Using a microprocessor knee (C-Leg) with appropriate foot transitioned individuals with dysvascular transfemoral amputations to higher performance levels: a longitudinal randomized clinical trial

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C-Leg vs NMPK

Major Findings

C-Leg compared to NMPK:

- 50% of amputees improve gait speed related classification of Mobility Grade from K2 to K3 when using C-Leg (p=0.008)
- Self-selected Gait speed increased by 0.1m/s

Gait speed shows

- Participants using the MPK + 1M10 achieved higher clinical scores in balance, self-reported mobility, and fall safety
- Participants using the NMPK + 1M10 showed no statistically significant improvement (p’s>0.05)

Population

| Subjects: | 10 (4 males) unilateral transfemoral amputees currently using an NMPK |
| Previous prosthesis: | Dysvascular or diabetic unilateral transfemoral amputation |
| Amputation causes: | 63.0 ±/9 years |
| Mean age: | 5.8±8.1 years; at least 6 months or more post-prosthetic fitting |
| Mean time since amputation: | K2 |
| MFCL: | |
Using a microprocessor knee (C-Leg) with appropriate foot transitioned individuals with dysvascular transfemoral amputations to higher performance levels: a longitudinal randomized clinical trial

**Study Design**

Prospective longitudinal crossover Randomized Controlled Trial

![Clinical trial design schematic and outcome assessment time points (T1, T2, and T3). Randomization to NMPK + 1M10 acclimation and trial period followed by a crossover to MPK + 1M10 acclimation and trial period (or vice versa).](image)

**Results**

| Category          | Outcomes                                      | Results for C-Leg                                                                                                                                                                                                 | Sig.* |
|-------------------|-----------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------|
| **Level Walking** | Gait speed (10-m walk test)                   | 0.1 m/s (p=0.009) improvement in MPK group, 66% transition above K3 level (K3=0.88±0.39 m/s)                                                                                                                         | ++    |
|                   |                                               | [10MWT: MPK = 0.76 (0.28) m/s, NMPK = 0.66 (0.29) m/s]                                                                                                                                                              |       |
|                   | Walking Distance (6-minute walk test)         | [6MWT group averages in meters: MPK = 145.2 (110.3), NMPK = 147.5 (112.0)] (p>0.05)                                                                                                                                     | 0     |
| **Safety**        | Balance (Berg Balance Scale)                  | Participant balance scores improved (BBS ≥50.5/56) (p>0.05).                                                                                                                                                        | +     |
|                   |                                               | [BERG: MPK = 44 (13), NMPK = 39 (15)]                                                                                                                                                                               |       |
|                   | Balance (Timed Up and Go)                     | TUG (p>0.05) [TUG in seconds: MPK = 25.3 (14.1), NMPK = 29.0 (16.3)]                                                                                                                                              | 0     |
|                   | Fear of falling (modified Falls Efficiency Scale) | Significantly improved mFES scores (self-reported falls efficacy) when using the mEPK C-Leg (p=0.03).                                                                                                              | ++    |
|                   |                                               | [mFES: MPK = 9.33 (0.69), NMPK = 8.51 (1.03)]                                                                                                                                                                         |       |
| **Activity, Mobility, ADLs** | Activity (Prosthesis Evaluation Questionnaire) | 78% of participants reported higher PEQ scores while using MPK (ability walk on different terrain and surfaces). These improved scores matched K3 MFCL performance level when using MPK C-Leg (p=0.008). | ++    |
|                   |                                               | [PEQ-A: MPK = 81.92 (18.74), MPK = 16.8 (11.2), NMPK = 19.6 (12.4)], (p>0.05).                                                                          |       |
|                   | Activity (Four Square Step Test)              |                                                                                                                                                                                                                   | 0     |
|                   |                                               | [FSST: MPK = 16.8 (11.2), NMPK = 19.6 (12.4)], (p>0.05).                                                                                                     |       |
| Category                                 | Outcomes                          | Results for C-Leg                                                                 | Sig.* |
|-----------------------------------------|-----------------------------------|----------------------------------------------------------------------------------|-------|
| Mobility (Amputee Mobility Predictor)   |                                   | For both interventions clinically meaningful improvement was observed in group mean AmpPro scores. However, not high enough to match K3 level ($p=0.008$). \[AMPPro: MPK = 36 (5), NMPK = 35(6)\] | ++    |

**Author’s Conclusion**

“This longitudinal clinical trial investigated the benefit of providing an MPK C-Leg+appropriate foot in individuals with transfemoral amputation from dysvascular or diabetic conditions at MFCL K2 level who are currently using a predicate NMPK+foot combination. Statistically significant and clinically meaningful improvements were observed in gait performance, safety, and self-reported measures (PEQ-A) when using the MPK C-Leg+1M10 foot combination in comparison to their baseline condition (i.e. predicate NMPK+foot).” (Jayaraman et al, 2021)