Development and Efficacy of a Mobile Real Time Visual Feedback System for Gait Training in Lower Extremity Limb Loss

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Gait dysfunction in those with trans-femoral and trans-tibial limb loss can lead to degradation of the intact and surgical limb, causing a risk of osteoarthritis and decreased bone density. Those affected with lower limb loss are still rising in number, and gait deviations remain a significant factor in function and quality of life for these individuals. Chronic compensation from dysfunctional gait patterns have been shown to have additional consequences of low back pain and increased energy cost. Real time visual feedback follows the motor learning theory that internalization of a new neuromuscular pattern is enhanced when the patient's focus is directed externally. We developed a system to provide real time mobile visual feedback (MOVISU-FIT) for gait training using kinetic data derived from the user's prosthetic limb itself and displayed wirelessly to smart glasses. Creating mobility in combination with real time knowledge of performance during gait training with MOVISU-FIT enhanced automaticity therefore retention beyond the initial frame of rehabilitation.

Our goal was to develop, and assess the feasibility and efficacy of, a gait training system that provided real time visual feedback derived from kinetic sensor data within the prosthetic limb and was mobile and wearable for those with lower limb loss. The development then allowed preliminary pilot data analysis of the efficacy of this type of training on gait performance (symmetry and frontal plane pelvic motion), pain and functional measures. In addition, this project and its findings expanded our ability to assess the impactful factors on

not only this type of training and feedback, but also on gait parameters that were retained beyond the end of training in this patient population.

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List of Abbreviations

%stance	Percent Stance
DPT	Doctor of Physical Therapy
ADL	Activities of Daily Living
API	Application programming interface
app	Application, Mobile phone/tablet
APTA	American Physical Therapy Association
BT	Bluetooth
CSV	Comma Separated Variable
DCM	Data Collection Module
DPT	Doctor of Physical Therapy
Fz	Force in the Z Axis (Along Pylon)
Hz	Hertz
ICCs	Intra Class Correlation Coefficents
IL	Intact Limb
IRB	Institutional Review Board
KgF	Kilogram-force
LCI-5	Lower Extremities Capability Index
LE	Lower Extremity
LoA	Limits of Agreement
Mdiff	Mean Difference

MOVISUFIT Mobile Visual Feedback in Real Time

N Newtons

OA Osteoarthritis

PFJP Patellofemoral Joint Pain

PI Primary Investigator

PLP Phantom limb pain

PT Physical Therapist

PTs Physical Therapists

RLP Residual Limb Pain

RTMVF Real Time Mobile Visual Feedback

SD Standard Deviation

SDDiff Standard deviation for the mean difference

SUS System Usability Scale

TF Transfemoral

TT Trans-tibial Limb Loss

UMPC Ultra-mobile personal computer

US United States

USB Universal Serial Bus

V0 Initial prototype of feedback system

V1 Version 1

V2 Version 2

V3 Version 3 Prototype

Preface

This PhD. Dissertation contains the results of research and development undertaken at the Department of Rehabilitation Science and Technology of the University of Pittsburgh and the Master of Science in Orthotics and Prosthetics Department and Program. It was conducted under the supervision of Dr. Goeran Fiedler between June 2015 and February 2020. This work was made possible through funding from the Milbank Injured Solder's Award from the Foundation for Physical Medicine and Rehabilitation, the Pitt Innovation Challenge (PInCh) Award through the Innovation Institute and the Clinical and Translational Science Institute (CTSI). University of Pittsburgh, and the National Science Foundation (NSF) First Gear and Second Gear Awards.

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during difficult times. He was my first phone call after losing my father. I also would not have been able to conduct this work without the support and guidance of Dr. Mary Ann Miknevich who has been countlessly gracious in her time and support. I would like to remember Jon Akins, PhD. He was instrumental in Dr. Fiedler agreeing to take me on as a student and I sought his advice and counsel many times even before moving to the RST department. He was a doctoral student as well when he taught one of my lectures in Biomechanics and assisted my getting in touch with Dr. Chambers.

The MSPO program faculty and staff have also been a critical part of my abilities to pursue this research with Bob Maguire and Zachary Kitzmiller Anzelone assisting during extended hours and providing in-depth education and support in the area of Orthotics and Prosthetics. Special thanks also are to the following students that have been critical team members; Austin Frownfelter, Kyle Umanski, Liang Zhou, Kristianna Mitchell, Katee Coleman, and Ish Davis and Joe Gao. The CTSI members of PInCh are due a thank you I cannot express enough; Dana Farrell, Dr. Michael Flock, and Phillip Cicco. Without their support the project would not be where it is today. I would like to thank Dr. Garrett Grindle, and Josh Brown for their efforts and support when the project needed to be feasible and able to progress.

Finally, I would like to remember my father, Kenneth Kutina PhD. To try to describe the intelligence, humor, and love and support I received from my father in pursuit of my academic dreams is almost impossible. He passed away during this journey and it is because of him that I have the drive and keen interest in academia that I do. He was with Case Western Reserve University for the tenure of nine presidents from Senior Associate Dean of the Medical School, to Vice President for Institutional Planning of the University. He was also a triple

graduate of the University. I hope I have made him proud. He knew and stated I had excellent mentorship on this dissertation committee. Thank you finally, to my mother for her strength, her example, and support beyond measure, and my big brother, David, who has always championed my success and who we both know is the smarter one of the two of us.

1.0 Introduction

1.1 Motivation

Gait dysfunction is an impairment that can affect multiple patient populations, both neurologic and orthopedic, and become chronic and linger for years [1-7]. There are subsets of the patient population that are particularly vulnerable to problematic and chronic gait dysfunction such as; People with Parkinson's, Stroke, Osteoarthritis (OA), and Limb Loss [6, 8-13]. In 2007, patients with limb loss compiled approximately 1.7 million people and it has been estimated that by 2050, this rate will more than double to 3.6 million in the United States [14-17]. A five-year study following those with lower limb loss reported almost 34% of participants not being able to walk two years after surgery [18]. This is of clinical concern in that forced compensations from the loss of sensory feedback, neuromuscular control, and along with a rise in concomitant pain that affect forward propulsion and weight acceptance throughout the gait cycle, could have the consequence of destructive secondary joint issues and increased energy cost [19]. In addition, lack of plantar flexion and normal ankle motion in artificial limbs are linked to most gait deviations in those with limb loss, including asymmetrical gait timing. Other typical deviations include trunk shifts, which can result in low back problems as well as increased misdirected loads through the ankle, knee and hip of both the surgical and intact limbs, putting the patient at higher risk of cartilage degradation and secondary complications of arthritis [19]. Recent studies have demonstrated that not only can the kinematic variables that are a part of these dysfunctional lower extremity movement patterns be retrained, but also retained [8, 20-24]. Therefore, if an improved gait pattern can be re-trained, perhaps we could not only avoid further degradation of the low back

or contralateral limb, but also restore neuromuscular support and appropriate load bearing on the affected side. Gait retraining as an intervention has demonstrated promise in many of the aforementioned populations, including the limb loss population [8, 25-28]. This could lead to improved lower extremity function, which leads to improved energy consumption and extended life of the prosthesis as well [23]. Several studies have investigated the use of treadmill training and treadmill training combined with real-time feedback, including visual feedback, and have demonstrated positive results [29-31]. However, of the studies that have been performed on gait retraining very few have been performed on the limb loss population, and it does not appear that there have been any recent studies performed utilizing real-time visual feedback that is originating from the user's prosthesis itself. Symmetry has been an issue in gait in those with limb loss, and as analysis has evolved from only qualitative to quantitative measurements of temporal, kinetic and kinematic variables and combinations of all, the most prominent asymmetries have been determined as shortened stance times and decreased ground reaction forces [31-33].

Real time Visual Feedback with feedback parameters derived from the user's prosthesis itself has allowed new insights into gait rehabilitation in this population and facilitate the investigation into potential biomechanical variables that could be provided as feedback to improve gait. Feedback and training using derived quantitative feedback, if successful, could allow increased efficiency in identifying problematic regions of biomechanical dysfunction, improve patient compliance as it is tailored to the patient specifically and not based solely on clinical observation, and also provide a new gateway of remote training. The clinician will have the possibility of identifying parameters that have not been available to be provided as feedback thus far and determine their potential effects, whether harmful, counterproductive, or whether they may improve patient function. Improved portable methods of gait training have been reported as highly

desirable by current Physical Therapists attending a large APTA Conference during our own customer discovery and surveying during the development phase. This was performed via the 1st Gear Program through the National Science Foundation (NSF) program for innovation and development within the University of Pittsburgh. Additional surveys were acquired from other leaders in the limb loss rehabilitation field locally and Veterans' Association Rehabilitation, as well as sports and outpatient orthopedics for a variety of settings and populations. Many Clinicians reported they are forced to use apps on their own mobile phones, which delineated for us how clinicians are forced to devise this treatment on their own currently and demonstrates their desire for improved quantitative data output for gait analysis.

The overall goal of this research was to develop and test the efficacy of a real time mobile visual feedback (RTMVF) gait training system for those with lower limb loss on the primary outcome measures gait symmetry, pain and function (as measured by the Six Minute Walk Test. A secondary purpose of this study was to examine the effects of the program on improving gait performance as measured by frontal plane pelvic motion, and patient reported function as measured by the Health and Quality of Life, Functional Status Measure, and Lower Extremity Capabilities Index-5 (LCI-5) surveys. Findings of this project will expand the knowledge of how well this form of training can affect the retention of retrained neuromuscular patterns gained via the RTMVF gait retraining program in this patient population, its usability, and it's potential as an augmentation to improve current treatment strategies.

The work described here is innovative in that it progresses from the previous limitations noted in the literature and combines two mobile implementations. In this research study we implemented a technique that has not been evaluated previously, combining mobile assessment of outcomes and real time visual feedback that is delivered directly from the user's prosthesis. The

results from this work will have significant applications and potential, in that it is implementing extrinsic feedback, which has previously been reported to increase motivation and retention, as well as internalization of motor learning [27, 29, 34, 35]. This was displayed on smart glasses, creating a mobile environment in which the training can occur with novel feedback from the integrated sensor. The integrated sensor being utilized has been currently found valid for the measurement of joint forces and moments [36]. This, in combination with mobile assessment of kinematic and temporal-spatial gait outcomes, completes a novel way of training and assessing improvements in dysfunctional gait kinematics. It has been demonstrated that those with limb loss have greater difficulty on unlevel surfaces, and truly mobile gait retraining allowing for real time visual feedback while walking outside of the clinic has not been tested [37]. It is our goal that the visual feedback be individualized per patient and simplified as appropriate. To reach this point of integration and success, it is critical for the patient to understand what gait corrections provide the desired feedback and learn to self-correct. Through this work remote training can be an option and patients may be able to take the system home which could improve compliance and as a result, functional outcomes. Therefore, the ultimate knowledge gained from this study will provide a foundation for the appropriate application and use of these new technologies in the rehabilitation of gait dysfunction.

1.2 Clinical Complications and Gait Dysfunction

Mobility, return to function, and return to normal gait is an ever-prevalent issue amongst variable populations. Gait dysfunction is known to occur with many underlying health conditions. Prominent risk factors for gait deviation have been noted, such as; hypertension, stroke, and

arthritis, and every year about 795,000 Americans suffer a stroke, and 185,000 undergo major limb amputation [34, 38-40]. In 2007 it was estimated that among adults in the United States (US) adults, "nearly 27 million have clinical osteoarthritis and another 5.0 million have fibromyalgia" [41, 42]. For example, a previous study determined knee osteoarthritis (OA) presents as a risk to nearly 50% of the population [16, 43]. However, when a traumatic lower limb loss occurs, the prevalence of knee OA was found to be as high as 27% (men 28.3%, women 22.2%) and of hip OA as high as 14% (men 15.3%, women 11.1%) when compared with the sample cohort of the general population [44]. This previous study compared the prevalence of such issues in age-adjusted men and women in this cohort of healthy individuals from the general population and the findings of knee OA were far lower than those with traumatic lower limb loss (men 1.58% and women 1.33%) as well as hip OA (men 1.13% and women 1.33%) [44]. It was not found that the level of limb loss decreased the risk and implies that clinical practices and prevention to reduce the risks of OA are prudent in the limb loss community.

Gait dysfunction is lingering after current rehabilitation programs and treatment. Deviations after Total Hip Replacement, a common intervention for hip OA, have been reported to linger for one to four years [4, 6, 45-47]. Gait deviations after perceivably less complex injuries, such as Achilles tendon repairs, are noted greater than 10 years after surgery [5]. Novice runners are increasing in the US by approximately one million per year, and of those with lower extremity injury and knee pain, 60% are returning to their doctor within a three to five-year period even if they have received one of the current rehabilitation programs [48, 49]. However notably, a recent study of runners with lower extremity injury demonstrated training with real time visual feedback reduced the risk of injury one year later by 62% [49].

There are a variety of additional conditions which have been associated with problematic and chronic gait dysfunction, such as; Parkinson's, Anterior Cruciate Ligament (ACL) injury, Patellofemoral Joint Pain (PFJP) and Limb Loss [8, 30, 33]. Individuals with limb loss, who compile approximately two Million people in the US, present with similar deviations to the other populations at risk of gait dysfunction mentioned previously [14]. Inappropriate load bearing or asymmetry during gait in people with limb loss has been shown to increase the risk of OA predominantly of the involved limb [44].

With the expected aging of society and increasing prevalence of obesity and other lifestyle diseases, the number of people in need of gait training will further rise. For example, older adults now comprise a much greater component of the population than ever before, and factors associated with assessment and treatment of mobility issues are critical. In a recent study of 488 community-residing men and women aged 60 and older, 32.2% of participants presented with impaired gait [13]. In an earlier study of similar adults, gait abnormalities were associated with greater risk of institutionalization and increased mortality rates [16]. Regardless of the patient's age, gait deviations increase the risk of joint degeneration [50, 51], accidental falls and reduced gait economy [52], thus limiting mobility and participation. In a 2007 study, 59 Million Americans reported back pain within the last three months [53], and chronic back pain is a risk factor associated with gait deviations.

1.3 Gait Dysfunction in the Limb Loss Population

Gait dysfunction in those with trans-femoral and trans-tibial limb loss can lead to degradation of the intact and surgical limb, causing a risk of OA and decreased bone density.

Chronic compensation from dysfunctional gait patterns has been shown to have additional consequences of low back pain and increased energy cost. Annually, 185,000 upper or lower extremity (LE) amputations are performed [40, 54]. According to a 2010 survey, of the service members with traumatic limb loss from Vietnam War and Operation Iraqi /Enduring Freedom, 78.2% and 90.5% respectively are using prosthetic devices to improve functional mobility [55-57].

Evidence suggests that fewer than half of individuals with transfemoral limb loss meet or exceed pre-injury levels of mobility within a year [58]. This denotes a significant need to provide additional modes of Physical Therapy (PT) gait interventions to maximize and maintain gait performance [1, 14]. More than half of lower limb prosthesis users suffer from pathological back pain, with 63% reporting gait difficulties and 49% reporting pain in the non-surgical limb [59-61]. Fall risk is increased in prosthesis users, with 52% reporting one or more falls in the preceding year [62]. Inefficient gait patterns, if left unchecked, can cause increased energy consumption and decreased gait speed [23]. Once functional impairments begin to occur, including decreased gait speed needed for crossing the street and decreased walking endurance to perform shopping tasks, psychological consequences are not far behind [1, 63].

Rehabilitation following limb loss is a complex process involving physical and psychological components [57, 64]. Rehabilitation of walking, and in those with gait difficulties, involves the re-education of motor timing, and recreating automatic unconscious patterns. Pain-related neuromuscular deviations can also become destructive.

Changes in spatiotemporal patterns frequently create inherent gait asymmetries in this population. Musculoskeletal structures may be involved increasingly in performing roles in stabilization or weight transfer during walking that they were not designed to perform, secondary

to the gait deviation. Therefore, of consideration should be the impact these gait deviations have on pain. If these imbalances can cause overuse syndromes in the intact limb, as well as chronic muscular and joint integrity issues throughout the trunk and hip, pain must be considered as a possible consequence. Accommodating the prosthesis, through hip hiking or vaulting for example, can put patients at risk for pain in the intact limb, residual limb, as well as their back. In a 2016 literature review of gait training interventions in those with limb loss >60%, report they have experienced back pain secondary to these issues and almost 50% report pain in their intact limb (IL) [65]. Nearly 95% of the individuals with limb loss surveyed reported experiencing more than one type of pain in the previous four weeks, which was not limited to gait-related pain. Phantom limb pain (PLP), as well as residual limb pain (RLP) that is a consequence of overuse injuries from gait compensation, is highly reported and can be disruptive to gait training [59, 61, 66]. PLP was reported most often (79.9%) [65]. In this systematic review, the pain is not inconsequential with those who reported pain rating it severe (7-10) on a 10-point scale. [65]. In addition, 25% of those, regardless of the pain cause or type, reported it to be extremely bothersome [65]. The frequency, duration and intensity of both PLP and RLP are related to levels of disability reported by the Chronic Pain Grade [66]. One study reported that back pain may be an overlooked problem after amputation, stating that 71% of their participants reported it as an issue [67]. Typically, these symptoms are seen in the preceding four weeks and this should inform follow-up periods in research studies.

The long-term consequences of asymmetric gait and improper joint loading that have been documented in patients with lower limb loss carry over into functional activities as well [1]. Decreased gait speed can also be a consequence of pain and asymmetrical gait. This begins to

deplete quality of life (QOL) as pain, whether PLP or RLP has been directly linked to decreased prosthetic use [63].

However, very few studies have examined loading of the lower limb as a method of intervention or feedback and training, to also improve deficits in symmetry [1, 68, 69]. Auditory feedback as an augmentation to training has been applied to make the prosthesis user aware of successful and more functional loading of their involved limb however, this was only discussed in two additional studies [70, 71].

1.4 Gait Training and Rehabilitation

Gait performance and modification based on real time feedback of kinetic variables, versus raw video or mirror, has been demonstrated to significantly improve problematic gait parameters in patient populations with lower extremity orthopedic issues such as knee OA, and PFJPS [8, 21, 29, 30, 68]. Previous promising work on gait retraining has included the OA population, both of the knee and hip, and the limb loss population [23, 31]. It is important to note that intervention upon a gait deviation either in a healthy patient (eliciting more toe out motion during loading to unload the medial compartment) or one with severe impairment can elicit meaningful effects, for example a significant reduction in knee abduction moment for OA patients, or decreased pain and dynamic valgus in those with PFJPS, all related to problematic biomechanical dynamics [6, 23, 72]. Therefore, if a dysfunctional gait pattern can be re-trained, perhaps we could not only avoid further degradation of the low back or contralateral limb, but also restore neuromuscular support and appropriate load bearing on the effected side [73].

It now appears critical to examine what mode of motor learning pattern may be most effective. A recent review of different learning approaches highlighted observational practice, focus of attention, feedback and self-controlled practice [74-78]. However, it has been reported that learning theories are not typically practiced within the limb loss rehabilitation population [79]. Historically, the treatment paradigm has been device-driven and predominantly trial and error without data related to optimization that end-users seek to maximize their return to function.

This study is addressing a reported need to close this gap between design, research, and clinical treatment as it will test an intervention that is multidisciplinary in design and implementation. The end-users in this case, those with limb loss, require expertise from a multitude of disciplines, and although this may be more difficult, to collaborate in this way, it does present a large potential for translational impact [80]. In summary, movement-related goals are necessary when considering the training for use of the device and rehabilitation of these individuals.

1.4.1 Gait Training and the Use of Feedback During Rehabilitation

Gait retraining with augmented sensory feedback has demonstrated the ability to improve dysfunctional LE impairments and resultant gait deviations that can cause secondary musculoskeletal issues [8, 23, 31]. Traditional sensory approaches include haptic feedback, auditory and visual feedback, including mirror retraining, as well as raw video and large-scale optical systems with instrumented treadmills (Figure 1) [22, 39, 44].

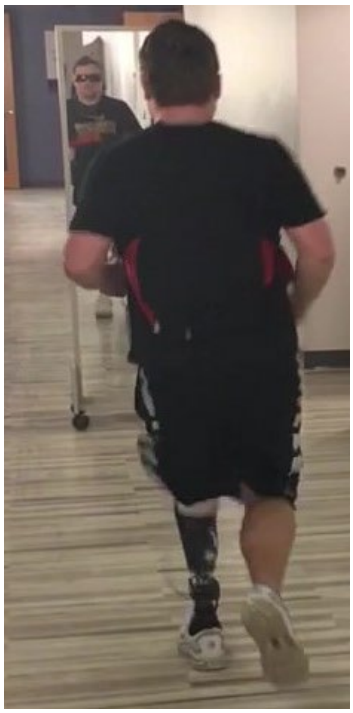

Figure 1 Real Time Visual Feedback Constrained to Mirror Retraining. This demonstrates the limit and lack of realism, and distraction the participant experiences.

Real time feedback, to enhance either kinematic or kinetic variables, has demonstrated immediate and with longer-term and more rapidly acquired effects on several gait biomechanical variables among various populations. However, very few studies have been performed within the limb loss population [24, 31]. Studies including sports medicine injuries and/or OA have demonstrated success with gait retraining using auditory feedback, as well as mirror retraining [22, 73, 81, 82]. Several studies have demonstrated retention of the pattern up to three to six months [29, 83, 84]. However, in a recent systematic review regarding real-time kinematic, temporospatial and kinetic biofeedback during gait retraining, only three out of seven studies reported follow-up testing [85]. In addition, due to the expense and tightly controlled laboratory conditions of many of these studies, the training is not being performed in a realistic environment where injuries or gait deviations typically take place such as ramps, slopes, or unlevel surfaces. The use

instrumented treadmills and motion capture systems to assess gait kinematic and temporal-spatial outcomes of gait retraining interventions have also been a limitation of previous work as it limits clinical translation.

With the continued influx of wearable sensors that have been deemed reliable and valid to measure patient gait performance outcomes, we used commercially available technology to provide gait evaluation, not only in a mobile fashion but also less expensive manner. This project has assisted in development towards clinical usage with the advancements in the wireless mobile application. This added functionality has the potential to provide clinicians with more accurate and easier reassessments of clinical outcomes by providing additional functionality of remote capabilities and quantitative data beyond qualitatively assessing gait when a patient returns between visits.

1.4.2 Gait Training and Real Time Visual Feedback

Gait training with real-time visual feedback has demonstrated significantly positive results as this allows the patient to receive immediate knowledge of their performance [8, 21, 86]. Visual feedback has been revealed as the fastest integration into the motor learning system [74-76]. Real time visual feedback follows the motor learning theory that internalization of a new neuromuscular pattern is enhanced when the patient's focus is directed externally. Video and mirror feedback can be used; however, limitations include the lack of mobility, realism, and enough quantity of steps the patient can review. It has been found that if a patient is being given cues that direct their attention inward (versus externally to a color cue), such as "think about how your leg is swinging forward" or "tighten your hip muscles", that this actually hinders and neurologically "constrains"

[87] motor learning (Figure 2). The patient literally becomes more self-conscious, at a physiological level.

Figure 2 Illustration of PI (DPT) Applying Verbal CuesThis Figure Depicts the Participant's Attention Becoming Internally Focused, Slowing Him Down. This is Demonstrating the Deterioration of Automaticity Secondary to Creating an Internal Focus of Attention (RTMVF Prototype V1).

Providing an external focus of attention, in a wearable mobile fashion, could facilitate the patient to develop more rapid improvement in their error detection and correction mechanisms which then more effectively become more automatic. Gait/running retraining with real time visual feedback as an intervention has demonstrated promise in populations including those with Athletic Overuse Injuries, OA, Parkinson's Disease as well as Limb Loss with findings of improvement within three weeks and retention of up to six months to a year [8, 26, 28, 88, 89]. This form of

feedback has again traditionally been generated using a laboratory instrumented treadmill and optical system (Figure 3).

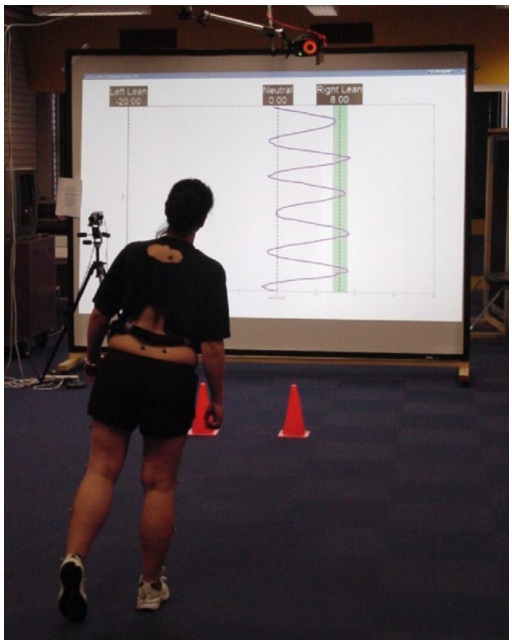

Figure 3 Real Time Biofeedback Set-up for Training and Gait Modification TrialsPhoto M.A Hunt et al. 2011.

One recent study using a Head Up Display noted immediate effects on multiple parameters. However, the population was heterogeneous and there was no longer-term follow-up [90]. This form of feedback has demonstrated immediate effects from kinetic changes to more symmetrical stance times during the gait cycle and improved energy consumption in individuals with limb loss [91]. Real time visual feedback has been compared to raw video, mirror retraining and computerized real-time visual feedback however, instrumented treadmills were used with no longitudinal follow-up. Many studies in this arena were on healthy individuals and not a symptomatic population, whereas our study examined a limb loss population that is truly demonstrating a gait deviation.

Rehabilitation training for individuals with limb loss typically involves gait retraining with verbal and tactile cues from a PT [92]. This may also include modes of learning, such as observation and demonstration as well as repeated practice or positive imagery. Typically, clinicians in outpatient clinics are limited to the use of a mirror or video for visual feedback, which have limitations in that only a limited portion of gait can be assessed for error and corrected by the patient [8, 21, 22, 73, 93-97]. For more continuous or timed feedback, a treadmill must be used however, this is not representative of a natural surface for training.

Real time feedback visual regarding peak vertical ground force and stance phase symmetry has yielded improvements in gait symmetry in the limb loss population. However, as shown in Figures 4, this was on an instrumented treadmill with a screen, and additional work has been scarce [31].

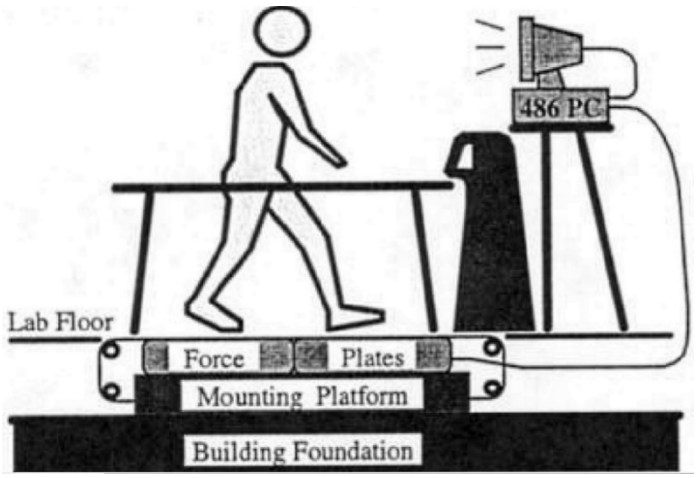

Figure 4 Cleveland Clinic Foundation (CCF) Treadmill Set-Up for Real-Time Gait Analysis and Visual FeedbackPhoto Dingwell et al, 1996

Improved function after shorter durations of RTVF training, such as two to six weeks, for the Patellofemoral Joint Pain Syndrome (PFJPS) patient population has also been previously

reported [29, 30]. All of these findings support the theory of an external focus of attention leading to greater internalization of motor learning [74-78, 98]. Symmetry has been an issue in gait for those with limb loss and as analysis has evolved from only qualitative to quantitative measurements of temporal, kinetic and kinematic and combinations of all, the most prominent asymmetries have been previously determined as shortened stance times and decreased ground reaction forces [33]. The feedback variables of choice considered for this project follow this prior evidence.

1.4.3 Feedback and Motor Learning During Gait Training

A primary criticism of recent studies is the lack of understanding as to what may allow a greater internalization of the retrained gait and a resultant "naturalized" pattern [24, 84, 99]. This study builds on the evidence found prior, by removing the feedback in a fade-out pattern to improve internalization [30], as well as implantation of a systematic training protocol and an external focus of attention (the effects of movement seen on the feedback display). These have both been demonstrated as training strategies to improve motor learning, however, have not been widely used in the limb loss population for gait retraining. If patients are relearning how to move, they are recovering previously learned strategies or possibly acquiring new compensatory movements [100]. Deliberate practice is advised to be combined with additional technological innovations [79]. However, in the field of prosthetics, both in rehabilitation and research, it appears the focus may be on advancing prosthetic technology, not on the training strategies [79].

With the previous evidence of improved function with decreased frequency and duration of training, and greater internalization of motor learning, these studies demonstrated that the external focus of attention has positive effects. They also found that it can increase retention of

up to three months post RTVF treadmill training when a systematic training protocol is used with the feedback and with a fade-out feedback approach to decrease dependency [29, 30] [74-78, 98] [30]. It has been demonstrated in the literature that providing continuous real time feedback leads to a decrease in actual learning and retention of motor skills. In these prior works, this decrease occurs secondary to the learner becoming dependent upon that feedback. It becomes a substitute for his or her own innate error-detection and error-correction capabilities [87]. Therefore, in this study the faded feedback approach as demonstrated by Noerhen et al in the PFJPS population [29] was implemented to avoid this dependence.

These approaches implementing real time feedback have both been demonstrated as training strategies to improve motor learning. However, they have not been widely used for those with limb loss for gait retraining [79]. At the time of a 2012 review, no published guidelines existed for a consistent paradigm of care for those with lower limb loss, including how to use their prostheses [79]. In another systematic review of exercise programs for patients with lower limb loss, there was a trend towards increased improvement of resisted exercises and walking, however, augmented therapy and feedback was not emphasized [101]. Rehabilitation studies for those with limb loss have focused on individual tasks, or strength and flexibility. In addition, few have utilized learning theories, particularly focus of attention, but rather practice, strength and conditioning, and specific tasks [28, 68, 92]. If more variable practice is performed versus training focused on individual skills, like donning or doffing the prosthesis, learners will become more adaptable, and their ability to recognize patterns and make corrections will increase. However, no published research at the time has assessed the feasibility and efficacy of applying variable versus constant practice in individuals with lower limb loss [79]. Clinicians could use various types of surfaces during gait training to create a more variable practice structure and that is a potential

direction, if feasible, this intervention could proceed [79]. Physical Therapists commonly use physical guidance in application of rehabilitation during gait training, which may be appropriate in patients with limb loss for safety considerations initially, however this could hinder retention of locomotor skills by creating dependence [79]. More importantly, no studies have been performed to truly assess how feedback should be gradually reduced, or in what fashion, in this population [79].

As stated earlier, an important criterion for motor learning and physical rehabilitation is the transfer of motor skills to contexts beyond those originally practiced [102]. It was noted that for continuous activities such as walking, variable practice has greater effects on internalization of motor learning [79]. Given the research that demonstrates that those with lower limb loss have difficulty adapting to uneven terrain, it seems reasonable to suggest that applying these theories of variable practice, would be quite appropriate [78]. In addition, mobilizing the training may allow for further progression to gait training involving varying speeds and terrain and will encourage the learner to compare and contrast the methods and strategies used at each session [103].

When considering motor learning, focus of attention has become an important aspect to training. The advantage of focusing on the outcome of one's movements (external focus) is that the performer's attention is shifted away from his or her own movements and toward the effects of those movements. The "constrained hypothesis theory" states that the focus of movement on one's own extremities promotes a more conscious type of control that constrains the motor system and decreases or disrupts utilization of unconscious or automatic processes. An external focus directs the attention of the learner on the effects of their movements (different walking strategies changing the colors in their display vs. focusing on their own extremity alignments) and reduces their attentional demands [74-78].

1.5 Conclusion

With the introduction of wireless abilities to provide sensing feedback from the prosthesis, rehabilitation research using RTVF could be projected into a multitude of exciting avenues. Ease of use and restoration of ambulation significantly predicted continued use of the prostheses in past studies and therefore implies the importance of the knowledge of gait retraining. [104]. Thus, we hypothesized that providing practice of adapting a participant's gait in response to visual cues, outside of controlled settings, would improve walking, particularly symmetry and endurance. Previous methods of providing the external visual cue have been mirrors, projection onto a screen, while on a treadmill or in a lab setting. Our system, we hypothesized, may demonstrate feasibility, and efficacy in providing these cues in a more realistic manner and independent of the environment. In preparation for future larger trials, our aim was to preliminarily test the efficacy of delivering real time visual feedback for feasibility and calculating potential sample sizes.

2.0 Development of Real Time Mobile Visual Feedback (RTMVF) System

2.1 Introduction

The primary goals of the initial prototype RTMVF V0 were to design a system that provided a patient visual feedback cues that were derived from an integrated load cell within the limb. The integrated load cell had available wireless, or very low profile and modest wired capabilities. The overall goal was to design a system based on the iPecs Sensor (College Park Industries, Fraser, MI) to provide real time feedback based on the kinetic data the sensor could provide. Discussions were conducted with the engineering team of the iPecs and many modifications were considered to obtain the high-quality data from the sensor. The purpose of the development included how to efficiently apply custom algorithms to the data, in real time, without creating excessive overhead in terms of computing burden and delaying the system. Figure 5 delineates the decisions that were conducted in the development process. The first step in the process was to have our first participant to train with and without verbal cues and gait corrections.

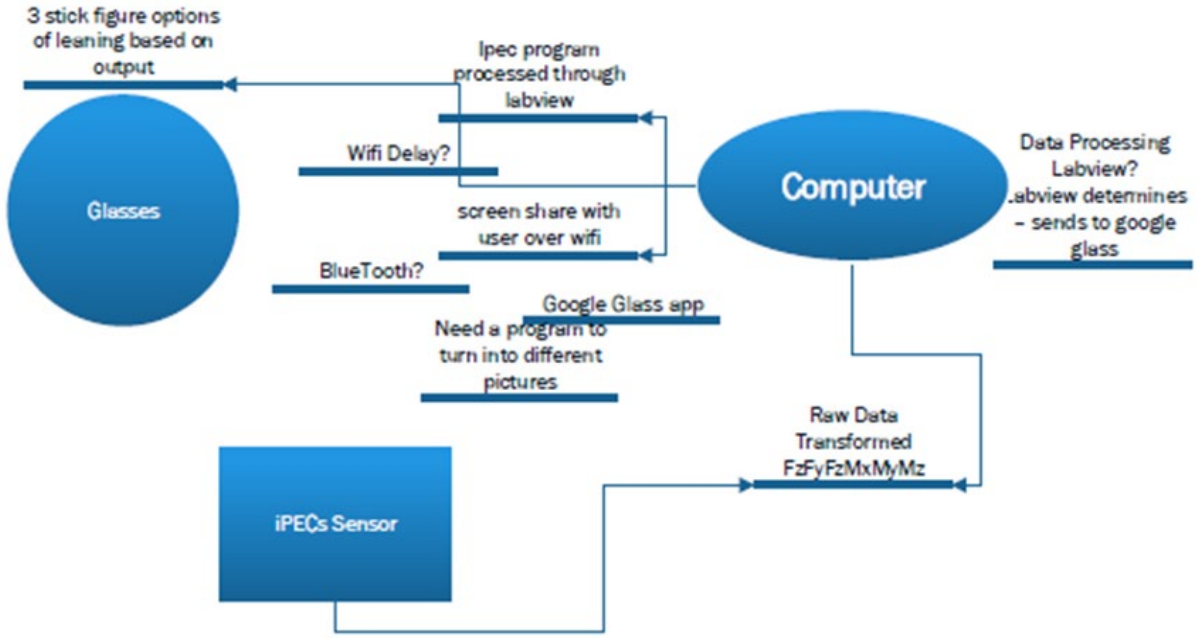

Figure 5 Initial Conceptual Framework Challenges and Connectivity

The goal was to then analyze the data compared to the cues and to determine what variables could not only be derived, but also be used as visual feedback. Real time feedback should not be overly complicated, nor should it demand upon the physiology to adjust too many training parameters at once. The initial idea was to compare what variables changed significantly when the clinician noted "good" on the video of the gait trials and to find ranges in corroborating kinetic data from the sensor that could be used as a feedback variable. If the range was determined to signify too low of an amount (for example Fz/axial force), too high (overcompensation) or the ideal range this would inform the decision to trigger the visual feedback cue. The color would then be chosen to signify a meaningful cue to the patient. For instance, if a variable related to loading the limb was too low, the color would be red, ideal would be green, and initially it was decided yellow would be a warning of overcompensation. There were issues that occurred with

this ambitious development, as the sensor did not have a time stamp and it was very difficult to synchronize the participant's steps with a graph of the vertical ground reaction force (Fz).

Initially, to determine the timing and accuracy of the color changes on the glasses display (based on step detection and the %stance calculated from that step) and wireless connectivity potential, the iPecs sensor was connected via Universal Serial Bus (USB) cable to the ultra-mobile portal computer (UMPC) where the real time calculation for gait events was performed. The Vuzix Smart Glasses (M100, Vuzix, West Henrietta, NY) were connected via Wi-Fi and screen sharing was implemented to determine if the glasses would change color appropriately with the change in %stance and to quantify delay (Figure 6). The connectivity of the Wi-Fi was inconsistent and the was a delay (greater than 800milliseconds) from the timing of the calculation shown on the screen, to the time the color was changed on the glasses and this was deemed too long (greater than 1 step). However, it has been reported that motor learning can be improved when knowledge of results (KR) is provided with a slight delay following the completion of the movement. It is stated that this allows the learner sufficient time to first evaluate his or her own movement strategy before then producing their own error estimates [79]. Therefore, some delay was not altogether harmful to the potential efficacy per these reports.

This prototype did allow us to see that we could provide rudimentary communication to the glasses from changes in loading the prosthesis integrated system. Furthermore, it was demonstrated successfully that changes in colors in the glasses could occur secondary to corroborating steps detected by Fz and calculations of %stance This was completed using a JAVA application with a C++ pipeline from the sensor to the JAVA program that communicated changes in colors in the glasses based on the single threshold algorithm using a 10N singular lower threshold crossing. The 10N threshold was based by previous work using the iPecs Sensor where

heel strike during stepping was found reliable at a lower threshold of 7N [36]. Give the exploratory nature of the initial prototype the lower threshold was raised to ensure the prosthesis was being loaded during a heel loading event. It was deemed early on by the PI that the color change was easily seen, not distracting, and the screen of the glasses did not obscure the patient's vision and potentially obscure foot placement obscure foot placement [105].

In the next iteration of testing, the step detection algorithm was tested for reliability and accuracy by testing on a prosthesis modified to be worn on the bent knee of several able-bodied testers.

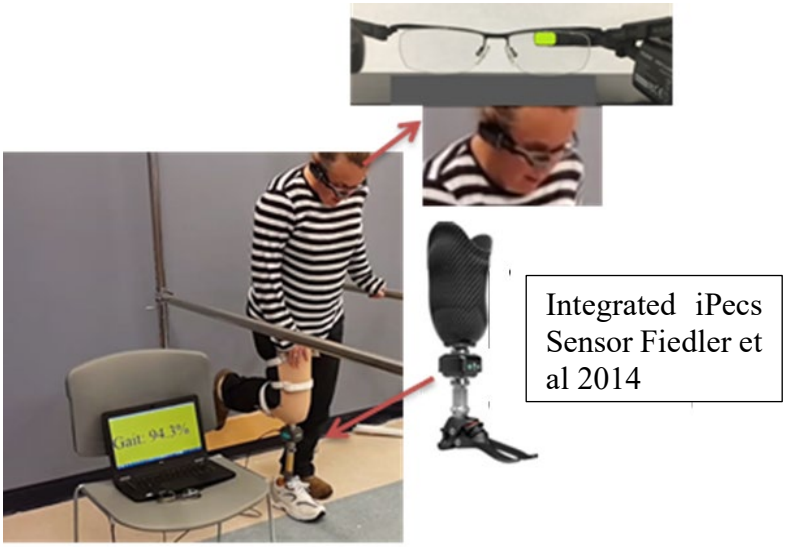

Figure 6 Prototype V0 of Initial Feedback Loop This initial prototype used screen sharing between the UMPC and the glasses. Real time feedback was relayed from the iPecs sensor after transformation by our custom algorithm into percent stance warnings. The PI was in parallel bars for safety only, secondary to kneeling on the pseudo-prosthesis, whereas the goal end-users were fully immersed in prosthesis.

2.2 Development of V1 Prototype

2.2.1 Data Flow, Hardware Design, and Connectivity

There were many design considerations that were considered towards the development of a prototype that could move beyond screen sharing given the limitations of Wi-Fi use (Figure 7). In addition, the algorithm appeared to have a delay greater than 800ms and need additional criterion to improve accuracy of detection of gait events. Therefore, progression was made to Prototype V1. Both prototypes receive data from the iPecs sensor, however given the testing outlined in subsection 2.1, using Wi-Fi was not a tenable solution given the need for a self-contained system that could be truly mobile. BT would provide this. In addition, screen sharing was going to create too long of a delay (greater than 800ms) and the %stance calculations using the single lower threshold was not depicting acceptable color ranges.

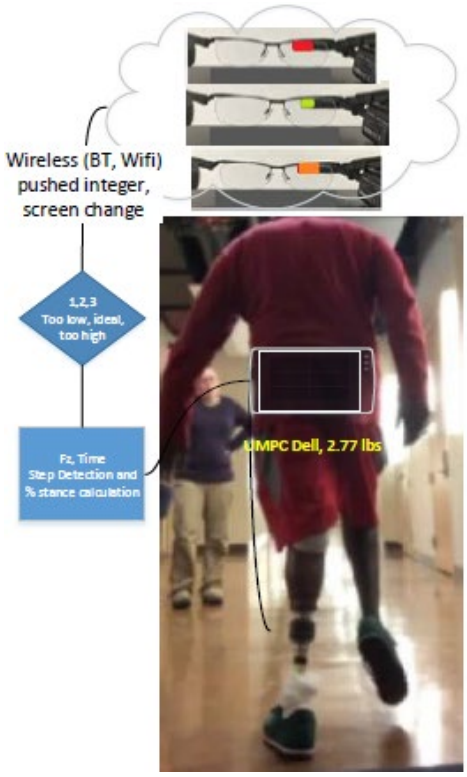

Figure 7 Design Concept Diagram of Proposed V1 Prototype.

An integrated sensor may allow more expansive gait analysis than qualitative or mobile phone based programs, or basic software options available currently in the clinic and creating a system where the feedback is provided on smart glasses, may provide even more individualized training than relying on data that is collected externally and post hoc from accelerometers, or pressure sensitive mats. The iPecs consists of a lightweight, small (4.57cm H × 7.1cm W × 8.1cm D) [36], six degrees of freedom (three forces and three moments) force transducer designed to fit easily into a lower limb prosthesis. The first step was to determine connectivity options based on the design criteria:

- Hardware connectivity must not be restrictive or cumbersome to users.
- Connectivity between sensor and the smart glasses (M100, Vuzix)must allow for real time speed

- Application of calibration matrix without extra debugging hardware needed to be included.
- User software must facilitate adequate computing speed, as well as modifiability and accessibility for the clinician to adjust parameters for feedback to user and data collection.
- Variables should be detectable by sensor and meaningful for the patient
- Data processing and feedback generation must, when calculating the variable and feedback signal, not create too much of a delay (e.g., waiting until next heel strike is confirmed)
- Have an ideal range from which intuitive feedback that is simple given smart glasses design, can be provided to the user.

Figures 8 illustrates the decision-making process to meet the above criteria.

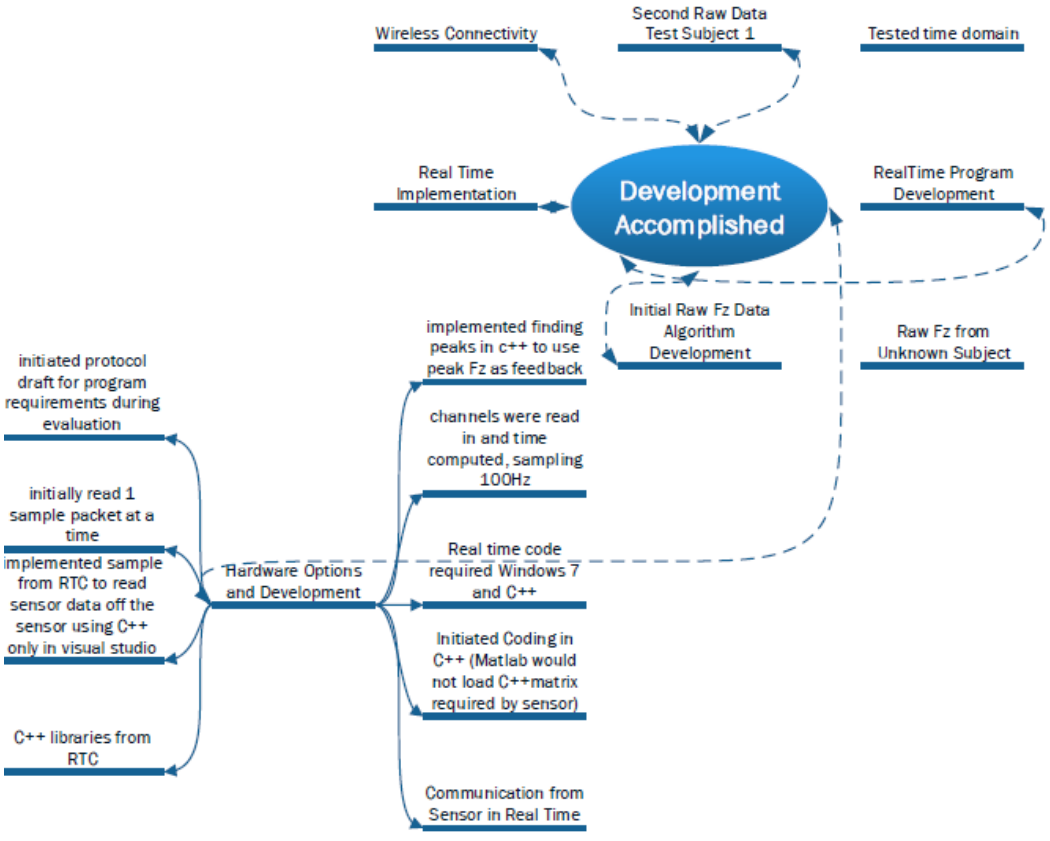

Figure 8 Development of custom software and connectivityFz (axial force), RTC (iPecs manufacturer).

To achieve that goal, a connection system had to be devised to most quickly assemble a prototype yet remain as unobtrusive as possible in connectivity between the sensor, data processor, and the visual display. The traditional use of the system uses a Data Collection Module (DCM) amplifier that is connected to a computer, and the software from the iPecs software graphs of the six signals. The six signals include the three degrees of freedom and therefore three torques (about the medial, lateral, axial planes) and three Forces (x, y, and z planes).

The device is semi-permanently installed as part of the load-bearing structure of the limb prosthesis connecting to the rest of the device using standard adapters (Figure 9).

Figure 9 PI Turning on the Sensor for Testing after Prosthetist Installation.

The orientation of the axes for the sensor are vertically pointing axis (Z+ upward and parallel to the pylon), anterior and posterior pointing Y-axis (Fy+ forward and perpendicular to the pylon) and a X-axis that is Fx+ to the right and Fx- to the left perpendicular to the pylon

(Figure 10). Moments are produced and calculated using Right Hand Rule. For example, a positive Mx+ was considered as counterclockwise as viewed from the left (during toe push off) an Mx- is produced by heel loading. A My+ is counterclockwise when viewed from the front (Knee abduction if right leg as above) and Mz+ was considered counterclockwise from above. Data collected by the sensor originates from a coordinate system located at the center of the sensor and therefore the system rotates and translates with movement of the prosthesis [36].

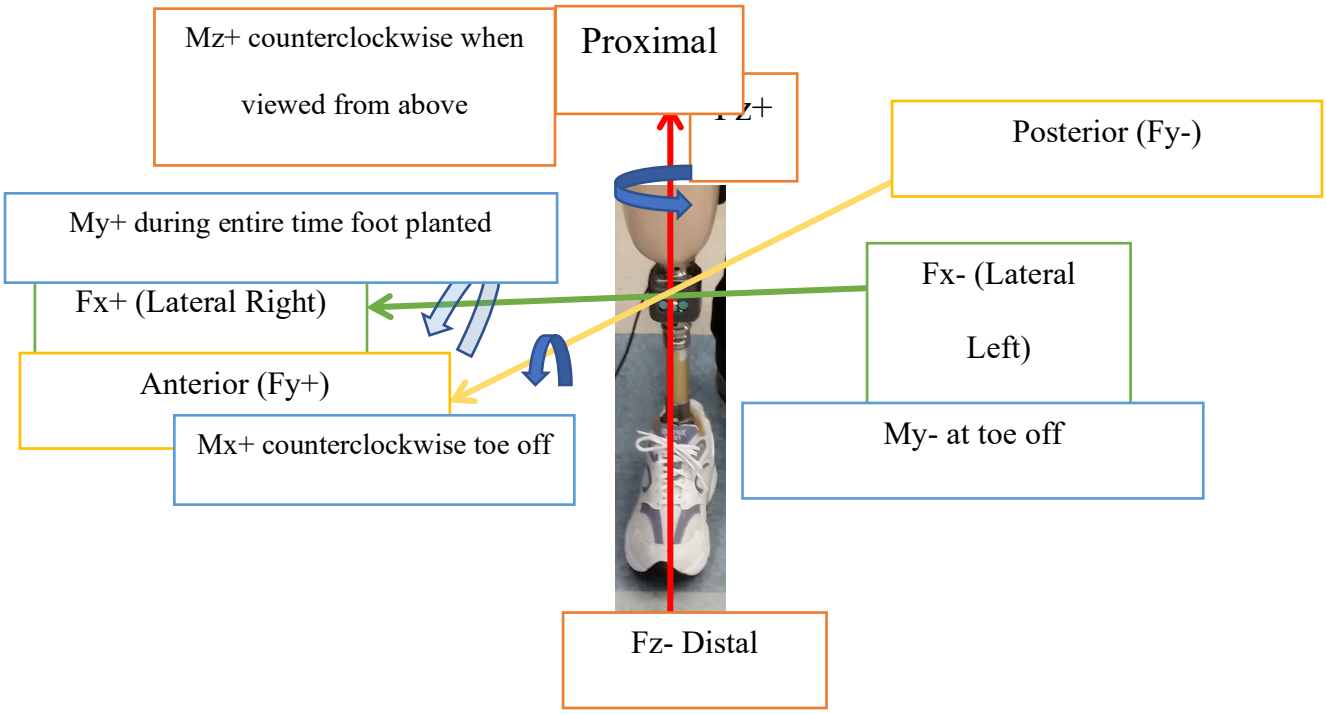

Figure 10 Coordinate System of the iPecs

Data can be streamed to the PC, but only processed post-hoc. Therefore, the protocols for accessing the live data from the sensor itself had to be procured and a program to retrieve these, process them, and determine a variable to provide feedback upon, had to be designed. The design goal was met by creating a neoprene slim fitting pouch that contained the UMPC and fit snugly at

the low back. A single, lightweight USB cord extended from the sensor to the UPMC.Connectivity between the different components is via a USB cable between the load cell and the ultramobile PC, and via BT to the smart glasses. In this configuration, the lightweight computer is being carried in a pouch on a waist belt by the user (Figure 11).

Figure 11 Application of Dell Ultrabook in Neoprene Waist Pouch

2.2.2 Feedback Design and Display V1

Initially the Google Glass (Explorer Model, 2015) was proposed, and initial concepts included screen sharing the graphs from iPecs Lab software, however it was found that Google Hangout no longer existed for screen sharing, and the glasses design in itself was prohibitive of allowing forced visual information. Initial findings were that no screen sharing applications were available. In addition, since the google glass design was not that of a virtual reality view but rather in essence a peripheral screen, it did not seem feasible to provide what had been demonstrated in previous literature as a more immersive experience, with large screens.

Initial research of smart glasses alternatives and choices to be used was based on the following criteria:

- Battery Life
- Wireless connectivity preferably BT
- Not dependent on external device/controller such as a phone
- Android Application Programing Interface (API) level to allow for ease in development of image user would see
- Ability to change display placement over (right or left eye)
- Lack of reflection – Usability in bright environments
- Unobstructed view of foot placement (some glasses had inferior placement of screen)
- Promising future of progression

The final choice of Vuzix M100(Vuzix, West Henrietta, NY) was made because the model fit the above criteria, were award winning and a more advanced powerful design was going to be released within a reasonable timeframe with significant functionality and user upgrades

These smart glasses contain, positioned at the fringe of the user's normal field of view, a small-sized display, the contents of which are signaled to change via BT based on the step data calculations regarding the primary variable of interest (in this case percent stance). The display has a resolution that is comparable with small computer screens, yet its position and intended purpose in our context advises against the conveyance of very complex visual information. Therefore, the simple color warnings were used.

A "warning" approach was determined to be the ideal method of feedback delivery in that it was simple, intuitive (red, yellow, green) so as to cue the participant if they were starting to ambulate in a manner that was not loading involved limb correctly. Given concerns related to

providing real time visual feedback that did not create cognitive overload, and that it was a peripheral placement, the idea of a simple color-coded signal of harmful gait was undertaken. Other ideas included hardwiring the glasses to the UMPC as a second screen, but this was found to be too risky for the hardware integrity.

2.2.3 Algorithm Development

The algorithms for step detection and assessment were initially hardcoding of peaks and lower threshold crossings in Fz using the programming language C++. However, due to error and difficulty with visualization, which limited the immediate ability to determine the generation of the gait curve and its accuracy, and given this would require extensive initial programming in the C++ language, a post processing analysis was performed to determine which algorithms would provide the least error. Given this kinetic data and force and moment curves, MATLAB (MathWorks 2015b), was chosen to first develop the algorithms as large amounts of data can be easily visualized and complicated calculations can be performed quite quickly. Initial algorithms were based on axial Fz (in the time domain) as this variable has been validated against force plate data [36].

Data from a previous study [36] was analyzed post-hoc for patterns to determine the best method to create a step detection algorithm. Approximately 10 steps of Fz raw data from an unknown subject was analyzed with MATLAB for mean Fz over the duration of walking. Then the mean value was designated as threshold and subtracted from the peak values to create a zero axis. The program was written to find where Fz crosses this threshold and then find the slopes (derivative of Fz) at those points. Steps were detected based on the rising slope and falling slopes of Fz data points about these zero crossings. Peaks were identified as the local maxima located

above the zero crossing behind the mid-point and in front of the midpoint. The slopes at this mean point (zero crossing) were then used to find the lower threshold crossings (initially set at 7n based on previous work by Fiedler et al. [36] This threshold was refined and increased to 15n. Interpolated values of 15N could be found and this time would be the heel strike. Toe off was found in the same way by finding the location of the first falling slope and interpolated to 15N and the time of that final fall was deemed Toe off.

Initial calculations done without interpolation of exact 15N crossing over estimated percent stance phase by 1.5-2.46% overall. Oscillations in the force signal during swing phase would be classified as threshold crossings and this was not valid. Interpolation to exact 15N and implementing a second higher threshold improved specificity of step detection. If a sliding average was used over the whole Fz signal, the % stance variable would increase in variability by 2-3%. Therefore, interpolation was implemented over initial smoothing of the raw data. The onboard sensor software was performing averaging of readings before each data packet was sent from the sensor at the selected sampling rate, and the data was filtered enough that with interpolation our step detection events were able to be identified. The noise peak to peak amplitude was quantified at approximately ± 3N. Therefore, the lower threshold when raised for initial algorithm testing to 15N, ensured gait events at the lower thresholds were more reliably detected given the initial exploratory phase of algorithm testing. Established methods were implemented to validate the detection of steps by the real time program however, the low pass filter that exists on the iPecs is akin to force plate filtering. It was decided that with the hardware and software filters that were in place, no additional filtering was used in the real time program.

After Institutional Review Board (IRB)approval (# PRO15120426), an initial participant was asked to walk under several conditions with and without guided feedback, with the iPecs

sensor installed. The iPecs sensor was calibrated. Data received from sensor over iPecs data transmission protocols was stored in Comma Separated Variable (CSV) format. Initial analysis was done on raw data using MATLAB to determine heel strike, loading, and toe off from the iPecs Fz Channel. The second iteration of algorithms tried to be predictive in when steps would occur, (for example trying to assume every 0.5 second a heel strike would be found), and we would display a certain number of seconds of data at a time on the screen graphically. We started with five seconds of data was displayed at a time to allow steps to be correlated with video (Figure 10). However, this did not work as the sensor was operating over radio frequency, which could cause some drift, and drop out (which later was rectified in further development described below) and there was no initial time stamp on the sensor where we could identify as specifically with a video time stamp. In addition, the video frame rate was 30 frames per second and the sensor was sampling at 100Hz and the steps were difficult to correlate. In addition, this logic would cause some large steps to be erroneously detected as more than 1 step and when multiple peaks would be found this would also create this erroneous detection. Therefore, the algorithm for step detection was then re-evaluated and rewritten based on new data (Figure 12).

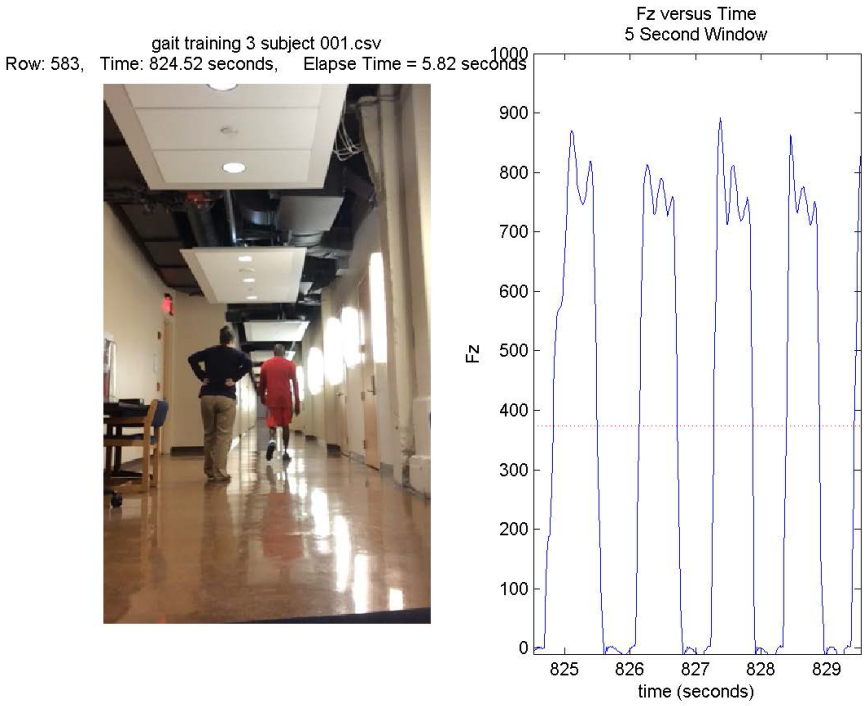

Figure 12 Second Iteration of Gait Event Detection SystemCorroborating Steps as Measured by Fz Data to Video

The algorithm was changed to ignore steps if no area under the curve was calculated, or if any of the step detection times were equal, the step be ignored. This eliminated 11 artifacts that were single peaks, and the error rate improved from >10% to 3% (Figure 13). Video and written documentation of "good" steps was used to validate step detection.

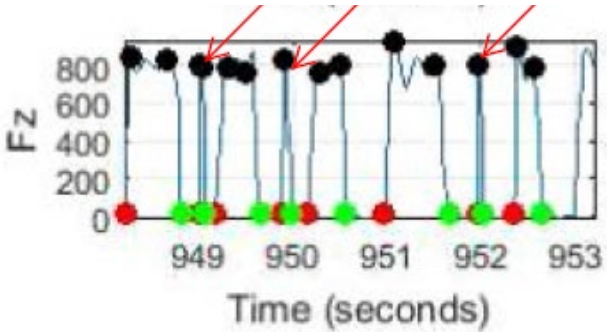

Figure 13 Sample of gait training trial 3 with MATLAB Fz graph output The heel strikes (red) and toe off (green) and peaks (black) are demarcated as determined by algorithm 1. Red arrows indicate Fz artifacts removed from algorithm calculation and detection.

The architectural framework of the final system that was RTMVF is depicted in Figure 14. The work on the development was published for the International Society for Prosthetics and Orthotics World Congress [106].

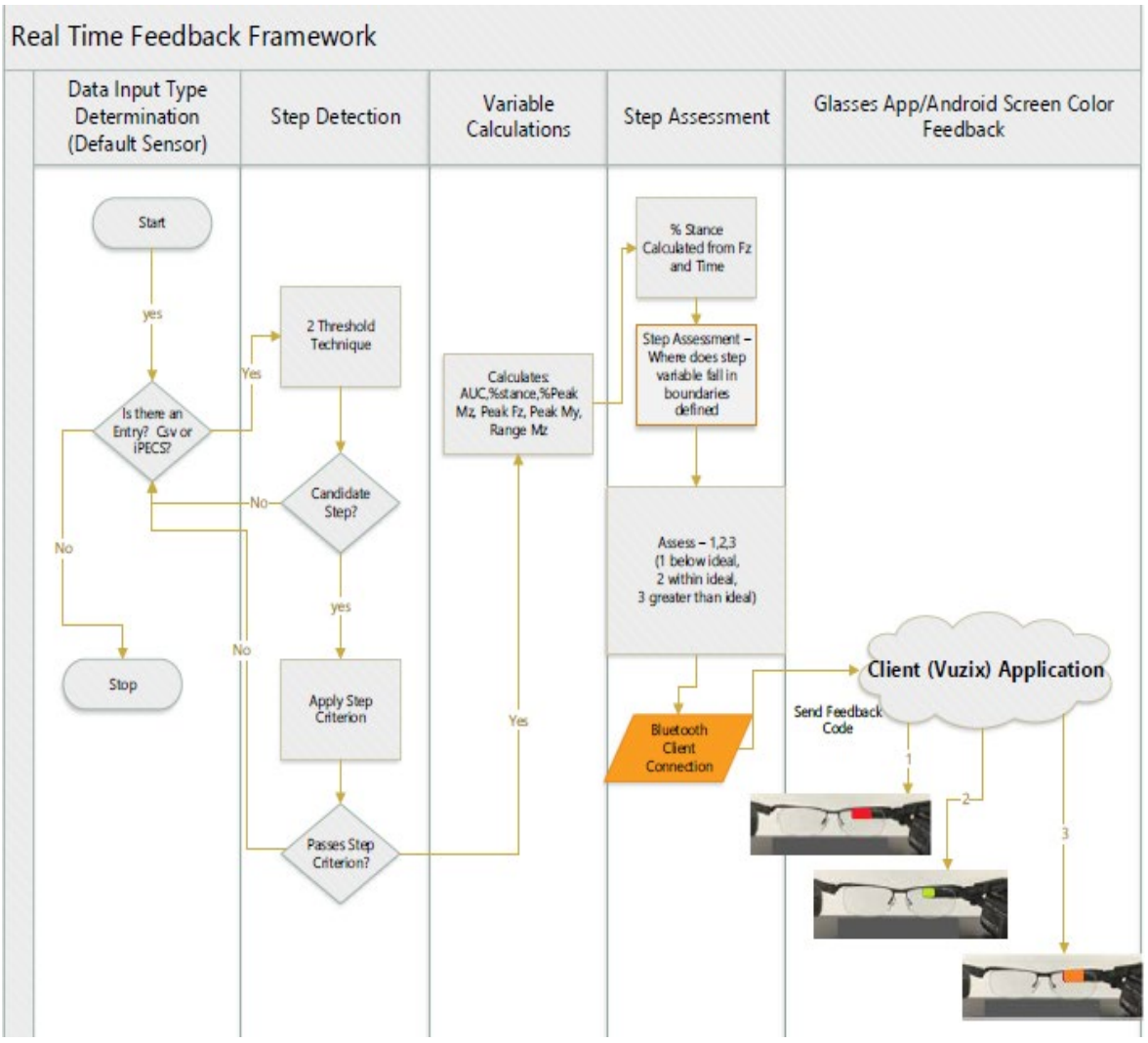

Figure 14 Architectural Framework of V1 Prototype RTMVF System The colors above correspond to < 58% overall decreased stance on the limb - Red (Percent Stance Phase calculation), between 58% and 63% - Green "ideal", >63% - Orange "excessive double limb stance". These colors correspond to percent Stance Phase calculations. **Development Prototype V2 (Android Wireless prototype)**

2.3.1 Introduction

The primary function of the RTMVF prototype was to enable unencumbered gait training in a self-contained system that could be used by the individual over realistic terrain. To fill the

gap in the current research and training paradigms, the purpose of this development was to progress the system to one that can become truly mobile and apply the methods of motor learning “in the wild”. The purpose then of this development was to fully realize the potential of wireless gait training. Therefore, a similar integrated load cell (sensor) that was also installed within the prosthesis, however, was wireless and provided data streaming over BT versus USB was procured. We replaced the iPecs with the Europa+ (Orthocare Innovations, Seattle, WA) a wireless integrated load cell. The Europa, is a lighter, and smaller integrated force and moment sensor measuring 37.5mm x 64mm x 79mm (1.48”x 2.52”x 3.11”) and weighing 275g (9.68 oz) (figure 15).

In conjunction with the migration to a wireless integrated force sensor, a mobile application (app) was developed that could downsize the data processing and implement clinician and user preferences. This also included the possibility of remote accessibility and training.

Figure 15 Installation of Europa+ Sensor into Pylon by Prosthetist (Co-I)

2.3.2 Design Criteria

Listed below are the design and development goals of the V2 (Version 2) wireless prototype.

Usability and Patient and Clinician Preferences

- Refinement of system in response to initial feedback from outpatient Physical Therapists (PT)s, and Beta subject testers
- User-friendly functionality implemented in mobile app for patient.
- Usability testing and iterative design refinement with eight new subjects to achieve usability of at least 68% on a System Usability Scale (SUS).

Mobile App Functions

- Transfer code to mobile application as interface to remove middle processing component on patient.
- Bluetooth (BT) communication
- Mobile ability to start/stop program, store step/raw data at the end of training session or evaluation session.
- Physical Therapist (PT) evaluation tool for initial option to set individual "good" steps for each patient to be their own gold standard
- User-friendly mobile interface with options to adjust the program, algorithms, thresholds, and patient specific anthropometric data for accuracy of feedback.

- Confirmation Tool of feedback color participant is viewing simultaneously for PT/Clinician during training to ensure PT guidance is correlated to desired visual feedback.

2.3.3 Methods

To assess step detection, percent stance, stance time and step time, the MOVIUFIT prototypes V1 and V2 migrated to a wireless integrated sensor (Europa, Orthocare Innovations, Seattle WA) for the axial force component needed in the algorithm. Collecting and processing the data was performed by our custom-made application (MOVISUFIT) designed for a mobile android phone. This algorithm and data processing were migrated from the previously validated and reliability tested C code into a Java program to run on a phone. The raw axial force data and the subsequent calculations were stored locally on the device via Bluetooth and remotely on a server through WIFI communication. The MOVISUFIT app performs analysis in real time and stores the data once "stop" is initiated on the phone.

2.3.4 V3 (Version 3) Algorithm Refinement

The initial migration from C++ to Java caused some errors in the assignment of the states defined in our algorithm. There were two issues – regarding the lower threshold and the most accurate detection of the gait events captured with initial contact or final loss of contact from the floor. Initially, immediately following the migration to Java, if during the time phase between toe off, and heel strike, if the force travelled above the lower threshold and then back down again, (as could happen secondary to the weight of the prosthetic through the swing phase of gait creating false rises above the lower threshold) this was being assigned as either to a zero, or back to the

initial state of the state machine of the algorithm. Therefore, to create the algorithm to be robust to this noise at low signal levels, the state machine was altered to simply reset to the previous state it was in, rather than assuming a "zero" state. This is essentially telling the algorithm to wait and stay in the state for which the criteria have been met, and once all the events occur, then further criterion was in place to accept or toss the resultant step. This allowed the algorithm to be able to handle the transitions from loading to unloading. Figure 14, portrays visually the required corrections and the resultant smoother system of states. It was corrected to be able to detect that if the lower threshold was crossed upward then downward, both in transition from states 3 to 4 and 4 to 5 (Figures 16-17) the algorithm would reset to the previous state and wait for the rules of the next state versus assigning the gait events to 0 which was occurring.

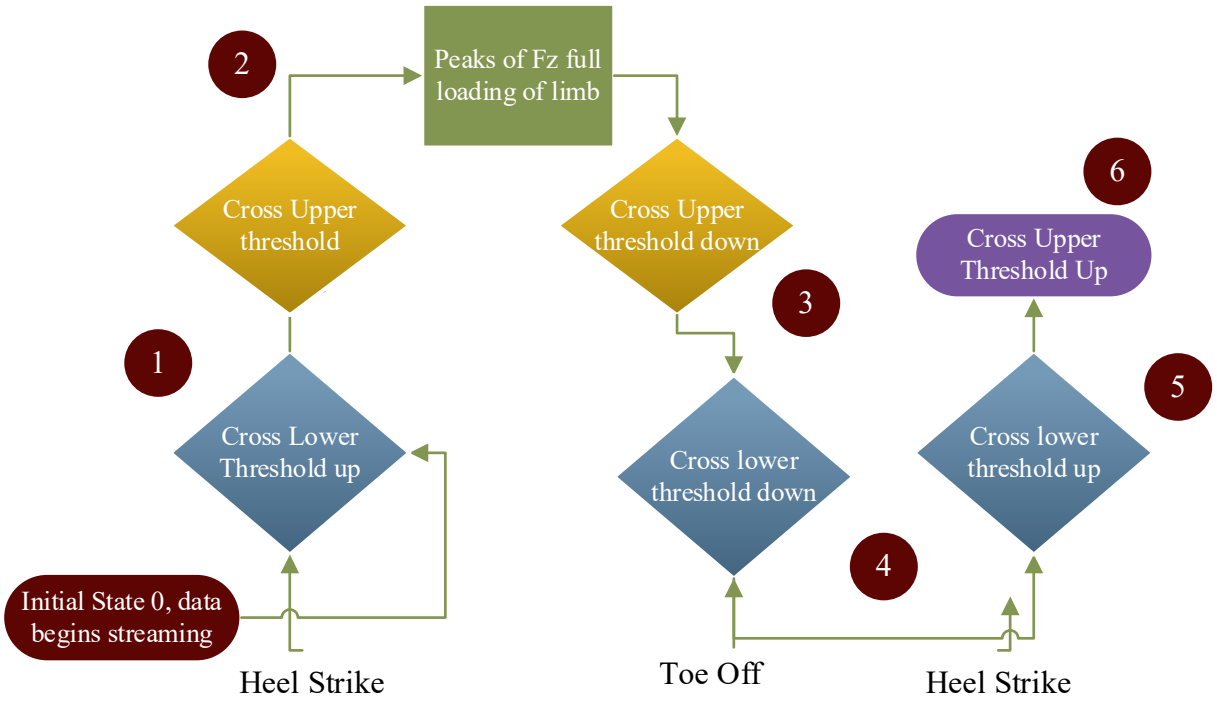

Figure 16 Step Transition diagramDefinition of States as Fz Travels Through Gait Cycle.

The solution was also to create an initial state and define that as the beginning of the gait detection cycle. By including this state, the algorithm predicted a spike in the signal that occurred very early in the data streaming from the Europa sensor. To not have this erroneously counted as the initiation of step, this new "initial state" definition assisted with filtering out erroneous steps. As seen in the diagram below more specifically, it was necessary to differentiate between state 0 and 4. Also, state 4 could be assigned as an initial state, as it is down near the lower threshold. However, this will not work because if you are in the stepping sequence where in the loop you have arrived at state 6, and we define our initial state as state 4, then the load has crossed the double thresholds, and the algorithm would incorrectly conclude that a step has occurred.

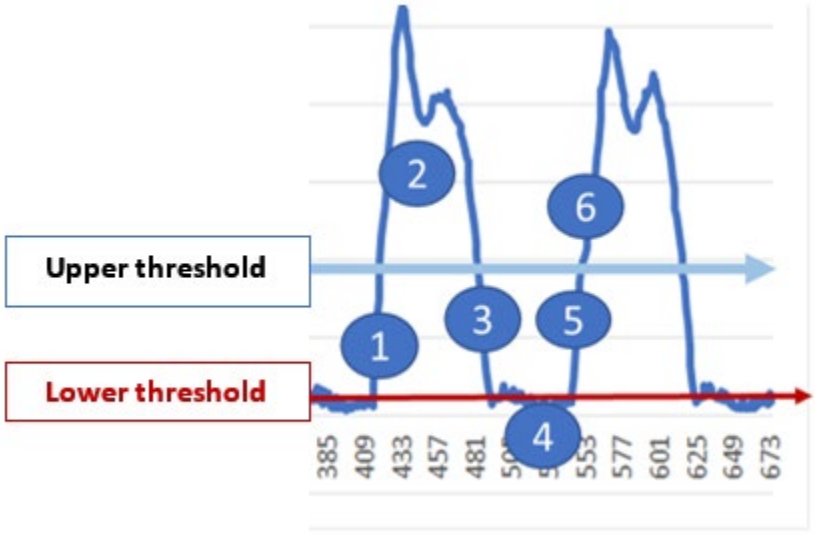

Figure 17 State transition DiagramDiagram Depicts the Improvements in Detection of Steps from the Fz or Axial Loading Force

Another example is if the system is in section 6 of a step loading cycle, and you do not have any initial state defined, then the algorithm may consider the interval between 1 – 4 as a

candidate step. This was solved by this definition of the initial state as well and another check was put in place during state 4 of the gait cycle detected by Fz. The algorithm is continuously needing to check the candidate step against the criterion that we have designed, to ignore steps that are not walking or should not get feedback.

2.4 Results

2.4.1 Visual Feedback

The smart glass model was updated to the Vuzix 400, (Vuzix, West Henrietta, NY) which provided more adjustability and battery life (Figure 18). In addition, the feedback color for the increased stance phase (too long) was adjusted from yellow to orange secondary to reports it looked lime green and orange was preferable. Also, when participants were producing steps that were not actual steps or did not meet our criterion, grey was provided as feedback instead of the visual feedback remaining the same color as the previous step unless triggered to a different color. This correction made the feedback more accurate and less confusing.

Figure 18 Participants Testing Updated Vuzix Smart GlassesPI adjusting glasses and starting custom app on the glasses. B-C) participants adjusting and starting their glasses for gait training, D) Co-I as he is adjusting the sensor in prosthesis. This diagram illustrates the participants wearing and adjusting the latest version of Vuzix smart glasses which improved portability comfort and usability. The new M400 model glasses by Vuzix could be used on either side right or left, were more balanced in weight, and more easily adjustable.

2.4.2 Algorithm Adjustment

Figures 19 and 20 portray the new Fz or axial force curve, and step detection with the wireless sensor. The heel strike and toe off interpolated times are delineated in orange and grey – orange is heel strike. This sensor measured in KgF (Kilogram force) units versus N (Newtons) and even though it appears the detection of events is satisfactory, here the sensor was not tared correctly. A development priority was to ensure the step detection and determine the appropriate signaling required to calibrate the sensor as a zero baseline would provide more accurate time of lower threshold gait events. This could have affected the calculations of some of the stance

duration times, creating increased variability. The improvement in the tare function lowered the thresholds (Figures 19 to 20) so gait event detection became more accurate.

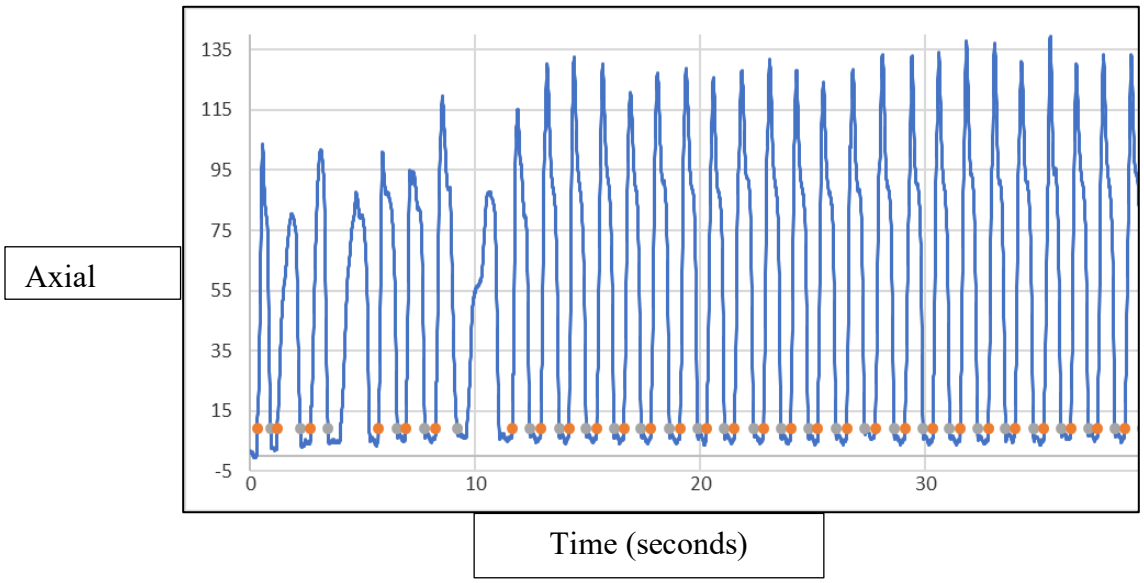

Figure 19 Axial force vs. Time Graphical Display Reliability and Validity Data Axial Force vs. Time Gait Testing Data from a Participant During Reliability and Validity Testing with Heel Strike and Toe Off Times Being Validated Graphically. The Heel Strike and Toe Off Interpolated Times are delineated in Orange and Gray – Orange is Heel Strike.

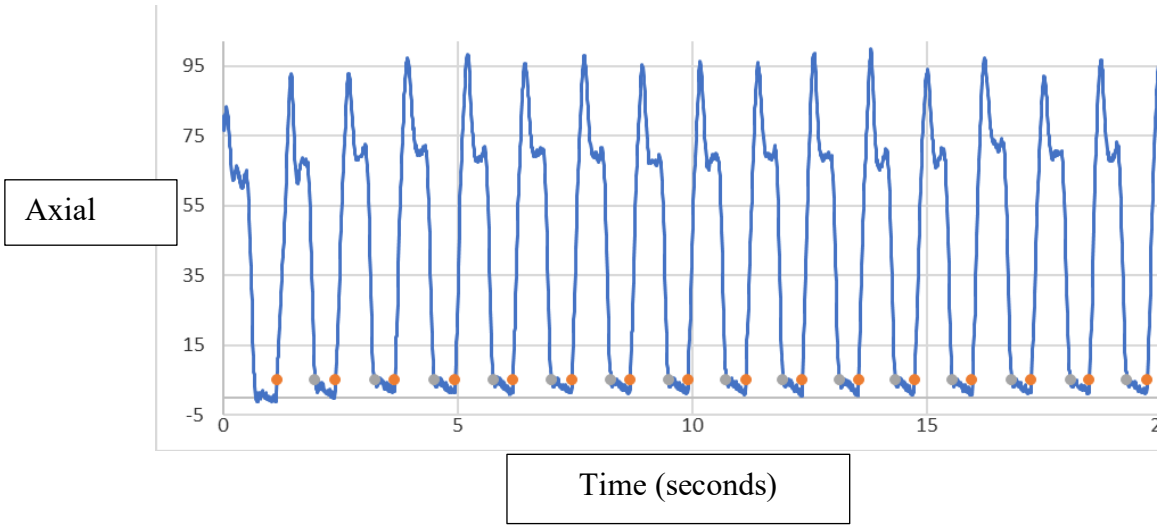

Figure 20 Interpolated times to 5 KgF with the zero baselineCorrect Zero Baseline Function Working in Software, the Detection Events are Improved in Accuracy as Seen by the Orange Heel Strikes and Grey Toe Off Time Much Closer to the Lowest Point of Actual Increase in Loading on the Sensor Increasing the Curve.

2.4.3 Evaluation Methods

The wireless system was extensively tested by the PI and team members using a pseudo-prothesis as seen with the development of the V0 prototype. This was used to first establish the transmission of the data wirelessly in the new programming language (JAVA) and then applying the appropriate hex code provided by the Orthocare Innovations company to communicate with the sensor and calibrate. We built the app from there using the pseudo prosthesis to establish step detection and communication from the phone to the smart glasses using the same BT communication as previously established. The new algorithm was tested in this way with team members extensively and absence of delay after heel strike for triggering the color in the glasses to change was ensured prior to participant testing.

Once this was established two individuals, both with transfemoral limb loss, assisted with the development of the connectivity and algorithm testing in the V2 wireless prototype. In

addition, through the training process, the output (step data) from the algorithm was repeatedly assessed to ensure accurate step detection and calculations of %stance. Patient preferences towards user interface on the android screen were accounted for and implemented. Participants underwent the initial baseline assessment as described in chapter 3 which included walking at a self-selected speed for short 30m distances in a level hallway. The addition of the screen for the clinician allowed confirmation of each step detected and the color provided, and the DPT was able to ensure that the step counter matched the steps taken. Once it was determined that the algorithm was detecting steps accurately and connectivity was able to be maintained, the participant returned for their training which is outlined in chapter 4.

The Europa+ sensor was installed in the prosthesis and the android phone was connected over BT to initiate data streaming. The participant was instructed on how to use the glasses, and the colors they would see. A DPT walked with the patient first, through level hallways only, to determine that the system was detecting steps by observing the rate of detection on the android phone app screen (custom MOVISUFIT app). This was to ensure that the color change was not delayed from the second heel strike of the involved leg (with the integrated sensor) and that the colors appeared correct given the expertise of the DPT in gait analysis.

Initially, this first session of training with the new prototype was accomplished with a standardized set of instructions explaining to the participant what the red, green, and orange signified when displayed in their smart glasses. This was associated with apparent gait deviations depicted initially. In this first session, the DPT employed verbal cues, demonstration, and clinician guided tactile cues. The end of the first session (15 minutes) was concluded with practice trials by the participant to ensure safety and continuity of the feedback system.

Post-hoc analysis of the data processed by the app which included custom “step data”, was performed to ensure the calculations were accurate and corroborated with the raw data from the sensor’s Fz output which was used for step detection. Time stamps of the gait detection events output by the android app were corroborated with the raw data.

2.4.4 Development of Mobile Android Application

The improvements to the mobile phone app touch screen user interface significantly improved ease of use, and notably, patient enthusiasm. A function was added to the interface, as initially there was no method for participants to see if they had made progress that day. Therefore, a new application was made computing averages of “reds” “greens” and “yellows” for the participants to immediately see their progress from the previous session (Figure 21).

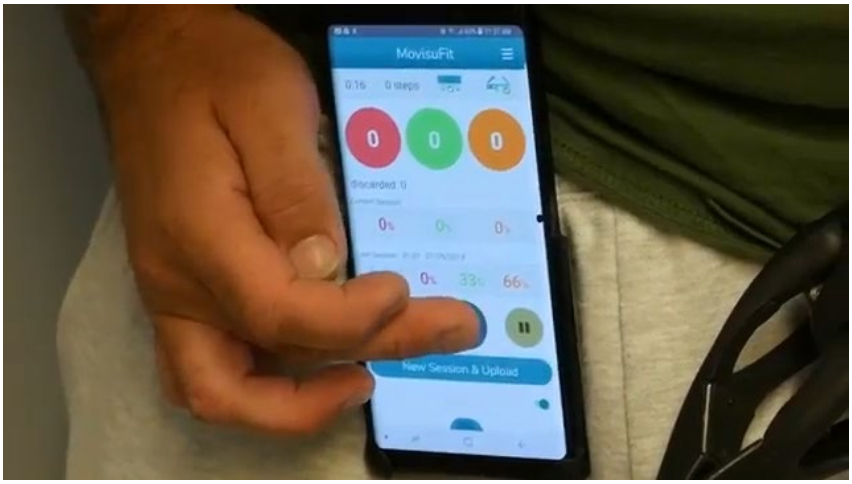

Figure 21 Improved User Interface of Android AppImproved user interface of Android app in response to participant feedback. The number of reds, greens, and oranges can be seen by the participant, or clinician which was reported as “motivating”. In addition, below are %’s of each color and were totaled once each session was completed so participant could receive feedback regarding their performance.

No longer having to carry a computer at the low back was much easier and felt more natural for the participants (Figure 22).

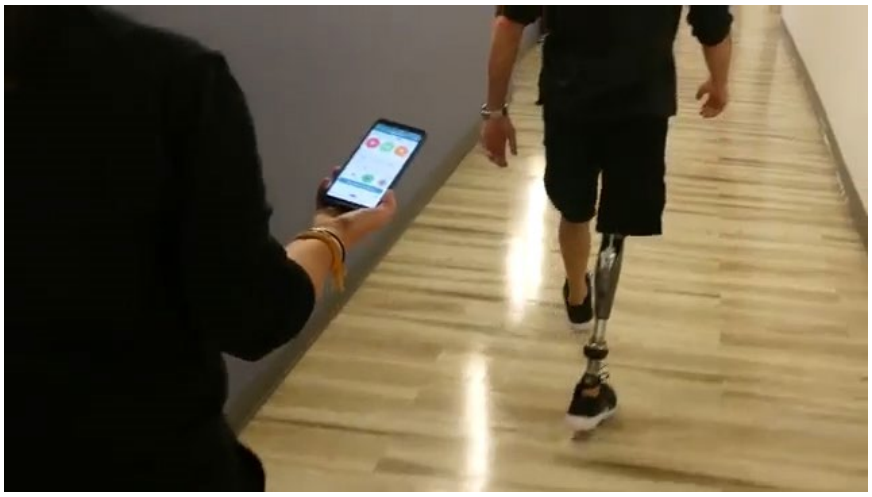

Figure 22 Participant Training with Wireless Capacity.

The ability to change thresholds and parameters in midst of training was extremely helpful toa clinician to ensure that the participant is receiving appropriate feedback. The participants have different prostheses and they had different gait deviations. Therefore, it was required to be able to adjust their step detection thresholds during training (Figure 23).

Figure 23 PI adjusting thresholds

2.4.5 Limitations

Bluetooth connectivity was a key issue and noted complaint in the usability surveys. The sensor software was initially advertised as open source to be able to stream and process the data live. However, the libraries were not provided for true wireless connectivity without a dongle. A basic BT connection was established connectivity was still not as consistent as desired and is a focus for future development.

2.5 Cloud and Web Portal Development V2

The goal of further developing the system was to achieve the ability to receive and modify that participant data and feedback remotely, and not rely on the phone memory and lay the

groundwork for potential future studies that would allow the participant to try the system at home. In addition, through customer discovery related to commercialization efforts it had been discovered that clinicians desired a way to remotely monitor and check in on how their patients are doing with office visits frequently having to be spread over time (Figure 24).

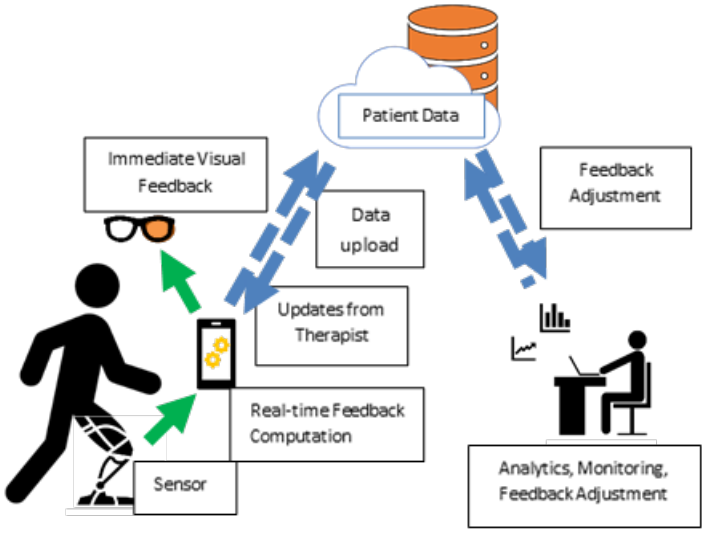

Figure 24 Design for cloud abilities and remote training.

Cloud storage was added to the Mobile Visual Feedback In real Time (MOVISUFIT) system as a solution to storage limitations, automaticity of data visualization and feedback effectiveness monitoring, but also with the goal in mind that a website could be created in the future that ran calculations the patient desired to see about their progress. The cloud database enabled the MOVISUFIT system to be adjustable remotely by clinicians, and in the future, there will be the possibility for patients to log in and have access to graphs and visualization of their progress. The cloud database was designed and built to visualize the data and patient performance quickly and easily. The advantages of using a cloud database are that it 1) allows the system to expand storage easily and perform backup and 2) facilitates a web application that is accessed by

participants and researchers to perform data analyses and visualization from remote locations. Potential limitations with this method, however, are ensuring security is strict enough that HIPAA violations would not occur, and therefore only research team members had access to the data, and it was identified by subject ID only. To also thwart this issue, no personal information was stored, only kinetic or kinematic data.

In previous prototypes, the researchers needed to extract the files from the computer as csv files and convert them to excel files to perform analyses. In the V2 prototype the data was all stored on the Samsung phone device and needed to be extracted in the same manner. A disadvantage to the earlier versions is the demand to have the user and the clinician physically in the same location post training, to access the data within the computer (V0) or smartphone (V2). Also, once the dataset becomes large, offline analysis requires extensive time to compile and perform calculations. However, in the V3 prototype with the cloud data base added to the software, settings were developed to better enable clinicians to perform subjective gait analysis, to identify potential feedback variables, and retain patient-specific parameters for the gait feedback variable and adjustable threshold settings, for example, facilitate this functionality. The MOVISUFIT app can upload the gait training and feedback data into a server for data storage and backup. The web service can be used to extract the data from the server and perform the data visualization on a webpage for clinicians. This web service would enable the clinicians to adjust the feedback parameters in the MOVISUFIT app remotely.

2.5.1 Methods Cloud Database Development

Google Firebase is the web service where the prototype website was constructed for the MOVISUFIT portal, which runs on google cloud platform behind the scenes therefore, we used

the operating system provided by that system. The data transmission method between the google cloud firebase and the MOVISUFIT app was a web protocol with reasonable restrictions for initial development. Google provides a high level of operational abilities therefore it was a simpler level to initiate this type of database storage and remote abilities for this prototype. The Android app stores different variables into different tables in the database system, which was created in order to allow the team to customize coaching parameters remotely. The MOVISUFIT app creates the original coaching parameters and this file is uploaded to the server when the app first executes. On the server side, the clinicians may adjust the feedback parameter and step detection threshold information as well as adjust the thresholds that determined the color and quality feedback seen by the patient. We saved the feedback parameters and other clinician settings on the database as well as the app.

The app checks the file on the server each day, and the feedback and step detection thresholds and parameter will refresh if the file on the server is different than the file in the MOVISUFIT app. When the app starts, it will fetch the clinician parameters from firebase and update the values on the app. If the clinicians change the values of the parameters on the app, they can "save & upload" to save the parameters to the firebase. The variables selected to present with the website portal included all of the gait variables we calculated through previous prototypes including: Heel Strike and Toe off times, Step number, %Stance, Stride Time Duration, Stance Duration, Peak Axial Force, Peak Medial or Lateral Torque, Area under the Force Curve, and if the system was paused, the reason for the pause was inserted in the table. The calculations and processing for these values are performed in the mobile app during the gait training.

2.6 Conclusion

The development of the wireless prototype was successful in implementing the design criteria and acting upon the trends of patient preferences. The findings of this development and beta testing gave us imperative information on preferences for training, feedback, and usability. The ability to quickly accommodate to differences in gait was critical to build the prototype system. Future work goals are to apply improved connectivity solutions and potential upgrades in smart glasses where the visual feedback is more integrated into the lenses themselves potentially reducing cognitive demand. In addition, considerations towards one participant's suggestions such as a game-like application which does have promise. During Customer discovery via Second Gear during an APTA conference, many new applications were applying this game approach, and it was motivating to use this type of feedback that was more of a game-like experience. It continues to be determined however, if this is applicable in the gait or running rehabilitation or performance setting.

3.0 Reliability and Validity

3.1 Introduction

Gait Analysis provides clinicians valuable quantitative information beyond what is subjectively and qualitatively possible. Typically, Physical Therapists rely on observational gait analysis or mobile apps that have not been validated, to provide some form of assessment or in the case of mobile apps quantitative data. Based on extensive customer discovery during a three-day conference with the American Physical Therapy Association (APTA), we found that the majority of PTs are either interested in using, or are already using, mobile app-based systems for gait analysis. Observational or subjective gait analysis has poor to moderate reliability and validity [107]. Gait Analysis can provide valuable information to indicate areas of improvement when justifying treatment protocols towards reimbursement, or to gain understanding of a patient's area of dysfunction and target the treatment appropriately. Gait analysis and its feedback can provide relevant outcomes for the limb loss population, particularly spatial-temporal outcomes such as gait speed and symmetry, as well as energy conservation [23, 31]. Temporal-spatial gait parameters have been shown to be significant indicators of injury/disease, falls, and quantification of the effect of interventions which allows clinicians to justify and measure treatment efficacy [108]. In addition, wearable systems consisting of inertial motion sensors, in-shoe force sensors, smart glasses, and integrated sensors, have been developing quickly in the last five years [109-111]. In order to interpret clinical and research findings from the MOVISUFIT prototype and its processed gait data and draw comparisons with published works, the reliability and validity of the processing algorithm was assessed.

The purpose of this work was to assess reliability and validity of the spatiotemporal measurements of %stance, stride time (s) and stance phase duration (ms) of the MOVISUFIT system during walking over ground at a self-selected speed. We hypothesized the that the results would demonstrate excellent test-retest reliability (ICC 3, k) > 0.80) for stance duration (ms), % Stance, and stride time (s). The validity was established by performing Bland-Altman plots performed to determine the level of agreement between the MOVISUFIT algorithm as compared to the inertial wearable sensor G-Walk. We hypothesized good to excellent levels of agreement amongst calculations of %stance, stride time (s), and stance duration (ms).

3.2 Methods

3.2.1 Participants

Subjects for this study were recruited from the prosthetics and orthotics clinic and department within the University of Pittsburgh and via established relationships with UPMC Physical Medicine. Inclusion criteria for this test were use of a trans- tibial or trans-femoral prosthesis for ambulation, absence of acute or chronic health conditions that would affect prosthesis use.

The criteria also included that the prosthesis was used for ambulation and contained modular components to allow for installation of the integrated load cell within the components below the joint, and the ability to walk without aids for at least 30 minutes. Patients were excluded if they had had surgery < one year prior, history of seizures, or uncontrolled medical conditions

that would impact exercise. This work was approved by the IRB of the University of Pittsburgh and the subjects gave informed consent prior to testing.

3.2.1.1 Instrumentation

MOVISUFIT

Collection and data processing were performed by our custom-made application (MOVISUFIT) designed for a mobile android phone. To assess the spatiotemporal parameters %stance, stance duration time (ms), and stride time (s), data collection and processing were performed by our custom-made application (MOVISUFIT). The gait data source was a prosthesis-integrated load cell (Europa, Orthocare Innovations, Seattle, WA.) which can measure kinetic gait variables in lower limb prostheses (Figure 25). The device is semi-permanently installed as part of the load-bearing structure of the limb prosthesis connecting to the rest of the device using standard adapters. This is referenced in figure 15 chapter 2.The raw axial force data and subsequent calculations were stored locally on the device via BT and remotely on a server through WIFI communication.

The MOVISUFIT app performs analysis in real time and stores the data locally on the Android mobile device.

The calculations for the MOVISUFIT variables were as follows:

1) $MOVISUFIT\ Stride\ Time = Next\ heel\ strike\ time - Previous\ heel\ strike\ time$
2) $MOVISUFIT\ \%stance\ = \frac{toe\ off\ time - previous\ heel\ strike\ time}{next\ heel\ strike\ time - previous\ heel\ strike\ time} \times 100$
3) $MOVISUFIT\ stance\ duration\ (ms) = \ toe\ off\ time - previous\ heel\ strike\ time$

G-Walk: To validate the MOVISUFIT systems measurements, spatial-temporal data was concurrently collected by the inertial triaxial sensor (G-Walk, BTS Engineering). The collection rate is 100Hz and the data is streamed via BT and stored locally on a PC the PI carried alongside the subject as they performed their walking. The G-Walk is a 70x40x18mm sensor unit weighing 37g, which contains an accelerometer, gyroscope, and magnetometer (Figure 25).

Triaxial sensors, worn at the waist, have demonstrated consistent reliability and validity in many populations and have been used in gait studies with success for the last 10 years [112]. Triaxial accelerometers alone, have been found reliable and valid in many studies, with Intraclass Correlation Coefficients (ICC)s, 0.77 to 0.96, and the G-Walk adds a triaxial gyroscope and magnetometer decreasing the risk of error from drift in any one plane of acceleration [113-116].

It has been reported that the G-Walk has excellent intertrial reliability (ICC values between 0.84 and 0.99). Concurrent validity of the G-Walk was examined against the GAITRite (CIR Systems Inc, Havertown, PA) and demonstrated excellent levels of agreement for speed, cadence, stride length, and stride duration (range = 0.88-0.97).

The G-Walk has been found to be reliable and valid for gait symmetry and balance measures in older adults, people with cerebellar ataxia, and individuals with limb loss [117-120]. In a study assessing the reliability and validity of a single triaxial accelerometer worn at the waist, it was surmised that it was a valid instrument for mean spatiotemporal parameters in prosthetic gait [119]. Small errors in detecting heel contact were found to be systematic and therefore, inconsequential for gait symmetry.

3.2.2 Procedures

Testing was performed in the Department of Rehabilitation Science and Technology at the University of Pittsburgh. The MOVISUFIT system was provided to the participants, which included placing the Europa integrated sensor into the prosthetic limb of the subject by a certified Prosthetist. To insert the sensor and integrate it with the pylon, their modular prosthesis was fitted with the sensor by shortening or replacing the standard pylon adapter in the endoskeletal prosthesis [36]. Leg length measurements, markings, and photographs were performed pre and post installation to ensure the prosthesis was not aligned differently than the participant's original alignment, to create consistency between the two gait assessments and to preserve an alignment acceptable to the subject [121].

3.2.2.1 Protocol Reliability

To assess Reliability, each participant was instructed to walk at a self-selected comfortable speed. The four participants performed five trials over a level hallway measuring 50m on two occasions at least five days apart. The sensor was installed and removed for the testing sessions. On these same days, the participants also performed walking tasks that were not avoiding distractions, ramps, or turns. The data was collected in real time on the app, and calculations were also performed in real time, then the custom app creates two files, a "step data" file and a "raw" data file, which are stored locally on the phone and on the cloud database, when the app is stopped, The step data includes the calculations below. Data was collected on the mobile phone app and in the G-Walk G-Studio software and was analyzed post hoc. Subjects wore the same pair of shoes on both test days. The following temporal gait measurements were evaluated: stride time (s), stance duration (ms), and Percent Stance (out of 100% gait cycle).

The following are the equations for those calculations:

$$MOVISUFIT\ Stride\ Time = Next\ heel\ strike\ time - Previous\ heel\ strike\ time$$

$$MOVISUFIT\ \%stance\ = \frac{Toe\ off\ time - Previous\ heel\ strike\ time}{Next\ heel\ strike\ time - previous\ heel\ strike\ time}$$

$$MOVISUFIT\ stance\ duration\ (ms) = \ toe\ off\ time - previous\ heel\ strike\ time$$

Based on research conducted by comparing similar force detected temporal parameters and a triaxial accelerometer, the reliability was considered as excellent when the ICC was >0.75, good if between 0.40-0.75, and poor if < 0.40 [122]. In previous work using accelerometry as the primary method to detect symmetry issues in those with transfemoral limb loss a minimum of 20 strides was recommended [119, 123]. Mean values for each gait parameter were calculated.

3.2.2.2 Protocol Validity

Validity between the MOVISUFIT system and the G-Walk were evaluated using Pearson correlation coefficients (r) and Bland-Altman 95% limits of agreement (LoA). To assess validity, participants were fitted with the G-Walk sensor which is worn around the waist in an elastic belt at L5-S1 spinal levels (Figure 25). Percent Stance (%Stance), stance phase duration milliseconds (ms), and stride time duration (seconds), were extracted from the G-Walk data to serve as the validation standard for the respective variables. For each trial, these spatiotemporal gait characteristics were concurrently recorded by the MOVISUFIT system and the G-Walk inertial sensor and software. Each participant performed five trials, only steps that could be congruently matched between G-Walk and MOVISUFIT were used with the goal of 20 steps. The step data was averaged over these trials.

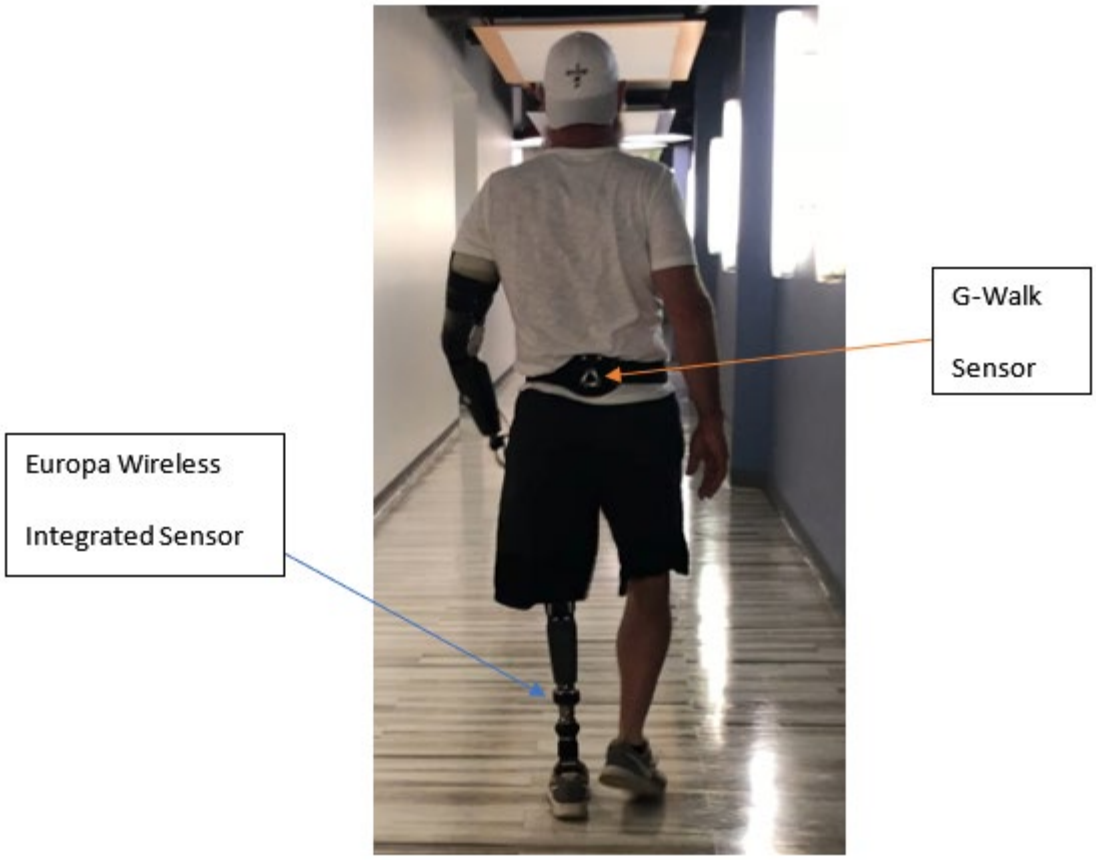

Figure 25 Participant Conducting Over Ground Validity AssessmentInstalled is the Wireless Europa Sensor and the G-Walk Inertial Sensosr is Worn at the Low Back.

3.2.3 Data Analysis

Our system detected all the actual steps whereas the inertial sensor, due to its reliance on acceleration, drops steps at the beginning and end of each trial or if any turning was detected. Therefore, we removed the steps that did not get detected by the G-Walk in our analysis and only included synchronous steps. Outcomes were calculated from initial contact of the involved heel to the next heel strike of the same heel per steps confirmed by raw data analysis (Axial Force in

the Europa and Accelerometry in the G-Walk), and timing. The calculations for the MOVISUFIT variables were as follows:

1) $MOVISUFIT\ Stride\ Time = Next\ heel\ strike\ time - Previous\ heel\ strike\ time$
2) $MOVISUFIT\ \%stance\ = \frac{toe\ off\ time - previous\ heel\ strike\ time}{next\ heel\ strike\ time - previous\ heel\ strike\ time} \times 100$
3) $MOVISUFIT\ stance\ duration\ (ms) = \ toe\ off\ time - previous\ heel\ strike\ time$

The G-Walk G-Studio software does not display step by step calculations of %stance or automatically of stride time only averages over the steps captured. Therefore, in the Bland-Altman plots for those comparisons, in terms of stance phase duration, %stance, and stride times, averages of the steps taken during over ground walking on a level surface were used to compare measures. Stride time was manually calculated from the G-Walk G-Studio output for one participant and those comparisons are demonstrated. Lastly, G-Walk measures were always subtracted from the MOVISUFIT measures, so a negative bias indicates the MOVISUFIT measures were smaller.

3.2.3.1 Statistical Analysis Reliability

Reliability was determined by ICC's, and the (3, k) model with absolute agreement was used with 95% confidence intervals [124]. The final statistic was performed by compiling the averages across 5 trials, per subject, between two testing days at least 5 days apart for a total of 10 trials. The final average calculated was then compared between day one and day two, with a single mean for each participant from the averaged trials on each day.

3.2.3.2 Statistical Analysis Validity

Concurrent validity of the MOVISUFIT system was assessed by comparing stride duration(s), stance duration(ms), and %stance as measured simultaneously with the GWALK

sensor. To assess the disbursement and level of agreement, first Bland-Altman plots were used with four initial participants as were used for the reliability testing. The Bland-Altman plots were constructed from five trials of concurrently collected data, where steps could be matched from the G-Walk and MOVISUFIT for four participants. The data was averaged over each trial, trial providing 5 data samples per subject for 20 data samples for each plot. In consideration for the Pearson's measure of agreement to assess validity, each variable was collected and averaged across 20 steps over 5 trials for four additional participants for a total of eight samples. An alpha of .05 was used for all statistical testing as well as 95% confidence intervals. All statistical analysis was performed using SPSS, Version 29 (IBM Corporation, Armonk, NY).

3.2.4 Results

Four participants were included in the Reliability study (Table 1).

Table 1 Subject Demographics Reliability Study

TT = transtibial, TF	Gender	Age (years)	Weight (kg)	Height (m)	Prosthesis
1	F	56	113.0	1.67	TT
2	M	60	83.0	1.70	TT
3	M	47	65.3	1.70	TF
4	M	48	81.6	1.52	TF
Mean ± SD	**1 F, 3 M**	**52 ± 6**	**85.7 ± 19.8**	**1.65 ± .08**	**2 TT, 2 TF**

(F = Female, M = Male, kg = kilogram, m = meters, TT = transtibial, TF = transfemoral, SD = standard deviation)

3.2.4.1 Test-retest Reliability

At preferred walking speed, the ICC's for all gait measures tested were 0.8 or higher, except for stance phase durations, which had an ICC of 0.728, (Tables 2 and 3). When assessed during walking in busy hallways and not avoiding distractions, turns or ramps, the parameters were also highly reproducible, apart from Stance Phase Duration.

Table 2 Test retest ICC values MOVISUFIT controlled self-selected speed flat over ground walking (ICC = Intraclass Correlation Coefficient, SD = Standard Deviation, α = 0.05, ms = milliseconds, s = seconds, CI = Confidence Interval) The averages of all the steps collected on Day 1 were averaged across 5 trials, and compared to the average calculations across all the steps calculated per subject across the 5 trials on Day 2.

	Day 1	Day 2	ICC (3, k) [95% CI]	p Value	N
Gait Variables	Mean ± SD	Mean ± SD			
Stride Time (s)	1.21 ± 0.10	1.23 ± 0.10	0.96 [0.76-0.99]	$p < 0.001$	4
Stance Phase Duration (ms)	750.0 ± 46.6	750.0 ± 50.9	0.73 [0.61-0.89]	$p < 0.001$	4
Percent Stance (%)	61.7 ± 2.3	61.4 ± 2.6	0.95 [0 .65-0.99]	$p = 0.002$	4

Table 3 Test-retest ICC Values MOVISUFIT Normal Walking Over Ground with Challenges (ICC = Intraclass Correlation Coefficient, SD = Standard Deviation, α = .05, ms = milliseconds, s = seconds, CI = Confidence Interval). The averages of all the steps collected on Day 1 were averaged across 5 trials and compared to the average calculations across all the steps calculated per subject across the 5 trials on Day 2.

	Day 1	Day 2	ICC (3, k) [CI]	p Value	N
Gait Variables	Mean ± SD	Mean ± SD			
Stride Time (s)	1.25 ± 0.08	1.26 ± 0.09	0.785 [0.406 - .993]	P =	4
Stance Duration (ms)	715.62	721 ±	0.697 [0.496 -0.827]	P =	4
Percent Stance (%)	61.2 ± 2.81	61.83 ±	0.907 [0 .394 -	P <	4

3.2.4.2 Validity and Bland-Altman Plots

Bland-Altman plots with 95% LoA were used for the analysis of the agreement between the two measures comparing MOVISUFIT measures to G-Walk measures and for investigation into the presence of bias. The same 4 participants as detailed in the test-retest reliability performed 5 trials each and the parameters were averaged across the steps during each trial providing 5 samples per participant for the plots.

Table 4 Summary of Results Obtained from Four Subjects who Performed 5 Trials The Summary variables displayed in the Bland-Altman Plots are listed and the results include the mean differences ($\bar{d}$) and Standard Deviation of the Diff (SDdiff), with the Limits of Agreement (LoA) calculated comparing MOVISUFIT versus G-Walk on level ground. The 95% LoA was computed by calculating (d) ± (1.96×SDdiff) for the upper and lower boundaries. *Negative differences indicate MOVISUFIT higher than G-Walk

Gait Variable	($\bar{d}$)	SDdiff	95% LoA		N
			Lower	Upper	
Stance Phase duration (ms)	0.86	31.22	-60.34	62.06	20
stride time (s)	-0.014*	0.06	-0.14	0.12	20
%stance (out of 100% gait cycle)	0.47	1.88	-3.21	4.16	20

Stance Phase Duration

Figure 26 demonstrates the Bland-Altman plot comparing all four participants stance phase duration times (ms) across 5 trials with 20 steps per trial for a total of 20 data samples per plot. There is a slight positive bias of 0.86 indicating that MOVISUFIT systematically calculated a higher stance duration than G-Walk G-Studio output. Greater than 95% of the samples do not fall within the LoA however it appears to be a single outlier. The steps per participant were matched between their MOVISUFIT and G-Walk steps, and the compiled into two columns where the ($\bar{d}$) and SDdiff was calculated. A one sample t-test was performed comparing the differences of the ($\bar{d}$) against zero, and the results were not significant with p = 0.903. This indicates there is agreement and it was reasonable to proceed with the Bland-Altman plot. The LoA were calculated by adding and subtracting 1.96 × SDdiff from the ($\bar{d}$). The LoA were -60.34 to 62.06.

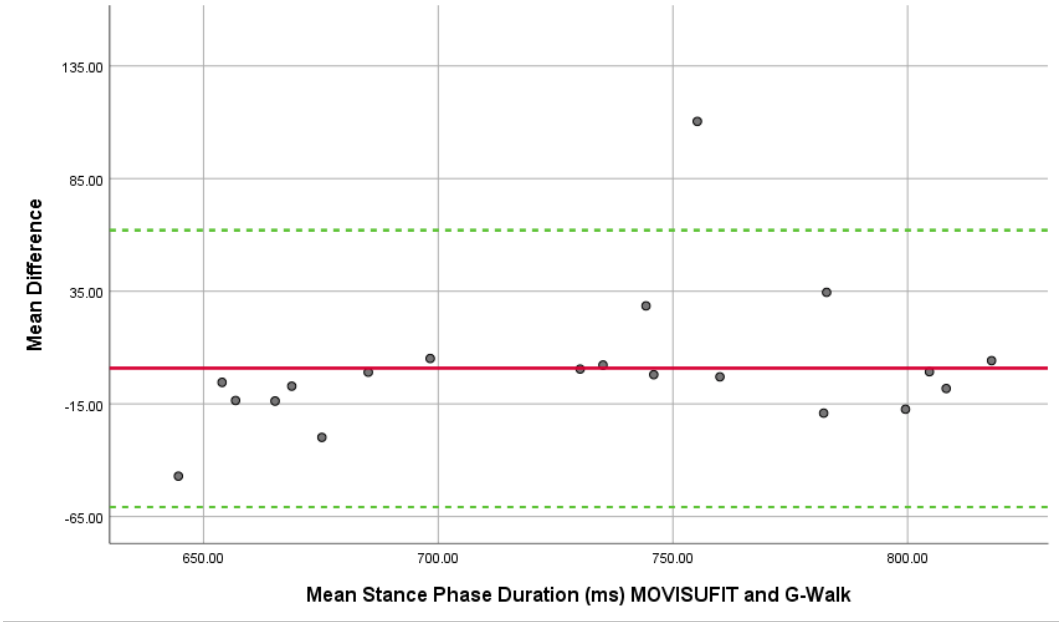

Figure 26 Bland-Altman Plot for Stance Duration Phase for 4 SubjectsEach data point represents an average of the 5 trials per participant. With 4 participants there are 5 samples each for a total of 20 samples. The solid red line is the bias, or mean of the mean difference, and the green dashed lines are the upper and lower LoA.

Stride Time Subject 3 Only - Step by Step Comparison:

Figure 27 demonstrates the levels of agreement amongst stride times for subject 3, over 18 steps during one testing trial. The derivation of the stride times per step from G-Walk data was exceedingly tedious as the graphs from the accelerometer and gyroscope had to be engineered carefully to determine what G-Studio considered a heel strike and toe off. There were two separate times they provided toe to toe and heel to heel. These were noted from the G-Studio output and heel to heel times were added manually, and a stride time was calculated and compared to the corresponding steps from MOVISUFIT during that 50m distance. There was extreme difficulty secondary to the issue that they calculated steps, it appeared, from toe off to toe off and the lower

thresholds were difficult to determine. Figure 27 demonstrates the LoA between the stride times for these corresponding steps calculated by MOVISUFIT versus G-Walk.

The points that are above the upper confidence interval imply that 95% of the stride times do not fit within the LoA and implies lack of agreement potentially. These appear to be outliers however, because the bulk of the other step times appear grouped primarily around or below the ($\bar{d}$) which was -0.008, nearly zero indicating good agreement between the two measures. The mean difference was also negative, meaning G-Walk calculated systematically higher stride times than MOVISUFIT however this is negligible at -0.008. A linear regression demonstrated a B unstandardized coefficient of the mean stride time close to zero (0.007) and the test was not statistically significant. Therefore, there was no proportional bias. There is a small amount of cluster at the lower mean stride times and the differences are negative with differences from the values above the 95% confidence interval and overall implies there may be systematic lower stride times provided by MOVISUFIT than the G-Walk.

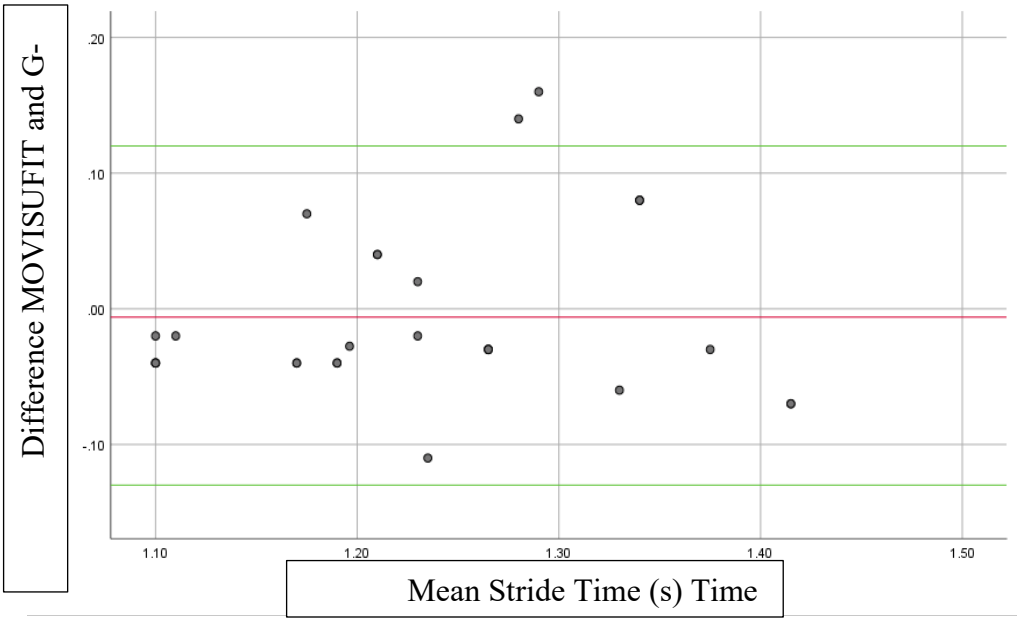

Figure 27 A Bland-Altman plot displaying the mean difference and 95%LoA over a total of 18 steps for subject 3The solid red line is the ~~d~~, and the green solid lines above and below represent the 95% limits of agreement.

Validity Stride Time All Four Participants

Figure 28 shows the Bland-Altman plot displaying the mean difference and 95% LoA for stride times over five trials and all four participants. The ~~d~~ and SDdiff are displayed in table 5. The stride times have excellent agreement with a ~~d~~ of -0.014 which is very close to a zero difference, all of the stride times fall within the LoA. A one sample t-test was not significant with $p = 0.87$, when comparing the mean difference to zero. The mid-range stride times cluster about the zero difference, and it appears increased variability begins with higher and much lower stride times.

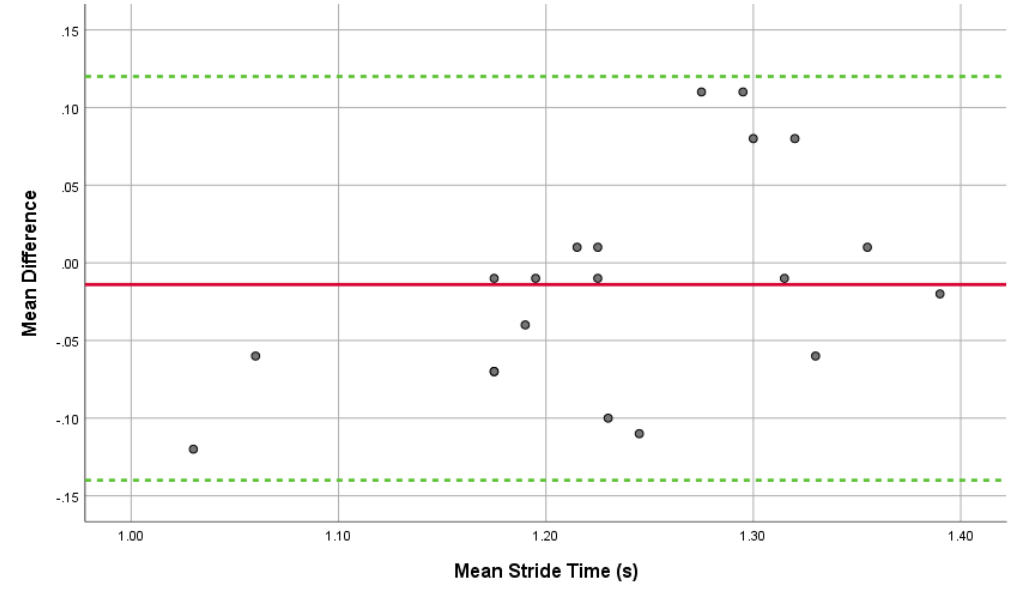

Figure 28 Bland-Altman plot showing d of stride times and 95% limits of agreementMean stride times calculated from four participants averaged over 5 trials each for 20 samples. All stride times were compiled from corresponding MOVISUFIT and G-Walk steps and an average of total MOVISUFIT versus G-Walk steps are displayed. The solid red line is the $\bar{d}$ and green dashed lines are the 95% limits of agreement.

Validity % Stance

Figure 29 shows a Bland-Altman plot of the ~~d~~—between the %stance calculations across five trials with all four participants totaling 20 samples. The plot does indicate the two measures do not agree with the outlier beyond the LoA, however further analysis indicates this is secondary to the taring issue creating systematic difference with that participant of larger differences between the two measures. This was corrected, therefore leaving the other measures within the LoA. The bias was 0.47 and this is clinically reasonable however this does indicate bias demonstrating MOVISUFIT systematically calculates higher % stance than G-Walk. All but one sample fall within the LoA which ranged from 3.21 to 4.16. This upper limit is higher than desired at greater than 2% however the mean difference is far less, and this larger upper lower limit appear to be due

to the first two data points. It was commonly witnessed that at the initiation of the gait trial, participants would have much higher or lower steps than the middle portion of the trial. This could be secondary to a natural uncertainty or nervousness of feeling stable or walking in an unfamiliar setting. Initiating a gait test could naturally cause some decrease in symmetry until a self-selected gait speed which is comfortable is found. A linear regression was performed given the bias, and the unstandardized coefficient was close to zero B = -0.043, and the result was not statistically significant indicating no proportional bias, p = 0.762.

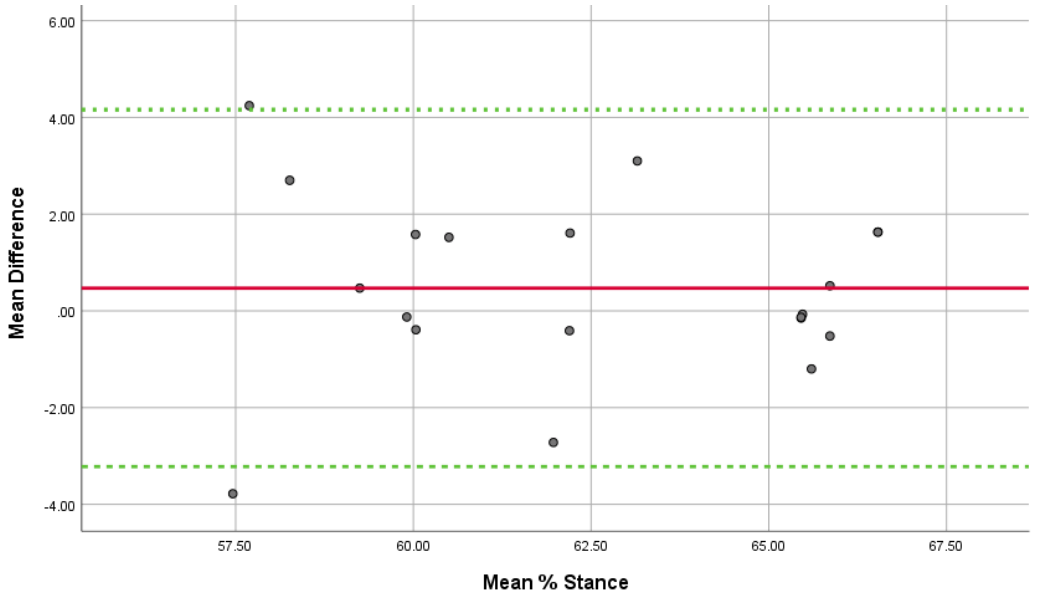

Figure 29 Bland-Altman Plot Displaying Mean Difference and 95% LoA for % Stance Between MOVISUFIT and G-Walk Data points represent averages of 5 trials for each of the four participants for a total of 20 samples. The solid red line is the mean and green dashed lines are the 95% LoA.

3.2.4.3 Validity Pearson Correlation

Pearson correlation coefficients were used for additional analysis of the agreement between the two measures comparing MOVISUFIT measures to G-Walk measures for 4 additional participants for a total of 8 subjects. Table 5 demonstrates the characteristics of the 8 participants.

Table 5 Subject Demographics Pearson Correlation Testing(F = Female, M = Male, kg = kilogram, m = meters, TT = transtibial, TF = transfemoral, SD = standard deviation)

Participant	Gender	Age (years)	Weight (kg)	Height (m)	Prosthesis
1	F	58	59	1.49	TT
2	F	56	113	1.67	TT
3	M	60	83	1.70	TT
4	M	47	65.3	1.70	TF
5	M	48	81.6	1.52	TF
6	M	46	124.7	2.00	TF
7	M	36	94.8	1.83	TF
8	M	55	80.3	1.80	TF
Mean ± SD	2 F, 6 M	50 ± 8	87.71 ± 22.36	1.71 ± 0.17	3 TT, 5 TF

Pearson correlation Coefficients indicated strong associations ($r > 0.80$) (Table 6).

Table 6 Pearson Correlations Between MOVISUFIT as Compared to G-WalkAs Tested During Controlled Self-Selected Speed Flat Over Ground Walking

Gait Variable	G-Walk	MOVISUFIT	Pearson Correlation r (p value)	N
Stance Phase Duration(ms)	727.42 ± 62.22	729.71 ± 69.45	0.86 (p = 0.007)	8
Stride Time (s)	1.18 ± 0.11	1.21 ± 0.08	0.85 (p = 0.008)	8
Percent Stance	60.89 ± 1.63	60.26 ± 2.52	0.86 (p = 0.007)	8

The results of the averaged trials for the 8 participants were assessed graphically for linear agreement comparing MOVISUFIT versus G-Walk. These are displayed in Figures 30 – 32.

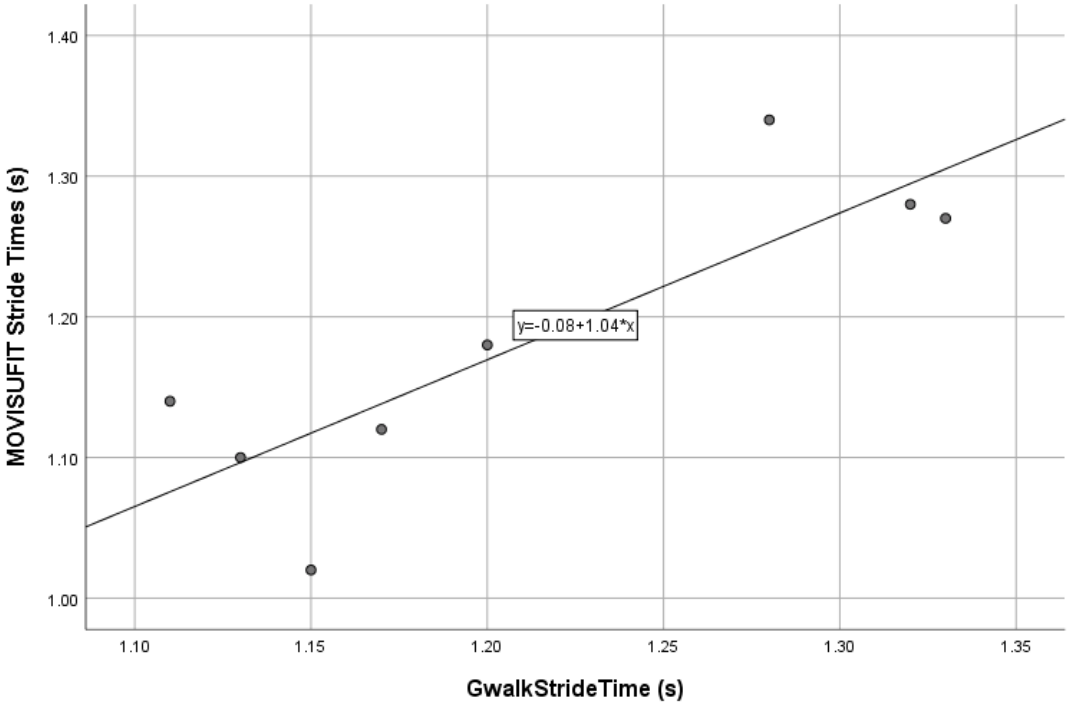

Figure 30 Graphical display MOVISUFIT Average Step Times Versus G-WalkIllustrated are the average step times across 5 trials or each of 8 participants. The line is fit to demonstrate the correlation.

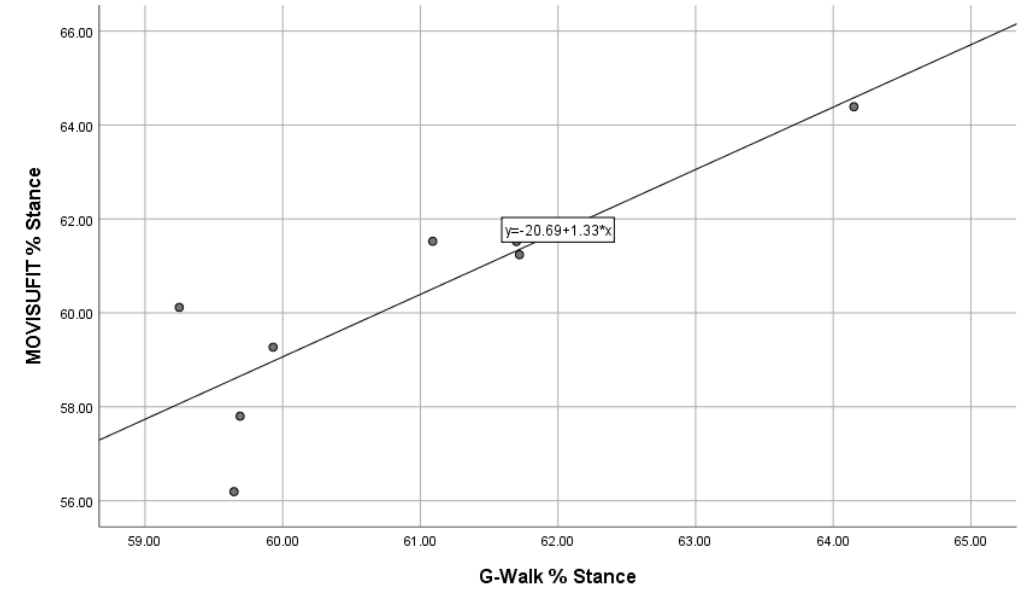

Figure 31 Graphical Display MOVISUFIT Average % Stance versus G-WalkAverage step times across 5 trials or each of 8 participants. The line is fit to demonstrate the correlation.

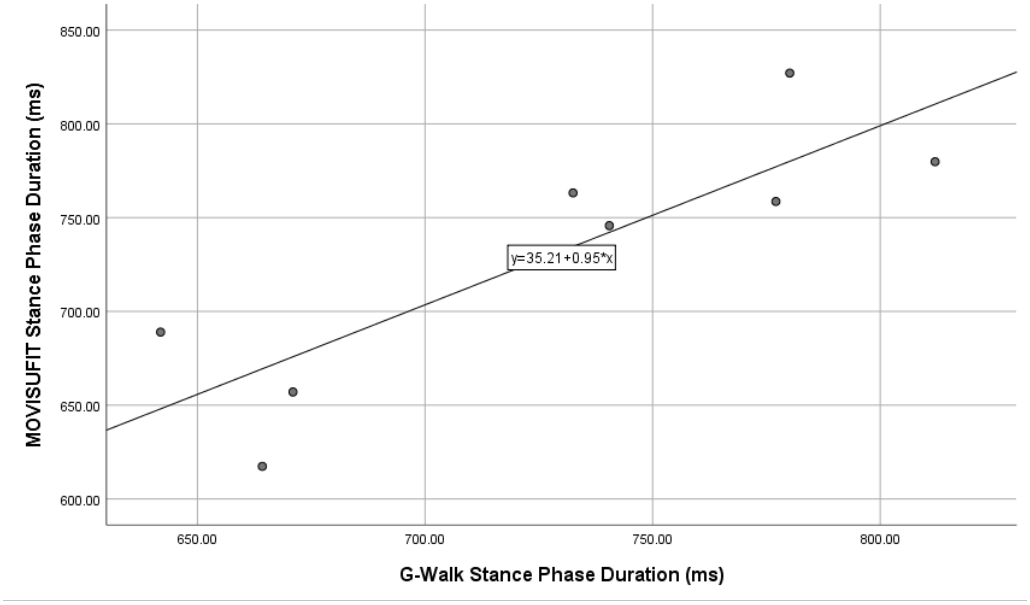

Figure 32 Graphical display MOVISUFIT Average Stance Phase Duration Time (ms) Versus G-WalkAverage stance phase duration time (ms) across 5 trials or each of 8 participants. The line is fit to demonstrate the correlation.

3.3 Discussion

The current data provide early and innovative evidence that a system such as MOVISUFIT, collecting kinetic data from within a prosthetic load cell and deriving spatiotemporal parameters is a reliable measure for step detection, detection of gait events, %stance, Stride Duration, and Stance Duration. %stance demonstrated a good low level of bias with a mean difference of 0.475, however the first two data points did increase the LoA to a larger amount. It was commonly witnessed that at the initiation of the gait trial, participants would have much higher or lower steps than the middle portion of the trial. This could be secondary to a natural uncertainty or nervousness of feeling stable or walking in an unfamiliar setting. Initiating a gait test could naturally cause

some decrease in symmetry until a self-selected gait speed, which is comfortable, is found. On average % stance differences did not go above 3% which is clinically acceptable [125].

Stride time durations demonstrated almost zero bias with mean difference of -0.002 and also overall mean differences ±0.05 which is clinically acceptable [125]. Different patients have different stride times, and those with transfemoral limb loss tended to have longer strides. This could bias the results and future work should separate the two groups. Based on previous work this is explained by evaluation of temporal parameters and inertial measurement units (IMU), worn at the lower back and the results indicated identification of the initial foot contact is critical for accuracy and robustness [126]. Our system uses first contact of the heel at the beginning and end of a stride and stance duration, whereas the G-Walk does not appear to, however the exact algorithm is unknown and proprietary. This previous work found that temporal parameters were less accurate when final foot contact was the basis for determining parameters which is also what the G-Walk uses differently than our algorithm [126].

Stance duration detection was subpar, however, in terms of reliability in distracted settings as well as agreement with G-Walk. It has been reported however, that although the G-Walk demonstrated high levels of agreement for stride time and cadence, it has however only moderate levels (0.47) of association for determining gait cycle phases single versus double limb support and swing stance duration [125]. This is a potential explanation to the reduced ability to find agreement particularly with stance phase duration times. This is addressed in potential for future work.

The step by step variability was high, and this needs to be considered along with the variability that is inherent in amputee gait. There may have also been adjustment period to the change in their prosthesis after installing the sensor, and a longer time should have been provided.

Stance duration was our initial priority to validate, as this is the portion of the gait cycle which our feedback parameter is derived and it was the only variable that could be provided as step by step comparisons readily by the G-Studio system. However, the difficulties described with G-Walk detecting toe off events made this more difficult. However, it was positive that other measures were more robust and corroborated this previous finding that stance times were more difficult to assess validity and like this previous work our findings also demonstrated strong agreement of other the other parameters stride time, and %stance, which the latter was our feedback variable [125]. Initially, it was a concern that the G-Walk does tend to drop steps, if a participant is turning or slowing down or accelerating, and corroborating matching steps was not going to be possible. However, if the sample steps were determined to be assessed within the same time and duration the validity was determined to be assessable. .

Stance phase duration was correlated strongly between sensors with $r = 0.894$ when walking over ground on a flat surface with a very specific distance. It does provide evidence that the system can calculate stance duration time accurately from which the feedback variable can be derived. There did exist a bias in earlier trials of estimating % stance (systematically higher than the G-Walk) however this was improved with the algorithmic adjustment referenced in chapter two regarding the calibration to a zero baseline and lower threshold detection. The bias still exists however is 3.15 which is acceptable as a mean difference [125].

Stride times were strongly reliable (ICC > 0.8) for both conditions. Stride times are an important variable as those are determined by the lower threshold gait events. It was unexpected that these would be more strongly correlated than the other parameters, given the G-Walk G-Studio software calculates them differently than our force derived time points. However, being internally consistent provides confidence that we can assess future improvement in symmetry of stride times.

Initially, it was concerning that %Stance was correlated only modestly with the G-Walk with a Pearson's R = 0.702. However, the difference in methods also is an explanation.

Our findings suggest that MOVISUFIT is a reliable and valid tool to measure stride time, % stance, and stance duration during walking. This is promising for future designs and iterations to progress the innovation to more complex feedback.

3.4 Limitations

Limitations of the current study are that we are unaware of the algorithm that G-Walk uses which is prohibitive in determining an underlying exact explanation for the results. Furthermore, we measured spatiotemporal parameters on those with TT and TF and this could affect the accuracy of the results, however a system should be able to tolerate those differences. Also, validity in this study was examined at a self-selected speed, and not over other terrain and turns as reliability was, and speed can affect accuracy [127]. This is demonstrated in these Bland-Altman plots . In addition a recent study compared the G-Walk's validity against the GAITRite system and it was found in their results that gait measures that rely on final foot contact such as toe off, which stance duration does, should be cautiously interpreted and revealed poorer validity. This is an explanation of our difficulty to statistically agree with that measure from G-Walk as well.

Given the small sample size, this study could have limited internal and external validity. With lower external validity, our findings could not be as generalizable beyond the specifications of this study sample [128]. An additional limitation is in measuring validity and reliability, additional measures could have been used, such mean differences or Standard Error of Mean. Order effects, such as fatigue, can make the interpretation of the data difficult. In this instance,

the interventions were not randomized. However, participants would obviously remember the previous time they underwent the test, and this could cause boredom, and decreased effort during the test. It could also affect their outcomes that if, for example, each time the 6MWT was performed before the G-Walk tests. This could cause fatigue therefore we performed G-Walk tests prior to the 6MWT. This sequence was intended to not fatigue the patient prior to a test that examines quality of gait, although it could bias the results given that the sequence is predictable. Also, simply doing repeated testing could lead to improved performance or increased skill as the participant becomes more familiar with the measurement.

One of the most difficult limitations of the study is synchronizing the force-based timing data against an inertial sensor using an accelerometry based algorithm. When analyzing our raw data against G-Walk for both prototypes, it was very difficult to align them step to step, particularly if any turns were taking place. Our %stances initially, with the MOVISUFIT prototype, were systematically biased higher than G-Walk data for most participants, and that was discovered to be a software taring issue. As the app became more sophisticated, the timing of the taring needed to be during the live data streaming. With the interface advancements of pausing during training, which was extremely helpful for the clinician to document a reason for the pause for later post hoc analysis, the taring was not being performed for several trials, resulting in elevated lower threshold event detections. However, when examined on gait trials performed within five days, the reliability was excellent.

3.5 Future Work

Given the findings of moderate to excellent reliability of the MOVISUFIT system and the finding of strong correlations with G-Walk stride time indicates the system is reliable and valid for measuring stride times and calculating % stance. As this is a marker of a potential feedback variable or indicator of improvement that the system can accurately measure, these findings are promising. Future research should investigate MOVISUFIT's validity and reliability in clinical populations during different gait conditions or activities once a new feedback variable is introduced as well. In addition, future work could validate the system against an instrumented treadmill, GAITRite, or a more robust inertial sensor system such as XSens (XSens Technologies B.V., The Netherlands).

4.0 Efficacy of the RTMVF and MOVISUFIT Systems

4.1 Introduction

In the limb loss population, there is a documented inadequate reorganization of the functional motor pattern and deficits such as loss of active plantar flexion must be accommodated. Evaluation of clinical biomechanics offers the possibility of investigating the consequences of compensatory actions but also potentially the treatment of them. Whereas in prior treatment protocols and applied research the training was task specific and based on other evidence and on the evidence in this project, the direction of focus and attention can expand beyond traditional forms of training and practice. To improve adaptability to new gait patterns, it is well established that specifically practicing step and stride parameters in clinical settings does improve mobility outcomes [101]. However, evidence from studies of motor learning indicate a potentially superior method of motor learning, or re-educating motor skills, and that is when practice is in response to external cues. These responses to external cues enhance and access directories of motor control within our physiology. Visual cues, in this realm, have been demonstrated as more critical than auditory cues in the control of gait training, particularly when training gait adjustments in response to the environment. Thus, we hypothesized that providing practice of adapting a participant's gait in response to visual cues, outside of controlled settings, would improve walking symmetry and endurance. As stated earlier previous methods of providing the external visual cue have been mirrors, projection onto a screen, while on a treadmill or in a lab setting. Our system, has the advantage of providing these cues in a more realistic manner and not limited to space. In preparation for future larger trials, our aim was to preliminarily test the efficacy of delivering real

time visual feedback in a method that was not limited to clinical settings. The study aimed to establish feasibility and effect size for calculating potential sample sizes.

The purpose of this study was to develop and examine the efficacy of a the RTMVF and MOVISUFIT gait training systems for those with lower limb loss on improving gait performance as defined by; Gait symmetry, pelvic symmetry in the frontal plane, and additional functional measure 6MWT. A secondary purpose of this study was to examine pain and function as defined by the patient reported outcome measures LCI-5, OPUS HQOL, Functional Status Measure, and the Chronic Pain Grade. It was expected that the training will trigger earlier self-modification, within the participants, of overexertion and poor mechanics resulting in the chronic pain syndromes caused by load imbalances.

4.2 Methods

4.2.1 Subjects

A-priori sample size was estimated based on limited previous works involving similar outcomes and treatment interventions. Based on a study by Dingwell et al., who used real time visual feedback and measured symmetry as an outcome, a training intervention yielded a mean difference in symmetry of 4% resulting in an effect size of 0.53 with 12 subjects (however six healthy, six amputees) [31]. Therefore, with an a-priori power analysis of $\propto = 0.05$ and $\beta = 0.20$ we proposed to recruit eighteen individuals allowing for an attrition rate of 20%.

Prior to the baseline measurements or any research procedures, goals, contents and methods of the study were explained to the subjects. All subjects provided written informed

consent in accordance with the (IRB# PRO15120426). After signing the consent form, participants were scheduled to perform baseline testing.

Participant recruitment followed the approach outlined in chapter 3.2.2.1 recruited by flyers in the MSPO clinic, web-based postings, print media and direct contact with potential subjects that were seen in local lower limb loss rehabilitation focused clinics. Initial screening was performed by the Co-I or PI when a participant contacted them regarding the study. If the potential participant passed the screening, they were invited to complete the consent form as described above, and once consent was provided, attend a testing session. Participants were compensated for their time.

Participants with unilateral transtibial (TT) or transfemoral (TF) limb loss were enrolled regardless of the type of prosthesis. However, the prosthesis had to be modular to accommodate the sensor. The participants were included if they were over 18 years of age, wore their prosthesis for at least one year, could perform at least 15 minutes of walking without an assistive device and had a gait deviation per the licensed Doctor of Physical therapy who was also the PI for this study.

Exclusion criteria consisted of bilateral lower limb amputations, the use of an assistive device to ambulate, undeclared medical conditions that presuppose proper prosthesis use, vision impairments incompatible with smart glass use, history of seizures and any co-morbidities that prevent the participant from walking for 15 minutes.

4.2.2 Study Design

The study design was a single cohort prospective repeated measures design to evaluate the efficacy of the RTMVF/(MOVISUFIT) system during gait training. The repeated measures allowed the investigation of changes over time, to provide preliminary effect sizes for a larger

conformational trial. The trainer was a licensed physical therapist, the PI, therefore blinding to the intervention was not possible.

In order to identify differences, pre and post tests were performed with an additional datapoint one month following the conclusion of training (one-month follow-up) to determine retention of training gains. Qualitative and quantitative assessments were performed at three time-points, at baseline, post training and at a one-month follow-up. Tests and interventions were undertaken in the MSPO and RST departments in the Bakery Square location of the University of Pittsburgh.

4.2.3 Evaluation and Assessments

Participants did not receive any other treatment of rehabilitation program throughout the duration of the study. In each testing session, participants were fit with the iPecs integrated load cell or the Europa integrated load cell. Photographs, leg length measurements, evaluation by one or two Prosthetists as well as markings were made to ensure alignment matched their pre-training alignment. They then were fitted with the glasses and instructed how to place the screen in a manner in which it did not obstruct their vision but allowed them to see the color displayed comfortably and safety.

4.2.4 Outcome Variables

4.2.4.1 Quantitative

The variables chosen as outcome variables were done so for their demonstrated association with various downstream secondary orthopedic issues seen in this population. Gait symmetry,

chosen as the primary outcome variables for gait quality. The proprietary symmetry index from GWALK was used, where the perfect symmetry is defined as 100%. Percent stance, and pelvic obliquity in the frontal planes were considered as secondary outcome variables related to gait quality. Pelvic motion and obliquity have been reported to be significantly different pre and post training with real time feedback [22, 70]. Pelvic obliquity has also been listed as a significant gait deviation in those with lower limb loss in systematic reviews [90, 129]. G-Walk reports a Pelvic Obliquity Index which they report is a quantification of how much the accelerometry curves from the left to the right in the frontal plane are similar in profile. It is computed using cross-correlation and applied to the two curves. If they perfectly overlap, the index is 100, because the curves would have the same value for every frame captured (Gabe Glasser, G-Walk, BTS, Bioengineer).

The other Proprietary Symmetry Index from the mobile Gait Lab G-Walk was used as the outcome measure to determine gait symmetry improvements. It is calculated the same way as the pelvic obliquity index, in that it quantifies how much the profile of the right curve is similar to the profile of the left curve. The number is computed using the mathematical function cross-correlation applied to the two curves. If the curves perfectly overlap, the index is 100 and it means that the two curves have the same value for every frame, however in this case it is right versus left legs.

The Functional test (6MWT) was chosen as it is a strong predictor of accuracy and totality of step counts accounting for 38-54% variance [12, 130]. An individual's self-selected walking speed has been reported as a reliable measure "validated in this population", and a strong predictor of disability [131-134].

4.2.4.2 Self-Reported Data

Four validated questionnaires were used to assess pain and function. Pain has been correlated to gait deviation and decreased prosthetic use [1, 63]. Therefore, the first, the Chronic Pain Grade, (CPG) was used to assesses both disability and the varying forms of pain that occur within this population. The CPG has demonstrated good internal consistency. Cronbach's alpha was 0.9132, and the item-total correlations ranged from 0.69 to 0.82 against the 36-Item Short Form Survey (SF-36)which has been validated in the amputee population [66, 135]. The three additional patient-reported measures were regarding function and quality of life. The Orthotic and Prosthetic User Survey (OPUS) was garnered for its Lower Extremity Functional Survey (FSM), and its Health and Quality of Life Survey (HQOL) . Disability Points were calculated converting the scores to four ranges of points. A conversion of Question 4 was made to points from a 3-level rating of the statement "Days in last six months are you kept from usual activities because of your pain?". The disability points were then added to this converted question 4 and created a total point scale.

The Lower Extremity Capabilities Index – 5 (LCI-5) was chosen as a disease-specific, self-administered instrument for assessing locomotor abilities generally considered essential for basic and advanced Activities of Daily Living (ADLs) of people with lower-limb amputation. The ability to perform ADLs are an enabling factor associated with long-term prosthetic use [104]. It is a 4-level ordinal scale (0–3 points; ranging from "not able" to "able to accomplish the activity alone") scores the degree of a person's perceived independence in performing each of 14 activities while wearing the prosthesis with a possible maximum score of 56. Higher scores reflect greater locomotor capabilities with the prosthesis and less dependence on assistance. The LCI-5 correlated in all criterion measures (p range, 0.61-0.76) with the Rivermead Mobility Index and

Function Independence Measure (FIM)instrument, but the LCI-5 shows larger effect size and a lower ceiling effect [136].

4.2.5 Gait Retraining

Participants participated in a standardized gait training program (4 weeks, 2 times per week), which successively increased its level of endurance by progressing from 15 to 30 minutes of training time over the first 4 sessions, then maintained30 minutes over the last 4 sessions (Table 7). The participants received real time visual feedback, as outlined in Chapter 2, from either the MOVISUFIT or RTMVF prototypes. The participants either used the iPecs integrated sensor with USB connection to a Surface Pro or Ultramobile PC, and wireless Vuzix smart glasses to receive the red, yellow, or green visual feedback, or the MOVISUFIT prototype using the wireless Europa sensor, and Android phone for data processing and feedback transmission to the Vuzix Smart glasses (M100 - M300). Both sensors provided an Axial Force (Fz)which was incorporated into the same algorithm to define the feedback parameters.

During the first visit, participants were trained by the Doctor of Physical Therapy (DPT)(PI) using verbal cues, and demonstration and education, to assist the participant in associating the feedback colors with their gait pattern and compensatory mechanisms observed by the therapist (Figure 33). Each participant was videotaped to assess their gait deviation and provide a reference during training for the DPT, and upon initial screening previous surgeries and history were documented. There were a few key gait deviations that presented across the cohort including ipsilateral trunk lean to affected side, excessively long stride on the uninvolved side, decreased heel strike, and arm swing and negotiating slopes without significant decreased time on the involved limb. Once the participants presented with a stable walking pattern, data was

collected at 100Hz throughout the training sessions and processed into feedback provided per step. If the participant needed to rest, the system could be paused, and data collection could continue again once training ensued at the same sampling rate.

Figure 33 PI Training participant with RTMF system visit 1 associating colors to gait mechanics

Participants received the gait retraining by the PI (DPT) as outlined in Table 7. Each session was approximately 30 minutes to 1 hour and included fitting the sensor and subsequent RTMVF/MOVISUFIT gait training. The training was systematically increased from 15 minutes to 30 minutes over the first 4 visits. We utilized a faded feedback protocol over the last four sessions to help internalize motor learning [23, 26, 29, 137]. (Table 7, Figure 34.).

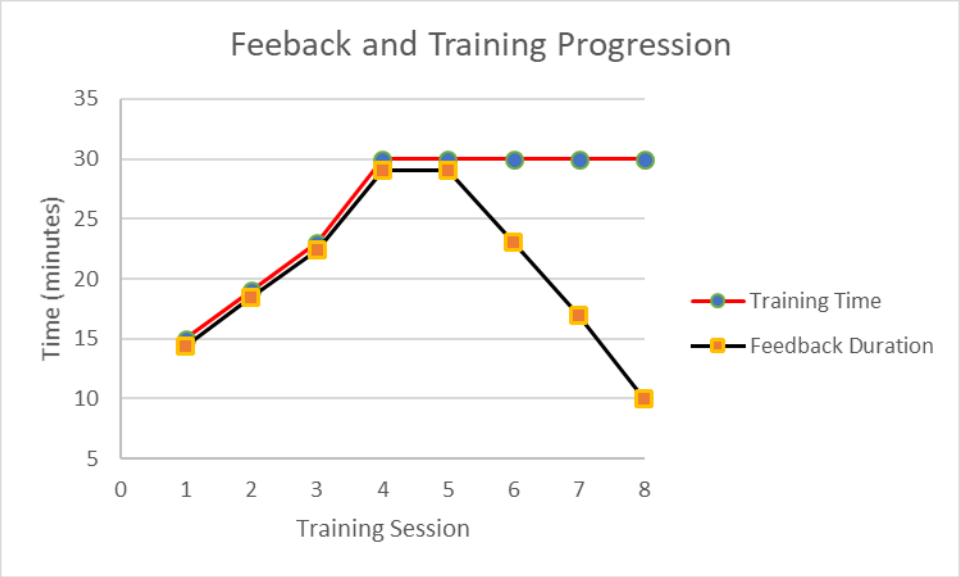

Figure 34 Faded feedback and Systematic Training ProtocolBased on Noerhen et al 2013 for Reference

http://dx.doi.org/10.1136/bjsm.2009.069112.

An external focus directs the attention of the learner on the effects of their movements (different walking strategies changing the feedback they see on the screen vs. focusing on their own extremity alignments) and reduces their attentional demands [8, 73, 78, 99]. Training over a brief accommodation period at the initial training session included educating the patient on what the red, yellow, and green feedback colors indicated about their gait pattern, and the first session did include verbal cues and training to assist the patient in learning adjustments that could be made to trigger the color changes.

Table 7 Intervention and Data Collection Protocol

Baseline Visit (Time 1):Informed Consent, Baseline Gait Assessment[1] Patient Reported Outcome Measures[1]		
Training Week 1	Visit 2:	15 min Gait Training
	Visit 3:	20 min Gait Training[1]
Training Week 2	Visit 4:	25 Min Gait Training
	Visit 5:	30 min Gait Training
Training	Visit 6:	30 min Gait Training1a with feedback first 20 min
	Visit 7:	30 min Gait Training1a feedback first 15 min only[1c]
Week 4	Visit 8:	30 min Gait Training with feedback first 7 min only[1c]
	Visit 9:	30 min Gait Training with feedback first 2.5 min only
Training Week 5	Visit 10: Post Training Testing	Time 5: (Minimum of two to five days after visit 9 Gait Trial Gwalk2, 6MWTt,) CPG, LCI – 5, OPUS HQOL and FSM LCI-5
Weeks 6-10		Independent Practice of New Pattern without Device & PT
1 Month Follow-up	Visit 11:	1 Month Post Gait Training Intervention Reassessment[6]
[1] Baseline Prosthesis Alignment, Physical Therapy Evaluation (Strength, ROM), Baseline Walk Trial (3 sessions of 1 min Standardized Distance Level Hallway, 5 min rest in-between or until discomfort is <3/10), NPRS, 6-minute Walk Test (6 MWT), LCI-5		
[1a] Gait Training with Mobile Device with Verbal (VC) and tactile cues (TC) from licensed PT (PI) for over ground training of patient of associated neuromuscular patterns with associated changes in visual display.		
[1b]Fade out of feedback, decreasing feedback each session to internalize pattern begins and incrementally is decreased each session.		
[2] G-Walk Trial Patient walks (3 sessions, Standardized Distance Level Hallway next to Physical Therapist while wearing GWALK and data is collected on laptop.		
[5a] Independent		
[6] One-Month Post Gait Trial Reassessment: 1) G-Walk Sensor standardized distance of level hallway (to assess retention) 2) 6 MWT 3) CPG 4) LCI – 5 5) OPUS HQOL and FSM		

Subjects navigated a variety of level hallways, level sidewalk, and lobbies and elevators. Data was collected (raw data of time, all spatiotemporal variables, Fz, moment(M) produced in 3 planes (My, Mz, Mx), peak Fz, range and max Mz) throughout training for further post hoc analysis on biomechanical risk factors and assessment of potential feedback parameters.

4.2.6 Statistical Analysis

Histograms, Boxplots, and Shapiro–Wilk tests were utilized to test assumptions of normality and no extreme outliers in the dependent variable. Mauchly's Test of Sphericity was also performed. Repeated Measures Analysis of Variance (ANOVA) was conducted to assess if there was a change in the parameters of interest over three time points, with the last being a one-month follow-up to assess retention. If there were significant differences, pairwise comparisons were performed. Sidak corrections were performed amongst the repeated pairwise comparison and paired sample T tests were performed, however. even though there can be risk of Type I error, if the alpha is not adjusted, however in this case they were deemed appropriate given the exploratory nature of the study. If there were results containing ordinal data, a Wilcoxon Signed Rank Test was used,

4.3 Results

The a-priori power analysis stated 18 would be recruited with 20% attrition rate. The previous work prior to this study at the time was limited to one study that was similar in Dingwell et al. Their study consisted of 12 participants, however 6 were with limb loss, and their effect size

was our goal. 18 subjects recruited with a 20% attrition rate is 12 subjects. We recruited and tested 14, with 10 able to complete the full one month of training, therefore this is a higher sample size than previous work. Fourteen subjects participated in the study, four were involved in the development and feasibility aspect described earlier. Ten participants completed the entirety of the gait training but two did not complete the one-month follow-up for different reasons which were assessed post-hoc. One participant was not able to complete follow-up because funding expired. For the other participant, the reasons are unknown. Therefore, eight participants with unilateral trans-femoral or trans-tibial lower limb loss completed this study.

All participants exhibited at least a K3 level of walking (based on Medicare's functional classification level) and characteristics, including, age, height, mass and time in prosthesis can be found in Table 8. As referenced in the subject section of chapter 3, subsection 3.2.1, the first three participants were involved in development and feasibility testing. Subjects four to eight participated in the training study, but subjects 11 and 14 did not complete the one-month follow-up.

Table 8 All participant demographics, Kg = Kilogram, M = male, F = female, m = meters, BK (below knee), AK (above Knee)

ID	Age (years)	Mass Kg	Height (m)	Gender	Prosthesis	Involved Limb	Time since surgery (years)
1	59	81	1.8	M	BK	left	23
2	67	59.1	1.82	M	BK	right	15
3	22	124	1.85	M	BK	left	5
4	58	59	1.49	F	BK	right	12
5	46	94.43	1.7	F	BK	right	8
6	57	114.3	1.68	F	BK	left	2
7	69	113.4	1.78	F	BK	right	8
8	66	59	1.52	F	BK	right	8
9	46	124.7	2.01	M	AK	left	1
11	61	83	1.7	M	BK	right	35
12	49	65.3	1.69	M	AK	right	26
13	36	94.8	1.83	M	AK	left	2
14	55	80.3	1.8	M	AK	left	10

4.3.1 Gait Symmetry

Results are seen in Table 9. Three GWALK trials were averaged at each time point for each subject for an n of 16. averaged across each participant.

Table 9 Descriptive Statistics of the Gait Symmetry Index Provided by G-Walk

	Mean ± SD	N
Symmetry Index Baseline	82.58 ± 10.05	8
Symmetry Index Final	90.30 ± 7.32	8
Symmetry Index One -Month Follow-up	88.38 ± 7.92	8

The main effect of training was significant ($F(2,14) = 5.38$, $p < 0.05$, $\eta 2 = 0.435$). Using Sidak's correction, pairwise comparisons were conducted, and further pairwise comparisons were

not significant. However, given the experimental nature of the study a paired samples t-test was performed and baseline to post training was significant with t (7) = 2.45, p < .05 and a Mdiff of 6.47 and SD=7.5. From Baseline to Post Training, Cohen's f =0.88, which is very large. Using the mean of the difference, (Mdiff) and the baseline SD, which is done in some conventions if there is no control group, the effect size is d = 0.77 which is large. The difference between Baseline to One-Month Follow-up was examined experimentally with a paired-samples t-test and was not significant but is worthwhile to report with t(7) = 2.35 and p=.05 precisely. The mean difference (Mdiff) was 4.7, and the effect size = 0.823 if we use the SDdiff. This is a greater than a moderate effect. The difference from Post Training to One-Month follow-up was not significant, p = 0.577, with a Md of 1.955 and an effect of 0.24 which is small.

4.3.2 Six Minute Walk Test (6MWT)

A one-way repeated measures ANOVA was conducted to compare the effects of RTMVF/MOVISUFIT training on the 6MWT measured in Meters. There was a significant effect of training (F (2,14) = 7.345, p = 0.007, η2 = 0.512), which translates to a Cohen's f(V) = 1.024, which is very large (Table 10).

Table 10 Descriptive Statistics 6MWT-Distance in meters (m)

	Mean ± SD	**N**
Baseline 6MWT Distance (m)	303.82 ± 64.62	8
Final 6MWT Distance (m)	394.17 ± 120.52	8
One Month Follow-Up 6MWT Distance (m)	396.95 ± 138.64	8

Pairwise comparisons found a significant difference between Baseline and Post Training with Mdiff = 90.35, p=0.024, d=1.29 using the baseline SD. There was no significant difference between baseline and the One Month Follow-up. The Mean difference was even larger than the Baseline to Final difference, (Mdiff = 93.13) However, the variability of the mean difference was larger with SDDiff = 102.34. An individual paired-samples T-test was conducted and yielded t(7) = 2.547, p = 0.037, (Mdiff = 93.13, SDDiff = 102.34). This effect size then was f(v) = 0.94 which is large. There was no significant difference from post training to the One Month Follow up with a Mdiff = 2.781, SDDiff =54.39, p = 0.999.

4.3.3 Pelvic Obliquity in the Frontal Plane

The pelvic obliquity in the frontal plane is measured as an index referenced in section 4.2.4.1 where a cross correlation is applied to the two accelerometry curves from either side of the pelvis and an index is generated depending on how much they overlap. 100 would be they overlap perfectly. Therefore, it is a unitless measure from 0-100 where 100 is perfectly overlapping without asymmetry. A repeated Measures ANOVA did not find a significant effect of training (F (2,14) = 1.60, p >.051, $\eta 2$ = 0.186). However, this translates to a Cohen's D effect size f(V) = 0.48 which is a moderate effect size. The means and SDs are shown in Table 11.

Table 11 Mean and Standard Deviation (mean ± SD) of the Pelvic Symmetry Index

	Mean ± SD	**N**
Baseline	44.96 ± 15.64	8
Post Training	54.07± 17.36	8
One Month Follow-up	53.08 ± 19.31	8

The Pelvic Symmetry Index was provided by G-Walk in the frontal plane and measured at the three time points. The baseline to post training means increased in symmetry by 20.3% however it was not significant with p = 0.08, however the effect size using Mdiff and SD diff resulted in a Cohen's d of 0.57 which is moderate. The effect size from baseline to one-month follow-up was calculated using the Mdiff and SDdiff was also moderate with Cohen's d = 0.44. The increase in symmetry remained greater than 18% at the one-month follow-up.

4.3.4 OPUS Health and Quality of Life Index (HQOL)

HQOL scores were converted to Rasch Scores per the OPUS guidelines, and the means and SD for the three time points can be seen in Table 12. A repeated measures ANOVA did not find significant results,(p = 0.148). However, the mean difference from one month to baseline was 3.99. When $\eta 2 = 0.271$ was converted to Cohen's f, the effect size was 0.609. A paired-samples t-test was not significant, however, the Cohen's D calculated from the Mdiff and the SDdiff was 0.56 which is a moderate effect.

Table 12 Mean and Standard Deviations (Mean ± SD) Health Quality of Life (HQOL) Survey Rasch Scores

	Mean ± SD	**N**
Baseline	58.85 ± 8.91	8
Post Training	61.08 ± 8.25	8
One Month Follow-Up	62.84 ± 7.64	8

4.3.5 Chronic Pain Grade

A repeated measures ANOVA including the three assessments did not find significant differences ($p = 0.0322$) however, paired-samples t-tests were conducted at the pre to post training level to illuminate apparent improvements (Figure 35).

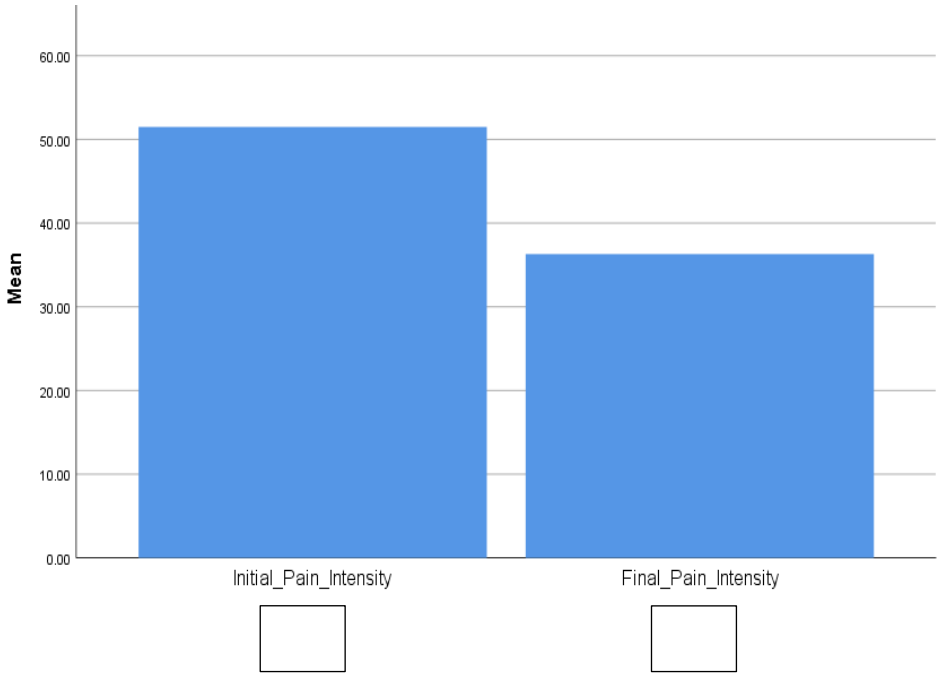

Figure 35 Mean of Pain IntensityA) baseline average across participants, B) post training mean across participants.

When examined more closely, on average, participants did have lower Pain Intensity post training (M= 44.16, SD = 23.41) than pre training (M =53.33 , SD = 17.457) which was not statistically significant. However, Cohen's D was 0.40 which is moderate (Table 13).

Table 13 Mean ± SD of Pain Intensity at the Three Time Points.

	Mean ± SD	N
Baseline Pain Intensity	53.33 ± 17.45	8
Post Training Pain Intensity	44.16 ±23.41	8
Pain Intensity One Month Follow-	42.91 ±24.19	8

There was a significant difference in the repeated measures pre training and post training with t = -2.687 (1,19) p = 0.007. The negative indicates a reduction in pain (Figure 36).

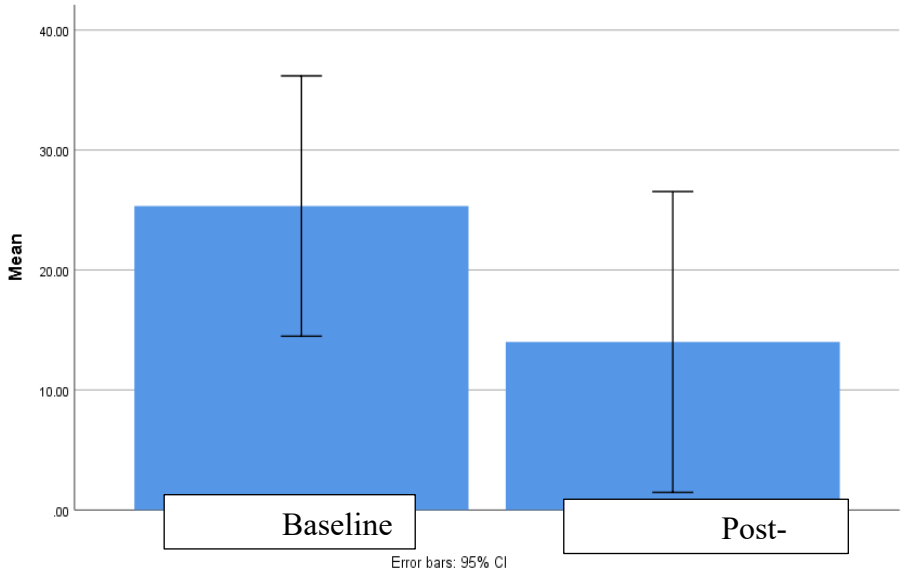

Figure 36 Reduction in Disability Scores Pre to Post Training with 95% CI.

However, secondary to the fact the points are all added, a ratio outcome can be considered, and a repeated measures ANOVA was also executed. On average the participants did reduce their total disability points from pre training (M= 2.4, SD = 1.35) to post training (M =0 .5, SD = 0.97) and it was significant F (1,7) = 25.186, p = 0.001.

4.3.6 OPUS Functional Status Measure

The means and standard deviations for the pre and post treatment results of the OPUS Functional Status Measure (FSM) are show in in Table 14. The raw scores were converted to Rasch Scores to allow for analysis in ratio/scale measures.

Table 14 Mean and Standard deviation (SD) OPUS Functional Status Measure Rasch Scores

	Mean ± SD	**N**
Baseline	53.08 ± 3.75	8
Post Training	55.40 ±4.44	8
One Month Follow-up	55.68 ± 4.01	8

A repeated measures ANOVA resulted in an F (2,14) = 3.334, p = 0.065, $\eta 2$ = 0.323. Cohen's definitions of effect size based on $\eta 2$ indicates there is a large effect, f = 0.69. Given the borderline alpha result and the experimental nature of the study, a post hoc paired-samples t-test was used to compare the mean differences pre training and post training on the OPUS Functional Status Measure (FSM). A Cohen's d was calculated as 0.7. Differences from baseline to One Month follow-up were not statistically significant. However, with a mean difference of 2.6, and SD = 4.05, Cohen's D was 0.64 which is a large effect size.

4.3.7 Lower Extremity Capabilities Index – 5 (LCI-5)

On average ,the participants improved their LCI advanced level sub scores from pre training (M= 24.9, SD = 6.98) to Post Training (M = 26.7, SD = 2.31)but the difference was not

statistically significant $p > 0.05$. However, the mean difference exhibited a Cohen's D of 0.39 which is a moderate effect size. Figure 37 depicts the before and after values in the functional score.

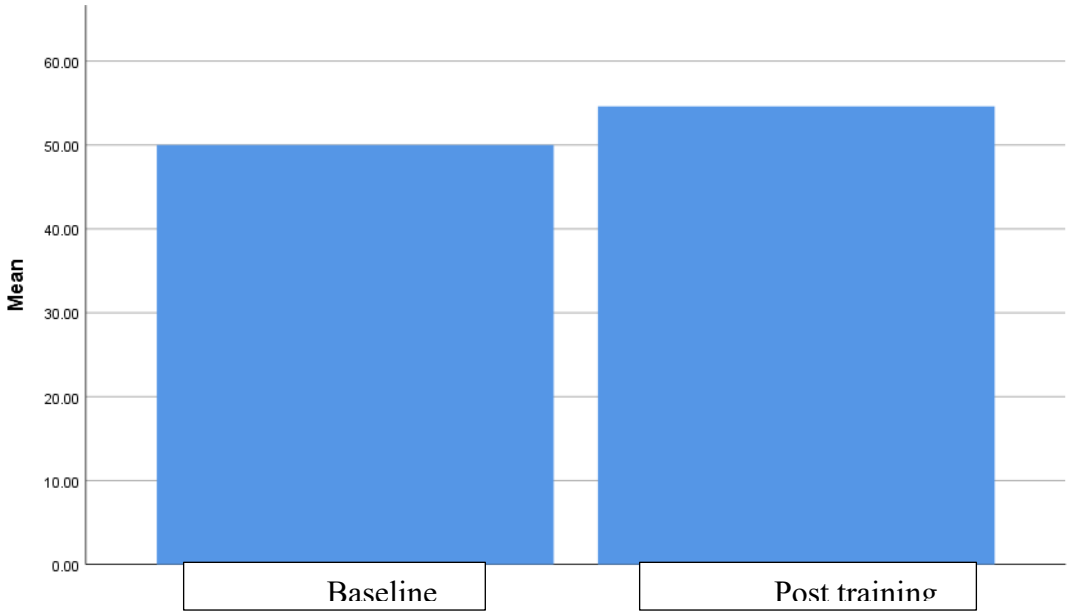

Figure 37 Mean differences in total C=LCI scores from pre to post training (N = 8).

4.4 Discussion

This study provided gait training with real time visual feedback for over-ground walking in a more naturalistic environment to assess the efficacy of the treatment on the parameters Gait Quality as measured by Symmetry and Pelvic Obliquity, as well as Pain and Function as measured by CPG, 6MWT, OPUS FSM, HQOL and LCI-5. Studies have compared real time visual feedback in this population prior, however currently it is not known if those have been effective beyond the

laboratory setting with virtual reality, treadmill training, or with visual feedback. This environment and type of training might encourage a greater internalization of the new motor patterns.

It was found that most of the parameters measured were maintained at an improved level than at the baseline level, which is a critical finding of the pilot data. This included Symmetry which has the most significant improvement of the outcome measures with a 9.4% increase from pre to post training and maintained a 7% increase at one month. Dingwell at al found a 4% improvement as an effect size of 0.56 [31]. Our intervention achieved that result at one month and double that immediately post training. One study with auditory feedback found almost a 26.5% improvement in symmetry, however this was demonstrated in one subject out of a total sample size of three [70]. The total mean % change of the three subjects pre to post, was 9.9% ± 14.5 which we were able to achieve within 2% at the one-month follow-up post the conclusion of training. They similarly trained with repeated visits with a total of 6 over 3 weeks, which is a higher intensity than our program [70]. We implemented a lower intensity program and maintained similar results for a month post training.

The findings related to the 6MWT are the most encouraging of the findings as the 6MWT has been directly correlated to higher functionality [131]. The risk factors related to gait speed are also well documented as decreased endurance and increase energy expenditure in those with limb loss, so this finding is considered clinically relevant [133]. Also, that the results continued to progress at the one month follow up indicated that the new more efficient patterns were internalized to a greater degree than with traditional training with an improvement of 91meters from pre to post training and 93 meters at one month. The MDC of the 6MWT was reported as 1.47m, and clinically meaningful differences are results >45m, and our results demonstrate twice that elevation [138].

Pelvic Obliquity was also improved by 20% and maintained at an 18% improvement at the one month follow up. Previous studies found that Pelvic Obliquity effect sizes were -0.68 for the intact limb, and -0.82 for the prosthetic limb with an average of -0.70 [139]. Initially, based on limited previous work such as this, we considered that our findings would be meaningful if the effect size was >0.6. Our effect size was an improvement in obliquity not negative and Cohen's D was 0.57 which is bordering on the originally hypothesized outcome. Further analysis would have to be performed to elucidate the findings here secondary to the post hoc findings were not a part of the initial aims related to the pelvis. Previous data in the mentioned study was collected regarding the intact versus the prosthetic limb and the findings appeared influential in the improvement of symmetry [139]. This is potential future work from this study in that the pelvic obliquity should be assessed in different activities, as well as potentially involved versus uninvolved limbs. In a systematic review of spinal, pelvic and hip movement asymmetries in people with lower limb loss, it was stated that those studies that did compare pelvic obliquity in the frontal plane against healthy controls noted a total increase in pelvic obliquity [90, 129]. Our findings support this with significant differences however, further investigation is recommended comparing the intact versus involved limb and potentially other planes. Previous research predominantly, although limited, reported a mean difference of two degrees[90]. It is a significant finding, however, that changes from our training protocol were sustained from baseline to post training with a mean difference of 20%, and then to one month with 18%. Given the conflicting evidence regarding intact versus involved limb, these results are interpreted carefully.

The reported MDC for the LEFS subscale of OPUS is reported as 10.3. Our results regarding the change in LEFS scores were not statistically significant. However, our findings demonstrated an effect size of f = 0.69 which is greater than moderate, but this was with a mean

difference in Rasch score of 2.4 which is less than the MDC and therefore most likely not clinically significant.

The OPUS also contains the HQOL scale which was assessed in this study and the MDC is 9.2 and our result from pre to post training was 3.08 and the difference to one month was 4.01 reaching half the MDC [138]. However, this is of relevance in that the improved HQOL score continued to improve after the conclusion of training which provides evidence of retention with this type of intervention.

Our findings show reduction of pain with pre to post training, which was also retaining this decrease, at the one-month follow-up. The mean differences were not statistically significant, with Mdiff = 9.17 from pre to post training and 10.41 from baseline to one month. However, in previous studies it was found that the pain scale was sensitive to change with an effect size of 0.41 and our effect size was 0.40 using a paired-samples t-test [140]. This implies a potentially clinically relevant finding, particularly with continued retention at one month.

4.4.1 Limitations

This study did lose two subjects to follow-up and sample size was reduced to eight. With a lower sample size, we are less able to control if some other extraneous factor is responsible for the change [128]. Small sample size reduces the power of the study, which is its ability to detect an effect if there is one. The power of a study gauges our ability to avoid type II errors, which is when the null is not rejected when it should have been. This depends on the size of the effect because large effects are easier to notice and increase the power of the study.

Repeated Measures ANOVA has its advantages in that it can require fewer participants and eliminates the issues of differences on an individual basis between participants than independent

samples. However, disadvantages exist as well. If there are inconsistent treatment effects, there is no longer consistent individual differences between the participants. The differences could potentially reverse, and if this occurs, it could appear as though there is no difference. If there are consistent treatment effects from on participant to another, t this will produce a larger value for F.

Finding participants with enough of a deviation to improve with self-report questionnaires and still recruit participants that can walk and tolerate the training was difficult. Given this conflict, the choice of the LCI-5 did not appear appropriate, and even though it was touted to not have a ceiling effect, it provided inconsistent results here. Secondary to the data not being normally distributed and being ordinal data, several different tests were performed. First, as this is another repeated measure test, and the sums of the Survey data can be considered ratio data in some instances, a repeated measures ANOVA was attempted. This did not find significant differences; however, the data was not normally distributed. A Wilcoxon Ranked test was attempted, and results were also not significant. It may be argued that this survey did not adequately quantify the participant function.

Due to the varying deviations many of the participants, presented with, and considering the variability that ensued with training and the participant working on their adaptation to the feedback, future work could look at the individual's outcomes versus pooled data. Normative data exists in small amounts for gait variability in the limb loss population however, this variability could provide a necessary conduit to assessing that outcome. It was determined after the data analysis that there were approximately three key gait deviations. Too short of stance time both in single and double limb stance, and too short single limb stance amid prolonged double limb stance would benefit from further examination and delineation as a feedback variable. It was determined that both too short of single limb and double limb stance were occurring by examining the raw

data Fz force curves, and to receive a red in the glasses, the stance had to be < 58%. When examining the force curves and the amount of area under the curve outside of the peak to peak area, it was not likely that a red could be received with increased double limb stance as well. When participants would receive a yellow predominantly, this was based on too long of a total percent stance. It was determined post hoc looking at the raw force curves that the peak to peak area was still low, but the overall area under the curve was large. Development was initiated to determine the ratio of peak to peak time versus the time outside of this single limb loading phase, given the published ratios, and this was established in one of the android apps. It was not able to be implemented at this time, however, would be a prudent progression. Some concern did regard the level of changing feedback and not to incite cognitive overload, however the timeline and funding period did not allow for further development in this direction. To be able to detect which issue is occurring could be impactful in this population as a feedback variable but for clinicians to know which deviation it is, would be a fairly simple calculation of the peak to peak time of the force curve over the total stance time. We provided orange feedback color, when %stance was too high, but it is likely, and preliminarily appeared to be the case, that single limb stance was still too short, and double limb stance was too high. Post hoc analysis may continue regarding the stance on the unaffected side and the potential for future feedback parameters exists. The final deviation was a significant trunk lean causing a decrease in %stance that was clearly below the lower boundary.

4.4.2 Future Work

Given the results of this pelvic obliquity finding, it would be prudent future work to examine the involved side and the frontal plane pelvic drop opposite the trunk lean and determine if changes occur in the specific angle versus a proprietary measure. Also, a clinical single limb

stance test for Gluteus Medius weakness would be a good clinical screen to determine if there is a drop initially at baseline.

Following the guidelines of levels of evidence, the most prudent next step would be to compare this intervention to the standard of care. At this time, it is not recommended to compare against a sham intervention, as we want to understand how this intervention is comparable to what we are currently practicing as an intervention in the clinic. In addition, methods to preserve alignment and weight could be better standardized when the sensor is installed, and this would ensure any changes or instability in the variability in the participants' gait are not due to accommodating to changes in the prosthesis. This work is also critically delving into the issues of cognitive demand during real time visual feedback. There are many variables that can effect, both positively and negatively, the effects of providing such feedback, and strategies should be investigated, for example, in terms of how the glasses provide the feedback (not in the periphery, in the lens of the glasses, which is available now). It is key to not have the participant become dependent on the feedback, and this could be avoided by also programming the system to automatically interrupt the feedback at varying amounts of time. A study to assess multiple variables of feedback could also research effects of the treatment. By performing a study that investigates the predictors of feedback color change from the kinetic data collected throughout this study, a more predictive model could be tested. An additional direction and possibility is there could be a more effective variable to provide as feedback, or perhaps it does need to be individualized per patient.

Of course, further studies could also investigate this method providing the kinetic data from a source not integrated in the prosthetic but located in a different location, thus perhaps lowering variability at each visit while getting accustomed to any change. A unique study would be to

compare whether this made a difference in the outcomes. The choice of functional outcome measures would also be a suggested change for the next work.

4.4.3 Conclusion

Traditionally, clinicians do not have a system allowing over-ground real time feedback training at their clinic and are left to qualitatively assess gait based on scales or (as was found via customer discovery at an APTA conference) use gait analysis apps from their own mobile phones that have not been validated. Being able to train participants over ground is also critical in that it has been documented that for patients with transtibial or transfemoral amputations, walking on the treadmill was about two and a half times more energetically costly than walking over ground [12]. This study provides a foundation for sample size estimation for a larger study, particularly for the outcomes of symmetry, six-minute walk distance, and pain. The retention of all the outcomes at an improved level is a promising finding for this method of feedback, suggesting the facilitation of automaticity of new motor patterns with real time visual feedback.

5.0 Usability

5.1 Introduction

The evaluated feedback system was designed with those with limb loss in mind, with the integrated sensor and a design that is least cumbersome. However, for any future designs a sensor system that is downsized would logically be a design criterion.

The initial prototype included the smallest yet high-powered Dell Ultrabook that could be used, to provide the power for real time feedback and not have any delays or processing issues, and yet be just around one kg The neoprene waist belt could be snug and lightweight polypropylene plastic was added for stiffness in one plane to improve the comfort and stability while the participant was walking. A single micro USB cable connected the sensor to the computer, and the glasses were programmed to be wireless, which took research and developmental effort, as we could easily have pursued a wired alternative. A surface laptop (Microsoft, 2017) was then used to make the system even lighter, which was also appreciated. The first outcome from the experimental activities is that all the subjects could easily wear the system and successfully walk, and only one reported that they would like to not have to wear the computer around the waist, however they could tolerate it. Also, the participant was only 1.49m and this did make space for it difficult.

5.2 System Usability Scale

To assess usability, a standard System Usability Scale (SUS) was used as a Likert scale from strongly agree to strongly disagree. In addition, some specialized questions were added. The initial questions included "Would I use the system frequently?", "Is it unnecessarily complex?", and "Was it easy to use?". All of these are important factors of a feasible or usable system. Eighty-one and one-third percent reported they strongly or slightly agreed they would use it frequently, 87.5% reported they strongly or slightly disagreed that the system was too complex, and 86.8% reported they strongly or slight agreed the system was easy to use.

Understanding the technical aspects and frustrations in developing the system was also key and the usability survey facilitated any frustrations by the participants to be clearly resourced. In terms of needed Tech support to use, 46% disagreed, 25% were unsure, while 30% slightly or strongly agreed they would. Eighty-seven- and one-half percent found the various functions well integrated. In terms of whether there was too much inconsistency in the system, 12.5% slightly agreed, and 68% disagreed, with 18% being unsure. Overall, this is a satisfactory result, given the difficulty of development and that some participants were more than 50years old and were not familiar with smart glasses technology. Eighty-seven and one half of the participants felt that other people would learn to use the system quickly. Appendix A contains the responses to the SUS survey and the frequencies.

5.2.1 Scoring the SUS

Based on previous research using this scale in this department and from literature searches, it was decided a-priori that good usability score was greater than70 [141]. To score the SUS, the

odd items were subtracted by one, and the even numbered items were subtracted by five. This normalizes all the values from 0 to 4 (with four being the most positive response). These were then added and multiplied by 2.5, which converts the possible values from 0 to 100 instead of from 0 to 40. Based on previous findings, using the scores as a percentile rank and treating the score as a "grade" is the most efficacious method to process the responses. This normalizes the scores. The SUS sore is not to be considered a percentage but rather interpreted as a grade, and a study of 500 uses of the survey on developed products reports that a score > 80.3 is required to get an A, and this is also a point where users are more likely to be recommending the product to a friend [142-144]. Scoring at the mean score of 68, for instance, is equivalent to a C grade, and below 51 is an "F", which places your product in the bottom 15%. The distribution of scores from 0 to 100 can be seen in Figure 38.

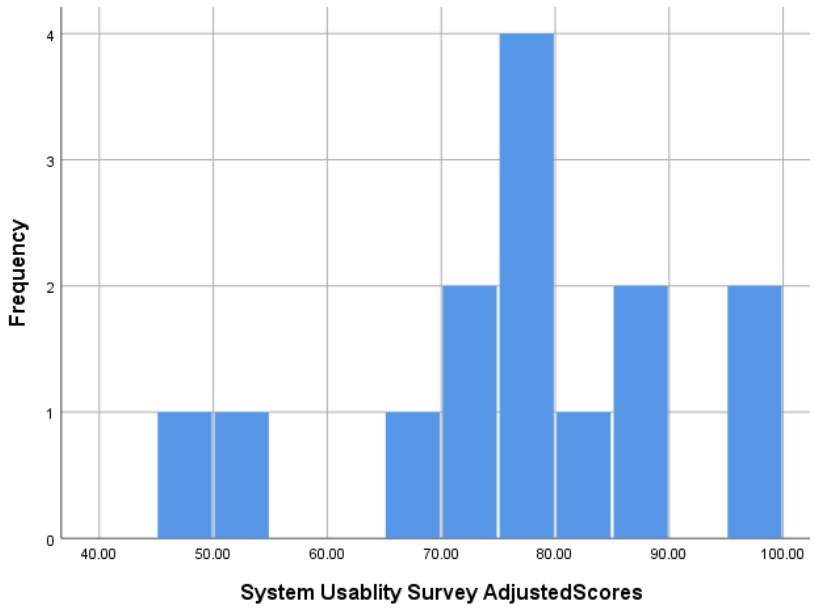

Figure 38 Distribution of the adjusted SUS Scores 0 – 100 at 20th Percentiles.

The total average score was 78.59 which is better than the average score of 68% when scoring using the adjusted scores and percentiles [142-144]. Therefore, we can reject our null hypothesis and report we did achieve usability. The goal at the outset of the study was to create a system that scored greater than 70%, and if the score is > 80.3 the subject is likely to recommend the product to a friend and we are < 2% from that score.

5.2.2 Custom Survey Questions

The following custom questions were added to the survey "Would you take the system home?", "Do you think it is appropriate for Gait Training in a PT environment for Prosthetic Users?", "Why would it be helpful to have this in the clinic for gait training?", "Did you feel safe using the system?", What did you like best?", and "What did you like least?". The answers were grouped, and the frequency of responses demonstrated as nominal data are shown in tables 15-16.

Table 15 Would You Take the System Home?

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	**no**	2	14.3	14.3	14.3
	yes	11	78.6	78.6	92.9
	not sure	1	7.1	7.1	100.0
	Total	14	100.0	100.0	

Interestingly, in Table 16, the answer was overwhelmingly yes, that subjects felt this system was appropriate for PT clinics.

Table 16 Is it Appropriate to Use for Gait Training in PT Environment for Prosthetic Users?

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	yes	14	100.0	100.0	100.0

In Figure 39, regarding safety (a critical part of feasibility and usability), 78.6% reported they agree or slightly agree that they do feel safe using the system, and only 11.4% reported they did not feel safe. In future work, it would be prudent to determine what caused an issue of feeling unsafe.

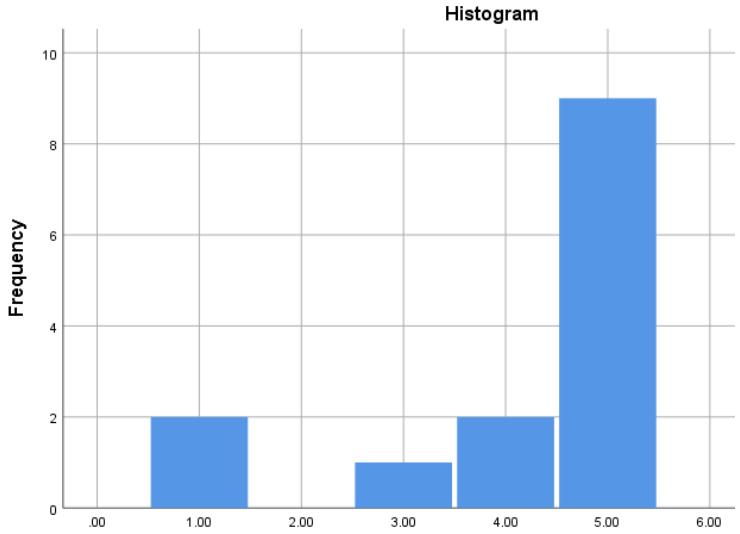

Figure 39 Did you feel safe using the system?

5.2.3 Smart Glasses

Most interestingly, the response to the glasses was positive, in that they were quickly adapted to by most. A specialized question was added to the survey "What did you like About Using Smart Glasses for This Training?" The most common responses are summarized in Table

17. The instant feedback and seeing that they were walking correctly appeared to be the most popular features.

Table 17 Percent responses to the survey question "What do I like about Using smart glasses for this training?"

Common Variables in Responses:	Frequency	Percent
Instant Feedback	3	21.4
See If I am Walking Correctly	4	28.6
Color System	2	14.3
Lightweight	1	7.1
Colors define walking, So I can see how I am Doing	3	21.4

In terms of what subjects did not like about the system, the overwhelming response was connectivity at 35.7%. This is understandable and addressed in the next chapter with Future Work. Twenty-eight and two-thirds percent reported "nothing" and there was one answer each to "weight of glasses", "tech issues", and "design of glasses".

The final custom question was "What did you like Best About the System?" The frequencies and %Responses are seen in Table 18.

Table 18 What did you like Best about The System?

	Frequency	Percent
Teaches me about my walking, improves my walking	5	35.7
Improving my weightbearing on prosthesis	6	42.9
Hill and ramp training	1	7.1
Helped me work on my Step length	1	7.1

5.3 Conclusion

The SUS results indicate that the participants felt that this was a usable system. Participants responded in majority that “improving the weightbearing” on their limb, and the “real time feedback” as well as the “colors” were the best parts of the system. We feel this demonstrates promising results in that, even though the system was under development as participants were using it and did have issues with connectivity, users overall still reported that the system provided them with useful and helpful information about their walking. Most importantly, on the question of whether to include this training in the clinical environment all responses were “yes” .

6.0 Dissertation and Study Conclusion

6.1 Summary

Based on the results from the research project described in this dissertation, the RTMVF and MOVISUFIT systems significantly increased Gait Symmetry, Pelvic Obliquity, Gait speed, and clinically decreased pain and improved function in lower limb prosthetic users. The findings from this study at the One Month Follow-up are relevant as they support the hypothesis that this type of training does improve retention of improved biomechanical parameters, pain, function, walking speed, and endurance. It was challenging to progress the prototype, and work through developmental delays or connectivity issues. However, this experience supported the need to revise the system to perhaps migrate to a sensor that is developed by our lab or other methods of collecting the kinetic data. The study participants demonstrated different responses to the HQOL and FSM outcome measures, which may motivate a different mode of measuring these outcomes. With a larger sample size, the observed effect is expected to not only be clinically significant but statistically significant as well.

Findings from the development study in Chapter 2 demonstrated that the algorithm and the speed of feedback, as well as the mobile app functionality are important issues related to training compliance. Individual preferences for types of feedback were considered. A potential conclusion from the results of this work related to development and usability is that heightened interest in the novel concept was a beneficial factor. However, that does not diminish the potential positive impact this new approach may have, as with physical therapy training, compliance and enthusiasm for the training and trust in the clinician patient relationship are all key factors in improving

perceptions of how successful training has been. The recommendations from clinicians (which were not included here) primarily focused on remote training, and an app-based system, which we have developed. The feedback from the patients regarding a wireless system, downsizing the system, and improving the app functionality in terms of what information regarding the session is immediately available to them for knowledge of results, was implemented in updates to the system for improvement.

Findings from Chapter 3 demonstrated that RTMVF and MOVISUFIT have excellent reliability in terms of stride time, % stance, and stance duration, however with curved and distracted testing, the system had decreased reliability of stance duration. Some explanations for this include the tendency for a person with limb loss to employ protective mechanisms, when there are surprises, for example, in the in a hallway, the sudden opening, or closing, of doors into their path. This could lead to an overcompensation of protecting the involved limb and a wide variability in step parameters until normalcy is reached again. The design of the glasses may need to change to a more centralized "within lens" type of feedback, which may allow patients to feel they are not looking away from their central vision. It may also decrease cognitive demand. We are in discussions with Vuzix currently with promising potential to determine a potential collaboration.

Findings from Chapter 4 indicate that those who received the training program significantly improved their symmetry, pelvic obliquity and gait speed/endurance. They also reduced their level of pain, with a clinical effect size of 0.40 which is moderate. Unfortunately, some portions of the Chronic Pain grade were not yet analyzed, and it would be prudent future work to examine the other levels of disability more closely. A participant's perception and view of their own function and quality of life is frequently key to beginning or maintain rehabilitation programs.

Two participants were excluded from the analysis because they did not complete the one-month follow-up. This may also have affected the results. One participant who was lost to follow-up did improve his 6MWT-distance from 459.94 meters at baseline to 552.5m post training. As outlined in chapter 4, changes are considered clinically relevant if they are >45m. This participant improved by 92.56m therefore, they demonstrated double the clinically significant threshold as well. The other participant did not provide a reason for not attending a one-month follow-up. He was not as accustomed to technological solutions and did not have a smart phone, therefore perhaps the intervention was not comfortable for him. However, they did remarkably well and improved in all areas of measurement. His symmetry improved from 86.07 to 94.3, which is greater than the MCID of 4-9% at 13%. His 6MWT-distance improved from 324.95 to 371.36 meters, which is just over the MCID, and his pain intensity score was reduced from 40 to 6.67. His pelvic obliquity index provided by G-Walk as a cross correlation of the accelerometry planes, improved from 73.53 to 81.03. He reported on his usability surveys that he felt the training "improved his posture" and that he liked the real time feedback and learning how to put more weight on his prosthetic leg. This was facilitated by the feedback secondary to it providing him information that he was not spending as much time on that limb. It is believed this was his way of incorporating the feedback into his own mechanism of improved symmetry because it worked for him, he significantly improved. The one other participant that was loss to follow-up secondary to the closing of the funding period, significantly improved his 6MWT-distance, however their symmetry decreased. This participant's gait deviation was not as pronounced as some of the other participants' and a different feedback variable may have been more appropriate for his gait deviation as it was more specific to pelvic motion and weight transfers.

7.0 Future Work

Examining other variables that were also collected while the patients were gait-training including medial and lateral torque, anterior posterior torque, and other calculated spatial-temporal variables could greatly benefit feedback choice. Future work in this population should focus on determining single limb stance duration from the sensor data to investigate which deviation is being elicited and whether feedback regarding that decreased stance could be beneficial.

Future work would also benefit from employing machine learning and perhaps a more sophisticated form of feedback that incorporates more than one channel. However, motor learning theories do address that it is prudent not to challenge the patient with adjusting too many parameters at once. In addition, the data that was collected in terms of the other biomechanical and kinetic variables could use a regression analysis to find predictors of poor step quality. These could not only be involved as different feedback variables but also could be a part of prosthetic prescription and modification as it entails quantitative, not qualitative, gait assessment and feedback.

Appendix A System Usability

	Strongly Disagree	Slightly Disagree	Unsure	Slightly Agree	Strongly Agree
I think I would Use This System Frequently	0	0	2	7	4
I found system Unnecessarily Complex	5	7	1	0	0
I thought System was Easy to Use	0	0	1	6	7
I would need Tech support to use	1	5	3	2	3
I found function well integrated	0	0	1	7	5
Too much inconsistence in the System	4	7	2	1	0
I would imagine most people would learn to use quickly	0	1	1	7	5
I found the system cumbersome to use	7	3	2	1	1
I felt Very confident Using System	1	0	1	4	8
I needed to Learn A lot of Things Before I could Get Going with The System	4	7	3	0	0

Appendix B Publications and Conference Abstracts

Appendix B.1 **Kutina, K. Fiedler, G. "Feasibility of a Mobile Feedback System for Gait Retraining in People with Lower Limb loss – A technical Note"**

Wearable Technologies for Active Living and Rehabilitation – Technical Note

RATE

Journal of Rehabilitation and Assistive Technologies Engineering
Volume 6: 1–5

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Feasibility of a mobile feedback system for gait retraining in people with lower limb loss—A technical note

Goeran Fiedler and Krista Kutina

Abstract

Gait retraining in people with musculoskeletal and/or neurological impairments requires sustained dedicated efforts by the patient and the rehabilitation therapist. Various technical approaches have been proposed and utilized to improve the effectiveness of training interventions. Among the most promising approaches is the provision of real-time feedback information to the patient, which has been used with success on treadmill-based interventions in the past. We are describing a mobile visual feedback system that is intended to work in the user's everyday-life environment. The data are captured by a small mobile load cell, processed in a wearable computer, and displayed to the user via smart-glasses. Preliminary testing of the initially selected feedback variable stance/step ratio (i.e., the duration of a step's stance phase in relation to the overall step's duration) confirmed that data quality is sufficient for purposes of generating feedback information and that the chosen variable is responsive to changes in gait symmetry. The presented work may inform future studies and developments on the topic of mobile visual feedback for gait rehabilitation.

Keywords

Gait deviation, gait training, load cell, smart glasses, visual feedback

Date received: 31 July 2017; accepted: 22 October 2018

Introduction

Gait deviations are frequently observed as a symptom in patients with musculoskeletal and/or neurological impairments. They are very prevalent among people with lower limb loss, where they can be mostly attributed to the inevitable differences between sound and prosthetic leg. For users of lower limb prostheses, gait deviations can be the cause and the symptom of gait instability, falling and fear of falling, overuse injuries, and impaired mobility.

However, gait deviations and the associated acute and chronic medical problems are not limited to individuals with lower limb loss, and gait retraining has the potential to benefit a great number of patients beyond this population. Due to the range of possible underlying pathological conditions[1,2] and the wide spectrum of individual coping strategies, gait deviations manifest themselves in a variety of forms. These include fairly minor bilateral asymmetries of step pattern or arm swing, as well as severe favoring of one leg over the other with associated compensatory trunk and arm motions.

It has been (inconclusively) debated which level of asymmetry constitutes a pathological gait deviation,[3] since it was found that even healthy able-bodied people present gait asymmetries either because it is functional to utilize legs differently or because of laterality (limb dominance). Accordingly, the prevalence of gait deviations can only be roughly estimated based on the known prevalence of some underlying conditions. So it is known that every year about 795,000 Americans suffer a stroke,[4] 1.4 million are diagnosed with traumatic brain injury,[5] and 185,000 undergo major limb amputation. A study from 2007[6] estimated that

> among US adults, nearly 27 million have clinical osteoarthritis . . ., 711,000 have polymyalgia rheumatica,

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> 228,000 have giant cell arteritis, up to 3.0 million have had self-reported gout in the past year . . ., 5.0 million have fibromyalgia . . ., [and] 59 million have had low back pain in the past 3 months

Old age is associated with many of the discussed pathologies, and therefore with a propensity to gait deviations. One respective study found abnormal gait in 35% of community-residing adults aged 70 years and older.[7] Gait deviations' prevalence and severity in this population was correlated with a greater risk of institutionalization and death. Regardless of the patient's age, gait deviations increase the risk of joint degeneration,[8] accidental falls,[9] and reduced gait economy,[10] thus limiting mobility and participation.

Untreated, gait dysfunction can become chronic, even after the underlying pathology has been addressed. Physical therapy for gait retraining is therefore commonly prescribed to patients recovering from stroke, limb amputation, or other pertinent conditions. Such training typically comprises, in addition to strengthening and range-of-motion exercises, a number of therapy sessions. These sessions are typically spaced out over several weeks in which the therapist observes the patient's gait and provides corrective feedback. While generally effective, this approach is very time- and personnel-intensive, which often necessitates a limitation on the duration of such provided training. After the cessation of training sessions, and even in between training sessions, patients are at risk of reverting to their abnormal gait pattern, especially in cases where the treated gait deviation has manifested itself over long periods of time already. To mitigate this risk, patients may be advised to continue practicing in front of a mirror which provides a simple form of visual feedback.

More sophisticated approaches that have been proposed include augmented sensory feedback, which has been reported to improve dysfunctional lower extremity impairments and related gait patterns including in those with lower limb loss[11]: The patient walks on an instrumented treadmill, while stationary gait analysis equipment generates pertinent gait data that are displayed to the patient via a computer screen in real time. A common criticism of these previous studies is based on the associated expense and tightly controlled laboratory conditions. These circumstances may limit translatability of the approach to realistic clinical environments, as the required equipment (instrumented split-belt treadmills), gait analysis personnel, and time are often unavailable in clinical settings.

More recently, mobile data collection and feedback systems have been utilized to overcome some of these shortcomings. One such approach is based on an array of wearable accelerometer sensors, attached to trunk, legs, and arms of the user, a processing unit, and an in-ear speaker that provides standardized verbal feedback corresponding to the gait deviation that is detected by the sensors.[12] Notable limitations of providing feedback in that manner are that the voice commands may be perceived as interfering with regular communication, and—importantly—that the specificity of the commands is not conducive to effective motor learning. By obeying commands such as "increase right step length!", "swing arms!", or "tighten your hip muscles!", the user focuses on the internal mechanisms of proper gait. It has been shown that providing an external instead of internal focus of attention yields better motor learning success.[13,14]

Overall goal of our research is to design a system that provides real-time mobile visual feedback (RTMVF) for gait training. The feasibility of such a system is currently being investigated in a cohort of people with lower limb loss, a population that was selected because use of limb prostheses is often associated with gait deviations and because the mechanical limb provides an ideal platform for the necessary sensor equipment. Even though people with limb loss make up only part of the overall population with gait deviations, they offer unique opportunities to test and refine the technology before it will subsequently be applied more generally. We describe here the development of the system components, the selection of meaningful feedback variables from the available sensor output, and the initial validation of the measured and processed gait data.

Methods

The RTMVF system was developed utilizing commercially available and/or previously validated componentry (Figure 1). Gait data source is a prosthesis-integrated load cell (i-Pecs, RCT Electronics, Dexter, MI) capable of measuring precisely kinetic gait variables in lower limb prostheses. The device is semi-permanently installed as part of the load-bearing structure of the limb prosthesis connecting to the rest of the device using standard adapters. Ground reaction forces and moments of force data can be collected up to 850 Hz and transferred wirelessly or by cable connection to a laptop computer for further processing. In order to provide visual feedback to the patient, a wearable head-up display (M300, Vuzix, West Henrietta, NY) was used. These "smart glasses" contain, positioned at the fringe of the user's normal field of view, a small-sized display, the contents of which are retrieved from the computer via Wi-Fi or Bluetooth connection.[15,16] The display has a resolution that is comparable with small computer screens, yet its position and intended purpose in our context advises

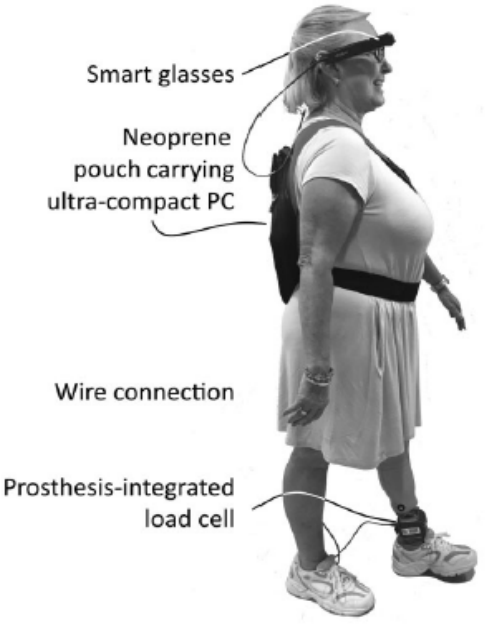

Figure 1. Mobile gait feedback system in use. PC: personal computer.

against the conveyance of very complex visual information.

Connectivity between the different components is currently realized using cable connection between load cell and laptop computer, and Bluetooth to the smart glasses. In this configuration, the lightweight computer is being carried in a pouch on a waist belt by the user.

Feasibility of the system was evaluated using the feedback variable "Stance/step time ratio," (i.e., the duration of a step's stance phase (From initial ground contact to toe-off) in relation to the overall step's duration measured from one initial ground contact to the next initial ground contact on the same side). This parameter correlates with some typical gait deviations in lower limb prosthesis users, and it lends itself to easy capturing by lower cost, prosthesis-independent sensor equipment for potential translation into the clinic and/or adaptation for different patient populations. Stance and swing components of step cycles were derived by an algorithm that analyzed various components of the axial force curve (the sensor's Fz is roughly equivalent to vertical ground reaction force in an external coordinate system[17]) to determine the appropriate crossings of a 15 N and 100 N threshold (Visual Studio Community 2015). For examining the sensor data graphically and quantitatively, different strategies were tested to harden the algorithm to outliers and measuring artefacts.[18] Timing parameters were established to help the algorithm detect transition steps and turns as non-representative steps for gait analysis and feedback purposes.

A target window of stance/step ratio was established between 0.59 and 0.63, resulting in three discrete output states: Too short stance phase (below 59% of step cycle), desirable stance phase (59%–63%), and too long stance phase (above 63%). The three states were represented by different feedback colors, displaying a red (for too short stance phase), green (desirable stance phase), or yellow (too long stance phase) screen to the user. The most accurate calculation of stance phase duration with respect to the total step cycle requires the entire step cycle in question to be timed. This makes the feedback information available only after a given analyzed step is completed. Accounting for this inevitable latency, the validity of the system in generating feedback variables was investigated in a small sample of steps.

Inclusion criteria for this test were use of a transtibial prosthesis for ambulation, absence of acute or chronic health conditions that would affect prosthesis use, and ability to walk without aids for at least 30 min. Demographic data and mobility score (PLUS-M[19]) were recorded. The test participant was equipped with the RTMVF system and a waist-worn "mobile gait lab" (G-Walk, BTS Engineering, Milan, ITA) and was asked to traverse in self-selected walking speeds repeatedly across a 30-m level walkway. Step phase durations were extracted from the G-Walk data to serve as the validation standard for the respective variables computed from the prosthesis sensor data by our algorithm. Gait symmetry index, a proprietary variable output by the G-Walk software, was recorded as well and correlated to the i-Pecs derived stance/step ratio in order to investigate its appropriateness as feedback variable for gait training. The variable is a composite index that is based on acceleration and gyroscope data through the step cycle. An index of 100 signifies perfect symmetry between the left and the right step with respect to ground contact forces, trunk tilt, and temporal parameters. Bivariate correlation analysis was conducted using IBM SPSS Statistics (Version 24).

Results

The participant was a 61-year-old female, weighing 58.5 kg and 1.49 m tall, who had been using transtibial prostheses for 12 years and had a PLUS-M score at the 79th percentile.

A total of 67 steps were analyzed. Correlation between RTMVF step ratio data and reference data was strong, with a Pearson correlation coefficient of $R = 0.813$ ($p < 0.001$).

Correlation between variables stance/step ratio and overall gait symmetry index (Figure 2) across eight data

Declaration of conflicting interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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Guarantor

GF.

Contributorship

Both authors researched literature, conceived the study, and developed the protocol. KK lead system development and testing, including IRB approval application, subject recruitment, and data collection/analysis. GF wrote the first draft of the manuscript. Both authors reviewed and edited the manuscript and approved the final version of the manuscript.

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Appendix B.2 **Kutina, K. Fiedler, G. "Variation of Ground Reaction Force Measurements Across Different Prosthesis-integrated Load Cells."**

5.050
Variation of Ground Reaction Force Measurements Across different Prosthesis-integrated Load Cells

Krista Kutina, Goeran Fiedler
University of Pittsburgh, Pittsburgh, USA

BACKGROUND
With miniaturized electronic components becoming more readily available, their integration into artificial limbs has become increasingly common. Load cells can help clinicians and researchers obtain a comprehensive picture of the effects of prosthetic alignment changes and other interventions.[1, 2] In recent years, a number of dedicated load cells for such purposes has been developed and marketed, making it conceivable that their data is interpreted equivalently across devices.

AIM
The aim of this study was to quantify any differences in force data put out concurrently by two different commercially available prosthesis-integrated load cells.

METHOD
Two load-cells for integration into lower limb prostheses (ipecs, RTC electronics, Dexter, MI,[3] and Europa, Orthocare Innovations, Tahoma, WA [4]) were installed into the same knee-bent prosthesis simulator (Figure 1, left). Both streamed force data at 100 Hz during a 10-meter walk test, including a sharp turn. In post-processing, the collected vertical ground reaction force data was time-synchronized by aligning the first peaks of both plots with each other. A bivariate correlation analysis was conducted across a sample of 1000 data points (i.e., 10 seconds of gait data). Likewise, root mean squared error (RMSE) was computed across the same sample.

RESULTS
Visual inspection confirmed the generally good correlation between force data from both devices (Figure 1, right). The correlation efficient was 0.819 ($p<0.001$), and the RMSE was 164 N.

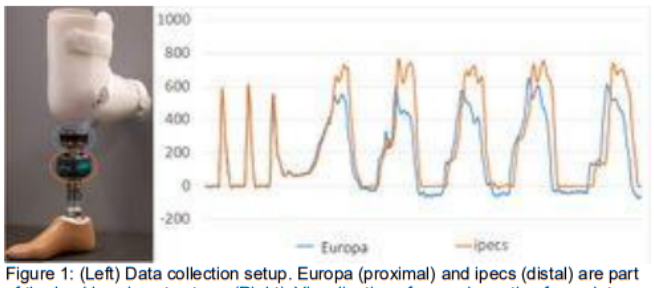

Figure 1: (Left) Data collection setup. Europa (proximal) and ipecs (distal) are part of the load bearing structure. (Right): Visualization of ground reaction force data

DISCUSSION AND CONCLUSION
Our findings illustrate the inevitable differences in equipment when measuring the same variable, in this case vertical ground reaction force. Without a gold standard, it cannot be determined which of the devices was more accurate, but the deviation between two instruments that may commonly be assumed to deliver identical data was quantifiable. For a cursory gait assessment in the clinic, this deviation may be negligible. In research, limited external validity can be of greater consequence.

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Appendix B.3 **Kutina, K. Fiedler, G. "Correlation between unilateral step timing variables and gait symmetry in users of lower limb prostheses"**

CORRELATION BETWEEN UNILATERAL STEP TIMING VARIABLES AND GAIT SYMMETRY IN USERS OF LOWER LIMB PROSTHESES

Krista Kutina[1], Goeran Fiedler[1]
University of Pittsburgh[1]

INTRODUCTION

Gait deviations may be caused by a number of different underlying conditions, including lower limb loss, which affects approximately 2M Americans[1]. The effectiveness of physical therapy for gait retraining is often challenged by logistical constraints, such as the limited number of therapy sessions a patient may be able to attend.

In order to enhance and sustain training effects, it feedback training has been utilized with good success, for instance by having patients observe their gait in a mirror. More pertinent kinetic variables are available for feedback in treadmill based training[2]. Recently, mobile feedback systems have been proposed, deriving the respective data from wearable sensor equipment and using, for instance, headphones to convey the corresponding feedback information[3].

We have developed a mobile system that combines a prosthesis-integrated load cell, a portable computing unit, and smart-glasses to provide real-time visual feedback in an unobstructed, intuitive and effective way to the patient. The nature of the visual feedback mode allows the application of learning theory that recommends an external focus of attention for best training effects and retention of same.

Preliminary data from ongoing feasibility testing was analyzed to investigate which gait parameters are most suitable as feedback variables for the improvement of gait symmetry.

METHOD

Subject: Data from one subject, active enough to walk pain free for at least 30 minutes, is reported here.

Apparatus: The real-time mobile visual feedback system was realized using a load cell (iPecs, RTC Electronics, Dexter, MI) that can be temporarily installed into the pylon structure of a prosthesis, an ultra-mobile PC, worn in a waist pouch, and a wearable head-up display (M300, Vuzix, West Henrietta, NY), connected by a single USB cable and Bluetooth. The variable of stance/step ratio was derived from the iPecs data and used for feedback information.

Procedures: Over the course of several training sessions with the feedback system, spanning multiple appointments in a five-week-span, iPecs and G-Walk symmetry data were collected.

Data Analysis: Bivariate correlation between stance/step ratio and overall gait symmetry index was calculated using data points from 8 different sessions.

RESULTS

The test subject was a 61 years old, female, weighing 58.5 kg and 1.49 m tall, who had been using trans-tibial prostheses for twelve years.

Stance/step ratio was strongly correlated to Gait symmetry (Figure 1), with a correlation coefficient of R = 0.735. The system was also validated against the G-Walk sensor with correlations between stance phase duration over 67 steps r = .814, p<.05.

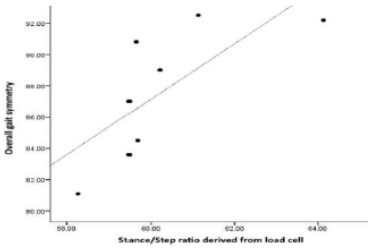

Figure 1. Scatter plot with linear trend line, illustrating relationship between variables stance/step ratio and gait symmetry index.

DISCUSSION

Our results suggest good utility of the chosen variable stance/step ratio for the purposes of generating gait training feedback. The nature of this variable, which is comparably easily measurable with a variety of equipment options, would allow adoption of this method for other populations with gait deviations, including those who do not need artificial limbs. Our findings, though preliminary, should motivate the analysis of a larger data sample that will be necessary to improve statistical and clinical significance.

CONCLUSION

Stance/step ratio is correlated to gait symmetry.

CLINICAL APPLICATIONS

Improved method for gait retraining, as the one here investigated, will allow users of prostheses to maximize the benefit of their devices for rehabilitation success.

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American Academy of Orthotists & Prosthetists
44th Academy Annual Meeting & Scientific Symposium
February 14 – 17, 2018

FPTH14

Appendix B.4 **Kutina, K. Fiedler, G. "Providing Mobile Visual Feedback to Lower limb Prosthesis Users"**

PROVIDING MOBILE VISUAL FEEDBACK TO LOWER LIMB PROSTHESIS USERS

Krista Kutina[1], Katie Coleman[1], Goeran Fiedler[1,2]
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INTRODUCTION

In many situations it is important to provide up-to-date feedback or other relevant information to users of lower limb prostheses. Such information may be directly or indirectly safety-relevant or simply desired out of self-consciousness [1], and includes anything from the battery status in a microprocessor-controlled knee (MPK) to the symmetry of the gait pattern [2]. The former is usually communicated through vibration alarm units that many MPKs have been equipped with, while the latter may be assessed by the prosthesis user observing their own gait in reflective surfaces, such as shop windows. Other important information, such as on the spatial position of the artificial limb and the bending angle of joints, is gauged either by proprioception, direct observation (usually requiring some kind of accommodative posture), or a combination of both.

There are notable limitations to all these approaches. Vibration alarms cannot convey a very large spectrum of information, and they are known to lose effectiveness if used too frequently. Visual observation requires more or less pronounced body contortions, that may result in adverse effects by themselves. Use of reflective surfaces is limited to the few sites where such surfaces are available.

With the advent of wearable head-up displays in recent years, most prominently, the Google Glass device, it should become possible to provide relevant information on prosthesis status and gait pattern, as well as other helpful feedback, to users of lower limb prosthesis. The declared purpose of "smart glasses" of most any kind is to display useful contextual information in an unobtrusive and convenient manner to the user [3]. Hereby, substantial differences exist, depending on the intended main use and the ideal user profile.

Goal of this research was to compare the utility of several commercially available "smart glass" models for use in the limb loss population.

METHOD

Three different smart glass devices (Figure 1) were obtained and evaluated by the authors according to a number of pre-defined criteria, including how severely the glasses obstructed the relevant field of view, on a scale from 0 to 10. Other comparison variables included the glasses' weight, battery life, and connectivity (rated 0 to 10). Descriptive statistics were applied to report the findings.

Figure 1: Tested "smart glasses" from left to right: Google Glass (Google, Mountain View, CA), Recon Jet (Recon Instruments, Vancouver, BC), and M100 (Vuzix, West Henrietta, NY).

RESULTS

The found differences between devices are illustrated in Figure 2.

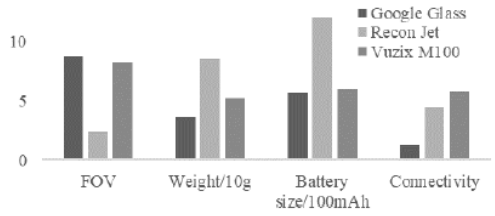

Figure 2: Comparison of smart glasses

DISCUSSION

Based on our findings, the Vuzix M100 is most suitable for the purposes of providing prosthesis-related information to users of lower limb prostheses. The biggest drawbacks with the other tested devices were the restriction of the important lower portion of the field of view (Recon Jet) and the technical complexity of connecting to a computer or smart phone (Google Glass). While the Recon Jet is optimized for use in competitive bicyclists (who view the road through the upper portion of their glasses) and the Google Glass is designed to work in an environment of manufacturer-provided apps, they cannot very well be adopted for other uses.

The small number of testers for this data collection limits the generalizability of our findings. Yet, it appears likely that the identified differences between devices would be the same for other users. Evaluating other outcome variables may have led to different findings. Also, the tested devices may not be representative of other devices of the same model, due to manufacturing tolerances, battery age, or model updates. Generally, this technology can be expected to mature rapidly over the next years, resulting in the increased availability of upgraded or entirely new models.

CONCLUSION

Of the tested devices, the Vuzix M100 is the best option for provision of visual feedback information to prosthesis users.

CLINICAL APPLICATIONS

Wearable head-up displays, or "smart glasses" may soon be used to enhance the capacities of artificial limbs and optimize the way users are interacting with them.

ACKNOWLEDGEMENT

Supported by a Milbank Grant by the PMNR Foundation.

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Appendix B.5 **Kutina, K. Fiedler, G. "Developing a Mobile Feedback System for Gait Retraining in People with Lower Limb Loss"**

DEVELOPING A MOBILE FEEDBACK SYSTEM FOR GAIT RETRAINING IN PEOPLE WITH LOWER LIMB LOSS

Krista Kutina[1], Goeran Fiedler[1]
[1]University of Pittsburgh

BACKGROUND

Gait dysfunction is an impairment that can effect multiple patient populations [1, 2], both neurologic and orthopedic, including those with limb loss, and become chronic and linger for years. It has been frequently reported that gait retraining with augmented sensory feedback improves dysfunctional lower extremity impairments and related gait patterns including those of amputees [3]. However, a primary criticism of these previous studies is due to the expense and tightly controlled laboratory conditions, conducted with instrumented treadmills and optical systems, many of the findings have had difficulty being applied to realistic clinical environments.

AIM

Progressing from this previous limitation, the overall goal is to design a system based on an integrated load cell sensor to provide real time mobile visual feedback (RTMVF) to transtibial amputees for gait training. We describe here our first prototype.

METHOD

Translating current positive findings of real time visual feedback into a clinical application was attempted by providing the visual real time feedback directly from the patient's limb displayed on smart glasses. Objective here is to create a mobile more realistic environment in which the training can occur.

Our work took advantage of existing and validated technology in the form of a prosthesis-integrated load cell (ipecs, RCT Electronics, Dexter, MI) and a variety of commercially available wearable head-up displays. After testing several models, including the Google glass system (Google, Mountain View, CA) and the Recon jet (recon instruments, Vancouver, BC), we implemented Vuzix M100 smart glasses (Vuzix, West Henrietta, NY) in our prototype.

Establishing connectivity between the different components posed continuing challenges. The current prototype uses cable connections between the load cell, a laptop computer, and the smart glasses. Given that all those components have Bluetooth capabilities; an updated wireless prototype is anticipated for future iterations of the development project.

RESULTS

Our initial protoype (Figure 1) allows the capturing, processing and displaying of load cell gait data in close to real time. Initial feasibility tests suggest that a patient can be fitted with the system in about 30 minutes, most of which time is required for the installation of the load cell into the prosthesis structure. Battery life of the head-up display is currently the limiting factor in use time, though without affecting the commonly allocated one-hour time frame for gait therapy sessions.

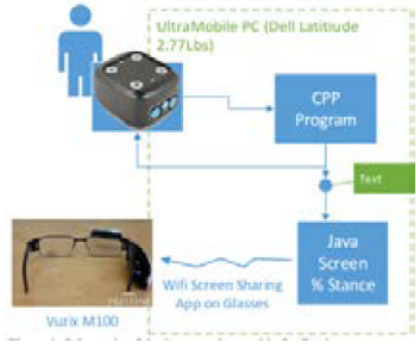

Figure 1. Schematic of the integrated wearable feedback system

DISCUSSION & CONCLUSION

The presented effort is anticipated to provide the groundwork for subsequent research to determine how to best convert the raw data to the visual warning signal resulting in a (RTMVF) gait training system for transtibial amputees.

Long term goals are the effective supplementation of traditional therapist-based gait retraining with a wearable "assistant" that can provide comparable feedback on a patient's gait deviations. This should help improve outcomes for patients who have limited access to specialized health care, and who are therefore at risk of adapting habitual gait deviations following limb loss and prosthesis provision.

In order to achieve this, our group is working to develop and test algorithms for the detection of individual gait deviations and feedback modalities next.

In conclusion, a mobile gait analysis and feedback system as described provides the technical prerequisites for enhanced gait retraining approaches in people with lower limb loss.

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[1] Prince, et al. Gait & Posture 5.2 (1997): 128-135.
[2] Perry and Burnfield. "Gait analysis: normal and pathological function." (1992): 271-279.
[3] Dingwell, Davis, and Frazder. Prosthetics and Orthotics International 20.2 (1996): 101-110.

ACKNOWLEDGEMENTS

This work is supported by a Milbank Grant by the PM&R Foundation

Appendix B.6 **"The Use of an integrated Load Cell as A Mobile Gait Analysis System to Detect Gait Events in People with Lower Limb Loss"**

THE USE OF AN INTEGRATED LOAD CELL AS A MOBILE GAIT ANALYSIS SYSTEM TO DETECT GAIT EVENTS IN PEOPLE WITH LOWER LIMB LOSS

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[1]University of Pittsburgh

BACKGROUND

Gait impairments can effect patients with various health conditions [1, 2], including neurologic pathologies and musculoskeletal disabilities such as lower limb loss. Uncorrected, gait deviations can become chronic and cause additional comorbidities. Gait retraining with augmented sensory feedback was shown to improve gait patterns in people with lower limb prostheses [3]. A noted limitation of the respective studies is the lacking transferability of findings from tightly controlled laboratory conditions into real-life conditions, as the required equipment (instrumented split-belt treadmills), gait analysis personnel, and time are often unavailable in clinical settings. Mobile gait data collection equipment offers the opportunity of addressing this shortcoming, which requires the development of adapted data post-processing and analysis methods.

AIM

The purpose of this work was to investigate the utility of a validated prosthesis-integrated load cell (IPECs, RCT Electronics, Dexter, MI) to detect deviations from healthy gait based on kinetic data in transtibial amputees. In this work, we investigated the effect of verbal cueing and time on kinetic output from the IPECs to inform future choice of variables for feedback.

METHOD

Initially raw data (6 values, Fx,Fy,Fz,Mx,My,and Mz) from a single transtibial amputee test subject, weighing 188lbs and 54yo, with an apparent clinical gait deviation of dynamic Valgus (KAbM) and Varus (KAdM) in the frontal plane was used to design a step detection algorithm (Matlab 2015b, Mathworks). The patient was asked to ambulate with the IPECs sensor under several conditions, including a trial with and without guided feedback. The sensor data was examined graphically then quantitatively to develop algorithms to accurately detect steps and gait parameters to be used as feedback to the patient. Four variables were calculated including; #steps, Stance Duration, Peak Fz, and My. Transition steps, and turns were not removed from the analysis at this time as the IPECs sensor is to be used as a "mobile gait lab".

RESULTS

162 (158 correct) total steps during the feedback trial were derived from specialized Matlab algorithms placing the accuracy > 95%. The cueing by the Therapist regarding KAbM and KAdM with verbal and tactile cues in the sagittal plane and frontal plane, did not result in changes kinetically in the variable My ($p=.66$). Clinical judgement was used to determine improvements. However, the clinically judged improved steps were found to have significantly ($p<.05$) less %stance ($M=50.9\pm25.6$) than those not deemed improved ($M=59.6\pm14.29$). The Peak Fz was significantly different between ideal stance (58-63%) and over ideal (> 63%) during Baseline and Video Taped trials ($p<.05$).

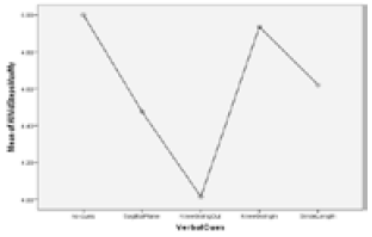

Figure 1. MaxMy Means as Distributed across Verbal Cues

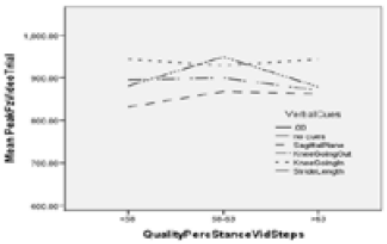

Figure 2. Peak Fz Means as Distributed across Percent Stance Quality, organized by Clinical "goods"

DISCUSSION & CONCLUSION

This case subject presented with apparent significant valgus moment during stance, however this variable from the IPECs does not seem appropriate for feedback as his MaxMy apparently stabilized the most from stride length feedback (Fig 1.). Therefore, other variables/modifications to the algorithm may be needed. From initial baseline testing, the subject's average peak Fz decreased by almost 150 N overall. Therefore, the variable chosen for feedback may not be individualized per patient deviation, but rather based on previous findings [3] that providing Peak Fz feedback can improve stance symmetry. In order to determine variables that are correlated to typical gait deviations and thus suitable as feedback to improve gait, further testing is required. This should include investigating how the parameters calculated would respond to a different gait deviation and improving the accuracy of the step detection algorithm for a mobile system.

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ACKNOWLEDGEMENTS

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Appendix B.7 **"Kutina, K. Fiedler, G. Developing a Gait Event Detection Framework for Implementation into A Real Time feedback System Based on Data from a Prosthesis Integrated Load Cell"**

DEVELOPING A GAIT EVENT DETECTION FRAMEWORK FOR IMPLEMENTATION INTO A REAL TIME FEEDBACK SYSTEM BASED ON DATA FROM A PROSTHESIS INTEGRATED LOAD CELL.

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INTRODUCTION

Gait dysfunction is an impairment that can effect multiple patient populations (Prince,et al 1997; Perry and Burnfield, 1992), including those with limb loss, and become chronic and linger for years. It has been frequently reported that gait retraining with augmented sensory feedback improves dysfunctional lower extremity impairments and related gait patterns including those of amputees (Dingwell, et al, 1996). However, these previous studies have been criticized for the expense and tightly controlled laboratory conditions, which made translating findings to realistic clinical environments limited.

Overall goal of our research is to design a system to provide real time mobile visual feedback (RTMVF) to lower limb amputees for gait training. Feedback variables should be detectable by a prosthesis-integrated sensor and be meaningful for the user. Low latency in calculating feedback variables was another objective. We report on the development of mathematical algorithms to accurately detect gait events from a prosthesis-integrated sensor providing kinetic data only. The algorithms and mathematic models are an important first step in the process of integrating both hardware and programmatic components into a RTMVF system.

METHOD

The current prototype consists of load cell (ipecs, RCT Electronics, Dexter, MI), a laptop computer, and smart glasses (M100, Vuzix, West Henrietta, NY), connected by cables and WiFi. Initial algorithms based on raw sensor data from one subject with gait deviations unknown, determined what could be calculated given raw output. Detecting step cycles entailed sensing slopes at the approximate mean of Fz (the sensor's equivalent to vertical ground reaction force) and a lower 10N threshold crossing. Proximal and distal forces and moments of interest were extracted as possible feedback variables as well.

RESULTS

It was found that all variables of interest could be determined from the data, such as; the Peak proximal and distal moments, Peak Fz, Peak My, and range and Peak of Mz. Loading and toe off peaks were found efficiently, however refinement was needed as it was found that oscillations during swing phase were counted erroneously. For Prototype V.0 (Figure 1) a single threshold was implemented, for feasibility and latency testing. The delay is less than 1sec, however algorithms needed to be refined by the addition of several criterion including a double threshold for sufficient accuracy in detecting actual gait events.

Figure 1. Prototype of Feedback Device: Real Time kinetic feedback as relayed from sensor regarding percent stance.

DISCUSSION

The prototype allowed the evaluation of several potential feedback variables. Finding peak to peak values was insufficiently accurate (>5%) and required non-automated method to improve. Conversely, % stance suggests itself as easily calculated in real time and providing potentially meaningful information. Further testing is needed to assess the value of additional variables and to determine the appropriate target window for feedback purposes

CONCLUSION

Our findings suggest that generating and conveying RTMVF on gait variables is possible using our approach.

CLINICAL APPLICATIONS

The potential is to utilize the positive current findings regarding real-time visual feedback, to mobilize this type of training over ground, outside of the clinic, or even at home.

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ACKNOWLEDGEMENTS

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Appendix C Patent Application

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(19) **United States**

(12) **Patent Application Publication**

Kutina et al.

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(43) **Pub. Date: Apr. 25, 2019**

(54) **SYSTEM AND METHODS FOR GAIT AND RUNNING FUNCTIONAL IMPROVEMENT AND PERFORMANCE TRAINING**

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(72) Inventors: **Krista Lee Kutina**, Pittsburgh, PA (US); **Goeran Fiedler**, Pittsburgh, PA (US)

(21) Appl. No.: **16/106,298**

(22) Filed: **Aug. 21, 2018**

Related U.S. Application Data

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Publication Classification

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A61B 5/11 (2006.01)

A61B 5/00 (2006.01)

(52) **U.S. Cl.**

CPC ***A61B 5/112*** (2013.01); *A61B 5/1038* (2013.01); ***A61B 5/486*** (2013.01)

(57) **ABSTRACT**

A gait analysis and training system is provided, as well as methods of training, e.g., retraining gait in a patient. The system provides real-time external feedback to a patient is portable so that use is not limited to a clinic.

SYSTEM AND METHODS FOR GAIT AND RUNNING FUNCTIONAL IMPROVEMENT AND PERFORMANCE TRAINING

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of U.S. Provisional Patent Application No. 62/576,339, filed Oct. 24, 2017, which is incorporated herein by reference in its entirety.

[0002] The present disclosure relates to devices, systems, and methods for gait and running analysis and training of an individual based on sensed information relayed in real time in a wearable fashion.

[0003] Gait dysfunction is an impairment that can effect multiple patient populations, both neurologic and orthopedic, and become chronic and linger for years. There are subsets of the patient population that are particularly vulnerable to problematic and chronic gait dysfunction such as Parkinson's disease, stroke, osteoarthritis (OA), and limb loss. In 2007 patients with limb loss compiled approximately 1.7 million people and it has been estimated that by 2050, this rate is expected to double to 3.6 million in the United States. This is of clinical concern in that forced compensations from the loss of sensory feedback, neuromuscular control, and pain that affect forward propulsion and weight acceptance throughout the gait cycle, could have the consequence of destructive secondary joint issues and increased energy cost. In addition, lack of plantar flexion and normal ankle motion are linked to most amputee gait deviations, including asymmetrical gait timing. Other typical deviations include trunk shifts which can result in low back problems as well as increased misdirected loads through the ankle, knee and hip of both the surgical and intact limbs putting the patient at higher risk of cartilage degradation and secondary complications of arthritis. Not only can the kinematic variables that are a part of these dysfunctional lower extremity movement patterns be retrained, but they also can be retained. Gait retraining as an intervention has demonstrated promise in many populations, including the amputee population. This could lead to improved lower extremity function, which leads to improved energy consumption and to extended prosthesis life as well. Symmetry also has been an issue in amputee gait, and, as analysis has evolved from only qualitative to quantitative measurements of temporal, kinetic and kinematic, and combinations of all, the most prominent asymmetries have been determined as shortened stance times and decreased ground reaction forces.

[0004] Additional populations are at risk for gait or lower extremity loading issues if biomechanical discrepancies are present. Once chronic compensations begin, it is not hard to imagine how this triggers a cascade of secondary musculoskeletal issues. These compensations can become stubborn ingrained patterns. These chronic compensations then cause degradation of secondary joint tissues and can increase the already staggering 50% risk of osteoarthritis (OA) that we have in our lifetime. These secondary complications can be costly, cause increased energy costs, cause secondary injuries, and loss of function and quality of life.

[0005] When the pathological gait pattern has become habitual, gait retraining and associated physical therapy can help mitigate the adverse effects. A persisting problem with this objective has been the lack of effective methods that promote motor learning and retention. The traditional approach is to use demonstration, verbal cues, targeted strengthening in a non-dynamic manner. This includes providing instructions to the patients on how to change their motion patterns and is limited by the time constraints that come with scheduled appointments, as well as by the nature of the feedback, which almost inevitably focuses the attention of the patient internally (e.g., by giving instructions on how to move an extremity or load the limb with landing cues).

[0006] Methods and devices useful for training or retraining a gait or running pattern are desirable, not only to avoid further improper compensations that can cause secondary injuries or degradation to other orthopedic structures, but to improve recovery times, and improve prevention strategies.

SUMMARY

[0007] In one aspect, a gait analysis, training, and retraining system comprising: a sensor configured to measure one or more attributes of gait of a patient; and a controller in communication with a sensory output device, the controller configured to, repeatedly, monitor a patient's gait in real-time and to provide real-time feedback to the patient receive and process information from the sensor representative of one or more attributes of the gait of the patient; generate a data set corresponding to the information from the sensor representative of one or more attributes of the gait of the patient; compare the generated data set to reference data indicating optimal values for a data set corresponding to the information from the sensor representative of one or more attributes of the gait of a patient; and cause the display to provide feedback comprising gait analysis based, at least in part, on the comparison between the generated data set and the reference data and at least indicating in the feedback if the generated data set is within defined tolerances relative to the reference data.

[0008] In another aspect, a method of analyzing and/or training gait in a patient, the method comprising, using a computer-implemented process, repeatedly, receiving and processing, in a computer, information from a sensor on the patient configured to measure one or more attributes of gait of a patient representative of one or more attributes of the gait of the patient during one or more physical actions relating to gait, performed by the patient; generating, in the computer, a data set corresponding to the information from the sensor representative of one or more attributes of the gait of the patient; comparing, in the computer, the generated data set to reference data indicating optimal values for a data set corresponding to the information from the sensor representative of one or more attributes of the gait of a patient; and generating, with the computer, an output causing a sensory output device to provide feedback comprising gait analysis based, at least in part, on the comparison between the generated data set and the reference data and at least indicating in the feedback if the generated data set is within defined tolerances relative to the reference data.

BRIEF DESCRIPTION OF THE DRAWINGS

[0009] These and other features and characteristics of the present disclosure, as well as the methods of operation and functions of the related elements of structures and the combination of parts and economies of manufacture, will become more apparent upon consideration of the following description and the appended claims with reference to the

accompanying drawings, all of which form a part of this specification, wherein like reference numerals designate corresponding parts in the various figures. It is to be expressly understood, however, that the drawings are for the purpose of illustration and description only and are not intended as a definition of the limit of the invention.

[0010] FIG. **1**A is a schematic drawing of an exemplary wearable sensor device including an inertial measurement unit according to an aspect of the disclosure; FIG. **1**B is a schematic drawing of internal circuitry of one version of the exemplary wearable sensor device of FIG. **1**A; FIG. **1**C is a schematic drawing of internal circuitry of another version of the exemplary wearable sensor device of FIG. **1**A;

[0011] FIG. **2** is a schematic drawing of a trans-tibial prosthesis with an integrated sensor.

[0012] FIG. **3** is a schematic drawing of a movement analysis system including the wearable sensor device of FIG. **1**A;

[0013] FIG. **4** is a flow chart of an exemplary process for data collection from a wearable sensor device with an F/T sensor, or inertial measurement unit, according to an aspect of the disclosure.

[0014] FIG. **5**: Exemplary architectural framework of preliminary real time system to be tested. The described colors correspond to Red (Percent Stance Phase calculation<58%, Green "ideal, Percent Phase Calculation between 58% and 63%, and Orange "overcompensation" corresponds to percent Stance Phase calculations>63% however a cut off is set to 80%.

[0015] FIG. **6** provides graphs showing an exemplary data set obtained from and/or calculated from an F/T sensor in prosthesis (trans-tibial amputation) including Fx, Fy, Fz values, distal Mx (dMx, at ankle), proximal My (pMy, at knee), and proximal Mz (pMz, at knee).

[0016] FIG. **7** is a flow chart of a process for analyzing a data set obtained from an F/T sensor, or inertial measurement unit, according to an aspect of the disclosure.

[0017] FIG. **8** provides real time ground reaction force feedback as relayed from i-Pecs™ sensor.

[0018] FIG. **9** is a schematic of an integrated wearable feedback system.

[0019] FIG. **10**: Correlation between stance/step ratio (the feedback variable) and overall gait symmetry.

DETAILED DESCRIPTION OF THE INVENTION

[0020] The use of numerical values in the various ranges specified in this application, unless expressly indicated otherwise, are stated as approximations as though the minimum and maximum values within the stated ranges are both preceded by the word "about". In this manner, slight variations above and below the stated ranges can be used to achieve substantially the same results as values within the ranges. Also, unless indicated otherwise, the disclosure of these ranges is intended as a continuous range including every value between the minimum and maximum values.

[0021] As used herein, the singular form of "a", "an", and "the" include plural referents unless the context clearly dictates otherwise.

[0022] As used herein, the terms "right", "left", "top", "bottom", and derivatives thereof shall relate to the invention as it is oriented in the drawing figures. However, it is to be understood that the invention can assume various alternative orientations and, accordingly, such terms are not to be considered as limiting. Also, it is to be understood that the invention can assume various alternative variations and stage sequences, except where expressly specified to the contrary. It is also to be understood that the specific devices and processes illustrated in the attached drawings, and described in the following specification, are examples. Hence, specific dimensions and other physical characteristics related to the embodiments disclosed herein are not to be considered as limiting.

[0023] A "patient", "athlete", or "subject" is a human, and those terms do not imply or require any clinician-patient relationship.

[0024] As used herein, the terms "communication" and "communicate" refer to the receipt or transfer of one or more signals, messages, commands, or other type of data. For one unit or component to be in communication with another unit or component means that the one unit or component is able to directly or indirectly receive data from and/or transmit data to the other unit or component. This can refer to a direct or indirect connection that can be wired and/or wireless in nature. Additionally, two units or components can be in communication with each other even though the data transmitted can be modified, processed, routed, and the like, between the first and second unit or component. For example, a first unit can be in communication with a second unit even though the first unit passively receives data, and does not actively transmit data to the second unit. As another example, a first unit can be in communication with a second unit if an intermediary unit processes data from one unit and transmits processed data to the second unit. It will be appreciated that numerous other arrangements are also possible.

[0025] As used herein, the term "gait" refers to the manner of locomotion, and in the term of humans, includes the manner of bipedal locomotion, including, for example and without limitation, walking, jogging, running, or sprinting. This includes, in humans, dynamic lower extremity movement pattern in a weight-bearing position with forward movement. The gait cycle includes a stance phase and a swing phase. "Stance" refers to that portion or phase of the gait cycle during which the foot contacts the ground, and can be referred to in terms of a percentage (e.g. stance %) of the gait cycle. "Swing" refers to that portion or phase of the gait cycle where the foot is not in contact with the ground.

[0026] As indicated above, when a patient's focus is directed to their extremities as described, this drives their attention internally and increases self-consciousness about body movements and performance which neurologically constrains motor learning. The preponderance of evidence suggests that changing the attention to an external focus where the patient is looking to the effects of their movements on an external feedback cue enhances motor learning.

[0027] Real time visual feedback (RTVF) applies and follows this motor learning theory that internalization of a new neuromuscular pattern is enhanced when the patient's focus is directed externally. The patient receives immediate knowledge of their performance, and their attention is directed externally, to the effect their gait pattern changes have on an external cue.

[0028] Patients and clinicians, upon early customer discovery, are requesting the ability to extend their training beyond the visit. Clinicians also are asking for dynamic, not static immobile interventions that are more realistic to how a patient really moves and experiences their pain. Clinicians

report a desire to know when their patients are having gait trouble out in the world, to better be able to prioritize treatment and be more effective.

[0029] Performance at higher levels, including running, benefits from real time visual feedback from sensed information on the user themselves. Training running performance with real-time visual feedback has demonstrated significantly positive results in reducing forces that cause overuse loading injuries, as well as re-educating patterns that could lead to injury and also provide faster responses during rehabilitation. When left unaddressed, it has been reported that 70-90% of those individuals return to their medical providers within 5 years. Real-time visual feedback allows the runner to receive immediate knowledge of their performance and is the fastest integration into the motor learning system versus other forms of bio feedback which do not provide long-lasting results. Video and mirror feedback can be used, however, limitations include the lack of mobility, realism, and provide only a limited quantity of steps the athlete can review.

[0030] A wearable system that provides real time feedback for gait functional improvement and running performance addresses the limitations of conventional approaches by providing immediate, specific, and intuitive feedback, which directs the user's focus of attention externally as is recommended according to established learning theory.

[0031] According to aspects and embodiments of the invention, provided herein is a gait or running analysis, monitoring, remote training, training in the athlete's environment or patients natural environment or realistic surfaces, functional and performance improvements, reductions in recovery time and rapid detection of prevention strategies, retraining, mobile and portable real time visual feedback gait and optionally monitoring system for a patient, the system comprising: a sensor configured to measure one or more attributes of gait or lower extremity load bearing dynamic function or performance of a patient or athlete; and a controller in communication with a visual, e.g., any wearable (e.g., smart) display, such as a head up display (HUD) output component, the controller configured to, repeatedly (e.g., two or more times), monitor a patient's gait in real-time and to provide real-time feedback to the patient: receive and process information from the sensor representative of one or more attributes of the gait of the patient or athlete; generate a data set corresponding to the information from the sensor representative of one or more attributes of the gait of the patient; compare the generated data set to reference data indicating optimal values for a data set corresponding to the information from the sensor representative of one or more attributes of the gait of a patient or athlete; and cause the display to provide feedback comprising gait analysis based, at least in part, on the comparison between the generated data set and the reference data or the patient/athlete's own baseline data and at least indicating in the feedback if the generated data set is within defined tolerances relative to the reference data.

[0032] In other aspects or embodiments, a method of analyzing and/or training for functional and performance improvements in gait, running, and dynamic lower extremity loading in a patient or athlete is provided. The method comprises: placing a sensor configured to measure one or more attributes of gait of a patient on the patient; and, repeatedly, to monitor a patient's gait in real-time and to provide real-time feedback to the patient: receiving and processing information from the sensor representative of one or more attributes of the gait of the patient during one or more physical actions relating to dynamic loading of the lower extremities during activities including gait, walking or running, and optionally, standing performed by the patient; generating a data set corresponding to the information from the sensor representative of one or more attributes of the gait of the patient; comparing the generated data set to reference data indicating optimal values for a data set corresponding to the information from the sensor representative of one or more attributes of the gait of a patient; and causing a wearable display to provide feedback comprising gait analysis based, at least in part, on the comparison between the generated data set and the reference data and at least indicating in the feedback if the generated data set is within defined tolerances relative to the reference data.

[0033] In yet another aspect or embodiment, a smart device processor implemented method for analyzing and/or training gait in a patient based on information received from a sensor configured to measure one or more attributes of gait of a patient on the patient adapted to be performed on a portable computing device is provided. The method comprises, repeatedly, to monitor a patient or athlete's dynamic lower extremity movement pattern or gait in real-time and to provide real-time feedback to the patient or athlete: receiving and processing information from the sensor representative of one or more attributes of the gait of the patient or athlete during one or more physical actions relating to dynamic lower extremity movement pattern, gait or walking, and optionally, standing performed by the participant; generating a data set corresponding to the information from the sensor representative of one or more attributes of the gait of the patient; comparing the generated data set to reference data indicating optimal values for a data set corresponding to the information from the sensor representative of one or more attributes of the gait of a patient; and causing a wearable display to provide feedback comprising gait analysis based, at least in part, on the comparison between the generated data set and the reference data and at least indicating in the feedback if the generated inertial, spatiotemportal, force or moment data set is within defined tolerances relative to the reference data.

[0034] According to an aspect of the disclosure, feedback devices and systems are provided for training (including retraining) and improving the performance and function of dynamic lower extremity overground movement patterns as well as gait and running movement of a patient. The devices and systems provide a signal, based on sensor data, that serves as an external focus of attention through, e.g., a visual display or through other sensory input able to provide a signal that can serve as an external focus of attention, such as an audio or haptic signal. In aspects, a visual signal may be used as an external focus of attention, to avoid desensitization, which can occur with haptic or causing an excessive cognitive demand such as audio signals. The visual signal can be provided by a head up display (HUD), but for mobile devices and systems the visual signal may be provided by specialized glasses including a visual display, e.g., as described below. In aspects, the sensor device is a force/torque sensor (F/T sensor) and/or a biometric device configured to obtain acceleration, positioning, and/or angular motion data for the subject. Sensor data is provided by a sensor that is worn or otherwise incorporated into a prosthesis or other device placed on the body or in a weight

bearing location from the lower extremities of the patient (that is the sensor is a "wearable sensor"), for example, under the foot, on a foot, ankle, knee, leg, hip, or back of a patient. Data is obtained from the sensor, and is converted by a processor or other computing device to a simple signal, e.g., a binary or ternary, string, or integer, signal indicative of the gait of the patient being within or outside of tolerances. For example, the sensor can include commercially available F/T sensors, or motion and movement sensors, such as an inertial measurement unit or in-shoe pressure unit.

[0035] Because the device is used for gait training and the improvement of function and performance of dynamic lower extremity over-ground movement patterns, the action and activity includes, for example, walking, jogging, running, or sprinting. In a rehabilitative context, such as after an illness, injury, condition, amputation, or treatment that affects an individual's gait. In aspects, the device and system are mobile, meaning they are configured to be worn on a patient, and can be used in settings outside a clinic. For example, a system may include a force sensor, a computer, and smart glasses. The sensor may be incorporated into a prosthetic or otherwise is worn on or affixed to the patient's body, or under the foot to capture loading patterns, the glasses are worn by the patient, and the computer is carried in a pouch, pack, backpack, or any other suitable carrier on the patient's body or is entirely wireless, and communication is through a smart device for processing. The sensor and glasses are in communication with the computer or handheld processing device, via any suitable interface, wired or wireless, e.g., as described in further detail below.

[0036] An F/T sensor is a device that measures components of force and torque (moment) in more than one axis and communicates that data to a computer, e.g., a processor. A common type of F/T sensor is a six-axis sensor that measures all components of force, including force in three axes (Fx, Fy, and Fz) and moment or torque in three axes (Mx, My, and Mz, alternatively Tx, Ty, and Tz). Multi axis F/T sensors are described in the art and are commercially available, such as the i-Pecs Tech Sensor System load cell sensor (commercially available from RTC Electronics of Dexter, Mich. See, Fiedler et al. Criterion and Construct Validity of Prosthesis-Integrated Measurement of Joint Moment Data in Persons with trans-tibial Amputation. *J Appl Biomech.* 2014 June; 30(3): 431-438) or F/T transducers or sensors from ATI Industrial Automation of Apex, N.C., among many others). F/T sensors can be configured into a prosthesis as described herein, or into a shoe, e.g., as an attachment, or as an insert for a shoe, permitting acquisition and output of force and moment data. Although in many instances a six-axis F/T sensor may be preferred for the detailed data produced, sensors that have lower capabilities (such as Fz only) may be utilized, so long as meaningful data that can be used to determine the presence and/or quality of steps and other relevant activities can be derived from the output data from the sensor. Data can be transmitted from the F/T sensor by wire (e.g., USB, Ethernet, etc.), or wirelessly (e.g., by Bluetooth).

[0037] An inertial measurement unit is an electronic device that measures and reports movement and positioning data (e.g., an inertial data set), velocity, acceleration, and angular rate using a combination of accelerometers and gyroscopes. Inertial measurement units are commonly used in inertial navigation systems for aircrafts. When used in an aircraft, an inertial measurement unit is used for detecting a current rate of acceleration in multiple axis (e.g., acceleration in the x, y, and z directions) with one or more linear accelerometers, and for detecting rotational attributes like pitch, roll, and yaw, using one or more or angular accelerometers and/or gyroscopes. Measurements from the accelerometers and gyroscopes can also be used for calculating changes in position of the device. In one example, a commonly used inertial measurement unit design includes three accelerometers positioned to measure acceleration along three axes which are orthogonal to one another (e.g., the x, y, and z axes). The inertial measurement unit also includes three gyroscopes placed in a similar orthogonal pattern for measuring rotational position of the sensor device around each of the axes. Information from the six sensors can be combined together using different positioning algorithms to determine an absolute or relative position of the wearable sensor device.

[0038] While acceleration and angular momentum information can also be collected from multipurpose electronic devices, such as smart phones, which use the innate mobile device accelerometer technology to obtain angular motion data, such smartphone devices are not meant to be worn on the person's torso and therefore require assistance of an additional person to collect movement data, thus requiring at least a specialized harness. In addition, data received from accelerometers on smart phone devices generally do not have the requisite level of accuracy provided by the wearable sensor devices disclosed herein. For example, the innate accelerometer technologies used by smartphone devices may not have an appropriate range or specificity to measure data for some assessments. As will be appreciated by one of ordinary skill in the art, accuracy and precision of the assessments are needed to identify proper gait and dynamic lower extremity over-ground movement patterns from measured movement data.

[0039] The sensor device desirably is sufficiently lightweight and of small enough size to not interfere with a patient's range of motion. The sensor device allows for real-time data acquisition and analysis of the subject to produce real-time output to a patient without needing input and/or analysis of collected data by a clinician. Another advantage is that assessments based on information measured by the sensor device can be performed at any location, meaning that individuals do not need to travel to a specialized lab or clinic to perform training activities. In addition, they do not rely on subjective visual analysis of movement patterns.

[0040] In aspects, the sensor device communicates, e.g., wirelessly, with a nearby computing or communication device (referred to herein as an intermediary device), such as a portable computing device, cellular telephone, smart phone, or Internet gateway device, to drive data collection, analysis and output to a wearable display, such as a smart display or an HUD, or any other wearable visual smart display technology. Visual cues directed to training are superior to audible and haptic feedback as they are the quickest to be sensed by patients, and are not subject to desensitization and interference. This intervention correctly applies the true desired external focus of attention that provides a direct "effect" of the incorrect movements and correct patterns on an external display versus simply providing raw data. This improves the individual's ability to integrate the training into their own automatic error detec-

tion processes. In aspects, the intermediary device comprises a controller configured to implement software for receiving and processing information from the sensor device and for providing feedback that indicates to the user the effect of their movements, e.g., via a wearable visual display, e.g., an HUD, or other wearable visual smart technology, based on the movement information. In aspects, feedback includes displaying indicia on the display indicative of the quality of the patient's gait, which is a real time use of the motor learning theory external focus of attention and provides the "effect" of the patient's movements qualitatively on an external cue versus displaying raw sensor data. In one aspect, the indicia indicates proper gait within predetermined or on the individual's own baseline tolerances and indicates improper gait dynamic lower extremity over-ground movement patterns falling outside those tolerances, for example, with a red signal indicating improper gait and a green signal indicating proper gait, for example, displayed on a display in the peripheral vision of the patient in a completely portable fashion untethered or requiring the patient to be indoors. In other aspects, the indicia indicates proper gait within predetermined tolerances, and indicates improper gait, specific deficiencies, and/or specific corrective actions to be taken to correct the improper gait. For example, providing a green signal indicating proper gait, and one or more additional signals, such as solid red signal if a parameter is below ideal, and a solid yellow signal if a parameter is above ideal. That said, in training, in aspects, it may be preferable to provide the simplest feedback.

[0041] In one aspect, the signal is binary or ternary, but the system provides a graded transition between signals as the patient's activity approaches optimal. For example, in a binary system, the out of tolerance signal may be yellow, and the in-tolerance signal may be green, with a stepwise transition from yellow to green, for example, in two, four, eight, 16, 32, 64, or 128 graded steps, as the patient's walking or running motion approaches an appropriate gait.

[0042] In one aspect, the signal to the patient provides an external focus of attention. Audible corrective measures or feedback typically drives a patient's focus to internally regard their limb and corrective measures, and specifically how a limb is moving. Haptic signals often are missed. Therefore, in one aspect, the signal to the patient is visual, and in aspects, the signal provided to the patient via the display is binary (that is, providing only two signals, such as two different color signals), indicating the effect of their corrections and directing them to that effect on the colors on the wearable screen within tolerances or outside of tolerances. In other aspects, the signal is ternary, e.g., sending three different colors to the display, one color indicating "above tolerances", a second color indicating "below tolerances", and a third color indicating "within tolerances", such as the above-mentioned red, yellow, and green scheme.

[0043] The described colors are merely illustrative of the multitude of possible indicia available to those of ordinary skill, including: colors, flash patterns, shapes, positioning on the display, text, or any other shape, icon, pattern, sounds (e.g., in a built in speaker, ear-bud or any sound transducer), vibrations, etc., that can be indicative of any measurable feature relating to gait. The focus is directed to the effect of movement on an external feedback cue, versus isolating limb actions which is internally directed focus.

[0044] According to one aspect of the disclosure, baseline data is obtained from one or more sources, including parameters obtained from literature, parameters from one or more individuals other than a patient, and/or from the patient walking in a correct manner, e.g., as determined by a clinician. The baseline also may be detected via processing at that individuals baseline for the desired dynamic lower extremity over-ground movement pattern that needs training. Data is then obtained from the sensor, such as from an F/T sensor in a prosthetic or in a wearable device, such as a shoe, e.g., in the sole of a shoe, for example, as a shoe insole, shoe outsole, cover, or other attachment, or from an inertial measurement unit worn by the patient or incorporated into a prosthetic device.

[0045] The sensor device and feedback system is worn either in a clinic, or in the real world, and provides direct, real-time feedback to the patient, thereby training the patient to walk, jog, run, or sprint with a proper dynamic lower extremity over-ground movement patterns. Measured results can be stored in a database of inertial data sets (e.g., .csv or similar files) either automatically or manually at the request of a clinician, programmer, or system administrator. In some instances, measurement is performed on the subject two or more times, such as during an initial patient evaluation and after the training has been followed for a few days or weeks. Baseline data, or a data set acquired at the earlier or initial time point can be compared to a data set acquired at the later time. The deviation between the data sets at different time points can be analyzed either automatically by a computing device (e.g., the intermediary device), or by a user, technician or administrator, to decide whether actions or activities (e.g., a recommended treatment regimen) or tolerances of the device (e.g., the criteria used to distinguish gait falling within specifications or outside of specifications) need to be changed to achieve a desired outcome, such as improvement in gait. Results of the analysis are used to improve future treatment recommendations either for a particular subject or for all subjects using the devices and systems described herein.

[0046] In the examples provided herein, the quality of a patient's gait is measured by or represented by the stance % criteria. That is, raw sensor data, e.g., Fz data, is converted by one or more computer processes to produce a stance % value. An optimal stance % range of values for a desired gait is determined, and during a therapeutic session, when a patient walks or runs, a signal is sent to the patient when the patient's gait is within the optimal range, and a different signal is sent when the patient's gait is outside the optimal range. Stance % is one of many criteria that may be used as a measure of the quality of the patient's gait. Raw data from the sensors, e.g., spatial-temporal force or moment data, can be used to generate values including, without limitation: stride (heel to heel), stride length, cadence, force (e.g., Fz), torque of knee, and any other useful measure of gait quality. Criterion, such as cadence and stance %, can be combined. Two or more sensors can be placed on a patient's body and/or incorporated into a device, to generate useful data.

Sensor Device

[0047] FIGS. **1**A-**1**C show an exemplary sensor device **10** for collecting movement information for a subject. In some examples, the device includes a housing **12** enclosing circuitry for collecting force, torque, and/or movement information. The housing **12** can be formed from a lightweight, rigid material such as plastic or brushed aluminum. In some instances, the housing **12** can include various removable

covers or other openings for accessing interior components of the device **10**, such as batteries, sensors, memory cards, and other items. The housing **12** can also include one or more ports **14**, such as a USB, Ethernet, Thunderbolt, or Firewire port, for wired connection between the sensor device **10** and other computing devices. In some instances, the device **10** can include one or more visual indicators **16**, such as LEDs, on or extending through the housing **12** for conveying information to a user. For example, a green-color LED **18** can be turned on when the device is ready to use. A red or yellow colored LED **20** can be turned on to indicate to the user that the device **10** is not ready to collect data if, for example, the device battery is depleted or if the device **10** does not include sufficient memory to record assessment measurements. In some instances, a visual indicator **16** can also be used to indicate when the device **10** is in wireless communication with another computer device and/or when the device **10** is uploading data to another computer device.

[0048] In some examples, the sensor device **10** includes a harness, band, adhesive patch, or another connection mechanism for affixing or mounting the sensor device **10** to the patient. In other examples, the sensor device **10** may be incorporated into a prosthetic or wearable device, such as a shoe. In one aspect, device **10** includes a strap for attaching the device **10** to the user's waist, torso, or hips. The strap includes a connector, such as a buckle or hook and loop fastener (e.g., Velcro™), for attaching ends of the strap together to hold it in place, e.g., around the subject's waist. In other examples, the sensor device **10** can be attached to a necklace or collar and worn around the subject's neck. In still other examples, the device **10** can be affixed to the individual's clothing using a clip, clasp, or similar fastener.

[0049] With specific reference to FIG. **1**B, internal circuitry of a sensor device **10** is illustrated. The sensor device **10** includes electronic circuitry, such as an F/T sensor **30**, enclosed within the housing **12** for measuring movement information of the subject wearing the device **10**. The device **10** also includes a storage module **36**, comprising transitory or non-transitory computer readable memory for storing information collected by the F/T sensor **30**.

[0050] The F/T sensor **30** comprises movement sensors, such as a three-axis force sensor **32** and a three-axis torque sensor **34** of a six-axis F/T sensor. In some examples, the F/T sensor **30** includes three orthogonally positioned accelerometers and gyroscopes. With specific reference to FIG. **1**C, internal circuitry of a sensor device **10** is illustrated. The sensor device **10** includes electronic circuitry, such as an F/T sensor **30**, enclosed within the housing **12** for measuring movement information of the subject wearing the device **10**. The device **10** also includes a storage module **36**, comprising transitory or non-transitory computer readable memory for storing information collected by the F/T sensor **30**.

[0051] With specific reference to FIG. **1**C, internal circuitry of a sensor device **10** is illustrated. The sensor device **10** includes electronic circuitry, such as an inertial measurement unit **40**, enclosed within the housing **12** for measuring movement information of the subject wearing the device **10**. The device **10** also includes a storage module **36**, comprising transitory or non-transitory computer readable memory for storing information collected by the inertial measurement unit **40**.

[0052] The inertial measurement unit (IMU) **40** comprises movement sensors, such as one or more single axis or multi-axis accelerometer(s) **42** and one or more gyroscope (s) **44**. In some examples, the inertial measurement unit **40** includes three orthogonally positioned accelerometers and gyroscopes. An accelerometer measures acceleration. Most accelerometers can also measure tilt. The accelerometer was originally a large device, but with the continued advances in the field of micro-electromechanical systems (MEMS) technology, accelerometers are presently available in sizes of less than 1 or 2 mm, with 3-axis measurements. A gyroscope measures orientation. In one aspect of the device **10**, a gyroscope is used to determine changes in the orientation of the subjects' body to help identify the physical activity being performed. Gyroscopes based on MEMS technology are now also widely commercially available. Commercial chips that combine a 3-axis accelerometer and a 3-axis gyroscope are commercially available. One non-limiting example of a useful device is the WAX9 IMU, commercially available from Axivity Ltd. of York, UK, having accelerometer and gyro functionality as well as Bluetooth connectivity, a magnetometer, a barometric sensor, a temperature sensor, a micro-USB connector, suitable firmware, and a processor.

[0053] In some examples, the sensor device **10** also includes a timer or clock. The timer is used to record a time when certain data is collected. The acquisition time can be stored by the storage module **36** along with the collected data for providing a time-stamped record of physical activities performed by the subject.

[0054] As shown in FIGS. **1**B and **1**C, the sensor device **10** also includes a communications module **38** for wired or wireless communication with an external computing device. In some examples, the communications module **38** transmits collected data from the device **10** to another computer device automatically substantially in real time. In other examples, sensed information is collected and stored in the storage module **36** and uploaded to the computer device as a batch file transfer. Uploads can occur periodically according to a predetermined schedule or, for example, in response to an event, such as a request from the external computer device or when the sensor device **10** is in proximity (e.g., within range for file transfer via short-range wireless data transmission) to the computer device. In some examples, the communications module **38** is a wireless transceiver, such as a transceiver employing IEEE 802 wireless networking standards, by Bluetooth®, Wi-Fi, ZigBee, LAN, WAN, or cellular connection, or combinations thereof. Wired data transmission may occur via USB, Firewire, or Ethernet networking standards.

[0055] In aspects, the wearable sensor device also includes power management components, such as a rechargeable battery **50** and associated control circuitry. For example, the control circuitry can monitor battery parameters such as charge remaining. In some examples, the device **10** provides output to a user when the battery **50** needs to be recharged or when the battery **50** is too depleted to continue data collection.

Prosthesis

[0056] With reference to FIG. **2**, in aspects, a trans-tibial prosthesis device **51** is depicted in schematic and not in scale for ease of depiction. The device **51** comprises: a socket **52**, configured to receive a stump of a patient, an interface **53**, a pylon **54**, and a foot portion **56**. A sensor **58**, such as an F/T sensor, as described herein, is provided in-line with the

pylon **54**. Sensor **58**, such as an i-Pecs™ sensor, may comprise a wired or wireless communications interface as described herein.

Movement Analysis System

[0057] A movement analysis system **100** including one or more sensor devices **10** is shown in FIG. **3**. The movement analysis system **100** can be configured to obtain data from the sensor device(s) **10** for the purpose of sensing, analyzing, and training the gait of a patient. Data for the patient can be transmitted either directly or indirectly to a central device or server. For example, as shown in FIG. **3**, the data is received by an external computer network **110** comprising one or more computing devices (computers) **112** in communication with storage devices **114** comprising computer readable memory comprising databases of movement results for various subjects.

[0058] Intermediary Device

[0059] In some examples, data from the sensor device(s) **10** is first transmitted to an intermediary device **116**, which receives data from the one or more sensor devices **10** and transmits the data to the computer network **110**. The intermediary device **116** can be a dedicated electronic device comprising non-transitory computer readable memory with instructions for receiving, processing, communicating/transmitting, and providing feedback about the information from the one or more sensor devices **10**.

[0060] In other examples, the intermediary device **116** is a multipurpose electronic or computer device capable of performing processes for data collection and analysis (referred to herein as a computer). In the context of computing, a process is, broadly speaking, any computer-implemented activity that generates an outcome, such as implementation of a mathematical or logical formula, operation, or algorithm. For example, the intermediary device **116** can be a portable computer device, laptop computer, tablet, microcomputer (e.g., Raspberry Pi or Arduino), or smartphone (such as an Apple iPhone or a Samsung Galaxy). Other examples include a workstation, a server, a laptop, a tablet, a smart device, a web-enabled telephone, a web-enabled personal digital assistant (PDA), a microprocessor, an integrated circuit, an application-specific integrated circuit, a microprocessor, a microcontroller, a network server, a Java™ virtual machine, a logic array, a programmable logic array, a micro-computer, a mini-computer, a large frame computer, or any other component, machine, tool, equipment, or some combination thereof capable of responding to and executing instructions. The portable computer device can be configured to execute instructions from a software application (e.g., an App) which controls health monitoring and collection of data from the sensor device(s) **10**. For example, an App can be one or more of an operating system (e.g., a Windows™ based operating system), browser application, client application, server application, proxy application, on-line service provider application, and/or private network application. The App can be implemented by utilizing any suitable computer language (e.g., C\C++, MATLAB, UNIX SHELL SCRIPT, PERL, JAVA™, JAVASCRIPT, HTML/DHTML/XML, FLASH, WINDOWS NT, UNIX/LINUX, APACHE, RDBMS, including ORACLE, INFORMIX, and MySQL). The App can comprise health, fitness, and/or physical movement analysis software. In some instances, the App can be downloaded to the device **116** from an external source, such as the external computer network **110**. Following initial installation of the App, the device **116** can be configured to receive instructions, updates, or additional software from the external source either according to instructions included with the App or in response to a request from the external source.

[0061] In other examples, the intermediary device **116** is another medical, exercise, or patient monitoring device located in close proximity to the subject. For example, various types of exercise and medical equipment may include microprocessors for controlling device function. Instructions for receiving, processing, and providing feedback about sensed movement information from the one or more sensor device(s) **10** can be loaded or downloaded to any such devices for implementing the patient monitoring and feedback systems discussed herein.

[0062] Controller

[0063] In some examples, the intermediary device **116** comprises a controller **118** for executing functions related to receipt, analysis, and transmission of sensed movement data. In some examples, a controller is a central processing engine including a baseline processor, memory, and communications capabilities. For example, the controller **118** can be any suitable processor comprising computer readable memory **120** and configured to execute instructions either stored on the memory **120** or received from other sources. Computer readable memory **120** can be, for example, a disk drive, a solid-state drive, an optical drive, a tape drive, flash memory (e.g., a non-volatile computer storage chip), cartridge drive, and control elements for loading new software.

[0064] In some examples, the controller **118** includes a program, code, a set of instructions, or some combination thereof, executable by the device **116** for independently or collectively instructing the device **116** to interact and operate as programmed, referred to herein as "programming instructions". In some examples, the controller **118** is configured to issue instructions to one or more of the sensor devices **10** to initiate data collection and to select types of measurement information that should be recorded. In other instances, the sensor device(s) **10** is configured to automatically transmit all sensed movement data to the intermediary device **116** either in real time or at periodic intervals without first receiving initiation instructions from the controller **118** to initiate sensing and data transmission.

[0065] In either case, as will be discussed herein, the controller **118** is configured to receive and process movement information from the sensor device(s) **10** for activities performed by the subject. Processing can include applying filters and other techniques for removing signal artifacts, noise, baseline waveforms, or other items from captured signals to improve readability. As discussed in greater detail in connection with the discussion of FIGS. **4** and **5**, processing information includes data analysis techniques, such as quantifying various movement parameters based on received data, corroborating or calibrating data from multiple sources, and/or analyzing generated movement parameters to draw conclusions about the subject.

[0066] In one example for analyzing received data, the controller **118** is configured to compare one or more inertial data sets obtained from the sensor device(s) **10** with reference data comprising one or more reference inertial data sets stored on the computer readable memory or received from external sources, such as the computer network **110**. For example, the reference inertial data sets can be stored on the storage device **114** and transmitted to the intermediary

device **116** via the computer network **110**. In some examples, the reference inertial data sets include average parameter values or target parameter values for individuals having similar physical characteristics to the subject. The controller **118** can be configured to determine one or more deviations, if any, between the inertial data set(s) and the reference inertial data set(s), and, if one or more deviations is present, generate a list of one or more activities or actions (e.g., a recommended treatment regimen) that the subject could perform as a corrective measures to address the identified deviations between the subject's inertial data set and the average or target data set for similarly situated individuals. Possible corrective actions, in the form of a treatment regimen or treatment protocol, can also be stored on a database on the storage device **114** and transmitted to the intermediary device **116** by the computing network **110** when required.

[0067] Communications Module

[0068] In some examples, the intermediary device **116** comprises a communications module **122** associated with the controller **118**. In that case, the controller **118** is configured to cause the communications module **122** to transmit the raw, processed, or analyzed data from the wearable sensor device(s) to remote sources, such as the external computer network **110**. In other examples, the data is uploaded from the intermediary device **116** to an internet webpage or other remotely accessible database.

[0069] The communications module **122** comprises a short range data transceiver for communication with the communications module **38** (shown in FIG. **3**) of the sensor device(s) **10**. For example, the short range data transceiver may be a Bluetooth® transceiver, Zigbee transceiver, or similar data transmission device, as are known in the art. In other examples, the short range data transceiver can be a radio-frequency (RF) near-field communication device. In other examples, the communications module **122** comprises a wired data transmission interface. In that case, the sensor device **10** can be connected to the intermediary device **116** using a USB cable or similar data transmission cable. The communications module **122** can also include a long-range wireless data transceiver **124** for communication with the computers **112** of the external computer network **110**. For example, long range data transmission can use WiFi, cellular, radio frequency, satellite, and other known data transfer devices and protocols. Communication between the sensor device(s) **10**, the external computer network **110**, and, if present, the intermediary device **116** can be encrypted by any useful method. In that case, the communications module **122** can be configured to receive encrypted data from the sensor device **10** and process the encrypted data to remove encryption so that the received device can be analyzed. The communications module **122** can also be configured to encrypt data prior to long-range data transmission to the external computer network **110**. For example, the devices **10**, **112**, **116** can use encryption, data redaction, and/or security mechanisms to ensure data privacy and that the system comports with privacy standards, such as the U.S. Health Insurance Portability and Accountability Act (HIPAA) standards.

[0070] Input/Output Components

[0071] In some examples, the intermediary device **116** further comprises an input component **126** and an output component **128** in communication with the controller **118**, which allow the user to interact with and receive feedback from the intermediary device **116**. The input component **126** includes one or more of a keyword, touchpad, computer mouse, trackball, or other data entry accessory, as are known in the art. In other examples, input components **126** include a microphone for capturing audio data entry by a user or optical or motion sensors for capturing gestures performed by the user. The input component **126** can be used to enter information about the subject which can be used to analyze the measurement data and/or to assist in gait analysis and training regimens. For example, information about the subject's gender, age, height, weight, activity level (e.g., recreationally active, occupationally active, soldier, elite athlete), and other relevant information can be entered via the input component **126**. The input components **126** can also be used to interact with a user interface by, for example, being able to toggle through instruction screens for positioning the sensor device **10** on the subject and for performing different types of activity assessments. User interface screens that can be shown on a visual display and used for entering information and guiding a user in collecting information about a subject are shown in FIGS. **6**A to **6**E and discussed herein.

[0072] In some examples, the input/output components **126**, **128** is a touch screen display. In other examples, output component **128** includes a visual display, speakers, haptic output devices, and/or other types of feedback devices as are known in the art. The output component **128** can provide feedback to the clinician or subject about the subject's physical condition and, in particular, feedback based on movement information captured by the sensor device **10** to guide the patient to reproduce a proper gait.

[0073] In one aspect, the output components **128** include a "head up display" (HUD), as are broadly-known in the art, or any wearable visual display or smart display technology. Commercial examples of such displays include: Google Glass 2.0, Recon Jet™ (Recon Instruments), Glass (X, Mountain View, Calif.), and Vuzix M100 or M300 (Vizix Corporation, West Henrietta, N.Y.). Wearable displays can be any form, so long as they place a visible display, e.g., on glasses or another wearable device, capable of producing an indicia of the status of a patient's gait. Depending on the nature of the indicia desired and/or necessary to guide the patient, the display may be as simple as providing small LEDs or similar structures, or fiber optic displays, or as complex as a color display capable of displaying complex images. Optionally, haptic (e.g., vibration) sensations or audible signals also may be produced by the display device, or a connected transducer, such as an earbud or vibrator. Certain display devices also are capable of producing input data relating to movement and position of the patient, including accelerometer and gyroscope functionality, which can be used in addition to a dedicated sensor device worn on the waist, hips or torso—so long as a relevant measurement of one or more aspects of the gait of the patient can be ascertained from such input data.

[0074] In addition to providing feedback, in some examples, the controller **118** is configured to cause the output component **128** to provide visual or audio instructions to the user or subject related to the movement assessment being performed, such reminders that assist the patient to remember what to focus on when walking. More than one output component **128** may be utilized, such as a screen for a clinician in addition to the display device.

[0075] The components of the sensor device **10**, intermediary device **116**, and external computer devices **112** can be

combined in various manners with various analog and digital circuitry, including controllers, filters, ADCs (analog-digital chips), memory, communication devices and/or adaptors. Especially, but not exclusively with respect to the sensor device **10**, as devices become smaller and processors become more powerful and use less energy, it is possible to integrate many more sensors, such as microelectromechanical systems (MEMS) or nanoelectromechanical systems (NEMS), onto single chips. MEMS accelerometers, gyroscopes, gas sensors, thermometers, humidity sensors, and magnetometers are readily available from commercial sources and/or are abundantly described in the art. Technologies such as package on package (PoP) and system on a chip (SoC) integrated circuit packages allow manufacture of very small devices with significant capacities. For example, smart phones use PoP technologies to stack memory and processors in a very small volume. One example of a SoC is a microcontroller (MCU), which is a small computer on a single integrated circuit typically containing a processor core, memory, and programmable input/output peripherals. MCUs also may include timer module(s) and analog-to-digital converter(s) for, e.g., converting analog sensor output to a digital signal.

[0076] External Database

[0077] With continued reference to FIG. **3**, in some examples, the intermediary device **116** is in communication with the storage device **114** of the external computer network **110**. For example, the intermediary device can receive information including patient information and reference data sets from databases stored on the storage device **114**. For example, the storage device **114** can comprise a database of patient electronic health records for subjects. A health record contains personal information for the subject such as a subject's name, age, weight, height, body mass index (BMI), and blood pressure. A health record can also contain information about assessments previously performed by the subject or about a subject's history of past injuries. The intermediary device **116** can, for example and without limitation, store, communicate the personal information, and combine the personal information with the inertial data set information for communication to other external computer devices, such as the computer device **112**. In some examples, the intermediary device **116** is also configured to redact private information from the personal information prior to communication of the personal information. The received patient information is used by the computer device **112** to improve analysis of the sensed movement information.

[0078] The storage device **114** may comprise a database of reference data sets with movement information for a wide range of subjects, or parameters based on other sources, such as from research studies. The database can be used to obtain reference datasets for other individuals with similar characteristics (e.g., physical characteristics, occupational or activity level, and/or medical history) as the subject. Physical measurements for the subject can be compared with reference data sets for improve specificity and accuracy in gait analysis and feedback. In some instances, reference data sets are based on statistical (e.g., average) values for segments of a population (e.g., segments of the overall population with physical characteristics similar to the subject) or for the population generally. In other examples, a set of reference data sets is provided from the database for individuals with varying degrees of proper or improper gait. In one example, the database includes a reference data set or individual classified sets for an individual with fully- and properly-functional legs (no injury history), as well as for individuals with one or two prosthetic lower extremities, different types of prosthetics (above the knee, below the knee, below the ankle, etc.), and/or classified by one or more motions characteristic of a proper or improper gait. The measured inertial data set for the patient can be compared to inertial data sets for others, or other reference values, to assess progress or to assess the type of corrections needed to achieve a desired target motion. As information for different subjects is obtained, processed, and analyzed, the database can be expanded in an iterative manner to improve specificity and accuracy in gait training.

Information Collection Processes

[0079] FIGS. **4**, **5**, and **7** are flow charts illustrating processes for monitoring movement of the subject using the sensor device, processing and analyzing information sensed by the sensor device, and providing feedback to a patient via the display relating to gait, as described above. These processes are performed using the wearable sensor device (s), intermediary device, and external computer network, e.g., as shown in FIG. **3**. The processing and data analysis techniques discussed herein can be performed by the intermediary device and/or by remote computer devices of the external computer network. In some instances, processing and data analysis functions are distributed between multiple computer processors on different devices. In one example, initial processing and data analysis, is performed by the controller of the intermediary device and feedback is sent directly to the display. More sophisticated data analysis and reporting functions can be performed on remote computer devices of the external computer network (e.g., in the cloud).

[0080] As shown in FIG. **4**, the sensor device or intermediary device guides the user or subject through an initial setup process. In the example shown by box **210**, during the setup process, the user is instructed to input patient demographic information about the subject's physical condition and other information. For example, in response to requests by the wearable sensor device or the intermediary device, the user or subject provides demographic information (e.g., age, weight, height, dominant limb) and/or activity level/type information for the subject. The subject can also be identified as a member of a particular group of interest. For example, the subject may identify that he or she is a member of a particular sports team, military branch, cohort, etc. Assessment results for identified members of a group can be compared together during data analysis.

[0081] Based on the entered information, as shown at box **212**, the sensor and/or intermediary device is configured to select a battery of evidence-based assessments to collect movement data for the subject. For example, one or more force or torque value (e.g., Fx, Fy, Fz, Mx, My, and/or Mz), is obtained from the sensor and/or a parameter is calculated (e.g., percent of time foot is contacting the ground (% stance), AUC of any value, peak forces or moments, range of any force or moment, proximal (e.g., knee) forces, such as pMy or pMz, or distal (e.g., ankle) forces, such as dMx) from the raw data. As illustrated in the flowchart of FIG. **5**, based on input from the sensor, a step is identified from one or more parameters, and is distinguished from motions (or lack thereof) that does not indicate stepping. For example, periodic fluctuations in Fz might indicate a step motion (see, exemplary data in FIG. **6**).

[0082] As with distinguishing stepping motions from non-stepping motions, any combination of measured or calculated forces during stepping can be compared to reference values, and if such measured or calculated forces fall within predetermined tolerances based on the reference values, a signal is passed to the HUD indicating the patient's walking motion is within tolerances. If such measured or calculated forces during stepping fall outside predetermined tolerances, a signal is passed to the HUD indicating the patient's walking motion is outside tolerances, indicating that the patient should self-correct. As training advances, and a patient spends increased time within tolerances, a clinician or a software process can decrease the range of tolerable motions so that the patient can further fine-tune her gait.

[0083] A process for analyzing the quantified or normalized values to provide feedback to the user or subject for injury prediction and treatment recommendation is shown in FIG. **5**. As shown in FIG. **7**, the obtained parameter value(s) may be analyzed by comparing the derived values to measurements obtained from other subjects, the patient, or other sources, such as from published data or parameters, and stored in a database. In some examples, the other subject data includes average values based on measurements for a group of similarly situated individuals. In other examples, reference values are calculated or derived from data for the general population.

[0084] Referring to FIG. **7**, as shown at box **310**, the process begins when the values for the measurements of interest are received. As described herein, the values are derived from movement data collected by the sensor device (s) worn by the subject while performing the assessment(s). In one example, the received values include values derived from multiple data sets, such as a first data set and a second data set. The process also includes identifying characteristics of the subject so that reference values may be obtained, as shown at box **312**. Subject characteristics include the subject's age, history of previous injuries, and/or the subject's activity level and/or level of occupational activity. In one example, this characteristic information is provided by the user or subject as discussed above. In other examples, subject information is automatically downloaded from a remote source, such as a patient health record.

[0085] As shown at box **314**, benchmark or reference data sets are obtained from external sources, stored on one or more databases of the computer network, and downloaded to the computer device or intermediary device as needed. In one example, derived force, torque or stance measures are compared to benchmarks determined through analysis of collected normative data. Specific entries or values from the database or data set are selected based on the provided demographic information about the subject.

[0086] As shown at box **316**, the measured reference values for the subject are then compared to the reference values from the database. The results of the comparison can be used to determine a derivation between the measured data and reference data sets. Comparison of one data set to another can be accomplished by any method, for example and without limitation, by differencing methods. A variety of other methods and data formats are amenable to such comparisons. For example, a computer process, such as a table, a matrix, a statistical representation, an object, an equation, an image, compressed data, and combinations thereof can be used in manners which are apparent to those of ordinary skill in the art.

[0087] As shown at box **318**, the derived data set and/or results of the comparison between the data set and reference values are used for gait analysis and training, and thus output is transmitted to an HUD so that the patient can self-correct if outside of tolerances during walking or other activity relating to gait. For example, reference values can be viewed as cutoff points for tolerances associated with a certain training activity.

[0088] As shown in box **320**, the training process is repeated as necessary, and as shown in box **322**, a report can be generated.

EXAMPLE 1

[0089] It is the purpose of this example to develop and examine the effects of a real time mobile visual feedback (RTMVF) gait training system for individuals with amputation. A secondary purpose is to examine the effects of this program on improving gait performance (symmetry and frontal plane pelvic motion) pain and functional measures. In addition, findings of this project will expand the knowledge of how well this form of training can affect the retention. Removal of feedback in a fade out pattern to improve internalization, as well as a systematic training protocol and an external focus of attention (the effects of movement seen on the feedback display) can be used. These have both been demonstrated as training strategies to improve motor learning, however have not been widely used in the amputee population for gait retraining. One of the primary criticisms of the previous studies is limitation due to the expense of instrumented treadmills and motion capture systems to assess gait kinematic and temporal-spatial outcomes of gait retraining interventions. With the advent of wearable sensors that have been deemed reliable and valid to measure patient gait performance outcomes commercially available elements are utilized to provide gait evaluation not only in a mobile fashion but also in a less expensive manner. This could also have important implications towards further clinical usage as clinicians could benefit from further knowledge beyond qualitatively assessing gait when a patient returns between visits.

[0090] This work is innovative in its use of current positive findings of real time visual feedback by providing the visual real time feedback directly from the patient's prosthetic limb. This is displayed on smart glasses creating a mobile environment in which the training can occur with novel feedback from the integrated sensor. The integrated F/T sensor being utilized has been found valid for the measurement of joint forces and moments. This, in combination with mobile assessment of kinematic and temporal-spatial gait outcomes completes a novel way of training and assessing improvements in dysfunctional gait kinematics. It has been demonstrated that amputees have greater difficulty on non-level surfaces. Truly mobile gait retraining, allowing for real time visual feedback while walking outside of the clinic, has not before been tested.

[0091] For initial testing, the patient ambulates with the integrated i-Pecs™ sensor (RTC Electronics, Dexter, Mich.) (see, e.g., sensor **58** of FIG. **2**) which is programmed to communicate directly with smart glasses via Bluetooth to provide the RTMVF of vertical ground reaction force (VGRF) feedback to the patient as they walk (FIG. **8**). The i-Pecs™ has been demonstrated as valid for ground reactive force and joint moment data collection data in this population. Amputees have been demonstrated to have decreased

VGRF through the involved limb which has been demonstrated to relate to decreased stance time. Therefore, we will initially utilize VGRF data as the display and ask the patient to match their curve with the normal curve (see, e.g., FIG. **8**). Participants will undergo gait retraining. Upon initial evaluation, a standardized checklist of gait deviations will be utilized to review at each subsequent session. These then will remain the standardized deviations for that patient for 8 visits, and the same cues will be used, per deviation, across patients. These cues will be used to associate their gait changes to the feedback changes they are seeing on the display of their smart glasses. Each session will include 1 hour, twice a week for 4 weeks and will include RTMVF training and gait focused physical therapy. It will be randomized how each patient starts their 1-hour session. A faded feedback protocol will be utilized over the last four session to help internalize motor learning. An external focus directs the attention of the learner on the effects of their movements (different walking strategies changing the force curves they seen on the screen versus focusing on their own extremity alignments) and reduces their attentional demands.

[0092] While several examples and embodiments of the sensor device, movement analysis and training system, and processes for providing real-time gait training based on sensed movement data are shown in the accompanying figures and described hereinabove in detail, other examples and embodiments will be apparent to, and readily made by, those skilled in the art without departing from the scope and spirit of the invention. For example, it is to be understood that this disclosure contemplates that, to the extent possible, one or more features of any embodiment can be combined with one or more features of any other embodiment. Accordingly, the foregoing description is intended to be illustrative rather than restrictive.

EXAMPLE 2

[0093] Gait dysfunction is an impairment that can effect multiple patient populations, both neurologic and orthopedic, including those with limb loss, and become chronic and linger for years. It has been frequently reported that gait retraining with augmented sensory feedback improves dysfunctional lower extremity impairments and related gait patterns including those of amputees. However, a primary criticism of these previous studies is due to the expense and tightly controlled laboratory conditions, conducted with instrumented treadmills and optical systems, many of the findings have had difficulty being applied to realistic clinical environments. Progressing from this previous limitation, a system is provided based on an integrated load cell sensor to provide real time mobile visual feedback (RTMVF) to trans-tibial amputees for gait training.

[0094] Translating current positive findings of real time visual feedback into a clinical application was accomplished by providing the visual real time feedback directly from the patient's limb displayed on smart glasses, with the objective of creating a mobile more realistic environment in which the training can occur. The system included a prosthesis-integrated load cell (ipecs, RCT Electronics, Dexter, Mich.) and a variety of commercially available wearable head-up displays. After testing several models, including the Google glass system (Google, Mountain View, Calif.) and the Recon jet (recon instruments, Vancouver, BC), we implemented Vuzix M100 smart glasses (Vuzix, West Henrietta, N.Y.) in the prototype (see FIG. **9**).

[0095] Establishing connectivity between the different components is an ongoing process. The current prototype uses cable connections between the load cell, a laptop computer, and the smart glasses. Given that all those components have Bluetooth capabilities; an updated wireless prototype is anticipated for future iterations of the development project.

[0096] The initial prototype (FIG. **9**) allows the capturing, processing and displaying of load cell gait data in close to real time. Initial feasibility tests suggest that a patient can be fitted with the system in about **30** minutes, most of which time is required for the installation of the load cell into the prosthesis structure. The prototype is anticipated to provide the groundwork for subsequent work to determine how to best convert the raw data to the visual warning signal resulting in an RTMVF gait training system for trans-tibial amputees.

[0097] Long term goals are the effective supplementation of traditional therapist-based gait retraining with a wearable "assistant" that provides comparable feedback on a patient's gait deviations. This should help improve outcomes for patients who have limited access to specialized health care, and who are, therefore, at risk of adapting habitual gait deviations following limb loss and prosthesis provision.

EXAMPLE 3

Methods

[0098] The RTMVF system was developed utilizing commercially available and/or previously validated componentry, essentially as described in FIG. **9**. Gait data source is a prosthesis-integrated load cell (i-Pecs, RCT Electronics, Dexter, Mich.) capable of measuring precisely kinetic gait variables in lower limb prostheses. The device is semi-permanently installed as part of the load-bearing structure of the limb prosthesis connecting to the rest of the device using standard adapters. Ground reaction forces and moments of force data can be collected at up to 850 Hz and transferred wirelessly or by cable connection to a laptop computer for further processing. In order to provide visual feedback to the patient, a wearable head-up display (M300, Vuzix, West Henrietta, N.Y.) was used. These "smart glasses" contain, positioned at the fringe of the user's normal field of view, a small sized display, the contents of which are retrieved from the computer via Wi-Fi or Bluetooth connection. The display has a resolution that is comparable with small computer screens, yet its position and intended purpose in our context advises against the conveyance of very complex visual information.

[0099] Connectivity between the different components is currently realized using cable connection between load cell and laptop computer, and Bluetooth to the smart glasses. In this configuration, the lightweight computer is carried in a pouch on a waist belt by the user.

[0100] Feasibility of the system was evaluated using the feedback variable "Stance/step time ratio", (that is, the duration of a step's stance phase (from initial ground contact to toe-off) in relation to the overall step's duration measured from one initial ground contact to the next initial ground contact on the same side). This parameter correlates with some typical gait deviations in lower limb prosthesis users,

and it lends itself to easy capturing by lower-cost, prosthesis-independent sensor equipment for potential translation into the clinic and/or adaptation for different patient populations. Stance and swing components of step cycles were derived by an algorithm that analysed various components of the axial force curve (the sensor's Fz is roughly equivalent to vertical ground reaction force in an external coordinate system, Fiedler G, et al. Criterion and Construct Validity of Prosthesis-Integrated Measurement of Joint Moment Data in Persons With Trans-Tibial Amputation. *Journal of Applied Biomechanics*. 2014; 30(3):431-438) to determine the appropriate crossings of a 15N and 100N threshold. Examining the sensor data graphically and quantitatively, different strategies were tested to harden the algorithm to outliers and measuring artefacts (Kutina K, Fiedler G. The Use of an Integrated Load Cell as a Mobile Gait Analysis System to detect Gait Events in People with Limb Loss. Paper presented at: ISPO 16th World Congress 2017; Cape Town, South Africa). Timing parameters were established to help the algorithm detect transition steps and turns as non-representative steps for gait analysis and feedback purposes.

[0101] A target window of stance/step ratio was established between 0.59 and 0.63, resulting in three discrete output states: too short stance phase (below 59% of step cycle), desirable stance phase (59-63%), and too long stance phase (above 63%). The three states were represented by different feedback colors, displaying a red (for too short stance phase), green (desirable stance phase), or yellow (too long stance phase) screen to the user. The most accurate calculation of stance phase duration with respect to the total step cycle requires the entire step cycle in question to be timed. This makes the feedback information available only after a given analysed step is completed. Accounting for this inevitable latency, the validity of the system in generating feedback variables was investigated in a small sample of steps.

[0102] Inclusion criteria for this test was use of a trans-tibial prosthesis for ambulation, absence of acute or chronic health conditions that would affect prosthesis use, and ability to walk without aids for at least 30 minutes. Demographic data and mobility score (PLUS-M[19]) were recorded. The test participant was equipped with the RTMVF system and a waist-worn "mobile gait lab" (G-Walk, BTS Engineering, Milan, ITA), and was asked to traverse in self-selected walking speeds repeatedly across a 30-m level walkway. Step phase durations were extracted from the G-Walk data to serve as the validation standard for the respective variables computed from the prosthesis sensor data by our algorithm. Gait symmetry index, a proprietary variable output by the G-Walk software, was recorded as well and correlated to the i-Pecs derived stance/step ratio in order to investigate its appropriateness as feedback variable for gait training. The variable is a composite index that is based on acceleration and gyroscope data through the step cycle. An index of 100 signifies perfect symmetry between the left and the right step with respect to ground contact forces, trunk tilt, and temporal parameters. Bivariate correlation analysis was conducted using IBM SPSS Statistics (Version 24).

Results

[0103] The participant was a 61-year-old female, weighing 58.5 kg and 1.49 m tall, who had been using trans-tibial prostheses for twelve years and had a PLUS-M score at the 79th percentile.

[0104] A total of 67 steps were analyzed. Correlation between RTMVF step ratio data and reference data was strong, with a Pearson correlation coefficient of R=0.813 ($p<0.001$).

[0105] Correlation between variables stance/step ratio and overall gait symmetry index (FIG. **10**) across eight data collection sessions was strong as well (R=0.735), indicating that the feedback variable is a good proxy for the primary outcome of interest.

[0106] Latency of feedback was less than 1 second and was not perceived as problematic by the test subject. The test suggests that a patient can be fitted with the system in about 30 minutes, most of which time is required for the installation of the load cell into the prosthesis structure.

[0107] Findings suggest that our system measures step cycle components with sufficient validity. None of the analyzed steps were classified improperly, and deviations between the two utilized data capture systems did on average not exceed 66 milliseconds or 10.2 percent, a discrepancy that can be deemed acceptable, and may be attributable to the difference in generating kinetics data based on accelerometry (G-Walk) and strain gages (i-Pecs). This leaves the slight delay in displaying the feedback information that is owed to the processing of load cell gait data, as potentially the most relevant difference to treadmill based feedback systems for gait training. Whether the mobile feedback may still be considered "quasi real-time", and may thus allow the assumption that the function mechanism of the tested methodology is in principle comparable to more conventional approaches, should be tested in a larger scale study.

[0108] Our pilot data collection illustrated the advantages of providing real time visual feedback with a mobile system, in terms of efficiency, clinical applicability, and representativeness of data. Once the short preparations, involving attachment and calibration of the equipment, were concluded, collecting gait data on a substantial number of steps required not more time than the participant spent taking those steps. One person was able to administer the test session, as the patient was able to walk safely and in her regular fashion without being notably encumbered by the wearable equipment. The environment in which the training and data collection can occur is very realistic, as the system can be used on most any indoor and outdoor walking surface, including slopes, stairs, and uneven terrains. Even though only one simple variable was extracted and analyzed for the current study, more of the sensor's raw data (3-axial forces and moments) may prospectively be harvested to refine the detection of gait deviations and to inform better feedback displayed to the patient.

[0109] Our single subject pilot study did not allow investigating which modifications to the algorithm may be needed on an individual basis. It may be assumed that other users require slightly different feedback information, depending on the severity of their gait deviation and their ability to make the prescribed corrections. Such users may, for instance, benefit from adjustments to the size and location of the "target window" for the proper stance/step ratio.

[0110] Findings of the current study support the goal of effectively supplementing traditional therapist-based gait retraining. By expanding patients' exposure to gait therapy interventions beyond the limited sessions with their therapist, training effects should onset swifter and should be better sustainable. In conclusion, a mobile gait analysis and feedback system holds promise for enhanced gait retraining

approaches in people with lower limb loss, training or retraining of people with gait abnormalities, and training and rehabilitation of athletes.

[0111] The following numbered clauses describe various aspects of the invention:

[0112] 1. A gait analysis, training, and retraining system comprising:

a sensor configured to measure one or more attributes of gait of a patient; and

a controller in communication with a sensory output device, the controller configured to, repeatedly, monitor a patient's gait in real-time and to provide real-time feedback to the patient: receive and process information from the sensor representative of one or more attributes of the gait of the patient;

generate a data set corresponding to the information from the sensor representative of one or more attributes of the gait of the patient;

compare the generated data set to reference data indicating optimal values for a data set corresponding to the information from the sensor representative of one or more attributes of the gait of a patient; and

cause the display to provide feedback comprising gait analysis based, at least in part, on the comparison between the generated data set and the reference data and at least indicating in the feedback if the generated data set is within defined tolerances relative to the reference data.

[0113] 2. The system of clause 1, wherein the sensory output device is a wearable display, such as a wearable smart display device or head up display (HUD).

[0114] 3. The system of clause 1, wherein the sensory output device is a sound transducer, such as a headphone, or a haptic device, such as a vibration motor.

[0115] 4. The system of clause 1, wherein the sensor is a force, or a force and torque (F/T sensor) configured to measure forces and torque applied to a leg of a patient.

[0116] 5. The system of clause 4, wherein the F/T sensor is a six-axis F/T sensor.

[0117] 6. The system of clause 4, wherein the force sensor measures at least Fz (force applied in a superior direction toward the head of a patient).

[0118] 7. The system of clause 4, wherein the F/T sensor is provided in a leg prosthesis, such as a trans-tibial, or a trans-femoral prosthesis.

[0119] 8. The system of clause 4, wherein the F/T sensor is configured to be wearable by a patient.

[0120] 9. The system of clause 8, wherein the wearable F/T sensor is provided in a shoe, a shoe insert, a shoe outsole, or a shoe attachment.

[0121] 10. The system of clause 1, wherein the sensor is a wearable inertial measurement unit configured to be worn by the patient comprising at least one accelerometer and/or at least one gyroscope.

[0122] 11. The system of clause 10, wherein the inertial measurement unit comprises three orthogonally positioned accelerometers for measuring acceleration along the x, y, and z axes and three gyroscopes oriented along the x, y, and z axes respectively.

[0123] 12. The system of any one of clauses 1-11, wherein the sensory output device is a display providing a binary signal comprising a first visual signal when the generated data set is within defined tolerances relative to the reference data and a second visual signal different from the first visual signal when the generated data set is not within defined tolerances relative to the reference data.

[0124] 13. The system of clause 12, wherein the display provides a color signal indicating when the generated data set is not within defined tolerances relative to the reference data.

[0125] 14. The system of clause 1, wherein the controller and the sensory output device communicate wirelessly.

[0126] 15. The system of any one of clauses 1-14, wherein the reference data is obtained from:

a patient performing the one or more physical actions in an optimal, desirable, or clinically acceptable manner, for the one or more physical actions; and/or

one or more other patients, including statistical data, algorithms, or other values derived from data obtained from other patients.

[0127] 16. A method of analyzing and/or training gait in a patient, the method comprising, using a computer-implemented process, repeatedly:

receiving and processing, in a computer, information from a sensor on the patient configured to measure one or more attributes of gait of a patient representative of one or more attributes of the gait of the patient during one or more physical actions relating to gait, performed by the patient;

generating, in the computer, a data set corresponding to the information from the sensor representative of one or more attributes of the gait of the patient;

comparing, in the computer, the generated data set to reference data indicating optimal values for a data set corresponding to the information from the sensor representative of one or more attributes of the gait of a patient; and

generating, with the computer, an output causing a sensory output device to provide feedback comprising gait analysis based, at least in part, on the comparison between the generated data set and the reference data and at least indicating in the feedback if the generated data set is within defined tolerances relative to the reference data.

[0128] 17. The method of clause 16, wherein the sensory output device is a wearable display device.

[0129] 18. The method of clause 16 or 17, wherein the patient has a lower extremity amputation having a leg prosthesis, such as a trans-tibial, or a trans-femoral prosthesis, and the sensor is integrated into the prosthesis.

[0130] 19. The method of clause 16 or 17, wherein the patient is missing a leg or a portion thereof below the hip, femur, knee, or ankle.

[0131] 20. The method of clause 16 or 17, wherein the patient has a gait imbalance, such as from injury, surgery, congenital defect, disease or condition, such as, without limitation, from an ankle, leg, hip, or spine injury, multiple sclerosis, osteoarthritis, cerebral palsy, spinal cord injury, post-polio syndrome, post-stroke conditions, old age.

[0132] 21. The method of any one of clauses 16-20, wherein the sensor is a force and torque (F/T sensor) configured to measure forces and torque applied to a leg of a patient.

[0133] 22. The method of clause 21, wherein the F/T sensor is a six-axis F/T sensor.

[0134] 23. The method of clause 21, wherein the force sensor measures Fz (force applied in a superior direction toward the head of a patient).

[0135] 24. The method of clause 21, wherein the F/T sensor is provided in a leg prosthesis, such as a trans-tibial, or a trans-femoral prosthesis.

[0136] 25. The method of clause 21, wherein the F/T sensor is provided in a shoe, a shoe insert, a shoe outsole, or a shoe attachment.

[0137] 26. The method of any one of clauses 16-25, wherein the sensor is a wearable inertial measurement unit configured to be worn by the patient comprising at least one accelerometer and/or at least one gyroscope, e.g., wherein the inertial measurement unit comprises three orthogonally positioned accelerometers for measuring acceleration along the x, y, and z axes and three gyroscopes oriented along the x, y, and z axes respectively.

[0138] 27. The method of any one of clauses 17-26, wherein the display provides a first visual signal when the generated data set is within defined tolerances relative to the reference data and a second visual signal different from the first visual signal when the generated data set is not within defined tolerances relative to the reference data.

[0139] 28. The method of any one of clauses 17-27, wherein the display provides a color signal indicating when the generated data set is not within defined tolerances relative to the reference data.

[0140] 29. The method of any one of clauses 17-28, wherein the controller and the display communicate wirelessly.

[0141] 30. The method of any one of clauses 12-25, wherein the reference data is obtained from:

the patient when performing the one or more physical actions in an optimal, desirable, or clinically acceptable manner, for the one or more physical actions; and/or

one or more other patients or sources, including statistical data, algorithms, or other values derived from data obtained from other patients or sources.

[0142] The present invention has been described with reference to certain exemplary embodiments, dispersible compositions and uses thereof. However, it will be recognized by those of ordinary skill in the art that various substitutions, modifications or combinations of any of the exemplary embodiments may be made without departing from the spirit and scope of the invention. Thus, the invention is not limited by the description of the exemplary embodiments, but rather by the appended claims as originally filed.

What is claimed is:

1. A gait analysis, training, and retraining system comprising:

a sensor configured to measure one or more attributes of gait of a patient; and

a controller in communication with a sensory output device, the controller configured to, repeatedly, monitor a patient's gait in real-time and to provide real-time feedback to the patient:

receive and process information from the sensor representative of one or more attributes of the gait of the patient;

generate a data set corresponding to the information from the sensor representative of one or more attributes of the gait of the patient;

compare the generated data set to reference data indicating optimal values for a data set corresponding to the information from the sensor representative of one or more attributes of the gait of a patient; and

cause the display to provide feedback comprising gait analysis based, at least in part, on the comparison between the generated data set and the reference data and at least indicating in the feedback if the generated data set is within defined tolerances relative to the reference data,

wherein the controller and the sensory output device optionally communicate wirelessly.

2. The system of claim **1**, wherein the sensory output device is a wearable display, such as a wearable smart display device or head up display (HUD) or a sound transducer, such as a headphone, or a haptic device, such as a vibration motor.

3. The system of claim **1**, wherein the sensor is a force, or a force and torque (F/T sensor) configured to measure forces and torque applied to a leg of a patient, such as a six-axis F/T sensor.

4. The system of claim **3**, wherein the force sensor measures at least Fz.

5. The system of claim **3**, wherein the F/T sensor is provided in a leg prosthesis, such as a trans-tibial, or a trans-femoral prosthesis.

6. The system of claim **3**, wherein the F/T sensor is configured to be wearable by a patient, such as in a shoe, a shoe insert, a shoe outsole, or a shoe attachment.

7. The system of claim **1**, wherein the sensor is a wearable inertial measurement unit configured to be worn by the patient comprising at least one accelerometer and/or at least one gyroscope, such as three orthogonally positioned accelerometers for measuring acceleration along the x, y, and z axes and three gyroscopes oriented along the x, y, and z axes respectively.

8. The system of claim **1**, wherein the sensory output device is a display providing a binary signal comprising a first visual signal when the generated data set is within defined tolerances relative to the reference data and a second visual signal different from the first visual signal when the generated data set is not within defined tolerances relative to the reference data, optionally the display provides a color signal indicating when the generated data set is not within defined tolerances relative to the reference data.

9. The system of claim **1**, wherein the reference data is obtained from:

a patient performing the one or more physical actions in an optimal, desirable, or clinically acceptable manner, for the one or more physical actions; and/or

one or more other patients, including statistical data, algorithms, or other values derived from data obtained from other patients.

10. A method of analyzing and/or training gait in a patient, the method comprising, using a computer-implemented process, repeatedly:

receiving and processing, in a computer, information from a sensor on the patient configured to measure one or more attributes of gait of a patient representative of one or more attributes of the gait of the patient during one or more physical actions relating to gait, performed by the patient;

generating, in the computer, a data set corresponding to the information from the sensor representative of one or more attributes of the gait of the patient;

comparing, in the computer, the generated data set to reference data indicating optimal values for a data set corresponding to the information from the sensor representative of one or more attributes of the gait of a patient; and

generating, with the computer, an output causing a sensory output device to provide feedback comprising gait analysis based, at least in part, on the comparison between the generated data set and the reference data and at least indicating in the feedback if the generated data set is within defined tolerances relative to the reference data,

wherein the controller and the display optionally communicate wirelessly.

11. The method of claim **10**, wherein the sensory output device is a wearable display device.

12. The method of claim **10**, wherein the patient has a lower extremity amputation having a leg prosthesis, such as a trans-tibial, or a trans-femoral prosthesis, and the sensor is integrated into the prosthesis.

13. The method of claim **10**, wherein the patient has a gait imbalance, such as from injury, surgery, congenital defect, disease or condition, such as, without limitation, from an ankle, leg, hip, or spine injury, multiple sclerosis, osteoarthritis, cerebral palsy, spinal cord injury, post-polio syndrome, post-stroke conditions, or old age.

14. The method of claim **10**, wherein the sensor is a force and torque (F/T sensor) configured to measure forces and torque applied to a leg of a patient, such as a six-axis F/T sensor.

15. The method of claim **14**, wherein the force sensor measures Fz.

16. The method of claim **14**, wherein the F/T sensor is provided in a leg prosthesis, such as a trans-tibial, or a trans-femoral prosthesis.

17. The method of claim **14**, wherein the F/T sensor is provided in a shoe, a shoe insert, a shoe outsole, or a shoe attachment.

18. The method of claim **10**, wherein the sensor is a wearable inertial measurement unit configured to be worn by the patient comprising at least one accelerometer and/or at least one gyroscope, e.g., wherein the inertial measurement unit comprises three orthogonally positioned accelerometers for measuring acceleration along the x, y, and z axes and three gyroscopes oriented along the x, y, and z axes respectively.

19. The method of claim **10**, wherein the display provides a first visual signal when the generated data set is within defined tolerances relative to the reference data and a second visual signal different from the first visual signal when the generated data set is not within defined tolerances relative to the reference data, wherein the display optionally provides a color signal indicating when the generated data set is not within defined tolerances relative to the reference data.

20. The method of claim **10**, wherein the reference data is obtained from:

the patient when performing the one or more physical actions in an optimal, desirable, or clinically acceptable manner, for the one or more physical actions; and/or

one or more other patients or sources, including statistical data, algorithms, or other values derived from data obtained from other patients or sources.

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