis⁶. Patients experienced high wearing comfort with the GenuTrain. This also confirms the measurements from an experimental comparative study that investigated the wearing comfort of seven knee supports made from different textile materials. The material used in the GenuTrain exhibited significantly greater lateral extension compared to the other products. As a result, it demonstrated the greatest ability to adapt to the wearer's anatomy⁷.

As the observational study concerned non-interventional documentation of treatment, the end point of the treatment duration or the point of foreseeable recovery were determined using qualitative instead of quantitative data. Based on the study design, a period of 8 to 12 weeks can be assumed.

The investigation results postulate the use of the GenuTrain as a first priority in response to pain and instability in an international context.

⁵ BSell, S., Zacher, J., Lack, S. (1993): Proprioception decline in the osteoarthritis knee; Z. Rheumatol, 52: 150-155

⁶ Schween R, Gehring D, Gollhofer A (2015); Immediate Effects of an Elastic Knee Sleeve on Frontal Plane Gait Biomechanics in Knee Osteoarthritis.; PLOS 1 one 10(1): e0115782. doi:10.1371/journal.pone.0115782

⁷ HOHENSTEIN LABORATORIES GMBH & CO.KG: EXPERIMENTAL, TECHNICAL STUDY INTO THE THERMOREGULATORY CAPACITY OF KNEE SUPPORTS. Pp. 1–3