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

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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.

15. SUBJECT TERMS
Prosthesis fit, socket comfort, strain, stress, digital image correlation, finite element analysis

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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 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?

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	Annuall y	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	50
Create and mesh the model using 3D solid elements	2-3	50
Determine material properties through experiments and/or literature	3-5	0
Assign material properties to elements	4-5	0
Perform analysis for standing and walking activities	5-9	0
Major Task 4: N=1 Clinical Study		
Subtask 1 – Recruit and enroll subject	7-12	0

Subtask 2 – Administer protocol		0
Liner fitting and limb shape capture visit #1		0
Socket fitting visit #2	7-12	0
Socket fitting visit #3 (if necessary)	7-12	0
DIC measurement with replica socket	7-12	0
Milestone Achieved: First subject enrolled	9	0

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	0
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	0
FEA predicted strains and stresses compared to DIC	12-22	0
Milestone Achieved: Data analysis complete and reported	23	0

What was accomplished under these goals?

1. **Provide direct measurements of strain on the residual limb using digital image correlation (DIC).**
   a. ***Major activities:***
      i. A plastic plug that simulated a residual limb was first used to assess the accuracy of strain measurements through a clear diagnostic socket, to finalize the testing methodology before human subjects testing, and to compare with the FEA with a known shape and material properties. First, a clear PETg diagnostic socket was polished and a silicone plug was fabricated to simulate a residual limb. The plug was created with a black dye and speckled with white acrylic paint to enhance the contrast. After inserting the plug back, the speckled pattern is clearly visible.

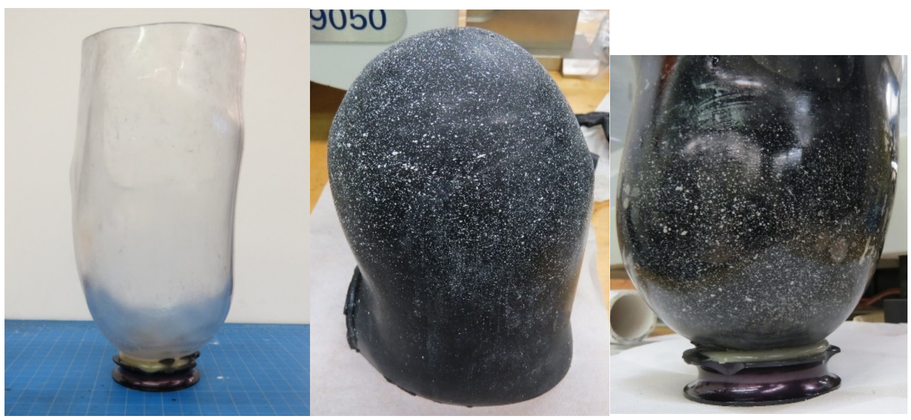


Figure 1 (Left) Diagnostic socket, (Middle) Black silicone plug with white acrylic paint speckle pattern, (Right) Plug inserted into diagnostic socket

      ii. Two 2 megapixel LaVision cameras were used in conjunction with two LED LaVision lights. The cameras were mounted on 410 Junior Geared Tripod Heads which allow for fine rotations to easily point and focus the cameras onto our point of interest. The lights were mounted on Photo Variable Friction Arms which allows for the lights to be easily moved to different positions. The cameras and the lights were connected to a LaVision computer which uses a programmable timing unit (PTU) to synchronize the capture images and activation of the lights.

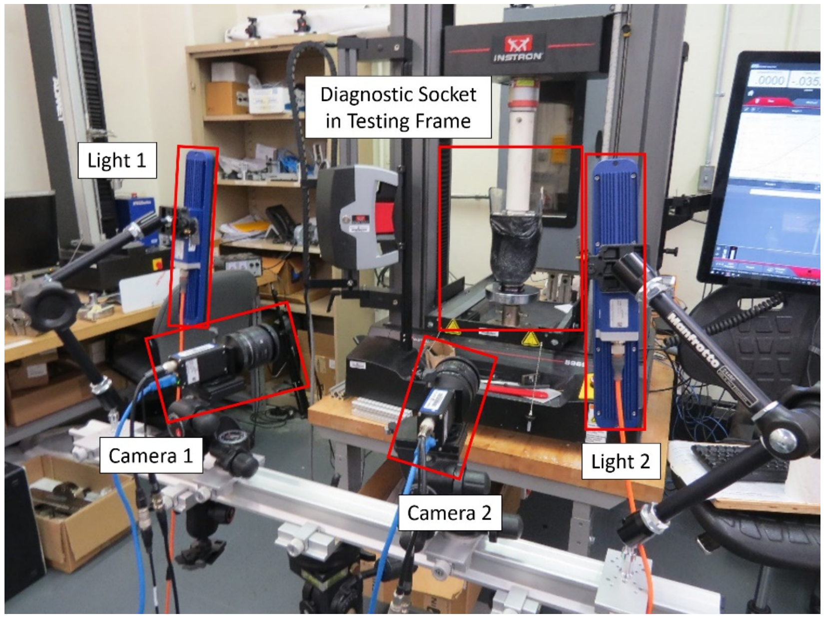


Figure 2 Testing configuration with LaVision lights and cameras focused on diagnostic socket placed in INSTRON testing frame

iii. Loads were applied to the plug using the Instron and the fixture below.

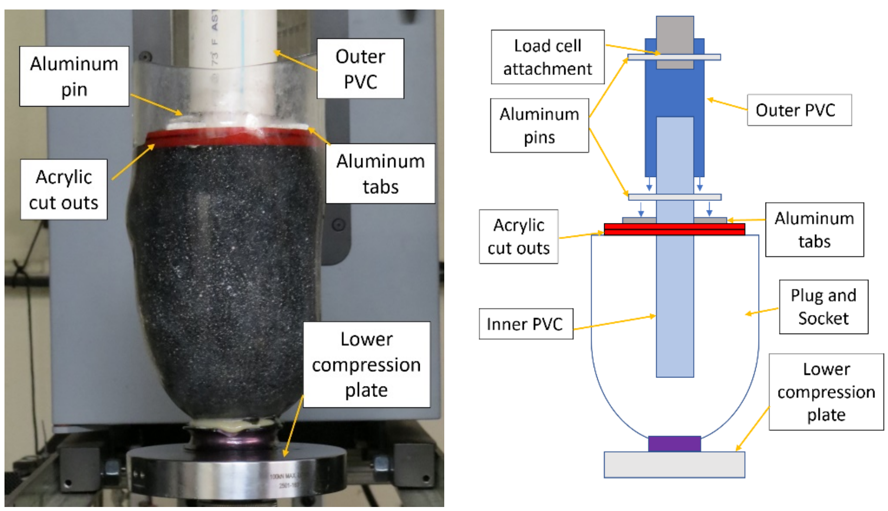


Figure 3 Setup for simulating loads using the Instron testing frame

iv. A FEA model of the rubber plug and diagnostic socket was created in Abaqus to validate the DIC results and to improve the model analysis as well as the experiments. A full nonlinear contact analysis was employed to estimate the stresses and strains on the simulated residual limb. The shape of the simulated residual limb was measured using a custom high-precision laser scanning system. A "Full-Newton" technique has been utilized for the solution and boundary conditions have been developed for the same. A "small sliding" formulation has been incorporated for the analysis with a surface-to-surface type.

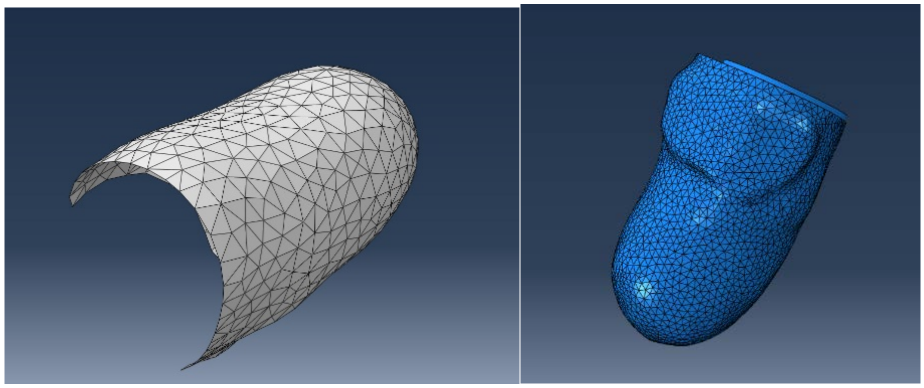


Figure 4 FEM model of socket (left) and the rubber plug (right)

v. To be consistent with the loading applied to the plug during DIC experiments, a small plate-like structure with a hole was incorporated into the model and is also in contact with the top surface of the plug. Since this plate is also in contact with a surface, contact analysis was also been defined for this plate with respect to the top surface of the plug.

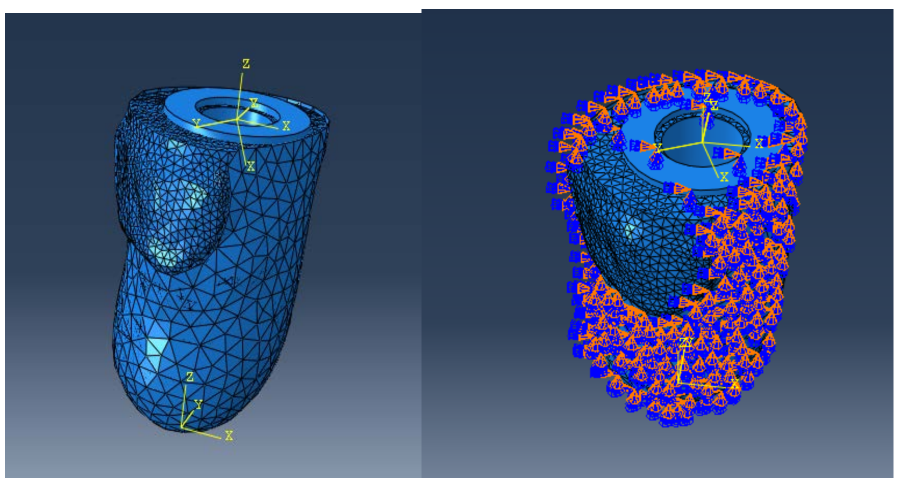


Figure 5 Assembled model of socket with simulated residual limb (left) and the model with corresponding boundary conditions. (right) The blue triangles are shell elements that make up the socket and the orange triangles are the applied boundary conditions.

b. *Specific objectives:*

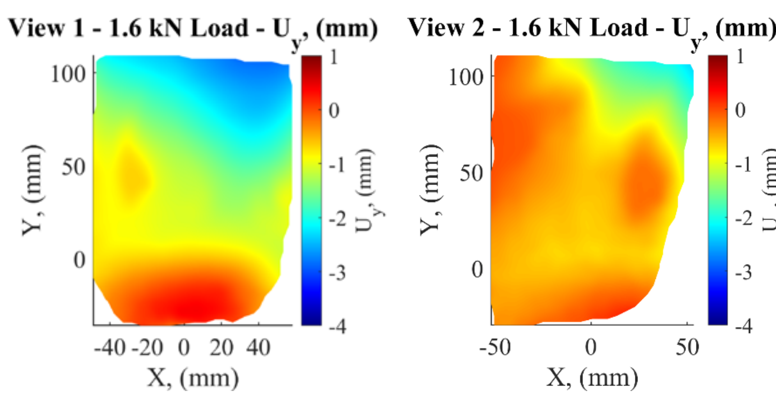
i. *To improve FEA estimates of skin strain on the residual limb using direct measurements of strain from state-of-the-art digital image correlation (DIC) experiments.* As outlined in the Major Activities, a simulated residual limb and clear diagnostic socket was first employed in both the

DIC and FEA activities to access viability of the experiments for measuring strain, to validate the FEA results for the socket and rubber plug with known properties, and to improve the DIC measurement techniques.

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*.

c. Significant results:

i. Data from the DIC experiments with the rubber plug was collected as the Instron testing frame applied a linearly increasing load with a maximum force of 1.6 kN. Six views around the bottom of the residual limb were recorded, giving a full 360-degree estimation of displacements and strains on the simulated residual limb. The displacement field in the y-direction (longitudinal axis) for each of the 6 views is shown below. Red areas indicate a positive displacement (up) and blue areas indicate negative displacement (down). These results are currently being stitched together to form a full 3D view of the simulated residual limb with displacements and strains overlayed. Developing the methodology to accurately combine the six views from the six cameras into a full 3D representation required significant time and effort.



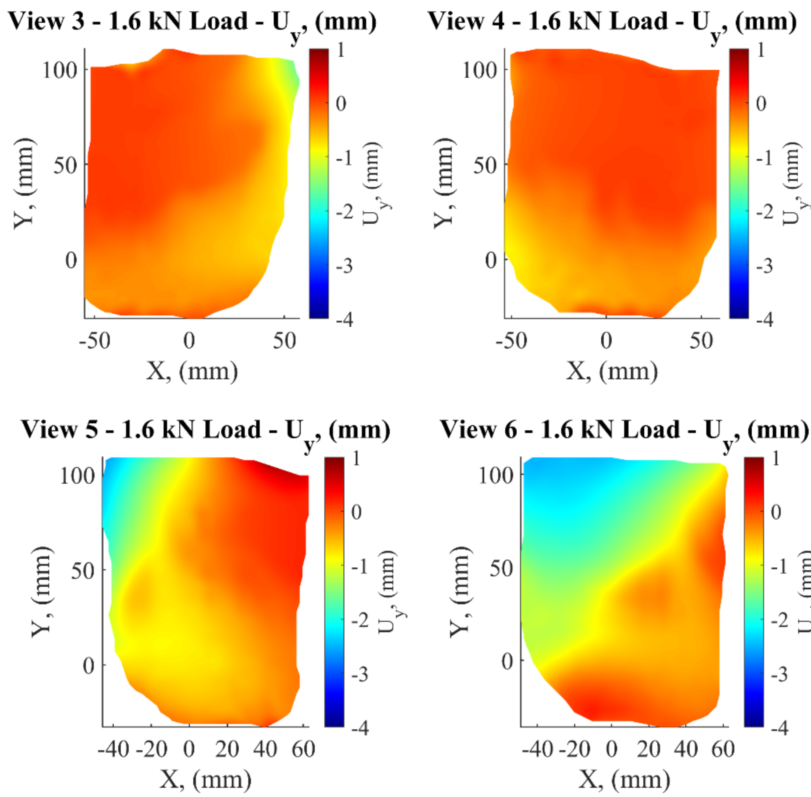
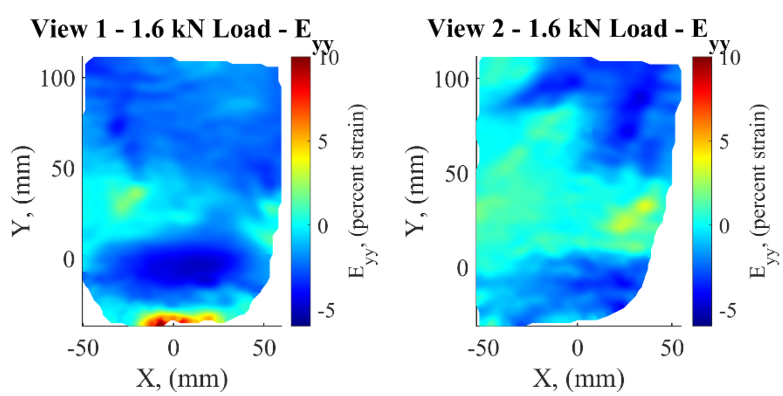


Figure 6 DIC results illustrating vertical displacements along longitudinal axis of the simulated residual limb during loading at 1.6 kN inside the diagnostic socket.

ii. Using the displacement data, the corresponding strain field ε_{yy} can be calculated as shown below for the 6 views. This is the principal strain field along the longitudinal axis on the surface of the simulated residual limb. As expected, most of the residual limb is in compression (blue areas). Similarly, the principle strain ε_{xx} as well as the shear strain ε_{xy} can be calculated, which can also contribute to discomfort.



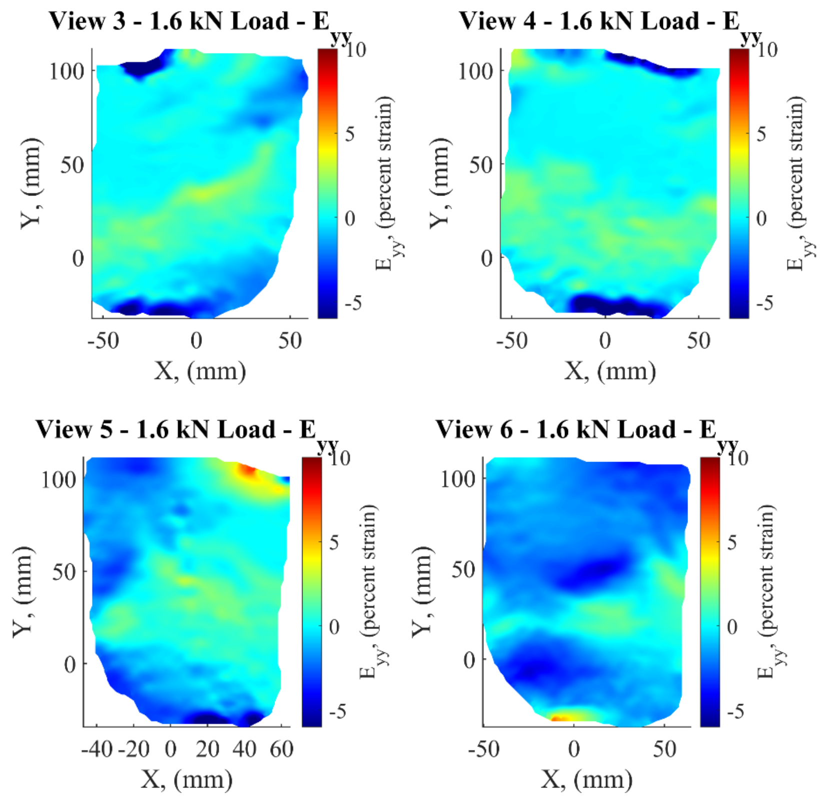


Figure 7 DIC results illustrating strains along longitudinal axis of the simulated residual limb during loading at 1.6 kN

iii. A custom algorithm that maps the 3D FEA results onto the 3D DIC results was developed. This algorithm enables comparisons between the analytical (FEA) and experimental (DIC) results, and to quantify differences in their displacement and strain values. Shown below are the displacements in the longitudinal axis for both the FEM and DIC for View 1. The preliminary results demonstrate good agreement between the experiments and FEA studies.

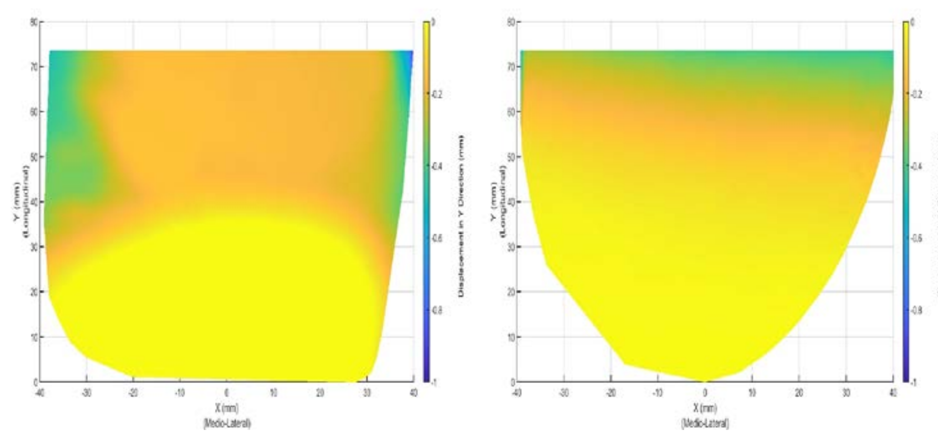


Figure 8 (Left) Displacement contour from the FEM analysis and (Right) Displacement contour from DIC analysis

d. Other Achievements:

i. One of the challenges with measuring strain on the residual limb is the presence of the liner between the socket and the limb. Our initial efforts described above were somewhat idealized by not including this liner. Since such liners are commonly use in practice by prosthesis users, a new simulated residual limb has been cast that allows space for a liner between the simulated residual limb and socket. By using the validated FEM results at the liner-socket interface, our aim is to be able to predict the stresses and strains at the liner-limb interface by knowing the material properties of the liner.

Figure 9 (Left) Pouring liquid silicone rubber into the socket to fabricate another plug for laboratory testing, and (Right) Fully cured silicone plug

ii. We are currently working on a new technique that hopefully will allow us to see through the socket and the liner at the same time. This will provide a major advance forward by allowing simultaneous experimental measurements of displacement and strain on the plug surface and liner while loading in a socket. The primary difficulty in doing so using traditional DIC methods, however, is creating two speckle patterns on each surface, the linear sock and the limb, that can be uniquely identified from one another and independently tracked. The idea for this work is to use a dual stereo-DIC setup using 4 total cameras fluorescent orange and matte black speckled patterns, as depicted below. The results of this technique would provide full field, 3D displacements and strains over the surface of both the residual limb and the liner sock, while still in the socket. This will provide direct measurement of the interaction between the socket, liner, and limb that can be readily used to inform and validate the finite element model predictions.

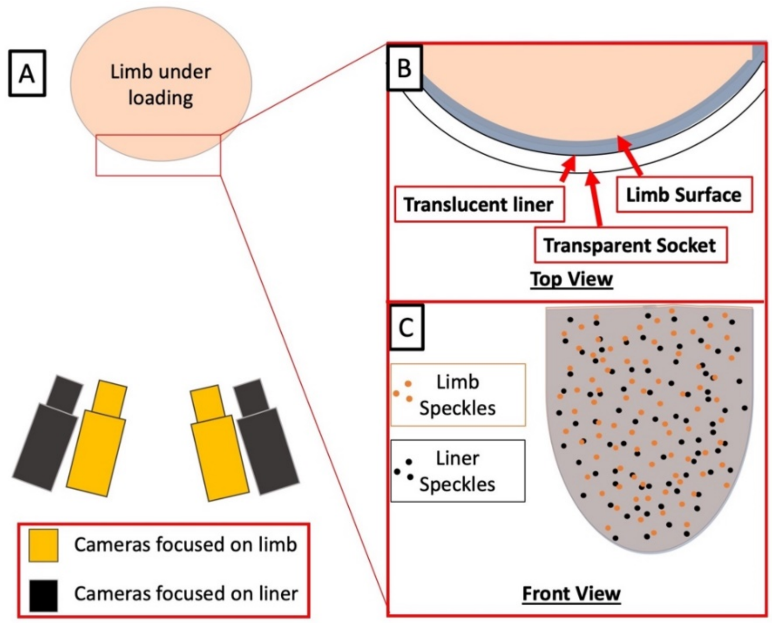


Figure 10. Setup of dual stereo-DIC system for measuring surface liner and limb strains. A) Setup of two camera pairs facing limb, with one pair focused on liner and one on the limb surface. B) Top view of limb under loading, with outer liner sock and transparent socket visible. C) Front (camera) view of limb in socket, with orange fluorescent speckle pattern applied to limb surface and black speckle pattern applied to liner outer surface.

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

Nothing to Report

How were the results disseminated to communities of interest?

Nothing to Report

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

1. ***Complete the DIC and FEA validation using the simulated residual limb***. This will include exploring different loading conditions, different liners, different liner thicknesses, and exploration of the 4 camera proposed DIC experiment.
2. ***Recruit and enroll human subjects***. The first visit will include diagnostic socket fitting and limb shape capture the high precision laser scanning system we have developed. The solid model of the residual limb obtained from the laser scanning system can then be imported into Abaqus FEA for meshing and future analysis when comparing to the measured strains with the DIC.
3. ***Conduct DIC experiments with human subjects.*** We will measure strains on the liner and/or residual limb (if able to use 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)

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. We anticipate applying for a no cost extension at the end of the project.

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:	

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 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
- **Location of Organization:** *Exton, PA*
- **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:

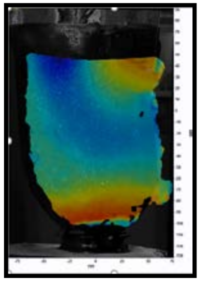
1) *Apply state-of-the-art digital image correlation (DIC) experiments along with FEA to measure skin strain in vivo during prosthesis use.*
2) *Compare strain and socket fit measurements between contemporary clinical socket shaping strategies*

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*

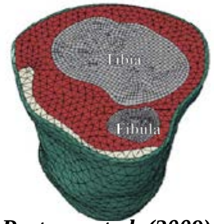
Speckled Simulated Residual Limb in Diagnostic Socket

Measured Displacements during Loading



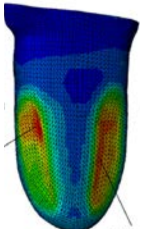
Preliminary results demonstrate the ability to measure displacements through a clear diagnostic socket.

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