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PRINCIPAL INVESTIGATOR: Tracie Shea, Ph.D.

CONTRACTING ORGANIZATION: Brown University in Providence in State
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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 project has obtained local IRB approval and pre-approval from the DoD. Hardware has been tested and validated and subject recruitment will begin with DoD HRPO approval. **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). This program was closed last year and is no longer generating information. **Program 3B:** “Analysis of Gait Mechanics of Amputees Using a New Lower Limb Prosthesis” (Matthew Williams, Ph.D.). The gait lab has been established in a new facility and is being used to quantify human motion in a variety of research projects. **Program 4:** “Virtual reality and Motion Analysis to Characterize Disabilities in Lower Limb Injury” (Susan D’andrea, Ph.D., lead investigator). This project focuses on the use of virtual reality as a tool to assess physical function. The project will utilize information gather using VR with an emulated injury and apply similar procedures to assess patients with ACL injury to document functional mobility from injury onset through rehabilitation. Currently, local IRB approval is being sought for this project.

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PROGRAM 1
“ESTABLISHING THE PARAMETERS OF VIRTUAL REALITY ENVIRONMENTS IN THE
TREATMENT OF PTSD”
M. Tracie Shea, Ph.D.

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 primary objective of the current project is to evaluate the utility of a Full Spectrum Warrior, a PC software application for use with Virtual Reality (VR) technology, 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. The overall goal is to 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. Skin conductance (SC) and heart rate variability (HRV) in response to the VR challenge in combat-exposed OIF/OEF veterans with a PTSD diagnosis will be compared to SC and HRV in combat-exposed veterans who do not have a diagnosis of PTSD on neutral, and combat-standardized VR challenges to determine the specificity of the VR challenge to PTSD. The purpose of this work derives directly from congressional mandates to improve the care and outcome for veterans with limb trauma and the common 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.

Preliminary testing of the Biopac MP 100 data acquisition system was conducted, and programmed settings for psychophysiology data capture (i.e., heart rate and galvanic skin response parameters) have been obtained. A standardized progressive presentation of VR scene stimuli has been developed and refined, reflecting increasing doses (VR exposures with more stimulus elements included). Programming of the Full Spectrum Warrior software to automate scene presentation during administration of VR task, to ensure standardization of delivery and timing of scene presentations has been completed.

Recruitment efforts for the study are currently ongoing. The first participant completed the VR study on 9/23/2012. Since September 2012, 39 participants have consented and enrolled in the Virtual Reality study protocol. Of these 39 participants a total of 33 participants have completed Virtual Reality protocol in its entirety (i.e., Assessment Visit and completion of VR Task Visit). Four individuals consented and completed the Assessment Visit of the study; however, they were later excluded from the study and did not complete the VR Task Visit. Of the 4 individuals excluded from the study, 2 failed to meet inclusion criteria (i.e., were not

currently engaged in therapeutic treatment), 1 individual elected to drop from the study prior to the VR Task Visit, and 1 individual was lost to follow-up (i.e., did not return phone calls to schedule the VR Task Visit). Entry of assessment data for all 39 participants has been completed and preprocessing of psychophysiological data for individuals who have completed the VR task is currently in process.

KEY RESEARCH ACCOMPLISHMENTS

- Recruitment efforts are currently ongoing.
 - Study staff have presented information and distributed recruitment materials at Providence VAMC clinics (i.e., Primary Care clinics, Returning Veterans clinic, etc.), Veteran events (i.e., Yellow Ribbon and PDHRA's), and at local community OEF/OIF Task Force meetings.
 - Recruitment materials have been posted in targeted high traffic locations throughout Providence VAMC.
- **Current Enrollment:** Since the last annual progress report submission in September of 2011, 38 Veteran participants have enrolled in the study to bring our total enrollment to 39 participants. Of these 39 participants, currently 33 participants (i.e., 10 veterans with a PTSD diagnosis and 23 veterans without a PTSD diagnosis) have completed the VR study in its entirety.
- **Data Analysis:** Data entry for all 39 participants enrolled in the study has been completed, and preprocessing of available psychophysiological data (i.e., skin conductance and heart rate analysis) is currently in progress.

REPORTABLE OUTCOMES

We expect to complete the following remaining accomplishments in the upcoming months:

- Complete recruitment and assessment of the remaining 19 combat-exposed OEF/OIF veterans (i.e., 16 veterans with a PTSD diagnosis and 3 veterans without a PTSD diagnosis) to achieve the protocol recruitment goal of N=52 (i.e., 26 veterans with a PTSD diagnosis and 26 veterans without a PTSD diagnosis).
- Complete implementation of VR protocol with all study participants.
- Complete preprocessing of psychophysiological and assessment data.
- Conduct data analyses to test hypotheses regarding differential responding to VR stimuli based on absence or presence of PTSD diagnosis.
- An optimal level of arousal to the VR task, or dose response curve, will be identified so as to maximize our ability to find differences between PTSD+ and PTSD- groups.
- Report results from initial analyses at relevant national conferences, and write manuscript reporting findings for submission to a peer reviewed journal.

CONCLUSIONS

REFERENCES

N/A

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

INTRODUCTION

Under the original scope of work for this thrust we investigated the adaptation and implementation of the Virtual Iraq application for a large Virtual Reality (VR) display, the Cave at Brown University. While relatively uncommon, Caves (large, partially or fully enclosed VR display screen systems) are the epitome of visual VR environments, offering full visual/spatial immersion in the virtual world presented by the application. Caves also present complex display system characteristics which must be supported by a successful software application and its supporting middleware, including (typically) distributed execution on multiple host platforms, multiple synchronized display channels on non-coplanar screens, and head and gesture tracking for input to rendering and animation controls.

Two potential approaches were explored. The first involved the use of Virtual Iraq on its native Microsoft Windows and Gamebryo game engine. While this approach would require little modification to the Virtual Iraq application, it would require significant work to adapt Windows and Gamebryo to allow synchronization of the display channels. In addition, the Brown Cave is normally used with the Linux operating system, in a mode which permits disparate application development use by several research groups. Our use of Windows/Gamebryo would require reserved, dedicated time, and incur the Cave usage charges originally included in the contract budget.

The second possible approach involved the use of the Linux operating system and a rendering/animation system suitable for the Virtual Iraq environment. Unlike Windows, for Linux there is readily available low-level software for multi-channel display synchronization; however, a different rendering/animation system would have to be found which could both support the multi-channel VR display and also import the Virtual Iraq models and animation descriptions.

Ultimately, we chose the Linux platform and the XVR (eXtreme Virtual Reality) system developed by VRMedia of Italy. This eliminated the requirement for dedicated Cave time, freeing the associated funds.

Our primary scope was to investigate the adaptation of the Virtual Iraq application to advanced display technologies. In the course of our work we learned of a particularly exciting line of new consumer display technology developed to support stereographic entertainment content (e.g., 3D movies). These display products are essentially large screen televisions, and are targeted at the home theater market. Initially available as DLP projection televisions, there have been subsequent short-lived plasma-based products, and there soon will be LED-based products.

BODY

For clinical application of Virtual Iraq these displays have significant advantages over HMDs (Head-Mounted Displays). They have higher brightness, contrast and acutance, present a wider field of view, are less confining, require no fit adjustment, and present little difficulty in sanitizing the required shutter glasses. In addition, they are relatively inexpensive and widely available.

In order to facilitate the use of these displays by the PTSD research and treatment community, we re-budgeted our remaining funds in FY10 to purchase displays and rendering computers to be configured in two settings: 1) as a vehicle simulator and mini-Cave in the Brown VR lab; 2) as a treadmill display in the Providence VA Gait Lab. The display in the Brown VR lab also

requires a motion capture system. The gait lab display will use the gait lab's existing motion capture system. Our schedule for much of this work has been constrained by the availability of suitable technology in the consumer market

KEY RESEARCH ACCOMPLISHMENTS

Our 2012 work has focused on three areas:

- Configuration and testing of the single-panel display for the Providence VA/ Gait Lab - We have acquired and configured a computer system and single panel Mitsubishi projection television for installation in the Gait Lab. This computer system will also be capable of driving the Gait Lab's multipanel immersive stereo display due to be installed in the Fall of 2012.
- -We have identified and worked with an immersive display vendor to design a display suitable for use with the Gait Lab's prototype real-time-actuated treadmill. This treadmill is suitable for use as a haptic interface device in virtual environments. The display system is being installed in Fall 2012
- Display technology tracking - we are in the process of upgrading the CAVE technology with state of the art equipment for a more immersive environment. Dr. D'Andrea will continue to collaborate with the research staff to incorporate a treadmill in this environment.

REPORTABLE OUTCOMES

- A new VR display has been designed and being installed in the Gait Lab.
- The CAVE has been reconfigured to a state-of-the-art facility.

CONCLUSIONS

N/A.

REFERENCES

N/A

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

INTRODUCTION

Recent studies have found that approximately 31% of recent combat injuries requiring amputation resulted in a trans-femoral amputation (Stansbury, 2008). For trauma victims, conventional, standard of care prosthetics for trans-femoral amputees have metabolic costs approximately 33% higher than those of able-bodied individuals during level-ground walking (Waters and Mulroy, 1999), as well as marked gait asymmetry, which can lead to higher prevalence of hip and back pain and osteoarthritis (Edhe et al., 2001), (Gailey et al., 2008). As a result, individuals using these devices, on average, walk approximately 45% slower in order to compensate for the increased physical demand and altered gait. Still, they fatigue sooner and are able to walk less distance than able-bodied individuals. More advanced prosthetics (such as the C-Leg and Rheo Knee) can alleviate some, but not all, of these issues particularly at speeds above customary walking speed (Taylor et al., 1996), (Johansson et al., 2005).

To address these limitations, a novel, variable impedance, transfemoral prosthesis system is being developed in the MIT Media Lab (Martinez-Villalpando & Herr, 2009) which is intended to provide a more natural gait, while also being able to supply additional power during swing phase. The AAA Knee consists of a modular robotic knee coupled to a conventional energy storage and release carbon-fiber prosthetic foot. The knee itself (mechanism and electronics) fits within the form factor of conventional prosthetic knees (26x8x7 cm, 3.2kg) so as to not encumber or interfere with cosmesis. The knee is capable of 0-120° of flexion and is able to produce an output torque of 80Nm.

BODY

The overall objective of this study was to ascertain the potential metabolic and gait improvements of the AAA Knee over conventional prosthetic knee systems (standard of care knee with carbon-fiber foot). To that end, the following evaluations were performed:

- Determine the metabolic cost of transport using the AAA Knee and a conventional standard of care knee at three speeds corresponding to slow, medium, and fast walking speeds for above-knee amputees (0.75, 1, and 1.25 m/s).
- Evaluate gait symmetry by analyzing the kinetic, kinematic, and muscle activity patterns (EMG) of the affected and non-affected legs.

WORK PERFORMED

The study consisted of five unilateral trans-femoral amputees (eight recruited, 3 drop outs – One due to other time commitments, two due to injuries not related to the project). Despite the relatively low population size, sufficient power was achieved based upon post-hoc analysis using G*Power 3 (Faul et al., 2007). Prosthetic users were capable of ambulating at the K3 level in that they were capable of walking with variable cadence and without additional support. Subjects performed all tasks using both a conventional standard of care prosthetic knee (C-Leg) and foot and the AAA Knee.

A. Metabolic Evaluation

Subjects had their rate of oxygen consumption and carbon-dioxide production measured while standing still and while walking on a level track at 0.75, 1, and 1.25m/s – speeds that

correspond to slow, medium, and fast gait for above-knee amputees. The metabolic cost of transport (MCOT, a measure of the amount of food energy required to cover a meter of distance) for each subject using each knee system was computed from the oxygen consumption and CO2 production rates normalized by subject mass.

B. Gait Symmetry Evaluation

Each subject's gait symmetry was evaluated by comparing the performance of each leg to the other. Of critical investigation was the similarity in performance between the amputated leg using each prosthetic knee and the non-affected leg. Gait performance was assessed based on gait kinematics, kinetics, and the activity of the major hip muscles.

Gait was measured using an IR-based multi-camera motion capture system to record subjects' gait kinematics and two force-plates in the walkway captured ground reaction forces. Surface EMG signals were collected from the muscles of the unaffected leg and the hip extensors (gluteus maximus) of both legs. Specific gait performance measures for each leg included hip, knee, and ankle moments and powers, maximum ground reaction forces, stand and swing times, stride frequency, and mean rectified EMG. These were compared as the ratio between the non-affected and affected sides (right to left in the case of able-bodied subjects).

RESULTS TO DATE

A. Metabolic Evaluation

The affect on MCOT due to using the AAA Knee was significant ($p < 0.05$) for most subjects across all three speeds (Fig. 1, circled points). However, not all subjects improved their performance (defined as a reduction in MCOT). The impact of using the powered knee is correlated to residual limb length – those with shorter residual limbs have a reduced MCOT, while those with longer residual limbs show a detriment, with an increased MCOT.

It is believed that this limb length-MCOT correlation is due to the reduced physical capabilities of above knee amputees with short residual limbs. With a shorter limb, the individual has both less muscle mass and a shorter lever arm to produce hip torque. Given the nature of transfemoral gait where prosthetic knee extension is produced by rapid hip flexion, those with short residual limbs must exert a greater amount of effort at the hip to generate the same knee extension behavior compared to amputees with long residual limbs. By using the AAA Knee with powered swing extension, they are able to reduce their effort and let the machine do the work for them. Those with longer residual limbs show an increase in MCOT while using the AAA knee as they have less need for the device and its relative newness and increased weight is more of a hindrance than a help.

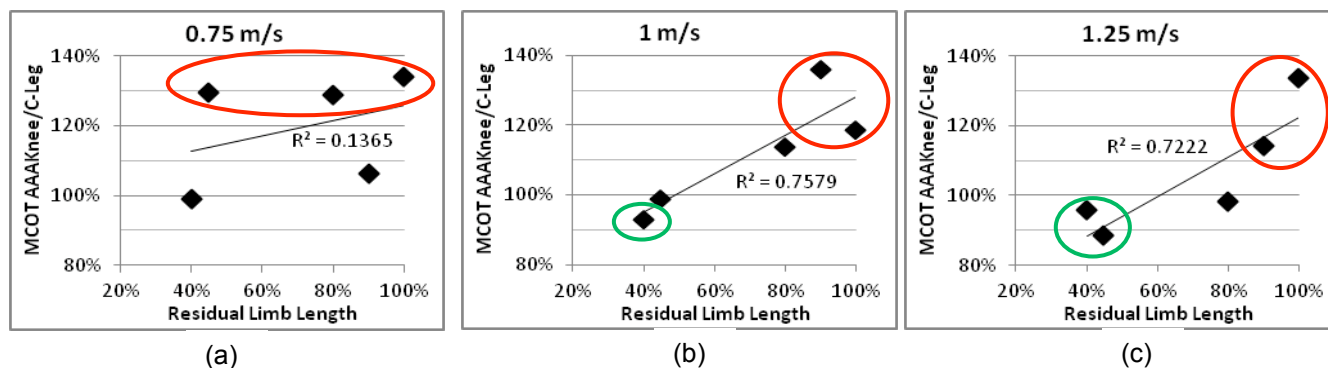


Figure 1. Plot of the percent difference in MCOT (AAA Knee / C-Leg) walking at (a) 0.75 m/s, (b) 1 m/s, and (c) 1.25 m/s. Circled points indicate significant differences ($p < 0.05$) between prosthesis conditions – Green are significant decreases in MCOT, red significant increases in MCOT while using the AAA Knee. It can be seen that at the slowest speed (a), subjects increased or exhibited no difference in MCOT, with no correlation between limb length and performance. At the faster speeds (b & c), there is a distinct correlation between performance and residual limb length.

Those with longer residual limbs also have more ability to “fight” the device compared to amputees with shorter limbs who are less able to exert counter-control to the knee due to their reduced hip torque capacity. This is largely a function of training and learning to trust and adapt their gait to the novel prosthetic. All subjects tested, while comfortable with the AAA Knee for these tests, had decades of using conventional knees requiring them to “kick out” their prosthesis, an action not required with the powered knee. It is thought that with increased training time, on the order of weeks to months, the MCOT for all limb lengths could be reduced while using the AAA Knee.

B. Trunk Lean Angle

One of the most striking trends to emerge from this work is the reduction in trunk lean angle while using the AAA Knee. While using a conventional prosthesis, above knee amputees have significant upper body involvement to assist in knee extension. They typically lean to their affected side in stance in and then swing their body over to the intact side during prosthesis swing in order to generate additional torque at the hip. This is considered a “bad habit”, and over time, may result in hip and back pain and osteoarthritis due to the unnatural loading pattern. Despite this, many to most amputees exhibit this behavior.

The amount of lean exhibited by subjects while using the powered device was significantly lower for 4 of the 5 subjects (Fig. 2b-e). The one subject who did not reduce their lean angle (Fig. 2a) already had the least amount of lean and exhibited a near-able bodied gait while using their conventional knee. The pattern of reduced lean angle was observed across all speeds.

KEY RESEARCH ACCOMPLISHMENTS

- All data collected from five of eight subjects
- Analysis routines created
- Full data analysis underway

REPORTABLE OUTCOMES

- Using the variable impedance prosthetic knee studied in this project, amputee subjects showed improvement in gait related to:
 - Metabolic rate for those with shorter residual limbs
 - With sufficient training and accommodation, amputees with longer residual limbs may also show a metabolic benefit
 - Significant reduction in trunk lean angle
- Overall, using the device studied improved gait compared to a conventional prosthetic knee

FUTURE WORK

- Further investigation of joint movements, powers, and overall leg to leg symmetry
- Analysis of EMG patterns in the affected side hip extensors and intact side muscles
- Publication of results (currently in process) in VA Journal of Rehabilitation Research and Development

CONCLUSIONS

An above knee amputation and the use of conventional passive prosthetic knees can have a significant, detrimental impact upon gait. By using a powered device, gait can be improved, by reducing affected side lean during stance and for those with shorter residual limbs, reducing the metabolic cost of transport. These improvements by themselves could markedly reduce the occurrence of chronic back and hip pain and osteoarthritis and allow users to walk further and more comfortably.

Anecdotally, all subjects, even those who showed an increase in MCOT enjoyed using the device and given a choice, would have liked to “take it home and keep it.” Subjects reported feeling more “open”, “being free-er” and that walking required less effort, despite the increase in MCOT measured in some subjects. This speaks to the strong possibility of even further improvement in gait given a longer accommodation and training time.

REFERENCES

1. Ehde DM, Smith DG, Czerniecki JM, Campbell KM, Malchow DM, Robinson LR. Back pain as a secondary disability in persons with lower limb amputations. *Arch Phys Med Rehabil* 2001;82(6):731-4.
2. Faul F, Erdfelder E, Lang AG, Buchner A. G*Power 3: a flexible statistical power analysis program for the social, behavioral, and biomedical sciences. *Behav Res Methods* 2007;39(2):175-91.
3. Gailey R, Allen K, Castles J, Kucharik J, Roeder M. Review of secondary physical conditions associated with lower-limb amputation and long-term prosthesis use. *J Rehabil Res Dev* 2008;45(1):15-29.
4. Johansson JL, Sherrill DM, Riley PO, Bonato P, Herr H. A clinical comparison of variable-damping and mechanically passive prosthetic knee devices. *Am J Phys Med Rehabil* 2005;84(8):563-75.
5. Stansbury LG, Lalliss SJ, Branstetter JG, Bagg MR, Holcomb JB. Amputations in U.S. military personnel in the current conflicts in Afghanistan and Iraq. *J Orthop Trauma* 2008;22(1):43-6.
6. Taylor MB, Clark E, Offord EA, Baxter C. A comparison of energy expenditure by a high level trans-femoral amputee using the Intelligent Prosthesis and conventionally damped prosthetic limbs. *Prosthet Orthot Int* 1996;20(2):116-21.
7. Martinez-Villalpando EC, Herr H. Agonist-antagonist active knee prosthesis: a preliminary study in level-ground walking. *Journal of rehabilitation research and development*. 2009;46(3):361.
8. Waters RL, Mulroy S. The energy expenditure of normal and pathologic gait. *Gait Posture* 1999;9(3):207-31.
9. Waters RL, Perry J, Antonelli D, Hislop H. Energy cost of walking of amputees: the influence of level of amputation. *J Bone Joint Surg Am* 1976;58(1):42-6

APPENDIX A: Conference presentation at the American Society of Biomechanics 2012.

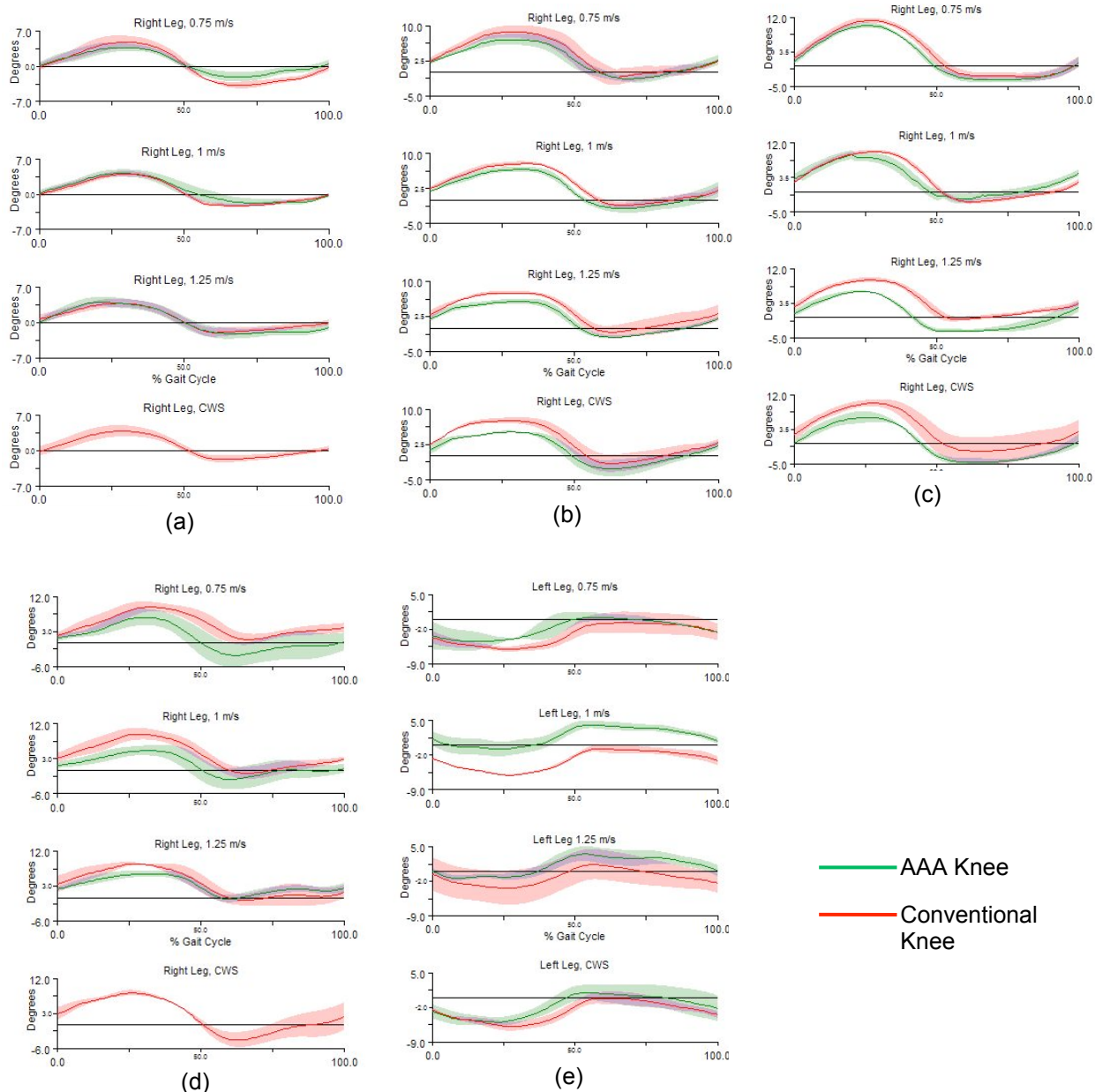


Figure 2. Plot of trunk lean angle (average and standard deviation) over the gait cycle of the affected leg for all subjects across all speeds, including customary walking speed (CWS). All subjects except one (a), exhibited marked reduction in trunk lean angle across all speeds while using the AAA Knee compared to their conventional prosthesis. Note that (e) is a left-leg amputee, such that his lean is inverted relative to the others.

PROGRAM 4

VIRTUAL REALITY AND MOTION ANALYSIS TO CHARACTERIZE DISABILITIES IN LOWER LIMB INJURY

INTRODUCTION

In military personnel performing physically demanding jobs, anterior cruciate ligament (ACL) ruptures occur at an incidence rate 10 times that of the general population (Owens et al., 2007). Following surgical reconstruction and/or physical therapy, it is important to undergo a proper examination to determine when a patient is ready to return to work and normal daily activities. While the patient's time of not working should be minimized, returning to work prematurely comes at the risk of re-tearing the ACL. Furthermore, such repeated injury dramatically increases the risk for developing osteoarthritis.

The extent of a locomotor impairment is typically assessed on the patient's ability to make gross motor movements in a controlled test setting. However, locomotion in daily living transpires in complex environments, and involves navigating various objects and agents such as other pedestrians, stairs, and moving cars. This necessitates adaptation of locomotion to fit the requirements and constraints of the environment; this behavior is referred to as *functional mobility*. In contrast to qualitative assessment tools, such as the standing hop test, the literature lacks tools for the quantitative assessments of functional mobility.

Virtual reality (VR) offers the flexibility to create a range of environments to probe locomotor behaviors. Here, we explore one such environment as an assessment tool to probe the nature of locomotor impairments associated with a torn ACL and the recovery process.

BODY

A figure-of-eight course was developed in Brown University's Virtual Environment Navigation Laboratory (VENLab). In a previous study we demonstrated that this course is highly effective in probing the functional mobility of subjects with an emulated lowerlimb disability (Gérin-Lajoie *et al.*, 2010; Rhea *et al.* 2010).

The current project extends this research to patients with ruptured ACLs. The study has a longitudinal design to test each patient at three time points: prior to their ACL-reconstruction, and two times post reconstruction (specifically, three and 12 month post the date of their surgery).

The functional mobility assessment consists of gait analysis (data on movements of limb segments and joints during locomotion) as well as path analysis (path and speed data on walking the figure-of-eight route in virtual reality (VR)). These gait and path data will be compared to standard clinical evaluations (KT-1000) and quality of life questionnaires (KOOS; SF-36) assessed over the same time frame. Additionally, intraoperative surgical data (location/laxity of the reconstructed ligament precise to the mm) for each patient will be compared to measures of functional mobility to determine if patients with a particular type of reconstruction are better able to adhere to obstacles in the environment, thus creating a more adaptive, effective locomotor pattern.

We achieved several critical accomplishments and are on track to complete the project in September 2013:

1. Starting in March 2012, we began the recruitment phase of the study. Since then, we have tested nine ACL-patients in the VENLab. Five patients have returned for their 3-month follow-up visit, with more subject visits scheduled.
2. Following collection, we have processed the data. The data for gait analysis for the pre-surgical time points have been fully tracked, and we have begun to analyze the pre-operative data set for calculation of joint angles and tibial rotation with respect to the femur (see below).
3. We established new methods for analyzing the route and speed characteristics of the path data in virtual reality.
4. In August, we submitted a conference paper on our preliminary results (submitted to Orthopedics Research Society Annual Meeting, 2013). We plan to submit a second paper in October the Gait and Clinical Movement Analysis Society for presentation at the 2013 annual meeting in Cincinnati, OH.

KEY RESEARCH ACCOMPLISHMENTS:

- Eight ACL-patients have been enrolled thus far
- Each patient successfully completed the first test-date (prior to surgical reconstruction)
- Five of these eight subjects have returned for their second test-date (3-months post-surgical reconstruction)
- All motion capture data has been processed for the presurgical time point. The obtained data set is currently being analyzed for joint angles and tibial rotation
- A protocol has been developed to study the VR data, and the analysis of the speed and position data is ongoing
- The protocol has been approved for continuing review by three local IRBs, as well as the DoD IRB.

REPORTABLE OUTCOMES:

Conference submissions

- Robert M. Shalvoy, Hugo Bruggeman, Susan D'Andrea, William Warren, Roy K. Aaron Virtual Environmental Navigation to Quantify Functional Disability in ACL-Deficient Knees, Orthopedics Research Society, San Antonio, TX, 2013

Conference Presentations

- Elizabeth I. Drewniak-Watts, Robert M. Shalvoy & Susan E. D'Andrea, Brown University. Computer Navigation as an Investigational Tool for ACL Reconstruction. *36th Annual American Society of Biomechanics Meeting*, Gainesville, FL, August 15-18, 2012.

CONCLUSION

This project uses gait and path data for assessment of the functional mobility following an anterior cruciate ligament. The most substantial accomplishment of this project during the past year has been the recruitment and testing of ACL patients at the pre-operative and 3-month post-operative time points. This implies that we are on schedule to complete all data collection by the September 2013 deadline. Reports base on preliminary analysis have been submitted to two conferences with meetings in 2013. This impact of our work may provide a quantitative assessment of functional mobility following ACL injury.

REFERENCES

2. Gérin-Lajoie, M., Ciombor, C.McK., Warren, W.H., & Aaron, R.K. (2010). Using ambulatory virtual environments for the assessment of functional gait impairment: A proof-of-concept study, *Gait and Posture*, 31, 533-536.
3. Gérin-Lajoie, M., Ciombor, C.McK., Warren, W.H., & Aaron, R.K. Using virtual reality navigation and motion tracking for the assessment of functional gait impairment. Orthopedic Research Society, Las Vegas, NV, February 2009.
4. Hausdorff, J. M., Peng, C. K., Ladin, Z., Wei, J. Y., Goldberger, A. L. 1995. Is walking a random walk? Evidence for long-range correlations in stride interval of human gait. *Journal of Applied Physiology*, 78, 349-358.
5. Owens B.D., Mountcastle S.B., Dunn W.R., DeBerardino T.M., & Taylor, D.C. Incidence of anterior cruciate ligament injury among active duty U.S. military servicemen and servicewomen. *Military Medicine*, 172, 90-91.
6. Rhea, C.K., Gérin-Lajoie, M., Kiefer, A.W., Warren, W.H., & Aaron, R.K. (under review). Constraining motion at the knee changes gait dynamics in a functional mobility task. *Clinical Biomechanics*.
7. Rhea, C.K., Gérin-Lajoie, M., Ciombor, D.McK., Warren, W.H., & Aaron, R.K. Recurrence quantification analysis of walking path trajectories in a functional mobility task with imposed constraints. North American Society for Psychology in Sport and Physical Activity, Tucson, AZ, June, 2010
8. Slifkin, A.B., Newell, K.M. 1999. Noise, information transmission, and force variability. *Journal of Experimental Psychology: Human Perception and Performance*, 25, 837-851.
9. Stergiou, N., Moraiti, C., Giakas, G., Ristanis, S., Georgoulis, A.D. 2004. The effect of walking speed on the stability of the anterior cruciate ligament deficient knee. *Clinical Biomechanics*. 19, 957-963.

APPENDIX B: Conference abstract submission which is referenced in the “Reportable Outcomes” sections.

SUPPORTING DATA:

Data collected in the VEN lab has generated interesting results for the Figure of Eight path. When forced to walk at different and faster speeds, participants did walk faster ($F(2,14)= 13.7$, $p=.0005$), however, there was no speed difference between knees (i.e. whether the injured knee was on the inside or on the outside of the turns)(Table 1). The observed speeds also changed (slowed down), as a function of the turn manipulations (Table 2; $F(2,14)= 4.1$, $p=.04$) . Again, this effect was equal between knees.

Table 1. Manipulating the Speed (self selected, or enforced at a baseline or at a faster speed). Data of speed and radius are divided in three columns, one per knee (inside, outside), and a difference between the two

	Speed (m/s)			Radius (cm)		
	inside	outside	diff	inside	outside	diff
speedSelf	.80	.78	.02	86	79	7
speedB	1.0	.98	.02	109	98	11
speedF	1.1	1.0	0.1	105	97	8

When forced to walk at different turn radius, participants did actually changed the radius of their turns (Table 2; $F(2,14)= 5.7$, $p=.015$), and the observed radius was different between the knees (wider radius with the injured

knee on the inside of turns; $F(1,7) = 5.7$, $p=.029$). Furthermore, the observed difference between knees was also found for manipulations of speed (Table 1); when forced to walk faster the difference in radius remained and even appeared to increase compared to the baseline condition ($F(1,7)= 10.8$, $p=.013$).

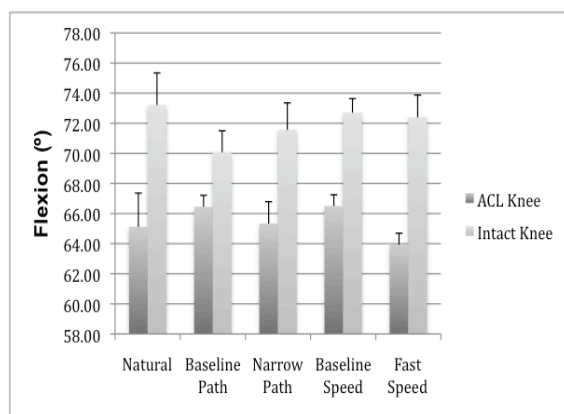
Table 2. Manipulating the Radius (self selected, or enforced at a baseline or at a narrow turn radius). Data of speed and radius are divided in three columns, one per knee (inside, outside), and a difference between the two

	Speed (m/s)			Radius (cm)		
	inside	outside	diff	inside	outside	diff
radiusSelf	.80	.78	.02	86	79	7
radiusB	.86	.84	.02	90	86	4

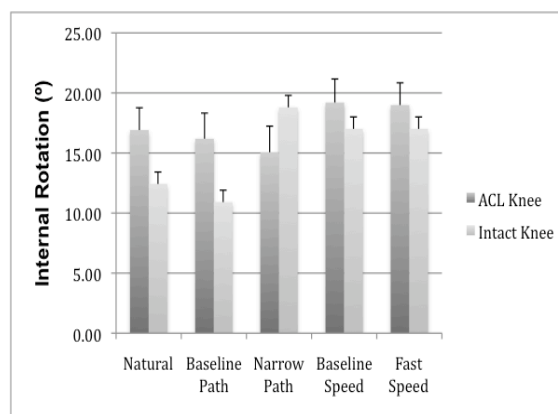
So, for ACL patients, their injury especially was most apparent in the radius data, irrespective of the nature of the manipulation (speed and radius).

KNEE ROTATION

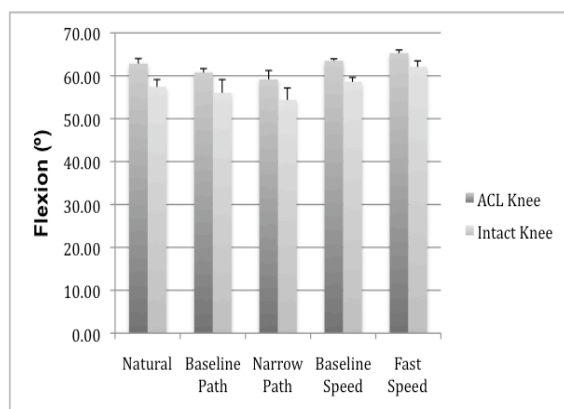
In addition to collecting data at the VENLab data at the pre-surgical and three-month post-operative time points, we have also begun to process and analyze the kinematic data for each visit. The graphs below display flexion and internal rotation angles for two subjects collected during their pre-operative visits. Each patient is subjected to five conditions, as described above. During each trial, subjects complete several figure-8 patterns. The data below represents the means and standard deviation for each subject at each condition for both their injured and intact knees. Graphs A. and B. display the data for an 18 year old female who ruptured her ACL during a high school tennis match. Upon visiting the laboratory for testing, she presented with a noticeable limp and required a break in between trials. Graphs C. and D. display the data for a nineteen year old male who had been ambulating on his ruptured ACL for approximately five months prior to the visit. While he believes that he ruptured his ACL while downhill skiing, he was not positive. He had no noticeable limp or impairment from his injury other than occasion instability while participating in sports such as basketball and football. Due to the vast differences in these subjects' injuries and condition leading up to the lab visit and surgery, it is difficult to draw conclusions about findings. However, once we have analyzed additional subjects, we expect to find some noticeable kinematic patterns.



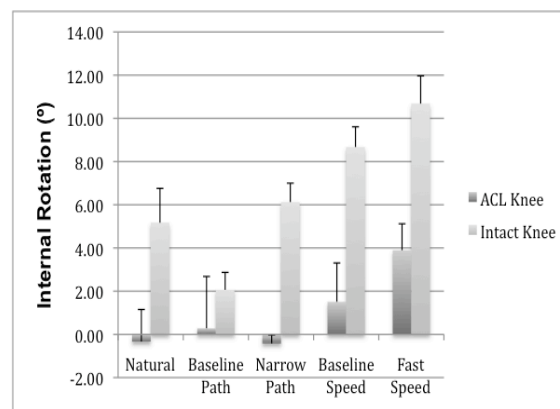
(A)



(B)



(C)



(D)

APPENDIX A: SUPPLEMENTARY DOCUMENTATION FOR PROGRAM 3B

ELECTROMYOGRAPHIC EFFECTS OF USING A POWERED ANKLE-FOOT PROSTHESIS

^{1,3}Matthew R. Williams, ²Alena Grabowski, ³Hugh Herr, and ¹Susan D'Andrea

¹Center for Restorative and Regenerative Medicine, PVAMC, Providence, RI, USA

²University of Colorado Boulder, Boulder, CO, USA,

³Massachusetts Institute of Technology, Cambridge, MA, USA

email: mrw8@mit.edu

INTRODUCTION

Individuals with a transtibial amputation typically walk 15% slower, have a 25% higher metabolic cost of transport, and exhibit asymmetric gait patterns compared to non-amputees [1]. Over time, individuals with a unilateral leg amputation using current passive-elastic prosthetic feet also have an increased risk of joint and back pain and osteoarthritis likely due to altered gait patterns [2]. Recently, in contrast with passive-elastic prostheses, a novel, powered ankle-foot prosthesis has been shown to lower the metabolic demands of level ground walking, increase preferred walking speed, and restore normative biomechanics in people with unilateral transtibial amputations [3]. Given these changes in amputee gait, it is hypothesized that use of this powered ankle-foot prosthesis would normalize the electromyography (EMG) patterns of people with unilateral transtibial amputations compared to non-amputees.

METHODS

Seven subjects with a unilateral, transtibial leg amputation and an equal number of age-weight-height-sex matched non-amputee subjects were asked to walk across a level 10m walkway while electromyography from the biceps femoris, gluteus maximus, and rectus femoris of both legs was recorded. Subjects walked at five different speeds - 0.75m/s, 1m/s, 1.25m/s, 1.5m/s, and 1.75m/s. Surface EMG was collected at 1 kHz during gait using a wireless EMG system (Delsys Myomonitor, Boston, MA). Prior to walking, each subject's maximum voluntary contraction (MVC) for each muscle was recorded during a 10 second maximum effort, isometric contraction against resistance.

EMG from MVCs and walking trials were processed identically. EMG signal processing consisted of motion artifact identification (any value

greater than ± 3 standard deviations from the mean) and removal, rectification, and a 2Hz low-pass filter to yield an envelope of the EMG signal. The walking EMG signals for each muscle were then normalized to the corresponding MVCs such that the EMG reported for each muscle is on a 0-100% MVC scale. The EMG for each muscle was then averaged and compared across each speed in non-amputees, subjects using both a powered prosthesis, and conventional prosthesis.

RESULTS AND DISCUSSION

The affected leg of subjects with an amputation had greater biceps femoris muscle activity while using both the powered and passive-elastic prostheses compared to that of non-amputees (21% vs. 8%), (Fig. 1b), particularly during stance phase. The unaffected leg of subjects with an amputation using a passive-elastic prosthesis produced greater biceps femoris muscle activity during the swing phase (13%) compared to that of subjects with an amputation using the powered prosthesis (5%) and to that of non-amputees (5%), (Fig. 1a).

Subjects with an amputation exhibited much lower rectus femoris muscle activity in their affected leg while using the powered prosthesis compared to using a passive-elastic prosthesis (12% vs. 49%), but still greater than the muscle activity of non-amputees (7%), (Fig. 1d). Subjects with an amputation using the powered prosthesis had lower rectus femoris muscle activity in their unaffected leg compared to using a passive-elastic prosthesis (11% vs. 15%), but had greater muscle activity than non-amputees (5%) during stance phase (Fig. 1c). During swing phase, subjects with an amputation using a passive-elastic prosthesis produced greater rectus femoris muscle activity (12%) compared to that while using the powered prosthesis (5%) and to that of non-amputees (6%). There were no

differences in rectus femoris muscle activity of the unaffected leg between subjects using the powered prosthesis and non-amputees during swing phase.

Gluteus maximus muscle activity of the affected leg was consistently greater in subjects using a passive-elastic prosthesis (40%) compared to subjects using a powered prosthesis and to non-amputees (25% and 20% respectively from late stance through swing), (Fig. 1f). Gluteus maximus muscle activity of the affected leg was greater in subjects using the powered prosthesis compared to that of non-amputees but follows a similar pattern of activation. Gluteus maximus muscle activity of the unaffected leg was greater in subjects using a passive-elastic prosthesis compared to subjects using the powered prosthesis (58% vs. 34%), (Fig. 1e) and to non-amputees (25%) at lower speeds, with a decreasing amount of difference between conditions with increasing speeds.

Overall the EMG patterns of subjects using the powered prosthesis are more similar to those of non-amputees compared to while using a passive-elastic prosthesis. There is both a reduction in the magnitude of muscle activity as well as activation patterns that are similar to those of non-amputees. However, subjects using the powered prosthesis had greater muscle activity in the biceps femoris compared to non-amputees and similar activity compared to when they used a conventional prosthesis. The increased biceps femoris muscle

activity in subjects with an amputation could be due to an increased need to stabilize the body immediately after heel strike. It is also possible that the biceps femoris compensates for the compromised gastrocnemius function in people with a transtibial amputation.

CONCLUSIONS

Passive-elastic prosthetic feet, while enabling individuals to walk, do not allow people with a transtibial amputation to fully replicate the walking patterns of non-amputees. By using a powered prosthesis, people with a transtibial amputation exhibit leg muscle activity that more closely matches that of non-amputees during level-ground walking. This improvement in biomimicry is thought to allow transtibial amputees to walk with a more natural, and therefore healthier gait.

REFERENCES

1. Waters, R. L., Perry, J., Antonelli, D. & Hislop, H. *J Bone Joint Surg Am* **58**, 42–46, 1976.
2. Gailey, R., Allen, K., Castles, J., Kucharik, J. & Roeder, M. *J Rehabil Res Dev* **45**, 15–29, 2008.
3. Herr, H. M. & Grabowski, A. M. *Proc. Biol. Sci.* **279**, 457–464, 2012.

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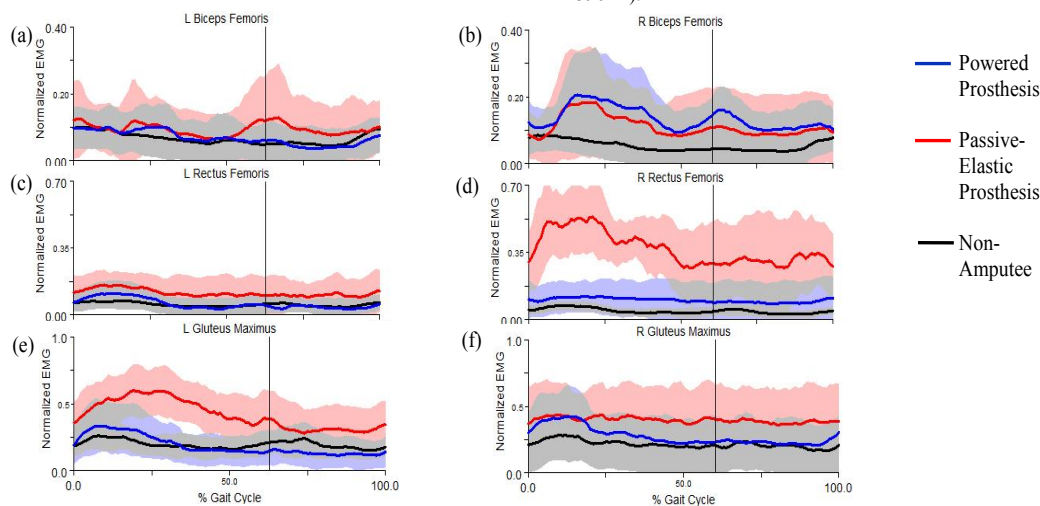


Figure 1: Mean normalized EMG during the gait cycle of three muscles for the unaffected leg (left column) and affected leg (right column), averaged across five speeds. Shaded portions represent ± 1 standard deviation. The vertical line in each plot represents the transition from stance to swing phase.

APPENDIX B: SUPPLEMENTARY DOCUMENTATION FOR PROGRAM 4

Virtual Environmental Navigation to Quantify Functional Disability in ACL-Deficient Knees

Robert M. Shalvoy, Hugo Bruggeman, Susan D'Andrea, William Warren, Roy K. Aaron

Introduction

For many orthopedic conditions and procedures, objective functional assessment of disability or outcome, respectively, is lacking. This greatly hampers the understanding of musculoskeletal pathomechanics and the development of evidence-based outcome assessments. Gait and motion studies have been helpful in delineating kinematics, but movements are constrained to a walkway. The Virtual Environment Navigation Laboratory (VENlab) permits movement in environmental space and assesses pathway geometry in response to an infinite number of visual challenges thus providing the opportunity to assess gait function in a variety of lower extremity disorders and treatments (Fig 1). We have shown that the VENlab is sensitive and specific to an emulated disability created by the use of a knee immobilizer.¹ These studies have shown that a Δ -loop area- Δ -loop speed mechanistic relationship exists (Fig 2). Patients choose one of two adaptive strategies, reducing speed but maintaining pathway geometry or maintaining speed and altering pathway geometry. The purpose of this study is to explore the gait abnormalities of anterior cruciate ligament (ACL)-deficient knees to virtual obstacle challenges in environmental space. The hypothesis is that VENlab assessment can quantitatively characterize patterns of functional adaptation to gait disabilities.

Methods

The research was conducted with IRB approval by The Lifespan Academic Medical Center. The studies were conducted in the VENLab, a 12 by 12 m room allowing free environmental walking while viewing a computer-generated virtual environment in a helmet-mounted display (SR80A, Rockwell Collins, USA). Three-dimensional positions/orientations of the subject's head were tracked at 60 Hz (IS-900, Intersense, USA). Control software (Vizard, WorldViz, USA) updated the virtual scenes in real-time (67 ms latency). Patients walked a figure-of-eight pathway determined by two posts that were placed 6 m apart. Patients walked the pathway under 5 conditions: 1. Self-selected path and speed; 2. Controlled baseline-speed (thresholds at .8 m/s); 3. Controlled faster-speed (threshold at 1 m/s); 4. Controlled baseline-path (constant radius of .8m); 5. Controlled narrow-path (constant radius of .6m). For speed conditions, a walking speed below the set speed triggered an auditory feedback signal. Similarly, for pathway conditions, walking outside a path marked by small virtual spheres floating at chest height triggered an auditory feedback signal (Fig 3). Patients were instructed to speed up, or to realign their path, upon hearing the auditory signal. For each condition, patients walked 5 full laps of the figure-of-eight route. The observed data of the head's position over time was filtered (Butterworth, 2nd order, double-pass, 6 Hz) and analyzed for the mean speed and mean radius during each turn. The radius was measured as the distance between the instantaneous position of the path with respect to the post of that turn. Data was analyzed using a repeated measures ANOVA. 1. We analyzed whether the manipulations of speed and path produced differences from the self-selected speed and path. 2. We analyzed, by comparison to the condition of self-selected path and speed, whether the manipulation of path affected the speed and vice versa, whether the manipulation of speed affected the path. 3. We evaluated asymmetry in turns, to test if there was a difference between the injured knee being on the inside or outside of the turn.

Results

Ten patients with ACL-deficient knees (age 18-42; 5 males and 5 females) followed a figure of eight course under several conditions-self selected speed and pathway, controlled speed, and controlled pathway geometry. The first analysis demonstrated that when the pathway was constrained to a turn radius of 0.6m or speed was confined to 1.0m/s, patients adapted well ($p < 0.002$ and $p < 0.0001$, respectively). The adaptations were asymmetric with respect to whether the injured knee was on the inside or the outside of the turn. Under confined conditions, when the injured knee was on the inside of the turn, speed slowed ($p=0.03$) and the radius of turn was wider ($p=0.02$). The effect of controlling speed and pathway geometry was next assessed. Patients exhibited the same mechanistic relationship as was previously observed. When the turn radius was controlled, the mean speed decreased from 0.78m/s to 0.71m/s ($p < 0.002$). When speed was controlled, the mean radius increased from 0.91 to 1.01m ($p=0.03$). These data are the first demonstrations of mechanistic gait adaptations of the pathway geometry and speed in a ligament-deficient knee and provide the first demonstration of the ability to characterize gait of an injured knee in 2x2 environmental space.

Discussion:

This study identified: 1.) A figure of eight locomotor task that will demonstrate deficiencies in ligament deficient knees; 2.) Outcome measures - speed and pathway geometry - that can, through tracking of body motion in space, discriminate between normal walking and gait with a ligament deficient knee; and 3.) Virtual environments can be created that can be used to assess discrete joint abnormalities.

Significance:

These studies provide for the first time physiological techniques that can provide objective assessment of function of the lower extremity. An infinite number of virtual environmental challenges can be created specific to particular joint kinematics that can increase understanding of joint pathomechanics and provide guidelines for assessment of treatment outcomes.



Figure 1: VENLab with inertial ceiling tracking to assess pathway geometry and speed.

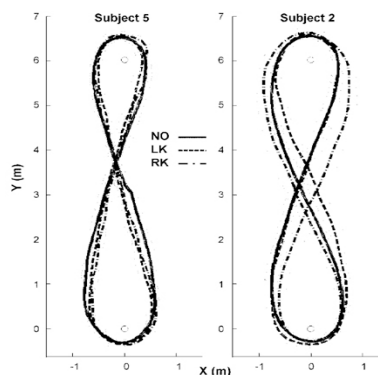


Figure 2: Mechanistic spatio-temporal gait relationships. Subject 5 maintained pathway and reduced speed. Subject 2 maintained speed and altered pathway.

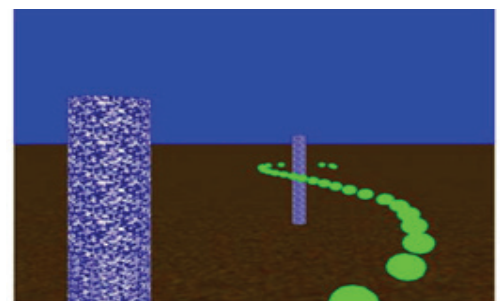


Figure 3: Virtual figure of eight pathway with sphere guidance.