Underwater Treadmill Training in Adults with a Unilateral Transtibial Amputation

By

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ABSTRACT

A unilateral transtibial amputation (TTA) propagates secondary physical conditions and complications that may negatively impact quality of life and health. Often, there are challenges to balance, posture, and functional mobility. Underwater treadmill training (UTT) is an alternative modality for people with a TTA that can address these concerns. Series case studies were conducted with three adults (1 female, 2 males) with a TTA to establish the efficacy of UTT within this population and to better understand the challenges to activities of daily living (ADL) and physical activity (PA).

Participants completed a 6-week underwater treadmill training protocol and participated in a focus group. Pre-, mid-, and post-UTT measures of balance, fall risk, center of pressure, and weight distribution were assessed. Pre- and post-assessments of walking capacity and balance confidence were also measured and cardiovascular responses to exercise were monitored during the UTT. Outcomes of training increased balance, reduced fall risk, and improved weight distribution from left to right and front to back with increased reliance on the prosthetic limb. Balance confidence during PA and functional mobility improved. Cardiovascular responses and rate of perceived exertion were positive and linearly associated with walking bout time and walking speed, respectively. The focus group revealed themes of a need for increased planning and decreased tolerance when performing ADL. Residual limb symptoms underscored themes of challenges with cardiovascular and resistance training exercises. Participants also noted being more active post-amputation to increase health or physical fitness and attempt to return to pre-amputation levels of PA. Reponses also highlighted themes of improved balance or posture while standing or ambulating and increased confidence

while performing activities with a prosthesis following UTT. Improved muscular fitness was also a consistent theme with all improvements resulting in increased exercise tolerance.

Overall, UTT was an effective and safe training modality which yielded improvements in physical performance and function for people with a TTA. Participation in UTT can increase physical fitness to minimize objective and subjective challenges associated with completing ADL and being physically active in those with a TTA.

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CHAPTER I

INTRODUCTION

Yearly, over 150,000 people undergo amputations of the lower limb in the United States (Molina & Faulk, 2021). An amputation is the loss of a portion of, or an entire limb, at different levels (e.g., below knee or above knee), caused by factors such as trauma, cancer, and vascular diseases (Gallagher & MacLachlan, 2001). While the etiology of a lower limb amputation (LLA) and type of prosthetic varies amongst populations, there are common challenges to balance, gait, posture, weight distribution, and physiological responses to physical activity (PA). An amputation is often considered to be systemic in nature, leading to misalignment and impairments in various systems of the body and altered movement strategies (Matjaĉić & Burger, 2003).

Following a LLA, uneven or asymmetrical weight distribution is a direct reflection of the missing portion of the limb and significantly affects balance and posture. A common LLA that possesses these significant physical limitations is the unilateral transtibial amputation (TTA). A person with a TTA typically has absent muscles and sensory receptors which reduce feedback going to the brain to assist in decision making related to balance and gait (Petrofsky & Khowailed, 2014). The loss ultimately results in reorganization of the motor centers, which leads to asymmetrical weight distribution due to compensatory shifts (Soares et al., 2009). Reduced participation and activation of the residual leg musculature during standing or walking (Isakov, 1996) also leads to muscular atrophy (Hewson, 2020). As a result, people with a TTA tend to have an asymmetrical center of pressure (CoP) and greater postural sway during tasks that require balance and an erect posture (Moisan, 2021). One of the most common compensations by people with a TTA is the movement of the intact limb toward the midline of the body while simultaneously externally rotating the lower limb (Engsberg, 1994). A direct result of this movement strategy is increased swing time for the prosthetic limb compared to the intact limb (Mattes, 2000), as well as increased limb loading to the intact limb during ambulation (Vrieling, 2008).

Consequently, participation in exercise and PA are also affected following a TTA. For example, people with a TTA experience a greater HR while walking when compared to able-bodied people (Gailey et al., 1994). In addition, people with a TTA display slower walking paces (Powers et al. 1998) and have increased rates of oxygen consumption (VO_2) while ambulating (Esposito et al., 2014). Thus, with uncharacteristic movement patterns as well as increased energy consumption during locomotion, performance of and participation in PA are negatively impacted.

Typically, people with a LLA have decreased adherence to and performance of PA (Bussmann et al., 2004). Insufficient PA levels contribute to excess body fat. According to one health survey, 29.5% of people with a LLA are obese and 54.4% are overweight (Sutton, 2011). Thus, it is important to address and minimize the ongoing challenges that people with a TTA face through rehabilitation or training.

After an amputation, a rehabilitation or training program is vital to optimize function with a prosthesis for normal activities of daily living (ADL) and to contribute to overall health (Bussmann et al., 2004). The main purpose of TTA rehabilitation is to incorporate an effective training method to regain or improve balance for functional independence (Matjaĉić & Burger, 2003). Balance training has shown success in improving medio-lateral balance control (Sethy et al., 2009), increasing duration of balance on the residual limb during stance, improving timed up and go test performance, and increasing walking speed (Matjaĉić & Burger, 2003). Results from task-specific balance training have also demonstrated improvements to trunk control, motor skills, and a reduced number of falls following training (Kaufman et al., 2014). These improvements indicate balance training may positively influence proprioceptive input, reaction time, and muscular control for better balance and posture (Yaggie & Campbell, 2006).

Nevertheless, while various training modalities and methodologies can provide and produce countless benefits for people with a TTA, they do however, have limitations. Common training modalities include variations of a moving platform that creates perturbations and a treadmill. This equipment can prove to be expensive or unobtainable to community members. An additional limitation of prior research includes the lack of comfort in various modalities. These uncomfortable situations can intensify stress for the individual who is already overwhelmed with impacts associated with the newly acquired or congenital TTA. Many modalities and protocols are also not tailored to the wide variety of demographics associated with and etiologies of a TTA. The lack of accommodation to this special population could prove to be detrimental in rehabilitating or training a person with a TTA. Furthermore, there is a need for research to better understand this special population and the perceived benefit of training modalities for those with a TTA.

An underwater treadmill (UTT) is an innovative modality that may be beneficial to individuals with a TTA by incorporating safety and comfort while creating a training effect. The ease of modifying training variables such as intensity, duration, and the water environment make this modality valuable to researchers and clinicians alike. This form of aquatic exercise may improve balance, motor function, muscular strength, and mobility (Bressel et al., 2014). Specifically, UTT has shown to be advantageous for numerous special populations by enhancing balance, leg strength, cardiorespiratory function, and walking speed and distance (Conners et al., 2019; Stevens et al., 2015; Yoo et al., 2014). It is believed these improvements can be applied to individuals with a TTA due to the unique properties associated with water.

The underwater environment during UTT is different from that of walking out of water because of the beneficial characteristics of water. Water's benefits include viscosity, hydrostatic pressure, turbulence, and drag force (Bates & Hanson, 1996). The viscosity and buoyancy of water can relieve stress on weight bearing joints and create postural stability for those with impaired balance (Yoo et al., 2014). The drag force also produces resistance while walking. Other attributes of this aquatic therapy reside in participants feeling an increased sense of comfort while ambulating in the underwater treadmill (Cutler et al., 2017). This modality is underutilized in training, and to the authors' knowledge, HAS only been applied in one instance to populations with a unilateral TTA (Mathis et al., 2018).

Overall purpose

Thus, the purpose of the first study in this dissertation was to evaluate the effects of a 6-week underwater treadmill training (UTT) protocol on balance, posture, functional mobility, and cardiovascular responses for people with a unilateral TTA. It was hypothesized that an UTT protocol would produce changes to the outcome measures. Utilizing a focus group, the purpose of the second study in the dissertation was to investigate the common challenges to ADL and exercise for those with a TTA, and to highlight the perceptions of performing an UTT intervention.

CHAPTER II

REVIEW OF LITERATURE

This literature review begins with a synopsis of the prevalence of LLAs and an overview of the demographics most associated with this procedure. The etiology of amputation follows, with an overview of common surgical practices and prosthetics associated with a LLA. The next section is designed to explain the anatomical, pathophysiological, and biomechanical implications of a transtibial amputation (TTA) on balance, posture, gait, and physical activity (PA). Included throughout are qualitative results and subjective feedback further justifying the impacts of possessing a TTA. The review concludes with descriptions of commonly utilized interventions for balance training following a TTA and the introduction of both an UTT as a training modality following a TTA and a focus group as means to receive subjective feedback about UTT training.

Prevalence of LLA

An amputation is the necessary surgical removal of a limb or part of a limb because of extraneous circumstances or situations to save the life of a person (Ali & Fatima Haider, 2017). Young adults (20 years - 40 years) have a greater occurrence rate of amputation than older adults (41 years - 60 years; Ali & Fatima Haider, 2017). The higher rate in this younger age group is potentially associated with more frequent participation in activities considered risky (Ali & Fatima Haider, 2017). Rates of amputation may also be lower in older adults because they have additional comorbid diseases, higher mortality rates, and generally, relatives do not support amputation due to shorter life expectancies (Ozkan & Adanas, 2021). In addition to age, the likelihood of undergoing an amputation also differs by sex. Males have a higher incidence of amputation (Ali & Fatima Haider, 2017). Often, males are more actively involved in accidental and environmental risks due to occupations, vocational activities, and lifestyle activities (Ali & Fatima Haider, 2017; Sabzi Sarvestani & Taheri Azam, 2013). In one review of 100 cases of amputation, 56 cases were caused by traffic accidents, 9 cases were due to bomb blasts, 7 were caused by gunshot, and 4 cases were the result of electric shock (Ali & Fatima Haider, 2017). Socioeconomic factors such as low income, limited or no insurance, and minority status also contribute to the likelihood of undergoing a major amputation. Minorities with a low income were more likely to receive care at hospitals with fewer resources, limited vascular surgery, and angiography capacity, increasing the need for an amputation (Henry et al., 2011; Regenbogen et al., 2009). Furthermore, minorities without private insurance and with lower incomes also experienced an increased risk of major amputation (Henry et al., 2011).

While the demographic factors of age, sex, and socioeconomic status have strong associations with the incidence of limb amputation, there are also physiological causes of a LLA. The etiology can dictate the level of amputation, appropriate surgical process, and the type of prosthetic an individual might employ following amputation.

Etiology of LLA

The causes of limb loss are diverse and can be categorized by congenital anomalies, trauma, infection, poor blood circulation, and/or tumors (Ozkan & Adanas, 2021). The most common causes of amputation are complications associated with poor blood circulation and infection in the legs (Cristian, 2006). Inadequate blood circulation and infection are commonly attributed to peripheral vascular disease (PVD) and/or diabetes (Cristian, 2006).

According to one statistic, vascular disease represents the cause of 82% of all amputations that occur yearly in the United States (Adams et al., 1999). Deposits of cholesterol and other substances in the walls of the blood vessels, which negatively impact blood flow is characteristic of PVD (Cristian, 2006). Inadequate blood flow restricts delivery of oxygen and nutrients and may lead to significant injury or cell death (Cristian, 2006). When this occurs, infection can develop and potentially lead to amputation (Huang et al., 2018).

Diabetes is also a contributor to the need for amputation. Diabetes is characterized by hyperglycemia leading to inadequate insulin secretion, reduced insulin action, or both (Powers & Howley, 2011). Approximately 90% to 95% of all cases with diabetes, have Type 2 diabetes (American Diabetes Association, 2016). From 1990 to 1991, 58% of 14,555 cases of nontraumatic amputations were associated with diabetes (Armstrong et al., 1997). Diabetes affects the body's blood circulation by increasing development of hypertension and accumulation of cholesterol (Powers & Howley, 2011). One of the most serious complications of diabetes is critical limb ischemia caused by obstructed peripheral circulation or bacterial infections (Huang et al., 2018). Infections can stem from ulcers or unknown injuries due to a lack of sensation in the affected area (Cristian, 2006; Huang et al., 2018). As the infection progresses, a tissue can become necrotic, leading to the need to remove the tissue by amputation (Huang et al., 2018). Although infection and poor blood circulation are the most common causes of LLAs, trauma also has a significant role.

Trauma to the lower extremity accounts for approximately 20% of patients with an amputation when associated with severe wound contamination and significant tissue loss (Molina & Faulk, 2021). The sources of traumatic amputation are diverse. High-energy traumatic injuries or events can lead to acute amputation (Molina & Faulk, 2021). Furthermore, patients may present with a mangled extremity from an accident or explosion, not amenable for reconstruction (Ali & Fatima; Haider, 2017; Molina & Faulk, 2021). Some patients undergo a below knee amputation (BKA) because of the intense chronic pain that may be associated with lower extremity trauma (Adams & Lakra, 2022). Moreover, those who suffer from a severe traumatic lower extremity injury who initially possessed the potential for limb salvage may become candidates for an amputation due to infection, improper bone or hardware coverage, high pain levels, or the lack of determination for reconstructive protocols (Molina & Faulk, 2021).

In summary, PVD and diabetes impair blood circulation. Inadequate blood supply ultimately leads to infection or necrosis of the limb thus requiring an amputation. In contrast, patients could present with a distorted limb from trauma which requires amputation to prevent future infection or death. Regardless of the cause of amputation, the surgical process of amputating a lower extremity is often an imperative route to saving a life.

Surgical osteotomy

The most common lower limb osteotomies are TTA and transfemoral amputations (TFA). Of 1,221 people with an amputation, 41.8% had a TTA and 34.5% had a TFA (Krueger et al., 2012). Depending on the viability of the soft tissues to provide adequate bone coverage, blood supply, and severity of the injury or condition, amputation level varies (Molina & Faulk, 2021). Furthermore, the decision to perform an amputation is often dependent on the clinical status and quality of the soft tissue at the desired level of amputation with the primary goal being to excise the non-viable and infected tissue (Molina & Faulk, 2021). Overall, the level of amputation is dependent on characteristics that vary from patient to patient.

A unilateral TTA is an amputation that involves the removal of the foot, ankle complex, distal tibia, and fibula, along with any corresponding soft tissue structures (Adams & Lakra, 2022). There are many ways to perform a TTA, but one of the most significant differences is guillotine as opposed to complete (Adams & Lakra, 2022). A guillotine amputation is a surgical process that occurs quickly in hopes of controlling infection or blood loss or when completing a near total amputation of a severely injured extremity at the bedside (Adams & Lakra, 2022). The guillotine method is effective because it allows the distinction of viable from non-viable tissue over hours or days before closure is performed (Adams & Lakra, 2022). In contrast, a complete amputation results in a closed, sutured stump directly after the removal of the transtibial portion of the leg (Adams & Lakra, 2022).

Both a guillotine and complete amputation start with the surgical process of removing the transtibial portion of the leg with an incision 12 to 18 cm from the tibial tubercle. An anterior skin flap is reserved to include the anterior two-thirds of the leg, while a posterior flap is drawn 150% longer than the anterior flap to ensure proper coverage for closure (Adams & Lakra, 2022). The tibial and fibular shafts are then cut with a power saw and the distal tibia and fibula fused together to create a solid weight-bearing surface (Adams & Lakra, 2022; Molina & Faulk, 2021). The posterior tissue is divided, with a thinned portion of the soleus attached to the anterior tibial cortex and the gastrocnemius secured to the posterior tibia for padding of the residual limb (Adams & Lakra, 2022; Molina & Faulk, 2021).

Even following a successful below knee amputation (BKA) procedure, complications involving perioperative morbidity and mortality can arise (Molina & Faulk, 2021). Amputation due to complications with diabetes had 1-, 3-, and 5-year mortality rates of approximately 15%, 38%, and 68%, respectively (Larsson et al., 1998). In a review of 2,879 people with amputations, it was suggested the most common post-operative complications included pneumonia (22%), acute kidney injury (15%), deep venous thrombosis (15%), acute lung injury/acute respiratory distress syndrome (13%), osteomyelitis (3%), and flap failure (6%). Furthermore, wound complications such as dehiscence, seroma, and hematoma, can occur in 12% to 34% of patients with a BKA (Low et al., 2017; Morisaki et al., 2018). The above factors are significant because they are potential risk factors for morbidity and mortality in patients with a BKA.

The timely performance of a BKA can ultimately be lifesaving when the progression of a disease or severe trauma occurs (Adams & Lakra, 2022). While the surgical process is vital, the minimization of post-operative risks associated with a TTA is also imperative to prevent morbidity and mortality. Following TTA, a prosthetic must be implemented to allow locomotion and PA.

Prosthetics

Following a unilateral TTA, a prosthetic device is utilized and intended to allow ambulation and performance of daily activities (Gailey et al., 2008). However, appropriate prosthetic fitting that minimizes complications during ambulation and ADL can be challenging. It is estimated between 30% and 100% of people with a LLA report problems with socket fit and/or prosthetic alignment that cause discomfort or residual limb complications (Gailey et al., 2008). Due to a prosthetic substituting for a part of the body, the overall prescription is based on types of activities the person will participate in while wearing the prosthesis (Fernandes et al., 2018). There are several criteria considered when selecting prosthetic components.

The first component to a transtibial prosthetic is the frame. Frames can either be an exoskeleton or an endoskeleton (Fernandes et al., 2018). Exoskeletons are composed of heavy steel pylons that connect the components of the prosthetic (Fernandes et al., 2018). In contrast, endoskeleton frames are hard shells with fillers inside that are lightweight from incorporating carbon and titanium pylons (Fernandes et al., 2018).

Selecting an appropriate suspension system with the use of liners is the next step for determining the correct prosthetic. The most common suspension liners are pin-lock or vacuum-assisted suction (Fernandes et al., 2018). Vacuum liners are beneficial in preventing separation of the liner by applying negative pressure (Street, 2006). Additionally, vacuum liners have been shown to maintain residual limb volume by compartmentalizing fluid in the limb, increasing circulation and hydration of the soft tissue (Beil et al., 2002; Street, 2006). In contrast, pin-lock suspension liners concentrate forces to the distal end of the residual limb creating distal tissue stretch (Kistenberg, 2014). Most people with a TTA prefer the pin-lock suspension over the vacuum-assisted suspension due to the ease of application and removal of the prosthesis (Gholizadeh et al., 2014).

The socket is often considered the most vital component of a prosthetic because it integrates the prosthesis to the ground (Kumar et al., 2017). The goal of a socket is to allow patients to have uniform distribution of pressure throughout the stump (Fernandes et al., 2018). The performance of the socket is influenced by the materials used and the acumen of the prosthetist to establish the type and quantity of the matrix and reinforcement materials for the socket (Kumar et al., 2017). Furthermore, the body mass, cause of TTA, and activity of the person with a TTA are vital for determining correct fit (Kumar et al., 2017). Even with all these aspects properly evaluated and determined, determining the correct socket can still prove to be cumbersome. Difficulties arise because people with TTA can have changes in stump circumference from edema or gradual decreases in stump diameter with progressive stump maturity (Hachisuka et al., 1998). However, liners are utilized as an inexpensive and helpful alternative to changing the overall socket. Socket liners reduce movement and minimize chafing due to friction between the skin and the socket (Kumar et al., 2017). Typically, liners are composed of a flexible, cushioning material and are worn over the residual limb for protection (Kumar et al., 2017). Because circumference and diameter of the residual limb, and activity levels of the patient can change over time, liner replacement is an approach used to prolong the use of the socket (Kumar et al., 2017).

The foot is the final component of the TTA prosthetic and is ultimately utilized to transfer load to the floor (Kumar et al., 2017). Choosing the correct foot is dependent on the level of activity of the person with the TTA (Fernandes et al., 2018). A fixed foot is classified as the simplest form to allow shock absorption and an articulated foot allows dorsal and plantar flexion (mono-axial) or possibly inversion, eversion, and rotation (multi-axial; Fernandes et al., 2018). Finally, a dynamic articulated foot stores energy to be returned during stride to allow adaptations to various irregular surfaces (Fernandes et al., 2018). Patients with limited mobility who use their prostheses for short distances generally utilize a fixed foot or the mono-axial foot (Fernandes et al., 2018). In contrast, patients who ambulate with a dynamic foot can walk > 164 ft on irregular surfaces, as well as navigate ramps and stairs, without the use of walking aids (Fernandes et al., 2018). Furthermore, running requires specially designed energy blades such as a J-shaped blade for sprinting and a C-shaped blade for jogging (Fernandes et al., 2018). As described, it is imperative to properly select the type of foot based upon the activity level of the patient, but there are multiple variables that can make this decision difficult.

The selection of a prosthetic for a person with a TTA can be complicated and is not considered an exact science. The asymmetry caused by losing a limb and using a prosthetic limb for ambulation and PA can negatively impact balance, posture, and gait as explained below.

Impacts of TTA on balance and posture

The ability to maintain posture is a prerequisite to balance control during standing and locomotion. Even though the concepts of posture and balance are distinct from one another, they are interdependent and vitally important to one another. Balance is the ability to change from one posture to another while maintaining proper body equilibrium within the base of support (Ku et al., 2014). The ability of humans to control balance and posture depends on the integration of the visual, vestibular, and proprioceptive systems of the body (Horak, 2006). Multi-factorial components can contribute to balance or lack thereof for a person with a BKA, but Horak (2006) suggested there are six sub-components required to maintain balance: (1) biomechanical constraints, (2) movement strategies, (3) sensory strategies, (4) orientation in space, (5) control of dynamics, and (6) cognitive processing. The following paragraphs provide an overview of how these sub-components impact balance and posture, in conjunction with the central nervous system (CNS) in those with a unilateral TTA.

People with a unilateral TTA have sensory deficits stemming from missing the foot and ankle complex as well as the associated muscles. Following a TTA, there are asymmetrical center of pressure (CoP) excursions and ankle dorsiflexion angles, and greater postural sway when compared to pre-TTA (Moisan et al., 2021). The lack of sensorimotor feedback from the residual limb causes postural reorganization (Rusaw, 2019). There is decreased proprioceptive feedback from the loss of the foot/ankle and receptors localized in the skin, subcutis, joint capsules, ligaments, tendons, and muscles (Isakov et al., 1992).

The CNS integrates afferent information from the sensory systems in the cerebellum and prefrontal cortex for postural and balance control (Horak & Shupert, 1994; Mihara et al., 2008; Ouchi et al., 1999; Peterka, 2002). However, sensory input from the intact leg, but not necessarily the residual leg, alters CNS data processing, resulting in adaptive control from cortical structures responsible for decision making (Petrofsky & Khowailed, 2014). Additionally, an amputation can cause impairments to spinal reflexes (Childers et al., 2014). When spinal reflexes are impaired, it leads to greater control of the cortical structures in the brain (Childers et al., 2014). Validation of greater cortical structure control was demonstrated by people with a TTA possessing delayed electromyography (EMG) patterns in the residual limb (Childers et al., 2014). An additional reaction occurs in response to these sensory deficits by placing an increased demand to the intact limb while simultaneously trying to maintain demand on the prosthetic limb to provide spatial information about the position of center of mass (CoM; Isakov et al., 1992; Mouchnino et al., 1998; Mouchnino et al., 2006; Viton, 2000). Thus, due to the lack of sensory input and potential spinal reflex impairments, the body relies on the cortical structures in the brain responsible for decision making and adaptations. Alternatively, with complex balance tasks, individuals with both intact limbs reduce cortical control and spinal processing takes over for swift responses (Petrofsky & Khowailed, 2014). This spinal reflex does not require decision making to occur by the brain and occurs as a reactive response for balance and posture control. Due to the time sensitivity to maintain or adjust balance and posture, a delayed response as opposed to a quick response from the spine could be the difference between falling or not.

Inaccurate sensory information is commonly referred to as *sway-referencing* (Rusaw, 2019), A sway-referenced support surface is a surface that rotates to appropriately correspond to or react to the movement of an individual's CoP (Rusaw, 2019). In reference to a person with a TTA, the side with the prosthetic foot and support surface is still integrating mechanical forces to and from the residual limb and socket (Rusaw, 2019). However, because there is no active ankle moment, *sway-referencing* occurs which negatively impacts posture and balance (Rusaw, 2019). Posture assessment can be divided into three categories: (1) measurement of the displacement of different body segments; (2) measurement of the displacement of CoP; and (3) measurement of the muscle activity that controls posture (Isakov et al., 1992). It has been stated that limits of stability commonly stem from the control of the area over which an individual moves their CoM to maintain equilibrium without changing the base of support (Horak, 2006). However, people with a TTA lose half of their base of support following amputation and must reorganize motor control for balance and posture (Soares et al., 2009). This creates a disadvantage to an already complicated process to maintain posture and balance.

On average, people with a TTA have 45% of their body weight on the prosthetic leg (Nederhand et al., 2012), and have a positive increase of ground reaction force directed anteriorly to the intact limb (Rusaw, 2019). Individuals with a TTA have a CoP position shift approximately 5 cm anterior to that of the intact limb during quiet standing (Rougier & Bergeau, 2009). Furthermore, these individuals have significantly greater problems controlling CoP excursions in the antero-posterior direction than the medio-lateral direction (Buckley et al., 2002). To attempt to maintain equilibrium the CoP of the residual limb is shifted anteriorly and laterally, with contralateral forces in the intact limb, guided posteriorly and laterally (Rusaw, 2019). Improper balance and posture can be obtained from these improper compensatory responses to possessing a TTA. As a result of the compensations made by a person with a TTA, abnormal weight distributions occur, and correct anatomical position is offset. Positional shifts can further be explained by the lack of ankle torque generation to restore equilibrium in the sagittal plane along with the inaccurate somatosensory input from the side of the TTA (Ku et al., 2014). Furthermore, CoP excursions are greater in the intact limb than in the prosthetic limb during reactive balance responses (Rusaw, 2019). This is relevant because this further explains the anterior shift of support surface toward the intact limb (Bolger et al., 2014; Rusaw, 2019). Another explanation is that the intact leg has better control of motor function, as opposed to the residual limb, because it is not missing any musculature or portions of the leg.

The resulting anterior shift can be beneficial for the knee of the residual leg. Following a TTA, the biceps femoris muscle offers little to no protection against hyperextension when large external knee extension moments occur from plantar flexion (Blumentritt et al., 1999). This alignment increases the stresses placed on the ligaments of the knee and anterior knee capsule and causes the upper body to balance over the CoP of the prosthetic foot (Blumentritt et al., 1999). To counter this additional stress, it was concluded that when the load line was approximately 15 mm anterior to that of the anatomical knee center, the alignment of the prosthetic would be optimal (Blumentritt et al., 1999). This allows increased comfort, more energy efficient standing, and less mechanical load on the knee for the person with a TTA (Blumentritt et al., 1999). While an anterior shift can prove to be beneficial for the residual limb, it could be the result of overuse in the intact leg. Also, the shift for proper prosthetic alignment could cause a countermovement in the intact leg, leading to uncharacteristic posture.

Another component which contributes to sensory deficits is the loss of associated muscle following a TTA. According to Evarts (1981), extero-receptors resolve inputs from the environment. Furthermore, muscular responses from proprioceptive inputs are mild (Evarts, 1981). These mild inputs cause the muscle spindles to have an exaggerated muscle contraction after small perturbations (Evarts, 1981). Nevertheless, because the muscular responses are amplified after small external stimuli, this can cause an individual with a TTA to inaccurately measure and respond to obstacles. Inaccurate measurement and responses to motor control during standing or walking balance creates problems for people with a TTA by causing disorientation. As a result of missing muscle, afferent responses increase postural instabilities (Evarts, 1981), which dramatically affects people with a TTA.

An additional source of postural instability is muscle atrophy and/or muscular imbalances. Typically, there is reduced participation and activation of the residual limb muscles in activities such as standing and walking following a TTA (Isakov et al., 1996). This disuse leads to atrophy of the thigh muscles in the residual limb, negatively impacting physical function (Hewson et al., 2020). A potential explanation of poor physical function from muscular atrophy could be due to the size of the muscles and frequency of utilizing leg muscles in daily activities. Muscles associated with the legs are large and create a high amount of force when activated for daily activities. Additionally, the leg musculature is used in almost all daily activities. If the muscles are smaller in size, then the force of the muscle contraction will consequently decrease. The decrease in force production produced by muscular contractions could decreases physical function and motor control, making ADL more challenging for a person with a TTA. According to Schmalz et al. (2001), the quadriceps are weaker and atrophy to a greater extent than the hamstrings in the residual limb. Schmalz et al. (2001) also proposed the cross-sectional areas and mean thicknesses of the rectus femoris, vasti, and sartorius muscles were smaller in the amputated limb than that of the intact limb. These results align with Renstrom et al. (1995), suggesting that the mean muscle fiber area of the vastus medialis of the residual limb is 74% of that of the intact limb.

The atrophy of the vastus intermedius and/or rectus femoris muscles is/are possibly due to the reduction of motor activities (Schmalz et al., 2001). The cause of the reduction of motor activities may be due to the reduction of mass and increasing number of stretch reflexes between muscle fibers and the interstitium, at the respective muscle (Reimers et al., 1993). Consequently, when the number of stretch reflexes increases because of the reduction in motor activities, muscle contractions increase to protect the muscle from strain or injury. While this is a positive factor for muscles in an able-bodied person, the increase in frequency of stretch reflex responses causes atrophy by hindering muscles to go through the full range of motion. When a muscle does not go through the full range of motion this could potentially lead to incomplete or partial disuse of the muscle, leading to atrophy and weakness. Eventually, it was proposed, fat cells invade the disused muscle, which does not normally occur in healthy muscles (Reimers et al., 1993). As fat cells invade, contractions and/or force production of the muscles can be minimized, which can limit control of balance and posture.

Incomplete or partial range of motion of a muscle can lead to muscular strength deficits in the amputated limb (Renstrom et al., 1995). Isokinetic concentric and eccentric peak torques and maximal average isometric torque generation were significantly less in the residual limb's quadriceps and hamstrings as opposed to the sound limb muscles (Isakov et al., 1996). The asymmetry of torque generation at the respective muscle can ultimately cause a decrease in strength of the residual limb thigh muscles, which can compromise performance ability, balance, and muscle activity during prosthetic usage (Isakov et al., 1996). Multiple researchers have concluded range of motion deficits of 30% or more in the amputated limb during extension (Isakov et al., 1996; Moirenfeld et al., 2000; Renstrom et al., 1983). These results align with Powers et al. (1996) who concluded there was a larger deficit in peak isometric hip extension torque in the residual limb and intact limb when compared to healthy counterparts.

In summary, the effects of abnormal sensory feedback and muscular imbalances caused from a TTA lead to unstable balance and posture. These bilateral deficits could prove to be detrimental to motor patterns and safety during activities that require balance and postural control (Moirenfeld et al., 2000). The deficits in balance and posture can negatively impact gait.

Gait following TTA

The gait of a person with unilateral TTA is modified due to the body's appropriate, yet abnormal, responses to compensate for the missing portion of the leg. Typically, able-bodied people stand with two feet on the ground to form a rather stable base due to even weight distribution. Furthermore, humans are bipeds and locomote with one foot in contact (walking), no feet in contact (running), or both feet in contact (standing) with the ground (Winter, 1995). However, people with a TTA have smaller push-off forces, longer swing times, increased strides lengths and decreased stance time for the residual limb as opposed to the intact limb, during ambulation (Mattes et al., 2000). As a result, inertial asymmetry, improper biomechanics, and altered kinetics can substantially alter locomotion. Therefore, it is necessary to evaluate multiple parameters of gait and how each variable causes different outcomes for locomotion following a TTA.

People with a unilateral TTA have atypical locomotion strategies leading to practical concerns with walking and running (Gallagher & MacLachlan, 2001). Gait performance in a person with a unilateral TTA is dependent on optimal prosthetic fit and the strength of the quadricep and hamstring muscles (Isakov et al., 1996; Renstrom et al., 1983). Many people with a TTA walk with at least one gait deviation due to faults in the prosthetic, lack of proper gait training, development of poor habits, or abnormal compensations (Gailey et al., 2008). As a result, poor mechanics during gait and asymmetries develop (Adamczyk & Kuo, 2015). One of the most common compensations of people with a TTA is the movement of the intact limb toward the midline of the body while simultaneously externally rotating the lower limb (Engsberg et al., 1994). This posture, along with increased stance time, is thought to be utilized to improve medial/lateral stability during gait (Gailey et al., 2008). Another common adjustment strategy is increasing limb-loading to the non-affected side/limb (Vrieling et al., 2008).

During the push-off phase for a person with a TTA, several asymmetries have been recorded including an increase in intact-limb collision work and overall work performed over the CoM (Adamczyk & Kuo, 2015). Further, people with a TTA use the non-amputated limb more often as the leading limb to initiate gait (Vrieling et al., 2008). Prolonged single-limb stance duration in the trailing non-amputated leg for larger propulsive impulse is also characteristic of a person with a TTA (Vrieling et al., 2008). Consequently, people with a TTA tend to have a slower mid-stance, longer stance phase, and a slower CoM velocity on the prosthesis side when compared to the intact limb (Adamczyk & Kuo, 2015). This was documented by Hak et al. (2013) who found that a person with a TTA has decreased step length in response to gait adaptability tasks. It is interesting to note that individuals with TTAs also have an increased step width (Hak et al., 2013). It was reported that the prosthetic limb side had greater stride duration, swing duration, and stride length (Isakov et al., 2000). In addition, Powers et al. (1998) found people with a TTA demonstrated reduced stride length when compared to control participants (1.21 m vs. 1.42 m). Although stride lengths for people with a TTA in

Powers et al. (1998) study differed from Isakov et al. (2000) study, it may represent how numerous individual characteristics per TTA can impact or alter gait. All the factors addressed above may contribute to a slower walking velocity in people with TTA (Powers et al, 1998).

It is also reported that the stiffness of the prosthetic foot, absence of ankle dorsiflexors, and sensory deficits can cause a decrease in posterior CoP shift during ambulation (Vrieling et al., 2008). This is significant because it triggers the CoP trajectory to be more near the forefoot during the transition to single-limb stance on the trailing prosthetic limb (Vrieling et al., 2008). Ultimately, this could alter the ability to decelerate gait during locomotion. To terminate gait or decelerate, people with a TTA favor the non-affected limb, have a decreased peak braking ground reaction force, and have a longer production of braking force in the intact limb with decreased gait termination velocity (Vrieling et al., 2008).

In conclusion, a unilateral TTA can lead to significant gait deviations. Compared to able-bodied people, a person with a TTA has diverse strategies, stride lengths, and propulsion mechanisms for ambulation. Thus, it is important to fully understand the biomechanical origins that cause abnormal gait regarding the ankles, knees, and hips.

Gait following TTA – Ankle

The loss of the muscles associated with the ankle complex is considered one of the main causes of gait deviation (Umberger & Rebenson, 2011). The muscles of the ankle that plantar flex the foot are responsible for generating about 80% of the mechanical power during the gait cycle (Winter & Sienko, 1988). Normally, the ankle plantarflexes 10 degrees after initial contact which provides flat foot contact with the ground for a stable base and weight transfer to the alternate limb (Perry & Burnfield, 2010). However, with a TTA people spend the first 20% of the gait cycle in heel only contact (Powers et al., 1998). A primary reason for this heel only contact is the reduction of ankle power in the residual limb (Adamczyk & Kuo, 2015). Ankle power for an individual with a TTA is greatly reduced during the push-off phase, which starts approximately 2%-3% before the initiation of stride and continues to about 12% of that stride (Adamczyk & Kuo, 2015). Furthermore, this results in significantly reduced positive work on the body's CoM, which leads to greater dissipation of mechanical energy during the contact of the intact limb with the ground (Adamczyk & Kuo, 2015). According to Vrieling et al. (2008), the absent ankle plantar flexors cause a reduced peak anterior ground reaction force in the leading prosthetic limb and in the trailing prosthetic limb. It was hypothesized that this caused a decreased gait initiation velocity (Vrieling et al., 2008).

It is also proposed that the loss of the ankle necessitates energetic costly compensations by other parts of the body (Umberger & Rebenson, 2011). Esposito and Miller (2018) used musculoskeletal modeling and simulations (pre-limb vs. post-limb loss) of people with two intact biological legs and those with a unilateral TTA and a prosthetic limb to study energy cost. The five muscles removed to model limb loss accounted for, on average, 20% of the gross metabolic cost during simulated walking (Esposito & Miller, 2018). Further, with a 10% loss of muscle strength, increased activation of additional muscles was necessary to produce compensatory forces for attenuating gait deviation (Esposito & Miller, 2018). It was concluded the compensations made by other muscles exceeded the energy saved by the absent ankle muscles resulting in an increased cost of locomotion (Esposito & Miller, 2018). In addition to the loss of the ankle musculature, there are also compensatory strategies utilized by people with a TTA at the knees during locomotion.

Gait following TTA – Knee

With the loss of the lower portion of the leg, different movement strategies are needed at the knee during locomotion. Initial knee flexion is significantly later and occurs at 17.3% of the gait cycle when compared to able bodied individuals where it occurs at 13.2% of the gait cycle (Powers et al., 1998). The significantly longer time to produce flexion during ambulation may increase the likelihood of falling and cause inappropriate habits to be obtained. Similarly, Schmalz et al. (2001) found the knee joint motion pattern of the amputated limb exhibited reduced stance phase flexion. A reduction in flexion during the stance phase could be due to the likelihood that most people are required to perform a kicking motion with the prosthetic to obtain proper extension of the knee. It was also observed that the maximum residual knee flexion had significantly delayed timing in midstance when compared to the intact leg and control, non-dominant leg (Orekhov et al., 2019). The requirement to focus on a new set of walking motions (i.e., kicking the prosthetic forward during locomotion) and lack of sensation may be the reason most people with a TTA walk slower or are at higher risk of falling.

These knee motion patterns are, in part, due to the angular variation associated with a TTA (Soares et al. 2009). People with a TTA demonstrated an external knee extension moment throughout the stance phase, except for two brief periods where knee flexion moment is evident (Powers et al., 1998). The substantial demand on the knee extensors during the stance phase were interpretated to control knee flexion during weight acceptance (Powers et al., 1998). During the initial 40% of the gait cycle, individuals with a TTA had significantly decreased peak knee flexion angles (9.5 degrees) when compared to control participants (18.6 degrees; Powers et al., 1998). Additionally, Orekhov et al. (2019) suggested the maximum residual knee flexion angle was significantly lower in midstance, and the residual swing flexion angle was higher compared to the intact leg. Gailey et al. (2008) observed the proximal tibial, peak knee, internal abduction moment was 56% greater on the intact knee than the prosthetic limb side knee.

One of the main contributors to altered activity at the knee is the irregular knee musculature in people with a TTA. Powers et al. (1998) found the vastus lateralis, semimembranosus, and biceps femoris long head all exhibited significantly greater EMG intensity during gait. Greater EMG intensities in the muscles of both legs may indicate that the body is requiring increased contractions for motor control to account for the missing portions of the leg during gait. In conjunction, the biceps femoris long head and the vastus lateralis had increased intensity/activity through 56% and 29% of the gait cycle for weight acceptance, respectively (Powers, 1998). Specifically, the activity of the biceps femoris long head continued beyond the initial double limb support and into the mid- and terminal stance (Powers, 1998). Further justification was provided by Isakov et al. (2001) who concluded that for adequate control of the lower limb during gait, the bicep femoris muscle is activated vigorously along with the quadriceps at the beginning of the stance phase. More vigorous contractions of the muscles in the leg are necessary to better control motor function during ambulation. Evidence by Powers (2008) highlighted the co-contraction of the quadriceps and hamstrings could be an attempt to stabilize the knee during weight acceptance. Even though there is significant atrophy to the extensor muscle group and minor atrophy of the dorsal muscle group in the knee, this is considered typical (Schmalz et al., 2001). However, the overall effect of abnormal knee musculature following a TTA affects the knee during the gait cycle by decreasing power output and torque.

The irregular muscle activation patterns explained above could be responsible for altered knee biomechanics during gait for a person with a TTA (Orekhov et al., 2019). People with a TTA had higher knee extension torque in the intact leg when compared to the residual leg during the gait cycle (Orekhov et al., 2019). In addition, Powers et al. (1998) established a person with a TTA had near zero knee power throughout the stance phase during gait. The greatest difference in knee power between the control and TTA group was seen during initial contact with the ground (Powers et al., 1998). The peak positive power was 0.60 W/kg-m for the control group, which was significantly greater than the TTA group who recorded 0.08 W/kg-m during gait (Powers et al., 1998).

These compensations in movement strategies employed during locomotion for those with a TTA are directly related to the variations in knee biomechanics. Even though the body attempts to adapt to these gait deviations, the knees are still challenged. The loss of the ankle complex directly reflects abnormal biomechanics to the knee joints, which leads to the hip making necessary adjustments for motion during gait.

Gait following TTA - Hip

While gait deviations typically arise from the loss of the ankle complex, the increased absorption and generation of energy in the hip of the residual limb is considered the main compensatory gait strategy for people with a unilateral TTA (Soares, 2009). Typically, ambulation consists of the first negative power phase that occurred at 0-8% of gait cycle (H1a) and the remaining positive power phase at 8-30% of the gait cycle (H1b; Grumillier et al., 2008). Not surprisingly, people with a TTA tend to have an increased load placed on the hip of the intact limb (Gailey et al., 2008). Additionally, the hip of the residual limb is also administered to increased load during locomotion (Mattes et al., 2000). During the gait cycle of a person with a TTA, as load is added to the distal aspect of the prosthetic limb, the intact and prosthetic shank and foot attempt to match the inertial properties of the distal load (Mattes et al., 2000). As a result, the hip experiences a proportionally greater increase of inertia due to the amount of mass placed below the knee and the additional mass required to match the mass of the intact limb (Mattes et al., 2000). This can have consequences to the half-period of oscillation of the leg and ultimately swing time of the prosthetic leg. Mattes et al. (2000) referred to this half-period oscillation of the leg as a pendulum swinging about the hip. Due to the greater inertial properties applied to the hip to equal distal loads and an increased half-period oscillation, a compensatory response of increased swing time for the prosthetic leg occurs (Mattes et al., 2000).

The increased load and inertia placed on the hips causes the dynamics of the hips to be altered during the gait cycle for a person with a unilateral TTA. Grumillier et al. (2008) stated the hip joint of the intact limb consistently moved in flexion during the initial period of the stance phase and flexion peaked at approximately 8% of the gait cycle. In contrast, the peak of hip flexion for the prosthetic limb was reached during approximately 92% of the gait cycle during the oscillation phase, immediately followed by hip extension throughout the first half of the stance phase (Grumillier et al., 2008).

The impact of unequal timing for hip flexion and extension, between the sides of the hip with the prosthetic and intact limb, causes there to be asymmetry in weight distribution during the gait cycle. The potential cause of the lopsidedness is the weight difference amongst the intact and residual limb. To compensate for the missing portions of the leg, both sides of the hips adapt different timing strategies for hip flexion and extension during locomotion. Improper alignment and symmetry in weight distribution is unfavorable for people with a TTA because of the importance of avoiding irregular compensations to the kinetic chain while walking.

Indicative of people with a TTA, the initial hip flexion during the H1a phase is followed by a large extension movement during the H1b phase and was significantly larger than the prosthetic limb (Grumillier et al., 2008). This abnormal phase distribution ultimately leads to increased total work values during the combined H1a phase and H1b phase, and singular H1a phase for the prosthetic and intact limb when compared to an able-bodied person (Grumillier et al., 2008). The increased work by the hip throughout the gait cycle indicates that people with a TTA need to expend more energy to perform the same locomotion patterns as a person with both intact limbs. Furthermore, the increased hip flexion moment evident in people who have unilateral TTAs is likely related to the forward trunk lean to augment forward progression over a relatively solid ankle (Anzel et al., 1993). Such a compensation would lead to the movement of the body’s CoM anterior to the hip joint center, causing a greater hip flexion moment and demand on the hip extensors (Powers et al., 1998).

An additional movement strategy documented by Underwood et al. (2004) is the contralateral limb hip had a 29% greater internal abduction moment than the prosthetic side hip. Royer and Koenig (2005) also reported that people with a TTA had a 33% greater internal abduction moment at the contralateral hip. These compensatory hip strategies are a response to the different inertial properties that are required to produce locomotion. Greater internal abduction at the contralateral hip can be detrimental for a person with a TTA because it requires the hip on the prosthetic side to counteract. The counteraction of both sides of the hip negatively impacts gait by imposing bad mechanics and habits for locomotion.

In summation, gait is altered following a TTA. A TTA not only causes uncharacteristic movement strategies using various compensations, but it also introduces problems to the skeletal system to properly accommodate those strategies. Ultimately, the ankle, knee, and hip are required to adapt to this stimulus, which leads to challenges and/or problems in gait for those with a TTA. Because gait is an important factor regarding physical activity, an abnormal gait caused by a TTA can have detrimental outcomes to exercise and/or PA (Gailey et al., 2008).

The effects of altered physiological responses to PA in those with a TTA

Altered physiological responses to PA can hinder the adherence and performance of PA in those with a TTA. One of the main components leading to abnormal cardiovascular responses to PA is an elevated heart rate (HR) response in those with a unilateral TTA as opposed to those without a TTA (van Schaik et al., 2019). Walking with a TTA has been documented to induces a 16% greater HR when compared to control participants (Gailey et al., 1994). Esposito et al. (2014) observed that when compared to able-bodied participants, those with TTA experienced a 20% higher HR across five walking speeds, as well as larger differences in HR with increasing walking velocities (Esposito et al., 2014). It is thought HR is elevated to compensate for the decrease in stroke volume from the decreased contractile capacity of the myocardium following major limb loss (Kurdibaylo, 1996). With an elevated HR during ambulation, people with a TTA are expending more energy to perform PA. The utilization of more energy could lead to increased fatigue and decreased time spent performing PA.

There is also an altered VO_2 consumption during locomotion for a person with an amputation when compared to someone that has both lower limbs intact (Esposito et al., 2014). An increased VO_2 during walking was demonstrated by Gailey et al. (1994) who found a 16% increase in the group with a TTA compared to a control group. Gailey et al. (1997) also documented greater metabolic cost to walk an equivalent distance compared to able-bodied individuals. Similarly, during comfortable walking speeds and fixed walking speeds, people with a unilateral TTA had a 12% and 26% higher metabolic cost of walking, respectively when compared to control participants (Houdijk et al., 2009). In a systematic review, the relative aerobic load during walking was found to be higher in people with a LLA than in the control group (Wezendberg et al., 2013). It has also been suggested the increased energy expenditure required for ambulation, particularly in the presence of multiple chronic diseases, is associated with decreased PA following a TTA (Lin & Bose, 2008).

The increased metabolic responses to walking following a TTA most likely reside from the missing musculature of the leg. Muscles are a vital component to balance, posture, and motor functions. Esposito et al. (2018) demonstrated that with a 10% strength loss there was a significant increase in the metabolic cost of walking, even if the decrease in strength was only in the residual limb. Missing muscle, especially in the leg, can prove to be detrimental to proper control of motor function while ambulating, also leading to an increase in the fear of falling. Collectively, the loss of strength, motor function control, and increased fear of falling could also contribute to the slower walking velocities observed in people with a TTA. Slower walking speeds may impact physical fitness by not allowing an overload training effect to occur. Further validation of this was indicated by Bragaru et al. (2011) who suggested that individuals with a TTA have lower physical fitness due to the amputation itself, in addition to the underlying disease that may have caused the need for an amputation. Furthermore, decreased physical fitness may also stem from the missing musculature of the residual limb. The deficiency of plantar flexion at the ankle, which causes the hip to compensate with costly metabolic outcomes, contributes to the greater metabolic cost of walking (Houdijk et al., 2009). Ultimately, the lack of plantar flexion by the prosthetic and abnormal hip compensation can create overuse injuries or deficient utilization of muscles while walking. Consequently, performance of PA is negatively impacted following a TTA.

The performance of endurance activities is impacted for a person with a TTA due to fatigue of the various muscles needed to ambulate. This has been documented by an increase in rating of perceived exertion (RPE) associated with the significant levels of muscular fatigue on the intact limb during gait in those with a TTA (Moirenfeld et al., 2000). The more a person with a TTA uses the intact limb musculature, the quicker fatigue sets in and negatively impacts the physiological responses to and performance of PA. As a result of these uncharacteristic physiological responses, it is common for individuals with a TTA to have decreased engagement in PA compared to those without a TTA (Bussmann et al., 2004). Bussmann et al. (2008) indicated people with an amputation performed a lower percentage of dynamic activities such as walking, cycling, body transitions and other body movements, compared to persons without known impairments. Participants with an amputation were physically active 6.0% of the time, while able-bodied participants were physically active 11.9% of the time in a 48-hour period (Bussmann et al., 2008). The performance of ADL is also impacted following an amputation. In group discussions with people possessing an artificial limb, participants noted physical activities were most affected using a prosthetic after an amputation (Gallagher & MacLachlan, 2001).

In sum, HR, VO_2, and muscular fatigue are increased during locomotion in a person with a TTA. These physiological changes can negatively impact the performance of PA, exercise, and ADL following a TTA. Due to the importance of adherence to exercise and PA for all humans, it is important to understand the factors that limit PA and the positive and negative outcomes associated with various training modalities so appropriate adaptations can be made. Thus, it would be helpful to incorporate various modalities of PA, including those that minimize the dependence on the intact limb, so the benefits of PA can be maximized for those with a TTA.

Training modalities for TTA

The main purpose of rehabilitation following a TTA is to help the individual regain or improve balance to maintain functional independence (Matjaĉić & Burger, 2003). This is important because balance impacts multiple variables associated with weight distribution, CoP, and gait. Through balance training, a person can improve acquisition and recognition of proprioceptive feedback for balance and proper body positioning in space (Cuğ et al., 2012). This will assist with intermuscular coordination between the agonist and the antagonist muscles, allowing enhanced control of joints and reduced joint stiffness (Behm & Colado, 2012). Furthermore, improvements following balance training may provide increased control (improved balance and posture) during multiple fitness-related activities. Thus, rehabilitation is critical to establish proper postural control with the hope of avoiding the development and acquisition of inappropriate compensation strategies, leading to improved mobility and function (Matjaĉić & Burger, 2003).

One method that has led to positive changes in balance in people with a TTA is the use of perturbations on oscillating platforms. Sethy et al. (2009) found positive outcomes utilizing Phyaction Balance exercise on a moving platform which generated perturbations. After 6 weeks of balance training, there was a statistically significant improvement in the medio-lateral and anterio-posterior global balance performance (Sethy et al., 2009). The improvement in the medio-lateral balance control was greater than the anterior-posterior balance control (Sethy et al., 2009). Greater medio-lateral control was attributed to completely missing or lack of ankle coordination on the residual limb because of the non-existent ankle joint (Sethy et al., 2009). The ankle strategy that is necessary for proper directional control is unable to be utilized while balancing in perturbed antero-posterior directions (Sethy et al., 2009). A possible reason for better balance control in the medio-lateral direction is the way the ankle joint is constructed on a prosthetic. For ambulation, the prosthetic must allow plantar-flexion and dorsi-flexion to occur. However, while some prosthetics allow slight inversion and eversion, the range of motion of the ankle joint compared to an intact ankle joint is unmatched. It is important the prosthetic should not allow too much inversion or eversion because an individual with a TTA is lacking feedback information for control of the ankle. Without the ability to properly control the ankle during ambulation, the likelihood of falls and a sedentary lifestyle increase.

Similarly, Van Ootegham et al. (2008) found continuous and different amplitude oscillations using a translating platform improved adaptations to compensatory balance control by reducing the magnitude of CoM displacements. Adaptations are better understood by explaining that the prosthetic provides some spatial information to connected and surrounding body parts. Still intact joints and remaining tissues could potentiate new roles of acquiring and sending proprioceptive information to maintain or better control balance. Over time, the brain adapts and learns how to accurately receive and respond to this feedback leading to increased balance for people with a TTA.

Positive outcomes for people that possess a unilateral TTA have also been demonstrated with dynamic balance training with cognitive feedback and repetitive conditions (Matjaĉić & Burger, 2003). This form of dynamic balance training is possible with the use of a BalanceReTrainer, where balancing efforts are measured while participants perform computer-based balance-training tasks (Matjaĉić & Burger, 2003). The addition of cognitive tasks while physically balancing on a platform adds a level of complexity to better simulate real-world situations. With the use of an EMG, researchers documented participants improved their standing balancing efforts with increased utilization of muscles at the pelvis in the sagittal and frontal planes, the ankle muscles in the sagittal plane, and the ankle and hip muscles in the frontal plane (Matjaĉić & Burger, 2003). Improvements to balancing efforts from five days of training (20 min per day) on the BalanceReTrainer led to improved duration of standing on the prosthetic leg by 4.3 ±

4.5s. Furthermore, walking speed during the 10m walk test was increased and the amount of time to perform the timed up and go test was reduced from balance training (Matjaĉić & Burger, 2003). Ultimately, dynamic balance training can offer improved functional capabilities and postural stability for better control and performance during daily living following a TTA (Viton et al., 2000). An enhanced sense of control could prove to be pivotal for people with a TTA in motor control and performance.

Improved balance can also be seen through fall prevention training for people with a TTA (Kaufman et al., 2014). Fall prevention training includes walking on an ActiveStep Treadmill™ while benign or extreme postural disturbances (static perturbation, static walk, and e-trip) are delivered in a bidirectional manner (Kaufman et al., 2014). Six, 30-minute training sessions lead to greater trunk control, increased acquisition of motor skills, and a reduced number of falls acutely and for 6 months post training (Kaufman et al., 2014). Thus, it is concluded that fall prevention is achieved by increasing muscular strength, power, and improving reaction time to be able to stabilize the body more successfully after external disturbances occur.

Nevertheless, while balance training offers multiple benefits, it may also have some undesirable outcomes for people with a TTA. Petrofsky and Khowailed (2014) indicated potential negative aspects to balance and posture following eight sensorimotor balance training tasks. During the 2x2x2 repeated measure study, people with a unilateral TTA performed balance tasks of increasing difficulty with eyes open and closed, feet in tandem or apart, and on a foam surface or a firm surface (Petrofsky & Khowailed, 2014). An important, yet undesirable outcome produced by the study was that as tasks became more difficult, postural sway increased (Petrofsky & Khowailed, 2014). It was suggested that due to the loss of the limb and associated sensory input, this form of balance training could cause supplemental problems to balance and posture for those with a TTA. A potential theory as to why balance is negatively impacted is because more cognitive effort is required for various tasks related to motor function control. For a person with a TTA, any task that requires maintaining balance is already complicated or difficult when coupled with the lack of sensory input. The increased focus to perform said tasks can be beneficial through application to real world activities or situations for people with a TTA. However, because a time delay exists for reflexes to occur from the length of sensory neurons of the leg to the motor neurons (Dalpozzo et al., 2002), people with a TTA could exhibit decreased balance or performance throughout and post training.

Another common problem with balance training for participants with a TTA is the exposure to unstable situations (Matjaĉić & Burger, 2003). While this is necessary to create an overload training effect, it also runs the risk of increasing falls during training. Further, most often, participants enter research studies with bad habits or improper compensation strategies. Gailey et al. (2008) suggested that in addition to pre-existing physical limitations, people with an amputation develop secondary poor habits and compensations. The introduction of new techniques for controlling balance and posture in training could hinder future movement as the process of relearning proper form can be intimidating, potentially causing slower movement and/or lack of adherence.

Unanticipated results from a 6-week balance exercise program for people with a LLA (Miller et al., 2017), could also prove to be detrimental to balance. The exercise program performed by participants in this study focused primarily on stretching, core and lower extremity strength and flexibility, static and dynamic balance, and gait (Miller et al., 2017). There were significant changes in residual limb size and shape from weight loss during the study (Miller et al., 2017). These results are important because of the detrimental effect they could have on the control of and confidence in utilizing the prosthetic. Miller et al. (2017) reported that those who demonstrated weight loss experienced issues with proper socket fit/comfort. The consequence to declining socket variables is that participants have less control of the prosthetic while performing PA (Miller et al., 2017). Additional space within the socket can create unwanted movements of the residual limb in all planes of motion. During movement or maintenance of balance, the space between the socket and residual limb can produce asymmetrical weight distribution or atypical compensation strategies.

An additional concern that can occur because of balance training includes extreme asymmetrical weight distribution because of increasing confidence in utilizing the prosthetic. According to Moisan et al. (2022), individuals with a TTA exhibit asymmetrical load distributions and greater antero-posterior and medio-lateral CoP excursions for the intact limb compared to the amputated limb during quiet standing tasks. Additionally, during eyes closed conditions, individuals with a TTA demonstrated greater medio-lateral COP excursions (Moisan et al., 2022). In eyes closed situations during training, individuals may have less postural stability, leading to an increased risk of falling (Moisan et al., 2022). Additionally, as an individual becomes more confident in controlling balance, they could take unnecessary risks and/or push the boundaries of their abilities during various tasks of daily living.

Overall, there is a paucity of balance training modalities available for those with a TTA, especially once clinical rehabilitation in complete. Proper control of balance and posture is a necessity for people with a TTA to perform PA. Prior research highlights different methodologies and modalities which offer a multitude of benefits, while also minimizing risks or negative outcomes. However, to accommodate a variety of the postive and negative aspects of training, advances in alternative modalities for acute and long-term management of TTA have been made.

Underwater treadmill training

To accommodate the impacts and/or enhance training modalities previously discussed, an underwater treadmill may serve as an innovative intervention for those with a TTA. Previous literature has demonstrated that an aquatic treadmill has the potential to improve balance, muscle strength, motor function, and mobility for healthy and special populations (Bressel et al., 2014).

Specifically, UTT could be advantageous for people with a TTA because of water's natural ability to create an overload training effect. Evidence for this potential was demonstrated by an individual with a TTA who improved walking speed, balance, and decreased the risk of falling after an 8-week underwater treadmill program (Mathis et al., 2018). The hydrodynamics of water offers unique properties that have profound physiological and biological effects (Baxi et al., 2018). The viscosity of water potentiates an additional variable, drag force, that could aid in rehabilitation. Drag force challenges the cardiovascular system using resistance that is proportional to the effort exerted (Cole & Becker, 2004). Furthermore, hydrostatic pressure (i.e., pressure exerted by water on a submerged body) is also believed to aid cardiovascular function by promoting venous return (Cole & Becker, 2004).

Various UTT protocols have been applied to special populations and propagated multiple benefits to balance, strength, and functional mobility. One study found that people with an incomplete spinal cord injury had significant improvements to balance following an 8-week (3x per week) UTT protocol with staggered increases to speed and time (Stevens et al., 2015). Significant improvements were made to balance, leg strength, walking speed, and 6-minute walk distance by 39%, 57%, 61%, and 82%, respectively (Stevens et al., 2015). An additional study utilizing UTT for 8-weeks (3x per week) indicated advances in cardiorespiratory function and leg strength for individuals with type 2 diabetes (Conners et al., 2019). Resting HR values were on average 10% lower and the peak torque of the hamstrings as well as the quadriceps were greater following UTT (Conners et al., 2019). Although these populations are dissimilar to people with a TTA because the limbs are intact, results and proposed benefits could potentially be applied.

Water also provides a safe and effective tool in reducing force on joints (Kuptniratsaikul et al., 2019). Buoyancy results in less stress and pressure on bone, muscle, and connective tissue by equaling out the amount of body weight to the weight of the water displaced (Cole & Becker, 2004). The gradual progressive loading of major joints in using the prosthetic can lead to improvements in balance and posture, and gait for ADL (Kuptniratsaikul et al., 2019). It was reported that a patient with a TFA had reduced biomechanical load on the hip joint and hip abductors during aquatic ambulation (Cutler, 2017). Due to the benefits of utilizing aquatic training, people with a TTA could potentially gain improvements and/or maintenance of fitness without the risk of injury and/or impact loading (Cole & Becker, 2004). Without these risks, improvements could be made to gait biomechanics (Cole & Becker, 2004). These improvements were further documented by a patient with a TFA that demonstrated a 900% increase in ambulation time prior to fatigue following therapy with an aquatic ambulation protocol (Cutler, 2017). Other positive attributes of aquatic training include participants feeling more relaxed and thus further stretching when immersed in water (Cutler, 2017). This relaxation and increased stretching were suggested to be the cause of water inhibiting a natural response of muscle tension when persons with an amputation feel threatened by a perceived fall (Cutler, 2017).

Additional benefits reside in the ease of implementing UTT. Due to UTT not requiring the presence of multiple therapists or professionals, it makes it easier to administer and obtain subjective feedback throughout the protocol. Key variables such as walking speed, temperature, and time can be monitored and manipulated throughout UTT. This allows a gradual and systematic increase in exercise load, allowing participants with a TTA to safely explore individual characteristics of balance, posture, and gait while improving their cardiovascular endurance in a safe environment. Further, subjective feedback can be expressed throughout the protocol to provide participant comfort and/or obtain additional information about perceptions.

UTT is unique because it could potentially be more feasible, easily accessible, and reap greater benefits as opposed to traditional rehabilitation for people with a unilateral TTA. Proposed advantages to balance and gait with the use of UTT could allow for secondary benefits such as increased strength and physiological responses to PA to develop. All these improvements could be valuable for people with a TTA in reducing sedentary lifestyles and encouraging increased adherence to PA. Overall, UTT could harmoniously create an overload training effect to improve the many impacts and challenges to possessing a TTA.

Overall summary

Due to the prevalence of people with a TTA and the difficult trials they face daily, there is an overwhelming need to expand literature so appropriate accommodations can be made. Numerous etiologies such as trauma, vascular disease, infections, and even cancer can be the direct cause of undergoing surgical osteotomy. When coupled with the number of diverse prosthetics even more challenges are presented to individuals with a TTA. Add in the subjective decisions made by a clinician and personalized patient needs for a prosthetic and the initial problem becomes extraneously labor some to solve. Subsequently, the complexity to possessing a TTA creates many challenges which adversely affect various systems in the body for control of motor function.

Balance and posture are characteristically the first impacted variables for people with a TTA. Inaccurate or lack of sensory feedback and muscular imbalances from missing a portion of the limb compromises the body's inability to maintain proper balance and weight distribution. This atypical control and positioning are represented by people with a TTA shifting 55% of their body weight to the intact limb (Nederhand et al., 2012), and CoP excursions in the antero-posterior plane of motion (Buckley et al., 2002). Typically, people with a TTA walk with decreased push-off forces and stance times, as well as increased swing times and stride lengths (Mattes et al., 2000). Ultimately, these abnormalities can severely impact walking inertias, biomechanics, and kinetics.

However, the systemic reaction that a TTA causes to the body does not end with balance and gait. The effects of a TTA can be translated to the body's physiological responses to PA. Elevated HR values have been demonstrated by people with a TTA during PA (van Schaik et al., 2019). Additionally, greater metabolic cost to walking have been seen in individuals with a TTA (Gailey et al., 1997). While these outcome measures could be a result of increased muscular fatigue or slower walking velocities, they are indicative of decreased performance and PA. To combat these results and influences of possessing a TTA, various training modalities have been utilized. Rehabilitation in the form of training is a promising combatant to the disadvantages commonly possessed by individuals with a TTA. Different methodologies and modalities have demonstrated progressions in balance and posture, strength, and gait. Still, certain negative outcomes and limitations exist in the literature that need to be addressed.

People with a TTA are not typically exposed to aquatic modalities during rehabilitation and training. In conjunction, if rehabilitation and training are meant to attenuate potential challenges faced by those with a TTA, then UTT could be a viable option. The water's unique properties can not only create an overload training effect through resistance during underwater ambulation, but it also allows populations with a TTA to learn proper form without the risk of high impact or loaded stress. Because the UTT modality only covers objective measures, it is important to receive participant perspectives of common daily obstacles and if the proposed training method was advantageous or momentous. Overall, an UTT program could potentially address and improve the impacts that a person with a TTA encounters during ADL or exercise, and when coupled with a focus group could indicate if said protocol is meaningful to participants for future applications to rehabilitation or training.

Thus, the purpose of the current study is to evaluate the effects of an UTT protocol regarding balance, posture, and cardiovascular responses to exercise for people with a unilateral TTA. In addition, the secondary aim of this study is to explore and describe the impacts of an UTT protocol from the perspective of the people with a TTA, utilizing a focus group.

CHAPTER III

THE EFFECTS OF UNDERWATER TREADMILL TRAINING ON BALANCE, POSTURE, MOBILITY, AND CARDIOVASCULAR RESPONSES FOR ADULTS WITH A UNILATERAL TRANSTIBIAL AMPUTATION

Introduction

Approximately one-third of all lower limb amputations (LLA) occur at the transtibial portion of the leg (Imam et al., 2017). Causes of this form of surgical osteotomy include infection or loss of adequate blood supply from diabetes, vascular disease, and trauma-related incidents (Cristian, 2006). Following a unilateral transtibial amputation (TTA), people can be fitted with a prosthetic that assists with ambulation and performance of daily living activities (Gailey et al., 2008). However, the prosthetic does not fully account for the lack of proprioceptive feedback associated with the loss of the limb (Isakov et al., 1992; Petrofsky & Khowailed, 2014) leading to asymmetrical balance or posture (Soares et al., 2009). Over time, individuals with lower limb loss face a variety of issues that may limit their ability to ambulate, thus affecting quality of life and increasing risk of hypokinetic diseases (Gailey et al., 2008).

Typically, people with a TTA have more of their body weight over the intact limb (Rusaw, 2019). They also have a decreased ability to control postural shifts in the antero-posterior direction as their center of pressure (CoP) is shifted anteriorly and laterally on the residual limb side (Buckley et al., 2002; Rusaw, 2019). Consequently, the intact limb develops contralateral forces directed in the posterior and lateral directions. As a result of these changes, most people who use a lower body prosthesis walk with at least one gait deviation (Gailey et al., 2008).

During ambulation, individuals with a TTA have increased step width (Hak et al., 2013), but a decreased stride length (Powers et al., 1998) when compared to able-bodied controls. Similarly, people walking with a TTA possess slower mid-stance and longer stance phase on the residual limb than the intact side (Adamczyk & Kuo, 2015). The residual limb experiences reduced knee flexion in the stance phase (Schmalz et al., 2001). This improper timing and flexion of the residual knee could be detrimental for locomotion by generating a kicking motion. In addition, the hips experience increased loads (Gailey et al., 2008; Mattes et al., 2000). While these adaptations are essential for a person with a TTA to ambulate, their biomechanics and kinetics are considered abnormal and can be detrimental to the performance of physical activity (PA; Gailey et al., 2008).

An underwater treadmill has become a viable option for several populations in the last decades due to improved acute and/or chronic adaptations within fitness or therapy contexts (Barbosa et al., 2009). Following an underwater treadmill training (UTT) protocol, improvements have been demonstrated to balance, cardiorespiratory function, leg strength, and multiple walking parameters such as speed and duration in those with Type 2 Diabetes (Conners et al., 2019), incomplete spinal cord injuries (Stevens et al., 2015), and stroke (Yoo et al., 2014). Furthermore, favorable outcomes to balance and ambulation variables have been seen in those with an amputation following UTT (Cutler, 2017; Mathis et al., 2018). The unique characteristics of the aquatic environment include drag force, buoyancy, viscosity, and hydrostatic pressure, which are beneficial for muscular resistance, decreased joint stress, and cardiovascular function, respectively (Cole & Becker, 2004; Cutler, 2017; Yoo et al., 2014). These adaptations and benefits could be valuable for people with a TTA. Importantly, UTT has been demonstrated to be safe and allows ease of implementing measurable outcomes offering the ability to modify training variables during participation.

Even though exercising in water offers many advantages to balance, gait, and cardiovascular function, it is underutilized in people with a TTA. Thus, the purpose of this study was to investigate the effects of a 6-week UTT protocol on balance, posture, functional mobility, and cardiovascular responses to exercise for people with a TTA. The hypothesis of this study was a 6-week UTT procedure would produce changes in balance, posture, functional mobility, and cardiovascular responses to exercise for a person with a unilateral TTA.

Materials and Methods

Participants

Three participants ($N = 3$) with unilateral TTAs (males, $n = 2$; females, $n = 1$) were recruited via email from a university in the southeast region of the United States. Participants met the following inclusion criteria: (1) unilateral below knee amputation or unilateral ankle disarticulation amputation; (2) 18-64 years of age; (3) amputation from trauma, comorbidities, or disease progression/complications; (4) use of prosthetic for at least a year; (5) use of prosthetic 8+ hours a day; (6) less than 6' in height (to accommodate height restriction in treadmill); and (7) ability to walk with prosthetic for a minimum of 45 continuous minutes. Participants were screened using the American College of Sports Medicine (ACSM; Liguori et al., 2021) algorithm process to determine if medical clearance was necessary prior to the start of UTT. If medical clearance was recommended, written documentation from a medical professional was required before participant enrollment in the study. No medical clearance was necessary for any of the participants. Participant descriptive characteristics are outlined in Table 1.

Procedures

The protocol for this study was approved by and conducted in accordance with the local institutional review board (see Appendix A). All participants completed an inclusion criteria background survey and were evaluated to determine if medical clearance was needed. Participants read and signed the informed consent document prior to participation. The UTT protocol was modeled according to a prior methodology for people with a TTA (Mathis et al., 2018). Due to the lack of research for individuals with a TTA, procedures for this study were also designed in reference to UTT for other special populations, such as adults with Type 2 Diabetes (Conners et al., 2019) and people with incomplete spinal cord injuries (Stevens et al., 2015).

Prior to the start of the 6-week UTT, participants had a familiarization session in the underwater treadmill (HydroTrack Plus Underwater Treadmill System) and on the BTrackS Balance Tracking System. During the familiarization session participants were able to explore various methods necessary to ambulate in the UTT and balance on the BTrackS system, while utilizing their prosthetic. While participants familiarized themselves with the underwater treadmill, they also self-selected a walking speed ranging between 1.2 mph and 2.0 mph that they could maintain for a minimum of 15 minutes in the underwater treadmill. Water height was set to the xiphoid process for each participant, and water temperature was 88-93 degrees Fahrenheit. Participants were instructed to utilize the same shoes and type of prosthetic during the training protocol

Table 1

Descriptive Characteristics of Participants

Participant	Sex	Age (years)	Years post-TTA	TTA Side	Liner Type	Prosthetic Foot	Cause of TTA
1	M	25	9	Left	Pin-lock	Fillauer All Pro	Surgical complication for leg discrepancy
2	F	58	15	Right	Vacuum -assisted suction	ESAR	Surgical complication following trauma related event
3	M	19 [a]	17	Right	Vacuum -assisted suction	Össur	Unsuccessful exploratory TTA because of cancer [b]

Note. TTA = Transtibial amputation; M = Male; F = Female; ESAR = Energy storing and returning prosthetic foot. [a] Participant 3 turned 20 years old during the study. [b] Participant 3 required two separate TTA surgeries due to unsuccessful exploratory study to eradicate cancer.

Pre- (within 1 week of first session), mid- (first session of week 4), and post-testing (within 1 week of last session) included the BTrackS Balance Tracking System which assessed BTrackS Balance (BBT) measurements and BTrackS Posture (BPT) measurements. The BBT and BPT trials were performed shoeless with eyes closed and hands on hips. Foot position was recorded for consistency amongst trials. For the BBT, the participant stood as still as possible on the balance platform and completed three, 20-second trials. The BBT measures provided Fall Risk Assessment (FRA) data based on the total area covered by both prosthetic limb and non-affected limb, represented by the average sway distance from center of pressure (CoP) accounting for the individual's sex and age. For the BPT, participants stood motionless while data were captured every 30 seconds (5x) to assess global postural alignment and weight bearing asymmetry.

In addition to assessing balance, pre- and post-testing measurements included a 16-question Activity-Specific Balance Confidence (ABC) Scale (Powell & Myers, 1995) and a 6-minute Walk Test (6MWT; Enright, 2003). The ABC provided participant confidence related to balance during various mobility activities. The ABC assessment is an 11-point scale with 10-point increment answers ranging from 0% to 100% (i.e., 0% no confidence and 100% completely confident). If participants did not currently perform the activity in question, they were to imagine confidence in performing the activity. The 6MWT was administered to analyze aerobic fitness and functional mobility. During the 6MWT, participants walked around a path on a gymnasium floor, specified by cones and painted lines on the floor. Participants were instructed to follow the designated path and told to immediately stop once the six minutes was over for the total measurement of distance walked.

UTT protocol

The 6-week UTT protocol included 18 sessions (3 days per week, minimum of 24 hours between sessions). Each session included three walks on the underwater treadmill, interspaced with self-determined rest periods (ranging from 1 minute to 2 minutes). Table 2 represents the following parameters for the UTT protocol. During week 1, walking bouts were set to 8 minutes at 70% of the self-selected walking speed determined in the familiarization session. Walking speeds were increased by 10% of the week 1 speed at the start of weeks 3 and 5. The duration of walking bouts was increased to 10, 12, and 15 minutes in weeks 2, 4, and 6, respectively. Participants wore a Polar HR sensor (Polar T31 coded transmitter) around the chest, just below the pectoralis minor muscle to record heart rate (HR) displayed on a Polar FT1 Watch. The HR of participants was recorded every minute during the underwater treadmill walking bouts. After each walking bout, participants rated overall perceived exertion (RPE) on a 1-10 scale (1 = very light activity, 10 = max effort activity). Specific UTT protocol parameters and cardiovascular responses to UTT for participants 1, 2, and 3 are outlined in Table 3, Table 4, and Table 5, respectively. Participants were able to miss two training sessions as long as they did not occur within the same week. If participants missed more than two training sessions or missed two sessions in the same week they were removed from the study. None of the participants missed more than two sessions nor two sessions in the same week.

Table 2

Participant UTT Protocol Parameters

Week	Day	Speed Percentage (mph)	Time Per Bout (min)	Total Time Per Session
1	1 2 3	70%	8	24
2	4 5 6	70%	10	30
3	7 8 9	80%	10	30
4	10 11 12	80%	12	36
5	13 14 15	90%	12	36
6	16 17 18	90%	15	45

Notes. Each participant completed 3 bouts of underwater treadmill walking per day/session. Each walking bout was followed by a 1-2 min rest period. Participant HR was measured every minute of underwater treadmill walking. RPE was recorded after each successful walking bout. HR = Heart rate; RPE = Rate of perceived exertion; mph = Miles per hour.

Table 3

Participant 1 Underwater Treadmill Training Protocol Parameters and Cardiovascular Responses

Week	Day	Speed (mph) / Duration (min)	HR (bpm)	RPE	Distance Per Day (miles)	Total Weekly Miles
1	1	1.4/24	74	[2, 2, 2]	0.56	
	2		80	[3, 4, 4]	0.56	
	3		77	[2, 4, 4]	0.56	1.68
2	4	1.4/30	78	[2, 3, 3]	0.70	
	5		80	[2, 2, 3]	0.70	
	6		74	[3, 4, 5]	0.70	2.10
3	7	1.6/30	83	[3, 4, 5]	0.80	
	8		80	[2, 4, 4]	0.80	
	9		83	[2, 3, 3]	0.80	2.40
4	10	1.6/36	83	[3, 5, 6]	0.96	
	11		79	[3, 4, 5]	0.96	
	12		74	[3, 4, 5]	0.96	2.88
5	13	1.8/36	86	[3, 6, 7]	1.08	
	14		84	[5, 6, 6]	1.08	
	15		87	[5, 6, 7]	1.08	3.34
6	16	1.8/45	88	[6, 7, 7]	1.35	
	17		87	[6, 6, 7]	1.35	
	18		86	[4, 5, 6]	1.35	4.05

Note. Participant HR (bpm) was recorded each minute and averaged each day. Participant RPE was recorded after each bout of exercise (3 per session) and represented by [#, #, #] for each day. HR = Heart rate; RPE = Rate of perceived exertion; bpm = Beats per minute; mph = Miles per hour.

Table 4

Participant 2 Underwater Treadmill Training Protocol Parameters and Cardiovascular Responses

Week	Day	Speed (mph) / Duration (min)	HR (bpm)	RPE	Distance Per Day (miles)	Total Weekly Miles
1	1	0.84/24	98	[2, 4, 5]	0.10	
	2		100	[4, 5, 7]	0.10	
	3		103	[2, 3, 3]	0.10	0.30
2	4	0.84/30	105	[2, 3, 5]	0.13	
	5		100	[3, 4, 6]	0.13	
	6		104	[2, 2, 3]	0.13	0.39
3	7	0.96/30	101	[2, 3, 4]	0.16	
	8[a]		-	-	-	
	9		106	[2, 5, 7]	0.16	0.32
4	10	0.96/36	100	[2, 4, 6]	0.19	
	11		106	[3, 4, 7]	0.19	
	12		103	[3, 4, 4]	0.19	0.57
5	13	1.08/36	105	[4, 6, 7]	0.21	
	14		105	[3, 6, 7]	0.21	
	15		107	[3, 4, 4]	0.21	0.63
6	16	1.08/45	100	[3, 6, 7]	0.25	
	17		105	[2, 4, 6]	0.25	
	18		103	[2, 3, 4]	0.25	0.75

Note. Participant HR (bpm) was recorded each minute and averaged each day. Participant RPE was recorded after each bout of exercise (3 per session) and represented by [#, #, #] for each day. HR = Heart rate; RPE = Rate of perceived exertion; bpm = Beats per minute; mph = Miles per hour. [a] Day 8 in Week 3 for participant 2 was missed and therefore not included in the table.

Table 5

Participant 3 Underwater Treadmill Training Protocol Parameters and Cardiovascular Responses

Week	Day	Speed (mph) / Duration (min)	HR (bpm)	RPE	Distance Per Day (miles)	Total Weekly Miles
	1		82	[2, 2, 2]	0.56	
1	2	1.4/24	81	[2, 2, 2]	0.56	
	3[a]		-	-	-	1.20
	4		72	[2, 2, 2]	0.70	
2	5	1.4/30	78	[2, 2, 2]	0.70	
	6		78	[2, 2, 2]	0.70	2.10
	7		93	[3, 3, 3]	0.80	
3	8	1.6/30	75	[3, 3, 3]	0.80	
	9		79	[3, 3, 3]	0.80	2.40
	10		84	[3, 3, 3]	0.96	
4	11	1.6/36	78	[3, 3, 3]	0.96	
	12		92	[3, 3, 3]	0.96	2.88
	13		94	[4, 4, 4]	1.08	
5	14	1.8/36	108	[4, 5, 5]	1.08	
	15		93	[4, 5, 5]	1.08	3.34
	16		97	[4, 4, 4]	1.35	
6	17	1.8/45	94	[5, 5, 5]	1.35	
	18		98	[4, 4, 4]	1.35	4.05

Note. Participant HR (bpm) was recorded each minute and averaged each day. Participant RPE was recorded after each bout of exercise (3 per session) and represented by [#, #, #] for each day. HR = Heart rate; RPE = Rate of perceived exertion; bpm = Beats per minute; mph = Miles per hour. [a] Day 3 in Week 3 for participant 3 was missed and therefore not included in the table.

Data management

The average CoP path length from three BBT 20-second trials (displayed in cm) was determined to generate a percentile ranking in comparison to a BTrackS Balance Tracking System normative database, represented by people similarly aged and of the same sex. Based on the baseline BBT percentile rank, the post-baseline BBT result yielded either an increase or decrease in percentile ranking. In addition, a FRA (low 0-30; moderate 31-38; high 39+) was determined based on the number of standard deviations a BBT result was from the result of an average adult aged 20-39 years (BTrackS normative database). Percent changes were calculated. The average of five BPT trials (30 second separation) were calculated for changes weight distribution as measured by CoP (x-axis, y-axis) from an ideal central location between the ankle joints of the participant. A shift in these values towards zero reflected improved postural alignment. The BPT results also yielded a percentage of postural alignment (left, right, front, back) with values approaching 50% reflecting more equal weight distribution. Percent changes were calculated. Ratings from each of 16 ABC scale questions were averaged to generate an overall ABC score percentage. The 6MWT results were recorded based on the total distance a participant can walk in a total time. The pre- and post-tests, and the percent change were calculated for the ABC scale and 6MWT. The HR (bpm) from each minute of the UTT walking sessions were averaged to create a session average. An average session HR was calculated. A RPE value was measured after each walking bout (3 per session) and was kept as individual outcomes from each walking bout.

Data analysis

Raw data were entered into SAS (version 9.4) and reviewed for any errors or missing values. Pre-tests, post-tests and percent change were reported for the 6MWT and ABC scale. The impact of session (pre-, mid-, post-test) on weight distribution as measured by BPT (center of pressure x-axis, center of pressure y-axis, left, right, front, back) was explored. Pre-, mid-, and post-test scores and FRA category from the BBT were reported. The impact of speed and duration on HR and on RPE was explored as well.

Results

Pre- and post-test assessments were conducted approximately one week preceding and following UTT, respectively. Mid-test assessments were completed directly before the first UTT session of week four. All participants completed UTT without any untoward events. No negative consequences were demonstrated to balance, posture, functional mobility, and cardiovascular responses to exercise during UTT and no falls or slips occurred during UTT or testing. Additionally, no harm to any of the participant's prosthetics was relayed to investigators. Participant 1 performed all 18 UTT sessions while both participants 2 and 3 completed 17 of 18 sessions. Participants utilized the same prosthetic, liner, and foot throughout UTT and assessments.

BBT

Results from BBT data indicated UTT produced an improvement in balance for participant 1 and maintained balance for participants 2 and 3 (see Table 6). Specifically, FRA (i.e., balance) results indicated participant 1 improved balance from pre-test to

Table 6

Participant BTrackS Balance Test (BBT) Results Regarding Fall Risk Pre-, Mid-, Post-Testing

Participant	Testing Session	FRA	FRA Classification	FRA Percentile Ranking	FRA Percent Change from Pre-test
1	Pre	56	High	0	-
	Mid	41	High	4	27
	Post	35	Moderate	8	38
2	Pre	12	Low	99	-
	Mid	11	Low	100	8
	Post	12	Low	99	0
3	Pre	16	Low	91	-
	Mid	17	Low	86	-6
	Post	16	Low	91	0

Note. The BBT included three, 20-second trials performed shoeless, hands-on hips, and eyes closed to obtain the average CoP path length in centimeters. Fall risk was calculated based on the number of standard deviations BBT results were from average adult 20-39 years. FRA = Fall risk assessment; BBT = BTrackS Balance Test; UTT = Underwater treadmill training; CoP = Center of pressure.

mid-test, and again at post-test and decreased fall risk categories from high to moderate. Results from the pre and post BBT signified both participant 2 and 3 possessed established balance with relatively high FRA percentile ranking and the lowest fall risk classification, maintained from pre- to post-testing.

Raw BBT data showed a decrease in CoP path length and/or size indicating an improvement to CoP from pre-test to mid-test and pre-test to post-test for all participants (see Figure 1). This visual representation shown by the raw BBT results indicates balance was either improved and/or maintained for all participants during or following UTT.

BPT

Posture and/or weight distribution was enhanced following UTT. Figure 2 displays improved CoP in the x axis for all participants. Furthermore, participants 1 and 3 increased utilization of their residual limb to maintain appropriate posture across the training period (see Table 7). The largest shift to the side of the body with the prosthetic was displayed by participant 1. Results also indicated improved CoP in the y axis for participant 1 as well as maintained CoP for participants 2 and 3 (see Figure 2).

ABC scale

Results from the ABC assessment indicate all participants increased balance confidence in performing various activities mentioned in the ABC. Participant 1 had the largest change in perceived balance control (Pre = 87%, Post = 99%, Δ = 12%). Participant 2 reported an 84% pretest score and an 88% post-test score to represent a 4% change. The ABC results also indicated a 98% pre-test score and a 99% post-test score, showing a 1% change from pre-test to post-test for participant 3. Participant 3 had the

Participant 1

Pre-test

Mid-test

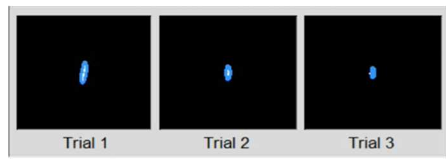
Post-test

Participant 2

Pre-test

Mid-test

Post-test



Participant 3

Pre-test

Mid-Test

Post-Test

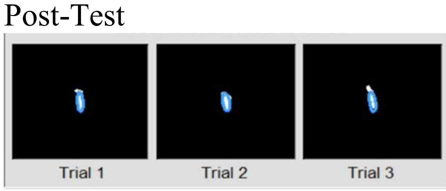


Figure 1.

Participant Raw BTrackS Balance Test (BBT) Trials Pre-test, Mid-test, and Post-test

Note. The BTrackS Balance Test displayed the total area covered for center of pressure in each of the three 20-second trials per assessment.

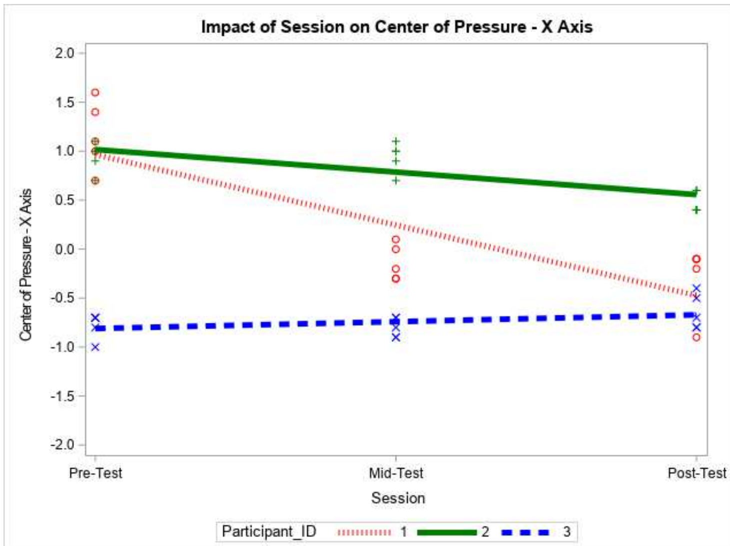
Table 7

Participant BTrackS Posture Test (BPT) Results for Center of Pressure and Weight Distribution Percentage Pre-, Mid-, and Post-Testing

			Percentage					
ID		Testing Session	Left	Right	Front	Back	CoP-X Axis	CoP-Y Axis
1		Pre	47.6	52.4	85.4	14.6	1.16	10.96
		Mid	50.4	49.6	82.6	17.4	-0.14	10.18
	Change from pre-test		**2.8**	**2.8**	**2.8**	**2.8**	**-1.3**	**0.78**
		Post	50.4	49.6	80.6	19.4	-0.28	9.44
	Change from pre-test		**2.8**	**2.8**	**4.8**	**4.8**	**-1.44**	**1.52**
2		Pre	50.6	49.4	64.0	36.0	0.94	4.26
		Mid	48.0	52.0	63.8	36.2	0.94	4.32
	Change from pre-test		**2.6**	**2.6**	**0.2**	**0.2**	**0**	**0.06**
		Post	49.0	51.0	66.0	34.0	0.48	4.98
	Change from pre-test		**1.6**	**1.6**	**2**	**2**	**0.46**	**0.72**
3		Pre	51.4	48.6	62.2	37.8	-0.78	3.76
		Mid	51.6	48.4	56.4	43.6	-0.8	1.98
	Change from pre-test		**0.2**	**0.2**	**5.8**	**5.8**	**-0.02**	**1.78**
		Post	51.4	48.6	61.8	38.3	-0.64	3.76
	Change from pre-test		**0**	**0**	**0.4**	**0.4**	**0.14**	**0**

Note. During the BPT, participants stood motionless, shoeless, and with hands on hips while postural data and weight distribution was recorded every 30 seconds for five trials. The CoP-X axis and CoP-Y axis represented the CoP in the horizontal axis and vertical axis, respectively. Improved postural alignment is reflected by the shift of CoP-X axis and CoP-Y axis towards zero. Improved weight distribution for left, right, front, back is represented by values approaching 50%. BPT = BTrackS posture test; CoP = Center of pressure.

A.



B.

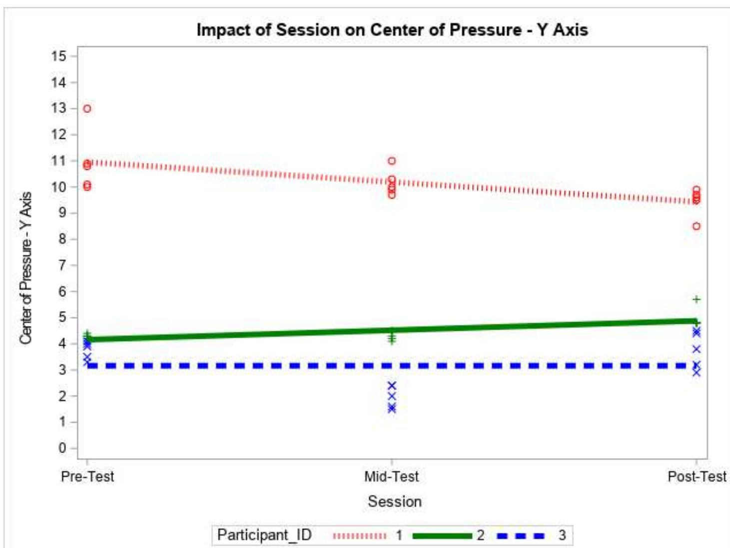


Figure 2.

Impact of Session Timeframe on Center of Pressure – X axis and Y axis

Note. A = BTrackS Posture Test CoP in the x-axis. Negative numbers indicate left and positive numbers indicate right. B = BTrackS Posture Test CoP in the y axis. Negative numbers indicate back, and positive numbers indicate forward. Improved posture is indicated by the numbers getting closer to zero.

highest pre-test ABC score amongst participants, thus indicating little improvement that could occur during the post-test (i.e., ceiling effect).

Functional mobility

Participant 1 walked 1,353 ft during the pre-test and 1,259 ft during the post-test for a decreased distance walked of 94 ft. Participant 2 also had a decreased walking distance of 108 ft from pre-test (1,378 ft) to post-test (1,270). Data for participant 3 signified the farthest pre-test walking distance (1,743 ft) and the only increased walking distance from pre-test to post-test (1,815 ft) by 72 ft.

Cardiovascular Responses to Exercise

The UTT protocol revealed changes to HR when both session speed and time per walking bout increased, for all participants (see Table 3-5). Positive linear relationships were present between average session HR and walking bout speed and average session HR and session walking bout time (see Figure 3). The linear relationship (i.e., slope) for participant 3 revealed the largest increase in average HR per walking bout because of either an increase to walking speed or walking time compared to participants 1 and 2. Participants' RPE per walking bout also indicated a positive linear relationship for both walking bout speed and walking bout time (see Figure 3).

Discussion

The underwater treadmill is an innovative modality, currently underutilized in the rehabilitation of individuals with a TTA. Data from this study indicate training in an underwater treadmill concurrently enhances balance, weight distribution symmetry, and ambulation, while decreasing fall risk, and increasing cardiovascular responses to endurance training.

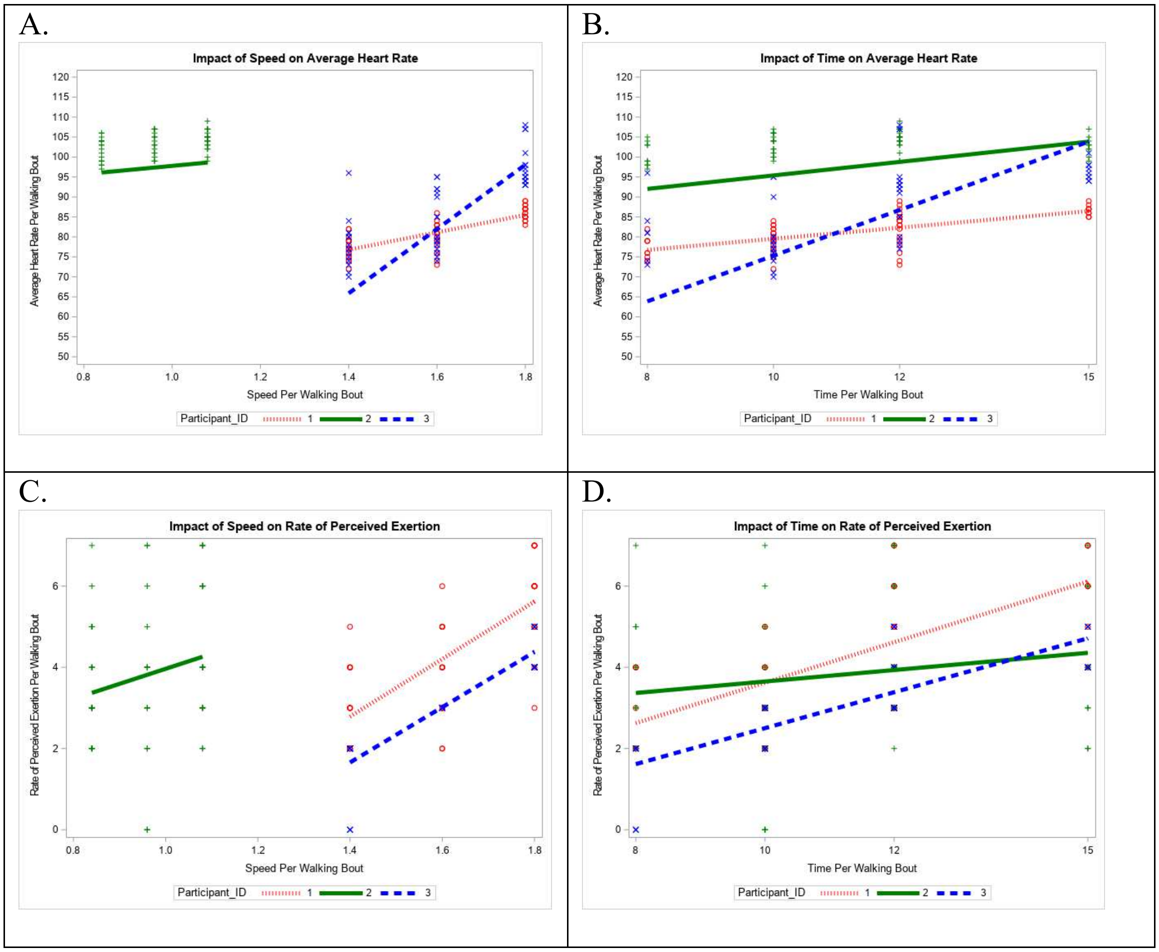


Figure 3

The Impact of Increased Underwater Treadmill Walking Speed and Time on Average HR and RPE

Note. The speed was indicated by miles per hour. The amount of time was represented by minutes for three walking bouts each underwater treadmill training session. RPE = Rate of perceived exertion; HR = heart rate.

Balance and posture

Participants' balance and posture improved following the 6-week UTT program. According to BBT data, participant 1 exhibited the largest improvement in balance with a 38% change in FRA from the pre-test. This participant is also the only one who improved fall risk categories from high to moderate. The difference in years post-TTA amongst the participants could be associated with the variation in FRA results. Participant 1 underwent amputation approximately nine years before the study as opposed to 15 and 17 years for participants 2 and 3, respectively (see Table 1). According to Zhang et al. (2021), experience or the number of years following a TTA has an impact on balance measurements. Specifically, balance parameters (ellipse shift area, path length, average velocity) are significantly larger for a novice than for a person with a greater number of years post TTA (Zhang et al., 2021). At 9 years post-TTA, participant 1 may not be categorized as a novice, as but did utilize a prosthetic device for fewer years than participants 2 and 3. Additionally, participant 1 had the highest pre-test BBT value at 56 (indicating poorer balance), so there was greater room for balance improvements. Further, the identical FRA scores of 12 and 16 from pre-test to post-test for participants 2 and 3, respectively, suggests UTT conveyed no negative consequences to balance (see Table 6). Although participants 2 and 3 did not increase balance from pre-test to post-test, they did demonstrate significant balance control when compared to healthy counterparts (Goble & Baweja, 2018). Overall, when looking at the potential of UTT to assist in balance control in those with a TTA, UTT could prove to be more beneficial for people with a newly acquired TTA, those within the first several years following the TTA, or those with poor balance.

Another factor to include when interpreting BBT results is balance confidence noted by the ABC scores. Following training, balance confidence increased in all participants. Participant 1 had the largest increase (12%) from pre-test to post-test compared to participants 2 (4%) and 3 (1%). The greater time since amputation may explain the smaller increases by the latter two participants (Miller et al., 2002). It is important to note, no participant recorded being 100% confident in maintaining balance while walking outside on an icy sidewalk, but all participants did increase confidence for this specific activity from pre-test to post-test. Nevertheless, all participants increased ABC scores, which illustrates UTT has the capability to maximize perceptions of balance confidence in performing activities that require balance. In addition, the consistent increase of ABC scores amongst participants may highlight that UTT is an alternative modality for those with low prosthetic confidence or high fall risk.

The UTT protocol also aided in improving weight distribution and/or posture. Typically, people with a TTA have a decreased capacity to control posture in the antero-posterior direction as opposed to the medio-lateral direction (Buckley et al., 2002). Data from the pre-test BPT (see Figure 1) confirmed this but did indicate that UTT could increase postural control. Participant 1 CoP results portrayed a baseline weight distribution of 85.4% towards the front and 14.6% to the back. Following training, there was a 4.8% change posteriorly (see Table 7). This was the largest percent change from pre-test to post-test amongst all participants. However, participant 3 also recorded a large posterior percent change of 5.8% during mid-test from 62.2% front and 37.8% back during pre-test to 56.4% front and 43.6% back during mid-test. This was the largest overall percent change and largest percent change from pre-test to mid-test when compared to other participants. Following mid-test participant 3 only had a 0.4% change in front to back posture following UTT. Following the UTT protocol, BPT data signified participants were either able to preserve (participant 2) or develop greater equilibrium (participant 1, participant 3) for front to back (antero-posterior) weight distributions.

Weight distribution from left to right (medio-lateral) was also evaluated. According to the pre-test BPT data, participant 2 showed weight distributions of 50.6% left and 49.4% right and participant 3 displayed 51.4% left and 48.6% right. In comparison, participant 1 had a more unequal weight distribution at 47.6% left and 52.4% right (see Table 7). Participant 1 displayed the largest positive change in weight distribution from pre-test to post-test for left to right (2.8%). Participant 2 showed a 2.6% and 1.6% change in left to right weight distributions from pre-test to mid-test and pre-test to post-test, respectively. Moreover, the more symmetrical weight distribution was apparent as soon as mid-testing for participants. Mid-test data also demonstrated positive changes to left and right CoP for participant 1 (2.8%) and participant 2 (2.6%). The smallest difference in left to right distributions can critically impact balance and posture for people with a TTA and increase the risk of falling (Ku et al., 2014). Therefore, the demonstrated improvements in weight distribution are meaningful relative to participant safety during ambulation.

The liner difference between participant 1 and the other two participants may have contributed to this outcome. Participant 1 utilized a pin-lock liner compared to the vacuum-assisted liner employed by participants 2 and 3. Previous research has indicated significantly higher socket comfort in vacuum-assisted liners versus pin-lock liners (Seth et al., 2021). Thus, comfort and control may be associated with the more symmetrical pre-test left to right weight distribution of participants 2 and 3. However, the positive changes in symmetry demonstrated by all three participants following the UTT highlight the potential of the underwater treadmill to be an effective modality for improving prosthetic control for people with a TTA in addition to potentially decreasing fall risk.

Characteristically, people with a TTA have more weight placed on the sound limb compared to the residual limb (Nadollek et al., 2002). Furthermore, people with a TTA have a CoP position directed anteriorly to the intact limb while standing (Rougier & Bergeau, 2009). A significant outcome of the UTT was an increased reliance on the residual limb compared to the intact limb for participants 1 and 3 (see Figure 2). Participant 1 utilized a prosthetic on the left leg as opposed to participant 3 on the right leg. When compared to pre-test BPT data, participant 1 shifted CoP to the residual limb by 1.30 cm at mid-test and 1.44 cm at post-test, and participant 3 shifted CoP to the residual limb by 0.20 cm at mid-test and 0.14 cm at post-test (see Table 7). This information is significant as it illustrates that UTT may produce a training effect on residual limb muscles. Reducing stress on the joints during aquatic ambulation permits people with a lower limb amputation to regain sufficient strength in the residual and intact limb (Cutler, 2017). When joint compression forces are minimized due to the buoyancy of water, participants can fully exert energy in overcoming the denser medium (Prins & Cutner, 1999). Thus, without wasted energy from stress on the joints, increased muscular effort can occur and subsequently improved strength can be obtained while ambulating in the underwater treadmill.

Functional mobility

The water-based training allowed participant 3 to increase the distance covered in the land-based 6MWT by 72 ft. This outcome aligns with Cutler (2017) who found the reduced-gravity environment of the UTT provides individuals with amputations an environment to ambulate further and longer without fear of injury or falling. Participant 3 also differed at pre-test, covering the greatest distance (1,743 ft) as opposed to 1,353 ft and 1,378 ft walked by participants 1 and 2, respectively. The pre-test 6MWT results suggest participant 3 possessed greater cardiovascular endurance and/or was more physically fit, compared to participants 1 and 2 at the start of the study. In contrast, participants 1 and 2 decreased 6MWT walking distance following UTT by 94 ft and participant 2 decreased 108 ft.

Possessing an amputation for a long period of time is often associated with secondary physical conditions, including osteoarthritis, osteoporosis, back pain, and other musculoskeletal problems (Gailey et al., 2008). The nature of these negative impacts of a TTA is remissions and exacerbations, which cause performance variations based on inflammation on a given day. The variability in the performance of participants 1 and 2 could be related to the heterogeneity of the condition and not a reflection of training. In addition, existing data from literature does confirm minimal detectable chances of clinically meaningful differences amongst people with an amputation. Cotrobas-Dascalu et al. (2022) suggested that traditional kinesiotherapy programs have a greater impact on gait and/or functional capacity regarding travelled distance compared to hydrokinetic therapy programs. While the mixed 6MWT results could be perceived as a negative outcome, aerobic training, like UTT, is beneficial to overall cardiovascular health and assists in reducing the cardiovascular responses to activities of daily living and exercise, so there may be benefits that were not apparent using the 6MWT. One example is that all participants were able to increase both their speed of walking and the length of their walking bouts across the training period, without detrimental effects, demonstrating improved functional capacity.

Cardiovascular responses to exercise

Based upon HR outcomes (see Tables 3-5, Figure 3), the cardiovascular responses were appropriate for all participants during UTT. There was a positive linear relationship between HR and walking duration as well as HR and walking speed. It is well documented that any increase in exercise intensity whether it be duration or speed, subsequently increases HR. Participants' RPE also increased when UTT session time and/or duration per walking bout increased as well as with increased walking speed (see Figure 3) showing this assessment of intensity was appropriate for this sample This is beneficial because it is representative of UTT potentially being able to create an appropriate overload to the cardiovascular system for people with a TTA. These results signify the underwater treadmill is an appropriate and safe modality to be used during rehabilitation and/or training for a person with a TTA and that intensity can be appropriately monitored using RPE.

Conclusions

Numerous challenges are evident for people with a TTA, which negatively impact walking, balance, and posture. This study adds to the body of literature regarding TTA rehabilitation or training by demonstrating that UTT has the potential to produce changes in balance, posture, functional mobility, and cardiovascular responses to exercise.

Moreover, participants in this study did not experience any injuries, falls, increased pain, or negative consequences to the prosthetic demonstrating the safety and efficacy of this modality (see Figure 4). The findings of this study should be substantiated by future exploration to determine the most effective training protocols.

Figure 4

View of an Individual with a Transtibial Amputation Walking in the Underwater Treadmill

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APPENDIX FOR STUDY I

APPENDIX A

IRB Approval Letter

IRB
INSTITUTIONAL REVIEW BOARD
Office of Research Compliance,
010A Sam Ingram Building,
2269 Middle Tennessee Blvd
Murfreesboro, TN 37129
FWA: 00005331/IRB Regn. 0003571

MIDDLE TENNESSEE STATE UNIVERSITY

IRBN001 - EXPEDITED PROTOCOL APPROVAL NOTICE

Friday, October 15, 2021

Protocol Title	***Underwater Treadmill Training in Adults with Unilateral Below Knee or Ankle Disarticu21-2174 4vWellSonlation Amputations***
Protocol ID	**21-2176 4i**
Principal Investigator	**Zachary Norred** (Student)
Faculty Advisor	Jennifer Caputo
Co-Investigators	Samantha Johnson, Sandra Stevens, and Samir Abdeljawad (sia2i)
Investigator Email(s)	*zrn2c@mtmail.mtsu.edu; jenn.caputo@mtsu.edu*
Department	Health and Human Performance
Funding	**NONE**

Dear Investigator(s),

The above identified research proposal has been reviewed by the MTSU IRB through the **EXPEDITED** mechanism under 45 CFR 46.110 and 21 CFR 56.110 within the category *(4) Collection of data through noninvasive procedures* under the subcategories 4a and/or 4e. Refer below for the IRB actions:

IRB Action	**APPROVED for ONE YEAR**		
Date of Expiration	**5/31/2022**	*Date of Approval*: 5/20/21	*Recent Amendment*: 10/15/21
Sample Size	THIRTY (30)		
Participant Pool	*Target Population:* Primary Classification: **General Adults (18 or older)** Specific Classification: **Individuals with an unilateral below knee amputation or an unilateral ankle disarticulation**		
Type of Interaction	☐ Non-interventional or Data Analysis ☐ Virtual/Remote/Online interaction ☒ **In person or physical interaction – Mandatory COVID-19 Management**		
Exceptions	Collection of participant details is permitted for contact purposes and to allow a potential COVID-19 tracing if needed		
Restrictions	**1. Mandatory SIGNED Informed Consent.** **2. Other than the exceptions above, identifiable data/artifacts, such as, audio/video data, photographs, handwriting samples, personal address, driving records, social security number, and etc., MUST NOT be collected. Recorded identifiable information must be deidentified as described in the protocol.** **3. Mandatory Final report (refer last page).** **4. MANDATORY screening of risky participants** **5. CDC guidelines and MTSU safe practice must be followed**		
Approved Templates	*IRB Templates:* Recruitment Email and SIGNATURE Informed Consent *Non-MTSU Templates:* NONE		
Research Inducement	NONE		
Comments	NONE		

Post-approval Requirements

The PI and FA must read and abide by the post-approval conditions (Refer "*Quick Links*" in the bottom):

- ***Reporting Adverse Events:*** The PI must report research-related adversities suffered by the participants, deviations from the protocol, misconduct, and etc., within 48 hours from when they were discovered.
- ***Final Report:*** The FA is responsible for submitting a final report to close-out this protocol before **5/31/2022** **(Refer to the Continuing Review section below)**; REMINDERS WILLNOT BE SENT. **Failure to close-out or request for a continuing review may result in penalties** including cancellation of the data collected using this protocol and/or withholding student diploma.
- ***Protocol Amendments***: An IRB approval must be obtained for all types of amendments, such as: addition/removal of subject population or investigating team; sample size increases; changes to the research sites (appropriate permission letter(s) may be needed); alternation to funding; and etc. The proposed amendments must be requested by the FA in an addendum request form. The proposed changes must be consistent with the approval category and they must comply with expedited review requirements
- ***Research Participant Compensation:*** Compensation for research participation must be awarded as proposed in Chapter 6 of the Expedited protocol. The documentation of the monetary compensation must Appendix J and MUST NOT include protocol details when reporting to the MTSU Business Office.
- ***COVID-19:*** Regardless whether this study poses a threat to the participants or not, refer to the COVID-19 Management section for important information for the FA.

Continuing Review (The PI has requested early termination)

Although this protocol can be continued for up to THREE years, The PI has opted to end the study by **5/31/2022** **The PI must close-out this protocol by submitting a final report before 5/31/2022 Failure to close-out may result in penalties that include cancellation of the data collected using this protocol and delays in graduation of the student PI.**

Post-approval Protocol Amendments:

The current MTSU IRB policies allow the investigators to implement minor and significant amendments that would fit within this approval category. ***Only TWO procedural amendments will be entertained per year*** *(changes like addition/removal of research personnel are not restricted by this rule).*

Date	Amendment(s)	IRB Comments
10/15/2021	Participant inclusion criteria is altered (details on file). Permitted to alter the recruitment script accordingly.	IRBA2022-304

Other Post-approval Actions:

The following actions are done subsequent to the approval of this protocol on request by the PI/FA or on recommendation by the IRB or by both.

Date	IRB Action(s)	IRB Comments
05/20/2021	PI's qualification is updated	Refer Caputo email

COVID-19 Management:

The PI must follow social distancing guidelines and other practices to avoid viral exposure to the participants and other workers when physical contact with the subjects is made during the study.

- The study must be stopped if a participant or an investigator should test positive for COVID-19 within 14 days of the research interaction. This must be reported to the IRB as an "adverse event."
- The MTSU's "Return-to-work" questionnaire found in Pipeline must be filled by the investigators on the day of the research interaction prior to physical contact.
- PPE must be worn if the participant would be within 6 feet from the each other or with an investigator.
- Physical surfaces that will come in contact with the participants must be sanitized between use
- **FA's Responsibility:** The FA is given the administrative authority to make emergency changes to protect the wellbeing of the participants and student researchers during the COVID-19 pandemic. However, the FA must notify the IRB after such changes have been made. The IRB will audit the changes at a later date and the FA will be instructed to carryout remedial measures if needed.

Data Management & Storage:
All research-related records (signed consent forms, investigator training and etc.) must be retained by the PI or the faculty advisor (if the PI is a student) at the secure location mentioned in the protocol application. The data must be stored for at least three (3) years after the study is closed. Additional Tennessee State data retention requirement may apply (*refer "Quick Links" for MTSU policy 129 below*). The data may be destroyed in a manner that maintains confidentiality and anonymity of the research subjects.

The MTSU IRB reserves the right to modify/update the approval criteria or change/cancel the terms listed in this letter without prior notice. Be advised that IRB also reserves the right to inspect or audit your records if needed.

Sincerely,

Institutional Review Board
Middle Tennessee State University

Quick Links:
- Post-approval Responsibilities: http://www.mtsu.edu/irb/FAQ/PostApprovalResponsibilities.php
- Expedited Procedures: https://mtsu.edu/irb/ExpeditedProcedures.php
- MTSU Policy 129: Records retention & Disposal: https://www.mtsu.edu/policies/general/129.php

CHAPTER IV

A QUALITATIVE APPROACH TO UNDERSTANDING CHALLENGES TO ACTIVITIES OF DAILY LIVING AND PHYSICAL ACTIVITY, AND THE EXPERIENCE OF UNDERWATER TREADMILL TRAINING FOR ADULTS WITH A TRANSTIBIAL AMPUTATION: A PRELIMINARY STUDY

Introduction

An amputation is the complete or partial loss of a limb precipitated by several factors (i.e., accidents, cancer, vascular disease; Gallagher & MacLachlan, 2001). One common procedure of surgical osteotomy is the unilateral transtibial amputation (TTA). Individuals with a TTA face several challenges sustaining a healthy level of physical activity (PA; Mandel et al., 2016), in part, due to physical restraints affecting motor function and control. A person with a TTA may have balance deficits and postural instability (Evarts, 1981; Rusaw, 2019), gait alterations (Gailey et al., 2008), and different physiological responses to PA (Houdijk et al., 2009; Moirenfeld et al., 2000; van Schaik et al., 2019). These objective factors have been previously researched as they embody the most prevalent acute issues associated with prosthetic function and control following the amputation (Gallagher & MacLachlan, 2001). Additionally, it is important to understand the subjective experiences of those with a TTA relative to physical activity (PA) and exercise.

Previous research utilizing qualitative approaches have provided documentation of multiple issues faced by people with a TTA. Gallagher and MacLachlan (2001) reported people with a TTA discussed physical implications of having an amputation and practical considerations that someone with a prosthesis must account for daily. Due to commonly reported pain in the stump and improper prosthetic fit, prosthetic use and mobility were impeded by people with a lower limb amputation (LLA; Gallagher & MacLachlan, 2001). Participants also expressed issues related to running, environmental situations (i.e., snow/ice, wet floors, leaves on footpath, etc.), maintaining or controlling balance, and preventing falls (Gallagher & MacLachlan, 2001). In work by Hafner et al. (2016), people with a TTA described challenges performing continuous or constant motions (walking or running) and changing posture or position (sitting down in a confined space or squatting). Individuals with a LLA also discussed concerns of unpredictable prosthetic behavior or movements during PA, thus limiting mobility (Hafner et al., 2016).

One method of obtaining subjective information from people with a TTA is by employing a focus group with open-ended questions. The data collected from focus groups are useful when the goal is to explain perceptions of an amputation or prosthetic and the associated daily living experiences (Gallagher & MacLachlan, 2001). Furthermore, the use of focus groups are particularly beneficial in evolving training or rehabilitation programs for prosthetic-users (van Twillert et al., 2013). Ultimately, the primary goal to develop clinically meaningful methodologies or modalities for people with a TTA may be better achieved utilizing a focus group.

Due to the complex and comprehensive impact of having an amputation, it is important to not only concentrate on the physical, medical, and prosthetic factors, but also participant experiences and perspectives (Gallagher & MacLachlan, 2000). Therefore, the purpose of this preliminary study was to utilize a focus group for the exploration of common challenges to performing activities of daily living (ADL) and PA in individuals with a TTA, and to investigate participant's perspectives of a 6-week underwater treadmill training (UTT) protocol.

Materials and Methods

Participants

Adults (*N* = 3) with a unilateral TTA (males, *n* = 2; females, *n* = 1) volunteered to participate in this investigation after completing a 6-week UTT protocol. All participants met the following inclusion criteria: (1) unilateral below knee amputation or unilateral ankle disarticulation amputation; (2) 18-64 years of age; (3) amputation from trauma, comorbidities or disease progression or complications; (4) use of prosthetic for at least a year; (5) use of prosthetic 8+ hours a day; (6) participants less than the height 6' tall; and (7) ability to walk with prosthetic for a minimum of 45 minutes. In addition, other than participation in a previous investigation including UTT, following amputation, none of the participants underwent any form of aquatic therapy during rehabilitation or their own training. The participants were sampled to ensure diverse perspectives, different prosthetic limbs, and etiologies of the amputation. Specific participant characteristics follow:

Participant 1

This participant was a 25-year-old male who lost the left transtibial portion of his leg approximately nine years ago. During childhood a leg length discrepancy was observed, requiring osteotomy surgery to achieve leg length equilibrium and alignment. The osteotomy surgery included amputating the transtibial portion of the bone to lengthen the leg. The surgery was unsuccessful and resulted in an amputation. Following the amputation, he completed physical therapy and prosthetic rehabilitation. The participant has a prosthetic including a pin-lock suspension liner with a Fillauer All Pro foot. The participant estimates the circumference of the residual leg is approximately three times smaller than prior to amputation, requiring seven different prosthetic limbs to accommodate proper fit of the liner. The participant performs aerobic and/or resistance training four times throughout the week.

Participant 2

The 58-year-old female participant underwent osteotomy surgery to the right transtibial portion of the leg approximately 15 years ago. The amputation was the result of a series of failed surgeries to repair the right ankle following a trauma-related event. Consequently, the participant was fitted with a vacuum-assisted suction liner with an energy return articulating ankle-joint foot. Prior to the amputation, the participant was unable to walk unassisted without pain. Directly following the TTA, the participant underwent rehabilitation and training for proper control and function of the prosthetic limb regarding balance and posture, gait, and situational experiences. Due to changes in stump size and comfort, the participant has been fitted for 15 different prosthetics since the TTA. The participant performs normal daily activities, but no consistent or specific exercise and PA. The participant performed physical therapy for low back pain before and during the study approximately one time each week. The participant did not perform physical therapy on the same day of UTT.

Participant 3

The 19-year-old male participant had fibrosarcoma approximately 17 years ago, requiring a TTA to the right leg. The initial amputation was an exploratory surgery to find an alternative method to ratifying the cancer. However, the results and procedure were unsuccessful. As a result, the participant underwent an osteo-myoplastic procedure to produce a functional residual limb. After this surgery, the participant was fitted with a vacuum-assisted valve liner including an Össur foot and performed 6 months of rehabilitation. The participant performs aerobic and resistance exercise 4 to 6 times a week.

Procedures

All study procedures were conducted in accordance with institutional review board (IRB) approved methods. Participants read and signed an informed consent document prior to participation. All participants completed an inclusion criteria background survey and were approved to partake in the study. Permission was requested by each participant to audio record the focus group session and to take notes. All participants complied and the audio and recorded notes were transcribed by researchers to facilitate analysis. Participants were ensured of confidentiality.

Prior to the qualitative study, participants underwent a 6-week UTT protocol (18 sessions, 3 days per week) utilizing an underwater treadmill (HydroTrack Plus Underwater Treadmill System) with three walking bouts per session and staggered increases to walking duration and speed.

Focus group protocol

Roughly one year following the 6-week UTT protocol, the participants partook in a virtual focus group using a computer application (Zoom). The focus group session lasted approximately one hour until a saturation point was reached (i.e., no new information emerged) in discussion. Participants were required to turn on their microphone and turn off the camera on their computer for the entirety of the focus group session. The focus group audio recording was downloaded from Zoom and transcribed by a private YouTube account. The YouTube account was only accessible by study investigators. Immediately following the completion of the YouTube transcript, the account and transcription was deleted. Prior to the study focus group, two investigators conducted a trial focus group on Zoom and transcribed the recordings by YouTube to ensure quality results and data.

To portray necessary information on the participant's perspective of the impacts to possessing a TTA and the influence of the UTT protocol, a set of 15 pre-determined, open-ended questions were formulated into an interview guide (see Table 1). Each question was displayed on the computer screen for participants to maintain topic discussion. Each participant was given as much time as necessary to respond before moving to the next participant and/or question. The questions were asked in a set order. The order of participant responses was conducted according to set sequential order. After all responses were completed for the given question, participants were allowed to provide additional details or responses during open discussion with the other participants. Depending on the question responses the primary moderator asked the participants to provide additional perspectives or details. Questions were devised from multiple investigators and modeled after previous research exploring qualitative perspectives to using a prosthetic (Gallagher & MacLachlan, 2001; Hafner et al., 2016).

One primary moderator was present for the entirety of the focus group session. One assistant investigator was present for troubleshooting during the focus group. The moderator was otherwise non-directive, non-evaluative, and supportive during the focus

Table 1

Focus Group Guided Questions

General perspectives of the impacts of possessing a TTA.

1. What are the most common challenges/problems that arise when utilizing an artificial limb (prosthetic)?
2. How do those challenges/problems impact your activities of daily living?

General perspectives of the impacts a TTA has on exercise or physical activity.

3. Did your level of physical activity change following your amputation? If so, how?
4. Could you describe what you find to be most difficult when performing exercise and/or physical activity?
5. What forms of exercise or physical activity are most difficult for you and why?
6. What kind of exercise or physical activity do you find to be most beneficial for yourself and why?
7. Did your prior prosthetic rehabilitation or training accommodate you to perform exercise or physical activity? If so, how? If not, why?

Specific perspectives of the UTT protocol.

8. Was the UTT protocol beneficial for you? If so, how? If not, why?
9. What initial changes, if any, did you notice during the implementation of the underwater treadmill training?
10. What changes, if any, did you notice after the 6-week underwater treadmill training?
11. Do you think your weight distribution between your prosthetic limb and intact limb changed while walking or standing following the UTT? Please explain.
12. Do you think your balance and posture changed after the 6-week underwater treadmill training? Please explain.
13. Would you continue to perform underwater treadmill training if it was made available to you? Why or why not?

Additional perspectives or comments and identification of topic importance.

14. Is there anything that has not been discussed that you would like to add or comment on?
15. What was the most important topic discussed?

Note. UTT = Underwater treadmill training; TTA = Transtibial amputation.

group. Following the focus group, two investigators conducted a debrief to review material. The debrief was not included in the audio recording.

Data Management

The focus group audio recording was transcribed verbatim by YouTube to create an initial transcript draft. Two investigators coded, edited, and verified the accuracy of the Zoom audio recording with the YouTube transcript.

Once the YouTube transcript and notes, and UTT notes were verified, similar responses and/or quotes were copied and pasted into Excel to form the final transcript. The focus group transcript and notes were coded and grouped by the two moderators into themes associated with the impacts of a TTA during daily living and exercise and/or PA, and the influence of a UTT protocol. Each participant was given a specific highlight color code for the associated responses (i.e. yellow = Participant 1, red = Participant 2, green = Participant 3). Moderator notes from the Zoom meeting were bolded and underlined. Moderator statements and/or questions during the focus group were capitalized. Comments of participants were single-spaced, with double spacing between speakers. Wording and grammar were not altered. If in the event words were unintelligible "…" was utilized to indicate words or phrases missing from transcript. Parentheses indicated laughter, loud voices, shouting, and someone interrupted, and other. All responses were coded until data were exhausted.

Data Analysis

Focus group data were analyzed based on literature pertaining to practical applications of applied science (Krueger, 1988). An abbreviated abridged transcript analysis was conducted for the focus group discussions to identify themes from only relevant and useful portions of the discussion. A classical analysis strategy was employed in Excel to summarize and group responses and/or data.

A constant comparative analytic framework was used to analyze participant responses. Analytic themes were prioritized based on response frequency. Numerous responses relating to similar concepts or categories were coded for identification of themes related to the frequency of the response.

Results

Based on review of the focus group transcript, sets of primary themes emerged for the impacts of a TTA in performing ADL and PA or exercise and the influence of the previously completed UTT protocol. Every instance a response was relevant to either a main theme or category, it was recorded and reflected by the frequency (i.e., one response could attribute to multiple relevant categories). Examples of participant responses were paraphrased with the intent to avoid grammatical errors. No personal opinions and/or conclusions from the investigators were added to these example responses. The responses obtained from the focus group proved to be insightful to better understand this special population.

Impacts of TTA on performing ADL

The themes that emerged were increased planning required to perform ADL and decreased tolerance during ADL (see Table 2). The theme of increased planning required was expressed frequently and defined as the alternative methods in which participants either conducted or did not implement various ADL. The reasons why increased planning was required to conduct various occupational duties or tasks was a common topic during

Table 2

Focus Group Themes and Example Responses to the Impacts of a TTA on Performing Activities of Daily Living

Theme	Category	Participant / Frequency (ID/#)	Example Paraphrases (Participant #)
Increased planning required	Occupation	1/2 2/4 3/0	Going to the gym before or after work can be difficult because if I do one thing that is considered high impact and then stand on my prosthetic for 10 to 12 hours, it is difficult if not harder the next day. (1)
	Extracurricular and/or hobbies	1/0 2/6 3/1	I definitely was active in volunteering and hobbies. However, a lot of activities I have had to put on hold or not do because of the limitations and management of discomfort and activities to get through what I have to do at work. (2) I really beat the heck out of my residual limb and sometimes if I go too hard on it throughout the week I might not be able to do the things I want to do all the time because I just need a small break. (3)
Decreased tolerance	Fatigue	1/2 2/3 3/0	Standing for long duration or walking for long duration is challenging. (2) If I want to go to the grocery store, it is hard for me to go after work because my residual leg gets fatigued throughout the day. (2)

Table 2

Focus Group Themes and Example Responses to the Impacts of a TTA on Performing Activities of Daily Living

Theme	Category	Participant / Frequency (ID/#)	Example Paraphrases (Participant #)
	Residual limb symptoms during ADL	1/2 2/2 3/1	General housework can be challenging due to the sores, little hot spots, and/or bruises on the tibia especially when I am vacuuming. The forward and backward motion of walking is pretty wearing on my residual limb. (2) The biggest problem for me has been the residual limb and the irritations within the prosthetic socket when I am walking or running. (3)

Note. ADL = Activities of daily living; TTA = Transtibial amputation.

the focus group. In addition, participants mentioned the necessity to increase planning for inclusion or exclusion from extracurricular activities or hobbies. Another common theme expressed throughout the focus group was decreased tolerance. This theme was defined as the inability for participants with a TTA to withstand fatigue and residual limb symptoms while performing ADL.

Impacts of TTA on performing PA and/or exercise

Themes of increased challenges in performing PA and/or exercise following a TTA, decreased tolerance, and increased PA and/or exercise following a TTA emerged (see Table 3). The theme of increased challenges in performing PA and/or exercise following a TTA included circumstances which participants found cumbersome or strenuous while undergoing PA or exercise. Endurance and resistance activities commonly emerged as the most challenging PA and/or exercise following a TTA. Additionally, the increased PA and/or exercise following TTA theme was portrayed as any improvement to physical fitness with the intent to maintain or regain pre-TTA function. Again, a decreased tolerance was mentioned regarding residual limb symptoms while performing various activities involving PA and/or exercise.

Perspectives on UTT

Following the UTT protocol, themes emerged regarding improved balance and/or posture, improved confidence, improved muscular fitness, and increased exercise tolerance (see Table 4). Improved balance and/or posture was outlined by perceptions of improvements made to personal weight distribution symmetry or stability while maintaining static standing or locomotion. The theme of improved confidence was

Table 3

Focus Group Themes and Example Responses to the Impacts of a TTA in Performing PA and/or Exercise

Theme	Category	Participant / Frequency (ID/#)	Example Paraphrases (Participant #)
Increased challenges to performing PA and/or exercise	Endurance activities	1/2 2/6 3/1	What has been challenging for me is walking long distances or even walking on a treadmill. My tibia is pretty pronounced and I get sore, but long distance walking mostly affects my hips and my back. Right now I cannot walk on the treadmill at all. (2)
	Resistance activities	1/4 2/1 3/2	I think for me the most difficult activity is probably weighted squats. Due to the way that my limb is I get a digging sensation in my hamstring from the back of my socket. Also, just the added weight while squatting can be something difficult to push through, pain tolerance wise. (3)
Decreased tolerance	Residual limb symptoms during PA and/or exercise	1/1 2/1 3/2	Squat movements or any other similar motions causes a lot of back issues. I cannot feel much of my residual limb at this point because I have beaten it up so much, but I know I do get skin abrasions and I have had to switch liners because it has torn my skin up so much over the years. (1)
Increased PA and/or exercise following TTA	Return to pre-TTA function	1/3 2/2 3/3	I went from a car wreck and a lot of surgeries with no activity and when I finally had the amputation my level of activity went way up. (2)

Table 3

Focus Group Themes and Example Responses to the Impacts of a TTA in Performing PA and/or Exercise

Theme	Category	Participant / Frequency (ID/#)	Example Paraphrases (Participant #)
			I need to beat my leg up as much as possible to treat it as normal as possible. This has really helped me to desensitize my leg and been beneficial to me, compared to taking it easy. I would create more problems for myself if I didn't become as active as I am now. (1)
	Increase ROM and/or strength	1/1 2/1 3/2	Multi-muscle compound movements like a clean or something similar where I can use multiple muscles of the body at the same time is beneficial. Regular activities does not isolate one muscle, but rather the whole body, so I think that doing things that require compound movements is really beneficial. (3)
			I think what is beneficial is yoga and chair yoga which requires controlled slow movements and stretching. This activity keeps me active and although it may not improve cardio, it does not hurt my limb, works my core, and minimized weight on my residual limb. (2)

Note. TTA = Transtibial amputation; PA = Physical activity; ROM = Range of motion.

Table 4

Focus Group Themes and Responses to the Influence of UTT for People with a TTA

Theme	Category	Participant / Frequency (ID/#)	Example Paraphrases (Participant #)
Improved balance and/or posture	Standing	1/4 2/0 3/2	I do feel that my balance did improve. I work on my feet all day, so long durations of standing in one place is required. However, I noticed that as soon as the study concluded, long duration standing at work felt better. An example of this is that I work on projects for at least two to three hours at a time while standing in the same spot. Instead of shifting from my intact leg to my prosthetic side, I felt symmetrical between the two limbs while working. This also helped me stand up straight as well. (1)
	Ambulating	1/2 2/0 3/2	It felt like I was not favoring my intact limb as much. Actually, after the underwater treadmill training I feel like I was more consciously aware of equally distributing my weight between both limbs while walking. Ultimately, I feel like I already possessed proper gait, but after the study it was better. (3)

Table 4

Focus Group Themes and Responses to the Influence of UTT for People with a TTA

Theme	Category	Participant / Frequency (ID/#)	Example Paraphrases (Participant #)
Improved confidence	Prosthetic confidence	1/1 2/0 3/3	There were things that I felt like I could not do based upon my lack of confidence in my prosthetic. However, I feel like as I performed underwater treadmill training, I built up more confidence in my prosthetic and my ability to use it. I increased the types of exercises that I could do. (3)
	Ambulating confidence	1/2 2/2 3/0	It was definitely easier to walk on the treadmill and perform similar activities. I felt like I improved my heel strike and I improved my stride. All of those things I noticed improvements and after the study was over when I reconsidered how I walked on a treadmill before. (2)
Improved muscular fitness	Strength	1/3 2/2 3/1	A result of the underwater treadmill training was my lower back muscles and hip flexors definitely got stronger, so I was able to do more perform more activities. (1) The underwater treadmill helped my core muscles a lot, which I did not expect. My legs muscles are pretty strong, but core muscles are weak, so the underwater treadmill had a positive impact on those. (2)

Table 4

Focus Group Themes and Responses to the Influence of UTT for People with a TTA

Theme	Category	Participant / Frequency (ID/#)	Example Paraphrases (Participant #)
	Endurance	1/2 2/4 3/0	My stamina built up in my leg muscles and my core improved as a result of the underwater treadmill training. I was able to continue walking on land and on the treadmill for long durations. I increased my mileage to two miles per day and walked about four times a week, so the underwater treadmill was greatly beneficial. (2)
Increased exercise tolerance	Overcoming physical challenges	1/2 2/1 3/2	As a result of underwater treadmill training, the exercises I was doing while isolating my limb got more complicated and the leg workouts that I was performing got more intense. I feel like I was able to push through those activities and intensities more because of the underwater treadmill training. (3)

Note. UTT = Underwater treadmill training; TTA = Transtibial amputation.

frequently expressed during the focus group and defined as the overall increased certainty utilizing the prosthetic limb during various physical activities. Improved muscular fitness was stated as the capability of UTT to result in recognizable differences to muscular strength and muscular endurance. Finally, the increased exercise tolerance theme was perceived by researchers as the capability of UTT to allow participants to push through physical challenges and/or inabilities imposed by possessing a TTA.

Discussion

The study was conducted to develop a greater understanding of the experiences of individuals with a TTA in performing ADL and participating in PA. Additionally, feedback was acquired on the use of an underwater treadmill as a training modality for individuals with a TTA.

Impacts of TTA on performing ADL

Discussion among the focus group participants clearly portrayed the complexity of attempting to perform ADL, even years following a TTA (see Table 2). Typically, therapy or rehabilitation programs focus on the development of postural control utilizing various exercises intended to control balance and weight shifting for proper execution of activities (Matjaĉić & Burger, 2003). While rehabilitation is beneficial in creating a foundation for locomotion and/or balance, it may not prepare people with a TTA for the increased challenges associated with performing multiple ADL. Participant responses generated a theme of needing increased planning relative to the completion of ADL. Having a TTA altered their approach to hobbies or other activities that could potentially cause fatigue, pain, or complications in the residual limb. Planning was required so the residual limb symptoms would not negatively impact their ability to perform occupational tasks or other duties. Additionally, sometimes individuals with a TTA limited participation in extracurricular activities to be able to make it through a shift at work or the remainder of responsibilities for a given day. Perceptions also may suggest that longer duration activities and the older people with a TTA become, multiple ADL become more difficult

Understanding the response of their body to increased activity is important for people with a TTA. It may be helpful to educate and increase awareness among people with a TTA of signs and symptoms that indicate they are approaching the maximum tolerance of their residual limb. This could help clarify when to stop or limit their performance of an ADL. Gaining an understanding of how their body recovers from a challenge is also important in being able to plan participation in future endeavors. These insights would also be valuable to include in rehabilitation programs, especially for those returning to work.

Responses also revealed the theme of decreased tolerance while performing ADL. Moirenfeld et al. (2000) suggested people with a TTA have a higher perceived exertion due to exaggerated muscular fatigue. Furthermore, Gailey et al. (2008) determined extended use of a prosthetic increases the likelihood of secondary physical conditions such as pain and/or musculoskeletal problems. Participant responses align with these findings as residual limb symptoms during ADL were noted by all participants. Fatigue, coupled with residual limb symptoms during ADL, could impact the performance of various activities and/or prohibit participation in some occupational and extracurricular activities. Together, the themes of decreased tolerance for completion of ADL and a need to plan when to perform ADL highlight the challenges of a TTA on completing everyday tasks such as house cleaning and grocery shopping. The consequences of expending too much energy during these tasks, in addition to potential pain caused to the residual limb, are important to address in finding hobbies and occupations. The ability to set priorities is important in being able to complete the most important tasks each day for a person with a TTA.

Impacts of TTA on performing PA and/or exercise

Participants noted increased challenges to executing PA and/or exercise (see Table 3). Specifically, endurance activities (swimming, walking, running, etc.) were more difficult. Hafner et al. (2016) also indicated people with a TTA regularly describe issues with endurance activities. Problems accomplishing resistance activities (weighted squats, pushups, leg extension, etc.) were also mentioned by participants. Residual limb pain was mentioned as the primary factor making these activities difficult.

An unexpected outcome was all participants reported an increase in PA and/or exercise following surgery. Comments from participants highlighted a drive and the motivation to return to pre-TTA function and preserve overall health. These results also suggest people are aware of the negative health implications associated with a TTA. Subsequently, participants increased PA, ROM, and/or strength to either prevent secondary conditions or optimize physical fitness. Furthermore, this outcome highlights the importance of factors to include in rehabilitation or training in relation to preferred methods of increasing ROM and/or strength training.

Perspectives of UTT

Each participant successfully completed 6-weeks of UTT approximately a year prior to participation in the focus group. Perceptions to the influence of UTT were reported and analyzed to conclude various mutual themes (see Table 4). From the focus group discussions, a theme related to improved balance and/or posture from the UTT emerged. Participants 1 and 3 indicated their static and dynamic balance improved during and after participating in UTT. The improvements to their standing and ambulating balance benefited them in performing long duration occupational tasks and/or improving their gait. Participant 2 indicated that balance did not change because of UTT noting a perception of established balance prior to training. Nonetheless, participant interpretations suggests that UTT has the capability to alter perceptions of balance or posture outside of the laboratory setting.

There was also increased confidence and improved muscular fitness from the UTT protocol. Results highlighted that not only were participants able to perform more intense activities, but also more complex activities due to the perceived advancement in prosthetic and ambulating confidence. Response data highlighted that some participants were able to sustain or improve upon the muscular strength and endurance, obtained from UTT. Further, the increased muscular strength and endurance could prevent unwarranted falls and reduce comorbidities commonly associated with people possessing a TTA.

Due to the perceptions that UTT improved muscular strength and endurance, the challenges to performing PA and ADL could be minimized. Further, participants described UTT as beneficial in allowing them to overcome physical challenges by increasing their exercise tolerance. The theme of UTT leading to increased exercise tolerance may potentially support people with a TTA in performing more PA and/or exercise without negative side effects such as fatigue and pain. Increased PA could again reduce the likelihood of comorbidities and symptoms associated with a TTA. All of

These themes support UTT as an advantageous training modality for adults with a unilateral TTA.

Participant responses addressed a desire that UTT be incorporated into physical therapy or rehabilitation programs. These suggestions were due to feelings of their participation in UTT as beneficial to their personal recovery processes. Further exploration of the incorporation of UTT into rehabilitation programs for this special population are warranted.

Conclusions

There are many challenges faced by people following a TTA. This study fills a gap in the literature regarding qualitative studies to better understand these challenges and the potential benefits of UTT for people with a TTA. This study highlighted the additional effort required by people with a TTA in planning out their daily activities to minimize residual limb symptoms and fatigue and maximize their ability to work or perform extracurricular activities. Negative residual limb symptoms also make it more difficult for people with a TTA to participate in and complete activities of daily living. However, the desire to be physically active was apparent among participants. One method of becoming more physically active while also obtaining improved physical function could lie with utilizing UTT. These improvements ultimately led to participants feeling an increased ability to overcome physical challenges. Overall, these perceptions and UTT proved to be subjectively and clinically meaningful for those with a TTA. Nevertheless, there is a need for advances in prosthetics and medical care to minimize residual limb symptoms to assist in both ADL and PA. Additional research on training modalities that minimize residual limb symptoms while concurrently improving multiple components of fitness and function are also needed.

Chapter IV References

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APPENDICES FOR STUDY II

APPENDIX A

IRB Approval Letter

IRB
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Office of Research Compliance,
010A Sam Ingram Building,
2269 Middle Tennessee Blvd
Murfreesboro, TN 37129
FWA: 00005331/IRB Regn. 0003571

MIDDLE TENNESSEE STATE UNIVERSITY

IRBN001 - EXPEDITED PROTOCOL APPROVAL NOTICE

Friday, October 15, 2021

Protocol Title	***Underwater Treadmill Training in Adults with Unilateral Below Knee or Ankle Disarticu21-2174 4vWellSonlation Amputations***
Protocol ID	**21-2176 4i**
Principal Investigator	**Zachary Norred** (Student)
Faculty Advisor	Jennifer Caputo
Co-Investigators	Samantha Johnson, Sandra Stevens, and Samir Abdeljawad (sia2i)
Investigator Email(s)	*zrn2c@mtmail.mtsu.edu; jenn.caputo@mtsu.edu*
Department	Health and Human Performance
Funding	**NONE**

Dear Investigator(s),

The above identified research proposal has been reviewed by the MTSU IRB through the **EXPEDITED** mechanism under 45 CFR 46.110 and 21 CFR 56.110 within the category *(4) Collection of data through noninvasive procedures* under the subcategories 4a and/or 4e. Refer below for the IRB actions:

IRB Action	**APPROVED for ONE YEAR**		
Date of Expiration	**5/31/2022**	*Date of Approval*: 5/20/21	*Recent Amendment*: 10/15/21
Sample Size	THIRTY (30)		
Participant Pool	*Target Population:* Primary Classification: **General Adults (18 or older)** Specific Classification: **Individuals with an unilateral below knee amputation or an unilateral ankle disarticulation**		
Type of Interaction	☐ Non-interventional or Data Analysis ☐ Virtual/Remote/Online interaction ☒ **In person or physical interaction – Mandatory COVID-19 Management**		
Exceptions	Collection of participant details is permitted for contact purposes and to allow a potential COVID-19 tracing if needed		
Restrictions	**1. Mandatory SIGNED Informed Consent.** **2. Other than the exceptions above, identifiable data/artifacts, such as, audio/video data, photographs, handwriting samples, personal address, driving records, social security number, and etc., MUST NOT be collected. Recorded identifiable information must be deidentified as described in the protocol.** **3. Mandatory Final report (refer last page).** **4. MANDATORY screening of risky participants** **5. CDC guidelines and MTSU safe practice must be followed**		
Approved Templates	*IRB Templates:* Recruitment Email and SIGNATURE Informed Consent *Non-MTSU Templates:* NONE		
Research Inducement	NONE		
Comments	NONE		

Post-approval Requirements

The PI and FA must read and abide by the post-approval conditions (Refer "*Quick Links*" in the bottom):

- ***Reporting Adverse Events:*** The PI must report research-related adversities suffered by the participants, deviations from the protocol, misconduct, and etc., within 48 hours from when they were discovered.
- ***Final Report:*** The FA is responsible for submitting a final report to close-out this protocol before **5/31/2022** **(Refer to the Continuing Review section below)**; REMINDERS WILLNOT BE SENT. **Failure to close-out or request for a continuing review may result in penalties** including cancellation of the data collected using this protocol and/or withholding student diploma.
- ***Protocol Amendments***: An IRB approval must be obtained for all types of amendments, such as: addition/removal of subject population or investigating team; sample size increases; changes to the research sites (appropriate permission letter(s) may be needed); alternation to funding; and etc. The proposed amendments must be requested by the FA in an addendum request form. The proposed changes must be consistent with the approval category and they must comply with expedited review requirements
- ***Research Participant Compensation:*** Compensation for research participation must be awarded as proposed in Chapter 6 of the Expedited protocol. The documentation of the monetary compensation must Appendix J and MUST NOT include protocol details when reporting to the MTSU Business Office.
- ***COVID-19:*** Regardless whether this study poses a threat to the participants or not, refer to the COVID-19 Management section for important information for the FA.

Continuing Review (The PI has requested early termination)

Although this protocol can be continued for up to THREE years, The PI has opted to end the study by **5/31/2022** **The PI must close-out this protocol by submitting a final report before 5/31/2022 Failure to close-out may result in penalties that include cancellation of the data collected using this protocol and delays in graduation of the student PI.**

Post-approval Protocol Amendments:

The current MTSU IRB policies allow the investigators to implement minor and significant amendments that would fit within this approval category. ***Only TWO procedural amendments will be entertained per year*** *(changes like addition/removal of research personnel are not restricted by this rule).*

Date	Amendment(s)	IRB Comments
10/15/2021	Participant inclusion criteria is altered (details on file). Permitted to alter the recruitment script accordingly.	IRBA2022-304

Other Post-approval Actions:

The following actions are done subsequent to the approval of this protocol on request by the PI/FA or on recommendation by the IRB or by both.

Date	IRB Action(s)	IRB Comments
05/20/2021	PI's qualification is updated	Refer Caputo email

COVID-19 Management:

The PI must follow social distancing guidelines and other practices to avoid viral exposure to the participants and other workers when physical contact with the subjects is made during the study.

- The study must be stopped if a participant or an investigator should test positive for COVID-19 within 14 days of the research interaction. This must be reported to the IRB as an "adverse event."
- The MTSU's "Return-to-work" questionnaire found in Pipeline must be filled by the investigators on the day of the research interaction prior to physical contact.
- PPE must be worn if the participant would be within 6 feet from the each other or with an investigator.
- Physical surfaces that will come in contact with the participants must be sanitized between use
- **FA's Responsibility:** The FA is given the administrative authority to make emergency changes to protect the wellbeing of the participants and student researchers during the COVID-19 pandemic. However, the FA must notify the IRB after such changes have been made. The IRB will audit the changes at a later date and the FA will be instructed to carryout remedial measures if needed.

Data Management & Storage:
All research-related records (signed consent forms, investigator training and etc.) must be retained by the PI or the faculty advisor (if the PI is a student) at the secure location mentioned in the protocol application. The data must be stored for at least three (3) years after the study is closed. Additional Tennessee State data retention requirement may apply (*refer "Quick Links" for MTSU policy 129 below*). The data may be destroyed in a manner that maintains confidentiality and anonymity of the research subjects.

The MTSU IRB reserves the right to modify/update the approval criteria or change/cancel the terms listed in this letter without prior notice. Be advised that IRB also reserves the right to inspect or audit your records if needed.

Sincerely,

Institutional Review Board
Middle Tennessee State University

Quick Links:

- Post-approval Responsibilities: http://www.mtsu.edu/irb/FAQ/PostApprovalResponsibilities.php
- Expedited Procedures: https://mtsu.edu/irb/ExpeditedProcedures.php
- MTSU Policy 129: Records retention & Disposal: https://www.mtsu.edu/policies/general/129.php

APPENDIX B

IRB Minor Revisions Form

IRB
INSTITUTIONAL REVIEW BOARD
Office of Research Compliance,
010A Sam Ingram Building,
2269 Middle Tennessee Blvd
Murfreesboro, TN 37129

MIDDLE TENNESSEE STATE UNIVERSITY

Form IRBF020a - MINOR REVISIONS REQUEST FORM

Use this form to request ONLY minor amendments to a previously approved protocol

Addition or removal of co-investigators who have completed appropriate training - UNLIMITED
Correct typographical errors and omissions – UNLIMITED
Reasonable extension or modification to the participant sample size – No restriction

1. GENERAL INFORMATION

1.1 Protocol Title: Underwater Treadmill Training In Adults With Unilateral Below Knee Or Ankle Disarticulation 21-2176 4i

1.2 Protocol ID: 2121764 **Expiration Date:** 5/31/22 **Today's Date:** 8/30/22

1.3 Primary Investigator (PI) Information:

☐Faculty/Staff ☒Graduate ☐Undergraduate ☐Other

Name	Zachary Norred	
MTSU Email	zrn2c@mtmail.mtsu.edu	
Alternative Email (if student)	znorred88@gmail.com	
Address/Office Location	Middle Tennessee State University AMG 215	
Telephone Number	8179831859	
Department/Unit and Office	Health and Human Performance	
CITI training expiration date	4/27/25	☒ Check if Training is Current

1.4 Faculty/Senior Investigator Information (Skip if same as PI)

Name	Jennifer Caputo	
MTSU Email	jenn.caputo@mtsu.edu	
Telephone Number	6158985547	
Office Location & Department	AMG 104	
CITI training expiration date		☒ Check if Training is Current

*The application documents MUST be emailed to irb_submissions@mtsu.edu by the faculty investigator. Suggested subject line to the email is "Protocol Addendum"

DO NOT CONVERT THIS APPLICATION TO PDF – There are embedded XML features

2. TYPE OF AMENDMENTS

2.1 Addendum request submission status:

☒ New request
☐ Resubmission (explain below);

2.2 Addendum type (select ALL that apply):

☒ **Minor Amendments** (unlimited)
These changes can be implemented immediately after emailing this request form and the PI/FA is not required to wait for an official notice.

☒ Add co-investigators (Section3.1)
☐ Remove co-investigators (Section 3.2)
☐ Errors & Omissions (Section 3.3)
☐ Participant Sample Size (Section 3.4)
☒ OTHER non-procedural (use Section 3.5)

☐ **Significant Amendments** – STOP use Form IRBF020b or the OLD ADDENDUM FORM

Future Upgrades:

Use Form IRBF020b "Significant Amendments" for procedural changes and other amendments not listed in Section 2.2

Use Form IRBF020c when making both types – minor & significant – amendments simultaneously

3. AMENDMENT PARTICULARS

3.1 ADD Co-Investigator(s) – Fill this section if you are requesting to add the following investigator(s) to this protocol. Simply hit enter to add more lines and keep the columns consistent for each investigator proposed to be included. .

#	FULL NAME	**Email ID** (5-letter code for MTSU students)	CITI ID Number
00020626	Dana Fuller	dana.fuller	50506799

I, Zachary Norred, assure that the above mentioned individuals have completed CITI training. I understand that this protocol could be suspended if the training information provided here is inaccurate.

☒ **Check this box** if ONLY IF have read and agree with the above statement.

IMPORTANT INSTRUCTION:

Mail this application to irb_submissions@mtsu.edu
*PROVISION: Addition of above mentioned investigators can be implement without having to wait for an approval notice once the applicant has **checked the above box** and emailed to irb_submissions@mtsu.edu. Check your sent-mail folder to ensure the request email has been sent before implementing the proposed amendments.*
RESTRICTION: However, the applicant(s) may be liable for IRB action if the Office of Compliance determines that the information provided here is inaccurate

3.2 REMOVE Current Co-investigator(s) – Fill this section if you are requesting to remove the following investigator(s) from the protocol. Simply hit ENTER to add more lines**.**

Name	Email	REMARKS (if any)

IMPORTANT INSTRUCTIONS:

No further action is required by the investigators to remove the above listed investigators once the form has been emailed to irb_submissions@mtsu.edu

3.3 CORRECTIONS to Errors or Omissions – Requisition to correct errors, such as spelling, grammar, and other unintentional mistakes in ANY of your document(s). Simply hit ENTER to start a new line.

Document Type	Current Text	Proposed Correction
Example 1 - Protocol Application Example 2 – Recruitment email	In Page 3, 1st Paragraph, misspelled as "Genetics"" Opening sentence: "Dear Colleagues"	Change to "Gentiles" Dear Recipient

I, Click here to enter text., assure that the above mentioned corrections are unintentional mistakes and I fully understand that this protocol could be suspended if the information provided here is inaccurate.

☐ **Check this box** ONLY if you have read and agree with the above statement

DEFINITION

Corrections of "unintentional" errors or omissions that were inadvertently introduced to any of the previously reviewed and approved documents

The proposed correction(s) must not alter the methods, procedure, consent process or other assurances provided in the original protocol

PROVISION: The investigators can implement the requested minor changes without having to wait for an approval notice once they agree with the following statement and email this form.

RESTRICTION: However, the applicant(s) may be liable for IRB action if the Office of Compliance determines that the information provided here is inaccurate

3.4 EXTEND PARTICIPANT SAMPLE SIZE - Fill this section of you are requesting to add or reduce the previously approved sample size.

a) Has the sample size extended prior to this request? Choose an item.
b) What is the current sample size?
c) What is the proposed sample size?
d) Will there be a change in the approved target population
e) Will the revision(s) lead to an alternation in the consent form? Choose an item.
f) Provide a reason for the requested sample size change (remember to include any statistical reasons):

3.5 NON-PROCEDURAL Alterations – Changes not listed explained within sections 3.1-3.4:

Description	Current	Proposed Correction

I, Click here to enter text., assure that the above mentioned non-procedural amendments would not change the actual protocol in any way. I fully understand that this protocol could be suspended if the information provided here is inaccurate.

☐ **Check this box** ONLY if you have read and agree with the above statement

4. ATTACHMENTS AND ENCLOSURES

Select what is attached with this application:

☒ CITI training certificates for adding investigator(s)
☐ Revised Application to include the proposed change in language
☒ Revised Recruitment information

☒ Revised consent form
☒ Revised Surveys/questioners/interview scripts
☒ OTHER(S), Specify: Focus Group Question file and Focus Group Script file

5. INVESTIGATOR (PI or/and FA) COMMENTS

Enter your note to the reviewer and other comments related to this amendment request:
Seeking approval to add a minor addendum to the current study 21-2176 4i.

Roughly one year following the 6-week UTT protocol, the same participants will partake in a private virtual focus group using the computer application (Zoom). The focus group session will last approximately one hour until a saturation point is reached (i.e., no new information emerged) in discussion. Participants will be required to turn on their microphones and turn off the camera on their computers for the entirety of the focus group session. Participants will be ensured of confidentiality. The focus group audio recording will be downloaded from Zoom and transcribed by a private YouTube account. The YouTube account will only accessible by the primary study investigator. Immediately following the completion of the YouTube transcript, the account will be deleted. Prior to the study focus group, two investigators will conduct a trial focus group on Zoom and transcribe the recordings by YouTube to ensure quality results and data.

A set of 15 pre-determined, open-ended questions are formulated into an interview guide (see attached Focus Group Question file). Each question will be displayed on the computer screen for participants to maintain topic discussion. Each participant will be given as much time as necessary to respond before moving to the next participant and/or question. The questions will be asked in a set order. The participants will be asked the questions in a set sequential order. Questions were devised from multiple investigators and modeled after previous research exploring qualitative perspectives to using a prosthetic (Gallagher & MacLachlan, 2001; Hafner et al., 2016).

The primary investigator will be present for the entirety of the focus group session. One assistant investigator will be present for any technical troubleshooting during the focus group. The primary investigator will start the focus group by stating instructions to participants according to a pre-determined script (see Focus Group Script file). The primary moderator will read from the script, provide focus group instructions, and ask the pre-determined questions. Before each question, the primary moderator will inform the order of participant responses. The primary investigator will be otherwise non-directive, non-evaluative, and supportive during the focus group. Following the focus group, the two investigators will conduct a debrief to review material. The debrief will not included in the audio recording.

6. DECLARATION

Protocol amendments must be requested only by a faculty member. Therefore, a Faculty Sponsor must read and endorse this section if the applicant is a student

I certify that:

1) this project is under my direct supervision

2) I have read this application thoroughly and I am fully aware of the activities to be performed under this protocol addendum

PI/Faculty Signature __Jennifer L. Caputo__
Date __9/1/2022__

(Enter your name and TODAY's date in the space provided)

Minor amendments listed in 3.1, 3.2 and 3.3 can be implemented immediately after submitting this form by email to irb_submissions@mtsu.edu and the PI is not required to wait for an action notice from the IRB. An official notice to confirm the IRB action will be sent in a timely fashion (1-2 weeks)
Check your "sent" folder of your email to ensure that the request has been sent before you implement the proposed changes
Amendments listed in 3.4 & 3.5 and all significant amendments will require an IRB approval before they can be implemented

APPENDIX C

IRB Minor Revision Approval Email

☆ WL **William Langston**
Re: Protocol Addendum
To: Jenn Caputo, Cc: William Langston, Zachary Norred, irb_submissions

September 26, 2022 at 6:12 PM
Details

I have your progress report. Consider the end date of the project extended to 5/31/2023

I have reviewed your minor revisions form. Everything seems to be complete to add the focus group to the project. We don't have the capability to unlock the forms, so if you're actually sharing the consent form with participants (which seems unlikely over zoom) you will need to type up a clean copy and send that to the compliance office GA CCed on this email. He will put a stamp on it for you and send it back. This seems like a good case for non-documented consent since they can just leave the zoom call if they want to withdraw and you can not use their data in that case. So, you can just review the consent and get them to agree and that will be fine.

To sum up, your revisions are approved and your date has been extended.

Good luck with the research!

Will

Dr. William Langston
He/him/his
Professor of Psychology
william.langston@mtsu.edu

See More from Jenn Caputo

WL **William Langston**
Re: Protocol Addendum
To: Zachary Norred

November 3, 2022 at 11:24 AM

The email is the approval. We don't have access to letter forms right now, so that will have to do.

Dr. William Langston
He/him/his
Professor of Psychology
william.langston@mtsu.edu

See More from Zachary Norred

CHAPTER V

OVERALL CONCLUSIONS

The focus of this dissertation was to determine the effectiveness of a 6-week UTT protocol for adults with a unilateral TTA. The first study was designed to assess how UTT affected physical outcomes including balance, posture, functional mobility, and cardiovascular responses to exercise. The second study was a qualitative overview of how a unilateral TTA impacts performance of ADL and PA and perceptions of the impact of UTT on physical performance and function.

The training study included 3 participants. Outcome measures were assessed pre- (within 1 week of the start of training), mid- (first session of week 4), and post-testing (within 1 week of the end of training). The BTrackS Balance Test (BBT) and BTrackS Posture Test (BPT) were assessed pre, mid, and post while the Activity-Specific Balance Confidence Scale (ABC) and 6-minute walk test (6MWT) were assessed during pre- and post-testing. While walking in the underwater treadmill, HR was recorded each minute and RPE was measured at the end of each walking bout. Prior to the start of the UTT, participants completed a familiarization day to equipment and their preferred walking speed in the underwater treadmill was determined. The week 1 walking bout speeds were initially set to 70% of the self-selected walking speed while initial walking bout times were 8 minutes. Training sessions included three walking bouts with systematic and gradual increases to walking speed (mph) and time (min). Walking speeds for each participant increased by 10% increments of week 1 in weeks 3 and 5. Walking bout time increased by 2 minutes at weeks 2 and 4 then increased by 3 minutes per waking bout at week 6.

Following UTT, there were improvements to balance noted by a decrease in Fall Risk Assessment (FRA) scores and CoP path length or size. The preservation of balance was also demonstrated amongst participants with identical pre-test and post-test FRA scores. Improved and/or preserved equilibrium while controlling postural weight distributions between left to right (medio-lateral) and front to back (antero-posterior) directions were demonstrated by participants during the BPT. The BPT also indicated participants increased utilization of the residual limb thus leading to more symmetrical weight distributions. All participants increased confidence in managing or controlling balance while performing various activities specified in the ABC assessment. However, no participants recorded a 100% balance confidence score primarily due to all participants not being 100% confident in controlling balance walking on an icy sidewalk. The 6MWT results were mixed amongst participants with two participants decreasing distance traveled and one participant increasing distance walked from pre-UTT to post-UTT. However, because UTT is considered a form of aerobic training, it is likely to improve cardiovascular function and responses as training proceeds or increases.

A positive linear relationship was demonstrated for participant's HR and RPE as walking speed and time (duration) increased in the underwater treadmill. This demonstrated walking in an underwater treadmill evoked appropriate cardiovascular responses to exercise. The outcomes also showed UTT could produce an overload to the cardiovascular system for people with a TTA.

Approximately one year following the completion of the UTT study, the same participants volunteered to participate in a one-hour focus group. During the focus group, participants were asked to respond to a set of 15 pre-determined, open-ended questions followed by a brief period of open discussion. Following the focus group, common responses and/or perceptions were assessed and coded into similar themes and categories.

Responses revealed common experiences and difficulties accomplishing ADL with a theme of increased planning required to conduct or perform various occupations or extracurricular activities. A theme of decreased tolerance such as fatigue and residual limb symptoms while performing ADL also emerged. Participants noted increased challenges and tolerance to performing PA and/or exercise with specified difficulties during cardiovascular endurance and resistance activities due to residual limb pain. Unexpectedly, a theme of increased PA and/or exercise was commonly described with attempts by participants to return to pre-amputation function and/or improve physical fitness such as strength or range of motion. Finally, common themes of improved balance or posture, improved confidence and improved muscular fitness were described to be positive outcomes of UTT. These improvements provided context to why participants reported the theme of increased exercise tolerance during and following UTT.

Overall, current findings highlight the efficacy of a 6-week UTT protocol for people with a unilateral TTA. Challenges regarding balance, posture, functional mobility, and the ability to be physically active following a TTA were documented in both studies. When coupled with variations in liner type, years since the amputation, and individual preferences, TTA rehabilitation or training can be difficult to personalize. Thus, the consequences of possessing a TTA can have a dramatic impact on the performance of ADL and PA or exercise. As amputation is a life-altering event there is a need for accommodations to minimize functional difficulties and future health concerns. An alternative tactic or modality to minimizing these challenges is the employment of UTT.

The positive changes to balance, posture, ambulation, and cardiovascular responses to exercise seen during and following UTT are imperative for those with a TTA. These effects could prove to be beneficial for increased adherence to PA and help with minimizing functional restrictions following a TTA. The underwater treadmill provided a safe environment with individualized parameters. It is believed that diversifying TTA rehabilitation programs with UTT and applying this modality as early as possible can produce advancements in motor and functional rehabilitation during pre- and post-prosthetic phases. Furthermore, by adapting traditional TTA rehabilitation programs with the addition of UTT, the process of training can be optimized by providing improved physical performance and function of the residual limb, thus decreasing future disability.

Focus group participants highlighted outcomes of UTT that were subjectively and clinically meaningful. Participants indicated that following UTT, they could complete ADL or PA more easily due to improved physical parameters (balance and/or posture and muscular fitness) and overall confidence while utilizing their prosthetic or ambulating. The impact of this training on physical and psychological parameters highlights the potential widespread benefits that can be applied to several aspects of life for those with a TTA.

While these initial case studies provided promising evidence, there is opportunity for continued research into the use of UTT to assist those with a TTA. As the time post-amputation varied for the participants in this study, additional research is needed to determine the most appropriate timeframes to utilize UTT relative to amputation and transitioning to a prosthetic. As UTT was safe and effective for current participants, larger sample size can be incorporated in extending the application of this modality. It will also be helpful to investigate specific exercise prescriptions to determine those most effective programs for individuals with varying levels of physical activity and functional abilities. Future research can assist in establishing the use of an underwater treadmill for future generations undergoing an amputation and participating in TTA rehabilitation programs.

DISSERTATION REFERENCES

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