Reference

Charlotte E. Bosman [1], Bregje L. Seves [1], Jan H. B. Geertzen [1], Behrouz Fard [2], Irene E. Newsum [3], Marieke A. Paping [4], Aline H. Vrieling [1] and Corry K. van der Sluis [1].

Comparing Microprocessor-Controlled and Non-Microprocessor-Controlled Prosthetic Knees Across All Classified Domains of the ICF Model: A Pragmatic Clinical Trial

Prosthesis 2025, *7*(4), 89; DOI: 10.3390/prosthesis7040089. OpenAccess

Products

C-Leg, Kenevo

Major Findings

With C-Leg, Kenevo and Rheo compared to NMPKs:

→ Using an MPK can lead to significant improvements in all classified ICF domains especially in daily living situations

→ Improved walking abilities with MPK compared to NMPK

- Participants reported significantly improved balance, walking confidence, safety and self-reported walking abilities ($p \leq 0.01$)
- Significantly higher walking distance during 6-minute walk test (Δ +37.8 ± 38.8m, $p < 0.001$)
- Significant decrease in number of stumbles and falls (Δ -3.7, $p < 0.001$)

→ Higher satisfaction with MPK than NMPK

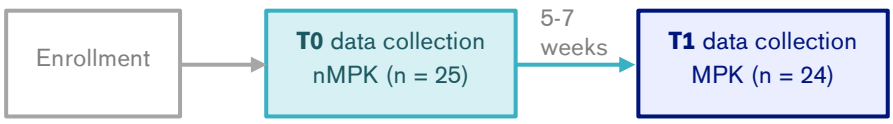
- More satisfied with their participation (in activities and involvement in life)
- Experience fewer restrictions according to USER-P ($p = 0.003$)
- Greater satisfaction with the appearance and utility of the MPK ($p < 0.01$)
- Less social burden according to PEQ ($p = 0.004$)
- Better well-being reported (Score VAS 0-100; Δ +11.4, $p = 0.018$)

Population

Subjects:	25 participants (6 female, 19 male)
Amputation level:	unilateral: transfemoral (84%), knee disarticulation (16%); (left side: 52%)
Previous knee prosthesis:	NMPKs
Study knee prosthesis:	**MPKs:** C-Leg (40%), Kenevo (36%), Rheo (24%)
Amputation causes:	vascular disease (44%), trauma (20%), malignancy (16%), infection (8), other (12%)
Median age:	57 years (range: 19-75 years)
Time since amputation:	median: 2 years (range 1-53 years)
MFCL:	n.a.

Study Design

Multicenter pragmatic clinical trial design:



Patients were assessed in a within-subject design - first in the control condition using their non-microprocessor prosthetic knee (nMPK), followed by evaluation under the experimental condition with the microprocessor-controlled knee (MPK).

During the baseline assessment (T0), all patients used their personal nMPK. One week later, the MPK was provided. Throughout the intervention period, participants

received 30 minutes of physical therapy twice per week. After 5–7 weeks of MPK use, follow-up data were collected (T1), replicating the same testing procedures conducted at baseline.

The overall study consists of four measurement points, of which the first two are presented in this paper. These first assessments were integrated into the standard of care process.

Results

Functions and Activities								Participation	Environment
Level walking	**Stairs**	**Ramps, Hills**	**Uneven ground, Obstacles**	**Cognitive demand**	**Metabolic Energy Consumption**	**Safety**	**Activity, Mobility, ADLs**	**Preference, Satisfaction, QoL**	**Health Economics**

Category	Outcomes	Results for MPKs vs NMPKs *	Sig.[a,b,c]
Level Walking	ABC-NL (n=23)	Significant increase in balance confidence with MPK. (data not normally distributed → not possible to determine whether the MDC_{90} was reached)	
		NMPK: 56.9 (8.7-79-4) | MPK: 83.6 (23.8-96.3) | Mean difference: -4	++
	6 MWT (n=25)	Significantly longer distance covered with MPKs (+37.8 ± 38.8m), however below the MDC_{90} threshold of 45m.	
		NMPK: 290.3 ± 80.8 | MPK: 330.9 ± 99 | Mean difference: 37.8 ± 38.8	(++)
	TUG test (n=25)	Significant decrease of TUG test time with MPK. (data not normally distributed → not possible to determine whether the MDC_{90} was reached)	
		NMPK: 15 (8.6-31.4) | MPK: 12 (6.4-32.3) | Mean difference: -3.7	++
Activity, Mobility, Activities of Daily Living (ADLs)	Activ8 – activity monitor (n=21)	No significant difference in active time per day or walking intensity between MPK and NMPK.	
		Active time: NMPK 27.2 ± 7.9 | MPK 29.9 ± 8.9 | Mean difference 1.1 ± 5.5	0
		Walking intensity: NMPK 1226 (976-1782) | MPK 1258 (1006-1845) | Mean difference -1.4	0
	Walking aids	A quarter of the participants who used walking aids with the NMPKs were able to walk without walking aids with the MPK, and one participant made use of one crutch instead of two.	++
		None: NMPK 13 (52) | MPK 15 (60)	
		One crutch / cane: NMPK 2 (8) | MPK 2 (8)	
		Two crutches / canes or walker: NMPK 10 (40) | MPK 7 (28)	
		∑ NMPK n = 25 | ∑ MPK n = 24	
	PEQ-A	– Sig. increase in walking confidence, concentration and safety with the use of MPKs compared to NMPKs	

<table>
<tr><th>Category</th><th>Outcomes</th><th>Results for MPKs vs NMPKs *</th><th>Sig.[a,b,c]</th></tr>
<tr><td>Preference, Satisfaction, Quality of Life (QoL)</td><td></td><td>– Sig. decrease in number of falls and stumbles with the use of MPKs compared to NMPKs
<table><tr><th></th><th>NMPK</th><th>MPK</th><th>Mean difference</th></tr><tr><td>Concentration (n=24)</td><td>53 (7.3-85.7)</td><td>88.3 (47.8-100)</td><td>-4.0</td></tr><tr><td>Confidence (n=23)</td><td>61.6 (24.6-90.6)</td><td>78.7 (32.8-91)</td><td>-3.2</td></tr><tr><td>Safety (n=24)</td><td>77.5 (23.3-100)</td><td>96 (37.3-100)</td><td>-3.4</td></tr><tr><td>Falls and stumbles (n=23)</td><td>7 (0-50)</td><td>0 (0-27)</td><td>-3.7</td></tr></table></td><td>++
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<tr><td></td><td>PEQ</td><td>Sig. improvements with the use of MPK compared to NMPK, e.g.:
- in all 5 questions related to transfers using MPKs,
- in the appearance of the MPK compared to the NMPK (surpassed the MDC_{90} threshold of 14),
- in two of the three questions related to self-efficacy
– Sig. decrease in the occurrence of back pain, but no difference in nearly all other pain-related questions with MPK compared to NMPK
– One question related to importance resulted in a significant difference
(Remaining data not normally distributed → not possible to determine whether the MDC_{90} was reached)
<table><tr><th></th><th>NMPK</th><th>MPK</th><th>Mean difference</th></tr><tr><td>Appearance (n=24)</td><td>62.3 ± 19.8</td><td>77.7 ± 17</td><td>15.5 ± 22.5</td></tr><tr><td>Frustration (n=23)</td><td>60.3 ± 32.6</td><td>73 ± 27.7</td><td>14.6 ± 31.8</td></tr><tr><td>Perceived response (n=24)</td><td>93 (63.2-100)</td><td>95.6 (58.2-100)</td><td>-1.5</td></tr><tr><td>Social burden (n=24)</td><td>75.3 (24.3-98)</td><td>93 (42-100)</td><td>-3.1</td></tr><tr><td>Sounds (n=24)</td><td>76.8 (14.5-100)</td><td>97 (19.5-100)</td><td>-1.5</td></tr><tr><td>Ambulation (n=24)</td><td>53.6 (17.8-77)</td><td>82.4 (50.3-93.6)</td><td>-4.1</td></tr><tr><td>Residual limb health (n=23)</td><td>86.7 (37-97.8)</td><td>88 (45-100)</td><td>-1.3</td></tr></table></td><td>++
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<tr><td></td><td>USER-P (n=25)</td><td>– Sig. less restrictions with MPK
– Sig. greater satisfaction with MPK
– No significant difference in the frequency scale
<table><tr><th></th><th>NMPK</th><th>MPK</th><th>Mean difference</th></tr><tr><td>Frequency</td><td>31.2 ± 11.2</td><td>33.9 ± 13</td><td>2.1 ± 7.9</td></tr><tr><td>Restrictions</td><td>44.4 (16.7-62.5)</td><td>55.6 (23.8-66.7)</td><td>-3.2</td></tr></table></td><td>0
++</td></tr>
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Category	Outcomes	Results for MPKs vs NMPKs *			Sig.[a,b,c]
		Satisfaction	55.6 (22.2-72.5)	77.5 (61.1-100)	-4.0	++
	SQUASH(n=25)	No significant difference in SQUASH (NMPK: 1782; MPK: 1995; mean difference: -1.8)				0
	Utility & Well-being	Significant improvement in the utility of the MPK compared to the NMPK. The improvements in score surpassed the MDC90 threshold of 12. Participants reported sig. better well-being.				
			NMPK	MPK	Mean difference	
		Utility	62.1 ± 13.5	79.5 ± 14.5	17.2 ± 16	++
		Well-being	69.3 ± 23	81 ± 14.7	11.4 ± 18.6	++

[a] no difference (0), positive trend (+), negative trend (–), significant (++/––), not applicable (n.a.) significance set at $p<0.05$; trends set at $0.1>p>0.05$

[b] in order to prevent a type-I error due to multiple testing, the Benjamini–Hochberg procedure was used to calculate the adjusted p-values

[c] effect sizes of significant results were medium to large (Cohen's *d*, Wilcoxon effect size (*r*)) classified by authors as small ($d = 0.2$, $r = 0.1$), moderate ($d = 0.5$, $r = 0.3$) or large ($d = 0.8$, $r = 0.5$)

* results are displayed as (mean ± SD) or median (range) if not specified otherwise

Author's Conclusion

"The effectiveness of MPKs compared to NMPKs across all classified domains of the ICF model was investigated. As was hypothesized based on the existing literature, we found significant improvements with the MPK compared to the NMPK in all classified domains of the ICF model. Participants using an MPK significantly improved their walking ability in terms of distance, speed and self-reported walking ability, compared to using an NMPK. Furthermore, we found a significant increase in balance and walking confidence and sense of safety, which was also reflected in a significant decrease in number of stumbles and falls with the use of an MPK compared to an NMPK. Lastly, participants using an MPK were significantly more satisfied with their participation, their prosthesis and their walking ability, compared to using an NMPK. We therefore recommend considering all classified ICF domains when selecting or evaluating a new prosthetic knee, rather than focusing solely on regaining or improving walking ability." (Bosman et al., 2025)

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