Reference

Brüggemann G-P, Willwacher S, Fantini Pagani CH.

Institute of Biomechanics and Orthopaedics, German Sport University Cologne, Germany.

Evaluation of biomechanical efficacy of a new orthosis concept for ankle injury therapy.

SportOrthoTrauma 2009, 25:223-230.

Products

Malleo TriStep

M1: Basic orthosis + foot shell+ cross strap (Immobilisation and stabilisation)

M2: Basic orthosis + cross strap (Stabilisation)

M3: Basic orthosis (Sensomotor support)

Major Findings

With Malleo TriStep (M1, M2, M3) compared to wearing no orthosis (BA), Aircast Air-Stirrup, DJO (RE), Tape (TA):

→ For all static measures, the Malleo TriStep (especially M1) led to a high restriction of the max. inversion angle compared to wearing no orthosis:

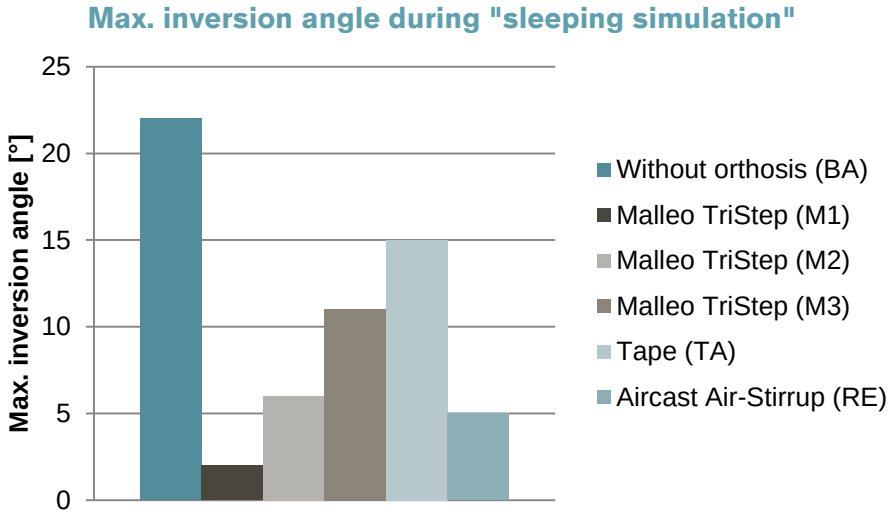
	M1	M2	M3	TA	RE
Unexpected tilting (30° supination)	-66.7%	-28.2%	-15.4%	-30.7%	-46.2%
"Sleeping simulation"	-90.9%	-72.7%	-50%	-31.8%	-77.3%

→ Based on the subjective assessment of the subjects, the M1 supported the stability and safety of the patient the most.

With Malleo TriStep (M2, M3) compared to wearing no orthosis (BA):

→ Improved safety due to significant decrease of max. inversion angle and plantarflexion with Malleo TriStep (M2 & M3) while walking and running:

	Max. inversion angle	Max. plantarflexion
Walking (1.8 m/s):	Decrease up to 47.2%	Decrease up to 29.2%
Running (2.5–3.5 m/s):	Decrease up to 51.9%	Decrease up to 30.8%



Max. inversion angle during "sleeping simulation" (fixed horizontal position, no muscle activity). Max. inversion angle was measured after removing the fixation.

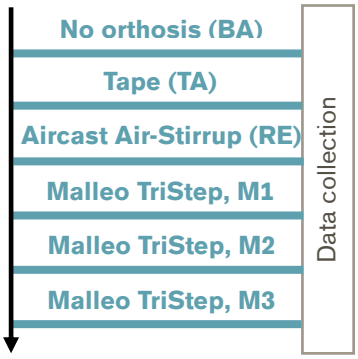
Population

Subjects:	17 patients (10 male, 7 female)
Mean age:	25 ± 2.4 yrs
Mean body mass:	74 ± 6 kg
Exclusion criteria:	Ankle injury within the last 12 months

Study Design

Observational, comparative:

Measurement 1:



Measurement 2:

Measurement 1:
With all conditions 3 types of static measures were performed. Test A simulated an unexpected tilt (30° supination and 30° supination + 10° plantarflexion) of the ankle by a pneumatic platform. Test B proofed the stabilisation of the ankle while standing 30 seconds on one leg on an instable underground. Test C was a "sleeping simulation" (fixed horizontal position, no muscle activity). Fixation was removed quickly.

Measurement 2:
Gait (1.8 m/s) and running (2.5 & 3.5 m/s) measurements were performed on a treadmill with three conditions (BA, M2 and M3).

Results

Functions and Activities						Participation
Biomechanics – Static measures	**Biomechanics – Gait analysis**	**X-Ray**	**EMG**	**Functional tests**	**Clinical effects**	**Satisfaction**

Category	Outcomes	Results for Malleo TriStep	Sig.*
Biomechanics – Static measures	Max. inversion angle	**During unexpected tilting (30° supination) all conditions (except M3) showed significant reductions:**	

M1 vs. BA	M2 vs. BA	M3 vs. BA	TA vs. BA	RE vs. BA
66.7% lower	**28.2% lower**	15.4% lower	**30.7% lower**	**46.2% lower**
++	**++**	+	**++**	**++**

During unexpected tilting (30° supination + 10° plantarflexion) significant decreases were recorded only for M1:

M1 vs. BA	M2 vs. BA	TA vs. BA	RE vs. BA
28° lower	12° lower	12° lower	18° lower
++	+	+	+

For the "sleeping simulation" all inversion angles are significantly reduced compared to BA:

M1 vs. BA	M2 vs. BA	M3 vs. BA	TA vs. BA	RE vs. BA
90.9% lower	**72.7% lower**	**50% lower**	**31.8% lower**	**77.3% lower**
++	**++**	**++**	**++**	**++**

Category	Outcomes	Results for Malleo TriStep				Sig.*
	Max. eversion/inversion angle	For the max. eversion/inversion angle during standing 30 sec on one leg, 3 of 5 results were noted as significant:				
		M1 vs. BA **28.9%** **lower** **++**	**M2 vs. BA** **13.3%** **lower** **++**	M3 vs. BA 0% 0	TA vs. BA 6.7% lower +	**RE vs. BA** **20%** **lower** **++**
Biomechanics – Gait analysis	Walking (1.8 m/s)	**The max. inversion angle while walking was significantly reduced with M2 and M3 condition:**				
		M2 vs. BA **47.2% lower** **++**		**M3 vs. BA** **13.3% lower** **++**	**M2 vs. M3** 14.3% lower +	
		No significant results for the eversion angle were found				0
		Plantarflexion while walking was significantly reduced:				
		M2 vs. BA **29.2% lower** **++**		**M3 vs. BA** **22.2% lower** **++**	**M2 vs. M3** **8.9% lower** **++**	
	Running (2.5 m/s)	**During running (2.5 m/s), the max. inversion angle was significantly decreased:**				
		M2 vs. BA **49.1% lower** **++**		**M3 vs. BA** **34.5% lower** **++**	**M2 vs. M3** **22.4% lower** **++**	
		No significant results for the eversion angle were found				0
		Plantarflexion while running (2.5) was significantly reduced:				
		M2 vs. BA **27.8% lower** **++**		**M3 vs. BA** **20.5% lower** **++**	**M2 vs. M3** **9.2% lower** **++**	
	Running (3.5 m/s)	**M2 reduces the max. inversion angle while running (3.5 m/s) by half:**				
		M2 vs. BA **51.9% lower** **++**		**M3 vs. BA** **36.8% lower** **++**	**M2 vs. M3** **23.8% lower** **++**	
		No significant results for the eversion angle were found				0
		During running (3.5 m/s) plantarflexion was significantly reduced with M2 and M3:				
		M2 vs. BA **30.8% lower** **++**		**M3 vs. BA** **20% lower** **++**	**M2 vs. M3** **13.6% lower** **++**	
EMG	Standing 30 sec on one leg	No significant reduction of activity was found for Mm. peronei.				0
	Latency time (time from tilting to muscle reaction)	No significant differences.				0
Clinical effects	Visual Analog Scale (VAS) (0 “no stability” – 10 “best possible stability”)	According to the VAS during standing 30 sec on one leg, the M1 (8.6) was found to support the stability and safety of the patient the most. Afterwards the M2 (6.5), RE (5.7) and TA (4.9) follow.				n.a.

* no difference (0), positive trend (+), negative trend (–), significant (++/––), not applicable (n.a.)

Author's Conclusion

"The progressive use of the MTS orthosis concept (M1, M2, M3) is a tool for the therapy of ankle injuries. It leads to a progressive and systematic load decrease of the injured structures, without influencing the initiation of the neuromuscular system in the post-severe phase of rehabilitation in a negative way. A further randomized, prospective clinical study with subjects with ankle injury has to be done. This should prove if a therapy with a progressive or stepwise load increase after short decrease with MTS (as an exclusive primary immobilisation, without any further treatment with functional orthosis) leads to a quicker and more sustained restore of the health of the capsular ligamentous apparatus." (Brüggemann, 2009)