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TITLE: Improved Patient Outcomes in Prostheses Fit Through Integrated 3D Digital Image Correlation and Finite Element Analysis

PRINCIPAL INVESTIGATOR: Dr. Michael Philen, PhD

CONTRACTING ORGANIZATION: Virginia Polytechnic Institute and State University
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13. SUPPLEMENTARY NOTES

14. ABSTRACT

The broad objective of this two-year research program is to advance and apply finite element analysis (FEA) based estimates of skin strain to improve our understanding of how clinical socket shaping strategy affects strain and socket fit. The two main aims of the research are (1) to improve FEA estimates of skin strain on the residual limb using direct measurements of strain from state-of-the-art digital image correlation (DIC) experiments and (2) to compare these strain measurements between contemporary clinical socket shaping strategies.

In the first reporting period, we have successfully measured the strains using DIC on a plastic plug (simulated residual limb). The strains were measured through a clear diagnostic socket while a load was applied using a uniaxial testing frame. Finite element models of the simulated residual limb and the diagnostic socket were created and analyses were performed to replicate the DIC experiments. Preliminary results demonstrate good agreement between the experiments and analysis.

In the second reporting period, we have successfully measured the strains through a diagnostic socket using DIC with a local participant. A computational model (i.e. FEM model) of the residual limb was created using scanned geometry of the participant's residual limb . The results show good agreement between the analysis and experimental results. The team is confident with modeling and DIC approach and are preparing for testing with five human subjects at Ottobock for the four clinical socket shaping strategies (e.g. total surface bearing vs. specific load bearing, volume matched vs over-sized volume vs under-sized volume).

15. SUBJECT TERMS

Prosthesis fit, socket comfort, strain, stress, digital image correlation, finite element analysis

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W81XWH2110220/Improved Patient Outcomes in Prostheses Fit Through Integrated 3D Digital Image Correlation and Finite Element Analysis

Contents

Introduction:

Prosthesis fit is a critical concern for individuals with an amputation as a poor fit can lead to discomfort, soft tissue injuries, debilitating pain, and mobility limitations. Related to fit, the load bearing skin and muscles of the residual limb are subjected to large shear and transverse strains, which can result in discomfort, irritation, and the cascade of adverse outcomes listed above. The ability to measure these strains would greatly benefit socket design and clinical evaluation and improvement of prosthesis fit. The broad objective of this two-year research program is to advance and apply finite element analysis (FEA) based estimates of skin strain to improve our understanding of how clinical socket shaping strategy affects strain and socket fit. The two main aims of the research are (1) to improve FEA estimates of skin strain on the residual limb using direct measurements of strain from state-of-the-art digital image correlation (DIC) experiments and (2) to compare these strain measurements between contemporary clinical socket shaping strategies (e.g. total surface bearing vs. specific load bearing, volume matched vs over-sized volume vs under-sized volume) to better understand the relationship between the socket shape, strain, and fit. Five civilian adults with a unilateral below knee amputation will be recruited through Ottobock (originally Ability Prosthetics and Orthotics) and the testing with human subjects will be performed at one of their clinics.

Keywords:

Prosthesis fit, socket comfort, strain, stress, digital image correlation, finite element analysis

Accomplishments:

What were the major goals of the project?

NOTE: APO represents Ability Prosthetics and Orthotics. APO is now Ottobock. To be consistent with proposal, APO will be used throughout annual report.

1. **Specific Aim 1: Improve FEA estimates of skin strain on the residual limb using direct measurements of strain from state-of-the-art digital image correlation experiments**

Major Task 1: Human Subject Research Approval	Months	Progress (% completed)
Subtask 1 – Prepare human subject research protocol		
Coordinate with APO	1-3	100
Prepare IRB submission	1-3	100
Coordinate with VT IRB	1-3	100
Coordinate with HRPO	1-6	100
Submit amendments, adverse events and protocol deviations as needed	As Needed	100
Submit continuing review	Annually	100
Milestone Achieved: VT IRB Approval	3	100
Milestone Achieved: HRPO Approval	6	100
Major Task 2: Prepare Study Staff and Equipment		
Subtask 1 – Prepare DIC Equipment		
Prepare DIC Equipment	1-6	100
Test equipment at APO	1-6	0
Subtask 2 – Human subject and protocol specific training		
Provide human subject research training	1-6	100

Provide study protocol specific training	1-6	0
Milestone Achieved: DIC Equipment prepared	6	50
Milestone Achieved: Training complete	6	50
Major Task 3: Develop FEA model of residual limb		
Obtain representative geometry of soft tissue and bone structure	1-2	75
Create and mesh the model using 3D solid elements	2-3	75
Determine material properties through experiments and/or literature	3-5	75
Assign material properties to elements	4-5	75
Perform analysis for standing and walking activities	5-9	50
Major Task 4: N=1 Clinical Study		
Subtask 1 – Recruit and enroll subject at VT	7-12	100
Subtask 2 – Administer protocol		75
Liner fitting and limb shape capture visit #1		100
Socket fitting visit #2	7-12	50
Socket fitting visit #3 (if necessary)	7-12	0
DIC measurement with replica socket	7-12	75
Milestone Achieved: First subject enrolled	9	75

2. **Specific Aim 2: Compare strain measurements between contemporary clinical socket shaping strategies (e.g. total surface bearing vs. specific load bearing, volume matched vs over-sized volume vs under-sized volume) to better understand the relationship between the socket shape, strain, and fit**

Major Task 1: N=4 Clinical Study	Months	Progress (% completed)
Subtask 1 – Recruit and enroll subjects	12-18	25
Subtask 2 – Administer protocol		0
Liner fitting and limb shape capture visit #1		0

Socket fitting visit #2	12-18	0
Socket fitting visit #3 (if necessary)	12-18	0
DIC measurement with replica socket, TSB, and PTB sockets visit #4	12-18	0
DIC measurement under and over-sized sockets visit #5	12-18	0
Milestone Achieved: Last subject enrolled	18	0
Major Task 2: Data Analysis		
Process strain measurement data from DIC experiments	12-20	15
FEA predicted strains and stresses compared to DIC	12-22	15
Milestone Achieved: Data analysis complete and reported	23	0

What was accomplished under these goals?

1. **Specific Aim 1: Improve FEA estimates of skin strain on the residual limb using direct measurements of strain from state-of-the-art digital image correlation experiments**
   a. ***Major activities since last Annual Report:***

In preparation for our future human subject testing at Ottobock (previously Ability Prosthetics & Orthotics) with five participants for the four different clinical socket shaping strategies (e.g. total surface bearing vs. specific load bearing, volume matched vs over-sized volume vs under-sized volume), we recruited a local participant to help with improving the testing protocol and to identify any unforeseen issues before travelling to Ottobock (Figure 1).

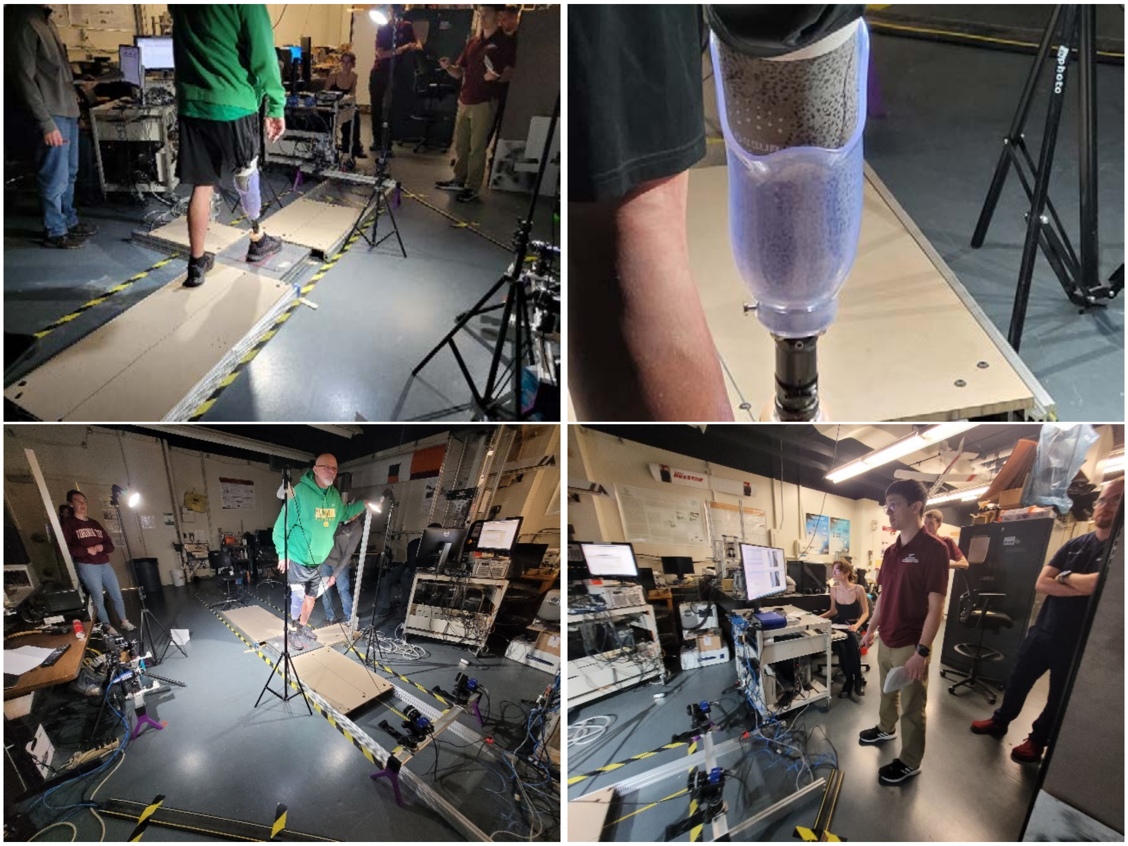


Figure 1 Human subject testing at Virginia Tech

Finite Element Analysis

Geometry:

Before donning the socket, the geometry of the participant's residual limb was scanned using a custom-designed laser scanning system we developed for measuring shape and volume change in the residual limb (Figure 2).

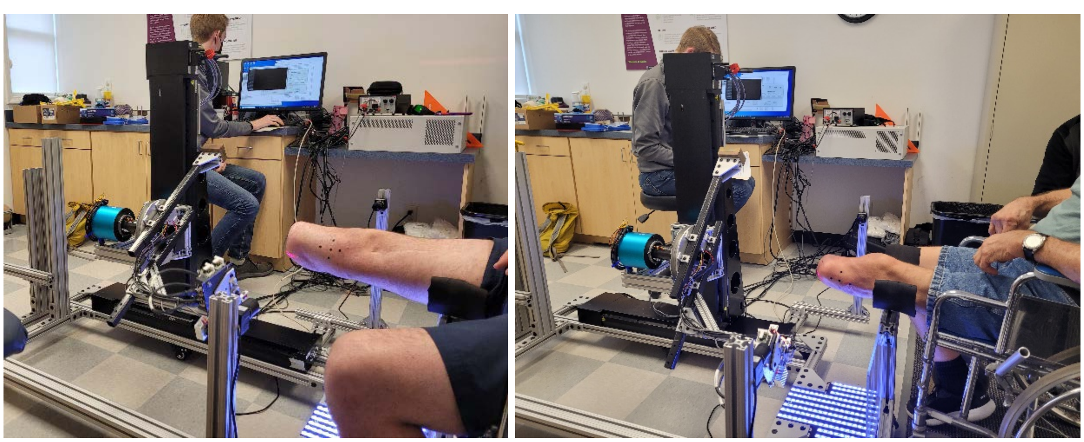


Figure 2 Custom laser scanning system for measuring shape and volume change

The scanned geometry was used for developing the FE model of the residual limb. The laser scanning system was also used to obtain the geometry of the socket. The final 3D models were imported to Abaqus (Dassault Systèmes, Vélizy-Villacoublay, France) as our finite element (FE) software.

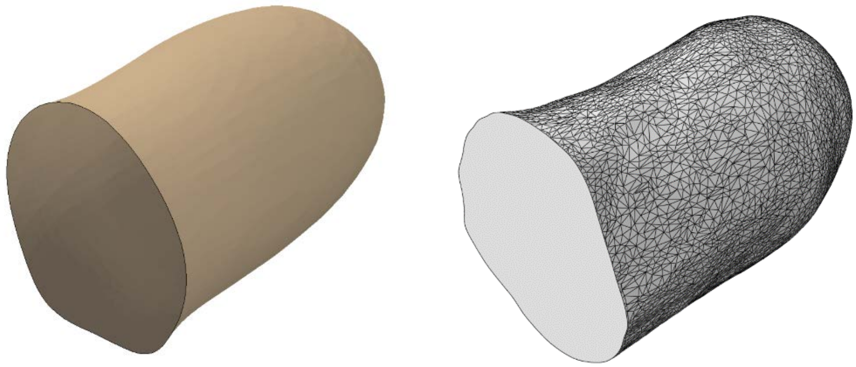


Figure 3. Scanned geometries of the prosthetic socket (left) and residual limb (right)

Since the laser scanner can only scan the outer surface of the limb and magnetic resonance imaging (MRI) is required for obtaining bone geometries, a free-access tibia model was implemented. The liner was assumed to have the same outer surface as the residual limb. Figure 4 depicts the final assembly of our FE model:

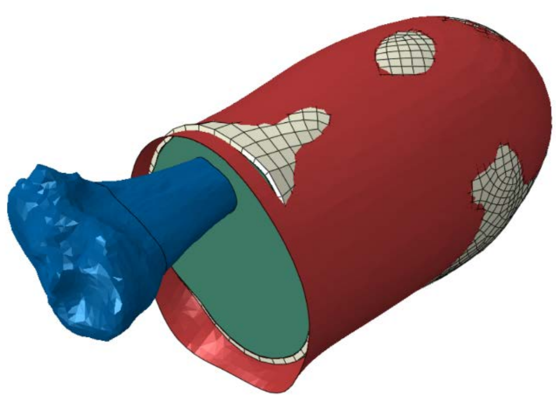


Figure 4. Final assembly of the FE model in Abaqus

Material Properties:

Skin, muscles, ligaments, fat, and tendons were all integrated into homogeneous soft tissue for a simpler simulation. Earlier FE models used linear material properties for soft tissues due to the lack of experimental data. However, with more advancements in FE models of residual limbs, hyperplastic material properties were proposed for soft tissues. Similarly, the soft tissue of the residual limb was modeled using the Mooney-Rivlin strain energy function. Table 1 demonstrates the constitutive parameters for the Mooney-Rivlin model of soft tissue:

Table 1. Mooney-Rivlin constitutive parameters of average flaccid muscle

			Constitutive Parameters		
Section	**Section Type**	**Strain Energy Function**	**C_{10} (KPa)**	**C_{11} (KPa)**	**D1 (MPa^{-1})**
Soft Tissue	Uniform, Homogeneous	Mooney-Rivlin	4.25	0	2.36

Linear elastic, homogeneous, and isotropic material properties were selected for the liner, tibia, and prosthetic socket (Table 2).

Table 2. Material properties of FE model sections

Section	Section Type	Material	Young's Modulus (MPa)	Poisson's ration
Tibia	Uniform, Homogeneous	Human bone	9000	0.3
Liner	Uniform, Homogeneous	Silicone gel	0.38	0.39
Socket	Uniform, Homogeneous	PETG	2100	0.33

Interaction and contact:

The final FE model consists of two prominent interactions: liner-skin and liner-socket. An automatic surface-to-surface contact was applied for contact analysis. Skin and socket were chosen as master surfaces for the liner-skin and liner-socket contact, respectively. Tangential and normal behaviors of the contacts were also defined. As for the tangential behavior, the friction coefficient at the liner-socket interface was set to 0.5, which was commonly used in the literature. Skin and liner were assumed to be tied and no relative displacement occurred between them. A penalty hard contact normal behavior was also specified so that the nodes of the slave surface would not penetrate the master surface.

Meshing:

Due to the complex geometries involved in the models, structured meshing techniques using brick elements could not be performed. Hence, a free meshing technique using linear four-node hybrid tetrahedral elements (C3D4HS) was implemented for the soft tissue. The liner was meshed with 8-node linear brick, hybrid, and constant pressure elements (C3D8H). Details for the number of elements and their type are provided in Table 3:

Table 3. Meshing elements of different model sections

Section	Element Type	Number of elements
Tibia	C3D4	1155
Liner	C3D8HS	2504
Socket	S4	820
Soft Tissue	C3D4H	83015

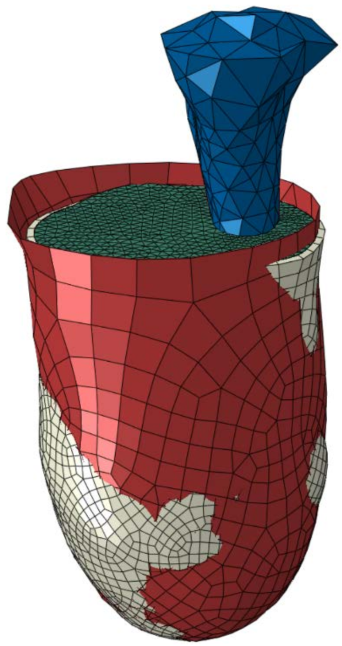


Figure 5. Overall view of the assembly after meshing parts

Overclosure:

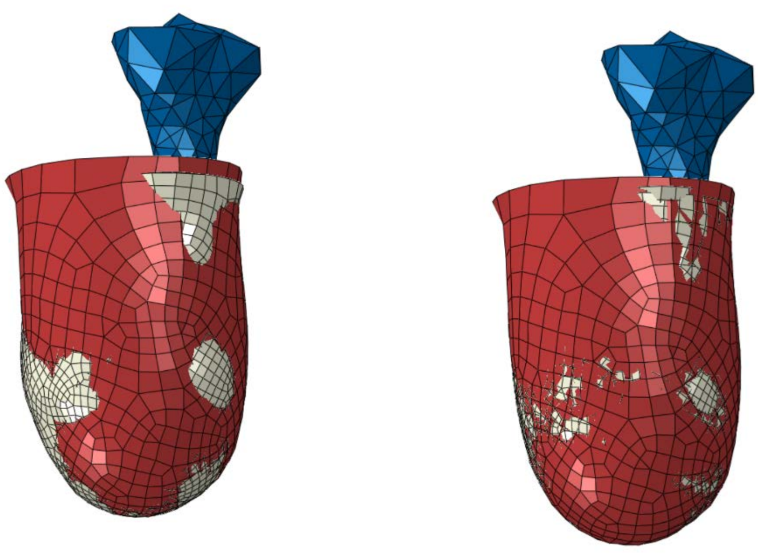


Figure 6. Overall assembly before (left) and after (right) removing the overclosure

A donning procedure was simulated prior to applying loads. To be more specific, since the socket and stump do not have similar shapes, pre-stresses can be generated when patients wear the prosthetic socket. No loads are applied in this step, and the FE solver tries to remove the initial overclosure caused by shape difference by deforming the stump so that its nodes are not penetrating the socket surface. As a result, pre-stresses on the residual limb would occur, and this step simulates the donning process. Figure 6 illustrates this process in which the residual limb deforms so that the initial overclosure is removed:

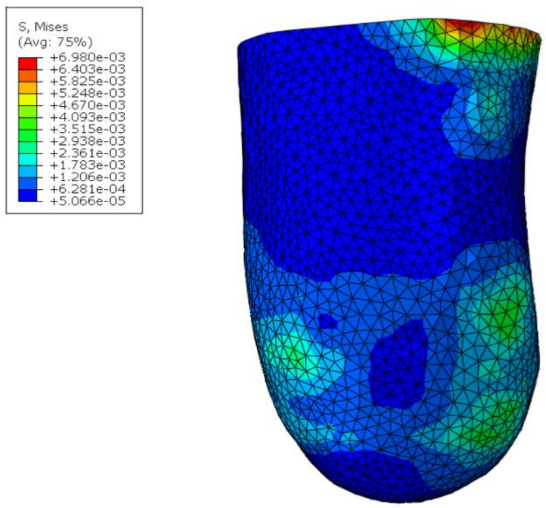


Figure 7. Von-Mises stress distribution on the residual limb surface after removing the overclosure

Loading and Job analysis:

In order to better simulate the gait cycle of an amputee, loading conditions in the FE model should be similar to the real world. Therefore, ground reaction forces during the gait cycle of our subject were collected and imported into our FE software.

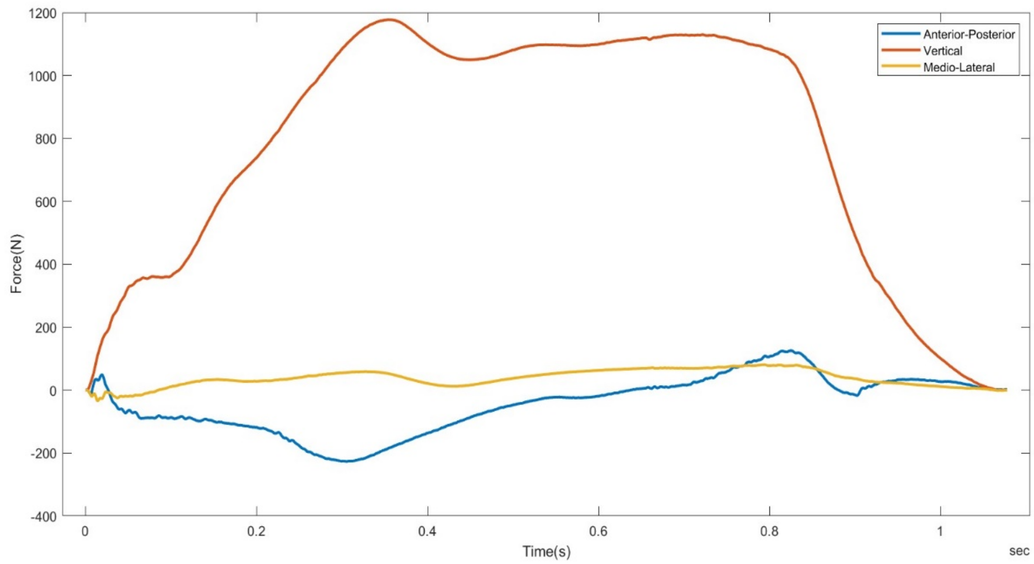


Figure 8. Measured ground reaction forces during a gait cycle

Once every aspect of the FE model was determined, job simulations was performed. The simulation consisted of two steps: overclosure and loading. The first step was to remove the overclosure caused by the shape difference between the residual limb and the prosthetic socket, and the second step was to apply loads and boundary conditions and calculate deformations and stresses.

Digital Image Correlation:

This phase of the project placed major importance on performing DIC analysis on a residual limb during a normal gait cycle. A testing procedure was developed to isolate important points within a step cycle that should be further investigated by DIC. This included positioning the DIC cameras on the anterior and lateral faces of the residual limb and socket. A second, 5-megapixel camera was added to capture the anterior face in a higher resolution than previously available.

Figure 9. LaVision 5MP Camera

Additionally, new wide-angle lenses were acquired which provided the necessary depth-of-field and picture area to capture the entire motion of the socket from just before heel strike to just after toe lift.

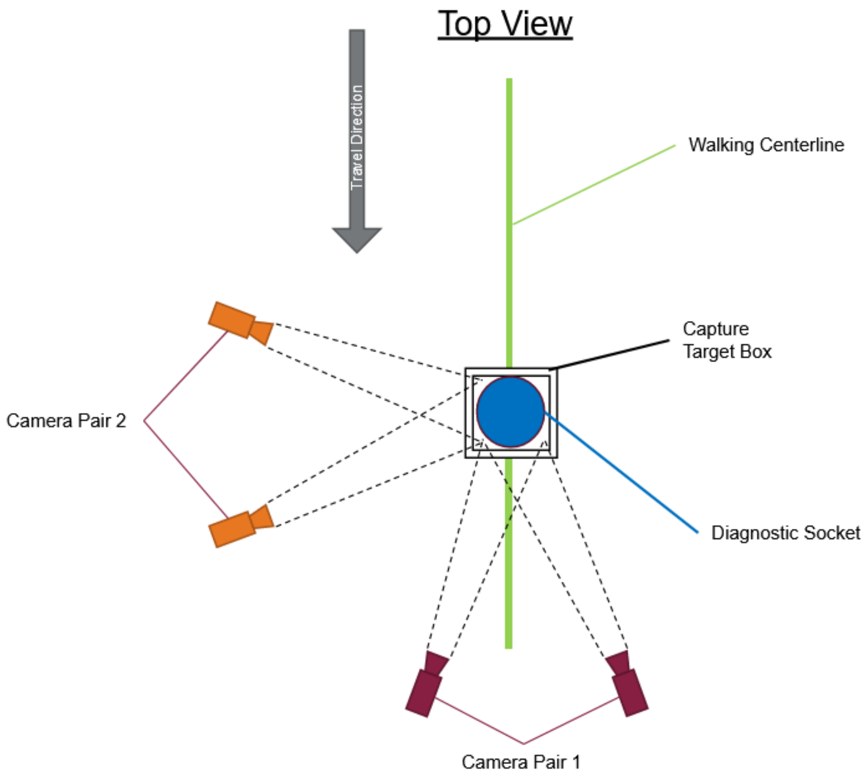


Figure 10. Diagram of the new camera setup to perform DIC while the subject is walking.

a. Specific objectives:

i. *To improve FEA estimates of skin strain on the residual limb using direct measurements of strain from state-of-the-art digital image correlation (DIC) experiments.* In a manner consistent with the Major Activities, a clear diagnostic socket was used on an initial human test subject, where DIC analysis was performed to capture the surface strain of many portions of the gait cycle. This provided a preliminary dataset used to link DIC and FEA strain values, and gain insight on necessary improvements of the DIC technique.

ii. *To compare these strain measurements between contemporary clinical socket shaping strategies (e.g. total surface bearing vs. specific load bearing, volume matched vs over-sized volume vs under-sized volume) to better understand the relationship between the socket shape, strain, and fit.*

b. Significant results:

i. DIC testing on an initial human subject demonstrated the feasibility of measuring surface strain during a gait cycle. With the new positioning of DIC cameras directed at the anterior and lateral sides of the subject's residual limb, further insight was gained on the strain behavior under a dynamic load case. Combining these surface strain data with measurements from a floor-mounted three-axis force plate provides additional tools used to correlate FEA simulations.

ii. Figure 11 depicts Von-Mises strain estimation of FE model. When compared with DIC results, the FE model is well capable of estimating strains on the liner surface.

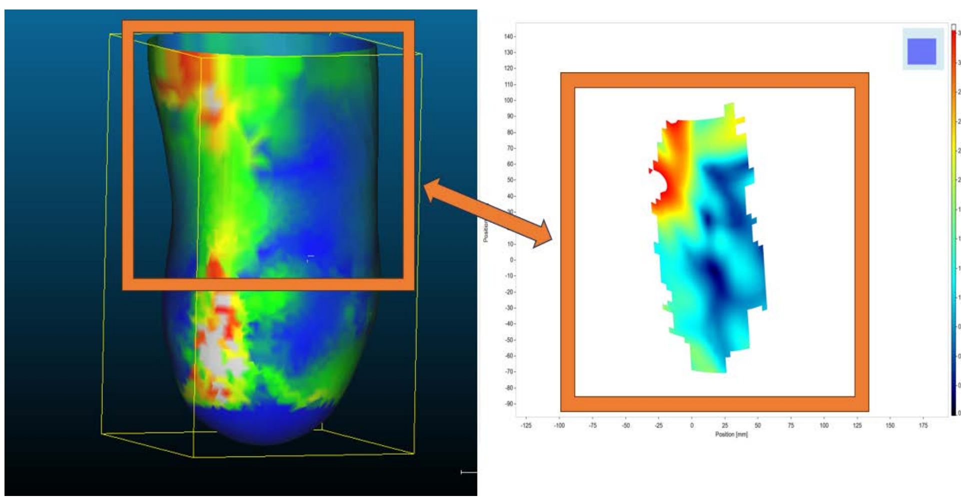


Figure 11. Estimated von mises strain on the liner outer surface by FEA (Left) vs measured liner outer surface by DIC (right) (The orange boxes demonstrate the areas that correspond to each other in FEA and DIC)

c. Other Achievements:

i. A testing procedure for eliminating previous shortcomings discovered in the initial human subject DIC testing. As a method to increase the probability of viable DIC datasets, it was found helpful to dissect and individually scrutinize different phases of the gait to isolate two distinct variables: angle of socket and residual limb (glare reduction), and amount of body weight applied to the ground (socket loading). These smaller DIC trials within the larger test proved to be helpful in creating rudimentary FEA simulations of simplified load cases, and provide quantitative values used in these simulations.

ii. Additional progress was made in determining a speckling method of the liner used by the patient during the DIC trials. Due to the large camera capture area required, traditional speckling methods proved inconsistent and yielded undersized speckles. Thus, a new method was developed using 3D printed ‘stamps’ with speckle diameter and density controlled by the designer to suit the needs of each camera pair and focal length. Various inks were also tested, attempting to create the highest contrast between the liner and speckle. It was determined that a black fabric dye was the most effective in permeating the fabric material, increasing contrast, and robust against interactions with other surfaces.

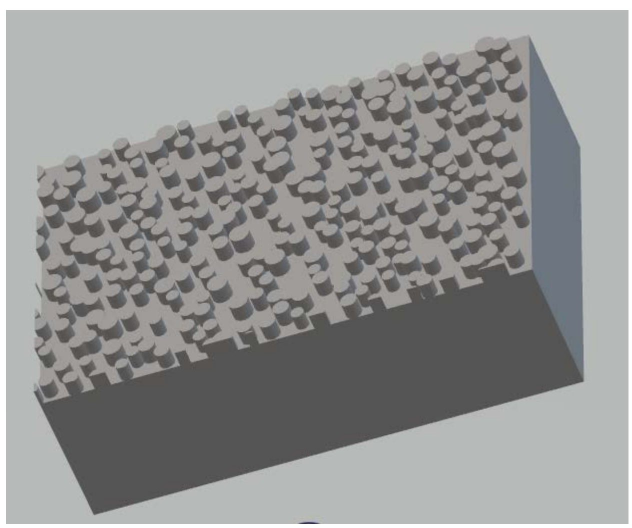


Figure 12. A 3D computer model of a stamp used to speckle the liner for DIC testing.

iii. Bone geometry has been one major limitation of our FE modeling. Since the laser scanner can only scan skin surface, bone shapes of the residual limb cannot be obtained. One solution can be using bone geometries from other works that have used magnetic resonance imaging for obtaining tibia and fibula 3D models. In this regard, an open-source code has been implemented to generate bone models. Different bone sizes and shapes have been tested (Figure 13) in the FE model to see if there is a significant difference in results and how FE estimations are sensitive to changes in bone geometry. By taking a look at the results (Figure 14), there is not much differences between strain fields on the liner outer surface when the bone geometry changes; however, the distribution of shear stresses and contact pressures has yet to be investigated.

Figure 13. Assembly of short (left), medium (middle), and long (right) bones in the residual limb

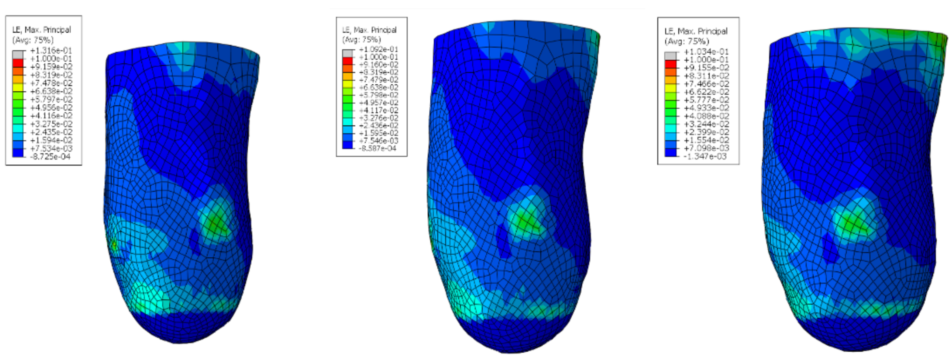


Figure 14. Maximum principal strains on the liner surface in different bone geometries

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

The GRA Mohammadreza Freidouny presented at the 46th Annual Meeting of the American Society of Biomechanics at Knoxville Tennessee

How were the results disseminated to communities of interest?

A short video covering the research project was created and sent out to all Virginia Tech employees and students in the VT daily news email.
https://news.vt.edu/videos/k/2023/04/1_i2xs13mp.html

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

1. ***Conduct DIC experiments with human subjects at Ottobock.*** As discussed in accomplishments, we have conducted DIC experiments with a human subject at Virginia Tech to prepare and optimize the testing protocol for the human subject testing at Ottobock. We have started recruiting five human subjects at Ottobock. The four diagnostic sockets will be fabricated in the near future for each participant. The visit to Ottobock is currently being planned for October for the experiments. The participants will be asked to perform standing and walking activities while measuring the strains on the liner through the four different diagnostic sockets using the DIC. We will measure strains on the liner using a 4-camera system for the different clinical socket shaping. strategies (e.g. total surface bearing vs. specific load bearing, volume matched vs over-sized volume vs under-sized volume).
2. ***Compare strain and socket fit measurements between contemporary clinical socket shaping strategies.*** As discussed in accomplishments, we have shown good agreement between the experimental results and the computational results for the one human subject recruited at Virginia Tech. This preliminary work resulted in the improvement of the computational model and testing protocol. The participants recruited through Ottobock will complete the standing and walking procedures, strain measurements, and subjective socket performance assessments described in Aim 1 using all four sockets. The data analysis will then be performed before the end of the project.

Impact:

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

The project is providing impact in the following areas:

Engineering: The research is leading to new DIC techniques that can provide improved experimental and analysis methods for engineers.

Clinical Treatment of Amputees: The research using engineering tools such as DIC and FEA will improve our understanding of the relationship between the socket shape, strain, fit, and comfort. It will also provide quantitative results comparing socket fitting strategies commonly used among prosthetists.

What was the impact on other disciplines?

The project encompasses both the engineering/clinical treatment disciplines, both of which are described in the previous section.

What was the impact on technology transfer?

The research could lead to the adoption of new experimental methods by prosthetists and orthotists for improving the comfort and fit of sockets and orthotics.

What was the impact on society beyond science and technology?

Nothing to Report

Changes/problems:

Changes in approach and reasons for change

No changes in the approach

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

There are delays relative to the award date (04/01/2021). This date occurs in the middle of the Spring semester and as typical with all new graduate research assistants (GRAs), the GRA that we recruited would not start until August 16th. However, due to COVID, visas were delayed for many of our international students, including the GRA recruited for this project. He did not get his visa in time and did not start until January 2022. To minimize progress delays, we hired a GRA to start the project in the Fall semester. More recently, the lab where the research is being conducted was shut down for 10 weeks starting in May 2023 to relocate to a new location as the current building is planned for demolition in the near future. There was approximately a 6-month delay in getting the NCE approved from the submission date to the approval date. Our collaborator at Ottobock could not start recruiting human subjects until the NCE was approved.

However, with these delays, I am confident we can meet objectives with the NCE in place.

Changes that had a significant impact on expenditures

No changes in expenditures

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

No changes in use or care of human subjects.

Significant changes in use or care of human subjects

No changes in use or care of human subjects.

Significant changes in use or care of vertebrate animals.

Not applicable

Significant changes in use of biohazards and/or select agents

No changes in use or care of human subjects.

PRODUCTS:

Nothing to Report

Participants & other collaborating organizations

What individuals have worked on the project?

Name:	Michael Philen
Project Role:	*PI*
Researcher Identifier (e.g. ORCID ID):	*0000-0002-3526-8811*
Nearest person month worked:	1
Contribution to Project:	Dr. Philen is advising students, managing the administrative aspects of the grant, and providing engineering expertise.
Funding Support:	

Name:	Michael Madigan
Project Role:	*Co-PI*
Researcher Identifier (e.g. ORCID ID):	*0000-0002-4299-3851*
Nearest person month worked:	1
Contribution to Project:	Dr. Madigan is co-advising the students and is providing expertise related to the human subject testing.
Funding Support:	

Name:	Vachas Polepeddi
Project Role:	GRA
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	4
Contribution to Project:	Vachas is performing FEA analysis.
Funding Support:	

Name:	Mohammadreza Freidouny

Project Role:	GRA
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	4
Contribution to Project:	Reza is assisting with FEA and DIC research.
Funding Support:	

Name:	Masaki Hada
Project Role:	Graduate Student
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	1
Contribution to Project:	Masaki is assisting with the DIC research.
Funding Support:	

Name:	Abbie Bailey
Project Role:	Undergraduate Student
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	1
Contribution to Project:	Abbie is assisting with the DIC research
Funding Support:	

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

Nothing to Report

What other organizations were involved as partners?

Ability Prosthetics and Orthotics (now Ottobock) is a subcontractor on the project. Human recruitment and testing with human subject will occur at one of their clinics.

- **Organization Name:** Ability Prosthetics and Orthotics – Now Ottobock
- **Location of Organization:** Salt Lake City, *UT*
- **Partner's contribution to the project**

- **Collaboration**: We have regular online meetings with AP&O to discuss research progress.

Special reporting requirements

- **COLLABORATIVE AWARDS:**
- **QUAD CHARTS:** Included in the Appendix

Appendices:

Improved Patient Outcomes in Prostheses Fit through Integrated 3D Digital Image Correlation and Finite Element Analysis

Log Number: OP200081

PI: Philen, Michael **Org:** Virginia Tech, Ability P&O, **Award Amount:** $350K

Objective, Specific Aims, and Approach

Objective: The overall objective of this two-year research program is to increase our understanding of the relationship between prosthesis fit and strains on the residual limb.

Specific Aims:

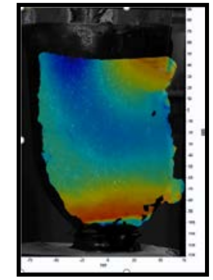
1) *Apply state-of-the-art digital image correlation (DIC) experiments along with FEA to measure skin strain in vivo during prosthesis use.*
2) *Compare strain and socket fit measurements between contemporary clinical socket shaping strategies*

Approach:

1) *Scan residual limb before and after donning socket to predict initial strains and stresses using FEA.*
2) *Apply DIC to replica diagnostic socket to obtain static strain measurements on the residual limb during standing and time-varying strains during walking.*
3) *Repeat DIC measurements with 1) total surface bearing design; 2) specific load bearing design; and 3) total surface bearing sockets with oversized and undersized by 1% of global volume.*
4) *Explore the relationships between predicted strains on the residual limb and socket fit from various socket shape techniques*

Speckled Simulated Residual Limb in Diagnostic Socket

Measured Displacements during Loading

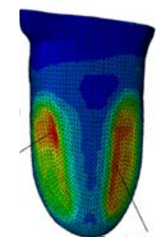


Preliminary results demonstrate the ability to measure displacements through a clear diagnostic socket.

Finite Element Model of Residual Limb

Portnoy, et al. (2009)

Predicted Strain



Meng, et al. (2020)

- **Greater understanding of the relationships between the strain and socket shape**
- **Significantly improve the validity of FEA methods**
- **Provide crucial insight into the soft tissue strain distribution on the residual limb**
- **Assist prosthetists with the socket process**

Timeline

Activities CY	21	22	23	24
Create a FEA model of 3D geometry of the residual limb and the internal bone structure of a transtibial amputee				
Conduct DIC tests with human subjects using different socket shapes				
Determine relationships between predicted strains on the residual limb and different socket shapes				

Goals and Milestones

CY21 Goal – Develop FEA model of the residual limb

CY22 Goal – Application of DIC for strain measurements on residual limb

- 1) Strain measurements on a simulated residual limb.
- 2) Measurements between DIC and FEA show good agreement

CY23 Goal –Relationships between predicted strains on the residual limb and different socket shapes achieved.

- FEA models of all participants validated and accurate prediction of strains on residual limb provide greater insight into soft tissue strain distribution
- Results confirm that DIC-FEA can assist prosthetists with the socket process