COLLECTED STUDIES
FROM BAUERFEIND

CONTENTS

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®
Active support for 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%
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

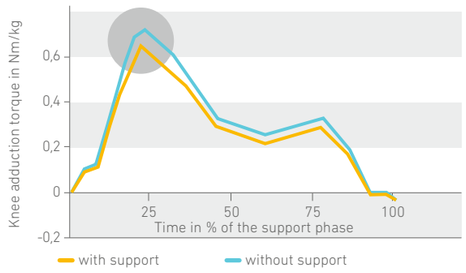
The knee adduction in the affected (= diseased) leg was significantly reduced by the knee support at the beginning and at the peak of the floor contact phase (by an average of 2°; no picture).

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

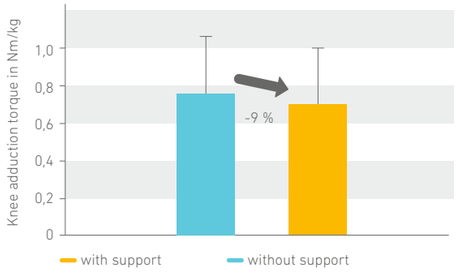
With GenuTrain, a significant reduction of the maximum pressure value of up to -25% in the hindfoot area was measured.

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

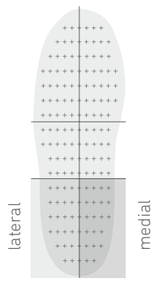
Knee adduction torque

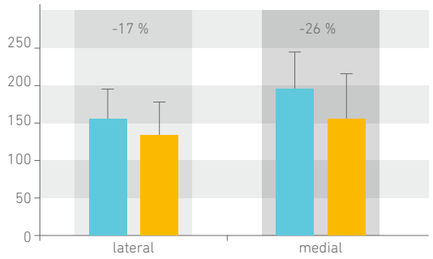


Maximum knee adduction torque



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 | 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
State Hospital 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®
Active support for relief and stabilization of the knee joint

METHODOLOGY

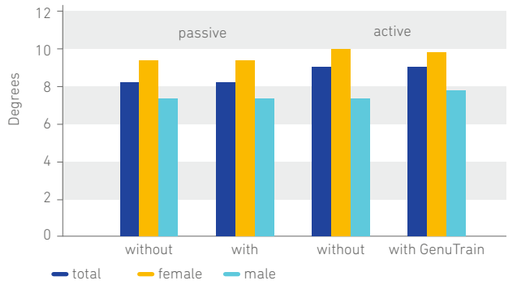
Patients:	n = 59 in total, n = 34 women, n = 25 men, age: 69.8 years
Healthy subjects:	n = 80 in total, n = 46 women, n = 34 men, age: 68.6 years (= control group 1)
Healthy subjects:	n = 30 in total, n = 20 women, n = 20 men, age: 23.5 years (= control group 2)
Test support:	GenuTrain knee support (Bauerfeind 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 severe osteoarthritis of the knee, confirmed in an X-ray. (45 patients with grade IV, 5 with grade III, and 5 with grade II: osteoarthritis grades in accordance with Kellgren)

RESULTS

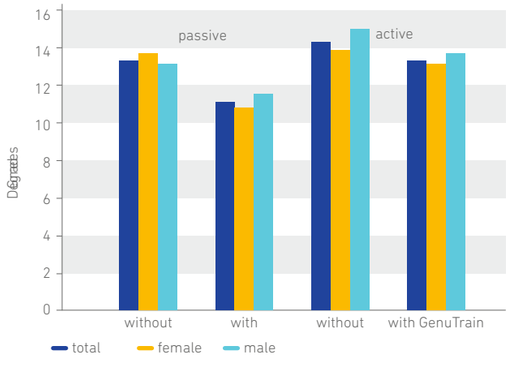
The group over 50 years old showed an average of 8.3° in the passive test and 8.8° in the active test. The differences between the two groups were statistically significant in both the active and the passive test. The knee support had no demonstrable effect in test subjects with no knee joint problems. 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% in the "passive" test and by 12% 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 the randomized and controlled study was to demonstrate the effect of knee supports in terms of range of motion, pain reduction, and physical mobility in patients suffering from osteoarthritis of the knee. 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: a verage 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.

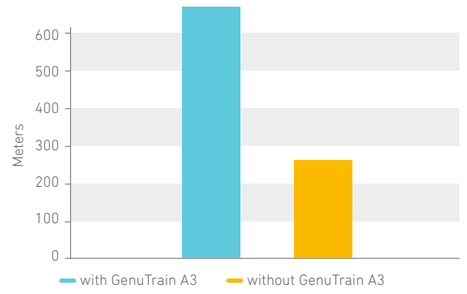
The distance walked without pain increased significantly – by a factor of 2.4 – with GenuTrain A3. Patients with osteoarthritis of the knee remained pain-free for longer with GenuTrain A3.

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**

GenuTrain® A3
Active support for the treatment of complex knee complaints

Pain-free distance



2.4 times the walking distance (without pain) with GenuTrain A3

Source:
Reer R et al.; The effect of a knee support in osteoarthritis; Orthopädie Technik, 8/2005

LumboTrain®

PROSPECTIVE STUDY OF THE TRUNK 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, Jena

Should the use of lumbar supports be viewed critically or rated as beneficial? The study examined the question of what effect the use of lumbar supports has on the trunk muscles when walking and under static loading. The myograms recorded provide information about the extent to which the muscles of the trunk are active under loading, both with and without a lumbar support.

LumboTrain®
Active support for muscular stabilization of the lumbar spine

METHODOLOGY

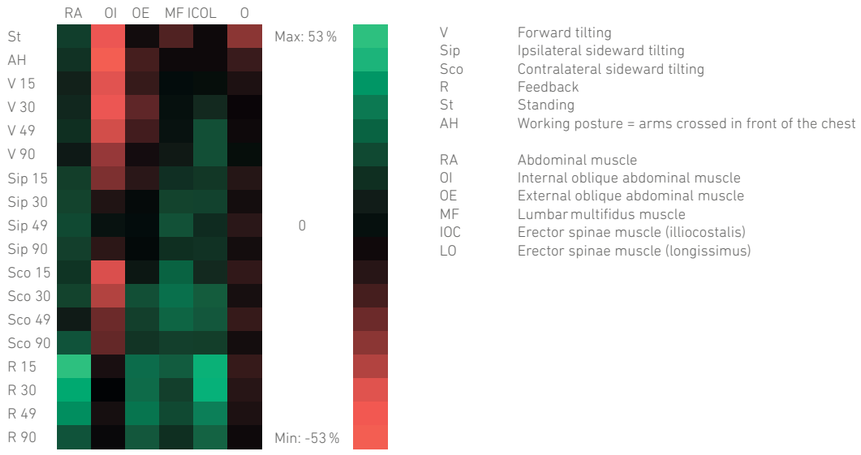
Sample:	n = 42 healthy subjects, age: 18–30 years
Test support:	LumboTrain lumbar support (Bauerfeind AG)
Test method:	• Dynamic analysis: gait analysis, treadmill (no picture) • Static analysis in the CTT Centaur, BfMC; Picture 1
Inclusion criteria:	• Healthy test subjects with no back pain, adequate 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% 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% 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%. 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 sideward tilting
Sco	Contralateral sideward tilting
R	Feedback
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)

Source:
Data has been submitted for publication.

LumboTrain®
CONTROLLED TRIAL OF A BACK SUPPORT IN PATIENTS WITH NON SPECIFIC LOW BACK PAIN

Valle-Jones J., C.; Walsh H.; O´Hara J.; O`Hara H.; Davey N., B.;
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.

LumboTrain®
Active support for muscular stabilization of the lumbar spine

METHODOLOGY

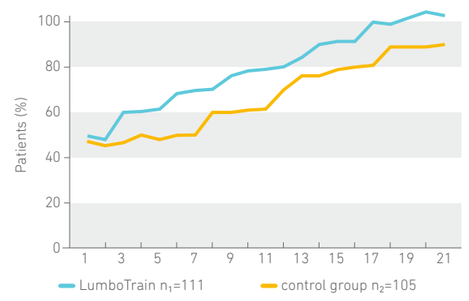
Study design:	Randomized, controlled, two-arm clinical study
Sample:	• n = 216, n = 111 with the support, 105 = control group without the support • Average age: 43 years, average weight: 68.1 kg • 113 = male, 97 = female
Test method:	• Treatment with the support during the day (optional at night), plus 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 due to conditions such as rheumatoid arthritis or spinal fractures; intervertebral disk pathology, pregnancy

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% of patients in the support group were able to work again, as against 73% 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% lower than that of the control group after three weeks.

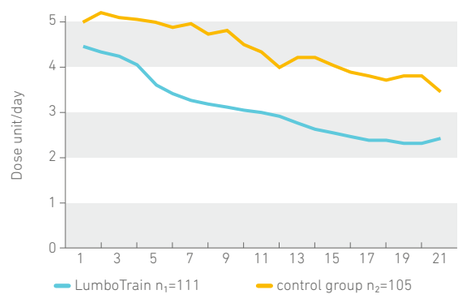
→ **Significantly less pain during activity, at rest, and at night with LumboTrain (no picture)**
→ **Significantly less restriction of movement with LumboTrain**

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®

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® and LumboLoc®

LUMBAR SUPPORTS TO PREVENT RECURRENT LOW BACK PAIN AMONG HOME CARE WORKERS

Pepijn D.D.M., Roelofs, MSc; Sita M.A. Bierma-Zeinstra, PhD; Mireille N.M. van Poppel, PhD; Petra Jellema, PhD; Sten P. Willemsen, MSc; Maurits W. van Tulder, PhD; Willem van Mechelen, MD, PhD; and Bart W. Koes, PhD 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% and can be up to 72% 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 due to conditions such as rheumatoid arthritis or spinal fractures; pregnancy

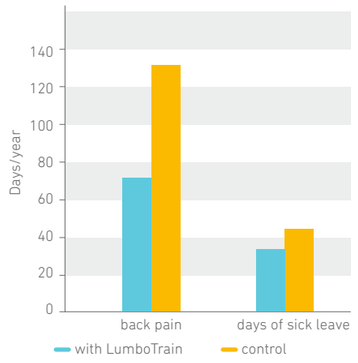
RESULTS

In the support group, 78% 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% 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®
Active support for muscular stabilization of the lumbar spine

LumboLoc®
Orthosis for relief of the lumbar spine

Days of back pain and days of sick leave per year



52 days
with less back pain in the year
with LumboTrain®

4.8 days
fewer of inability to work
with LumboTrain®

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

EpiTrain®

CONTROLLED TRIAL OF AN ELBOW SUPPORT IN PATIENTS WITH ACUTE PAINFUL CONDITIONS OF THE ELBOW: A 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.

METHODOLOGY

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

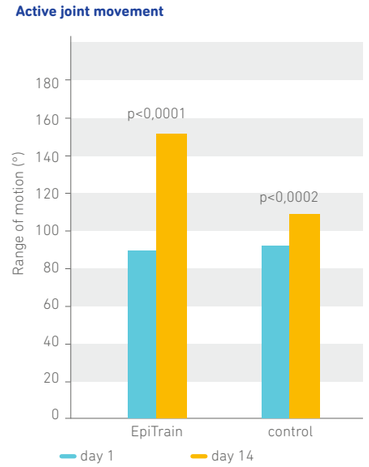
EpiTrain®
Active support for targeted compression of the elbow

RESULTS

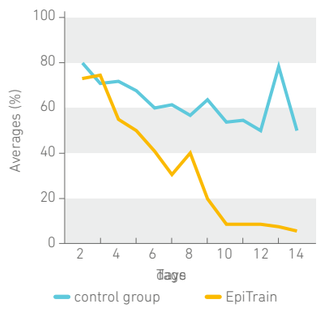
After 14 days, the pain felt by the group with EpiTrain had reduced by 50 units, in comparison with a reduction of only 19 units in the control group. The difference in pain reduction by the support is significant from day 6 to day 14 and can therefore be traced back to EpiTrain. The patients who were able to return to work with no restrictions increased from 47% at the start of treatment to 86% after 14 days in the EpiTrain group. In the control group, just 27% of patients were able to return to work with no restrictions at the start and 46% 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**

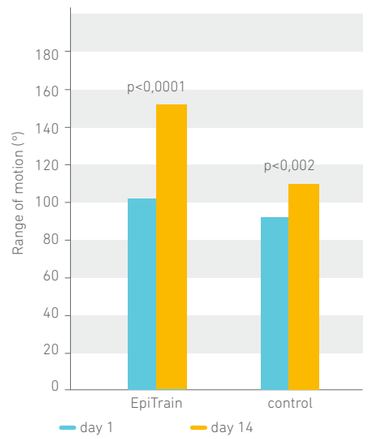
Active joint movement



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



Passive joint movement



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)

ManuTrain®

ACUTE WRIST AND FOREARM COMPLAINTS; RAPID RETURN TO FITNESS WITH MUSCLE ACTIVATING SUPPORT

Spallek M., Baunatal

Industrial mass production is often associated with working in set rhythms and performing stereotypical tasks, such as on the assembly line or other assembly activities. As with office work, this can lead to overloading and disorders of the muscles, tendons, and ligaments. In the case of predominantly manual activities, these problems are often localized in the wrist area or the distal forearm and range from significant pain during movement through to irritation or chronic tenosynovitis. The main question investigated in this study was whether the use of an anatomically shaped, knitted double-stretch support for wrist and forearm problems in a company health center showed any advantages over the "standard treatment" otherwise commonly used of applying antiphlogistic salves and compression and support bandages.

ManuTrain®
Active support for the wrist

METHODOLOGY

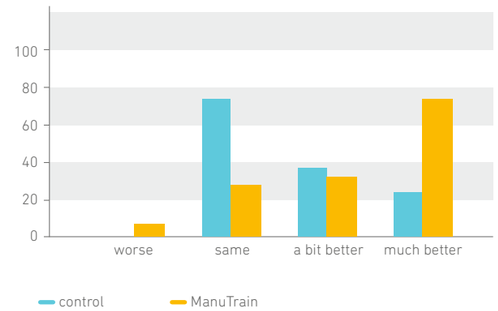
Study design:	Randomized, controlled parallel group study
Sample:	n = 84 (57 = ManuTrain group; 27 = control group)
Test support:	ManuTrain wrist support (Bauerfeind AG)
Test method:	Test duration: 14 days; self-assessment by patients using patient diaries for recording information such as restricted function, ability to work, and feeling of pain using a VAS score for pain at rest, at night, and during movement. The control group was given a standard treatment (application of antiphlogistic salves in conjunction with an elastic bandage). The support group was given a wrist support. The investigation was performed in a large company in the metalworking industry.
Inclusion criteria:	• Patients with irritation and overloading (tendomyopathy) of the forearm and finger muscles and the tendons and ligaments • Wrist bruising, tenosynovitis (with some crepitus). Epicondylitis with an effect on the forearm and wristarea
Exclusion criteria:	Patients with suspected fractures, conditions after surgery in the wrist area less than six months ago

RESULTS

The statistical analysis revealed that the pain intensity data given by the patients in both groups was no different at the start of the study. Accordingly, any changes in this data must be seen to have a direct connection with the treatment. After two weeks of treatment, 61.4% of the support group described their pain as "much better." Meanwhile, 59.3% of the control group rated their pain levels as "unchanged." 18 patients in the support group had no pain after two weeks, as opposed to only 2 patients in the control group. It is worth noting that 33% of the patients in the control group were also assigned to an alternative workplace with a limited range of activities in addition to receiving treatment, while such a change in workplace was only necessary for 12% of the support group.

→ **ManuTrain reduces wrist pain**
→ **ManuTrain enables a quicker return to work**

Effect on complaints after two weeks of treatment (%)



Source:
Spallek M, Akute Handgelenk- und Unterarmbeschwerden; Schnell wieder fit mit muskelaktivierender Bandage [Acute wrist and forearm complaints; rapid return to fitness with muscle activating support];
Ärztliche Praxis, Vol. 44, no. 20, pp. 12-14. 1992

MalleoTrain®
CONTROLLED TRIAL OF AN ANKLE SUPPORT IN 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®
Active support for muscular stabilization of the ankle

METHODOLOGY

Randomized, controlled parallel group study

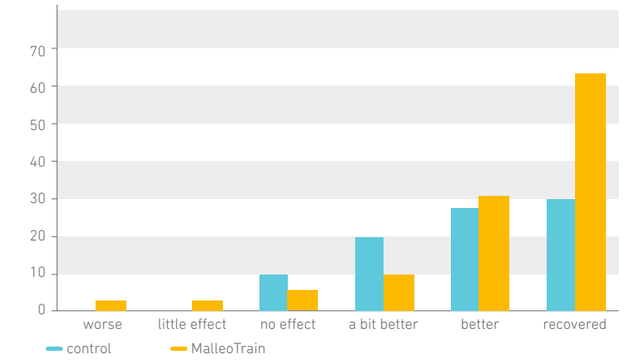
Sample:	n = 220 (153 = male, 67 = female/118 = MalleoTrain group; 102 = control group, wrapped support: Tubigrip), age: 35.2, (14–78) years, body weight: 69.0 (44–101 kg), height: 170.7 cm (155–188 cm)
Test support:	MalleoTrain ankle supports (Bauerfeind AG), Tubigrip (Seton)
Test method:	Test duration: 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% 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% of patients in the MalleoTrain group were free of pain again or almost pain-free, as against 67% in the control group. 95% 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 (%)



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®

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

Multi-center cohort study

Sample:	n = 244, age: 10–57 years
Test support:	MalleoTrain ankle supports (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®
Active support for muscular stabilization of the ankle

Source:
Blandfort R, Hess H, Lippay F;
Die MalleoTrain – Bandage im klinischen Großversuch [The MalleoTrain support in a large-scale clinical trial]
Sportverl, Sportschaden, Vol. 5, pp. 42-44, 1991

MOS-Genu®

THE EFFECT OF VALGUS BRACES ON MEDIAL COMPARTMENT LOAD OF THE KNEE JOINT – IN VIVO LOAD MEASUREMENTS IN THREE 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.

METHODOLOGY

Test subjects:	Number: 3; age [in years]: 64, 71, 60, weight [kg]: 103, 96, 96, height [cm]: 177, 175, 175
Time since surgery [months]:	23, 12, 6
Mechanical axis angle:	3° varus, 4° varus, 1° varus
Test orthoses:	MOS-Genu (Bauerfeind AG); Genu Arthro (Otto Bock Health Care GmbH)
Test method:	• Three 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

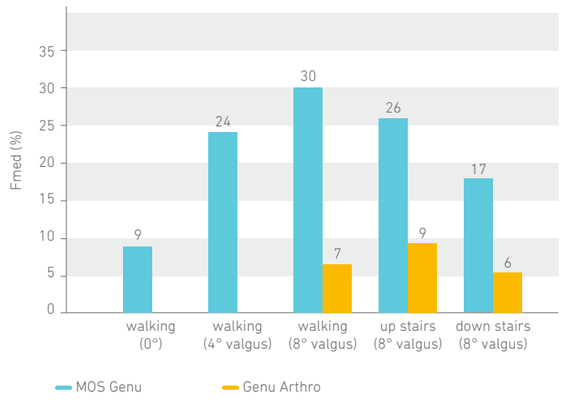
MOS Genu®
Orthosis for stabilization and correction of the knee joint

RESULTS

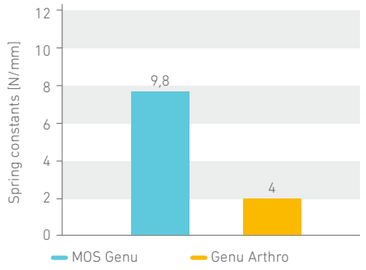
By wearing MOS Genu, a reduction in force of 9% is possible even in the neutral position (0°), while the relief achieved with an 8° valgus adjustment is 30%. The results demonstrate that relief of the medial compartment is achieved with both orthoses. However, in this comparison, MOS Genu achieves significantly 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° 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

FUNCTIONAL PERFORMANCE PARAMETERS AND THE EFFECT OF TWO FUNCTIONAL ORTHOSES ON THE STABILITY OF PATIENTS WITH ACL RUPTURES

Strutzenberger G., Braig M., Sell S., Boes K., Schwameder H.
Department of Sport and Sportscience, Karlsruhe Institute of Technology (KIT), BioMotion Center, Karlsruhe

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

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%) • > 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

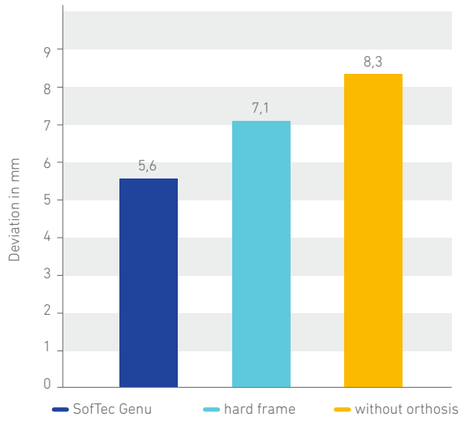
SofTec® Genu
Orthosis for stabilization of the knee joint

RESULTS

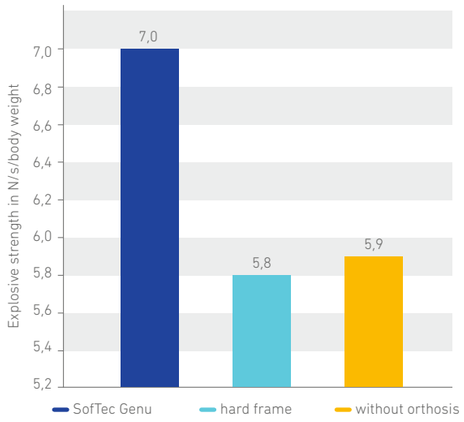
The results show that mechanical stabilization is achieved with both orthoses, with SofTec Genu achieving values that are virtually comparable with a healthy knee. In the case of complex movement sequences, SofTec Genu is superior to the hard-frame orthosis. The counter movement jump showed a significant 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**

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 et al.; 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
Orthosis for stabilization of the knee joint

METHODOLOGY

Randomized, controlled prospective cross-sectional study

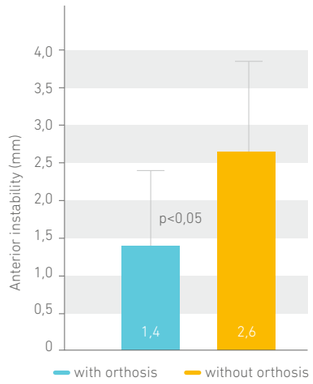
Sample:	n = 20 women, n = 26 men, age: 24.8 ± 3.6 years, height 176.3 ± 12.7 cm, weight 73.4 ± 10.9 kg
Test orthosis:	SofTec Genu soft orthosis (Bauerfeind AG)
Measurement systems:	KT-1000 knee ligament arthrometer (MEDmetric Corp., San Diego, CA, USA) → anterior instability
Test method:	KT-1000 measurement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

RESULTS

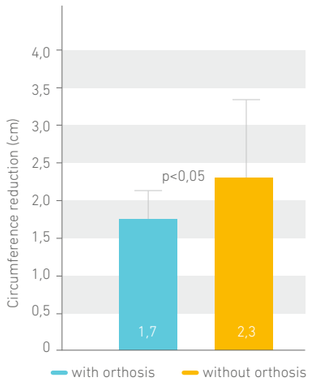
Eight weeks after the anterior cruciate ligament rupture confirmed by arthroscopy, the group treated with the orthosis showed 46% (1.4 ± 0.9 vs 2.6 ± 1.2 cm) less development of anterior instability, which is statistically significant ($p<0.05$), compared to the control group without any orthosis (Picture 2). Treatment with the orthosis also significantly reduced ($p<0.05$) the post-traumatic reduction in thigh muscle circumference by about 25% (1.7 ± 0.4 vs 2.3 ± 0.5 cm) (Picture 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
[The use of external knee joint stabilizers – influencing mechanical stabilization and physical performance];
Sportverletzung/Sportschaden, Vol. 15: 62–67 (2001)

SofTec® Genu and SecuTec® Genu

AXIAL CONGRUENCE AND AXIAL MIGRATION OF KNEE ORTHOSES IN PRACTICE – RESULTS OF KINEMATIC INVESTIGATION

Berschin G., Schneider V., Sommer H. M., Institute of Sports Science and Motology, Philipps University of Marburg

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

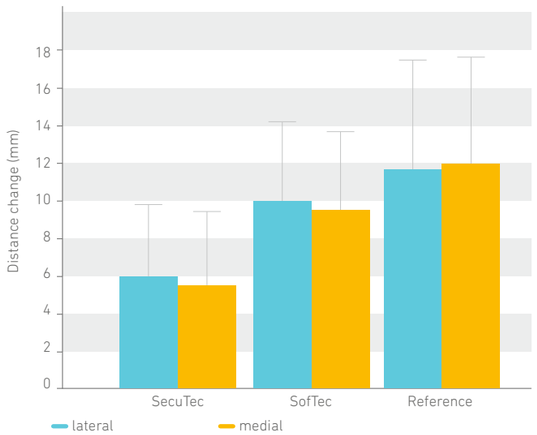
The results of the maximum distance changes in the gait cycle (axial congruence) show a median deviation of about 5.6 mm between the orthosis and joint compromise axis for SecuTec Genu. This incongruence measurement is significantly lower than the reference values available for other orthoses on the market. For 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**

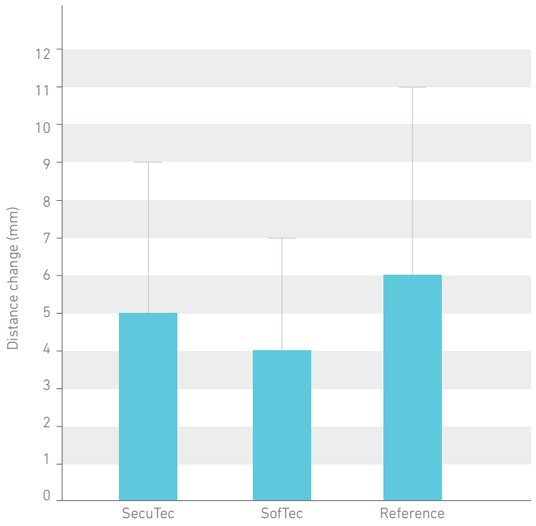
SofTec® Genu
Orthosis for stabilization of the knee joint

SecuTec® Genu
Orthosis for stabilization of the knee joint

Axial congruence
maximum distance change (average)



Axial migration
maximum distance change (average)



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

SofTec® OA

A MODERN VALGUS 3-POINT ORTHOSIS FOR THE TREATMENT OF MEDIAL GONARTHROSIS

Heerwaarden R. J., Gaasbeek R. D. A., Plitz W., Orthopedic Department of Sint Maartenskliniek Hospital, Nijmegen, Medical University of Munich

In most cases, gonarthrosis develops in the medial compartment of the knee joint. The loss of cartilage mass causes the leg axis to gradually move into a varus misalignment that places more strain on the medial compartment. When the knee joint is under load, this leads to an increase in symptoms. Reducing the varus misalignment can relieve the medial compartment, thus alleviating the symptoms. This study investigates the changes in symptoms of patients with gonarthrosis effected by valgus correction.

METHODOLOGY

Patient group:	n = 20 (12 men, 8 women); average age 53 years (18–70 years)
Average time spent wearing the orthosis:	9 hours/day for 6 weeks; gonarthrosis severity grade II = 10 patients; grade III = 7 patients; grade IV = 3 patients (gonarthrosis classification in accordance with Ahlbäck) The varus misalignment of the leg was between 1° and 14° with an average of 5.1°.

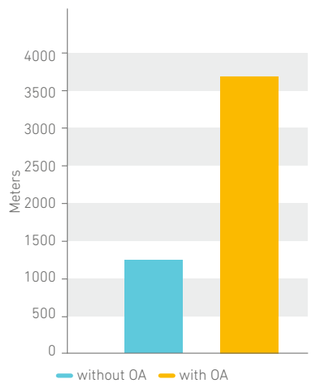
RESULTS

After wearing the orthosis for six weeks, there was a significant improvement in all pain parameters recorded. There was a strict correlation between the feeling of pain and the time spent wearing the orthosis. Pain intensity fell from an initial VAS score of 6.2 to a VAS score of 2.8 after six weeks. The average distance that patients could walk without pain rose from 1,165 meters to 3,630 meters. 17 patients were also in less pain during rest phases. 10 patients who were taking painkillers before the study significantly reduced their consumption or even stopped taking painkillers altogether after wearing the orthosis for six weeks. 18 patients felt that their stability and knee functionality improved thanks to the knee orthosis.

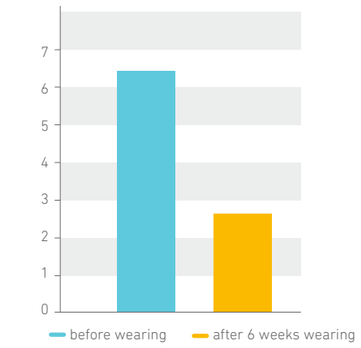
- → **SofTec OA reduces pain by 54% after wearing it for six weeks**
- → **SofTec OA increases patients' mobility from 1 km to 3.5 km on average**

SofTec® OA
Orthosis for relief of the medial knee compartment

Pain-free distance in meters



Feeling of pain before and after six weeks of treatment with SofTec OA, Visual Analog Scale (VAS)



Source:
Heerwaarden R J, Gaasbeek R D A, Plitz W;
An Innovative Valgus Bracing Orthosis for The Treatment Of Medial Gonarthrosis;
Medizinische Orthopädische Technik, Vol. 3, 2005

SacroLoc®

EXPERIMENTAL, COMPUTER-BASED STUDY OF THE EFFECT OF ORTHOSES ON THE SACROILIAC JOINT AND ITS LIGAMENTS

Sichting F., Rossol J., Soisson O., Klima S., Milani T., Hammer N.
Department of Human Locomotion, Technische Universität Chemnitz and Institute of Anatomy, University of Leipzig

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 (Picture 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 (Picture 2) were investigated.

METHODOLOGY

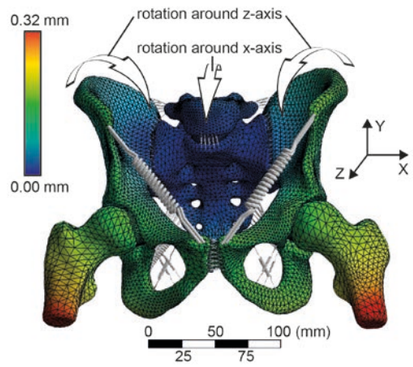
Sample:	Computer model of a healthy male volunteer: 29 years old, height of 185 cm, weight of 69 kg; based on computer tomography data (Somatom Volume Zoom Scanner, Siemens AG, Erlangen, Germany)
Test orthosis:	SacroLoc pelvic orthosis (Bauerfeind AG)
Test method:	MRI (Magnetom Trio, Siemens AG, Erlangen,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

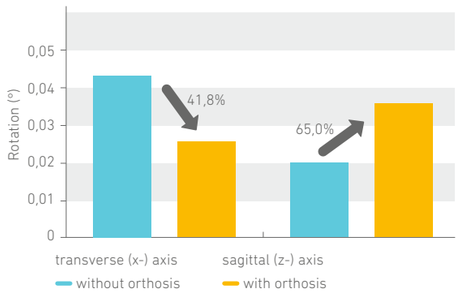
RESULTS

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 Picture 3). 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% and 14% reduction respectively in the stretching observed; data table not shown).

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

SacroLoc®
Orthosis for stabilization and relief of the pelvis and the sacroiliac joints





Source:
Sichting et al.;
Pelvic Belt Effects on Sacroiliac Joint Ligaments: A Computational Approach to Understand Therapeutic Effects of Pelvic Belts, Pain Physician 2014; Vol. 17: pp. 43–51 • ISSN 1533-3159

SacroLoc®

MEDICAL EFFECT OF SI JOINT BACK ORTHOSES ON THE CLINICAL AND FUNCTIONAL PARAMETERS OF PATIENTS WITH SI JOINT PAIN

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

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.

SacroLoc®
Orthosis for stabilization and relief of the pelvis and the sacroiliac joints

METHODOLOGY

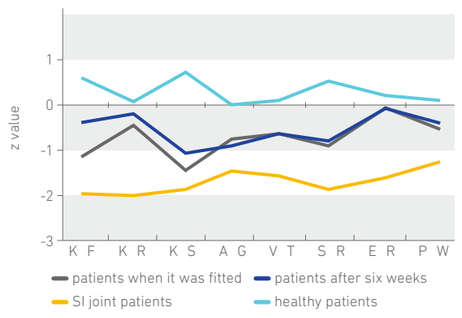
Test groups:	Healthy test subjects, n = 17, age: 18–80 years, average age 43; patients with SI joint syndrome, n = 17, age: 18–80 years, average age 45
Test orthosis:	SacroLoc pelvic orthosis (Bauerfeind AG)
Test method:	• EMG to measure muscle activity in the muscles when walking • Gait analysis to 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

RESULTS

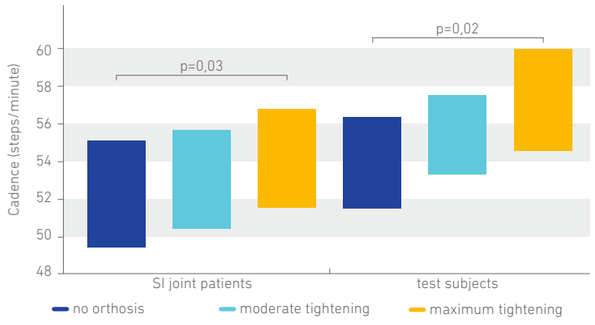
When using the SacroLoc pelvic orthosis, SI joint patients showed a significant improvement in health-related quality of life, particularly in terms of the SF-36 subscores after six weeks, which illustrate the patients' physical health. The pain suffered by SI joint patients, measured using the one-dimensional 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 picture). 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:
Soisson O, Lube J, Germano A, Hammer K-H, Josten C, Sichting F, Winkler D, Milani T L, Hammer N;
Pelvic Belt Effects on Pelvic Morphometry, Muscle Activity and Body Balance in Patients with Sacroiliac Joint Dysfunction;
PLoS ONE 10(3): e0116739. doi:10.1371/journal.pone.0116739

MalleoLoc®
FUNCTIONING OF THE ANKLE ORTHOSIS DURING SIMULATED INVERSION OF THE UPPER ANKLE JOINT

Gehring D., Lohrer H., Nauck T., Wißler S., 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% to 40% 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.

MalleoLoc®
Orthosis for the stabilization of the ankle

METHODOLOGY

Sample:	n = 17 men, age: 25.7 ± 4.4 years
Test orthoses:	MalleoLoc ankle orthosis (Bauerfeind AG)
Measurement 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 play sport aged between 18–35 years with unilateral chronic ankle instability (FAAM-G score (2) < 95%)

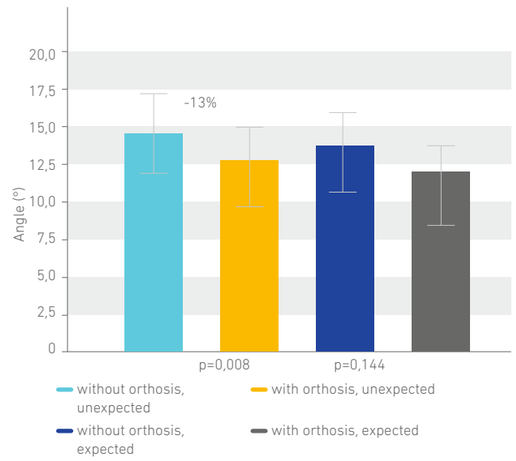
RESULTS

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 (Picture 1). Picture 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.

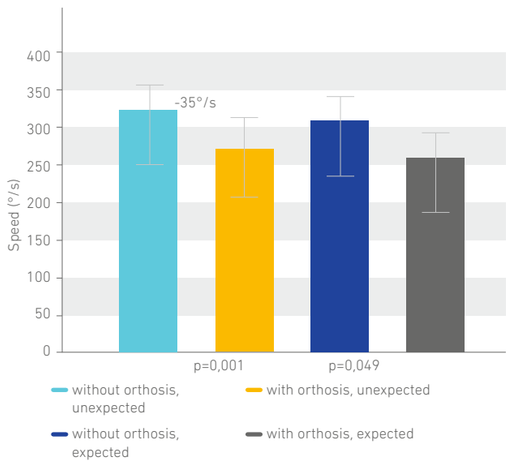
→ **MalleoLoc stabilizes the ankle and significantly reduces the risk of damaging supination movements**

→ **MalleoLoc enables a normal movement process while walking**

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

ErgoPad® redux heel

EFFECT OF DIFFERENT ORTHOTIC CONCEPTS AS FIRST LINE TREATMENT OF PLANTAR FASCIITIS

Walther M., Kratschmer B., Verschl J., Volkering C., Altenberger S., Kriegelstein S., Hilgers M.; Munich

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

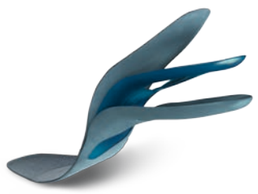
Prospective, randomized, controlled clinical study

Sample:	n = 30 (9 = male, 21 = female)
Test foot orthoses:	Three industrially produced foot orthoses: ErgoPad redux heel (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

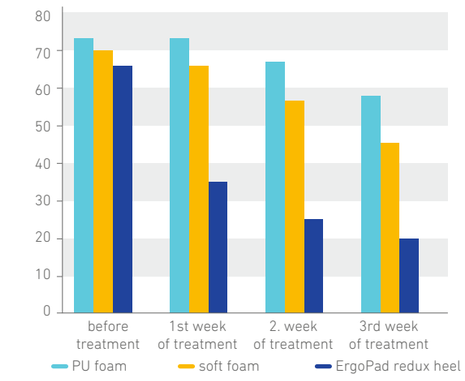
The thin cushioning foot orthosis had no demonstrable effect on maximum pain or average pain. Both the soft foam foot orthosis and the soft foam foot orthosis with a synthetic core significantly reduced pain, with the foot orthosis with a synthetic core producing better results in terms of effect size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

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



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

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

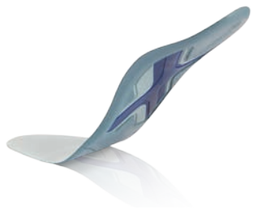


Source:
Walther M, Kratschmer B, Verschl J, Volkering C, Altenberger S, Kriegelstein S, Hilgers M;
Effect of different orthotic concepts as first line treatment of plantar fasciitis;
Foot Ankle Surg. 2013 Jun;19(2):103-7. doi: 10.1016/j.fas.2012.12.008. Epub 2013 Feb 19.

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 of 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
Foot orthosis for natural mobility of the feet

METHODOLOGY

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

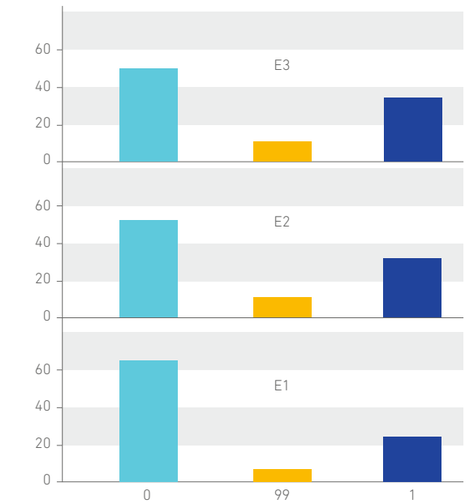
RESULTS

Improved guidance of the movement process
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% ("soft" core), 34% ("medium" core), and 36% ("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.

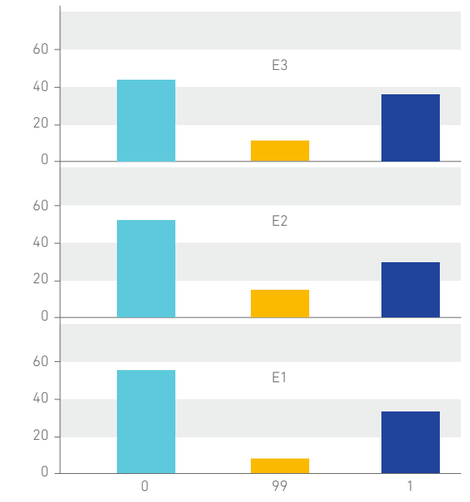
Reduced eversion
Increasing fatigue and/or high levels of strain (being very overweight/carrying heavy loads) increase the buckling or inward-sinking of the lower ankle.
The responder analysis showed that the use of the foot orthoses resulted in a clinically significant reduction (> 2°) in maximum eversion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

→ **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 responded 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