BAUERFEIND®

STUDIES

COLLECTED STUDIES
ORTHOPEDICS / FOOT ORTHOPEDICS

Clinical and experimental studies conducted by Bauerfeind

CONTENTS

STUDIES ABOUT TRAIN ACTIVE SUPPORTS AND ORTHOSES

STUDIES ABOUT ORTHOPEDIC FOOT ORTHOSES

GenuTrain®

Effectiveness and long-term effect of a knee support in patients with chronic instability following ACL reconstruction

Sole, G., Hammer, N., et al., Centre for Health, Activity and Rehabilitation Research, School of Physiotherapy, University of Otago

Surgical reconstruction of a torn cruciate ligament with subsequent rehabilitation is the most frequent treatment in young, active patients.
In a post-operative setting, reports show medium-term to long-term impairment of and restriction in knee functionality, in addition to the risk of re-rupture.
Clinical studies suggest that potential consequences following cruciate ligament reconstruction may include persistent thigh muscle deficits, a changed gait, and lower levels of physical activity.
It has been discussed that supports may improve/normalize gait by improving proprioception and sensorimotor control, thus increasing knee joint function and the patient's confidence in their own knee.

The objective of the study was to examine the stabilizing effect of the GenuTrain knee support in patients with chronic instability (at least 5 months after surgery) following ACL rupture and ligament reconstruction at baseline as well as 6 weeks after wearing the product.

GenuTrain®
Activation, relief and stabilization of the knee joint

METHODOLOGY

Sample:	n = 34 patients; Part 1: acute effect: n = 34 (crossover, randomized) Part 2; 6 weeks of wearing the product: n = 17 with support = BG = intervention group, n = 17 without support = KG = control group
Age:	27 ± 7 years, height: 173.0 ± 10 cm, weight: 72.9 ± 10.7 kg, BMI: 24.4 ± 3.2, sex;
Test support:	GenuTrain knee support (Bauerfeind AG)
Test method:	Different types of single-leg jumps Data collection using a load sensing platform and measuring horizontal jump length
Investigation period:	1st measurement: acute effect, 6 weeks of wearing the support 2nd measurement: 6 weeks after the first measurement
Inclusion criteria:	Patients with ACL rupture and ACL reconstruction at least 5 months to 5 years in the past, patients with revision procedures or previous ACL ruptures on the other knee, patients with problems related to the pelvis or lower back as well as the lower extremities. BMI above 30 or IKDC-SKF value < 40 or > 80
Study design:	Crossover design for the acute effect; two-arm, randomized, controlled clinical study with 6-week long-term follow-up (evidence level 1b)

RESULTS

Single-leg horizontal jump, acute effect:
During jumps with the support on the injured leg, the distance increased significantly by 3.6 percent (95 percent CI 0.4–6.8 percent, p = 0.025) compared with jumping without a support on the injured leg.

A reduction in different jumping abilities was also observed between the healthy and the injured side of -9.3 percent (-12.4 percent, -6.1 percent) without a support to -6.0 percent (-9.2 percent, -2.8 percent) when wearing the support. During the acute phase, the deficit on the injured side compared with the healthy side decreases by a third when wearing the GenuTrain. This corresponds to an increase in jumping ability of 5 cm for the injured leg when a support is being worn (Fig. 1)

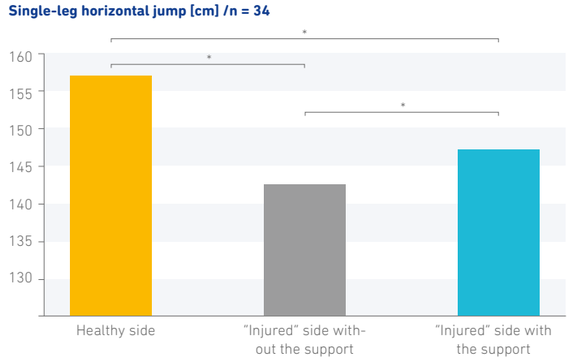


Fig. 1: Single-leg horizontal jump Y axis = jumping length [cm], (α<0.05; power, β = 80%; one-way ANOVA)

Single-leg horizontal jump (step-down hop test); acute effect:
During the single-leg jump without the support on the injured leg, the max. knee angle of the injured side is only 91.9 percent of the max. knee angle of the healthy side.
When jumping with the support on the injured leg, a max. knee angle was recorded that corresponded to 98.2 percent of the healthy side (Fig. 2)

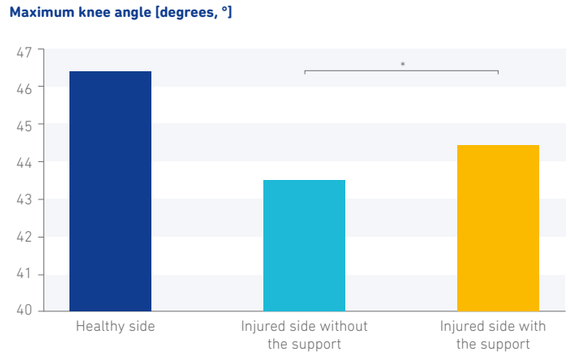


Fig. 2: Step-down hop test, Y axis = max. knee angle [degrees °], (α<0.05; power, β = 80%; one way repeated ANOVA)

Single-leg horizontal jump (step-down hop test); long-term effect:
After six weeks of wearing the GenuTrain, test subjects recorded a reduced standing phase during the step-down hop test with the injured leg (minus 22 percent).
Results indicate that the GenuTrain can improve jumping performance, over an extended period as well.

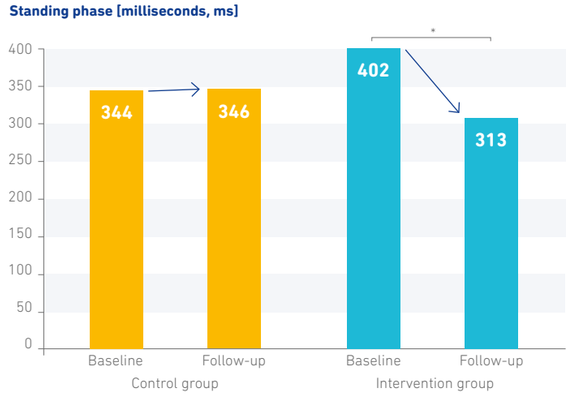


Fig. 3: Step-down hop test, Y axis = standing time [milliseconds, ms], baseline = T0, at the beginning of the test; follow-up = T1 after 6 weeks; (α<0.05; power, β = 80%; one way repeated ANOVA)

- → **GenuTrain increases performance and knee coordination**
- → **After 6 weeks of wearing the GenuTrain, there was no decrease in the acute effect**
- → **After 6 weeks, there were fewer instances of impaired knee function (knee locking) when using GenuTrain**
- → **After six weeks, there was a reduced standing phase during the step-down hop test.**

Sources:

Sole, G., Lamb, P., Pataky, T., Klima, S., Navarre, P., and Hammer, N.
Immediate and 6-week effects of wearing a knee sleeve following anterior cruciate ligament reconstruction: a cross-over laboratory and randomised clinical trial
BMC Musculoskeletal Disorders (2021) 22:655

Sole, G., Lamb, P., Pataky, T., Pathak, A., Klima, S., Navarre, P., and Hammer, N.
Immediate and six-week effects of wearing a knee sleeve following anterior cruciate ligament reconstruction on knee kinematics and kinetics: a cross-over laboratory and randomised clinical trial
BMC Musculoskeletal Disorders (2022) 23:560

GenuTrain®

Evaluation of the biomechanical mode of action of the GenuTrain knee support

Schween R., Gehring D., Gollhofer A.
Institute of Sport and Sport Science at the University of Freiburg

One postulated effect of GenuTrain is that it relieves and stabilizes the knee joint. The aim of this study was to investigate the biomechanical mode of action of knee supports in patients walking with a pathological gait – patients suffering from osteoarthritis of the knee in this particular comparative cross-sectional study. The study focused particularly on the adduction of the knee joint and the associated joint torque, because these aspects are considered to be connected to the development of osteoarthritis of the knee. The study compared the kinematics and kinetics of walking with and without a knee support.

GenuTrain®
Activation, relief and stabilization of the knee joint

METHODOLOGY

Sample:	n = 31 (16 females, 15 males)
Age:	51 ± 9 years for females, 54 ± 6 years for males
Test support:	GenuTrain knee support (Bauerfeind AG)
Test method:	3D kinematics and kinetics (Vicon)
Data analysis:	Variance analysis with significance level of 5 percent
Inclusion criteria:	• Age: 25 – 65 years • Unilateral or unilaterally pronounced bilateral osteoarthritis of the knee
Exclusion criteria:	• Neurological impairments • Endoprostheses for the knee, hip, and ankle • A definite intolerance of the physiological stresses occurring during the study

RESULTS

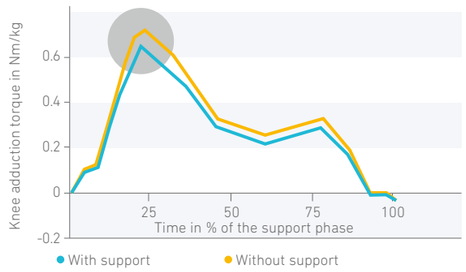
The knee adduction in the affected (= diseased) leg was significantly reduced by the knee support at the beginning and at the peak of the floor contact phase (by an average of 2°; no figure).

The maximum knee adduction torque in the affected leg was significantly reduced when wearing the knee support (by an average of 9 percent).

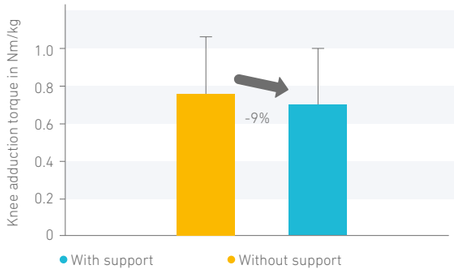
With GenuTrain, a significant reduction of the maximum pressure value of up to -25 percent in the hindfoot area was measured.

→ **GenuTrain affects the neuromuscular control of the gait**
→ **GenuTrain relieves and stabilizes the knee**

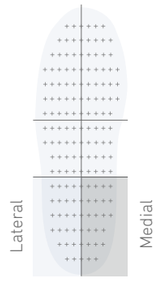
Knee adduction torque

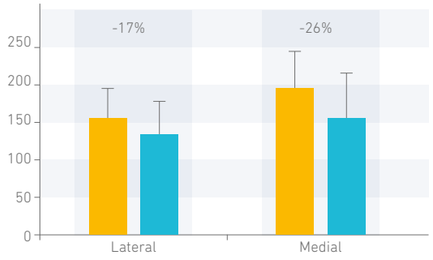


Maximum knee adduction torque



Pressure in the hindfoot area





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

GenuTrain®

Proprioception decline in the osteoarthritic knee

Sell S., Zacher J., Lack S.
Tübingen University Department of Orthopedic Surgery / Wildbad StateHospital for Rheumatic Diseases

In the early stages, osteoarthritis is limited to changes in the articular cartilage. Accompanying inflammatory responses then also occur as part of the overall condition at a later date. In general, the development of osteoarthritis is a process involving multiple aspects, in which changes on a mechanical and molecular biological level and traumatic, genetic, and hormonal factors play a significant role. Proprioception decline is also a major part of this pathogenetic process. The frequently altered gait – that often cannot be explained solely by pain or the age of the patient – already indicates proprioception decline.
The aim of the study is to measure the effect of a knee support on the proprioception of patients with polyarthritis.

GenuTrain®
Activation, relief and stabilization of the knee joint

METHODOLOGY

Patients:	n = 59 in total, n = 34 women, n = 25 men, age: 69.8 years
Healthy subjects:	n = 80 in total, n = 46 women, n = 34 men, age: 68.6 years (= control group 1)
Healthy subjects:	n = 30 in total, n = 20 women, n = 20 men, age: 23.5 years (= control group 2)
Test support:	GenuTrain knee support (Bauerfeind AG)
Test method:	• TTDPM – (Threshold to Detection of Passive Motion) = angle reproduction test • The supine test subjects are to position a leg model at an angle that corresponds to the one at which they feel their knee is positioned. The patient's leg has previously been positioned at a corresponding angle by a second person ("passive" angle reproduction test). • The supine test subjects are to position their knee at an angle that they are shown using a leg model ("active" angle reproduction test). • The patients were unable to see their legs in any of the tests.
Inclusion criteria:	Patients with pronounced osteoarthritis of the knee, confirmed by X-ray (45 patients with grade IV, 5 with grade III, and 5 with grade II: osteoarthritis grades in accordance with Kellgren)

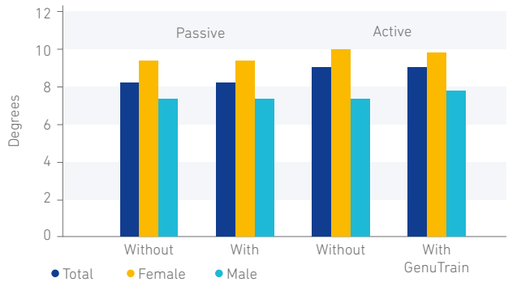
RESULTS

The group over 50 years old showed an average of 8.3° in the passive test and 8.8° in the active test. The differences between the two groups were statistically significant in both the active and the passive test. The knee support had no demonstrable effect in test subjects with no knee joint problems. The osteoarthritis group had considerably disrupted proprioception values compared with the two control groups. This was evident in both the active and passive tests. A positive effect of the knee support on proprioception was demonstrated in all test methods. With GenuTrain, proprioception is significantly improved in cases of chronic inflammatory knee joint complaints, thus increasing joint stability. Joint perception was improved by 14 percent in the "passive" test and by 12 percent in the "active" test.

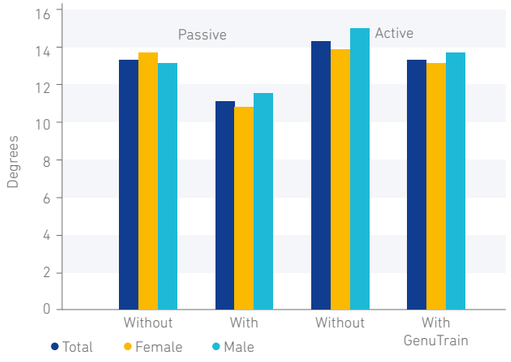
→ **GenuTrain improves proprioception in patients with joint perception deficits**

→ **GenuTrain provides neuromuscular stabilization for the knee**

Proprioception in the angle reproduction test
Control group, age = 50 years



Proprioception with osteoarthritis in the angle reproduction test
Total study population



Source:
Sell S, Zacher J, Lack S; Proprioception decline in the osteoarthritic knee; Z. Rheumatol, 52: 150 – 155: (1993)

GenuTrain® A3

The effect of a knee support in osteoarthritis

Reer R., Jörn H., Ziegler M., Braumann K.-M.
Movement Medicine Research, Department of Sports Medicine, University of Hamburg

The aim of this randomized and controlled study was to demonstrate the effects of knee supports regarding range of motion, pain reduction, and physical mobility in patients suffering from osteoarthritis of the knee/arthritis. The osteoarthritis patients were examined before and after six weeks of treatment and wearing a knee support.

METHODOLOGY

Patients:	n = 39 (n = 19 with the support; n = 20 without the support), age: average of 62 years
Test support:	GenuTrain A3 knee support (Bauerfeind AG)
Test method:	Possible pain-free walking distance; SF-36 score, WOMAC score
Inclusion criteria:	Patients with grade 1 – 3 osteoarthritis (Kellgren) confirmed in an X-ray

RESULTS

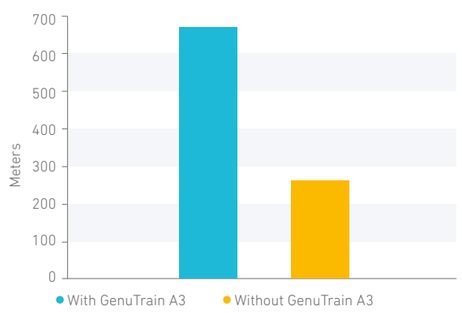
Following six weeks of treatment with the support, patients with the knee support showed lower values for pain and higher values for feeling of stability in the knee and physical function/mobility than the control group in the WOMAC score.

The distance walked without pain increased significantly – by a factor of 2.4 – with the GenuTrain A3. Patients with osteoarthritis of the knee remained pain-free for longer with GenuTrain A3.

Patients with osteoarthritis of the knee who used GenuTrain A3 had better health-related quality of life than patients without a support (SF36 Score).

→ **GenuTrain A3 reduces joint pain**
→ **GenuTrain A3 improves physical mobility**

Pain-free distance



2.4 times
the walking distance
(painless)

With GenuTrain A3

GenuTrain® A3
Activation and stabilization for complex knee complaints such as osteoarthritis of the knee

Please note:
This study was conducted using the previous model.

Source:
Reer, R., Jörn, H., Ziegler, M., Braumann, K.-M. ; The effect of a knee support in osteoarthritis; Orthopadie Technik, 8 / 2005

GenuTrain® OA

Conservative treatment of knee problems. Effects of a semi-flexible knee orthosis on pain perception, physical activity, and functional abilities of patients suffering from medial osteoarthritis of the knee

Stetter, B.J.; Fiedler, J.; Arndt, M.; Stein, T.; Sell, S., Institute of Sports and Sports Science, Karlsruhe Institute of Technology (KIT)

INTRODUCTION

Osteoarthritis of the knee (KOA) causes pain, physical restrictions, and a loss of function that can prevent patients participating in domestic, professional, or social activities, thus reducing quality of life (QoL). Studies have also shown that KOA is associated with impaired joint proprioception.

The objective of this study was to examine the effects of a new semi-flexible knee orthosis on pain perception, physical activity, and functional abilities.

METHOD

- Clinical study/prospective, one-arm, controlled
- Six weeks of monitoring
- Data collection using questionnaires (KOOS, Lequesne Score), visual analog scale (VAS), activity sensor (movisens®), and 6-min walking test (6-MWT)
- Patients: n = 24 (10 women, 14 men), 61.4 ± 7.3 years, BMI: 26.4 ± 4.1 kg/m²
- Moderate, unilateral, medial osteoarthritis of the knee
- Kellgren Lawrence (KL) Score: KL 2 = 6 / KL 3 = 12 / KL 4 = 6
- Support wearing duration: on average at least 5 hours per day for six weeks
- Measurement, Week 0 without a support: Baseline
- Measurement, Week 6 with the support: Long-term effect

GenuTrain® OA
Targeted relief and stabilization to encourage increased activity in cases of osteoarthritis of the knee

Pain levels, physical activity, and functional abilities were examined in 24 patients suffering from symptomatic medial osteoarthritis of the knee. The study protocol followed a pre-test/post-test design. Data was collected one week before the start (pre-test, Week 0, no orthosis) and during the sixth week of treatment using the orthosis (post-test, Week 6, with the orthosis). The overall test period was 7 weeks.

Patients were asked to wear the orthosis during all everyday activities for at least 5 hours per day. Activities also included medical exercises and sports. The recommendation was to take off the orthosis for extended periods of sitting, such as office work.

RESULTS

The wearing duration objectively recorded using an integrated sensor in the orthosis was 5.13 ± 2.95 h/day on average.

The data evaluated for the osteoarthritis patients showed that pain levels in all measurement situations in Week 6 was significantly lower than before treatment started (Week 0).
Pain at night (-43.2%), pain when walking (-45.8%), pain when taking the stairs (-41.4%), and pain when sitting (-48.1%) significantly reduced when the knee orthosis was worn. (Fig. 1)

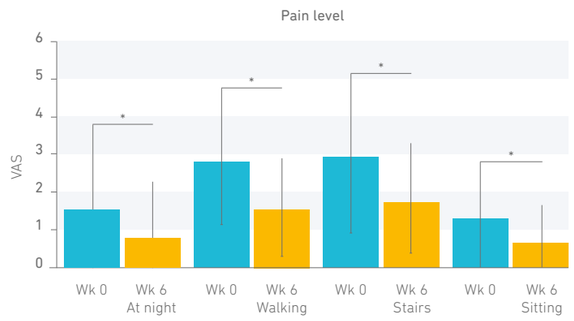


Fig. 1: Pain perception during different situations;
Week 0 = without orthosis and Week 6 = with orthosis

Physical activity measured when using the GenuTrain OA during Week 6 showed an average increase of 20.2 minutes with intensive physical activity (+50.6%), while there were no significant changes during mild to moderate physical activity. (Fig. 2)

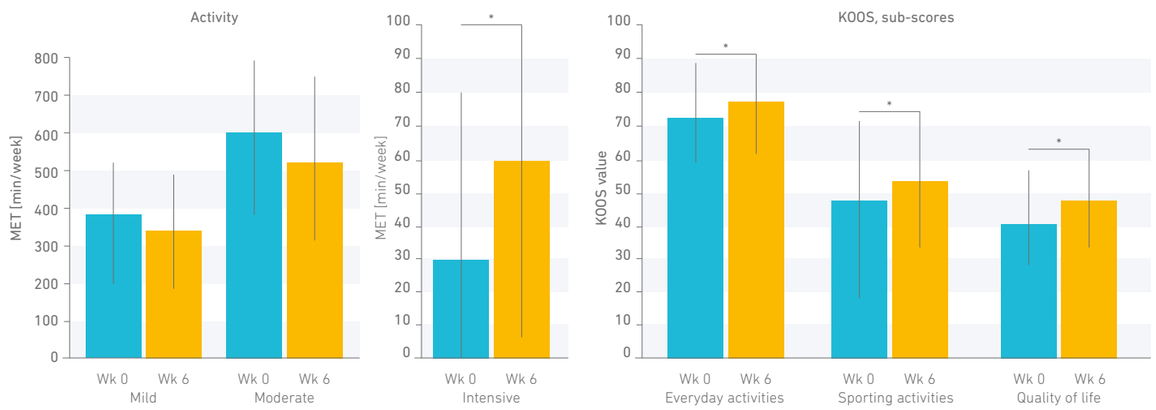


Fig. 2: Activity specified in Metabolic Equivalent (MET) minutes per week, categorized by mild, moderate, and intensive activity;
Mild: MET < 3; Moderate: MET 3-6; Intensive: MET > 6
1 MET: 1 kcal/kg*h or 4.184 * kJ/kg/*h and 1 MET x 16.8 = 1 watt

When the orthosis was used (Week 6), the distance covered during the 6-minute walking test increased by 5% compared to before treatment with the orthosis (Week 0). (Fig. 3).

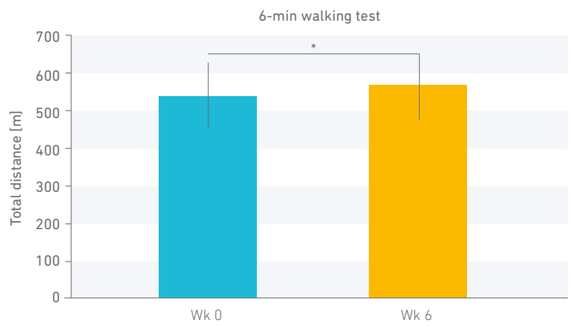


Fig. 3: Functional ability**; 6-min walking test specified in meters

Patients also reported feeling less restricted during everyday activities (+4%) and sporting activities (+16%) as well as noticing improved quality of life (+13.4%). (Fig. 4)

Fig. 4: KOOS value scale: 0 = extreme restrictions, 100 = no restrictions
Roos & Lohmander, 2003 [9]

Conclusion:

- → **Reduces pain by 48.1%**
- → **Increases physical activity by 50.6%**
- → **Increases mobility by 5%**
- → **Improves quality of life by 13.4%**

** Functional abilities:
The sum of all abilities and skills of a person when handling proposed tasks. This primarily refers to the ability to handle everyday requirements in the household, family, workplace, and leisure as well as during the study's functional test.

Source: Stetter, B.J.; Fiedler, J.; Arndt, M.; Stein, T.; Sell, S. Impact of a Semi-Rigid Knee Orthotic Intervention on Pain, Physical Activity, and Functional Capacity in Patients with Medial Knee Osteoarthritis. J. Clin. Med. 2024, 13, 1535. https://doi.org/10.3390/ jcm13061535

GenuPoint®

Evaluation of the pain-reducing and proprioceptive effect of the patellar tendon support

Zwerver, J.; v. d. Akker-Scheek, I.; de Vries, A.
Institute for Sports Medicine; University Medical Center Groningen (UMCG)

Jumper's knee (patellar tip syndrome, patellar tendinopathy) is a chronic, painful, and degenerative condition of the patellar tendon that is the result of overloading. The condition is caused, among other things, by repeated, unaccustomed, and/or violent tensile stresses with a "mismatch" between the physiologically tolerated tensile stress and actual tensile stress. A very common symptom is pain at the patellar tendon insertion point. In this study, the effect of a patellar tendon support on pain development and the proprioception of the knee in athletes with patellar tendinopathy is investigated.

GenuPoint®
Targeted relief and guidance of the patellar tendon

METHODOLOGY

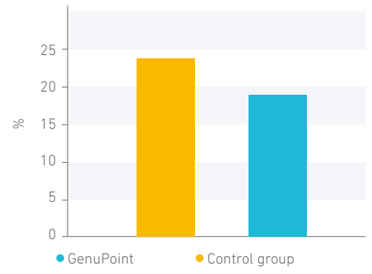
Sample:	n = 28 (8 females, 20 males), age: 18 – 50 years
Test support:	GenuPoint patellar tendon support (Bauerfeind AG)
Test method:	Test set-up 1: functional stress tests with and without the patellar tendon support, two-week wearing test during sporting activity International questionnaire [VAS] on pain and comfort Test set-up 2: angle reproduction test with the "MR Cube" from "FysioRoadmap monitored rehab systems"
Inclusion criteria:	• Age: 18 – 50 years • Unilateral or bilateral patellar tendinopathy • Knee complaints due to patellar tendinopathy greater than 80 on a 100-point VISA-P score (Victorian Institute of Sport Assessment-Patella score) • A knee condition that has existed for more than three months
Exclusion criteria:	• Acute knee pain • Knee complaints less than 80 on a 100-point VISA-P score • Patients with other knee conditions • Corticosteroid treatment in the last three months • Neurological impairments • Daily use of painkillers over the past year

RESULTS

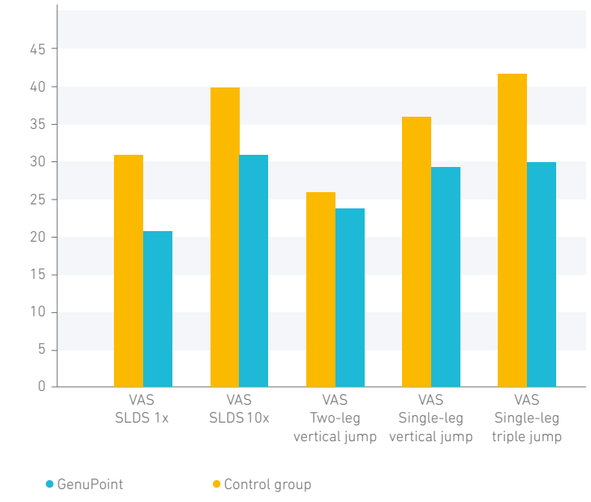
In functional tests, such as one-legged squats, one-legged and two-legged jumps, and a triple hop, young athletes with chronic patellar tip syndrome showed a significant reduction in pain in the affected knee when GenuPoint was used. In the triple hop, a 10.3-point reduction in pain was measured on average on the 100-point VAS scale. This value indicates that wearing the patellar tendon support causes a significant and clinically relevant reduction in pain. Test subjects with low proprioceptive capability (n = 15) showed a 17.2 percent improvement (from 23.2 to 19.2) in joint perception through wearing the patellar tendon support.

→ **Less pain with GenuPoint**
→ **Improved proprioception with GenuPoint**

Analysis of the active angle reproduction test
Difference from the correct leg position during the extension test expressed as a percentage



Pain when carrying out functional squats and jumping exercises in accordance with the Visual Analog Scale (VAS)



Source:
Astrid J.de Vries; Inge van den Akker-Scheek; Svenja L.Haak; Ron L.Diercks; Henk van der Worp; Johannes Zwerver
Effect of a patellar strap on the joint position sense of the symptomatic knee in athletes with patellar tendinopathy
Journal of Science and Medicine in Sport; 20, 11, S. 986-991, 2017

MOS-Genu

Relief of the medial knee compartment using valgus orthoses – invivo measurement in three test subjects

Kutzner, I.; Küther, S.; Heinlein, B.; Dymke, J.; Bender, A.; Halder, A.; Bergmann, G.
Julius Wolff Institute, Charité – Berlin University Hospital

The study compared two hard-frame orthoses with a monocentric joint. The study examined former patients with medial osteoarthritis of the knee in everyday situations, such as walking and climbing stairs. The relief effect was determined using a special endoprosthesis that recorded the forces that occurred. The aim of the study was to investigate the relief effect on the medial compartment.

MOS-Genu
Correction and stabilization after complex knee injuries or corrective osteotomy

METHODOLOGY

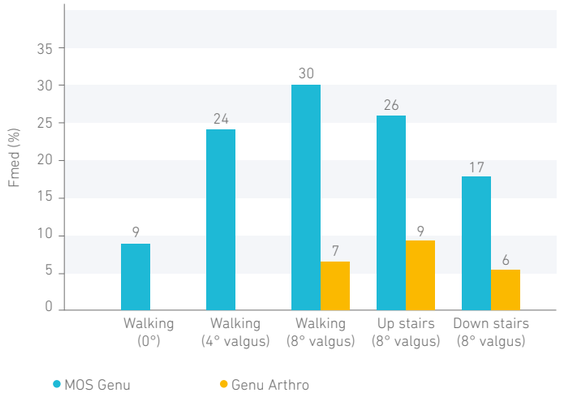
Test subjects:	Number: 3; age [in years]: 64, 71, 60, weight [kg]: 103, 96, 96, height [cm]: 177, 175, 175
Time, post-operative [months]:	23, 12, 6
Mechanical axial angle:	3-degree varus, 4-degree varus, 1-degree varus
Test orthoses:	MOS-Genu (Bauerfeind AG); Genu Arthro (Otto Bock Health Care GmbH)
Test method:	• 3 activities with (x) repetitions: walking (30), going upstairs (5), going downstairs (5) • Endoprosthesis with sensors for wireless force/torque measurement
Inclusion criteria:	• Endoprosthesis following osteoarthritis in the medial compartment • No pain

RESULTS

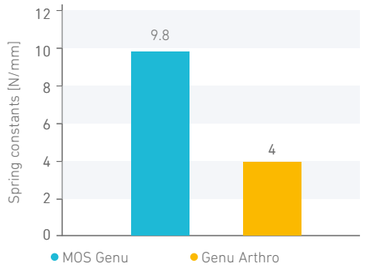
By wearing the MOS-Genu, a reduction in force of 9 percent is possible even in the neutral position (0 degrees), while the relief achieved with an 8-degree valgus adjustment is 30 percent. The results demonstrate that relief of the medial compartment is achieved with both orthoses. However, in this comparison, MOS Genu achieves significantly better results. The test method examines the effect of OA orthoses during activities with which an average patient is confronted in everyday life. The measurements demonstrate that the forces on the medial compartment can be significantly reduced with an OA orthosis. Even with a 4-degree valgus adjustment, the system provides significant relief.

→ **Significant reduction in the medial, axial forces through use of MOS Genu**

Reduction of the medial, axial forces



Measurement of orthosis stiffness with 100 N load



Source:
Kutzner, I.; Küther, S.; Heinlein, B.; Dymke, J.; Bender, A.; Halder, A.; Bergmann, G;
The effect of valgus braces on medial compartment load of the knee joint – in vivo load measurement in three Subjects / In: Journal of Biomechanics, 44 (2011), S. 1354 – 1360.

SofTec® Genu

Effect of two different knee orthoses in patients with ACL problems

Focke, A.[1]; Steingrebe, H.[1,2]; Möhler, F.[1]; Ringhof, S.[1,3]; Sell, S.[2,4]; Potthast, W.[5,6]; Stein, T.[1]

1) BioMotion Center, Institute of Sports and Sports Science, Karlsruhe Institute of Technology (KIT), Germany
2) Sports Orthopedics, Institute of Sports and Sports Science, Karlsruhe Institute of Technology (KIT), Germany
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A common type of knee injury is a torn anterior cruciate ligament (ACL rupture). It occurs particularly often during sports that involve a lot of stop-and-go-movements, jumping, rotations, and quick changes in speed or direction.
Orthoses are frequently used for rehabilitation following cruciate ligament injuries. Different orthosis concepts are available for this, such as hard-frame and soft orthoses. Studies comparing the effectiveness of the different concepts have had inconsistent results. However, during most of these studies, movements with little translation and rotation knee movement were chosen.

Thus, the objective of this study was to examine the impact of two different orthosis concepts (hard-frame and soft orthosis) on knee joint kinematics in patients with ACL problems.

SofTec® Genu
Active and passive stabilization of the knee joint – ideal for long-term treatment

METHODOLOGY

Sample:	n = 17 (10 women)
Test orthoses:	SofTec Genu soft orthosis (Bauerfeind AG), 4TITUDE hard-frame orthosis (DONJOY)
Data analysis:	Variance analysis with significance level of 5 percent
Inclusion criteria:	• One-sided, non-reconstructed rupture of the ACL • Unstable knee joint (tibial laxity, deficits during hop tests) • Aged between 18 and 60 • Moderate sporting activities • Contralateral leg free from injuries
Exclusion criteria:	• Injuries to the PCL or other knee joint structures • Osteoarthritis of the knee, K-L grade 2-4
Study design:	Randomized, prospective cross-sectional study (evidence class 1b)

RESULTS

The soft orthosis and the hard-frame orthosis significantly reduce the maximum knee angle during walking in the frontal plane; the hard-frame orthosis by 81.0 percent, the soft orthosis by 88.6 percent (Fig. 1)

In the transverse plane, there is a significant angle reduction with the soft orthosis compared with not using any orthosis by 18.8 percent, and by 42.3 percent with the hard-frame orthosis compared with not using an orthosis (no figure).

The difference between the two orthoses is not significant for both movement tasks.

When test subjects changed direction by 180°, the orthoses significantly reduced the angle in the transverse plane: the soft orthosis to nearly neutral 0 degrees, the hard-frame orthosis to -0.8° (Fig. 2)

The difference between the two orthoses is not significant for this movement task.

For movements with moderate intensity and mainly frontal load on the knee joint, the use of the knee joint orthosis designs examined here can be recommended based on these results. Overall, the results showed that both orthosis designs positively influence knee joint kinematics during walking and when changing direction by 180°, compared with control conditions without an orthosis.

→ **Both the SofTec Genu and the hard-frame orthosis stabilize the knee joint during movement**
→ **Both orthoses provide the knee joint with protection**

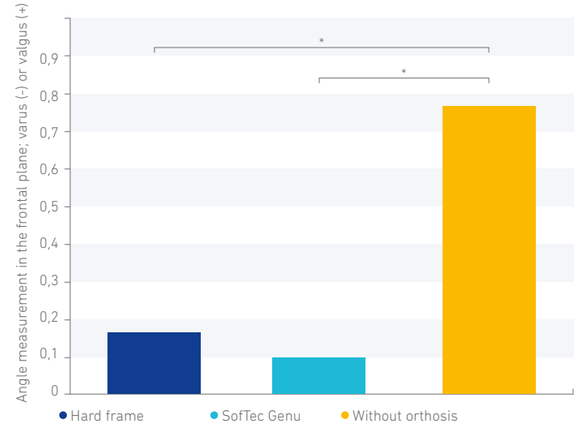


Fig. #: Maximum knee angle, frontal plane. Movement task: Walking, maximum angle in the frontal plane while walking on a tilting load sensing platform

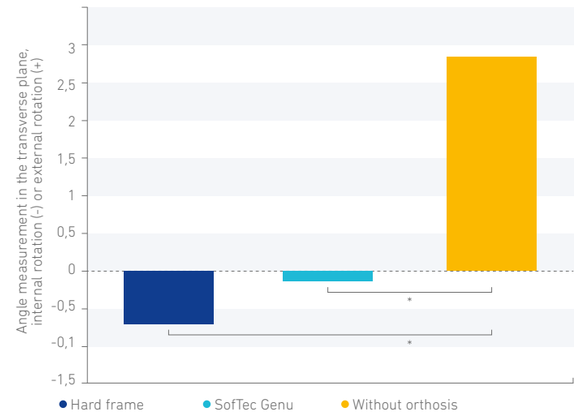


Fig. #: Maximum knee angle, transverse plane, with ground contact.
Movement task: 180° change in direction, maximum angle in the transverse plane while walking on a tilting load sensing platform

Source:
Focke A, Steingrebe H, Möhler F, Ringhof S, Sell S, Potthast W and Stein T (2020)
Effect of Different Knee Braces in ACL-Deficient Patients.
Front. Bioeng. Biotechnol. 8:964. doi: 10.3389/fbioe.2020.00964

SofTec® Genu

The use of external knee joint stabilizers – influencing mechanical stabilization and physical performance

Strutzenberger G., Braig M., Sell S., Boes K., Schwameder H.
Institute of Sports and Sports Science, BioMotion Center, Karlsruhe Institute of Technology

Functional knee orthoses are used, amongst other things, for the treatment of instability of the knee joint or in the recovery phase after replacement of the cruciate ligament. In order to achieve an optimum treatment result, the orthosis should not restrict joint kinematics and should protect the joint from unwanted movements. In the design of the orthosis, adjustment of the pivot and stabilization effect are particularly important. In the study, both types of orthosis are subjected to a series of different tests of varying degrees of complexity. The aim is to examine the effect of the orthoses in everyday activities.

METHODOLOGY

Study design:	Randomized, controlled prospective cross-sectional study
Sample:	n = 28, age: 40 ± 13 years
Test orthoses:	SofTec Genu soft orthosis (Bauerfeind AG), 4TITUDE hard-frame orthosis (DONJOY)
Test method:	KT-1000 measurement, counter movement jump (selection)
Inclusion criteria:	• Age: 18 – 60 years, recent or previous unilateral untreated rupture of the ACL, at least wound healing phase 3 (rehabilitation) • KT 1000 measurement (20 pounds) injured/healthy comparison > 3 mm • One-legged long jumps (symmetry index SI > 85 percent) • > 1 instance of giving way since injury
Exclusion criteria:	• Osteoarthritis of the knee, Grade II – IV • Injury of the posterior cruciate ligament, other injuries and conditions of the locomotor system, meniscal suturing

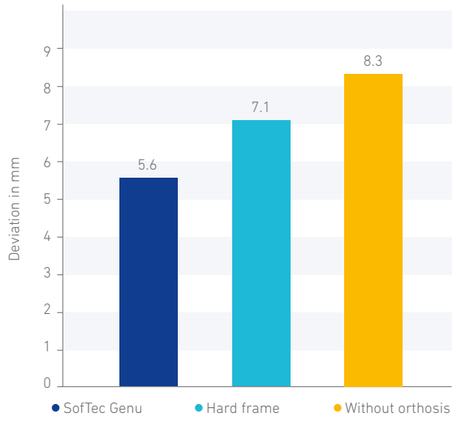
RESULTS

The results show that mechanical stabilization is achieved with both orthoses, with SofTec Genu achieving values that are virtually comparable with a healthy knee. In the case of complex movement sequences, SofTec Genu is superior to the hard-frame orthosis. The counter movement jump showed a significant increase in explosive strength. In conclusion, it can be said that, in terms of functionality, the SofTec orthosis achieved better results than the hard-frame orthosis.

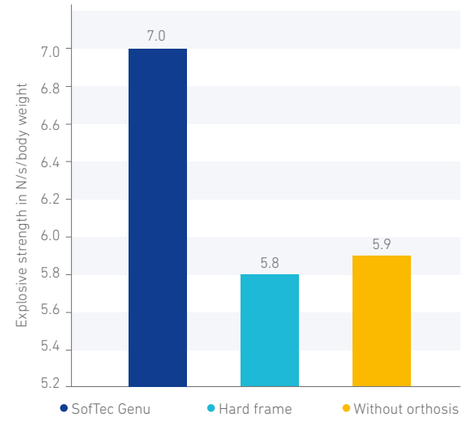
→ **SofTec Genu stabilizes the knee mechanically and functionally**
→ **SofTec Genu provides security during movement**

SofTec® Genu
Active and passive stabilization of the knee joint – ideal for long-term treatment

Passive stability, tibial shift [mm] following ACL rupture treated conservatively
KT-1000 measurement with 98 N



Active stability following ACL rupture treated conservatively, explosive strength
Counter Movement Jump



Source:
Strutzenberger G., Braig, M., Sell, S., Boes, K., Schwameder, H.; Effect of Brace Design on Patients with ACL Ruptures; Int J Sports Med 2012; 33: 934–939

SofTec® Genu

The use of external knee joint stabilizers – influencing mechanical stabilization and physical performance

Reer R., Nagel V., Paul B., Edelmann H., Braumann K.-M.
Sports and Movement Medicine Research, University of Hamburg

In addition to the effect of orthoses on mechanical and functional stabilization, their influence on physical performance also plays a role in preventative and rehabilitative considerations. With regard to the application of orthoses, it can be concluded that, apart from having a positive effect on mechanical and proprioceptive stability, a suitable orthosis is both extremely comfortable to wear and should not hinder the wearer when putting the knee under physical strain. The aim of this study was to determine the development of the static measurable anterior instability of the knee joint in anterior cruciate ligament rupture confirmed by arthroscopy with and without external protection and to make a comparison in order to record the influence of external stabilizers upon the development of the anterior instability.

SofTec® Genu
Active and passive stabilization of the knee joint – ideal for long-term treatment

METHODOLOGY

Study design:	Randomized, controlled prospective cross-sectional study
Sample:	n = 20 women, n = 26 men, age: 24.8 ± 3.6 years, height 176.3 ± 12.7 cm, weight 73.4 ± 10.9 kg
Test orthosis:	SofTec Genu soft orthosis (Bauerfeind AG)
Measuring systems:	KT-1000 knee ligament arthrometer (MEDmetric Corp., San Diego, CA, USA) → anterior instability
Test method:	KT-1000 measurement and thigh circumference measurement straight after ACL rupture confirmed by arthroscopy and eight weeks later

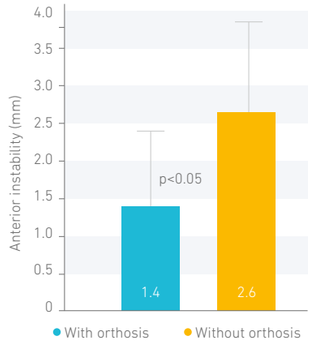
RESULTS

Eight weeks after the anterior cruciate ligament rupture confirmed by arthroscopy, the group treated with the orthosis showed 46 percent (1.4 ± 0.9 vs 2.6 ± 1.2 cm) less development of anterior instability, which is statistically significant ($p<0.05$), compared to the control group without any orthosis (Fig. 2). Treatment with the orthosis also significantly reduced ($p<0.05$) the post-traumatic reduction in thigh muscle circumference by about 25 percent (1.7 ± 0.4 vs 2.3 ± 0.5 cm) (Fig. 4). Of the 23 test subjects, 19 came to the overall conclusion that the SofTec orthosis provided "good support and was reasonably comfortable to wear." The fact that there were no significant differences in the assessment of important features such as supportive effect, feeling of security, and performance during sport when wearing the SofTec knee orthosis frequently compared with wearing it once is proof of the knee orthosis' long-term tolerability.

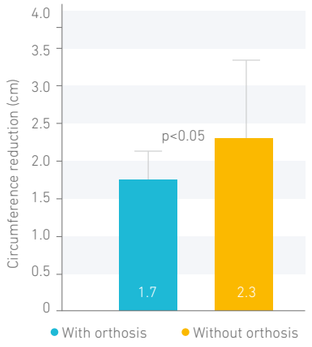
→ **SofTec Genu stabilizes the knee joint**

→ **SofTec Genu boosts muscle activity**

Anterior instability



Reduction in thigh muscle circumference



Source:
Reer R, Nagel V, Paul B, Edelmann H, Braumann K-M,
Die Anwendung äußerer Kniegelenkstabilisatoren – Einflussnahme auf mechanische Stabilisierung und körperliche Leistungsfähigkeit.;
Sportverletzung / Sportschaden, Jahrgang 15: 62–67 (2001)

SofTec® Genu and SecuTec® Genu

Axis Congruency and Axis Migration on Knee Orthosis – Results of Kinematic Investigation

Berschin G., Schneider V., Sommer H., M.
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The effectiveness of knee orthoses in stabilizing the joint and their positive influence on the knee's biomechanics have been measured and demonstrated in various studies. However, the security of orthoses' positions during everyday wear had not yet been investigated. The orthosis joint axis and knee joint axis must be largely congruent (axial congruence) to prevent a negative impact on the knee. The aim of the study is to investigate two orthoses with different design principles (hard frame vs knitted fabric design) to determine their mechanical properties in terms of axial congruence and axial migration when worn.

METHODOLOGY

The orthoses were worn by eight healthy, male test subjects on a treadmill and their security of position was investigated at different speeds. The test set-up enabled the orthoses' fit and any change in it to be measured visually during a specific stress. The combined stress when walking and running was recorded simultaneously using DV video cameras from five angles and analyzed using 3D video movement analysis software (SIM1 Motion 6.1). The measurements were accurate to 1 mm. Points on the orthoses marked with reflective marker balls (0 = 12 mm) and specified anthropometric points on the legs served as the basis for calculation.

RESULTS

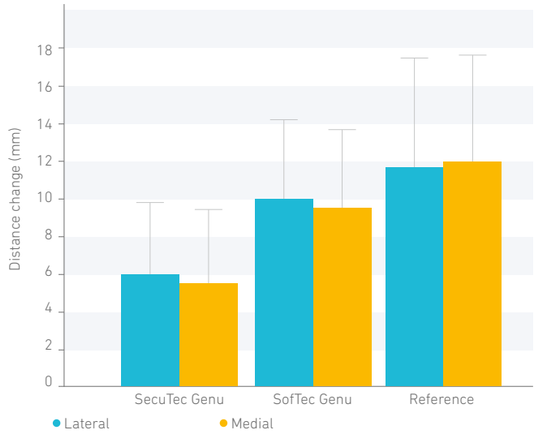
The results of the maximum distance changes in the gait cycle (axial congruence) show a median deviation of about 5.6 mm between the orthosis and joint compromise axis for the SecuTec Genu. This incongruence measurement is significantly lower than the reference values available for other orthoses on the market. For the SofTec Genu, the median of the measurements was 9.5 mm, which is also below the reference values for other hard-frame orthoses. Even during the running movement, only slight shifts of the orthosis axis were measured, which indicates good migration prevention. The two orthoses from Bauerfeind also produced better values for axial migration than the reference orthoses.

- → **SecuTec Genu and SofTec Genu stay securely in position during movement**
- → **SecuTec Genu and SofTec Genu provide better protection for the cruciate ligaments than the reference orthoses during movement**

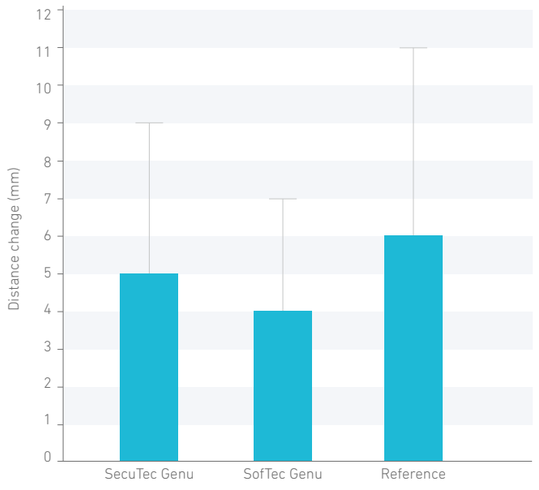
SofTec® Genu
Active and passive stabilization of the knee joint – ideal for long-term treatment

SecuTec® Genu
Stabilization with restriction in the range of motion in cases of complex knee injuries

Axial congruence
Maximum distance change (average)



Axial migration
Maximum distance change (average)



Source:
Berschin G, Schneider V, Sommer H M;
Axis Congruency and Axis Migration on Knee Orthosis – Results of Kinematic Investigation;
Medizinische Orthopädische Technik, Vol. 3, 2003

CoxaTrain®

The impact of a hip orthosis on gait biomechanics, pain perception, hip proprioception, and the functional abilities of patients suffering from mild to moderate osteoarthritis of the hip

Steingrebe, H., Stetter, B. J., Sell, S., Stein, T.
Karlsruhe Institute of Technology (KIT), Karlsruhe, Germany

Pain and restricted hip function have a negative impact on quality of life in people suffering from osteoarthritis of the hip (HOA). Previous studies about hip orthoses designed to provide mechanical relief to the hip joint had some positive results. In addition, research has frequently demonstrated that HOA patients exhibit changes in gait biomechanics.
In a comprehensive study design, the goal of this study was therefore to examine the influence of unilateral HOA and a functional hip orthosis on gait biomechanics, pain perception, hip proprioception, and the functional abilities of patients suffering from mild to moderate HOA.

CoxaTrain®
Stabilization and reduction of pain in the hip joint

METHODOLOGY

Sample: n = 42 (21 HOA, 21 healthy) (details see Tab. 1)

Test orthosis: CoxaTrain hip orthosis (Bauerfeind AG)

Inclusion criteria:
- Radiologically proven HOA (Kellgren Lawrence Score 2–4)
- Functional deficits, measured using the Harris Hip Score; (65-95 of 100)
- Hip pain in the last three months during everyday movements
- Asymptomatic contralateral hip joint

Exclusion criteria:
- Additional damage and/or pain of a musculoskeletal and/or neurological nature in the area of the lower extremities and the torso
- Secondary HOA

Objective criteria:
- Biomechanical movement analysis: spatial/temporal gait parameters, joint kinematics (joint angle), joint dynamics (joint torque)
- VAS 10-point scale: Pain level
- 6 minute walking test (6MWT): functional abilities

Objective criteria:

1st measurement date: test without orthosis, reference period: recording pain for 7 days without orthosis

2nd measurement date: test with orthosis after a brief period of getting used to the medical aid
Intervention period: recording pain for 7 days with orthosis

3rd measurement date: test with orthosis after wearing it for one week

RESULTS

Without the orthosis, the test subjects from the HOA group exhibited much worse performance during the 6MWT than the control group. After the one-week intervention phase, the distance covered was significantly greater than that without the orthosis or after brief orthosis use (Fig. 1). The orthosis had no impact on the pain level before or after being subjected to strain during the 6MWT.

The average wearing duration of the orthosis during the intervention period was 10.1 ± 3.5 hours per day. During the intervention phase, pain perception during activities involving walking as well as pain at night (walking: 18.4 ± 18.1; pain at night: 13.9 ± 15.9) were much lower than during the reference period (walking: 25.7 ± 15.3; pain at night: 17.0 ± 17.6) (Fig. 2). 18 of 21 test subjects showed a reduction in pain during activities involving walking.

After medium-term orthosis use, a significant increase in walking speed and step length was detected compared with patients not wearing an orthosis or when the orthosis was worn for a short time only. In the sagittal plane, short-term orthosis use resulted in a reduction in the maximum flexion angle and, under both orthosis conditions, in an increase in maximum extension torque compared with not wearing an orthosis. Additionally, under both conditions when wearing the orthosis, there was a significant increase in the movement radius of the pelvic tilt as well as pelvic rotation.

→ **CoxaTrain reduces pain at night**
→ **CoxaTrain reduces pain during walking**
→ **CoxaTrain improves mobility**

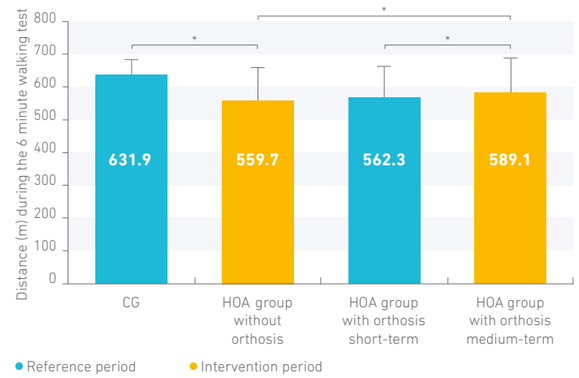


Fig. 1: Average values of distance covered [m] during the 6 minute walking test for the control group (CG) and the HOA group under different orthosis conditions.
*indicating significant differences for α<0.05.

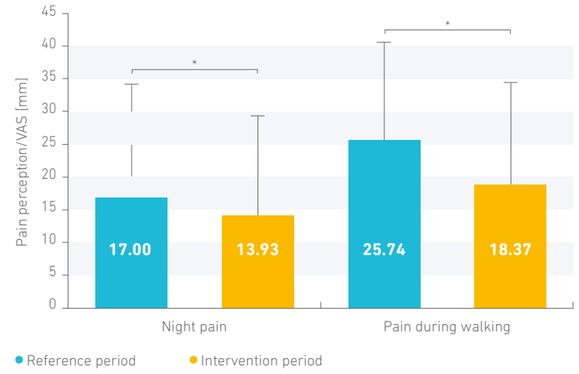


Fig. 2: Comparison of pain perception in the HOA group without a hip orthosis (reference period, 7 days) with the pain perception in the HOA group with a hip orthosis (intervention period, 7 days); 10-point visual analog scale depicted in mm, VAS 10 = 100 mm.
*indicating significant differences for α<0.05.

Source:
Steingrebe H, Stetter BJ, Sell S, Stein T
Effects of Hip Bracing on Gait Biomechanics, Pain and Function in Subjects With Mild to Moderate Hip Osteoarthritis. Front. Bioeng. Biotechnol. 10:888775_2022_doi: 10.3389.

LumboTrain® straight
LumboTrain® waisted

Prospective study of the torso muscles under the influence of compressive lumbar supports

Anders, C. et al.
Jena University Hospital, Clinic for Trauma, Hand and Reconstructive Surgery, Division for Motor Research, Pathophysiology and Biomechanics

The acute lumbar back pain refers to pain episodes which occur for the first time or after at least six pain-free months and last for a maximum period of six weeks. Possible causes for this non-specific, acute, lumbar back pain could be tense muscles or fasciae, overstretched ligaments, or shortened tendons. There is, however, no clear causal link between symptom description, clinical findings, and image-based diagnostics. Since the symptoms have no clear causes, a multimodal and multidisciplinary approach, where lumbar supports are an inherent part of the treatment, is the best course of treatment. However, critics argue that lumbar supports could weaken the trunk muscles because of the relieving characteristics. The study examined the question of what effect the use of lumbar supports has on the trunk musculature when walking and under static loading for patients with non-specific, acute, lumbar back pain.

LumboTrain® straight
Activation, relief, and stabilization of the lumbar spine

METHODOLOGY

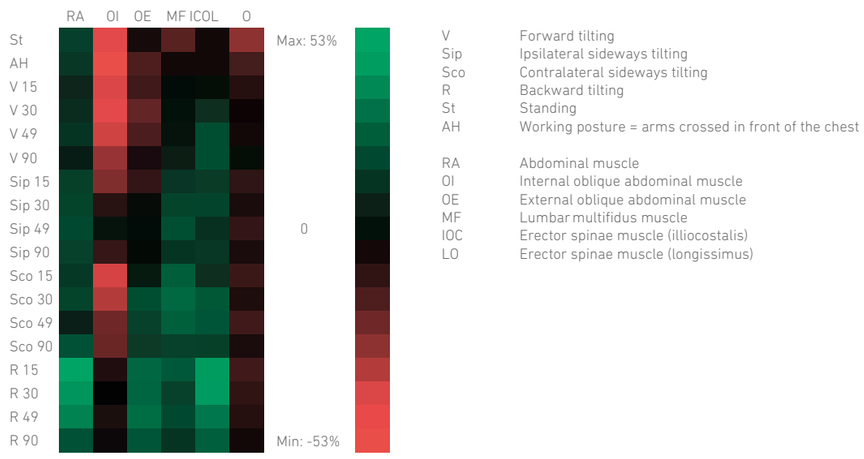
Sample:	n = 42 healthy subjects, age: 18–30 years
Test support:	LumboTrain lumbar support (Bauerfeind AG)
Test method:	• Dynamic analysis: gait analysis, treadmill (no picture) • Static analysis in the CTT Centaur, BfMC; figure 1
Inclusion criteria:	• Healthy test subjects with no back pain, adequate constitution and coordination for the measurements
Exclusion criteria:	• Restricted joint mobility, patients with chronic or acute pain, pathological joint positions, fractures, ligament injuries, muscle injuries, soft tissue damage, or somatoform disorders

RESULTS

Two of the three back muscles studied [MF, ICO] showed an increase in their EMG activity of up to 46 percent with LumboTrain. The third muscle studied [LO] revealed no significant change in its activity under the influence of LumboTrain. Repression of the back muscle activity by LumboTrain can therefore be refuted. The activity of the lateral trunk muscles [OI, OE], however, was reduced by up to 50 percent depending on the situation. This decrease in activity does not, however, constitute an inactivation of the muscle; instead it is suggested that this relates to relief effected by LumboTrain. With LumboTrain, the abdominal muscle [RA] showed an average activation of 25 percent. Overall we can assume a positive influence of LumboTrain on muscular activity.

→ **LumboTrain activates the back muscles**
→ **Muscle atrophy can be refuted**

Activation profile of the trunk muscles



V	Forward tilting
Sip	Ipsilateral sideways tilting
Sco	Contralateral sideways tilting
R	Backward tilting
St	Standing
AH	Working posture = arms crossed in front of the chest
RA	Abdominal muscle
OI	Internal oblique abdominal muscle
OE	External oblique abdominal muscle
MF	Lumbar multifidus muscle
IOC	Erector spinae muscle (illiocostalis)
LO	Erector spinae muscle (longissimus)

Please note:
This study was conducted using the previous model.

Source:
Hubner, A., Niemeyer, F., Schilling, K., Anders, C.;
Effects of an abdominal belt on trunk muscle activity during treadmill walking;
Biomech Open Lib, 1(1): 7–15; 2017

LumboTrain® straight
LumboTrain® waisted

Prospective study of the trunk musculature under the influence of compressive lumbar supports in patients with acute lumbar back pain

Anders, C. et al.
Jena University Hospital, Clinic for Trauma, Hand and Reconstructive Surgery, Division for Motor Research, Pathophysiology and Biomechanics

The acute lumbar back pain refers to pain episodes which occur for the first time or after at least six pain-free months and last for a maximum period of six weeks. Possible causes for this non-specific, acute, lumbar back pain could be tense muscles or fasciae, overstretched ligaments, or shortened tendons. There is, however, no clear causal link between symptom description, clinical findings, and image-based diagnostics. Since the symptoms have no clear causes, a multimodal and multidisciplinary approach, where lumbar supports are an inherent part of the treatment, is the best course of treatment. However, critics argue that lumbar supports could weaken the trunk muscles because of the relieving characteristics. The study examined the question of what effect the use of lumbar supports has on the trunk musculature when walking and under static loading for patients with non-specific, acute, lumbar back pain.

LumboTrain® straight
Activation, relief, and stabilization of the lumbar spine

METHODOLOGY

Sample:	n = 36 in total; n = 24 men; n = 12 women; age [years] = 29-63; BMI [kg/m2] = < 26
Test support:	Lumbar support (LumboTrain, Bauerfeind AG)
Test method:	• Gait analysis (OEMG), treadmill • Pain diary, static analysis in the CTT Centaur, BfMC
Inclusion criteria:	• Patients with unspecified, acute, lumbar back pain, BMI less than or equal to 26 [kg/m²], adequate constitution and coordination for the measurements
Exclusion criteria:	• Restricted joint mobility, patients with chronic pain, pathological joint positions, fractures, ligament injuries, muscle injuries, soft tissue damage, or somatoform disorders

RESULTS

The back muscle activity (Fig. 1) of the support group is higher than the muscle activity of the control group (see Fig. 1) for all three assessment dates U1-U3 (U1 = max. two days after diagnosis, U2 = one week after U1, U3 = three weeks after U1). The increased activity of the back muscles in the support group is around 16 percent, around 21 percent after a week, and around 13 percent after three weeks compared to the control group at the time of treatment with the support.
After three weeks of wearing the lumbar supports, the measured muscle activity in the support group is higher than in the control group. This argues against any muscle atrophy caused by wearing lumbar supports. A habituation effect from wearing the support is also not shown, because the activity values in the support group remain at the same high level over three weeks and do not drop to the values of the control group.

In each case, at the start of the assessment, BEFORE measurement on the treadmill, the difference in VAS pain values (Fig. 2) in the control group "fell" by 0.9 VAS points from U1 to U2, and from U1 to U3 by 0.8 VAS points. In the support group, the differences were 0.4 points (U1 to U3) and 0.6 points (U1 to U3) lower.

The values could reflect the normal healing process for acute back pain, where the severity of pain can be seen as a predictor for the stage of recovery. The difference in the amount of pain perceived by the support group on the various assessment dates was lower. This could be a reflection of the pain-relieving effect of a support. At U1, the perception of pain has clearly reduced partly due to the support, so the differences between U2 and U3 are not as great.

Pain during movement: the difference in the VAS pain value after the EMG test on the treadmill in the support group from U1 to U2 "fell" by 1 VAS point, and from U1 to U3 by 1.3 VAS points. The difference values in the control group only fall by 0.4 points in each case. The support group shows a greater pain reduction than the control group. This highlights the active principle of supports with a pain-reducing effect, most notably during movement.

→ **LumboTrain activates muscles**
→ **LumboTrain relieves pain during movement**

EMG back muscles:

Fig. 1: Representation of the amplitude curves of all the muscles studied, averaged at 4 km/h, entire group, (men and women).
X-axis: 0 percent - 100 percent = entire Floor contact phase of the foot in one step, y-axis coordination pattern, muscle activity in µV .i = ipsilateral foot/floor contact phase; c = contralateral foot / floor contact phase

Representation of the difference in the perception of pain at the assessment dates U1 – U3; using the visual analog scale (VAS).

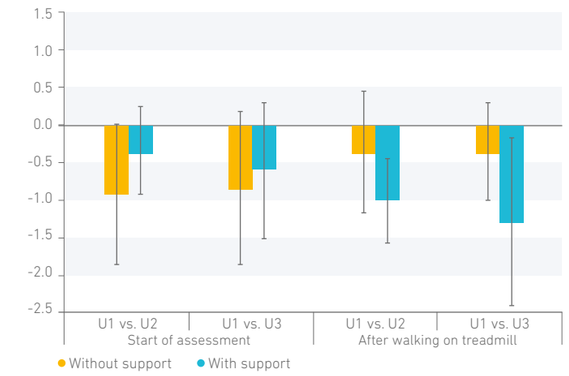


Fig. 2: Representation of the differences in pain: negative figures indicate a reduction against the first value (U1); U1, max. two days after diagnosis, U2 = a week after U1; U3 = three weeks after U1. Within the VAS scale: 0 (no pain) to 10 (highest level of pain imaginable)

Please note:
This study was conducted using the previous model.

Source:
Anders, C., Hübner, A.
Influence of elastic lumbar support belts on trunk muscle function in patients with nonspecific acute lumbar back pain
PLoS ONE 14(1): e0211042. https://doi. org/10.1371/journal.pone.0211042; 2019

LumboTrain® straight
LumboTrain® waisted

Prospective study using a lumbar support in patients with non-specific back pain

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Medical Consulting Centre; Essex

In cases of lumbar back pain, it is often possible to link the symptoms to an injury such as lifting heavy objects or extreme back twisting due to a fall. Pathological lesions are discussed as one of the possible causes of pain. When the pain arises without injuries to the bones or intervertebral disks, it is known as non-specific back pain. The treatment approaches depend on the symptoms. Apart from drugs such as analgesics and muscle relaxants, physiotherapy or supports are also used. The aim of the study is to demonstrate the effectiveness of lumbar supports in cases of non-specific back pain.

METHODOLOGY

Study design:	Randomized, controlled, two-arm clinical study
Sample:	• n = 216, n = 111 with the support, 105 = control group without the support • Average age: 43, average weight: 68.1 kg • 113 = male, 97 = female
Test method:	• Treatment with the support during the day (optional at night), plus standard treatment • Only standard treatment by way of comparison (control group)
Observation period:	21 days; data collection via questionnaire and information provided voluntarily by patients
Inclusion criteria:	• Patients with non-specific lumbar back pain for the first time • Patients with chronic lumbar back pain • Patients with increasing lumbar back pain due to further lumbar pathology • All findings were confirmed in an X-ray to rule out exclusion criteria
Exclusion criteria:	Specific back pain caused by rheumatoid arthritis or vertebral fractures for example; pregnancy

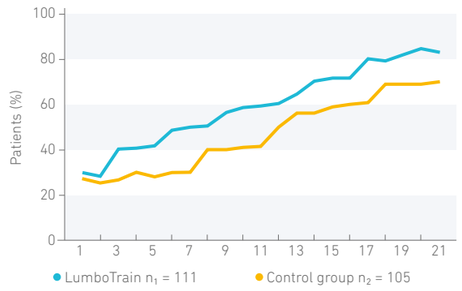
LumboTrain® straight
Activation, relief, and stabilization of the lumbar spine

RESULTS

After as little as three days, almost a third more patients had recovered in the support group than in the control group, i.e. they were able to work again. After three weeks, 83 percent of patients in the support group were able to work again, as against 73 percent of patients in the control group. Painkiller consumption fell in the support group from 3.4 dose units per day at the start to 1.4 dose units and was 52 percent lower than that of the control group after three weeks.

→ **Significantly less pain during activity, at rest, and at night with LumboTrain (no figure)**
→ **Significantly less restriction of movement with LumboTrain**

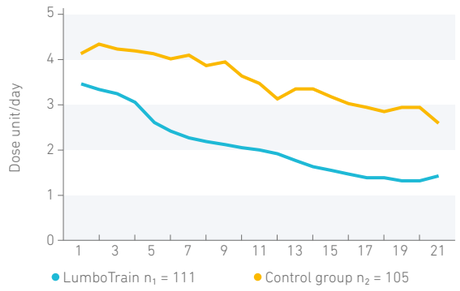
Percentage of patients fit for normal work at the start and end of the study period



18%
more people able to work in comparison

with LumboTrain

Painkiller use during the study period Dose units per day



52%
less painkiller use in comparison

with LumboTrain

Please note:
This study was conducted using the previous model.

Source:
Valle-Jones J, C, Walsh H, O´Hara J, O`Hara H, Davey N, B, Controlled trial of a back support (LumboTrain) in patients with non specific low back pain; Curr. Med. Res. Opin., (1992), 12, 604,

LumboTrain® straight / LumboTrain® waisted and LumboLoc®

Lumbar supports for the prevention of back pain in domestic care staff

Pepijn D.D.M., Roelofs, MSc, et al., Department of General Practice, Erasmus Medical Center, Rotterdam

Lumbar back pain is a very common condition that results in high costs and many days of absence due to illness. The one-year prevalence is specified as 15–40 percent and can be up to 72 percent among home care workers. The study was designed to investigate the effect of lumbar supports on working home care personnel when used specifically during work. In particular, the reduction in pain and days of illness with or without taking sick leave were evaluated in home care workers with a medical history of recurring and/or acute lumbar back pain.

METHODOLOGY

Study design:	Randomized, controlled two-arm study
Sample:	n = 360, n = 183 with the support, 177 = control group without the support
Test method:	Observation period: 12 months; data collected: number of days with lumbar back pain, number of days of sick leave
Inclusion criteria:	Workers with a confirmed history of back pain occurring twice or more often in the last 12 months on at least two consecutive days
Exclusion criteria:	Specific back pain caused by rheumatoid arthritis or vertebral fractures for example; pregnancy

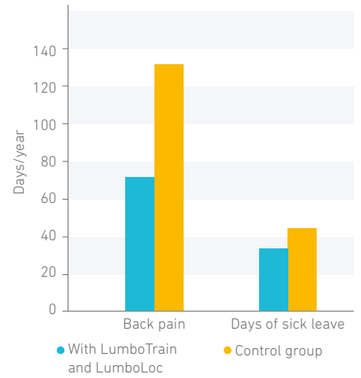
RESULTS

In the support group, 78 percent of patients wore the support on at least one out of three days on which they said they were suffering from back pain. The test subjects wore the support on an average of 5.5 days each month. This was 90 percent of the days per month on which they had back pain. The “home care” workers in the support group had less back pain than the people in the control group on 52 days of the year. The test subjects in the support group had taken 4.8 fewer days of sick leave due to back pain than those without the support after 12 months.

LumboTrain® straight
Activation, relief, and stabilization of the lumbar spine

LumboLoc®
Stabilization and relief of the lumbar spine

Days of back pain and days of sick leave per year



52 days
fewer with back pain during the year

with LumboTrain and LumboLoc

4.8 days
fewer of inability to work

with LumboTrain and LumboLoc

Please note:
This study was conducted using the previous LumboTrain model.

Source:
Roelofs, P, Birma-Zeinstra, S., van Poppel, M., Jellema, P., Willemsen, S., P., van Tulder, M., W., van Mechelen W., Koes, B., W.; Lumbar Supports to Prevent Recurrent Low Back Pain among Home Care Workers;
Ann Intern Med. 2007;147:685-692. (ISRCTN registration number: ISRCTN73707379)

SacroLoc®

Experimental, computer-based examination of the effects of orthoses on the sacroiliac joints (SI joints) and their ligaments

Sichting F., Rossol J., Soisson O., Klima S., Milani T., Hammer N.
Institute of Applied Movement Sciences, Chemnitz Technical University and Institute of Anatomy, Leipzig University

Lower back pain (SI joint syndrome) is a common clinically diagnosed condition involving a high level of suffering for affected patients. The objective of this study was to examine the impact of pelvic orthoses on the osteoligamentous pelvic girdle using a computer model based on the application of the finite element method (FEM). Geometric and mechanical data of the bones, cartilage, and pelvic ligaments were used to create the FEM pelvic model (Fig. 1). Furthermore, Bauerfeind's SacroLoc orthosis was integrated into the FEM computer model. Finally, the mobility of the SI joint, as well as the strain on the SI joint ligaments with and without the orthosis (Fig. 2) were investigated.

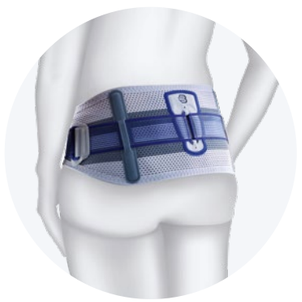
METHODOLOGY

Sample:	Computer model of a healthy male volunteer: 29 years old, height of 185 cm, weight of 69 kg; based on computer tomography data (Somatom Volume Zoom Scanner, Siemens AG, Erlangen, Germany)
Test orthosis:	SacroLoc pelvic orthosis (Bauerfeind AG)
Test method:	MRI (Magnetom Trio, Siemens AG, Erlangen, Germany), electromyography (Bagnoli-8, Delsys Inc., Boston, USA), gait analysis

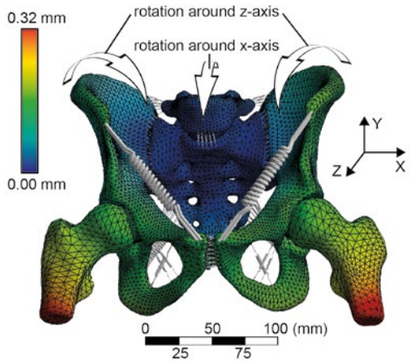
RESULTS

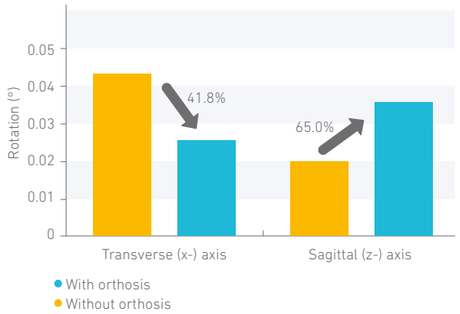
Use of the computer model made it possible to display in 3D the nutation movement of the SI joint that is typical for this joint and controlled by ligament structures (see Fig.). The change in kinematics brought about by SacroLoc indicated a measurable reduction in the strain on the SI joint's ligaments, primarily the sacrospinal and sacrotuberal ligaments (18 percent and 14 percent reduction respectively in the stretching observed; data table not shown).

→ **SacroLoc relieves the SI joint's ligament structures**



SacroLoc®
Stabilization of the pelvis and targeted relief of the sacroiliac joints





Source:
Sichting, F., Rossol, J., Soisson, O., Klima, S., Milani, T., Hammer, N.;
Pelvic Belt Effects on Sacroiliac Joint Ligaments: A Computational Approach to Understand Therapeutic Effects of Pelvic Belts, Pain Physician 2014; Vol. 17: S. 43-51 · ISSN 1533-3159

SacroLoc®

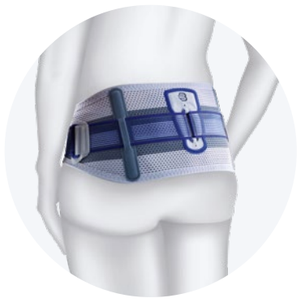
Medical effects back orthoses on clinical and functional parameters of patients suffering from pain in the sacroiliac joint (SI joint)

Hammer N., Klima K.-H., Mobius S., Milani R., Lange T. M., Schleifenbaum J. S., Soisson S., Winkler O., Institute of Applied Movement Sciences, Chemnitz Technical University and Institute of Anatomy, Leipzig University

Back orthoses are one of the methods successfully used to treat SI joint syndrome by combating pain and increasing mobility. However, as yet, there is no evidence-based data to confirm this effect. The aim of this study is to compare clinical and functional data regarding SI joint syndrome in healthy patients and in SI joint patients using a pelvic orthosis.

METHODOLOGY

Test groups:	Healthy test subjects, n = 17, age: 18 – 80 years, average age 43; patients with SI joint syndrome, n = 17, age: 18 – 80 years, average age 45
Test orthosis:	SacroLoc pelvic orthosis (Bauerfeind AG)
Test method:	• EMG to measure muscle activity in the muscles when walking • Gait analysis to measure the cadence, walking speed • SF-36 score to quantify health-related quality of life • Numeric Rating Scale (NRS) to quantify SI joint-related pain symptoms
Investigation period:	Six weeks (follow-up study)
Inclusion criteria:	• Diagnostically verified chronic SI joint syndrome • Adequate constitution and coordination for the measurements
Exclusion criteria:	• Restricted joint mobility and osteoarthritis in areas other than the SI joint, arthritis, pathological joint positions • Chronic pain in areas other than the SI joint • Fractures, ligament injuries, muscle injuries, soft tissue damage



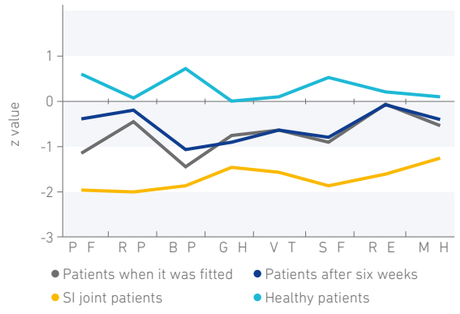
SacroLoc®
Stabilization of the pelvis and targeted relief of the sacroiliac joints

RESULTS

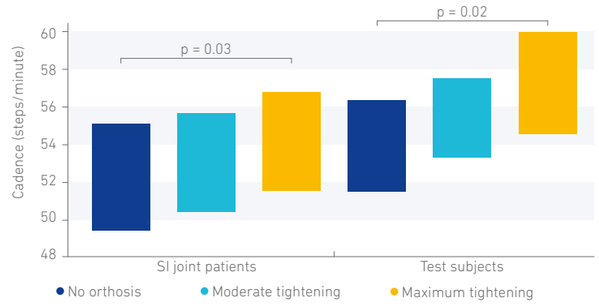
When using the SacroLoc pelvic orthosis, SI joint patients showed a significant improvement in health-related quality of life, particularly in terms of the SF-36 subscores after six weeks, which illustrate the patients' physical health. The pain suffered by SI joint patients, measured using the one-dimensional pain intensity scale (NRS; 0 = no pain, 10 = maximum possible pain), was 5.0 ± 1.9 in the retrospective survey. Under moderate and maximum tightening, the NRS score changed immediately to 3.4 ± 2.1 and 4.0 ± 1.9 (no figure). The cadence (number of steps per minute) of SI joint patients and healthy test subjects in the control group increased by two or four steps per minute when they wore the pelvic orthosis compared to the test situation without the pelvic orthosis. Walking speed was also influenced by the use of the pelvic orthosis.

→ **SacroLoc reduces SI joint-related pain**
→ **SacroLoc influences the leg/pelvic muscles**
→ **SacroLoc increases health-related quality of life in patients with SI joint syndrome**

SF-36 Score



Cadence (number of steps per minute)



Source:
Hammer N, Möbius R, Schleifenbaum S, Hammer K-H, Klima S, Lange JS, et al. Pelvic Belt Effects on Health Outcomes and Functional Parameters of Patients with Sacroiliac Joint Pain. PLOS ONE. 2015;10(8):e0136375.

EpiTrain®

Prospective study using an elbow support in patients with acute elbow pain: pilot study

Valle-Jones J.-C., Hopkin-Richards H., general practice,
Burgess Hill, Brighton

Pain and movement restrictions affecting the elbow are often seen in patients who have overstrained themselves during sport or have had an accident in which they twisted their arm severely and / or hyperextended their elbow. The duration of the symptoms ranges from a few days to several weeks, with an average of two weeks. The study was conducted to measure the effect of EpiTrain in comparison with a standard support for the elbow.

EpiTrain®
Relief and stabilization of the elbow joint

METHODOLOGY

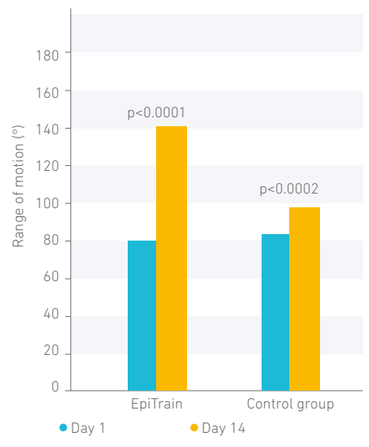
Study design:	Randomized, controlled, two-arm clinical study
Sample:	n = 35 (22 = male, 13 = female / 19 = EpiTrain group; 16 = control group, Tubigrip), age: 40 (18 – 66) years, body weight: 76.5 (50 – 84 kg), height: 169 cm (156 – 183 cm)
Test support:	EpiTrain elbow supports (Bauerfeind AG) and Tubigrip (Seton)
Test method:	Test duration: 14 days; self-assessment by patients using patient diaries for recording information such as restricted function, ability to work, and feeling of pain using a VAS score for pain at rest, at night, and during movement. Measurement by the treating physician of active and passive joint mobility in degrees.
Inclusion criteria:	Patients with active, recurring, and persistent elbow problems/pain
Exclusion criteria:	• Patients with arthritis and/or osteoarthritis • Patients with chronic pain • Patients with nerve disorders or bone injuries • Patients with conditions affecting both elbows • Patients who regularly take painkillers

RESULTS

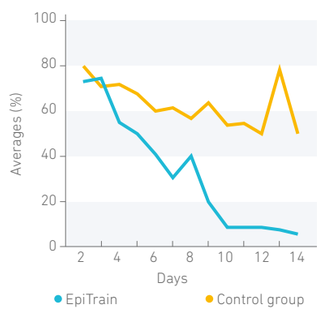
After 14 days, the pain felt by the group with EpiTrain had reduced by 50 units, in comparison with a reduction of only 19 units in the control group. The difference in pain reduction by the support is significant from day 6 to day 14 and can therefore be traced back to EpiTrain. The patients who were able to return to work with no restrictions increased from 47 percent at the start of treatment to 86 percent after 14 days in the EpiTrain group. In the control group, just 27 percent of patients were able to return to work with no restrictions at the start and 46 percent were able to do so after 14 days. The joint mobility measurements increased from an initial 80° to 141° in the EpiTrain group and from 83° to 98° in the control group. A significantly greater increase in mobility was demonstrated in the support group than in the control group.

→ **EpiTrain significantly reduces elbow pain**
→ **EpiTrain increases joint mobility**

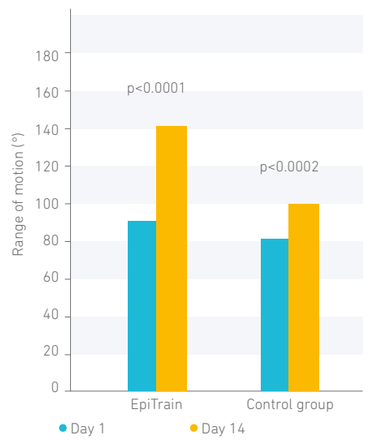
Active joint movement



Feeling of pain during activity, Visual Analogue Scale (VAS)



Passive joint movement



Please note:
This study was conducted using the previous model.

Source:
Valle-Jones J-C, Hopkin-Richards H;
Controlled trial of an elbow support (EpiTrain) in patients with acute painful conditions of the elbow: a pilot study
Cum. Med. Res. Opin., 12,224 – 233, (1990)

MalleoTrain®

Effect of a compression support on patients with recent ankle sprains study publication of selected results

Heß, T., et al.; Institute of Applied Movement Sciences, Chemnitz Technical University

Ankle supports/orthoses and classic tape bandages reduce the incidence of ankle sprains. When sprains do occur, tape bandages as well as supports/orthoses help reduce the severity of the injury. With the exception of triple ligament or syndesmosis injuries, most lateral collateral injuries in the ankle can be managed using conservative, early functional treatment.

The objective of this study is to investigate the effect of an elastic compression support, MalleoTrain, on the ankle stability of patients with unilateral acute supination trauma during early post-traumatic healing. On the one hand, the study tried to find out which acute effect the support had on joint stabilization of the injured ankle.

On the other hand, researchers examined whether the ankle support showed a stabilizing effect after being worn for 14 days, even if, after this wearing period, it was not worn at the time of measurement.

MalleoTrain®
Relief and stabilization of the ankle

METHODOLOGY

Sample:	n = 64 patients; n = 32 with support = IG = intervention group, n = 32 without support = CG = control group / age: 34.8 ± 11.8 years, // n = 20 healthy test subjects; age: 33.0 ± 10.8 years
Measurement systems and test procedures:	Center of Pressure (CoP) single-leg stand, (measurement of the arc length deviation for 20 sec.) pain scale and instability scale (10-point VAS [Visual Analog Scale])
Investigation period:	1st measurement: acute effect, 5th week after injury (= NU1; follow-up examination 1), n = 64 followed by 2 weeks of wearing the support for IG, n = 32 and CG without support, n = 32 2nd measurement: 7th week after injury (= NU2; follow-up examination 2), the measurements after 2 weeks (7th week after injury) were taken for CG and IG WITHOUT a support being worn at the time
Inclusion criteria:	Initial diagnosis of a unilateral, recent supination trauma (upper ankle sprain, lateral collateral ligament lesion), clinical consultation no later than 3 days after the injury, still suffering from symptoms 2 to 3 weeks after the injury
Exclusion criteria:	Bony avulsion, fractures, any other injuries and/or conditions that impair gait or balance Age: <18 or >65 years

RESULTS

Center of Pressure [CoP];
a biomechanical measure for balance:
Five weeks after the injury, patients demonstrate a significant difference in quasi-static balance skills when standing on one leg. On average, the CoP length on the healthy side is 77.5 ± 30 mm shorter than on the injured side without a support (Fig. 1). Wearing the MalleoTrain significantly improves balance skills (postural joint stability) and approximates to the level on the healthy side.

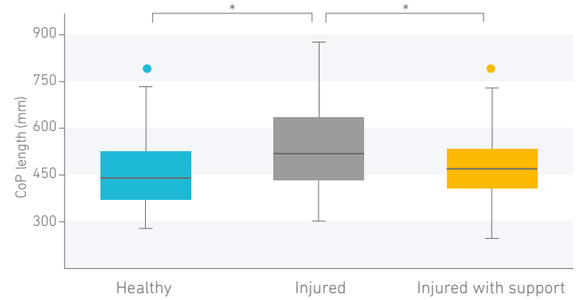


Fig. 1: Improvement in balance skills by wearing the support (acute effect, after the 5th week), data distribution and dispersion at the time of examination NU1 (n = 64); * p <0.05

15 patients suffer from pain when walking without the support. With the MalleoTrain, this figure can be decreased to 6 patients, constituting a reduction of 60 percent. In the same way, wearing the support while walking decreases the number of patients who have a subjective feeling of instability from 13 to 4 patients, corresponding to a 70 percent improvement (NU1; Fig. 2).
On a positive note, it is worth pointing out that long-term wearing of an ankle support for two weeks does not lead to a measurable negative effect in patients. What is more, the number of patients who no longer exhibited swelling in the ankle was significantly higher among those who wore a support for two weeks (66.6 percent), compared to the control group without a support (41.9 percent) (NU2, Fig. 3).

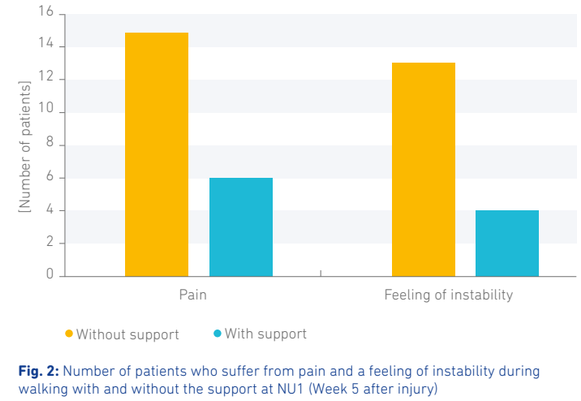


Fig. 2: Number of patients who suffer from pain and a feeling of instability during walking with and without the support at NU1 (Week 5 after injury)

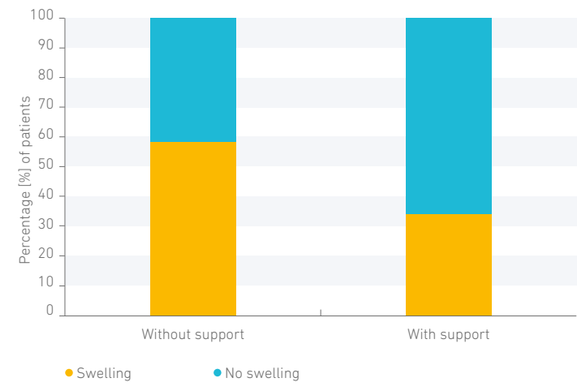


Fig. 3: Percentage of patients with and without a support showing swelling of the ankle at NU2 (Week 7 after injury)

→ **Improved postural stability and increased sense of balance**
→ **Less pain**
→ **Faster reduction of swelling**

Source: Heß, T.; Milani, T.L.; Kilper, A.; Mitschke, C.
Immediate Effects of Wearing an Ankle Bandage on Fine Coordination, Proprioception, Balance and Gait in the Subacute Phase of Ankle Sprains.
Life 2024, 14, 810. https://doi.org/10.3390/life14070810

MalleoTrain®

Prospective study using an ankle support for acute ankle injuries

O´Hara J., et al.; Burgess Hill, Sussex

Ankle injuries are very common and occur in both sport and everyday life. The standard treatment for minor ankle injuries involves painkillers and various forms of taping, supports, and orthoses. Frequent and intensive physiotherapy can also accelerate the healing process. The aim of the study was to investigate the effect of an anatomically shaped, knitted double-stretch support in treating ankle injuries in comparison with treatment using a standard wrapped support.

MalleoTrain®
Relief and stabilization of the ankle

METHODOLOGY

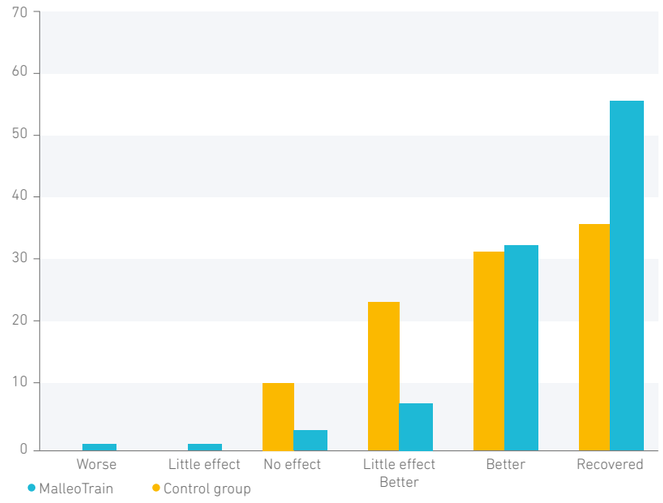
Study design:	Randomized, controlled parallel group study
Sample:	n = 220 (153 = male, 67 = female / 118 = MalleoTrain group; 102 = control group, wrapped support: Tubigrip) age: 35.2, (14 – 78) years, body weight: 69.0 kg (44 – 101 kg), height: 170.7 cm (155 – 188 cm)
Test support:	MalleoTrain ankle supports (Bauerfeind AG), Tubigrip (Seton)
Test method:	Test duration: 14 days; both groups received a standard treatment: Rest, cooling, and mild painkillers (if required), plus MalleoTrain vs Tubigrip Self-assessment by patients using patient diaries for recording information such as restricted function, ability to work, and feeling of pain using a VAS score for pain at rest, at night, and during movement.
Inclusion criteria:	Patients with acute supination trauma for the first time (grades I and II) confirmed in an X-ray
Exclusion criteria:	• Patients with chronic pain • Patients with bone injuries or severe ligament injuries (grade III)/5 • Patients who regularly take painkillers

RESULTS

The patients in the MalleoTrain group took 51 percent less painkillers than the control group during the two-week treatment period (11.0 vs 25.6 dose units/14 days). After 14 days, 88 percent of patients in the MalleoTrain group were free of pain again or almost pain-free, as against 67 percent in the control group.
95 percent of patients were very satisfied with MalleoTrain.

→ **MalleoTrain reduces pain**
→ **With MalleoTrain, patients were pain-free again more quickly**

Effect on complaints after two weeks of treatment (%)



Please note:
This study was conducted using the previous model.

Source:
O'Hara J, Valle-Jones C J, Walsh H, O'Hara H, Davey N B, Hopkin-Richards H and Butcher R M Controlled trial of an ankle support (MalleoTrain) in acute ankle injuries
Br J Sp Med 1992; 26(3)

MalleoTrain®

Support in a large-scale clinical trial

Blandfort R., Hess H., Lippay F.
Saarland Hospital

In previous biomechanical studies, the pressures exerted by various support types on a model based on the human foot in the different soft tissue and bone areas were measured. MalleoTrain's knitted fabric exerts targeted compression on the ankle in conjunction with two anatomically shaped pads. As the pads lie over the soft tissue parts of the joint in anatomically correct positions, the desired compressive effect is achieved exactly where it is needed – over the soft tissue, and limited where it is not needed – over the protruding bones. The aim of the study is to examine the medical effectiveness of MalleoTrain in addition to its biomechanical function.

METHODOLOGY

Study design:	Multi-center cohort study
Sample:	n = 244, age: 10 – 57 years
Test support:	MalleoTrain ankle support (Bauerfeind AG)
Test method:	Post-operative and conservative treatment of ankle injuries
Inclusion criteria:	Patients with partial and total fibular ligament ruptures, syndesmosis ruptures, and conditions after ankle fractures and post-traumatic or post-operative swelling

RESULTS

The study revealed that, with the MalleoTrain support and without treatment with medication or any other local methods, any swelling of the periarticular soft tissue subsided within an unusually short period of time, pain was reduced, and a largely normal range of function could be achieved.

Patients who had had surgery for total talofibular ligament ruptures received the MalleoTrain support alone after 10 days of immobilization in a cast with no negative impact on healing and subsequent stability. Furthermore, even total lateral upper ankle ligament ruptures were treated conservatively with the MalleoTrain support alone and stable healing outcomes were achieved.

Ability to work and play sports returned an average of two weeks earlier than with immobilization in a plaster cast. Patients also no longer needed any medication, physiotherapy, or physical therapy.

MalleoTrain®
Relief and stabilization of the ankle

2 weeks
earlier able to return to work and exercise

with MalleoTrain®

80 %
after 6 weeks without problems

with MalleoTrain®

Please note:
This study was conducted using the previous model.

Source:
Blandfort R, Hess H, Lippay F;
Die MalleoTrain – Bandage im klinischen Großversuch
Sportverl, Sporschaden, Vol.5, S. 42 – 44, 1991

MalleoLoc®

Effectiveness of the MalleoLoc orthosis in the reduction of chronic mechanical ankle instability

Wenning, M., Department for Orthopedics and Trauma Surgery, Freiburg University Hospital
Gehring, D., Gollhofer, A., Institute of Sport and Sport Science at the University of Freiburg

The study presented here examines the effectiveness of the MalleoLoc orthosis in the reduction of chronic mechanical ankle instability (MAI). For this, the innovative 3SAM method (3D arthrometric ankle measurement using MRI), a combination of the high-resolution 3D MRI technique and the mechanical/functional approach of arthrometric measurement, was used to determine 3D joint congruency. Using this method, the goal was to quantify the mechanical component of chronic ankle instability, by measuring the joint congruency area or the cartilage contact area (CCA).

METHODOLOGY

Study design:	Controlled quasi-experimental study
Sample:	• Control group (= healthy volunteers) n = 25 (16 women, 9 men) • MAI group (= patients with mechanical ankle instability) n = 25 (16 women, 9 men)
Examination method:	3SAM = 3D arthrometric ankle measurement using MRI
Indication:	Mechanical ankle instability (MAI)
Test orthosis:	MalleoLoc
Inclusion criteria for control group:	• No previous ankle injuries • Mechanically stable during clinical examination
Inclusion criteria for MAI group:	• Chronic ankle instability (according to Gribble et al. 2013) • CAIT <24 (Cumberland Ankle Instability Tool) • No acute injury within the 3 months prior to the MRI examination • Mechanical instability found during clinical examination
Outcome measurements:	3D joint congruency / cartilage contact area (CCA) (talofibular, talotibial horizontal, talotibial vertical)

MalleoLoc®
Increased stabilization of the upper and lower ankle

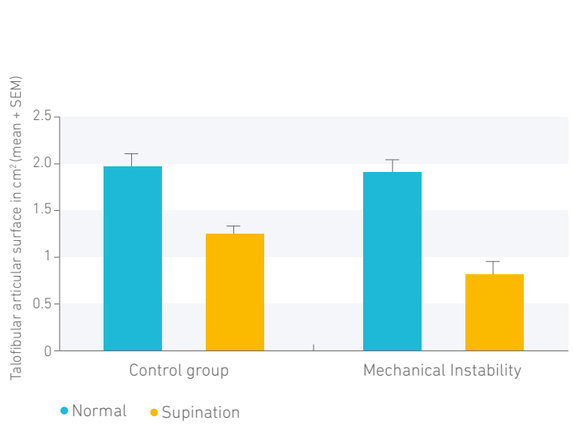
RESULTS

The 3D joint congruency was determined both in the control group and MAI group. The measurements included the "talofibular" contact area as an indicator for lateral osseous stabilization, "talotibial horizontal" as the horizontal weight-bearing area and "talotibial vertical" as an indicator for medial osseous stabilization.

The measurements were carried out in the normal position (neutral zero) and in a functional position (plantar flexion/supination). In the MAI group, the parameters were also determined in the functional position, with the test subjects wearing the MalleoLoc ankle orthosis.

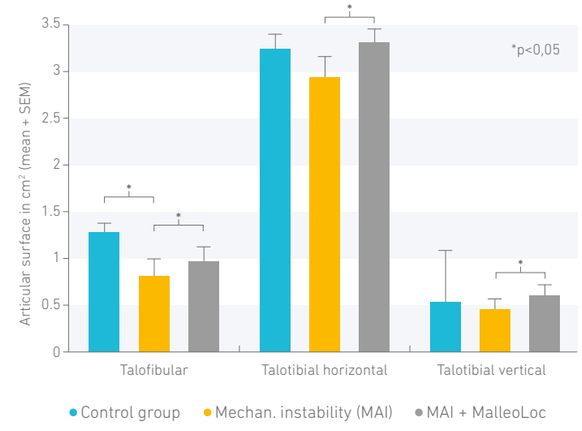
Source:
Eberbach, H., Wenning, M., Gehring, D., et al.,
Efficacy of a semirigid ankle brace in reducing mechanical ankle instability evaluated by 3D stress-MRI
J Orthop Surg Res (2021) 16:620
https://doi.org/10.1186/s13018-021-02750-6

Comparison of joint congruency in the normal and functional positions



→ **There is a reduction in joint congruency in the functional position, both in healthy subjects and patients with mechanical ankle instability**
→ **Patients with mechanical instability lose more of the articular surface in the functional position compared with the healthy control group**

Impact of an orthosis on joint congruency



→ **In a functional position, joint congruency is reduced in patients with chronic mechanical ankle instability**
→ **The MalleoLoc significantly improves joint congruency**

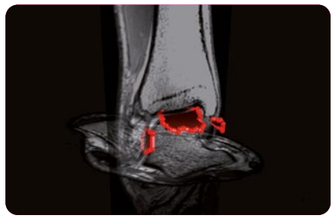


Fig.: MRI scan of the articular surfaces (talofibular, talotibial vertical and talotibial horizontal) with orthosis; ventral view of the right foot in a functional position

Assessment of the ankle orthosis by the subjects examined

Parameter	Control group	MAI
Stability	7.2	8
Comfort	5.2	5

Very poor (0) — Very good (10)

→ **The MalleoLoc provides significant stabilization to healthy subjects as well as patients**

Acknowledgment
M. Wenning was supported as a fellow in the Berta-Ottenstein Program for Clinician Scientists at Freiburg University's Faculty of Medicine.

MalleoLoc®

Functioning of the ankle orthosis during simulated inversion of the upper ankle joint

Gehring D., Wissler S., Lohrer H., Nauck T., Gollhofer A.;
Department of Sport and Sport Science, University of Freiburg

The most common injury in sport is ligament injuries affecting the upper ankle joint, which make up 25 percent to 40 percent of all traumas. In addition to physiotherapy and tape bandages, supports and orthoses are used for acute treatment and later on in the rehabilitation phase. The use and benefits of these aids have been demonstrated and confirmed many times over. The aim of this investigation was to evaluate the function of the MalleoLoc ankle orthosis during a simulated ankle inversion, taking into account a dynamic injury scenario.

METHODOLOGY

Sample:	n = 17 men, age: 25.7 ± 4.4 years
Test orthoses:	MalleoLoc ankle orthosis (Bauerfeind AG)
Measuring systems:	3D kinematics (Vicon MX), electromyography
Test method:	17 test subjects were asked to walk at a normal speed over a trapdoor with and without the orthosis on their foot. The test was repeated with and without anticipation of the trapdoor's behavior (opening or closing). Muscle activity was measured during the inversion phase and a comparison of the response of the peroneus muscle under all conditions was performed.
Inclusion criteria:	Active men who exercise, aged between 18 and 35 years, with unilateral chronic ankle instability (FAAM-G score (2) < 95 percent)

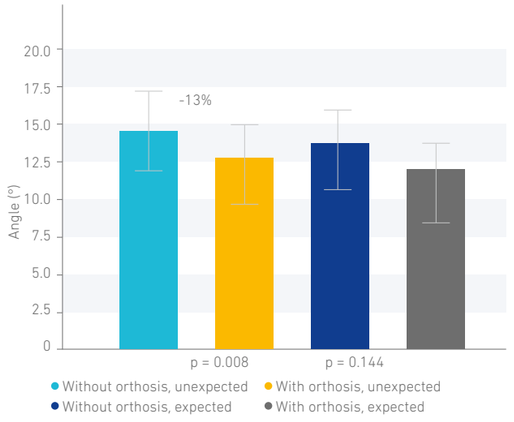
RESULTS

The results show that a reduction in the maximum joint inversion and the inversion speed was achieved with the orthosis.
A reduction in maximum joint inversion was observed in all tests. However, the degree of inversion was much smaller when test subjects did not anticipate the trapdoor's behavior (Fig. 1).
Figure 2 shows a reduction in the maximum speed of joint inversion. It was much greater when subjects did not anticipate the trapdoor's behavior. In the simulation of the sprain movement, the orthosis did not affect plantar flexion while walking.

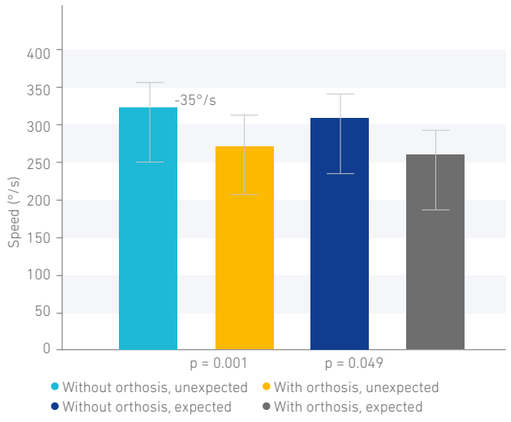
- → **MalleoLoc stabilizes the ankle and significantly reduces the risk of damaging supination movements**
- → **MalleoLoc enables a normal movement process while walking**

MalleoLoc®
Increased stabilization of the upper and lower ankle

Maximum inversion angle



Maximum speed of inversion



Source:
Gehring D, Wissler S, Lohrer H, Nauck T, Gollhofer A;
Expecting ankle tilts and wearing an ankle brace influence joint control in an imitated ankle sprain mechanism during walking;
Gait Posture. 2014 Mar;39(3):894-8. doi: 10.1016 / j.gaitpost.2013.11.016. Epub 2013 Dec 4

MalleoLoc® L / MalleoLoc® L3

Stabilization of the ankle joint during simulated supination using the ankle orthoses MalleoLoc® L and MalleoLoc® L3

Gehring D., Lohrer H., Nauck T., Wisler S., Gollhofer A.
Department of Sport and Sport Science, University of Freiburg

In-depth knowledge of the functional stabilization of the ankle joint is a prerequisite for developing prevention measures against typical injuries to the ankle. The analysis of numerous clinical and biomechanical studies reveals two basic principles of joint stabilization: active (the neuromuscular system) and passive (ligaments, joint contact, and joint capsule) functional joint stabilization.
Supination trauma often occurs as a result of a combination of excessive inversion of the ankle and pronounced internal rotation of the ankle. The aim of this study, therefore, was to examine the effect of orthoses on the control of the ankle during walking while simultaneously provoking supination. Specifically, the study intended to investigate the extent to which the ankle joint is stabilized using the newly developed MalleoLoc L and MalleoLoc L3.

METHODOLOGY

Study design:	Controlled laboratory study
Sample:	n = 20 subjects, age: 22.3 ± 2.8 years, 13 women and 7 men
Test orthoses:	MalleoLoc L/L3 (Bauerfeind); Malleo Dynastab Boa (Thuasne)
Measuring systems:	3D motion analysis (Vicon MX)
Test method:	By means of a specially designed platform, the ankle's supination movement that is characteristic of a lateral ankle injury was imitated. As such, the subjects stood or walked barefoot with and without an orthosis on the platform, which could abruptly be tilted to result in 24° inversion and 15° plantar flexion. In addition, the subjective feeling of stability with and without shoes when walking and during "agility tests" was recorded.
Inclusion criteria:	Athletic, active persons aged "18–35 years" verified unilateral, chronic ankle instability based on the Cumberland Ankle Instability Tool (CAIT score < 25), prior history of recurring ankle traumas

MalleoLoc® L
Lateral stabilization of the ankle

MalleoLoc® L3
Lateral stabilization of the ankle – removable in three stages

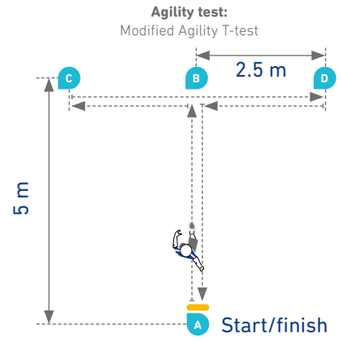
RESULTS

Inversion is one of the characteristic rotations of the ankle joint when there has been an injury to the lateral capsular ligament structures. This study shows that both the MalleoLoc L3 and the MalleoLoc L showed a significantly reduced inversion speed (-20.6 percent and -13.4 percent respectively) when walking compared to when no orthoses were worn. When walking on the tilting platform, the MalleoLoc L3 also showed a significant reduction in the max. inversion angle (-22.1 percent) and the inversion speed (-43.5 percent) compared to when no orthoses were worn. The reference orthosis also showed a significant reduction in the inversion angle (-18.7 percent), but no significant reduction in the inversion parameter compared to the condition in which no orthoses were worn. All three orthoses stabilized the ankle, leading to a significant reduction in the max. internal rotation speed (C: -12.1 percent, L: -12.1 percent, L3: -13.1 percent).

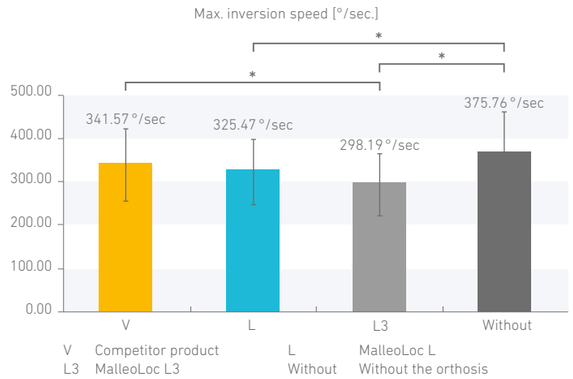
The subjective sense of stability is also an important prerequisite for the patient to safely transition back to normal mobility. The agility test puts more strain on the ankle joint than normal walking due to the required change of direction. In this situation, the MalleoLoc L3 was perceived to have a significantly greater stabilizing effect than the reference orthosis, whilst the MalleoLoc L achieved average stability characteristics. A comparable result was also seen when walking barefoot, whilst the subjectively perceived stabilization in shoes resulted in similar values for all three orthoses.

- → **The MalleoLoc L and L3 increase joint stabilization and secure the ankle joint**
- → **MalleoLoc L and L3 provide a high feeling of stability both with and without shoes**

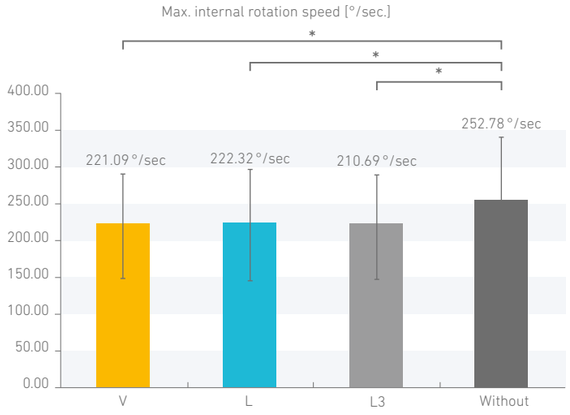
Sense of stability

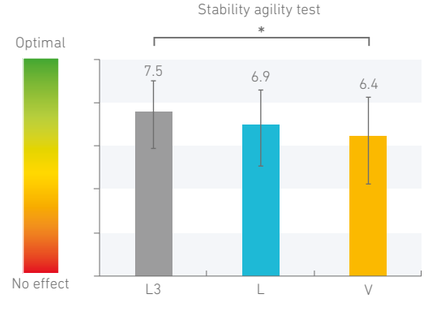


Inversion



Internal rotation





Source:
Gehring, D., Münch, M., Gollhofer A.
Laboratory study: Nachweis von antisupinatorischen Effekten von Orthesen innerhalb des Verletzungsmechanismus
Orthopädieschuhtechnik_10_26-29_2018

AirLoc®

Comparison of a tape bandage and a semi-rigid orthosis in patients with ankle injuries: prospective study

Lardenoye S., Theunissen E., Cleffken B., Brink P.,
de Bie R., Poeze M.
Department of Surgery, Division of Traumasurgery,
Maastricht University

Acute ankle injuries are the most common musculoskeletal injury. 50 percent of the injuries occur when doing sport and 75 percent are classified as supination traumas. The lateral collateral ligament complex of the ankle joint is affected in 85 percent of cases.
A lateral collateral ligament injury in the upper ankle is the most common sports injury, affecting around 1 in 10,000 people doing sport each day.
The functional treatment for these dislocation traumas is a generally widespread and recognized treatment. However, no study-based statement can currently be made as to which functional treatment option is the most effective. The aim of the study is to investigate the effectiveness of the treatment with ankle orthoses in comparison to a tape bandage in terms of patient outcomes and patient satisfaction.

METHODOLOGY

Study design:	Prospective, randomized, controlled (two-arm)
Sample:	n = 100 total;
Indication:	Supination trauma after 5-7 days, Grades II and III
Test orthosis:	U-shaped (AirLoc, Bauerfeind AG), non-elastic tape bandage (Leukotape, Beiersdorf)
Test method:	Wearing period of four weeks plus eight weeks of physical therapy, including proprioceptive training, initial collection of data on patient satisfaction and skin condition via patient questionnaire and numeric scales. The functional parameters have been collected using the Karlsson scoring scale and the range of motion determined.

AirLoc®
Movement-limiting ankle orthosis with adjustable air cushions

RESULTS

According to information provided by patients, the wearing comfort and treatment satisfaction are significantly better with AirLoc than with taping. In the taping group, 59 percent of patients experienced complications such as contact dermatitis, blisters, skin changes, and skin irritation. This figure was significantly lower in the orthosis group at 15 percent (p<0.0001).
The information on pain and the functional outcome was comparable in both groups.

Conclusion:
Using ankle orthoses in the treatment of supination traumas led to fewer complications and greater patient satisfaction than treatment with a tape bandage. This is consistent with other studies that also showed a comparable outcome in terms of functionality and pain perception.

44%
fewer complications with ankle treatment than with taping

With AirLoc®

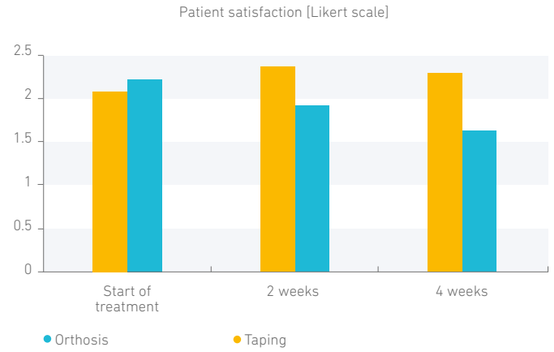


Fig. 1: Patient satisfaction during functional treatment for supination trauma. Representation of the average values on a Linkert scale (extremely satisfied = 0, dissatisfied = 5). The patients are significantly more satisfied with semi-rigid orthoses than patients treated with taping (p< 0.0001).

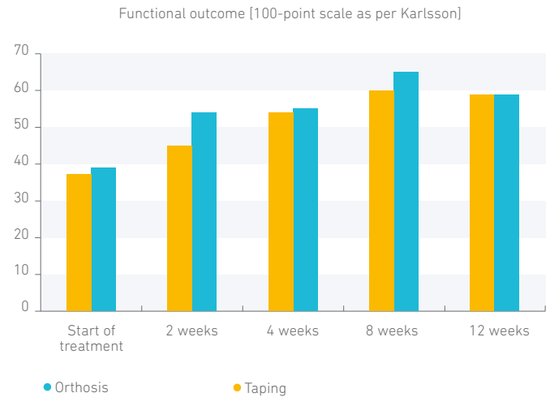


Fig. 2: Functional outcome as per Karlsson during treatment for supination trauma. Representation of the average values on a scale of 0 (no function) to 100 (optimal function).

Please note:
This study was conducted using the previous model.

Source:
Lardenoye, S., Theunissen, Ed., Cleffken, B., Brink, P., R., G., de Bie, R., A., Poeze, M.:
The effect of taping versus semi-rigid bracing on patient outcome and satisfaction in ankle sprains: a prospective, randomized controlled trial
BMC Musculoskeletal Disorders 2012, 13:8; http://www.biomedcentral.com/1471-2474/13/81

ErgoPad® redux heel 2

Comparison of different orthopedic health care concepts in the initial treatment of plantar fasciitis

Walther M., Kratschmer B., Verschl J., Volkering C., Altenberger S., Kriegelstein S., Hilgers M.
Specialist Center for Foot and Ankle Surgery, Schön Klinik, Munich-Harlaching

Plantar fasciitis is inflammation of the plate of connective tissue on the sole of the foot. Minor injuries around the tendon insertion point result in an accumulation of calcareous tissue in the insertion region of the plantar flexor tendons and plantar aponeurosis. One option for the conservative treatment of chronic heel and ankle pain is the use of orthopedic foot orthoses. Customized foot orthoses combine medial support with a specially designed recess for the aponeurosis on the sole of the foot and adequate cushioning for the heel, thereby providing additional relief for the affected structures. This study investigated the extent to which industrially pre-fabricated foot orthoses could also achieve this effect.

METHODOLOGY

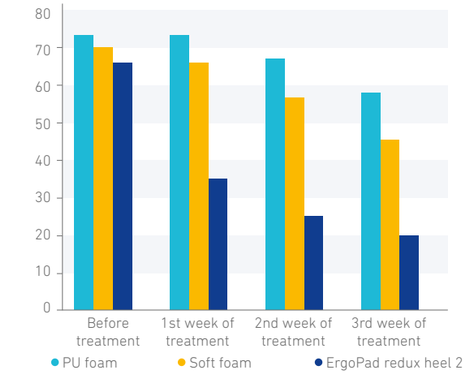
Study design:	Prospective, randomized, controlled clinical study
Sample:	n = 30 (9 = male, 21 = female)
Test foot orthoses:	Three industrially produced foot orthoses; ErgoPad redux heel 2 (Bauerfeind AG), a synthetic foot orthosis that relieves calcaneal spurs, a thin PU foam foot orthosis (from the Internet), a traditional soft foam foot orthosis (Springer)
Test method:	Investigation period: three weeks; measurement parameters: maximum pain, average pain (Visual Analog Scale – VAS), duration of pain per day, walking distance and subjective comfort of the foot orthosis, weekly check-up of study participants
Inclusion criteria:	Patients with plantar fasciitis and no other conditions

RESULTS

The thin cushioning foot orthosis had no demonstrable effect on maximum pain or average pain. Both the soft foam foot orthosis and the soft foam foot orthosis with a synthetic core significantly reduced pain, with the foot orthosis with a synthetic core producing better results in terms of effect size and time spent wearing the orthosis before the effect was felt.

→ **ErgoPad redux heel 2 reduces pain caused by calcaneal spurs**

Maximum pain in accordance with the Visual Analog Scale (VAS), out of 100



ErgoPad® redux heel 2
The supporting foot orthosis for combating chronic heel and ankle pain or calcaneal spurs

Please note:
This study was conducted using the previous model.

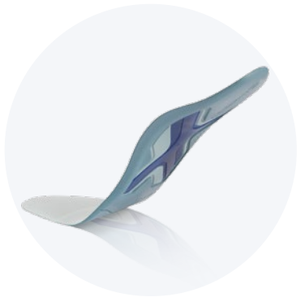
Source:
Walther M, Kratschmer B, Verschl J, Volkering C, Altenberger S, Kriegelstein S, Hilgers M;
Effect of different orthotic concepts as first line treatment of plantar fasciitis;
Foot Ankle Surg. 2013 Jun;19(2):103-7. doi: 10.1016/j.fas.2012.12.008. Epub 2013 Feb 19.

ErgoPad® weightflex 2

Evaluation of comfort and the movement process when wearing orthopedic orthoses

Grau S., Krauß I., Barisch-Fritz B.
Sports Medicine Institute, Eberhard Karls University, Tübingen

Orthopedic orthoses with a longitudinal and transversal arch support are used to correct the foot position and relieve the tarsal joints. They cushion the step and reduce pressure peaks. Until now, little research has been done into the importance of the fit of the shoes and orthoses and the properties of the foot orthoses when it comes to perceived comfort and whether this can also change the movement process. The aim of this study was therefore to examine the influence of orthopedic orthoses with three different levels of support and firmness (with soft, medium, and strong orthotic cores) on perceived comfort and the movement process of the foot and the lower leg.



ErgoPad® weightflex 2
The particularly flat supportive foot orthosis for changing shoes frequently

METHODOLOGY

Study design:	Prospective, randomized, controlled clinical study
Sample:	n = 52 (27 = male, 25 = female), age: 47 – 61 years
Test foot orthoses:	Orthopedic orthosis (ErgoPad weightflex 2 with a soft (E1), medium (E2), and strong (E3) orthotic core), (Bauerfeind AG)
Test method:	• Comfort questionnaire, evaluation of the foot orthoses with regard to heel support, arch support, flexibility, fit, comfort, and stability • Examination of the fit between the foot and the shoe, capturing a three-dimensional image of the foot and toe area using a scanner system (DynaScan4D): classification of the fit according to "wide," "good," "narrow." • Kinematic gait analysis (Vicon): checking the angle of the joint between the lower leg and hindfoot as well as between the hindfoot and forefoot • Responder analysis, differentiated view of the individual test subjects' responses with regard to the variables being investigated
Inclusion criteria:	Test subjects who are 40 years of age or older

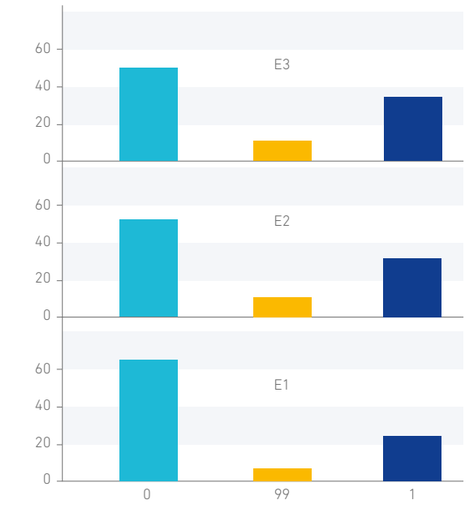
RESULTS

Improved movement guidance
The responder analysis1 showed that the foot orthoses could reduce the total extent of foot movement in the frontal plane by a statistically significant 27 percent ("soft" core), 34 percent ("medium" core), and 36 percent ("strong" core). As the test subjects generally responded positively to the foot orthoses, they could help guide the foot to move in the desired manner.

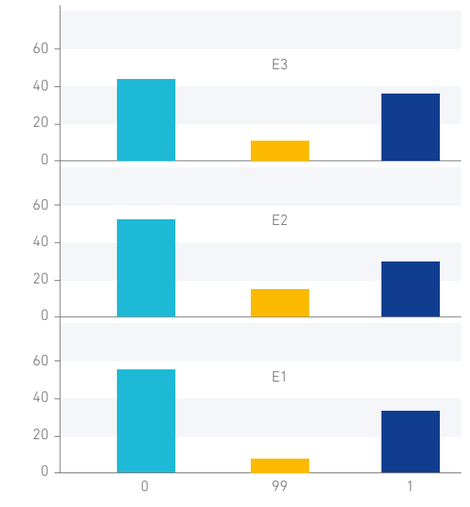
Reduced eversion
Increasing fatigue and/or high levels of strain (being very overweight/carrying heavy loads) increase the buckling or inward-sinking of the lower ankle.
The responder analysis showed that the use of foot orthoses resulted in a clinically significant reduction (> 2 degrees) in maximum eversion compared to the neutral condition in 34 to 39 percent of all test subjects (soft: 34 percent, medium: 32 percent, strong: 39 percent).

→ **ErgoPad weightflex 2 improves movement process guidance**
→ **ErgoPad weightflex 2 reduces eversion**
→ **The physiological movement process is maintained**

Responder analysis: improved guidance of the movement process



Responder analysis: reduced eversion



● Positive responder: the test subject responded in line with the aim of the foot orthosis treatment
● Negative responder: the test subject reacted contrary to the aim of the foot orthosis treatment
● Neutral response: the test subject showed no clinically relevant difference between the foot orthosis treatment and the control condition

ViscoSpot®

Comparison of individually made and standard foot orthoses in the initial treatment of proximal, plantar fasciitis

Pfeffer G., Bacchetti P., Deland J, et al.
Department of Orthopaedics, University of California

Plantar fasciitis is a common cause of chronic heel and ankle pain. Each year, 1.5 percent of people over 16 suffer from acute heel pain syndrome. Women are more commonly affected than men; the frequency increases with age and with patients' body mass index (BMI). Plantar fasciitis can occur if day-to-day strain is greater than the loading capacity of the bone and ligament structures in the foot. Foot misalignments and leg length differences as well as long periods of standing, walking, or running at work or during sport promote the occurrence of the condition.
85 percent of symptoms are cured or alleviated in the first six months using non-surgical treatment regimes. The range of treatment methods used spans from orthopedic foot orthoses, shoe modifications, anti-inflammatory medicines, stretching exercises, radiotherapy, and cortisone injections through to surgical measures. Several treatment methods are often combined as part of non-surgical treatment regimes. There is, however, no consensus about which non-surgical treatment is most effective. This study investigates the effectiveness of four different foot orthoses in connection with stretching exercises compared to the latter alone.

METHODOLOGY

Study design:	Multi-center, 15 centers with a total of n = 236 patients, 160 women, 76 men
Age:	> 16 years
Five-arm study:	Group 1: stretching exercises Groups 2-5: stretching exercises PLUS foot orthosis Group 2: custom-made polypropylene foot orthosis Group 3: silicone heel cushion Group 4: rubber heel cushion Group 5: felt heel cushion
Treatment period:	Max. eight weeks Self-assessment of symptoms using FFI (foot function index) questionnaire
Inclusion criteria:	Indication: Plantar fasciitis; duration of symptoms = six months or less; no previous treatment
Exclusion criteria:	Patients with systemic diseases, local neurological diseases, sciatica, severe musculoskeletal conditions

RESULTS

The patients in the group with ViscoSpot had the best results after eight weeks. 95 percent of patients were completely symptom-free or had much less pain.
In the group with stretching exercises alone, the same could be said for just 71 percent of patients. The combination of a foot orthosis and physiotherapy is more effective than a foot orthosis or stretching exercises alone.
ViscoSpot in combination with physiotherapy is a clear recommendation for initial treatment in cases of acute chronic heel and ankle pain.

→ **ViscoSpot relieves pain**

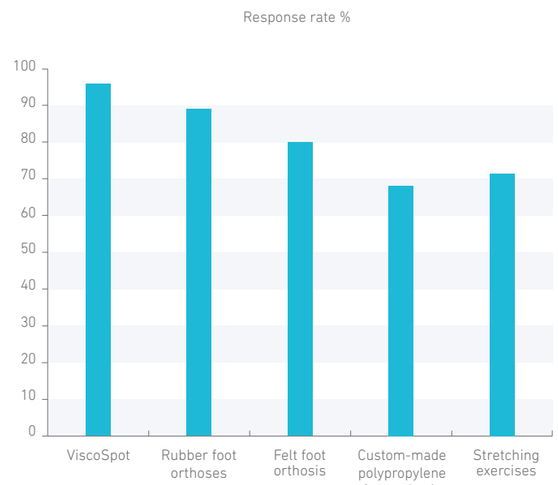


Fig. 1: The response rate is defined as the clearly reduced perception of pain exhibited by patients in comparison to a non-response rate where the perception of pain is unchanged or has even worsened.

95%
of patients with clear pain relief

with ViscoSpot

ViscoSpot®
Viscoelastic heel cushions for the treatment of heel spurs

Source:
Glenn Pfeffer et al.;
Comparison of Custom and Prefabricated Orthoses in the Initial Treatment of Proximal Plantar Fasciitis
Foot and Ankle International, 1999, Vol.:20, No.4, S. 214 – 221

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