Reference

Bruce Carse[1], Helen Scott[1], Laura Brady[1] and John Colvin[1]

Evaluation of gait outcomes for individuals with established unilateral transfemoral amputation following the provision of microprocessor controlled knees in the context of a clinical service

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Products

Kenevo, C-Leg 3, C-leg 4, Genium

Major Findings

With MPK Knees (C-Leg 3/C-leg 4/Kenevo/Genium and Rheo 3/Rheo XC/Linx) versus nMPKs in routine clinical practice:

→ MPK provision offered significant improvements in gait and mobility for the patients

- Significant reduction in gait deviations as measured by the Gait Profile Score by -9.8% ($p<0.01$) compared to non-MPK
- MFCL classification improved for 68% of K2 and K3 patients and did not decrease for any, including K4 subjects:
  - 60% of the K2 subjects (n=5) changed to K3
  - 71% of the K3 subjects (n=17) changed to K4
- Further significant improvement for other parameters:
  - Clinically meaningful increase in walking velocity of +0.13 m/s (+12.9%, $p<0.01$)
  - Greater step length (+9.4%, $p<0.01$)
  - Lower vertical ground reaction force symmetry index (-23.8%, $p<0.01$)
  - Less deviation of the center of mass (-20.3%, $p<0.05$)

→ MPK use shifts the gait pattern towards physiological values compared to nMPK use but remains different to the healthy control group

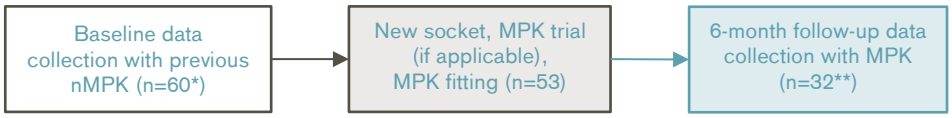
Population

Subjects:	PP*: 32 subjects (26 male, 6 female) and 10 unimpaired healthy controls
Amputation level:	Transfemoral (31), Knee disarticulation (1)
Previous knee type:	Polycentric (8), Hydraulic yielding (10), SA(WA)* (10), SA(AC)* (1), HOKL* (1), SAKL* (1), Fluidic controlled hydraulic (1)
MPK type:	Rheo Knee 3 (2), Rheo Knee XC (11), C-Leg 3 (7), C-Leg 4 (1), Linx (2), Kenevo (8), Genium (1)
Amputation causes:	Mechanical trauma (16), Infection (4 (soft tissues 3/4, bone 1/4)), Peripheral arterial disease (PAD) without diabetes mellitus (4), PAD with diabetes mellitus (1), Tumor (5), Other (2)
Mean age:	52.1 ± 15.8 years, (reference cohort: 31 ± 5 years)
Mean time since amputation:	17.9 ± 15.4 years
MFCL*:	K2 (5), K3 (17), K4 (10)

*PP = per protocol (gait measures at baseline and 6-months follow up);
SA(WA) = single axis (weight activated); SA(AC) = single axis (alignment-controlled); HOKL = hand operated knee lock; SAKL = semiautomatic knee lock;
MFCL = Medicare Functional Classification Level (K-levels)

Study Design

Retrospective cohort study design:



* eligible for MPK through Scottish Specialist Prosthetics Service (SSPS) (enrollment n=68, ITT n=60)

** n=28 total lost to follow-up: did not proceed to MPK provision (7); rejected MPK (6); declined to attend (2); medical issues (1); socket fit issues (7); other (2)

Each patient received a tailored prosthetic prescription with trial periods of two different MPKs offered when the MPK prescription was unclear. All subjects received a new socket with 10 of 32 changing the type of socket and 5 of 32 the type of suspension system. Patients attended a mean of 2 ± 1 physiotherapy sessions before MPK provision and 8 ± 4 sessions after MPK fitting.

The testing procedure involved the patient walking at a self-selected comfortable speed back and forth along a 12-m walkway for 5 minutes while wearing a portable cardiopulmonary system for capturing oxygen consumption. A 3D motion capture system (Vicon, Oxford, UK) was used afterwards to collect full body spatiotemporal, kinematic, and kinetic gait data during level walking. This data was used for measuring gait deviations based on kinematic variables for calculating the Gait Profile Score and for measuring other gait outcomes.

Gait outcomes were compared with suitable participants at baseline (using nMPKs) and 6 months post-MPK provision. Suitable participants for study inclusion were identified retrospectively from a group of patients who used the SSPS. Only the patients that were followed up were deemed suitable for inclusion in this study.

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 nMPKs vs. MPKs [a]	Sig.[b,c,d] (vs. nMPK)
Level Walking	**Gait profile score (GPS) (°)**	Improved GPS values indicating reduced gait deviations with provision of MPK (moderate effect size). Post-hoc analysis revealed that only the sagittal plane hip kinematics improved significantly.	++[c]
	Walking velocity (m/s)	Improved walking velocity with provision of MPK (moderate effect size).	++

nMPK	MPK	Healthy controls
11.2 ± 2.2°	10.1 ± 2.1°	5.4 ± 0.7°

nMPK	MPK	Healthy controls
0.88 ± 0.26 m/s	1.01 ± 0.25 m/s	1.41 ± 0.10 m/s

Category	Outcomes	Results for nMPKs vs. MPKs [a]	Sig.[b,c,d] (vs. nMPK)
	Step length (m)	Improved step length with provision of MPK (moderate effect size).	++
		nMPK: 0.58 ± 0.11 m; MPK: 0.64 ± 0.11 m; Healthy controls: 0.74 ± 0.06 m	
	Vertical ground reaction force symmetry index (F_z)	Improved vertical GRF (Fz) symmetry index with provision of MPK (small effect size).	++
		nMPK: 18.9 ± 16.3; MPK: 14.4 ± 9.3; Healthy controls: 1.3 ± 1.2	
	Center of mass (CoM) deviation	Less CoM deviation with provision of MPK (moderate effect size).	++
		nMPK: 2.2 ± 1.2 %; MPK: 1.7 ± 0.75 %; Healthy controls: 0.8 ± 0.18 %	
	Base of support	No change of base support with provision of MPK.	0
		nMPK: 340 ± 63 mm; MPK: 338 ± 59 mm; Healthy controls: 238 ± 32 mm	
	Step length symmetry ratio	No change of step length symmetry ratio with provision of MPK.	0
		nMPK: 0.87 ± 0.09; MPK: 0.88 ± 0.1; Healthy controls: 0.97 ± 0.03	
	Step time symmetry ratio	No change of step time symmetry ratio with provision of MPK.	0
		nMPK: 0.84 ± 0.1; MPK: 0.85 ± 0.1; Healthy controls: 0.96 ± 0.04	
	Medicare Functional Classification Level (MFCL)	15 of 32 participants improved their MFCL • 3 of 5 who were K2 changed to K3 • 12 of 17 who were K3 changed to K4 No participant experienced a reduction in MFCL.	n.a.
Metabolic Energy Consumption	**Net nondimensional normalized (NNN) oxygen cost**	No improvement of NNN oxygen cost with provision of MPK (p = 0.09). • An average weight increase of 1.2 ± 3.2 kg at the 6-month follow up compared to baseline may have contributed to lack of improvement in oxygen cost. • Oxygen cost with MPK remained far above normal reference values for healthy adults	0

Category	Outcomes	Results for nMPKs vs. MPKs [a]			Sig.[b,c,d] (vs. nMPK)
		nMPK	MPK	Healthy controls	
		0.40 ± 0.12	0.42 ± 0.13	0.26 ± 0.05	

[a] results given in (mean ± standard deviation)
[b] No difference (0), positive trend (+), negative trend (–), significant (++/––), not applicable (n.a.), significance set at $p < 0.05$; trends set at $0.1 > p > 0.05$
[c] Statistically significant difference after Bonferroni-Holm adjustment for two-sided p-values (adjusted $p < 0.05$)
[d] Cohen's D effect sizes classified by authors as small (<0.3), moderate (>0.3 and <0.5) or large (>0.5)

Author's Conclusion

"This study found that there were significant improvements in most of the gait outcome measures after MPK provision to a large and diverse group of TFAs in the context of a specialist prosthetics service. Despite significant improvements, there remained a marked difference between participant outcomes and those of normal healthy adults, and those of high-functioning military TFAs. Although the technological advances in MPK design continue, it seems appropriate that research effort be focused on other contributing factors such as socket design and physical rehabilitation of the patient to improve these gait outcomes further." (Carse et al., 2021)

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