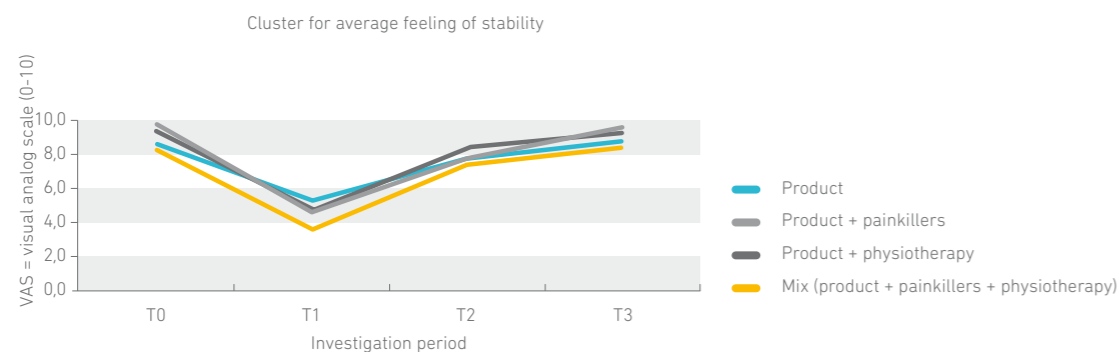


**Fig. 5: Feeling of stability T0–T3** – clustered by treatment regime (product, product and physiotherapy, product and painkillers, mix (product, physiotherapy, and painkillers))



In addition, patients rated the use of the MalleoTrain Plus with a high to very high level of wearing comfort (8 out of 10 points on a ten-point visual analog scale) in the course of treatment (73 percent, T2) and at the point of foreseeable recovery (87 percent, T3). 87.9 percent of patients rated the support as easy to very easy to handle in the course of treatment (T2).

### SUMMARY & DISCUSSION

The international observational study showed that the MalleoTrain Plus was prescribed following a supination trauma in around 70 percent of all treatments, including ligament rupture and chronic instability as a result of a previous supination trauma. The investigation showed an increase in the feeling of stability and a reduction in pain.

An earlier clinical study by O'Hara et al.\* with the MalleoTrain support without a tensioning strap demonstrated the pain-reducing effect of the Train active knit for pain at rest and night pain.

The improvement in patient mobility observed in this investigation was also noted in a study by Blandfort et al.\*\*. Patients whose treatment involved use of the support regained mobility more quickly than those given standard treatment without the support, allowing them to work and do sport.

Patients found the MalleoTrain Plus very comfortable to wear. One reason for the high wearing comfort is the very good clothing-physiological properties of the Train active knit. This was confirmed by measurements of an experimental, textile-physiological comparative study which involved examining seven knee supports made from different textile materials, measuring aspects such as their transverse stretching and their warmth and water vapor permeability. The results can be transferred to the MalleoTrain as

both the GenuTrain and the MalleoTrain are made from the same Train active knit.

The Train active knit exhibited substantially greater transverse stretching compared to the other products made from other materials. As a result, the Train active support demonstrated the greatest ability to adapt to the wearer's anatomy.

The results for pain reduction and stabilization separated by treatment regime show that treatment with the support alone had almost the same results as the combination of a support with further types of treatment.

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 eight to twelve weeks can be assumed.

### Sources:

\* J. O'Hara MB, ChB, J. C. Valle-Jones MRCS, LRCP, H. Walsh MB, BSc, H. O'Hara MRCS, et al. Controlled trial of an ankle support (Malleotrain) in acute ankle injuries Br J Sp Med 1992; 26(3);

\*\* R. Blandfort, H. Hess, F. Lippay Die MalleoTrain Bandage im klinischen Großversuch Sportverletzung, Sportschaden; Issue 1; 5th volume; P. 1-54; March 1991

## SUMMARY OF SELECTED RESULTS

# INTERNATIONAL OBSERVATIONAL STUDY ON THE EFFECTIVENESS OF THE MALLEOTRAIN PLUS IN THE CONSERVATIVE TREATMENT OF SPORTS INJURIES

BAUERFEIND.COM

### INTRODUCTION

An ankle sprain is the most common sports injury. The frequency of a supination trauma to the upper ankle is around one incident per 10,000 people, per day.

18 percent of all supination traumas have a sport-related cause. Sports with quick changes of direction such as ball sports or activities done on uneven ground such as football, tennis, or hiking are particularly likely to cause injury.

The mechanism of injury in an upper ankle supination trauma consists of a combination of plantar flexion, adduction, and an inversion of the foot. This can cause damage to the fibular ligaments. Ligament rupture only occurs in around ten percent of all traumas. Most commonly affected is the anterior talofibular ligament, accounting for 65 percent of cases. The aim of early functional treatment is to restore mobility in the joint and reduce pain.

The MalleoTrain Plus stabilizes the ankle joint, relieves pain, and helps to achieve faster mobilization.

What is the patient's perception of this after a sports injury or supination trauma? Answering this question was the aim of the observational study.

### STUDY DESIGN

non-interventional, prospective, observational, transnational, multi-center

### METHODOLOGY

Sample: 215 prescriptions for the MalleoTrain Plus ankle support by nine specialists in the fields of orthopedics, surgery, trauma surgery, and sports medicine from study centers in Germany, Italy, Canada, Austria, Poland and Singapore.

Product: MalleoTrain Plus (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  
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. descriptive statistics for the different points in time

Two assessment dates:  
a) Based on the overall data  
b) Examination of the effectiveness of the different treatment regimes: ankle support without additional prescription, ankle support and physiotherapy, ankle support and painkillers, ankle support, physiotherapy, and painkillers (mix)

Evaluation of data:  
Inclusion criteria:

- Patients regardless of age and gender
- 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 strain or a trauma (e.g. tendomyopathy, bruising, sprains, e.g. supination), inflammation
- Documentation of at least two of the three visits following primary treatment

## RESULTS

The demographic data of the patients treated with the MalleoTrain Plus showed the following:

**Table 1: Demographic data**

<b>Prescriptions</b>	215
<b>Age</b>	42 ± 19.0 years
<b>Men</b>	81
<b>Women</b>	134
<b>Countries</b>	Germany, Italy, Canada, Austria, Poland, Singapore

In six countries, (see table 1) the MalleoTrain Plus is most commonly prescribed for an ankle sprain (supination trauma) (53.8 percent). 11.4 percent of all patients included in the study exhibited chronic instability. 10.1 percent of patients suffered from osteoarthritis of the ankle joint.

**Table 2: Patient symptoms**

<b>Sprains</b>	53.8%
<b>(chronic) instability</b>	11.4%
<b>Osteoarthritis</b>	10.1%
<b>Arthralgia/irritation/excessive strain</b>	8.9%
<b>Ligament rupture</b>	7.6%
<b>Peritendinitis</b>	5.1%
<b>Fracture</b>	7.6%

Prior to injury, more than half of the patients practiced recreational sport (62.4 percent). 37.6 percent of patients were not taking part in any sports activities prior to their injury.

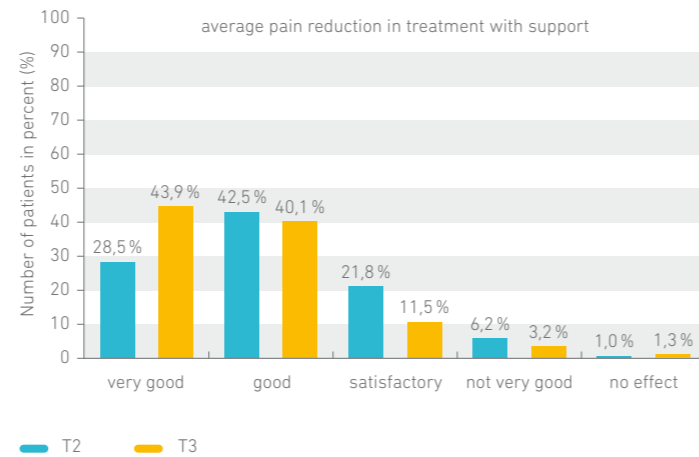
The study results revealed an improvement of the dorsal extension and plantar flexion in the ankle from investigation period T1 to T3:

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

Angular measurement in degrees	Dorsal extension	Plantar flexion
<b>T1 (n=202)</b>	15.2	28.6
<b>T2 (n=197)</b>	17.4	32.4
<b>T3 (n=159)</b>	19.8	35.2
	<b>Standard deviation</b>	
<b>T1</b>	8.0	11.8
<b>T2</b>	7.2	10.4
<b>T3</b>	5.9	10.2

In addition to the range of motion of the ankle joint, the patients' individual perceptions of pain were also examined over the course of treatment. 71 percent of patients (T2) 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 13 percent to 84 percent (T3).

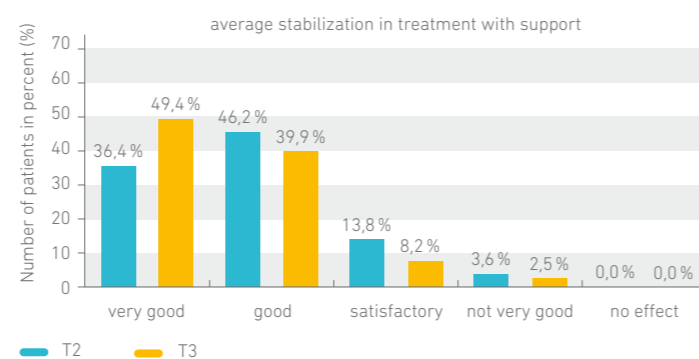
**Fig. 1: Assessment of patients' pain relief when wearing the support (T2, T3) Overall data (options: very good, good, satisfactory, not very good, no effect)**



The consumption of painkillers was also closely linked to pain relief. At the start of treatment (T1), 63.9 percent of patients needed pain medication occasionally to up to three times a day. During treatment, the number of patients with this consumption of painkillers fell to 59.9 percent (T2). At the end of treatment (T3), only 39.8 percent of patients were still taking painkillers, while more than half no longer required them (60.3 percent).

Patients were also asked about their feeling of stability at the examination points. During treatment (T2), 82.6 percent of patients reported good to very good stability when wearing the ankle support. At the end of treatment (T3), this rating was given by 89.3 percent of patients.

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

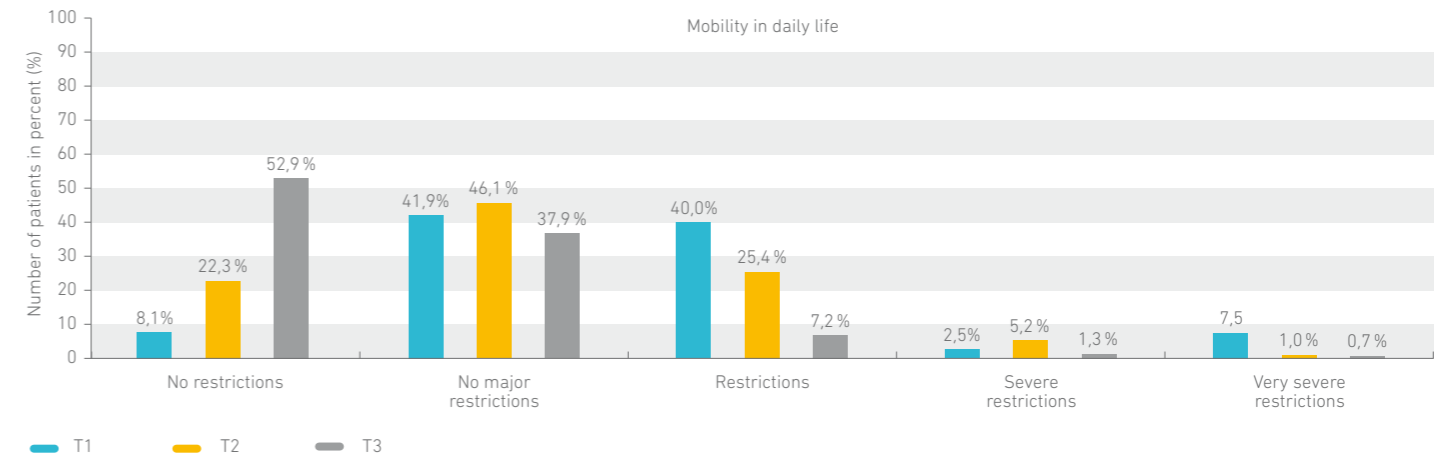


During treatment, patients were also asked to rate their mobility. At the time of injury (T1), 50.0 percent of patients experienced restrictions, which extended to very severe restrictions, in their mobility.

Over the course of treatment (T2), this figure decreased to 31.6 percent. More than half of the patients (68.4 percent) were either already no longer experiencing restrictions at all or were not experiencing major restrictions at this point in time, and had regained mobility in their daily lives.

At the time of foreseeable recovery, this figure increased further. At the end of treatment, 90.8 percent of patients experienced either no restrictions at all or no major restrictions in their mobility in their daily lives.

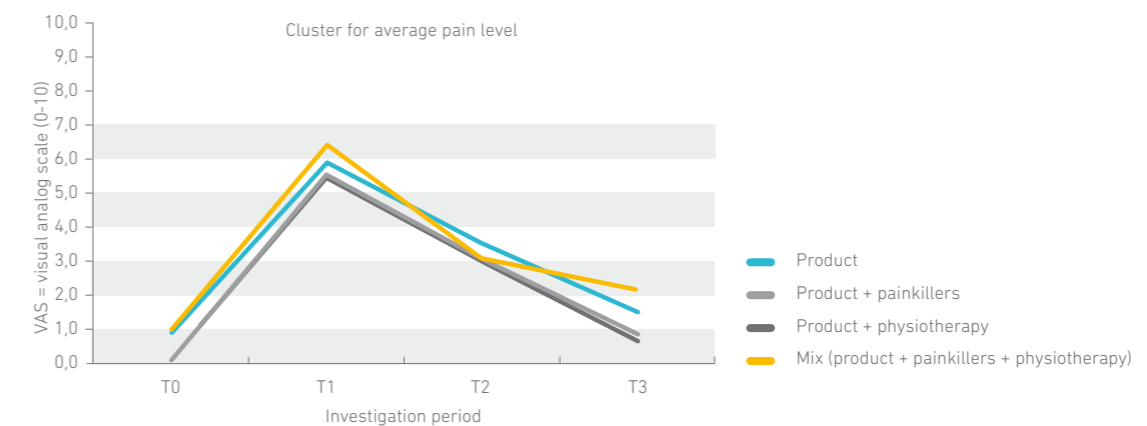
**Fig. 3: Evaluation of mobility in daily life (T1, T2, T3) Overall data**



Following overall evaluation of the patient results, 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 MalleoTrain Plus as well as painkillers and the MalleoTrain Plus (T1–T3. VAS Δ: 5.0/4.9). There was a slightly lower reduction in pain when using the MalleoTrain Plus alone and when using a mix of product, painkillers, and physiotherapy. (T1–T3. VAS Δ: 4.4/4.3).

**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:

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 ankle joint by the end of treatment (T3).