AWARD NUMBER: W81XWH-22-2-0046

TITLE: Electromagnetic Suspension of Prosthetic Limbs

PRINCIPAL INVESTIGATOR: Tyler Clites

CONTRACTING ORGANIZATION: University of California, Los Angeles, CA

REPORT DATE: October 2023

TYPE OF REPORT: Annual

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

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1. REPORT DATE	2. REPORT TYPE	3. DATES COVERED
October 2023	Annual	01Sep2022-31Aug2023

4. TITLE AND SUBTITLE
Electromagnetic Suspension of Prosthetic Limbs

5a. CONTRACT NUMBER
W81XWH-22-2-0046

6. AUTHOR(S)

Tyler R. Clites, William Flanagan

E-Mail:

5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)

University of California, Los Angeles
Los Angeles, CA 90095-1406

8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)

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

10. SPONSOR/MONITOR'S ACRONYM(S)

11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION / AVAILABILITY STATEMENT

Approved for Public Release; Distribution Unlimited

13. SUPPLEMENTARY NOTES

14. ABSTRACT

Despite improvements in prosthetic limb devices, most patient-reported problems relate to how these devices are attached to the body. These problems, such as heat/sweating, skin irritation, and tissue damage, lead to reduced prosthesis use and high abandonment rates. This research aims to develop a novel prosthetic limb attachment paradigm for above-knee amputation with the potential to solve these problems without introducing a chronic infection risk (such as in percutaneous osseointegration). The proposed system is composed of a subcutaneous ferromagnetic implant in the residual bone, and an external electromagnet housed at the bottom of the socket. Magnetic attraction between the implant and the electromagnet thus allows the transfer of tensile loads (suspension forces requires to hold a prosthesis onto the body) from the prosthesis directly to the bone across a closed skin envelope. This project will entail the design of the implant and electromagnet, development of a control system, and evaluation of the attachment system using a robotic simulator with model limbs.

15. SUBJECT TERMS
None listed.

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			USAMRDC
Unclassified	Unclassified	Unclassified	Unclassified	18	19b. TELEPHONE NUMBER *(include area code)*

TABLE OF CONTENTS

	Page
1. Introduction	4
2. Keywords	4
3. Accomplishments	4
4. Impact	13
5. Changes/Problems	13
6. Products	14
7. Participants & Other Collaborating Organizations	15
8. Special Reporting Requirements	18
9. Appendices	18

1. INTRODUCTION:

Despite improvements in prosthetic limb devices, most patient-reported problems relate to how these devices are attached to the body. These problems, such as heat/sweating, skin irritation, and tissue damage, lead to reduced prosthesis use and high abandonment rates. This research aims to develop a novel prosthetic limb attachment paradigm for above-knee amputation with the potential to solve these problems without introducing a chronic infection risk (such as in percutaneous osseointegration). The proposed system is composed of a subcutaneous ferromagnetic implant in the residual bone, and an external electromagnet housed at the bottom of the socket. Magnetic attraction between the implant and the electromagnet thus allows the transfer of tensile loads (suspension forces requires to hold a prosthesis onto the body) from the prosthesis directly to the bone *across a closed skin envelope*. This project will entail the design of the implant and electromagnet, development of a control system, and evaluation of the attachment system using a robotic gait simulator with model silicone limbs.

2. KEYWORDS:

prosthetic limb attachment, surgical implants, electromagnetics, amputation

3. ACCOMPLISHMENTS:

What were the major goals of the project?

Specific Aim 1: Develop ferromagnetic implant and define operative approach to implant placement.	**Expected Timeline**	**Percent Completion**
Major Task 1.1: Establish geometric envelope, bony attachment points, and soft tissue treatment plan for the ferromagnetic implant.	Months	%
Subtask 1: Obtain HRPO approval for cadaver research.	0-4	100
Subtask 2: Perform first cadaveric dissection session to define implant envelope. *Requires 2 cadaveric leg specimens*.	5-8	100
Subtask 3: Fabricate dummy implants and perform second cadaveric dissection session to determine fixation strategy and coverage plan. *Requires 2 cadaveric leg specimens*.	9-11	100
Subtask 4: Finalize surgical plan and perform operative simulation. *Requires 2 cadaveric leg specimens*.	12-14	
Milestone(s) Achieved: Surgical design completed.		
Major Task 1.2: Optimize implant geometry in context.		
Subtask 1: Parameterize preliminary implant model based on priorities from cadaver dissection.	5-6	100
Subtask 2: Optimize implant geometry in JMAG.	10-12	100
Subtask 3: Fabricate prototype implants and validate model predictions on static testbench.	13-16	
Milestone(s) Achieved: Implants fabricated and validated.		
Major Task 1.3: Prepare documents for FDA pre-sub meeting		
Subtask 1: Host kickoff meeting with FDA Consultant.	4	100
Subtask 2: Work with FDA consultant to draft pre-submission documentation.	5-12	100
Milestone(s) Achieved: FDA pre-submission documents completed.		100
Specific Aim 2: Design external electromagnetic hardware and implement control system.	**Expected Timeline**	**Percent Completion**
Major Task 2.1: Optimize electromagnet design.	Months	%
Subtask 1: Parameterize electromagnet model.	3-5	100

Subtask 2: Optimize electromagnet design in JMAG.	6-9	100
Subtask 3: Fabricate prototype electromagnet and validate model predictions on static testbench.	10-13	100
Milestone(s) Achieved: Electromagnet fabricated and validated.		100
Major Task 2.2: Simulate dynamic system in software, and identify key elements of controller.		
Subtask 1: Generate Simulink model of electromagnet design and limb dynamics.	14-15	
Subtask 2: Simulate control architectures and evaluate for robustness and stability.	16-18	
Milestone(s) Achieved: Candidate controllers identified.		
Major Task 2.3: Evaluate and fine-tune controller on testbench.		
Subtask 1: Assemble dynamic testbench.	5-10	100
Subtask 2: Implement controller for testbench motor to simulate dynamic loading on the implant.	11-18	30
Subtask 3: Tune and validate electromagnet control strategies on dynamic testbench.	19-24	
Milestone(s) Achieved: Electromagnet controller finalized.		
Major Task 2.4: Schedule and attend pre-submission meeting with the FDA.		
Subtask 1: Send pre-submission documents to the FDA and schedule pre-submission meeting.	13	
Subtask 2: Attend pre-submission meeting with FDA.	16-18	
Milestone(s) Achieved: FDA pre-submission meeting completed.		

Specific Aim 3: Validate complete electromagnetic system in model residual limbs.	**Expected Timeline**	**Percent Completion**
Major Task 3.1: Create residual limb models.	Months	%
Subtask 1: Obtain IRB and HRPO approval for human subjects research.	0-9	100
Subtask 2: Mold residual limbs from persons with above-knee amputation.	10-18	25
Subtask 3: Create physical residual limb models for each subject.	13-20	
Milestone(s) Achieved: Residuum models ready for evaluation.		
Major Task 3.2: Fabricate custom prosthetic sockets.		
Subtask 1: Fabricate two thermoplastic “check” sockets (conventional and electromagnetic) for each residual limb model.	21-24	
Subtask 2: Embed electromagnet in electromagnetic sockets.	25-26	
Milestone(s) Achieved: Sockets ready for evaluation.		
Major Task 3.3: Evaluate performance with gait-relevant motion.		
Subtask 1: Implement dynamic trajectory on KUKA robot.	18-26	
Subtask 2: Evaluate pistoning in electromagnetic and conventional socket at each of three simulated limb volumes.	27-33	
Subtask 3: Perform statistical analyses to evaluate performance.	30-34	
Subtask 3: Prepare manuscripts and summary reports.	31-36	
Milestone(s) Achieved: Experimental study complete, manuscript submitted for peer review.		

What was accomplished under these goals?

Major Task 1.1, subtask 1: OHRO approval was obtained for cadaver research

Major Task 1.1, subtask 2: The first cadaveric dissection was completed to investigate 3 objectives for a *primary amputation*: implant size, implant shape, and estimating tissue thickness.

A preliminary implant design (**Fig. 1**) was used to evaluate the fit of this geometric envelope in the residual limb. A mid-length transfemoral amputation was performed, with residual tissue kept long to allow for coverage of the implant. The implant was positioned at the distal end of the residual femur and successfully covered with residual muscles (**Fig. 2**). The oval shape was found preferable over a circular implant because it allowed for more implant material to fit within the limb envelope and there were no concerns raised from Co-I Bernthal or Co-I Stavrakis regarding implant extrusion due to this shape. Based on the tissue coverage around the implant, design features on the implant, such as attachment holes or porous sections, were proposed and will be evaluated in a later dissection.

The tissue thickness beneath the implant was estimated by measuring the combined thickness of the hamstrings, skin, and fascia. This was found to be 7mm when compressed which was within the expected range that magnetic suspension would be feasible.

Suturing the skin closed around the implant was not performed because the implant was not fixed to the bone and did not have attachment points for soft tissue coverage. Despite this, the size of the implant would have allowed complete closure. Full bone fixation, tissue coverage, and skin closure will be investigated in subsequent dissections.

The surgical procedure for a *revision amputation* was discussed with Dr. Bernthal and Dr. Stavrakis, and a consensus was reached that there would be no changes with regards to implant geometry for a revision amputation compared to a primary amputation. In the revision case, the distal end of the residual bone would be resected by the amount required to fit the implant's height into the residual limb. Tissue coverage would then proceed identically to the primary amputation case. This procedure was confirmed to be viable based on measurements taken in the first dissection.

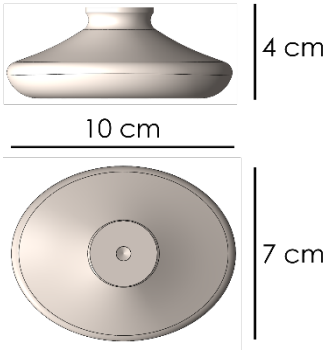


Figure 1. Preliminary implant geometry.

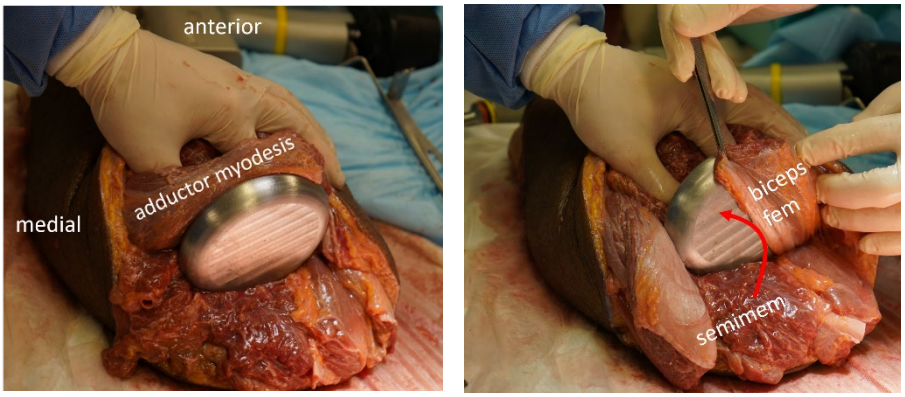


Figure 2. Implant size and fit within a residual limb. This size of implant could be successfully covered with the residual muscles.

Major Task 1.1, subtask 3: A second dissection was performed using the new two-part implant and the coverage strategy was discussed (**Fig. 3**). The two-part implant brought up new questions about adding areas for tissue ingrowth, since we would prefer ingrowth into metal but the top cover of the implant would be a lightweight plastic. One potential addition that will be investigated further will be metal "washers" of a porous material that could be added to the cover to enable areas of tissue ingrowth.

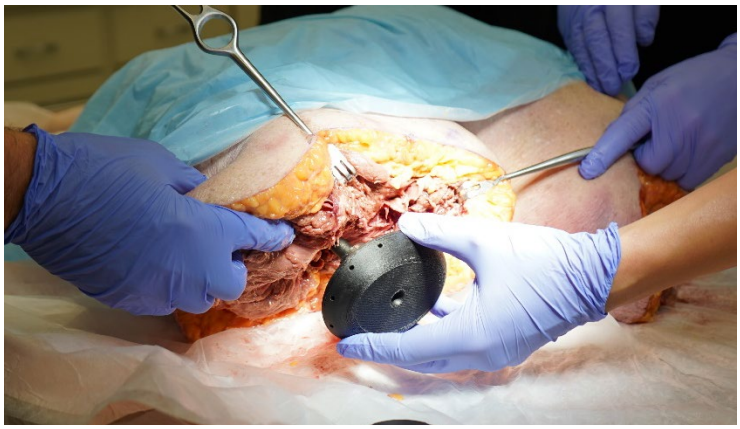


Figure 3. Testing the implant size/shape in a cadaveric dissection

Major Task 1.2, subtask 1: The implant design was fully parametrized as shown in **Fig. 4** to consider maximum allowable curvature along with implant geometrical envelope.

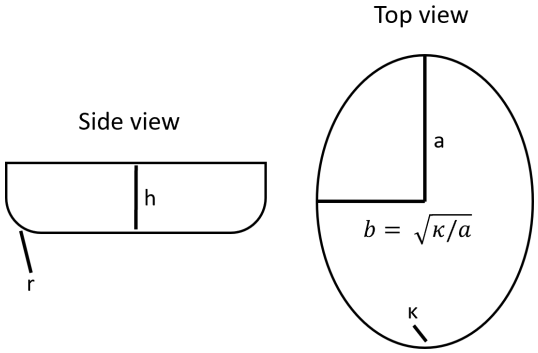


Fig. 4: Parametrized implant to consider curvature constraints on the ellipse based on the major axis length (a), the maximum curvature in the ellipse (κ), implant height (h), and the fillet radius along the bottom (r)

Major Task 1.2, subtask 2: The parametrized implant was optimized in JMAG. It was found that of the parameters (**Fig. 4**), only the height (h) was optimizable. All other parameters (major axis diameter a and fillet radius r) strongly preferred the maximum material condition (large a, small r). These would be constrained by anatomical limits, with a being set to the maximum that could fit within the limb. The fillet radius, r, was set to the smallest value that still provided a blunt corner such that it would not present an extrusion risk. With h as the only variable, implants with differing heights were sampled in JMAG and evaluated by the change in mass along with the change in average power required to suspend a prosthesis during gait (**Fig. 5**). An implant height of 13mm was found to decrease mass by 41% while only increasing average power by 3.8%.

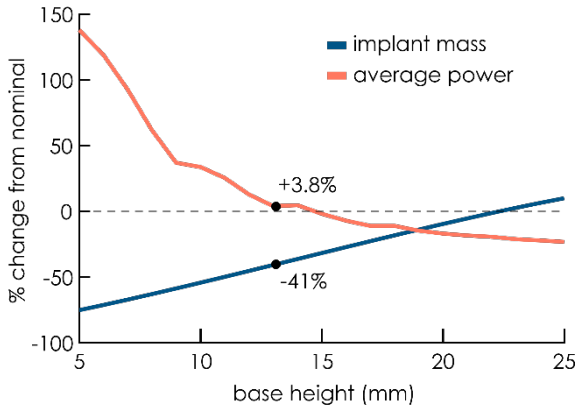


Figure 5. Implant optimization. A base height of 13mm reduced the mass by 41% compared to the previous implant design while only increasing average power during gait by 3.8%.

Major Task 1.3, subtask 1: The kickoff meeting with the FDA consultant was held.

Major Task 1.3, subtask 2: FDA presubmission documents have been drafted and completed.

Major Task 2.1, subtask 1: A preliminary model (**Fig. 6**) of the electromagnet was created in JMAG simulation software. The preliminary implant model (**Fig. 1**) geometry was imported into JMAG and set at a gap distance of 17.5mm. This distance is well above the measured tissue thickness during the dissection to allow for a factor of safety during design. With the JMAG simulation environment configured, the parametrization and optimization of the electromagnet can be performed.

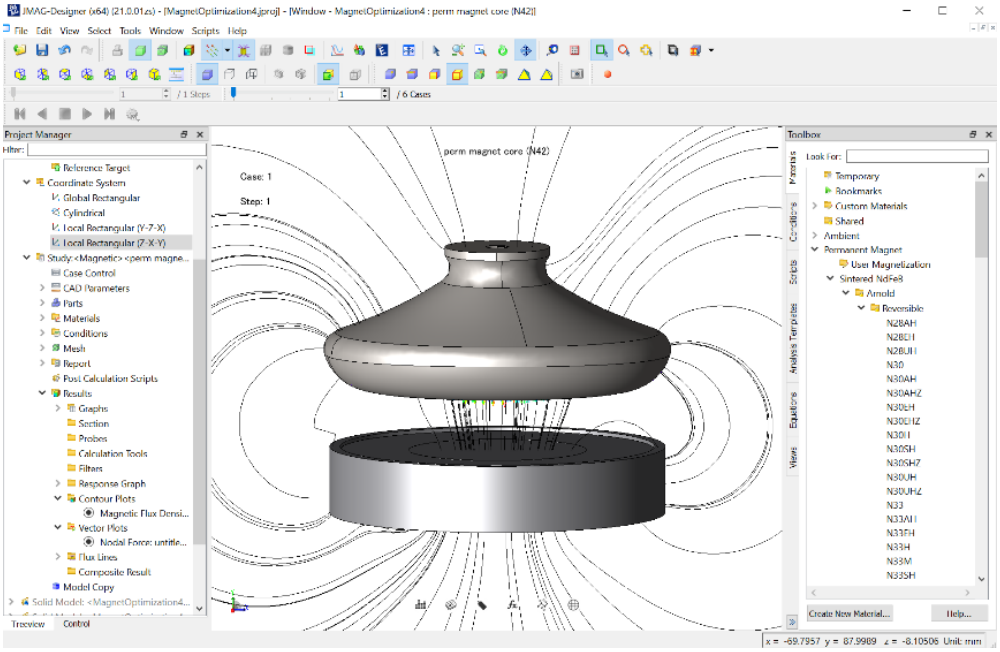


Figure 6. JMAG simulation environment with the implant and electromagnet to drive optimization of the electromagnet.

The electromagnet design was fully parameterized as shown in **Fig. 7**. The magnet design incorporates a permanent magnet core to provide a passive force and reduce the power required

during operation. The strength of this core will be limited during the optimization process to prevent excessive pressures on the limb when no current is running through the coil.

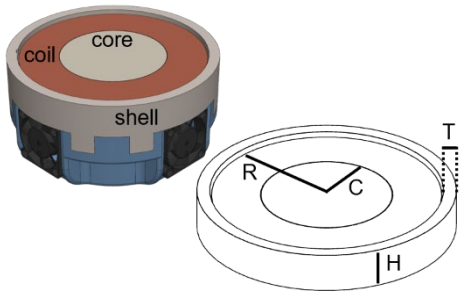


Fig. 7: Parametrized magnet to optimize the core radius (C), coil radius (R), shell thickness (T), and magnet height (H)

Major Task 2.1, subtask 2: A cost function for this optimization was formulated as:

$$J = C_f * \left(F_{p,max} - F\right) + C_m * J_m^2 + C_0 * J_0^2$$
$$J_m = 9.81 * (M_{sock} - M_{allow});\ J_0 = F_0 - F_{0,allow}$$

Where C_f, C_m, C_0 are weights for the force cost, mass cost, and 0-current force cost, respectively. The 0-current force cost is added due to the design incorporating a permanent magnet core. This cost is used to limit the allowable strength of the core. J_m and J_0 are constraint costs restricted to be positive (and 0 otherwise).

Using the previously described cost function, with $(C_f, C_m, C_0) = (1, 0.5, 1)$, the optimized electromagnet had a core radius of 28mm, core height of 9.5mm, coil radius of 46.3mm, and shell thickness of 5.7mm (**Fig. 8**). Based on manufacturer capabilities and practical constraints (integer wire layers, wire gauge) that were intentionally not considered during optimization (due to resulting discontinuities), the manufactured magnet had a core radius of 28mm, core height of 9.5mm, coil radius of 49.1mm, and shell thickness of 5mm. Despite the differences from the optimum, this still produced a magnet similar in optimization cost value.

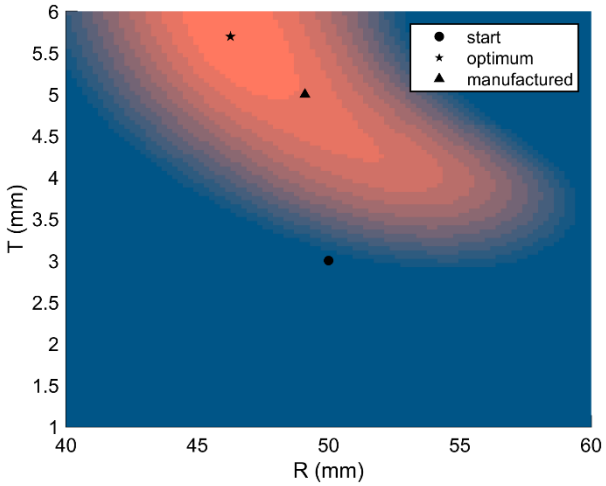
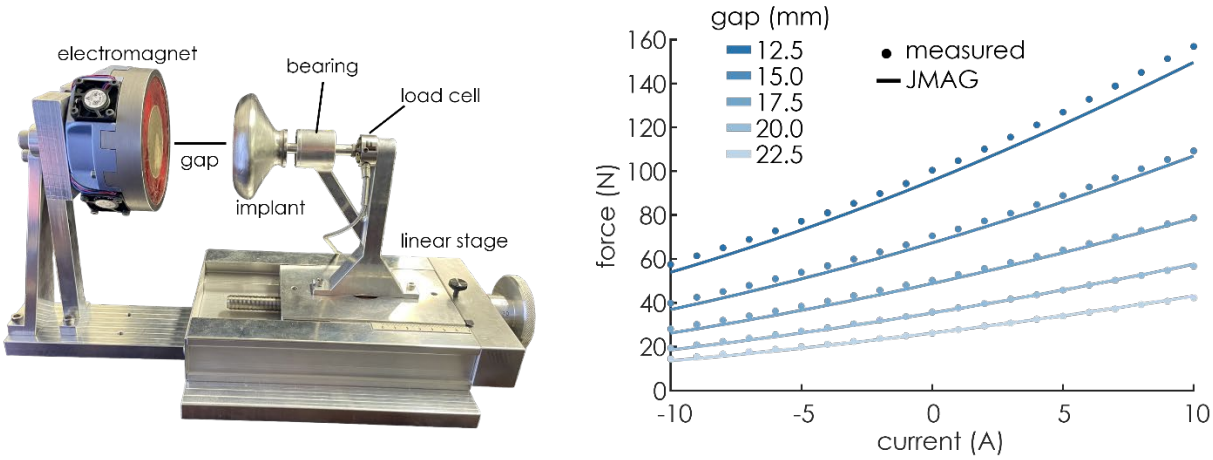


Figure 8. Optimization cost (warmer is better) as a function of coil radius (R) and shell thickness (T).

The electromagnet design was manufactured and validated on the static testbench. As a function of electromagnet current and gap distance, the measured forces on the implant closely agreed with JMAG simulations (**Fig. 9**), with a 4.2% root-mean-square percentage error.



(a) (b)

Figure 9. Electromagnet validation. (a) The manufactured electromagnet was validated using a static testbench where the current and gap distance could be controlled. (b) The measured force on the implant closely agreed with the expected forces from JMAG simulations as a function of both gap distance and current, with a root-mean-square percentage error of 4.2%.

Major Task 2.3, subtask 1: A motor (Maxon 664195 combination) and ballscrew (Misumi BSX1205-300) have been chosen for the design of the dynamic testbench. These parts will allow the testbench to simulate the dynamic loading profile expected during gait.

The dynamic testbench was designed and manufactured as seen in **Fig. 10**. The implant is fixed to the carrier of a ball screw such that it can be moved axially relative to the electromagnet by a brushless DC motor.

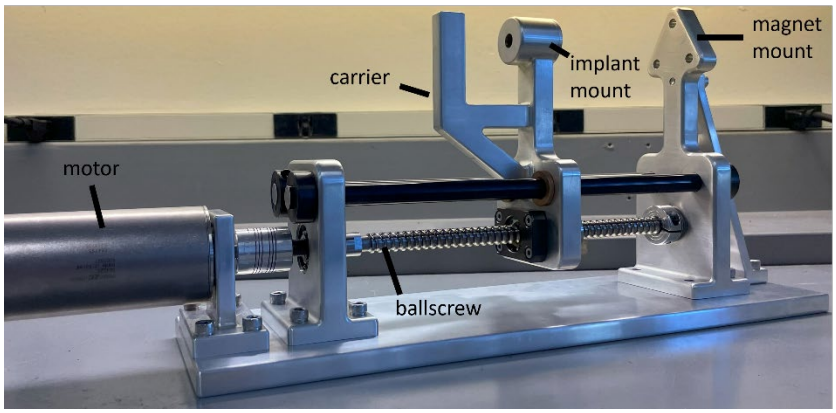


Figure 10. Dynamic testbench design. The implant is mounted on the carrier of a ballscrew that is driven by a brushless DC motor. This moves the implant axially relative to the electromagnet mounted at a fixed end.

Major Task 2.3, subtask 2: The electronics and control for the dynamic testbench were created, and the testbench was characterized. The testbench itself must be able to recreate the dynamics of walking to accurately test our system. Frequency analysis of the system (**Fig. 11**) performed using sinusoidal test signals found the bandwidth of the testbench to be 40Hz, well above the ~1Hz characteristic frequency of walking. The maximum acceleration of the system was found to be 15m/s^2, which is also well above the acceleration due to gravity that would act on the prosthesis. The potential limiting factor for the testbench is the maximum speed of the carrier, which was found to be 0.25m/s. This should be acceptable for our testing because the objective of our system to ensure proper attachment is a velocity of 0m/s.

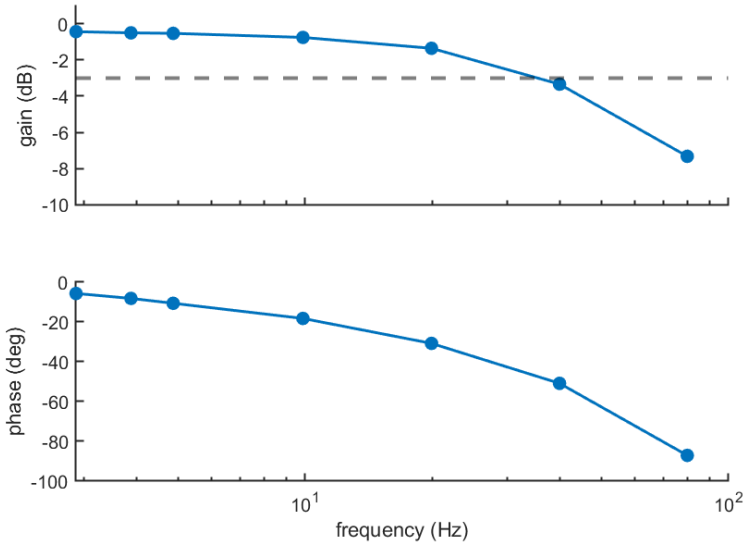


Figure 11. Bode plot of the dynamic testbench characterization in the frequency domain. The testbench has a bandwidth of 40Hz based on a -3dB gain cutoff.

Major Task 3.1, subtask 1: The revised research plan to reclassify this experiment as non-human subject research was approved. This reclassification was due to this experiment using only de-identified plaster molds of residual limbs along with previously published x-rays (publicly available). Because the investigators will have no access to subject identifiers, this would not qualify as human subjects research:

> "Certain categories of research do not meet the regulatory definition of human subjects research, such as research with coded or de-identified data or specimens for which the investigator has no access to subject identifiers"
>
> *HUMAN SUBJECT RESEARCH DEFINITIONS, CATEGORIES, AND RESOURCE INFORMATION*
> https://cdmrp.health.mil/pubs/pdf/humanresource.pdf

Major Task 3.1, subtask 2: A mock residual limb design has been created in CAD software (**Fig. 12**). The limb shape was based on a de-identified scan of a residual limb provided by the collaborating prosthetists at the West Los Angeles VA, and the skeleton was based on publicly available bone models and aligned to published x-ray imaging of residual limbs. A mold will be created such that silicone can be poured into the residual limb shape to simulate the soft tissue.

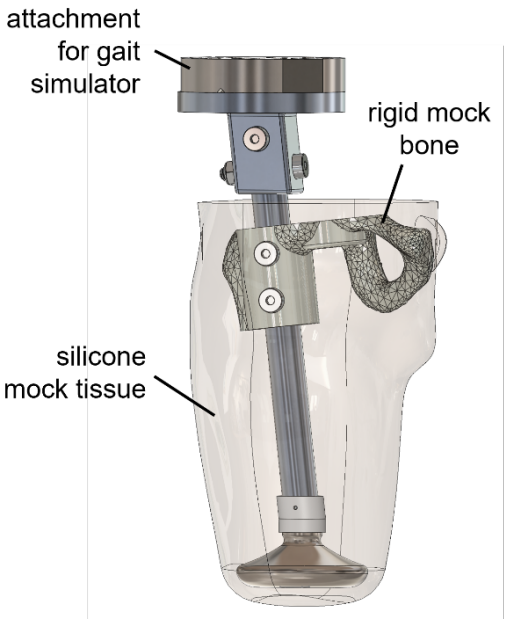


Figure 12. Mock residual limb design. The limb shape was based on a de-identified scan of a residual limb and the skeleton was based on publicly available x-ray imaging.

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

This project has provided research opportunities for the lead graduate student, in addition to multiple undergraduate students and master's students. These students have gained experience and training with various equipment, such as:

- motion capture
- instrumented split-belt treadmills
- industrial robotic arms
- C-arm x-ray machine
- electromyography
- sonomicrometry
- surgical methods and cadaveric dissections

Professional development activities have included multiple conferences:

- Southern California Robotics Symposium (2022, 2023)
- NSF Disability and Rehabilitation Engineering (DARE) conference (2023)
- American Academy of Orthopaedic Surgeons (AAOS) annual meeting (2023)
- MHSRS 2023

How were the results disseminated to communities of interest?

Outreach activities have included volunteering at sports clinics for persons with movement challenges through the Challenged Athletes Foundation (CAF) Community Weekend (Oct. 2022) along with attending multiple amputation clinics at the West Los Angeles Veterans Affairs Medical Center. PI Clites also shared results from this research at the Society for Women Engineers, Los Angeles annual meeting, as well as at an UPLIFT seminar at Aerospace Corp, focused on the diversity, equity, and inclusion implications of our research.

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

In the upcoming quarter, we will focus our efforts on the following tasks.:

Major Task 1.1, subtask 4: A dissection will be performed to simulate the final operative procedure with the optimized implant design.

Major Task 1.2, subtask 3: The optimized implant will be manufactured and validated.

Major Task 2.2, subtask 1: A Simulink model of the attachment system will be created.

Major Task 3.1, subtask 2: One physical residual limb model will be molded.

4. IMPACT:

What was the impact on the development of the principal discipline(s) of the project?
The current state of this work (through the journal publication currently under review) provides a general design framework for creating magnetic limb attachment systems that could be used for other amputation levels (e.g. upper extremity or below knee).

What was the impact on other disciplines?
The general design framework mentioned above could also provide a design roadmap for creating magnetic suspension systems not related to prosthetic limb attachment, such as in material handling processes.

What was the impact on technology transfer?
Nothing to Report

What was the impact on society beyond science and technology?
Nothing to Report

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
Nothing to Report

Changes that had a significant impact on expenditures
We were delayed in bringing in paid staff to begin work on this project. In the meantime, a fellowship student was working on the project. We have since been able to hire postdoctoral fellows to work as planned, and expect to be back on track with the approved budget by the time of our next annual report.

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

Significant changes in use or care of human subjects
This project was reclassified such that it does not qualify as human subjects research. This reclassification was due to this experiment using only de-identified plaster molds of residual limbs along with previously published x-rays (publicly available). Because the investigators will have no access to subject identifiers, this would not qualify as human subjects research:

"Certain categories of research do not meet the regulatory definition of human subjects research, such as research with coded or de-identified data or specimens for which the investigator has no access to subject identifiers"

HUMAN SUBJECT RESEARCH DEFINITIONS, CATEGORIES, AND RESOURCE INFORMATION
https://cdmrp.health.mil/pubs/pdf/humanresource.pdf

This change was approved by the USAMRDC OHRO and the UCLA IRB Office on 3/23/2023.

Significant changes in use or care of vertebrate animals
N/A

Significant changes in use of biohazards and/or select agents
N/A

6. PRODUCTS:

- **Publications, conference papers, and presentations**

Journal publications.

1. Will Flanagan, Kai Becraft, Haley Warren, Alexandra I. Stavrakis, Nicholas M. Bernthal, Thomas J. Hardin, and Tyler R. Clites. "Prosthetic Limb Attachment via Electromagnetic Attraction through a Closed Skin Envelope". IEEE Transactions on Biomedical Engineering. (UNDER REVIEW)
   acknowledgment of federal support: yes

Books or other non-periodical, one-time publications.
Nothing to Report

Other publications, conference papers and presentations.

1. Will Flanagan, Gabriel Olin, Alexandra Stavrakis, Nicholas Bernthal, Tyler R. Clites. "Computational modeling of electromagnetic prosthetic suspension". NSF DARE conference. March 2023, Los Angeles, CA. Poster presentation.

2. Will Flanagan, Kai Becraft, Alex Stavrakis, Nicholas Bernthal, Tyler R. Clites. "An electromagnetic attachment paradigm for lower extremity prosthetic limb devices". AAOS annual meeting. March 2023, Las Vegas, NV. Oral and paper presentation

3. Will Flanagan, Alexandra Stavrakis, Nicholas Bernthal, Tyler R. Clites. "Prosthetic Attachment via Electromagnetic Attraction Across the Tissue Gap". MHSRS. August 2023, Kissimmee FL. Poster presentation

- **Website(s) or other Internet site(s)**
  Nothing to Report

- **Technologies or techniques**
  Nothing to Report

- **Inventions, patent applications, and/or licenses**
  1. U.S. Provisional Application No. 63/374,016, filed August 31, 2022 and the accompanying PCT Application No. PCT/US23/31684, filed August 31, 2023. Titled "*SYSTEM AND METHOD FOR IMPROVED ATTACHMENT OF ASSISTIVE DEVICES"*

- **Other Products**

  Nothing to Report

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Name:	*Tyler Clites, PhD*
Project Role:	*PI*
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	*2*
Contribution to Project:	*Dr. Clites has provided the initial foundation and preliminary work for the proposed system. He also advises Mr. Flanagan's work and further developments of the system.*

Name:	*Nicholas Bernthal, MD*
Project Role:	*Co-I*
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	*1*
Contribution to Project:	*Dr. Bernthal provided surgical expertise during dissections and feedback on the implant design/surgical procedure.*

Name:	*Alexandra Stavrakis, MD*
Project Role:	*Co-I*
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	*1*
Contribution to Project:	*Dr. Stavrakis provided surgical expertise during dissections and feedback on the implant design/surgical procedure.*

Name:	*Thomas Hardin, PhD*
Project Role:	*Co-I*
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	*1*
Contribution to Project:	*Dr. Hardin provided feedback on the materials and coatings to be used for the implant.*

Name:	*Rachel Gehlhar, PhD*
Project Role:	*Postdoctoral Scholar*
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	*3*
Contribution to Project:	*Advised on control strategy and human-device mechanical interactions. Modeled gait biomechanics.*

Name:	*Will Flanagan*
Project Role:	*Graduate Student*
Researcher Identifier (e.g. ORCID ID):	*0000-0001-5973-1324*
Nearest person month worked:	*9*

Contribution to Project:	*Mr. Flanagan has worked to design and optimize the electromagnetic attachment system using electromagmetic simulation software and CAD.*
Funding Support:	*National Science Foundation Graduate Research Fellowship Program*

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

For **PI Clites**, the following changes occurred.

The below award is now active:

Project Title:	**An Implanted Ankle-Foot Prosthesis: Co-engineering Body and Machine to Treat Ankle-Hindfoot Pathology**
Name of PI on Award:	Tyler Clites
Source of Support:	National Institutes of Health (NIH)
Total Award Amount:	
Total Award Period:	08/15/2022 – 06/30/2027
Location of Project:	UCLA
Funding Officer:	Michael Morse Office of the Director (OD) Email: morsem@od.nih.gov
Percent Effort:	3 months
Project Goals:	Develop compliant implanted prostheses. *There is no overlap with the proposed work.*
Specific Aims:	1. Advance a pipeline for development of novel implants. 2. Create and validate prototype implants for two pathologies.

The below award has concluded:

Project Title:	**An Implanted Ankle-Foot Prosthesis to Treat Ankle-Hindfoot Pathology**
Name of PI on Award:	Tyler Clites
Source of Support:	NIH Rehabilitation K12 Training Program
Total Award Amount:	
Total Award Period:	09/01/2021 – 08/31/2022
Location of Project:	UCLA
Funding Officer:	N/A
Effort:	9 months
Project Goals:	Perform preliminary biomechanical analyses to establish design constraints for a novel implant. *There is no overlap with the currently proposed work.*
Specific Aims:	1. Understand interplay between anatomy and surgical approach. 2. Evaluate distal foot compliance in the context of proposed surgical methodology.

For **Co-I Bernthal**, the following changes have occurred:

The below awards are now active:

Project Title:	Leveraging Platelets as First Responders Against Prosthetic Joint Infection
Name of PI on Award:	Bernthal, N.

Source of Support:	NIH/NIAMS
Award Number:	N/A
Total Award Amount:	
Total Award Period:	09/23 to 08/28
Location of Project:	University of California, Los Angeles
Funding Officer:	Not assigned
Effort:	1.8 Calendar Months
Project Goals:	The major goals of this project is to advance platelet-based approaches to reduce joint infection. *There is no overlap with the current work.*
Specific Aims:	1. Characterize the role of platelets in preventing periprosthetic joint infection 2. Optimize platelet antimicrobial activity without impacting clotting, 3. Identify novel therapeutics that usher in an era of "immunotherapy" aimed at preventing prosthetic joint infection via "super-charging" platelet antimicrobial function.
Project Title:	Oncologic, Functional, and Psychosocial Outcomes of Upper Extremity Tumor Patients
Source of Support:	American Society for Surgery of the Hand
Award Number:	3966
Total Award Amount:	
Total Award Period:	10/22 to 09/25
Location of Project:	University of California, Los Angeles
Funding Officer:	N/A
Effort:	0.6 Calendar Months
Project Goals:	Establish a prospectively collected registry that will capture and consolidate patients with tumors of the upper extremity to study their diseases and outcomes. *There is no overlap with the current work.*
Specific Aims:	1. Establish registry of patients. 2. Study diseases and outcomes.

For **Co-I Stavarakis**, the following changes have occurred:

The below awards have concluded:

Project Title:	**Evaluation of the effect of prophylactic pre-arthroplasty antibiotics on infection burden and alteration of the gut microbiome; can this effect be tempered by probiotic use?**
Name of PI on Award:	Alexandra Stavrakis
Source of Support:	UCLA Faculty Research Grant
Total Award Amount:	
Total Award Period:	07/01/2019 – 07/01/2022
Location of Project:	UCLA
Funding Officer:	N/A
Percent Effort:	N/A
Project Goals:	N/A
Specific Aims:	N/A

Project Title:	**Low-Complexity, Rugged, and Versatile Hydrogel Wound Dressings in the Era of Prolonged Field Care**
Name of PI on Award:	Nicholas Bernthal
Source of Support:	Department of Defense
Total Award Amount:	
Total Award Period:	05/01/2020 – 04/03/2023
Location of Project:	UCLA
Funding Officer:	McKean, Joshua: Joshua.d.mckean3.civ@mail.mil
Percent Effort:	N/A
Project Goals:	Develop a novel hydrogel that can be used in battlefield injuries to provide antimicrobials, analgesics, and tranexamic acid locally
Specific Aims:	3. Investigate antibiotic release profile and optimize response release of antibiotics and analgesics from PEG-diacrylate hydrogels and hydrogel composites 4. Evaluate the efficacy of the novel hydrogel using an established mouse model of open femoral shaft fracture

For **Co-I Hardin**, the following changes have occurred:

The below awards have concluded:

Project Title:	**Harry S. Truman Fellowship**
Name of PI on Award:	Thomas Hardin
Source of Support:	Sandia Laboratory Directed Research & Development
Total Award Amount:	
Total Award Period:	10/01/2019 – 09/30/2022
Location of Project:	Sandia National Laboratories
Funding Officer:	N/A
Percent Effort:	100%
Project Goals:	Machine learning of atomic structure of glassy materials. No overlap w/this proposal.
Specific Aims:	N/A

What other organizations were involved as partners?
Organization Name: Greater Los Angeles VA Orthotics and Prosthetics Clinic
Location of Organization: Los Angeles, CA
Contribution: Collaborations. Provided expert opinions on system design along with molding custom prosthetic sockets used for system testing.

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS:

QUAD CHARTS:
The associated Quad Chart has been provided in the attachments of this document.

9. APPENDICES: