Reference

Kaufman K*, Bernhardt K*, Symms K**.

*Motion Analysis Laboratory, Mayo Clinic, 200 First Street SW, Rochester, MN 55905, USA.**Hanger Clinic,10910 Domain Drive,Suite 300,Austin, Tx 78758, USA

Functional assessment and satisfaction of transfemoral amputees with low mobility (FASTK2): A clinical trial of microprocessor-controlled vs. non-microprocessor-controlled knees

Clinical Biomechanics 58 (2018) 116-122.

Products

C-Leg Compact, Rheo 3, Orion 2, Plié 3, NMPKs

Major Findings

With C-Leg Compact, Rheo 3, Orion 2 and Plié 3 compared to NMPKs:

Transfemoral amputees with limited mobility clearly benefit from MPKs:

→ Activity

- Subjects spent significantly less time sitting ($p = 0.01$) and increased the amount of upright activity ($p = 0.02$).

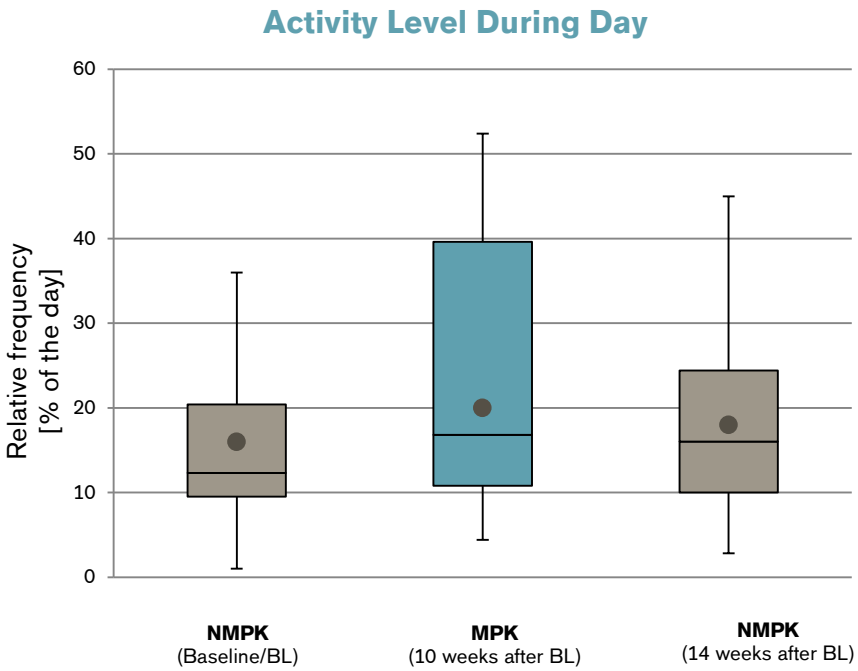
- Complexity of the gait, as measured by the entropy**, increased by 25%, indicating a less pathological movement.

→ Safety

- Significant reduction in falls ($p = 0.01$)

→ Satisfaction:

- Significant improvement in PEQ satisfaction subscales ($p < 0.01$).
- Greatest improvements were seen in subscales ambulation, appearance and utility.



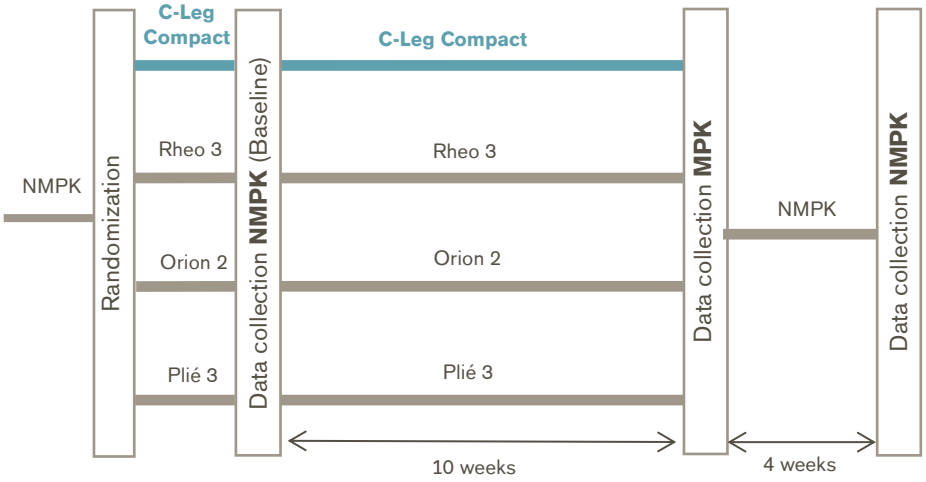
Activity in the free-living environment for the three time points of the study. When using the MPK, there was a significant increase in the amount of active time during the day ($p = 0.02$) (Kaufman et al, 2018).

Population

Subjects:	50 (28 males) unilateral transfemoral amputees
Previous prosthesis:	Polycentric knee, friction brake, hydraulic, pneumatic
Amputation causes:	Peripheral arterial disease (50%), Total knee arthroplasty infection (14%), infection (12%), trauma (10%), deep vein thrombosis (8%), cancer (4%) and blood disorder (2%)
Mean age:	69 ± 9 years
Mean time since amputation:	1.5 years
MFCL:	K2 (n=48) and K3 (n=2)

Study Design

Interventional, non-randomized, crossover study



Results

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	NMPK (Baseline)	MPK (after 10 weeks on MPK)	NMPK (after 4 weeks on NMPK)	Sig.*
Safety	**Falls**	2.0 (IQR: 0.0 – 6.0)	**0.0 (IQR: 0.0-6.0)**	3.0 (IQR: 0.0-3.0)	--
Activity, Mobility, Activities of Daily Living (ADLs)	**Time spent sitting**	61 ± 5%	**52 ± 3%**	64 ± 3%	--
	Time being active	16 ± 2%	**20 ± 2%**	18 ± 2%	++
	Complexity of the gait (entropy**)	0.14 (IQR: 0.05–0.27)	**0.17 (IQR: 0.07-0.32)**	0.16 (IQR: 0.07–0.45)	+
Preference, Satisfaction, Quality of Life (QoL)	**PEQ**	There was a significant improvement in PEQ satisfaction sub-scales when using the MPK. The greatest improvements were in **ambulation, appearance and utility**.			++

* no difference (0), positive trend (+), negative trend (–), significant (++/––), not applicable (n.a.)

** the sample entropy is used for assessing the complexity of physiological time-series signals. In this case, a more physiological gait is characterized by higher entropy i.e. a more complex, random gait pattern.

Author's Conclusion	"This clinical trial confirmed that the provision of a MPK to patients with a TFA and low, i.e. K2, mobility will result in improved function in the free-living environment, a reduction in falls and subsequently improved patient satisfaction." (Kaufman et al., 2018)