Evidence for the Benefits of Microprocessor Controlled Prosthetic Knees

Andreas Kannenberg, MD PhD, Executive Medical Director North America
Passive microprocessor-controlled prosthetic knees

- Genium / X3
  (Ottobock, Germany)

- C-Leg (4) / C-Leg Compact

- Rheo Knee
  (Össur, Iceland)

- Orion
  (Endolite, UK)

- Plié
  (Freedom Innovations, USA)
Different principles of the passive MPKs (1)

**Default stance**
- Genium / X3
- C-Leg / C-Leg Compact
- Kenevo
- Orion
- Plié

Always in stance resistance, unless switched into swing.

“Whether a stumble or fall will result from an unexpected step onto a flexed knee depends greatly on the MPK default setting. MPKs with swing phase knee resistance default settings require great compensatory movements; otherwise, falls occur even in younger people whose amputation etiologies were nondysvascular.”

**Default swing**
- Rheo Knee

Always in swing resistance, unless switched into stance.

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Different principles of the passive MPKs (2)

Separate simultaneous control of flexion and extension resistance
- Genium / X3
- C-Leg / C-Leg Compact
- Kenevo
- Orion

High stance flexion resistance for stumble recovery during low extension resistance for swing.

!!! SAFETY !!!

One resistance only for both flexion and extension at a time
- Rheo Knee
- Plié

Needs to switch into stance first in case of a stumble to provide high flexion resistance.
Different principles of the MPKs (3)

**MP stance and swing control**
- Genium / X3
- C-Leg
- Rheo Knee
- Orion

**MP stance control**
- C-Leg Compact
- Kenevo

**MP switch, but non-MP stance and swing control**
- Plié
English language publications on different MPKs

- C-Leg / C-Leg Compact: 49 publications
- Genium/X2: 10 publications
- Rheo Knee: 5 publications
- Orion: 1 publication
- Plié: 1 publication
Safety of the C-Leg:
Less stumbles and falls, improved balance

Wetz HH et al., Orthopäde 2005, 34: 298-319
Chin T et al., POI 2006, 30(1): 73-80
Segal AD et al., JRRD 2006, 43: 857-870
Kaufman KR et al., Gait & Posture 2007, 26: 489-493
Schmalz T et al., Gait & Posture 2007, 25: 267-278
Kahle JT et al., JRRD 2008, 45: 1-14
Drerup B et al., Orthopädie-Technik 2008, 3: 169-174
Blumentritt S et al., J Prosthet Orthot 2009, 21 (1): 2-15
Hafner BJ et al., JRRD 2009, 46 (3): 417-434
Blumentritt, S et al., Orthopädie-Technik 2010, 11: 788-799
Systematic Review of C-leg Research

- 18 studies comparing the C-leg to mechanical prosthetic knees were reviewed
  - 7 studies on safety
  - 8 studies on energy efficiency
  - 3 studies on cost-effectiveness (Sweden, Italy, Netherlands)

- Methodologic quality of the safety and energy efficiency studies was rated low to moderate
- Methodological quality of the cost-effectiveness studies was rated high

Safety – Summary of the systematic review

“Five of these seven studies provide consistent, statistically significant findings of improvements in self-reported reduction of stumbles and falls and improved balance. Additional non-statistically significant improvements support the latter findings and include knee stability in conditions resulting in collapse of other knees and improved balance confidence.”

“In total, these seven studies provide a grade “B“ recommendation.“

Blumentritt S et al., 2009

Study design

Biomechanical study comparing the safety of the C-leg, 3R80, and Mauch SNS (3C1) in repeated challenges in three experienced TF amputees (2 K4, 1 K3)

Tested challenges:
- sudden stop on the prosthetic side
- sidestepping on the prosthetic side
- stepping onto an obstacle (under the heel, midfoot, forefoot)
- tripping (interruption of knee extension during terminal swing)
Sudden stop on the prosthetic leg

<table>
<thead>
<tr>
<th>Sudden stop on the prosthetic side</th>
<th>Sudden stop on the prosthetic side with step to the side</th>
</tr>
</thead>
<tbody>
<tr>
<td>safe</td>
<td>safe</td>
</tr>
<tr>
<td>C-leg</td>
<td>safe</td>
</tr>
<tr>
<td>safe</td>
<td>safe</td>
</tr>
<tr>
<td>Hybrid</td>
<td>safe</td>
</tr>
<tr>
<td>compensatory movements</td>
<td>compensatory movements</td>
</tr>
<tr>
<td>incidental knee collapse</td>
<td>incidental knee collapse</td>
</tr>
<tr>
<td>Adaptive</td>
<td>incidental knee collapse</td>
</tr>
</tbody>
</table>

Sudden stop on the prosthetic leg (C-Leg)

Courtesy Micheal Leach, Otto Bock USA
Tripping...

...caused by a rapid tug on a thin cord attached to the prosthetic foot to interrupt swing extension at different knee angles.

Tripping

Hybrid Knee  C-leg

Tripping at different knee angles

<table>
<thead>
<tr>
<th>Knee Flexion Angle at Perturbation</th>
<th>C-leg</th>
<th>Hybrid</th>
<th>Rheo</th>
<th>Adaptive</th>
</tr>
</thead>
<tbody>
<tr>
<td>10° - 20°</td>
<td>13</td>
<td>0</td>
<td>7</td>
<td>15</td>
</tr>
<tr>
<td></td>
<td>20</td>
<td>9</td>
<td>6</td>
<td>21</td>
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<td></td>
<td>24</td>
<td>10</td>
<td>2</td>
<td>21</td>
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<td>26</td>
<td>4</td>
<td>3</td>
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<td>28</td>
<td>4</td>
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<td></td>
<td>31</td>
<td>12</td>
<td>8</td>
<td>30</td>
</tr>
<tr>
<td></td>
<td>33</td>
<td>9</td>
<td>1</td>
<td>32</td>
</tr>
<tr>
<td>21° - 35°</td>
<td>29</td>
<td>10</td>
<td>2</td>
<td>21</td>
</tr>
<tr>
<td></td>
<td>27</td>
<td>5</td>
<td>3</td>
<td>33</td>
</tr>
<tr>
<td></td>
<td>35</td>
<td>14</td>
<td>1</td>
<td>34</td>
</tr>
<tr>
<td></td>
<td>36</td>
<td>18</td>
<td>5</td>
<td>36</td>
</tr>
<tr>
<td></td>
<td>39</td>
<td>29</td>
<td>4</td>
<td>36</td>
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<td></td>
<td>42</td>
<td>27</td>
<td>4</td>
<td>37</td>
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<tr>
<td></td>
<td>43</td>
<td>14</td>
<td>2</td>
<td>39</td>
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<td></td>
<td>45</td>
<td>34</td>
<td>8</td>
<td>37</td>
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<td></td>
<td>48</td>
<td>26</td>
<td>6</td>
<td>40</td>
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<td>49</td>
<td>27</td>
<td>1</td>
<td>42</td>
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<td></td>
<td>49</td>
<td>29</td>
<td>7</td>
<td>44</td>
</tr>
<tr>
<td></td>
<td>50</td>
<td>34</td>
<td>7</td>
<td>45</td>
</tr>
<tr>
<td>35° - 55°</td>
<td>52</td>
<td>37</td>
<td>6</td>
<td>48</td>
</tr>
<tr>
<td></td>
<td>53</td>
<td>26</td>
<td>1</td>
<td>50</td>
</tr>
</tbody>
</table>

Maximum “knee perturbation angle“ that can be compensated by the different MP knees:

- C-leg 35°
- Rheo 30°
- Hybrid 30°
- Adaptive 20°
- Mauch SNS/Ca-Tech 20°
- Other mechanical knees 10°

- no problems
- heavy compensation
- fall

# Safety outcomes in the K2 population

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Safety related outcome measures</td>
<td>Number of stumbles and falls</td>
<td>VAS on number and frequency of stumbles and falls, confidence while walking and frustration with falls</td>
<td>Timed up and go test (TUG), Activity-specific Balance Confidence Scale (ABC scale)</td>
</tr>
<tr>
<td>Results with statistical significance (p&lt;0.05) in favor of the MPK</td>
<td><strong>Number of falls</strong> decreased 81% from 2.1±1.5 to 0.4±0.7 (p=0.05)*.</td>
<td><strong>Stumble frequency</strong> decreased 15.8% (p=0.05).</td>
<td><strong>TUG</strong> decreased 28% from 24.5 s to 17.7 s (p=0.018).</td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Number of falls</strong> decreased 80% (p=0.01).</td>
<td><strong>Balance</strong> (ABC) improved 26% from 60.1 to 75.7 (p=0.001).</td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Falls frequency</strong> decreased 4.5% (p=0.01).</td>
<td></td>
</tr>
<tr>
<td>Results with statistical trend (p&lt;0.10) in favor of the MPK</td>
<td>none</td>
<td><strong>Confidence while walking</strong> improved 12% (p=0.08).</td>
<td>none</td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Frustration with falls</strong> decreased 23.4% (p=0.06).</td>
<td></td>
</tr>
<tr>
<td>No statistical difference between MPK and NMPK</td>
<td>Number of stumbles</td>
<td><strong>Embarrassment with falls</strong> Number of stumbles Frequency and number of semicontrolled falls</td>
<td>none</td>
</tr>
<tr>
<td>Results with statistical significance (p&lt;0.05) or trend (p&lt;.10) in favor of the NMPKs</td>
<td>none</td>
<td>none</td>
<td>none</td>
</tr>
</tbody>
</table>

*post-hoc statistical analysis of published raw data using the Wilcoxon signed rank test*
non-MPK

C-leg

Courtesy of Michael Leach, CPO, Ottobock
Which clinical benefits can be supported by evidence?

C-Leg/Compact vs. non-MPK’s


Which clinical benefits can be supported by evidence?
C-Leg/Compact vs. non-MPK’s in K2 patients

- Up to 80% reduction in falls, reduced risk of falling, improved balance confidence
- 14-25% faster walking speed on level ground
- 20% faster walking speed on uneven terrain
- 30% faster slope descent, improved quality of stair descent
- Improved performance in activities of community ambulation – about 50% of K2
- Improved mobility level to K3
- Improved indoor ADL performance

Improved slope ambulation and reduced cognitive load

Courtesy of Dale Berry, CPO, Hanger Clinic
Improved stair ambulation and multi-tasking

Courtesy of Dale Berry, CPO, Hanger Clinic
The Genium Bionic Prosthetic Knee: A Further Advancement of MPKs

Andreas Kannenberg, MD PhD, Executive Medical Director North America
Clinical study Genium v. C-Leg v. able-bodied subjects

**Objective**
to compare Genium and C-Leg in K3 unilateral TF amputees in terms of:
- function
- safety
- quality of life

**Study population**
- 20 amputees (16 males, 4 females, age 46.5 ± 14.2 yrs)
  - unilateral MFCL-3 TF or knee disarticulation
  - experience with the C-Leg for at least 1 year
- 5 able-bodied subjects as physiologic controls
Study design Genium v. C-leg

- Enrolled patients
- Randomization
- C-Leg
- Genium
- C-Leg
- Genium
- C-Leg

2 weeks
acclimation: 67.9±27.1 days

acclimation: 67.9±27.1 days

2 weeks

60 days
Genium v. C-Leg

Outcome measures

Prosthesis Evaluation Questionnaire (PEQ) and its subdomains
- Ambulation
- Utility
- Well-Being
- Perceived response
- Sounds
- Residual limb health
- Social burden
- Frustration
- Appearance

measure perceived prosthetic function and prosthesis-related quality of life using an ordinal scaling (0-7).

Results: PEQ (*p≤ .05)

Results: PEQ

Histograms

- Utility
- Social burden
- Residual limb health

- C-Leg
- Genium
Results: Individual PEQ items and aggregate score

<table>
<thead>
<tr>
<th>Survey Section</th>
<th>Valued Scale</th>
<th>Item</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>No.</td>
<td>Topic</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>Prosthesis</td>
<td>Utility</td>
<td>Comfort standing when using your prosthesis</td>
</tr>
<tr>
<td>1</td>
<td>Prosthesis</td>
<td>Utility</td>
<td>How often you felt off balance</td>
</tr>
<tr>
<td>4</td>
<td>Mobility</td>
<td>Ambulation</td>
<td>Ability to walk in close spaces using prosthesis</td>
</tr>
<tr>
<td>4</td>
<td>Mobility</td>
<td>Ambulation</td>
<td>How you felt using prosthesis going down stairs</td>
</tr>
<tr>
<td>4</td>
<td>Mobility</td>
<td>Ambulation</td>
<td>Ability to walk up steep hill using prosthesis</td>
</tr>
<tr>
<td>4</td>
<td>Mobility</td>
<td>Ambulation</td>
<td>Ability to walk down steep hill using prosthesis</td>
</tr>
<tr>
<td>4</td>
<td>Mobility</td>
<td>Ambulation</td>
<td>Ability to walk on slippery surfaces using prosthesis</td>
</tr>
<tr>
<td>5</td>
<td>Satisfaction</td>
<td>N/A</td>
<td>How satisfied with your prosthesis</td>
</tr>
<tr>
<td>5</td>
<td>Satisfaction</td>
<td>N/A</td>
<td>How satisfied with how you are walking</td>
</tr>
<tr>
<td>5</td>
<td>Satisfaction</td>
<td>N/A</td>
<td>How satisfied with training on current prosthesis</td>
</tr>
</tbody>
</table>

*Comparisons were considered statistically significant at a Bonferroni corrected α of p ≤ 0.025.

**Aggregate PEQ score (items of all subdomains) is significantly higher when using Genium (p<.001).**

Physical Functional Performance Measure (PFP-10)

10 ADLs
- Carry a weighted pot a distance of 1 m
- Donning and removing a jacket
- Place and remove a sponge from an adjustable shelf
- Floor sweeping with broom and dustpan
- Pick up four scarves from the floor
- Sit and stand up from the floor
- Carry groceries
- Stair climbing
- Moving laundry from washer to dryer
- 6 minute walk test

PFP-10 Subdomains
- Upper body strength
- Upper body flexibility
- Lower body strength
- Balance and Coordination
- Endurance

Results: PFP-10 subdomains

Results: PFP-10 subdomain summary

Able-bodied subjects v. amputees with Genium
- significantly higher score only in the endurance domain (p=.05)
- no differences in the CS-PFP total score and the other 4 domains

Able-bodied subjects v. amputees with C-Leg
- Significantly higher scores in the CS-PFP total score and 4/5 domains, except upper body strength

Genium v. C-Leg
- Significantly higher CS-PFP total score (p=.03)
- Significantly higher scores in 3/5 domains (upper body flexibility, balance, endurance), except upper body strength and lower body strength
Study design

14 wounded servicemembers with a unilateral transfemoral amputation were studied for

- the self-sected strategy to ascend stairs (Stair Assessment Index [SAI])
- gait biomechanics during walking upstairs

when using the Ottobock X2® MP controlled prosthetic knee (mean acclimation 130 ± 41 days) as compared to the C-Leg (12 pts.) or the Total Knee (2 pts.).

## Stair Assessment Index (SAI)

<table>
<thead>
<tr>
<th>Score</th>
<th>Mobility Descriptor</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Cannot do/ refuses to do</td>
</tr>
<tr>
<td>1</td>
<td>Needs assist</td>
</tr>
<tr>
<td>2</td>
<td>With rail and assistive device, step-to pattern</td>
</tr>
<tr>
<td>3</td>
<td>With rail, step-to pattern</td>
</tr>
<tr>
<td>4</td>
<td>With assistive device, step-to pattern</td>
</tr>
<tr>
<td>5</td>
<td>Without rail or assistive device, step-to pattern</td>
</tr>
<tr>
<td>6</td>
<td>With rail and assistive device, skipping step pattern</td>
</tr>
<tr>
<td>7</td>
<td>With rail, skipping step pattern</td>
</tr>
<tr>
<td>8</td>
<td>With assistive device, skipping step pattern</td>
</tr>
<tr>
<td>9</td>
<td>Without rail or assistive device, skipping step pattern</td>
</tr>
<tr>
<td>10</td>
<td>With rail and assistive device, step-over-step pattern</td>
</tr>
<tr>
<td>11</td>
<td>With rail, step-over-step pattern</td>
</tr>
<tr>
<td>12</td>
<td>With assistive device, step-over-step pattern</td>
</tr>
<tr>
<td>13</td>
<td>Without rail or assistive device, step-over-step pattern</td>
</tr>
</tbody>
</table>

## Results

### Self-selected stair ascend strategy

<table>
<thead>
<tr>
<th></th>
<th>step-over-step (A)</th>
<th>step-to (B)</th>
<th>skip-step (C)</th>
</tr>
</thead>
<tbody>
<tr>
<td>X2</td>
<td>10</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>C-Leg / NMPK</td>
<td>1</td>
<td>10</td>
<td>3</td>
</tr>
</tbody>
</table>

Results

Stair Assessment Index (SAI) - medians

<p>| | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>X2</td>
<td>11</td>
<td>(step-over-step with handrail use)</td>
<td></td>
</tr>
<tr>
<td>C-Leg</td>
<td>5</td>
<td>(step-to without handrail use)</td>
<td></td>
</tr>
</tbody>
</table>

→ Significantly improved quality of stair ascend (p=.005).

Which clinical benefits can be supported by evidence?
Genium/X3 vs. “standard“ MPK´s (e. g. C-Leg)

- improved and more consistent, speed-independent toe clearance due to improved swing knee flexion control (Bellmann et al. 2012, Lura et al. 2015)
- improved swing release and toe clearance in small steps (Bellmann et al. 2012)
- safe walking backwards (Kannenberg et al. 2013)
- improved knee flexion and thus toe clearance in slope ascent and descent (Bellmann et al. 212, Lura et al. 2015), greater perceived ease of slope negotiation (Kannenberg et al. 2013)
- tendency to greater ease of uneven terrain negotiation (Highsmith et al. 2014, Kannenberg et al. 2013)
- Greater perceived safety and ease of ADL execution (Kannenberg et al. 2013) and improved prosthetic function (Highsmith et al. 2014)
- improved ability to stand still for longer periods of time (Bellmann et al. 2012)
Genium/X3: Stair climbing
Genium/X3: Stepping over obstacles

Stepping over obstacles with the prosthesis (left leg)
Thank you for your attention.

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