Spring 2021

Feasibility Study to Measure the Impact of a Specialized Core Exercise on Metabolic Efficiency and Stability during Walking for Above Knee Amputees

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Feasibility Study to Measure the Impact of a Specialized Core Exercise on Metabolic Efficiency and Stability during Walking for Above Knee Amputees

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Abstract

The objective of this study is to determine the feasibility of improving the gait of above-knee (AK) amputees by performing daily core exercises aimed to provide an efficient and stable walking pattern. The goal of the exercise is to strengthen core muscles and form temporary neural connections in the brain aimed at improving metabolic efficiency and stability. We will be implementing the Wright Balance Core 360 Exercise Technique for completion by our subjects. Motion capture technology will be utilized in conjunction with a metabolic oxygen consumption analyzer to collect stability and metabolic efficiency data while amputees walk on a treadmill. By performing these core exercises for eight consecutive weeks, it is our hope that participants with AK amputations will experience significant improvement during walking through increased stability and efficient metabolic expenditure. This feasibility study aims to determine the extent to which improvements are realized in these two areas with the hope that amputee patients will experience increased confidence while participating in physical activity as well as reduced risk of injury due to falls. This study was delayed due to the COVID-19 pandemic; however, despite the setbacks, the team was given the opportunity to not only learn about rehabilitation of amputee patients, but gained hands-on experience working with the gait lab instrumentation as well as familiarity with conduction of a human subject research study. It is intended that once vaccinations are complete, patients from Yanke Bionics will be recruited, and the full feasibility study will be completed.

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Introduction

A transfemoral, or above-knee (AK), amputee is an individual who has undergone an amputation which involves removing the leg from the base of the femur (sometimes higher) to the foot [Berke 2008]. Post-amputation, it is common for amputees to develop musculoskeletal imbalances which can affect ambulation, stability, and quality of life of the patient [Gailey 2008]. Many of these disparities are caused by favoring the amputated limb, which adds more stress to their stable side and increases the possibility of osteopenia and osteoporosis developing on the side of the residual limb [Gailey 2008, Marshall 2016]. Restoring mobility of the patient is of high priority, and physical therapy is offered to patients postoperatively in the majority of hospitals [Berke 2008]. In order to return functionality to the patient, it is imperative to initiate a strong and successful exercise program to encourage coordination and balance by stimulating the brain and strengthening the core muscles of the trunk [Berke 2008].

As lower limb amputees adjust to bearing weight on their residual limb, their body and mind must relearn to distribute load in the weeks after surgery [Gailey 2008, Marshall 2016]. The muscles that are used to facilitate daily ambulatory tasks must be trained to recompense for the residual limb [Marshall 2016]. Even after an amputation, the brain is constantly trying to achieve proprioception, or awareness of the body in space, to maintain stability and encourage fall prevention [Yigiter 2002]. To create locomotion, the following must be developed: stability, balance, coordination, flexibility, and strength. Development in these areas allows for the body to encourage safe and efficient muscle recruitment and control with posture improvement as an additional benefit to balanced gait and locomotion [Hibbs 2008]. Inner core muscles control stability of trunk and pelvis. These muscles together provide stabilization, postural support, restore normal functions that may be lost due to injury, and prevent future injury [Hibbs 2008]. When muscle control is improved, balance and locomotion are subsequently refined.

Furthermore, walking with a prosthesis compared to normal ambulation requires an additional energy expenditure of 65-100% for an above knee prosthesis [Marshall 2016 and Ward 1995]. Thus, it is equally vital to improve metabolic efficiency by reducing energy expenditure. Metabolic efficiency is the improvement of the body's ability to utilize its energy stores more effectively through exercise implementation. Insufficient research has been conducted on the efficacy of physical conditioning of AK amputees on metabolic cost, leaving room for investigation of the potential benefits of core training for metabolic cost reduction during ambulation [Ward 1995]. The benefits of establishing a daily exercise routine include:

1. Helping to maintain anatomical and neurological equilibrium of the body
2. Exercising to boost endorphins in the body to overcome emotional or mental distress
3. Evenly strengthening core muscles to improve gait and balance
4. Reducing pain associated with improper muscle recruitment [Johns Hopkins Medicine Health Library]

In addition to the metabolic cost reduction, daily activity and exercise are critical components to avoiding joint pain, physical deterioration, physical ailments, and other musculoskeletal imbalances [Johns Hopkins Medicine Health Library].

The added benefits of the exercises performed in this study stem from the concept of creating temporary neural connections. This concept has been applied in studies surrounding physical rehabilitation of patients with Parkinson's Disease (PD). For example, a study conducted by Petzinger examined the effects, specifically neuroplastic, of exercise intervention on the cognitive and automatic components of motor control in PD patients [Petzinger 2013]. Due to the positive outcome, the temporary neural connections formed by the PD patients can be applied to other impairments, notably lower-limb amputees. One study published by Frontiers in Human Neuroscience conducted an experiment to test the neuroplasticity and whole-brain functional connectivity of lower-limb amputees versus that of healthy controls. Their findings showed a decrease in functional connectivity in the sensorimotor network following lower limb amputation and suggest the need for more research to be conducted in the future on how to recover motor function [Zhang 2018]. Exercise regimens found to be most beneficial in forming these connections while improving gait and balance are focused on core strengthening, muscle flexibility, and increasing the focus needed to perform tasks. PD patients who have received goal based physical therapy treatment that recruit numerous muscle groups and provide mental stimulation to perform exercise have experienced improvement in motor control through enhanced neuroplasticity and increased synaptic connections [Petzinger 2013]. The Cleveland Clinic has experimentally obtained similar results in an 8-week study conducted to analyze the effects of forced exercise cycling on PD patients [Cleveland Clinic 2016]. However, they also found the improvements only lasted for approximately 4 weeks and gradually decreased over that span of time. For this reason, clinicians suggest including regular and ongoing forms of mentally stimulating exercise for patient therapy. The information gathered in these clinical investigations provides background for the exercise regimen utilized in this study.

The Wright Balance® Core 360 Exercise Program (by Wright Balance Technology) is a low demand, highly impactful set of core symmetry, balance, and strengthening exercises. Through Yanke Bionics, the research team has become introduced to the exercise methods of and affiliated with Dr. David Wright ( )—who theorizes that the results of these exercises can be seen and felt immediately after the exercise sequence has been executed due to the temporary neural connections that are made while executing them. The immediate results and corrections experienced set this program apart from all others. After performing the daily exercise program for one week, taking 1 or 2 days of rest will not disrupt the symmetrical benefit to the core. After three consecutive weeks performing these daily exercises, the individual can go up to 1 week without exercising and still experience the improvement [Wright 2020]. The effects of the exercises will last if they are executed properly and incorporated into a daily routine. A subset of the Wright Balance® Core 360 Exercises were selected and modified for use in this study to target the core muscles acting in the transverse, sagittal, and coronal planes of motion. By maintaining a controlled, neutral spine position during any exercise, patients gain stability and core strength since the body is utilizing the entire core. Ultimately, the intent of the Wright Balance Technique is to create core symmetry, strengthen the core muscles, and improve balance by recruiting muscles in each of the core regions: lower, middle, and upper.

While there are studies that discuss how an amputation affects the metabolic efficiency while walking of an AK prosthesis, there are no existing clinical trials that suggest a simple exercise program to collectively improve gait and stability while increasing metabolic efficiency in above-knee prosthesis users. Thus, the purpose of this study is to collect data to determine the feasibility of improving the efficiency and stability of amputees during walking when performing specialized daily core exercises for eight consecutive weeks. In addition to the overall improvement of the amputees' metabolic and physical health, this study will help determine the feasibility and teachability of the exercises. Therefore, our hypothesis is that by performing a daily core strength and coordination exercise program for 8 consecutive weeks, participants with a transfemoral amputation will experience a significant improvement in stability and a reduction of metabolic expenditure while walking.

Methods

The Institution Research Board (IRB) for the protection of human subjects at The University of Akron approved this study. Additional measures were accounted for in the subject testing due to the COVID-19 Pandemic. Subjects will be recruited from Yanke Bionics Inc (Akron, OH) or its varying satellite locations. Inclusion criteria included an individual over the age of 18 with a transfemoral, unilateral amputation, in which has an above-knee prosthesis. Persons of K-2 or K-3 level of activity were preferred, where individuals will either show the ability or potential for ambulation and the ability to traverse low level barriers (K-2) or most environmental barriers (K3). Individuals must eliminate all other exercising activities for the duration of the study in order to keep data consistent. Exclusion criteria that limited amputees from participation included the inability to walk, underlying health issues that would worsen with exercise, and transtibial, bilateral-transfemoral, bilateral-transtibial or Symes amputees.

Participants

Participants that met the inclusion criteria were given a predetermined start date to begin data collection. Each individual will be given a personal Fitbit Charge 3 personal tracking device to monitor and advise completion of the exercise program. The Fitbit Charge 3 personal tracker will be used to provide heart rate, sleeping habit, and daily activity level data for the purpose of graphical comparison over eight weeks.

An Informed Consent document will be delivered to each participant outlining the study objectives, benefits, risks, and expectations. After the participants have accepted the expectations of the testing design, weekly laboratory sessions will be scheduled for data collection for the eight consecutive weeks for the trial duration.

Data Collection

The Vicon Nexus Motion Capture System will be used to monitor the weekly walking trial for the extraction of Center of Mass (CoM) movement, accelerometer data and gyroscope data from the participant while walking on the split belt treadmill. The 13 reflective markers will be placed on the subject after the room has been calibrated for the initiation of the trials. These markers will mostly be placed on the lower body, with three on each foot (one at the toe, one at the side of the ankle, and one at the back of the ankle, with the remaining markers at the knees, hips, and shoulders. The cameras surrounding the perimeter of the laboratory record motion data from the subject as he or she walks at a personalized velocity for eight minutes. This data collection is synched with the metabolic exchange cart data for comparison of relationships between energy expenditure and stability.

The Vicon Blue Thunder IMU sensor collects both accelerometer and gyroscope data at three axes. The accelerometer device will be attached to the heart rate monitor strap under the subject's shirt for the collection of acceleration data during the walking trial. This movement analysis hardware is fully integrated to the Vicon Nexus Motion Capture System for time synchronization ability and had a main purpose of gathering acceleration data for the subject for the analysis of gait stability.

The Timed Up-and-Go (TUG) assessment is used to establish an initial velocity and observe stability of the participant while standing and walking.

The Parvo Medics Metabolic System will be used in this study to monitor and capture metabolic efficiency (maximal oxygen uptake or VO2) for eight weeks while performing the daily exercise program. This equipment allows for collection of data surrounding the subject's metabolic exchange rate before, during, and after initiation of the daily exercise regimen. Through metabolic exchange data compilation over time, the variance in metabolic exchange can be monitored and analyzed. In the weekly lab sessions, the device will measure VO2 uptake for seven minutes while the subject walks on the treadmill at their first velocity. The Heart Rate monitor will serve to monitor and capture metabolic efficiency (VO2 uptake) for eight weeks while performing the daily exercise program. The purpose of the heart rate sensor is to observe the heart rate in the metabolic software during the seven-minute walking trial while walking at the subject's personalized velocity.

The Split-Best Treadmill Walking Trial is an eight-minute walking test to allow for the continuous dynamic measurement of the CoM data. The subject will be asked to walk on the treadmill for 8 minutes once a week for 8 consecutive weeks. The eight minutes of walking will be at the average velocity calculated from the TUG assessment.

For the eight-week study, the following will be completed at each session: COVID-19 Questionnaire, Pain Questionnaire, Exercise Regimen, and Walking Trial. Each participant will have completed the exercise regimen, thoroughly detailed in their weekly schedule.

The exercise regimen schedule, shown in Table 1 below, will be executed 4 days at-home with 1 day in lab session (allowing 2 days for rest) each week. This schedule is an example of what the weekly schedule may look like for the subjects. The "Scheduled Lab Session" is subject to change weekly. If this is the case, the lab day will be preceded and followed by two days of exercise with two days of rest in between.

Table 1: Example of weekly exercise schedule to be followed for 8-week period exercise.

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
REST	AT-HOME EXERCISES	AT-HOME EXERCISES	SCHEDULED LAB SESSION	AT-HOME EXERCISES	AT-HOME EXERCISES	REST

This exercise regimen includes transverse/frontal plane, sagittal plane and coronal plane exercises. The transverse/frontal place exercise includes dynamic wall push-ups. For the sagittal plane leg exercise, the participant completes the dying bug and back core strengthening exercises. To complete the exercise regimen, the coronal plane exercise is completed. For this exercise, the participant completes an oblique/side plank.

Data Processing

Subjects will be wearing a Fitbit Personal Tracker to monitor their weekly activity levels. This will ensure that, while performing daily exercises at home, the researcher will have access to the subject's heart rate. While in the lab each week, participants will be wearing a heart rate monitor and metabolic mask to measure oxygen levels while walking on the treadmill. Interim monitoring will consist of weekly pain assessments in the form of pinpointing where pain occurs on the body with the level of pain, as well as a psychological assessment to assure subjects are mentally capable of continuing with the study. Motion capture data is consolidated and stored on the Gait Lab computer station which can only be accessed through Dr. Noble's personal username and password. A second set of metabolic cart data is stored on a flash drive for which Dr. Noble and Serena Myers have access. At home exercise recordings and research assistant files are stored on the computers of each assistant who are the only individuals with access. Lastly, the pain analysis survey is saved on private a team drive only accessible by Dr. Noble and the research assistants.

Statistical Analysis

A plan for statistical analysis has been devised for future applications where a paired t-test will be utilized for comparison between two variables for one subject. ANOVA will be used to determine which results should be considered significant, and all data will be presented as a mean value with +/- standard deviations. The level of significance utilized will be a p-value of < 0.05, and MINITAB software will be used to conduct the test. The independent variable in this study is the implemented exercise regimen, where the dependent variables being analyzed are stability and metabolic efficiency.

Outcomes

Due to the COVID-19 pandemic, the proposed study has been fully prepared but not yet performed on AK amputee volunteer subjects. It is expected that this study will begin concluding the pandemic or at the time of complete vaccination of the participants.

Despite being unable to recruit amputees for in-person analysis at this time, safety provisions have been implemented at the University of Akron's gait lab in anticipation of future visits.

Participants will be asked to respond to a weekly COVID-19 questionnaire concerning their potential exposure. Should all volunteers answer "no" to the series of questions, they will be permitted to safely participate in the study. Additionally, all research team members have successfully completed The Collaborative Institutional Training Initiative Program as mandated by the University of Akron to follow and maintain good clinical practice as well as obey The Health Insurance Portability and Accountability Act Privacy Laws and Regulations for human subject research studies. Regarding Coronavirus, additional specialized certification has been completed through CITI with an emphasis on social distancing and minimizing exposure.

To ensure subject safety and protection, confidentiality will be maintained as outlined in the individualized informed consent forms to be reviewed by the study coordinator. In regard to physical protection, face masks will be provided for use within the lab and should be appropriately worn covering both the mouth and nose. Facial coverings will also be worn by research assistants at all times in combination with the use of a face shield during marker and metabolic mask application. Physical distancing will also be enforced when possible in addition to limiting the number of individuals coming in close proximity with the subjects. Handwashing regimens are also utilized to ensure participant protection and safety.

Academic Achievements

The research conducted in this experiment was delayed due to the COVID-19 pandemic. Despite the setbacks, the team was given the opportunity to not only learn about rehabilitation of amputee patients, but also how to incorporate safety protocols needed to continue these trials. The hands-on experience working with Yanke Bionics provided us with the information necessary to understand the rehabilitation process of amputees and challenges the patients face. While working with an established company such as Yanke, the team learned the importance of obtaining the correct certification in order to work with patients as well as obtaining documentation of consent from participants. The team was also given the opportunity to work with biomedical lab equipment that was not utilized in our studies at the University. As far as safety procedures go, the team learned to take on many different roles, as the number of people allowed in the lab at once was limited. Sanitization routines were also changed in order to keep the lab area as clean and disinfected as possible. Any researcher or assistant working directly with a patient or equipment touching a patient wore a mask, goggles, a face shield, and gloves at all times.

Individual responsibilities have been divided amongst research assistants to gain cumulative knowledge and practice regarding each component of study preparation and data collection. As research assistants, responsibilities include assisting the Principal Investigator and Study Coordinator in data collection, preparing excel reports for data analysis, acting as a point of contact between the research team, IRB, and other university departments, as well as aiding in developing the study procedure. Serena Myers' responsibilities include preparing the reflective markers and harness for subject arrival, assisting the subject in dressing and preparing for the lab sessions to begin, assembling the metabolic mask, and calibrating the metabolic cart. Sabrina Segretario's responsibilities include ensuring equipment is powered on and functioning properly with all power connections established in addition to performing harness adjustments, setting treadmill speed during walking trials, and application of the metabolic mask onto the subject.

Shaye Tiell’s responsibilities include, calibration of the gait lab, ensuring adequate camera setup, segmenting and labeling of anatomical marker placement, directing the Vicon software as well as monitoring the data collection during walking trials. Emily Tully is responsible for directing and supervising participants during in-lab exercise execution, taking the anthropometric measurements and other physical data of the subject, as well as administering the COVID-19 safety questionnaire and pain survey. The aforementioned responsibilities were executed on a student test subject during Spring 2021 semester.

Conclusion

As the most important outcome of our study, the team is hoping to measure and improve metabolic efficiency and stability during walking for AK amputee patients through daily core exercises. This information could be applied to future rehabilitation programs for amputee patients in order to maximize their mobility and quality of lifelong term.

Acknowledgements

We would like to thank Dr. Lawrence Noble for his leadership and guidance as well as Yanke Bionics for their financial support and intention to provide future patients for upcoming phases and possible clinical trials. We would also like to thank our readers, Dr. Audrey Nguyen, Dr. Adel Alhalawani, Dr. James Keszenheimer, and Dr. Francis Loth for their time and feedback.

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