

SUMMARY OF SELECTED RESULTS

INTERNATIONAL OBSERVATIONAL STUDY ON THE EFFECTIVENESS OF THE GENUTRAIN P3 IN THE CONSERVATIVE AND POSTOPERATIVE TREATMENT OF SPORTS INJURIES

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ABSTRACT

Both nationally and internationally, sports activities form an important part of a healthy lifestyle and play a key role in staying healthy¹.

Four out of ten Europeans over the age of 15 play sports at least once a week. Six out of ten Europeans play sports in order to keep healthy. However, these health benefits come with the risk of injury¹. In Europe, 6.2 million people a year receive hospital treatment due to sports injuries. The most common cause of these injuries is ball sports (42%), with football taking the top spot here (72%). After the ankle (27%), the knee joint is the second most commonly affected part of the body (18%)¹.

The aim of the observational study was to investigate the use of the GenuTrain P3 knee support in the conservative and postoperative treatment of sports injuries. It investigated the parameters of joint stability, pain level, range of motion, and everyday activities.

STUDY DESIGN

non-interventional, prospective, observational, transnational, multicenter

METHODS

Sample:	167 prescriptions for the GenuTrain P3 knee support by nine specialists in the fields of orthopedics, surgery, trauma surgery, and sports medicine from the international Bauerfeind companies, from study centers in Germany, Austria, Poland, Canada, the Middle East, Singapore, Hungary, and Italy.
Product:	GenuTrain P3 (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 ²
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 different points in time a) based on the overall data b) Examination of the effectiveness of the different treatment regimes: knee support without additional prescription, knee support and physiotherapy, knee support and painkillers, knee support plus physiotherapy and painkillers (mix)
Inclusion criteria:	<ul style="list-style-type: none">• Patients regardless of age and weight• Patients with a sports injury• Patients with instability (functional, anatomical deficits, e.g. ligament insufficiency, ligament rupture), joint pain and restricted movement due to inappropriate or excessive mechanical strain (e.g. tendomyopathy, bruising, sprains), inflammation• ≥ 29 prescriptions• Documentation of 2 of the 3 visits

¹ EuroSafe, Injuries in the European Union, Report on injury statistics 2010-2012, Amsterdam, 2014

² Neutral-zero measurement: Standardized orthopedic evaluation and documentation index for joint mobility.

RESULTS

The demographic data of the patients treated with the GenuTrain P3 showed the following:

Fig. 1: Demographic data

Prescriptions	n=167
Age	40 ± 18.3 years
Men	75
Women	92
Countries	Germany, Austria, Poland, Canada, the Middle East, Singapore

Prescribing practices of the study centers:

Before injury, ¾ of the patients (n=121) practiced recreational sports.

The GenuTrain P3 was prescribed to patients as a result of patellar knee pain in the majority of cases (n=93). Other indications for the treatment included joint instability and joint inflammation in the knee.

In relation to prescribing practices, the results showed that the product was most frequently prescribed on its own for the above-mentioned indications. This was followed by a combination of the product and physiotherapy (n=40). Supplementary painkillers were prescribed the least often (n=10).

Fig. 2: Patient symptoms

Symptoms	Joint pain: 55.7%
	Joint instability: 6.6%
	Joint inflammation: 8.4%
	Missing: 29.3%

Trend toward improvement in the measurable range of motion (ROM) in the knee joint:

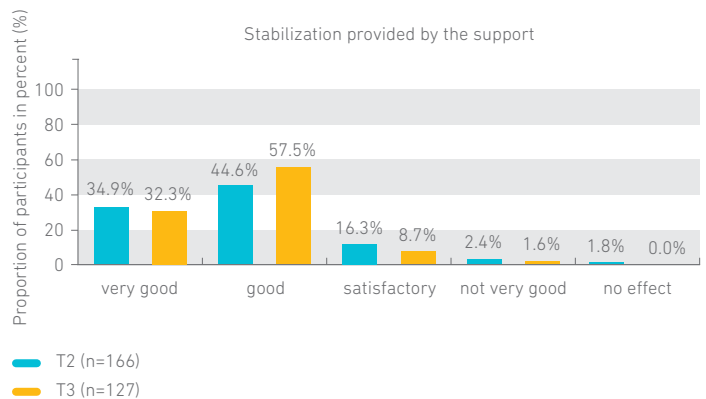
The investigation into the measurable range of motion (ROM) showed that, between the initial and final examination, the mobility of the knee joint exhibited a positive trend, with the flexion angle increasing from 125.9° ± 19.9 (T1) to 130.8° ± 25 (T3). Complete extension of 0° was also achieved at T3.

Improvement in stability:

During treatment, 79.5% of patients reported good to very good stabilization of the knee joint with the GenuTrain P3. At the point of foreseeable recovery (T3), 89.8% of patients rated their stability as "good" or "very good" when wearing the support.

89.8%
Good to very good stability at the end of treatment
with GenuTrain P3

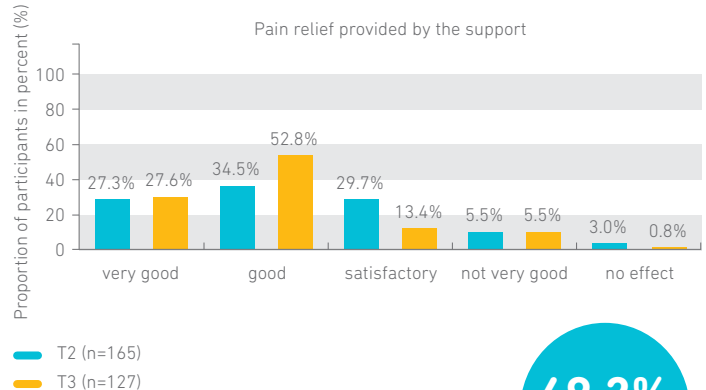
Fig. 3: Assessment of joint stability (T2, T3)



At the time point T2, 61.2% of patients reported "good" to "very good" pain relief. At the recovery point T3, 80% of the patients who wore the GenuTrain P3 rated their pain relief as "good" or "very good."

Reduction in pain level:

Fig. 4: Assessment of pain relief (T2, T3)



69.2%
No painkillers

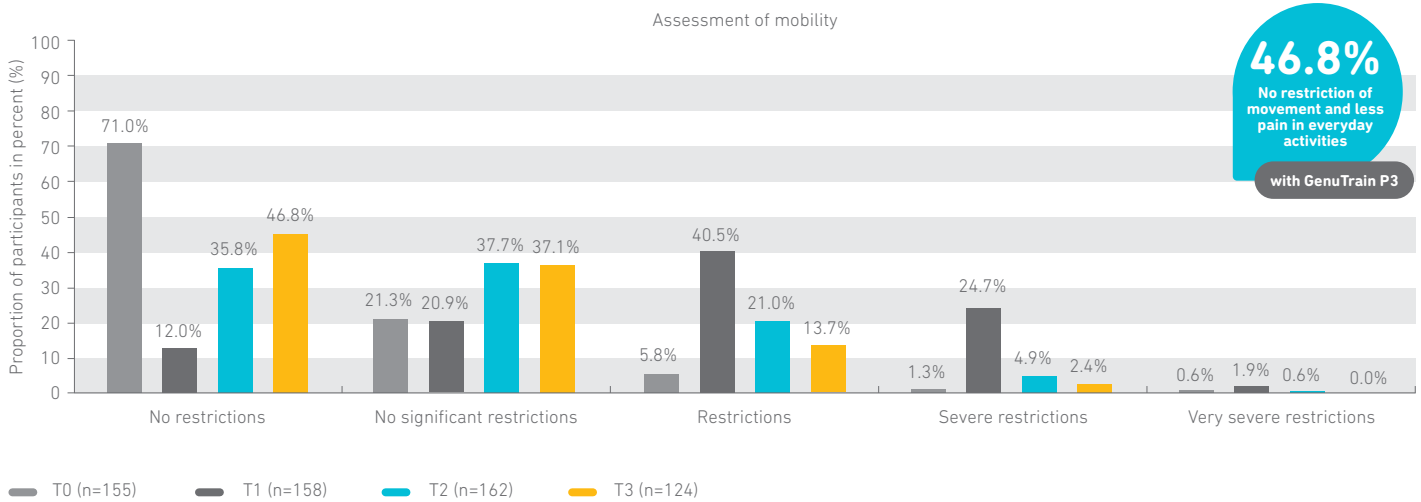
with GenuTrain P3

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

At the time of injury (T1), more than half the patients took painkillers (53.1%). This figure had dropped to 20.8% by T3. 69.2% were no longer consuming any painkillers.

Perceived improvement in daily activities:

Fig. 5: Frequency of subjective feeling of mobility in everyday life (movement capacity) based on selection criteria



Patients who wore the GenuTrain P3 exhibited improved mobility in everyday life. When commencing treatment (T1), many patients stated that they mostly felt “limited” (40.5%) or “very limited” (24.7%) when going about their everyday lives. However, the GenuTrain P3 was able to completely restore mobility in 46.8% of patients (T3).

At T2, 52.5% of patients experienced pain during daily activities. Only 27.5% experienced no pain in their everyday lives. At the point of recovery (T3), 53.2% of patients reported no pain, ¼ more than at T2.

Examination of the effects of different treatment regimes in sports injuries:

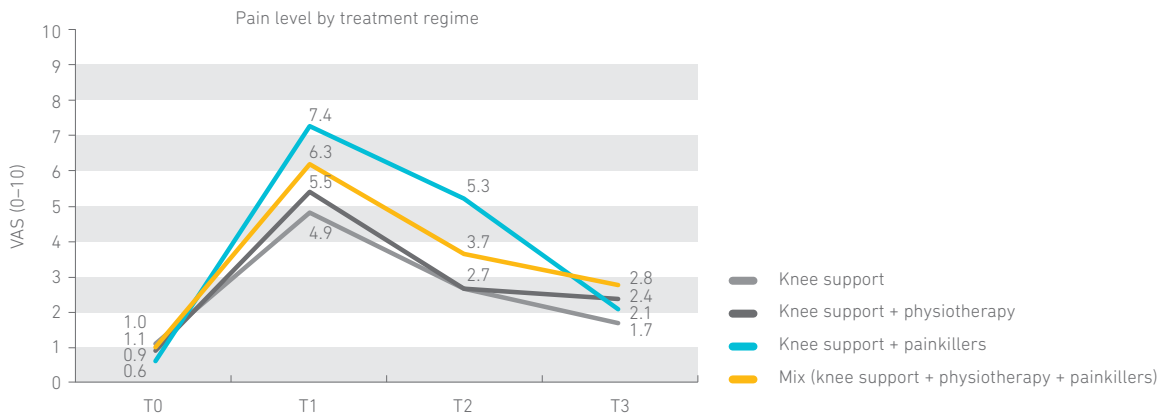
In addition, the different treatment regimes (use of a knee support with or without additional forms of treatment) were examined with regard to the parameters ‘stability’ and ‘pain.’

Patients who were prescribed the GenuTrain P3 on its own experienced the greatest stability in the knee joint (VAS: 8.8 ± 1.6) (T3). In the group of patients who were also prescribed painkillers, stability was rated as worse (VAS: 8.5 ± 1.4). The patients’ ratings for their initial feeling of stability at the point of injury (T1) were the same (VAS 5.6 (product), VAS 5.5 (product and painkillers)).

The same results were found for the patients’ pain levels. Patients who reported moderate pain on average at the start of treatment (4.9 on the VAS) were prescribed a GenuTrain P3. Patients with a higher average pain level at the time of injury (T1) (VAS: 7.4 out of 10) were also given painkillers.

Patients with the lowest pain level at the time of injury (T1: VAS 4.9) were prescribed the product on its own. For increasing levels of initial pain, the above-mentioned treatment regimes were prescribed in addition to the product or as part of a mix of the regimes. All treatment regimes achieved a reduction in pain.

Fig. 6: Pain level T0-T3 – clustered by treatment regime (knee support, knee support and physiotherapy, knee support and painkillers, mix (knee support, physiotherapy, and painkillers))



SUMMARY & DISCUSSION

The aim of the study was to investigate the use and action of knee supports following sports injuries, with a focus on the GenuTrain P3. ¼ of the study group practiced recreational sport. The GenuTrain P3 was prescribed as a result of joint pain in the majority of cases (55.7%). This postulates the use of the GenuTrain P3 as a first priority in response to pain, including in an international context. Far fewer patients were prescribed the support to treat instability and joint inflammation.

Patients reported feeling virtually completely stable and pain-free at the point of recovery as a result of wearing the GenuTrain P3. The use of the GenuTrain P3 in treatment enabled patients to return to their pretrauma condition in terms of pain and stability. An earlier RCT study also demonstrated that wearing a knee support leads to neuromuscular stabilization and reduction of strain on the knee joint³. An RCT study has already shown that wearing a Train active support can reduce back pain. Patients recovered more quickly and took fewer days off work⁴. This effect achieved with Train active supports was also demonstrated in the present study in the context of sports injuries to the knee.

The results showed that the patients' use of painkillers decreased as the study progressed. It is not possible to make any statements regarding the types of painkillers used.

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. A study conducted by Egloff et al. showed that injuries to the knee ligaments can lead to a reduction in sporting activity and promote the premature development of gonarthrosis⁵. With the GenuTrain P3, by the end of treatment (T3) the majority (83.9%) of participants were able to manage their daily lives without significant restrictions and return to the same level of sporting activity as before their injury. To conclude, these study results for treatment with the GenuTrain P3, including in combination with physiotherapeutic measures, indicate a positive effect on the patient's stability and pain level. Improvement of these parameters leads to a reduction in inappropriate and excessive mechanical stresses, and therefore also to a decrease in the likelihood of recurrent injuries.

³ Schween R, Gehring D, Gollhofer A (2015); Immediate Effects of an Elastic Knee Sleeve on Frontal Plane Gait Biomechanics in Knee Osteoarthritis. PLOS | one 10(1): e0115782. doi:10.1371/journal.pone.0115782

⁴ Roelofs et al; Lumbar Supports to Prevent Recurrent Low Back Pain among Home Care Workers; Ann Intern Med. (2007);147:685-692. (ISRCTN registration number: ISRCTN73707379)

⁵ Egloff Ch, Valderrabano V, Pagenstert G (2011); Knee injuries in sports – Partial tears of the ACL. DOI: <http://dx.doi.org/10.1016/j.orthr.2011.02.007>: 35-41