Quality of Life, Functional Performance, and User Satisfaction of Lower Limb Prosthesis Clients

by

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Abstract

Limb loss is more common than many people realize. There are over two million people with amputated limbs in the United States and the numbers are expected to double in 2050. Despite the advances in prosthetic device technology, less attention is on the prosthetic clients' perspective of their prosthetic rehabilitation experience. Limited information exists on lower limb prosthetic users' satisfaction and the various constructs related to it. Considering the challenges of access to adequate care and the significant cost associated with prosthetic rehabilitation, the use of home-based virtual care has not been investigated as a feasible alternative. Therefore, the purpose of this project was to explore the relationship between different aspects of the prosthetic users' experience and determine the feasibility of a virtual assessment of mobility at home. Study one examined the relationship between prosthetic device and service satisfaction, health-related quality of life, and functional movement in a diverse population of lower-limb prosthesis users. The results demonstrated that a reasonable number of civilian, veteran, and military lower limb amputees are not satisfied with their prosthesis and rehabilitation service. The reported prosthetic client discontent is linked to reduced mobility, balance confidence, fear of falling, and health-related quality of life. This suggests that measures aimed at improving amputees' lower limb functional movements and balance may improve prosthetic client overall satisfaction. Study two investigated the relationship between patient perception of lower extremity function and a home-based virtual evaluation of mobility in lower-limb prosthesis clients. The results revealed a strong correlation between the lower limb amputee self-report of movement with prosthesis in the home environment and the virtual assessment of mobility by a clinician. This suggests that the virtual assessment modality is a feasible

complement to in-person prosthetic rehabilitation visit. This project provides patient-centered feedback to inform lower limb prosthetic clients rehabilitation with improved clinical outcomes.

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List of Abbreviations

ABC	Activity-specific Balance Confidence
ADL	Activities of Daily Living
CSD	Client Satisfaction with Device
CSS	Client Satisfaction with Service
HRQOL	Health-related Quality of Life
LEFS	Lower Extremity Functional Status
MFES	Modified Functional Efficacy Scale
OPUS	Orthotics and Prosthetics Users Survey
TUG	Timed Up and Go

Chapter 1 – Introduction

Limb loss is a significant life-changing experience that affects activities of daily living, overall health, and quality of life.[1] Increasing incidence of dysvascular diseases and trauma,[2,3] have created a resurgence of limb amputation, especially in young and middle-aged people.[4] More than two million individuals have experienced limb amputation in the United States.[5] This number is expected to increase to about four million by 2050.[5] Lower limb amputations are about three to five times more common than upper limb amputations.[2,6] Lower limb loss presents an enormous economic burden with over $10 billion spent annually on lower extremity amputation-related medical care.[7] The rate of lower extremity amputation is four times more likely in Africans and African Americans than in Caucasians, widening the disparities in healthcare determinants and outcomes.[8]

Lower limb amputees experience substantial restrictions in their functional performance and overall quality of life. These changes are only partially mitigated by prosthetic rehabilitation.[9-11] Attempts at restoring movement to the premorbid state is one of the critical post-amputation rehabilitation goals.[12,13] To achieve these post-amputation goals, it is essential that the patient be satisfied with their prosthesis.[14,15]

Satisfaction is a multifaceted psychological construct shaped by many elements, including mental, physical, and social factors.[16] Patient satisfaction serves as a primary measure of healthcare quality, and it involves linking patients' clinical experience with their expectations.[12] Prosthesis satisfaction has been described as a biopsychosocial concept influenced by the esthetic and functional aspects of the prosthesis, including the status of the residual limb.[12,14,16] Previous studies reveal that about half of traumatic amputees in the military,[17] and the general population,[9] are not satisfied with their prostheses, with over 30%

rejecting their prescribed prostheses due to discomfort.[18] Research to date on the satisfaction of lower limb prostheses users is limited in scope, with studies strictly assessing satisfaction with gait,[14] or trauma etiology in below-knee amputees.[9,15] A recent systematic review evaluating prosthetic satisfaction in below-knee amputees revealed most studies were of low quality, had small sample sizes, utilized multiple unvalidated questionnaires, assessed temporary rather than a definitive prosthesis, and dated.[12,16]

The contributions of new technological advancements in lower-limb prosthetic devices and components in improving physical activity capabilities for individuals with lower-limb loss have been the focus of scientific literature over the past decades.[1] There appears to be limited information on how the various prosthetic products affect users' health-related quality of life in their home environment. Outpatient rehabilitation programs rely significantly on quality of life measures to evaluate patient progress and modify treatment plans accordingly.[19] Patients, Prosthetists, other clinicians, and stakeholders need this vital feedback to assess and optimize prosthetic device effectiveness and service delivery holistically.[20]

Patient-centered reporting instruments to measure relevant outcome measures of product and service satisfaction, functional performance with the device, and overall quality of life are minimal and have not been incorporated as standard clinical practice. These validated and reliable self-report instruments to evaluate clinical outcomes from the client's perspective are necessary feedback tools for prosthetic clinics.[21] The Orthotics and Prosthetics Users' Survey (OPUS) is a self-reported validated questionnaire with five components that measures the main rehabilitation outcomes of patient satisfaction, quality of life, and lower-limb walking ability.[21,22] The OPUS is rated on a 4- or 5- point Likert scale and consists of the Client Satisfaction with Device and Services (CSD & CSS), Upper Extremity Functional Status (UEFS), Lower

Extremity Functional Status (LEFS), and Health-Related Quality of Life (HRQoL).[21-24]

Access to appropriate physical therapy and prosthetic services is minimal, and this adds to the enormous economic burden of healthcare for prostheses users.[11,25,26] Known barriers of age, gender, race, education, geographical location, and socioeconomic status worsen the healthcare disparities and inequalities experienced by lower-limb amputees.[26] Programs that extend primary care into the home environment for adults with chronic disability (not amputees) have been shown to reduce emergency hospital visits, specialty visits, admission rates, and primary healthcare costs.[27] Home-based interventions targeted at overcoming the barriers restricting access to care via a virtual platform may improve healthcare outcomes.[28]

Thus, the purpose of this study is to evaluate the level of satisfaction of lower limb prosthetic clients (LLPC) with their prosthetic device and service, quality of life, overall functional mobility, and the relationships that exist between these clinical constructs. Our specific research aims are:

1. Specific Aim 1: Explore the relationship between LLPC level of satisfaction with their device and service with their health-related quality of life, lower extremity functional status, balance, and fall efficacy using validated electronic surveys.

2. Specific Aim 2: Determine the relationship between patient perception of lower extremity function and a clinician administered virtual assessment of lower extremity functional status of LLPC in a home environment.

Our hypotheses are:

1. Level of satisfaction of LLPC with device and service will have a positive

linear relationship with health-related quality of life, functional status, balance, and an inverse relationship with fall efficacy.

2. LLPC assessment of their functional status will have a linear relationship with the virtual clinician-administered functional mobility assessment.

Chapter 2 – Literature Review

Introduction

Limb amputation poses a significant social and economic burden, with 2.1 million Americans living with limb loss[5] and over $10 billion expended annually on lower extremity amputation-related care.[7] Lower extremity amputations are five times more likely than upper extremity[29] and involve the severance of one or more lower limb parts.[30] The most common causes of lower limb amputation include diabetes mellitus (DM), trauma, and peripheral vascular disease resulting from atherosclerosis.[3,30,31] Lower limb amputation involves a surgical operation conducted to treat complications of the conditions above and other poorly controlled lower limb infections.[31]

Post amputation, lower extremity amputees experience significant mobility limitations and overall quality of life, which is partially ameliorated by prosthetic rehabilitation.[9-11] Goal setting is an integral part of all rehabilitation and should involve the physician, physiotherapist, prosthetist, and other members of the multidisciplinary care team, but most importantly, the patient and their family.[32] One of the main post-amputation rehabilitation goals is to restore movement to as close to the premorbid state as possible,[12,13,33] through quality prosthetic rehabilitation post-surgery,[34] and overall improvement in quality of life.[33,35] Rehabilitation specialists also work with the patient to achieve prosthesis-aided independent ambulation, especially with activities of daily living (ADL).[36] Prosthetic rehabilitation post amputation presents physical, mental, and social challenges for the patient. Patients may have subsequent difficulty mastering the use of the prosthesis resulting in concomitant reduction in prosthesis utilization rates.[37]

Relevant Structural Anatomy

The lower extremity consists of the thigh, knee, lower leg, ankle, and foot. The thigh extends from the hip to the knee joint; it is divided into the anterior, posterior, and medial compartments. The anterior compartment muscles include the sartorius, rectus femoris, vastus lateralis, vastus medius, and vastus intermedius. The superficial femoral artery and vein also lie in the anterior compartment. The posterior compartment of the thigh consists of the biceps femoris muscle, semitendinosus muscle, semimembranosus muscle, and the sciatic nerve. The medial thigh compartment contains the adductor magnus muscle, gracilis muscles, the great saphenous vein and nerve, and the deep femoral artery and vein.[3,38]

The knee joint complex is made up of the distal segment of the femur, the patella (the largest sesamoid bone in the body), the proximal portion of the tibia[39], and to a lesser extent the proximal end of the fibula.[40] The preceding bones form the tibiofemoral joint (lateral and medial), patellofemoral, and superior tibiofibular joint which are component joints of the knee.[40,41] The knee joint is a type of gliding hinged synovial joint and plays a significant role in body weight bearing during activities of daily living. The knee is stabilized by the cruciate ligaments (anterior and posterior), collateral ligaments (medial and lateral), and the deep medial capsular ligaments.[40] During dynamic movement, the knee joint allows for six degrees of motion which include flexion-extension, external-internal rotation, varus-valgus angulation which are rotational movements and anterior-posterior glide, medial-lateral shift, and compression-distraction which are translational movements.[40,42]

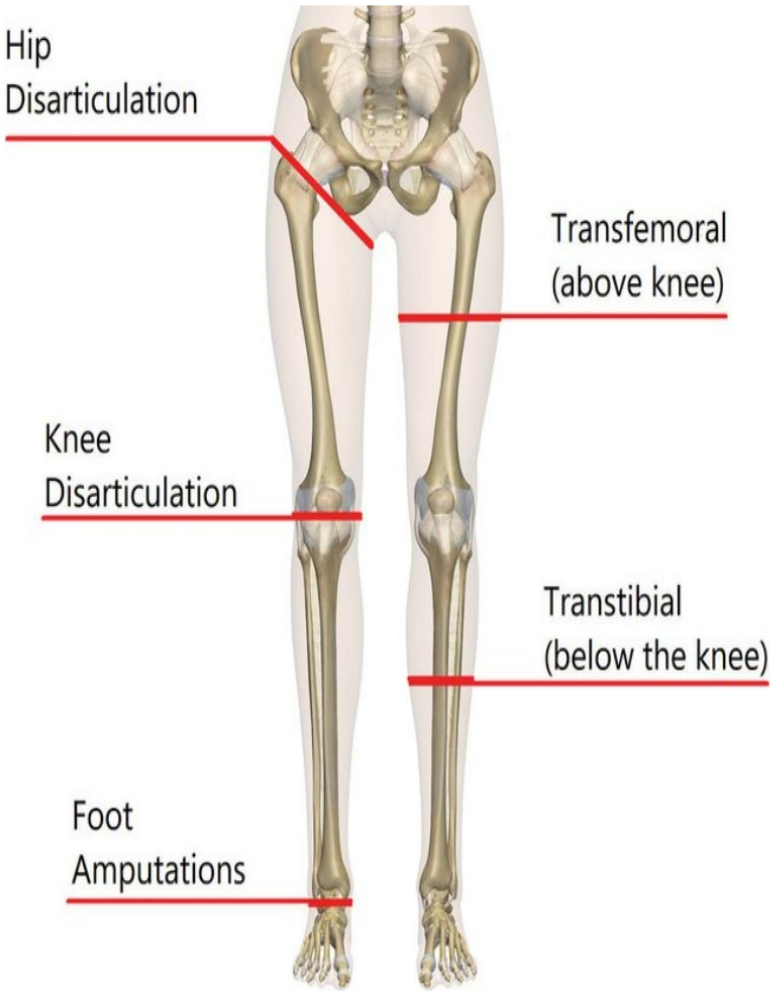
The lower leg is divided into the anterior, lateral, and posterior compartments. The contents of the anterior leg compartment include tibialis anterior muscle, extensor hallucis longus muscle, extensor digitorum longus muscle, peroneus tertius muscle, anterior tibial artery and vein, and

the deep peroneal nerve. The muscles of the lateral compartment include the peroneus brevis and peroneus longus.[3] The posterior compartment is subdivided into a deep and superficial segment. The deep posterior leg compartment is made up of the tibialis posterior muscle, flexor digitorum longus muscle, flexor hallucis longus muscle, posterior tibial artery and vein, tibial nerve, and peroneal artery and vein. The superficial posterior compartment contains the soleus muscle, gastrocnemius muscle, plantaris muscle, and sural cutaneous nerve.[3,38]

The ankle consists of two joints: the true ankle joint (talocrural or tibiotalar joint formed by the tibia, fibula, and talus bones) and the subtalar joint (talocalcaneal joint formed by the talus and calcaneus).[43] The main ligaments that provide structural stability to the ankle include the lateral ligaments (anterior and posterior tibiofibular ligaments, and calcaneofibular ligaments), medial ligaments (deltoid ligaments, plantar calcaneonavicular or spring ligaments).[44] These ligaments work in concert with the muscles and tendons of the lower leg to carry out the ankle movements. Dorsiflexion and plantarflexion occurs about the medio-lateral axis of the foot at the talocrural joint and inversion and eversion rotational movement occur along the long axis of the foot at the subtalar joints.[43,44]

The foot is made up of extrinsic and intrinsic muscles, and 26 bones divided into the hindfoot, midfoot, and forefoot. Seven tarsal bones make up the hindfoot and midfoot. The talus and calcaneus bones make up the hindfoot. While the cuboid, navicular, and three cuneiform bones make up the midfoot. The forefoot is composed of 5 metatarsals and 14 phalanges.[3,38]

Figure 2.1 Anatomical levels of lower limb amputation[45]



Levels of Amputation

Anatomically, amputation levels are classified into mutually exclusive groups, namely: pelvic, hip articulation, above-knee (transfemoral), through-knee (knee disarticulation), below-knee (transtibial), ankle, foot, and toe(s).[29] Although amputations can be done at any level, the transtibial (below-knee) and transfemoral (above-knee) remain the commonest amputation levels

accounting for more than 50% of lower limb amputations.[29,36] In the above-knee and below-knee amputations, the long bones of the lower limb, the femur, and tibia are surgically divided, respectively.[3] Irrespective of the level of amputation, the following surgical standards must be adhered to as much as possible: maintaining the maximum residual bone length, retaining joints, excision of diseased or dead tissue, blunting sharp distal bone ends into cone-shape or beveling the ends at a 45 degree angle to optimize prosthetic fit, preventing hematoma, edema, and pain management.[3]

Above Knee (Transfemoral) Amputation

Transfemoral amputation could be unilateral or bilateral. The distal attachments of the adductor tendon is secured to osteotomies created on the medial and lateral borders of the distal femur to preserve the length of the adductor muscles.[3,46] Depending on etiology and amputation level, about threequarters of the leg length is cut (muscle and bone) with a Gigli saw and the femoral vessels are suture-ligated, while the saphenous nerve is preserved.[3] Common indications for above knee amputations include trauma, diabetic foot gangrene, cancer, infections, burn injuries, and complications of artherosclerosis.[46]

Below Knee (Transtibial) Amputation

The distal anatomical structures in the leg (foot, ankle, and lower one-third of the tibia and fibula) are surgically cut through at about 12 – 18 cm from the tibial tubercle and removed with the use of the Gigli saw.[3] Care is taken to avoid pressure points by ensuring that the fibula is about 3 cm shorter than the tibia and edges filed.[3,46] Transtibial amputation level may vary

depending on the viability of the surrounding muscles and other soft tissues.[3] Common indicators for the below knee amputation are similar to that of the above knee.

Overview of Lower Limb Prosthetics

A lower limb prosthesis is an artificial substitute for a missing whole or part of the hip, thigh, knee, ankle, and or foot to restore the lower limb's function or form.[36] Stable post amputation surgery patients are moved to acute inpatient rehabilitation units, skilled nursing facilities, or discharged home with home care services. Post-surgical care aims to evaluate if the patient is a candidate for a prosthesis based on their level of lower limb function. This evaluation includes activities of daily living (ADL), basic mobility, strength training, and pain mitigation.[36]

K-classification types

The US Medicare created the functional classification levels or K levels rating system to evaluate prosthetic devices' necessity and possible advantage for patients' post-amputation. This functional classification method is codified into 5 K levels (K0, K1, K2, K3, K4 – Table 1) and is utilized by Medicare to determine clinical care reimbursement for prosthetic patients.[47,48]

Table 2.1

Medicare Functional Classification Level (MFCL) or K Classification System[36]

K level	Description
K0	Does not have the ability or potential to ambulate or transfer safely with or without assistance, and a prosthesis does not enhance quality of life or mobility.
K1	Has the ability or potential to use a prosthesis for transfers or ambulation on level surfaces at fixed cadence. Typical of the limited and unlimited household ambulator.
K2	Has the ability or potential for ambulation with low-level environmental barriers such as curbs, stairs, and uneven surfaces, typical of the limited community ambulator.
K3	Has the ability or potential for ambulation with variable cadence. Typical of the community ambulator who can traverse most environmental barriers and has vocational, therapeutic, or exercise activity that demands prosthetic utilization beyond simple locomotion.
K4	Has the ability or potential for prosthetic ambulation that exceeds basic ambulation skills, exhibiting high-impact, stress, or energy levels, typical of the prosthetic demands of the child, active adult, or athlete.

Figure 2.2 Initial prosthesis (lower extremity) with residual limb protector Photo credit Hanger Clinic.[36]

Prosthesis prescription

The ideal prosthetic prescription is developed to deliver the unique functional needs of the prosthetic client.[49] The prescription provides a complete description of the major components of the lower limb prosthesis. A prosthetic patients' medical history, coupled with physical and mental assessment, is conducted by the clinical care providers as part of the initial evaluation to determine if a lower limb prosthesis would benefit the patient.[36] The K level assessment is then used to classify the patient's functional level and determine the preferred lower limb prosthetic component. The K levels provide clinicians with a uniform scale for describing the ability or

potential for functional movement from K0 level which corresponds to no ability to K4 indicating the ability of an active individual.[50] Higher K levels corresponds to more advanced prosthetic aided mobility[36,47,50] and increased need for more sophisticated prosthetic components.[50]

The main elements of a lower limb prosthesis (Figure 2.2) include the suspension, socket, the skin-socket interface (cosmesis), pylon/connector, foot/ankle complex, and additional modular components like the knee unit and hip joint (depending on the amputation level).[36,46,48,51]

The initial stage of prosthetic fitting follows the healing and shrinking of the residual limb. A temporary prosthesis is developed as a rigid structure to protect the residual limb.[36] This temporary prosthesis (Figure 3) accelerates stump shrinkage and ambulation and can be used for a few months[52] to a year[36] with minimal discomfort in unilateral and bilateral lower limb amputees.[36,52] Afterward, a definitive prosthesis may be prescribed based on the assessment of the prosthetist and the ambulatory needs of the patient. This definitive prosthesis usually describes when a more permanent cosmetic stump covering is used. At this stage, changing the prosthesis socket – the main interface between the residual lower limb and the prosthetic limb is no longer necessary.[36]

Figure 2.3 Elements of a transfemoral prosthetic lower limb.[51]

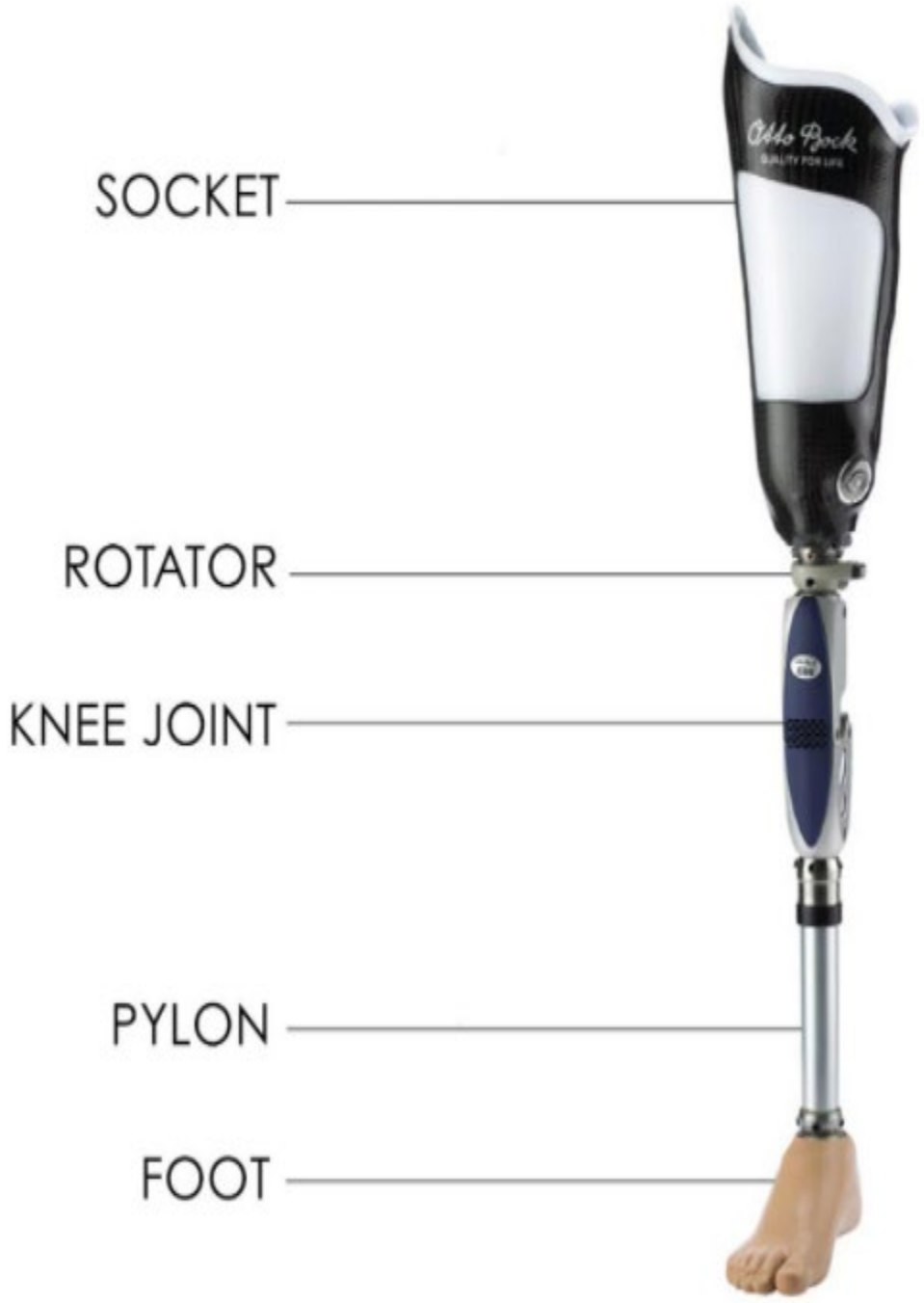


Figure 2.4 Prosthetic socket example (Ischial Containment Socket Design for transfemoral prostheses)[36]

Prosthetic Satisfaction

Patient satisfaction should play a significant role in healthcare quality evaluation and budget management.[12,14] About 30% of a cohort of Vietnam and Iraqi war veterans with traumatic lower limb amputations reported dissatisfaction with their prostheses irrespective of the level of amputation, source of prosthetic care, material and technological advancement of prosthetic device used.[17] A similar study in a group of civilians with traumatic amputations also revealed 57% patient dissatisfaction with prosthetic device fit or comfort after wearing the device for a cumulative period of 80 hours weekly.[9] Prosthetic device satisfaction is vital to achieving anticipated treatment outcomes.[14,15] Prosthetic device abandonment following complaints of discomfort, pain, and adverse skin reactions have also been reported.[17]

Patient satisfaction is influenced by physical and psychosocial factors[16] and involves linking a client's clinical experience with their expectations.[12] Available research focused on the satisfaction of lower limb prostheses users is limited in scope, with studies strictly assessing satisfaction with gait,[14] trauma etiology,[9] and in below-knee amputees.[15] A recent systematic review on physically active male transtibial amputee clients revealed considerable dissatisfaction with prostheses.[12] Further, the instruments for assessing satisfaction did not have similar evaluation parameters for prosthesis satisfaction, limiting comparison of outcome across the few included studies.[12] Gaps in the existing body of work suggests that a more in-depth review of satisfaction of prosthetic clients especially of the lower extremity is needed to unravel unmet patient expectations.

Quality of Life of Prosthetic Clients

Quality of life (QoL) remains one of the critical prosthetic rehabilitation outcomes, and it is

also employed to evaluate prosthesis adjustment.[19] There are minimal studies assessing the myriad of factors affecting the quality of life of lower limb prosthetic clients. Amputation involves many aspects of the patient's life, including economic, social, and mental.[19] Prosthesis use significantly affects the physical health aspect of QoL.[19] Prostheses aided mobility in the lower limb amputee has been strongly correlated with QoL in outpatients.[48]

Prosthesis use by bilateral lower limb amputee victims of the Sichuan earthquake in China was associated with improved quality of life and functional performance.[53] In a veteran population, health-related QoL was reported to be below 50% in those with unilateral below-knee, above-knee, and hip-level limb loss.[18] Lower limb amputee clients using microprocessor knee (MP-knee) prosthesis recorded significant improvement in quality of life outcomes.[1] There is a need to evaluate health-related QoL using instruments that reflect the multidimensional constructs it encompasses and also exploring the relationship with satisfaction in amputees.

Functional Mobility of Prosthetic Clients

Restoration of functional movement is one of the principal goals of prosthetic rehabilitation.[48] Functional mobility represents any normal range of motion movement needed to carry out activities of daily living (ADL). Studies in limb loss and non- limb loss populations have shown a strong relationship between the functional capacity of a prosthesis, functional mobility of the limb, higher QoL, and physical activity.[18] In addition, the surgical technique for amputation and the state of the residual limb may significantly affect functional movement with subsequent prostheses.[34]

Balance and Fear of Falling in Prosthetic Clients

Fear of falling and falls are associated with many health challenges, especially in the elderly.[54,55] A fall is a public health concern described as an unplanned event where an individual comes to a position of rest on a lower level or the ground from a higher position; it may or may not result in injury.[54,55] Lower limb prosthesis clients have an increased risk of falls, with over half experiencing an annual fall.[56] A secondary analysis of falls in ambulatory unilateral lower limb prosthesis clients also supported the high fall rate in this population with more base of support (BoS) than center of mass (CoM) falls.[56] The fear of falling has not been explored but anecdotal feedback from clinical interactions with lower limb amputees suggest that it may not be a major cause of worry. Nevertheless, the ability of prosthetic clients generally to carry out ADL safely has been linked with improved performance.[57] It is essential that an assessment of lower limb prosthetic clients fear of falling and its relationship with their overall satisfaction be conducted to optimize the client experience, performance, and minimize disability.

Orthotics Prosthetics Users' Survey (OPUS)

Clinically applicable constructs of the patient experience like satisfaction with device and service, quality of life, and functional performance are evaluated by the OPUS, thereby contributing to the provision of qualitative healthcare.[21,22]

Client Satisfaction with Device (CSD) and Client Satisfaction with Service (CSS)

Orthotics Prosthetics Users Survey (OPUS) subcomponent, Client Satisfaction with Device and Service (CSD/CSS) Measure. CSD/CSS is a 21-item validated combined survey instrument that measures the lower limb prosthesis clients (LLPC) opinion regarding statements assessing their level of satisfaction with their prosthetic device (CSD - 11 items) and prosthetic service

(CSS - 10 items) rated on 5-level Likert scale ranging from ‘Strongly agree’ to ‘Strongly disagree’.

Health-Related Quality of Life (HRQOL)

Orthotics Prosthetics Users Survey (OPUS) Health-related Quality of Life (HRQOL) Index – OPUS-HRQOL is a 23-item validated instrument that measures the frequency of occurrence of different aspects of the client experiences regarding the use of lower extremity prosthesis. This includes physical and psychological interactions (12-items rated on a 5-level Likert scale ranging from ‘Not at all’ to ‘Excessively’) and emotional experiences (11-items rated on a 5-level Likert scale ranging from ‘All the time’ to ‘None of the time’.

Lower Extremity Functional Status Measure (LEFS)

Orthotics Prosthetics Users Survey (OPUS) Lower Extremity Functional Status (LEFS) – OPUS-LEFS is a 20-item validated instrument that measures lower extremity daily activities, rated on a 5-level Likert scale ranging from ‘Very easy’ to ‘Cannot perform this activity’.

Activities-Specific Balance Confidence (ABC) Scale

ABC scale is a 16-item validated self-reported instrument for evaluating how confident the client is in carrying out various activities without losing balance or experiencing unsteadiness. The ABC scale is rated on a sliding scale of 0% corresponding to ‘No confidence’ to 100% representing ‘Complete confidence’.[58,59]

Modified Falls Efficacy Scale (MFES)

The MEFS is a 14-item validated self-reported measure of the client’s confidence to perform different everyday indoor and outdoor activities without falling. The MEFS is rated on a scale of

'0' to '10', with '0' representing 'not confident', 5 representing 'fairly confident', and 10 representing 'completely confident'.[54]

Timed-Up-and Go

The TUG is a validated measure of basic mobility that stratifies the risk of falling in the elderly population and lower limb amputees. The time it takes the patient to respond to a command to move from a sitting position to standing, and walking to and from a distance of 3m, and back to sitting at a self-selected and safe pace is recorded.[11,13,60]

Conclusion and Purpose Statement

Limb amputation is a life-altering and traumatic experience with increasing incidence and significant economic implications. There is a high rate of prosthetic rejection in military and civilian populations. Hitherto, limited studies have explored the multifaceted factors affecting prosthetic clients' satisfaction with prosthetic devices and service and how these impact overall functional performance and quality of life.

The purpose of the first study of this dissertation is to assess the level of satisfaction of lower limb prosthetic clients (LLPC) with their prosthetic device and service, quality of life, overall functional mobility, and the associations between these clinical constructs.

The second study, aims to contribute to prosthetic research by exploring virtual testing of functional mobility in the convenience of the patient's home environment to improve access to basic rehabilitation evaluation services while minimizing the challenges of commuting to distant rehabilitation centers.

The purpose of this body of work is to explore the relationship between LLPC level of satisfaction with their device and service with their health-related quality of life, lower extremity functional status, balance, and fall efficacy. In addition, we also want to determine the relationship between virtual functional status testing of LLPC and perception of same in a home environment.

Chapter 3 – Methods

Design

A cross-sectional study design governed this study. An anonymous online survey combining five validated instruments was used to investigate the relationship between LLPC level of satisfaction with their device and service with their health-related quality of life, lower extremity functional status, balance, and fall efficacy. A virtual online secure zoom platform was subsequently used to assess prosthetic functional mobility in the LLPC's home environment compared to an interviewer administered questionnaire assessing prosthetic lower extremity functional status. All protocols for this study were approved by the Auburn University Institutional Review Board (protocol number: 21-310 EP 2107).

The independent variables for the survey were health-related quality of life (HRQOL), lower extremity functional status (LEFS), measures of balance and fear of falling with the use of prosthetic legs. The dependent variables were the level of client satisfaction with prosthetic device (CSD) and service (CSS). Virtual testing component dependent variables were the mean time to complete the timed up and go (TUG) test and the interviewer administered LEFS scores.

Participants

1736 participants (1042 males, 675 females, 10 non-binary gender, 9 preferred not say) were recruited for the survey and 12 participants (5 females, 7 males) for the virtual testing component with flyers posted on several social media platforms involving prosthetic clients. The flyers were also shared to prosthetic client contacts by prosthetists, physical therapists, and other clinicians known to the research team. The targeted population was individuals with lower extremity prostheses in the United States. Participants were over the age of 19, with lower extremity amputation, and currently using any lower extremity prosthesis. Exclusion criteria

included individuals with 1) pre-existing medical conditions that can interfere with lower-limb function such as stroke or seizure disorders; and 2) pregnancy.

Survey Instruments

Independent variables:

Client Satisfaction with Device (CSD) and Service (CSS) components of the Orthotics Prosthetics Users Survey (OPUS).[21,22] CSD/CSS is a 21-item validated combined survey instrument that measures the lower limb prosthesis clients (LLPC) opinion regarding statements assessing their level of satisfaction with their prosthetic device (CSD - 11 items) and prosthetic service (CSS - 10 items) rated on 5-level Likert scale ranging from 'Strongly agree' to 'Strongly disagree'(Appendix A). The CSD (0.78) and CSS (0.74) show appropriate internal consistency based on data from the current survey and past studies in this population.[21]

Dependent variables:

Health-related Quality of Life (HRQOL) Index component of the Orthotics Prosthetics Users Survey (OPUS) – HRQOL is a 23-item validated instrument that measures the frequency of occurrence of different aspects of the client experiences regarding the use of lower extremity prosthesis (Appendix A). This includes physical and psychological interactions (12-items rated on a 5-level Likert scale ranging from 'Not at all' to 'Excessively') and emotional experiences (11-items rated on a 5-level Likert scale ranging from 'All the time' to 'None of the time'. The HRQOL has demonstrated a high intra-class correlation coefficient - ICC (0.91) with adequate test-retest reliability.[23]

Lower Extremity Functional Status (LEFS) component of the Orthotics Prosthetics Users Survey (OPUS) – LEFS is a 20-item validated instrument that measures lower extremity daily activities, rated on a 5-level Likert scale ranging from 'Very easy' to 'Cannot perform this activity' (Appendix A). The LEFS also showed a satisfactory ICC (0.67 – 0.96) and test-retest reliability.[23,61]

Activities-Specific Balance Confidence (ABC) Scale[58] – is a 16-item validated self-reported instrument for evaluating how confident the client is in carrying out various activities without losing balance or experiencing unsteadiness (Appendix A). The ABC scale is rated on a sliding scale of 0% corresponding to 'No confidence' to 100% representing 'Complete confidence'. The ABC scale has a high test-retest reliability[58] and is strongly predictive of gait speed, balance, and general mobility performance.[59]

The Modified Falls Efficacy Scale (MFES)[54] – a 14-item validated self-reported measure of the client's confidence to perform different everyday indoor and outdoor activities without fear of falling (Appendix A). The MFES is rated on a scale of '0' to '10', with '0' representing 'not confident', 5 representing 'fairly confident', and 10 representing 'completely confident'. The MFES has demonstrated significant construct validity (0.97), intra-class correlation coefficient -ICC (0.83), and test-retest reliability in different populations and countries.[54,62]

Virtual Study Measures

Timed up and go (TUG)[60] - Is a validated measure of basic mobility that stratifies the risk of falling in the elderly population and lower limb amputees. The time it takes the patient to respond to a command to move from a sitting position to standing and walking to and from a distance of 3 meters, and back to sitting at a self-selected and safe pace is recorded.

LEFS Interview - The 20-item LEFS questionnaire was administered to participants in an interview format.

Procedures

The first part of this cross-sectional study examined the relationship between prosthetic device and service satisfaction, health-related quality of life, functional performance, and fall efficacy in lower limb prostheses clients. Five validated questionnaires were combined into an online survey using Qualtrics®, Version 2020 (Qualtrics, Provo, UT, USA) (Appendix A). The 15-minute final composite survey included a general information section and the five instruments: 1) Satisfaction with Prosthetic Device and Service,[21,22] 2) Health-related Quality of Life,[21,23] 3) Lower-Extremity Functional Status,[21,23] 4) Activities-Specific Balance Confidence (ABC) Scale,[58,59] and 5) Modified Falls Efficacy Scale.[54] A snowball sampling method was used. A recruitment email with the Qualtrics® link was sent to interested participants.

The second part of the study explored the relationship between virtual functional status of lower-limb prosthetic clients and perception of the same in a home environment. Participants were recruited from the online survey respondents to complete a 10-minute home-based virtual testing of their lower extremity prosthetic mobility using the Timed-Up-and Go (TUG) test and a 5-minute interviewer-administered lower extremity mobility questionnaire for prosthetic users. The HIPAA compliant Auburn University Zoom Secure platform was used for the virtual component.

Online survey participants who indicated interest in the virtual testing component were contacted via email. The participants were sent the virtual study information letter with the Qualtrics link for informed consent, a video demonstration of the timed-up-and-go (TUG) test

instructions and set-up via electronic mail. In addition, the researcher sent a disposable measuring tape to participants via regular mail. A chaperone or caregiver was present with the participant for the virtual testing procedure to assist with the test set-up and ensure safety. A secure link of the HIPAA-compliant Auburn University secure Zoom platform was sent via email to participants who voluntarily gave informed consent. Participants were in their home environment wearing their lower-limb prosthesis and usual footwear. An armchair was placed at a marked starting point in participants home and a 3-meter uncluttered walk space was measured, and a mark placed on the floor using the provided measuring tape (Figure 1a & 1b). Participants completed one practice trial to become familiar with how the TUG worked with the investigator answering any question. After a five-minute rest period, the participants completed three timed and recorded iterations of the TUG procedure separated by 3-5 minutes rest as needed. These were directed by the researcher giving the following instructions to the participant: "On the word GO, you will stand up from the chair, walk to the line on the floor at your regular pace, turn around and walk back to the chair and sit down." The researcher started timing on the word "GO" and stopped timing when the participant sat again in the chair with their back resting against the backrest of the chair. The time in seconds to complete the TUG was recorded. The researcher also administered the 20-item Lower Extremity Functional Status questionnaire to the participant. The virtual testing component took about 15 minutes to complete. The researcher was blinded to the online survey results of participants who participated in the virtual testing before the data collection.

Figure 3.1 Timed-Up and Go Set-up

Figure 3.2 Timed-Up-and Go Test Demonstration

Statistical Analysis

Response data from online survey was exported from Qualtrics®. All continuous data were presented as means and standard deviations with categorical data presented as frequencies and percentages. Descriptive statistics were calculated for responses. Pearson correlation tests, multiple regression, and path analysis were performed to determine the relationship between variables and to determine if HOQL, LEFS, ABC, & MEFS (IVs) significantly predicts CSD/CSS (DV) respectively. *A priori* alpha level was set at 0.05 for statistical significance and all statistical analyses were performed using RStudio version 4.1.2.

For the virtual home-based assessment, descriptive statistics were calculated for the LEFS responses and virtual TUG test time. The reported LEFS scores were converted into a Rasch measure which provides appropriate weighted scores on an increasing linear scale with "0" representing the lowest measure of the lower extremity function and "100" representing the highest measure.[63] Bivariate Pearson correlation was used to measure the strength and direction of linear relationship between the LEFS and virtual TUG test scores. A simple linear regression was also calculated to assess the predictive value of TUG on LEFS scores.

Chapter 4 - Prosthetic device and service satisfaction, quality of life, and functional performance in lower limb prosthesis clients

Abstract

Introduction

The aim of this study was to characterize the relationship between prosthetic device and service satisfaction, health-related quality of life, and functional movement in a diverse population of lower-limb prosthesis users.

Materials and Methods

An online survey was conducted between September and December 2021 with previously validated questionnaires to collect data on prosthetic device and provider service satisfaction, quality of life, mobility, and fall efficacy.

Results

Participants were 1736 lower-limb amputees. Overall, 44% of participants reported dissatisfaction with prosthetic device, while 37% were dissatisfied with prosthetic service. Low functional mobility was reported by 58% of participants and 61% reported low health-related quality of life.

Lower extremity functional status ($\beta = 0.55$), health-related quality of life ($\beta = 0.08$), activity-specific balance scale ($\beta = 0.22$), and modified fall efficacy scale ($\beta = -0.07$) significantly predicted client satisfaction with prosthetic device ($p < 0.0005$, $R^2 = 0.47$). Satisfaction with provider service was significantly predicted by lower extremity functional status ($\beta = 0.44$), and balance confidence ($\beta = 0.18$) ($p < 0.0005$, $R^2 = 0.34$).

Conclusion and Clinical Relevance

Civilians, veterans, and service members reported low functional mobility, low quality of life, and moderate level of dissatisfaction with their lower extremity prosthetic device and provider service. Improvements in mobility, balance, quality of life, and fall efficacy may enhance device satisfaction. Prosthetic provider service satisfaction may be influenced by functional mobility and balance.

This study provides client-centered feedback to guide prosthesis prescription and rehabilitation with improved clinical outcomes in lower limb prosthetic users.

KEYWORDS – leg prosthesis, amputation, patient experience, rehabilitation, mobility.

Introduction

Limb loss is a significant life-changing experience that affects activities of daily living, overall health, and quality of life.[1] Increasing incidence of dysvascular diseases and trauma[2,3] have increased the rate of limb amputation, especially in young and middle-aged people.[4] Over two million individuals in the United States have had a limb or more amputated[5] and this number may double in the next two decades.[5] Lower limb amputees experience substantial restrictions in their functional movement and overall performance. These mobility challenges are only partially mitigated by using prosthesis.[9-11] Attempts at restoring movement to the premorbid state is a critical post-amputation rehabilitation goal.[12,13] To achieve post-amputation goals, it is essential that the patient be satisfied with their prosthesis.[14,15]

Satisfaction is a multipronged psychological construct with mental, physical, and social components.[16] Patient satisfaction, a primary measure of healthcare quality, involves linking patients' clinical experience with their expectations.[12] Prosthesis satisfaction has been described as a biopsychosocial concept influenced by the esthetic and functional aspects of the prosthesis, including the status of the residual limb.[12,14,16] Previous studies reveal a high rate of prosthetic rejection in military[17] and civilian populations[9] arising from device dissatisfaction. Research to date on the satisfaction of lower limb prostheses users is limited in scope, with studies strictly assessing satisfaction with gait,[14] or trauma etiology in below-knee amputees.[9,15] A recent systematic review evaluating prosthetic satisfaction in below-knee amputees revealed most studies were older, of low quality, had small sample sizes, utilized multiple unvalidated questionnaires, and assessed temporary rather than a definitive prosthesis.[12,16]

The focus of the scientific literature over the past decades has been on technological advancements in prosthetic components and devices to mitigate disability.[1] There appears to be

less emphasis on how the various prosthetic products affect users' health-related quality of life. Outpatient rehabilitation programs rely significantly on quality of life measures to evaluate patient progress and modify treatment plans accordingly.[19] Patients, prosthetists, other clinicians, and stakeholders need patient-centric feedback to assess and optimize prosthetic device effectiveness and provider service delivery.[20]

There is limited evidence regarding prosthetic clients' evaluation of the prosthetic service they receive and this feedback is required to review the quality of prosthetic rehabilitation services and training.[64] A few studies in low and middle income countries have reported the limited availability and accessibility of adequate prosthetic rehabilitation clinics and clinicians to the increasing amputee population.[11,65,66] However, the influence of aspects of prosthetic rehabilitation outcomes such as balance, falls, and general mobility on service satisfaction has not been previously investigated from the perspective of the lower limb amputee.

Thus, the purpose of this study was to use validated electronic surveys to evaluate the relationship between the level of satisfaction of lower limb prosthetic clients (LLPC) with their prosthetic device, provider service, health-related quality of life, lower extremity functional status, balance, and fall efficacy. We hypothesize that the level of satisfaction of LLPC with prosthetic device and provider service will have a direct positive relationship with health-related quality of life, functional mobility, balance, and a negative relationship with fall efficacy.

Methods

Design

A cross-sectional study was conducted using a composite survey created by combining five previously validated questionnaires into an online survey using Qualtrics®, Version 2020 (Qualtrics, Provo, UT, USA). The survey was used to investigate the relationship between LLPC level of satisfaction with their prosthetic device and provider service, health-related quality of life, lower extremity functional status, balance, and fall efficacy. All protocols for this study were approved by the University Institutional Review Board (protocol number: 21-310 EP 2107).

A snowball sampling method was used. A recruitment email with the Qualtrics® link was sent to interested participants. Subsequently, a follow-up email was sent every two weeks to remind participants to complete the study. The Qualtrics® survey remained open for one month.

The survey was divided into six sections: (1) patients' demographic and general prosthesis information; (2) patient satisfaction with prosthesis and prosthetic provider service; (3) health-related; (4) lower extremity functional performance with prosthesis; (5) activities-specific balance confidence (ABC) scale; and (6) modified falls efficacy scale (MFES). The complete survey content is provided in the supplementary material.

Participants

The survey was completed by 1736 participants between the ages of 19 and 80. Recruitment flyers were posted on several social media platforms often visited by prosthetic clients. Flyers were also shared to LLPCs by prosthetists, physical therapists, and other clinicians known to the research team. Participants included in the study were individuals with unilateral or

bilateral lower limb loss who self-reported as currently using any lower extremity prosthesis. Exclusion criteria included amputees with: 1) pre-existing medical conditions that can interfere with lower-limb function such as stroke or seizure disorders; and 2) pregnancy due to increased risk of falls.[67]

Survey Instruments

The dependent variables for the survey were the level of client satisfaction with prosthetic device (CSD) and service (CSD). The independent variables were health-related quality of life (HRQOL), lower extremity functional status (LEFS), measures of balance (ABC scale) and fall efficacy (MFES) with the use of prosthetic legs.

The Orthotics Prosthetics Users Survey (OPUS) Client Satisfaction with Device (CSD) and Service (CSS) Measure is a 21-item validated combined survey instrument that measures LLPCs reported evaluation of satisfaction with their prosthetic device (CSD - 11 items) and prosthetic service (CSS - 10 items) rated on 5-level Likert scale ranging from 'Strongly agree' scored 5, to 'Strongly disagree' scored 1. The CSD (0.78) and CSS (0.74) show appropriate internal consistency for the amputee population based on previous studies.[21,22]

Orthotics Prosthetics Users Survey (OPUS) Health-related Quality of Life (HRQOL) Index – HRQOL is a 23-item validated instrument that measures the frequency of occurrence of different aspects of the client experiences regarding the use of lower extremity prosthesis. This includes physical and psychological interactions (12-items rated on a 5-level Likert scale ranging from 'Not at all' scored 4, to 'Excessively' scored 0); emotional experiences (4-items rated on a 5-level Likert scale ranging from 'All the time' scored 4, to 'None of the time' scored 0; and 7-items rated on a 5-level Likert scale ranging from 'All the time' scored 0, to 'None of the time'

scored 4). The HRQOL has demonstrated a high intra-class correlation coefficient - ICC (0.91) with adequate test-retest reliability.[23]

Orthotics Prosthetics Users Survey (OPUS) Lower Extremity Functional Status (LEFS) – LEFS is a 20-item validated instrument that measures lower extremity daily activities rated on a 5-level Likert scale ranging from 'Very easy' scored 4, to 'Cannot do this activity' scored 0. The LEFS also showed a satisfactory ICC (0.67 – 0.96) and test-retest reliability.[23,61]

Activities-Specific Balance Confidence (ABC) Scale[58] is a 16-item validated self-reported instrument for evaluating how confident the client is in carrying out various activities without losing balance or experiencing unsteadiness. The ABC scale is rated on a sliding scale of 0% corresponding to 'No confidence' to 100% representing 'Complete confidence'. The ABC scale has a high test-retest reliability[58] ICC (0.88)[68] and is strongly predictive of gait speed, balance, and general mobility performance.[59]

The Modified Falls Efficacy Scale (MFES)[54] – a 14-item validated self-reported measure of the client's confidence to perform different everyday indoor and outdoor activities without fear of falling. The MFES is rated on a scale of '0' to '10', with '0' representing 'not confident', 5 representing 'fairly confident', and 10 representing 'completely confident'. The MFES has demonstrated significant construct validity (0.97), intra-class correlation coefficient -ICC (0.83), and test-retest reliability in different populations and countries.[54,62]

The reliability estimates from our current sample data showed good internal consistency (cronbach's alpha) for all the survey instruments: CSD (0.89), CSS (0.90), HRQOL (0.88), LEFS (0.93), ABC (0.96), MFES (0.97).

Statistical Analysis

Response data from the online survey was exported from Qualtrics®. All continuous data were presented as means and standard deviations with categorical data presented as frequencies and percentages. Descriptive statistics were calculated for responses. The reported scores OPUS-CSD, CSS, HRQOL, and LEFS were converted into Rasch measures. The Rasch measure provides appropriate weighted scores on an increasing linear scale from "0" representing the lowest measure of the parameter to "100" representing the highest measure.[63] Client Satisfaction with Device (CSD) Path analysis was used to determine the relationship between variables and to determine if HRQOL, LEFS, ABC, & MEFS (IVs) significantly predicts CSD/CSS (DV) respectively. Specific path analysis models were tested to find the model for determining the predictors of device (CSD) and provider service (CSS) satisfaction. The criteria that were employed for selecting the appropriate model were: (a) correct model stipulation based on theory; (b) appropriate fit indices; and (c) path coefficient directionality verified by multivariate linear regression analysis. The fit indices used for evaluating an appropriate predictive model includes chi-square (X^2) p-value > 0.05; comparative fit index (CFI) > 0.90; Tucker-Lewis index (TLI) > 0.95; root mean square error of approximation (RMSEA) ≤ 0.08; and standardized root mean square residual (SRMR) ≤ 0.05).[69] A priori alpha level was set at 0.05 for statistical significance and all statistical analyses were performed using RStudio version 4.1.2.

Results

Descriptive characteristics of the study sample are displayed in Table 1. A total number of 1736 participants (1046 males, 680 females, 10 non-binary gender) completed the survey. Ages were categorized as follows: young adults (19 - 39), middle-aged (40 - 59), and older adults

(≥60) for comparison. Participants included civilians (67%), Veterans (22%), and active duty military (11%). Trauma was reported to be the leading cause of amputation (78%), with participants predominantly Caucasian (78%). More than half of the participants had unilateral amputation (86%), with most having below knee amputation (39%).

Table 4.1

Demographics and general amputation information

		N (%)
Gender	Female	680 (39.2)
	Male	1046 (60.3)
	Non-binary	10 (0.5)
Age	19 – 39	1447 (83.4)
	40 – 59	270 (15.6)
	≥60	19 (1.0)
Race	White	1361 (78.4)
	Black	233 (13.4)
	Other (including mixed race)	136 (7.8)
	Unknown	12 (0.8)
Etiology of Amputation	Trauma	1358 (78.2)
	Diabetes	134 (7.7)
	Infections	177 (10.2)
	Cancer	58 (3.3)
	Unknown	9 (0.5)

Side of Amputation	Unilateral	1495 (86)
	Bilateral	241 (14)
Type of Amputation	Transtibial	677 (39)
	Transfemoral	415 (24)
	Foot (Toes/ Partial Foot)	380 (22)
	Ankle Disarticulation	215 (12)
	Hip Disarticulation	49 (3)
Status	Civilian	1171 (67)
	Veteran	379 (22)
	Active Duty	186 (11)

CSD, CSS, HRQOL, and LEFS survey responses are represented in summary plots (Figures 1 – 6). Overall mean CSD scores revealed that a little over half (56%) of the participants were satisfied with their prosthetic device. The main aspects of dissatisfaction include skin abrasion/ irritation (49%), comfort (48%), pain (48%), purchase/ maintenance cost (46%), and damage to clothes (47%) (Figure 1). Mean CSS scores demonstrated that overall, about 63% were satisfied with the standard of prosthetic clinical provider service. Major areas of dissatisfaction were clinic wait time (42%), appointment scheduling with prosthetist (41%), and level of partnership in decision making regarding clinical care and equipment (39%) (Figure 2).

More than half of participants reported low quality of life pertaining to their physical (59%), emotional (56%), and psychological health (67%) (Figures 3 – 5). Most participants (58%) recorded a low LEFS with about 20% reporting that they ‘cannot do’ or find it ‘very

difficult' to carry out daily functional mobility tasks like 'walk up steep ramps', 'walk in bad weather', or 'climb one flight of stairs without a rail' (Figure 6). Participants also reported an overall average level of self-confidence that they would not lose their balance when carrying out daily activities (mean ABC scores = 53 ± 20%) where 0% represents no balance confidence and 100% complete balance confidence. Participants also reported fair confidence in carrying out indoor and outdoor activities without falling (mean MFES scores = 6 ± 2) with 0 representing no confidence and 10 representing full confidence in not falling.

The path analysis model used to determine predictors of device satisfaction showed good fit indices (chi-square (X^2) = 97.1, degrees of freedom = 4, p-value < 0.01; comparative fit index (CFI) = 0.97; Tucker-Lewis index (TLI) = 0.88; root mean square error of approximation (RMSEA) = 0.12 (90% CI = (0.10; 0.14); standardized root mean square residual (SRMR) = 0.08). The health-related quality of life (β = 0.08), lower extremity functional status (β = 0.55), activity-specific balance scale (β = 0.22), and modified fall efficacy (MFE) scale (β = -0.07) significantly and directly predicted client satisfaction with prosthetic device ($p < 0.0005$, R^2 = 0.47) see Figure 7. The R-squared value corresponds to a large effect size and indicates that the CSD predictors model can explain 47% of the variance in client satisfaction with device (CSD).

The model selected for predictors of prosthetic clinical provider service satisfaction also showed good fit indices (chi-square (X^2) = 97.1, degrees of freedom = 4, p-value < 0.01; comparative fit index (CFI) = 0.97; Tucker-Lewis index (TLI) = 0.87; root mean square error of approximation (RMSEA) = 0.12 (90% CI = (0.10; 0.14); standardized root mean square residual (SRMR) = 0.07). The lower extremity functional status (β = 0.44), and activity-specific balance (ABC) scale (β = 0.18) significantly and directly predicted client satisfaction with prosthetic provider service ($p < 0.0005$, $R^2 = 0.34$) see Figure 8. The R-squared value indicates that the

CSS predictors model can explain 34% of the variance in client satisfaction with prosthetic service (CSS). Health-related quality of life has an indirect effect on CSS mediated by ABC scale ($\beta = 0.34$, $p < 0.001$). MFE scale also has an indirect effect on CSS mediated by ABC scale ($\beta = 0.72$, $p < 0.001$).

Figure 4.1

CSD Summary Plot showing the mean distribution of participant responses to the 11-item prosthetic client satisfaction with device (CSD) scale (N = 1736)

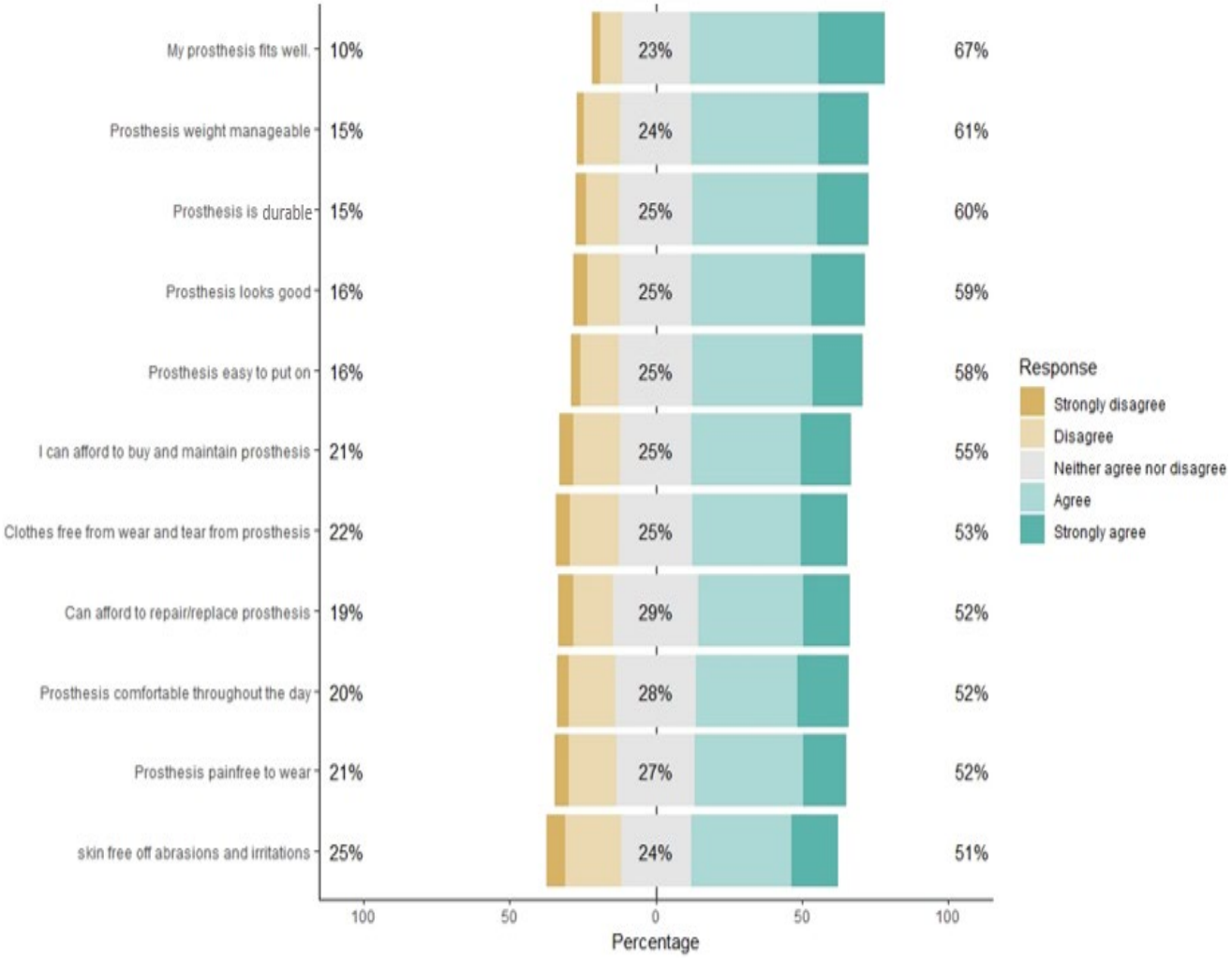


Figure 4.2

CSS Summary Plot showing the mean distribution of participant responses to the 10-item client satisfaction with prosthetic service (CSS) scale (N = 1736)

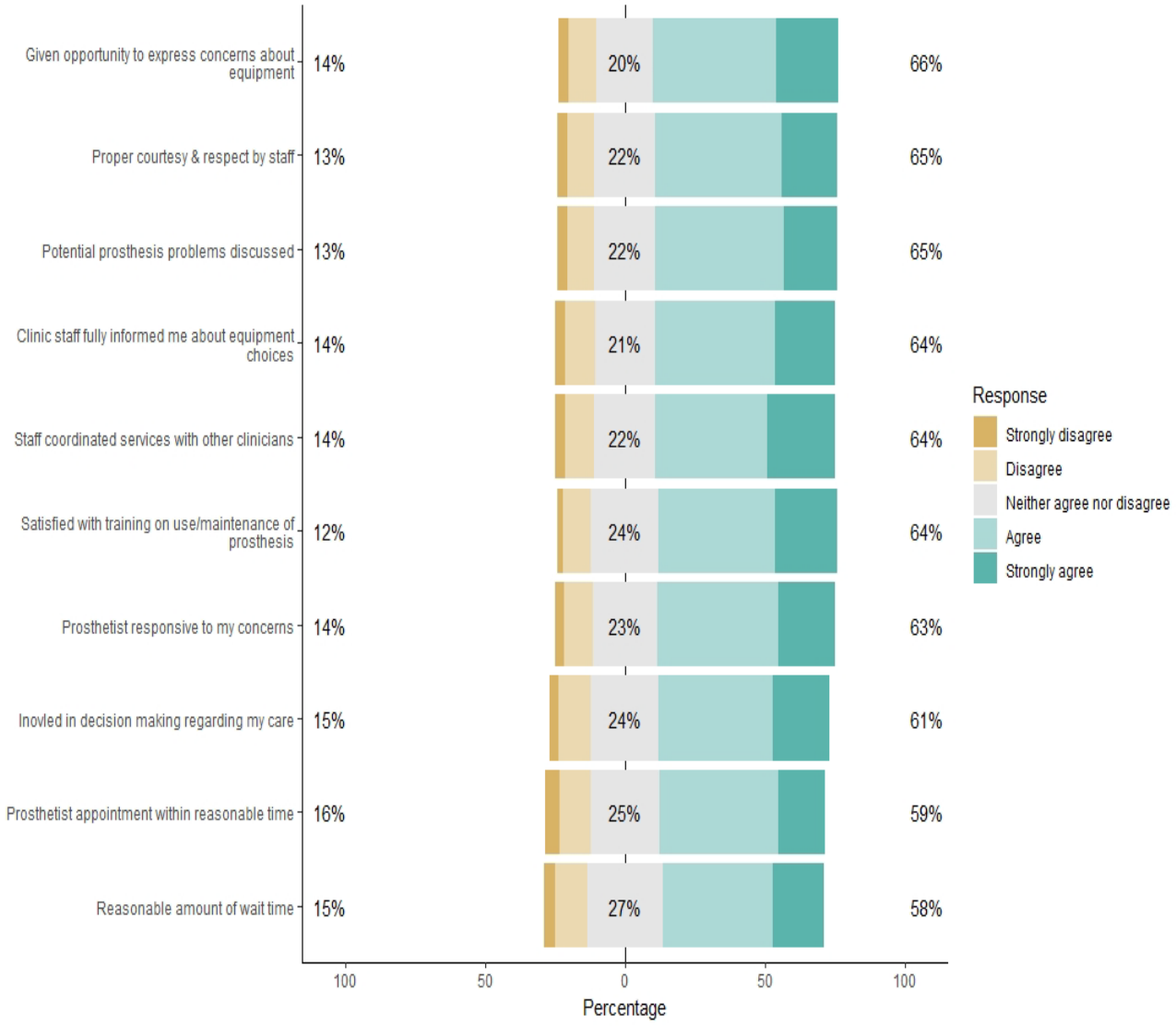


Figure 4.3

HRQOL Physical Health Summary Plot

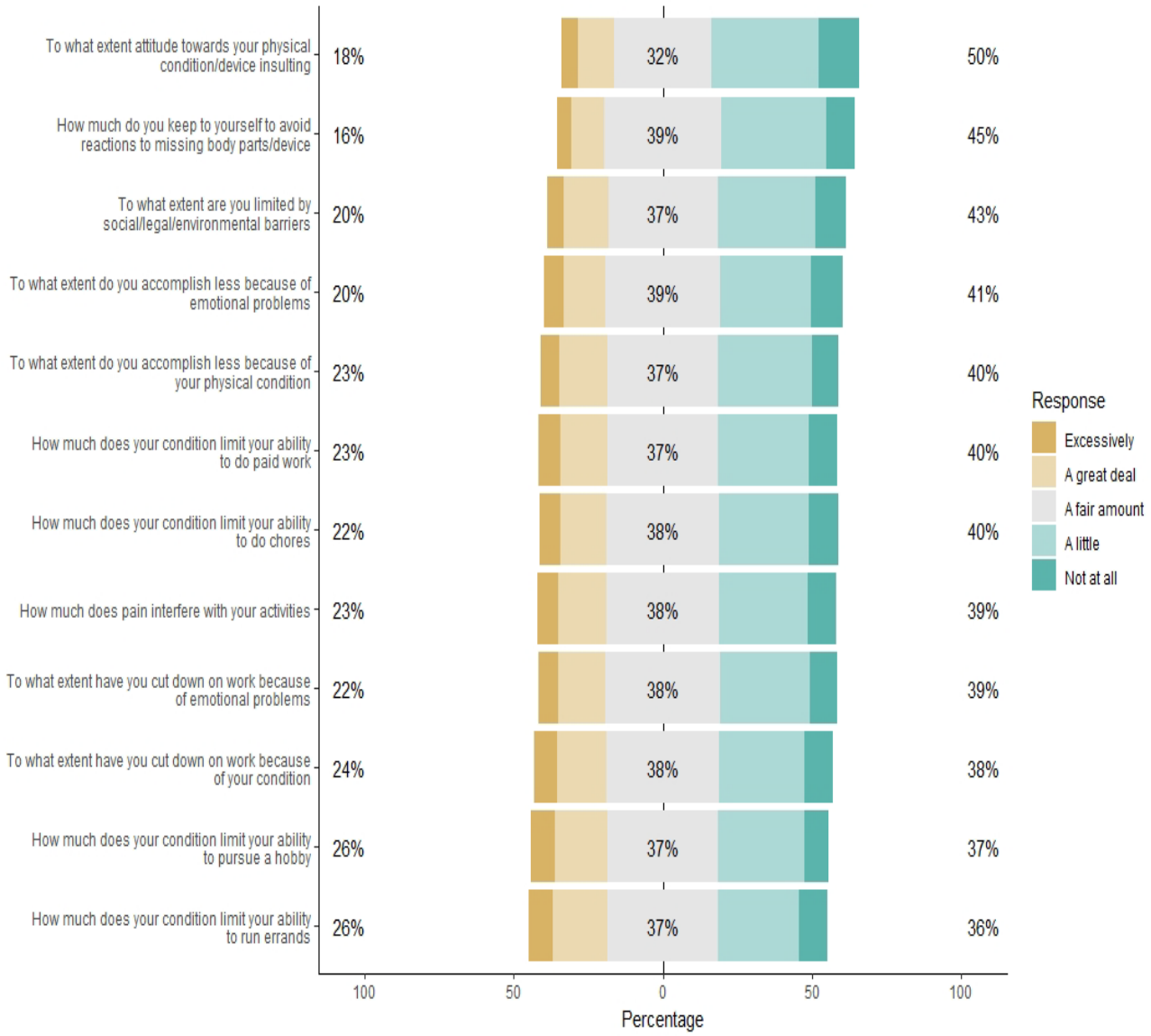


Figure 4.4

HRQOL Emotional Health Summary Plot

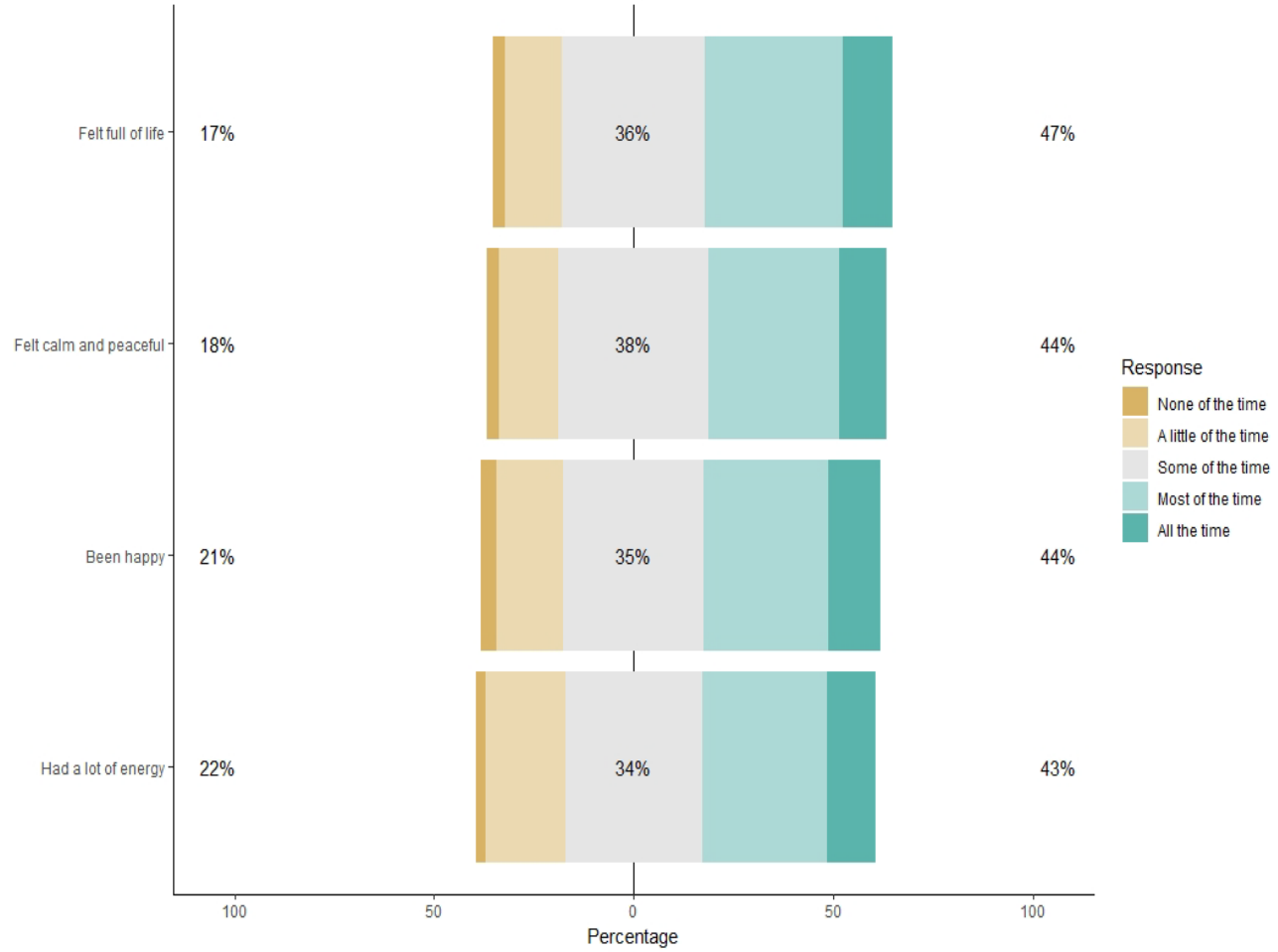


Figure 4.5

Psychological Health Summary Plot

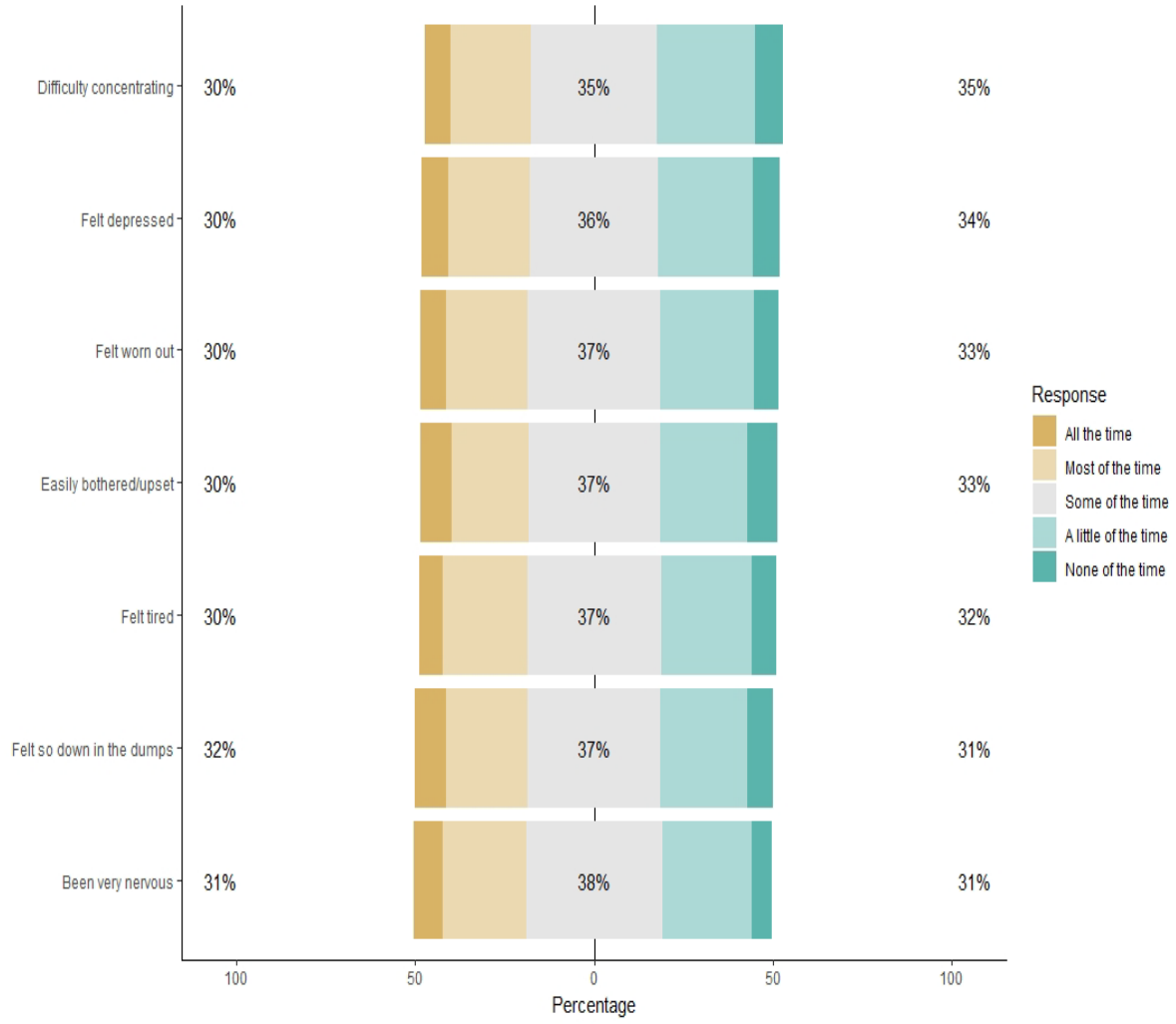


Figure 4.6

Lower Extremity Functional Status (LEFS) mean distribution of participant responses to 20-item LEFS scale

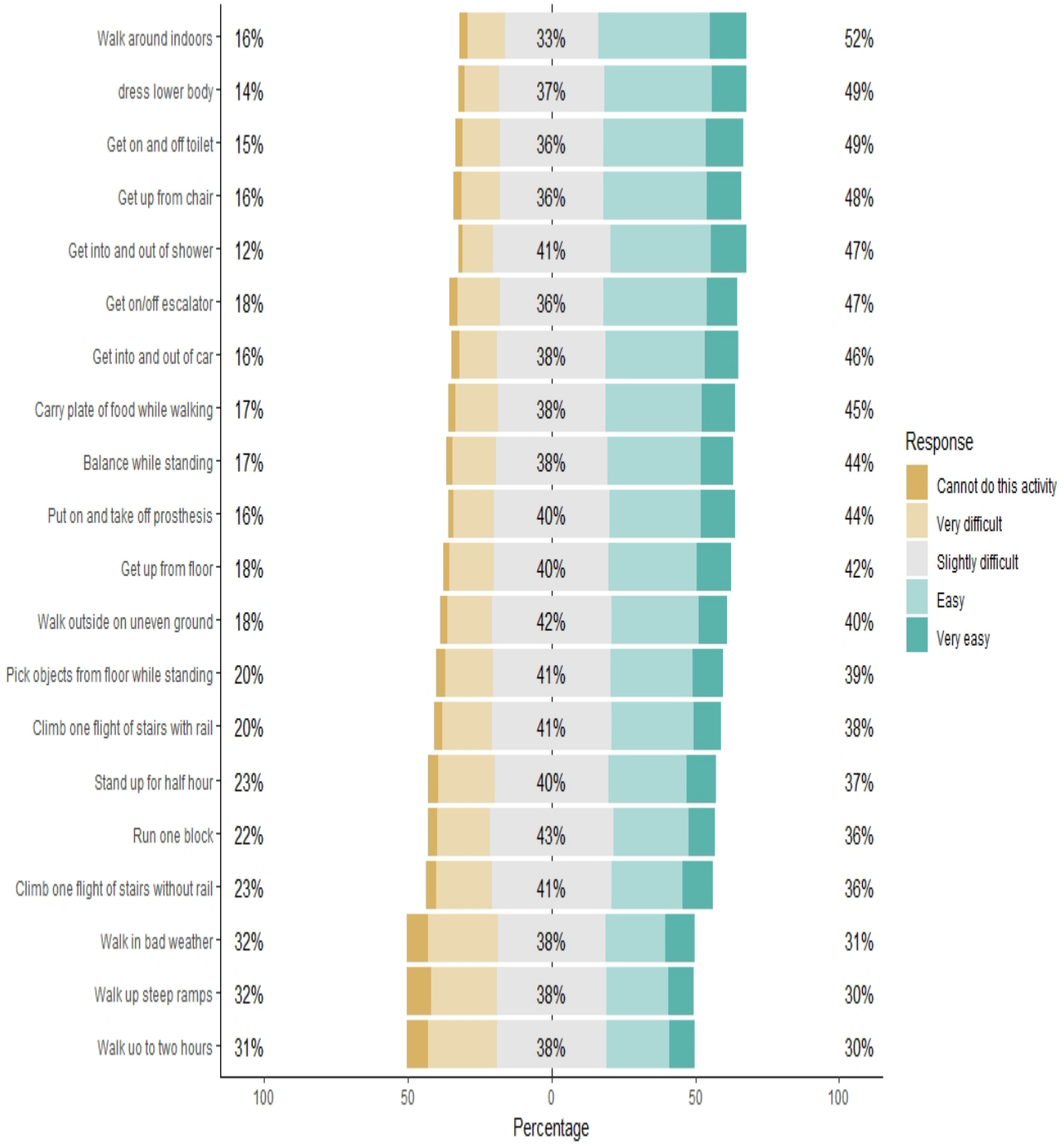


Figure 4.7

Path Analysis Chart showing the predictive relationship between client satisfaction with prosthetic device (CSD), health-related quality of life (HRQOL), lower extremity functional status (LEFS), balance (ABC), and fall efficacy (MFE)

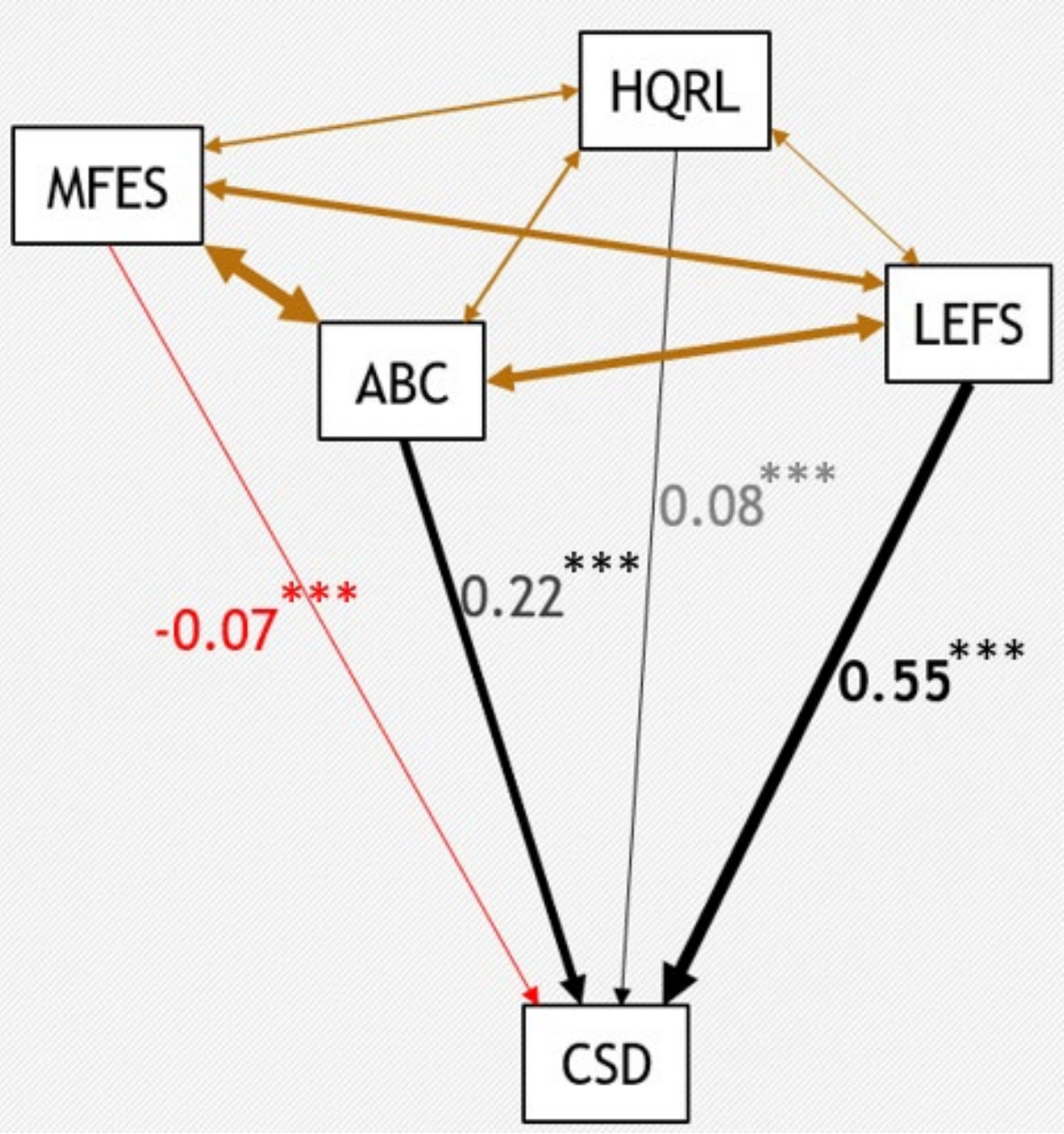
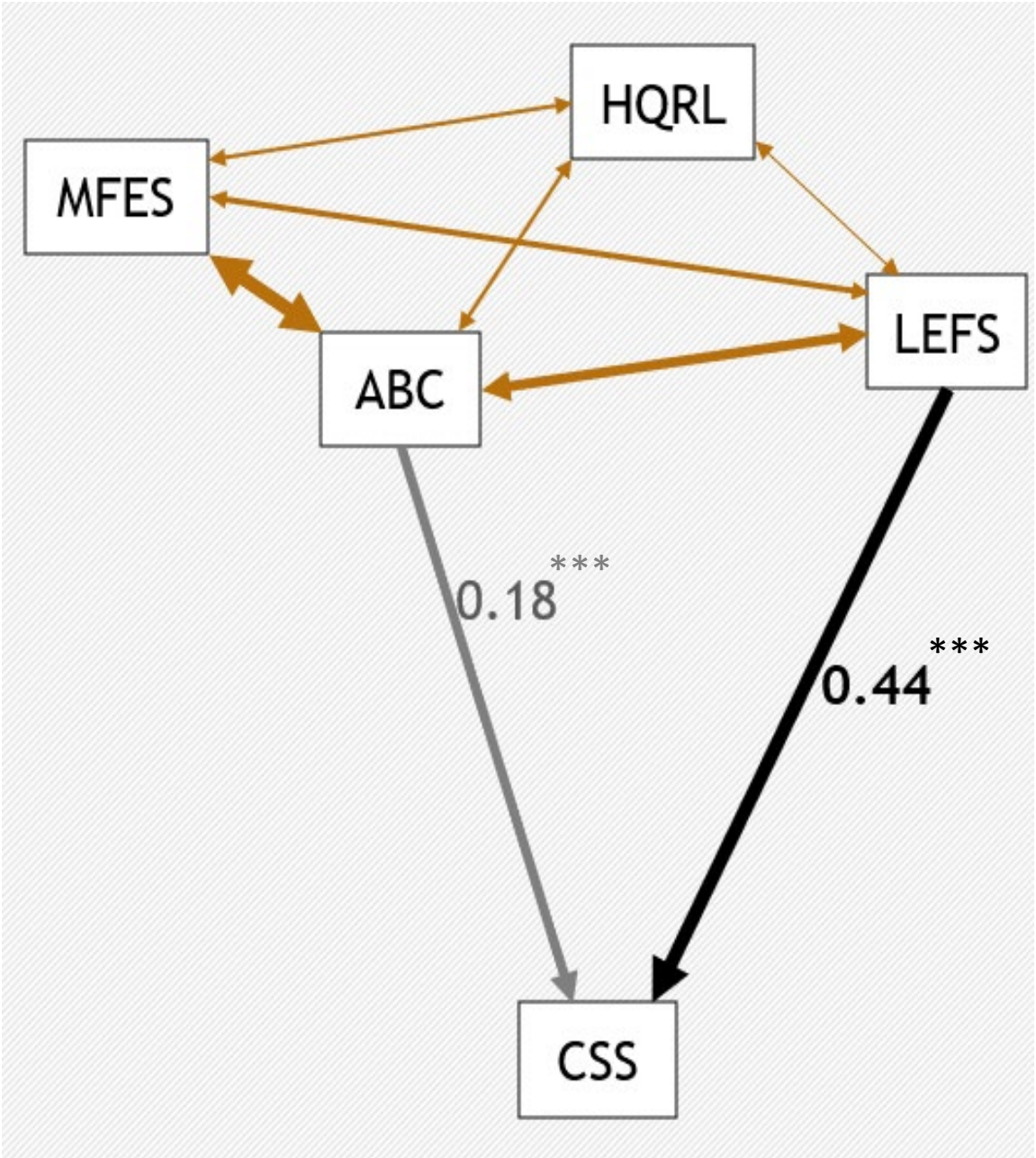


Figure 4.8

Path Analysis Chart showing the predictive relationship between client satisfaction with prosthetic clinician provider service (CSS), health-related quality of life (HRQOL), lower extremity functional status (LEFS), balance (ABC), and fall efficacy (MFE)



Discussion

This study examined prosthetic client satisfaction among civilian, veteran, and active-duty lower limb amputees using a composite survey. The results suggest that a sizeable number of lower limb amputees sampled desire more from with their prosthesis device and clinical provider service. These dissatisfaction ratings were associated with low functional mobility, and health-related quality of life. Balance confidence and participant fall efficacy scores also revealed that participants had a moderate level of confidence in maintaining balance and avoiding falls. The path analysis model suggested lower limb functional status, balance confidence, health-related quality of life, and fear of falling had a significant effect on determining prosthetic device satisfaction. Only lower extremity functional status and activity-specific balance confidence significantly influenced prosthetic provider service satisfaction. Overall, interventions targeted at improving balance, fall risk, and functional movement may significantly reduced lower limb prosthesis rejection among amputees.

A few prior small studies have assessed prosthesis and prosthetic clinical provider service satisfaction using the validated component questionnaires that make up the Orthotics Prosthetics Users Survey (OPUS) with results that conflicted with our findings.[61,64,66 70] This current study is the first to explore satisfaction, quality of life, and functional performance in a larger population of lower limb amputees using psychometric instruments validated in the amputee population. These self-reported constructs from a larger and more diverse sample of lower limb prosthesis users, provide a clearer picture of the aspects of rehabilitation goals that is of greater importance to the lower limb amputee.

Our findings indicated that about 56% of participants self-reported high device satisfaction scores (mean CSD score > 50) where ‘0’ corresponds to the lowest possible mean

CSD score and '100' the highest possible mean CSD score. Our findings are lower than a study of orthoses and prostheses users that reported 83% device satisfaction rates,[71] but concur with a study of traumatic lower limb amputees that indicated 55% were satisfied with their device.[9] However, instruments used in these two studies (Short Form-36[9] and SERVQUAL[71]) were not validated in the amputee population. A recent study of a small sample of unilateral lower limb amputees using the validated OPUS-CSD survey reported 25% of respondents were dissatisfied with their prosthesis citing prosthesis cost as a significant problem.[64] The predominant areas of displeasure in the current study population were skin injuries, stump discomfort, pain, and high maintenance cost. This is similar to the findings in previous studies with about 25% of respondents reported wounds, skin irritation, and pain.[9] Considering the enormous financial burden of prosthetic care, cost mitigation and socket material design improvements may be required to alleviate the challenges reported by amputees.

Findings in the present study also suggested that about 63% of the studied lower limb amputee population were satisfied with their prosthetic clinical provider service (mean CSS score > 50) where '0' corresponds to the lowest possible mean CSS score and '100' the highest possible mean CSS score. Research suggests variations in prosthetic provider satisfaction in different countries with earlier findings reporting greater prosthetic provider service satisfaction rates of 93% in upper and lower limb amputees in Europe[71] and 97% in a small Saudi-Arabian lower limb amputee cohort.[64] Service wait time, scheduling challenges, and low level of patient partnership in decision making regarding clinical care and equipment were the major areas of dissatisfaction in the present study. Previous studies were conducted in climes where prosthetic provider services were provided at little or no cost to amputees.

The present study found approximately 58% of participants reported a low level of functional performance (mean LEFS score < 50) in their subjective ability to carry out movement related activities of daily living with their lower extremity prosthesis. A score of '0' corresponds to the lowest possible mean LEFS score and '100' the highest possible mean LEFS score. In contrast with the current study, a previous study assessing functional status of lower limb prostheses users reported a higher LEFS scores (mean LEFS = 51.53) in 30 traumatic transfemoral amputees.[72] A study in 82 veterans with combat-related lower limb amputation reported lower LEFS scores (mean LEFS = 45.7)[73] similar to the current study. However, these 2 previous studies used the raw LEFS scores in their analysis without converting to equivalent Rasch measures, allowing for easier comparison of the categorical measures and more generalization of the scores across different samples.[63] The path analysis prediction model used in the current study further suggests that improvement in mean LEFS scores has a direct effect on improving both prosthetic device and provider satisfaction. No study to date has compared the influence of lower limb daily function measured by LEFS on prosthetic satisfaction in amputees. Most participants in the present study reported significant challenges and the inability to carry out functional daily movement activities like 'walk up steep ramps', 'walk in bad weather', or 'climb one flight of stairs without a rail,' which suggests mobility limitations.

More than half of participants (59%) reported a low health-related quality of life pertaining to their physical, emotional, and mental health (mean HRQoL < 50) where '0' corresponds to the lowest possible mean HRQoL score and '100' the highest possible mean HRQoL score. This finding differs from that of a small cohort of Vietnam war veterans comprised of both upper and lower limb amputees. About 73% of war veterans reported

excellent, very good or good overall quality of life scores.[74] Another study assessing quality of life in 37 lower limb amputees reported a high quality of life with mean HRQoL of 50.2 ± 21.7.[75]

The path analysis revealed that health-related quality of life significantly influenced prosthetic device satisfaction but not service satisfaction (HRQoL: $\beta = 0.08$; $p < 0.0005$). This is comparable to the recent finding in 86 combat-related lower limb amputees revealing a significant positive relationship between device satisfaction and quality of life ($\beta = 0.0058$; $p = 0.004$).[76]

Overall, participants reported only a fair confidence in their ability to balance when carrying out daily activities (mean ABC scores = 53 ± 20%) where 0% represents no balance confidence and 100% complete balance confidence. Past studies have also shown minimal changes in balance confidence in lower limb amputees when followed up over a two year period.[77] The regression pathway analysis indicated that increasing balance confidence significantly improves both prosthetic device and provider service satisfaction in individuals with lower limb loss.

Participants also reported fair confidence in their ability to carry out indoor and outdoor activities without falling which translates to a moderate fear of falling (mean MFES scores = 6 ± 2) with 0 representing no confidence and 10 representing full confidence in not falling. A recent study of 52 unilateral lower limb loss patients revealed a high mean MFES[78] in contrast to the findings of the current study. The path analysis model suggests that prosthetic device satisfaction is significantly improved by reduction in fear of falling (lower mean MFES scores) and changes in fall efficacy has no observed effect on prosthetic provider service satisfaction.

Study Limitations

The cross-sectional design of the study limits the determination of a causal relationship between prosthesis device and clinical provider service satisfaction and their predictors. Therefore, the results should be interpreted through the lens of associations. The influence of participants' varying physical activity levels pre and post amputation on device satisfaction and lower extremity functionality may have been underestimated. Further, the surveys were not designed to independently assess patient experience with each prosthesis for bilateral lower limb amputees, although most of the participants had unilateral amputations. Finally, the inclusion of only current prosthesis users may have inadvertently excluded lower limb amputees who have already abandoned their device.

Summary

The present study suggests a relatively high level of prosthetic device and clinical provider service dissatisfaction exists among civilians, Veterans, and active-duty lower limb amputees. Better functional mobility and balance were both associated with prosthetic device and clinical provider service satisfaction. Health-related quality of life only predicted amputee device satisfaction. Risk of falling negatively impacted device satisfaction, with no observed influence on prosthetic clinical provider service satisfaction. Our findings provide clinicians much needed client-centered feedback to assess and optimize prosthetic device effectiveness and clinical provider service delivery to improve satisfaction with prosthetic prescription and improve rehabilitation outcomes. Clearly there is need for ongoing patient-centered feedback before, during, and after prosthesis prescription and amputee rehabilitation.

Chapter 5 – Virtual assessment of functional mobility in lower extremity prosthesis clients: a pilot study

Abstract

Introduction

This study characterized the relationship between patient perception of lower extremity function and an objective, home-based virtual clinician assessment of mobility in lower-limb prosthesis clients.

Methods

A clinician virtually administered functional mobility survey to assess perceived lower extremity functional mobility status. Participants then completed three iterations of the timed up and go mobility evaluation supervised by a clinician via a secure zoom platform. Eligibility criteria included: lower limb amputee currently using prosthesis, at least 19 years of age; with no stroke, seizure disorder, or pregnancy. Main outcomes were mobility survey scores and mean timed-up-and go duration.

Results

Twelve lower-limb amputees participated in the virtual study. Most participants (66 – 75%) responded “very easy” or “easy” to basic lower limb indoor ambulation and toileting tasks. About 83% of participants had significant difficulty or could not run or ambulate for up to two hours. Timed-up-and go test was faster (11.0 ± 2.9 seconds) than the reference range for transtibial prosthesis users and was negatively associated with the self-reported lower extremity functional status in the Pearson’s correlation analysis ($r = -.70$, $p = .02$).

Conclusion and Clinical Relevance

Self-perception of home-based prosthetic mobility of lower limb amputees and clinician mobility assessment via a virtual platform, is a feasible prosthetic care assessment modality that may reduce frequency of therapy visits, defray some rehabilitation costs, and minimize the travel burden to distant prosthetic clinics.

KEYWORDS – artificial limb, leg amputation, home-based rehabilitation, physical performance.

Introduction

Limb amputation creates an enormous socioeconomic challenge in America. Over two million people live with an amputated limb[5] resulting in over $10 billion in medical expenses annually.[7] Diabetes mellitus, trauma, and peripheral vascular disease resulting from atherosclerosis are the leading causes of amputations,[3,30,31,34] which occur more in the lower limbs.[29] Post amputation, prosthetic rehabilitation is used to partially ameliorate the mobility limitations and improve quality of life.[9-11,34]

Lower limb amputees experience many challenges during rehabilitation and re-integration back to their home environment. Adapting to new ways of moving with their prosthesis and learning to carry out basic activities of daily living can be a daunting task. Further, prosthetic prescription itself is a challenging process, often requiring multiple prosthetic socket designs and trials to improve fit, comfort, and reduce skin irritation.[26] Physical access to physical therapy clinics for follow up care often poses a significant barrier to lower limb amputees receiving quality prosthetic rehabilitation post hospital discharge.[26,65] Health care disparities compounded by limitations such as geographical location of prosthetic care, low socioeconomic status, poor education, and racial discrimination restrict access to adequate prosthetic rehabilitation services.[11,26,65]

Hospital-based outpatient care and home-based rehabilitation have been shown to be successful in cardiac rehabilitation patients with heart-failure,[79,80] and post-stroke geriatric patients.[81] Home-based care resulted in comparable patient outcomes with no additional financial burden to the patient or provider[79-81] and improved patient quality of life.[79,80] Although the use of home-based exercise interventions for lower limb amputees is uncommon, some studies have shown that it may be an effective method to improve mobility and quality of life in prosthesis

users post-amputation.[11,82] There is therefore a need to explore home-based care as an alternative means to assess rehabilitation progress and functional independence of the lower limb prosthetic user outside the hospital environment. Considering the challenges lower limb amputees face in accessing available prosthetic care, the home-based modality may help improve their functional independence and overall quality of life.

Thus, the purpose of this study was to evaluate the relationship between patient perception of lower extremity function using a validated electronic survey and a clinician administered virtual assessment of lower extremity mobility of lower limb prosthetic clients (LLPC) in their home environment.

Methods

Design

This observational study used the Lower Extremity Functional Status (LEFS) survey a component of the validated Orthotics Prosthetics Users Survey (OPUS)[22,23,63] and the timed-up-and go test (TUG),[60,61,83] administered by a clinician via a secure HIPAA compliant zoom platform. All protocols for the study were approved by the Auburn University Institutional Review Board (protocol number: 21-310 EP 2107). A snowball sampling method was used. A recruitment flyer was sent to clinicians and prosthetic rehabilitation centers and posted on several amputee-focused social media platforms. Further, recruitment emails were sent to interested participants and informed consent was obtained.

Participants

Twelve participants between the ages of 19 and 80 completed the study. Inclusion criteria were individuals 19 years or older with lower extremity amputation who were currently using

any lower extremity prosthesis. Exclusion criteria were lower limb amputees with: 1) pre-existing acute or chronic medical conditions that can interfere with lower-limb function such as stroke or seizure disorders; and 2) pregnancy (due to increased risk of falls).[67]

Study Instruments

The Lower Extremity Functional Status (LEFS) survey component of the Orthotics Prosthetics Users Survey (OPUS) is a 20-item validated instrument that measures lower extremity daily activities rated on a five-level Likert scale ranging from "very easy" scored four, to "cannot do this activity" scored zero. The LEFS also showed a satisfactory ICC (0.67 – 0.96) and test-retest reliability.[23,61]

The TUG test is a brief functional performance tool to assess basic mobility. This includes walking, turning while walking, balance and transfers.[61] Participants were allowed to use their walking aids (if any) during testing.[60]

The dependent variable for the study was the lower extremity functional status (LEFS) questionnaire scores as reported by the participants. While the independent variable was the mean timed-up-and go duration as recorded by the clinician.

Study Procedure

Interested participants were emailed the virtual study information letter with a Qualtrics link for the informed consent, a video demonstration of the set-up instructions, and demonstration of the TUG test. In addition, the researcher sent a disposable measuring tape to participants via regular mail so they could measure the distance for the TUG test. A chaperone or caregiver was present with the participant for the virtual testing procedure to assist with the test

set-up and ensure safety. A secure link of the HIPAA-compliant Auburn University secure Zoom platform was sent via email to participants who voluntarily gave informed consent.

Basic demographics were collected at the beginning of the zoom session and included age, biological sex, date of amputation, injury etiology, level of amputation, number of past devices, and number of sockets used post amputation. Participants were in their home environment wearing their lower-limb prosthesis and regular footwear and accompanied by a caregiver or acquaintance to insure safety. An armchair was placed at a marked starting point and ten-foot uncluttered walk space was measured and marked on the floor. Participants completed one practice trial to become familiar with the TUG test, with the investigator answering any questions. Participants rested for three minutes, then completed three timed and recorded iterations of the TUG procedure separated by 3-5 minutes rest as needed. The researcher gave the following instructions to the participant: "On the word GO, you will stand up from the chair, walk to the line on the floor at your regular pace, turn around, and walk back to the chair and sit down." The researcher started timing on the word "GO" and stopped timing when the participant sat again in the chair with their back resting against the backrest of the chair. The time in seconds to complete the TUG test was recorded. The researcher subsequently administered the 20-item LEFS survey to the participant. The virtual testing component took about 15 minutes to complete. Participants who completed the session were given the choice to receive a $50 electronic gift card.

Statistical Analysis

All continuous data were presented as means and standard deviations, with categorical data presented as frequencies and percentages. Descriptive statistics were calculated for the

LEFS responses. The reported LEFS scores were converted into a Rasch measure which provides appropriate weighted scores on an increasing linear scale with "0" representing the lowest measure of the lower extremity function and "100" representing the highest measure.[63] Bivariate Pearson correlation was used to measure the strength and direction of linear relationship between the LEFS and TUG test scores. A simple linear regression was also calculated to assess the predictive value of TUG on LEFS scores. A *priori* alpha level was set at 0.05 for statistical significance and all statistical analyses were performed using RStudio version 4.1.2.

Results

Descriptive characteristics of the study sample are displayed in Table 5.1. A total of 12 participants (5 females, 7 males) completed the study. Participants age ranged from 28 to 66 years (mean age of 48.3 ± 12.8 years) with the majority (66.7%) being middle aged or older and predominantly Caucasian (75%). Diabetes, peripheral vascular disease, infections, and trauma were the reported clinical indications for amputation. Most of the participants had unilateral amputation (91.7%), about half with below knee amputation (58.3%).

Table 5.1

Participant demographics and general amputation characteristics

		N (%)
Sex	Female	5 (41.7)
	Male	7 (58.3)
Age	19 – 39	4 (33.3)
	40 – 59	5 (41.7)
	≥ 60	3 (25.0)
Race	White	9 (75.0)
	Black	3 (25.0)
	Hispanic & Other	0 (0)
Etiology of Amputation	Diabetes & Vascular Diseases	3 (25.0)
	Trauma	4 (33.3)
	Infection	4 (33.3)
	Other	1 (8.3)
Amputation Type	Unilateral	11 (91.7)
	Bilateral	1 (8.3)
Amputation Level	Transtibial	7 (58.3)
	Transfemoral	5 (41.7)

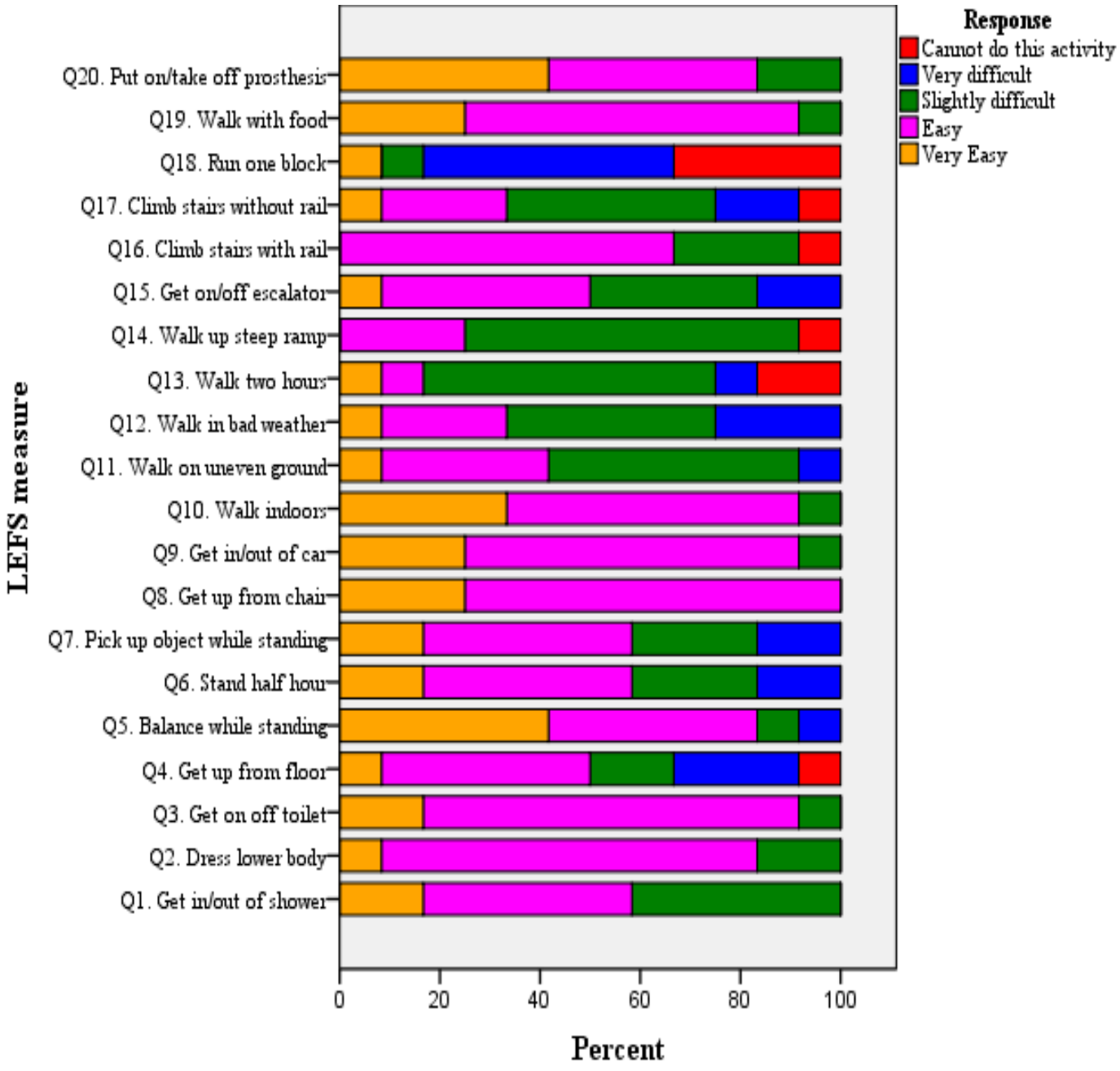
The LEFS survey response is represented in the summary plot (Figure 5.1). Overall, participants reported a mean LEFS score of 55.1 ± 4.4 indicating an average functionality with lower extremity prostheses (a score of '0' corresponding to the lowest level and '100'the highest level of lower extremity function with prosthesis). Most participants (75%) reported they found it

easy to ‘dress lower body,’ ‘get on and off the toilet,’ and ‘get up from a chair.’ About 66% of participants also reported they found it easy to ‘get in and out of a car,’ ‘climb one flight of stairs with a rail,’ and ‘carry a plate of food while walking.’ Half of the participants reported they find it very difficult to ‘run one block’ while an additional 33.3% of participants disclosed they cannot run one block with their prosthesis. About 25% of participants also revealed they found it very difficult to ‘get up from the floor,’ and ‘walk in bad weather.’ All (100%) of the participants stated they either had little or no difficulty, found it easy, or very easy to ‘get in and out of the tub or shower,’ ‘get up from a chair,’ ‘get into and out of a car,’ ‘walk indoors,’ ‘carry a plate of food while walking,’ or ‘put on and take off their prosthesis.

TUG data was analyzed using 11 participants. One participant was removed as an extreme outlier due to the time to complete the TUG task (outside two standard deviations from group mean value). The participant excluded was using a newly obtained transfemoral prosthesis during the testing which likely affected his results. Participants reported a mean TUG value of 11.0 ± 2.9 seconds ($N = 11$) which is within the reference range for normal TUG values of lower limb prosthesis users (12.3 ± 4.5 to 13.0 ± 5.6).[61]

Figure 5.1

Lower Extremity Functional Status (LEFS) Survey Analysis

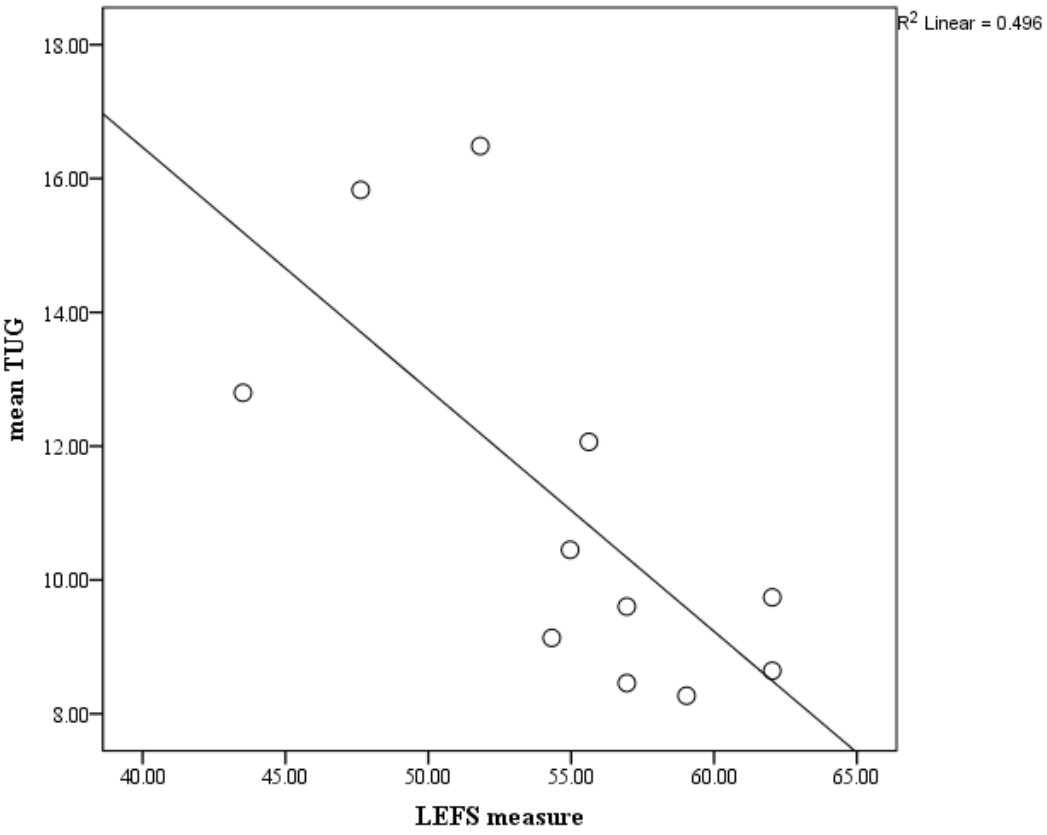


Note. Mean distribution of participant responses to 20-item LEFS scale, (N = 12)

A Pearson's correlation coefficient was computed to assess the relationship between LEFS and TUG. The scatter plot below (Figure 2) summarizes the results. Overall, there was a strong negative correlation between the mean LEFS scores and the mean TUG values, $r(9) = -.70$, $p = .02$. Increases in self-reported LEFS (higher self-ratings of ability to complete daily activities) correlated with decreases in time it took to complete the clinician virtually administered TUG test. A simple linear regression was calculated to predict LEFS scores based on TUG test time. A significant regression equation was found, $F(1, 9) = 8.854$, $p = .016$, with an R^2 of .496. Participants' predicted LEFS score is equal to 70.126 + (-1.371) (TUG value) when TUG is measured in seconds. For each second of the TUG test duration, participants' LEFS score decreased by a value of 1.371.

Figure 5.2

Pearson correlation between investigator recorded mean TUG and participant reported mean LEFS scores



Discussion

This study examined the relationship between how prosthetic clients judge their ability to function using their prosthesis compared to a virtual clinical functional assessment by a clinician. The results suggest lower limb prosthesis users accurately assess their ability to function when compared to the validated TUG assessment. The LEFS outcomes were negatively related to the TUG assessment, suggesting the quicker they completed the TUG (fewer seconds to complete, more functional capability), the higher their ability score on the LEFS. Patient self-reported

clinical outcome measures like LEFS are essential for evaluating the physical and functional impact of prostheses.[84,85] In this study, the virtually deployed LEFS reflected the patient experience at home and this perspective is necessary for shared-clinical decision making. Recent studies have demonstrated the usefulness of home-based care as part of the cardiac out-patient rehabilitation, [79,80] and the current study suggests that the virtual approach to home-based prosthetic rehabilitation assessment may be complementary to clinic-based assessment. This virtual modality may be useful to monitor rehabilitation progress and facilitate return to pre-amputation functional levels.

The results also suggest a virtual clinician-administered assessment can be an accurate evaluation of functional capability of prosthetic users. The virtually administered TUG test provided a reasonable and clinically relevant assessment regarding patient mobility during basic functional tasks outside the clinic setting. The ease and cost effectiveness of TUG test administration, combined with the observed correlation with self-reported LEFS measure enhances the translation to clinical practice.

The participants in this study reported basic activities of daily living such as getting in and out shower, walking indoors, getting on and off toilet, and getting up from a chair as either "very easy" or "easy". These ambulatory and toileting activities are an important part of routine prosthetic client evaluation and helps the clinician assess prosthetic rehabilitation.[86] The mean LEFS score of 55.1 ± 4.4 reported in the current study corresponds to a moderate level of lower extremity physical functioning and is similar to findings in a recent cross-sectional study of Malaysian transfemoral prostheses users (mean 51.53 ± 11.84).[72] Another study in a population of war veterans with combat-related amputation reported a comparable mean LEFS score of 45.7 ± 14.2.[73] These findings suggest both civilian and military populations report basic functional

mobility issues in non-clinical environments which can affect personal care, safety, and independent living.[86]

Participants reported activities requiring greater strength and balance, such as running, walking for longer periods, and walking up a steep ramp, as "very difficult," or "cannot do this activity." These findings are similar to past research in both trained service members,[73] physically inactive cohort of lower limb amputees[87] and a mixed population of orthotic and prosthetic clients.[21] This suggests that similarities in self-reported lower extremity function exist between different groups of prostheses users irrespective of physical activity levels. This limitation in performing more strenuous movements with lower limb prosthesis should be explored in subsequent research and inform future device or rehabilitation reviews.

The virtual TUG test scores obtained in the current study revealed that participants had a comparable task completion time to the standard reference range of expected TUG times for unilateral transtibial and transfemoral prostheses users (reference: 12.3±4.5 to 13.0±5.6 seconds).[61] This suggests participants in our study are representative of a broad population of prosthetic users with higher level of functioning than the general elderly population[88] or among other unilateral amputees.[89] This may be due to the younger average age of our population. The outlier excluded from the TUG analysis in the current study is representative of the variance in physical performance among lower limb prosthesis users as seen in clinical practice and is likely the result of the participant becoming accustomed to a new prosthetic.

The virtual clinical mobility test was negatively correlated to how the patients reported their ability to function at home. This significant negative linear association ($r = -0.70$) between the LEFS and the clinician evaluated mobility test (TUG) has also been demonstrated in other self-reported measures of lower limb function like the Prosthetic Limb Users Survey of Mobility

(PLUS-M) (r = -0.54)[90] and the Activities-specific Balance Confidence Scale (ABC scale) (r = -0.70).[90] The reports of high levels of balance confidence in all these studies likely has a direct impact on these findings. The simple regression calculation further suggests that the clinician administered TUG may predict the LEFS reported by prosthetic patients. This is the first pilot study to explore the direction, strength of association, and predictive properties of the TUG on lower extremity function in prostheses users using the LEFS instrument.

Study Limitations

The low sample size of this pilot study limits the detection of the true effect, and the cross-sectional design further limits the determination of a causal relationship between functional status with leg prosthesis and the mobility test. Therefore, the results should be interpreted cautiously. We also did not control for physical activity profile of participants, and this may introduce an important confounder.

Subsequent follow up studies should involve larger population of both unilateral and bilateral lower limb amputees, utilize wearable technology, and utilize the component TUG to obtain more clinically relevant information. Gait analysis from the virtual TUG recordings would also provide more clinically meaningful data to further evaluate persistent gait abnormalities with the prostheses.

Summary

This study demonstrated the relationship between how prosthetic clients judge their ability to function using their prosthesis to a virtual clinical functional assessment by a clinician. Our results support a virtual clinician administered assessment can be an accurate evaluation of

functional capacity of prosthetic users. Results from this study highlight lower limb amputees desire improved function in activities such as prolonged walking and running. These home-based assessments can be used to inform rehabilitation plans and contribute to quality-of-life improvement. More research is needed to explore the feasibility of other physical functioning tests in non-clinical settings in this population of interest.

Chapter 6 – Overview and Future Direction

Summary

This project examined the relationship between various self-reported measures of satisfaction, quality of life, and mobility of lower limb prosthetic users with a clinician-evaluated and virtually administered measure of functional movement in amputees. Two studies were developed to assess prosthetic users' perspective of their device, how it relates to their everyday function, and compare it to a clinical evaluation. The first study was designed to determine the relationship between the satisfaction of lower limb amputees with their prosthesis, prosthetic rehabilitation, health-related quality of life, and functional abilities. The second, was a pilot study to evaluate the association between patient's assessment of lower limb function at home with a clinician's evaluation of same using a virtual platform.

The data from the first study demonstrated, as expected, a substantial number of a diverse group of lower limb prosthesis users (civilian, veteran, and military) are not satisfied with their prosthesis and rehabilitation service. This dissatisfaction was closely related to reduced functional movement, health-related quality of life, moderate level of confidence in maintaining balance, and fear of falling. The predictive model suggested that interventions targeted at improving lower limb functional movements and balance confidence would ultimately lead to improved amputee satisfaction with prosthetic device and rehabilitation service.

The virtual pilot study data revealed that lower limb amputees accurately report their functional movement within and around the home environment when compared with a virtual assessment by a clinician. The study outcomes further suggested that amputees that virtually demonstrate higher functional capacity with their prosthesis would have a higher self-evaluation of their ability to carry out basic movement-related activities of daily life. These findings

support the addition of a virtual home-based assessment to current prosthetic rehabilitation care to monitor patient progress. This would make it possible to reduce the frequency of in-person rehabilitation visits by amputees saving them considerable stress and cost. Additionally, it provides a new opportunity for clinicians to offer more specialized care and check-ins in between in-person visits for amputees in a way that is cost effective and may be eligible for reimbursement by the Center for Medicare Services.

Findings from these two studies indicate that lower limb amputees require better functional outcomes from their prosthetic device and prosthetic rehabilitation. Also, the virtual modality for assessing amputee functional movements at home is accurate and could complement in-person rehabilitation follow-up clinic visits. Additionally, further work needs to be completed in this population to better understand challenges with executing prolonged ambulation and running with lower limb prostheses.

Finally, we had challenges in securing the willingness of amputees to actively participate in the virtual component of the project due to lack of trust in an unfamiliar clinician. This challenge can be overcome in follow-up studies by first establishing a strong relationship with the amputee community to build trust and buy-in. This can be achieved by finding advocates within the community and creating interactions between the clinical researchers and amputees via the many amputee support and advocacy social media platforms available.

Future Work

Subsequent research is needed to establish causal relationships between the various measures of the lower limb amputee experience, explore effective ways to assess functional capacity with prosthesis outside the clinical environment, and enhance restoration to pre-amputation functional levels with prosthesis.

Suggestions for future work in this population include: comparing other validated measures of prosthetic performance with the measures used in the present study; increasing the sample size for the virtual mobility assessment to increase study the power; use of the component TUG to characterize the subcomponents of TUG with wearable inertial sensors for higher accuracy; exploring gait analysis using video recordings of the virtual TUG to provide additional information to identify pathologic prosthetic gait; investigating the effects of a virtual exercise intervention in addressing the challenges amputees face in accomplishing more difficult movements.

Our laboratory is currently building on the pilot study and will be collecting more data to have a more representative sample of lower limb amputees. Plans to expand the project includes incorporating the physical activity profile of participants and stratifying amputees by amputation level, and device type. The end goal of this research is to contribute to improving the quality of life of lower limb amputees and improving the prosthetic rehabilitation process.

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Appendix 1: IRB Approval

AUBURN UNIVERSITY INSTITUTIONAL REVIEW BOARD for RESEARCH INVOLVING HUMAN SUBJECTS
RESEARCH PROTOCOL REVIEW FORM
FULL BOARD or EXPEDITED

For Information or help contact **THE OFFICE OF RESEARCH COMPLIANCE (ORC)**
Phone: 334-844-5966 **e-mail:** IRBAdmin@auburn.edu **Web Address:** http://www.auburn.edu/research/vpr/ohs/index.htm

Revised 04.01.2021 **Submit completed form to IRBsubmit@auburn.edu**

Complete this form using Adobe Acrobat Writer (versions 5.0 and greater). Hand written copies not accepted.

1. **PROPOSED START DATE of STUDY:** 09/20/2021 **Today's Date:** 09/03/2021

PROPOSED REVIEW CATEGORY (Check one): ☐ FULL BOARD ☒ EXPEDITED

SUBMISSION STATUS (Check one): ☐ NEW ☒ REVISIONS (to address IRB Review Comments)

2. **PROJECT TITLE:** Quality of Life, Functional Performance, and User Satisfaction of Lower Limb Prosthe

3. Oluwagbemiga DadeMatthews	Doctoral Candidate	School of Kinesiology	odd0003@auburn.edu
PRINCIPAL INVESTIGATOR	TITLE	DEPT	AU E-MAIL
301 Wire Road, Office 292, Auburn, AL 36849		334-524-7472	
MAILING ADDRESS		PHONE	ALTERNATE E-MAIL

4. **FUNDING SUPPORT:** ☐ N/A ☒ Internal ☐ External Agency: _____ ☐ Pending ☐ Received

For federal funding, list agency and grant number (if available). _____

5a. List any contractors, sub-contractors, other entities associated with this project:
N/A

b. List any other IRBs associated with this project (including Reviewed, Deferred, Determination, etc.):
N/A

PROTOCOL PACKET CHECKLIST

All protocols must include the following items:

- ☐ **Research Protocol Review Form** (All signatures included and all sections completed)
  (Examples of appended documents are found on the OHSR website: http://www.auburn.edu/research/vpr/ohs/sample.htm)
- ☐ **CITI Training Certificates** for all Key Personnel.
- ☐ **Consent Form or Information Letter** and any Releases (audio, video or photo) that the participant will sign.
- ☐ **Appendix A**, "Reference List"
- ☐ **Appendix B** if e-mails, flyers, advertisements, generalized announcements or scripts, etc., are used to recruit participants.
- ☐ **Appendix C** if data collection sheets, surveys, tests, other recording instruments, interview scripts, etc. will be used for data collection. Be sure to attach them in the order in which they are listed in # 13c.
- ☐ **Appendix D** if you will be using a debriefing form or include emergency plans/procedures and medical referral lists (A referral list may be attached to the consent document).
- ☐ **Appendix E** if research is being conducted at sites other than Auburn University or in cooperation with other entities. A **permission letter** from the site / program director must be included indicating their cooperation or involvement in the project. NOTE: If the proposed research is a multi-site project, involving investigators or participants at other academic institutions, hospitals or private research organizations, a letter of **IRB approval** from each entity is required prior to initiating the project.
- ☐ **Appendix F** - Written evidence of acceptance by the host country if research is conducted outside the United States.

The Auburn University Institutional Review Board has approved this Document for use from 07/17/2021 to ---------- Protocol # 21-310 EP 2107

Version Date (date document created): 03 September 2021 page 1 of __

Appendix 2: Approved Information Letter and Survey

Information Letter

INFORMATION LETTER

for a Research Study entitled

"Quality of Life, Functional Performance, and User Satisfaction of Lower Limb Prosthesis Clients"

Updated information letter LLPC study clean copy 07202021

You are invited to participate in a research study to assess the level of satisfaction of lower limb prosthetic clients with their prosthetic device and service. The study will equally explore the relationship of the level of satisfaction with health quality of life and assess lower limb functional performance. The study is being conducted by Dr. 'Gbenga DadeMatthews, PhD candidate at the Warrior Research Center, under the direction of Dr. JoEllen Sefton, Professor, and director of the Warrior Research Center, Auburn University Department of Kinesiology. You are invited to participate because you are currently using a lower limb prosthesis in the United States, are age 19 or older, do not have stroke or seizure disorder, and not currently pregnant.

What will be involved if you participate? Your participation is completely voluntary. If you decide to participate in this research study, you will be asked to complete an anonymous online questionnaire via Qualtrics. Your total time commitment for the survey will be approximately 15 minutes. You will also be asked if you will be willing to participate in a virtual home-based brief walking assessment and a 5-minute interview via Auburn University's secure Zoom platform at your convenience in the presence of your caregiver or chaperone. Your total time commitment for the test will be approximately 15 minutes. The virtual test will be recorded via Zoom. You can choose to participate in the online survey and not the virtual component. There will be a place on the survey to indicate your willingness to participate in the virtual home-based test.

Are there any risks or discomforts? There is a risk of coercion to participate by others; however, participation is completely voluntary, and there cannot be any negative consequences for choosing not to participate in any part or all of the study. Are there any benefits to yourself or others? There are no direct benefits to you if you participate in this study. Findings from this study aim to benefit the practice of prosthetists by improving patient experience and quality of life.

Will you receive compensation for participating? Survey participants can choose to be sent a $10 Amazon gift card. Participants in the virtual test can also chose to be sent an additional $10 Amazon gift card.

Are there any costs? There are no costs associated with your participation in this study.

If you change your mind about participating, you can withdraw at any time by closing your browser window during the survey or by informing the researcher during the virtual testing. If you choose to withdraw, your data can be withdrawn as long as it is identifiable. Once you've submitted anonymous data, it cannot be withdrawn since it will be unidentifiable. Your decision about whether to participate or stop participating will not jeopardize your future relations with Auburn University, the School of Kinesiology, or the Warrior Research Center.

Any data obtained in connection with this study will remain anonymous. We will protect your privacy and the data you provide by disabling the collection of any identifiable information through the Qualtrics and Zoom platform. The data obtained and the Zoom recording will be de-identified and retained for three years, then destroyed. Information collected through your participation may be presented at local, regional, and national professional conferences and published in a professional journal.

If you have questions about this study, please contact Dr. 'Gbenga DadeMatthews at odd0003@auburn.edu.

If you have questions about your rights as a research participant, you may contact the Auburn University Office of Research Compliance or the Institutional Review Board by phone (334) 844-5966 or e-mail at IRBadmin@auburn.edu or IRBChair@auburn.edu.

HAVING READ THE INFORMATION ABOVE, YOU MUST DECIDE IF YOU WANT TO PARTICIPATE IN THIS RESEARCH PROJECT. IF YOU DECIDE TO PARTICIPATE,

PROCEED WITH THE QUESTIONNAIRE.

YOU MAY PRINT A COPY OF THIS LETTER TO KEEP.

Dr. 'Gbenga DadeMatthews 06/30/2021
Investigator Date

The Auburn University Institutional Review Board has approved this document for use from _____ to _____. Protocol #_____

By continuing to the questionnaire, you are:
- consenting to participate,
- confirming that you are over the age of 19,
- currently using lower limb prosthesis, and
- not pregnant.

- ○ Yes
- ○ No

Demographic and General Prosthesis Information

Please enter your age (in years):

What is your gender?

- ○ Male
- ○ Female
- ○ Non-binary / third gender
- ○ Prefer not to say

The Auburn University Institutional Review Board has approved this Document for use from 07/17/2021 to ---------- Protocol # 21-310 EP 2107

Please enter your height (in feet and inches):

Feet

Inches

Please enter your weight (in pounds):

Weight (lb)

What is your race/ ethnicity?

- White
- Black or African American
- American Indian or Alaska Native
- Asian
- Native Hawaiian or Pacific Islander
- Hispanic or Latino
- More than one race/ethnicity
- Prefer not to identify

Please select one of the following option that best describes you.

- Veteran
- Active Duty
- Civilian

What is the highest level of education you have completed?

- High School/GED
- Some college
- Associate's degree
- Bachelor's degree

- ○ Master's degree
- ○ Doctorate degree

What is your estimated total household income annually?

- ○ Less than $20,000
- ○ $20,000 - $39,999
- ○ $40,000 - $59,999
- ○ $60,000 - $79,999
- ○ $80,000 - $99,999
- ○ More than $100,000

Please indicate the main cause of your lower limb loss:

- ○ Trauma/Accident (Blast injury, Blunt force, Burns, Car crash, etc)
- ○ Diabetes
- ○ Infections
- ○ Cancer
- ○ Other (Please specify) _____

When did the lower limb loss event/ diagnosis occur? (month/ year)

Month (Jan - Dec) _____

Year (yyyy) _____

Please specify which lower limb was affected.

- ○ Right
- ○ Left
- ○ Both

What type of lower limb amputation did you have?

(Check all options that apply)

Right Foot	Left Foot	Right Ankle	Left Ankle	Right Above Knee	Left Above knee	Right Below Knee	Left Below Knee	Right Hip	Left Hip
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

Was there any attempt to save the limb (salvage surgery):

- ○ Yes
- ○ No

If you answered yes to the preceding question, when did the limb salvage attempt take place?

- ○ less than 1 month after limb loss event/ diagnosis
- ○ 1 - 6 months after limb loss event/ diagnosis
- ○ greater than 6 months to 1 year after limb loss event/ diagnosis
- ○ greater than a year to 5 years after limb loss event/ diagnosis
- ○ greater than 5 years after limb loss event/ diagnosis

When was the lower limb amputation carried out? (month/ year)

Month (Jan - Dec)

Year (yyyy)

How many prosthetic device(s) including the current one, have you used?

- ○ 1
- ○ 2
- ○ 3
- ○ 4
- ○ 5 and above

If available, kindly attach pictures of prosthetic devices used in the past.

If available, kindly attach the picture of your current prosthetic device.

When did you receive your current prosthetic device? (month/ year)

Month (Jan - Dec)

Year (yyyy)

What challenges do you face in accessing rehabilitation services?
(check all options that apply)

- ☐ High cost of services
- ☐ High cost of prosthesis
- ☐ Distance of rehabilitation service from residence
- ☐ Inadequate insurance coverage
- ☐ Lack of adequate transportation
- ☐ Insufficient personnel (physical therapists, prosthetists, etc.)
- ☐ Communication/ language barrier
- ☐ Other (Please specify)

Satisfaction With Prosthetic Device and Service

Please mark the response that most closely reflects your opinion about your prosthesis and prosthetic service

	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree	Don't know/ Not Applicable
My prosthesis fits well	O	O	O	O	O	O

	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree	Don't know/ Not Applicable
The weight of my prosthesis is manageable	O	O	O	O	O	O
My prosthesis is comfortable throughout the day	O	O	O	O	O	O
It is easy to put on my prosthesis	O	O	O	O	O	O
My prosthesis looks good	O	O	O	O	O	O
My prosthesis is durable	O	O	O	O	O	O

	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree	Don't know/ Not Applicable
My clothes are free of wear and tear from my prosthesis	O	O	O	O	O	O
My skin is free of abrasions and irritations	O	O	O	O	O	O
My prosthesis is pain free to wear	O	O	O	O	O	O
I can afford the out-of-pocket expenses to purchase and maintain my prosthesis	O	O	O	O	O	O
I can afford to repair or replace my prosthesis as soon as needed	O	O	O	O	O	O
I received an appointment with a prosthetist within a reasonable amount of time	O	O	O	O	O	O

	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree	Don't know/ Not Applicable
I was shown the proper level of courtesy and respect by the staff	O	O	O	O	O	O
I waited a reasonable amount of time to be seen	O	O	O	O	O	O

	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree	Don't know/ Not Applicable
Clinic staff fully informed me about equipment choices	O	O	O	O	O	O
The prosthetist gave me the opportunity to express my concerns regarding my equipment	O	O	O	O	O	O
The prosthetist was responsive to my concerns and questions	O	O	O	O	O	O
I am satisfied with the training I received in the use and maintenance of my prosthesis	O	O	O	O	O	O

	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree	Don't know/ Not Applicable
The prosthetist discussed problems I might encounter with my equipment	O	O	O	O	O	O
The staff coordinated their services with my therapists and doctors	O	O	O	O	O	O
I was a partner in decision-making with clinic staff regarding my care and equipment	O	O	O	O	O	O

Health-Related Quality of Life

For the questions below, the term "physical condition" refers to the reason you use prosthetic device(s).

	Not at all	A little	A fair amount	A great deal	Excessively
How much do you keep to yourself to avoid people's reactions to a missing body part or your need for a device?	O	O	O	O	O

	Not at all	A little	A fair amount	A great deal	Excessively
To what extent do you find that people's attitudes toward your physical condition are insulting? ("physical condition" refers to the reason you use a prosthesis)	O	O	O	O	O
To what extent are you prevented from doing what you want to do because of social attitudes, the law, or environmental barriers?	O	O	O	O	O
How much does pain interfere with your activities (including both work outside the home and household duties)?	O	O	O	O	O

	Not at all	A little	A fair amount	A great deal	Excessively
To what extent do you accomplish less than you would like because of your physical condition?	O	O	O	O	O
To what extent do you accomplish less than you would like because of emotional problems?	O	O	O	O	O
How much does your physical condition restrict your ability to run errands?	O	O	O	O	O
How much does your physical condition restrict your ability to pursue a hobby?	O	O	O	O	O

	Not at all	A little	A fair amount	A great deal	Excessively
How much does your physical condition restrict your ability to do chores?	O	O	O	O	O
How much does your physical condition restrict your ability to do paid work?	O	O	O	O	O

	Not at all	A little	A fair amount	A great deal	Excessively
To what extent have you cut down on work or other activities because of your physical condition?	O	O	O	O	O
To what extent have you cut down on work or other activities because of emotional problems?	O	O	O	O	O

The questions below aim to assess the frequency of some emotional experiences in the past week.

During the past week, how often have you:

	All the time	Most of the time	Some of the time	A little of the time	None of the time
felt full of life?	O	O	O	O	O
felt calm and peaceful?	O	O	O	O	O
had a lot of energy?	O	O	O	O	O
been happy?	O	O	O	O	O

	All the time	Most of the time	Some of the time	A little of the time	None of the time
been very nervous?	O	O	O	O	O
felt so down in the dumps that nothing could cheer you up?	O	O	O	O	O
felt downhearted and depressed?	O	O	O	O	O
felt worn out?	O	O	O	O	O

	All the time	Most of the time	Some of the time	A little of the time	None of the time
felt tired?	O	O	O	O	O
been easily bothered or upset?	O	O	O	O	O
had difficulty concentrating or paying attention?	O	O	O	O	O

Lower Extremity Functional Performance with Prosthesis

Please mark the response that best describes how easy or difficult it is to carry out daily activities with your prosthesis.

How easy, or difficult, is it for you to:

	Very easy	Easy	Slightly difficult	Very difficult	Cannot do this activity
Get into and out of the tub or shower	O	O	O	O	O
Dress your lower body	O	O	O	O	O
Get on and off the toilet	O	O	O	O	O
Get up from the floor	O	O	O	O	O
Balance while standing	O	O	O	O	O
Stand for one-half hour	O	O	O	O	O
Pick up an object from floor while standing	O	O	O	O	O

	Very easy	Easy	Slightly difficult	Very difficult	Cannot do this activity
Get up from a chair	O	O	O	O	O
Get into and out of a car	O	O	O	O	O
Walk around indoors	O	O	O	O	O
Walk outside on uneven ground	O	O	O	O	O
Walk in bad weather (e.g., rain, snow, wind)	O	O	O	O	O
Walk up to two hours	O	O	O	O	O
Walk up a steep ramp	O	O	O	O	O

	Very easy	Easy	Slightly difficult	Very difficult	Cannot do this activity
Get on and off an escalator	O	O	O	O	O
Climb one flight of stairs with a rail	O	O	O	O	O
Climb one flight of stairs without a rail	O	O	O	O	O
Run one block	O	O	O	O	O
Carry a plate of food while walking	O	O	O	O	O

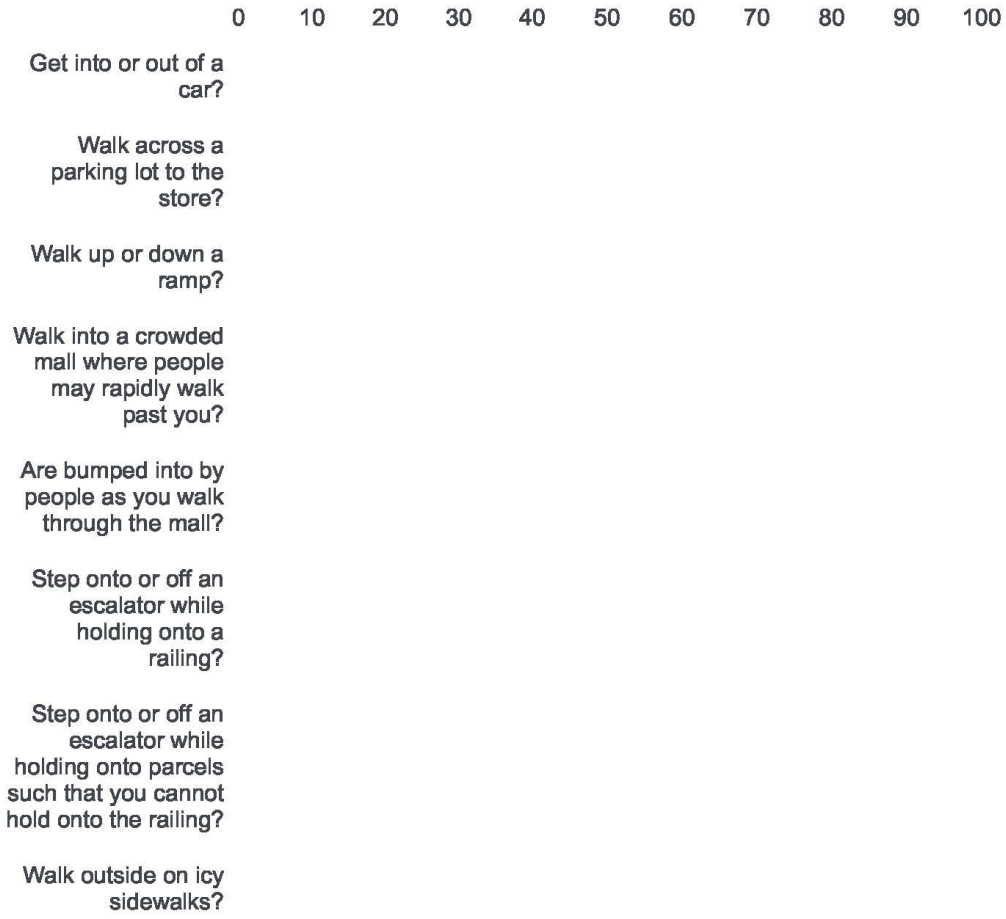
	Very easy	Easy	Slightly difficult	Very difficult	Cannot do this activity
Put on and take off prosthesis	O	O	O	O	O

Activities-Specific Balance Confidence (ABC) Scale

For each of the following activities, please indicate your level of self-confidence by choosing a corresponding number from the following rating scale in 10% increments (0% = "No confidence", and 100% = complete confidence).

How confident are you that you will not lose your balance or become unsteady when you...

	0	10	20	30	40	50	60	70	80	90	100
Walk around the house?											
Walk up or down stairs?											
Bend over and pick up an item from the front of a closet floor?											
Reach for a small can off a shelf at eye level?											
Stand on your tiptoes and reach for something above your head?											
Stand on a chair and reach for something?											
Sweep the floor?											
Walk outside the house to a car parked in the driveway?											



Modified Falls Efficacy Scale

On a scale of 0 to 10, please rate how confident you are that you can do each of the following activities with your prosthesis without falling.

0 = "not confident/ not sure at all"
5 = "fairly confident/ fairly sure
10 = "completely confident/ completely sure"

* If you have stopped doing the activity partly because of being afraid of falling, score a 0.

* If you do not currently do the activity for other reasons, please rate that item based on how you perceive you would rate it if you had to do the activity today.

	0	1	2	3	4	5	6	7	8	9	10
Get dressed and undressed											
Prepare a simple meal											
Take a bath or a shower											
Get in/out of a chair											
Get in/ out of bed											
Answer the door or telephone											
Walk around the inside of your house											
Reach into cabinets or closet											
Light housekeeping											
Simple shopping											
Using public transport											
Crossing roads											
Light gardening or hanging out the washing (rate whichever is more commonly performed)											
Using front or rear steps at home											

Virtual Testing Interest

Would you be willing to be contacted to participate in a related virtual prosthesis mobility testing study?

- ○ Yes
- ○ No

Do you have access to good internet service for uninterrupted zoom video conferencing?

- ○ Yes
- ○ No

Do you have a caregiver or family member who can be with you during the virtual testing procedure?

- ○ Yes
- ○ No

If you would like to participate in the subsequent virtual home-based brief walking assessment and interview, please contact Dr. DadeMatthews
odd0003@auburn.edu
Thank you.

Powered by Qualtrics

Appendix 3: Virtual Study Informed Consent

School of Kinesiology
301 Wire Road
Warrior Research Center
Auburn University, Alabama 36849-5323

Telephone: (334) 844-4483
Fax: (334) 844-1467

(NOTE: DO NOT AGREE TO PARTICIPATE UNLESS IRB APPROVAL STAMP WITH CURRENT DATES HAS BEEN ADDED TO THIS DOCUMENT.)

INFORMED CONSENT

"Quality of Life, Functional Performance, and User Satisfaction of Lower Limb Prosthesis Clients"

You are invited to participate in the above titled research study. This study is voluntary, you do not have to participate. The procedures, risks, and benefits are fully described in this consent form. The purpose of this study is to explore your level of satisfaction with your prosthesis and your ability to complete daily tasks. The study is being conducted by Dr. 'Gbenga DadeMatthews, MD and PhD candidate at the Warrior Research Center, under the direction of Dr. JoEllen Sefton, Professor, and director of the Warrior Research Center, Auburn University Department of Kinesiology. You are invited to participate because you are currently using a lower limb prosthesis, are age 19 or older, do not have stroke or seizure disorder, and are not currently pregnant.

What will be involved if you participate?

Your participation is completely voluntary. This study will involve a video assessment of your ability to complete some functional movements in your home virtually using Zoom. We will send you any tools you need to complete the tasks, and we will teach you how to use zoom and complete the tasks before the assessment. You will be in your home environment wearing your lower-limb prosthesis and usual footwear and a helper must be present with you during the virtual testing procedure. The task will involve you sitting in a chair, getting up and walking a short distance, and returning to sit in the chair. We will time how long it takes you to complete this task. We will also have you complete a 20 question survey about your ability to complete daily tasks. The testing should take about 15 minutes of your time. There are few risks associated with your participation. You could fall, that is why we require a helper to be present. You may feel coerced into participating, please remember your participation is completely voluntary. Your name and other information will be collected and information protected. But there is a small risk of breach of confidentiality. We have many measures in place to prevent this from happening.

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Precautions we will take to prevent these risks and discomforts

d) Risk of coercion: To minimize the risk of coercion, we will remind you in all communications that your participation in this study is completely voluntary and that there cannot be any negative consequence for choosing not to participate.
e) Risk of fall: This is comparable to the risk of fall while walking at home in an unsupervised environment. The presence of a helper during the walking test would be required, to minimize this risk.
f) Breach of confidentiality: To minimize this, all data obtained would password-locked, anonymized, saved on an external hard drive and kept in a locked cabinet in KINE room 241. In addition, faces and any other identifying material in the Zoom video recordings will be blurred, password-locked, saved on an external drive, and kept in a locked cabinet in KINE room 241. Only the project investigators will have access to the files. After a period of three years, the recordings will be destroyed.

What are the possible benefits of participating in this research?

c) There are no direct benefits to you if you participate in this study.
d) Findings from this study aim to benefit the practice of prosthetists by improving patient experience and quality of life.

Will I have to pay for anything if I take part in this research?

a) No, there are no costs associated with your participation in this study.

Will I be paid for my participation in this research?

a) You can choose to be sent a $50 Amazon gift card after completing the virtual test.

Any data obtained in connection with this study will remain anonymous. We will protect your privacy and the data you provide by disabling the collection of any identifiable information through the Auburn University Zoom platform. The data obtained and the Zoom video recording will be de-identified and retained for three years, then destroyed. Information collected through your participation may be presented at local, regional, and national professional conferences and published in a professional journal.

What if I decide not to participate in this research?

Your participation in this research is voluntary. You may decline to participate now or stop taking part in this research at any time without any penalty. Deciding not to participate now or withdrawing later does not harm or in any way affect current or future relationships with Auburn University, the School of Kinesiology, or the Warrior Research Center. If you choose to withdraw, your data can be withdrawn if it is identifiable.

If you have questions about this study, please contact Dr. 'Gbenga DadeMatthews at odd0003@auburn.edu or (334) 524-7472 or Dr. Sefton at jmsefton@auburn.edu or (334) 844-1694.

If you have questions about your rights as a research participant, you may contact the Auburn University Office of Research Compliance or the Institutional Review Board by phone (334) 844-5966 or e-mail at IRBadmin@auburn.edu or IRBChair@auburn.edu.

HAVING READ THE INFORMATION ABOVE, YOU MUST DECIDE IF YOU WANT TO PARTICIPATE IN THIS RESEARCH STUDY.

CONSENT DECISION OF RESEARCH PARTICIPANT

Please sign the form below and return to the investigator or click on the link or scan the QR code below to make your decision.

https://auburn.qualtrics.com/jfe/form/SV_0357bCWwAXfdJ0W

Your consent indicates your willingness to participate in the study. It also indicates that you have read the information provided above, you have been given an opportunity to ask questions, and they have all been answered to your satisfaction.

_____

Name of Participant

_____ _____

Signature of Participant Date

PERSON OBTAINING CONSENT

My signature certifies that the participant signed this consent form in my presence as his/her voluntary act and deed.

_____

Printed Name of Person Obtaining Consent

_____ _____

Signature of Person Obtaining Consent Date

Version Date (date document created): 18MAY2022

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Appendix 4: LEFS Survey

63125

Client ID

OPUS: Lower-Extremity Functional Status Measure

How easy, or difficult, is it for you to:	Very easy	Easy	Slightly difficult	Very difficult	Cannot do this activity	Do you typically wear an orthotic or prosthetic device to perform this activity?	
						No	Yes
1. Get into and out of the tub or shower	O	O	O	O	O	O	O
2. Dress your lower body	O	O	O	O	O	O	O
3. Get on and off the toilet	O	O	O	O	O	O	O
4. Get up from the floor	O	O	O	O	O	O	O
5. Balance while standing	O	O	O	O	O	O	O
6. Stand for one-half hour	O	O	O	O	O	O	O
7. Pick up an object from floor while standing	O	O	O	O	O	O	O
8. Get up from a chair	O	O	O	O	O	O	O
9. Get into and out of a car	O	O	O	O	O	O	O
10. Walk around indoors	O	O	O	O	O	O	O
11. Walk outside on uneven ground	O	O	O	O	O	O	O
12. Walk in bad weather (e.g., rain, snow, wind)	O	O	O	O	O	O	O
13. Walk up to two hours	O	O	O	O	O	O	O
14. Walk up a steep ramp	O	O	O	O	O	O	O
15. Get on and off an escalator	O	O	O	O	O	O	O
16. Climb one flight of stairs with a rail	O	O	O	O	O	O	O
17. Climb one flight of stairs without a rail	O	O	O	O	O	O	O
18. Run one block	O	O	O	O	O	O	O
19. Carry a plate of food while walking	O	O	O	O	O	O	O
20. Put on and take off orthosis or prosthesis	O	O	O	O	O		

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Appendix 5: Virtual TUG Record

Timed Up and Go Test (TUG) Scoring Sheet

Participant number: _____

Date: _____

Age (years): _____

Sex: _____

Time to complete TUG (seconds): _____

Lower-Limb Prosthetic Device Used:

Foot: _____

Ankle: _____

Below Knee: _____

Above Knee: _____

Hip: _____

Unilateral: _____

Bilateral: _____

Other:

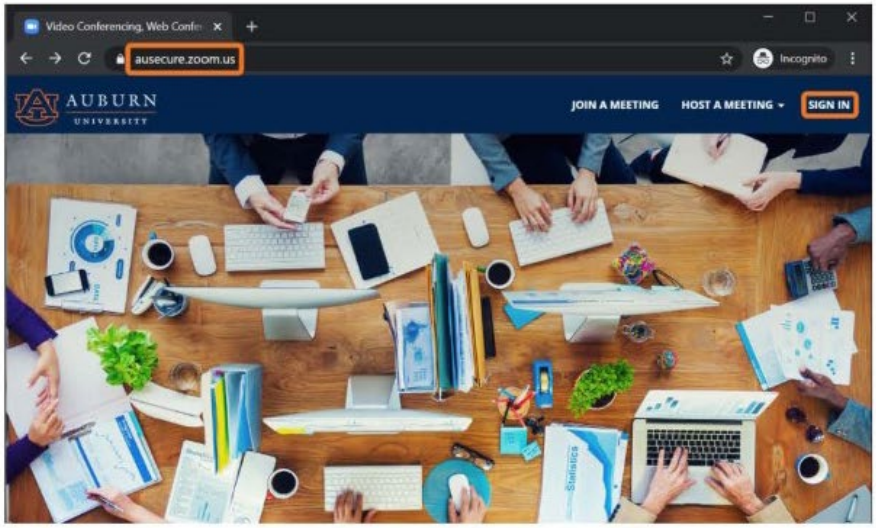
Stopped to rest: ____

Appendix 6: AU Secure Screenshot

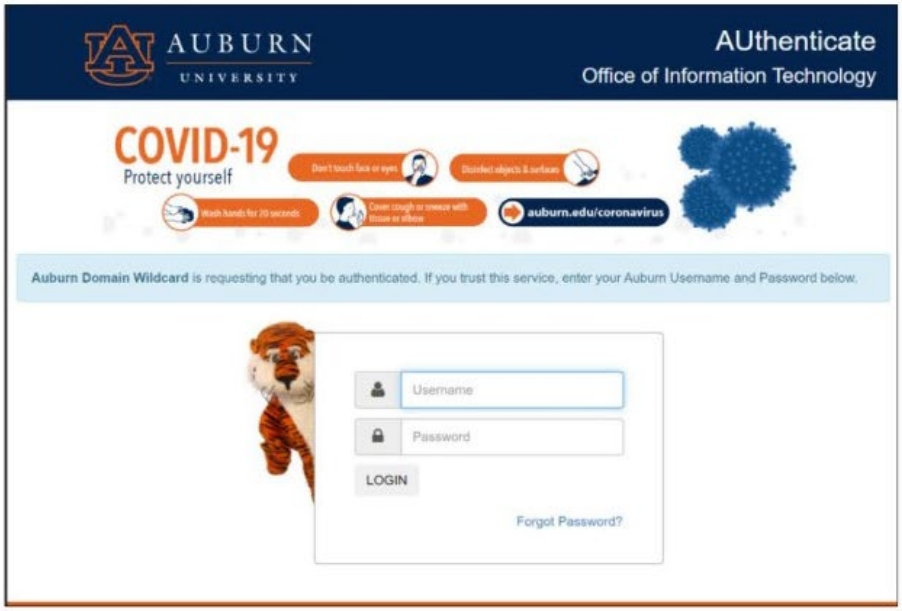
HIPAA-Compliant Zoom

Auburn University has a HIPAA-compliant version of Zoom available at ausecure.zoom.us. The secure version of Zoom will not work with the Canvas app, but meeting invitation links may still be shared by pasting the invitation into an announcement or page within your course. You may switch your account to the HIPAA-compliant Zoom by following these instructions:

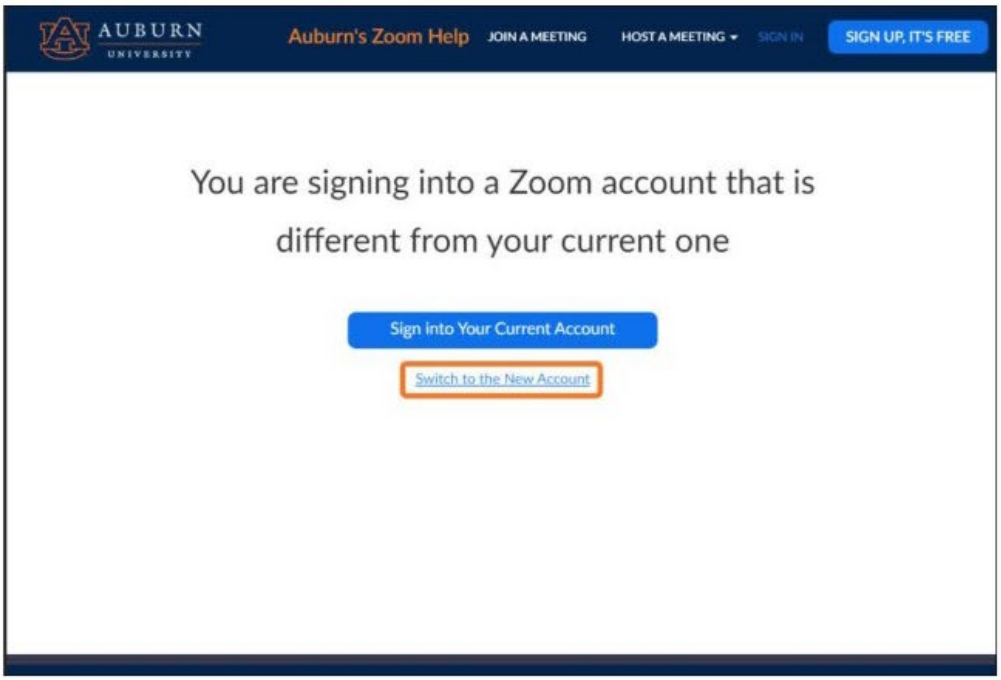
1. Navigate to ausecure.zoom.us – please note that you may need to use a different browser, or a private browsing window to reach this page if your browser redirects you to **auburn**.zoom.us. Verify that your browser is on **ausecure**.zoom.us before proceeding.



2. Click sign-in on the top right and log in with your AU credentials.



3. When prompted, choose the link to "Switch to the New Account".



4. Click the blue button that reads 'I Acknowledge and Switch'. You will now be logged into the ausecure version of Zoom.