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14. ABSTRACT The purpose of this project is to study the effects on bone health of exoskeleton-assisted gait in individuals with a complete spinal cord injury. Advanced biomechanical models of human locomotion are utilized to estimate the mechanical effects of the dynamic loading of the bone structures that takes place during exoskeleton-assisted gait. The estimated maximum energy equivalent strain is studied as a potential proxy of bone adaptation and correlated with high-resolution peripheral quantitative computed tomography data and with clinical measures (e.g. biomarkers of inflammation such as C-reactive protein and IL-6) that are collected longitudinally. The work carried out by the research team until now has been focused on the development of advanced biomechanical models. The research team is now scheduling data collections in study volunteers to start the experimental part of the project.					
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Introduction

While the scientific and clinical community has demonstrated a great deal of enthusiasm for the use of robotic exoskeletons to enable gait in individuals with a complete spinal cord injury, the health benefits of exoskeleton-assisted gait have not been studied and documented systematically. This project aims at starting to fill this gap. During the last year, the research team has developed advanced biomechanical models to estimate the mechanical effects on the bone structures of exoskeleton-assisted gait in individuals with a complete spinal cord injury. As we submit this annual report, we are scheduling study volunteers to initiate the experimental phase of the project. We anticipate gathering the first experimental data on exoskeleton-assisted gait in a first sample of individuals with a complete spinal cord injury in the next few weeks.

Keywords

biomechanical modeling, bone health, exoskeletons, gait, spinal cord injury

Accomplishments

What are the major goals of the project?

The study specific aims, as indicated in the Statement of Work, are the following:

- (1) To quantify the motions of and forces transmitted through the lower extremities during exoskeleton-assisted gait;
- (2) To explore the development of a model to predict the effects of regular exoskeleton-assisted gait on bone health, muscle mass, and functional outcomes.

Specific Aim 1 is associated with three major tasks: 1) to obtain human subject approval and prepare for the study; 2) to contact and screen prospective study participants; and 3) to enroll study participants and perform gait testing.

Specific Aim 2 is associated with two major tasks: 1) to explore ways of modeling the effects of exoskeleton-assisted gait; and 2) to perform data analysis.

What was accomplished under these goals?

Our research team has developed experimental procedures and modeling techniques suitable to collect and analyze data recorded during exoskeleton-assisted gait in

individuals with a complete spinal cord injury. In the following, we provide a summary of the techniques developed so far as part of the project.

The experimental set-up for the project relies upon two 6-channel force platforms (AMTI, Watertown, MA) embedded in a 12-m walkway that are used to record ground reaction forces and moments. Passive reflective markers are placed using double sided tape, both on the exoskeleton and on study volunteers. Because it will not be possible to place markers over anatomic locations covered by the Ekso, the calibrated anatomical system technique (CAST) approach will be used to model the lower extremities. This approach requires performing some anatomical calibration in order to calculate the position of the anatomical landmarks with respect to technical clusters of markers which can be freely placed on the user's segments. This approach allows estimating the position of anatomical landmarks even if covered by the exoskeleton.

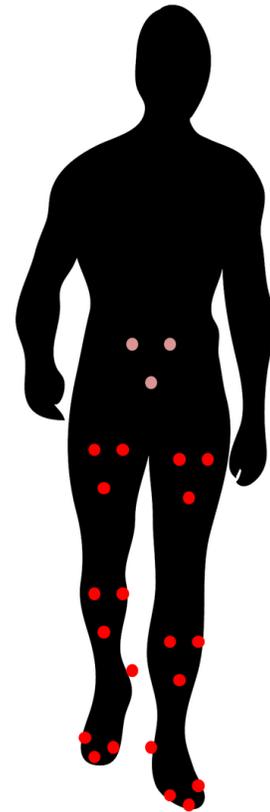


Figure 1. Schematic representation of how reflective markers are attached to different body segments to study the biomechanics of gait.

The experimental protocol that we have developed requires that one measures the mass and height of the subject as well as the length of the limbs in order to set up the Ekso. The latter is achieved by means of parametric tables provided by Ekso Bionics. Then a physical therapist helps the subject to don the exoskeleton. The data collection starts with the calibration of the anatomical landmarks which is carried out in a sequence of seated and standing positions. Several markers are placed on the exoskeleton to estimate its segment and joint kinematics.

For the dynamic trials the subject will have (see Figure 1):

- A cluster of three markers attached at the pelvis height, directly to the back of the exoskeleton, therefore assuming no relative motion between the user pelvis and the portion of the Ekso attached to it;
- A cluster of three markers attached to each thigh;
- A cluster of three markers attached to each shank;
- A cluster of three markers attached to each foot.

Anatomical landmarks such as tibial tuberosity, head of the fibula, medial and lateral epicondyles, medial and lateral malleolus, first/second/fifth metatarsal head, heel, anterior superior iliac spine and posterior superior iliac spine are calibrated at the

beginning of the data collection in static trials. Their absolute position is then computed from the clusters position and orientation obtained during the dynamic trials.

After the anatomical calibration, at least three walking trials with the subject stepping on a force platform with one foot are acquired. This is required for the computation of the inverse dynamics. A data flow diagram is shown in Figure 2.

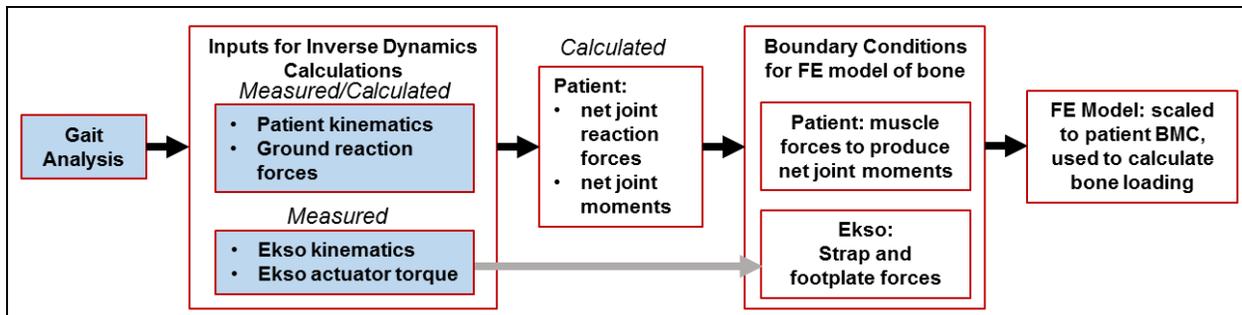


Fig. 2 Data collection and flow. Shaded boxes indicate data that will be collected and processed at Spaulding Rehabilitation Hospital. White boxes indicate calculations that will be performed at WPI.

Processed motion capture data, force plate data, and information about knee and hip actuator torques obtained directly from the Ekso during walking trials are transferred to Karen Troy’s team at Worcester Polytechnic Institute (WPI). Along with information about the patient and mechanical properties of the Ekso suit, masses and moments of inertia are used to calculate inverse dynamics of the patient+Ekso, henceforth referred to as the “lumped” model. Lumped inverse dynamics outputs consist of net joint reaction forces and net joint moments at the ankle, hip, and knee.

The net forces and moments from the lumped model are separated into Ekso and patient forces and moments by subtracting the Ekso-actuator torques and the torques required to move the Ekso suit through the dynamic motion. **The result consists of: 1) net joint reaction forces, moments, and kinematics for the patient only, and 2) actuator torques required to move the patient, which must be applied through the straps and foot-plates.**

For patients with complete spinal cord injury, we assume that joint moments generated by the subject arise from one of three possible sources: 1) passive muscle resistance, which may be worse if contractures are present; 2) spasticity; 3) experimental error. For the purpose of defining user safety parameters, we use a “worst-case” bone loading scenario in which we assume that subject’s joint moments arise from active spasticity

contractions. In this approach, we calculate muscle length change based on patient kinematics, and assign activations to muscles crossing the joint from largest muscle to smallest, until the calculated net joint moment is achieved. **The result consists of 1) muscle lines of action and activation forces during the gait cycle, 2) joint contact forces at the ankle, knee, and hip.** Note that joint contact forces are distinct from joint reaction forces, in that they represent the actual force transmitted from one joint surface to the next (e.g. tibia to femur), and are heavily influenced by muscle loading.

Joint contact forces, muscle forces, and Ekso strap and foot plate forces are summarized as time-series data. These datasets represent the forces applied to the bones of the lower extremities. Bone stress and strain are calculated using scaled finite element (FE) models. “Generic” FE models of the femur and tibia are scaled such that their material properties reflect average values for an individual with chronic spinal cord injury, based on measured bone mineral content (BMC). When available, dual energy x-ray absorptiometry (DXA) measures of subject-specific BMC are used to provide a subject-specific scaling factor. Boundary conditions consist of muscle forces, joint contact forces, and strap forces applied to the bone of interest. **The result is an estimate of the maximum energy equivalent strain, a scalar measurement shown to influence bone adaptation.** Factor of safety may also be calculated; however, we have not yet identified or validated an appropriate method to accomplish this goal.

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

The project is not meant to create training and professional development opportunities.

How were the results disseminated to communities of interest?

We intend to start disseminating the results of the project as soon as we have the opportunity to apply the algorithms developed by our team so far to data collected from study volunteers.

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

The primary goal of the next quarter of the project is to start collecting data from study volunteers and apply the biomechanical models developed so far by the research team to the datasets that will be collected from study volunteers. We anticipate deriving biomechanical estimates on mechanical strain on bone structures. We intend to

correlate the estimated mechanical strain data with imaging data and physiological data that we will gather longitudinally in the study population.

Impact

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

The work achieved so far has potential for significantly affecting the way exoskeleton-assisted gait is utilized in the clinic. Surprisingly, despite the enthusiasm in the clinical field for the use of robotic exoskeletons to enable gait in individuals with a complete spinal cord injury, clinical teams are not provided with appropriate tools to estimate or predict potential health benefits (e.g. bone health) associated with exoskeleton-assisted gait.

What was the impact on other disciplines?

The project that our team is carrying out is multidisciplinary in nature and hence the results of our studies are bounded to have an impact on multiple disciplines. Specifically, the biomechanical models that we have developed so far are expected to have a significant impact in the field of biomedical engineering. The primary impact of the experimental work that we are in the process of launching is expected to be clinical in nature. Overall, the combination of technical and experimental developments that are taking place as part of the project are expected to have a transformative impact on the clinical application of exoskeletons in individuals with a complete spinal cord injury.

What was the impact on technology transfer?

Although the project is not meant to generate results or products that would lead to a technology transfer, we anticipate that the methods that we have developed to estimate the effects on bone structures of exoskeleton-assisted gait will be of clinical interest. Hence, it is possible that the project might create technology transfer opportunities.

What was the impact on society beyond science and technology?

As we make progress with the project, we anticipate that the results of the studies to be carried out in individuals with a complete spinal cord injury will show the potential benefits of exoskeleton-assisted gait. Hence, the project might provide scientific evidence in support of the use of exoskeleton technology in individuals with spinal cord

injury. If our hypothesis that this technology has a positive impact on the health status of this patient population, we might achieve significant societal benefits due to the improved quality of life and societal integration.

Changes and Problems

Changes in approach and reasons for change

The results achieved so far in the project have shown that the scientific approach that we originally proposed is valid. Hence, there has been no need to change the proposed scientific approach so far.

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

We experienced significant delays in obtaining IRB approval for the proposed experimental procedures. Hence, we would like to request a revision of the originally proposed timeline. We intend to discuss this matter with the program officer assigned to our project and kindly request authorization to revise the timeline that we originally proposed. Because of the complexity of the proposed experimental procedures, we would like to kindly request an extension of the project of approximately nine months. As stated above, we will discuss this matter with the program officer assigned to our project.

Changes that had a significant impact on expenditures

Because of the delay that we experienced in regard to obtaining IRB approval, we have spent our budget at a slower rate than we originally anticipated. The experimental procedures that we will start in the next few weeks will require an increase in the rate at which we are spending the project budget. We will bring to the attention of the program officer assigned to our project and kindly request to revise the projected spending for the next year.

Other changes

None

Products

Publications, conference papers, and presentations

While we have not prepared any publication on this project as yet, we anticipate that we will soon start preparing a publication on the basis of the biomechanical data that we will start gathering in the next quarter.

Technologies or techniques

During the first year of the study, we developed software for the implementation of algorithms needed to study the biomechanics of exoskeleton-assisted gait in individuals with a complete spinal cord injury. This work is relevant to Specific Aim 1, Task 1. The specific implementation of the algorithms that we have adopted is an implementation that accounts for the small displacement between the exoskeleton and some of the body segments strapped to the exoskeleton. We have obtained IRB approval so that data can be collected from individuals with a complete spinal cord injury during exoskeleton-assisted gait. In parallel, Dr Troy's team at the Worcester Polytechnic Institute has worked on the experimental set-up for the computed tomography scans in addition to contributing to the development of algorithms to estimate mechanical strain on the bone structures. The work performed by Dr. Troy's team is relevant to Specific Aim 1, Task 1. For a detailed description of the techniques developed as part of the project, please see the section entitled "What was accomplished under these goals?" at the beginning of the report.

Participants & Other Collaborating Organizations

The following is the list of individuals who have worked on the project so far.

Name:	Paolo Bonato, PhD
Project Role	Principal Investigator
Institution	Spaulding Rehabilitation Hospital
Nearest Person Month Worked	1.60
Contribution to the Project	Dr Bonato has contributed to the development and amendment of the study protocol, the development of biomechanical procedures and algorithms for the study of exoskeleton-assisted gait, and the assessment of components of the camera-based motion capture system to evaluate their suitability for the study.

Name:	Leslie Morse, MD
Project Role	Co-Investigator
Institution	Spaulding Rehabilitation Hospital
Nearest Person Month Worked	1.24
Contribution to the Project	Dr. Morse has contributed to the development and amendment of the study protocol.

Name:	Karen Troy, PhD
Project Role	Co-Investigator (site PI)
Institution	Worcester Polytechnic Institute
Nearest Person Month Worked	1.60
Contribution to the Project	Dr. Troy has contributed to the development and amendment of the study protocol, the development of biomechanical procedures for the study of exoskeleton-assisted gait, the preparatory work to collect data using the scanning techniques at Worcester Polytechnic Institute.

In addition to the PI and Co-Investigators on the study, a research project coordinator (Mr. Ryan McIntosh), a post-doctoral student (Jean-Francois Daneault) and a research assistant (Alessandra Scarton) have assisted Dr. Bonato at Spaulding Rehabilitation Hospital. Also, a research engineer (Nathan Smith) and a doctoral student (Ying Fang) have assisted Dr. Troy at the Worcester Polytechnic Institute.

Quad Charts

The attached Quad Chart reflects the current status of the project and plans for the rest of the study.

Skeletal and Clinical Effects of Exoskeleton-Assisted Gait



Log Number A-18380

Award Number W81XWH-14-1-0611

PI: Paolo Bonato, PhD

Org: Spaulding Rehabilitation Hospital

Award Amount: \$379,188

Study/Product Aim(s)

- To quantify the motions of and forces transmitted through the lower extremities during exoskeleton-assisted gait.
- To explore the development of a model to predict the effects of regular exoskeleton-assisted gait on bone health, muscle mass, and functional outcomes.

Approach

To achieve the above-stated specific aims, we plan to pursue the following tasks. Task 1.1: to obtain human subject approval and prepare for the study. Task 1.2: to contact and screen prospective study participants. Task 1.3 to enroll study participants and perform gait testing. These tasks are relevant to achieving Aim 1. Task 2.1: to explore modeling the effects of exoskeleton-assisted gait. Task 2.2: to perform data analysis. These tasks are relevant to achieving Aim 2.



Accomplishments: We have developed detailed procedures for the performance of the study experimental procedures. We have worked with HRPO personnel to finalize the study protocols.

Timeline and Cost

Activities	14	15	16
Approval study procedures and set-up	█		
Screen and enroll study participants		█	
Modeling effects of Ekso-assisted gait		█	
Data analysis			█
Estimated Budget (~\$380K)	~\$60	~\$240	~\$80

Goals/Milestones (Example)

CY14 Goal – Detailed description of protocols and procedures

- Evaluation of the procedures and data collection set-up

CY15 Goals – System validation

- Obtain protocol approval
- Screen and enroll study volunteers
- Complete studies in a subset of subjects

CY16 Goal – Production readiness

- Complete studies in all subjects
- Perform data analysis

Comments/Challenges/Issues/Concerns

- If timelines change, comment here.
- If off by more than one quarter in spending, comment here.

Budget Expenditure to Date

Projected Expenditure: ~\$300K

Actual Expenditure: ~\$150K (estimate including WPI expenses based on expected invoices)

Updated: October 28, 2015