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# Malleo TriStep

Quality for life

# Clinical Study Summaries

This document summarizes clinical studies conducted with the Malleo TriStep. The included studies were identified by a literature search made on PubMed and within the journals Orthopädie-Technik, Medizinisch Orthopädische Technik, Neurologie & Rehabilitation and Journal of Pediatric Orthopaedics.

**Table of content:**

# 1 Overview table

The summaries are organized in three levels depending on the detail of information. The overview table (Level 1) lists all the relevant publications dealing with a particular product (topic) as well as researched categories (e.g. gait analysis, clinical effects, satisfaction, etc). By clicking on underlined categories, a summary of all the literature dealing with that category will open (Level 2).

For those interested to learn more about individual studies, a summary of the study can be obtained by clicking on the relevant reference (Level 3).

| Reference | | Category | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | Functions and Activities | | | | | | Participation |
| Author | Year | Biomechanics – Static measures | Biomechanics – Gait analysis | X-Ray | EMG | Functional tests | Clinical effects | Satisfaction |
| **Brüggemann** | **2009** | x | x | | x | | x | |
| **Total number: 1** | | 1 | 1 | 0 | 0 | 1 | 1 | 0 |

# 2 Summary of individual study

On the following pages you find the summary of study that researched Malleo TriStep. You find detailed information about the study design, methods applied, results and major findings of the study. At the end of the summary you also can read the original study authors' conclusions.

**Reference**

Brüggemann, G.-P., Willwacher, S., & Fantini-Pagani, C. H.

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

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

Sports Orthopaedics & Traumatology 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:**

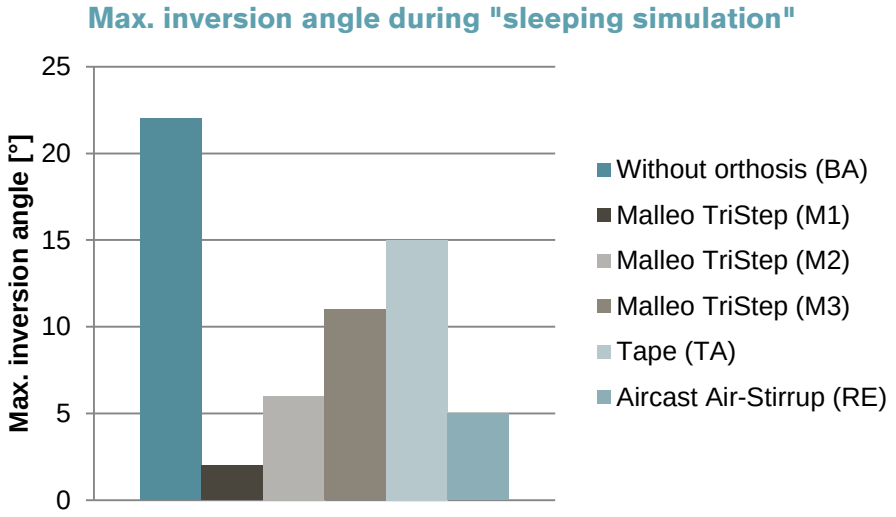
| | M1 | M2 | M3 | TA | RE |
|---|---|---|---|---|---|
| Unexpected tilting (30° supination) | -66.7% | -28.2% | -15.4% | -30.7% | -46.2% |
| "Sleeping simulation" | -90.9% | -72.7% | -50% | -31.8% | -77.3% |

**→ 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% |



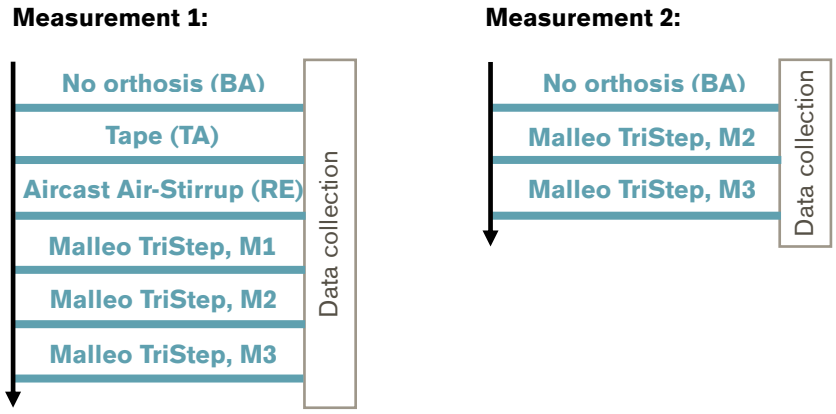

Max. inversion angle during "sleeping simulation" (fixed horizontal position, no muscle activity). Max. inversion angle was measured after removing the fixation.

## 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:**
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 measure | 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 |
| **++** | + | + | + |

| Category | Outcomes | Results for Malleo TriStep | Sig.* |
|---|---|---|---|
| | | For the "sleeping simulation" all inversion angles are significantly reduced compared to BA: | |
| | | **M1 vs. BA**<br>**90.9% lower**<br>**++** | **M2 vs. BA**<br>**72.7% lower**<br>**++** | **M3 vs. BA**<br>**50% lower**<br>**++** | **TA vs. BA**<br>**31.8% lower**<br>**++** | **RE vs. BA**<br>**77.3% lower**<br>**++** | |
| | 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**<br>**28.9% lower**<br>**++** | **M2 vs. BA**<br>**13.3% lower**<br>**++** | M3 vs. BA<br>0%<br>0 | TA vs. BA<br>6.7% lower<br>+ | **RE vs. BA**<br>**20% lower**<br>**++** | |
| 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**<br>**47.2% lower**<br>**++** | **M3 vs. BA**<br>**13.3% lower**<br>**++** | M2 vs. M3<br>14.3% lower<br>+ | |
| | | No significant results for the eversion angle were found | 0 |
| | | **Plantarflexion while walking was significantly reduced:** | |
| | | **M2 vs. BA**<br>**29.2% lower**<br>**++** | **M3 vs. BA**<br>**22.2% lower**<br>**++** | **M2 vs. M3**<br>**8.9% lower**<br>**++** | |
| | Running (2.5 m/s) | **During running (2.5 m/s), the max. inversion angle was significantly decreased:** | |
| | | **M2 vs. BA**<br>**49.1% lower**<br>**++** | **M3 vs. BA**<br>**34.5% lower**<br>**++** | **M2 vs. M3**<br>**22.4% lower**<br>**++** | |
| | | No significant results for the eversion angle were found | 0 |
| | | **Plantarflexion while running (2.5) was significantly reduced:** | |
| | | **M2 vs. BA**<br>**27.8% lower**<br>**++** | **M3 vs. BA**<br>**20.5% lower**<br>**++** | **M2 vs. M3**<br>**9.2% lower**<br>**++** | |
| | Running (3.5 m/s) | **M2 reduces the max. inversion angle while running (3.5 m/s) by half:** | |
| | | **M2 vs. BA**<br>**51.9% lower**<br>**++** | **M3 vs. BA**<br>**36.8% lower**<br>**++** | **M2 vs. M3**<br>**23.8% lower**<br>**++** | |
| | | 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**<br>**30.8% lower**<br>**++** | **M3 vs. BA**<br>**20% lower**<br>**++** | **M2 vs. M3**<br>**13.6% lower**<br>**++** | |

| 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.* |
|---|---|---|---|
| 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**

"In summary, a significant decrease in the KAM could be observed in subjects with knee varus alignment while using an AFO in different adjustments (4° valgus, neutral, and 4° varus). The orthosis was effective in changing the knee joint alignment and the knee joint lever arm in the frontal plane. Long-term effects on the KAM, symptoms, joint function, and compliance in patients with medial knee OA should be investigated in future studies. The use of AFOs designed to change the tibia position and thereby the knee joint alignment in the frontal plane could represent an alternative for conservative treatment of knee OA." (Fantini-Pagani et al. 2013)

↑ Back to overview table