Functional assessment and satisfaction of transfemoral amputees with low mobility (FASTK2): A clinical trial of microprocessor-controlled vs. non-microprocessor-controlled knees


With C-Leg Compact, Rheo 3, Orion 2 and Plié 3 compared to NMPKs:

Transfemoral amputees with limited mobility clearly benefit from MPKs:

→ Activity
  - Subjects spent significantly less time sitting ($p = 0.01$) and increased the amount of upright activity ($p = 0.02$).
  - Complexity of the gait, as measured by the entropy**, increased by 25%, indicating a less pathological movement.

→ Safety
  - Significant reduction in falls ($p = 0.01$)

→ Satisfaction:
  - Significant improvement in PEQ satisfaction subscales ($p < 0.01$).
  - Greatest improvements were seen in subscales ambulation, appearance and utility.

Activity in the free-living environment for the three time points of the study. When using the MPK, there was a significant increase in the amount of active time during the day ($p = 0.02$) (Kaufman et al, 2018).

### Products

C-Leg Compact, Rheo 3, Orion 2, Plié 3, NMPKs

### Major Findings

Reference

Kaufman K*, Bernhardt K*, Symms K**.

*Motion Analysis Laboratory, Mayo Clinic, 200 First Street SW, Rochester, MN 55905, USA. **Hanger Clinic, 10910 Domain Drive, Suite 300, Austin, Tx 78758, USA
**Population**

Subjects: 50 (28 males) unilateral transfemoral amputees

Previous prosthesis: Polycentric knee, friction brake, hydraulic, pneumatic

Amputation causes: Peripheral arterial disease (50%), Total knee arthroplasty infection (14%), infection (12%), trauma (10%), deep vein thrombosis (8%), cancer (4%) and blood disorder (2%)

Mean age: 69 ± 9 years

Mean time since amputation: 1.5 years

MFCL: K2 (n=48) and K3 (n=2)

**Study Design**

Interventional, non-randomized, crossover study

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**Results**

<table>
<thead>
<tr>
<th>Activities</th>
<th>Category</th>
<th>Outcomes</th>
<th>NMPK (Baseline)</th>
<th>MPK (after 10 weeks on MPK)</th>
<th>NMPK (after 4 weeks on NMPK)</th>
<th>Sig.*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Safety</td>
<td>Falls</td>
<td>2.0 (IQR: 0.0 – 6.0)</td>
<td>0.0 (IQR: 0.0-6.0)</td>
<td>3.0 (IQR: 0.0-3.0)</td>
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<tr>
<td></td>
<td>Activity, Mobility,</td>
<td>Time spent sitting</td>
<td>61 ± 5%</td>
<td>52 ± 3%</td>
<td>64 ± 3%</td>
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<tr>
<td></td>
<td>Activities of Daily</td>
<td>Time being active</td>
<td>16 ± 2%</td>
<td>20 ± 2%</td>
<td>18 ± 2%</td>
<td>++</td>
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<td></td>
<td>Living (ADLs)</td>
<td>Complexity of the gait</td>
<td>0.14 (IQR: 0.05–0.27)</td>
<td>0.17 (IQR: 0.07-0.32)</td>
<td>0.16 (IQR: 0.07–0.45)</td>
<td>+</td>
</tr>
<tr>
<td></td>
<td>Preference, Satisfaction,</td>
<td>PEQ</td>
<td>There was a significant improvement in PEQ satisfaction subscales when using the MPK. The greatest improvements were in ambulation, appearance and utility.</td>
<td>++</td>
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<td>Quality of Life (QoL)</td>
<td></td>
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</tbody>
</table>

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

** the sample entropy is used for assessing the complexity of physiological time-series signals. In this case, a more physiological gait is characterized by higher entropy i.e. a more complex, random gait pattern.
Author's Conclusion

"This clinical trial confirmed that the provision of a MPK to patients with a TFA and low, i.e. K2, mobility will result in improved function in the free-living environment, a reduction in falls and subsequently improved patient satisfaction." (Kaufman et al., 2018)