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14. ABSTRACT This grant consists of three projects, each with its own investigative team, as described below. Program 1: "Establishing the Parameters of Virtual Reality Environments in the Treatment of PTSD", (Tracie Shea, Ph.D. Lead Investigator). This innovative research project has not yet begun because of administrative difficulties in assigning an appropriate Principal Investigator. A meeting will be held in November 2009 between the overall project PI and the Program Officer to attempt to resolve this bottleneck. The project has also been delayed due to an extensive human subjects review. Program 2: "Framework for Comparison of Display Technologies as Routes of VR Exposure" (Samuel Fulcomer, Lead Investigator). This project is studying the usage of the Virtual Iraq scenario to run on advanced multi-panel displays and the development of new display technology. These studies are concentrating on the technical adaptation of the current scenarios designed for head mounted displays to more high fidelity advanced display techniques. Solution of these technical difficulties will make this display technology suitable for a variety of VA, DoD, and civilian environments. Program 3A: "Identifying Clinically Meaningful Improvement in Rehabilitation of Lower-Limb Amputees" (Linda Resnik, Ph.D., P.T., O.C.T. Lead Investigator). These studies have the goal of generating data to guide selection and interpretation of outcome instruments for lower limb amputees which would aid in evidence based guidelines of care. It is designed as a multisite study and to date has enrolled 85 subjects. The data set has been subjected to quality assurance techniques and preliminary descriptive statistics have been created. Further data analysis is awaiting continuing review by the Boston VA Medical Center IRB. Program 3B: "Analysis of Gait Mechanics of Amputees Using a New Lower Limb Prosthesis" (Susan D'Andrea, Ph.D., and Alena Grabowski, Ph.D.) This is a collaboration between two Center for Restorative and Regenerative Medicine laboratories, the prosthetics development group at the MIT Media Lab (Hugh Herr, Ph.D.) and the Gait and Motion Laboratory at the Providence VA Medical Center (Susan D'Andrea). This is a study of gait mechanics and metabolic energy expenditure of unilateral transtibial amputees using a new below knee prosthesis, "Power Foot". IRB approval has been obtained and ten individuals without amputations are currently being studied. The recruitment of ten amputees and development of the experiment cohort is being carried out. The source of the Power Foot has been identified. Data will be forthcoming.					
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PROGRAM 1
“ESTABLISHING THE PARAMETERS OF VIRTUAL REALITY ENVIRONMENTS IN
THE TREATMENT OF PTSD”

INTRODUCTION

Severity of trauma during deployment has consistently been shown to be among the strongest, if not the strongest, predictor of PTSD. Many if not most individuals experience some symptoms of PTSD after serious trauma exposure, but only some will develop PTSD. The ability to identify those at higher risk, particularly for chronic PTSD, is critical to targeting treatment and other preventive interventions. Moreover, early identification may play a significant role in reducing the need to provide intensive programs for all combat veterans. The purpose of this work derives directly from congressional mandates to improve the care and outcome for veterans with limb trauma and the common secondary presentation of PTSD.

Body

Full Spectrum Warrior (FSW) is a PC software application that simulates the experience of commanding a light infantry company. It was developed through collaboration between the Institute for Creative Technologies (ICT); entertainment software companies; the U.S. Army Training and Doctrine Command (TRADOC); and the Research, Development, and Engineering Command, Simulation Technology Center (RDECOM STC). The Army's Infantry School also contributed to its design. FSW can be run on a head-mounted display (HMD) unit to create a virtual reality (VR) environment that simulates deployment scenarios. The primary aim of the current project is to evaluate the utility of FSW in the early identification of individuals at risk for PTSD and as a diagnostic tool for objective assessment of PTSD in military service personnel returning from OIF/OEF.

Aim 1: Assessment of Individual Responses to Virtual Reality Stimuli:

Aim 1 will establish a dose response curve and determination of a standard combat VR challenge in 52 OEF/OIF combat veterans. Increasing doses are defined as VR exposures with more stimulus elements included.

Aim 2: Evaluating the Risk of Developing PTSD Using Individual Responses to Virtual Reality Stimuli:

Aim 2 will deliver a VR challenge, comprised of the dose identified in Aim 1 and a series of neutral VR scenes, to 50 OIF/OEF veterans who are at risk for developing PTSD, but without current PTSD (n.b.; these are different subjects than those described for Aim 1). One year post VR challenge, Clinician Administered PTSD Scale (CAPS) scores will be compared to the baseline CAPS score. Heart rate variability (HRV) in response to the VR challenge in OIF/OEF veterans who develop PTSD will be compared to HRV in veterans who do not develop PTSD on neutral, and combat-standardized VR challenges to determine the specificity of the VR challenge to PTSD.

KEY RESEARCH ACCOMPLISHMENTS

- The protocol for program 1 received pre-approval at the DoD on January 23, 2008.
- It received IRB approval from Brown University on June 19, 2008.
- It is currently under review at the Providence VA Medical Center.
- Work is estimated to begin on this task following final DoD HRPO approval.

REPORTABLE OUTCOMES

N/A IRB in progress.

CONCLUSIONS

N/A. Data collection has not yet begun. Program pending VA IRB approval and final DoD HRPO approval.

REFERENCES

N/A

PROGRAM 2: “FRAMEWORK FOR COMPARISON OF DISPLAY TECHNOLOGIES AS ROUTES OF VR EXPOSURE”

INTRODUCTION

Virtual Reality (VR) desensitization software programs, such as the Virtual Iraq and Virtual Afghanistan scenario programs that are traditionally used in post-traumatic stress disorder (PTSD) studies are often administered using Head Mounted Displays (HMDs). This project investigates the adaptation of the Virtual Iraq software application to run on alternative display platforms. This project involves adapting and porting Virtual Iraq to run on more advanced multi-panel displays such as the CAVE™, as well as the development of new advanced display technology that can practically be deployed in clinical settings.

BODY

The original Virtual Iraq application runs on a Microsoft Windows platform, and uses the Gamebryo scenegraph and rendering engine (developed by Emergent Technologies, and commonly used for computer video games). The Windows/Gamebryo platform does not provide a facility for graphical display on a multi-panel display; thus, we had to identify and integrate an alternative rendering system for use with the Virtual Iraq models and scenarios. After evaluating several possible approaches we selected the XVR open source system developed by VRmedia (www.vrmedia.it). XVR provides support for multi-panel displays and synchronization mechanisms for network-clustered rendering computers. We have ported the Virtual Iraq models and animation scenarios to XVR and have tested the system on Brown's 4-wall Cave, a room-like immersive virtual reality display. More recently, beginning in the 4th quarter of 2008, we began design work on a new three-panel display using stereographic-capable consumer projection TV's from Mitsubishi and Samsung. Three of the display engines from these displays can be used to create a low-cost, "U-shaped" immersive display that takes relatively little space, and is ideal for clinical installations. With props it can easily be configured as a vehicle simulator. Since we began work with these displays, the consumer market for large televisions has shifted away from projection televisions in favor of LCD and LED-based televisions, as the result of the manufacturers' abilities to produce larger LCD and LED panels. Samsung has discontinued production of the 3D-DLP models; however, we have continued to work with the Mitsubishi Laservue display, which uses a laser light source that produces a very large and more realistic color gamut than conventional displays.

KEY RESEARCH ACCOMPLISHMENTS

- Although the internal display engine should maintain the display clock of the input source, we have found that multiple displays exhibit output refresh clock skew that, without correction, makes them unsuitable for tiled 3D application.
- While a minor hardware modification should be possible to distribute a common clock to not only all participating displays, but also the source graphics adapters, we are now investigating the use of new, low-cost short throw projectors produced by the Benq and Viewsonic companies.
- These projectors utilize the 3D-DLP projection engines and expose great control over color adjustment.

- While offering a low-cost solution for stereographic vehicle simulator displays (\$3-5,000 for projectors and screen hardware), the use of projectors will require a somewhat larger footprint for projections staging (2-3 feet behind the screens, rather than the 1 foot required for the consumer televisions).

We expect that new versions of large consumer LED and LCD televisions, to be announced this fall, will also support field-sequential stereographic display; however, applications using these displays will be more expensive than those using the Benq or Viewsonic projectors.

REPORTABLE OUTCOMES

None to date.

CONCLUSIONS

Stereographic display technology is undergoing rapid change as the result of speculation around the growth of stereographic content in the consumer market. This has resulted in very promising, but short-lived technology, and the emergence of exciting new technology. In order to maintain flexibility in the platforms we develop, we will continue to work with the low-cost Benq projectors, but will also examine the anticipated 3D ready LED TV's. It is our reasonable expectation to have completed a 3-panel vehicle simulator using projection technology by the end of our current contract extension. As a result of this work we will be able to smoothly progress to later projects focusing on projective 3D displays for physical rehabilitation applications, and will disseminate our work for use in PTSD treatment venues.

REFERENCES

N/A

**PROGRAM 3A:
“IDENTIFYING CLINICALLY MEANINGFUL IMPROVEMENT IN REHABILITATION
OF LOWER-LIMB AMPUTEES”**

INTRODUCTION

Although dozens of measurement instruments are used to assess care outcomes for amputees, there is a dearth of research to guide selection and interpretation of existing instruments for clinical practice and small studies. Thus, there is no consensus among researchers or clinicians as to which outcomes measures are best in these cases. The results of this study will begin to build the evidence needed to choose and interpret measures by providing important data on the reliability and floor and ceiling effects of outcomes measures. In addition, results will provide important preliminary data needed for a planned study on the responsiveness of self-report measures.

BODY

Background: There is a dearth of research to guide selection and interpretation of existing instruments for clinical practice and small studies of lower limb amputees. **Objectives:** The purposes of this study are to 1) To compare test-retest reliability for self-report and performance-based measures; 2) To test a new scoring system for the PEQ; 3) To determine if any measures should be omitted from our future study due to prevalent floor or ceiling effects; To assess the feasibility of using a composite score of physical performance as an external criterion of change in our future study of measure responsiveness. **Methods:** This is a multi-site study with repeated subject measurements in both self-report and performance-based measures. Data was collected at two time points. The study included war-fighters with single lower-extremity amputations. Data analysis is ongoing and includes descriptive statistics, evaluation of test-retest reliability of each instrument, and floor and ceiling effects, comparison of summated PEQ scale with original. In addition we will create a composite performance measure and examine correlations between physical performance and self-report scores. **Results:** In total we have collected data from 85 subjects from all sites combined, with 16 subjects enrolled under DOD funding. No results as of yet. **Clinical Implications:** This study will build necessary evidence for choosing and interpreting measures to assess outcomes of care for amputees.

IRB approval for the study was granted by the Providence and Boston VA IRBs. Staff at both sites were trained in data collection methods. Subject accrual is completed with 85 subjects tested at two time intervals. Sixteen subjects were tested under the DOD approved protocol. All study data was double-entered and checked for errors using SAS. Inconsistencies in data entry were examined using source documentation, corrected and rechecked. Initial labeling and coding of the data was then performed. Preliminary examination of descriptive statistics was conducted. Summary scores for all tests and measures were calculated. The three OPUS scales used in this study required application of a scoring algorithm supplied by the instrument developer (Alan Heinemann). In September, 2009 Dr. Heinemann informed us that he had updated the scoring algorithm using pooled data from multiple studies. Thus, our scoring methodology needs to be updated.

Due to delays in getting on the Boston VA IRB calendar 8/10/09, approval of the continuing review at the Boston VA Medical Center is pending and all study related activities, including data analysis have been put on hold.

KEY RESEARCH ACCOMPLISHMENTS

- Subject accrual completed.
- Data double-entered into study data set
- Data checked for errors
- Data set cleaned and coded
- Preliminary examination of descriptive statistics conducted
- Summary scores of all measures calculated
- Initial scoring of the OPUS using IRT methods completed

REPORTABLE OUTCOMES

None to date.

CONCLUSIONS

None to date.

REFERENCES

N/A

**PROGRAM 3B:
“ANALYSIS OF GAIT MECHANICS OF AMPUTEES USING A NEW LOWER LIMB
PROSTHESIS”**

INTRODUCTION

The newest generation of limb prostheses are biomimetic in that they more closely simulate normal human movement. A novel lower limb prosthesis with a biomimetic ankle has been devised by Hugh Herr, of MIT and a Center for Restorative and Regenerative Medicine (CRRM) investigator. The gait mechanics and metabolic energy expenditure of unilateral transtibial amputees using this prosthesis are currently being examined and compared to age-, height- and weight-matched non-amputees to understand how closely the prosthesis approximates the biological ankle during walking.

BODY

The approved scope of work for this program is to 1.) establish a gait laboratory within the CRRM in a rehabilitation research facility at the Providence VA Medical Center and 2.) quantitate lower limb function for amputees with a new biomimetic prosthesis. The gait laboratory has been installed during the first year of this proposal during which Program 3A will be carried out. The Department of Computer Sciences at Brown University, where expertise in motion analysis exists, will provide software support as needed. A study of 20 subjects (10 amputee and 10 non-amputee) will be carried out to provide biomechanical and metabolic data comparing the new biomimetic ankle-foot prosthesis to a standard elastic storage and return (ESAR) prosthesis and to a biological ankle. The ability to alter gait speed is one of the fundamental qualities of the biomimetic ankle. Thus, this study will compare data for walking at 5 different speeds.

KEY RESEARCH ACCOMPLISHMENTS

- The gait laboratory has been established at University Orthopedics, 100 Butler Drive, Providence, RI.
- The gait laboratory includes an eight camera Qualisys (Gothenburg, SWEDEN) motion capture system along with software for tracking and processing data (purchased via a grant from the Rhode Island Science and Technology Council), two AMTI (Watertown, MA) force plates, a 16 channel wireless EMG system from Delsys (Boston, MA), a treadmill (Sole Fitness USA), and a Cosmed (Chicago, IL) K4b² portable metabolic analysis system. The gait laboratory equipment allows for full body motion analysis including kinematics, kinetics and muscle activity, as well as metabolic energy (oxygen consumption) analysis.
- The project entitled “Effects of Wearing a Powered Ankle-Foot Prosthesis on Amputee Walking” has been approved by the IRB and data collection has begun. So far, 6 of 10 amputee and 4 of 10 non-amputee subjects have been recruited to participate in the study. Subject recruitment and data collection will continue through the end of the year. Subsequently, the data will be analyzed and the results will be presented.

REPORTABLE OUTCOMES

None to date.

CONCLUSION

The gait and motion laboratory has been established and experimental data collection has begun.

REFERENCES

N/A