Microprocessor Controlled Knee Ankle Foot Orthosis (KAFO) vs. Stance Control vs. Locked KAFO: A Randomized Control Trial


**Products**

C-Brace

**Major Findings**

With C-Brace compared to unilateral KAFO or Stance Control Orthosis (SCO):

- Sign. Improvements in mobility and gait
  - Increased self-selected walking speed (10MWT, 6MWT)
  - Increased independence during descending stairs
- Sign. Improvements in static and dynamic balance
  - Increased BBS (scores < 40 associated with 100% fall risk)
  - Increased FGA scores
- Improvements in quality of life and satisfaction
- Sign. Reduction of self-reported falls

with C-Brace (5) versus SCO (38) or locked KAFO (15)

SSV = self-selected velocity; Error bars denote standard deviation

**Population**

- Subjects: 18
- Previous orthosis: SCO (n=5)
  - Locked KAFO (n=13)
- Epidemiology:
  - Poliomyelitis (n=9)
  - Peripheral nerve injury (n=2)
  - Traumatic SCI (n=4)
  - West Nile encephalitis (n=1)
  - Peripheral neuropathy (n=1)
  - Traumatic brain injury (n=1)
- Mean age: 54.6 ±12.9yrs
Randomized cross-over Trial:

- **Baseline assessment** c Randomized to C-Brace or SCO
- **1 month a** Data collection c Cross-over
- **1 month b + 1 month a** Data collection c Re-training with own orthosis (if necessary)

### Study Design

- **Fitting and Assessment** C-Brace & SCO
- **Current SCO/locked KAFO**
- **1 month a**

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### Results

**Functions and Activities**

<table>
<thead>
<tr>
<th>Category</th>
<th>Outcomes</th>
<th>Results for C-Brace vs SCO</th>
<th>Sig.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Biomechanics – Static measures</strong></td>
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<tr>
<td></td>
<td>6MWT [m]</td>
<td>278.64 (29.13)</td>
<td>331.25 (27.25)</td>
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<td>10MWT-SSV [m/s]</td>
<td>0.77 (0.07)</td>
<td>0.90 (0.06)</td>
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<tr>
<td></td>
<td>10MWT-FV [m/s]</td>
<td>1.03 (0.10)</td>
<td>1.14 (0.08)</td>
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<td></td>
<td>FGA</td>
<td>14.89 (1.11)</td>
<td>19.16 (0.70)</td>
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<td></td>
<td>Berg Balance Scale</td>
<td>35 (3)</td>
<td>42 (2)</td>
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<tr>
<td></td>
<td>5xSST [s]</td>
<td>21.8 (3.16)</td>
<td>22.03 (2.13)</td>
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<td></td>
<td>Cross Walk Test [s]</td>
<td>27.87 (3.33)</td>
<td>23.41 (2.52)</td>
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<tr>
<td><strong>Ramps and stairs</strong></td>
<td>HAI (descension 10° ramp)</td>
<td>6.16 (0.74)</td>
<td>7.39 (0.53)</td>
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<tr>
<td></td>
<td>SAI (descension flight of stairs)</td>
<td>2.61 (0.23)</td>
<td>7.50 (0.86)</td>
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<td>Ramp up [s]</td>
<td>20.74 (3.14)</td>
<td>16.07 (1.56)</td>
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<td>Ramp down [s]</td>
<td>23.05 (4.10)</td>
<td>17.51 (2.29)</td>
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<td>Stairs up [s]</td>
<td>41.40 (9.14)</td>
<td>39.10 (5.85)</td>
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<td></td>
<td>Stairs down [s]</td>
<td>39.39 (5.27)</td>
<td>36.87 (4.87)</td>
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<tr>
<td><strong>Clinical Effect</strong></td>
<td>mFES</td>
<td>8.11 (0.40)</td>
<td>7.91 (0.46)</td>
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<tr>
<td></td>
<td>Falls</td>
<td>15</td>
<td>5</td>
</tr>
</tbody>
</table>

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*a* home-use with community mobility monitoring

*b* 6 training visits in 1st month

*c* functional and subjective assessments

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The MPO, a knee-ankle-foot orthosis that dampens loaded knee flexion and speed adapted control of knee flexion and extension during the stance and swing phase, may allow improved gait speed, endurance, static & dynamic balance, quality of life, health status and reduced self-reported falls for individuals with lower-extremity impairments, due to increased safety and participation in their community. Users within a wide range of walking speed and postural stability may benefit from using the MPO." (Deems-Dluhy et al. 2020)