AWARD NUMBER: **W81XWH-20-1-0261**

TITLE: **Predicting Clinical Outcomes Using a Physical Platform to Simulate Orthoses with Different Characteristics**

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CONTRACTING ORGANIZATION: **Spaulding Rehabilitation Hospital, Charlestown, MA**

REPORT DATE: **August 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
August 2023	Annual	15Apr2022-14Apr2023

4. TITLE AND SUBTITLE

Predicting Clinical Outcomes Using a Physical Platform to Simulate Orthoses with Different Characteristics

5a. CONTRACT NUMBER

5b. GRANT NUMBER
W81XWH-20-1-0261

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)

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5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

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

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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

Ankle-foot orthoses (AFO's) are a tool commonly prescribed by healthcare practitioners to address gait and balance disturbances due to weakness, spasticity, or poor lower-limb muscle control. The selection of a suitable AFO is a time-consuming, iterative process that depends largely on the experience of the orthotist, who must take into consideration a patient's gait pattern, body mass, and activity level. To facilitate the selection of AFO's with characteristics that are optimized on a subject-by-subject basis, we propose the use of the ExoBoot developed by Dephy Inc as a platform to simulate the mechanical characteristics of different AFO's and assess which AFO design is best-suited for a given individual. The Dephy platform is uniquely suited to the task because it is equipped with sensors, real-time data logging, and precisely controlled torque delivery. Hence, the platform is capable of providing real-time kinematic data which can be used as an aid in selecting optimal AFO parameters.

15. SUBJECT TERMS

Orthotics, ankle-foot orthosis, robotics, stroke

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	22	19b. TELEPHONE NUMBER *(include area code)*

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1. INTRODUCTION:

To facilitate the selection of ankle foot orthoses (AFO's) with characteristics that are optimized on a subject-by-subject basis, we proposed the use of the ExoBoot developed by Dephy Inc as a platform to simulate the mechanical characteristics of different AFO's and assess which AFO design was best-suited for a given individual. The Dephy platform was deemed uniquely suited to the task because it is equipped with sensors, real-time data logging, and precisely controlled torque delivery. Hence, the platform was capable of providing real-time kinematic data which we used as an aid in selecting optimal AFO parameters.

2. KEYWORDS:

Ankle foot orthosis, stroke, rehabilitation robotics, gait

3. ACCOMPLISHMENTS:

What were the major goals of the project?

Aim 1) Determine the suitability of the Dephy platform to simulate AFO's with different characteristics on a test bench.
Task 1.1: Adapt existing powered AFO test bench to accommodate testing of passive AFO's
Task 1.2: Adjust Dephy platform parameters to replicate characterized AFO's
Aim 2) Evaluate the feasibility of using the Dephy platform during ambulation in stroke survivors to simulate the characteristics and performance of their habitual AFO.
Task 2.1: Finalize necessary documentation prior to study start
Task 2.2: Participant Recruitment and Data Collection
Task 2.3: Pilot Study Data Analysis
Aim 3) Explore the feasibility of using the Dephy platform to simulate the characteristics and performance of different AFO's and select the most suitable AFO characteristics on a subject-by-subject basis.
Task 3.1: Exploratory Data Analysis

What was accomplished under these goals?

The tasks related to Aims 1 and 2 were all accomplished as shown in the table below (see next page). The tasks related to Aim 3 were partially accomplished. Unfortunately, we experienced delays in obtaining local IRB approval and difficulties with recruiting study participants during the COVID period. We have ramped up recruitment and have collected data from 11 participants as of today. We contacted the program officer assigned to our project and agreed that we will continue the data collections and provide an informal report (based on interim analyses) as soon as we reach a first target of 15 participants. We will do so using laboratory discretionary funds.

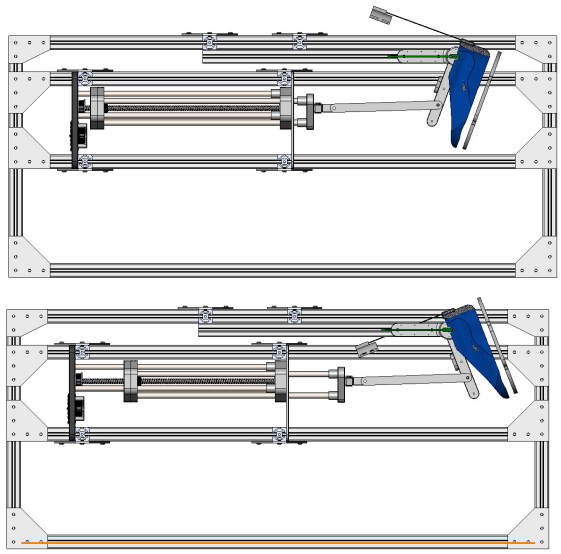
Specific Aim 1: Determine the suitability of the Dephy platform to simulate AFO's with different characteristics on a test bench.		
	Timeline	**Status**
Major Task 1: Prepare Dephy Platform for Simulation of AFO's	Months	
Sub Task 1: Adapt existing powered AFO test bench to accommodate testing of passive AFO's		
Evaluate mechanical requirements to accommodate passive AFO's in existing test bench	1-2	complete
Modify current test bench set-up to accommodate passive AFO's	2-4	complete
Milestone Achieved: Capacity to test passive AFO's on test bench	4	complete
Sub Task 2: Adjust Dephy platform parameters to replicate characterized AFO's		
Procure several types of passive AFO's	3-6	complete
Obtain stiffness, equilibrium position, and power generation characteristics of passive AFO's on test bench	4-6	complete
Determine any additional platform modifications needed to enable simulation of selected AFO's	4-6	complete
Modify platform control parameters while on test bench to reproduce performance characteristics of tested AFO's	5-6	complete
Determine and quantify the magnitude of differences between tested and simulated AFO's on test bench	5-6	complete
Milestone Achieved: Dephy platform with validated and preloaded AFO simulations	6	complete
Specific Aims 2 & 3: (2) Evaluate the feasibility of using the Dephy platform during ambulation in stroke survivors to simulate the characteristics and performance of their habitual AFO; (3) Explore the feasibility of using the Dephy platform to simulate the characteristics and performance of different AFO's and select the most suitable AFO characteristics on a subject-by-subject basis.		
	Timeline	**Status**
Major Task 2: Prepare Research Protocol for Submission		
Subtask 1: Finalize necessary documentation prior to study start		
Refine eligibility criteria, exclusion criteria, and screening protocol	1-3	complete
Finalize consent form, human subjects protocol, and case report forms	1-3	complete
Update data management plan to reflect any changes in protocol or device data	1-3	complete
IRB protocol submission	1-3	complete
SRH IRB review	1-6	complete
Military IRB review (ORP/HRPO)	1-6	complete
Submit amendments, adverse events, and minor deviations as needed	As Needed	complete
Coordinate with sites for annual IRB continuing review	Annually	N/A
Milestone Achieved: HRPO approval and SRH IRB approval	15	complete

Major Task 3: Pilot Study Execution	Months	Status
Sub Task 1: Participant Recruitment and Data Collection		
Conduct dry runs of data collection procedures	6-7	complete
Identify needed refinements to operating procedures to finalize manual of operations (MOP)	6-7	complete
Train study staff on data collection and management procedures included in MOP	6-7	complete
Milestone Achieved: 1st participant consented, screened, and enrolled; Study commenced	7-15	complete
Engage in participant recruitment	15-36	in progress
Participants complete study visits 1-4	15-36	in progress
Milestone Achieved: Pilot study protocol completed	15-36	in progress
Revise data and documentation for accuracy (Visits 1 & 2)	20-36	in progress
Perform statistical analysis (correlation) and share with all investigators	20-36	in progress
Disseminate findings (abstracts, presentations, publications, DoD)	20-36	in progress
Milestone Achieved: Report results from Aim 2 data analyses	20-36	in progress
Revise data and documentation for accuracy (Visits 3 & 4)	20-36	in progress
Perform exploratory analyses (Delphi method) and share with investigators	20-36	in progress
Disseminate findings (abstracts, presentations, publications, DoD)	20-36	in progress
Milestone Achieved: Report results from Aim 3 data analyses	20-36	in progress

Once again, please notice that our research team continues to work on the project and committed to complete the study using laboratory discretionary funds. Hence, tasks that are labeled as “in progress” are in fact ongoing activities.

In the following we provide a summary of the activities carried out over the past three years including the development of the device we used to characterize a set of AFOs commonly used in the clinic, the work concerning the simulation of AFOs with different mechanical characteristics using the ExoBoot by Dephy Inc, and the biomechanical studies in stroke survivors.

A significant amount of work was devoted to the development of the AFO characterization device. Our objective was to provide a platform to accurately characterize the mechanical characteristics during ankle flexion and extension of a wide range of custom and off-the-shelf AFOs commonly used in clinical practice. A literature review was performed, as well consultation with orthotists, prosthetists, and rehabilitation specialists to determine the necessary device requirements and an appropriate characterization device was designed, assembled, and tested accordingly (Figure 1A, and Figure 1B). Then, several sample AFOs were obtained to perform the above-mentioned characterization. These devices included custom molded polypropylene shell AFOs, plastic and carbon fiber posterior leaf spring (PLS) devices, and carbon fiber ground reaction orthotics with



1A

1B

Figure 1: (A) CAD representation of the designed characterization device and (B) actual manufactured product.

Identifier	Size/Side	Neutral Angle	ROM	1st Order			
				PF Constant (Nm/deg)		DF Constant (Nm/deg)	
				Excursion	Relaxation	**Excursion**	Relaxation
Blue Rocker	R/Sm	-1	-10 / 7	**2.16**	1.62	**2.32**	1.81
Ypsilon	R/Lg	-1	-13 / 8	**1.37**	1.33	**1.81**	1.74
Toe-Off	L/Sm	-1	-12.5 / 11	**0.89**	0.93	**1**	0.89
Ottobock WalkOn Reaction	L/Lg	-5	-13 / 3	**2.61**	2.5	**2.68**	2.63
Ottobock WalkOn Trimmable	R/Lg	-1	-12 / 13	**1.11**	0.9	**0.84**	0.82
Trulife	L/Lg	-1	-15 / 17	**0.62**	0.6	**0.68**	0.68
AMZN	L/Lg	-2	-15 / 17	**0.35**	0.32	**0.25**	0.23
Centri	L/Lg	35	-16 / 35	**0.1**	0.087	**n/a**	n/a
LowComPLS	L/Lg	-1	-9 / 13	**0.9**	0.77	**0.67**	0.53
Semi-rigid polypropylene	R/Lg	0	-7 / 7	**2.87**	2.52	**3.16**	2.8

Table 1. Mechanical characteristics of the AFOs chosen to test the ability of the proposed robotic platform to accurately emulate actual AFOs.

plantarflexion assist, all of variable stiffness. These devices were characterized over a variable range of motion, determined by their unique stiffness and typical use case. The stiffness of each device was modeled over its linear range as a first order stiffness constant (K) in both dorsiflexion and plantarflexion. Due to the effects of hysteresis, the AFOs stiffness were independently modeled for dorsiflexion and plantarflexion (Table 1).

A second portion of the work accomplished by our research team was devoted to preparing the platform for the data collections in human subjects. Specifically, we accomplished three major goals: 1) we modified the controller of the robotic platform to best fit the characteristics of the simulated AFOs; 2) we improved the graphical user interface on the tablet that enables changes in the platform parameters to facilitate its use by clinicians; and 3) we modified the inversion/eversion joint of the platform to improve ankle control.

Using the benchtop characterization rig shown in Figure 1, the AFO simulator was run through 10 degrees in both plantarflexion and dorsiflexion. This test was carried out eleven times per direction, from zero to ten newton meters per degree commanded stiffness in one Nm/deg increments. This test was performed to quantify the relationship between the commanded torque (as generated by the actuator) and the measured output torque (as derived from the benchtop characterization rig).

Characterization would occur by finding a best fit equation relating the commanded AFO device stiffness to the measured output of the device (*see equations below*). This exponential conversion function was then used to derive the optimal commanded stiffness to obtain the desired system stiffness as part of our device control strategy. By utilizing this compensation control strategy, the clinician would only need to input the desired stiffness. The AFO Simulator would then calculate the appropriate actuator stiffness to achieve that desired overall stiffness.

$$Kdf = 0.582 * (e^{1.014*k} - 1) \quad (1a)$$
$$Kpf = 0.3714 * (e^{1.408*k} - 1) \quad (1b)$$

In these equations, the measured output stiffness K is related to the commanded AFO simulator stiffness **k** in Nm/deg, with first equation relating the stiffnesses in dorsiflexion, and the second equation relating stiffnesses in plantarflexion. Using the exponential conversion functions *(*i.e., equations in the previous page*)* to adjust the commanded stiffness to compensate for the compressive losses, the AFO simulator was then tested against the target AFOs. The magnitude of difference between the target stiffness and actual stiffness was then measured with the benchtop characterization rig. Finally, the output data was used to directly compare the platform simulation of the target AFO to the actual AFO characteristics (see Figure 2, next page). The figure shows the ability of the platform to closely match the characteristics of the target AFOs. We derived quantitative measures of the accuracy of the simulation of the target AFOS by the platform for each one of the AFOs chosen by our clinical team for the proposed experiments. We discussed these results with our clinical team and concluded that the differences between the simulated and actual AFOs were clinically negligible. However, as discussed in our original proposal, the relevance of such differences must be determined on the basis of biomechanical data collected from stroke survivors, as planned for the following phases of the study.

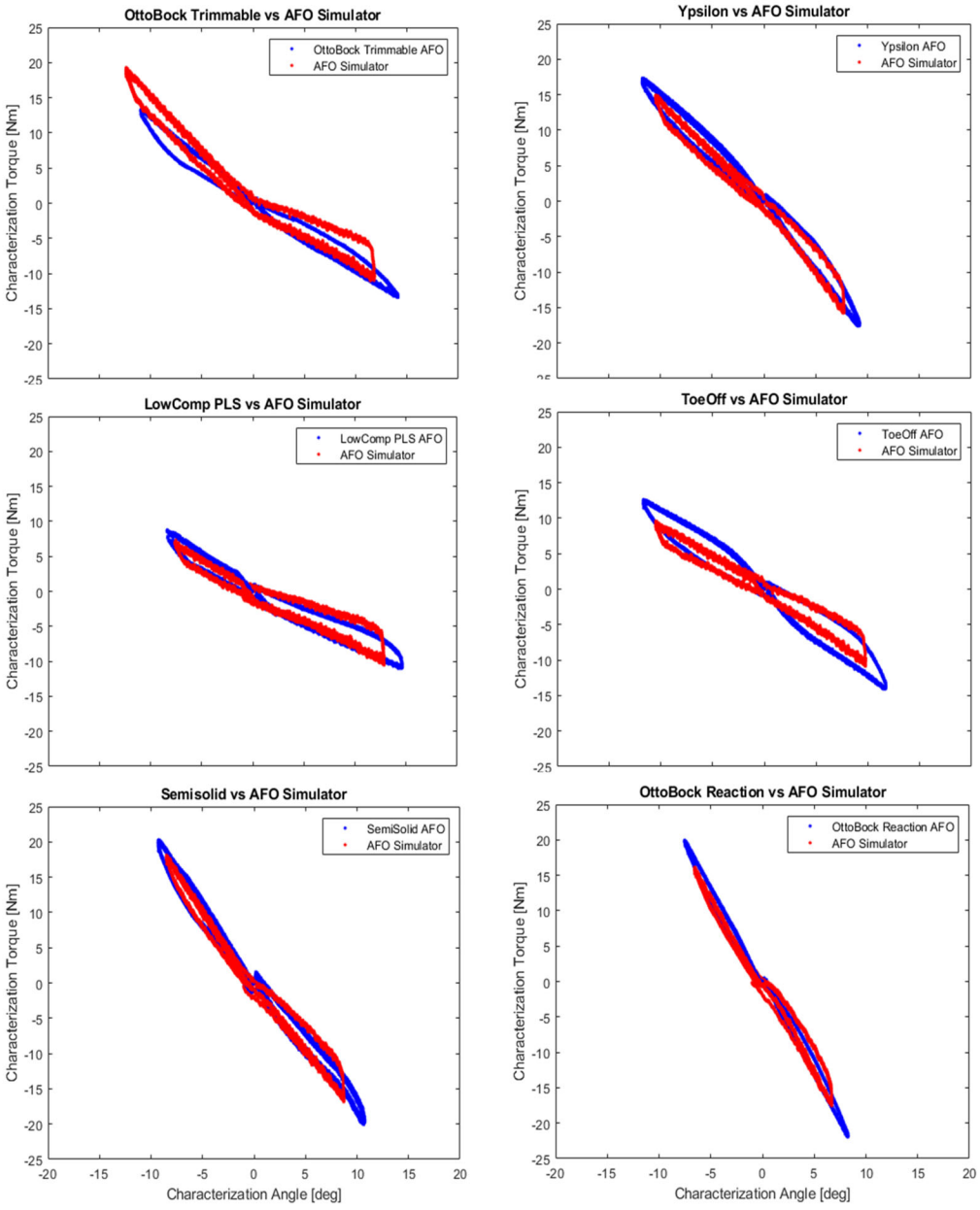


Figure 2. Comparison plots of the actual AFOs versus the platform simulations.

In addition to the above-summarized work, we devoted considerable time to identify potential improvements to the graphical user interface utilized to program the robotic system and set it to simulate different target orthoses. Together with the clinical team, we decided to switch from a text entry system to a visual drag and drop system for controller updates, as well as switching the unit system of user input from “device units” to more descriptive units of degrees and Newton-meters.

Next, after consultation with the clinical team, we decided to make significant modifications to the system inversion/eversion joint. Platform modifications were made to enable setting different

degrees of stiffness of the joint of the device spanning a full range from locking the joint to leaving it completely free to move. Also, we re-designed the system so as to enable such adjustments while the device is worn. These modifications were targeted to expand the applicable patient population.

The next phase of the study was focused on the collection of biomechanical data from stroke survivors in the above-described experimental conditions during four distinct study visits. We collected data in the laboratory as well as in and around the hospital building to simulate activities of daily living. Figure 3 shows one of the study participants in the laboratory and on one of the hospital stairwells. In the laboratory, we collect biomechanical data using a camera-based motion capture system equipped with ten infrared cameras and two force plates. Outside of the laboratory, we collect data using wearable sensors that enable tracking the kinematics of motion.

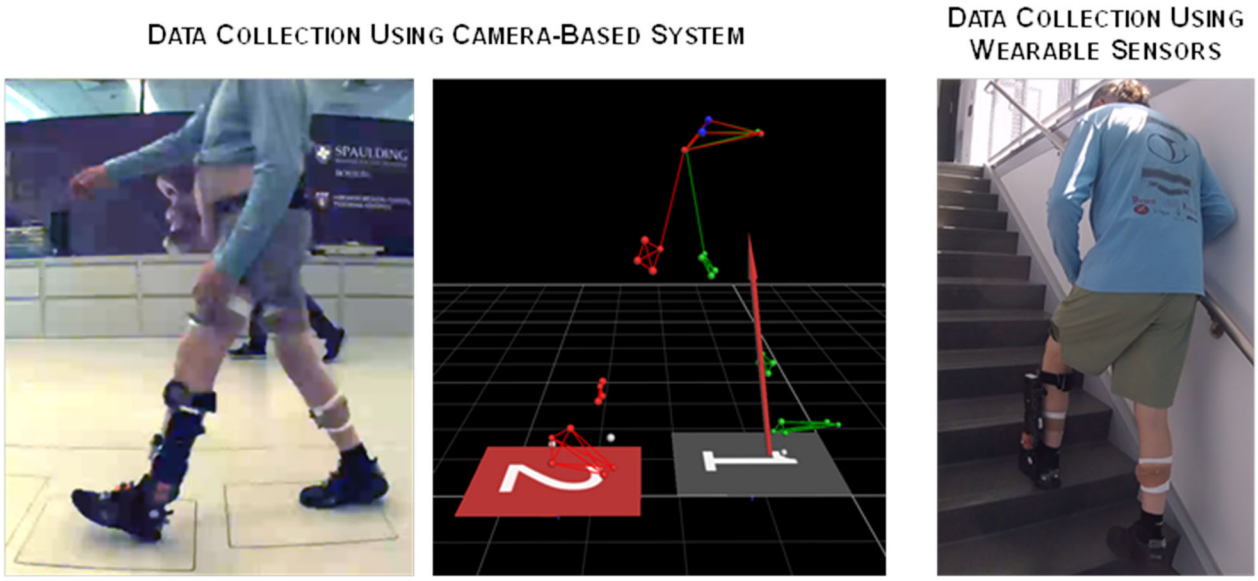


Figure 3. Data collection in the laboratory using a camera-based motion capture system (left and center panels) and outside of the laboratory (right panel) on a stairwell using wearable sensors (inertial measurement units).

We have now collected data from 11 participants with the characteristics shown in Table 2. As shown in the table, we have tested several types of AFOs, including solid and hinged AFOs as well as carbon fiber with lateral strut and polypropylene posterior leaf spring AFOs. Testing AFOs with different mechanical characteristics is an important aspect of the project because it allows us to identify potential limits of the Dephy platform, determine modifications needed for future studies, and evaluate the impact on the biomechanics of ambulation of a mismatch between the habitual AFO and the AFO simulated by the Dephy platform. In other words, it allows us to determine the sensitivity of gait parameters to changes in the AFO characteristics. In addition, the data collections aimed to identify optimal mechanical characteristics of a passive AFO and an active AFO (on a patient-by-patient basis) provide us with the opportunity to explore the potential impact of adjustments in the settings of the Dephy platform (as a replacement of the patient's AFO).

SubID	Impaired	AFO
DAFO-01	Left	Hinged AFO with posterior stop
DAFO-02	Left	Hinged AFO with anterior and posterior stop
DAFO-03	Left	Hinged AFO with posterior stop
DAFO-04	Right	Posterior Leaf Spring
DAFO-05	Left	Carbon Fiber Posterior Lateral Strut
DAFO-06	Left	Solid AFO
DAFO-07	Left	Hinged AFO with posterior stop
DAFO-08	Left	Posterior Leaf Spring with removable and flexible SMO?
DAFO-09	Left	Posterior Leaf Spring (loose strap)
DAFO-10	Left	Hinged AFO with posterior stop
DAFO-11	Right	Carbon Fiber Posterior Lateral Strut

Table 2. Impaired side and AFO types of the 11 stroke survivors tested in the project.

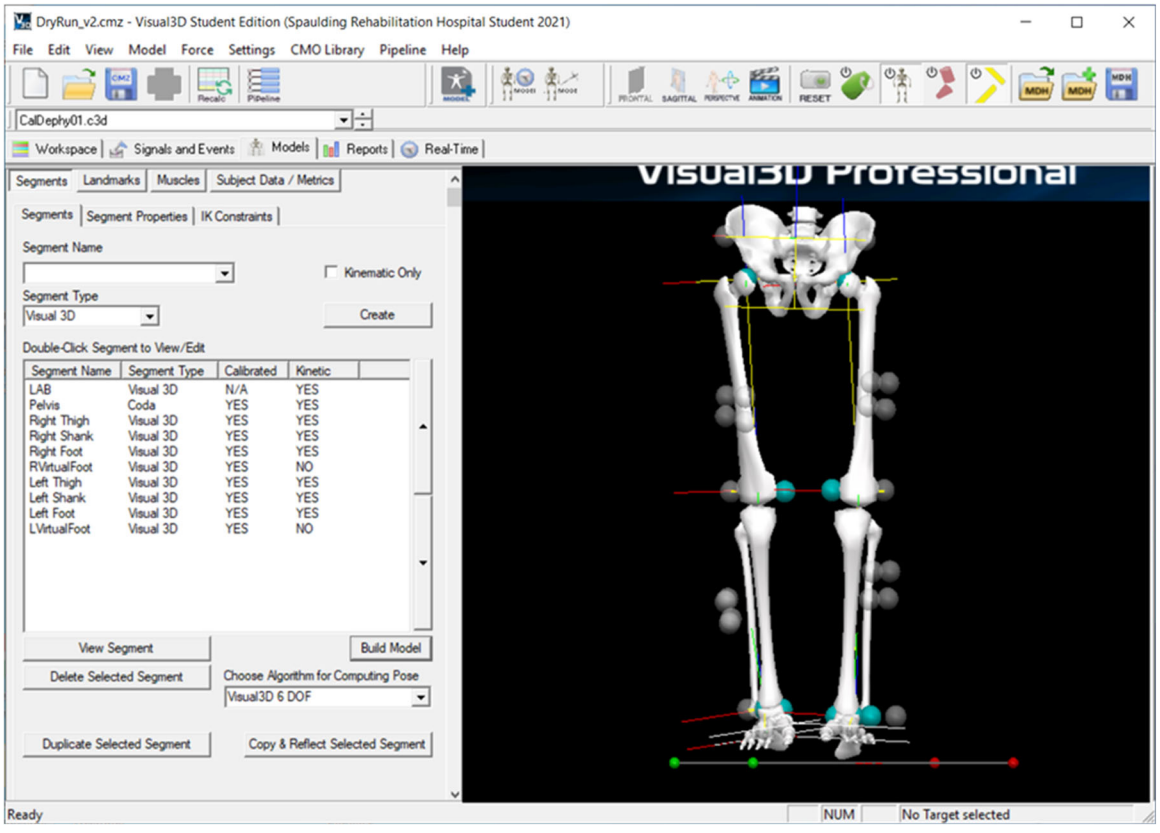


Figure 4. Software utilized to implement the biomechanical model used in the study to derive the kinematics and kinetics of movement from the motion capture data collected from stroke survivors.

A great deal of work was accomplished to develop suitable biomechanical models for the analysis of the data collected from stroke survivors. The use of simple biomechanical models relying on single reflective markers positioned on anatomical landmarks was not possible because the elements of orthotic devices covered the anatomical landmarks utilized by simple biomechanical models. Models were then developed based on an ad hoc choice of sets of reflective markers positioned on the body segments based on the available anatomical surfaces and on the mechanical stability of markers relative to the bones whose position and orientation in space was the target of the biomechanical data collection. Such sets of markers were organized in clusters and the position of anatomical landmarks was determined via a calibration procedure.

Figure 4 shows the graphical user interface of the software platform that we used to implement the model chosen for the project. This is a commercially available platform known as Visual3D, which is the most prominent software platform for biomechanical modeling of human movements. Data was collected using a VICON system relying on the Nexus software to track the reflective markers during both the calibration phase of the experiment (i.e., trials to be used to determine the position of anatomical landmarks) and the walking trials (i.e., trials during which only the clusters of reflective markers will be positioned on the body segments). The initial processing of the reflective marker trajectories was carried out using the Nexus software. Then the output file (in C3D format) was imported in Visual3D for the purpose of estimating joint kinematic and kinetics. Trials carried out while subjects walked using the ExoBoot by Dephy Inc were compared with trials during which subjects used their habitual AFO. This comparison allowed us to determine if the platform was accurately simulating the characteristics of the target AFO, not just on the bench but also during "actual" use by stroke survivors.

Figure 5 (next page) shows an example of AFO stiffness curves (i.e., torque vs angular displacement) and ankle angle during the gait cycle for two of the study participants. Plots are displayed for the habitual (i.e., the patient's own AFO) and the simulated (i.e., the ExoBoot set to simulate the mechanical characteristics of the patient's AFO. We chose this specific example as one participant's AFO was matched closely by the ExoBoot (see stiffness curves for DAFO-05) whereas the AFO of the second participant was simulated less accurately (see stiffness curves for DAFO-07). However, despite the different degrees of approximation offered by the ExoBoot for the AFOs of the two subjects, the ankle angular displacement patterns observed with the habitual AFO vs the simulated AFO (i.e., the ExoBoot) are highly similar. This is due, at least in part, to the fact that the pattern of ankle angular displacement in DAFO-07 does not appear to span a range including portion of the stiffness curves showing discrepancies between the habitual and the simulated AFO.

We do not want to rush to conclusions based on the data collected so far from 11 participants as we plan to perform more extensive analyses (to be discussed with the Program Officer assigned to the project) when we reach a first target of 15 study participants. Nonetheless, we see the results in Figure5 as extremely encouraging as the demonstrate both the ability of the ExoBoot by Dephy to simulate a wide range of AFOs and that very similar biomechanical marks trials collected while using the habitual AFO compared to the ExoBoot.

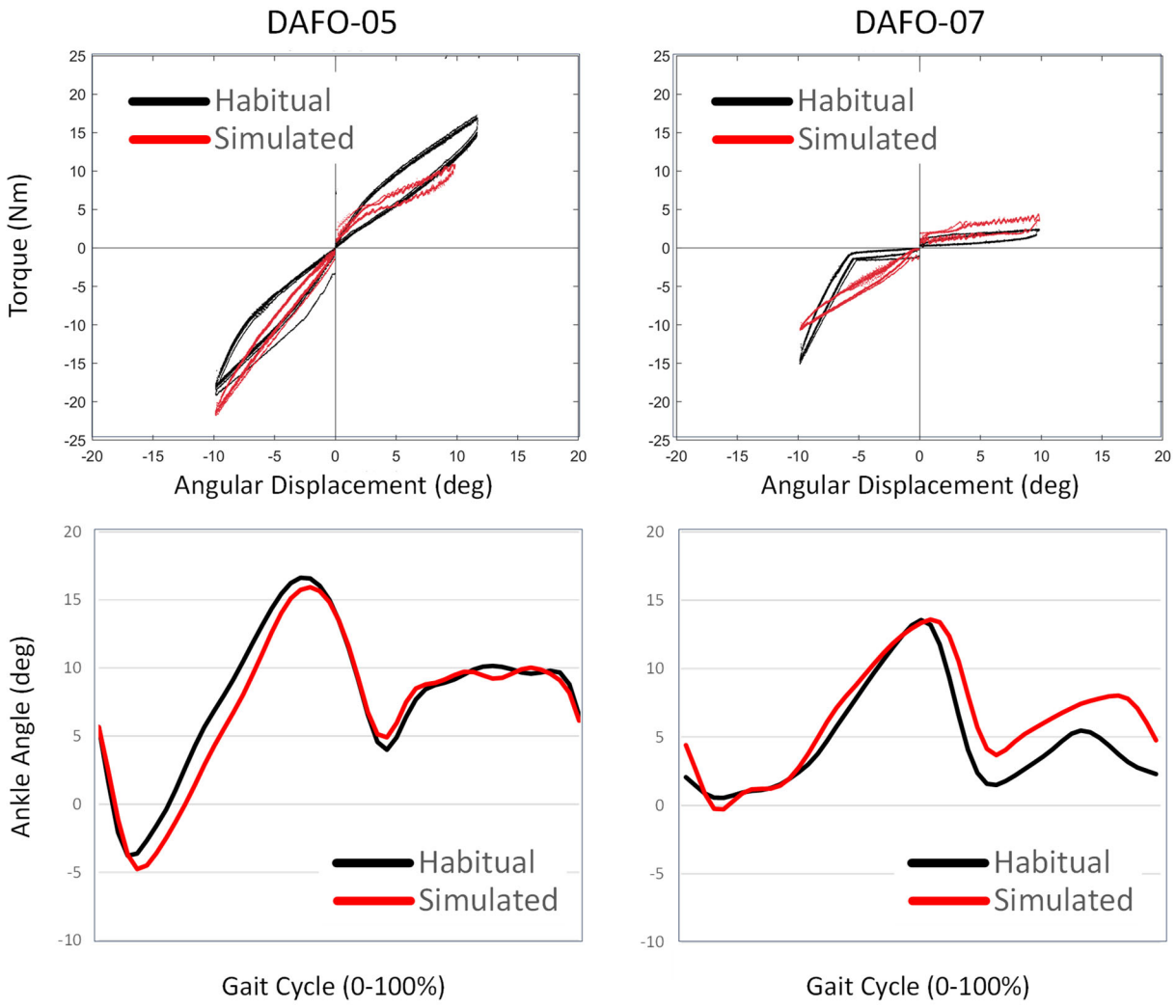


Figure 5. Comparison of data collected using the patient's own AFO (herein referred to as "habitual") and the ExoBoot (herein referred to as "simulated") on the bench (upper panel) and during level ground walking (lower panel) for two study participants (DAFO-05 and DAFO-07).

In conclusion, the work accomplished as of today shows: 1) that the robotic platform we chose for the project (the ExoBoot by Dephy Inc) provides the ability to simulate a wide variety of AFOs, and 2) that the biomechanics of ambulation with the habitual AFO and the ExoBoot are very similar. Whereas, as mentioned above, we continue to collect data to obtain sample representing an even wider variety of AFOs and we plan to perform more in-depth analyses in the months to come, the results shown in this report and biomechanical data not included in this report but that the research team has extensively examined suggest that traditional, passive AFOs could be replaced by robotic platforms that mimic their mechanical characteristics. We believe that this is of significant clinical relevance as it opens the possibility of adjustments in the AFO characteristics in response to the evolving needs of patients. This is highly relevant to the design of rehabilitation interventions in stroke survivors in the sub-acute phase of their recovery, when frequent adjustments are desirable but are not achievable with traditional, passive AFOs.

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

Nothing to report.

How were the results disseminated to communities of interest?

Whereas we have not formally presented the results at professional meetings or summarized the results in a journal paper, we intend to do so as soon as we reach our target of 15 study participants. We plan to prepare a publication for Journal of NeuroEngineering and Rehabilitation, a gold open access journal with readership both in the engineering and the clinical community.

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

While we are open to generate an informal report of future activities, we understand that an additional formal report would not be needed. Nonetheless, in the research activities that we plan to carry out over the next months, we anticipate completing the data collections 15 subjects and performing an in-depth comparison of the biomechanics of motion with the habitual AFO vs the ExoBoot. Additional reports will follow to compare the habitual AFO with the optimal AFO chosen on the basis of adjusting the ExoBoot parameters and visual observation of its effects on the biomechanics of gait in stroke survivors.

4. IMPACT:

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

We look upon the results of the study as a first step toward establishing the use of robotic AFOs in the subacute phase post-stroke. This would be nothing short of a “revolution” in the field of stroke rehabilitation.

What was the impact on other disciplines?

While it is too early to properly evaluate the impact in the field of rehabilitation and related fields, we anticipate a significant impact on the field of robotics as we used an approach that is unique and applicable beyond the simulation of AFOs.

What was the impact on technology transfer?

It is too early to assess the commercial potential of the proposed technology, we are uniquely positioned to facilitate the launch of a product to facilitate the selection of AFOs that are ideally-suited on a patient-by-patient basis. This is because our partner on the project (Dephy Inc) originated the technology platform that we are using and has full commercial control on future

developments of the platform. Besides, the study is in line with the business plans developed by Dephy Inc. Hence, if additional data collections provide results confirming that the platform is suitable to facilitate the choice of an optimal AFO in stroke survivors, we will be ready to pursue full development of the technology for its commercialization in the very near future.

What was the impact on society beyond science and technology?

If we are successful in advancing the ExoBoot technology to replace traditional passive AFOs, we could significantly improve the quality of life of many patients who use an AFO to improve their mobility.

5. CHANGES/PROBLEMS:

Changes in approach and reasons for change

As mentioned above, we have been in touch with the Program Office assigned to the project and have discussed the changes we proposed as we move along with the project activities. We are grateful for the help and support provided to make such decision. We will continue to work on the project by relying on discretionary funds available to our laboratory to complete this exciting investigation despite the technical and recruitment challenges (due to COVID) we ran into over the past 3 years.

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

Nothing to report.

Changes that had a significant impact on expenditures

Nothing to report.

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

Nothing to report.

Significant changes in use or care of human subjects

Nothing to report.

Significant changes in use or care of vertebrate animals

N/A.

Significant changes in use of biohazards and/or select agents

N/A.

6. PRODUCTS:

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

We plan to prepare a journal publication when we reach the target recruitment of 15 participants. We have not prepared any publications so far.

- **Technologies or techniques**

Nothing to report.

- **Inventions, patent applications, and/or licenses**

Nothing to report.

- **Other Products**

We anticipate that further studies will show the suitability of the ExoBoot to replace traditional, passive AFOs. We do not anticipate pursuing any product development before that. However, we expect that a follow-up project in sub-acute stroke survivors (motivated by the results presented in this study) will lead to the development of a new product.

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Name:	*Paolo Bonato*
Project Role:	*PI*
Nearest person month worked:	*2.4 cal months*
Contribution to Project:	*Responsible for all project activities*

Name:	*Luke Mooney*
Project Role:	*Co-PI*
Nearest person month worked:	*1.1 cal months*
Contribution to Project:	*Responsible for the robotic platform used in the study*
Name:	*Greg Schiurring*
Project Role:	*Lab manager*
Nearest person month worked:	*1.9 cal months*
Contribution to Project:	*Responsible for all regulatory documents*
Name:	*Jake Mooney*
Project Role:	*Consultant at Dephy Inc*
Nearest person month worked:	*1.5 cal months*
Contribution to Project:	*Responsible for setting bench tests robotic platform*
Name:	*Nick Benz*
Project Role:	*Project Manager at Dephy Inc*
Nearest person month worked:	*1.3 cal months*
Contribution to Project:	*Responsible for robotic platform development*
Name:	*Anne O'Brien*
Project Role:	*Research Therapist*
Nearest person month worked:	*0.75 cal months*
Contribution to Project:	*Responsible clinical evaluation of robotic platform*
Name:	*Catherine Adans-Dester*
Project Role:	*Research Therapist*
Nearest person month worked:	*1.0 cal months*
Contribution to Project:	*Responsible biomechanical assessment of robotic platform*
Name:	*Benito Pugliese*
Project Role:	*Research Engineer*
Nearest person month worked:	*1.0 cal months*
Contribution to Project:	*Contributed to the data collections and analysis*
Name:	*Eric Fabara*
Project Role:	*Research Fellow*
Nearest person month worked:	*0.5 cal months*
Contribution to Project:	*Contributed to the data analysis*

The project has been additionally aided by Dephy's member Matt Mooney and Robert Drillio (certified orthotist at Spaulding Rehabilitation Hospital).

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

The PI has completed several projects that were ongoing at the time of receiving this award. The following are projects that the PI completed:

Title: "PostureCheck: A vision-based compensatory-posture-detection tool to enhance performance of the BURT® upper-extremity stroke-therapy device"
Funding Agency: NIH (R43EB027525)
PI: Lioulemes, Alexandros and Bonato, Paolo (multiple PI's)
Start Date: 09/22/2018
End Date: 03/21/2020
Effort: 0.96 cal months

Title: "Wrist-worn Sensors for Tele-Rehabilitation of the Hemiparetic Upper-Extremity"
Funding Agency: NIH (R44HD084035-02)
PI: Gwin, Joseph
Start Date: 09/08/2015
End Date: 04/30/2020
Effort: 1.26 cal months

Title: "CPS: TTP Option: Synergy: Collaborative Research: Nested Control of Assistive Robots through Human Intent Inference"
Funding Agency: NSF (1544815)
PI: Bonato, Paolo (multiple PI's)
Start Date: 10/01/2015
End Date: 09/30/2020
Effort: 1.20 cal months

Title: "The Home Evaluation, Assessment, Rating and Training of Gait (HEART-Gait) System for Monitoring Toe-Walking Severity in Children with Cerebral Palsy"
Funding Agency: NIH (R43LM013104)
PI: Bamberg, Stacy
Start Date: 09/18/2018
End Date: 08/31/2020
Effort: 0.84 cal months

Title: "Enabling the Manipulation of Real Objects During Robot-Assisted Stroke Rehabilitation"
Funding Agency: NIH (R43 HD105546)
PI: Townsend, William and Bonato, Paolo (multiple PI's)
Start Date: 08/01/2021
End Date: 07/31/2023
Effort: 0.24 cal months

The PI is currently working on the following funded projects:

Title: “Mobile Tai Chi Platform for Fall Prevention in Older Adults”
Funding Agency: NIH (R42AG059491)
PI: Bonato, Paolo and Wayne, Peter (multiple PI’s)
Start Date: 09/15/2018
End Date: 08/31/2023
Effort: 1.20 cal months

Title: “REHAB-PAL - Rehabilitation Engagement at Home with a Socially Assistive roBot for Pediatric Adherence”
Funding Agency: NIH (R43HD106834)
PI: Stout, Andrew
Start Date: 10/01/2021
End Date: 09/30/2023
Effort: 0.10 cal months

Title: “Stepping Strong: Validating Normal Kinematic Motion in Residual Limb Musculature of Ewing Amputees”
Funding Agency: Stepping Strong Foundation (N/A)
PI: Bonato, Paolo
Start Date: 04/01/2022
End Date: 03/31/2024
Effort: 0.10 cal months

Title: “PostureCheck: A Vision-Based Compensatory-Posture-Detection Tool to Enhance Performance of the BURT® Upper-Extremity Stroke-Therapy Device”
Funding Agency: NIH (R44EB027525)
PI: Lioulemes, Alexandros and Bonato, Paolo (Multiple PIs)
Start Date: 07/01/2021
End Date: 06/30/2024
Effort: 1.20 cal months

Title: “Improving the Health Status of Dysvascular Amputees by Deploying Digital Prosthetic Interface Technology in Combination with Exercise Intervention”
Funding Agency: NIH (R44 HD110327)
PI: Turner, Troy and Bonato, Paolo (Multiple PIs)
Start Date: 07/01/2021
End Date: 06/30/2024
Effort: 1.90 cal months

Title: “Collaborative Research: NRI: Remotely Operated Reconfigurable Walker Robots for Eldercare”
Funding Agency: NSF (2133075)
PI: Bonato, Paolo
Start Date: 03/15/2022
End Date: 02/28/2025
Effort: 1.20 cal months

Title: “Achieving Optimal Motor Function in Stroke Survivors via a Human-Centered Approach to Design an mHealth Platform”
Funding Agency: NIH (R01 EB027777)
PI: Lee, Ivan
Start Date: 05/01/2020
End Date: 04/30/2025
Effort: 1.20 cal months

Title: “StrokeWear: A Novel Wrist Wearable Sensor System to Promote Hemiparetic Upper Extremity Use in Home Daily Life”
Funding Agency: NIH (R44 HD084035)
PI: Vaziri, Ashkan; Keysor, Julie; and Bonato, Paolo (Multiple PIs)
Start Date: 07/01/2022
End Date: 06/30/2025
Effort: 1.90 cal months

Title: “Center for Innovative NeuroTech Advancement - CINTA”
Funding Agency: NIH (U54 EB033650)
PI: Schachter, Steven and Bonato, Paolo (Multiple PIs)
Start Date: 07/01/2022
End Date: 06/30/2027
Effort: 1.90 cal months

Title: “SmartAssist™: Adaptive robotic assistance to maximize patient engagement with the Barrett Upper-Extremity Robotic Trainer (Burt)”
Funding Agency: NIH (R44 HD109106)
PI: Schachter, McDonald, Craig
Start Date: 03/01/2023
End Date: 02/28/2025
Effort: 1.40 cal months

What other organizations were involved as partners?

No additional partners were involved in the study. Spaulding Rehabilitation Hospital (primary site) and Dephy Inc (sub-awardee, responsible for the robotic platform used in the study) are the only organization contributing to the project.

8. SPECIAL REPORTING REQUIREMENTS

N/A

QUAD CHARTS:

See attachment.

9. APPENDICES:

None.

Predicting Clinical Outcomes Using a Physical Platform to Simulate Orthoses with Different Characteristics

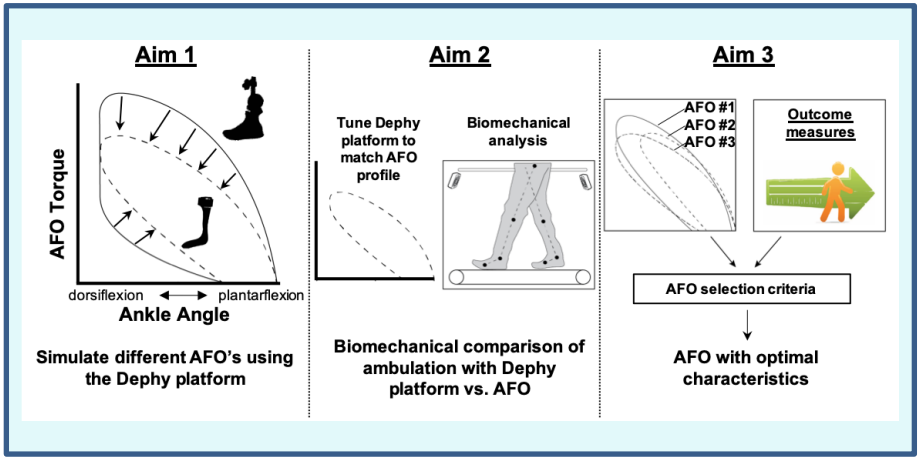
PI: Paolo BONATO, PhD **Org:** Spaulding Rehabilitation Hospital **Award Amount:** $350,000

Study Aim

- Determine the suitability of the Dephy platform to simulate AFO's with different characteristics on a test bench
- Evaluate the feasibility of using the Dephy platform during ambulation in stroke survivors to simulate the characteristics and performance of their habitual AFO.
- Explore the feasibility of using the Dephy platform to simulate the characteristics and performance of different AFOs and select the most suitable AFO characteristics on a subject-by-subject basis.

Approach

We propose to utilize the ExoBoot developed by Dephy Inc as a platform to simulate the mechanical characteristics of different AFO's and assess which one is ideally-suited for a given individual.



Timeline and Cost

Activities	Y1	Y2
Prepare Dephy Platform for Simulation AFO's		
Data for Simulation Habitual AFO's		
Data for Simulation Alternate and Powered AFO's		
Data Analyses and Reports		
Estimated Budget ($K)	**$219**	**$131**

Goals/Milestones

Y1 Goals

☒ Prepare Dephy platform for simulation of AFOs (see report for details)

☒ Start data collections with human subjects

Y2 Goals

☐ Complete data collections with human subjects (ongoing, will continue using lab funds)

☐ Analyze data to determine the suitability of the proposed approach to identify optimal AFO's on a subject-by-subject basis (ongoing, will continue using lab funds)

Budget Expenditures to Date

Projected Expenditures: ~ $350,000

Actual Expenditures: ~ $350,000