Impact of C-LEG on mobility, satisfaction and quality of life in a multicenter cohort of femoral amputees

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With C-Leg compared to previous knee joint (mostly non-microprocessor controlled knees “NMPKs”):

- **Significantly increased mobility**
  LCI-5 global score increased significantly by 11.2%

- **Higher satisfaction**
  QUEST 2.0 global score increased significantly by 19.6%

- **Improved physical quality of life**
  SF-36 v2 physical component score improved significantly by 11.4%

- **Higher daily use of the prosthesis and decreased use of walking aids.**

- **Reduced risk of falling**
  Number of subjects that reported of never falling increased from 9 (20%) with previous prosthesis to 39 (87%) with C-Leg.

**Population**

Subjects: 75 prosthetic users (55 women, 20 men):
- 89% transfemoral, 3% knee disarticulation,
  8% hip disarticulation
- 96% unilateral, 4% bilateral

Previous knee joint: 96% NMPK (83% free with hydraulic/pneumatic assistance, 7% free mechanical, 4% break knee, 2% locked knee) and 4% micro-processor controlled knee “MPK”.

Amputation causes: 59% traumatic, 27% tumor, 8% vascular, 2% congenital, 1% diabetic, 6% other

Mean age: 47.6 ± 14.1 years
Mean time since amputation: 15.8 ± 14.8 years
The study was conducted in 25 rehabilitation centers in France (detailed list of active investigators/centers can be found at the end of this document), with an inclusion period from May 13, 2013 to June 15, 2015. Clinical data was recorded for 100 participants, of which 75 were already prosthetic users at the time of enrollment and 25 who had not been fitted previously. During the study, 30 participants were lost to follow-up for different reasons. Data was analysed for 45 participants who were prosthetic users at enrollment and were assessed with C-Leg at T2. C-Leg data (T2) were compared to baseline (T0) conducted with the previous prosthesis. Furthermore, C-Leg data (T2) was collected for 11 participants having no previous prosthetic experience (no baseline).

<table>
<thead>
<tr>
<th>Category</th>
<th>Outcomes</th>
<th>Results for C-Leg compared to previous fitting</th>
<th>Sig.*</th>
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<tbody>
<tr>
<td>Safety</td>
<td>Number of falls</td>
<td>The number of subjects that reported of never falling increased significantly (from 9 with previous prosthesis to 39 with C-Leg)</td>
<td>++</td>
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</table>
| Activity, Mobility,           | LCI-5 (Locomotor Cability Index)  | The LCI-5 global score increased significantly by 11.2%.  
  Basic activities score: +9.8%  
  Advanced activities score: +13%  | ++    |
| Activities of Daily Living    |                                   |                                                                                                              | ++    |
| (ADLs)                        | Daily use                         | Higher number of participants that reported to use their prosthesis more than 12hours per day (17 with previous prosthesis to 25 with C-Leg) | ++    |
| Number of walking aids        |                                   | Significantly decreased used of walking aids:  
  The number of participants without walking aids increased from 21 with previous prosthesis (48%) to 34 (76%) with C-Leg  
  The number of participants that used at least one crutch decreased significantly (from 23 with previous prosthesis to 11 with C-Leg) | ++    |
| Preference, Satisfaction,     | QUEST 2.0 (Quebec User Evaluation  | The QUEST global score increased significantly by 19.6%.  
  Technology score: 26.1%  
  Service score: +6.5%  | ++    |
| Quality of Life (QoL)         | of Satisfaction with assistive Device) |                                                                                                              |       |
|                               | SF-36 (Short Form 36, v2)         | All sub-scores of SF-36 were increased, indicating a higher quality of life.  
  Physical component score: +11.4%  
  Mental component score: +5.8%  | ++    |

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

“This study suggests that active transfemoral amputees with a prescribed C-LEG may show improved locomotor ability, satisfaction and physical component of quality of life as compared with the experience with a previous mechanical device. Data also suggest that some moderately active amputees may benefit from such a device with electronically controlled stance and swing phases.” (Lansade et al., 2020)