DESIGN, DEVELOPMENT, AND TESTING OF AN INSOLE SENSOR SYSTEM FOR REAL-TIME GAIT FEEDBACK AND REHABILITATION

by

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STATEMENT OF THESIS APPROVAL

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ABSTRACT

The ability to walk is considered an essential motor function for normal human locomotion and transportation. Healthy ambulation is required of relatively all persons on a daily basis, and can be detrimentally affected by an array of different gait disorders. Following a diagnosis, traditional rehabilitative techniques often require the attention of a trained specialist, in addition to expensive instrumentation and training devices. Previous research has been performed regarding the use of insole mounted sensors to detect and quantify gait abnormalities with a comparable rate of accuracy to established systems. Sensory feedback derived from the gait data can be a versatile tool for use alongside established rehabilitative methods, with the potential to act as a standalone technique.

This thesis presents the continuing research into the usage and implementation of force sensitive resistor (FSR) based insoles, with respect to the development of a portable and intuitive feedback device for use in clinical gait modification. The new system design, titled the Adaptive Real-Time Instrumentation System for Tread Imbalance Correction, or ARTISTIC, incorporates a wireless insole system that can transmit gait data wirelessly via a Bluetooth connection. An Android mobile smartphone application, or app, was developed to receive the gait data, and provide the user with different forms of sensory feedback in order to modify their gait. Subjects were tested using each of the feedback methods to determine the efficacy of the ARTISTIC system in modulating their gait away from normal. As a result of the testing, it was determined that visual feedback resulted in a statistically significant (p < 0.05) change in gait ratio for all 12 human subjects. It is anticipated that further improvements will be made, to address suggestions provided by the test subjects as well as to strengthen alternative forms of feedback, such as audible and vibrotactile cues.

To my wife, my family, and the long list of mentors

throughout my academic journey.

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CHAPTER 1

INTRODUCTION

This section introduces the background and motivation for the development of insole instrumentation systems, along with the previous research that has been performed. The research and contributions that form the basis for this thesis are then presented, and the publication and dissemination of the results is discussed.

1.1 Background

Under typical human circumstances, walking is an integral motor function to provide a means for personal locomotion and transportation. Normal gait is an important characteristic attribute of walking, and can often be compromised by a range of different abnormalities and impairments [1]. One such abnormality, gait asymmetry, can be attributed to a variety of different pathological or traumatic causes, such as stroke, Parkinson's disease, multiple sclerosis, or a lower-limb amputation. Gait asymmetry, if left unaddressed, can lead to serious health defects including poor balance and higher possibility of falls, increased metabolic requirements, and osteoarthritis or permanent bone and joint damage [1].

Current methods for the treatment of gait asymmetry focus on correcting the underlying cause of the abnormality, with the assumption that the asymmetry will improve corresponding to treatment. With neurological disorders or traumatic injuries however, the gait asymmetry must be directly addressed in the context of the patient's current state of health. Due to the current inability to treat the cause of many types of gait asymmetry, medical devices and techniques have been developed to assist in the clinical treatment and rehabilitation of patients who are otherwise unable to walk normally.

Current medical technology has been designed to assist in correcting aberrant gait and has been shown to be very effective at characterizing the different components of a patient's gait. Such characterization is very useful to provide the rehabilitative clinician or physical therapist a large amount of information to assist in diagnosis and treatment of patients in whom gait asymmetries are manifested. One of the difficulties inherent to such diagnostic tools however, is related to the cost and size of the systems used.

In clinical settings, force plates or motion capture systems can be used to develop an extremely accurate representation of gait, along with any associated abnormalities. While this is a powerful method of feedback, such systems are expensive, and limited to their installation within the gait or physical therapy lab. Commercially available mobile systems for evaluating foot contact force have been developed, and are often used in clinical situations as well. These systems are too expensive for home use however, and often provide data that requires training or assistance to interpret. From an analysis of the current methods and devices available for gait analysis and feedback, previous research in the University of Utah Bioinstrumentation Laboratory has been focused on the development of an inexpensive, asymmetry focused instrumentation system.

1.2 Previous Work

The Lower Extremity Ambulatory Feedback System (LEAFS) has been developed using force sensitive resistors (FSRs) embedded in a silicon insole to measure foot contact force and stance timing. Previous versions of the insole have been used to

calculate the center of plantar pressure, and compare the result against the industry standards, such as a force plate. Initial design and experiments have also been performed to provide sensory feedback to assist patients in correcting gait asymmetries when walking using prosthetic limbs. Through research and development, these systems have been shown to provide accurate gait data in an inexpensive wireless package for a wide variety of possible implementations. Following the positive results of providing audible feedback for prosthetics training, it was determined that further revisions to the design and methods of feedback would be made [8].

1.3 Contributions

One of the difficulties inherent in the design and use of the LEAFS system is related to the need for computing power to process and display the gait information for interpretation by the user. Previous versions of the LEAFS system transmitted data wirelessly to a laptop computer, where it was then analyzed and conditioned using either Matlab® or LabView®. While this is an improvement on the stationary systems that required an installation inside a lab, it still did not provide a truly portable gait feedback system. This lack of portability is one of the major motivations for the work that was done for this thesis.

A major contribution of this thesis is the design and fabrication of an updated and simplified insole system. Previous versions of the LEAFS system made use of up to 10 FSRs [8], which vastly increased the complexity, cost, and potential for failure in each of the insoles. For the updated system, a set of two large FSRs per foot was used, one oriented under the heel, and one under the ball of the foot. Decreasing the amount of sensors used in the insole decreased the number of failure modes in the system as well as reducing the number of samples needed to be collected and analyzed. While the reduction in sensors also potentially results in a reduction in the accuracy of the sensors to detect gait events, it greatly increases the sampling rate of the microcontroller, and by correlation, the timing resolution of the insole system. The control circuit for the sensor was also redesigned, using a 5V Arduino microprocessor with twice the clock speed of the previous LEAFS version, and the addition of Bluetooth wireless connectivity, to replace the slower and insecure Xbee serial transmitters.

Another major contribution of this thesis is the feedback specifications, system architecture, and programming involved in creating a custom smartphone application to interface with the revised insole system. This application was designed to provide a modular and portable feedback device to receive the gait insole data, process the gait asymmetry of the user, and then provide intuitive and effective corrective sensory feedback. The application was modeled after successful sensory feedback trials to let the user choose between visual, audible, and vibrotactile feedback methods, or a combination of more than one [2-7]. The overall flexibility of the application, ability to install it on any Android powered smartphone, and accuracy of the output data established the revised system as a viable and effective modification to the previous laptop-based LEAF systems. The revised system was named the Adaptive Real-Time Instrumentation System for Tread Imbalance Correction, or ARTISTIC.

A third major contribution of this thesis is the design and implementation of a validation study to determine the efficacy of the ARTISTIC system at modifying the gait symmetry of study participants using various forms of feedback and target asymmetries.

1.4 Hypotheses Tested

In order to provide intuitive and effective gait feedback using the ARTISTIC system, a literature review was conducted to determine current methods of sensory stimulation being used in feedback devices. From this review, different methods of feedback were chosen in accordance with their expected effect on the gait of the system user. From this, **Hypothesis 1** states that the ARTISTIC feedback device will be able to modify the gait of the user as measured with a t-test with a significance level of 0.05. In addition to the recommendations and previous implementations of sensory feedback, different levels of proficiency were found to be associated with individual modes of sensory stimulation [3, 4]. It follows that **Hypothesis 2** states that the type of feedback preferred will be subject specific.

1.5 Overview

The following chapters in this thesis have been submitted, or have been prepared for submission for inclusion in conferences and journals.

In Chapter 2, a conference publication is presented describing the design, initial testing, and revisions made to the ARTISTIC system. This paper was submitted to the 2011 IEEE Engineering in Medicine and Biology Conference on April 15, 2011.

In Chapter 3, a draft manuscript is included that was submitted to a special topic of *IEEE/ASME Transactions on Mechatronics* on June 1, 2011. This paper includes the detailed design of the insole system, android application, and feedback methods. It also presents the statistical results of the validation study, future work, and system revisions

In Chapter 4, the main conclusions of the thesis will be presented, along with recommendations for future work on the ARTISTIC and related systems.

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CHAPTER 2

A WIRELESS SENSORY FEEDBACK SYSTEM FOR REAL-TIME GAIT MODIFICATION

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The paper included in the following pages has been accepted for inclusion in the 2011 Engineering in Medicine and Biology Conference (EMBC), August 2011.

A Wireless Sensory Feedback System for Real-Time Gait Modification

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Abstract-Current rehabilitation technology and techniques have proven effective at modifying and correcting gait abnormalities. They are however limited to laboratory and clinical settings, under the supervision of a specialist. Conventional techniques for quantifying gait asymmetries can be combined with sensory feedback methods to provide an intuitive and inexpensive feedback system for extra-clinical rehabilitation. A wireless feedback system has been designed to collect gait information, process it in real-time, and provide corrective feedback to the user. The corrective feedback can be presented through visual, audible, or vibrotactile methods, or a combination thereof. Initial results have led to improvement in the sensory interface of the device to maximize the corrective influence on inexperienced subjects. These preliminary findings suggest that the wireless feedback device can influence the gait of the user, and effectively adapt to their personal feedback preferences.

I. INTRODUCTION

In normal human behavior, walking is an integral motor function for means of locomotion and transportation. Normal gait is an important attribute of walking and can often be compromised by a range of different abnormalities and impairments. Due to the impact that gait abnormalities can have on the quality of life, many different methods of diagnosis, classification, and treatment have been developed [1]. One form of rehabilitative treatment, used in many different muscular and articulation disorders, is the use of sensory feedback to present corrective information to the patient [2-4]. While some investigation has been done into using sensory feedback to correct aberrant gait [4-6], the equipment used is often large and stationary, requiring the patient to attend therapy sessions in a gait or physical therapy lab [6,7].

Due to the personnel and equipment demands inherent to traditional gait rehabilitation, a portable feedback system would greatly increase the availability of treatment options for patients suffering from an abnormality. An effective rehabilitative method that could be used with minimal instruction from the therapist would accelerate the patients return to normal gait, while requiring less in the way of resources and clinical supervision. This paper presents work done to continue the development of an inexpensive insole sensor system to collect gait data, and the methods used to convert and present the data as sensory feedback to the user.

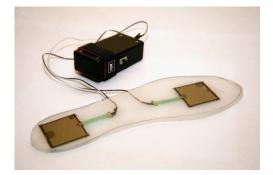


Fig. 1. Instrumented insole system and wireless data collection box

A. Previous Work

Sensor insole systems have previously been developed to collect ground force reaction and gait asymmetry data using force sensitive resistors (FSRs) mounted in silicon shoe insoles [8,9]. This insole system has been tested and verified to provide reliable gait data, for use in quantifying the gait ratio and gait index of a patient characterized as having an asymmetry [10]. Initial tests using sensory feedback have shown that audible feedback is an effective method of improving the gait of subjects who have undergone lower limb amputations and are walking on prosthetics in terms of decreasing trunk sway and improving stance time symmetry [11].

B. Motivation

The insole sensor systems have been shown to provide accurate and effective gait feedback, and are an improvement in terms of portability and adaptability to traditional gait sensors systems such as a force plate or motion capture camera. They are not however, entirely portable and still require the use of a laptop computer for data analysis and feedback. This paper presents the development, fabrication, and testing of a portable, unobtrusive feedback device for use with the insole sensor system, as shown in Figure 1.

II. METHODS AND DEVELOPMENT

A custom sensory feedback system has been designed and fabricated for use in gait rehabilitation. Initial tests have been performed to tune the feedback methods in anticipation of a device verification study. It is anticipated that 15 subjects will participate in the study, wherein the ability of the feedback system to introduce gait abnormalities in otherwise healthy participants will be quantified.

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A. System Design

The instrumented insole system has been designed to collect stance information from each individual foot, and transmit it to the feedback device for presentation to the user. As shown in Figure 1, each instrumented insole has two pressure sensors, oriented to record the initial (heel strike) and final (toe off) contact for each limb during subject ambulation. The silicon insole is designed for adaptability and implementation with different shoe sizes. The sensor setup is initialized simply by placing the instrumented insole inside the individual's shoes and in turn securing them to the foot.

The stance data is collected using an Arduino microcontroller contained in a small box attached to the subjects ankle. The data is then processed and transmitted to the feedback unit via Bluetooth wireless communication. The foot sensor system is completely contained within the insole and ankle box, providing an unobtrusive, durable, and adaptable system for use in a wide variety of rehabilitation environments.

In selecting an interactive device for use with the lower limb feedback system, a set of criteria were established. It was specified that the device must adequately provide three different methods of sensory feedback (visual, audible, and vibrotactile), and be lightweight and portable, so as not to burden the subject unnecessarily. A smartphone was selected for use due to the integrated sensory feedback systems, and relatively ubiquitous availability in modern society. In addition to fulfilling the required feedback criteria, the use of a smartphone also established the ability to develop an interactive feedback program that could run on existing hardware, rather than requiring the use of a dedicated feedback device.

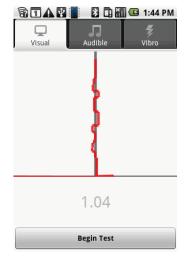


Fig. 2. Initial visual feedback display

The Android platform was chosen for development of a feedback application due to the unrestricted development and distribution structure of the Open Handset Alliance.

The primary feedback application was designed to control and present the user with three different feedback methods: visual, audible, and vibrotactile (see Figure 2) Upon startup of the application, the user is able to select from one of the three different sensory cues, or a combination of two or more. The stance time recorded by the insole sensors and subsequently transmitted to the smartphone is then used to determine the gait asymmetry ranking[10] and present it to the user according to their selected feedback preferences.

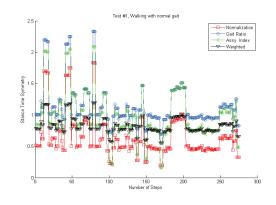


Fig. 3. Subject 1 walking test results

B. Feedback Design

For all three forms of feedback, a set of asymmetry thresholds was established, with the user able to select between strict and flexible feedback parameters. If the gait rating of the user falls outside of the specified limits, then the selected method of feedback will notify them of their asymmetry and allow them to correct it. For the audible feedback, this constitutes a single beep if they are spending too much time on their left limb, and a double beep if they are spending too much time on their right limb. Similarly, if they have initialized vibrotactile feedback, they will receive a short or long vibrating pulse corresponding to respective left and right gait asymmetries.

The method by which the visual feedback is presented is through a rapidly updated graph with the gait symmetry ratio normalized to fall nominally at 1 (see Figure 2). Deviations from the optimal gait ratio are easily recognizable to the user through visually observing the gait line to move to the left or the right. Visually observing the feedback line to fall to the right of the optimal ratio signifies that the user is spending too much time on their right foot, with the converse true for the left foot.

III. INITIAL DEVICE RESULTS

The initial testing of the device used three subjects who were asked to use the gait feedback system and provide feedback regarding the user interface. They were asked to walk normally while the feedback system recorded their stance time and displayed their gait symmetry ratio. The plot

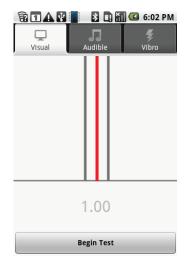


Fig. 4. Revised visual feedback display

of one such walk is shown in Figure 3, with several different methods of calculating the gait asymmetry as described by [10]. With regards to the efficacy of the device at providing feedback on their walk, there was a consensus among the test subjects that the graph updates were too sensitive and came too quickly for them to positively identify and respond. In addition, the subjects felt that the asymmetry thresholds at which vibrotactile or audible cues were given were arbitrarily difficult to remember and follow, with no definitive display for them to draw reference from.

The comments received regarding the feedback methods during the initial testing have resulted in changes to the visual display to make it more intuitive to the user. The visual display was updated to have a clearly delineated area bordered by the left and right gait asymmetry thresholds. The graph update was also changed to draw a single vertical line corresponding to each update of the asymmetry ratio, rather than an individual data point as was previously performed. The revised user interface (Figure 4) also updates less frequently, allowing the gait data to be fully addressed by the user without overloading them with information.

IV. DISCUSSION AND FUTURE WORKS

The purpose of designing an instrumented insole system that is capable of giving real-time feedback to the user is to reduce the need for bulky equipment and personnel resources in gait rehabilitation and therapy. In this respect, the device has been designed to take advantage of feedback systems that are already available to the prospective users, and provide them with a sensory interface that is both intuitive and effective.

In order to ensure that the feedback device and user interface meets the specified criteria, some initial testing was performed prior to beginning the device efficacy study. Through the suggestions received, changes were made to the different modes of feedback that improved the overall usability of the device. Through this detailed design and refinement process, the device has been improved and is now being used in a participant study to quantify its ability to influence the user's gait.

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CHAPTER 3

A WIRELESS SENSORY FEEDBACK DEVICE FOR REAL-TIME GAIT FEEDBACK AND TRAINING

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The paper included in the following pages has been submitted for publication in *IEEE/ASME Transactions on Mechatronics*.

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IEEE Transactions on Mechatronics

IEEE/ASME TRANSACTIONS ON MECHATRONICS

A Wireless Sensory Feedback Device for Real-Time Gait Feedback and Training

Christian Redd, Student Member, IEEE, Stacy Morris Bamberg, Senior Member, IEEE

Abstract—This paper presents a new sensing and feedback system for a personal gait rehabilitation device based on wireless transmission of ambulation data for real-time sensory feedback for assistive healthcare. An integrated force sensing insole was designed, using embedded force sensitive resistors (FSRs) that were sampled using a microprocessor, which then transmitted the data to an Android smartphone for presentation to the user. Experiments were performed to verify that the device captured accurate gait data, and was able to influence the gait of the subject. In addition, different sensory methods of feedback were tested to determine their individual efficacy at modulating the gait of study subject. The results show that the feedback system is capable of influencing the gait of the user, without the need for direct supervision by a rehabilitation specialist. In addition, a statistical analysis was performed to establish the reliability and repeatability of the system. From these results, this feedback system is established as a novel, inexpensive, and effective candidate for use in clinical rehabilitation of persons with gait abnormalities.

Index Terms—Wearable Sensors, Gait Rehabilitation, Sensory Feedback.

I. INTRODUCTION AND MOTIVATION

THE ability to walk is an essential motor function for normal human locomotion and transportation. Healthy ambulation is required of nearly all persons on a daily basis, and can be necessary for employment, recreation, and general movement. Due to the functional importance of walking, consideration must be given to the treatment and remediation of disorders affecting the ability to walk properly and without difficulty [1]. There are many different methods for evaluating and diagnosing gait problems, with different classifications for severity of the disorder based on the level of functionality as compared to a healthy gait [2]. Proceeding from the initial diagnosis, specialized rehabilitative techniques have been established and are used by clinical therapists to correct the abnormality [2, 3]. The objective of rehabilitation is to raise the functional walking ability of the patient to a level where they are able to perform normal tasks and are not at risk for subsequent health defects. Due to the high variability in the causes and manifestation of gait disorders, rehabilitative methods are often highly specialized to the individual patient [1]. Because of this specialized attention, there is a high resource demand, which is common to most forms of rehabilitative therapy. This resource demand includes the time spent with the therapist, expensive instrumentation and training devices, and the use of a gait lab and its associated overhead [1, 4].

Current systems used in gait rehabilitation and training include force plates, force mats, motion capture systems, instrumented treadmills, and insole sensor systems [5]. Force plates and force mats are ideal for use in stationary settings due to their high accuracy, but require training for use and are prohibitively expensive and large to be considered for implementation outside the clinic [5-7]. Instrumented treadmills are able to gather large amounts of step data, but are limited by their controlled environment and prescribed walking pattern [8]. In addition to stationary gait analysis systems, patient mounted systems are available to measure gait parameters [9]. While different implementations of these mobile systems have been evaluated and shown to provide accurate gait data [5], they are often prohibitively expensive (over US\$10,000) and require complicated peripheral equipment and specialized training for use [10-15]. In response to these specialized gait rehabilitation devices and their associated drawbacks, a novel insole sensor system has been developed to provide an inexpensive and accurate method for gait feedback and training [5,16]. This sensor system, previously titled the Lower Extremity Ambulatory Feedback System, was designed and validated against current clinical systems for use in gait training of subjects with unilateral trans-tibial amputations [5].

The purpose of this paper is to build upon this previous work in the design, manufacture, and verification of an inexpensive and portable gait feedback device for use by patients outside of the traditional clinical environment. The system is capable of determining common gait parameters through force sensitive resistors (FSRs) embedded in a custom insole that can be easily implemented in a patient's existing shoes. An anklemounted microcontroller provides sensor sampling and data collection capabilities, as well as the ability to transmit realtime gait data wirelessly via a Bluetooth serial connection. An extensive application (app) has been developed for the Android mobile phone operating system that enables an Android phone to receive the gait data and use the phone's functionality to provide effective and intuitive sensory feedback to the user. The overall low cost, ease of installation, and intuitive nature of the device provide for an effective method of gait modification, without the direct supervision of a clinician or rehabilitative specialist.

II. DEVICE DESIGN

The design priorities to develop this assistive personal care device and with respect to improvements being made on

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the previous system were: further simplifying the wireless communications protocol, improving the modularity and robustness of the system, and developing a highly customizable smartphone application that is capable of providing multiple modes of feedback in an intuitive and easy to use package. To accomplish these functionality goals, the design was separated into physical sections, which were then individually addressed to ensure that the completed subsystems integrated successfully into a reliable and inexpensive gait feedback device. The individual system design components are discussed here and titled the Adaptive, Real-Time Instrumentation System for Tread Imbalance Correction, or ARTISTIC.

A. Embedded Insole Sensors

The insole sensor system made use of force sensitive resistors (FSR, INTERLINK Electronics [17]) to sample plantar pressure data. The insole was molded from polydimethylsiloxane (PDMS), with two square FSRs embedded per foot; one sensor under the fore-foot, and one sensor under the hind-foot, as shown in Figure 1. This design departs from previous iterations in which a layout of up to ten FSRs per insole was used. This change in design greatly decreases the amount of data that is collected and analyzed, thereby simplifying the entire system and increasing the sampling rate. Two sensors per insole are sufficient to calculate gait timing and provide feedback on abnormalities [26], the parameters used to determine the users level of gait abnormality can still be effectively calculated, without extra and unnecessary data being sampled. The drawback to this simplification is that the ARTISTIC system is unable to evaluate the center of plantar pressure, which is capability that the previous LEAFS system had. The remaining components in the system are modular in their design however, and the ARTISTIC system could be easily modified to accept a greater number of insole sensors in a future iteration.

The FSRs are mounted in an orientation in which they will be immediately depressed upon heel-strike, and released upon toe-off. The FSRs are arranged in a voltage divider circuit that converts the resistance change caused by sensor activation into a change in electrical voltage. This corresponding voltage

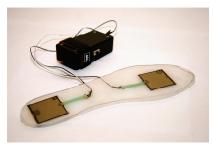


Fig. 1: ARTISTIC insole system; microcontroller, Bluetooth chip, and 9V battery are contained within the ankle-mounted box

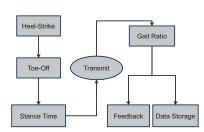


Fig. 2: Data flow in the ARTISTIC system

change is then sampled using the microcontroller's Analog to Digital chip for data analysis. The insole sensors are divided into two different sections, a fore-foot section, and a hind-foot section. By nature of this orientation, different shoe sizes can be accommodated through arrangement of the insole sections within the shoe.

B. Microcontroller and Wireless Data Transmission

The data is sampled from the insole sensors by an Arduino Pro Mini microcontroller, using the ATMEGA168 16MHZ microprocessor. A flowchart demonstrating the process flow is included in Figure 2. The FSR data is transmitted to the Arduino using two of the possible six analog input pins, any of which can be read simultaneously. The Arduino board is in turn connected to a BlueSMIRF Gold Bluetooth serial pipe for data transmission to the Android smartphone. The BlueSMIRF Gold chip is capable of wireless serial data transmission and receipt when paired with the feedback application running on the smartphone. Power to the microcontroller and associated circuits is provided by a standard Alkaline 9V battery, connected through a PQ3RD13 voltage regulator. All of the components associated with the microcontroller circuit are housed in a 1.5" x 4" plastic project box, which is strapped to the ankle during use, (Figure 1). This system, in addition to the embedded insole sensors comprises the entire lower-limb implementation of the ARTISTIC system.

C. Smartphone and Feedback Development

As noted previously, current systems that analyze gait and provide feedback to the user are stationary and often cost prohibitive [5]. In addition, they require the careful supervision of a rehabilitative therapist or specialized operational training. While the benefits of traditional gait rehabilitation and therapy are numerous and effective [4], there exists a lack of smart feedback systems for use in home or other non-clinical settings. A major motivation in the continuing development of this research is the ability to provide a nonintrusive wearable instrumentation system to augment and support traditional rehabilitation. In order to achieve this goal while still maintaining low-cost and accessibility, previous

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iterations of this insole system have relied on laptop computers running MATLAB® or LabView® to analyze and present gait data [5]. While the use of portable computers for data collection and presentation is a significant improvement upon stationary feedback installations, it still requires the use and possible transport of an unwieldy and heavy device for any time in which the user wants to employ the feedback system. Because of this, one of the major design specifications established for the development of the ARTISTIC system was the integration and development of a highly portable feedback device.

In the preliminary design phase, a literature search was performed to determine the different types of sensory feedback to be included in the next generation ARTISTIC feedback device. Different applications of sensory feedback had effectively made use of visual [18], audible [19], and vibrotactile [20, 21] methods to effect a motor response in test subjects. These three methods were chosen for investigation and used as feedback cues with the redesigned insole gait system. In addition to the feedback methods, another design specification concerned the form factor of the portable feedback device. The established requirements for the redesigned device were to: provide different modes of feedback from a fully integrated system, communicate wirelessly with the insole sensor, and be supported and carried with only one hand. Because a custom feedback device would increase both cost and complexity, a smartphone was selected for the ARTISTIC system.

At face value, smartphones offer a wide variety of useful and effective methods for conveying data to the user. They also include other desirable aspects for use in research applications including fast processors, large storage capacities, and several methods of wireless communication [22], and are relatively ubiquitous in much of modern culture. By developing a feedback protocol to work with the patient's existing phone, the need to carry an extra device is therefore mitigated. without sacrificing functionality or form. For the ARTISTIC system, it was decided that an Android smartphone would be used for developmental purposes, and during efficacy trials. The reason for choosing the Android platform over other competing platforms is due to its development and control by the Open Handset Alliance, allowing for greater accessibility and developmental freedom. The entire operating system and platform are open source and free, which allows for flexibility in development and greater creative license [23]

The benefit of developing a feedback protocol for use on the Android system is directly related to the ease in which the peripheral phone systems can be accessed and implemented within an application, or app. These peripheral systems include speakers, vibrating motors, touch sensitive display screens, input keyboards, and internal GPS and accelerometer units. In addition, wireless communication is available through the use of the Wi-FI service (IEEE 802.11) or bluetooth communication. A custom ARTISTIC application was designed and written for implementation on the Android system. This app uses the peripheral phone systems to provide visual, audible, or vibrotactile feedback cues to the user, and influence their gait accordingly.

III. ARTISTIC ANDROID APPLICATION

The design and interface of the ARTISTIC application is meant to allow the user to monitor and receive feedback regarding their gait at any time during normal walking. In order to accomplish this assistive healthcare feedback, an efficient and intuitive application layout was developed to allow the user to quickly connect to the insole sensors, and specify which singular method or combination of feedback that they desire. The final application layout makes use of a tabbed design in which each feedback method is quickly available via clicking on the corresponding tab, as in Figure 3. Due to the integrated nature of the app, clicking on a new tab does not end the previous method of sensory feedback, but rather allows the user to add new modes in combination.

The application algorithm used in the calculation of the user's gait rating is adapted from the traditional and widely used gait asymmetry ratio [24]. Using this method, the stance time (time from heel-strike to toe-off) from each insole is received, and a ratio is calculated by dividing the left foot stance time by the right foot stance time. This fraction is then centered at one, and displayed to the user. In this way, a longer stance time in the left foot will result in a higher gait asymmetry ratio, and trigger sensory feedback as necessary. For a longer stance time in the right foot, the converse is true. Due to the expected variance of the users gait about a target ratio, a acceptable offset band has been programmed into the algorithm, with the parameters being strict or flexible



Fig. 3: ARTISTIC Android application layout, figure adapted from [25]

depending on the preference of the user. For all subject testing performed in the validation of the device, strict parameters of target ratio \pm 0.1 were specified and used.

A. Data Logging

In addition to the feedback tabs available in the layout, the ARTISTIC application includes context menus for the user to specify their individual details and feedback preferences. This is a valuable component for researchers, as it allows them to easily use the application to log study data regarding the influence of the sensory feedback on the user. Once the user has entered all of their information into the application, it can restore their saved preferences, or be set to record data from their feedback session. At the conclusion of the walk, all of the information can be easily retrieved from the external Secure Digital (SD) card or via a usb or wireless connection for further data analysis.

B. Visual Feedback

The visual feedback tab is designed to present the user with an intuitive and simple interface containing their current gait details, and whether or not they fall within acceptable parameters, see Figure 5. The two gray lines denote the acceptable gait range, while a third line displays the user's current gait rating. When the user's gait falls within the given parameters the feedback line is displayed in green, when it falls without, the line changes to red. The parameters can be changed depending on the user's preferences, which will correspondingly adjust the range of the parameter bars in the visual feedback tab. In addition to the graphical representation of the user's gait rating, a numerical display is shown at the bottom of the screen, as in Figure 4. The numerical display updates with the current gait ratio each time the patient takes a step, so as to not overwhelm the user with a constant stream of information. The graphical display is deliberately designed to be simple and intuitive, so as to allow the user to quickly glance at the display to receive their current gait status.

C. Audible Feedback

The audible feedback tab provides the user with simple instructions for the initialization and protocols required to successfully start and follow the application's audible feedback. As shown in Figure 5, the user can specify whether they want strict or flexible feedback parameters, which adjusts the amount of gait deviation before the audible feedback system is engaged to alert the user. When the audible feedback is initialized, the phone plays unique tones corresponding to the user's gait being outside the acceptable range. These tones are nominally output through the phones speaker, but can be sent through headphones if the user prefers. The user can initialize audible feedback and then navigate away from the audible tab and still receive audible cues regarding their gait.

D. Vibrotactile Feedback

Similar to the audible feedback tab, the vibrotactile tab presents instructions regarding the initialization and subse-



Fig. 4: ARTISTIC visual feedback tab



Fig. 5: ARTISTIC audible feedback tab

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quent receipt of vibrotactile cues corresponding to the user's gait. The tab layout is generally identical to that shown in Figure 5, with the differing instructions and initialization parameters. When the vibrotactile feedback has been initialized, the phone will vibrate to let the user know that their gait has fallen outside the specified parameters. If the user's gait ratio is too high, corresponding to spending too much time on their left foot, the vibrator will give a long buzz. Conversely, if the user's gait ratio is too low, they will receive a short buzz. The vibrotactile feedback allows the user of the ARTISTIC system to receive silent, low-level feedback cues when the other methods of sensory stimulation are unable to be used, or ineffective due to the user's current environment

IV. DATA COLLECTION AND ANALYSIS

Following the completion of the ARTISTIC insole system and Android application, validation tests were carried out to verify the ability of the system to receive stance data from the insole sensors, and accurately present the resulting gait ratio to the user. These initial tests and the test subject's suggestions were then used to modify and further develop the individual sensory feedback methods. Next, the ARTISTIC system was used in a participant study to determine its efficacy at modifying the gait of the user [27]. The objective of the study was to determine whether the system could effectively induce a negative gait abnormality in a healthy participant population, meaning they have never been diagnosed with a gait problem. In addition to testing the efficacy of the system, the reliability and repeatability of the system was also tested under conditions that it could reasonably expect to experience during normal operation.

A. Experimental Procedures

The human subject testing protocol used in the validation of the ARTISTIC system was approved by the University of Utah Institutional Review Board, under the study number: IRB00047784. Twelve subjects were asked to participate in several walking tests to assess the systems ability to influence gait, as well as the corresponding effectiveness of each of the three different types of sensory feedback. Each subject was first introduced to the system, and given instructions on how to interpret the feedback cues. The subjects were given the



Fig. 6: Subject with ARTISTIC sensor system

choice of using their own shoes for the walking tests, or using sets provided by the research staff. They then installed the insole system inside their shoes, placed the shoes on their feet, and affixed the microprocessor box to their ankles, via Velcro(& straps (Fig. 6). Once the initial setup was finished, the subject was asked to walk normally down a two-hundred foot hallway, make a turn at the end, and return to the starting point. During this initial walk, the ARTISTIC system was initialized to receive and store gait data to provide a control against which subsequent walks would be compared.

Once the subjects had become familiar with the system and provided a control set of data, they were asked to perform a series of three walks over the study course. During each walk, they were randomly assigned a sensory feedback method as well as an offset gait ratio target. They were instructed to follow the feedback cues, and informed that if the cues were followed correctly, that they would be walking with an induced gait asymmetry, or "limp." Following the initial three tests, in which the subject experienced the use of each type of feedback, they were then surveyed to determine which feedback method they preferred. Next, they were asked to perform three additional walks using their feedback method of choice. The additional walks used target parameters with large offsets to determine the ability of the system to induce a large asymmetry in the gait of the subject. The order in which the walks were performed was determined using a Balanced Latin Square, thereby incorporating counterbalanced measures into the study design to minimize the effects of carryover and subject learning.

Following the completion of the walking trials, the subject was asked to fill out a usability survey concerning their experience with the ARTISTIC system. They were asked questions regarding their comfort level with the insoles, their opinion of the efficacy of different methods of feedback, and suggestions that they had for the continued modification and revision of the device.

B. Analysis

The raw data files collected from the twelve different subject testing sessions were first retrieved from the smartphone SD card, and then input into MATLAB[®] for statistical analysis of the results. The statistical analysis was broken down into two different sections.

1) Initial Tests: The raw data from the initial three walking tests was separated into visual, audible, and vibrotactile data sets. These data sets were then organized by the gait ratio asymmetry target that the study participant had been given through the ARTISTIC sensory feedback system. The mean values of these target sets were calculated, and compared against the corresponding set of control walks, using a Student's one-tailed t-test. Using this t-test, the null-hypothesis that the feedback given to the user has no effect on their gait could either be proved or disproved. If the null hypothesis was disproved, a statistical significance and confidence interval was then assigned to the statistical correlation. Evaluating each of the feedback methods in this way, the ability of the ARTISTIC system was determined, derived from the efficacy

of its feedback subsets. Following the statistical tests, a posthoc power analysis was performed using the results of the t-test, to ensure that the number of subjects was sufficient to ensure that a false positive was not obtained. Only statistical results with a power greater than 0.8 were reported in this paper.

2) Preferred Tests: In addition to the randomly assigned feedback tests, the subject was asked to provide their preferred method of feedback, and then participate in three further walking tests using that method. These preferred method data sets were populated using large gait ratio offsets of 0.5 or 1.5 to determine if the feedback device was capable of inducing an immediate and large gait asymmetry with a minimal amount of previous system learning. These data sets were similarly compared against the control group using one-tailed t-test to determine whether the feedback had influence on the gait of the subject. In addition, the mean gait ratio of these preferred subject tests was compared against the desired target offset to determine if the feedback was successful in attaining the specified large gait asymmetry. Due to the very small sample sizes of the audible and vibrotactile preferred feedback tests, those statistical tests are not reported.

V. RESULTS

From the statistical analysis of the initial subject tests, it was determined that the visual feedback was successful in modulating the normal gait of all of the test subjects. The calculated average stance ratios and standard deviations are given in Table I and II. The results of the analysis used to determine if the induced gait asymmetries differed from the control in a statistically significant way are included in Table III. From the p-values calculated, the visual and vibrotactile sensory feedback systems were verified to have induced a statistically significant variance in the subjects gait, while the tests for the audible feedback system showed that it did not. This corresponds to the results of the post-testing usability surveys, in which test subjects expressed difficulty in understanding and following the cues given by the audible system. In addition, a larger than expected variance was found in the gait ratios of the control tests (see Fig. 7) as compared to published standard [24]. This larger deviation could be a result of the implementation and weight (9 oz) of the microcontroller boxes on the subjects ankle.

The results of the preferred method subject tests correlated the findings of the initial subject tests, in that the preferred method of feedback for each subject was successful in modulating their gait (Table II). The majority of the subjects preferred the visual feedback system, with seven choosing it, three choosing vibrotactile, and two choosing audible, therefore statistical results for preferred feedback are only available for visual feedback. A post-hoc power analysis was performed to verify the strength of the statistical analyses. The statistical power was above the commonly established limit of 0.8 for all initial tests and the visual preferred test.

VI. DISCUSSION

The ARTISTIC system was successful in introducing a gait asymmetry in the subjects walking pattern, despite an

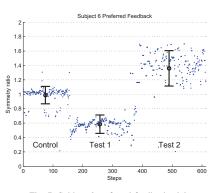


Fig. 7: Subject 6 preferred feedback trials

extremely short training process compared to what would be considered normal during a gait rehabilitation program. This result suggests that this system could be used for assistive health care to positively adjust the gait of a rehabilitative patient with relatively little specialized training. Such rehabilitative use was shown to be possible through the easy and modular application of the ARTISTIC system for subject testing, with no specialized equipment or environment needed. This validates the use of the ARTISTIC system, as well as its strengths with respect to ease of use and inexpensive implementation. With an approximate prototype cost of US\$225, it is an economical alternative to the more expensive options currently available.

The high preference of the testing subjects for use of the visual feedback system, as well as the feedback received from the usability survey suggests that it was the most intuitive form of feedback for them to use. While this does not necessarily reflect poorly on the audible and vibrotactile feedback methods, it can be concluded that further work should be done to improve the ease of use for the other two system components. which were shown to have promise for a high level of effectiveness in influencing the gait of the test subject. Due to the small number of subjects who chose the audible and

TABLE III: Statistical significance of feedback methods

Feedback	Target	P-Value	# of Subjects	Power	
		Initial Testi	ing		
Visual	1.25	0.0019*	6	0.98	
Visual	0.75	0.0443*	6	0.99	
Audible	1.25	0.0675	6	0.79	
Audible	0.75	0.0853	6	0.97	
Vibrotactile	1.25	0.0189*	6	0.45	
Vibrotactile	0.75	0.0475*	6	0.97	
	Р	referred Tes	sting		
Visual	1.5	0.0002*	7	0.99	
Visual	0.5	0.0119*	7	0.99	

* p less than 0.05

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TABLE I: Subject testing with and without the influence of sensory feedback

ID #	Control	Visual Feedback		Audible Feedback		Vibrotactile Feedback	
	Ratio mean \pm SD	Target	Ratio mean \pm SD	Target	Ratio mean \pm SD	Target	Ratio mean \pm SD
1	1.06 ± 0.03	0.75	0.81 ± 0.10	1.25	1.01 ± 0.08	1.25	0.95 ± 0.23
2	1.01 ± 0.11	1.25	1.13 ± 0.09	0.75	0.93 ± 0.12	0.75	0.90 ± 0.10
3	1.13 ± 0.05	0.75	0.89 ± 0.10	1.25	1.08 ± 0.12	0.75	1.05 ± 0.14
4	1.03 ± 0.04	1.25	1.20 ± 0.07	1.25	1.18 ± 0.10	0.75	0.89 ± 0.12
5	1.18 ± 0.04	0.75	0.78 ± 0.05	1.25	1.24 ± 0.04	0.75	0.91 ± 0.09
6	1.01 ± 0.10	1.25	1.55 ± 0.23	0.75	0.64 ± 0.07	0.75	0.63 ± 0.21
7	1.04 ± 0.02	1.25	1.17 ± 0.06	0.75	1.17 ± 0.08	1.25	1.41 ± 0.23
8	1.12 ± 0.08	0.75	0.82 ± 0.11	0.75	0.85 ± 0.12	1.25	0.93 ± 0.25
9	1.08 ± 0.13	0.75	0.99 ± 0.07	1.25	0.98 ± 0.09	0.75	0.99 ± 0.11
10	1.01 ± 0.06	1.25	1.11 ± 0.11	0.75	0.99 ± 0.13	1.25	1.21 ± 0.24
11	1.01 ± 0.12	0.75	0.75 ± 0.11	0.75	0.80 ± 0.13	1.25	1.32 ± 0.14
12	1.13 ± 0.06	0.75	0.90 ± 0.07	0.75	0.88 ± 0.07	1.25	1.22 ± 0.09

TABLE II: Subject testing with preferred choice of sensory feedback

ID #	Control	First Trial			Second Trial		
	Ratio mean \pm SD	Feedback	Target	Ratio mean \pm SD	Feedback	Target	Ratio mean \pm SI
1	1.06 ± 0.03	Visual	1.5	1.22 ± 0.09	Visual	0.5	0.71 ± 0.10
2	1.01 ± 0.11	Visual	1.5	1.21 ± 0.08	Visual	0.5	0.81 ± 0.11
3	1.13 ± 0.10	Audible	0.5	0.87 ± 0.12	Audible	1.5	0.90 ± 0.10
4	1.03 ± 0.04	Visual	0.5	0.65 ± 0.09	Visual	1.5	1.24 ± 0.08
5	1.18 ± 0.04	Visual	1.5	1.43 ± 0.15	Visual	0.5	0.62 ± 0.15
6	1.01 ± 0.10	Audible	0.5	0.59 ± 0.13	Audible	1.5	1.36 ± 0.25
7	1.04 ± 0.02	Visual	1.5	1.36 ± 0.22	Visual	0.5	0.64 ± 0.10
8	1.12 ± 0.08	Vibrotactile	0.5	0.96 ± 0.17	Vibrotactile	1.5	0.89 ± 0.15
9	1.08 ± 0.08	Vibrotactile	1.5	1.38 ± 0.39	Vibrotactile	0.5	0.96 ± 0.14
10	1.01 ± 0.06	Visual	0.5	1.11 ± 0.32	Visual	1.5	1.29 ± 0.19
11	1.01 ± 0.12	Visual	1.5	1.27 ± 0.28	Visual	0.5	0.69 ± 0.31
12	1.13 ± 0.06	Vibrotactile	1.5	1.30 ± 0.13	Vibrotactile	0.5	0.75 ± 0.13

vibrotactile feedback as their preferred method, a future study with a greater amount of people will need to be performed, so as to provide an acceptable sample size for statistical analysis.

From the preferred method testing, it was shown that the sensory feedback was capable of inducing large gait ratio abnormalities within each subject test. These resultant gait ratios, while large, did not quite reach the target offset in most of the tests. This result correlates with the earlier findings from the LEAFS system [5], that large permanent gait changes must be made gradually. In addition, the research performed on the LEAFS system showed a significant change in gait using an identical audible feedback method [5], which was not even statistically significant during trials using the ARTISTIC system. This further validates the possible use of the ARTISTIC system in rehabilitative training in addition to traditional clinical methods, and the importance of continuing to improve the individual feedback methods.

This initial study involved a relatively small subject pool, but still produced verification and results that built upon those from the previous LEAFS system. A post-hoc power analysis was performed to evaluate whether the subject size was sufficient to avoid the possibility of a false positive when using the t-test. These initial testing results demonstrate that the ARTISTIC system performed as designed, and identified specific areas to target for improvement. Further system improvements include modifying the vibrotactile and audible feedback components to provide a more intuitive sensory experience. One of these improvements includes the possibility of mounting vibromotors and/or buzzers in each of the microcontroller boxes to target the feedback to each side of the user.

Another long-term goal is the incorporation of the power supply, microcontroller, and wireless transceiver into the insole. This would be simpler for users to install and use, and would reduce the amount of connecting wires and need for ankle mounting.

Previous versions of the insole sensing system were limited by their data rate to a maximum resolution of stance time measurement of 8.8ms, thus introducing a source of error into the data measurement [5]. The revised ARTISTIC system is capable of sensing and transmitting data at 1000Hz, which corresponds to a decrease in the measurement resolution to 1ms, thereby increasing the accuracy of the system. Another source of error is the algorithm used for detecting heel-strike and toe-off. Due to different influencing factors, the gait patterns of the user can change substantially, thereby requiring

a robust and flexible algorithm to accurately capture gait data under all circumstances. While we have demonstrated that the threshold algorithm used here works well with multi-sensor insoles [28], a a future study to verify the accuracy of the system against the current industry standard would be valuable for validation. It is also anticipated that future iterations of the system will include greater numbers of sensors, and the capability to do so has already been built into the current version.

A potential weakness with the ARTISTIC system can be argued that it only treats the symptoms exhibited by patients with gait abnormalities, rather than the underlying physiological causes. However as stated previously, the current methods for addressing a gait abnormality in a clinical setting are to establish a diagnosis, and then prescribe a treatment [2]. In this respect, the ARTISTIC system can be used both as a diagnostic tool to gather gait data away from the clinic, as well as a subsequent treatment device. The strength of the system therein lies in its versatility and inexpensive implementation at many different levels in the rehabilitative process.

From these positive initial results, the next step is to use the ARTISTIC device in a participant study to determine its ability to positively rehabilitate subjects with gait abnormalities. These refinements and changes will serve to improve the system, and result in a valuable tool for wearable and independent gait feedback.

VII. CONCLUSION

A real-time feedback system for gait modification and training was developed and tested on healthy human subjects. The system was determined to behave as expected, and was successful at inducing a gait abnormality in the subjects. The tests performed indicate that visual feedback is the most intuitive and easy to follow form of feedback, while vibrotactile and audible feedback need further refinement. Both visual and vibrotactile feedback were demonstrated to result in significant changes to gait asymmetry. The custom application that was written to control the system performed well, with the ability to provide valuable and effective gait feedback to the user. This system has potential for use in the rehabilitation and training of subjects who have undergone lower limb amputations, suffered from a stroke, or who have Parkinson's disease. In this way, it can serve as a supplemental rehabilitation method for use both in the clinic, and as a personal assistive health care device.

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CHAPTER 4

CONCLUSIONS AND FUTURE WORK

4.1 Conclusions

This thesis documented the design, fabrication, programming, and validation of a novel feedback system for use in gait rehabilitation and training. The previous work with the LEAFS system was evaluated with respect to the success of audible feedback in training sessions of patients walking on lower-limb prosthetics. Following the evaluation, a set of sensory feedback protocols was established, and an Android application was written to provide feedback to the user of the device.

The sensor insole designed was revised, with the ARTISTIC system making use of two insole sensors per foot to determine the timing of stance events. The insole sensor control circuit was improved with the addition of a faster microprocessor, and a secure, fast Bluetooth communication chip. The revised insole system was designed to interface cleanly with the Android application, to provide an adaptable, mobile gait asymmetry feedback system. In addition, two hypotheses were tested:

<u>Hypothesis 1</u> stated that the revised ARTISTIC system would successfully demonstrate the ability to modify the gait of the test subject. Validation tests were performed to evaluate the ability of the ARTISTIC system to successfully modify the gait of the test subjects. Experimental results validated the hypothesis, showing that all three feedback methods were successful in introducing a gait asymmetry in the test subjects, with the mean asymmetry of the subject walk falling within the testing target parameters. In addition, visual feedback resulted in a statistically significant (p < 0.05) change in gait ratio for all 12 human subjects.

<u>Hypothesis</u> 2 stated that the preferred method of feedback used during the validation would be subject specific. Visual feedback was the most preferred method of feedback due to its ability to provide fine resolution in the feedback as compared to the vibrotactile and audible feedback methods. This preference for different methods of feedback validates the premises introduced in hypothesis 2.

4.2 Future Work

While the ARTISTIC system was shown to successfully influence the gait of the test subjects, there are still improvements to be made to the system.

Overwhelmingly, test subjects preferred the visual feedback to the audible and vibrotactile methods, which suggests more difficulty or concentration required when interfacing with the other two methods. This was most often due to a reported difficulty in understanding the meaning of the vibrating and audible cues, while the visual system was reported to be more intuitive. The vibrotactile feedback could be improved by mounting individual vibromotors on each of the ankles, to give clearer feedback as to which side of the body the feedback system is trying to influence. Improvements to the audible feedback system include changing the tones that are delivered to be more distinctive from one another, and adding support for the use of a headset to provide stereo feedback to each ear.

Previous versions of the LEAFS system were validated against a force plate and found to maintain high levels of accuracy. Due to the decrease in sensors in the ARTISTIC system, it is also expected that the sensory resolution will change from the previous validation tests. It would be valuable to perform a new validation test to determine the accuracy of the new system, to account for the decrease in sensors and increase in sensor size.

Finally, while the ARTISTIC system was found to successfully influence the gait of the test subjects, it has not been tested and validated in a rehabilitation setting. Use of the ARTISTIC system in correlation with long term clinical gait training would be valuable to determine the amount of improvement the subjects exhibited with and without the use of extra-clinical gait feedback.