Reference

T. Schmalz[1], S. Rauch[2], H. Drewitz[3], M. Bellmann[4], A. Kannenberg[5]

The Use of Reactive-Dynamic Orthotic Ankle Joints in Different Types of KAFOs: Results of Biomechanical Tests and Patient Evaluations

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Products

C-Brace

Major Findings

With C-Brace and Nexgear Tango (NGT) or conventional ankle joint (CAJ) compared to E-MAG Active / NGT and E-MAG Active / CAJ:

→ Reliable and safe switching from stance to swing phase

- With C-Brace, close to 100% reliability of switching in all cases (level walking, ramps, standing on inclines) independent of the ankle condition
- With E-MAG, high switching reliability only for level walking with both ankle conditions

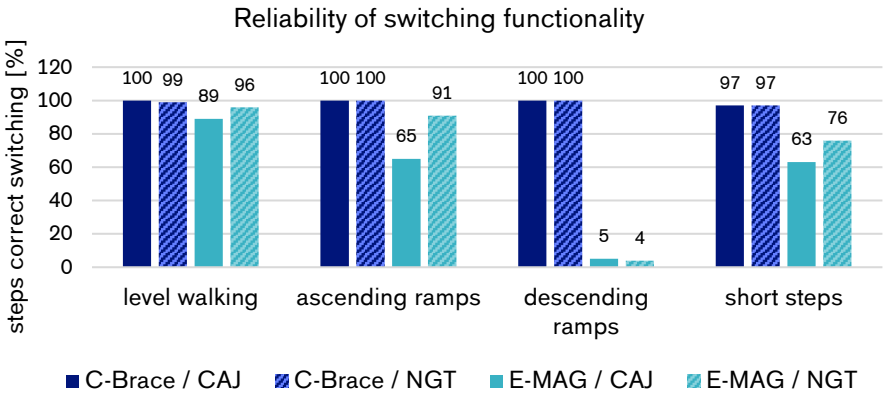


Figure 1. Percentage of steps with correct switching from stance to swing during the biomechanical tests. (CAJ = conventional ankle joint; NGT = Nexgear Tango orthotic ankle joint (reactive dynamic ankle = RDA)).

→ Beneficial biomechanical effects of NGT during level walking and descending and ascending ramps for both C-Brace and E-MAG

- Improved rollover mechanism due to significantly increased dorsiflexion (between 7 and 12 degrees) during late stance with NGT ($p<0.01$)
- Improved push off with NGT due to increased peak ankle power in late stance (C-brace: +245%, E-MAG Active: +288%, $p<0.05$)
- Easier swing phase initiation due to reduced external knee moment during stance with NGT (both: -20%, $p<0.05$)

→ Symmetrical weight distribution between the orthotic and the sound limb with NGT for both KAFOs while standing upwards

- Trend to increased dorsiflexion while standing with NGT for both KAFOs

→ Greater perceived usefulness with C-Brace than with E-MAG Active

- C-Brace was rated better than E-MAG Active across all motion tasks
- NGT was rated as beneficial by patients (better ratings than conventional ankle joints (CAJ) in both KAFOs)

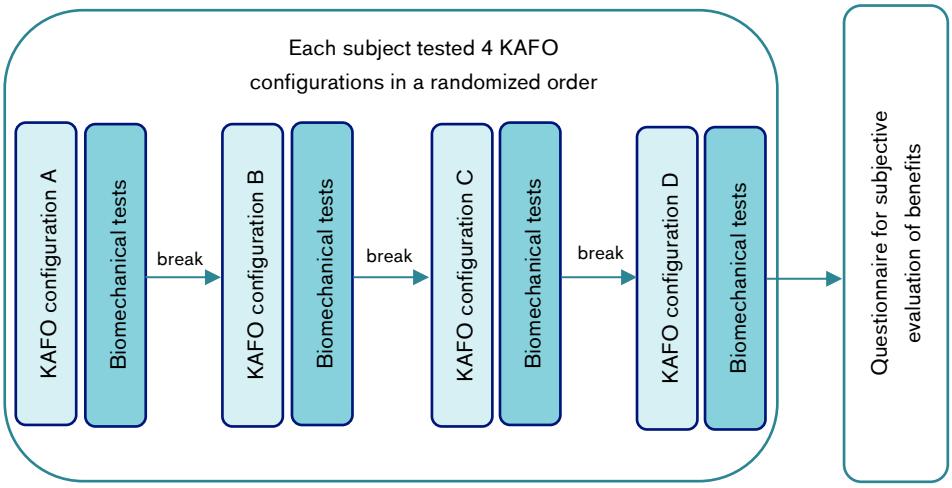
→ SCO functionality (stance control orthoses) can be slightly improved with reactive-dynamic ankles like the NGT

Population

Subjects:	n = 5 (3 female, 2 male)
Previous KAFO:	C-Brace (worn for 3 to 8 yrs)
KAFO in study:	C-Braces with CAJ were equipped NGT (represents RDA mechanism) E-MAG Active SCOs equipped with NGT were fabricated for each patient modular construction of NGT, allowed all orthoses to be adjusted to work as KAFOs with CAJ or NGT.
Mean age:	49 ± 16 yrs
Affected side:	2 left, 3 right

Study Design

Cross-sectional study based on biomechanical tests and patient-reported evaluations:



All patients had been users of the microprocessor-controlled C-Brace for periods between 3 and 8 years.

All four configurations **(C-Brace with NGT, C-Brace with CAJ, E-MAG with NGT and E-MAG with CAJ)** were tested with every patient in randomized order on the same day. Between the test procedures for each orthotic configuration, the patients rested for 45 minutes.

Results

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

Category	Outcomes	Results for C-Brace and E-MAG	Sig.[a,b]
Biomechanics – Gait analysis Level Walking	Self-selected walking speed	No sig. differences in **mean self-selected speed**:	0
	Step length asymmetry	No sig. differences in **step length asymmetry** between orthotic and sound limb:	0

C-Brace/CAJ	C-Brace/NGT	E-MAG/CAJ	E-MAG/NGT
1.02 m/s	0.98 m/s	0.90 m/s	0.96m/s

Category	Outcomes	Results for C-Brace and E-MAG				Sig.[a,b]
		C-Brace/CAJ	C-Brace/NGT	E-MAG/CAJ	E-MAG/NGT	
		0.04m	0.05m	0.05m	0.03m	
	Dorsiflexion in late stance	Mean maximum dorsiflexion in late stance was significantly increased with NGT compared to CAJ for both KAFOs ($p < 0.01$ for both):				++
		C-Brace/CAJ	C-Brace/NGT	E-MAG/CAJ	E-MAG/NGT	
		3.0° ± 1.3°	10.8° ± 3.5°	5.0°± 2.2°	11.8° ± 3.2°	
	Ankle power	Ankle power peak value was significantly increased with NGT ($p < 0.05$ for both):				++
		C-Brace/CAJ	C-Brace/NGT	E-MAG/CAJ	E-MAG/NGT	
		0.29 ± 0.06 W/kg	1.00 ± 0.26 W/kg	0.25 ± 0.14 W/kg	0.97 ± 0.54 W/kg	
	Knee flexion stance phase	Marginal and not significant differences in knee flexion during stance between all orthotic configurations.				0
	Knee flexion swing phase	Trend for higher knee flexion during swing phase with E-MAG Active:				+
		C-Brace/CAJ	C-Brace/NGT	E-MAG/CAJ	E-MAG/NGT	
		59°	59°	63°	65°	
	Knee joint moment	Significantly reduced external sagittal knee joint moment for the orthotic side with NGT compared to CAJ for both orthotic joints ($p < 0.05$ for both) (peak values at 40% GC):				––
		C-Brace/CAJ	C-Brace/NGT	E-MAG/CAJ	E-MAG/NGT	
		0.60 ± 0.18 Nm/kg	0.48 ± 0.15 Nm/kg	0.50 ± 0.14 Nm/kg	0.40 ± 0.11 Nm/kg	
Biomechanics – Gait analysis Ascending ramps	Dorsiflexion in late stance	Significantly increased **max. dorsiflexion in late stance** with NGT compared with CAJ for both ($p < 0.01$):				++
		C-Brace/CAJ	C-Brace/NGT	E-MAG/CAJ	E-MAG/NGT	
		3.8° ± 2.2°	13.4° ± 3.2°	5.9° ± 2.5°	16.6° ± 2.5°	
	Ankle power moment	**Significantly increased mean ankle power peak value** with NGT for both orthotic joints ($p < 0.05$ for both):				++
		C-Brace/CAJ	C-Brace/NGT	E-MAG/CAJ	E-MAG/NGT	
		0.30 ± 0.23 W/kg	1.04 ± 0.66 W/kg	0.34 ± 0.31 W/kg	1.02 ± 0.51 W/kg	

<table>
<tr><th>Category</th><th>Outcomes</th><th>Results for C-Brace and E-MAG</th><th>Sig.[a,b]</th></tr>
<tr><td></td><td>Knee flexion side stance phase</td><td>Similar knee flexion angles during stance phase for the orthotic side for all KAFO configurations:
- The joint was minimally flexed at initial contact and nearly fully extended between 20%and 50% of the gait cycle
- Maximum flexion angle was slightly but not significantly higher with E-MAG Active than with C-Brace</td><td>+</td></tr>
<tr><td></td><td>Sagittal knee moment</td><td>Significant reduction of peak sagittal knee moment values for the orthotic side with NGT in C-Brace (p<0.05).
Only a trend to reduced peak sagittal knee moment values for E-MAG Active with NGT.
<table><tr><th>C-Brace/CAJ</th><th>C-Brace/NGT</th><th>E-MAG/CAJ</th><th>E-MAG/NGT</th></tr><tr><td>0.78 ± 0.33 Nm/kg</td><td>0.67 ±0.34 Nm/kg</td><td>0.66 ± 0.32 Nm/kg</td><td>0.53 ± 0.17 Nm/kg</td></tr></table></td><td>––
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<tr><td></td><td></td><td>Orthotic side thigh segment angle
Similar values over the complete gait cycle for all configurations.</td><td>n.a.</td></tr>
<tr><td></td><td></td><td>Biomechanical parameters of the unaffected side
No significant effects resulting from the ankle joint configurations.</td><td>0</td></tr>
<tr><td>Biomechanics – Gait analysis
Descending ramps</td><td>Motion pattern</td><td>C-Brace: Microprocessor controlled hydraulic resistance for yielding motions enabled continuous flexion during weight bearing with mean maximum flexion angles of 64° (CAJ) or 66° (NGT).
E-MAG Active: Knee joint fully extended over the entire gait cycle.</td><td>n.a.</td></tr>
<tr><td></td><td></td><td>Biomechanical parameters for both KAFO configurations were mostly unaffected by the orthotic ankle joint used.</td><td>n.a.</td></tr>
<tr><td>Biomechanics – Gait analysis
Standing on Inclines</td><td>Vertical ground reaction force</td><td>- Trending lower for the orthotic side compared to the sound side
- Level ground: mean values between 45% and 47% bodyweight
- Decline: between 40% and 43% bodyweight</td><td>–</td></tr>
<tr><td></td><td></td><td>Significantly increased vertical ground reaction forces on orthotic side with NGT for both orthotic joints while standing on an incline (p<0.05):
<table><tr><th>C-Brace/CAJ</th><th>C-Brace/NGT</th><th>E-MAG/CAJ</th><th>E-MAG/NGT</th></tr><tr><td>37% BW</td><td>45% BW</td><td>38% BW</td><td>45% BW</td></tr></table></td><td>++</td></tr>
<tr><td></td><td>Dorsiflexion</td><td>Trend to higher dorsiflexion with NGT for both KAFOs (respectively 1° CAJ and 4° NGT).</td><td>+</td></tr>
<tr><td>Functional tests</td><td>Reliability of switching functionality</td><td>C-Brace:
- 100% for level walking, ascending ramps, descending ramps for CAJ and NGT
- 97% for short steps for CAJ and NGT</td><td>n.a.</td></tr>
<tr><td></td><td></td><td>E-MAG Active:
- Level walking 89% CAJ / 96% NGT
- Descending ramps: orthotic knee mechanism remained mainly in locked mode (5% CAJ / 4% NGT)
- Ascending ramps & short steps: switching reliability was lower with CAJ (65% & 63%) than with NGT (91% & 76%)</td><td>n.a.</td></tr>
</table>

Category	Outcomes	Results for C-Brace and E-MAG	Sig.[a,b]
Satisfaction	Perceived usefulness	Higher mean usefulness score for C-Brace than with E-MAG Active	
		Higher mean usefulness score with NGT than with CAJ for both KAFOs.	
		Significant differences ($p<0.05$) in mean usefulness scores for: - Level walking – C-Brace/NGT vs. E-MAG/NGT - Level walking – C-Brace/CAJ vs. E-MAG Active/CAJ - Short steps – C-Brace/NGT vs. E-MAG/NGT - Ascending ramps – C-Brace/NGT vs. C-Brace/CAJ - Descending ramps – C-Brace/NGT vs. E-MAG/NGT and C-Brace/CAJ vs. E-MAG/CAJ - Upward standing – C-Brace/NGT vs. C-Brace/CAJ - Downward standing – C-Brace/NGT vs E-MAG/NGT and C-Brace/CAJ vs E-MAG/CAJ and C-Brace/NGT vs C-Brace/CAJ	

[a] no difference (0), positive trend (+), negative trend (–), significant (++/––), not applicable (n.a.)
[b] significance set at $p<0.05$; trends set at $0.1>p>0.05$

Author's Conclusion

"It can be concluded that the novel RDA joint represents an additional and beneficial option for the individual optimization of KAFOs, in particular for patients who must master varying terrains and walking conditions frequently in their daily lives. Clinical Relevance: The use of the RDA new orthotic ankle mechanism tested in the present study results in relevant benefits, especially in gait situations in nonlevel conditions for KAFOs with different orthotic knee joint mechanisms. Therefore, this mechanism represents an additional option to optimize patient fittings with a KAFO." (Schmalz et al., 2025)

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