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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. Eight participants have been recruited and consented to participate in the study. Four participants have completed \geq week-long take home acclimation periods with the three commercially available MPKs, and one subject is in progress and has completed the take home period for one MPK. 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. Additional subjects are planned for collection over the remaining study period to aid in generation of the final <u>prescription algorithm</u> .						
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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 transfemoral patients 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- 32.5% 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– 32.5% 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- 32.5% completion

Major Task 4: Create Clinical Decision Algorithm

- Milestone: Clinical Decision Algorithm created- 0% 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 have received approval from the Georgia Tech IRB and DoD HRPO to conduct the study with human subjects. Formal MOUs were established with all manufacturers for take-home use of the three commercially available MPKs. In addition, we have added the Narrowing Beam Walking Test (NBWT) as a measure of balance ability to the functional measures for our protocol which has involved

fabrication of the beam itself. We have purchased equipment to conduct the AMP-Pro and 2-minute walk tests as well as the StepWatch activity monitor for home monitoring with the device when the participant is wearing it outside of the lab. Our team has gone through the manufacturer training for the Ossur Rheo and Power Knee and Otto Bock C-leg 4.0. We have completed adaptation of the new custom marker set and the OpenSim model for full body biomechanics data analysis. As a result, we have completed collection of the functional performance measures, patient reported outcomes and a full biomechanics dataset for four subjects with each of the three commercially available microprocessor knees (Ossur Rheo, Otto Bock C-leg 4 and Ossur Power Knee) and one additional subject with the Ossur Power Knee who is currently in process completing the study. In total, we have consented and recruited 8 individuals to date to participate in the study; 1 individual declined to participate any further following the initial visit prior to leaving with the first MPK.

For our research grade prosthetic knee and ankle, we have added a sit-to-stand controller and tested it on a single subject with transfemoral amputation for validation. We continue to work on an improved controller for the research grade prosthesis for ramp and stair ascent and descent tasks. We have additionally been testing our ramps and stair mode controllers in preparation for our first experiments with the research grade prosthesis with subjects.

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

We have collected a full biomechanics dataset for four subjects while wearing the Ossur Power Knee, Otto Bock C-leg 4, and Ossur Rheo Knee and one additional subject who is in progress and has completed the study with the Ossur Power 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. The research grade prosthesis protocol for ramp training has also been amended to use an inclined treadmill instead of an overground ramp in an effort at helping subjects accept and adapt more easily to the stance flexion provided by the device. Anecdotally, the single subject tested was able to acclimate to the stance flexion easier with the revised protocol over the treadmill. We intend to use this as a training mechanism for future participants prior to having them complete the full protocol with the research grade knee and ankle prosthesis.

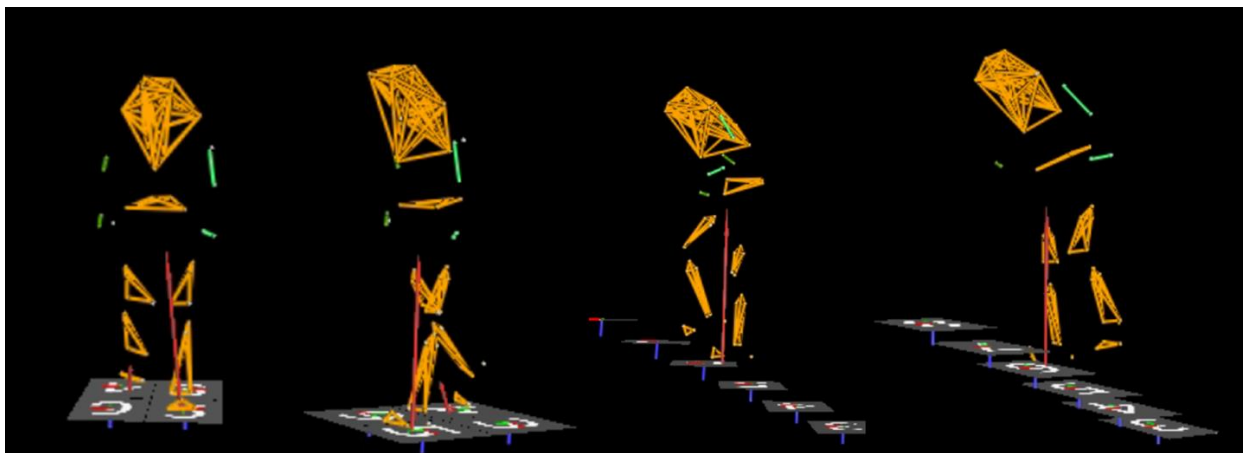


Figure 1: Ramp and Stair Ascent Vicon Data Demonstration

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

Anthropomorphic data has been collected for 5 subjects (*Table 1*) and patient preference data (*Tables 2-4* and *Figures 2-6*) has been collected for 4 subjects for the three commercially available MPKs and 1 subject in progress with just the Power Knee. *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 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 CR-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 1-5

<i>Subject</i>	<i>AmpNoProScore</i>	<i>Age (yrs.)</i>	<i>Height (m)</i>	<i>Weight (kg)</i>	<i>Amp Side</i>	<i>Age at Amp</i>	<i>Clinically Prescribed Knee</i>
1	35	69	1.95	102	Left	17	C-leg 3
2	41	36	1.75	74.7	Right	30	Plie 3.0
3	40	55	1.8	80.3	Right	46	X3
4	42	43	1.57	53.45	Left	18	Plie 3.0
5	41	44	1.79	92.2	Left	39	C-leg 3
Average		49.4	1.77	80.53			
Standard Deviation		12.9	0.13	18.47			

Table 2. PEQ data for Subjects 1-5, P=Power Knee, C=C-leg 4, R= Rheo, a score of 10 in each category indicates the max positive score

PEQ subscales

<i>Subject</i>		<i>Ambulation</i>	<i>Appearance</i>	<i>Frustration</i>	<i>Residual</i>					<i>Well Being</i>
					<i>Perceived Response</i>	<i>Limb Health</i>	<i>Social Burden</i>	<i>Sounds</i>	<i>Utility</i>	
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

Full PEQ for Subjects 1-5

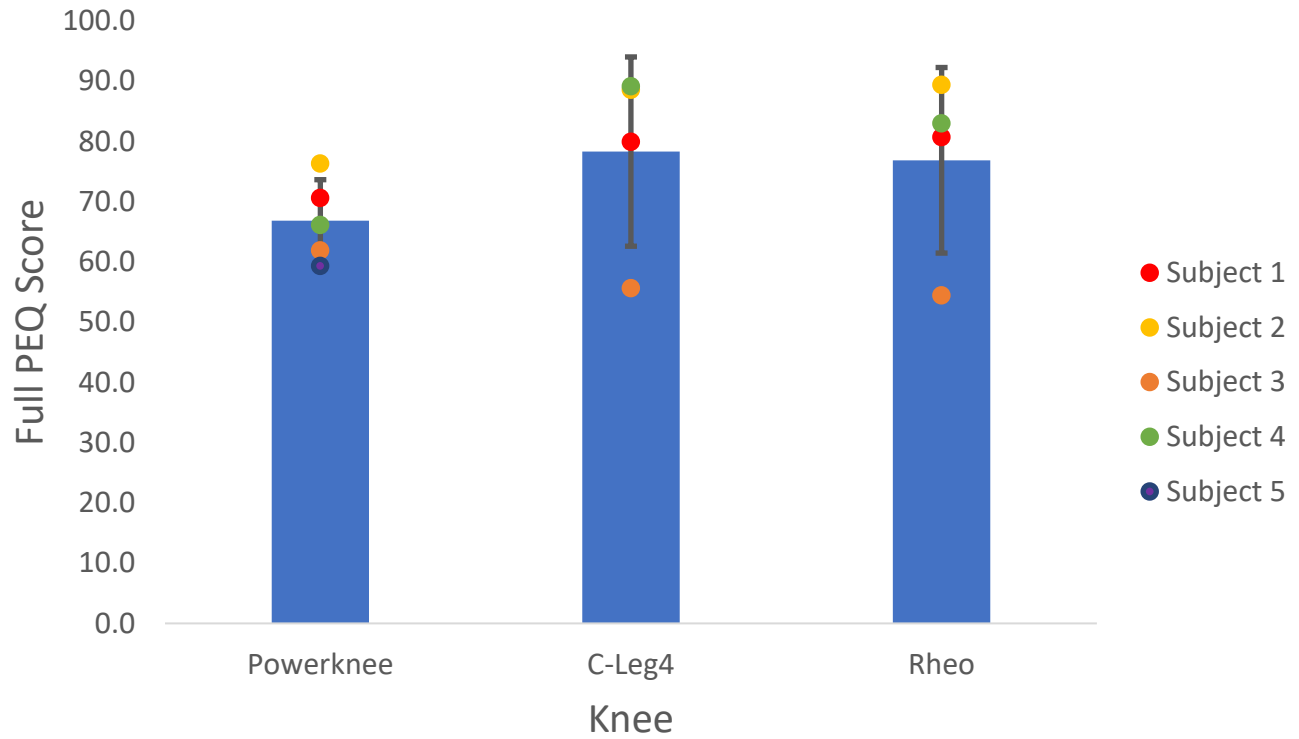


Figure 2. PEQ data for Subjects 1-5, a summed score of 90 indicates the max positive score

Table 3. CLASS subscales data for Subjects 1-5, 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	16
1	C	16	16	16	16	16
1	R	16	16	16	16	16
2	P	13	13	13	13	16
2	C	16	16	16	16	10
2	R	16	16	16	16	15
3	P	12	12	12	12	12
3	C	14	12	11	11	16
3	R	13	14	12	12	16
4	P	15	16	16	16	12
4	C	16	16	16	16	16
4	R	10	16	15	15	16
5	P	9	11	12	12	12

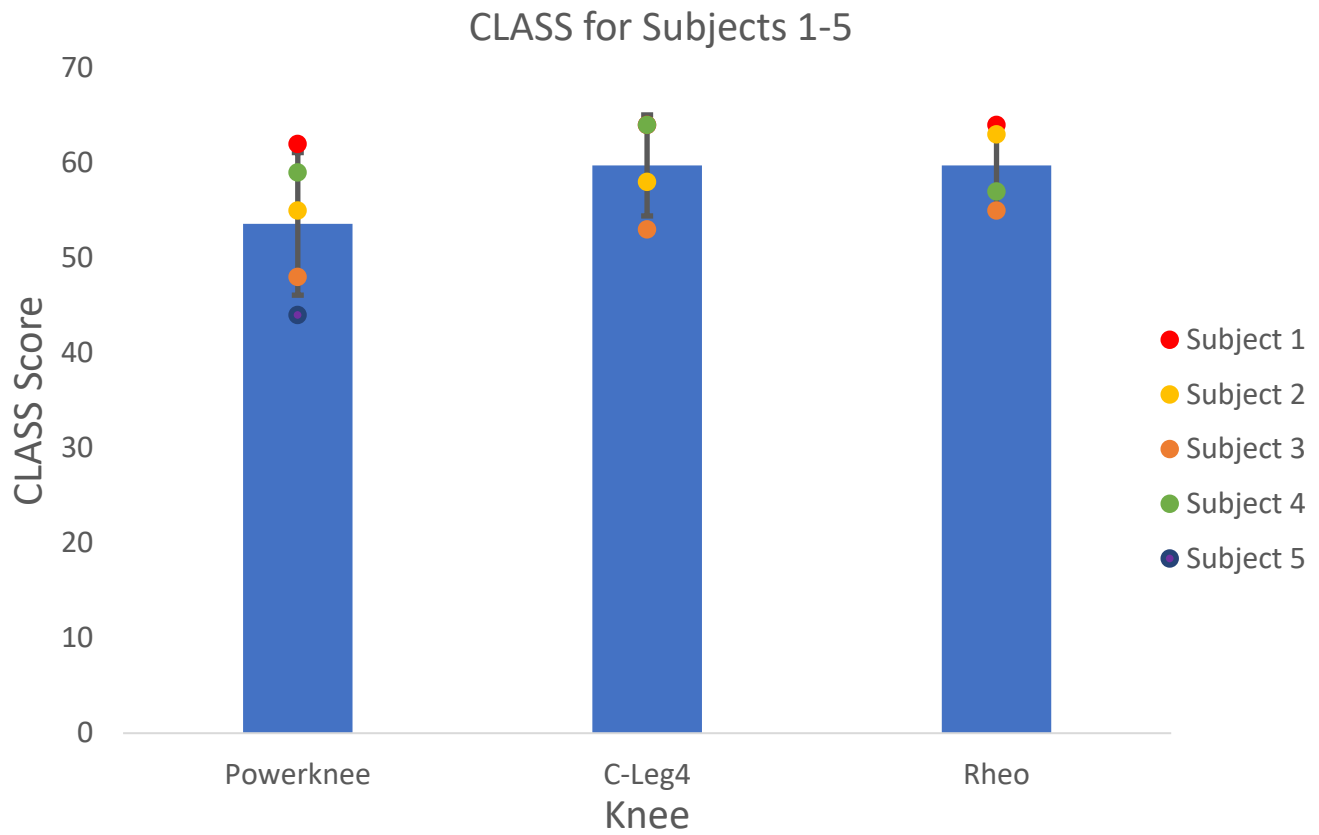


Figure 3. CLASS data for Subjects 1-5, a summed score of 64 indicates the max positive score

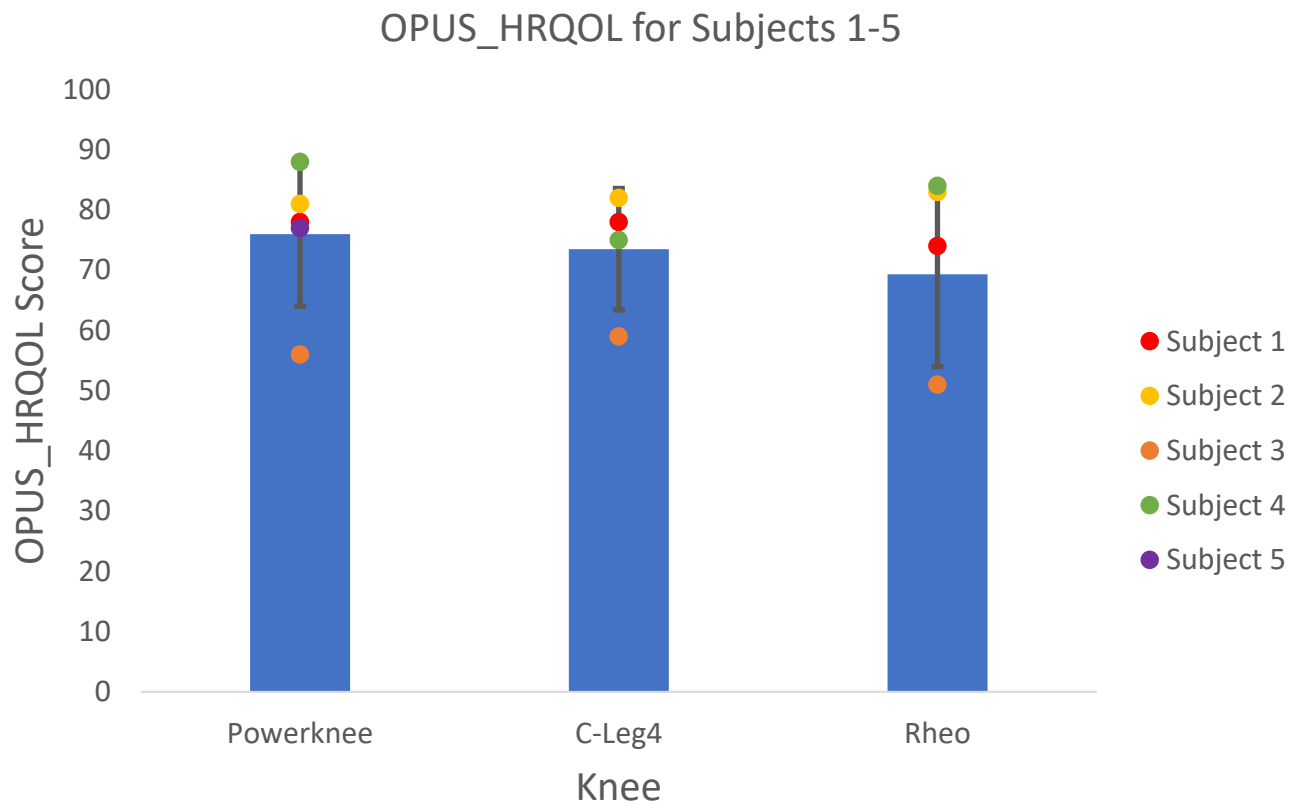


Figure 4. OPUS_HRQOL data for Subjects 1-5, a summed score of 92 indicates the max positive score

OPUS_LEFS for Subjects 1-5

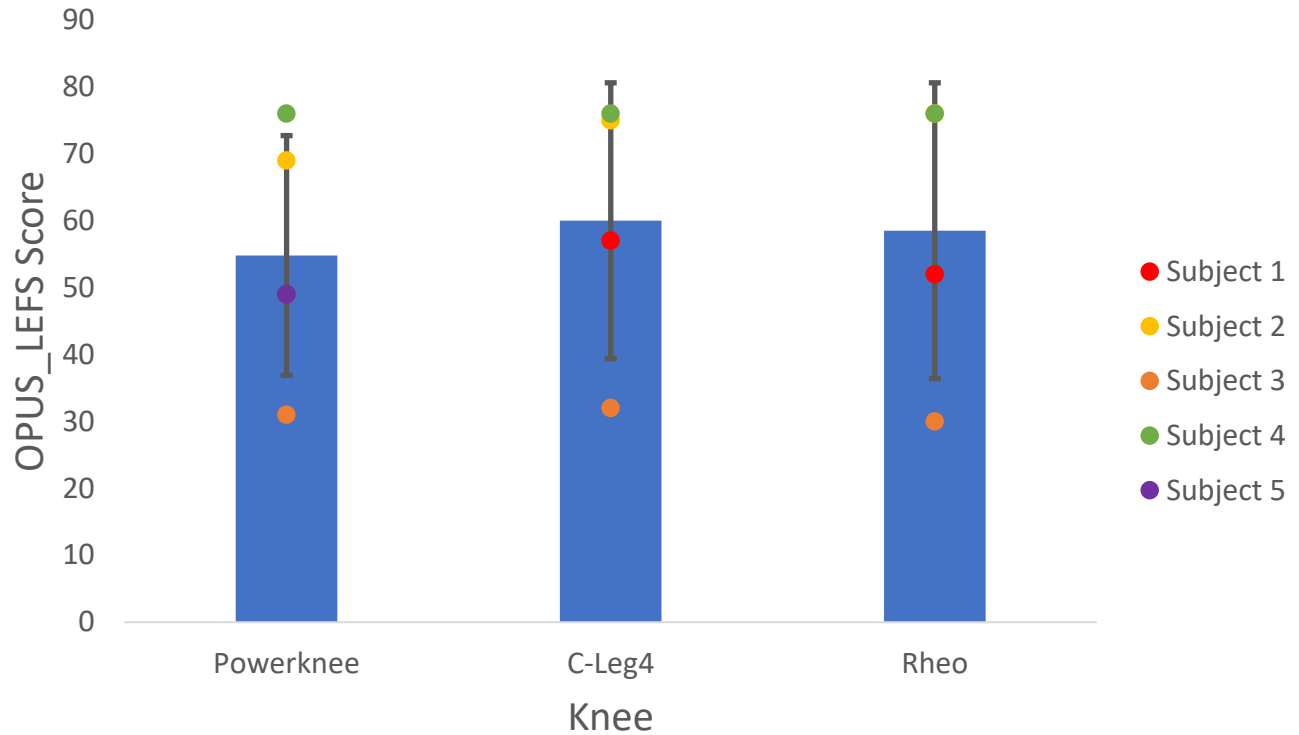


Figure 5. OPUS_LEFS data for Subjects 1-5, a summed score of 80 indicates the max positive score

Table 4. Modified VR-36 data for Subjects 1-5, 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	Role limitations due to Physical Health	Role limitations due to emotional problems	Social functioning	Pain	Energy/fatigue	Emotional well-being	Health change
1	P	50	65	100	100	100	57.5	85	88	50
	C	75	70	100	100	100	90	85	88	50
	R	70	75	100	100	100	90	80	92	50
2	P	95	100	100	100	100	100	85	96	75
	C	95	90	87.5	100	100	90	70	88	50
	R	90	95	100	100	100	90	80	92	75
3	P	65	40	62.5	58.3	50	32.5	35	76	50
	C	75	25	37.5	41.7	62.5	35	50	76	62.5
	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
	C	100	95	100	100	100	100	80	92	50
	R	100	95	100	100	100	90	80	72	50
5	P	70	65	75	83.3	100	100	60	88	50

Modified VR-36 for Subjects 1-5

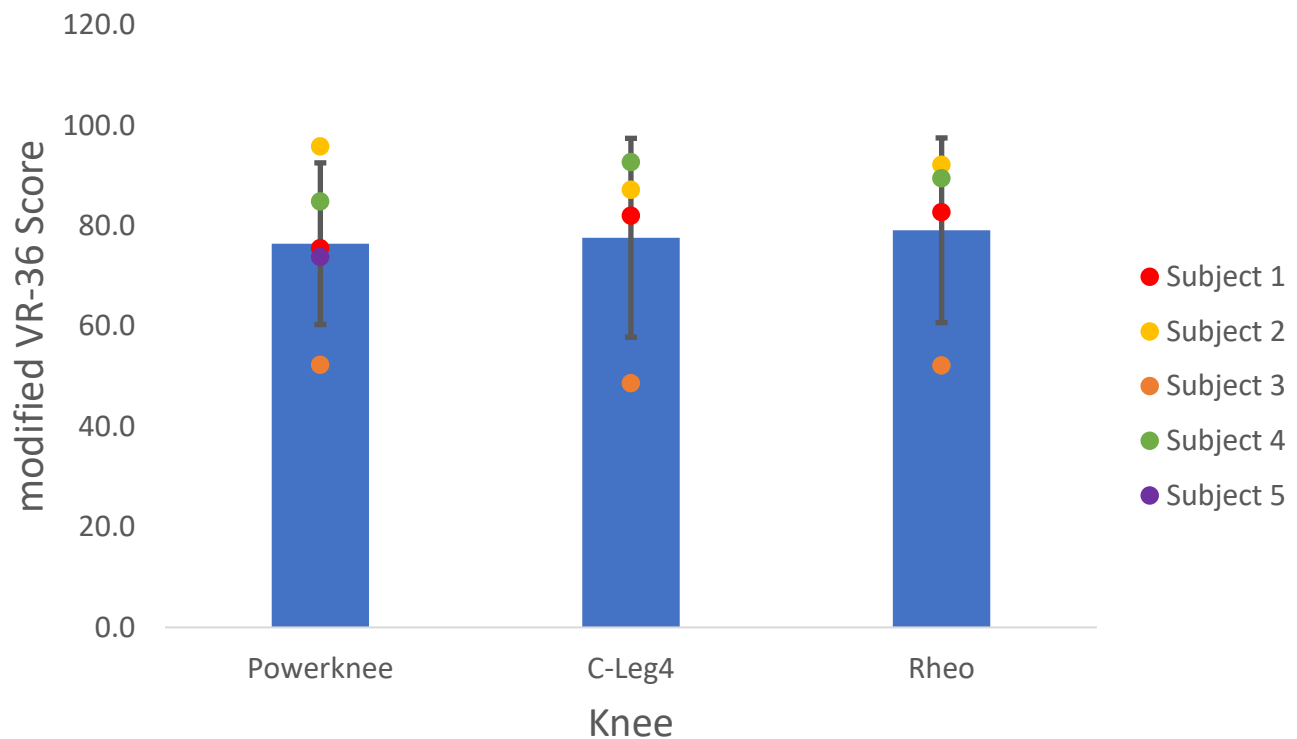


Figure 6. Modified VR-36 data for Subjects 1-5, an average score of 100 indicates the max positive score

Major Task 3: Data Analysis

Spatiotemporal data for each subject is shown in *Table 5* for ramp ascend speed, ramp descend speed, stair ascend speed, stair descend 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 about equal steps/day and cadence among the three commercial knees. The Vicon data from the ramps and stairs conditions will be used to compute the inverse kinematics and inverse dynamics of three major lower limb joints – hip, knee, and ankle. Inverse kinematic data for the average over the 4 completed subjects for the four ambulation modes for prosthetic side (*Figures 9-14*) and sound side (*Figures 15-20*) are shown for the three commercially available prosthetic knees. In these figures, knee inverse kinematics is the primary comparison since the knee is the factor being changed. *Figure 9* shows the ramp ascend inverse kinematics and dynamics on the prosthetic side and from the knee inverse kinematics, the Power Knee is shown to have more knee flexion than the other two commercial knees. *Figure 10* shows the ramp descend inverse kinematics and dynamics on the prosthetic side and from the knee inverse kinematics, all three commercial knees have about equal knee flexion. *Figure 11* shows the stair ascend using step over step inverse kinematics and dynamics on the prosthetic side and from the knee inverse kinematics, Power Knee is shown to have more knee flexion than the other two commercial knees. *Figure 12* shows the stair ascend using step to step inverse kinematics and dynamics on the prosthetic side and from the knee inverse kinematics, Power Knee is shown to have slightly more knee flexion than the other two knees but not by much. *Figure 13* shows the stair descend using step over step inverse kinematics and dynamics on the prosthetic side and from the knee inverse kinematics, all three commercial knees have about equal knee flexion. *Figure 14* shows the stair descend using step to step inverse kinematics and dynamics on the prosthetic side and from the knee inverse kinematics, Power Knee has slightly greater knee flexion than the other two commercial knees. On the sound side (*Figures 15-20*) for each ambulation mode, the inverse kinematics and dynamics are shown at each joint. From these figures, it is shown that there are not large

differences between the commercial knees on the sound side. Step-to-step and step-over-step is indicated in the various figures as subjects used different strategies depending on comfort level in the different knees. Using the joint power, the energy distribution for each ambulation mode was found and is shown in *Figures 21-26*. *Figure 21* shows the energy distribution during ramp ascend with the Rheo having the highest total energy used followed by the Power Knee and C-Leg and about equal energy distribution among joints. *Figure 22* shows the energy distribution during ramp descend with the Rheo having the highest total energy used followed by C-Leg and Power Knee and about equal energy distribution among joints. *Figure 23* shows the energy distribution during stair ascend using step over step with the Rheo having the highest total energy used followed by the Power Knee and C-Leg and greater energy used by the prosthetic knee side in the Power Knee and Rheo than in the C-Leg. *Figure 24* shows the energy distribution during stair ascend with step to step with the Rheo having the highest total energy used followed by the Power Knee and C-Leg and more energy used by the Rheo intact knee than the Power Knee and C-Leg. *Figure 25* shows the energy distribution during stair descend with step over step with the C-Leg having the highest total energy used followed by the Rheo and Power Knee and about equal energy distribution among joints. *Figure 26* shows the energy distribution during stair descend with step to step with the Power Knee having the highest total energy used followed by the C-Leg and Rheo and more hip intact energy and less knee intact energy used in the Rheo than the other two commercial knees. *Figure 27* shows distance traversed during the NBWT for subjects 1-4 in which Power Knee and Rheo Knee shows improved balance ability compared than C-leg. *Figure 28* shows WBAM for Subject 02 for the three commercially available knees where C-leg shows higher peaks in sagittal plane which correlates to the worse performance in distance traveled from *Figure 27*. *Figure 29* shows average whole body angular momentum across all knees of all subjects comparing the last stride immediately before fall to all other strides. *Figure 30* shows WBAM for Subjects 01-04 for each individual commercially available knee which only subject2 shows correlation between segment level and WBAM peak-to-peak values. Higher values of WBAM are indicative of reduction in stability. **It is worth noting that the trends summarized here are average trends seen across the entire cohort of the study thus far, and some individual users do not necessarily match the trends explained. This mismatch in average trend versus an individual's specific performance trends is of key interest for the development of a prescription algorithm for this study and will be examined in closer detail as more subjects are added.**

Table 5: Outcomes of performance tasks for each participant. P= Power Knee, C= C-leg 4.0, R= Rheo

Subject	Knee	Ramp Ascend Speed (m/s)	Ramp Descend Speed (m/s)	Stair Ascend (steps/min)	Stair Descend (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	1.19	117.19	15.98
	C	1.22	1.06	69.57	115.82	9.42	0.19	1.46	1.30	118.12	14.18
	R	1.10	0.87	61.35	109.11	13.42	0.16	1.45	1.30	127.14	15.24
02	P	0.91	0.75	59.08	117.58	16.60	0.38	0.93	1.09	106.97	12.06
	C	1.11	0.89	53.00	66.96	12.80	0.20	1.26	1.27	103.88	10.97
	R	1.08	0.87	49.78	114.60	14.90	0.23	1.25	1.19	119.49	15.42
03	P	0.78	0.73	42.20	79.34	10.70	0.36	0.75	1	111.42	11.98
	C	0.78	0.72	70.06	93.20	11.08	0.24	1.04	1.01	110.71	14.79
	R	0.78	0.63	49.39	80.78	12.70	0.13	0.99	0.99	117.12	16.81
04	P	1.04	0.91	83.24	48.42	11	No data	1.51	1.39	102.88	1.51
	C	1.08	0.98	45.33	49.46	12.7	.25	1.61	1.46	103.21	0.72
	R	1.02	1.04	49.93	52.96	10.83	.17	1.61	1.49	110.45	2.67
05	P	1.01	0.81	47.09	100.17	13.5	0.42	.94	0.97	117.74	14.88

Average Steps/Day for Subjects 1-5

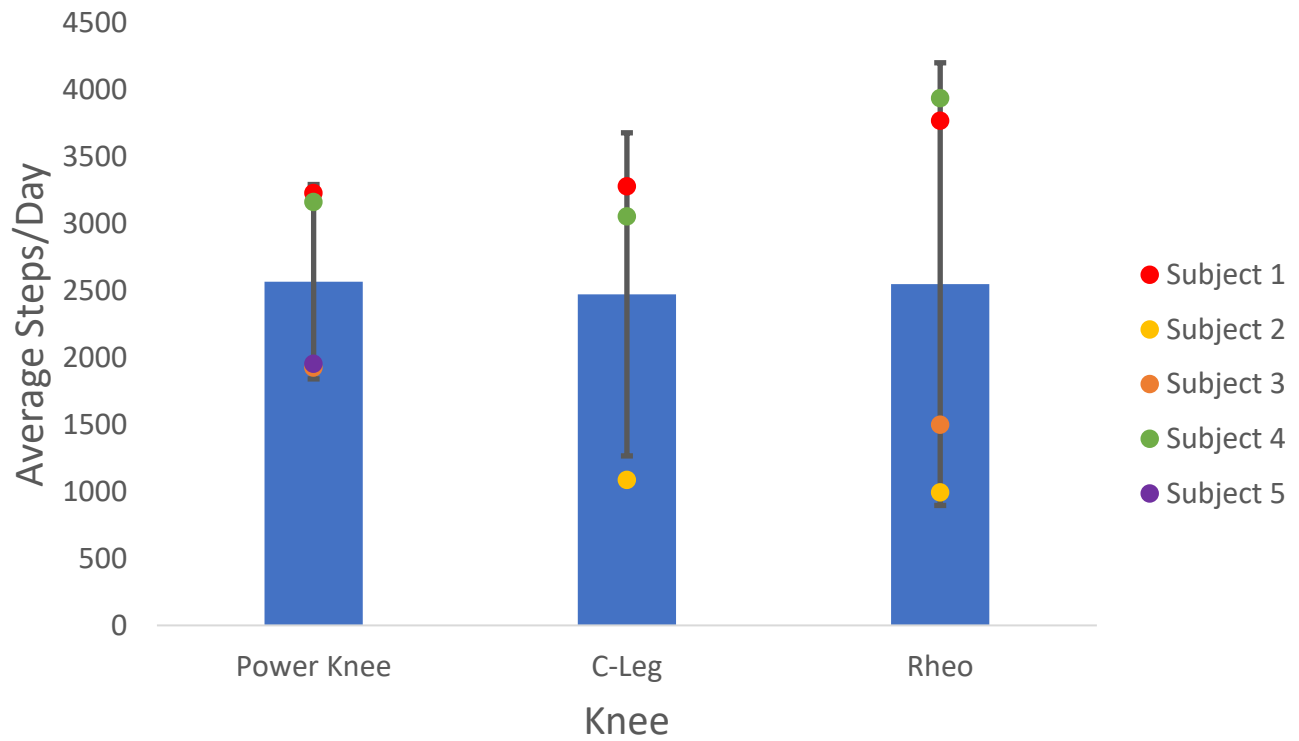


Figure 7. Average Steps/day from StepWatch for Subjects 1-5

Average Cadence for Subjects 1-5

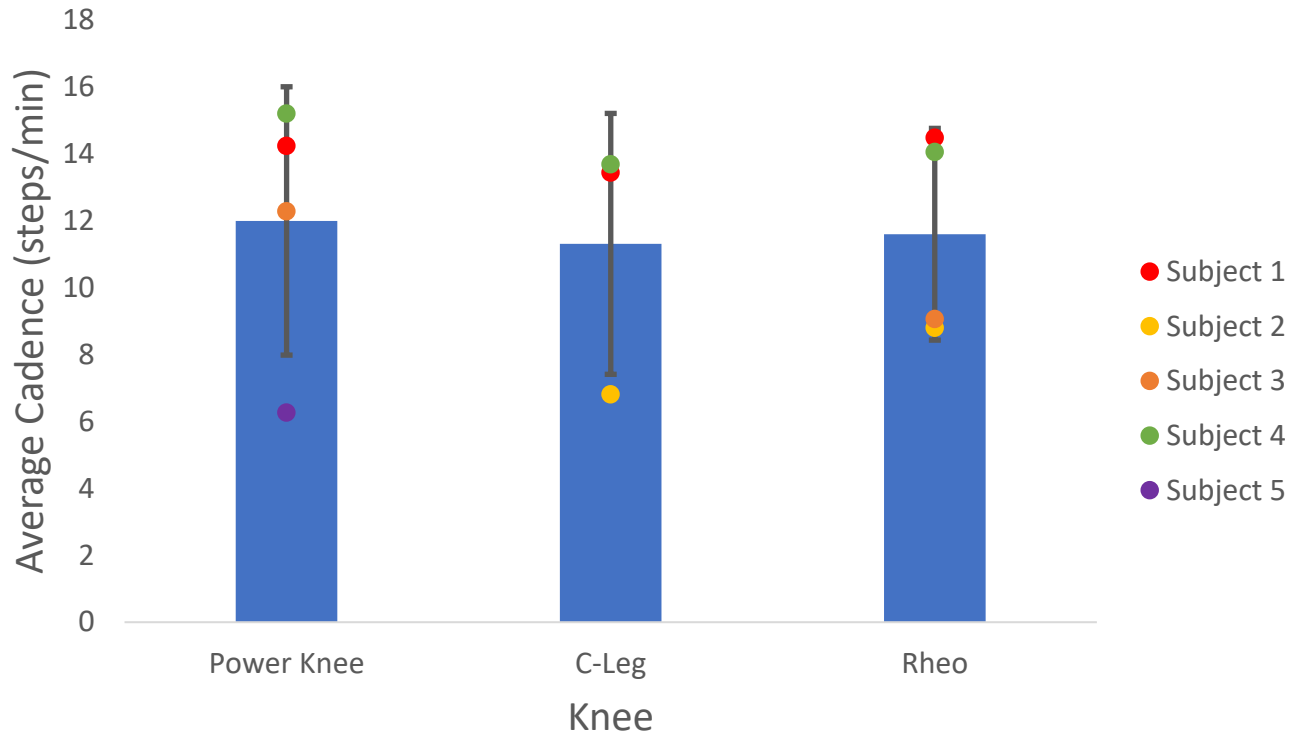


Figure 8. Average Cadence (steps/min) from StepWatch for Subjects 1-5

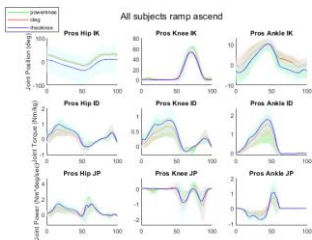


Figure 9: Ramp ascend prosthetic side inverse kinematics for subjects 1-4 for commercially available MPKs

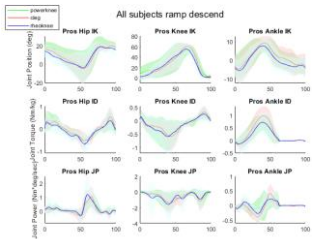


Figure 10: Ramp descend prosthetic side inverse kinematics for subjects 1-4 for commercially available MPKs

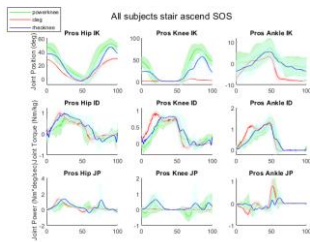


Figure 11: Stair ascend with step over step prosthetic side inverse kinematics for subjects 1-4 for commercially available MPKs (Power Knee (n=3), C-Leg (n=1), Rheo (n=2))

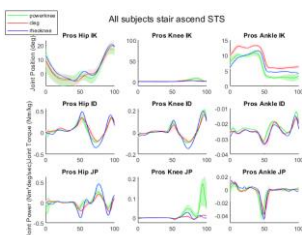


Figure 12: Stair ascend with step-to-step prosthetic side inverse kinematics for subjects 1-4 for commercial MPKs (Power Knee (n=1), C-Leg (n=3), Rheo (n=2))

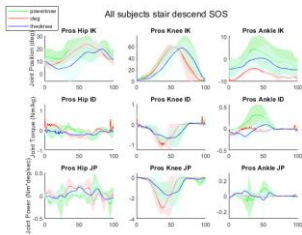


Figure 13: Stair descend with step over step prosthetic side inverse kinematics for subjects 1-4 for commercially available MPKs (Power Knee (n=3), C-Leg (n=1), Rheo (n=2))

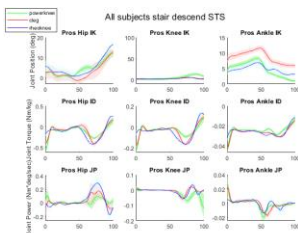


Figure 14: Stair descend with step-to-step prosthetic side inverse kinematics for subjects 1-4 for commercially available MPKs (Power Knee (n=1), C-Leg (n=1), Rheo (n=1))

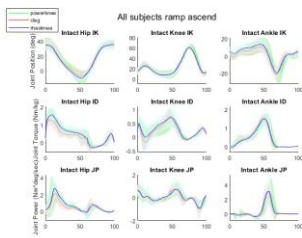


Figure 15: Ramp ascend sound side inverse kinematics for subjects 1-4 for commercial MPKs

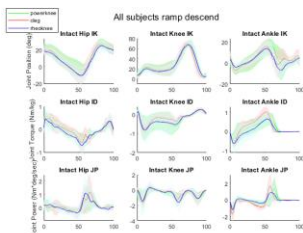


Figure 16: Ramp descend sound side inverse kinematics for subjects 1-4 for commercial MPKs

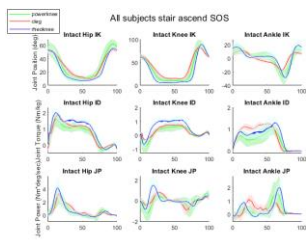


Figure 17: Stair ascend with step over step sound side inverse kinematics for subjects 1-4 for commercial MPKs (Power Knee (n=3), C-Leg (n=1), Rheo (n=2))

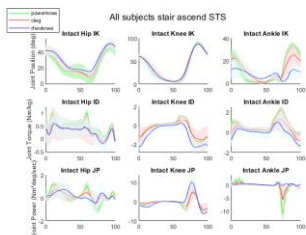


Figure 18: Stair ascend with step-to-step sound side inverse kinematics for subjects 1-4 for commercial MPKs (Power Knee (n=1), C-Leg (n=3), Rheo (n=2))

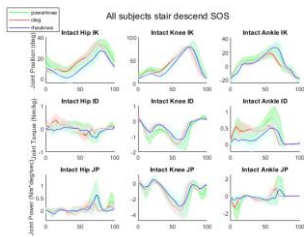


Figure 19: Stair descend with step over step prosthetic side inverse kinematics for subjects 1-4 for commercial MPKs (Power Knee (n=3), C-Leg (n=1), Rheo (n=2))

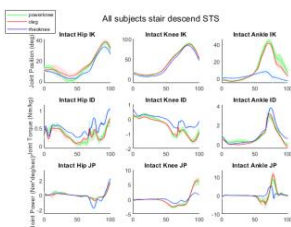


Figure 20: Stair descend with step-to-step sound side inverse kinematics for subjects 1-4 for commercial MPKs (Power Knee (n=1), C-Leg (n=1), Rheo (n=1))

Positive energy distribution for all subjects ramp ascend

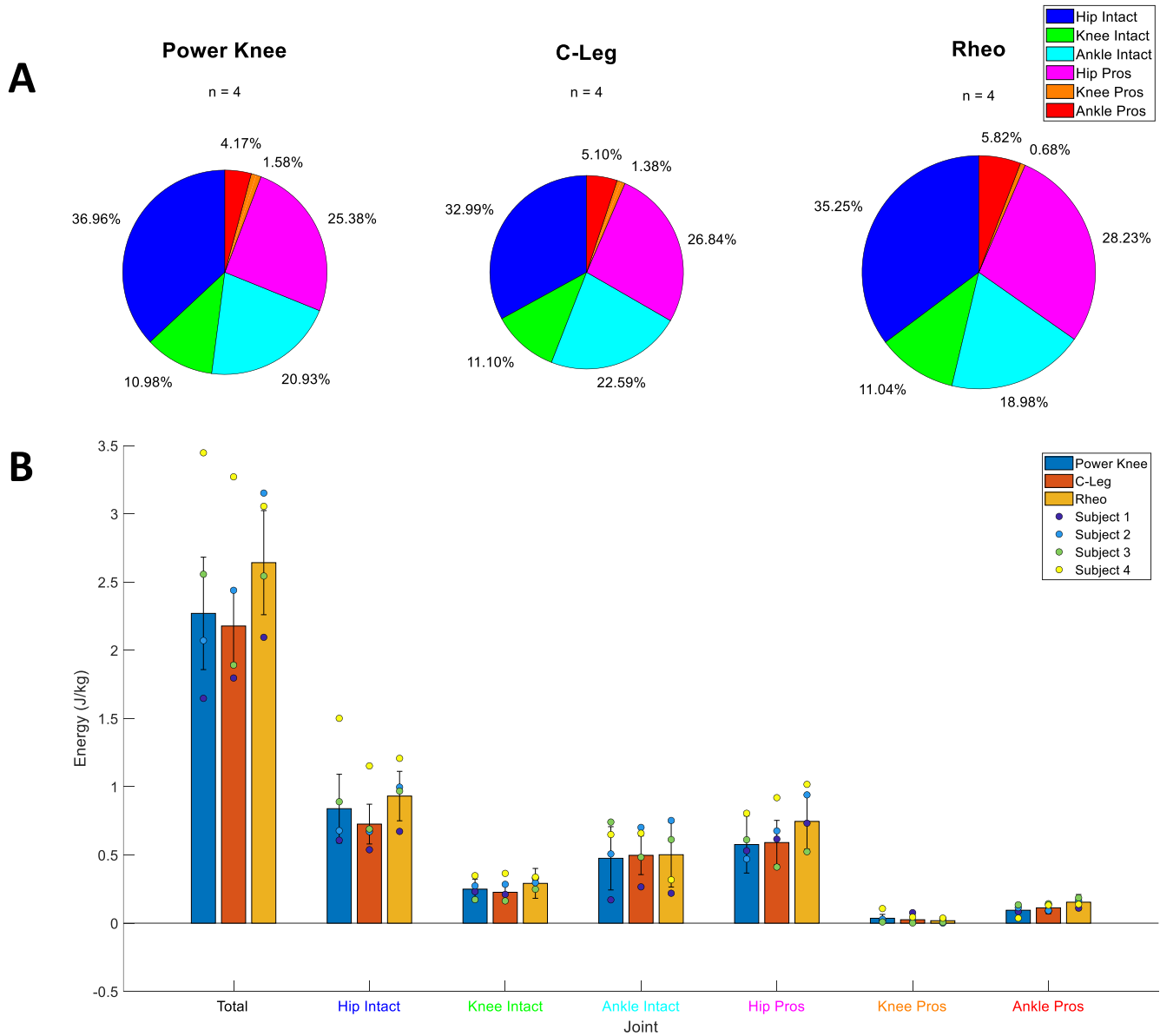


Figure 21: (A) Pie chart and (B) bar graph for ramp ascend energy distribution for subjects 1-4

Negative energy distribution for all subjects ramp descend

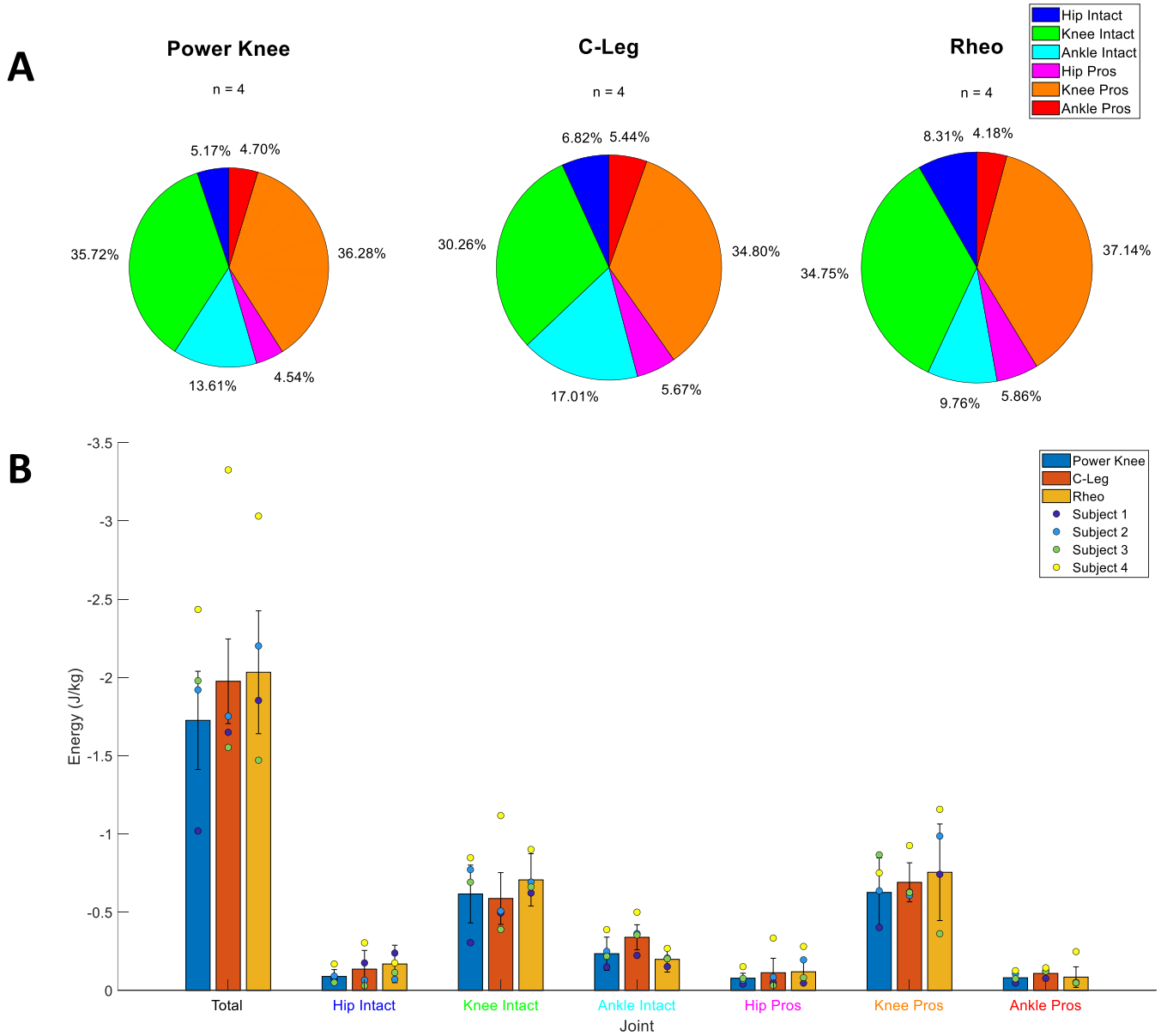


Figure 22: (A) Pie chart and (B) bar graph for ramp descend energy distribution for subjects 1-4

Positive energy distribution for all subjects SOS stair ascend

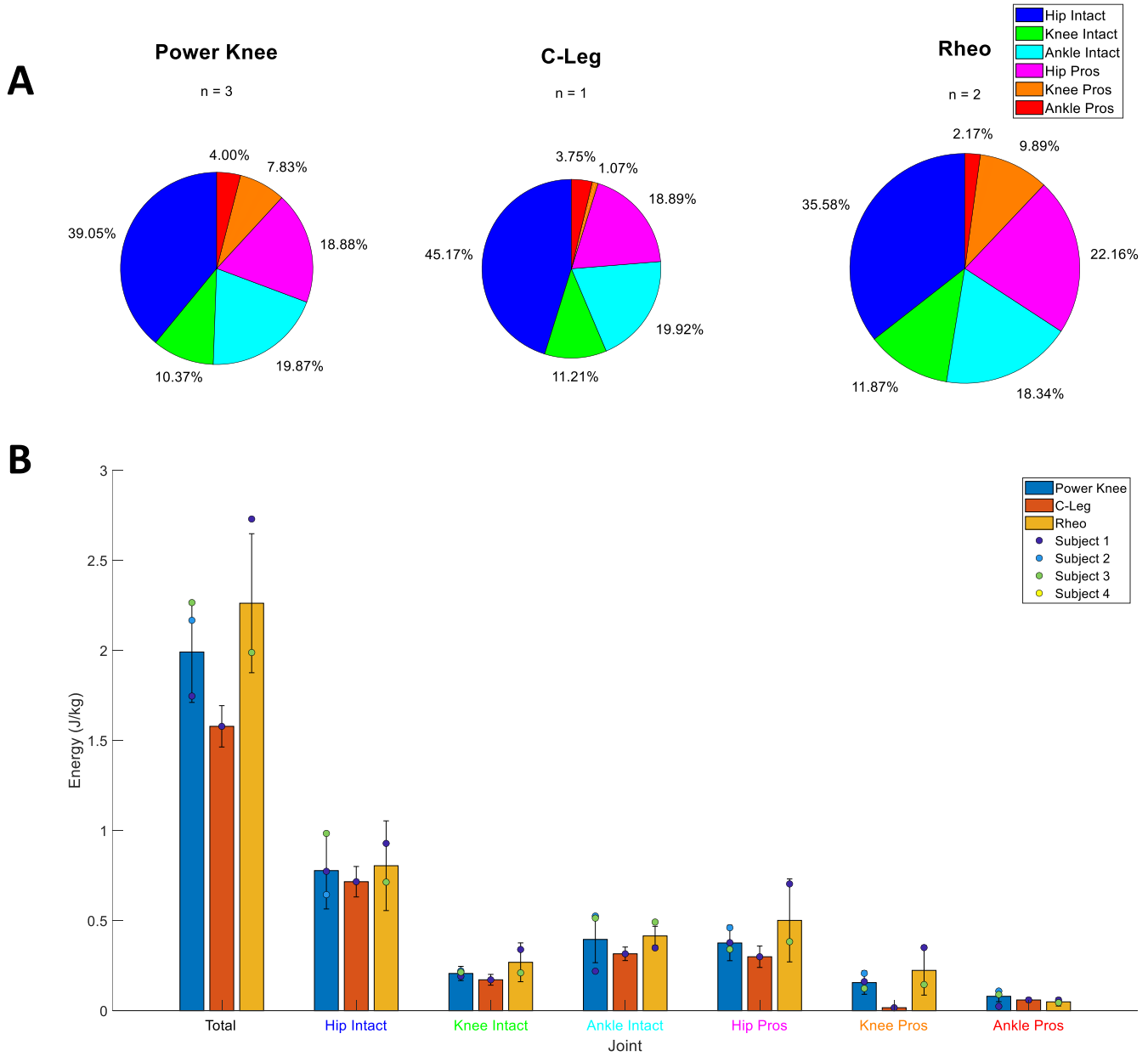


Figure 23: (A) Pie chart and (B) bar graph for stair ascend with step over step energy distribution for subjects 1-4 for commercial MPKs (Power Knee (n=3), C-Leg (n=1), Rheo (n=2))

Positive energy distribution for all subjects STS stair ascend

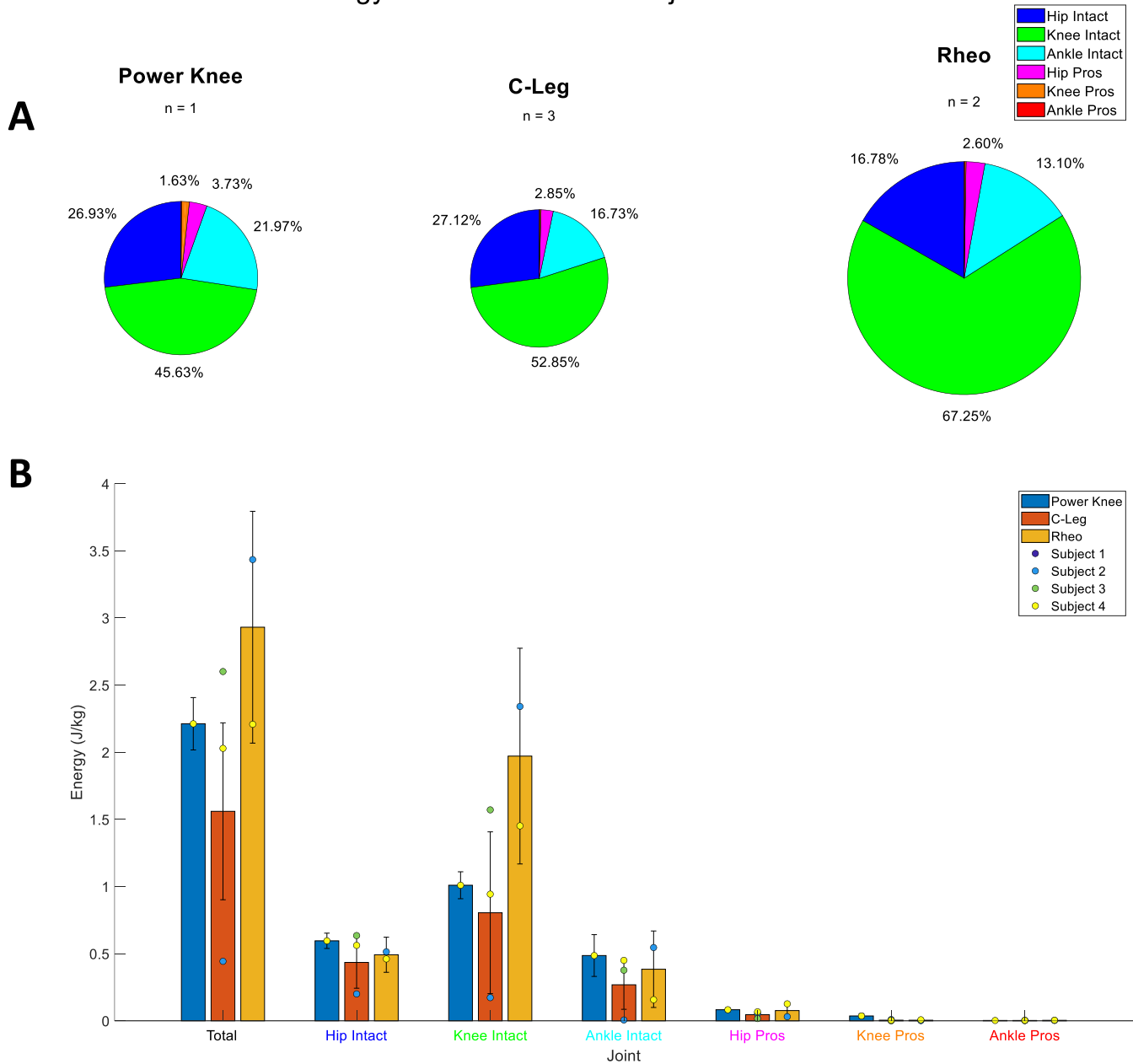


Figure 24: (A) Pie chart and (B) bar graph for stair ascend with step-to-step energy distribution for subjects 1-4 for commercial MPKs (Power Knee (n=1), C-Leg (n=3), Rheo (n=2))

Negative energy distribution for all subjects SOS stair descend

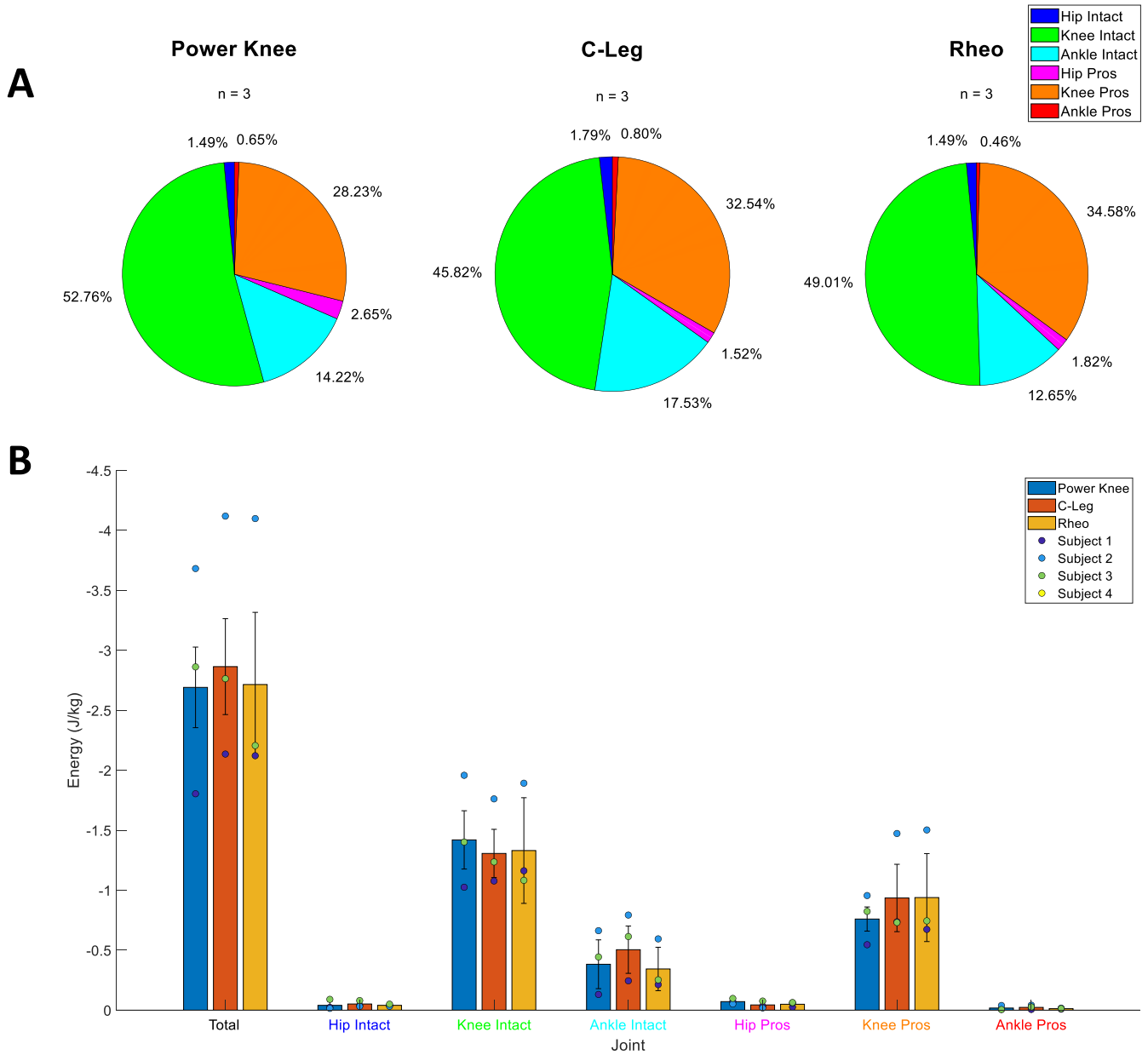


Figure 25: (A) Pie chart and (B) bar graph for stair descend with step over step energy distribution for subjects 1-4 for commercial MPKs (Power Knee (n=3), C-Leg (n=3), Rheo (n=3))

Negative energy distribution for all subjects STS stair descend

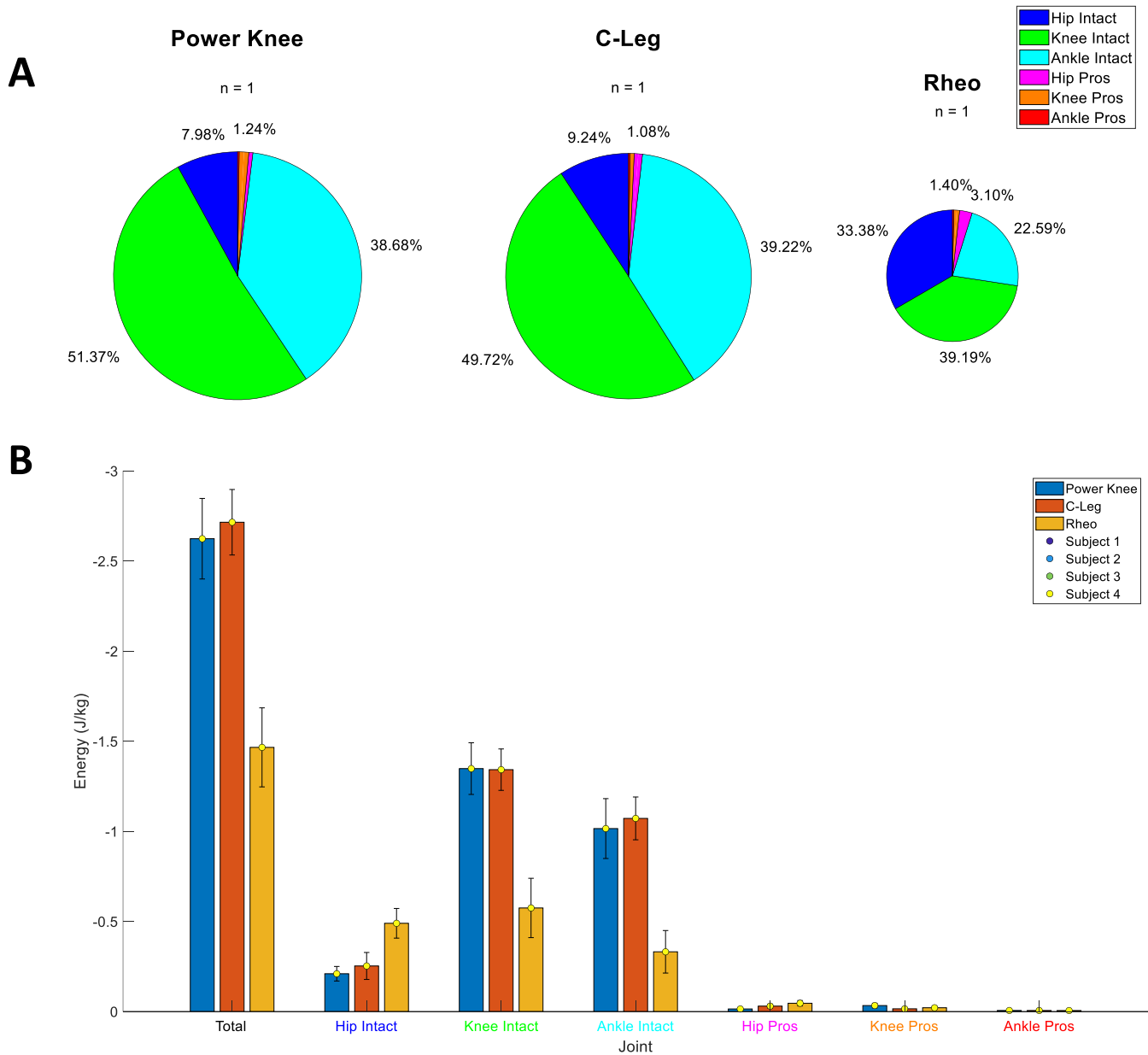


Figure 26: (A) Pie chart and (B) bar graph for stair descend with step-to-step energy distribution for subjects 1-4 for commercial MPKs (Power Knee (n=1), C-Leg (n=1), Rheo (n=1))

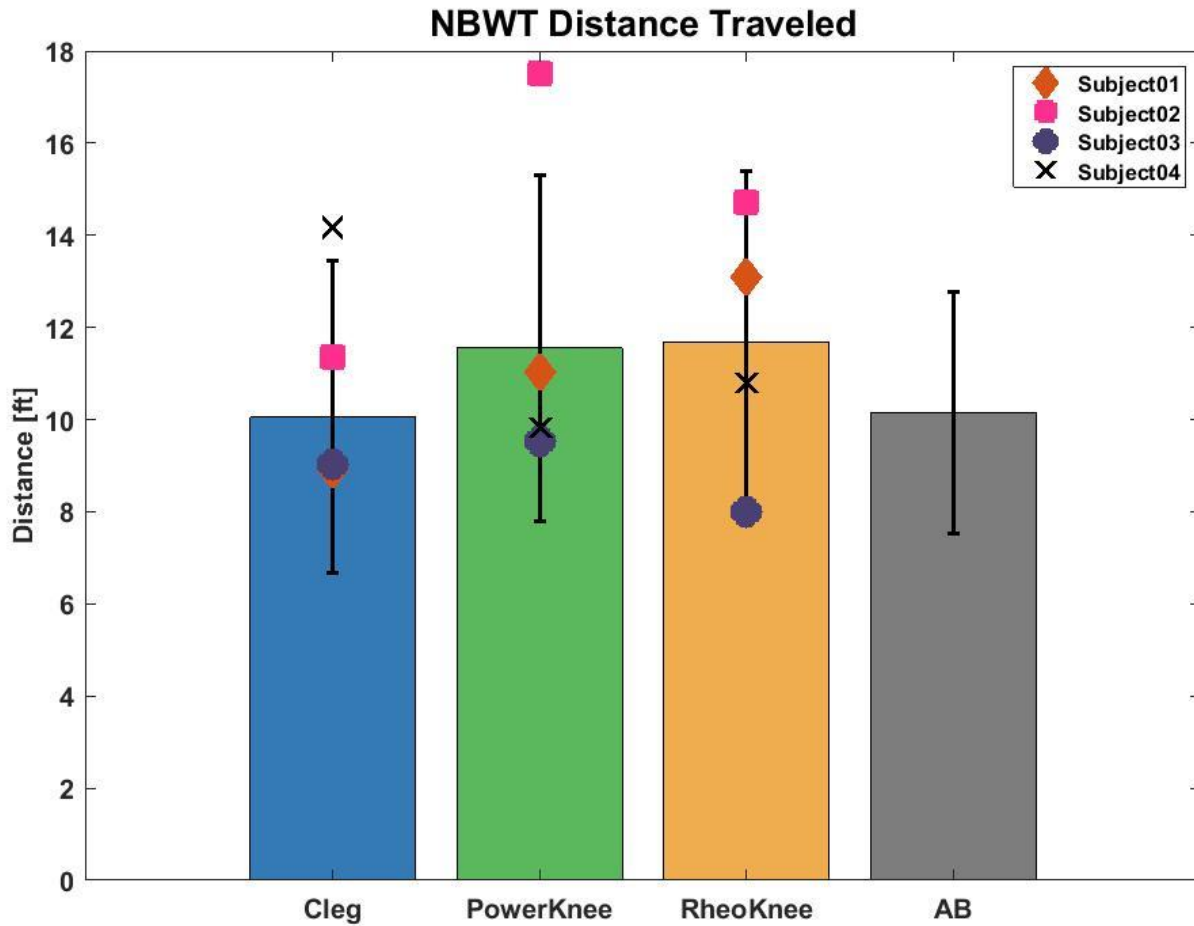


Figure 27: Averaged Distance Traveled on NBWT

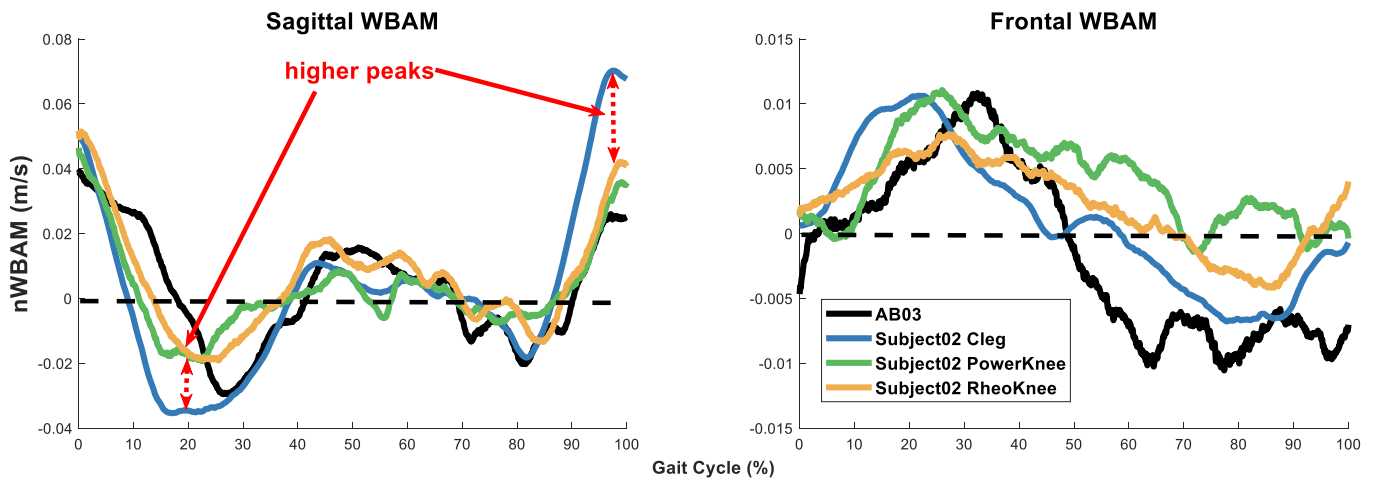


Figure 28: Comparison of Whole Body Angular Momentum (WBAM) Across Different Microprocessor Knees for Subject02

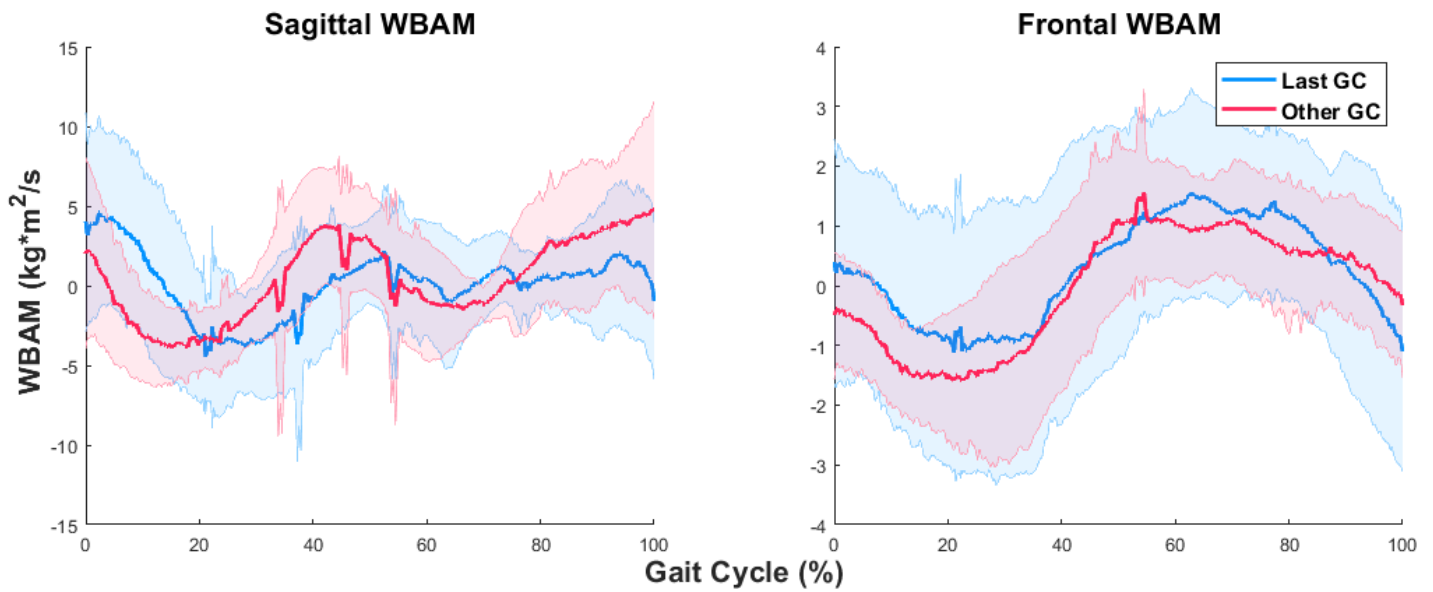


Figure 29: Whole Body Angular Momentum (WBAM) Comparison Between the Last Gait Cycle to the Other Gait Cycles (All commercially available knees for Subjects 01-04)

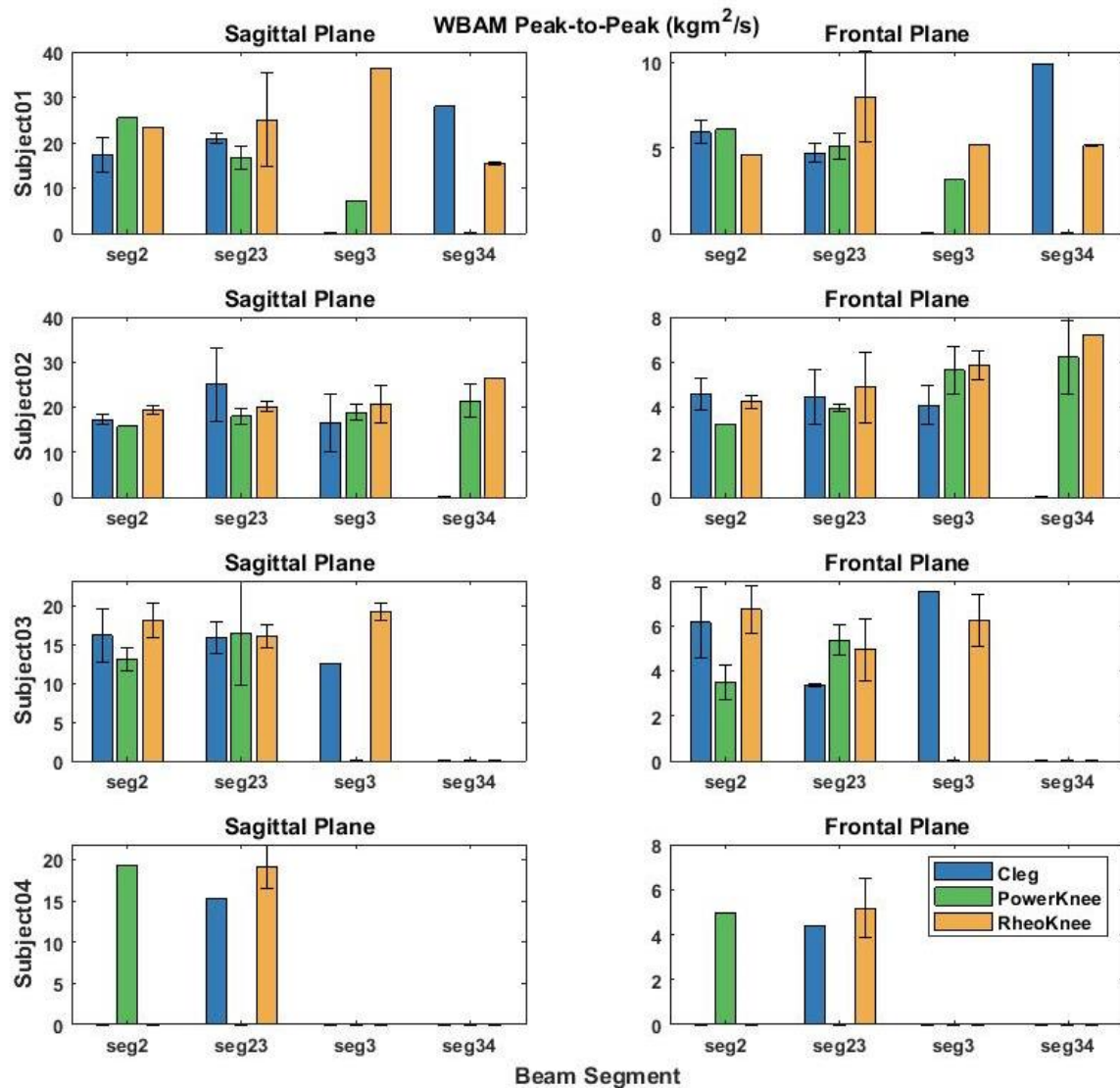


Figure 30: Whole Body Angular Momentum (WBAM) Peak-to-Peak value at Each Beam Segment of NBWT for Subjects 1-4 for each commercially available MPK.

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?

Initial data has been submitted and accepted for podium presentation at the AOPA (American Orthotic Prosthetic Association) September 2022 meeting in San Antonio, TX. The title of the presentation is: *Towards a Clinical Decision Algorithm for Prescribing MPKs in Individuals with Above Knee Amputation.*

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

In the next quarter, we plan to finish collecting and processing the biomechanics and patient reported outcomes for our sixth subject and continue recruiting and enrolling subjects for the study. We also hope to begin collecting data with the research grade prosthesis for subjects we have already collected data on (subjects 1-5) for as well as all future subjects we recruit.

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 these 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 to 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 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.

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*. AOPA September 2022, San Antonio, TX. Accepted for podium presentation.

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: 1
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: 1

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: Master's Student

Researcher Identifier:

Nearest person month worked: 11.5

Contribution to Project: Biomechanics setup/analysis and NBWT fabrication

Name: Sujay Kestur

Project Role: Master's Student

Researcher Identifier:

Nearest person month worked: 10

Contribution to Project: Biomechanics setup/analysis

Name: Gwyneth O'Sullivan

Project Role: Undergraduate Researcher

Researcher Identifier:

Nearest person month worked: 2.5

Contribution to Project: Biomechanics setup/analysis

Name: Adriana Staten

Project Role: Undergraduate Researcher

Researcher Identifier:

Nearest person month worked: 2

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: Ashley Bonner Galbraith
Project Role: MSPO Student
Researcher Identifier:
Nearest person month worked: 1
Contribution to Project: Clinical experiment assistance

Name: Jashalynn Maddox
Project Role: MSPO Student
Researcher Identifier:
Nearest person month worked: 1
Contribution to Project: Clinical experiment assistance

Name: Mariana Miller
Project Role: MSPO Student
Researcher Identifier:
Nearest person month worked: 1
Contribution to Project: Clinical experiment assistance

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