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14. ABSTRACT
The long-term objective of this project is to improve the outcomes of robot-assisted exercise interventions for limb salvage patients who suffered HELETs and facilitate return to work/duty. The project will fill current gaps in powered AFO technology by establishing novel ML methods to enable patient tailored AFO designs and self-adaptive active AFO assistance. Within the current reporting period, the project team has developed an efficient AFO design workflow, which leverages low-cost laser scan technology, open-source CAD software, and AM processes to generate orthotic designs that conform to the leg morphology while requiring minimal labor. After securing IRB approval from USAMRMC, the workflow was validated by 3D-printing subject-tailored AFOs for 10 able-bodied individuals. Bench tests are underway to characterize mechanical properties of the new AFOs, following which the team will carry out comfort tests with able-bodied individuals and HELET patients. Concurrently, the team has developed a removable, lightweight, high-performance cable-driven actuator and implemented a closed-loop controller that demonstrated excellent torque bandwidth under a wide range of loading conditions. Using ML stochastic models, the team also developed a subject-agnostic estimator of the biological ankle moment, which was tested at different walking speeds during treadmill tests with 10 able-bodied individuals. In near future, the ankle-moment estimator and the torque controller will be integrated into a reinforcement-learning (RL) assistive controller for the AFO, to be tested in able-bodied individuals and HELET patients.

15. SUBJECT TERMS
high-energy lower extremity trauma (HELET), ankle-foot-orthosis (AFO), machine learning (ML) additive manufacturing (AM)

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1. INTRODUCTION

The project proposes to address two major drawbacks of current orthotic technology for patients with reconstructed lower limb, namely the lack of automated procedures to fabricate AFOs that conform to a patient's body, to improve comfort, and the lack of control methods to self-tune the level of assistance of a powered AFO to the user's changing motor performance, to promote their active participation in the therapeutic exercises and ultimately enhance rehabilitation outcomes. The project team has been developing a new ML assisted design methodology for powered AFOs and a new ML-based optimal policy search to enable self-tuning of the AFO's assistive forces. Obtaining patient-tailored orthotic designs will help reduce excessive pressure points in the wearer's skin and relative motions between the human limb and the orthosis due to poor fit, thereby improving comfort and, ultimately, patient acceptance/satisfaction. Self-tuning the AFO assistance to the wearer's motor abilities will discourage users' over-reliance on the AFO and instead promote their active engagement in the walking exercises, which is a critical enabler of motor recovery. In the second part of the project (years 3 and 4) the team will test the proposed design and control methods at Kessler Institute for Rehabilitation with a group of individuals who sustained lower leg reconstruction. First, a single-session study will be carried out to assess safety, reliability, and comfort. Then, the clinical feasibility of the robotic intervention will be evaluated by studying pre/post changes in participants' self-selected walking speed and other standardized functional outcomes, following a 6-week rehabilitation program.

2. KEYWORDS

ADHDP: Action-Dependent Heuristic Dynamic Programming
AFO: Ankle-Foot Orthosis
AM: Additive Manufacturing
BLDC: brushless DC (motor)
CWS: Comfortable Walking Speed
DAQ: Data Acquisition Board
DEXter: Design Space Exploration Framework
DSCE: Design Space Composer and Explorer
FSR: Force Sensitive Resistors
GPR: Gaussian Process Regression
HELET: High-Energy Lower Extremity Trauma
IMU: Inertial Measurement Unit
LOOCV: Leave-one-out cross validation
MFO: Multi-Fidelity Optimizer
ML: Machine Learning
MLR: Multivariate Linear Regression
NRMSE: Normalized Root Mean Square Error
pHRI: physical Human-Robot Interaction
RL: Reinforcement Learning
ROM: Range of Motion
SEA: Series Elastic Actuator

3. ACCOMPLISHMENTS

This project has 3 major goals:

- ***establish a novel machine-learning (ML) assisted design methodology for additive-manufacturing (AM)-based, patient-tailored powered ankle-foot orthoses (AFOs)*** and characterize mechanical performance and perceived comfort of the generated designs.
- ***develop a new reinforcement-learning (RL) controller to automatically adjust the AFO assistance level on-the-fly***, during overground walking exercises, and evaluate its immediate and short-term training effects on the wearer.
- ***assess safety, reliability, biomechanical function, and clinical feasibility of the new patient-tailored AFOs*** at the exploratory level through single- and multi-session clinical tests with patients who suffered a high-energy lower-extremity trauma (HELET).

These 3 goals map to 3 corresponding research tasks, each consisting of several subtasks, as illustrated in the SOW table below. Percentage completion for each subtask (**as of the end of the progress report period YR1**) are indicated in the last column. Milestones are indicated in red.

	Timeline	Stevens (DZ Lab.)	Stevens (KP Lab.)	Kessler (KN Lab.)	% Compl.
Res. Task 1: ML-aided Design Methodology for Improved User Comfort of Powered AFO	Months				
Subtask 1 – Startup and IRB Approval (KF, SIT and USAMRMC ORP HRPO)	1-6	X	X	X	**100%**
Milestone 1 – IRB approval secured	6	X	X	X	**100%**
Subtask 2 – Design Space Composer and Explorer (DSCE)	1-9		X		**95%**
Subtask 3 – Multi-Fidelity Optimizers (MFO)	4-12		X		**90%**
Subtask 4 – 3D Scans and Fabrication of **α** Prototype (14 Able-bodied + 5 HELET)	10-15	X	X		70%
Subtask 5 – Mechanical Performance Testing of **α** Prototype	10-15	X	X		80%
Subtask 6 – Comfort & Fit Testing (14 Able-bodied + 5 HELET)	10-15	X	X	X	10%
Subtask 7 – Data Analysis & Manuscript Preparation (New Design Methodology)	16-18	X	X	X	0%
Res. Task 2: Individualized Powered AFO Assistance to Promote Gait Rehabilitation Outcomes	Months				
Subtask 1 – Fabrication of Control/Actuation Unit for Powered AFO	1-6	X			**95%**
Subtask 2 – Development of Ankle Moment Estimator	7-9	X			**95%**
Subtask 3 – Design and Implementation of RL Controller (**α** Prototype)	7-12	X			**66%**
Subtask 4 – Controller Evaluation: Fixed-gain vs. ILC vs. RL Controller (14 Able-bodied)	10-15	X	X		0%
Subtask 5 – Data Analysis & Manuscript Preparation (New RL Controller)	16-18	X	X	X	0%
Milestone 2 – Design methodology & RL control (**α** prototype) validated with 14 able-bodied and 5 HELET individuals, 2 technical papers submitted (design methodology, RL control)	18	X	X	X	
Subtask 6 – Development of β1 Prototype – Improve Design Methodology & RL Control Based on Results and User Feedback	16-24	X	X		0%
Res. Task 3: Clinical Feasibility of Patient-tailored powered AFO	**Months**				
Subtask 1 – Clinical Study – Enrollment & Scheduling	22-36			X	0%
Milestone 3 – Revisions to design/control (β1 prototype) completed, patient enrollment for clinical study started	24	X	X	X	
Subtask 2 – 3D Scans and β1 Prototype Fabrication (16 Controls, 16 HELET)	25-36	X	X		0%
Subtask 3 – Cross-sectional Study with β1 Prototype – Assess Safety, Reliability, Immediate Effects on Gait, Comfort (Single RAGT Session)	25-36			X	0%
Subtask 4 – Data Analysis & Manuscript Preparation (Safety, Comfort, Immediate Effects of AFO)	34-39	X	X	X	0%

Subtask 5 – Development of β2 Prototype – Refinements to Design Methodology and RL Control, Based on Results & User Feedback	34-39	X	X		0%
Milestone 4 – Cross-sectional clinical study completed, 1st clinical paper submitted (safety, comfort, immediate effects of AFO), further AFO refinements completed (β2 prototype)	39	X	X	X	
Subtask 6 – Pilot Longitudinal Study with Beta 2 Prototype – Clinical Feasibility (5 HELET; 6-week RAGT program)	37-42			X	0%
Subtask 7 – Data Analysis & Manuscript Preparation (Clinical Feasibility)	43-48	X	X	X	0%
Milestone 5 – Pilot longitudinal study completed, 2nd clinical paper submitted (clinical feasibility)	48	X	X	X	

What was accomplished under these goals?

1) Major Activities

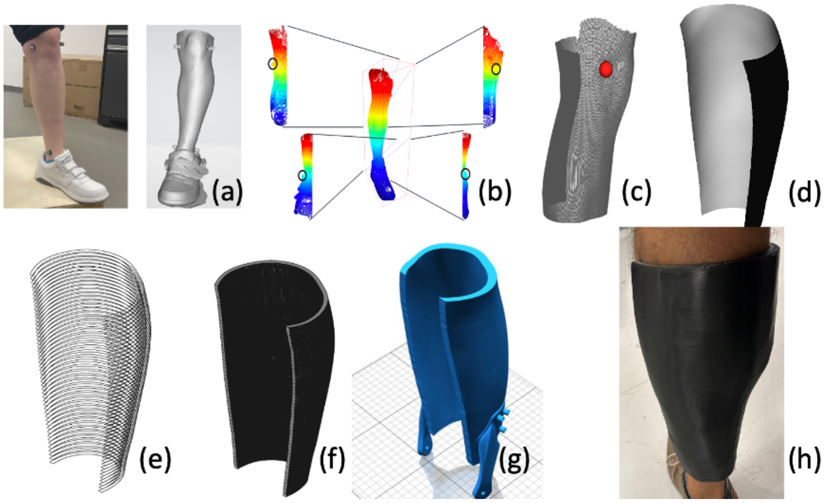


Fig. 1 – (a) Photo and leg scan point cloud of a healthy subject showing spherical markers placed on the knee and ankle joints. The point cloud is generated using a procedure described in a video communicated to the entire team. **(b)** The first tool in the DSCE methodology detects the locations of the spheres in the lower-left, lower-right, upper-left, and upper-right quarters of the point cloud **(c)** Spheres are detected using RANSAC algorithm and the coordinates of their centers are established **(d)** Point cloud is cropped and only the back of the leg is retained. The designer can further crop below the knee and above the ankle by specifying cut plane heights. An approximate surface is fitting using Ball Pivoting algorithm or using MFO algorithms. **(e)** NURBS curves are created on several cut planes and curves are closed with offsetting techniques. **(f)** Solid CAD model of shank created by lofting the closed NURBS curves **(g)** Assembly of the ankle components to the shank solid model. **(h)** Subject wearing a 3-D printed shank component to test the fit.

During this reporting period (**YR1**), the team has developed a new actuation unit for the powered AFO, which features a co-located cable-driven SEA powered by non-collocated brushless synchronous motor. For best mass distribution, the brushless motor is housed inside a custom-designed backpack unit, along with a motor driver, a battery pack, a controller, and a custom-engineered DAQ board. The team also developed a low-level torque controller for the SEA, and a ML ankle moment estimator informed by underfoot FSRs and IMU. Frequency response analysis and treadmill walking tests were carried out to evaluate the performances of the AFO actuator and the ankle-moment estimator, respectively, yielding encouraging results. On the design methodology side, the team developed a new digital design workflow that leverages low-cost laser scan technology and open-source CAD software to generate user-tailored AFO designs that conform to the leg morphology. Starting from the definition of an efficient 3D scanning procedure, the team has developed an automatic procedure with minimal user input to identify bony landmarks that guide the definition of the AFO shape and the position/orientation of key AFO components (e.g., ankle joint bearings, Velcro straps, etc.) relative to the user's leg. Major activities can be summarized as follows:

- Pochiraju's team at SIT created a scan-to-shank/ankle component synthesis pipeline informed by the patient's leg scan point cloud (part of **Task 1.2**) and requires minimal designer intervention. This multi-step pipeline includes methods for minimizing the scanning time, tools for generating low-dimensional surface representations from the scan point clouds, automatic shank geometry generation, and assembly of ankle and shoe parts into an anatomically defined reference frame. A demonstration video of the scanning method was created and shared with the project team. The team also reviewed 3D printing processes for producing the shank, ankle, and shoe modules with three short-filled nylon material systems. A material modulus and strength allowable table was created to be used in the analysis of compliance and failure behaviors. The design-allowable database assists designers in sizing the AFO and customizing the compliance required for the best patient fit. A system-level Finite Element Method (FEM) analysis was conducted and interfaced with the optimizers (**Task 1.3**) to determine the thickness and material-infill variations that produce the compliance as needed at the strap and ankle areas. The outcome of the design space composition task is the compose-HELET framework (DSCE and MFO: **Tasks 1.2 and 1.3**), which is a pipeline of six tools. These tools enable reorienting the data into an anatomical reference frame by identifying spherical markers, cropping the point data to retain the back of the leg, fitting a smooth surface, synthesizing the shank module geometry, and assembling the ankle and boot parts. They streamlined the design workflow that enables the generation of an individualized calf module from 3D scans of a person's lower leg (**Fig. 1**).

- Zanotto's team at SIT developed a new AFO design (**Task 2.1**), featuring a removable, lightweight, high-performance cable-driven SEA located next to the lateral malleolus. The SEA is remotely actuated from a backpack unit using a Bowden cable loop to transfer plantar- and dorsi-flexion torques to the ankle joint. The backpack unit, whose fabrication is being finalized, contains battery, motor driver, BLDC and driving spool, cable tensioning mechanism, DAQ, and control board. Bench test characterization indicated that this fist-of-its-kind SEA shows an excellent linear response with high torque capacity (+/-18Nm) and ample passive ROM (+/-25deg). Frequency response analysis demonstrated excellent closed-loop torque bandwidth even at moderate-to-high loading conditions. Using ML stochastic models (GPR), Zanotto's team also developed a subject-agnostic estimator of the biological ankle moment (**Task 2.2**), which was evaluated at different speeds (85%CWS to 115%CWS) during treadmill tests with 10 able-bodied individuals. Data-series from an 8-cell FSR array and a 6-DOF IMU, both embedded in smart insoles, are fed into the GPR models, resulting in very good accuracy (<9% RMSE). In the near future, the ankle-moment estimator and the torque controller will be integrated into a reinforcement-learning (RL) assistive controller for the AFO, to be tested in able-bodied individuals and HELET patients (**Tasks 2.3, 2.4**).
- Pochiraju's and Zanotto's team at Stevens Institute of Technology jointly worked on a new design of the powered AFO shell. The revised design (**Fig. 1**) streamlines the workflow required to efficiently develop 3D-printed orthoses that conform to the wearer's leg morphology and leverages the advantages of continuous-fiber 3D printing, thereby achieving the required strength with a lighter structure.
- Nolan's team at Kessler Foundation (KF) was responsible for developing a unified IRB protocol, which was approved by OHRO on 04/17/23. As the team continues working on the project into Q5, Nolan's team will lead the recruitment of 19 study participants and schedule their leg scan, comfort test, and walking sessions with the AFO.

2) Specific Objectives

- **Task 1.1 – Startup and IRB Approval** *[100% completion rate]*. Nolan's team at Kessler Foundation (KF) developed a unified IRB protocol for the project team which was approved by the KF IRB on 11/22/2022 and was submitted to HRPO on 12/14/22. Following the feedback received from OHRO on 01/19/23, a revised protocol was developed and shared with OHRO on 03/09/23. OHRO recommended submitting the revised protocol to KF IRB on 03/15/23. The revised protocol was approved by KF IRB on 04/11/23, and the KF approval letter was shared with OHRO that same day. OHRO issued the final approval letter on 04/17/23.
- **Task 1.2 – Design Space Composer and Explorer (DSCE)** *[95% completion].* The team developed a DSCE methodology that invokes six tools to process the data collected during the scanning step and synthesize CAD models for the orthosis components. The first tool set up an anatomical reference frame by detecting spherical markers in the scan point cloud. The scan is divided into four segments, with points corresponding to one marker in each segment. With the user identifying one or more points on a marker sphere, the first-step algorithm identifies nearest neighbor points. Using the Random Sample Consensus (RANSAC) method, the algorithm fits a sphere. Once the marker spheres are identified, four reference points are set up at the centers of the marker spheres. The four points (A-B at the ankle and C-D at the knee) set up a slicing plane that separates the front and the back of the leg scan. The second tool crops and denoises the segment of the point cloud that retains the back of the leg geometry. In step #3, the Ball Pivoting algorithm generates a smooth surface representation from the back of the leg point cloud. The surface representation will be a triangular mesh at the end of Step 3, which will be converted into a further smoothed series of optimally fitted Non-Uniform Rational B-Spline (NURBS) curves in Step 4. The triangular mesh is cut with parallel planes (users can select the number of cuts to tune the resolution), and a NURBS curve is fitted on each plane. In step 5, two different methods are used to construct closed cross-sections and lofted together to synthesize the solid geometry of the shank part. The closed sections are created by offsetting the NURBS curves using either a uniform thickness offset, or a circular geometry offset. The inside and outside surfaces have the same geometry in the uniform thickness offset, but a user-defined distance offsets the curves. In the circular geometry offset, the outer shell forms an arc of a circle, and the inner surface retains the patient's leg geometry. The cross-sections are then lofted together, and the to-end cross-sections are closed to form the solid model of the shank. In the last step, the ankle component is placed in the correct location and orientation and combined (Boolean union) with the shank geometry. While the thickness of the shank part near the ankle is determined to create an interference with the ankle part, the thickness at the top is determined by the compliance needed to strap the patient into the orthotic properly. The design produced by the six-step pipeline meets several geometric and compliance constraints and allows user-specified parametric variations. We intend to optimize the user-settable parameters based on maximizing patient comfort. We are working on methods for quantifying user comfort that can define the objectives for comfort optimization.
- **Task 1.3 – Multi-Fidelity Optimizers (MFO)** [90% completion rate]. Multiple optimization problems have been set up and solved in the DSCE pipeline. First of such optimizations is the problem of fitting a smooth

surface to a noisy, non-uniformly sampled, and incomplete point cloud. The problem of surface approximation is formulated as follows: Given a discrete point set $P = \{p \in R^3\}$, each point p represents a coordinate in Euclidean space. The objective is to recover the continuous surface S^* from where points p can be observed. Since there can be multiple solutions, the problem is ill-posed. To bound this problem, we need to provide additional information as a loss function.The technique selected as a loss function must help discover surface S, a geometry-aware approximation to S^*. The problem stated as a regularized optimization can formulated as $\min L(S; P) + \lambda R(S)$, where L is the difference between the proposed surface S and the observed point cloud P. The second term has two elements: R, the regularizer, which constrains the solution with a certain prior based on the geometry of the surface, while λ is just a scalar value representing a penalty. The optimization maximizes the fidelity of surface approximation by minimizing the difference between S and P. The second optimization is a simpler least squares regression to fit the points and edges in a cut plane and the surface generated from the point cloud to determine a NURBS curve. The knot points for the best fit NURBS curve are obtained by minimizing the square distance between the NURBS curve and the plane-surface intersection points. The third optimization problem solved during the DSCE phase is determining the thickness of the shank module so that it meets the geometric and stiffness constraints. The third problem entails finding feasible solutions for the thickness profiles which satisfy all the imposed constraints. The objective of maximizing comfort to this problem is yet to be added. *Work is in progress for proper parametrization of the patient comfort so it can be added to the shank assembly phase of the design composition. We are exploring strategies for using finite element analysis using high-fidelity* (Caveman, developed by Corvid Technologies) *and low-fidelity (beam on elastic foundation) methodologies.* The low-fidelity strategy models the contact response of the human limb as a map of pointwise forces of the elastic foundation. We are investigating methods for calibrating the elastic stiffness from the high-fidelity computational model or using pressure pad experimentation.

- **Task 1.4 – 3D Scans and Fabrication of α Prototype:** The team generated leg scans from 12 healthy subjects. The scanning procedure has been documented in a video and communicated to the entire team. The data from six subjects was processed into patient-customized shank designs using the

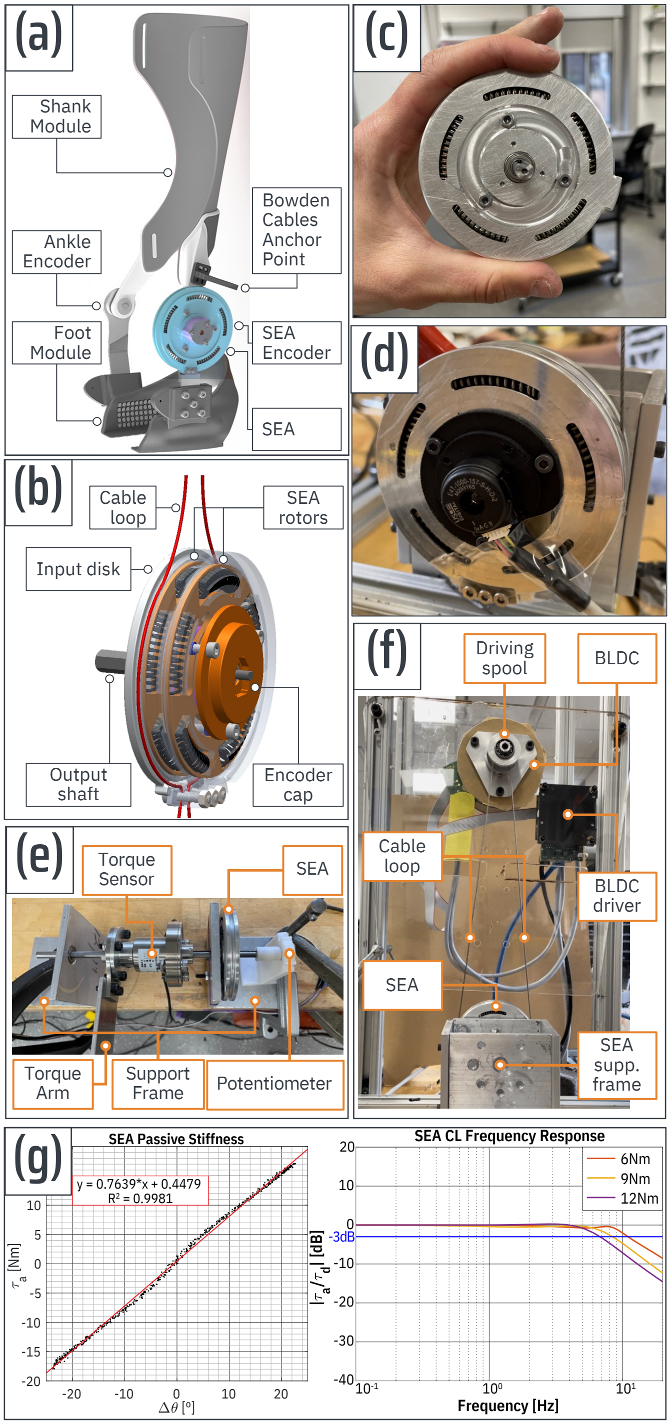
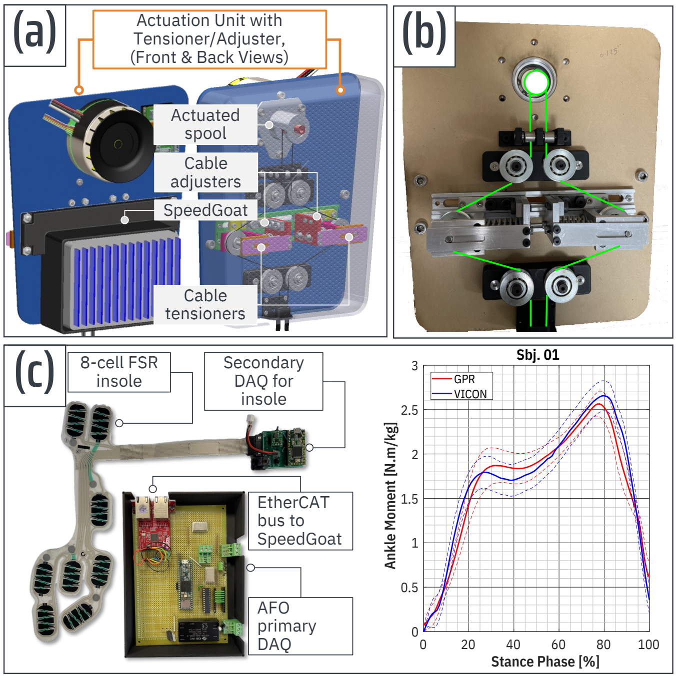


Fig. 2 – (a) CAD rendering of a representative subject-tailored AFO, showing the finalized SEA (cyan). **(b)** CAD rendering of the finalized SEA, featuring two paired rotors to increase passive stiffness (and therefore the range of applicable SEA torques) without sacrificing the SEA ROM. **(c-d)** Fabricated SEA shown with and without its miniature optical encoder. **(e-f)** experimental setup used for characterizing the SEA passive stiffness and its closed-loop torque performance, respectively. **(g-LEFT)** The SEA demonstrates a linear torque/angle behavior across its entire ROM. The maximum applicable torque in either direction is 18Nm, which corresponds to approximately 15% of the peak biological ankle torque for a 165lbs male walking at CWS. **(g-RIGHT)** The frequency response of the SEA closed-loop torque control demonstrates large torque bandwidth even at high load (f_{BW}=11.4Hz @6Nm, f_{BW}=8.3Hz @9Nm, f_{BW}=6.1Hz @12Nm), indicating good torque tracking performances in dynamic conditions.

DSCE methodology described in task 1. The assembly process for the shank with the ankle component has been established with three screws and ultrasonically welded nuts encapsulated into the 3D-printed shank component. The team designed and 3D printed prototypes of three major components of the orthotic: the shank, the ankle part, and the shoe brace. The team plans to use force sensor sheets to determine the contact pressures and conduct experiments to assess wearability and patient comfort with healthy subjects soon.



(d)

	MLR_1	MLR_2	MLR_3
NRMSE (SD)	12.53% (4.11%)	9.82% (3.44%)	**9.61% (3.24%)**
FSRs	sum of 8	HeeL, HeeR, Met3	HeeL, HeeR, Met3
Subj. Weight	√	√	-
Shoe Size	√	√	√
ang. vel. (ML)	√	√	√
Mod. Type	pointwise	pointwise	pointwise

	GPR_1	GPR_2	GPR_3	GPR_4
NRMSE (SD)	13.37% (4.36%)	12.06% (4.34%)	10.53% (3.54%)	**8.83%(2.91%)**
Kernel	Squared exp	Rational quad.	Rational quad.	Rational quad.
FSRs	sum of 8	sum of 8	HeeL, HeeR, Met3	HeeL, HeeR, Met3
Subj. Weight	√	√	√	-
Shoe Size	√	√	√	√
ang. vel. (ML)	√	√	√	√
Mod. Type	stance %	stance %	stance %	stance %

Fig. 3 – (a) Revised design of the AFO back actuation unit, featuring a new cable tensioner/adjuster to avoid cable slacking when the direction of the applied torque is reversed. **(b)** Actuation unit being assembled in Zanotto's laboratory, with green lines indicating the expected cable routing path. **(c-LEFT)** Two data acquisition (DAQ) boards were developed to collect real-time ground reaction forces from an 8-cell insole (left). These signals, along with data from an on-board IMU, are used as inputs to inference models that estimate the ankle moment in real-time. **(c-RIGHT)** output of the best-performing GPR model for a representative subject, comparing estimated ankle moment (red) with the ground truth from the force plates (blue). Solid lines correspond to the average ankle moment estimated at three speeds (CWS, 85%CWS, 115%CWS) during treadmill walking. **(d)** NRMSE for different linear (MLR-top) and learning-based (GPR-bottom) regression models, with the most accurate model for each type highlighted in red. The best GPR model outperformed the best MLR model. Additionally, for both regression models, best accuracy was achieved when including mediolateral angular velocity, 3 FSR cells (two under the calcaneus, one under the third metatarsal head), as well as the wearer's shoe size as inputs to the model.

- **Task 2.1 – Fabrication of Control/Actuation Unit for Powered AFO** *[95% completion rate]*. During this project reporting period, the team has developed a new lightweight AFO actuation unit. The unit consists of a removable, lightweight, high-performance cable-driven SEA located at the distal lower leg, next to the lateral malleolus (**Fig. 2a**). The SEA features an innovative double rotor design that is rigidly connected to the output shaft, and an input pulley that doubles as the SEA housing. Torques are transmitted from the input pulley to the output shaft through two sets of linear compression springs arranged circumferentially (**Fig. 2b**, **2c**). This results in a compact (18.5mm thick, 82mm diameter) and lightweight (0.18 kg) actuator that can exert relatively large torques (up to 18Nm, which corresponds to 15% of the peak ankle torque for a 75kg (165lbs) male walking at CWS, in line with state-of-the-art ankle exoskeletons) while guaranteeing an ample passive ROM (+/- 25 deg), for best user safety. Interaction torques are measured via a high-resolution (4000 PPR) miniature optical encoder (**Fig. 2d**). The SEA passive stiffness was determined via bench-testing using a precision load-cell as reference (**Fig. 2e**). Results showed excellent linearity across the entire ROM, as well as negligible hysteresis (**Fig. 2g**, **LEFT**). Subsequently, a cascaded torque-velocity PI controller was implemented in a compact control unit (SpeedGoat Unit Real-Time Target Machine). The closed-loop frequency response of the SEA was evaluated via bench testing (**Fig. 2f**) by applying a desired torque input (chirp signal swiping 0-20Hz over 30 seconds), at different amplitudes. The frequency response of the measured-over-desired-torque transfer function demonstrates excellent torque bandwidth even at high load (f_{BW}=11.4Hz @6Nm, f_{BW}=8.3Hz @9Nm, f_{BW}=6.1Hz @12Nm), indicating good torque tracking performances in dynamic conditions. In the intended application, the SEA will be powered by a non-collocated BLDC motor via a Bowden cable loop. To this end, the team designed a compact backpack actuation unit that houses Li-Po battery, motor driver, BLDC motor and driving spool, cable tensioner/adjuster, custom-engineered DAQ, and SpeedGoat Unit. The cable tensioner/adjuster will make it easier for wearers with limited mobility to don the AFO and keep the actuation cable loop taut during operation, (**Fig. 3a**). The new unit features a cable adjuster that allows the cable to be slack during the AFO donning procedures, and a cable tensioner controlled by pre-loaded springs, which keeps both sides of the cable loop taut, regardless of the direction of the SEA applied torque. The symmetric configuration reduces the reaction forces on the idle pulleys, thereby reducing friction losses. The backpack unit is currently being assembled (**Fig. 3b**). The team is currently working on determining the best cable routing path for the Bowden cables delivering torques from the backpack unit to the ankle SEA, following which the powered AFO and the backpack unit will be integrated into the same device (alpha prototype), thereby completing this task.

- **Task 2.2 – Development of Ankle Moment Estimator** *[95% completion rate]*. The team designed and fabricated two customized DAQ boards for the powered AFO, which enable real-time acquisition of IMU data and underfoot ground reaction forces through a 8-cell array of FSRs embedded into a shoe insole. These signals serve as inputs to the ankle moment estimator (**Fig. 3c, LEFT**). To develop the estimator, the team compared the performance of several linear (MLR) and learning-based (GPR) regression models. To train and test these models, tests were carried out with 10 able-bodied individuals, as they walked on a treadmill instrumented with force plates at different speeds (85%CWS, 100%CWS, and 115%CWS). Ground-truth data were obtained from the force plates and a marker-based motion-capture system using research-grade software (VICON Nexus Gait Plugin) to carry out inverse dynamics. Furthermore, in order to derive a subject-agnostic (generic) estimator that would apply to a large range of walking speeds, regression models were trained and tested using LOOCV (i.e., a model is trained using all walking data from (N-1) individuals, and tested on the remaining "N-th" individual over the range of walking speeds for that individual). The best-performing ankle estimation model, shown in **Fig. 3c, RIGHT** for a representative subject, achieved an overall accuracy of 8.83% in the subject pool, as measured by the normalized root-mean-square error (NMSRE). Due to the vast explanatory capability of learning-based regression models, GPR outperformed MLR for any given set of input features. Additionally, when analyzing different combinations of input features, it was found that including mediolateral angular velocity, 3 FSR cells (two under the calcaneus, one under the third metatarsal head), as well as the wearer's shoe size resulted in best performance (**Fig. 3d**). The team is currently working on combining the developed ankle moment estimator with a stance phase estimator, which will enable the real-time application of the GPR model, thereby completing this task.
- **Task 2.3 – Design and Implementation of RL Controller (α Prototype)** *[66% completion rate]*. Having completed the implementation of a closed-loop torque controller for the SEA and the ankle moment estimator, the team has two of the three building blocks required for the RL controller. The next step will include the implantation of an ADHCP model, which will be used to generate a stride-dependent RL assistive controller.

3) significant results and key outcomes

- Nothing to report.

4) other achievements

- IRB approval by OHRO.

5) Stated goals not met

The project team has made significant progress on both Res. Task 1 and Rest. Task 2 over the past 12 months. However, due to initial delays with machining custom-designed parts, the development of the AFO alpha prototype (Tasks 2.1~2.2) has taken longer than originally expected, pushing Task 2.3 into Q5. The team plans to recover these slight delays by involving additional graduate research assistants (master's students) in the research efforts.

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

So far, the project has involved one research engineer, 5 graduate research assistants (PhD students) and 3 undergraduate research assistants (summer interns), in addition to 3 project PIs and a clinical coordinator. Students learned how to carry out user-inspired biomechatronic design for physical Human-Robot Interaction (pHRI). In addition to advanced mechanical and electrical design skills, they learned how to design and implement a real-time control architecture that ensures safe interaction with the user. Students also learned how to embed learning-based methods into a design/fabrication workflow for additive manufacturing. Lastly, graduate students learned how to design and carry out experiments with able-bodied individuals to train supervised learning models and to evaluate their biomechatronic designs. Lastly, the learned how to present the project results to a technical audience, both in oral and written form.

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?

- **Complete the development of the Design Space Composer and Explorer (DSCE, Task 1.2) and the analysis on Multi-Fidelity Optimizers (MFO, Task 1.3).** The DSCE tool is complete, but for some minor refinements to the pipeline due to changes in the ankle and shoe component designs. The DSCE pipeline has been tested on the scans of six healthy subjects, and the process is being validated on six more scans. The team will continue to refine and correct the algorithms as indicated by the quality of results produced over more scan datasets. The MFO task is awaiting the availability of quantitative experimental data on contact forces to formulate patient comfort metrics. The task remaining is the addition of objective functions that can capture the extent of patient comfort to the MFO. The team will be ready to design and perform such experiments when the passive orthotic prototypes are available. We anticipate the completion of the remainder of the effort during the next quarter.

- **Proceed with Task 1.4~1.6 (3D Scans and Fabrication of α Prototype, Mechanical Performance Testing of α Prototype, Comfort & Fit Testing).** First, the project team will complete 3D scans of the lower extremities for the remaining 4 able-bodied individuals and 5 HELET patients recruited at KF, following the procedure developed in Task 1.2. Subsequently, the scan-to-CAD procedure finalized in Task 1.2 will be used to produce AFO prototypes tailored to each study participant via additive manufacturing techniques. Next, Pochiraju's and Zanotto's teams will characterize the mechanical properties of these devices using standard testing equipment. Subsequently, human tests will be carried out on the fabricated AFO prototypes to assess comfort and fit, using dedicated research-grade instrumentation (Xsensor) to quantify the interaction between the AFO structure and the user's skin. We expect the last two tasks to be completed within Q5.
- **Complete Task 2.3 (Design and Implementation of RL Controller for α Prototype), and Task 2.4 (Controller Evaluation: Fixed-gain vs. ILC vs. RL Controller)**. Upon completion of Tasks 2.1 and 2.2, Zanotto's team will have developed all the building blocks required to assemble an integrated wearable system (**α** Prototype) and develop a stride-dependent ADHDP controller, which is an actor/critic RL method for optimal policy search (Task 2.3). First, the team will perform preliminary tests on the **α** Prototype using a preliminary zero-torque controller. Subsequently, the ADHDP controller will be implemented to help the wearer achieve a target walking speed, using the estimated ankle torque as a reference to modulate the amount of assistance to be provided to the user. A standard ILC controller will also be implemented for comparison. After implementation and early testing, the team will start collecting data on 14 able bodied individuals to compare the immediate effects of the two controllers on the user's gait. We expect these tasks to be completed within Q5.

4. IMPACT

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

So far, the project has generated an innovative SEA design for physical Human-Robot Interaction (pHRI) applications requiring high torque and large ROM. The project has also resulted in a new digital design workflow that leverages low-cost laser scan technology and open-source CAD software to produce user-tailored AFO designs that align with the wearer's anatomical axes and conform to their leg morphology. These contributions lie at the intersection between wearable robotics and product design/manufacturing.

What was the impact on other disciplines?

We expect the findings from this project, once substantiated by additional experimental data over the next reporting period, will have the potential to affect future orthotics and prosthetics technologies.

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

Due to initial delays with machining custom parts, the development of the AFO alpha prototype (Tasks 2.1~2.2) has taken longer than expected, delaying Task 2.3 until Q5. The team has already reduced the impact of these delays by outsourcing most of the machining tasks to external vendors. While these delays are likely to affect Tasks 2.4 and 2.5, which depend on Task 2.3, the team will make up for these delays by hiring additional master's students to help with the research.

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.
Nothing to Report.

Significant changes in use of biohazards and/or select agents
Nothing to Report.

6. PRODUCTS

Publications, conference papers, and presentations

Nothing to Report (we expect the first technical publication to be submitted during Q6).

Website(s) or other Internet site(s)

Nothing to Report.

Technologies or techniques

So far, the project has produced a first-of-its-kind rotary SEA combining linear response, negligible hysteresis, high torque output, and large ROM, within a compact and lightweight package. The project has also resulted in a new digital design workflow that relies on low-cost laser scan technology and open-source CAD software to produce user-tailored AFO designs that align with the wearer's anatomical axes, conform to their leg morphology, and can be fabricated with affordable 3D printers. These contributions will be the object of technical publications to be submitted by Q6.

Inventions, patent applications, and/or licenses

Nothing to Report.

Other Products

Nothing to Report.

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Name:	*Damiano Zanotto*
Project Role:	*PI, Stevens Inst. of Tech.*
Researcher Identifier:	*0000-0003-3514-6889 (ORCID)*
Nearest person month worked:	*1*
Contribution to Project:	*Dr. Zanotto is responsible for Research Task 2 (Individualized Powered AFO Assistance) and for the overall project administration. During this reporting period, he has provided regular mentorship and guidance to the PhD students (M. Eraky, A. Li, Q. Zhao) responsible for the biomechatronic design and characterization of the ankle exoskeleton (AFO) and for the ankle torque estimator. He also participated in bi-weekly meetings with Pochiraju and his team to coordinate the work.*

Name:	*Kishore Pochiraju*
Project Role:	*Co-PI, Stevens Inst. of Tech.*
Researcher Identifier:	*0000-0002-0248-8658 (ORCID)*
Nearest person month worked:	*1*
Contribution to Project:	*Dr. Pochiraju is responsible for Research Task 1 (ML-aided Design Methodology for AFO). During this reporting period, he has provided regular mentorship and guidance to the PhD students (A. Teker, M. H. Rocha) responsible for optimizing the additive manufacturing procedures of the powered ankle orthosis (AFO). He also participated in bi-weekly meetings with Zanotto and his team to coordinate the work.*

Name:	*Karen J. Nolan*
Project Role:	*Co-PI, Kessler Foundation*
Researcher Identifier:	*0000-0002-4667-0873 (ORCID)*
Nearest person month worked:	*1*
Contribution to Project:	*Dr. Nolan is responsible for Research Task 3 (Clinical Feasibility of Patient-tailored powered AFO). During this reporting period, she led efforts related to the development and OHRO approval of the IRB protocol that will allow future tests with able-bodied individuals and HELET patients. She also participated in monthly meetings with the project team at Stevens and coordinated plans for the upcoming rectruitment of 5 HELET patients.*

Name:	Biruk Gebre
Project Role:	Research Engineer, Stevens Inst. of Tech.
Researcher Identifier:	0000-0001-5956-8280 (ORCID)
Nearest person month worked:	1
Contribution to Project:	Dr. Gebre is co-supervisor of the graduate students involved in this project. During this reporting period, he has been advising them in terms of mechatronic design and ongoing implementation of computational and generative design tools for the AFO design. He also participated in bi-weekly meetings with the project team at Stevens Institute.

Name:	Katherine (Goworek) Chervin
Project Role:	Senior Research Coordinator, Kessler Foundation
Researcher Identifier:	N/A
Nearest person month worked:	1
Contribution to Project:	Ms. Chervin serves as clinical research coordinator for the project. She has been working with Dr. Nolan on the development of the IRB protocol for the project and served as the main POC between the project team and both Kessler IRB and HRPO, coordinating the protocol modifications requested by HRPO. She has also taken a lead on rectuiting HELET patients.

Name:	Mohamed Eraky
Project Role:	Graduate Student (PhD Program in Mech. Eng., Stevens Inst.)
Researcher Identifier:	N/A
Nearest person month worked:	12
Contribution to Project:	During this reporting period, Mr. Eraky has worked on the mechatronic design of the powered AFO and its actuation unit.

Name:	Aytac Teker
Project Role:	Graduate Student (PhD Program in Mech. Eng., Stevens Inst.)
Researcher Identifier:	N/A
Nearest person month worked:	12
Contribution to Project:	During this reporting period, Mr. Teker has worked on the optimization of the 3D printed structure of the powered AFO.

Name:	Suraj Bose
Project Role:	Undergraduate Student (BE Program in Mech. Eng., Stevens Inst.)
Researcher Identifier:	N/A
Nearest person month worked:	1
Contribution to Project:	During this reporting period, Mr. Bose has helped streamlining the workflow to generate 3D printed AFO parts directly from 3D scans, working closely with Mr. Teker and Dr. Pochiraju.

Name:	Rumi Loghmani
Project Role:	Undergraduate Student (BE Program in Mech. Eng., Stevens Inst.)
Researcher Identifier:	N/A
Nearest person month worked:	1
Contribution to Project:	During this reporting period, Mr. Loghmani has taken a lead in the mechanical and electrical design of the backpack actuation unit. He has been working closely with Mr. Eraky and Dr. Zanotto.

Name:	Itai Geller
Project Role:	Undergraduate Student (BE Program in Biom. Eng., Stevens Inst.)
Researcher Identifier:	N/A
Nearest person month worked:	1
Contribution to Project:	During this reporting period, Mr. Geller has taken a lead in the development of the ankle moment estimator. He also contributed to the mechanical design of the backpack actuation unit.

Name:	Andy Li
Project Role:	Graduate Student (PhD Program in Mech. Eng., Stevens Inst.)

Researcher Identifier:	*N/A*
Nearest person month worked:	*1*
Contribution to Project:	*During this reporting period, Mr. Li has worked on the development of the cascaded torque-velocity control architecture for the SEA and on its frequency response analysis.*

Name:	*Qingya Zhao*
Project Role:	*Graduate Student (PhD Program in Mech. Eng., Stevens Inst.)*
Researcher Identifier:	*N/A*
Nearest person month worked:	*1*
Contribution to Project:	*During this reporting period, Ms. Zhao led efforts related to the development of the ankle moment estimator. She carried out human tests with able-bodied individuals to acquire data that she later used to train and test MLR and GPR models.*

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

- Damiano Zanotto is PI of the NSF project titled "NSF/FDA SIR: Towards the Establishment of a Validation Framework for Wearable Motion Analysis Systems: Development and Evaluation of an Open-Design Sync Platform", Award Number:2229538, 09/01/2022-08/31-2024, Award Amount:

- Damiano Zanotto is PI of the NSF project titled "I-Corps: AI-Enabled Shoe Insoles to Assess Walking Function in Real Life Environments", Award Number:2322980; 04/01/2023-09/30/2024; Award Amount:

What other organizations were involved as partners?

Nothing to Report.

8. SPECIAL REPORTING REQUIREMENTS

The project Quad Chart is provided as a separate attachment.