

AWARD NUMBER: W81XWH-21-1-0686

TITLE: Personalizing MPK Prescription for Individuals with Transfemoral Amputation

PRINCIPAL INVESTIGATOR: Aaron Young

CONTRACTING ORGANIZATION: Georgia Tech Research Corporation

REPORT DATE: August 2023

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Development Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for Public Release;
Distribution Unlimited

The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation.

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing this collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Department of Defense, Washington Headquarters Services, Directorate for Information Operations and Reports (0704-0188), 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302. Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number. **PLEASE DO NOT RETURN YOUR FORM TO THE ABOVE ADDRESS.**

1. REPORT DATE August 2023			2. REPORT TYPE Annual		3. DATES COVERED 15JUL2022 - 14JUL2023	
4. TITLE AND SUBTITLE Personalizing MPK Prescription for Individuals with Transfemoral Amputation					5a. CONTRACT NUMBER W81XWH-21-1-0686	
					5b. GRANT NUMBER W81XWH-21-1-0686	
					5c. PROGRAM ELEMENT NUMBER	
6. AUTHOR(S) Kinsey Herrin, Sujay Kestur, Sixu Zhou, Aaron Young E-Mail:Kinsey.herrin@me.gatech.edu					5d. PROJECT NUMBER	
					5e. TASK NUMBER	
					5f. WORK UNIT NUMBER	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) Georgia Institute of Technology 813 Ferst Dr NW Atlanta, GA 30332					8. PERFORMING ORGANIZATION REPORT NUMBER Annual Report #2	
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research and Development Command Fort Detrick, Maryland 21702-5012					10. SPONSOR/MONITOR'S ACRONYM(S) USAMRDC	
					11. SPONSOR/MONITOR'S REPORT NUMBER(S)	
12. DISTRIBUTION / AVAILABILITY STATEMENT Approved for Public Release; Distribution Unlimited						
13. SUPPLEMENTARY NOTES						
14. ABSTRACT In current prosthetic clinical practice, no Clinical Practice Guidelines exist to aid in the prescription of microprocessor prosthetic knees (MPKs) for individuals with amputation. The long-term goal of this study is to create a prescription algorithm for MPKs such that clinicians can predict success in a single MPK for a unique patient. Eleven participants have been recruited and consented to participate in the study. Ten participants have completed 2 week-long take home acclimation periods with the three commercially available MPKs. One subject withdrew from the study prior to being fit with the first MPK. Subjects have completed various performance-based tasks while full body biomechanics have been collected along with patient reported outcomes. Differences in some performance tasks including the beam walking task (a measure of balance) and speed over level ground terrain appear to show differences for some subjects between knees. Data collection is complete on all subjects at this time and we are now focusing on creating the prescription algorithm.						
15. SUBJECT TERMS Microprocessor prosthetic knees, MPK, biomechanics, transfemoral amputation, prosthetics						
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON	
a. REPORT	b. ABSTRACT	c. THIS PAGE			USAMRDC	
U	U	U	UU	32	19b. TELEPHONE NUMBER (include area code)	

TABLE OF CONTENTS

	<u>Page</u>
1. Introduction	1
2. Keywords	1
3. Accomplishments	1
4. Impact	24
5. Changes/Problems	25
6. Products	26
7. Participants & Other Collaborating Organizations	26
8. Special Reporting Requirements	28
9. Appendices	None included

1. Introduction

The long-term objective of this project is to personalize the prosthetic prescription process for individuals with a transfemoral amputation requiring a prosthetic knee. We aim to create a clinical decision algorithm for selection of an ideal MPK for an individual patient with transfemoral amputation (TFA) based on objective and patient reported data collected from that specific user. Our central hypothesis is that biomechanical and patient perceived differences will be detectable and predictable between different MPK components within a certain individual allowing for the creation of the first ever clinical decision algorithm for MPK component selection. The 3 specific aims of this project are to: (1) assess functional performance associated with use and wear of three different commercially available MPKs and one research grade powered knee in 10 individuals with TFA, (2) assess subjective patient reported preferences associated with use of the same four prosthetic knees along with collection of subject specific anthropomorphic characteristics that may correlate with MPK choice and (3) generate the clinical decision algorithm for MPK selection. Using this research, clinicians will be better able to prescribe specific MPKs for an individual based on biomechanical data and patient reported outcomes rather than reimbursement or prior experience with an MPK.

2. Keywords

Microprocessor prosthetic knees, MPK, biomechanics, transfemoral amputation, prosthetics

3. Accomplishments

a. What were the major goals of the project?

Specific Aims 1: Determine functional performance associated with three commercially available microprocessor knees and an open-source research grade powered prosthesis.

Major Task 1: Human subject functional data collection of N=10 patients with transfemoral amputation (TFA) ambulating over a diverse set of terrain

- Milestone: GT IRB and DoD HRPO approval received – 100% completion
- Milestone: Complete set of functional amputee data collected- 100% completion

Specific Aim 2: Assess patient reported outcomes for each prosthesis type

Major Task 2: Human subject subjective preferences and anthropomorphic data collection of N=10 transfemoral patients

- Milestone: Complete set of patient reported preferences and anthropomorphic amputee data collected– 100% completion

Specific Aim 3: Create a clinical decision algorithm for the 3 commercially available MPK prostheses which will allow clinicians to make a logical, structured decision on the best MPK to provide to their patient

Major Task 3: Data Analysis

- Milestone: Data analyzed- 100% completion

Major Task 4: Create Clinical Decision Algorithm

- Milestone: Clinical Decision Algorithm created- 10% completion

Major Task 5: Data Dissemination

- Milestone: Generate a composite score for each device for a specific user – 0% completion

b. What was accomplished under these goals?

In this year, we completed collection of the functional performance measures and patient reported outcomes for one subject with each of the three commercially available microprocessor knees (Ossur Rheo, Otto Bock C-leg 4 and Ossur Power Knee) for a total of ten subjects completed over the course of the grant. In addition, we have collected functional performance measures and patient reported

outcomes with the Open-Source Leg (OSL) for nine subjects. One subject was unable to return for testing in the OSL due to medical issues.

In the next year, we plan to finish processing and analyzing the biomechanics data of all ten subjects with the three commercial devices as well as the OSL data. We also plan to develop a clinical decision algorithm for the three commercial devices from the data collected.

Major Task 1: Human subject functional data collection of N=10 patients with TFA ambulating over a diverse set of terrain

We have collected a full biomechanics dataset for ten subjects while wearing the Ossur Power Knee, Otto Bock C-leg 4, and Ossur Rheo Knee. The subjects walk on different terrain conditions including level ground, ramps, stairs and perform the NBWT. Examples of the processed Vicon data are shown in *Figure 1* for ramp and stair ascent. In addition, the L-Test of functional mobility and the 2-minute walk test were added for the initial evaluation visit to enhance our baseline measurements and initial characterization of participants.

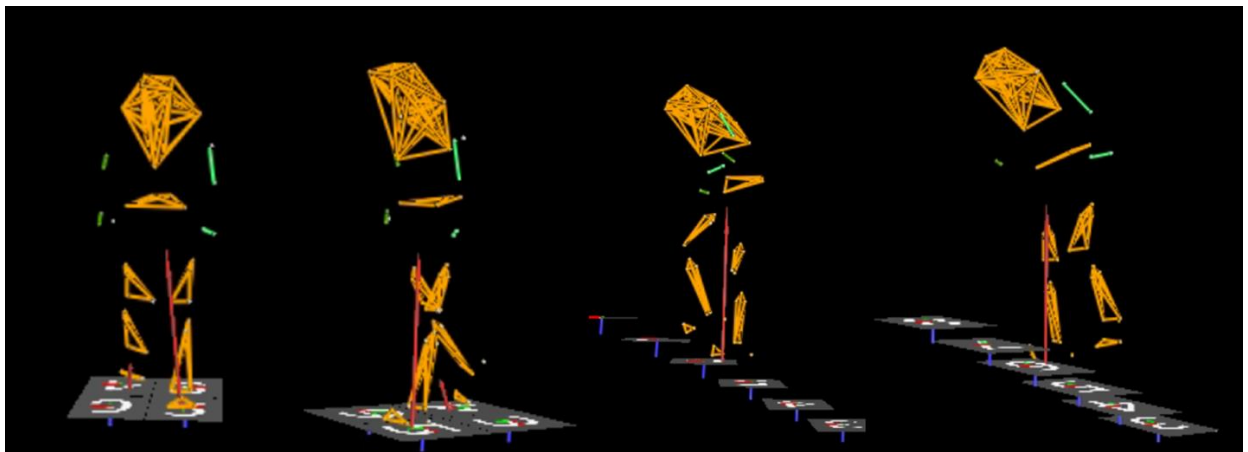


Figure 1: Ramp and Stair Ascent Vicon Data Demonstration

Major Task 2: Human subject subjective preferences and anthropomorphic data collection of N=10 transfemoral patients

Anthropomorphic data (*Table 1*) and patient preference data (*Tables 2-4* and *Figures 2-6*) have been collected for 10 subjects for the three commercially available. *Table 2* and *Figure 2* show the Full PEQ survey results with the C-Leg and Rheo having higher scores than the Power Knee. *Table 3* and *Figure 3* show the CLASS survey results with the C-Leg and Rheo having higher scores than the Power Knee. *Figure 4* shows the OPUS_HRQOL survey results with the Power Knee having the highest score followed by the C-Leg and Rheo. *Figure 5* shows the OPUS_LEFS survey results with the C-Leg having slightly higher scores than the Rheo and Power Knee. *Table 4* and *Figure 6* shows the modified VR-36 survey results with all three commercial knees having about equal scores. We have also added an additional survey for the initial visit to assess terrains and activities commonly encountered by subjects.

Table 1: Anthropomorphic data for subjects 1-10

<i>Subject</i>	<i>AmpNoProScore</i>	<i>Age (yrs.)</i>	<i>Height (m)</i>	<i>Weight (kg)</i>	<i>Sex</i>	<i>Amp Side</i>	<i>Age at Amp</i>	<i>Clinically Prescribed Knee</i>
1	35	69	1.95	102	M	Left	17	C-leg 3
2	41	36	1.75	74.7	M	Right	30	Plie 3.0
3	40	55	1.8	80.3	M	Right	46	X3

4		42	43	1.57	53.45	F	Left	18	Plie 3.0
5		41	44	1.79	92.2	M	Left	39	C-leg 3
6		32	49	1.7	102.7	M	Right	45	C-leg 4
7		35	55	1.79	103.35	M	Left	27	Proteor Quattro
8		42	30	1.73	82.65	M	Left	26	C-leg 4
9		41	59	1.55	57.55	F	Right	16	C-leg 4
10		32	52	1.75	74.84	M	Right	16	C-leg 4
Average		38.1	49.2	1.74	82.37				
Standard Deviation		4.12	11.41	0.12	17.97				

Table 2. PEQ data for Subjects 1-10, P=Power Knee, C=C-leg 4, R= Rheo, a score of 10 in each category indicates the max positive score

PEQ subscales

Subject		Ambulation	Appearance	Frustration	Perceived Response	Residual			Utility	Well Being
						Limb Health	Social Burden	Sounds		
1	P	7.9	8.8	5.0	10.0	9.3	10.0	3.0	8.1	8.5
1	C	8.9	9.6	9.0	10.0	9.5	10.0	5.5	9.5	8.0
1	R	9.0	9.0	7.0	9.8	9.5	9.7	9.5	9.3	8.0
2	P	8.4	9.6	3.5	8.8	10.0	6.0	10.0	10.0	10.0
2	C	10.0	8.6	10.0	10.0	10.0	10.0	10.0	10.0	10.0
2	R	10.0	9.6	10.0	9.8	10.0	10.0	10.0	10.0	10.0
3	P	7.3	7.2	4.5	8.6	5.7	6.7	8.0	7.5	6.5
3	C	5.4	6.4	3.0	8.6	4.7	3.7	9.5	8.4	6.0
3	R	6	6.4	4	8.8	4	4	9.5	7.25	4.5
4	P	10.0	9.4	5.0	6.0	8.8	8.7	1.0	7.3	10.0
4	C	10.0	9.8	10.0	10.0	9.5	10.0	10.0	9.9	10.0
4	R	9.1	9.2	7.0	10.0	8.7	10.0	10.0	9.0	10.0
5	P	7.3	7.8	6.0	8.0	6.2	8.3	1.0	5.8	9.0
5	C	10.0	9.8	10.0	9.6	8.2	10.0	8.5	9.5	10.0
5	R	9.4	5.6	2.5	8.0	8.0	9.3	1.0	6.6	8.5
6	P	9.9	10.0	10.0	10.0	9.0	10.0	5.0	9.6	10.0
6	C	9.1	10.0	10.0	10.0	8.0	10.0	10.0	9.9	9.5
6	R	9.6	10.0	10.0	10.0	9.3	10.0	7.5	9.8	10.0
7	P	7.1	8.6	5.0	7.0	9.5	9.0	1.0	7.5	6.0
7	C	9.6	10.0	10.0	10.0	9.7	10.0	9.0	9.9	9.5
7	R	8.4	9.4	9.5	9.6	9.3	10.0	8.5	8.9	9.5
8	P	8.6	10.0	8.0	10.0	9.0	10.0	3.0	9.1	10.0
8	C	9.7	8.8	10.0	10.0	9.3	10.0	10.0	9.5	9.5
8	R	9.1	8.8	10.0	10.0	8.2	10.0	9.5	8.6	8.5
9	P	7.3	9.8	1.0	4.6	9.3	10.0	1.0	6.9	10.0
9	C	10.0	10.0	10.0	10.0	9.8	10.0	10.0	9.9	10.0
9	R	9.6	10.0	7.5	9.6	9.7	10.0	8.5	9.5	10.0
10	P	8.9	9.0	8.0	9.0	9.0	10.0	8.0	7.9	8.5
10	C	9.0	9.6	10.0	10.0	7.7	10.0	9.0	8.1	9.0
10	R	9.0	9.6	8.0	10.0	8.7	10.0	9.0	7.9	9.0

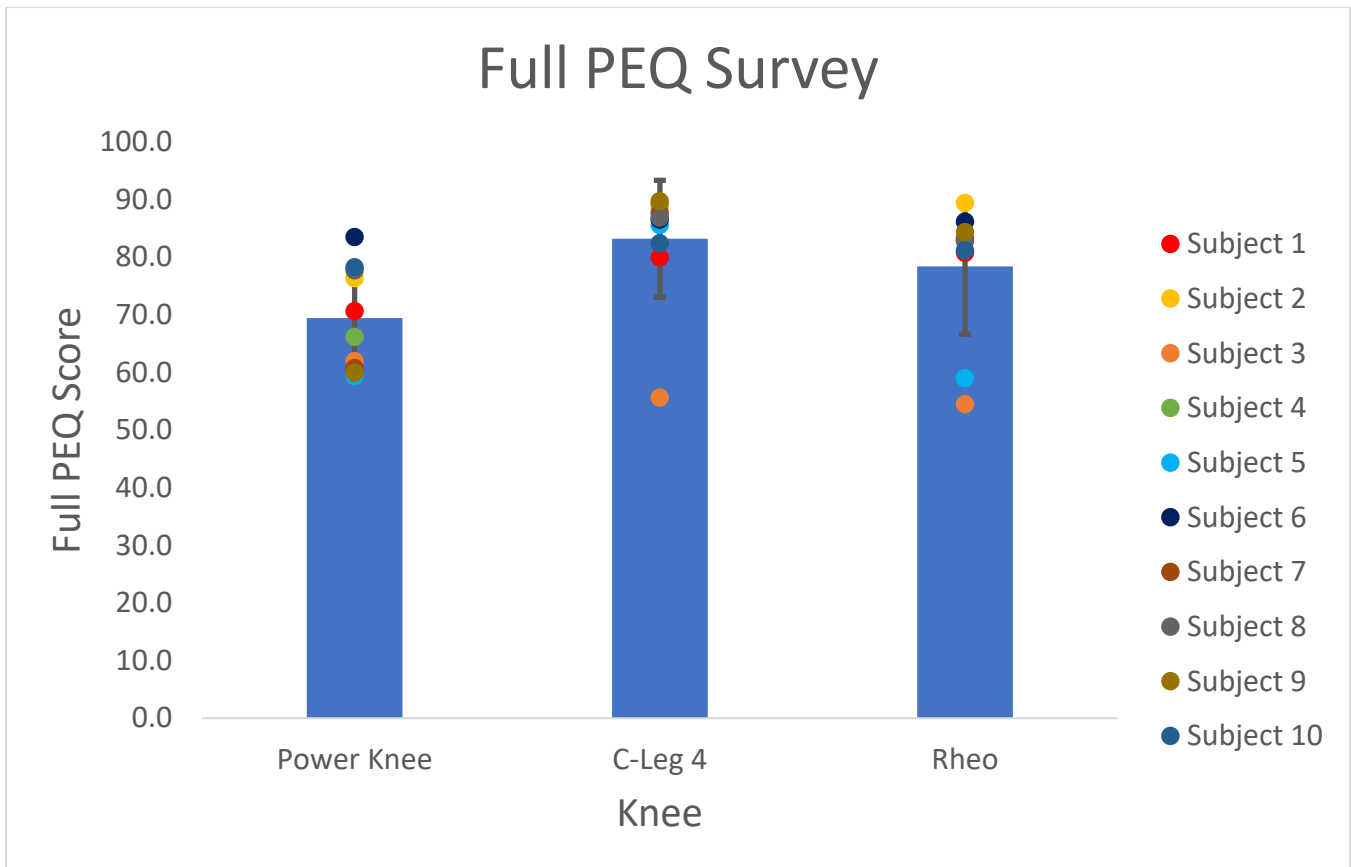


Figure 2. PEQ data for Subjects 1-10, a summed score of 90 indicates the max positive score

Table 3. CLASS subscales data for Subjects 1-10, P=Power Knee, C=C-leg 4, R= Rheo, a score of 16 for each category indicates the max positive score

		CLASS Subscales			
		Stability	Suspension	Comfort	Appearance
1	P	15	15	16	16
1	C	16	16	16	16
1	R	16	16	16	16
2	P	13	13	13	16
2	C	16	16	16	10
2	R	16	16	16	15
3	P	12	12	12	12
3	C	14	12	11	16
3	R	13	14	12	16
4	P	15	16	16	12
4	C	16	16	16	16
4	R	10	16	15	16
5	P	9	11	12	12
5	C	3	3	3	0
5	R	15	16	15	0
6	P	16	16	16	12
6	C	11	14	14	14
6	R	15	15	15	15
7	P	14	12	12	12
7	C	4	4	4	4
7	R	12	12	12	12

8	P	13	13	15	13
8	C	16	16	12	12
8	R	15	13	15	12
9	P	14	12	13	16
9	C	16	16	16	16
9	R	13	16	14	16
10	P	14	12	12	12
10	C	16	16	16	16
10	R	12	12	14	12

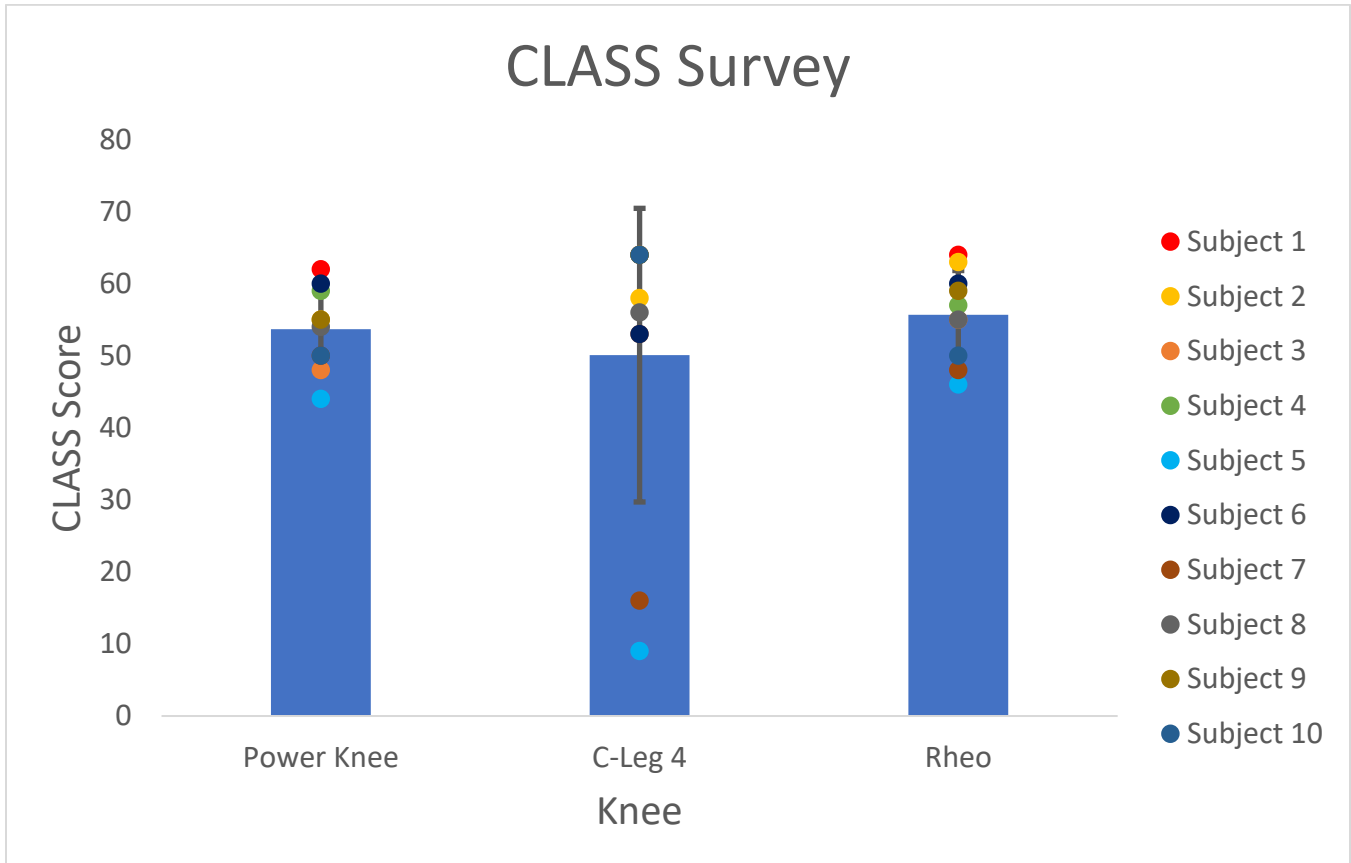


Figure 3. CLASS data for Subjects 1-10, a summed score of 64 indicates the max positive score

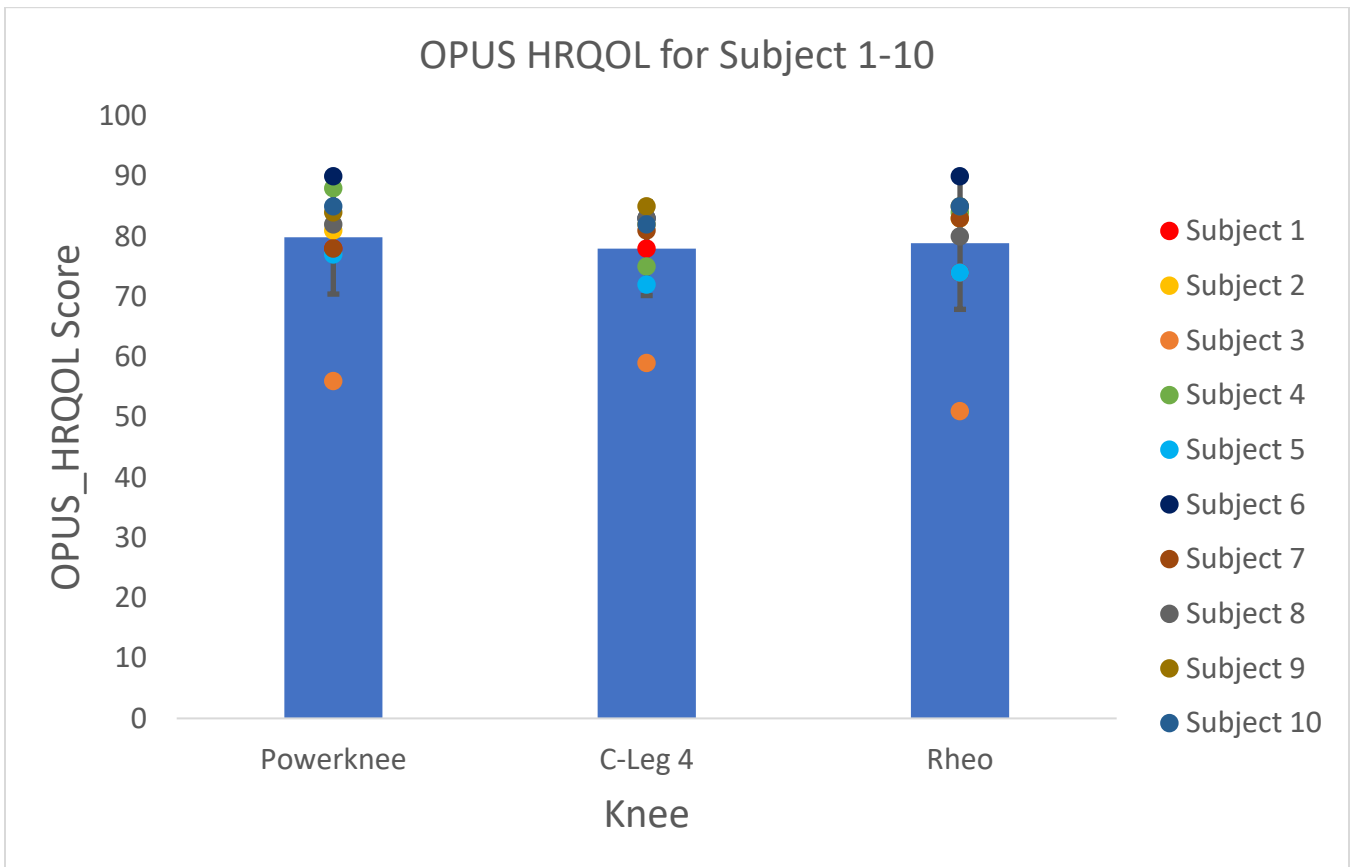


Figure 4. OPUS_HRQOL data for Subjects 1-10, a summed score of 92 indicates the max positive score

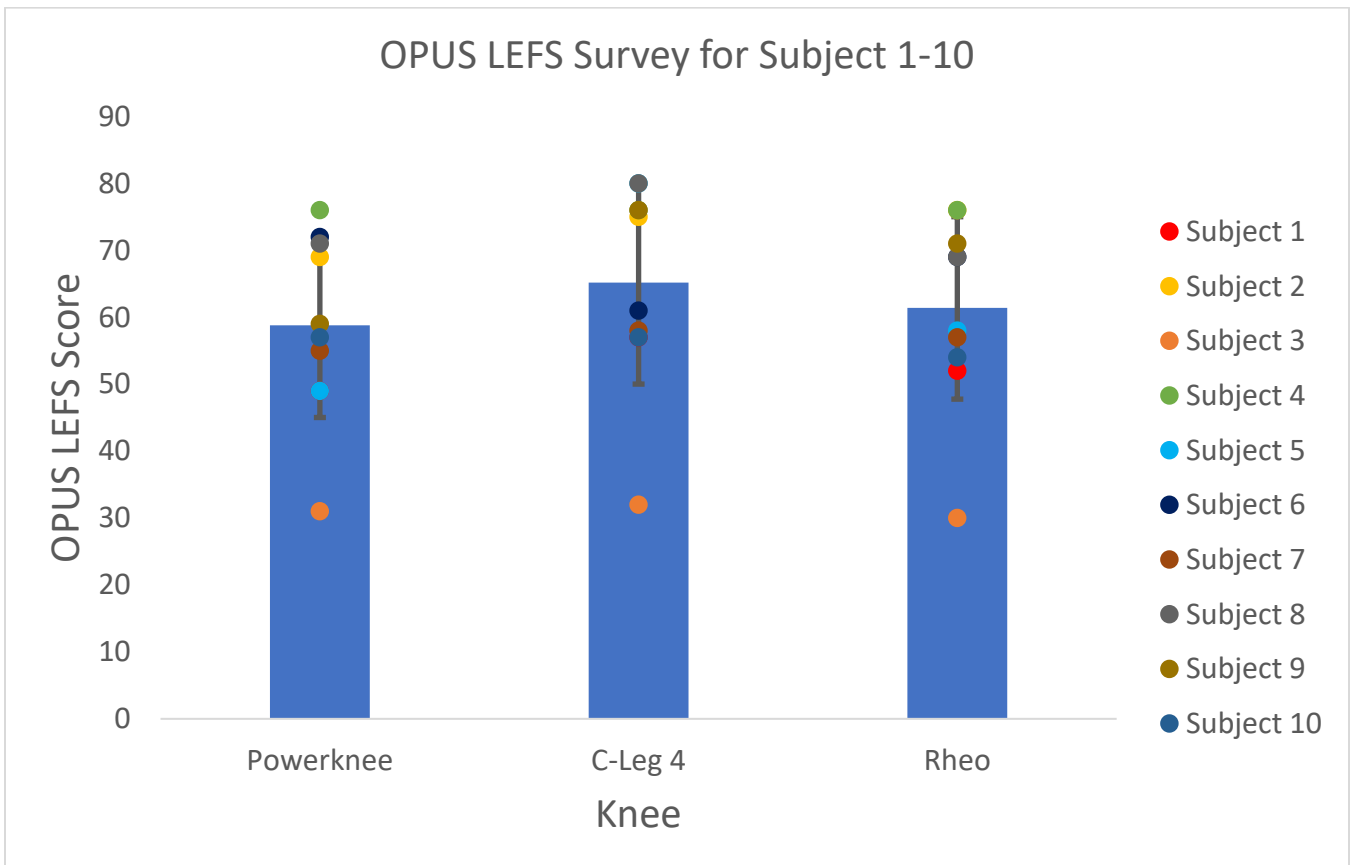


Figure 5. OPUS_LEFS data for Subjects 1-10, a summed score of 80 indicates the max positive score

Table 4. Modified VR-36 data for Subjects 1-10, P=Power Knee, C=C-leg 4, R= Rheo, a score of 100 in each category indicates the max positive score

Modified VR-36

Subject		General Health	Physical Functioning	Physical Health	Role limitations due to emotional problems	Role limitations due to social functioning	Pain	Energy/fatigue	Emotional well-being	Health change
1	P	50	65	100	100	100	57.5	85	88	50
1	C	75	70	100	100	100	90	85	88	50
1	R	70	75	100	100	100	90	80	92	50
2	P	95	100	100	100	100	100	85	96	75
2	C	95	90	87.5	100	100	90	70	88	50
2	R	90	95	100	100	100	90	80	92	75
3	P	65	40	62.5	58.3	50	32.5	35	76	50
3	C	75	25	37.5	41.7	62.5	35	50	76	62.5
3	R	65	40	31.25	66.7	75	32.5	40	76	62.5
4	P	80	90	81.25	100	100	77.5	80	88	50
4	C	100	95	100	100	100	100	80	92	50
4	R	100	95	100	100	100	90	80	72	50
5	P	70	65	75	83.3	100	100	60	88	50
5	C	60	100	100	100	100	100	60	88	100
5	R	75	95	62.5	75	100	70	80	80	50
6	P	85	95	100	100	100	100	95	96	100
6	C	80	95	100	100	100	100	90	88	100
6	R	80	100	100	100	100	100	95	80	100
7	P	75	80	100	100	100	90	50	84	50
7	C	60	80	100	100	100	90	45	80	50
7	R	55	85	100	100	100	90	50	92	50
8	P	100	85	81	92	100	77.5	80	96	100
8	C	100	80	100	100	100	90	80	96	100
8	R	90	85	81	92	87.5	90	80	80	100
9	P	95	85	100	100	100	90	80	96	100
9	C	90	95	100	100	100	100	90	100	100
9	R	90	80	100	100	100	90	90	96	100
10	P	85	100	100	100	100	100	85	92	50
10	C	75	90	100	100	100	100	85	92	50
10	R	85	90	100	100	100	90	80	92	50

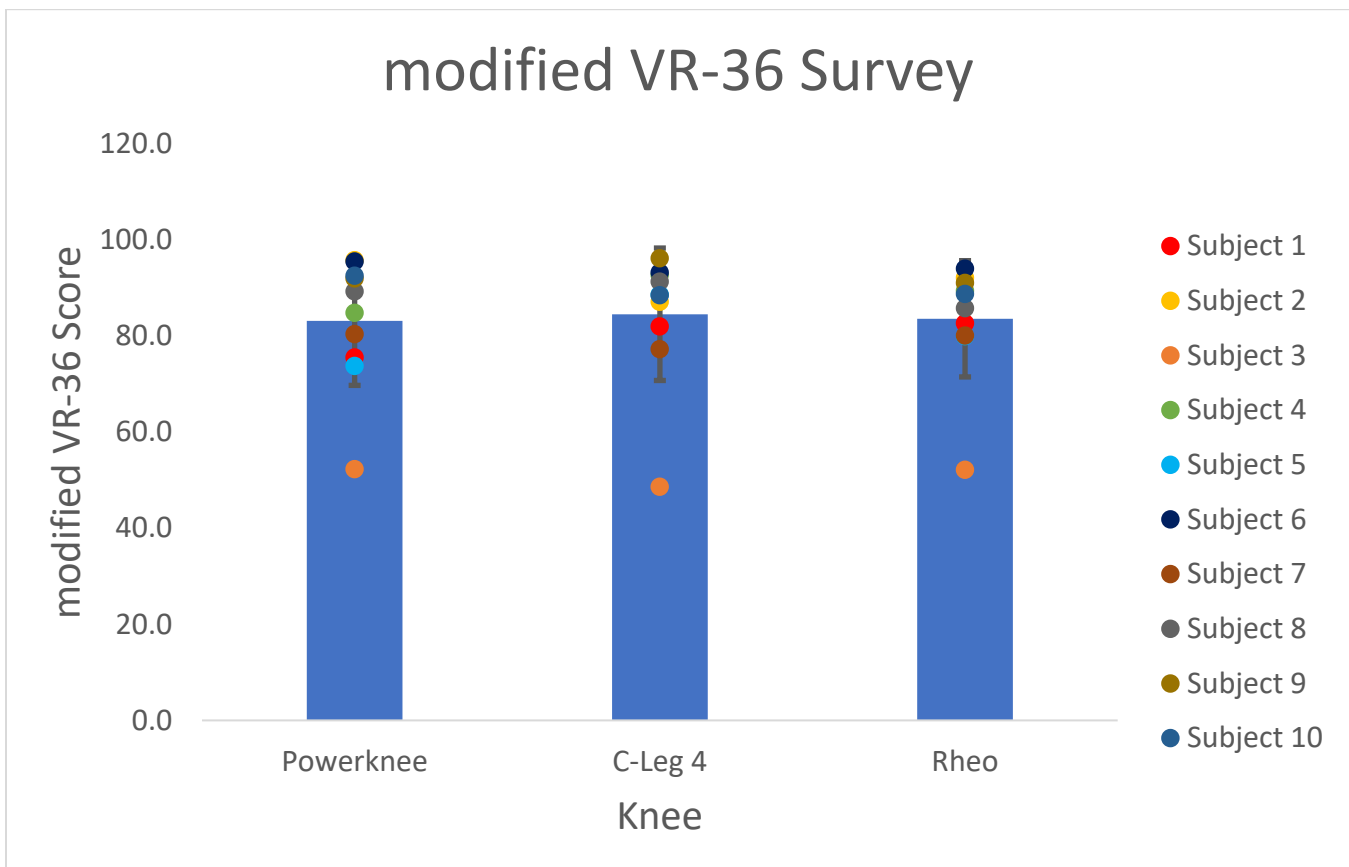


Figure 6. Modified VR-36 data for Subjects 1-10, an average score of 100 indicates the max positive score

Major Task 3: Data Analysis

Spatiotemporal data for each subject is shown in *Table 5* for ramp ascent speed, ramp descent speed, stair ascent speed, stair descent speed, NBWT distance, self-selected walking speed, Physiological Cost Index, 2-minute walk test speed, 10-minute walk test speed, Gait Variability Index and Stance Time % Asymmetry Index. The average steps/day and average cadence taken from the StepWatch are provided in *Figures 7-8* with C-Leg having slightly higher steps/day than the Power Knee and Rheo and the Power Knee having slightly faster cadence than the C-Leg and Rheo.

The Vicon data from the ramps and stairs conditions was used to compute the inverse kinematics, inverse dynamics, and powers of three major lower limb joints – hip, knee, and ankle. Average joint mechanics data for Subjects 1-10 across the four ambulation modes (ramp ascent/descent, stair ascent/descent) for prosthetic side (*Figures 9-13*) and sound side (*Figures 14-18*) are shown for the three commercially available prosthetic knees. *Figure 9* shows the ramp ascent joint mechanics on the prosthetic side and from the knee inverse kinematics, the Power Knee and C-Leg were found to have significantly more peak knee flexion than the Rheo ($p < 0.001$). *Figure 10* shows the ramp descent joint mechanics on the prosthetic side and from the knee inverse kinematics, the C-Leg was found to have significantly more peak knee flexion than the Rheo but not the Power Knee ($p = 0.027$). During stair ascent, subjects were encouraged to use step-over-step gait for the Power Knee and Rheo and step-to-step for the C-Leg as this is how these devices are intended to be used. Subjects who were not able to perform the appropriate stair ascent strategy were omitted from this section of data analysis. Additionally, subjects who were not able to properly trigger stair mode with the Power Knee and receive powered assistance were omitted as well. Therefore, when sample sizes were limited due to these reasons, we report effect sizes (as opposed to p-values) in an effort to show practical significance with effect sizes of 0.8 or higher interpreted as practical significance. *Figure 11* shows stair ascent using step-over-step joint mechanics on the prosthetic side and from the knee inverse kinematics, the Power Knee was found to have higher peak knee flexion than the Rheo with an effect size of 3.07 and a higher peak

power generated at the knee with an effect size of 0.83. *Figure 12* shows stair ascent of step-over-step vs. step-to-step joint mechanics on the prosthetic side and it was found that the Power Knee had more peak knee flexion with an effect size of 13.06 and more power generated with an effect size of 1.88 compared to the C-Leg. *Figure 13* shows the stair descent joint mechanics on the prosthetic side and there were no significant differences found between joint kinematics and kinetics. On the sound side (*Figures 14-18*) for each ambulation mode, the inverse kinematics and dynamics are shown at each joint. From these figures, it is shown that there were not significant differences between the commercial knees on the sound side.

Using the joint power, the energy distribution for Subjects 1-10 for each ambulation mode was found and is shown in *Figures 19-24*. Biological energy, which is the sum of the energy on the sound side as well as the prosthetic side hip, is calculated for each mode in addition to total energy which includes work completed by the prosthetic side knee and ankle. Each figure shows the energy distribution as a pie chart with positive energy for ascending tasks and negative energy for descending tasks, as well as a stacked bar graph with both the positive and negative energy. *Figure 19* shows the energy distribution during ramp ascent with the C-Leg having significantly lower total and biological energy than the Power Knee but not the Rheo ($p=0.01$). *Figure 20* shows the energy distribution during ramp descent with there being no significant differences in total or biological energy between the three knees. *Figure 21* shows the energy distribution during stair ascent using step-over-step with the Power Knee having less biological energy used than the Rheo with an effect size of 0.83. There was also greater positive energy used by the prosthetic knee side in the Power Knee than the Rheo with an effect size of 0.82. *Figure 22* shows the energy distribution of step-over-step vs. step-to-step stair ascent with the Power Knee having lower biological energy than the C-Leg with an effect size of 2.07. *Figure 23* shows the energy distribution during stair descent with there being no significant differences in total or biological energy between the three knees. *Figure 24* shows the energy distribution of step-to-step stair ascent with the C-Leg and Rheo with there being no significant differences in total or biological energy between two knees. The handrail usage was also calculated as a percentage of the subject's GRF over mass. Subjects with handrail usage above 15% BW were deemed not representative of the expected performance of a device and omitted from the data analysis. Two subjects were omitted from the data analysis of stair descent due to excessive handrail usage.

Figure 25 shows the receiver operating characteristic curve (ROC curve) for integrated whole body angular momentum (iWBAM) in all planes for subjects 1-10 where different colors are indicative of different knees. The ROC curve indicates the performance of a classification model at all classification thresholds where a larger area under the curve indicates better performance. *Figure 25* shows the transverse plane has the best performance score out of all three planes by using transverse plane integrated whole-body angular momentum as the metric to detect the fall.

Table 5: Outcomes of performance tasks for each participant. P= Power Knee, C= C-leg 4.0, R= Rheo, O= OSL; note NBWT, PCI and 2mwt are not shown for the OSL because these tasks were not tested in the OSL.

Subject	Knee	Ramp Ascent Speed (m/s)	Ramp Descent Speed (m/s)	Stair Ascent (steps/min)	Stair Descent (steps/min)	NBWT distance (ft)	PCI (beats/m)	2mwt speed (m/s)	10mwt speed (m/s)	GVI	ASI (Stance time %)
01	P	0.98	0.78	57.52	112.85	10.58	0.19	1.32	No data	117.19	15.98
	C	1.22	1.06	69.57	115.82	9.42	0.19	1.46	No data	118.12	14.18
	R	1.10	0.87	61.35	109.11	13.42	0.16	1.45	No data	127.14	15.24
02	P	0.91	0.75	59.08	117.58	16.60	0.38	0.93	.98	106.97	12.06
	C	1.11	0.89	53.00	66.96	12.80	0.20	1.26	1.19	103.88	10.97
	R	1.08	0.87	49.78	114.60	14.90	0.23	1.25	1.12	119.49	15.42
03	O	0.72	0.67	56.63	99.83				0.76	128.77	-14.66
	P	0.78	0.73	42.20	79.34	10.70	0.36	0.98	0.93	111.42	11.98
	C	0.78	0.72	70.06	93.20	11.08	0.24	1.04	0.95	110.71	14.79
	R	0.78	0.63	49.39	80.78	12.70	0.13	0.99	0.93	117.12	16.81
04	O	0.74	0.64	55.64	81.65				0.77	114.21	-20.99
	P	1.04	0.91	83.24	48.42	11	No data	1.51	1.26	102.88	1.51
	C	1.08	0.98	45.33	49.46	12.7	.25	1.61	1.34	103.21	0.72
	R	1.02	1.04	49.93	52.96	10.83	.17	1.61	1.34	110.45	2.67
05	O	0.47	0.42	48.60	59.14				0.72	110.07	17.47
	P	1.01	0.81	47.09	100.17	12.75	0.42	.94	0.97	117.74	14.88
	C	1.23	1.04	50.43	118.57	14.67	0.23	1.17	1.19	117.55	10.32
	R	1.09	0.79	43.71	78.91	17.33	0.38	1.05	1.11	120.15	9.19
06	O	0.83	0.70	57.55	73.87				0.93	121.27	-7.48
	P	0.59	0.43	33.47	44.54	3.70	0.25	0.80	0.74	125.46	18.13
	C	0.54	0.37	39.93	54.26	6.50	0.34	0.87	0.69	127.21	12
	R	0.62	0.44	36.34	53.32	8.50	0.71	0.93	0.85	128.05	11.32
07	O	0.46	0.43	37.77	50.98				0.51	138.08	-16.14
	P	0.68	0.51	50.65	91.74	13.2	0.25	0.70	0.62	120.52	21.11
	C	0.78	0.58	35.03	84.77	18.5	0.20	1.02	0.90	113.16	8.25
	R	0.76	0.56	38.85	82.37	11.75	0.26	0.89	0.85	128.10	8.46
08	O	0.41	0.49	46.43	60.83				0.41	135.12	21.43
	P	1.01	1.02	59.22	104.16	15	0.14	1.29	1.25	125.34	9.07
	C	0.89	0.90	47.47	123.41	14.5	0.22	1.24	1.25	111.48	6.59
	R	1.02	1.03	47.00	99.25	19.5	0.34	1.37	1.35	110.77	5.84
09	O	0.64	0.71	58.99	72.12				0.73	119.81	24.90
	P	0.88	0.87	55.54	117.20	9.75	0.43	1.23	1.19	116.63	-15.90
	C	0.96	1.03	54.67	112.96	12	0.38	1.24	1.09	117.26	-11.42
	R	1.06	1.14	56.62	104.10	13.1	0.43	1.25	1.33	120.31	-11.49
10	O	0.66	0.58	60.16	85.31				0.59	139.30	-11.72
	P	1.05	0.83	54.45	110.51	11	0.26	1.03	1.04	95.29	-12.60
	C	1.10	1.11	97.87	120.55	11	0.26	1.28	1.36	107.79	-10.61
	R	1.19	1.21	50.42	107.62	9	0.31	1.28	1.33	108.99	-8.72
0	O	0.82	0.80	57.35	86.31				0.97	98.07	-20.34

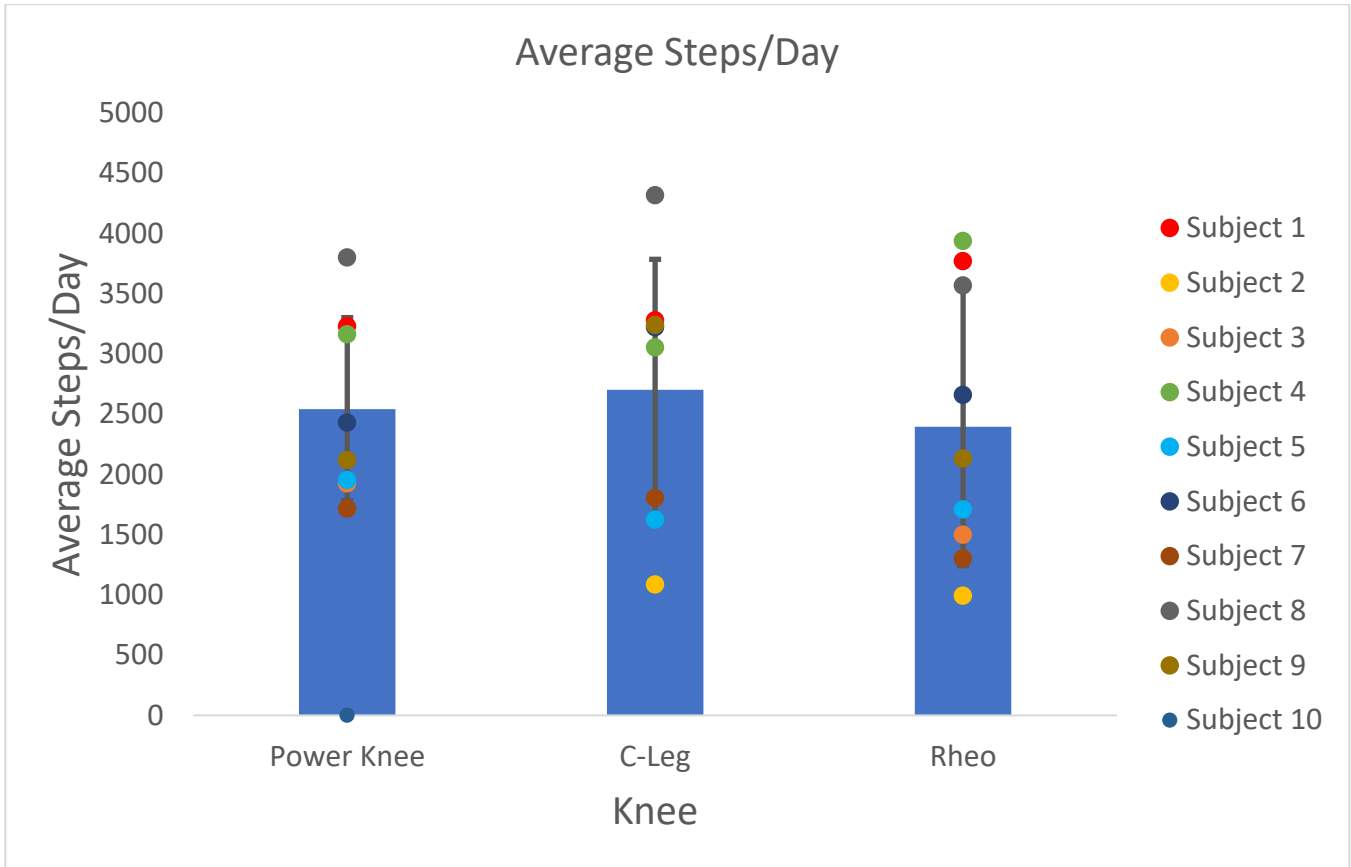


Figure 7. Average Steps/day from StepWatch for Subjects 1-10

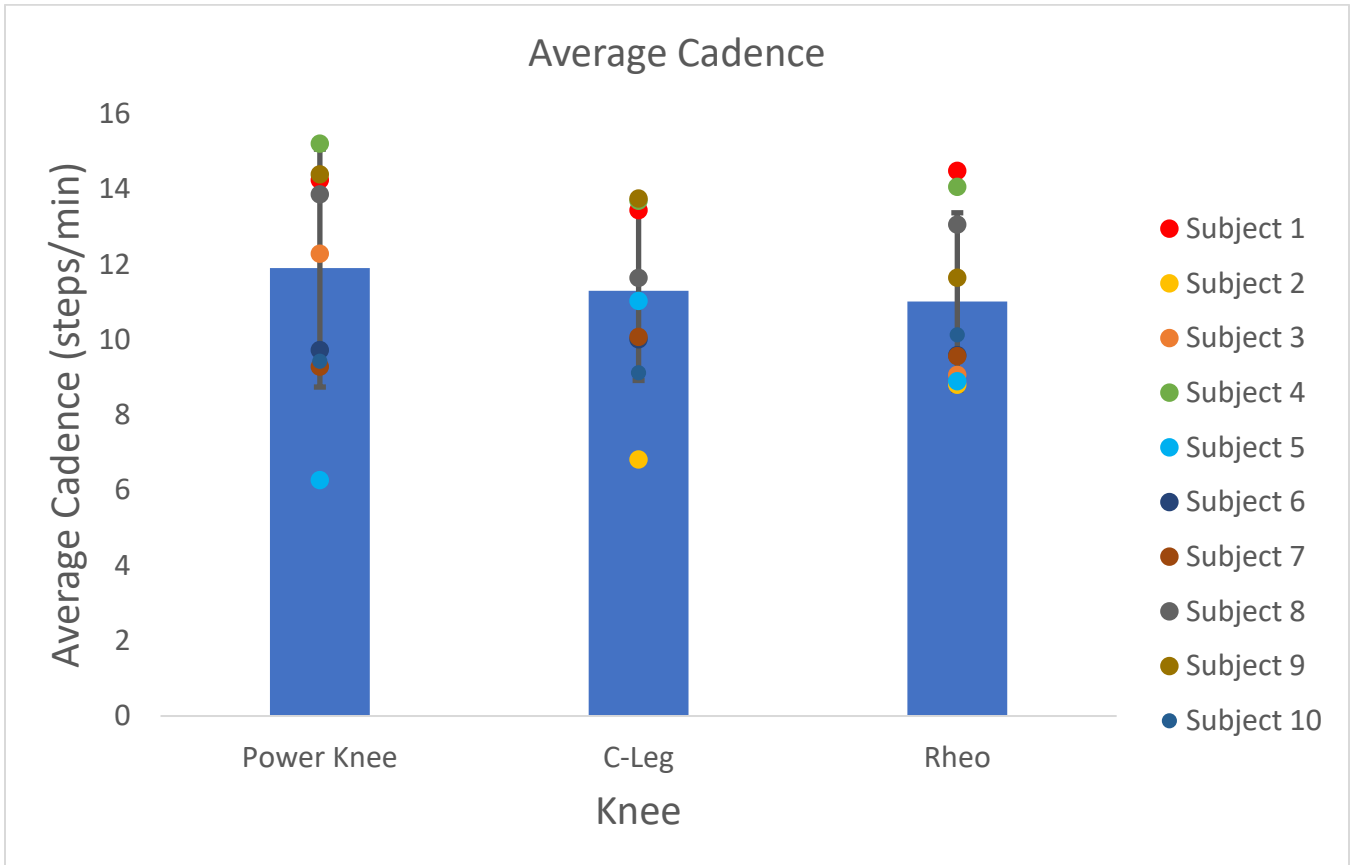


Figure 8. Average Cadence (steps/min) from StepWatch for Subjects 1-10

Ramp Ascent Prosthetic Side Joint Mechanics

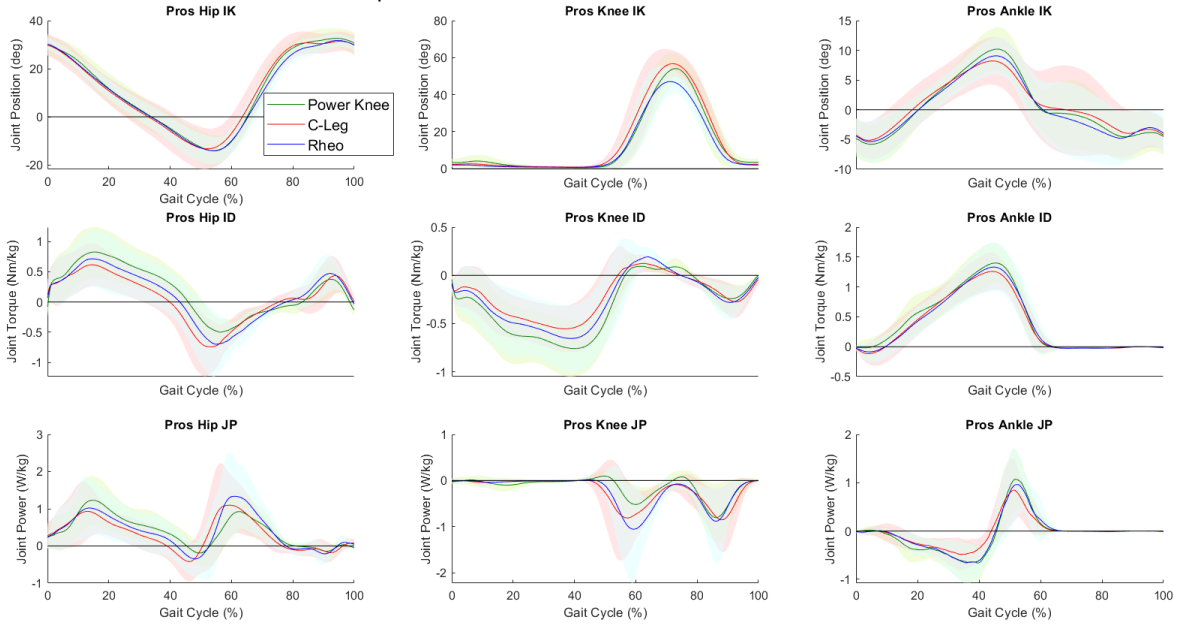


Figure 9: Ramp ascent prosthetic side joint mechanics for subjects 1-10 for commercially available MPKs

Ramp Descent Prosthetic Side Joint Mechanics

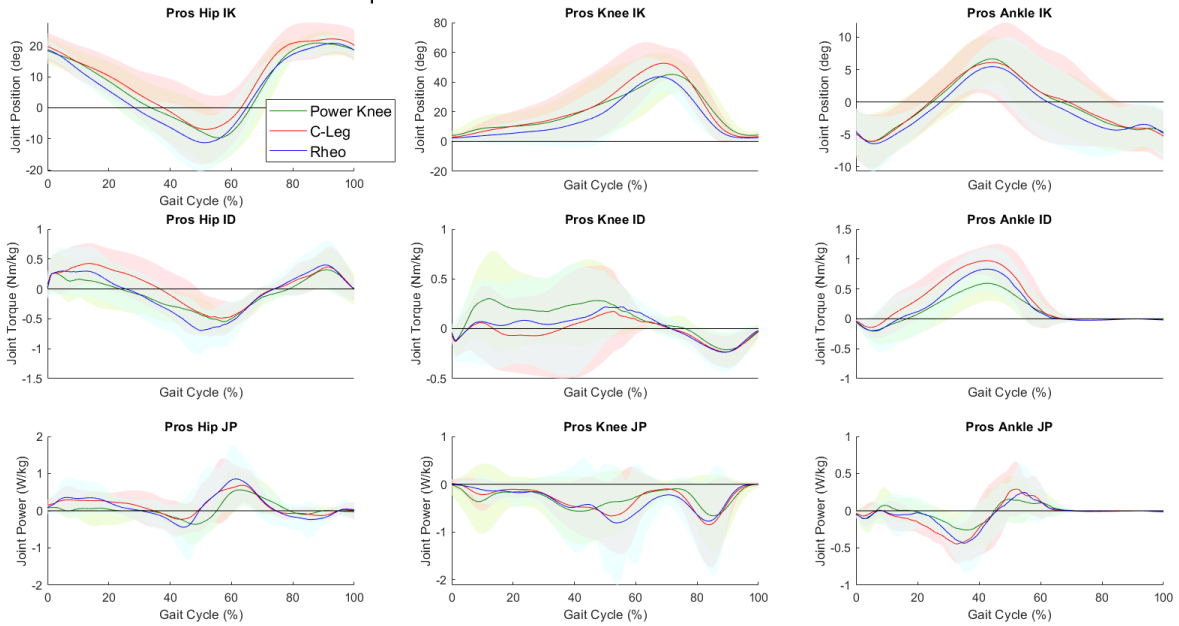


Figure 10: Ramp descent prosthetic side joint mechanics for subjects 1-10 for commercially available MPKs

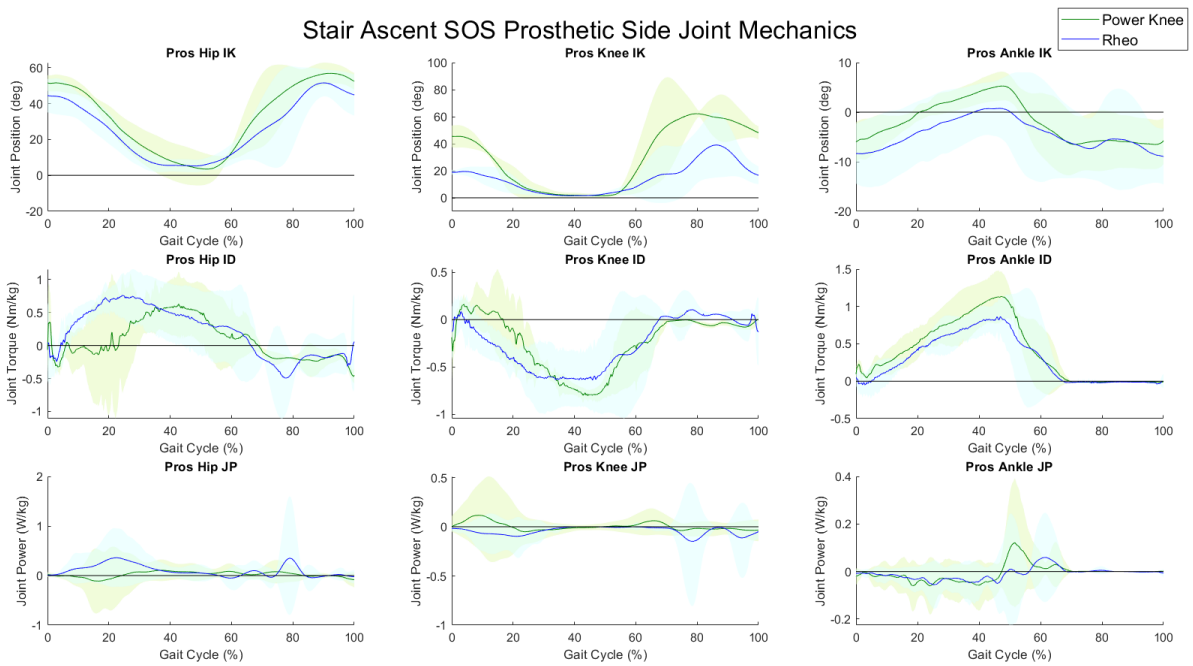


Figure 11: Step-over-step (Power Knee and Rheo) stair ascent prosthetic side joint mechanics for subjects 1-10 (n=3)

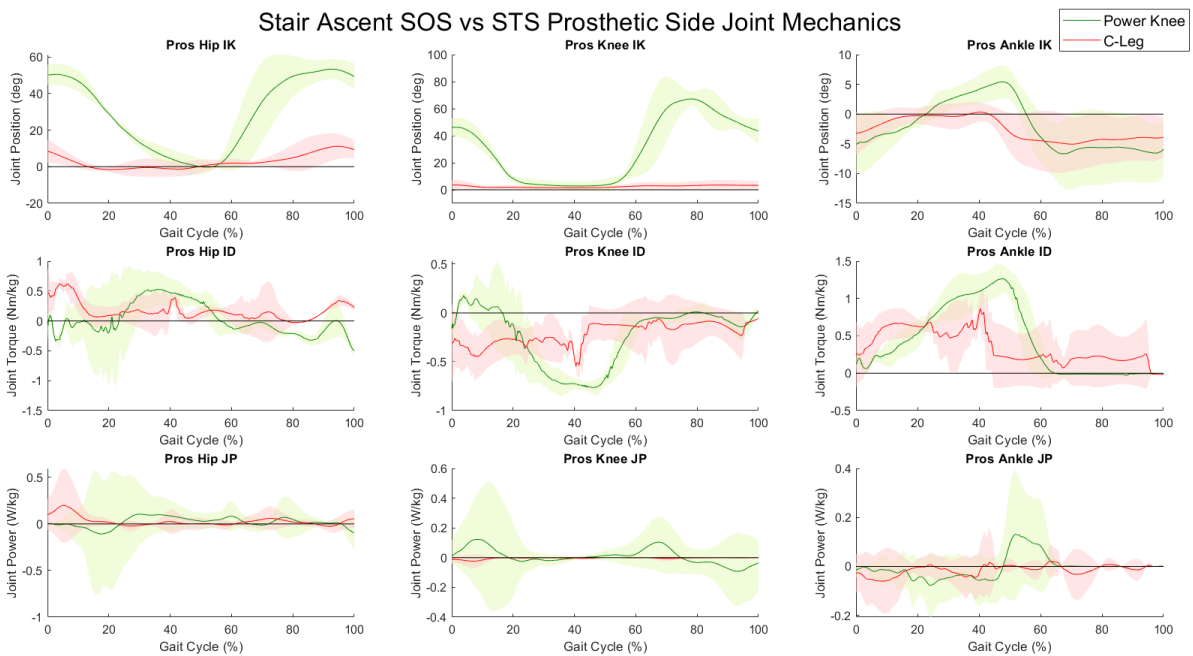


Figure 12: Step-over-step vs. step-to-step (Power Knee and C-Leg) stair ascent prosthetic side joint mechanics for subjects 1-10 (n=3)

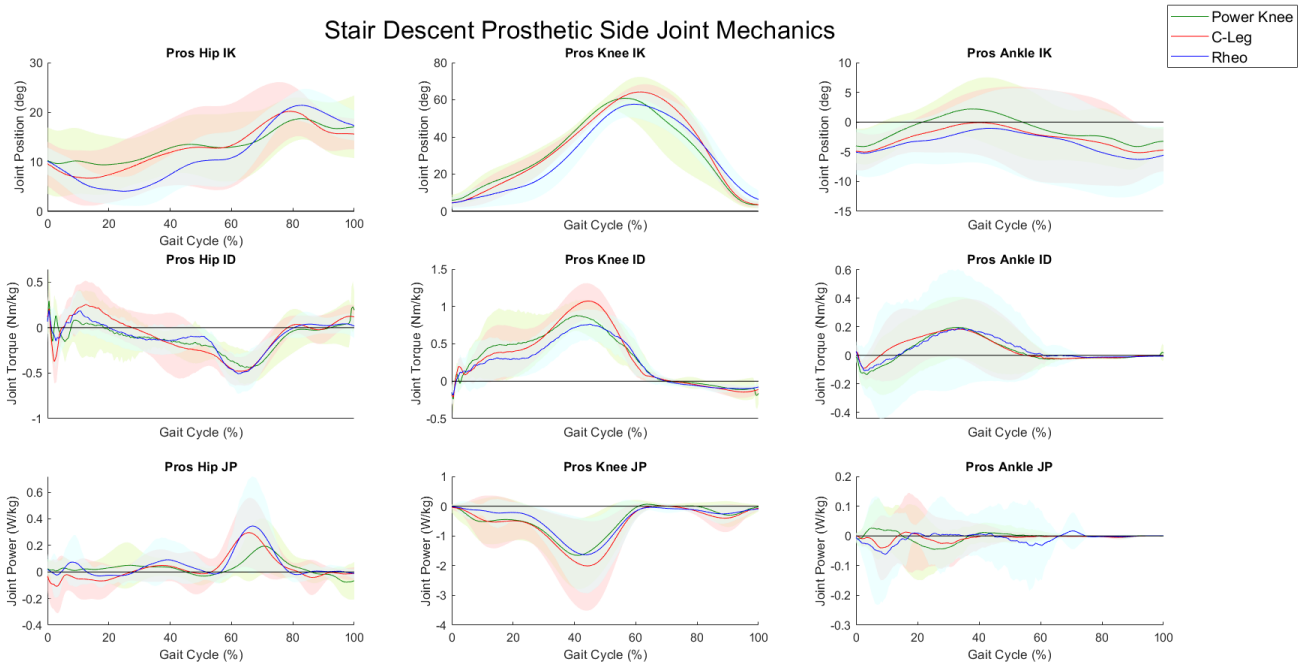


Figure 13: Stair descent prosthetic side joint mechanics for subjects 1-10 for commercially available MPKs (n=5)

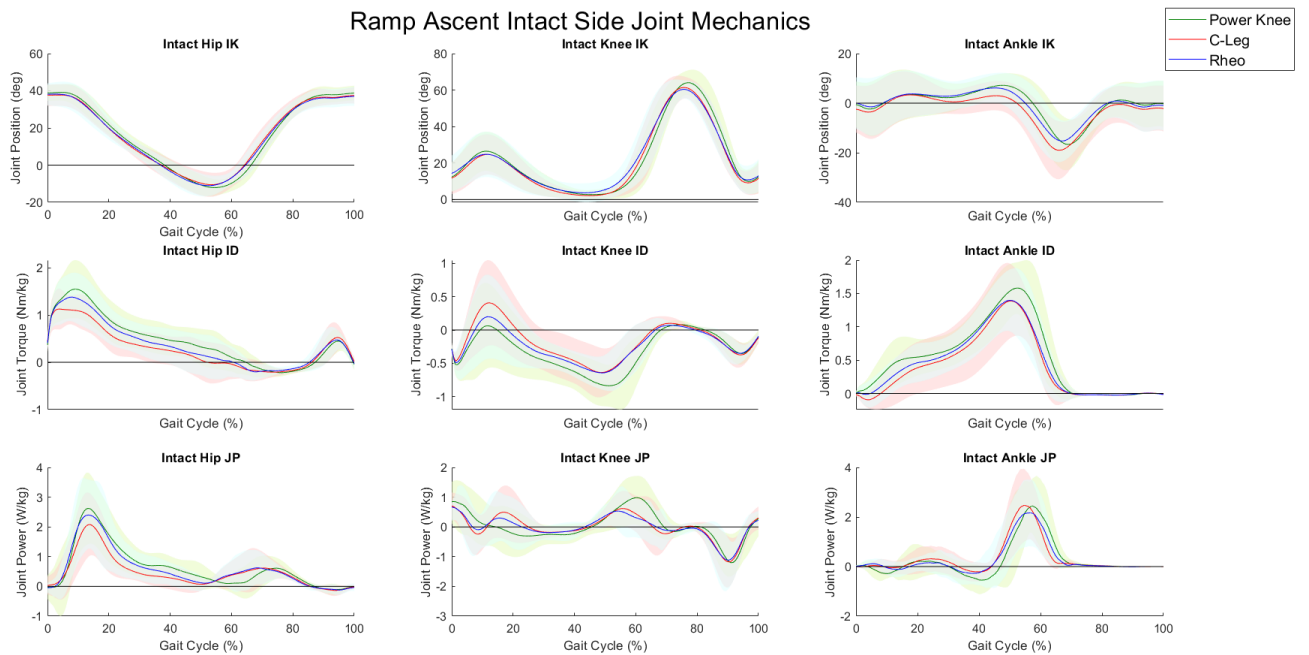


Figure 14: Ramp ascent sound side joint mechanics for subjects 1-10 for commercial MPKs

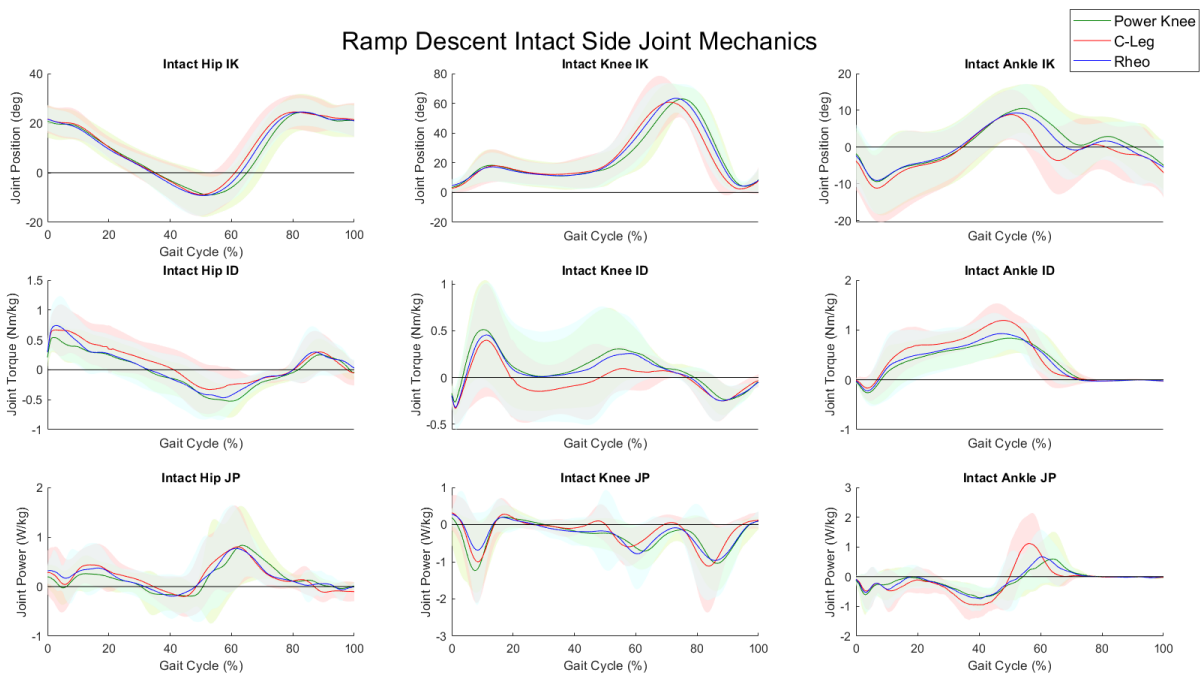


Figure 15: Ramp descent sound side joint mechanics for subjects 1-10 for commercial MPKs

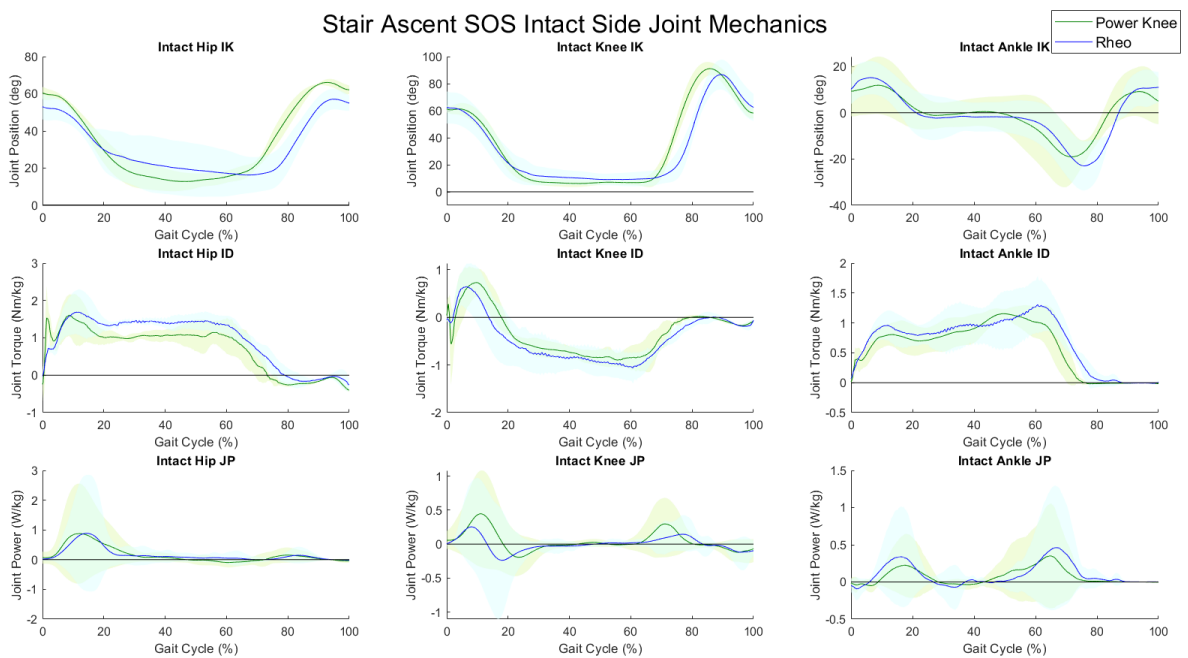


Figure 16: Step-over-step (Power Knee and Rheo) stair ascent sound side joint mechanics for subjects 1-10 (n=3)

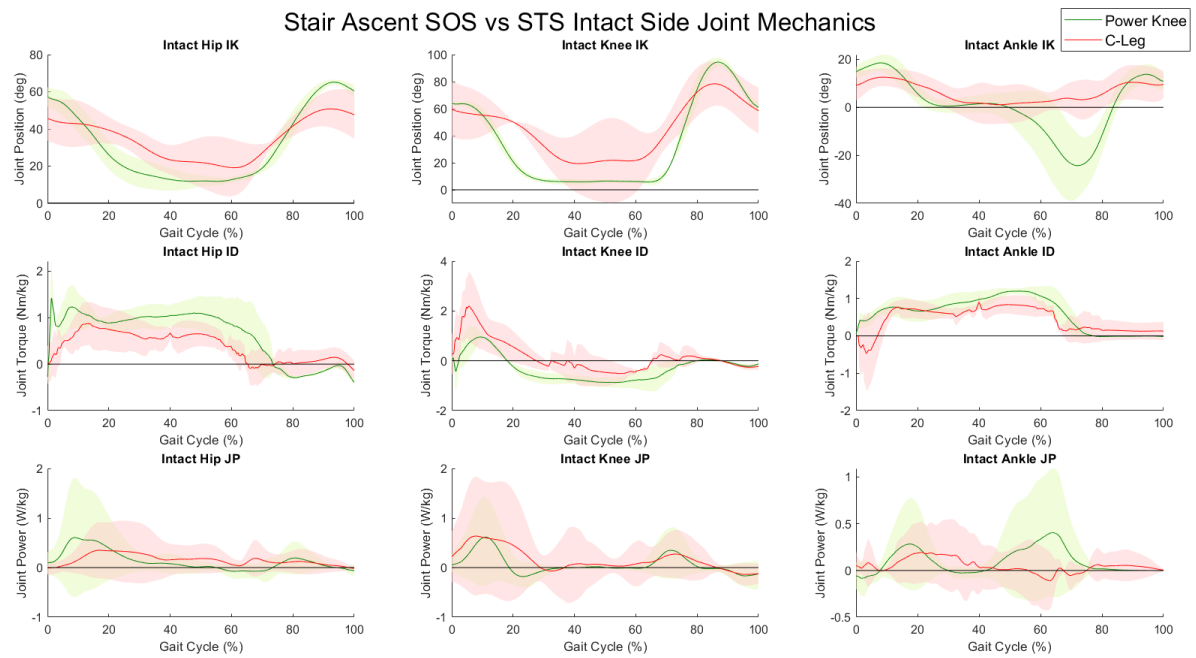


Figure 17: Step-over-step vs. step-to-step (Power Knee and C-Leg) stair ascent sound side joint mechanics for subjects 1-10 ($n=3$)

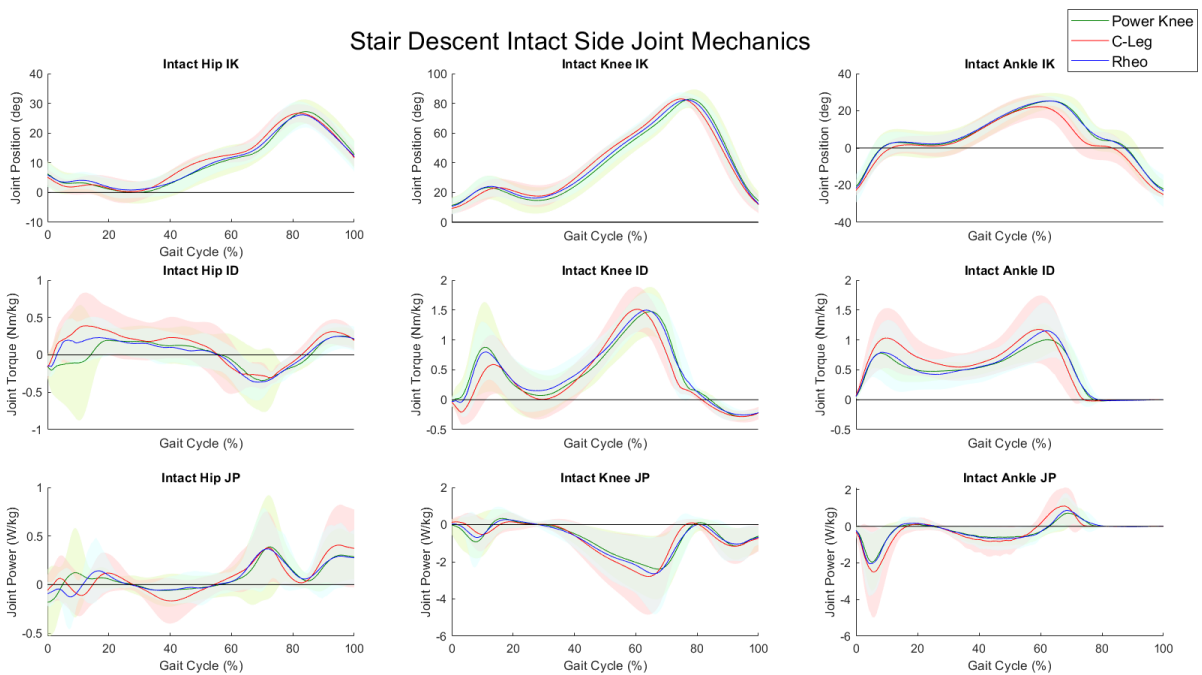


Figure 18: Stair descent sound side joint mechanics for subjects 1-10 for commercial MPKs ($n=5$)

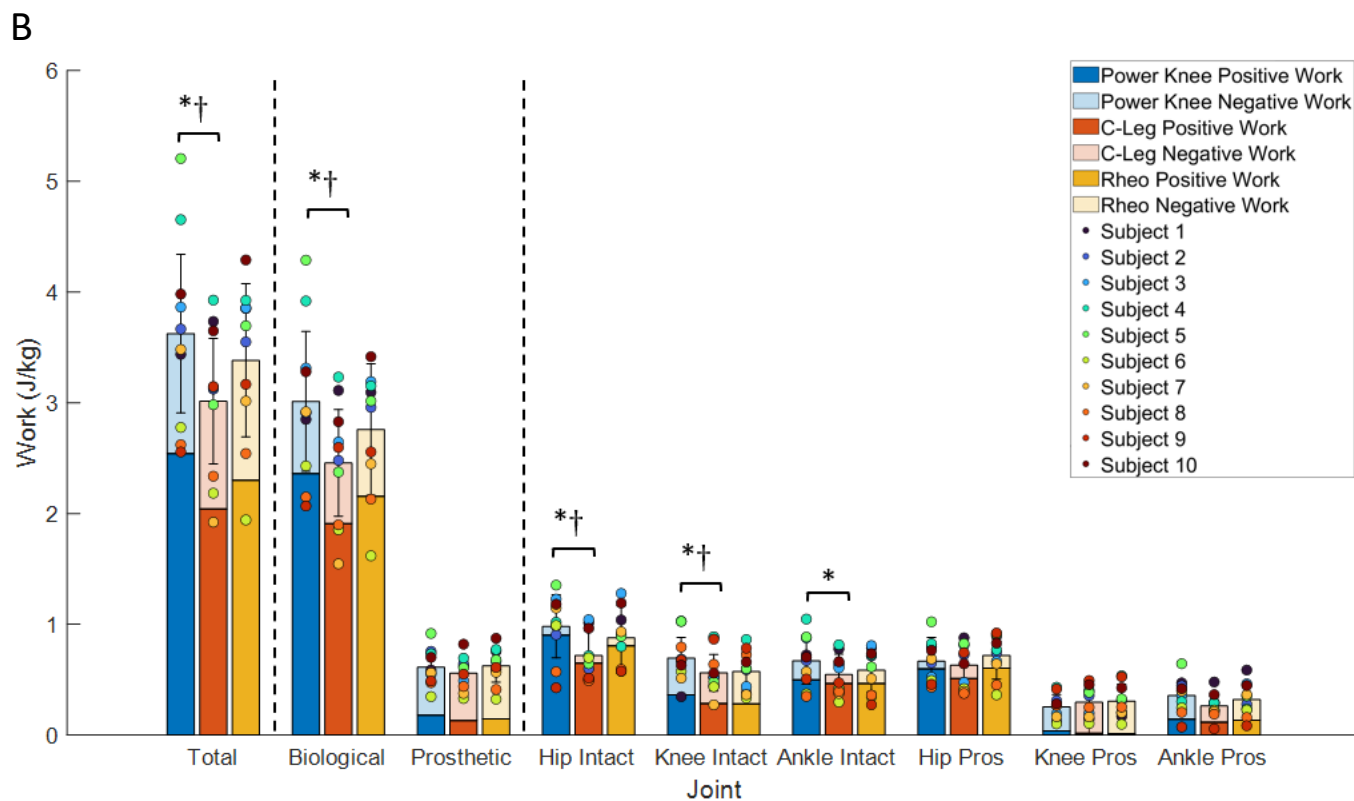
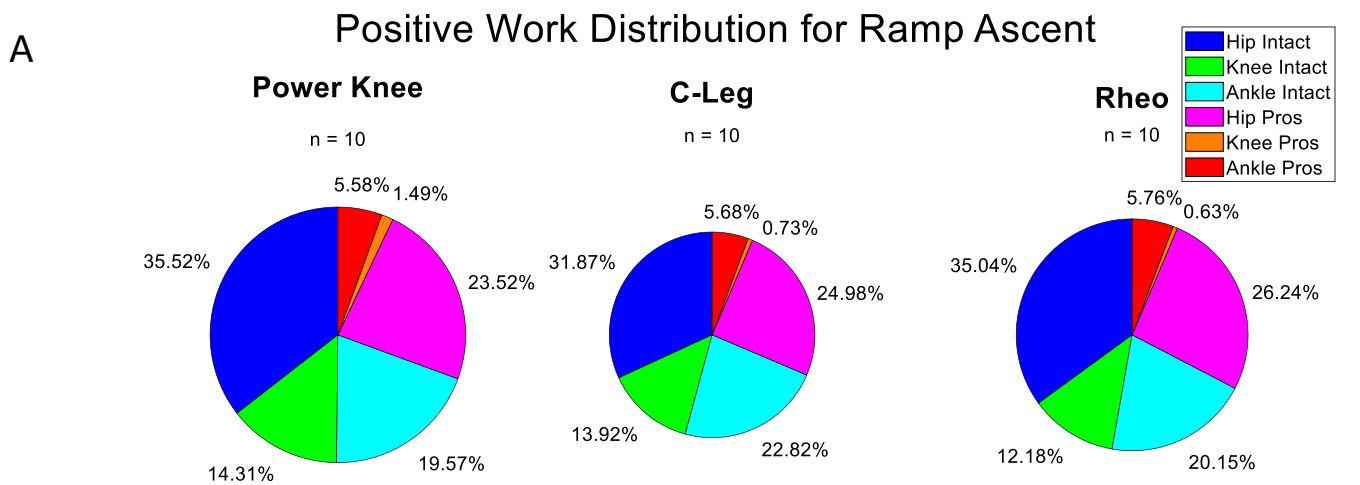


Figure 19: Positive joint energy distribution (A) and combined positive and negative joint energy (B) for ramp ascent. Negative energy is stacked on top of positive energy. Significant differences are indicated with a (*) for differences in total energy and a (†) for differences in positive energy.

Negative Work Distribution for Ramp Descent

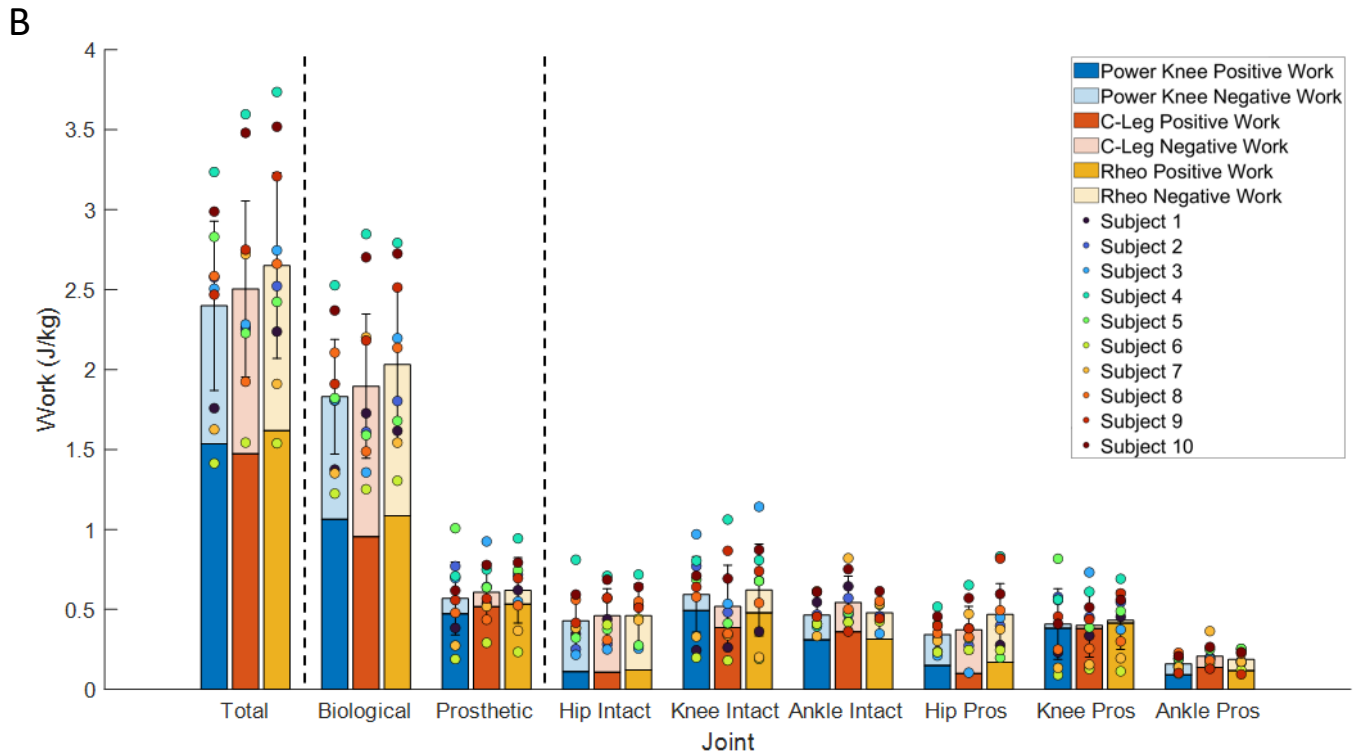
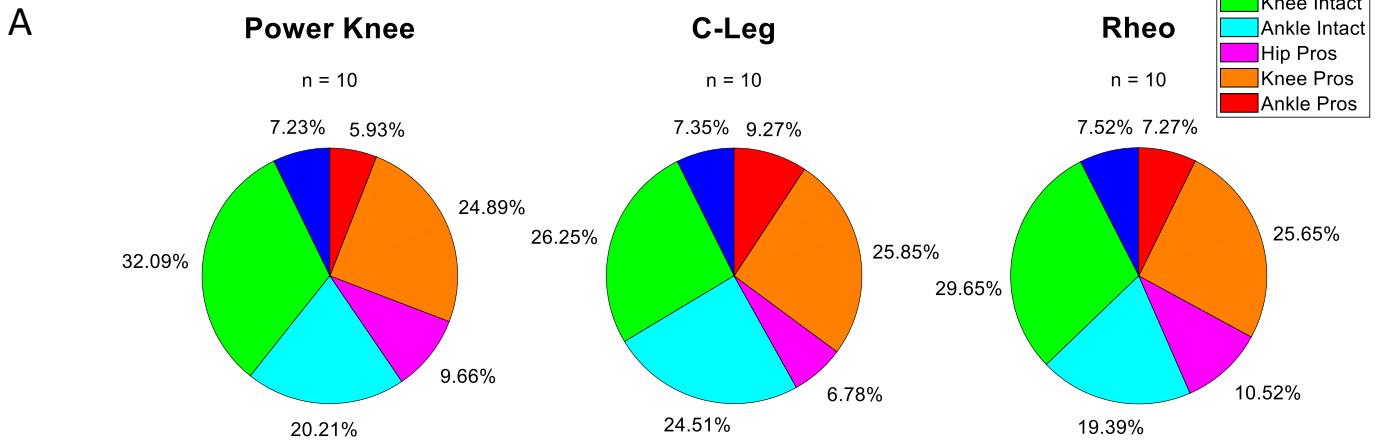
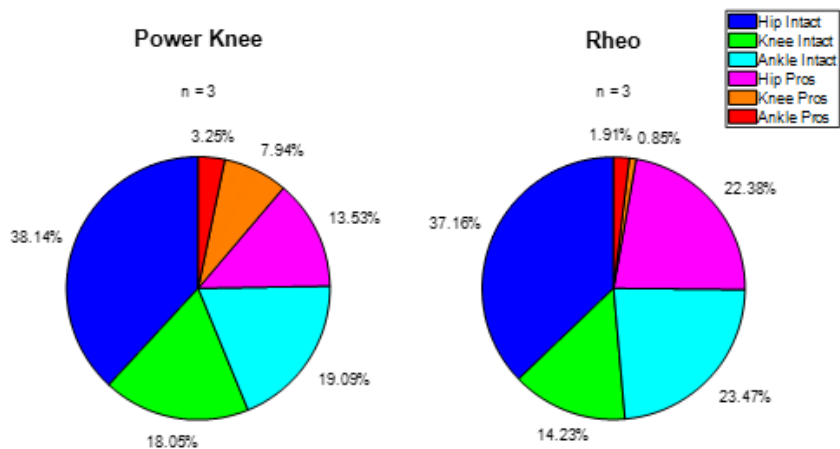


Figure 20: Negative joint energy distribution (A) and combined positive and negative joint energy (B) for ramp descent. Positive energy is stacked on top of negative energy. Significant differences are indicated with a (*) for differences in total energy and a (†) for differences in negative energy.

A

Positive Energy Distribution for SOS Stair Ascent



B

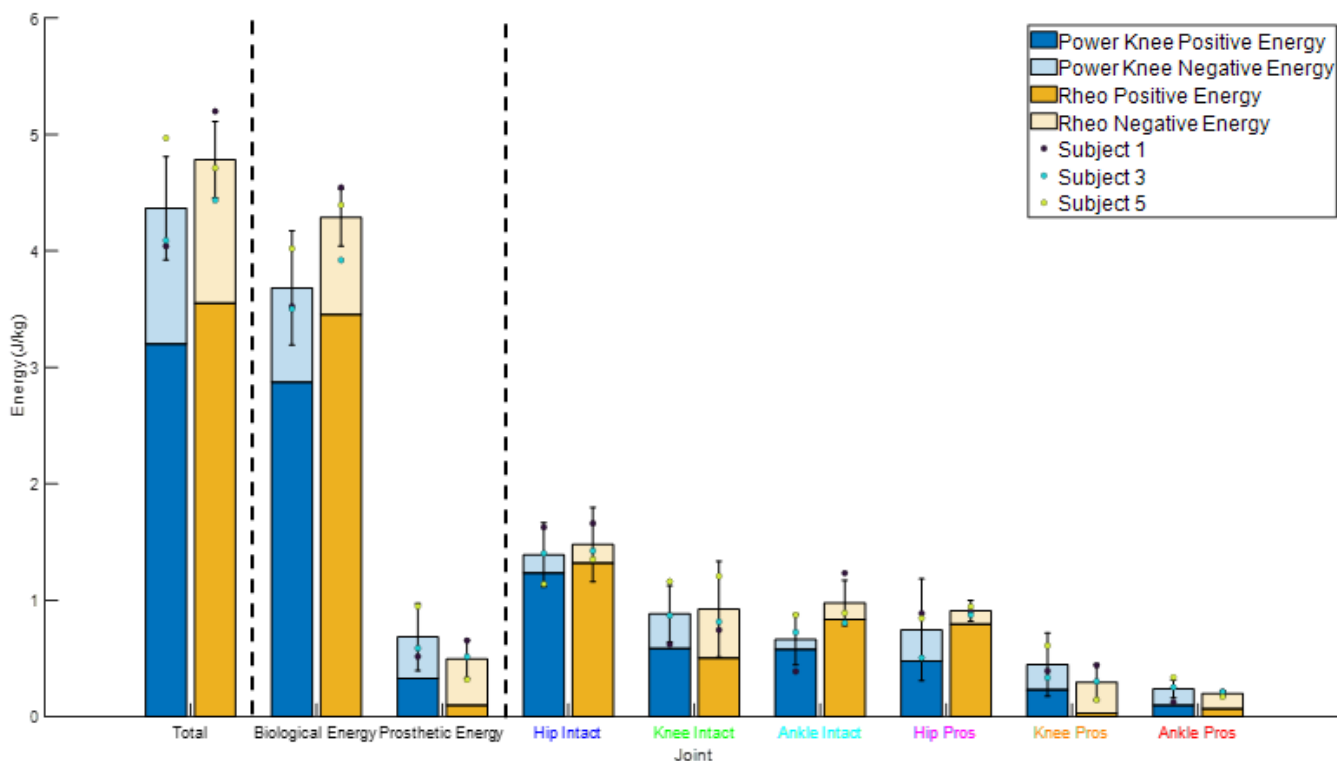
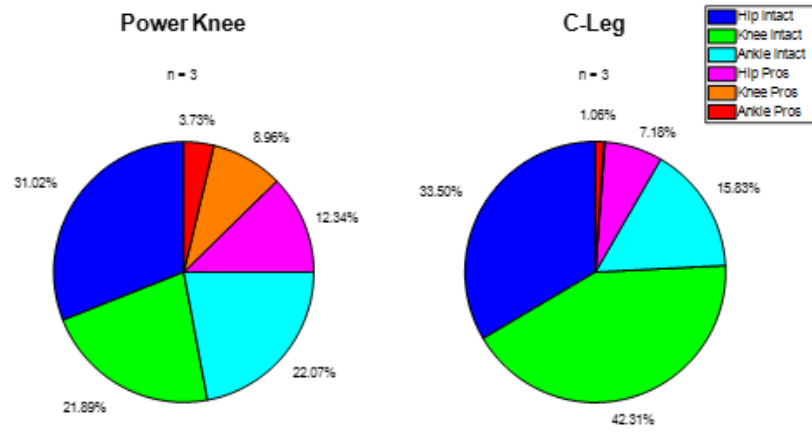


Figure 21: Positive joint energy distribution (A) and combined positive and negative joint energy (B) for step-over-step stair ascent. Negative energy is stacked on top of positive energy. Significant differences are indicated with a (*) for differences in total energy and a (+) for differences in positive energy.

A

Positive Energy Distribution for SOS vs STS Stair Ascent



B

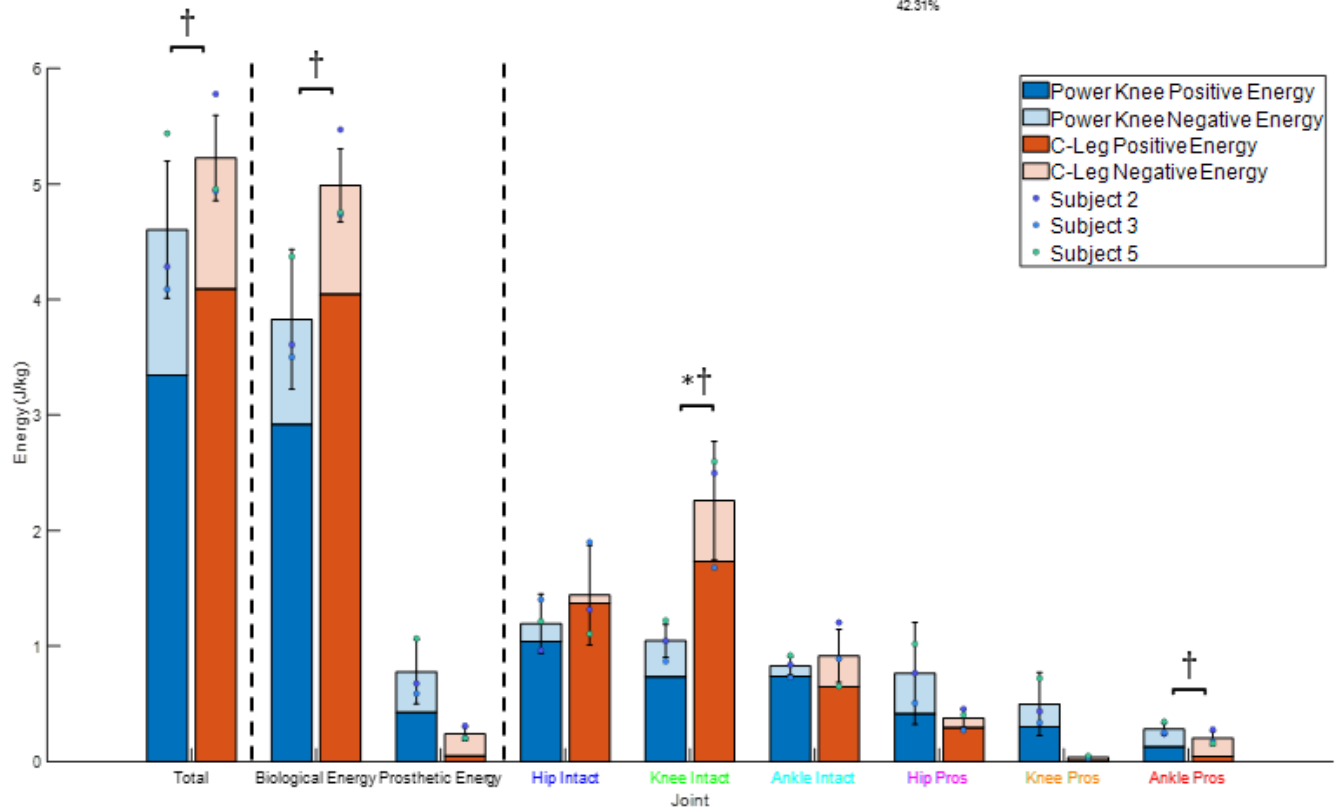


Figure 22: Positive joint energy distribution (A) and combined positive and negative joint energy (B) for step-over-step vs. step-to-step stair ascent. Negative energy is stacked on top of positive energy. Significant differences are indicated with a (*) for differences in total energy and a (†) for differences in positive energy.

Negative Work Distribution for Stair Descent

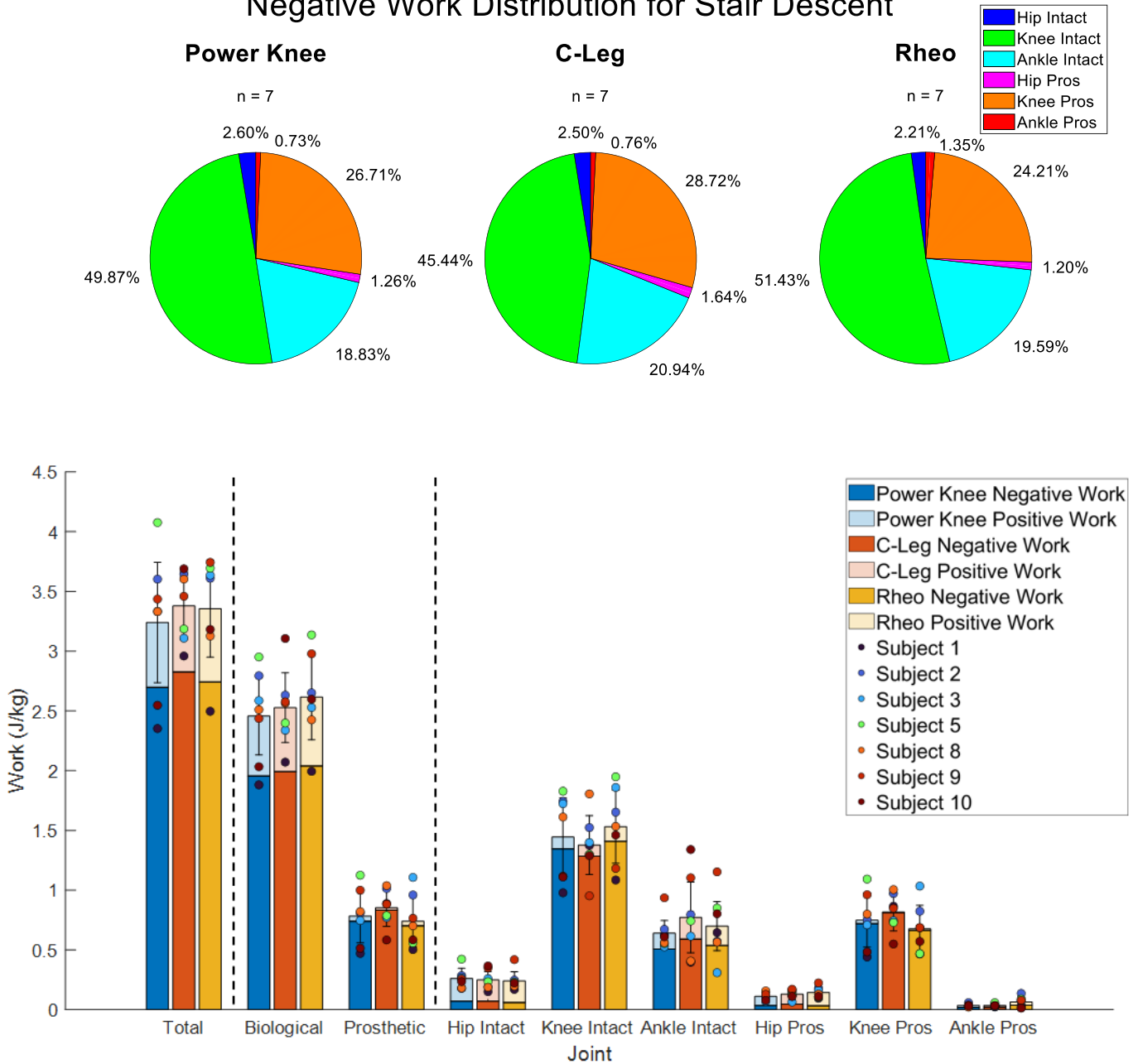
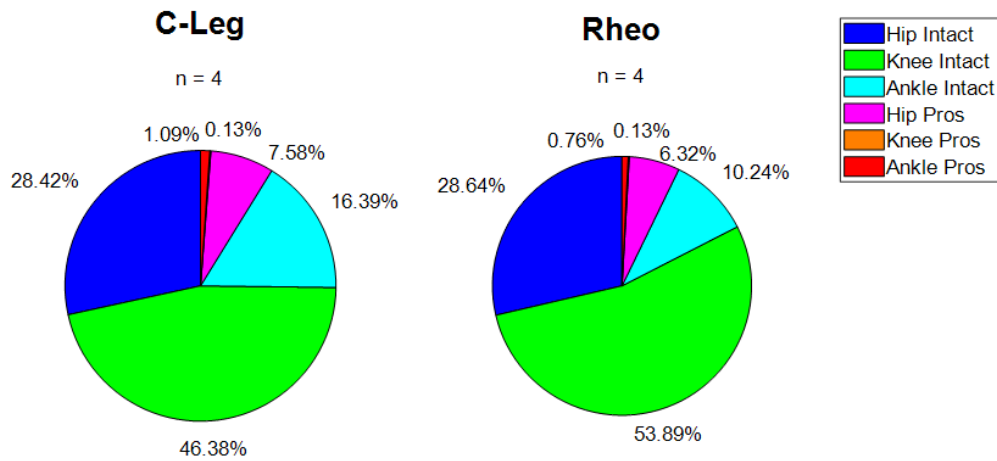


Figure 23: Negative joint energy distribution (A) and combined positive and negative joint energy (B) for stair descent. Positive energy is stacked on top of negative energy. Significant differences are indicated with a (*) for differences in total energy and a (†) for differences in negative energy.

A

Positive Work Distribution for STS Stair Ascent



B

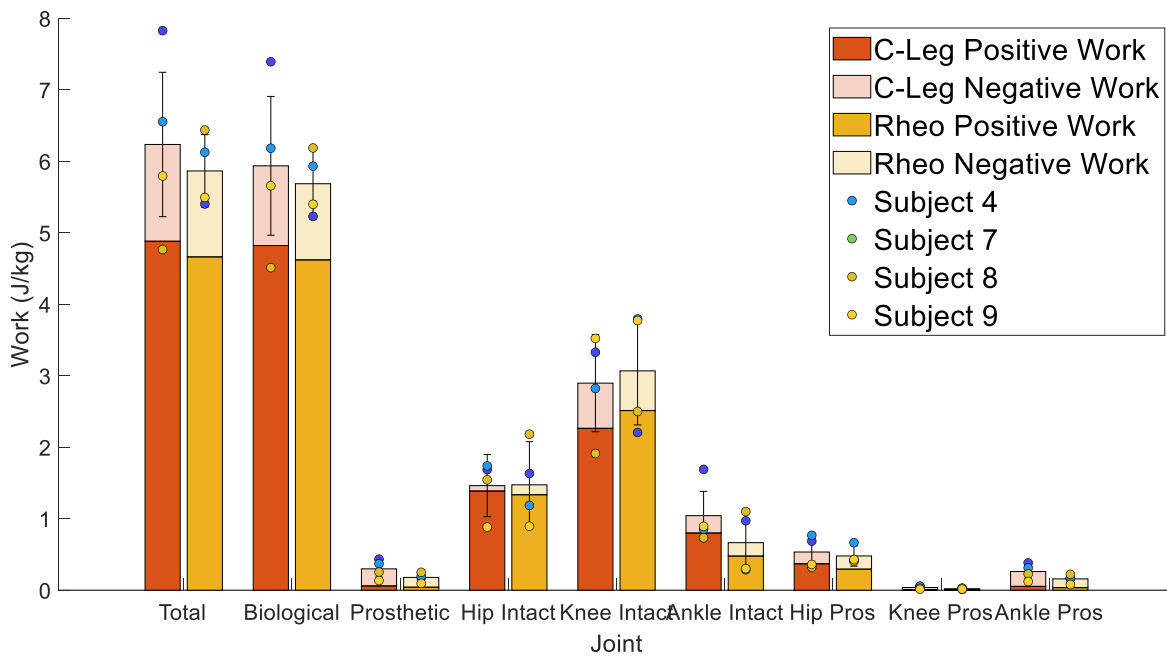


Figure 24: Positive joint energy distribution (A) and combined positive and negative joint energy (B) for step-to-step stair ascent. Positive energy is stacked on top of negative energy. Significant differences are indicated with a (*) for differences in total energy and a (†) for differences in negative energy

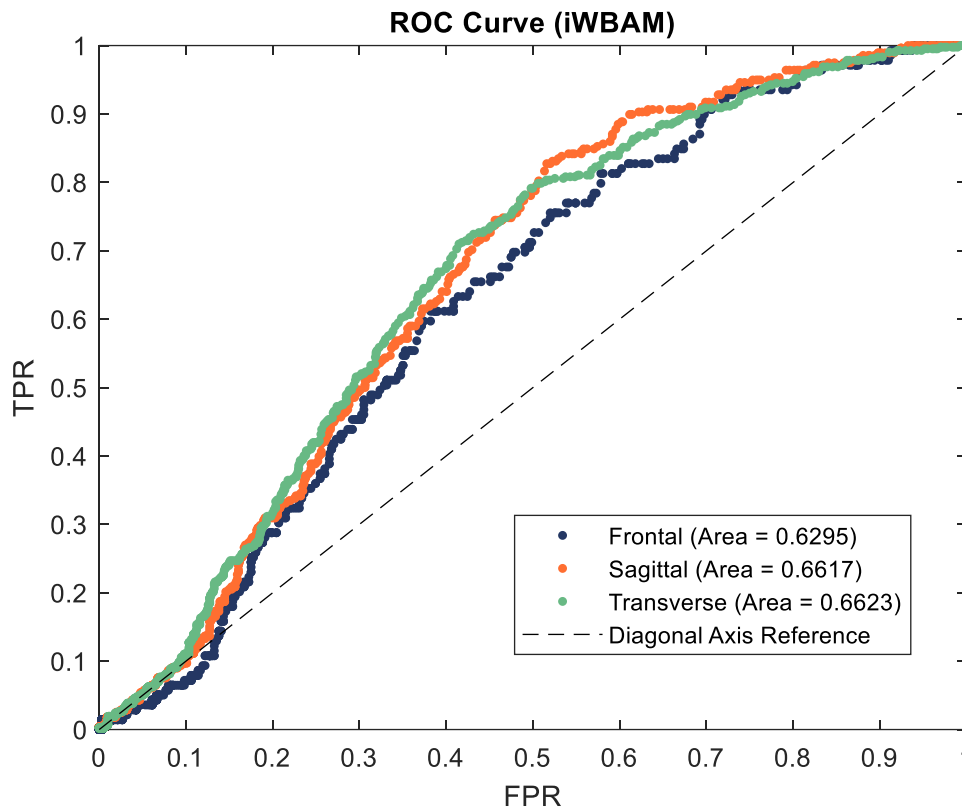


Figure 25: Receiver operating characteristic curve for iWBAM at three different planes. The area indicates the validity of using this metric to predict fall where larger area indicates more validity and largest area is 1.

c. What opportunities for training and professional development has the project provided?

The project has provided undergraduate and graduate students with multidisciplinary training in a biomechanics-based laboratory along with clinical training in prosthetics and patient/end-user interaction. Mechanical engineering and bioengineering undergraduate, masters and PhD students are working alongside clinical students (Master of Science in Prosthetics & Orthotics) and being trained by a multidisciplinary team inclusive of a clinician scientist, scientist/engineer and clinician collaborators. Students have received training in biomechanics software programs including Vicon Nexus data collection and processing in OpenSim. Project members have also received training on the 3 commercially available prosthetic knees through in-person training with manufacturer representatives.

d. How were the results disseminated to communities of interest?

We have presented study results at several conferences to communities of interest including rehab professionals (clinicians, prosthetists, orthotists, biomechanists, military health scientists and clinicians) through the American Orthotic & Prosthetic Association conference in September, 2022 in San Antonio, TX, the American Society of Biomechanics conference in August, 2023 in Knoxville, TN as well as the Military Health and Science Research Symposium in August, 2023 in Orlando, FL. Additionally, initial biomechanics data from this project was presented as a masters of bioengineering thesis and is currently in preparation for a manuscript to *Journal of Biomechanics*.

e. What do you plan to do during the next reporting period to accomplish the goals?

In the next quarter, we plan to finish processing and analyzing the biomechanics data of the remaining N=6 participants for the OSL data. All data on the MPKs has now been processed. We also plan to develop a clinical decision algorithm for the three commercial devices from the data collected.

4. Impact

a. What was the impact on the development of the principal discipline(s) of the project?

The data which has been collected thus far may allow current manufacturers of prosthetic devices to make improvements to their devices for end users. Our expansive set of both functional and patient reported outcomes for each knee will provide insight into areas for improvement for each knee. Additionally, the end goal for this study is the creation and implementation of a prescription algorithm for MPKs to be used by clinicians for prescribing the best MPK for an individual patient. This may lead to improvements in clinical practice and patient outcomes for the end-users of prosthetic technology.

b. What was the impact on other disciplines?

The engineering improvements made to the research grade prosthesis (the Open Source Leg) for ramp and stair ascent may have impacts on controllers used in other exoskeleton and prosthetic devices as assisting various modes of ambulation are important for other devices outside of the Open Source leg as well.

c. What was the impact on technology transfer?

The results of this project could highlight areas for improvement in current commercially available MPK technology and identify areas (both functional and patient perceived) in which certain MPKs are not as effective as others. These findings can assist prosthetic manufacturers in improving their devices to be more effective in these areas.

d. What was the impact on society beyond science and technology?

As mentioned previously, the clinical decision algorithm for MPK selection will better equip clinicians in selecting the proper MPK for a patient with transfemoral amputation. Along with making the clinician's selection process more evidence-based, this will also improve the quality of life of the patient as they are more likely to be prescribed an MPK that works best for them.

5. Changes/Problems

a. Changes in approach and reasons for change

Amendment #1 (approved by GT IRB 2/23/21)- Amendment to match inclusion/exclusion criteria in the protocol with the approved informed consent document

Amendment #2 (approved by GT IRB 8/5/21)- Request to add 2 additional sensor types and a beam walking test to protocol.

Amendment #3 (approved by GT IRB 8/23/21)- Request for approval of additional recruitment flyer to be posted at Atlanta VA which complies with Atlanta VA policies.

Amendment #4 (approved by GT IRB 01/13/22)- Request to use the Ossur Power Knee instead of the Plie knee for the protocol. Submitted to Nina Ofosu-Appiah at ninamarie.m.ofosu-appiah.ctr@mail.mil on 04.22.22.

Continuing review of protocol was approved by Georgia Tech IRB on 01.13.22 to expire on 01.14.23. Acknowledged by Nina Ofosu-Appiah on 01.14.22.

Amendment #5 (approved by GT IRB 04/15/22): Request to add an additional 7 question survey on commonly encountered terrain and activities at the participant's initial visit. Submitted to Nina Ofosu-Appiah at ninamarie.m.ofosu-appiah.ctr@mail.mil on 04.22.22.

Amendment #6 (approved by GT IRB 05.26.22): Request to add use of the treadmill during the study in addition to over ground conditions. Submitted to Nina Ofosu-Appiah at ninamarie.m.ofosu-appiah.ctr@mail.mil on 06.01.22.

Amendment #7 (approved by GT IRB 09.01.22): Personnel change only. Submitted to Nina Ofosu-Appiah at ninamarie.m.ofosu-appiah.ctr@mail.mil on 11.15.22.

Amendment #8 (approved by GT IRB 10.19.22): Increase enrollment from 12 to 17 participants. Submitted to Nina Ofosu-Appiah at ninamarie.m.ofosu-appiah.ctr@mail.mil on 08.07.23.

Amendment #9 (approved by GT IRB 12.19.22): Changes to broaden recruitment efforts to include outreach events, email lists, patient advocacy websites and online forums. Submitted to Nina Ofosu-Appiah at ninamarie.m.ofosu-appiah.ctr@mail.mil on 01.26.23.

Amendment #10 (approved by GT IRB 03.27.23): Request to add additional form of compensation for participants to now include gift card or check. Submitted to Nina Ofosu-Appiah at ninamarie.m.ofosu-appiah.ctr@mail.mil on 04.27.23.

b. Actual or anticipated problems or delays and actions or plans to resolve them

Nothing to report.

c. Changes that had a significant impact on expenditures

Nothing to report.

d. Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents

Nothing to report.

e. Significant changes in use or care of human subjects

Nothing to report.

f. Significant changes in use or care of vertebrate animals.

Nothing to report.

g. Significant changes in use of biohazards and/or select agents

Nothing to report.

6. Products

a. Publications, conference papers, and presentations

i. Journal publications

Nothing to report

ii. Books or other non-periodical, one-time publications

Nothing to report

iii. Other publications, conference papers, and presentations

- Kinsey Herrin, Sixu Zhou, Lee Childers, Aaron Young. "Towards a Clinical Decision Algorithm for Prescribing MPKs in Individuals with Above Knee Amputation." Podium presentation. AOPA September 2022, San Antonio, TX.
- Kestur, S. "Comparing the Biomechanics of Powered and Passive Microprocessor Knees during Community Ambulation Tasks." Master's of bioengineering thesis, Georgia Institute of Technology. May, 2023.
- Kinsey Herrin, Sujay Kestur, Jason Zhou, Lee Childers, Aaron Young. "Prescribing Based on the Individual: A Study Investigating Individual Trends Among Three Commercially Available MPKs" Podium presentation. MHSRS August 2023, Orlando, FL.
- Aaron J. Young, Jairo Y. Maldonado, Krishan Bhakta, and Kinsey Herrin. "Advances in AI Techniques for Recognizing User Intents such as Walking Speed for Robotic Lower Limb Prostheses" Podium presentation. MHSRS August 2023, Orlando, FL.
- Kinsey R. Herrin, Sujay Kestur, Sixu Zhou, Aaron Young. "Biomechanical outcomes associated with 3 commercially available microprocessor knees during level ground and stair ascent walking tasks" Poster presentation. American Society of Biomechanics August, 2023, Knoxville, TN.
- Sixu Zhou, Sujay Kestur, Aaron Young, Kinsey Herrin. "Integrated whole-body angular momentum during narrowing beam walking test using passive and powered knee prostheses." Poster presentation. American Society of Biomechanics August, 2023, Knoxville, TN.
- Sixu Zhou, Sujay Kestur, Kinsey Herrin, Aaron Young "Opensim model for biomechanical analysis with lower limb prostheses" Poster presentation. American Society of Biomechanics August, 2023, Knoxville, TN.

b. Website(s) or other Internet site(s)

Nothing to report

c. Technologies or techniques

Nothing to report

d. Inventions, patent applications, and/or licenses

Nothing to report

e. Other Products

Nothing to report

7. Participants & Other Collaborating Organizations

a. What individuals have worked on the project?

Name: Aaron Young
 Project Role: PI
 Researcher Identifier:
 Nearest person month worked: 2
 Contribution to Project: Management of the scientific and technical aspects of the project including oversight of the full clinical trial, advising on study design and conception, advanced data processing, ensuring compliance to study protocol and IRB standards, presenting the work and manuscript preparation

Name: Kinsey Herrin
 Project Role: co-PI

Researcher Identifier:
Nearest person month worked: 3
Contribution to Project: Direct oversight and hands on management of the grant as the primary clinician. Compliance to clinical/IRB protocols, managing the data collection during all trials as well as data analysis and clinical interpretation and applicability, presenting the work and manuscript preparation

Name: Lee Childers
Project Role: Consultant

Researcher Identifier:
Nearest person month worked: 0.1
Contribution to Project: Collaborate with team to help maintain clinical applicability to the military population throughout the study design process, data interpretation, and knowledge dissemination

Name: Sixu Zhou
Project Role: Graduate Student

Researcher Identifier:
Nearest person month worked: 24.5
Contribution to Project: Biomechanics setup/analysis and NBWT fabrication

Name: Sujay Kestur
Project Role: Graduate Student

Researcher Identifier:
Nearest person month worked: 23
Contribution to Project: Biomechanics setup/analysis

Name: Hanjun Kim
Project Role: Graduate Student

Researcher Identifier:
Nearest person month worked: 4
Contribution to Project: Experiment assistance, OSL Operation

Name: Jairo Maldonado
Project Role: Graduate Student

Researcher Identifier:
Nearest person month worked: 4
Contribution to Project: OSL Operation

Name: Christoph Nusslein
Project Role: Graduate Student

Researcher Identifier:
Nearest person month worked: 4
Contribution to Project: OSL Operation

Name: Gwyneth O'Sullivan
Project Role: Undergraduate Researcher

Researcher Identifier:
Nearest person month worked: 4.5
Contribution to Project: Biomechanics setup/analysis

Name: Adriana Staten
Project Role: Undergraduate Researcher
Researcher Identifier:
Nearest person month worked: 4
Contribution to Project: Biomechanics setup/analysis

Name: Carina D'Angelo
Project Role: Undergraduate Researcher
Researcher Identifier:
Nearest person month worked: 2
Contribution to Project: Biomechanics setup/analysis

Name: Saketh Chaluvadi
Project Role: Undergraduate Researcher
Researcher Identifier:
Nearest person month worked: 2
Contribution to Project: Biomechanics setup/analysis

Name: Tess Zhang
Project Role: Undergraduate Researcher
Researcher Identifier:
Nearest person month worked: 1
Contribution to Project: Biomechanics setup/analysis

Name: Rosario Reyes
Project Role: Undergraduate Researcher
Researcher Identifier:
Nearest person month worked: 3
Contribution to Project: Biomechanics setup/analysis

Name: Savannah Patenaude
Project Role: Undergraduate Researcher
Researcher Identifier:
Nearest person month worked: 3
Contribution to Project: Biomechanics setup/analysis

Name: Jason Miller
Project Role: Undergraduate Researcher
Researcher Identifier:
Nearest person month worked: 1
Contribution to Project: Biomechanics setup/analysis

Name: Donggeon Kim
Project Role: Undergraduate Researcher
Researcher Identifier:
Nearest person month worked: 1
Contribution to Project: Biomechanics setup/analysis

Name: Ashley Bonner Galbraith
Project Role: MSPO Student
Researcher Identifier:
Nearest person month worked: 3

Contribution to Project: Clinical experiment assistance

Name: Jashalynn Maddox

Project Role: MSPO Student

Researcher Identifier:

Nearest person month worked: 3

Contribution to Project: Clinical experiment assistance

Name: Mariana Miller

Project Role: MSPO Student

Researcher Identifier:

Nearest person month worked: 3

Contribution to Project: Clinical experiment assistance

Name: Nicholas Jansen

Project Role: MSPO Student

Researcher Identifier:

Nearest person month worked: 1

Contribution to Project: Clinical interpretation of patient reported data outcomes

Name: Will Ruark

Project Role: MSPO Student

Researcher Identifier:

Nearest person month worked: 1

Contribution to Project: Clinical interpretation of patient reported data outcomes

Name: Rachel Sanders

Project Role: MSPO Student

Researcher Identifier:

Nearest person month worked: 1

Contribution to Project: Clinical interpretation of patient reported data outcomes

b. Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?

Nothing to report

c. What other organizations were involved as partners?

Organization Name: Extremity Trauma and Amputation Center of Excellence (EACE)

Military Performance Lab, Center for the Intrepid, Brooke Army Medical Center

Location: 3551 Roger Brooke Drive, MCHE-ZSR-I

JBSA Fort Sam Houston, TX 78234

Partner's contribution to project: Clinical feasibility and applicability of protocols as well as interpretation of data collected to date.

8. Special Reporting Requirements

a. Collaborative awards: Not applicable

b. Quad Charts: Included