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14. ABSTRACT

Several studies have suggested that reciprocal relationships exist between physical and emotional injury and rehabilitation. Advances in surgical reconstruction, prosthetics, and rehabilitation are offering greater possibilities for more complete physical and emotional recovery. The reciprocal effects of physical and emotional injury are therefore particularly timely to investigate. The objective of this initial pilot study is to establish in our Center techniques with which to assess physical and emotional injury and recovery. The overall hypothesis of the study is that new techniques of functional restoration will have a positive effect on recovery from injury.

This proposal consists of three pilot clinical studies (Programs 1, 3a and 3b) and one computer graphic adaptation project (Program 2). These programs are designed to put in place in our Center for Restorative and Regenerative Medicine the techniques with which to quantitatively assess physical and emotional injuries. Programs 1 and 2 use VR to develop quantitative measurements for PTSD rehabilitation. Program 3 focuses on the quantitative assessment for physical rehabilitation.

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ABSTRACT

PURPOSE:

Several studies have suggested that reciprocal relationships exist between physical and emotional injury and rehabilitation. Advances in surgical reconstruction, prosthetics, and rehabilitation are offering greater possibilities for more complete physical and emotional recovery. The reciprocal effects of physical and emotional injury are therefore particularly timely to investigate. The objective of this initial pilot study is to establish in our Center techniques with which to assess physical and emotional injury and recovery. The overall hypothesis of the study is that new techniques of functional restoration will have a positive effect on recovery from injury.

This proposal consists of three pilot clinical studies (Programs 1, 3a and 3b) and one computer graphic adaptation project (Program 2). These programs are designed to put in place in our Center for Restorative and Regenerative Medicine the techniques with which to quantitatively assess physical and emotional injuries. Programs 1 and 2 use VR to develop quantitative measurements for PTSD rehabilitation. Program 3 focuses on the quantitative assessment for physical rehabilitation.

SCOPE:

Accurate quantitative assessments for physical and emotional injuries are limited, even as the increasing demand for this type of assessment is on the rise. American military personnel are being diagnosed with Post Traumatic Stress Disorder (PTSD) in rapidly increasing numbers. In 2003, over 1,000 military personnel were diagnosed while on deployment. By 2007, this figure had increased ten-fold. Meanwhile, the demand for prosthetic services is increasing nation wide due to a rise in conditions leading to amputation, including traumatic limb loss, and vascular or medical disease.

The end products of each of the programs in this project will address the increasing demand for quantitative assessments for these types of physical and emotional injuries. The end product of Program 1 will be a series of working VR environments tested clinically on combatants who have returned from operations in Operation Iraqi Freedom/Operation Enduring Freedom (OIF/OEF). The end product of Program 2 will be an adaptation of those VR environments to an alternative display platform. The end product of Program 3a will be improved physical performance measures as well as measures of the amputee's subjective experience of prosthetic satisfaction, quality of life, and mobility. The end product of Program 3b will be an assessment of the gait mechanics of the first lower limb prosthesis with a powered, biomimetic ankle.

CUMULATIVE SUMMARY OF MAJOR FINDINGS TO DATE:

Program 1: Data collection has not yet begun. The program is pending VA IRB approval and final DoD HRPO approval.

Program 2: The Samsung display provides wider field of view, much greater image fidelity and more comfortable viewing than the Emagin head-mounted display, and is well-suited to deployment in a clinical setting. In addition to providing enhanced realism in simulating the view from a HumVee or other vehicle, it will provide a more immersive visual presentation of other simulation scenarios without the confinement of a head-mounted display.

Program 3a: IRB approval for the study has been granted by the Providence and Boston VA IRBs. Staff at both sites were trained in data collection methods. Subject accrual has begun in Providence and Boston.

Program 3b: The establishment of the gait lab is underway. A location has been identified at the Brown University Department of Orthopaedics. Construction has begun and complete installation of the equipment is anticipated to finish according to our work plan (September 2008).

An eight camera Qualisys (Gothenburg, SWEDEN) motion capture system has been purchased along with software for tracking and processing data. Two AMTI (Watertown, MA) force plates and a 16 channel wireless EMG system from Delsys (Boston, MA) will complement the motion data and enable the lab to provide data for full body motion analysis including kinematics, kinetics and muscle activity.

Susan D'Andrea has been hired as director of the gait lab. Dr. D'Andrea brings many years experience to the position having worked with various motion capture systems in a variety of research settings. Her expertise will greatly benefit the lab.

In accordance with our work plan, the project entitled "Effects of Wearing a Powered Ankle-Foot Prosthesis on Amputee Walking" will begin after completion of the gait lab. This project will be carried out in the gait lab using the motion analysis system with the simultaneous measurement of energy expenditure. IRB documents are being prepared for pre-approval at the DoD HRPO. We anticipate submission of the IRB documents by September 30, 2008.

PROGRAM 1
"ESTABLISHING THE PARAMETERS OF VIRTUAL REALITY ENVIRONMENTS IN THE TREATMENT OF PTSD"

INTRODUCTORY STATEMENT

SUBJECT AND PURPOSE**:**

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.

SCOPE:

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.

APPROVED STATEMENT OF WORK TASKS

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 I). 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.

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

INTRODUCTORY STATEMENT

SUBJECT AND PURPOSE:

The principal effort of this program is in systems development and technology integration. The proposed project will investigate the adaptation of the Full Spectrum Warrior (FSW) software application to run on display platforms other than the eMagin Head-Mounted Display (HMD). This will include Brown University's Cave, an eight-foot immersive VR "room" with open ceiling and rear wall, as well as a high-resolution stereo wall display. These larger, less-confining displays will allow comparisons of the stress effects of the technology itself, through biometric monitoring during the presentation of benign virtual environments. They do not present the potential confounder of the sense of confinement of an HMD. HMDs prevent subjects from seeing their limbs and present the potential of a disembodiment experience and confinement stress. The Cave permits a free-standing experience. It offers potential advantages in clinical application, including facilitation of observation and the capacity for group therapy and the use of physical props. Since the virtual environments used in the development are specifically designed with warfighter stress scenarios, the work is clearly related to mandates to improve the care and outcome for veterans with limb trauma and the common secondary presentation of PTSD.

BACKGROUND:

The work of this program focuses on the development of new technologies for using Virtual Reality Exposure Therapy applications in evaluation and treatment of PTSD. In particular, we are using the Virtual Iraq/Virtual Afghanistan applications developed by Dr. Albert Rizzo and the USC Institute for Creative Technologies, and are adapting it to allow it to run in tiled and non-planar tiled displays (e.g., a four-wall Cave at Brown University, the Motek CAREN system at the Brooke Army Medical Center). A fundamental consideration in developing new display systems is the suitability of the underlying computer operating system and rendering system. In the case of the earlier versions of Virtual Iraq and its antecedent, Full Spectrum Warrior, the application was built on the Windows operating system using the Gamebryo computer game engine, which provides advanced graphics rendering and animation capabilities. Gamebryo provides a scenegraph, which is a retained description of the scene in a decomposed form that specifies objects, their properties, and global scene characteristics such as lighting. The scenegraph provides a facility for rendering the scene after the application supplies any updates to object and global properties (i.e., state information). Gamebryo uses the propriety Microsoft DirectX API for graphics rendering, and does not provide support for use of the OpenGL API. Thus, there is no Gamebryo support of the Linux operating system.

The Virtual Iraq/Virtual Afghanistan application includes predefined animation descriptions of simulation events, such as insurgent attacks, explosions and vehicle movements. These animation descriptions and the geometric model other artwork are

stored as files in the NetImmerse File Format (NIF). NIF is an open format, and various open source tools are available for manipulation of NIF data.

The Windows/Gamebryo platform does have advantages for use in a visual simulation application like Virtual Iraq:

- *Platform support* – Windows is well-supported by Microsoft, and a Windows-based system is easily managed with limited technical staff effort in clinical environments.
- *Integrated multimedia capabilities* – DirectX/Direct3D/DirectAudio libraries provide excellent integration of graphical and positional audio rendering capabilities, and are well supported by the Gamebryo engine. In rendering functionality in DirectX is richer in capability than in OpenGL, providing an easier path to visual fidelity in the simulation.

Unfortunately, because the API's are proprietary, and not extensible by the application programmer, there are barriers to easily adapting the Gamebryo application for use on tiled displays or on clusters of multiple computers:

- *Asynchronous stereo rendering* – There is no support for explicit stereo rendering in the DirectX API; thus, an interposing stereo driver from nVIDIA must be used to intercept the DirectX call stream, buffer it, and re-render the scene with a viewing offset for the second eye. The driver then manipulates the left/right fields for display on supported output devices (e.g., page-flipping for field sequential display). This is a problem for multiple displays, since there is no way to synchronize buffer swap calls among the rendering application instances. As a result, there will be no state synchronization among the scenes. Even in the case of state changes driven by retained animation descriptions (e.g., pedestrian locomotion), free-running asynchronous rendering and buffer swapping will result in loss of state synchronization.
- *No mechanism for event distribution* – State changes also occur due to external input such as head-tracking, therapist input or other interaction interface (e.g., vehicle controls in a HUMVEE simulator). All of these interaction events must be reliably propagated to all application instances, and must affect the instances within the same rendering period in order to maintain state synchronization.
- *No mechanism for rendering camera manipulation* – For planar tiled displays the screen transformation must be set for the appropriate viewing frustum (offset as appropriate for the tile). For non-planar displays, additional matrix changes are needed to accommodate off-axis cameras, as in Caves. In the case of curved displays, the screen transformation must include a plenoptic warp, preferably done in the GPU's texture shaders.

None of these disadvantages is present in a combination of the Linux operating system, nVIDIA Quadro graphics hardware, OpenGL drivers, and OpenGL-based scenegraph rendering engines (e.g., EONReality, XVR, etc.); however, the NIF data must be

converted to a form usable by the Linux-based software, and the therapist control interface must be re-implemented for the platform.

This leaves two approaches to supporting tiled and non-planar displays: 1) develop software facilities to address the inadequacies of Windows/Gamebryo, and 2) port the artwork, models, animation data and therapist interface to a Linux platform.

Our group's work to date has focused first on analyzing the existing Virtual Iraq application architecture and adding support for a new display platform, the Samsung 3D-DLP projection television. The Samsung display provides wider field of view, much greater image fidelity and more comfortable viewing than the Emagin head-mounted display, and is well-suited to deployment in a clinical setting.

Figure 1:
Emagin HMB

Figure 2:
NuVision Shutterglasses

Figure 3:
Virtual Iraq on the Samsung 3D-DLP HDTV & shutterglasses

SCOPE:

The intent of the project is to extend technology to allow a more systematic evaluation of patient response to stimuli in the virtual environment, and to enable new treatment modality (e.g., group therapy). It also has the potential to enable a more evidence-based design of treatment protocols, potentially lowering costs, increasing efficacy and improving the quality of life for many veterans with otherwise disabling post-traumatic psychological illness. Ultimately, the goal is understanding the potential benefits of varied technology well enough to design VR display environments, or new HMDs, that optimize the cost-benefit function for VRET assessment and treatment. The Cave is merely the evaluation platform for design options.

APPROVED STATEMENT OF WORK TASKS:

- Months 1-3: Software platform analysis and engineering design

- Months 4-11: Assembly of software components for distributed Microsoft Windows platform to drive Cave and wall display; Implementation of distributed parallel rendering architecture; Initial application testing with displays.

- Months 12-16: Analysis, design and implementation of biometric monitoring and head-tracking/interaction event recording components and database

- Months 17-20: Analysis, design and implementation of therapist interface abstraction and enhancement

- Months 21-22: Analysis, design and implementation of patient interface abstraction

- Months 23-24: Final software testing, documentation and report generation.

RESEARCH ACCOMPLISHMENTS

- We have developed two investigative approaches for adapting the application to support more advanced displays such as a vehicle simulator display being developed by our group, the Cave at Brown, and Motek CAREN systems incorporating Virtual Reality graphical displays.

  (1) The straightforward but tedious approach is to port the application to the Linux platform. To do this, we need to translate the Virtual Iraq building models, artwork, audio and animation descriptions into a format which can be imported by visual simulation software that has synchronization facilities. The following accomplishments are bringing us closer to that end:

  - We identified two candidate platforms for this approach, 1) XVR, a system developed by VRmedia (www.vrmedia.it) for the development of multimedia Virtual Reality content, and 2) Eon Reality, Inc.'s simulation software tools (www.eonreality.com).
  - We have begun working with XVR.
  - We have succeeded in running simple fully-synchronized, head-tracked XVR-based Cave applications, and
  - We have begun working with the Maya design software to translate Virtual Iraq models into a format that can be imported by XVR.
  - We have identified facilities at XVR for defining topologies for Caves and tiled displays, and handles event distribution and swap synchronization across the multiple rendering tasks.

  If this approach proves the more promising we will port the therapist interface using the Qt cross-platform application framework.

  The second path we are investigating involves adding explicit quad-buffered stereo rendering and event and swap synchronization to the Windows/Gamebryo platform.

  (2) We have identified the Gamebryo developer, Emergent Technologies, has developed a DirectX Command Buffer Library (CBL), which is a library that intercepts the DirectX call stream of Gamebryo, and can be used by the application developer to distribute the rendering stream to multiple execution threads. This is intended to allow the application to take advantage of multiple CPUs/cores.

We believe that it may be possible to use the CBL, in a fashion similar to the OpenGL Chromium library (chromium.sourceforge.net), to synchronize and modify the call stream executing on multiple nodes and distribute events to all participating nodes. In addition, the call stream can be buffered at this point for explicit stereo rendering. If we can then set refresh controller scan-out addresses and swap via OpenGL we can achieve stereo and swap synchronization across multiple graphics outputs using the DirectX-based Gamebryo application.

We are also planning a low-cost display which will provide a 180+-degree horizontal field of view and be highly suited to clinical deployment as a vehicle simulator display. It will use three of the 3D-DLP projection televisions of a new model about to be announced by Mitsubishi, and will cost approximately $5,000. In addition to providing enhanced realism in simulating the view from a HumVee or other vehicle, it will provide a more immersive visual presentation of other simulation scenarios without the confinement of a head-mounted display.

CONCLUSIONS TO DATE:

We believe that it may be possible to use the CBL, in a fashion similar to the OpenGL Chromium library (chromium.sourceforge.net), to synchronize and modify the call stream executing on multiple nodes and distribute events to all participating nodes. In addition, the call stream can be buffered at this point for explicit stereo rendering. If we can then set refresh controller scan-out addresses and swap via OpenGL we can achieve stereo and swap synchronization across multiple graphics outputs using the DirectX-based Gamebryo application.

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PROGRAM 3A:
"IDENTIFYING CLINICALLY MEANINGFUL IMPROVEMENT IN REHABILITATION OF LOWER-LIMB AMPUTEES:"

INTRODUCTORY STATEMENT

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 the self-report and performance-based measures; 2) To test a new scoring system for the Prosthetic Evaluation Questionnaire (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 will be collected at two time points. The study will include war-fighters with single lower-extremity amputations. Data analysis will include 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**: Subject enrollment is underway.

SUBJECT AND PURPOSE 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.

SCOPE & CLINICAL IMPLICATIONS: This study will build necessary evidence for choosing and interpreting measures to assess outcomes of care for amputees.

APPROVED STATEMENT OF WORK TASKS:

Months 1-3: Analysis of gait mechanics and kinematics in 15 normal subjects at 3 different gait speeds.

Months 3-9: Characterization of gait mechanics and kinematics of 15 subjects using the new biomimetic below knee prosthesis at several different gait speeds. Adjustments in the mechanics of the prosthesis will be carried out during this time so that several analyses may be required.

Months 9-12: Data analysis, scientific report writing, and information dissemination.

RESEARCH ACCOMPLISHMENTS:

IRB approval for the study has been granted by the Providence and Boston VA IRBs. Staff at both sites were trained in data collection methods. Subject accrual has begun in Providence and Boston.

PROGRAM 3B:
"ANALYSIS OF GAIT MECHANICS OF AMPUTEES USING A NEW LOWER LIMB PROSTHESIS."

INTRODUCTORY STATEMENT

SUBJECT AND PURPOSE:

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 of this prosthesis will be examined with motion analysis technology to describe how closely it approximates normal human walking.

SCOPE:

A. Establish a gait laboratory within the CRRM in a rehabilitation research facility at the Providence VA Medical Center.
B. Quantitate lower limb function for amputees with a new biomimetic prosthesis.

APPROVED STATEMENT OF WORK TASKS

A. The gait laboratory will be installed during the first year of this proposal during which Program 3A will be carried out.

B. The Department of Computer Sciences at Brown University, where expertise in motion analysis exists, will provide software support as needed.

C. Pilot study of 15 subjects will be carried out to provide initial data on the biomimetic qualities of the new ankle-foot prosthesis. This will be compared to gait mechanics and kinematics of 15 normal subjects at several gait speeds. The ability to alter gait speed is one of the fundamental qualities of the biomimetic ankle.

RESEARCH ACCOMPLISHMENTS

- The establishment of the gait lab is underway. A location has been identified in the Department of Orthopaedics at Brown University. Construction has begun and complete installation of the equipment is anticipated to finish according to our workplan (September 2008).

- An eight camera Qualisys (Gothenburg, SWEDEN) motion capture system has been purchased along with software for tracking and processing data with a grant from the Rhode Island Science and Technology Council. Two AMTI (Watertown, MA) force plates and a 16 channel wireless EMG system from Delsys (Boston, MA) will complement the motion data and enable the lab to provide data for full body motion analysis including kinematics, kinetics and muscle activity. Equipment for measuring oxygen consumption has been purchased.

- Susan D'Andrea has been hired as director of the gait lab. Dr. D'Andrea brings many years experience to the position having worked with various motion capture systems in a variety of research settings. Her expertise will greatly benefit the lab.

- In accordance with our work plan, the project entitled "Effects of Wearing a Powered Ankle-Foot Prosthesis on Amputee Walking" will begin after completion of the gait lab. This project will be carried out in the gait lab using the motion analysis system with the simultaneous measurement of energy expenditure. IRB documents are being prepared for pre-approval at the DoD HRPO. We anticipate submission of the IRB documents by September 30, 2008.

CONCLUSION:
The development of the gait and motion laboratory is on schedule and normative data is set to be collected. The first experimental data will be acquired according to protocol after IRB approval.

CONCLUSION

Program 1is undergoing intensive IRB study and review. It is expected to begin subject enrollment within this calendar year.

Program 2 has made some interesting discoveries about technology portability to various immersive environments. When this is completed, research on PTSD and rehabilitation programs will be facilitated in a Cave environment.

Program 3A is enrolling patients. Program 3B has completed construction; IRB approval is being sought with enrollment probable within the calendar year.