Reference	James H Campbell[1], Phillip M Stevens[1,2], Shane R Wurdeman[1,3] [1] Department of Clinical and Scientific Affairs, Hanger Clinic, Austin, TX, USA; [2] School of Medicine, University of Utah, Salt Lake City, UT, USA; [3] Department of Biomechanics, University of Nebraska at Omaha, Omaha, NE, USA

OASIS 1: Retrospective analysis of four different microprocessor knee types

Products	**C-Leg, Orion, Plié, and Rheo vs NMPK Benchmark**

|	
Major Findings	<u>Reduced number of injurious falls - C-Leg compared to NMPK Benchmark:</u> Injurious falls in the past 6 months were experienced by 5.8% of C-Leg users compared to 16.3% of NMPK users (p<0.05). Lowest number of injurious falls with C-Leg. However, no significant differences between the 4 MPK, but only C-Leg and Orion had significantly fewer injurious falls than NMPK. <u>C-Leg users reported highest Quality of Life (PEQ)</u> Individuals using C-Leg reported highest quality of life, followed by Orion, Rheo, and last Plié.
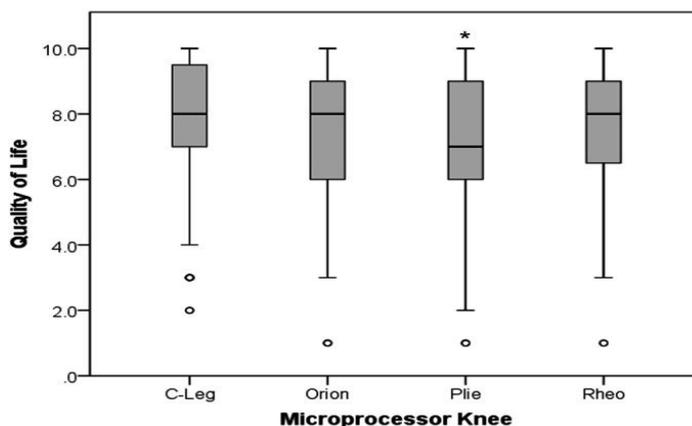
Figure 1:Campbell et al. 2020

Population	Subjects:	602
	Previous prosthesis:	n.a.
	Amputation causes:	vascular/diabetes; non-vascular/diabetes; unspecified
	Median age (yrs.)	C-Leg 61.23 [48.78,68.11]
	[Inter Quartile Range]:	Orion 57.97 [46.15,67.74]
		Plié 56.95 [46.76,65.27]
		Rheo 58.63 [44.67,66.22]
	Mean time since amputation:	not stated
	MFCL:	not stated

Study Design	cross sectional, multi centric, retrospective analysis (Patient reported outcomes packet as part of routine prosthetic care)

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	Sig.*
Safety	Number of injurious falls (past 6 months)	42 injurious falls reported (10% of 419 individuals; among all MPK users)	n.a.
	Reported injurious falls (past 6 months)	5.8% C-Leg users 9.2% Orion 13.3% Plié 14.0% Rheo Significance calculated vs 16.3% population benchmark (NMPK)	–– –– 0 0
Activity, Mobility, Activities of Daily Living (ADLs)	PLUS-M[1] - C-Leg - Orion - Rheo - Plié	49.40 (highest mobility reported) 48.30 48.30 47.20 No significant difference between the 4 MPK groups	0 0 0 0
Preference, Satisfaction, Quality of Life (QoL)	PEQ QoL[1] - C-Leg - Orion - Rheo - Plié	8 8 8 7 C-Leg > Plié	0 0 0 0 ++
	PEQ Satisfaction[1] - C-Leg - Orion - Rheo - Plié	8 8 8 7	0 0 0 0

* no difference (0), positive trend (+), negative trend (–), significant (++/––), not applicable (n.a.)
[1] Median Values were read with the help of PlotDigitizer (https://plotdigitizer.com/)

Author's Conclusion

"Our data indicate relative parity among the 4 microprocessor knees with regard to functional mobility and satisfaction. In contrast to mobility, neither satisfaction nor quality of life values reflected declines with aging. Finally, when compared to non-microprocessor knees, significant differences were observed across the microprocessor knee types in relation to the reduction of injurious falls." (Campbell et al., 2020)

Letter to editor by A. Kannenberg and A. Hahn:	- A cross-sectional study does not allow conclusions on causal relationships
	- No information on baseline status before MPK fitting. There is also the possibility of clinician bias in the selection of the different MPK that the study did not control for.
	- Absence of statistical differences does neither establish equivalence nor non-inferiority, so the legal term "parity" should be avoided.
	- Scientifically inappropriate wording "decline" implies a decrease over time but since the study is cross-sectional this may be misleading.
	- A recommendation to routinely assess the risk of falling in transfemoral amputees to guide the selection of an MPK should be considered.

Response to Letter:	- According to the authors, the publication was written without noting causality, but with many suggestive statements
	- Selection bias was acknowledged in the manuscript, but there is great value in the increased ecological validity when examining the outcomes of more than 600 MPK users.
	- Additional Two one-sided test (TOST) showed degree of equivalence among the four MPK models in the areas of mobility, SAT, and QoL
	- The word "decline" often is used by scientific community in a comparable context
	- In the publication already a suggestion was made that "when stability and falls reduction is considered a primary aim for MPK prescription, clinicians may consider the C-Leg or Orion."