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TITLE: Evaluation of Mechanical Loads on an Osseointegrated Implant During Locomotor Activities of Daily Living

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CONTRACTING ORGANIZATION: University of Maryland

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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. <u>And</u> 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.									
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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 tasks, 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.

Keywords

Individuals with lower extremity amputation	ILEA
Osseointegration/Osseointegrated	OI
Self-selected walking condition	SSW

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 tasks, 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	Completed (04/20/2023)	100
Data Collection	9-18	Completed (04/20/2023)	100
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, study preparation, subject recruitment, and data collections 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. At the end of this approval period, 10 participants have been recruited and their data collected. Data reduction and analysis have each been partially completed. Analysis of this data has been initiated by has not been fully completed at this point. 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 subject recruitment and data collections. Data reduction and analysis was also expected to be continued but not finalized due to the length of time required for subject recruitment. As a result, we applied for and received a no cost extension on the project until September 2024.

Methodology in brief

Briefly, the methods used in this project consisted of motion capture, force platforms, 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 force platforms, and reflective markers and motion capture cameras to collect the ground reaction force and movement of the body and soft tissue. Due to residual limb lengths, some participants were unable to have the iPEC placed in their prosthesis system. To supplement the measured abutment force data set from these participants, using the transformed and translated ground reaction force with rigid body assumptions is

being explored and compared in the participants where iPEC and ground reaction force were collected. Previous research conducted with individuals with trans-tibial amputation indicate that the transformed GRF should not be statistically different. However, this has not been confirmed with individuals with trans-femoral amputations. Therefore, comparing the iPEC data with the transformed ground reaction force using statistical tests of the difference between the two is being computed to confirm the validity of this method of analysis.

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 forces measured within the prosthesis system below the implant-prosthesis attachment point, joint kinetics, and joint angles, and vibration on the soft tissue of the residual limb during walking at three different speeds. Preliminary demographics are in Table 1 below. Statistical tests indicate there are no differences between the male and female participants in demographics, so the participants will be compared as a whole.

Table 1. Participant demographics (SD)

Gender	Age	Height (m)	Weight (kg)	Etiology	Time since amputation (years)	Time since OI surgery (years)	K Level	Residual limb length (cm)
N = 6 men	51.83 (13.08)	1.78 (0.18)	82.63 (27.98)	3 trauma, 2 cancer, 1 infection	7.39 (2.69)	2.71 (1.28)	3.67 (0.52)	21.22 (5.36)
N = 4 women	50.25 (11.35)	1.65 (0.09)	54.93 (14.97)	2 trauma, 2 cancer	22.14 (15.5)	2.54 (2.38)	3.50 (0.58)	16.70 (4.84)
N = 10	51.20 (11.77)	1.73 (0.16)	71.55 (26.73)	5 trauma, 4 cancer, 1 infection	13.59 (11.92)	2.64 (1.68)	3.60 (0.52)	19.41 (5.41)

To address Aim #1 investigating the relationship between walking speed, vibration on the tissue, and force transferred to the residual limb through the osseointegrated prosthesis, preliminary results have been computed. Figures 1 and 2 (at the end of the section) contain the average resultant (Fig. 1) and component (Fig. 2) forces at the abutment for the full sample size using the GRF in the local coordinate system of the iPEC to estimate the abutment force, with this axis system (Fig. 3) defined with Z aligned with the long axis of the bone and implant, Y in the anterior-posterior direction and X in the medial-lateral direction, with both X and Y defined relative to the long axis of the bone. The abutment force was measured while individuals walked at three self-selected speeds, with SSW referring to the preferred or normal, self-selected walking speed, while Fast and Slow refer to the self-selected faster than preferred and slower than preferred speeds respectively. Average walking speeds and standard deviations for the participants are reported in Table 2. When comparing the abutment force across walking speeds, there appears to be a general decrease in the abutment force magnitude as individuals walked faster (Fig. 1), with the peak abutment force decreasing by approximately 0.10 BW from the slow to fast walking conditions. However, this general

decrease in abutment force is not true for each component force, as the magnitude of the peak force increases by approximately 0.10 BW in the Y direction, but decreases by 0.04 BW in the X direction and 0.15 BW in the Z direction. Therefore, the results of the abutment force indicate that the overall magnitude of the abutment force may decrease slightly as individuals walk faster, perhaps due to an intact limb reliance strategy to compensate for the limitations of the amputated limb, but that there may be slight increases in abutment force in the Y direction as a result of the individual producing more force in the anterior and posterior direction as they walk faster. As a result of the decrease in abutment force with faster walking, the general assumption would be that the risk to the bone would be lower with faster walking, as lower forces being transferred to the bone would be expected to result in lower strain and stress placed on the bone. However, there is a possibility that the risk to the bone may still increase with faster walking, as the perpendicular force applied to the bone in the Y direction during faster walking may result in greater bending of the bone and therefore greater stress and strain. Additional analysis such as finite element analysis would be required to investigate whether greater perpendicular force, even with an overall decrease in abutment force magnitude results in greater bone stress and strain.

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

Gender	Slow	SSW	Fast
Average walking speed (m/s)	0.75 (0.15)	0.93 (0.14)	1.20 (0.23)
Average stance time (s)	0.87 (0.3)	0.77 (0.14)	0.67 (0.16)
Average stride length (m)	1.03 (0.08)	1.15 (0.16)	1.37 (0.29)

Preliminary joint kinetics and angles have been computed to investigate the differences between the limbs when using an osseointegrated prosthesis. Figure 4 (at the end of the section) contains the ankle, knee, and hip internal joint moments and angles 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 slight decrease in the force that is transferred into the tissue of the residual limb as individuals walk faster. Specifically, at the ankle and knee, the amputated limb has minimal changes in joint moments and angle as the individual walks faster. However, on the intact limb, there are increases in the joint moments and angles at all joints as the individual walks faster, perhaps to compensate for the limitations in the amputated knee and ankle. As a result of the increased joint moments on the intact limb with minimal changes on the amputated limb, it appears to there may be an increased reliance on the intact limb to generate the required power and work as the individual walks faster.

To address the relationship between walking speed and vibration, preliminary analysis of the markers on the thigh and below the abutment on the iPEC or the Axor II has been done using Fourier transforms. Figure 5 (at the end of the section) contains initial results for 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 had an initial large peak at a frequency below 1.5 Hz, and then a smaller peak at 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. 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 affect on the tissue, regardless of their amplitude. The shape of the power spectrum density 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 contains the peak amplitudes, power spectrum values, and frequencies for walking at the three self-selected speeds. Interestingly, the preliminary results indicate that the Slow walking condition has a higher peak amplitude but this peak amplitude occurs at a slight lower vibration frequency when compared to both the SSW and Fast conditions. This was not an expected result, but will be investigated to see whether it is maintained in the full data set after concluding data collections. When comparing the thigh and iPEC vibration data, the vibration amplitude and power spectrum density at all speeds is larger in magnitude on the thigh than on the iPEC (Table 3), indicating that the residual limb tissue may experience larger oscillations, even though the frequencies are similar. In addition, there is a slight increase in the frequency at which the peak amplitude and 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 there associated frequency of vibration when walking at three self-selected speeds

	iPEC				Thigh			
	Amplitude (arbitrary units)	Frequency (Hz)	Power Spectral Density (Hz ⁻¹)	Frequency (Hz)	Amplitude (arbitrary units)	Frequency (Hz)	Power Spectral Density (Hz ⁻¹)	Frequency (Hz)
Slow	12.62	0.98	1.10E-03	0.98	26.73	1.17	2.40E-03	1.07
SSW	10.53	1.17	6.81E-04	1.17	22.07	1.37	1.60E-03	1.27
Fast	9.84	1.37	5.86E-04	1.37	20.25	1.37	1.40E-03	1.37

Figure 5 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 largely attenuation of the vibration that is passed to the thigh from the iPEC. The attenuation begins to decrease as the frequency increases, with the Slow and Fast walking conditions showing that there may be some gain or increase in the vibration amplitude at frequencies above 30 Hz for the Slow condition, and at a few frequencies around 25 Hz and between 60 and 80 Hz for the Fast walking condition.

Resultant force at the abutment of the osseointegrated implant during walking at three speeds

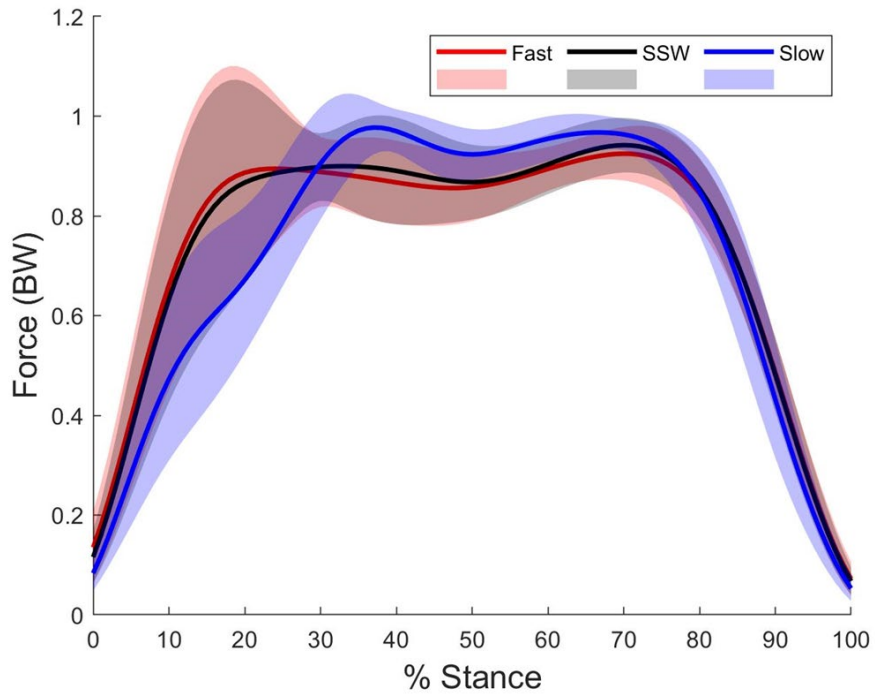


Figure 2. Average resultant force (BW) at the abutment, during walking at 3 self-selected speeds. **SSW** = self-selected or normal walking speed, **Fast** = fast walking speed, **Slow** = slow walking speed

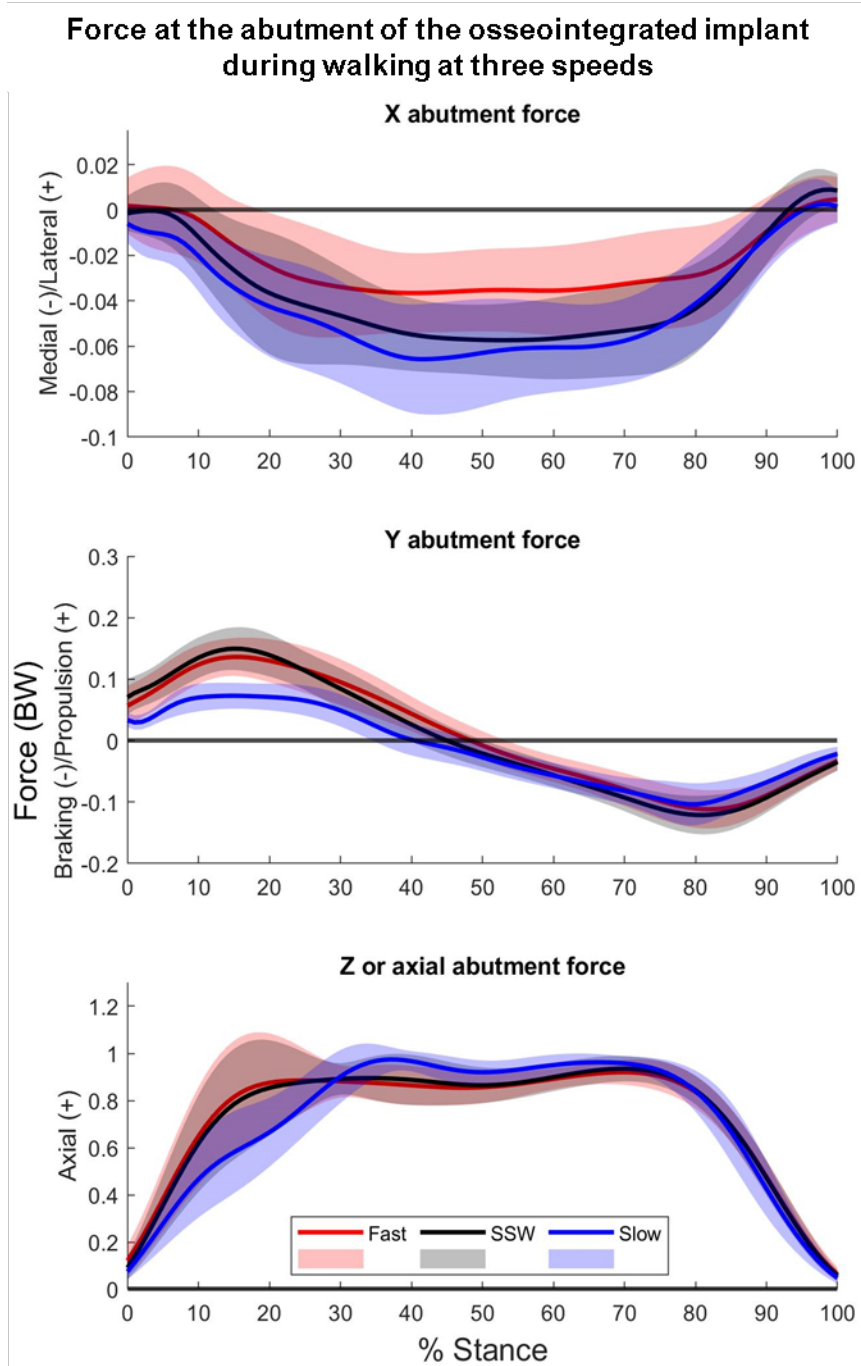


Figure 2. Average directional force (BW) at the abutment, during walking at 3 self-selected speeds. The axis directions are defined in Fig. 3, with each direction relative to the long axis of the bone and implant. **SSW** = self-selected or normal walking speed, **Fast** = fast walking speed, **Slow** =

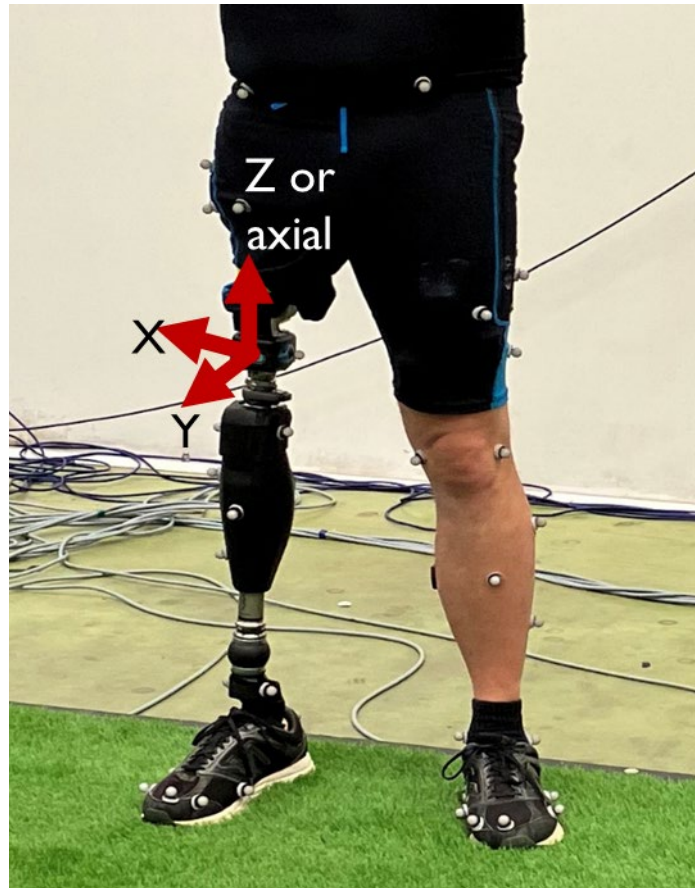


Figure 3. Local coordinate system at the iPEC location used to estimate the abutment forces through transforming the GRF from the global coordinate system to the local iPEC coordinate system. The axis directions are defined with the Z axis aligned with the bone and implant, the Y directed in the anterior-posterior direction relative to the long axis of the bone, and the X directed in the medial-lateral direction relative to the long axis of the bone.

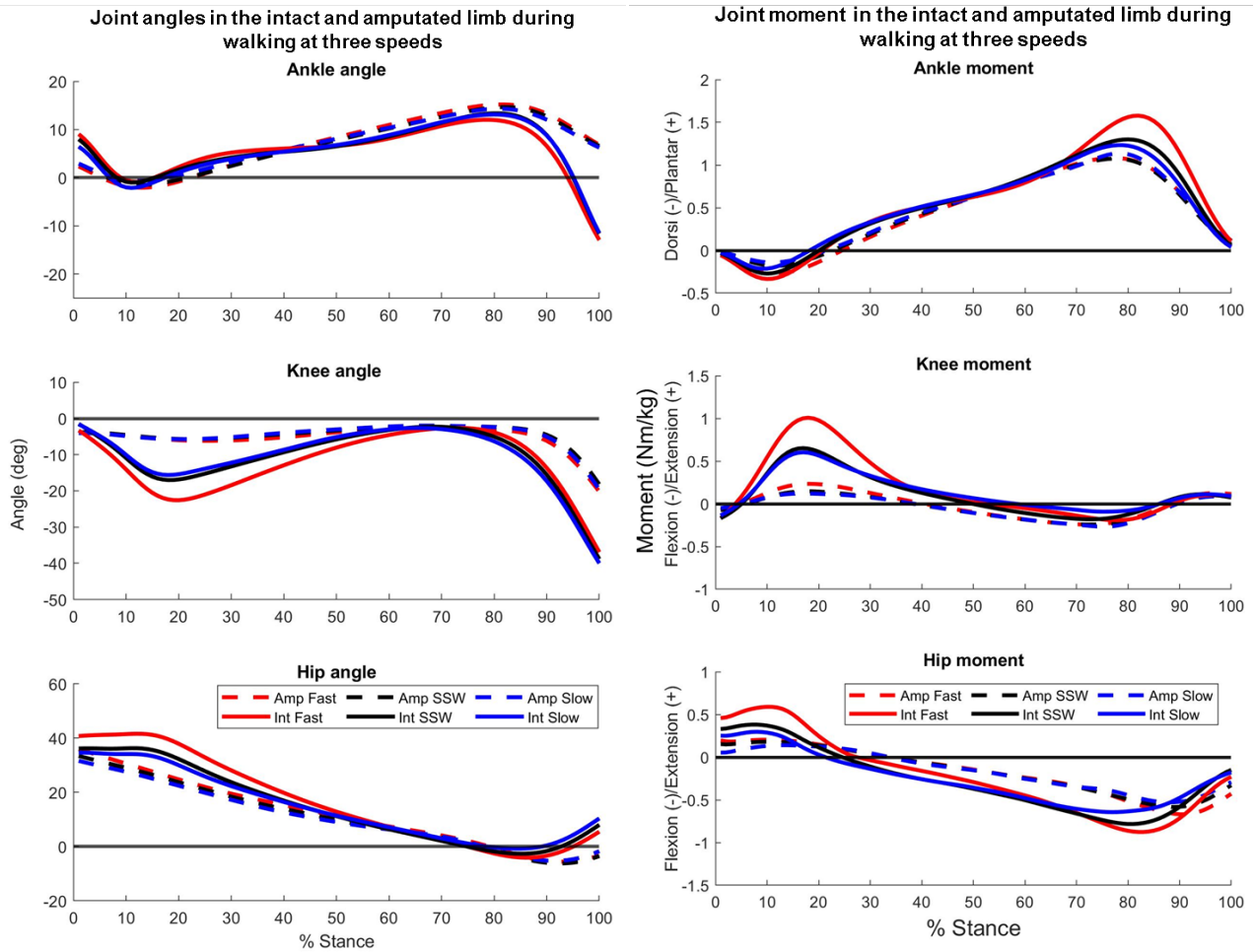


Figure 4. Average internal joint angles and moments during walking at 3 self-selected speeds. SSW = self-selected or normal walking speed, **Fast** = fast walking speed, **Slow** = slow walking speed, Dashed line = amputated limb, Solid line = intact limb

Average frequency spectra on the thigh and iPEC for 3 different walking conditions

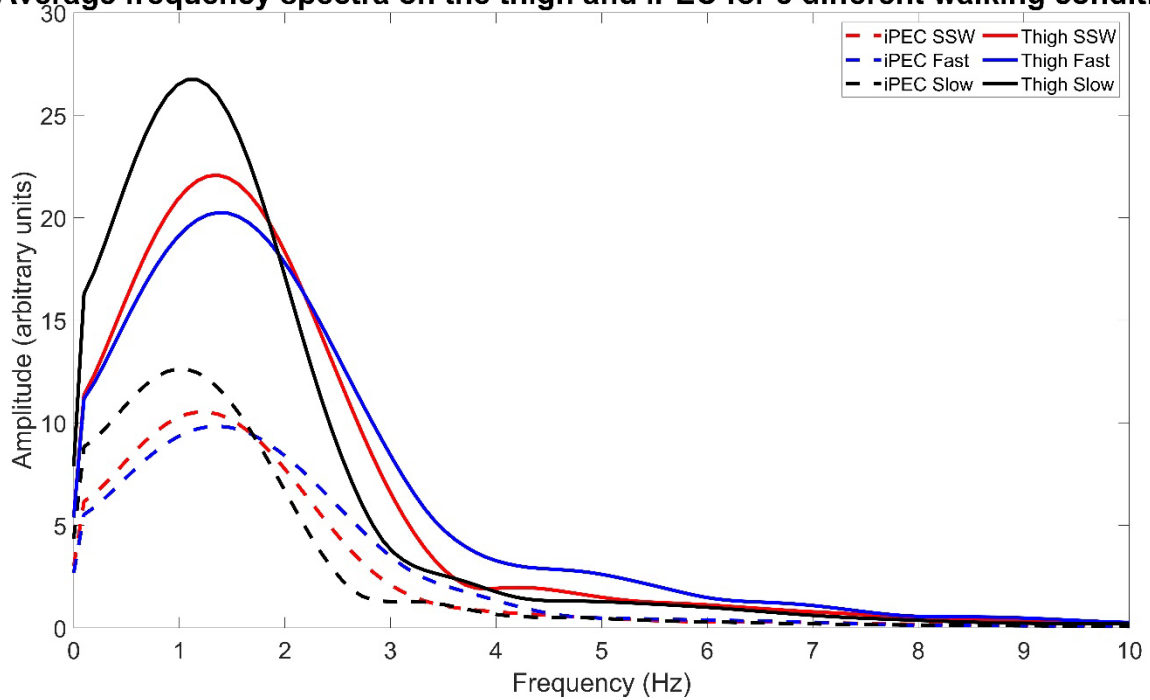


Figure 5. Average frequency spectrum when walking at 3 self-selected speeds. **SSW** = self-selected or normal walking speed, **Fast** = fast walking speed, **Slow** = slow walking speed

Average power spectra density on the thigh and iPEC for 3 different walking conditions

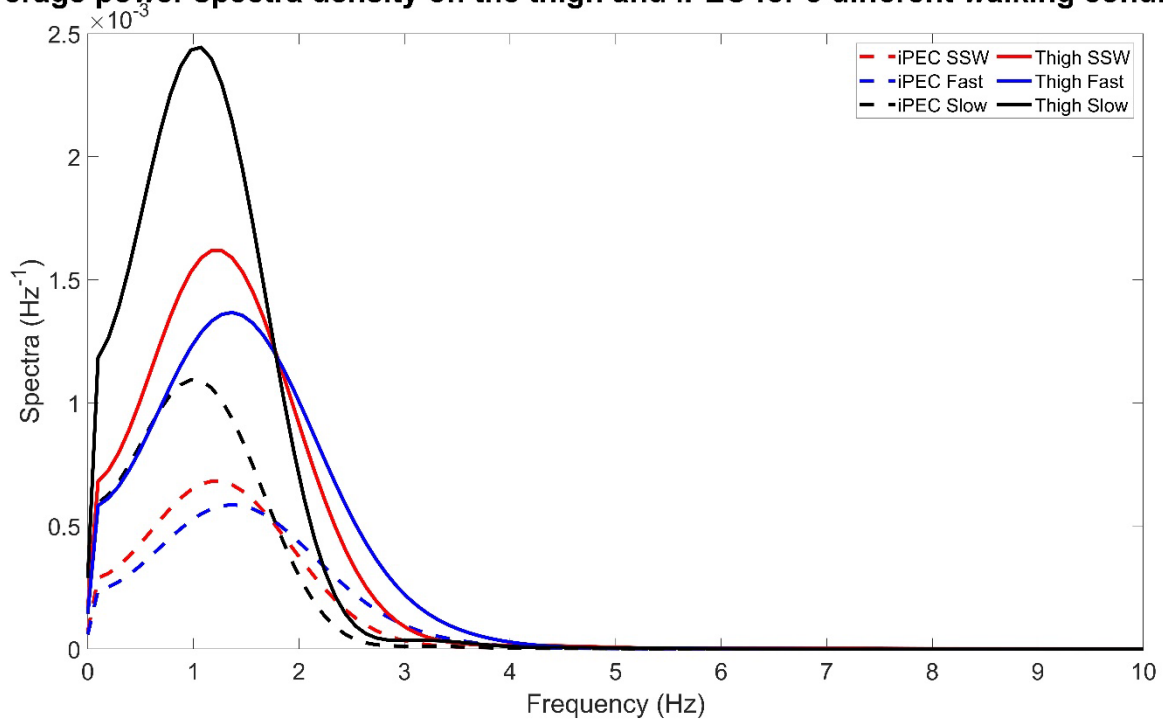


Figure 6. Average power spectrum when walking at 3 self-selected speeds. **SSW** = self-selected or normal walking speed, **Fast** = fast walking speed, **Slow** = slow walking speed

Average transfer function between the iPEC and thigh for 3 different walking conditions

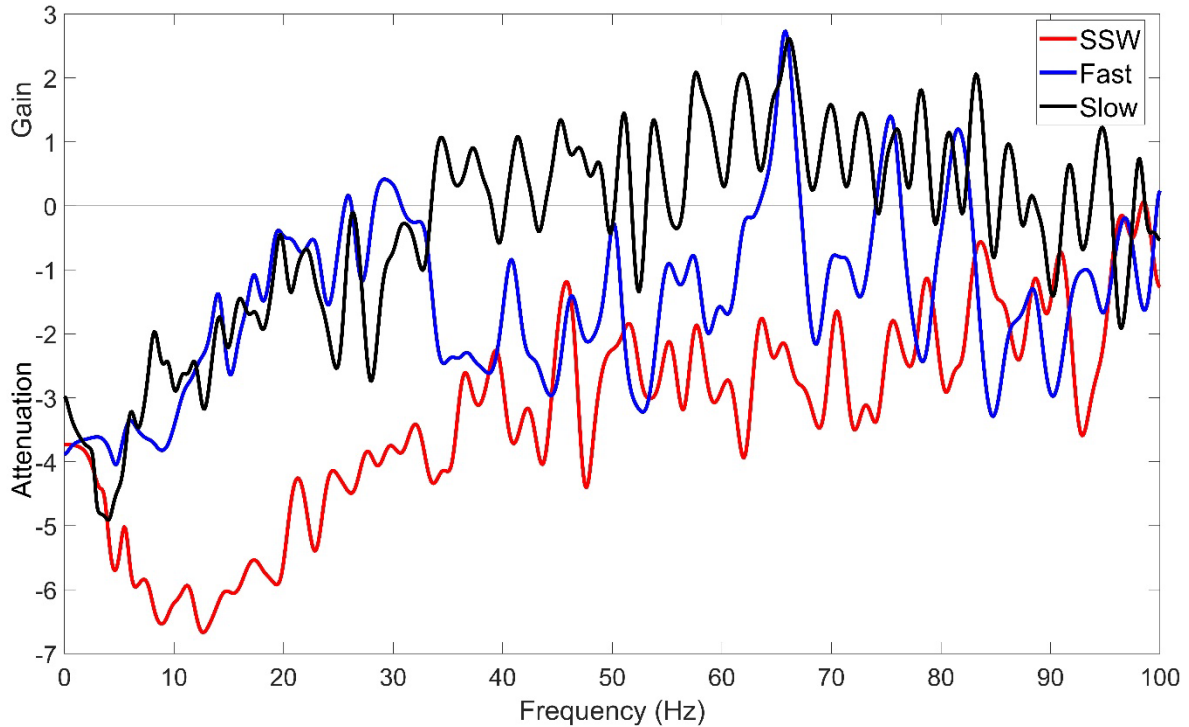


Figure 7. Transfer function representing the vibration that is passed from the iPEC to the thigh during ground contact when walking at 3 self-selected speeds. **SSW** = self-selected or normal walking speed, **Fast** = fast walking speed, **Slow** = slow walking speed

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, data reduction and dissemination is expected to occur. Analysis and statistics of the entire data set and activities of daily living are expected to be completed prior to the end of the next reporting period. Dissemination will begin slightly before the reporting period through publications and conferences, and will continue until September 2024 when the no cost extension is slated to end. The projected timeline for the remaining major tasks should still be feasible and we expect to achieve the tasks within the next reporting period.

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.

Changes/Problems

Changes in approach and reasons for change

Due to some participants having limited space between the knee, Axor II safety mechanism, and the abutment of the OI implant, the iPEC was unable to be placed in their prosthesis system. To replace the measurement of the abutment force, using the transformed and translated ground reaction force from inverse dynamics and rigid body assumptions is being explored. Previous research with individuals with trans-tibial amputation have indicated that the force measured by the iPEC at the abutment is not statistically different when compared to transformed ground reaction force. This has not been investigated with individuals with trans-femoral amputation, but statistical methods are being used to explore if the transformed ground reaction force differs from the iPEC force using participants with both data sources collected during walking.

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

Due to the limited local population, participant recruitment took slightly longer than expected. However, participant recruitment has been finalized, and all 10 participants were collected prior to the close of this reporting period. A no cost extension was requested to allow additional time for data analysis and reduction, and this has been granted.

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.

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.

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	
Contribution to project	Dr. Shim oversaw the entirety of the project and acted to supervise other personnel.
Funding support	

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

Name	D. Kurt Collier
Project Role	Technical Staff/Prosthetist
Researcher Identifier (ORCID ID)	N/A
Nearest person month worked	
Contribution to project	Mr. Collier assisted with subject recruitment and data collections.
Funding support	

Name	Jenna Burnett
Project Role	Graduate student
Researcher Identifier (ORCID ID)	0000-0001-7832-8135
Nearest person month worked	
Contribution to project	Ms. Burnett lead data collections and analysis, and contributed to project design.
Funding support	

Name	John Pope
Project Role	Graduate Student/Prosthetist
Researcher Identifier (ORCID ID)	
Nearest person month worked	
Contribution to project	Mr. Pope assisted with data collections and acted as a secondary prosthetist for the project.
Funding support	

Changes to support of the PI/Key Personnel

Nothing to report.

Other Organizations

Nothing to report.

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.

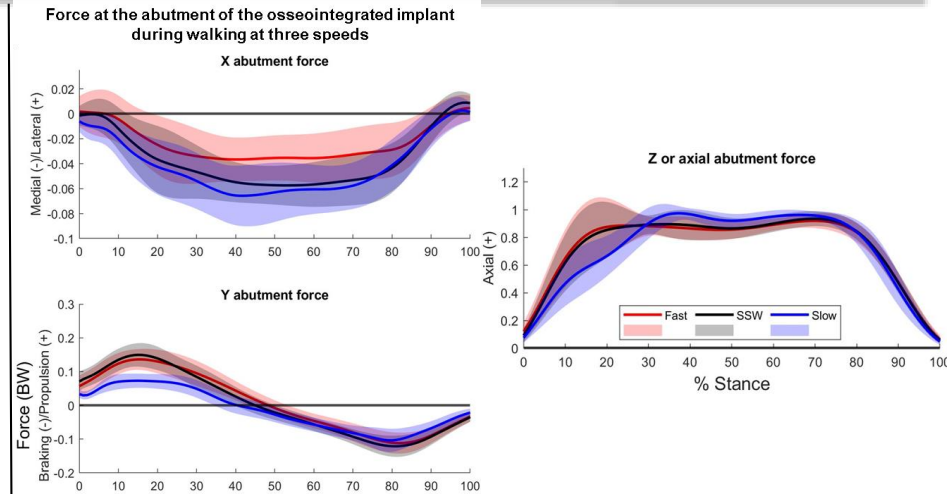


Figure 1. Average abutment force (SD) in the X, Y, and Z directions in the local coordinate system of the abutment while participants walked at three self-selected speeds. **SSW** = self-selected or normal walking speed, **Fast** = fast walking speed, **Slow** = slow walking speed

Timeline and Cost

Activities	Year	#1	#2	#3
Ethics Approval, Study Prep		█		
Subject Recruitment and Data Collections			█	
Data Reduction and Analysis			█	█
Statistical Analysis, Dissemination				█
Estimated Budget (\$349,778)		\$167K	\$87K	\$95K

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 ($n_{Y1} = 3$) (9 – 12 months)
 - ✓ Data collection of 3 participants (9 – 12 months)
 - ✓ Begin prelim data reduction and analysis (10 – 12 months)
- Year 2 Goal** – Data collection, analysis, and dissemination
- ✓ Subject recruitment ($n_{Y2} = 7$) (13 – 18 months)
 - ✓ Data collection of 7 participants ($n_{total} = 10$) (13 – 18 months)
- Year 3 Goal** – Data analysis and dissemination
- ❑ Data reduction and analysis (18 – 30 months)
 - ❑ Statistical analysis (18 – 30 months)
 - ❑ Dissemination of results (28 – 36 months)

9. Appendices

Nothing to report.