

STUDY PUBLICATION OF SELECTED RESULTS

EFFECT OF A COMPRESSION SUPPORT ON GAIT, BALANCE, FINE COORDINATION, AND SUBJECTIVE PERCEPTION OF PATIENTS WITH RECENT ANKLE SPRAINS

BACKGROUND

As a means of prevention, ankle supports/orthoses and classic tape bandages reduce the incidence of ankle sprains. [1,2] When sprains occur, tape bandages as well as supports/orthoses help reduce the severity of the injury. [1] Except for triple-ligament or syndesmosis injuries, most injuries to the lateral collateral ligaments of the ankle can be cared for with non-surgical/early functional treatment. Independent of the severity of the injury, the treatment regimen should be strictly adhered to for at least six weeks, and the individual phases of ligament healing should be respected. In these cases, it is useful to provide the patient with a modular orthosis, coupled with sensorimotor measures/physiotherapy. [3] Statistic evidence demonstrates that functional treatment options are better than immobilization in cases of mild to moderate ankle sprains. Functional treatment includes elastic supports, soft bandages, taping and also orthoses, combined with coordination training. [4]

The objective of this study, conducted under the direction of L. Niklaus¹, Dr. A. Kilper², Dr. L. Schütz² and Prof. T. Milani¹ at Chemnitz Technical University; Human Locomotion Department¹ and Chemnitz Hospital; Department of Orthopedics & Trauma Surgery², 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.

Two main aspects were given priority: 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. This would suggest a lasting effect and/or accelerated healing provided by the support, compared with the control group where no support was worn.

STUDY DESIGN

Randomized, controlled laboratory study (Evidence Level 1b)

METHODOLOGY

Sample:

n = 64 patients;
n = 32 with support = BG = intervention group,
n = 32 without support = KG = control group
Age: 34.8 ± 11.6 years,
height: 173.8 ± 11.8 cm,
weight: 78.7 ± 16.4 kg
Sex: m:f = 33:31;
injured side: r:l = 35:29
n = 20 healthy subjects
Age: 33.0 ± 10.8 years,
height: 173.4 ± 9.2 cm,
weight: 71.8 ± 11.6 kg
Sex: m:f = 8:12

Test supports:

MalleoTrain® (Bauerfeind AG)

Measurement systems and test procedures:

Center of Pressure (CoP) single-leg stand, (measurement of the arc length deviation for 20 sec.)
Gait parameters: step length, vertical ground reaction force
Pain scale and instability scale (10-point VAS [Visual Analog Scale])

Investigation period:

1st measurement:
acute effect, CW 5 after injury
(= NU1; follow-up examination 1),
n=64 Followed by 2 weeks of wearing the support for BG, n=32, and KG without support, n=32
2nd measurement:
CW 7 after injury
(= NU2, follow-up examination 2)
Both KG and BG measurements were taken after 2 weeks (CW 7 after injury) WITHOUT a support being worn at the time.

METHODOLOGY

Biometrics:	Dependent sample t-test; $\alpha \leq 0.05$; power: 80 percent
Inclusion criteria:	Initial diagnosis of a unilateral, recent supination trauma (upper ankle sprain, lateral collateral ligament lesion) Clinical consultation no later than 3 three 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 Previous ankle trauma within less than 1 year General chronic ankle instability

FINDINGS

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 ± 30.0 mm shorter than on the injured side without a support (t-test: $p=0.001$; see Table 1/Fig. 1).

Wearing the MalleoTrain significantly improves balance skills (postural joint stability) ($p=0.002$) and approximates to the level on the healthy side.

Compared with a healthy, age-matched comparator group, the CoP readings are increased, which could indicate patients' impaired balance on both sides (see Table 1).

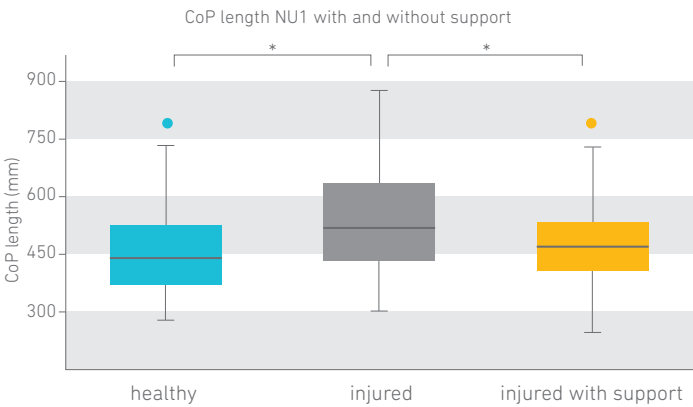


Fig.1: Improvement in balance skills by wearing the support (acute effect, CW 5), data distribution and dispersion at the time of measurement NU1 (n=64); * $p<0,05$; Source: [8]

CoP length	
Healthy side	$468,6 \pm 115,6$ mm
Injured side	$546,1 \pm 145,6$ mm
Injured side with support	$475,2 \pm 108,1$ mm
Healthy comparator group (n=20)	$433,0 \pm 136,2$ mm

Tab.1: MV $\pm$ SD for CoP measurements, single-leg stand, only at NU1 (n=64) with and without support for 20 sec. each For comparison, readings from a healthy comparator group (n=20) are provided; Source: [8]

PERCEPTION OF STABILITY AND PERCEPTION OF PAIN AS A RESULT OF WEARING THE SUPPORT DURING THE CoP LENGTH MOVEMENT TEST

When standing on the injured leg only, 37 percent of patients reported pain and 57 percent a feeling of instability in the ankle. Wearing the support reduced reports of pain and instability to 33 percent and 51 percent, respectively.

Independent of these figures, 86 percent of all patients rated their balance with the support as 'better' to 'much better' when directly compared to not wearing a support; (Fig. 2).



Fig.2: Balance perception: percentage of patients [%] during CoP single-leg stand at NU1; comparing without and with support; Source: [8]

 **MalleoTrain improves postural stability and balance perception.**

GAIT ANALYSIS; STEP LENGTH

When walking without a support (time: NU1), the step length on the healthy side is significantly shorter than on the injured side ($p=0.001$).

By wearing the MalleoTrain, the step length on the healthy side can be significantly increased ($p=0.008$), so that there is no difference in step length on both sides, as is the case with healthy subjects (see Fig. 3 and Table 2).

At NU2, no difference between the injured and healthy sides can be observed in both groups (for each t-test; $p=0.479$ and $p=0.672$, respectively). There is no longer any gait asymmetry. Wearing the MalleoTrain long-term during "normal" walking beyond CW 7 after the injury seems unnecessary for gait symmetry because the control group has also developed a rhythmic gait.

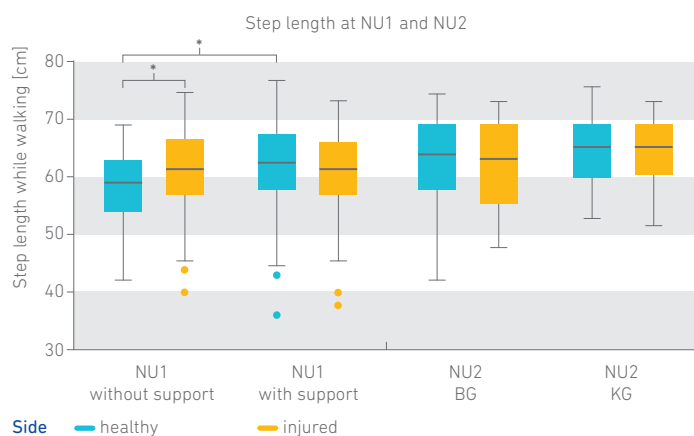


Fig.3: Step length; data location and distribution at NU1 and NU2;
 NU1 (CW 5 after injury): 64 patients with and without support
 NU2 (CW 7 after injury): BG = patients from the support group, WITHOUT support at the time of measurement, (n=32)
 KG = control group = patients WITHOUT support at the time of measurement, (n=32); Source: [8]

	NU1 n = 64		NU2	
	without support	with support	BG (n = 32)	KG (n = 32)
injured MW±SD	61,0±7,7 cm	61,0±7,3 cm	64,3±5,6 cm	64,8±5,6 cm
healthy MW±SD	57,7±6,1 cm	61,1±8,3 cm	62,5±7,5 cm	62,8±8,8 cm

Tab.2: Step length at NU1 with and without support, at NU2 both groups WITHOUT support; Source: [8]

PERCEPTION OF STABILITY AND PAIN AS A RESULT OF WEARING THE SUPPORT DURING THE GAIT ANALYSIS MOVEMENT TEST

Subjectively, 27 percent of patients rate walking with the support as much better, 40 percent as a little better, and 32 percent notice no difference, compared with not wearing the support. **About two thirds of patients noticeably benefit from wearing the MalleoTrain while walking (no figure).**

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.

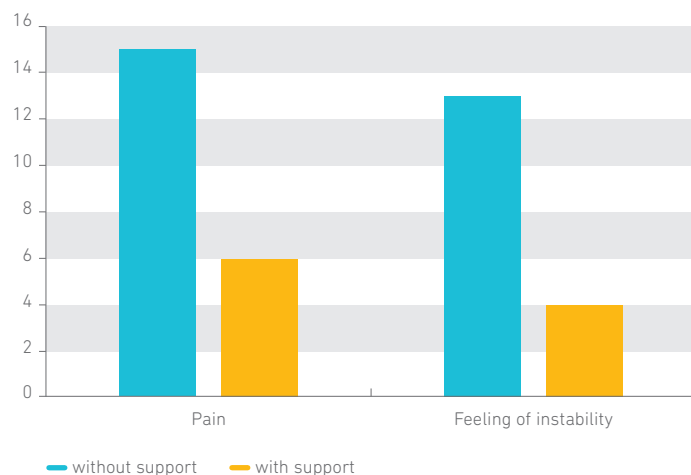


Fig.4: Number of patients who suffer from pain and a feeling of instability during walking with and without the support at NU1 (CW 5 after injury); Source: [8]

with MalleoTrain:
less pain, more stability

GAIT ANALYSIS; GROUND REACTION FORCE

Five weeks after the injury (NU1), patients put significantly less load on the injured side during normal walking without a support, both during weight transfer (ground reaction force; peak 1) and when pushing off (ground reaction force; peak 2), compared to the healthy side ($p=0.009$ and $p=0.001$, respectively; for each t-test). Wearing the MalleoTrain results in more load being put on the injured side during weight transfer when walking; **at peak 1, there is no longer a difference between healthy and injured with the support. (Tab.3:)**

With respect to time, there is no difference in the occurrence of peak 1 between the healthy and injured leg, and this is also not influenced by wearing the support. However, pushing off (peak 2) with the injured side when walking without a support occurs significantly earlier in the gait cycle, compared to the healthy side ($p=0.002$; t-test). **This difference no longer exists when walking with the MalleoTrain.** Due to the support, pushing off with the injured side occurs significantly later ($p=0.010$).

At seven weeks after the injury (NU2), no difference can be observed in both groups between weight-bearing on the healthy and injured sides when walking (BG: peak 1: $p=0.624$; peak 2: $p=0.034$; KG: peak 1: $p=0.559$; peak 2: $p=0.819$, respectively).

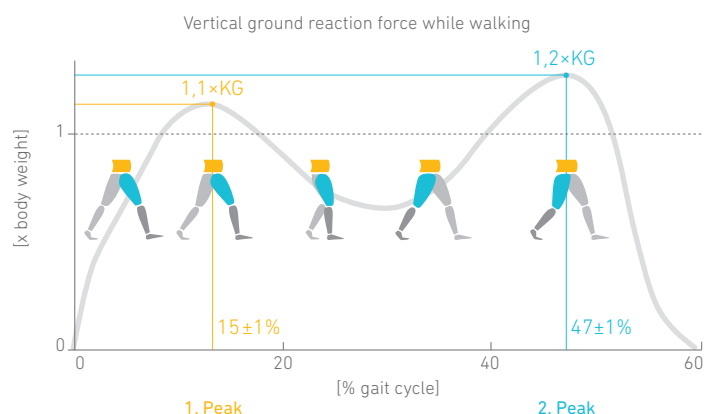


Fig.5: Standard curve of vertical ground reaction force while walking; Source: [8]

	n	Peak 1 [-fach KG]		time Peak 1 [%GZ]		Peak 2 [N]		time Peak 2 [%GZ]	
		healthy	injured	healthy	injured	healthy	injured	healthy	injured
NU 1 without support	64	1,065 ± 0,067 [814N]	1,051 ± 0,063 [804N]	17,2 ± 3,6	17,3 ± 3,3	1,110 ± 0,069 [853N]	1,080 ± 0,071 [838N]	47,4 ± 6,1	44,6 ± 6,2
NU 1 with support	64	1,070 ± 0,070 [813N]	1,0667 ± 0,066 [810N]	17,3 ± 3,6	17,8 ± 3,5	1,125 ± 0,064 [854N]	1,108 ± 0,081 [840N]	47,4 ± 6,1	46,4 ± 5,9

Tab.3: Extent of vertical ground reaction force peaks when walking at a speed chosen by the subject for the weight transfer (peak 1) and push-off (peak 2) phases; Values: relative [normalized to body weight] and absolute in [N] The time of occurrence in the gait cycle is also specified [S = support; WS = without support; GC = gait cycle]; Source: [8]



DISCUSSION

Earlier studies were able to demonstrate pain-reducing and stabilizing effects of ankle supports following supination trauma. Here, elastic supports significantly reduce pain at rest, at night and also during movement and improve patients' range of motion after such a trauma. [5]

In addition, ankle supports (as well as tape bandages) stabilize the ankle by reducing the range of motion of subtalar eversion compared with jumping bare-foot, and by restricting plantar flexion also when landing after jumps. [6]

The stabilizing effect of a support on the ankle during dynamic processes, such as balance skills and weight-bearing of the ankle when walking, was also observed in this study.

Patients reported a noticeable, relevant reduction in pain and a clearly perceivable stabilization of the ankle as a result of the support.

In a previous study, Blandfort et al. treated complete lateral ligament ruptures of the upper ankle conservatively, using only an ankle support, and achieved stable ligaments in their healing outcomes. On average, the ability to work and exercise returned two weeks earlier than with immobilization in a plaster cast. [7]

This indicates that early functional treatment promotes the healing process compared to classic immobilization.

This type of potentially accelerated healing could not be demonstrated for early functional treatment with a support compared with early functional treatment without a support, as was examined in this study.

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 support (41.9 percent).

CONCLUSION:

Functional tests show that the MalleoTrain acutely improves balance skills and important gait parameters in patients five weeks after a supination trauma.

The clinical relevance of the support's demonstrated effect is reinforced because, in parallel with the tests carried out, patients had a more secure feeling, increased ankle stability and less pain when wearing the support compared with not wearing it.

However, an accelerated healing process from wearing the support and/or a lasting effect of the support even when the support was not worn could not be demonstrated in the post-traumatic healing phase with the chosen parameters and the study design at hand.

81 percent of the participating patients were 'satisfied' to 'very satisfied' with the support after two weeks of wearing it.

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