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TITLE: Enhanced Autodiagnostic Adaptive Trainer for Myoelectric Prosthesis Users (eADAPT-MP)

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14. ABSTRACT Amputation of upper limbs, including hands and arms, is extremely devastating. Myoelectric prostheses provide the best functional equivalent of the missing limb, and utilize muscle activity from the residual limb to drive prosthetic hand movement. However, intensive training is required to control the myoelectric prosthesis, with the result that many amputees abandon their prosthesis. Difficult training has been implicated as the primary cause for device abandonment. Current training tools are expensive, restricted to use in the caregiver's office, do not embrace all aspects of device use, and do not provide feedback to the provider or amputee. Along with amputee care providers, we have recently developed the ADAPT-MP system, which uses a wireless muscle sensing band, a series of mobile games, and a web-based provider portal to improve myoelectric training. The ADAPT-MP system is inexpensive, mobile, encompasses all aspects of device use, and provides immediate training progress feedback to the user and provider. In the current effort, we used FDA recommendations to test the ADAPT-MP system for patient interaction, usability and durability, and will expand the software based on testing, and perform a controlled trial using recent upper limb amputees to compare how using the enhanced ADAPT-MP system alters amputee device use, quality of life, and ability to return to work/duty.					
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1. Introduction

More than 1,650 American servicemen have lost a limb due to traumatic injury in combat during the recent conflicts in Iraq and Afghanistan. The Auto-Diagnostic Adaptive Precision Trainer for Myoelectric Prosthesis Users (ADAPT-MP) system was designed to train upper limb amputees on myoelectric prosthesis control. Under the current effort, the ADAPT-MP system developed and tested under the Phase II SBIR program underwent extensive testing for patient interaction, usability, and durability following FDA CDRH guidelines in Applying Human Factors and Usability Engineering to Medical Devices. The CDRH guidelines outline how to measure and assess device user characteristics, use environments, and user interfaces critical to device success. The eADAPT-MP system will then be used in a randomized controlled trial (RCT) to evaluate the use of novel mobile pre-prosthetic training on compliance and skill outcomes. During the pre-prosthetic training phase, usability and durability data will be gathered via patient and provider questionnaire. The frequency and type of device failure and software bugs will be analyzed. Following myoelectric device arrival outcome metrics will be gathered including: compliance/abandonment as a primary outcome metric; skill of prosthesis use as a secondary outcome metric; and quality of life and work/social reintegration as other outcome metrics. Data from the Phase II SBIR RCT will also be assessed to determine the predictive value of acute assessments on long term outcomes.

2. Keywords

myoelectric prosthesis, amputation, electromyography, pre-prosthetic training, game-based training

3. Accomplishments

What were the major goals of the project?

1) Conduct Usability Evaluation of Existing System

Target Completion Date: Jan 30, 2018

Percent Completion: 100%

2) Collect Additional Clinical Trial Data

Target Completion Date: Sept 30, 2020

Percent Completion: 20%

What was accomplished under these goals?

1) Conduct Usability Evaluation of Existing System

The ADAPT-MP system underwent rigorous testing for patient interaction, usability, and durability following guidelines in the FDA CDRH standard: "Applying Human Factors and Usability Engineering to Medical Devices" as outlined in the 2018 annual report.

In summary, the ADAPT-MP system was found to be safe and effective for the intended users, uses and use environments. The ADAPT-MP system consists of 1) a physical interface: the Myo Gesture Control Armband (Thalmic Labs, Kitchener, Ontario Canada) a tablet, a charger block, and two chargers, and 2) a digital interface: a web provider portal and EMG setup application. During development of this system, upper limb specialists were consulted from Hanger Inc. to provide insight from a clinical viewpoint. Seven amputees tested the system, and a study was run on 12 able bodied participants to test the efficiency of the system. Feedback from all users was recorded to drive further development and enhancements, under a separate SBIR effort. A list of these future updates has been compiled in Table 1 by priority. System updates were kicked off during an SBIR Phase II enhancement effort (W81XWH-18-C-0106, start date Sept 24, 2018) and are expected to be completed in 6 months, by March 24, 2019.

Table 1: Table of enhancements to be focused on in the third phase of the ADAPT-MP development.

Enhancement	Description/ Purpose	Status
Mobile phone version (optimize for smaller screen)	Improved flexibility for users to play on both a tablet and mobile phone)	Complete.
iOS version of games	(Partially developed) Improve user access	In progress. ADAPT-MP functions on Android, and DI will expand to additional mobile platforms such as iOS.
Update current gameplay	Increase speed of Crush level 4; add infinite Claw level 4; add achievements and customization; display level maximum score	Complete.
Develop additional games	Increase user engagement/motivation with a larger selection of games; may be accomplished by re-skinning current games	Not started. Additional games are being considered for amputee rehabilitation that may also benefit general ataxia populations as well.
Add pattern recognition capabilities	Train additional skills needed to operate advanced functionality	In progress. DI has begun research into systems that can address pattern recognition and will begin exploring the steps towards integrating those capabilities with ADAPT-MP.
Add control over Myo band tactile feedback to existing and new games	Provide multimodal user feedback during training	Not started. DI worked with Thalmic labs to identify the possibility of leveraging tactile feedback and will continue to seek out new devices that provide those capabilities.
Improve ability to connect in noisy RF environments	Improve user access	Complete

Update UI provider web portal	Change UI for events in web portal: color code for which muscle should be used, then add symbols for pass fail (O – pass, X – fail, colored, etc...). Compress EMG display. Allow for multiple sessions to be displayed; add quick quantitative information for provider (e.g., where user is struggling/etc.)	In progress. UI/UX development has begun on the ADAPT-MP system. A list of updates is being developed for prioritization.
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2) Collect Additional Clinical Trial Data

DI has entered into agreements with outside organizations to conduct usability evaluations of the existing ADAPT-MP II system (Objective 1) and act as the sites to randomized, controlled trials (Objective 2). Specifically, DI has agreed with Dr. Michael Highsmith of the University of South Florida (USF), the largest polytrauma provider in the US, to perform randomized controlled trials.

DI has finalized NDA and SOW/budget agreements with USF. An initial IRB draft was provided to the subcontractor for their review and finalization, prior to multisite approval. Initial IRB drafts have been submitted to the USF and Tampa VA IRBs for review. Both sites have responded with edits, and these are being finalized.

In addition, DI and USF have approached the [Florida High Tech Corridor](#) (FHTC) for matching funds against a USF subcontract. The FHTC fosters applied research between Florida Universities (University of Florida, University of Central Florida, and University of South Florida) and high tech industry partners, and provides matching awards of up to \$150k to university partners. \$81,183 were solicited from the FHTC, and these funds were awarded in May 2019 for the sole purpose of USF/Tampa VA performing their data collection for the effort. The funds will be released upon approval of the USF/Tampa VA IRB.

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

The DI team was invited to speak about the ADAPT-MP system at the Military Health Systems Research Symposium in Orlando, FL in August 2018. MHSRS is the Department of Defense’s premier, annual scientific meeting which brings together DoD, industry, and academia to focus on health care initiatives to meet the unique needs of America’s Service Members. The title of the presentation was “Expanding traditional pre-prosthetic therapy: a mobile, game-based approach to myoelectric training” which focused on use of the ADAPT-MP system. This topic was presented in the session “Rehabilitation Following Limb Trauma and Amputation” (**Error! Reference source not found.**).

How were the results disseminated to the communities of interest?

DI submitted a publication titled “[Mobile, game-based training for myoelectric prosthesis control](#)” to Frontiers which was published on 6/22/18. This manuscript was based on DI’s work with the ADAPT-MP system on a healthy population. The publication has already received approximately 4,000 views

and due to the success of the article, we have been invited to develop a special issue / Frontiers Research Topic by the editors of Frontiers in Bioengineering and Biotechnology surrounding game-based rehabilitation.

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

During the next reporting period, the IRB updated documents and HRPO documents will be submitted, and once accepted, the study with USF/Tampa VA will begin. The ADAPT-MP updates developed under the SBIR effort has been completed, and its build is ready for implementation. DI has begun training USF/Tampa VA personnel in preparation for the study.

DI will be meeting with the COR, Jason Ghannadian, on site at Walter Reed on November 7th to discuss the current status of the effort. Additionally, DI plans on attending AAOP next year to demonstrate the updates made to ADAPT-MP to the clinician population. Jason Ghannadian is also setting up meetings between DI, the Shirley Ryan Ability Lab, and Liberating Technologies, Inc. to compare progress in our efforts and determine potential collaboration moving forward.

4. Impact

What was the impact on the development of the principal disciplines of the project?

The ADAPT-MP system increases access to engaging mobile rehabilitation tools for patients, while increasing provider efficiency via enhanced data availability. The ADAPT-MP system allows for telerehabilitation, which reduces the burden of travel on the patient, and the burden of scheduling patients for the providers. Providers can monitor patients by logging into the web portal which allows them to provide feedback as they see fit. Patients are given a system that is fun and engaging, while also having training that mimics activities of daily living.

What was the impact on other disciplines?

The ADAPT-MP system has the capabilities of being transferred from an amputee patient population to patients suffering from ataxias. Previous research has indicated the potential for significant brain and motor plasticity within specific ataxias, including the ability to improve motor function with consistent effort and therapy. Given the time and effort required to retrain upper limb motor systems following various ataxias including stroke, several groups have turned to game-based approaches to post-stroke recovery. The ADAPT-MP system could be used to rapidly develop the capability to train muscle control for ataxias (a parallel domain) by utilizing a mobile patient application, a web-based provider portal, and a portable EMG band.

What was the impact on technology transfer?

Following system enhancement and testing, DI plans to commercialize the ADAPT-MP system with Hanger's clinical network. Based on a strong commitment of support from Hanger, and multiple discussions occurred between DI and Hanger, and initial business partnership was developed and discussed at the Feb 2016 Hanger Ed Fair. As initially envisioned, Hanger, Inc. would become a reseller of the ADAPT-MP system based on their national reach and large customer base. As discussed with the Hanger executive team, ADAPT-MP added value to their company by:

1. Increasing trainee qualification rate through demonstration of cognitive capacity to operate prosthesis
2. Improving long term retention through improved quality of life due to game engagement
3. Improving Provider/Trainee relationship through provision of data through online portal to providers
4. Improving Quality of Life through training that improves ability to complete activities of daily living
5. Driving new insurance qualification standards by demonstrating the cognitive, physical and neurological function required to operate a myoelectric prosthesis.

Discussions with Hanger, and their subsidiary, Southern Prosthetic Supply (SPS), lead to a more refined business partnership. In the final business plan, SPS would acquire the ADAPT-MP system and provide it to Hanger's Upper Extremity Specialist team and users. Upon the provision of successful clinical outcome data, SPS will purchase the ADAPT-MP system, with an initial purchase of 30 units.

What was the impact on society beyond science and technology?

The ADAPT-MP system will drive new insurance qualification standards by demonstrating the cognitive, physical and neurological function required to operate a myoelectric prosthesis. These new insurance qualifications will reduce costs for healthcare in the government and civilian sectors. The ADAPT-MP system will lead to better control of myoelectric prostheses, and higher upkeep of the devices, which will also decrease healthcare costs, while increasing the opportunity for amputees to return to work. In addition, the ADAPT-MP system will be profiled by the Florida High Tech Corridor's magazine in Q4 2019 (interviews have been completed).

5. Changes/Problems

Changes in approach and reasons for change

DI worked with Hanger in Phases I and II of the ADAPT-MP project to gain insight into the wants and needs of civilian patients and providers. In this phase of work, DI is partnering with the DoD and VA to gain insight into the military population's perspective by subcontracting USF/Tampa VA. This will increase the applicability of the ADAPT-MP system to a wider audience.

Thalnic Labs rebranded to North, and is no longer continuing development for the Myo Band, therefore there was a need to identify new devices for use in the ADAPT-MP system. DI has identified new potential devices, such as CTRL-Labs, which are developing wireless EMG armbands. DI began communication with CTRL-Labs and is currently seeking to get a developer kit for testing to determine the usability of the kit with ADAPT-MP. However, DI also stockpiled Myo bands for use in the randomized controlled trial for this effort.

Actual or anticipated 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

Nothing to report

6. Products

Journal publications

Winslow, B. D., Ruble, M., & Huber, Z. (2018). Mobile, game-based training for myoelectric prosthesis control. *Frontiers in bioengineering and biotechnology*, 6.

Books or other non-periodical, one-time publications

Nothing to report

Other publications, conference papers, and presentations

Ruble, M. & Winslow, B. D. Expanding traditional pre-prosthetic therapy: a mobile, game-based approach to myoelectric training; presented during the Rehabilitation Following Limb Trauma and Amputation at MHSRS 2018.

Websites and other Internet sites

DI published information regarding the ADAPT-MP system from Phase II on our website (<http://designinteractive.net/adapt-mp/>). Information will be updated based on the results from the PORA efforts and the enhancement funds.

Technologies or techniques

Nothing to report

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:	Brent Winslow
Project Role:	Principle Investigator

Researcher Identifier:	https://orcid.org/0000-0001-7098-6336
Nearest person month worked:	1
Contribution to Project:	Dr. Winslow drafted and updated an IRB for submission to USF and HRPO and directed ADAPT-MP system usability analyses. Dr. Winslow also worked to finalize subcontracts and statements of work with subcontractors to perform the clinical evaluation.
Funding support:	W81XWH-17-1-0687

Name:	Mitchell Ruble
Project Role:	Program Manager
Researcher Identifier:	https://orcid.org/0000-0002-8331-2485
Nearest person month worked:	2
Contribution to Project:	Mitchell Ruble drafted the Florida HTC documentation, and has been working closely with USF to answer questions regarding the IRB documentation. Mitchell Ruble also worked to draft the statements of work, usability evaluation, and budgets.
Funding support:	Contract W81XWH-17-1-0687

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

The ADAPT-MP Phase II enhancement effort started on 9/24/2018; contract W81XWH-18-C-0106.

What other organizations were involved as partners?

Organization name: University of Southern Florida (USF)

Location of organization: Tampa, FL


Partner's contribution to the project: USF was added to this study to provide the perspective of the veteran population through clinicians that treat veterans. This feedback will help round out the ADAPT-MP system to be more applicable to a broader patient population. Tampa VA/USF will also recruit and test the bulk of the participants for this study and provide assistance through an application to the FHTC funds.

8. Special Reporting Requirement

Quad Chart

Auto-Diagnostic Adaptive Precision Training for Myoelectric Prosthesis users (ADAPT-MP)

Company: Design Interactive, Inc. **Phase II Contract #** W81XWH-14-C-0154
Awarded Amount to date: \$949,928.67 **COR:** Jason Ghannadian **Topic Number :** DHP14-011




Product Objective

- A low percentage of upper limb amputee Service Members return to duty due to lack of training for expensive myoelectric prostheses
- ADAPT-MP provides device agnostic, mobile, engaging, game-based pre-prosthetic training to improve user compliance, skill, quality of life, and return to work/duty
- ADAPT-MP use is associated with significant improvements in muscle control needed for successful myoelectric prosthesis operation

Key Benefits/ROI for the DoD

- ADAPT-MP is the first game-based, mobile pre-prosthetic training system, allowing users to train anywhere
- The system allows providers to monitor training progress and intervene via tele-rehabilitation, saving time and money
- Game-based training improves on current in-office training approaches and allows users to progress faster



The diagram illustrates the ADAPT-MP system architecture. It shows an EMG BAND connected via a Bluetooth symbol to a PATIENT MOBILE APP. The mobile app is connected to a SECURE SERVER (represented by a cloud icon), which in turn is connected to a PROVIDER PORTAL (represented by a computer monitor icon).

Timeline and Cost

Activities	CY	14	15	16	17	18	19	20
Phase I								
Phase II								
Phase II Enhancement								
Phase III Funding*								
Estimated Budget (\$M)		\$0.2	\$0.3	\$0.5	\$0.2	\$0.3	\$0.3	\$0.3

*Phase III funding – DHA Prosthetics Outcomes Research Award (PORA)

Transition Plan

1. Controlled clinical evaluation with the Tampa VA planned for FY19/20
2. A business partnership has been developed in collaboration with Hanger and Southern Prosthetic Supply (SPS) to supply ADAPT-MP to civilian, DoD, and VA markets.
3. Additional use cases: recovery following upper limb ataxias, such as post-stroke recovery or cerebral palsy

Updated: October 11, 2019 **FOUO**

9. Appendices

Appendix 1: ADAPT-MP MHSRS 2018 presentation

Expanding Traditional Pre-Prosthetic Therapy: A Mobile, Game-based Approach to Myoelectric Training

Military Health System Research Symposium 2018

Prepared By: *Mitchell Ruble*

Aug 2018

Conflicts of Interest

- *Mitchell Ruble and Brent Winslow are employees of Design Interactive*



Living with Limb Loss

- Around 2,000 upper limb amputations above the wrist/year¹
- Around 2,000,000 Americans live with limb loss²
 - Expected to double by 2050²
- More than 1,650 American service members lost a limb in combat in Iraq and Afghanistan³
- Upper limb loss significantly impacts quality of life

1. Dillingham, So Med J 2002

3. Fischer, Cong Res Serv Rep. 2015

2. Ziegler-Graham, Arch Phys Med Rehabil 2008

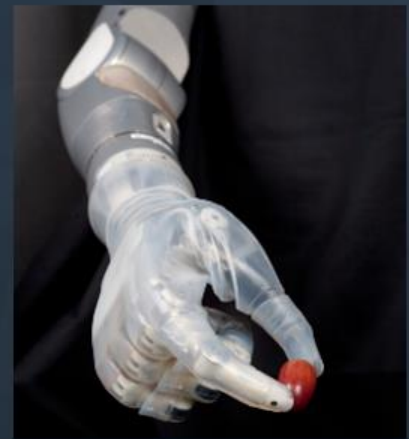


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3

Myoelectric Prostheses

- Free of straps and harnesses
- Noninvasive signal detection
- Utilize residual muscles, TMR
- Increased fidelity and control
- However, 30-50% abandonment rate⁴
- #1 Reason – Difficult training⁵



DARPA DEKA Arm

4. Silcox, J Bone Joint Surg 1993

5. Peerdeman, J Rehabil Res Dev, 2011

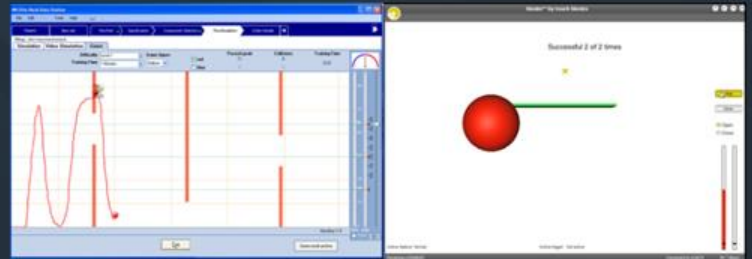


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4

Pre-Prosthetic Training and Its Limitations

- Pre-prosthetic training
 - Critical to learning how to utilize prosthesis
- Therapist guided voluntary muscle activation
 - Monotonous, no progress feedback
- Pre-prosthetic training software
 - Provides visual feedback, individualized training
 - In-office, expensive, does not collect and report data, wired



Paula® by Ottobock

Virtu-Limb by Touch Bionics



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ADAPT-MP

Auto-Diagnostic Adaptive Precision Trainer for Myoelectric Prosthesis Users

- Mobile, game based, device agnostic
 - Developed with Hanger clinicians
 - Amputee input provided
- ADAPT-MP
 - EMG Sensor Band
 - Patient Mobile Application
 - HIPAA Compliant Secure Cloud Server
 - Provider Portal







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Game Description	Interface	Training objective
Basic Activation (Volcanic Crush)		Teach basic control movements for successful prosthesis use (flexion, extension, co-contraction). Based on psychomotor vigilance task (PVT).
Temporal Sequencing (Dino Sprint)		Game teaches sequences of contractions (flexion, extension, co-contraction). Speed and difficulty increases with time.
Proportional Control (Dino Feast)		Teaches muscle isolation (flexor vs. extensor) and proportionality. Flexor targets and thresholds change dynamically.
Isolation and Movement (Dino Claw)		Similar to activities of daily living (ADLs), participants practice picking up, moving, and dropping objects. Isolation and proportionality reinforced



Basic Activation - Volcanic Crush





Game Description	Interface	Training objective
Basic Activation (Volcanic Crush)		Teach basic control movements for successful prosthesis use (flexion, extension, co-contraction). Based on psychomotor vigilance task (PVT).
Temporal Sequencing (Dino Sprint)		Game teaches sequences of contractions (flexion, extension, co-contraction). Speed and difficulty increases with time.
Proportional Control (Dino Feast)		Teaches muscle isolation (flexor vs. extensor) and proportionality. Flexor targets and thresholds change dynamically.
Isolation and Movement (Dino Claw)		Similar to activities of daily living (ADLs), participants practice picking up, moving, and dropping objects. Isolation and proportionality reinforced



Temporal Sequencing - Dino Sprint



Game Description	Interface	Training objective
Basic Activation (Volcanic Crush)		Teach basic control movements for successful prosthesis use (flexion, extension, co-contraction). Based on psychomotor vigilance task (PVT).
Temporal Sequencing (Dino Sprint)		Game teaches sequences of contractions (flexion, extension, co-contraction). Speed and difficulty increases with time.
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Isolation and Movement (Dino Claw)		Similar to activities of daily living (ADLs), participants practice picking up, moving, and dropping objects. Isolation and proportionality reinforced



Proportional Control – Dino Feast



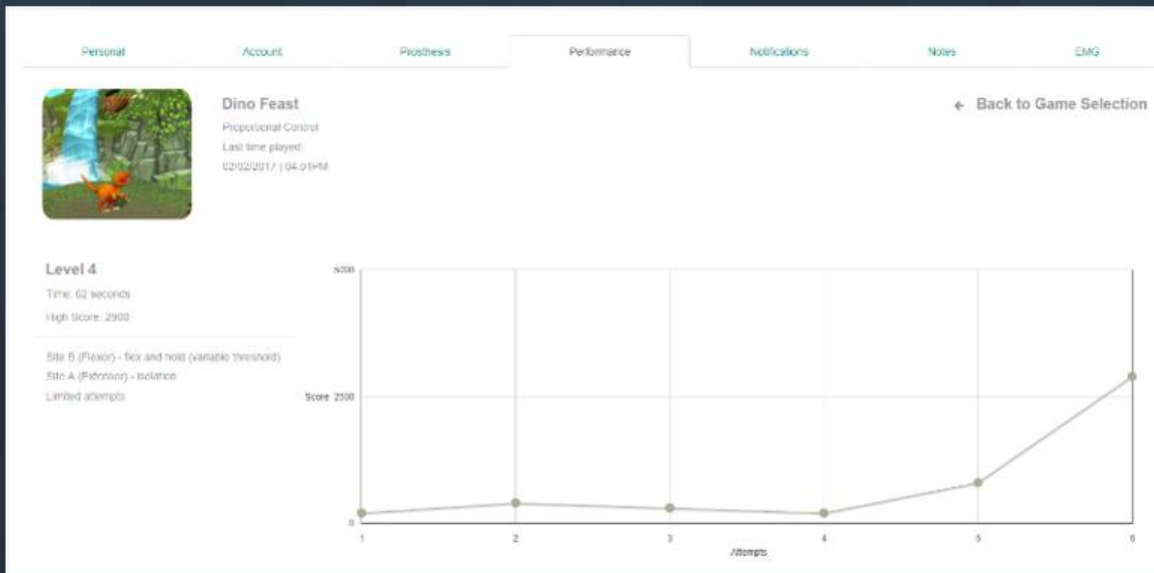
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Isolation and Movement – Dino Claw



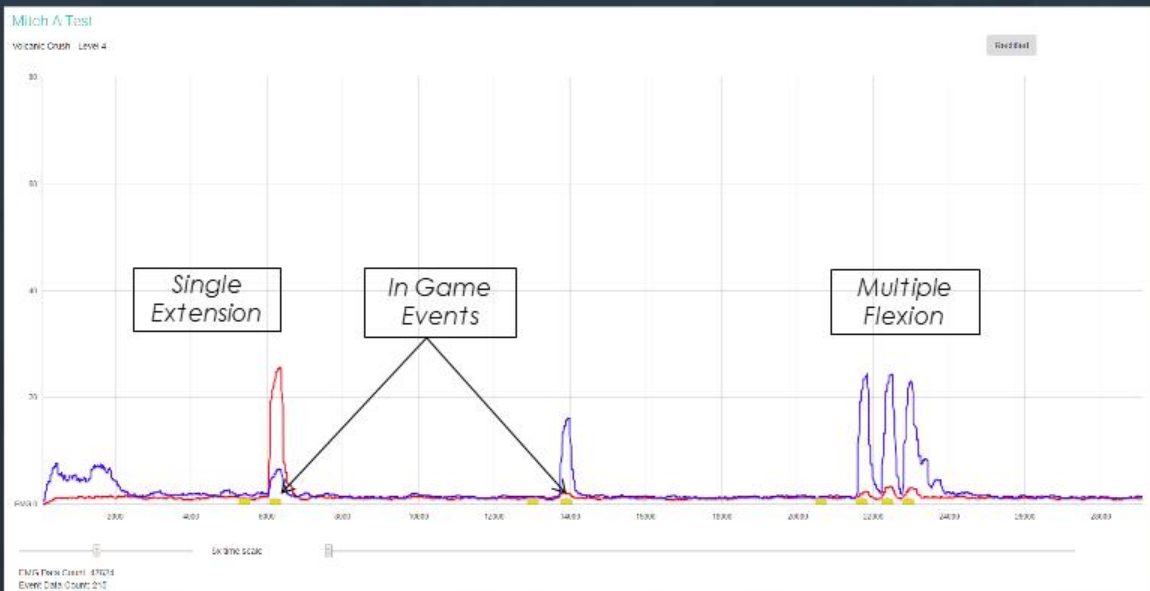
Provider Portal



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Provider Portal – Patient EMG



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Game Testing – Able Bodied Participants

- “Mobile, Game-Based Training for Myoelectric Prosthesis Control”
 - Brent Winslow, Mitchell Ruble, Zachary Huber
 - *frontiers in Bioengineering and Biotechnology*
- 12 able-bodied adult participants recruited
- Non-dominant limb was used to model motor learning associated with amputation⁶
- Participants were asked to utilize ADAPT-MP 20-30 minutes a day for the span of 1 week
- Measures included: surveys (UES, IMI, SUS), game performance, and EMG activity



6. Prahm, JMIR Serious Games 2017

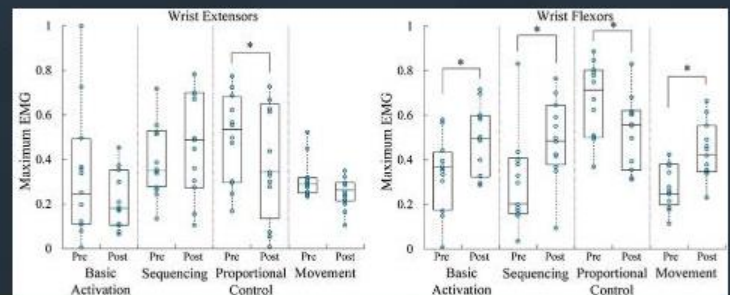
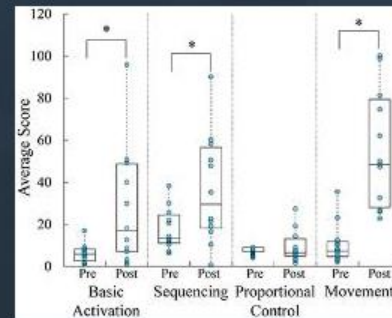


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Game Testing - Results

- ADAPT-MP significantly more engaging than current training⁶
- Participants significantly improved muscle control, sequencing, and isolation
- Participants significantly increased flexor muscle activity
 - Significantly decreased flexor and extensor activity in Proportional Control training game



6. Prahm, JMIR Serious Games 2017

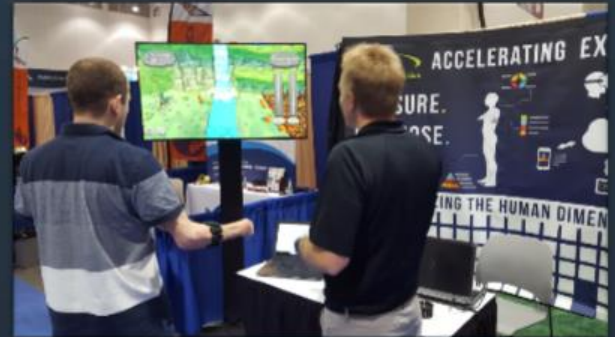


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Future Work

- *Enhance ADAPT-MP*
 - *Broaden user base*
 - *Adapt and broaden system for commercialization*
 - *Pattern recognition*
- *Human subjects research*
 - *Compare ADAPT-MP to current training*
 - *Myoelectric prosthesis users*



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