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TITLE: An Automatically Adjusting Dynamic Orthosis to Enhance Performance of Warfighters with Lower Limb Injury

PRINCIPAL INVESTIGATOR: Joan E Sanders PhD

CONTRACTING ORGANIZATION: University of Washington

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14. ABSTRACT The focus in Year 1 was on hiring personnel, generating new adjustable strut designs that overcame limitations in prior efforts, and testing performance in users walking on a treadmill. Mechanical testing machine results showed that a high range in PDE strut stiffness was achieved, spanning the range of stiffness adjustment expected during clinical use. In laboratory testing on able-bodied people, we demonstrated that the bending signal from strain gages bonded to the strut was comparable to the ankle angle measured using a rotary encoder mounted to the orthosis. Treadmill testing on able-bodied users showed a linear relationship between strut spacing and stance phase maximum strain gage bending. The slope of this relationship changed a meaningful amount when users relaxed their ankle during walking, suggesting a dependence on user physical ankle strength. This result suggests that the strain gage bending data will provide a meaningful signal for creating the control system for automated stiffness adjustment.								
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1. INTRODUCTION:

The rationale of this application is that Warfighters experience lower-limb injuries during combat that after surgical reconstruction may still limit their capability to return to duty. The objective is to create and test a technology to improve lower-limb injured Warfighters' maximum running speed, running endurance, as well as maneuverability during non-running activities. The aims are to design an adjustable-stiffness dynamic brace to accomplish these objectives. Initially, the brace is adjusted using a mobile phone app while the person wearing the brace runs and walks. From the knowledge gained during those experiments, we design an automatically adjusting dynamic brace that has sensors, a small motor, and a small computer within it to make adjustments without distracting the user. Appropriate adjustments are made in real time according to what the user is doing. The automatically adjusting dynamic brace is tested both in the laboratory and in 4-week home studies, and its performance is compared with results from wearing a traditional dynamic brace.

2. KEYWORDS:

Dynamic AFO, auto-adjusting, limb reconstruction, lower-limb injury, orthosis, IDEO brace, return to duty, surgical reconstruction

3. ACCOMPLISHMENTS:

What were the major goals of the project?

The major goals of the project during the first quarter of Year 1 were to hire personnel, create specification and planning documents, to pursue an initial design for participant data collection, and to collect initial test data to evaluate performance of the instrumentation.

Targeted and actual completion dates for important phases of the project are listed below:

	Timeline	Progress	Completion Date
Major Task 1: Complete specifications and evaluate design	Months		
Hire personnel	1-3	100%	Nov 15 2020
Create support documents	1-3	100%	Dec 01 2020
Use CAD and FEM to generate candidates designs	4-6	100%	Apr 30 2021
Mechanically test candidates	4-6	100%	Sep 01 2021
Select single design for further development	6	100%	Sep 01 2021
<i>Milestone Achieved: Signal variable-stiffness strut design selected</i>	6	100%	Sep 01 2021
<i>Milestone Achieved: Prototype mechanism fabricated and tested</i>	6	100%	Sep 14 2021
Major Task 2: Create electronics for DAQ and wireless control	Months		
Optimize componentry and circuit design, make board	7-9	100%	Aug 15 2021
Add mobile phone comm. and control of strut stiffness	7-9	100%	Jun 15 2021
<i>Milestone Achieved: Electronics and wireless comm. done</i>	9	100%	Aug 15 2021
Assemble, bench test, and modify if needed	10-12	100%	Sep 10 2021
<i>Milestone Achieved: Unit ready for participant testing</i>	12	100%	Sep 14 2021
Major Task 3: Prepare research protocol for controller develop.	Months		
Submit IRB and HRPO documents for Aim 2 approval	1-3	100%	Sep 14 2020
<i>Milestone Achieved: IRB and HRPO approval for Aim 2 obtained</i>	1-3	100%	Dec 18 2020
Major Task 4: Prepare research protocol for controller develop.	Months		
Recruit and enroll able-bodied participants	10-20	20%	
<i>Milestone Achieved: 1st Aim 2 participant enrolled</i>	13		
<i>Milestone Achieved: Aim 2 study begins</i>	13		
Complete able-bodied testing	13-22		
<i>Milestone Achieved: Able-bodied participant testing completed</i>	22		
Complete injury/reconstruction participant testing	16-28		
<i>Milestone Achieved: Limb injury/reconstr. partic. testing completed</i>	28		
Complete data analysis	13-30		
<i>Milestone Achieved: Automated control ready for out-of-lab testing</i>	30		
Major Task 5: Prepare research protocol for crossover study	Months		
Submit IRB and HRPO documents for approval	1-3	100%	Sep 14 2020
<i>Milestone Achieved: IRB and HRPO approval for Aim 3 obtained</i>	1-3	100%	Dec 18 2020
Major Task 6: Conduct crossover study protocol	Months		
Recruit and enroll limb injury participants	28-40		

<i>Milestone Achieved: 1st Aim 2 participant enrolled</i>	
<i>Milestone Achieved: Aim 3 study begins</i>	
Complete testing first set of participants	28-38
<i>Milestone Achieved: Testing on first set of participants completed</i>	36-38
Complete testing on second set of participants	32-46
<i>Milestone Achieved: Testing on second set of participants completed</i>	44-46
Complete data analysis	46-48
<i>Milestone Achieved: Manuscript submitted</i>	48
<i>Milestone Achieved: Final report submitted</i>	48

What was accomplished under these goals?

IRB approval from the University of Washington was obtained before the start date of the project. HRPO approval was obtained on Dec 18, 2020.

Double Strut Design #1

The double-strut design described in the grant application was enhanced in preparation for pilot subject testing. From data collected between grant submission and approval but before funding started, we found that the initial design was not sufficiently robust to tolerate mechanical loading during high-speed running on a treadmill. Once the current grant started, we began to pursue a more robust design. The key elements modified were the bearings and connectors between the struts. Because composite PDE struts were not available, we used aluminum struts at this stage in the project. Aluminum struts identical in shape to the PDE carbon-fiber struts were machined and instrumented. Strain gages were applied to measure bending moment and shear force applied to the strut in the sagittal plane (Fig. 1). Calibration of the double-strut design showed results that well matched theoretical calculation, verifying that the new design was performing as intended. The difference in sensitivity (calibration slope) for actual vs. theoretical results was 2.2% for shear and 0.4% for bending. The design achieved the desired stiffness range, from a PDE #3 to PDE #7 strut. A #3 to #7 range captures the range of most DAFO users, thus was an appropriate starting point for our strut design efforts.

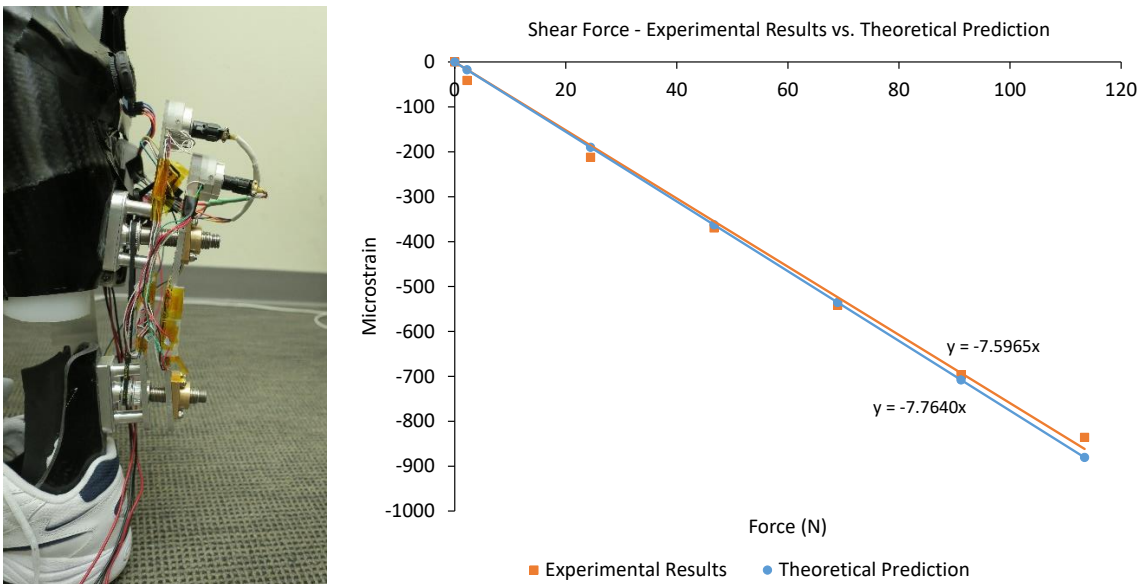


Fig. 1. Enhanced double-strut design ready for testing and calibration results. Left panel: double strut on an AFO. Right panel: Comparison of experimental results and theoretical strains measured at the gage locations.

As described in the initial grant application, we expected the bending channel in the strut to reflect the ankle angle in the AFO. To verify that this was indeed the case, we designed a measurement device to serve as a gold standard for ankle angle measurement. Two plates of aluminum were pinned to the DAFO, one at the cuff and the other at the level of the lateral metatarsal (Fig. 2). The other ends of the aluminum plates were pinned together at the level of the ankle. A rotary encoder was used to measure the angle between the two plates, providing a high-resolution measurement of ankle angle. A custom data acquisition system with an encoder chip and SD card was used to store data to the on-board data acquisition unit during testing.



Fig. 2. Independent ankle angle measurement device used to verify bending signal data.

A test orthosis was fabricated for each of two able-bodied individuals. Data were collected from strain gages mounted on the struts and from the angle encoder mounted to the orthosis.

For the first person, treadmill testing demonstrated that there were issues with the hardware connecting the struts together; they loosened during walking and running. This loosening affected the strain gage data (bending measurement) and reduced sensitivity to changes in strut spacing. For the second person, we glued (Loctite) the screws in place so as to reduce this problem. The results were more consistent with expectation.

Using the double strut during testing on the second person, we found that waveform shapes of strain gage bending data were consistent with expectation and were consistent with gait analysis ankle angle data reported in the literature (Fig. 3). Maximum plantarflexion occurs during late stance phase right before the push at toe off. It is this maximum that is of primary clinical interest since it is likely the most threatening time of gait for the orthosis user and metric from which strut stiffness should be adjusted.

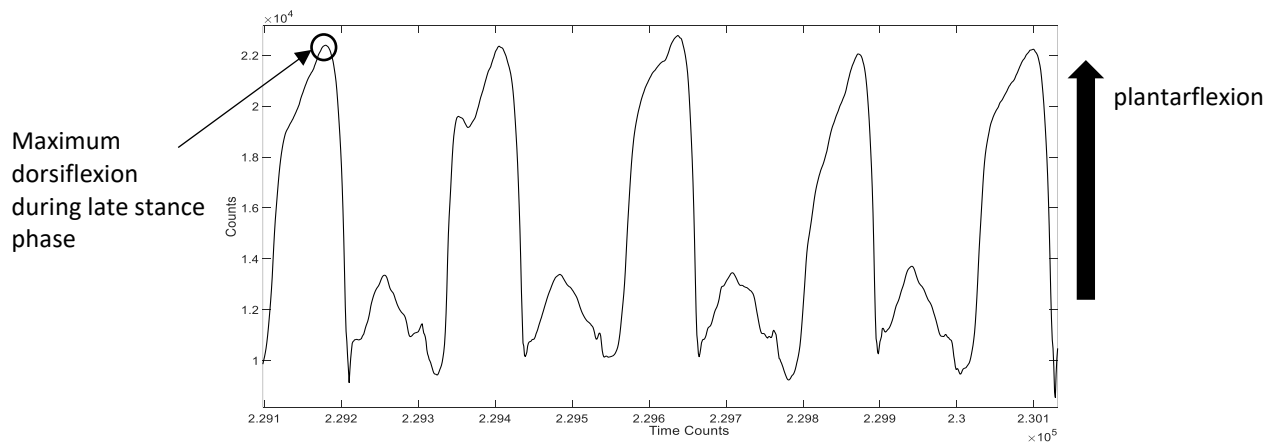


Fig. 3. Example bending data collected during walking trials. Curve shapes are similar to ankle angle data reported in the gait analysis orthotics literature.

We also found that there was much step-to-step variability in the strain gage bending data. At a strut spacing, there was considerable variability in the relationship between the bending data and the strut spacing. We hypothesized that this variability was due to the person’s gait variability, more specifically variability in the direction of their resultant force on the footplate. In other words, there was variability in the bending moment contribution from the sagittal shear force on the footplate. We subtracted out this contribution by subtracting the strain gage shear force multiplied by a constant (representative of moment arm length) from the strain gage bending data. The result from this effort substantially reduced the step-to-step variability in the maximum bending moment data.

We also found that the maximum bending decreased as the struts were moved further apart, as shown in Fig. 4. This is an exciting result because it demonstrates a measurable “plant gain.” The plant gain is the slope of the measured controller metric, in our case the strut strain gage signal, and the adjustment variable, in our case the strut spacing. When a person walks with our

instrumented AFO across a clinically meaningful range of strut spacing, we see a measurable and linear change in our controller metric.

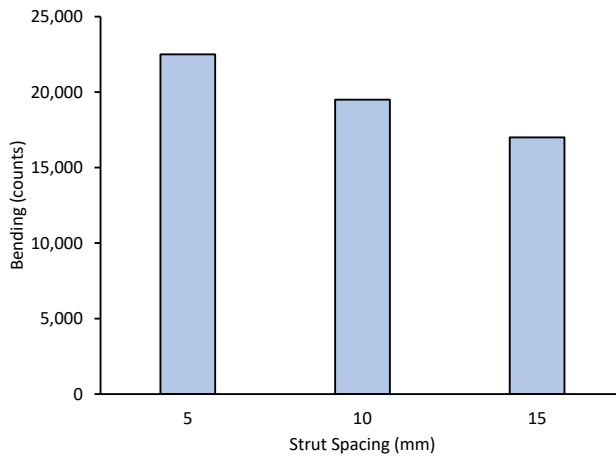


Fig. 4. Change in peak bending measurement from the bending sensor for different strut spacing. Intensity decreased for a wider spacing since the strut was stiffer. Means from approximately 100 steps per setting are shown.

To further develop and test the system, we continued testing on able-bodied people using modified versions of the original double-strut system. The motor to drive the belt and adjust strut spacing was mounted onto the DAFO and powered using a 3.7V lithium-ion battery.

Plant gain testing (adjusting strut spacing across its entire range while the person walked continuously on the treadmill) demonstrated an approximately linear relationship between maximum bending and strut spacing. The plant gain was approximately 650 LDC counts/mm change in strut spacing, which was considered acceptable. LDC counts are the raw measurement units from the bending strain gage signal conditioner. The linear relationship suggests a first order system, and thus that a proportional-integral (PI) controller will be adequate for auto adjustment. We conducted additional walking tests, first asking the person to relax his lower leg while walking (Relaxed), letting the DAFO do most of the work, and then using his lower leg muscles while walking (AnkleFire), sharing the work with the DAFO. There were clear differences in plant gain for these two conditions, suggesting that plant gains from people with lower-limb disability will be different than those from able-bodied individuals (Fig. 5). This result contradicts a suggestion in the literature that ankle angle for able-bodied participants and people with limb-disability are comparable when varying strut stiffness in a DAFO. We suspect this difference is apparent here in part because the sensitivity of our on-board sensors is so much greater than equipment used in laboratory gait analysis.

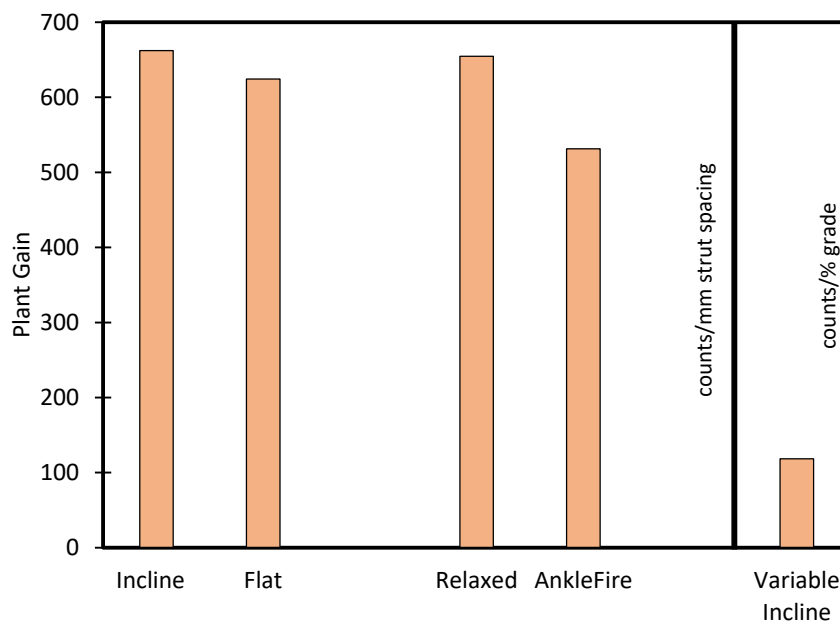


Fig. 5. Bar graph showing the plant gains in LDC counts/mm change in strut spacing for different test conditions.

Additional tests demonstrated a change in LDC counts per %grade in surface terrain (Fig. 5), suggesting that surface terrain may need to be considered in the control system design. Other researchers have demonstrated that surface terrain can be detected through inspection of gait data, thus we expect terrain angle to be identified in the strut or footplate signals. We note, however, that the plant gain during this test was very low, suggesting that it may not be a relevant variable. Experimental testing is necessary.

Double Strut Design #2

A next step was to pursue a more compact double strut design, thereby reducing the overall size and weight on the test orthosis. Using finite element analysis, we developed a new design that accomplishes the stiffness range of the original double strut but eliminates the leadscrew, bearing, frame, and belt at the top and bottom ends (Fig. 6). We identified the key design features that affected sensitivity. Example results showing that the range of strut stiffness can be adjusted using the thickness of the aluminum strut are shown in Fig. 7.

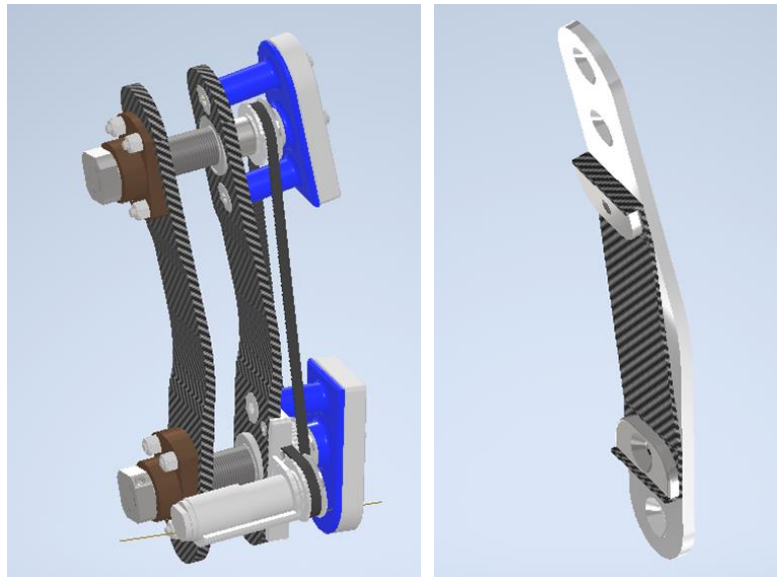


Fig. 6. Adjustable struts. Left: Initial design described in grant application. Right: New design.

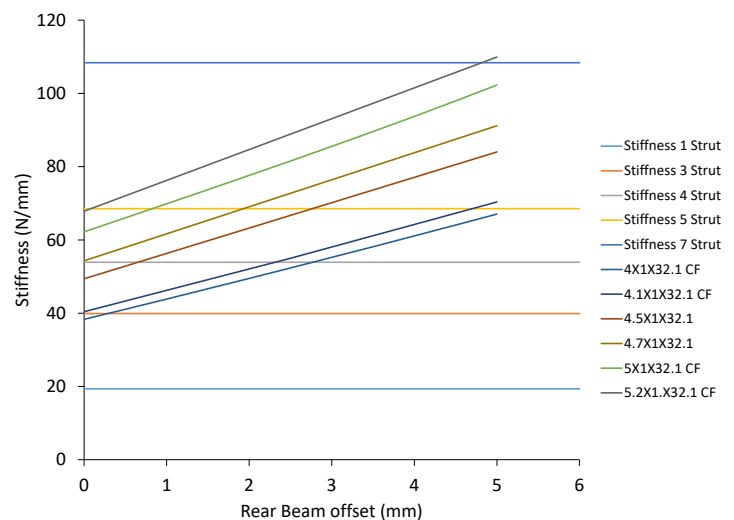
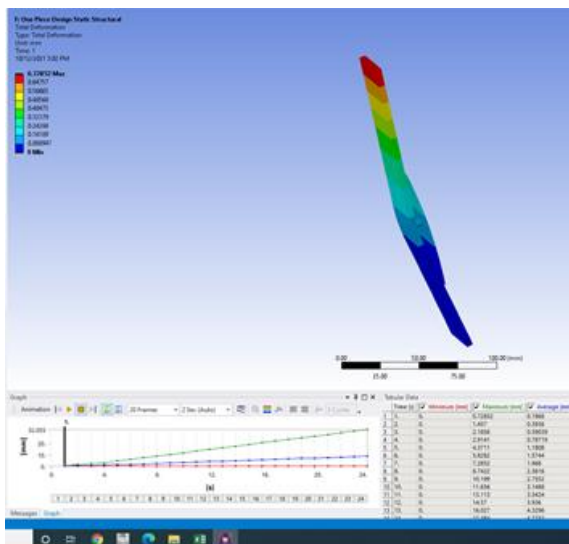


Fig. 7. Example model results. Left panel: Result from FE analysis showing the distribution of strain in the strut during load application. Right panel: Results showing that the stiffness range can be adjusted using the thickness of the aluminum strut.

The new design uses the double-strut concept but has a smaller and shorter posterior strut element. The posterior element is made of carbon fiber while the main strut is aluminum. Adjustment of strut spacing is achieved using a cam positioned between the two struts (not shown), driven by a motor. Computational modeling results demonstrated that a #3 to #7 range in PDE strut

stiffness was accomplished using this design. The lower and higher ends of the range are set primarily by the primary (anterior) strut thickness. Other design variables that strongly affected strut stiffness included material (aluminum vs. carbon fiber) and the width of both struts.

Prototype Testing of Design #2

An initial prototype was fabricated and tested in the testing machine apparatus as shown in Fig. 8 (left panel). Results demonstrated slippage between the carbon fiber and the aluminum at the sides of the carbon fiber element, distorting the uniformity of the load distribution across the width and causing less loading in the posterior strut element than intended. The application of epoxy at this interface failed to resolve the issue. To overcome the problem, we modified the design to include a curved lip at the ends of the carbon fiber posterior element (Fig. 8, right panel).

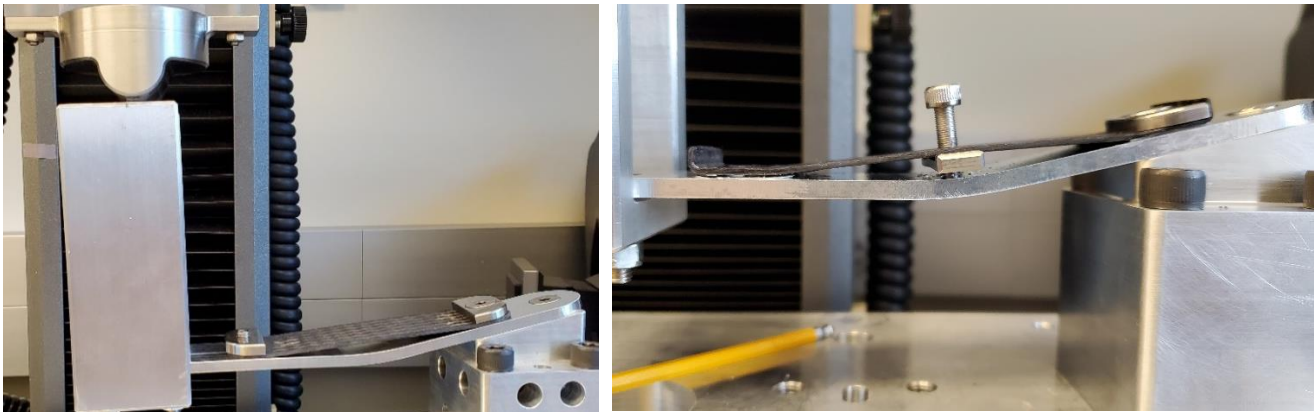


Fig. 8. Strut design #2 positioned in testing machine to measure strut stiffness. Left: Initial design. Right: modified design with curve up edges.

Additional testing demonstrated minimal stiffness change across the strut spacing range. We suspected this result was due to friction induced at the carbon strut/aluminum strut interface. When gun oil was applied between the carbon fiber and aluminum, results improved, and we obtained a high range of stiffness as illustrated in Fig. 9, approximately a #2 to #6 PDE stiffness range. The design is ready for preliminary testing on Aim #2 study participants.

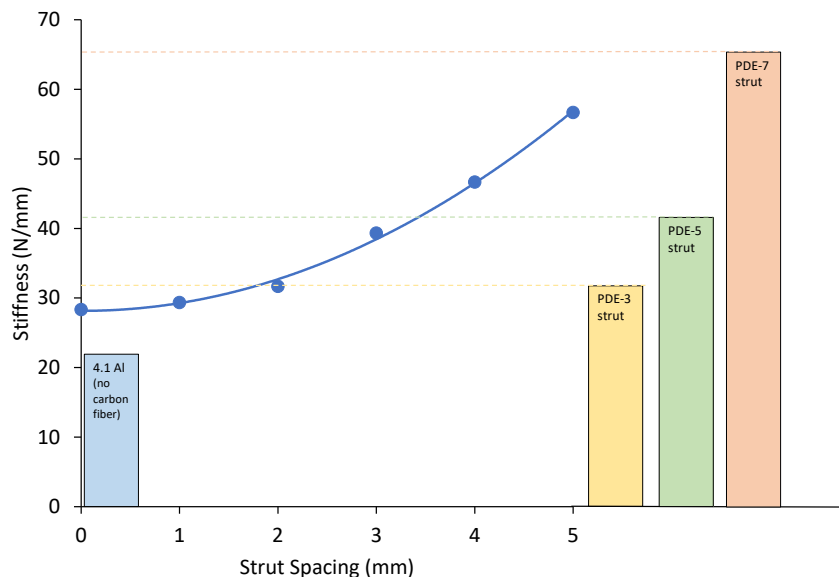


Fig. 9. Stiffness range accomplished with Design #2. Results from testing machine data. Stiffness of PDE struts 3, 5, and 7 are shown for comparison. The design accomplishes a high stiffness range, approximately #2 to #6.

So that we can determine the position, not just magnitude, of the resultant force on the bottom of the DAFO during walking and running, we added strain gage measurements to the footplate (Fig. 10). By assessment of the difference in moment between gages near the heel of the AFO, we quantify the footplate axial force. Information on both the magnitude and position of the

resultant force may provide insight relevant to controller design and how to best use the sensed variables to establish an effective control system metric on which to base a strut stiffness change. We also measure bending in the footplate. This location may be a more convenient means of measuring bending in the AFO than in the strut.

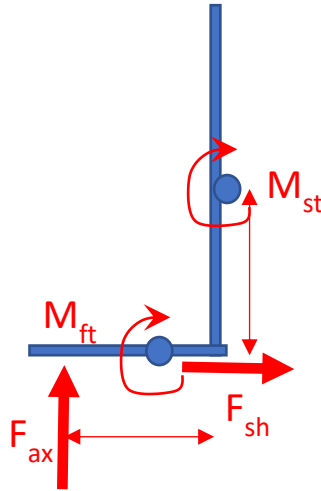


Fig. 10. Diagram illustrating the sensed measurements in the AFO. Axial force (F_{ax}), Shear force (F_{sh}), Bending moment in the foot (M_{ft}), and Bending moment in the strut (M_{st}) are measured.

The gage layout shown in Fig. 11 (left panel) had three different sets of shear sensing bridges, allowing us to establish which design(s) achieved adequate signal intensity. The strain gaged footplate was tested in a mechanical testing machine using the apparatus shown in Fig. 12. Linear relationships between applied load and footplate axial force sensor data were demonstrated. Linear relationships between applied bending moment and footplate bending moment data were also demonstrated. We further demonstrated that the spacing between strain gages necessary to generate an adequate axial force signal was 3.0 cm. Based on these results, we constructed future footplates with this spacing (Fig. 11, right panel).

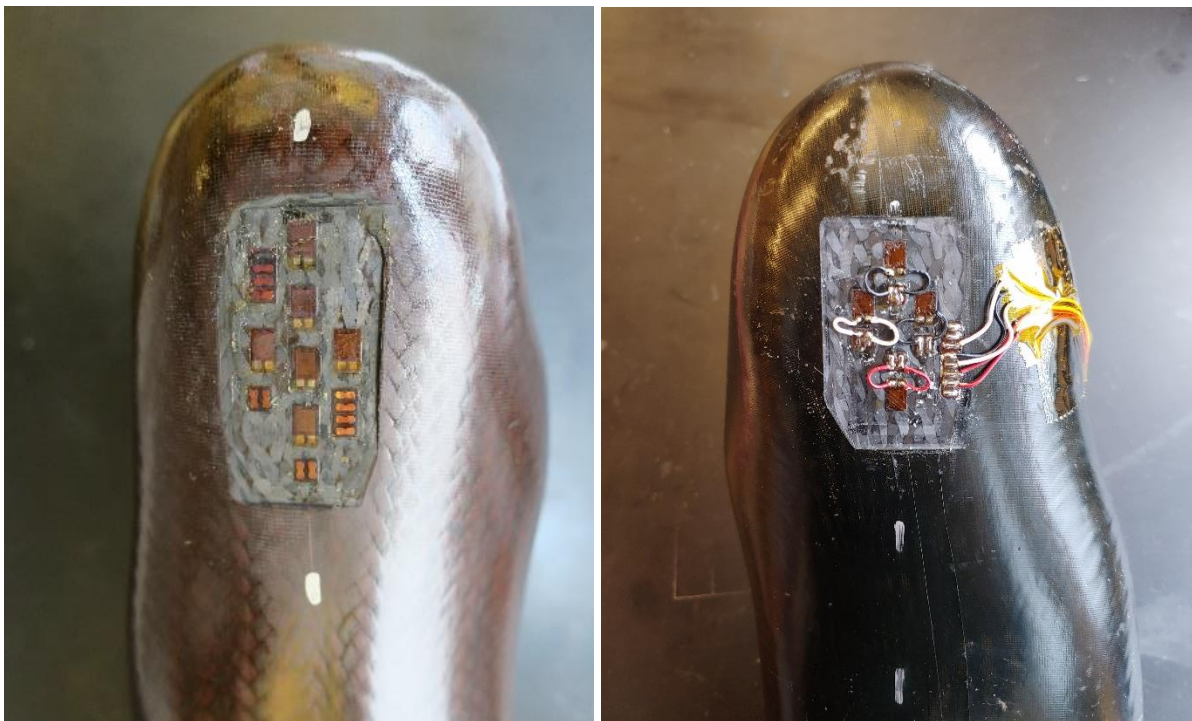


Fig. 11. Modified strain gage layout on the footplate for force and moment measurement. The gages are countersunk so that they will not be damaged during walking. We developed jigs to align the gages. Left panel: Original test layout to assess gage spacing. Right panel: Final layout, before placement of covering material to protect the gages and wires.



Fig. 12. Test set up for characterizing footplate strain gage sensitivity to ground reaction axial force. A white box with yellow tape is covering the strain gages and wires to minimize the risk of mechanical damage.

The signal conditioning circuit used for the strain gage signals was updated since some of the electronic parts were obsolete and additional functionality was needed to increase the dynamic range and to simplify the adjustment of amplifier gain. A new circuit board layout was completed, and a new housing design fabricated. The new design mounts to the rear of the AFO as shown in Fig. 13.

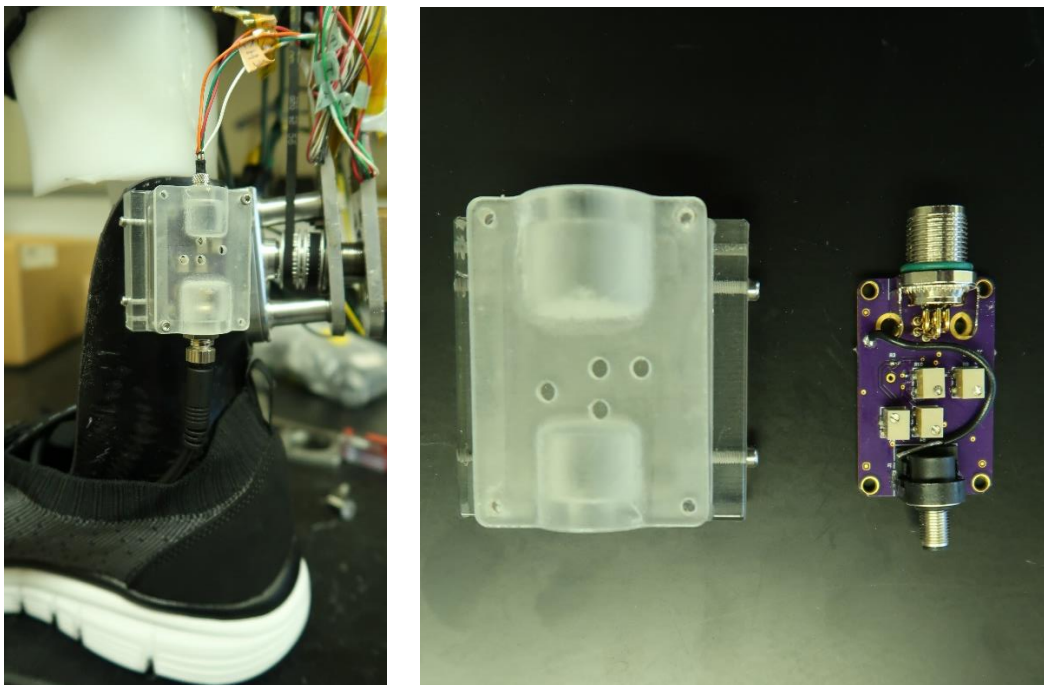


Fig. 13. New signal conditioner used to amplify strain gage signals from the strut and footplate. Left panel: Unit mounted within a housing affixed to the footplate. Right panel: Housing and circuit board with connectors.

A description of the new circuit is included below:

The differential signal amplifier board, designed to operate from a portable 3.3 - 5V supply, provides single-ended amplification and tuning for a Wheatstone bridge circuit. The design uses a low noise 3V voltage reference IC to provide bridge excitation

and dictate the instrument amplifier output range. This design increased the output range from the previous version with an upgraded instrument amplifier allowing an output range of 0.05V to 2.95V. It also improved signal stability with an additional potentiometer in the tuning network specifically for tuning the sensitivity to offset tuning and mechanical shock to the board, overall making it easier to tune and better for mobile, higher impact tests. Easy to secure connectors were added to improve the connection to a data acquisition module and the input bridge sensors.

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?

Our plan is to complete fabrication and data collection on the first test participant during the first quarter of Year 2. During the remaining three quarters, we expect to collect data on an additional five participants. Data will be prepared for analysis and discussed among the investigators.

4. IMPACT:

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

Nothing to Report.

What was the impact on other disciplines?

Nothing to Report.

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

We experienced delays due to COVID-19 restrictions between Mar and Sep 2020. Our plan to resolve the delay is to enhance recruitment and testing during Year 2 to get the project back on the original timeline.

Changes that had a significant impact on expenditures

Nothing to Report.

6. PRODUCTS:

Nothing to Report.

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

<i>Name:</i>	Joan Sanders, PhD
<i>Project Role:</i>	PI
<i>Researcher Identifier (ORCID ID):</i>	0000-0002-8850-243X
<i>Nearest person month worked:</i>	1
<i>Contribution to Project:</i>	Dr. Sanders coordinates the project, communicating regularly with Dr. Garbini and the research engineers on study-related issues

<i>Name:</i>	Joseph Garbini, PhD
<i>Project Role:</i>	Research Engineer

Researcher Identifier (ORCID ID):
Nearest person month worked: 1
Contribution to Project: Mechanical design and control system design

Name: Mathew Weissinger
Project Role: Research Engineer
Researcher Identifier (ORCID ID):
Nearest person month worked: 1
Contribution to Project: Mechanical design

Name: Andrew Vamos
Project Role: Research Engineer
Researcher Identifier (ORCID ID):
Nearest person month worked: 1
Contribution to Project: Control system design

Name: Ryan Carter
Project Role: Research Engineer
Researcher Identifier (ORCID ID):
Nearest person month worked: 1
Contribution to Project: AFO fabrication

Name: Katheryn Allyn
Project Role: Research Prosthetist
Researcher Identifier (ORCID ID):
Nearest person month worked: 1
Contribution to Project: Clinical advisor, orthotic support, recruitment

Name: Bailey Ramesh
Project Role: Research Engineer
Researcher Identifier (ORCID ID):
Nearest person month worked: 1
Contribution to Project: Control system development

Name: Gabriel Lake
Project Role: Research Engineer
Researcher Identifier (ORCID ID):
Nearest person month worked: 1
Contribution to Project: Electronic design

Name: Adam Krout
Project Role: Research Engineer
Researcher Identifier (ORCID ID):
Nearest person month worked: 1
Contribution to Project: Mechanical design

Name: Kendrick Coburn
Project Role: Research Engineer
Researcher Identifier (ORCID ID):
Nearest person month worked: 1
Contribution to Project: Sensor and instrumentation preparation

Name: Conor Lanahan
Project Role: Research Engineer
Researcher Identifier (ORCID ID):
Nearest person month worked: 1
Contribution to Project: AFO preparation

Name: Joseph Mertens

Project Role: Research Engineer
Researcher Identifier (ORCID ID):
Nearest person month worked: 1
Contribution to Project: Data collection

Name: Horace Wang
Project Role: Research Engineer
Researcher Identifier (ORCID ID):
Nearest person month worked: 1
Contribution to Project: Electronic design

Name: Nicholas DeGrasse
Project Role: Research Engineer
Researcher Identifier (ORCID ID):
Nearest person month worked: 1
Contribution to Project: Study execution

Name: Daniel Ballesteros
Project Role: Research Engineer
Researcher Identifier (ORCID ID):
Nearest person month worked: 1
Contribution to Project: Data processing and presentation

Name: Brian Larsen
Project Role: Research Engineer
Researcher Identifier (ORCID ID):
Nearest person month worked: 1
Contribution to Project: Instrumentation design

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

SANDERS, JOAN E

Previously active grant that has closed:

W81XWH-16-C-0020 (Sanders)

JWMP

“Automatic control of volume management systems for people with limb loss”

New grant that has started:

W81XWH-21-2-0003 (Childers)

OPORP

“Clinical translatability of reactive hyperemia measurements that can monitor adaptation of residual limb skin to socket wear”

GARBINI, JOSEPH L

Previous active grants that have closed:

Boeing Company (Garbini)

“Sanding Assist Automation”

W81XWH-16-C-0020 (Sanders)

JWMP

“Automatic control of volume management systems for people with limb loss”

What other organizations were involved as partners?

Nothing to Report.

8. SPECIAL REPORTING REQUIREMENTS

QUAD CHART:

An Automatically Adjusting Dynamic Orthosis to Enhance Performance of Warfighters with Lower Limb Injury

Log Number: DM190651

Award Number: W81XWH2010908

PI: Joan Sanders Ph.D.

Org: University of Washington

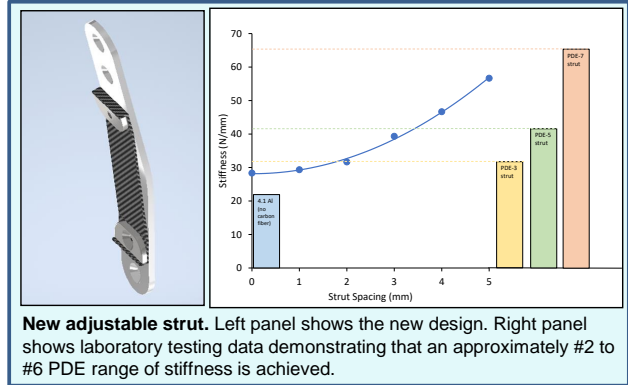
Award Amount: \$1.5M

Study Aims

- **Aim 1:** Create a motor-driven, variable-stiffness dynamic brace that adjusts across a stiffness range of 5 PDE-MCSS levels using a cell phone app
- **Aim 2:** Create a controller algorithm that adjusts strut stiffness for varying running speeds and terrains to maintain users' maximum dorsiflexion and ankle angle range near but not beyond their acceptable limits
- **Aim 3:** Conduct a randomized crossover study to compare performance of the automatic stiffness-adjusting dynamic brace to a traditional brace

Approach

A current prototype is extended into a fully functional design. Treadmill studies are conducted to identify relationships between strut stiffness and ankle angle across a range of running speeds and terrains. An algorithm to automatically adjust strut stiffness based on ankle angle is implemented in an on-board micro-controller. Activity is recorded while participants wear each brace (automatic, traditional) in their free-living environments for 4 weeks, and functional test and self-report data are collected. The automatic brace is expected to enhance running speed, endurance and user satisfaction.



Timeline and Cost

Activities	CY	20	21	22	23
Aim 1: Enhance prototype design		█			
Aim 2: Conduct lab testing			█		
Aim 3: Conduct small crossover study				█	
Estimated Budget (\$K)		\$346	\$383	\$379	\$392

Updated: 09/26/2021

Goals/Milestones

CY20 Goal – Finish design, IRB/HRPO approval, begin recruitment

Optimize geometry, add motor and mobile phone control

Characterize quality of measurement and operation

Accomplish IRB and HRPO approval

Recruit participants for lab testing

CY21 Goals – Continue lab testing, begin crossover study

Assess relationships of ankle angle, strut stiffness, and run speed

Recruit lower-limb injured participants for crossover study

CY22 Goals – Continue crossover study, begin to assess data

Continue 4-week testing in participant free-living environments

Compare data from intervention and control configurations

CY23 Goals – Complete crossover study and outcomes analysis

Disseminate results

Prepare final report

Comments/Challenges/Issues/Concerns

- none

Budget Expenditure to Date \$400,884

9. APPENDICES

Nothing to Report.