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CONTRACTING ORGANIZATION: University of Maryland, College Park, MD

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13. SUPPLEMENTARY NOTES

14. ABSTRACT

Individuals with lower extremity amputations (ILEA) experience decreased functionality and quality of life due to their missing limb and tissue, with the method of prosthesis attachment largely influencing the quality of life of the individual. Currently, there are two ways a prosthesis can be attached to the residual limb, either with a socket or a bone anchored or osseointegrated (OI) implant. While ILEA with OI prostheses currently represent only a small percentage of ILEA, research largely indicates that ILEA with a OI prosthesis have better overall functionality and performance across a variety of survey or clinical metrics when compared to a socket-based prosthesis, ostensibly due to the direct skeletal attachment created by the OI implant. Because of the functional and performance increase with an OI prosthesis, and the current clinical trials, it is likely that an increased number of ILEA will request and undergo the OI surgery as time passes. And while an OI prosthesis largely increases the quality of life and performance of the ILEA during day to day life due to the direct skeletal attachment of the prosthesis, it is equally likely that the direct skeletal attachment introduces unique biomechanical concerns and problems for the ILEA due to the high force and vibration which may be transferred directly to the residual limb from the prosthesis' contact with the ground. Therefore, this project is investigating the force and vibration that is measured at the residual limb of an individual who has a trans-femoral amputation that uses an OI prosthesis to during activities of daily living to establish the potential for long term health problems.

15. SUBJECT TERMS
None listed.

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1. Introduction

Individuals with lower extremity amputations (ILEA) experience decreased functionality and quality of life due to their missing limb and tissue, with the method of prosthesis attachment largely influencing the quality of life of the individual. Currently, there are two ways a prosthesis can be attached to the residual limb, either with a socket or a bone anchored or osseointegrated (OI) implant. While ILEA with OI prostheses currently represent only a small percentage of ILEA, research largely indicates that ILEA with a OI prosthesis have better overall functionality and performance across a variety of survey or clinical metrics when compared to a socket based prosthesis, ostensibly due to the direct skeletal attachment created by the OI implant. Because of the functional and performance increase with an OI prosthesis, and the current clinical trials, it is likely that an increased number of ILEA will request and undergo the OI surgery as time passes. And while an OI prosthesis largely increases the quality of life and performance of the ILEA during day to day life due to the direct skeletal attachment of the prosthesis, it is equally likely that the direct skeletal attachment introduces unique biomechanical concerns and problems for the ILEA due to the high force and vibration which transfers directly to the residual limb from the prosthesis' contact with the ground. Previous research indicates there is a risk for disastrous injuries such as bone fractures around the implant ostensibly due to high force transferred to the bone through the implant. In addition, long term exposure to vibration in the workplace has previously been associated with various cumulative tissue traumas, including overuse and back injuries, and neural and cardiovascular damage in the tissue. However, despite the possibility of disastrous and cumulative tissue injuries in an ILEA with an OI prosthesis, the force and vibration transferred to the tissue has largely been unstudied in ILEA for a variety of day to day activities. This project is investigating the force and vibration at to the OI implant and tissue of an ILEA during locomotors activities of daily living to characterize the unique biomechanical concerns associated with this attachment method, while maintaining the higher quality of life and performance afforded by an OI prosthesis. Specifically, this project is investigating (1) the relationship between walking speed, and kinetics and vibration at the abutment in ILEA with an OI prosthesis and (2) the kinetics and vibration during activities of daily living, including obstacle clearance, side step, stair ascent and descent, and Timed Up and Go tasks in ILEA with an OI prosthesis to profile the biomechanical concerns of activities of daily living.

2. Keywords

Description	Abbreviation
Individuals with lower extremity amputation	ILEA
Osseointegration/Osseointegrated	OI
Self-selected walking condition	SSW
iPEC force sensor placed in the prosthesis system	iPEC

3. Accomplishments

Major goals of the project

Study Specific Aims and Goals: (1) To investigate the relationship between walking speed, and kinetics and vibration at the abutment in ILEA with an OI prosthesis and (2) to quantify the kinetics and vibration during activities of daily living, including obstacle clearance, side step, stair ascent and descent, and Timed Up and Go tasks in ILEA with an OI prosthesis to profile the biomechanical concerns of activities of daily living.

Major Tasks

Task	Projected Timeline (months)	Current status (Date completed)	Percentage complete (%)
IRB Approval	1-3	Completed (07/09/2021)	100
Study Preparation	1-6	Completed (02/01/2022)	100
Subject Recruitment	9-18	In progress	30
Data Collection	9-18	In progress	30
Data Reduction and Analysis	10-21	In progress	10
Statistical Analysis	15-21	Not started	0
Dissemination	18-24	Not started	0

Specific accomplishments under these goals

Major Activities

The major tasks expected for this project are delineated above in the Major Tasks table. Of these tasks, IRB approval and study preparation have been fully completed. Study preparation required finalizing the protocol work flow, as well as building several pieces of equipment for the activities of daily living. Following the equipment building, preliminary tests of the equipment and the protocol were completed to finalize the equipment design and confirm safety with use. Subject recruitment, data collections, and data reduction and analysis have each been partially completed. At the end of this approval period, 3 participants have been recruited and their data collected. Analysis of this data is ongoing, and initial analysis results of selected trials can be seen in the figures below, and in the quad chart.

Specific objectives

The specific objects for this reporting period were to finalize the IRB and protocol, get IRB approval from the University of Maryland and the Department of Defense, complete study preparation, and initiate subject recruitment and data collections. Data reduction and analysis was also expected to be initiated.

Methodology in brief

Briefly, the methods used in this project consisted of motion capture and prosthesis system force measurement during activities of daily living in individuals with a trans-femoral amputation who use an osseointegrated (OI) prosthesis. The data collections consisted of inserting a force measurement device (iPEC Lab Tech, referred to as iPEC from here on out) into the prosthesis system just below the abutment or end of the implant to measure the forces and moments during activities, and then the use of reflective markers and motion capture cameras to collect the movement of the body and soft tissue. The activities of daily living conditions were walking at 3 different self-selected speeds (normal, slow, and fast speeds), walking across several surfaces (carpet, fake turf, stepping up onto a curb) to simulate object clearance during everyday tasks, standing up from a chair and walking forward, stair ascent and descent, and side stepping to avoid a simulated object. Data reduction methods used custom Matlab scripts and inverse dynamics to output the stride by stride forces measured below the abutment of the OI implant, and Fourier transforms of the reflective marker acceleration data on the residual limb to determine the transfer of vibration to the soft tissue during the activities of daily living.

Significant results

The preliminary results of selected trials from participants are included below. Data consists of aggregate resultant forces measured within the prosthesis system below the implant-prosthesis attachment point, joint kinetics, and vibration on the soft tissue of the residual limb during walking at three different speeds. Preliminary demographics are in Table 1 below.

Table 1. Preliminary demographics for current participants.

	Age	Sex	Height (m)	Weight (kg)	Time since amputation (years)	Cause of amputation	K Level	Time since OI surgery (years)	Residual limb length (cm)
Aggregate Demographics	57 (7.94)	3 Males	1.87 (1.13)	103.53 (17.40)	5.22 (1.38)	1 trauma, 1 cancer, 1 other	4 (0)	2.86 (0.99)	12.25 (1.06)

Data are means (standard deviations).

To address Aim #1 investigating the relationship between walking speed, vibration on the tissue, and force transferred to the residual limb through the osseointgrated prosthesis, preliminary results have been computed. Figure 1 (at the end of the section) contains the average resultant force measured at the abutment by the iPECs force sensor when participants walked at 3 different self-selected speeds. SSW refers to the baseline or normal, self-selected walking speed, while fast and slow refer to the self-selected fast and slow speeds respectively. Average walking speeds for the participants is in Table 2. Interestingly, initial results indicate there may not be a difference between the force that is transferred into the tissue when walking at different speeds.

Table 2. Average self-selected walking speeds for the three walking conditions

	Slow (m/s)	SSW (m/s)	Fast (m/s)
Aggregate Data	0.60 (0.066)	0.83 (0.17)	1.10 (0.32)

Data are means (standard deviations).

Preliminary joint kinetics have been computed to investigate the differences between the limbs when using an osseointegrated prosthesis. Figure 2 (at the end of the section) contains the ankle, knee, and hip internal joint moments for both the amputated and intact limb when walking at the three different speeds. Initial results indicate there may be differences at the joints which may help explain the similarity in the force that is transferred into the tissue of the residual limb.

To address the relationship between walking speed and vibration, preliminary analysis of the markers on the thigh and below the abutment on the iPEC has been done using Fourier transforms. Figure 3 (at the end of the section) contains the average vibration frequency spectra for the markers on the thigh and the iPEC at the three different walking speeds. The shape of the frequency spectra, regardless of walking speed or location had an initial large peak at a frequency below 1.5 Hz, and then a smaller peak at approximately a harmonic of the first peak. The frequency spectra then approached zero, with very small, essentially negligible peaks at higher harmonics of the initial peak. Meaningful frequencies were all below 10 Hz, so the frequency spectrum was cropped to only display the amplitudes of those frequencies. Interestingly, the preliminary results indicate that the Slow walking condition has a higher peak amplitude for both the thigh and iPEC locations (Figure 3; Table 3) but this peak amplitude occurs at a slight lower vibration frequency when compared to both the SSW and Fast conditions. The higher amplitude for the Slow condition was not an expected result, but will be investigated to see whether it is maintained in the full data set after concluding data collections. But, while the amplitude is higher in the Slow condition, this inverse relationship was not seen in the frequency values. As the speed increased, there is a slight increase in the frequency at which the peak amplitude is located for both the thigh and iPEC data, indicating that the vibration frequency increased with speed as expected.

Figure 4 (at the end of the section) contains the power spectrum density of the vibration on the thigh and iPECs for the three walking speeds. The power spectrum density is related to how the signal is distributed into the frequency components, with higher power spectrum density values at a frequency indicative of higher power. In other words, the power spectrum density values can help identify which vibrations may have a larger effect on the tissue, regardless of their amplitude. The shape of the power spectrum density, regardless of walking speed and location, indicates that most of the power of the frequency spectrum is contained around a single frequency below 2 Hz, with this frequency close to or equal to the peak amplitude frequency. Table 3 also contains the peak power spectrum values, and frequencies for walking at the three self-selected speeds at the iPEC and thigh locations. When comparing the thigh and iPEC power spectrum density data, the power spectrum density for the Slow walking condition is slightly higher on the iPEC than on the thigh, but very similar for Fast and SSW walking condition (Figure 4; Table 3). In addition, there is a slight increase in the frequency at which the peak power spectral density is located as the speed increases for both the thigh and iPEC data. For the iPEC, the frequency of the peak amplitude and peak power spectrum density were the same for each speed (Table 3). However, this is not true for the thigh. On the thigh, the peak amplitude and peak power density had different frequencies for the Slow and SSW walking conditions, perhaps indicating that there may be more power contained in the vibration frequencies that are lower than the peak amplitude frequency. Whether this is true will need to be investigated with the full data set after this project concludes data collections and analysis.

Table 3. Average peak amplitude, and peak power spectrum density with their associated frequency of vibration when walking at three self-selected speeds

	iPEC				Thigh			
	Frequency (Hz)	Amplitude (arbitrary units)	Frequency (Hz)	Power Spectral Density (Hz^{-1})	Frequency (Hz)	Amplitude (arbitrary units)	Frequency (Hz)	Power Spectral Density (Hz^{-1})
Slow	0.98	29.45 (13.40)	0.98	2.60E-03 (2.1E-03)	1.17	26.73 (8.70)	1.07	2.40E-03 (2.10E-03)
SSW	1.17	24.56 (6.96)	1.17	1.16E-03 (8.46E-04)	1.37	22.07 (6.94)	1.27	1.60E-03 (8.42E-04)
Fast	1.37	22.95	1.37	1.4E-03 (6.93E-04)	1.37	20.25 (5.36)	1.37	1.40E-03 (7.02E-04)

Data are means (standard deviations). There is no standard deviation for the frequency due to the standardized binning during a Fourier Transform.

Figure 5 (at the end of the section) contains the transfer function between the iPECs and the thigh, representing the proportion of the vibration that was transferred from the iPEC and ground contact into the tissue of the thigh. Negative values in the transfer function represent vibration attenuation, while positive values indicate vibration gain. Preliminary results indicate that, at the lower frequencies, there is some attenuation of the vibration in the SSW walking condition up to approximately 35 Hz, before the function transitions to gain above that frequency. However, in the Slow and Fast walking conditions, almost the entire transfer function indicates there is gain in the vibration from the iPEC to the thigh, as both walking conditions are positive above approximately 5 Hz.

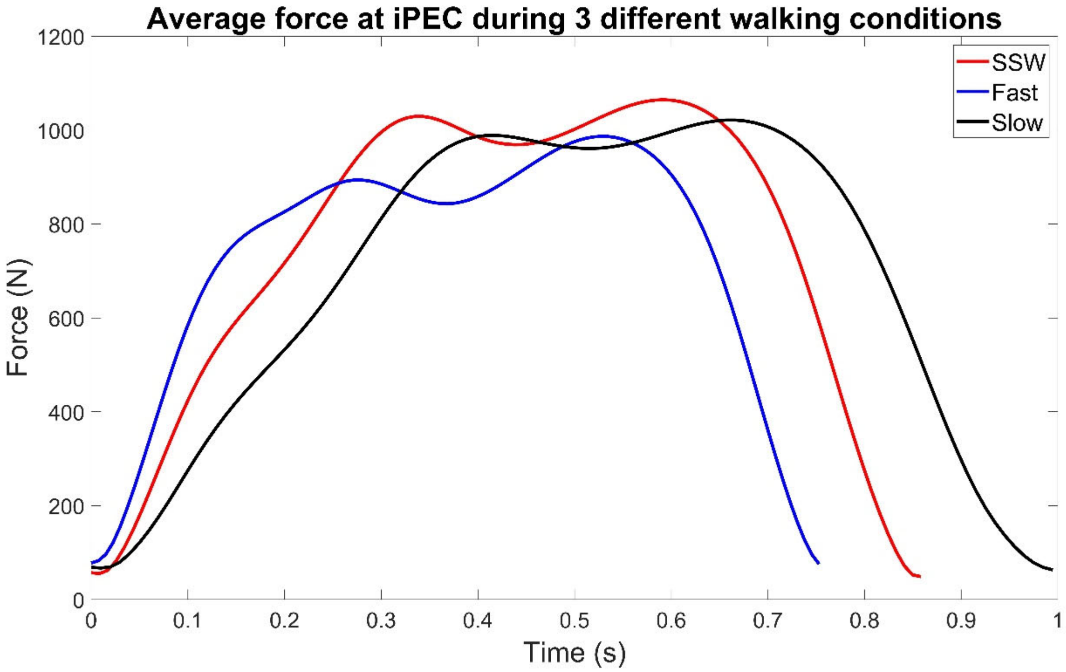

Figure 1. Average resultant force measured by the iPECs force sensor in the prosthesis system, below the abutment., during walking at 3 self-selected speeds. **SSW** = self-selected or normal walking speed, **Fast** = fast walking speed, **Slow** = slow walking speed

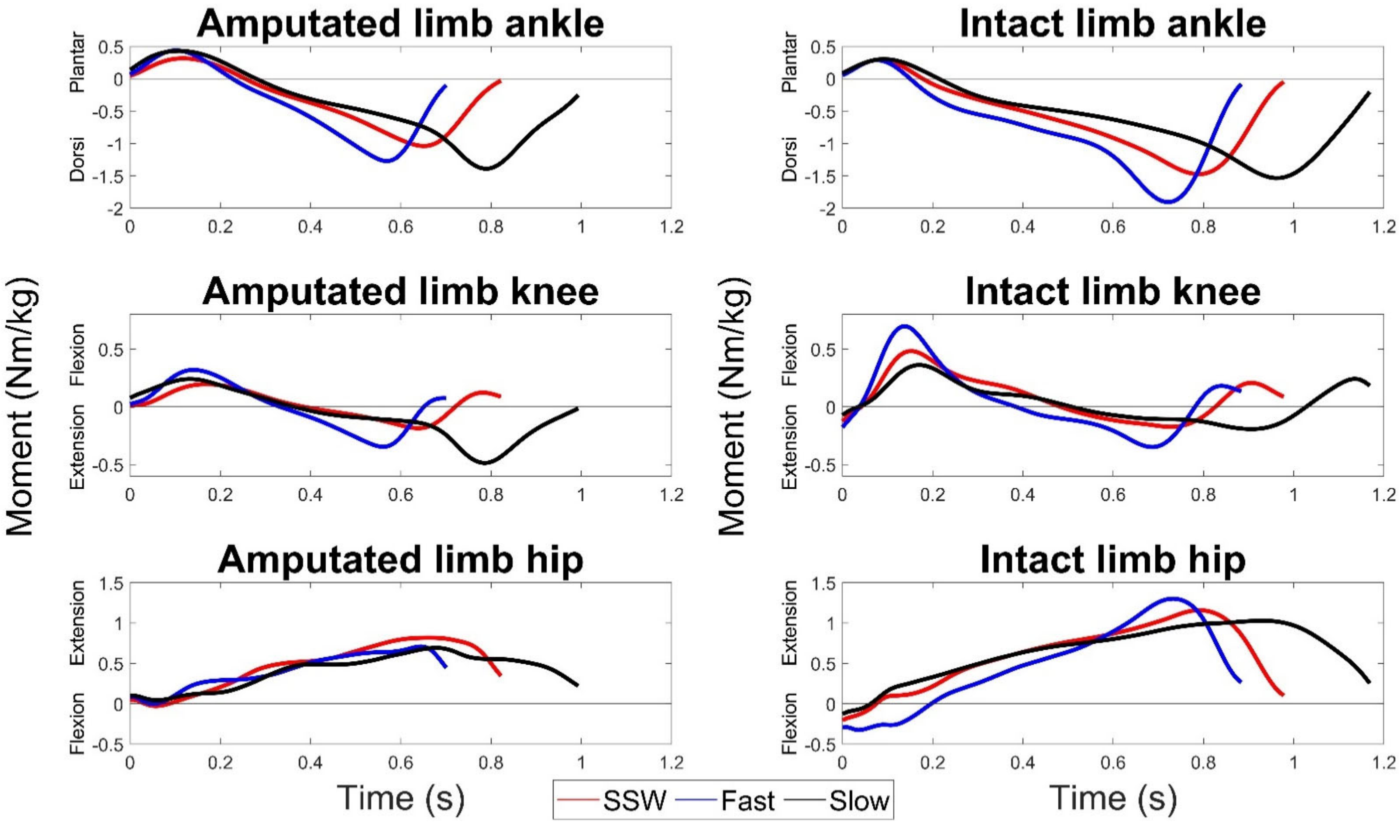

Figure 2. Average internal joint moments during walking at 3 self-selected speeds. **SSW** = self-selected or normal walking speed, **Fast** = fast walking speed, **Slow** = slow walking speed

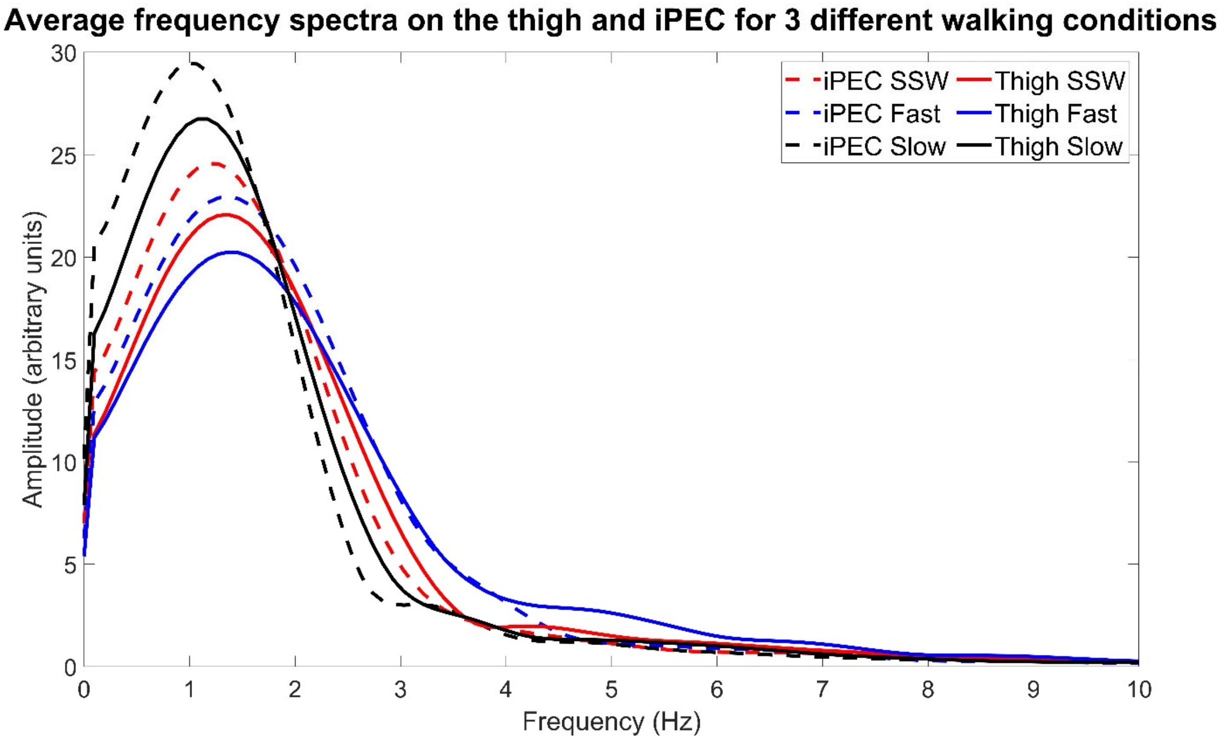

Figure 3. Average frequency spectrum when walking at 3 self-selected speeds. **SSW** = self-selected or normal walking speed, **Fast** = fast walking speed, **Slow** = slow walking speed

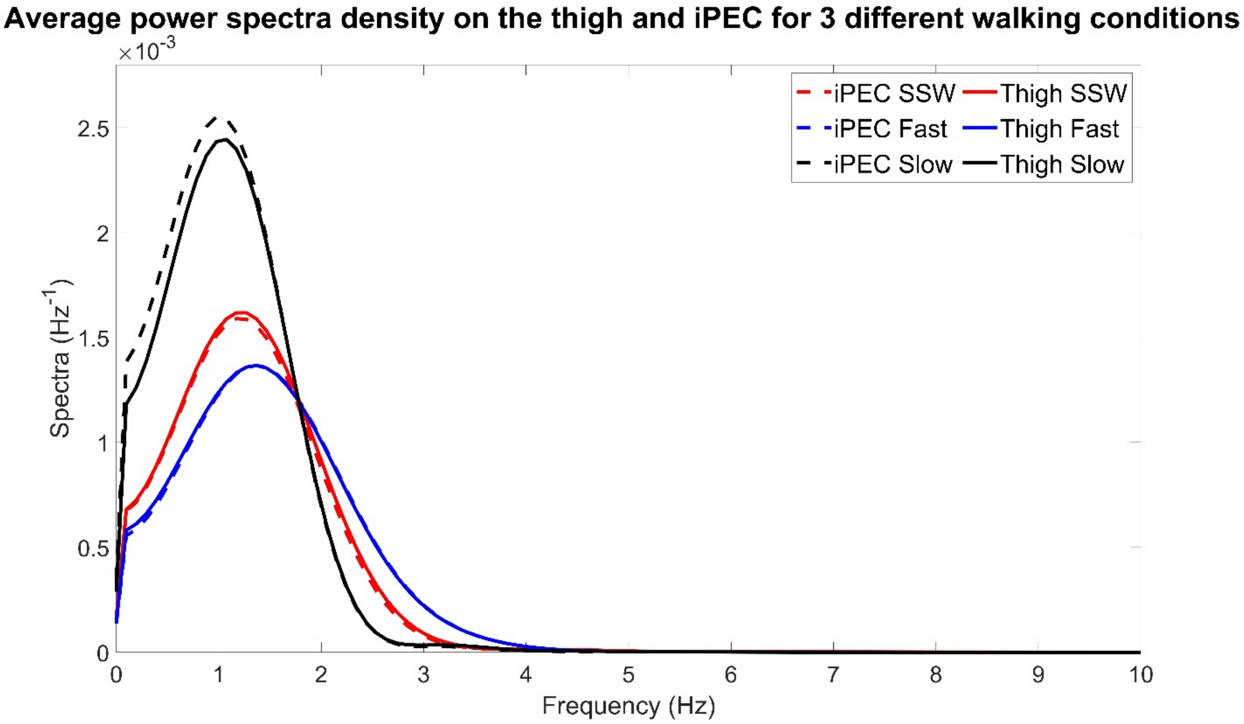

Figure 4. Average power spectrum when walking at 3 self-selected speeds. **SSW** = self-selected or normal walking speed, **Fast** = fast walking speed, **Slow** = slow walking speed

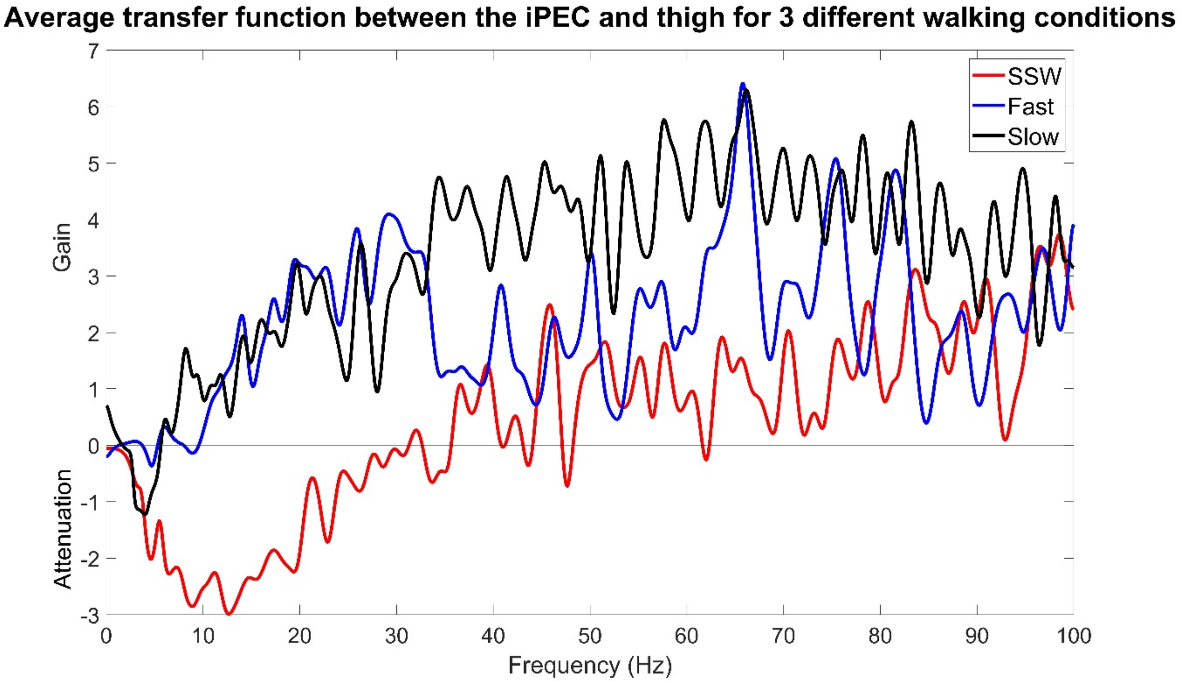

Figure 5. Transfer function representing the vibration that is passed from the iPEC to the thigh during ground contact when walking at 3 self-selected speeds. **SSW** = self-selected or normal walking speed, **Fast** = fast walking speed, **Slow** = slow walking speed

Training and professional development opportunities

Nothing to report.

Results dissemination

Nothing to report.

Plan for next reporting period to accomplish the goals

During the next reporting period, the remaining major tasks are expected to be completed. Subject recruitment and data collections will conclude within the first six months of the next reporting period. While data collections are occurring, initial data reduction and analysis and statistical analysis will begin. Analysis and statistics will be completed prior to the end of the next reporting period. Dissemination will occur slightly before the reporting period through publications and conferences. The projected timeline for the remaining major tasks should still be feasible and we expect the achieve the tasks within the next reporting period.

4. Impact

Impact on the development of the principal discipline

The results of this project will provide an initial baseline characterization of the forces and moments, as well as the vibration, passed to the osseointegrated (OI) limb of individuals who have a trans-femoral amputation. Minimal research has been conducted establishing the either the vibration or forces and moments experienced during different activities of daily living when using an OI prosthesis, and the results of this project will act to provide that foundational knowledge. In addition, the results of this project will help inform future work investigating the kinematics and kinetics associated with using a OI prosthesis and provide assistance to clinicians and prosthesis users as this technology becomes more common place.

Impact on other disciplines

Nothing to report

Impact on technology transfer

Nothing to report.

Impact on society beyond science and technology

The results of the project are likely to help inform clinicians and prosthesis users on the unique residual limb loading and long-term health concerns associated with using an OI prosthesis. By investigating the forces and moments at the OI implant, the results from this project will help establish how the loading at the residual limb and implant changes during locomotor activities of daily living and provide initial rationale for any proactive requirements to ensure long-term health in prosthesis users.

5. Changes/Problems

Changes in approach and reasons for change
Nothing to report.

Actual or anticipated problems or delays and actions or plans to resolve them
Slight delays were encountered with internal approvals for participant payments. The method used for participant payment changed vendors during the processing of the initial forms, so this led to a slight delay in receiving participant payments and delayed data collections. This has been alleviated and data collections, while slightly behind schedule, have begun, with 3 participants collected at this point.

Changes that had a significant impact on expenditures
Nothing to report.

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents
Nothing to report.

Significant changes in use or care of human subjects
Nothing to report.

Significant changes in use or care of vertebrate animals.
Nothing to report.

Significant changes in use of biohazards and/or select agents
Nothing to report.

6. Products

Publications, conference papers, and presentations
Nothing to report.

Website(s) or other Internet site(s)
Nothing to report.

Technologies or techniques
Nothing to report.

Inventions, patent applications, and/or licenses
Nothing to report.

Other Products
Nothing to report.

7. Participants and Other Collaborating Organizations

Personnel

Name	Jae Kun Shim, PhD.
Project Role	PI
Researcher Identifier (ORCID ID)	0000-0001-8880-4684
Nearest person month worked	2.25
Contribution to project	Dr. Shim oversaw the entirety of the project and acted to supervise other personnel.
Funding support	Nothing to report

Name	Ross H. Miller, PhD.
Project Role	Co-PI
Researcher Identifier (ORCID ID)	0000-0002-2924-7993
Nearest person month worked	0.32
Contribution to project	Dr. Miller assisted with data collections and initial analysis of the data through modeling and supervision of graduate students.
Funding support	Madigan Army Medical Center

Name	D. Kurt Collier
Project Role	Technical Staff/Prosthetist
Researcher Identifier (ORCID ID)	N/A
Nearest person month worked	1.8
Contribution to project	Mr. Collier assisted with subject recruitment and data collections.
Funding support	Nothing to report

Name	Jenna Burnett
Project Role	Graduate student
Researcher Identifier (ORCID ID)	0000-0001-7832-8135
Nearest person month worked	4.5
Contribution to project	Ms. Burnett lead data collections and analysis, and contributed to project design.
Funding support	Nothing to report

Name	John Pope
Project Role	Graduate Student/Prosthetist
Researcher Identifier (ORCID ID)	NA
Nearest person month worked	1.5
Contribution to project	Mr. Pope assisted with data collections and acted as a secondary prosthetist for the project.
Funding support	Nothing to report

Changes to support of the PI/Key Personnel
Nothing to report.

Other Organizations
Nothing to report.

8. Special Reporting Requirements

Collaborative Awards

Not applicable for this project.

Quad Chart

Evaluation of mechanical loads on an osseointegrated implant during locomotor activities of daily living

PI: Dr. Jae Kun Shim **Org:** Neuromechanics Research Core, University of Maryland, College Park **Award Amount**: $349,778

Study Aims

- **Aim #1:** To investigate the relationship between walking speed, and kinetics and vibration at the abutment in ILEA with an OI prosthesis
- **Aim #2:** To quantify kinetics and vibration during activities of daily living, including obstacle clearance, side step, stair ascent and descent, and Timed Up and Go tasks in ILEA with an OI prosthesis to profile the biomechanical concerns of activities of daily living

Approach

This research project is investigating the force and vibration transmitted to the tissue of an individual with lower extremity amputation (ILEA) through an osseointegrated (OI) prosthesis. The outcomes of this project will assist clinicians and medical care professionals in assessing biomechanical concerns of Service Members and Veterans with lower extremity amputations, as well as the general population. The data collected from this study will help establish whether additional measures should be investigated to mitigate force and vibration transmitted to the tissue while maintaining a high quality of life for ILEA and will assist clinicians by informing them of biomechanical concerns unique to ILEA with an OI prosthesis.

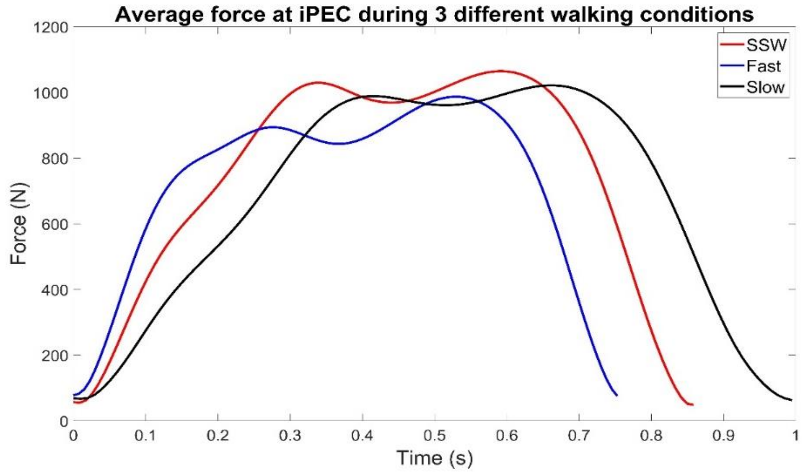

Figure 1. Preliminary data showing the force measured just below the OI implant while participants walked at three self-selected speeds. **SSW** = self-selected or normal walking speed, **Fast** = fast walking speed, **Slow** = slow walking speed

Timeline and Cost

Activities **Year**	**#1**	**#2**
Ethics Approval, Study Prep	🟩	
Subject Recruitment and Data Collections	🟩	🟩
Data Reduction and Analysis	🟩	🟩
Statistical Analysis, Dissemination		🟩
Estimated Budget ($349,778)	**$183K**	**$167K**

Goals/Milestones

Year 1 Goal – Study prep and initial data collections and analysis

✓ Ethic board approval (1 – 3 months)
✓ Test preparation (1 – 6 months)
✓ Subject recruitment (3 subjects) (9 – 12 months)
✓ Data collection of 3 subjects (9 – 12 months)
✓ Begin prelim data reduction and analysis (10 – 12 months)

Year 2 Goal – Data collection, analysis, and dissemination

☐ Subject recruitment (7 subjects) (13 – 18 months)
☐ Data collection of 7 subjects (13 – 18 months)
☐ Data reduction and analysis (13 – 21 months)
☐ Statistical analysis (15 – 21 months)
☐ Dissemination of results (18 – 24 months)

Updated: 05/13/2022

9. Appendices

Nothing to report.