

Reference

Kinsey Herrin^{1,2}, Sujay Kestur¹, Sixu Zhou^{1,2}, Gwyn O'Sullivan¹, Teresa Snow³, Walter Lee Childers^{4,5}, Aaron Young^{1,2}

Toward personalizing prosthesis prescription: A take-home study of three microprocessor-controlled prosthetic knees: A randomized crossover study

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Products

C-Leg 4.0

Major Findings

With C-Leg 4.0 compared to Rheo Knee-Model RM7, and Power Knee-PKA01 (Össur, Reykjavik, Iceland):

→ Patients may benefit from a more individualized MPK prescription

- In 83% of outcomes (10/12) there were individuals who performed best, beyond the defined clinically meaningful difference, on an MPK which is not the cohort's optimal MPK

→ Participants walked faster in C-Leg than Power Knee

- Significantly faster by 12% during the 2-MWT in C-Leg than in Power Knee (95% CI: 0.034-0.241, $p = 0.003$)
- 13% faster during ramp descent with C-Leg than in Power Knee (approaching statistical significance ($p = 0.051$))

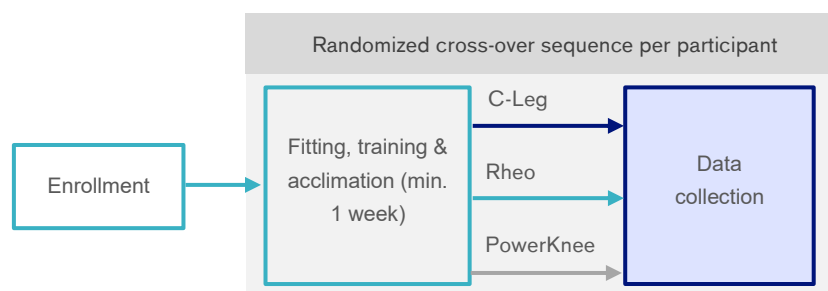
→ 18% greater satisfaction with C-Leg compared to Power Knee according to the Prosthesis Evaluation Questionnaire ($p = 0.006$)

Population

Subjects:	10 subjects (female (2), male (8))
Amputation level:	transfemoral, unilateral
Previous prosthesis:	<u>Clinically prescribed knee:</u> C-leg (3.0 (1); 4.0 (4); n.a. (1)), X3 (1), Plié (2), Proteor Quattro (1) <u>Clinically prescribed foot/ankle:</u> C-walk (1), Maverick Xtreme AT (1), Trias (2), Renegade AT (1), ProFlex (1), All Pro (1), LP Variflex with EVO (1), Shockwave (1), Accent (1)
Amputation causes:	trauma (6), iatrogenic (1), diabetes (1), blood clot (1), osteosarcoma of knee (1)
Mean age:	49.2 ± 10.8 years
Mean time since amputation:	20.3 years (range: 1-51 years)
MFCL:	K3 (4), K4 (6)

Study Design

Randomized crossover study:



Three different MPKs (C-Leg, Rheo, PowerKnee) were fit in each patient in random order. The clinically prescribed suspension, socket, and prosthetic foot were used whenever possible with the study knee, as well as any clinically prescribed specialty components. Patients were trained on each knee and then used it for a 1-week acclimation period. Afterwards, data was collected during an experimental session. Immediately after the session, the patient was fit with the next knee and entered the next acclimation phase. This procedure was repeated until data had been collected for each patient with all three knees.

Setting: Research laboratory and community environment.

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	Sig. ^{a,b}
Level Walking	10-meter walk test (10-MWT) *	<p>Most participants walked fastest on either or both C-Leg or Rheo:</p> <ul style="list-style-type: none"> 10% faster in C-Leg than in Power Knee (95% confidence interval [CI]: -0.225 to 0.007, p = 0.126) 11% faster in Rheo than in Power Knee (95% CI: 0.046 to 0.184, p = 0.015) C-Leg and Rheo were not significantly different (95% CI: -0.066 to 0.078, p = 0.852). <p>One participant walked equivalently fast on Power Knee and Rheo, four on C-Leg and Rheo, and one participant walked equivalently fast on all the MPKs.</p>	0 ++ 0
	2-minute walk test (2-MWT)	<p>Most participants walked fastest on Rheo or C-Leg:</p> <ul style="list-style-type: none"> 12% faster in C-Leg than in Power Knee (95% CI: 0.034–0.241, p = 0.003) 9% faster in Rheo than in Power Knee (95% CI: 0.031–0.163, p = 0.027) no significant differences between C-Leg and Rheo (95% CI: -0.069 to 0.151, p = 0.425). <p>Two participants walked equivalently fast on all three knees and four on C-Leg and Rheo.</p>	++ ++ 0
	Stance time asymmetry index	<p>ST asymmetry index was negative in all three knees which is indicative of increased stance time on the sound side.</p> <ul style="list-style-type: none"> no statistical differences between knees (p = 0.687) <ul style="list-style-type: none"> 44% lower in Rheo compared to C-Leg 36% lower in Rheo compared to Power Knee <p>Although Rheo was the cohort's optimal performing knee, a high degree of individual performance variability was seen in this measure across knees. For each MPK there was one participant with the individually lowest index. One participant performed equivalently on C-Leg and Power Knee, six performed equivalently on all three MPKs.</p>	0 0

Stairs **Stair ascent** Stair ascent strategies:

Category	Outcomes	Results for MPKs	Sig. ^{a,b}
		<ul style="list-style-type: none"> step-to-step: 8 of 10 in C-Leg step-over-step: 8 of 10 in Power Knee, and 6 of 10 in Rheo <p><u>Stair ascent speed:</u></p> <ul style="list-style-type: none"> 11% faster in C-Leg than Power Knee ($p = 0.229$) 15% faster in C-Leg than Rheo ($p = 0.229$) <p>Seven participants ascended equivalently fast on all three MPKs, two were fastest with C-Leg and one with Power Knee.</p>	n.a. n.a.
	Stair descent	No differences in stair descent speed ($p = 0.528$). 8 participants descended equivalently fast on all three knees, one equivalently fast on C-Leg and Power Knee, and one on Power Knee and Rheo.	0
Ramps, Hills	Ramp ascent	<p>Most participants ascended ramps fastest in C-Leg or Rheo:</p> <ul style="list-style-type: none"> 8% faster in C-Leg than in Power Knee ($p = 0.144$) 8% faster in Rheo than in Power Knee ($p = 0.024$) No differences in speed between Rheo and C-Leg ($p = 0.949$). <p>One participant ascended equivalently fast on Power Knee and Rheo, one on C-Leg and Rheo, three performed best on C-leg, three best on Rheo and two equivalently on all three.</p>	0 ++ 0
	Ramp descent	<p>Most participants descended ramps fastest in C-Leg or Rheo:</p> <ul style="list-style-type: none"> 13% faster in C-Leg than in Power Knee 12% faster in Rheo than in Power Knee <p>One participant descended equivalently fast in Power Knee and C-Leg, one on Power Knee and Rheo, two on C-Leg and Rheo. Two descended fastest on C-Leg, two on Rheo and two performed equivalently on all three MPKS.</p>	+ +
Uneven Ground, Obstacle Course	Narrowing beam walking test	<p>Most participants performed best on Rheo for this balance test:</p> <ul style="list-style-type: none"> 18% longer traverse with Rheo than Power Knee ($p = 0.082$) 7% longer traverse with Rheo than C-Leg ($p = 0.082$) <p>Three participants performed equivalently well as their Rheo performance using one of the other knees. Two participants performed best on Rheo, two equivalently on Rheo and C-Leg, one equivalently on Rheo and Power Knee and five performed equivalently on all three MPKS.</p>	0 (+) 0 (+)
Metabolic Energy Consumption	Physiological cost index (PCI)	<p>No statistical differences between knees for PCI</p> <ul style="list-style-type: none"> 13% lower with C-Leg than Power Knee ($p = 0.535$) 7% lower with C-Leg than Rheo ($p = 0.535$) <p>Three data points were removed due to errant experimental heart rate measures. One participant performed best on C-Leg, and one performed equivalently on C-Leg and Rheo. One participant performed equivalently on C-Leg and Power Knee, and four performed equivalently across all knees.</p>	0 0

Category	Outcomes	Results for MPKs	Sig. ^{a,b}
Activity, Mobility, Activities of Daily Living (ADLs)	Falls during community use	No significant differences in the average falls per day between the different knees (p = 0.943). <ul style="list-style-type: none"> Falls in total during community use: 10 falls in 228 days No falls on any knee: 4 out of 10 patients Most falls on Power Knee: 3 out of 10 patients (6 falls) Most falls on C-Leg: 3 out of 10 patients (3 falls) Most falls on Rheo: 1 out of 10 patients (1 fall) 	0
	StepWatch	Complete StepWatch data: n = 8 (due to experimental issues) <ul style="list-style-type: none"> 12% more steps on the prosthetic side in the C-Leg than Rheo 5% more steps on the prosthetic side in the C-Leg than Power Knee 	0 0
	Steps per day	<ul style="list-style-type: none"> No differences in steps per day between knees for any individual participants No differences observed across average max. cadence for the 5 most intensive minutes/day for any knee (p = 0.528) with participants performing well on multiple knees 	0 0
Preference, Satisfaction, Quality of Life (QoL)	Prosthesis Evaluation Questionnaire (PEQ) *	<i>(Higher scores indicate improved patient perception on the PEQ)</i>	
		<u>Full PEQ:</u> <ul style="list-style-type: none"> 18% higher scores with C-Leg than Power Knee (median C-Leg rank (2.7), Power Knee (1.3) (p = 0.006)) 12% higher scores with Rheo than Power (no differences in Rheo and Power Knee (p = 0.236)) 	++ 0
		<u>PEQ subscales:</u> <ul style="list-style-type: none"> Sounds: C-Leg and Rheo scored significantly more favorably than Power Knee (p = 0.003 and p = 0.038) Utility: C-Leg and Rheo scored significantly higher than Power Knee (p = 0.003 and p = 0.02) Frustration: C-Leg scored significantly more favorably than Power Knee (p = 0.030) 	++ ++ ++

^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 Following significant main effects for MPKs (alpha = .05), post hoc multiple comparisons were conducted across knees. Uncorrected p values from these comparisons were adjusted using the Holm-Bonferroni correction method to control family-wise error rate. All significant post hoc results reported are corrected p values.

* Collected data for 9 out of 10 participants due to addition of this outcome after enrollment of the first participant

Author's Conclusion

“We observed participants walked statistically faster over level ground and ramps while using either or both the C-Leg or Rheo compared to the Power Knee. In addition, we identified some individuals who performed their best in select outcomes on MPKs that were different from the cohort’s optimal-performing MPK for that outcome. Across the 12 outcomes we studied, 10 outcomes revealed individuals who performed their best beyond the defined clinically meaningful difference on a knee not identified as the cohort’s best MPK. These results are in line with a growing body of literature demonstrating individual-best is not always in line with the average for a given prosthetic component. Future research to elucidate techniques to

personalize the MPK prosthesis prescription based on these findings may enhance rehabilitation outcomes for these individuals." (Herrin et al.,2025)

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