Reference

Thomas Schmalz[1], Thomas Maximilian Köhler[1], Katharina Burkhardt[2], Annika Dlugoszek[1], Etienne Overdevest[3], Andreas Kannenberg[4], Malte Bellmann[1]

Evaluation of Biomechanical Effects and Patient Benefits of a New Orthotic Ankle Joint in Stance Control Orthosis Fittings

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Products

E-MAG Active with NexGear Tango

Major Findings

Stance-control orthosis (SCO, E-MAG Active) with NexGear Tango orthotic ankle joint (NGT) in two modes: (1) full functionality (SCO/NGT – greater range of motion, strong dorsi-/plantarflexion springs) vs. (2) conventional double-action mode (SCO/CAJ – limited range of motion, weak dorsi-/plantarflexion springs):

→ Reduced asymmetry between orthotic and sound limb with SCO/NGT compared to SCO/CAJ on incline and decline

- Significant increased load distribution by 4% Body weight (BW) on orthotic limb with SCO/NGT compared to SCO/CAJ for incline and decline standing ($p<0.05$)
- Signficant decreased load distribution by 4% BW on sound limb (contralateral side) for standing on incline and decline with SCO/NGT ($p<0.05$)

→ Decreased effort to switch to swing phase and more efficient movement pattern with SCO/NGT

- Enhanced reliability of switching of the orthotic knee from stance to swing phase mode with SCO/NGT vs. SCO/CAJ (especially on incline and during short-step walking – compare Figure 1)

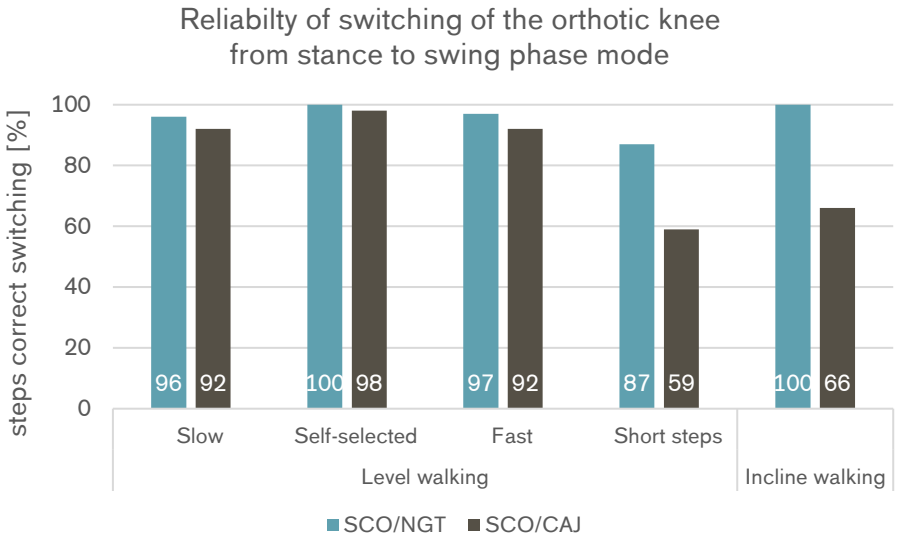


Figure 1: Number of steps with correct switching from locked to unlocked mode of the E-MAG Active knee joint combined with SCO/NGT or SCO/CAJ during different walking speeds

→ Clearly enhanced functionality walking on incline and decline with SCO/NGT

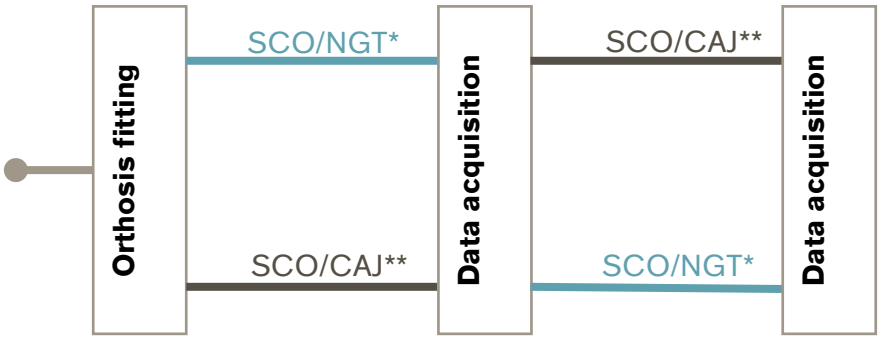
- Increased dorsiflexion of 5° in stance phase during incline walking with SCO/NGT vs. SCO/CAJ ($p<0.05$)
- Earlier transition from decelerating to accelerating forces during ramp ascent with SCO/NGT (at 28% Gait Cycle (GC)) vs. SCO/CAJ (at 34% GC)
  - mean ratio between decelerating and accelerating impulse is significantly reduced with SCO/NGT (SCO/CAJ: 1.48 ± 0.19 vs. SCO/NGT: 0.94 ± 0.24, $p<0.05$)

Population

Subjects:	6 patients with severe lower-limb muscle weakness (n = 2, female)
Indication:	Poliomyelitis (n = 3) Nerve lesion (n = 2) Juvenile arthritis (n = 1)
Previous Orthosis:	Stance-control orthosis (SCO, E-MAG Active) with conventional unilateral orthotic ankle joint design (17LA3N)
Mean age:	42 ± 16 years

Study Design

Randomized, cross-over study design:



* SCO/NGT: Stance-control orthosis (E-MAG Active) with NexGear Tango orthotic ankle joint in full functionality.
** SCO/CAJ: Stance-control orthosis (E-MAG Active) with NexGear Tango orthotic ankle joint in conventional double-action mode.

Patients included in the study were fitted with a Stance-control orthosis (SCO) using the E-MAG Active in combination with the NexGear Tango orthotic ankle joint (NGT). They performed 7 tests at the biomechanics laboratory including level walking at three different speeds (self-selected, slow, and fast), level walking with given short step length of 0.4m, ascending and descending a ramp (inclination 10° and length 3m) and standing on an incline of 10°, a decline of 10° and a level surface (0°) for 30s each. The tests were performed using both SCO with NGT in full functionality and with NGT simulating a conventional ankle joint (CAJ) with limited and uncontrolled range of motion. The order of the experimental conditions was randomized.

Results

Functions and Activities						Participation	Environment
Biomechanics – Static Measurement	**Biomechanics – Gait analysis**	**X-Rays**	**EMG**	**Functional tests**	**Clinical effects**	**Satisfaction**	**Health Economics**

<table>
<tr><th>Category</th><th>Outcomes</th><th>Results**</th><th>Sig.*</th></tr>
<tr><td>Biomechanics-
Static measures</td><td>Standing –
Sagittal ankle joint angle [°]</td><td>Sagittal ankle joint angle:
No differences between SCO/NGT and SCO/CAJ for all three standing conditions
(Incline 10°, Decline 10°, Level 0°)</td><td>0</td></tr>
<tr><td></td><td>Standing –
Load distribution (Ground Reaction Force, GRF)</td><td>Asymmetric load distribution between affected and sound limb while standing on incline/decline
<table>
<tr><th></th><th></th><th>affected side</th><th>sound side</th></tr>
<tr><td>GRF [% BW] SCO/NGT</td><td>Incline
Decline
Level</td><td>39
41
41</td><td>61
59
59</td></tr>
<tr><td>GRF [% BW] SCO/CAJ</td><td>Incline
Decline
Level</td><td>35
37
40</td><td>65
63
60</td></tr>
</table></td><td>++</td></tr>
<tr><td>Biomechanics – Gait analysis***</td><td>Self-selected walking speed</td><td>
<table>
<tr><th>Condition</th><th>SCO/NGT</th><th>SCO/CAJ</th></tr>
<tr><td>Level walking
•Slow
•Self-Selected
•Fast</td><td>[m/s]
0.67
0.89
1.13</td><td>[m/s]
0.71
0.99
1.10</td></tr>
<tr><td>Incline walking</td><td>Mean (SD)
0.37 (0.06)</td><td>Mean (SD)
0.37 (0.01)</td></tr>
</table></td><td>0</td></tr>
<tr><td></td><td>Step length asymmetry</td><td>
<table>
<tr><th>Condition</th><th>Asymmetry [m]
between both ankle joint conditions</th></tr>
<tr><td>Level walking
•Slow
•Self-Selected
•Fast</td><td>
0.01
0.05
0.02</td></tr>
</table>
Asymmetry between affected and sound side during inline/decline walking
<table>
<tr><th>Condition</th><th>Asymmetry [m]
SCO/NGT</th><th>Asymmetry [m]
SCO/CAJ</th></tr>
<tr><td>Incline walking</td><td>Mean (SD)
0.08 (0.06)</td><td>Mean (SD)
0.07 (0.05)</td></tr>
</table></td><td>0</td></tr>
<tr><td></td><td>Maximal dorsi-flexion at terminal stance</td><td>
<table>
<tr><th>Condition</th><th>SCO/NGT</th><th>SCO/CAJ</th></tr>
<tr><td>Level walking
•Slow
•Self-Selected
•Fast</td><td>[mean °]
7.6
8.8
8.7</td><td>[mean °]
5.0
4.6
4.5</td></tr>
</table></td><td>++</td></tr>
</table>

Category	Outcomes	Results**			Sig.*
		Incline walking	*Mean (SD)* 10.3 (2.6)	*Mean (SD)* 5.0 (3.8)	
	External sagittal moments	Using SCO/NGT, sagittal moments acting at the knee and hip joints tended to be reduced in late stance phase.			-
	Transition from decelerating to accelerating forces	Condition	SCO/NGT *[% GC]*	SCO/CAJ *[% GC]*	n.a.
		Incline walking	28	34	
	Ratio between deceleration and accelerating impulse	Condition	SCO/NGT *Mean (SD)*	SCO/CAJ *Mean (SD)*	--
		Incline walking	0.94 (0.24)	1.48 (0.19)	
Functional tests	Reliability of switching from stance to swing phase mode		SCO/NGT *[%]*	SCO/CAJ *[%]*	n.a.
		Level walking •Slow •Self-Selected •Fast •Short steps	 96 100 97 87	 92 98 92 59	
		Incline walking	100	66	

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

** SCO: Stance-control orthosis (here: E-MAG Active), NGT: NexGear Tango ankle joint, CAJ: Conventional Ankle Joint; GRF: Ground Reaction Force; A: Affected side, S: Sound side; SD: Standard Deviation; GC: Gait Cycle, BW: Body Weight

*** No significant differences of biomechanical parameters of the unaffected side, therefore not mentioned in detail in the paper; While decline walking, all patients used step-to pattern and the handrail. Due to that, no differences between the biomechanical parameters with both ankle joints could be expected.

Author's Conclusion

"The biomechanical results showed that for level walking with self-selected speed, the differences between both ankle joint principles were negligible, despite the slight facilitation of achieving the knee switching thresholds and thus functional reliability with the NGT. However, the use of the new ankle principle resulted in relevant benefits in gait situations in unlevel conditions and with higher demands. This is clearly supported by an increased reliability of the orthotic knee joint mechanism and more natural motion patterns. Based on the results of this study, it may also be assumed that walking on uneven ground is improved by increased and resistance-controlled dorsiflexion. Therefore, the new orthotic ankle joint principle represents an additional option to optimize patient fittings with SCOs. It may also be assumed that the new ankle joint principle is beneficial for users of locked KAFOs." (Schmalz et al. 2022)

Author's Affiliations:

[1]Clinical Research and Services/Biomechanics, Ottobock SE & Co. KGaA, Göttingen, Germany
[2]Technische Universität Chemnitz, Institute of Human Movement Science and Health, Chemnitz, Germany
[3]Global Research, Ottobock SE & Co. KGaA, Duderstadt, Germany
[4]Clinical Research and Services, Ottobock Healthcare LP, Austin, Texas