Official Title: Villency - Proof of Action: Foot Device, Balance and Sway, Kinematics of Walking

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Villency-Proof of Action: Foot Device, Balance and Sway, Kinematics of Walking

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**Abstract**

***Background:*** Limited evidence is available on experimental foot devices that are designed to improve functional features of balance, postural sway and walking gait via cutaneous stimulation to the plantar surface. There are numerous studies of shoe insert effects on motion features of the foot and gait, but these inserts are primarily to manage clinical conditions or injury. We propose that appropriately-designed, stimulatory - but not mechanically supportive - devices could enhance control of balance, postural sway and key features of walking gait in healthy people. This has yet to be tested.

***Purpose:*** There are two purposes to this proof of action study: 1). Determine the effect of an experimental foot device on static balance and center of mass displacement (sway) during standing; and 2). Determine the effect of an experimental foot device on walking gait temporalspatial parameters, ground reaction force patterns and joint forces, and relative foot pressure patterns.

***Methods:*** A proof of action repeated-measures study will be conducted in which healthy men and women (N=15) will be recruited to perform a series of balance and gait measures before using the foot device for a week and after the week of use. The following functional tasks will be performed at each time point: static balance on force plates (two-legged stance, one-legged stance and tandem stance), walking gait measures on an instrumented treadmill (at a preferred speed and a standardized speed) and walking measures on a pressure-sensor filled gait mat. For balance, the center of mass displacement, the variation about the displacement and the speed of the displacement will be calculated during post-processing. For gait, the ankle, knee and hip joint moments and joint excursion kinematics in the sagittal plane of motion will be calculated. The peak ground reaction force, the rate of impact loading and the impulses will be calculated during post-processing. A repeated measures analysis of variance will be used to determine whether significant improvements in the functional outcomes occurred. The one-week change scores in the functional task outcomes will be calculated, and effect sizes of the foot

device on the key functional variables will be determined using Cohen's *d*. Significance will be established at $p<0.05$.

***Application:*** The findings from this study will improve our understanding of foot device impact on functional performance in people without pre-existing conditions, and will help us create effect sizes for subsequent larger trials.

## Introduction

The human foot is the initial point of contact between the body and the environment, and is a critical point to provide sensory information to the central nervous system during dynamic and static tasks (Nurse et al. 2005). The specialized mechanoreceptors of the plantar surface of the foot influence balance, dynamic stability and motion correction strategies. Thus, cutaneous stimulation of the nerves in the foot can dramatically change the motion of the lower extremity. For example, during walking and running, stimulation of the foot nerves (through varied experimental methods) can directly impact $\alpha$-motorneuron output to the leg musculature (Nurse et al. 2005; Zehr et al. 1997). This output alters the kinematics of motion during gait.

A common application of this concept is the use of in-shoe devices, such as orthotics, to change foot movement. Shoe devices are frequently used to treat lower extremity injury (Dixon and McNally 2008) and manage clinical conditions such as ankle instability, osteoarthritis or sacroiliac joint pain (Cho and Yoon 2015; Hamyln et al. 2012; McKeon et al. 2012; Rao et al. 2009). Depending on the design, material and length, these devices have different effects on foot motion (Dixon and McNally 2008) and along the whole kinematic chain. Some evidence shows favorable improvements in postural stability with shoe insert orthotics over two weeks (Hamyln 2012) in individuals with ankle instability. Limited studies report immediate improvement in balance correction in response to fast, random postural perturbations with foot devices that facilitate sensation to the plantar surface (Maki et al. 1999). The increased plantar sensitivity does not appear to habituate over weeks, as shown by studies of older adults who can maintain their improved lateral stability over the long-term with the use of insoles (Perry et al. 2008).

The underlying theory is that these collective devices may, in part, improve plantar proprioception and motion control in loaded conditions. However, the design of most shoe devices is meant to change foot motion and mitigate impact forces rather than allow the foot to enhance the proprioceptive ability. For example, orthotics may allow foot motion in the metatarsals, but constrict or "support" the arch (Dixon and McNally 2008). Others are rigid and long to minimize foot splay, and others are partial length along the plantar surface and contact the heel surface only. Orthotics are comprised of different materials ranging from gels, foams, plastic and combinations of these materials at different thicknesses and contour levels. Some devices are intended to cushion and reduce shock (Ramanathan et al. 2008). Moreover, the studies that report effects of such devices have generally enrolled individuals with preexisting orthopedic conditions and are more likely to find effects on functional outcomes. The limited data from experimental foot devices or methods that increase plantar sensitivity show promise (Maki et al. 1999; Perry et al. 2008). These experimental methods modify contact surface with the foot and use ridges, bumps or other textured surface to theoretically stimulate the cutaneous nerves. The participants reported increased awareness of the contact surface and increased responsiveness to positional perturbations.

***Deficits in the Literature.*** There are two major challenges in interpreting the available evidence on the actions of these foot devices on balance and gait kinetics and kinematics. First, we have very little evidence of the shoe device impact or mechanism in the general healthy

population. Second, when using a foot device for the purpose of improving proprioception, the device should be simple and stimulate (but not mechanically support) the plantar surface of the foot. This evidence is sparse. Presently, we do not currently know how the motion, ground reaction forces and joint moments of the lower extremity joints are impacted with a proprioceptive foot device among the general healthy population.

We seek to expand the understanding and application of the foot device concept to healthy people for injury prevention and performance enhancement. We will determine whether a different design of foot device can improve static balance and gait parameters. Medicine trends are moving toward self-management of healthy movement and preventative strategies to injury. More evidence is needed to determine whether the type of foot device we will test here has potential to improve balance, posture and stability – all of which promote healthy movement and reduce injury risk over the long-term. Here, a proof of action study will be performed to determine the effect size of the foot device use on functional task outcomes of balance and gait in healthy people.

## Specific Aims

The Specific Aims of this study are to determine the effect of a foot device after one week of acclimation and use on functional variables of balance and gait. We will test the following hypotheses using the following specific aims:

1) ***Determine the effect of an experimental foot device on static balance and center of mass displacement (sway) during standing.***

***Hypothesis:*** Compared to the initial baseline measures, static balance will be improved as shown by reductions in the displacement of the center of mass, speed of motion of the center of mass and less trunk sway. We hypothesize that improvements in balance and sway will occur in two-legged stance, single-legged stance and in tandem stance.

2) ***Determine the effect of an experimental foot device on walking gait temporalspatial parameters, ground reaction force patterns and joint forces, and relative foot pressure patterns.***

***Hypothesis 2a:*** After one week, participants will demonstrate improvements in temporal spatial parameters (gait speed, stride width, swing time and single support time) compared to initial baseline measures. We also hypothesize that the rate of impact loading will be lower after one week of use.

***Hypothesis 2b:*** We hypothesize that there will be a shift in foot pressure patterns from the typical pattern to that of pressures that indicate transfer of body weight over the heel, lateral metatarsals and hallux.

## Methods

**Study Design:** This is a repeated-measures study in which participants will serve as their own control. Balance and gait measures will be collected during an initial visit and after one week of using the experimental foot device.

**Participants:** Healthy men and women (N=15) will be enrolled into the study. Participants must match all the following criteria to be enrolled:

***Inclusion:***

- Healthy men and women aged18 to 40 years
- Willing to maintain current level of physical activity during the study period of a week (no increase or decrease of activity level).

***Exclusion Criteria:***
- Moderate or severe obesity (body mass index $\geq$35kg/$m^2$)
- Known diagnosis of cardiovascular, orthopaedic, or neurological conditions, uncontrolled diabetes, or any condition that impacts normal walking ability
- Any current ankle, knee, hip or low back pain
- Currently using any knee or ankle brace on a regular basis for joint pains
- Severe back pain, prior spinal fusion or spinal deformity that would affect gait
- Major cardiac or pulmonary conditions and any orthopedic limitation that precludes their ability to independently walk for 10 minutes or longer
- Any major orthopedic injury within the prior 12 months

**Recruitment and Informed Consent:**
Participants will be recruited from the Gainesville area using flyers, online web ads and word of mouth. If interested, the potential participants will call or email the study team. The study coordinator will then explain the study in detail using the informed consent document as the basis of the discussion, and answer any questions from the participant. Participants can take the consent document to review the information carefully. If the individual does agree to pursue the study, written signatures on the informed consent will then be obtained. The participant will be given a copy of the informed consent document after it is signed and dated. Participants are free to withdraw from the study at any time. The protocol and consent documents identify the research team's obligations to the participant and the participant's obligations to the study while he or she is a participant.

**Study Schedule:**
Participants will be involved in a total of two study visits: initial baseline and one week. This study will include a series of descriptive variables and potential covariates, and objective assessments that relate to the Study Aims. Each visit will take place at the UF Orthopaedics and Sports Medicine Institute's (OSMI) Human Dynamics Laboratories. Every participant will receive standard procedural and safety instructions about each test. With the exception of the participant history, covariates and height and weight, all of the following outcome measures will be taken at baseline and one week.

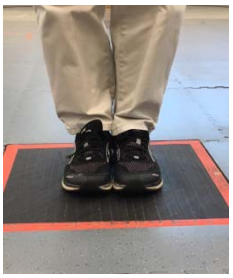
**Study Measurements:**
***Participant History and Covariates:*** A study-specific brief health history questionnaire will be completed during the initial visit which includes age, weight, body mass index, current medical issues, current activity level and type of shoe regularly worn for exercise and daily use. All answers will be self-reported.

***Body weight and height:*** Height and weight will be collected using a standard, medical grade scale during the initial visit.

***Functional Tasks and Preparation:*** The use of the foot device may impact how individuals react with the ground, causing changes in balance and postural shifting, impact loading rates and peak force development and pressure patterns as weight is transferred over the feet. As

such, functional abilities including balance and comprehensive gait analysis will be performed. These tests will provide insight on how the foot device potentially impacts the control of balance, and the speed and quality of walking gait. To track movement of body segments during the subsequent testing, reflective markers will be applied to anatomical landmarks and body segments using the methods of Kadaba et al. (1990). These markers will be placed on important anatomical landmarks and body segments (For the static calibration trials, markers will be placed bilaterally on the acromion processes, triceps, lateral elbows, forearms, wrists, posterior superior iliac spine, anterior superior iliac spine, anterior thigh, medial and lateral condyles of the femur, tibial tuberosity, medial and lateral malleoli, calcaneus, lateral to the head of the fifth metatarsal, and medial to the base of the hallux. An offset marker will be placed on the right scapular inferior angle. For the walking trials, medial knee and ankle markers will be removed. Offset markers will be used to facilitate automatic marker tracking. After calibrating the system, a static pose will be used to create a model for subsequent analysis). The pelvis segment will be developed from the anterior and posterior superior iliac spine markers, and the anterior orientation will be expressed relative to the horizontal as 0° of anterior tilt. Joint angular displacements of the ankle, knee, hip and pelvis in sagittal plant of motion will be calculated using commercially-available software (Visual3D, C-Motion Inc,, Germantown, MD, USA).

***Balance and Postural Sway Conditions*:** Each participant will perform three conditions of balance on the in-ground force plates (AMTI, Watertown MA). This measure is one of the most important variables in the study and was used to generate the sample size estimate. The three conditions will include two-foot stance, single foot stance and tandem balance stance. Following standardized instructions, participants will hold each position for 20-second intervals during which time force data will be captured at 1200 Hz. These collective measures will take roughly two minutes. This measurement technique is commonly used to assess postural stability and balance (Brown et al 2007; McKeon et al. 2012; Menz et al. 2017) and has demonstrated sensitivity to detecting change with shoe inserts that were designed to improve balance and gait (Menz et al. 2017). The images below show the three balance conditions:



A.

B.

C.

*A. Two-foot stance:* Participants will be asked to place their feet together and hold their arms at their sides. Participants will stand looking straight ahead and hold as still as possible.

*B. Single foot balance:* Participants will be asked to stand on the dominant foot and hold the other foot up, such that the knee creates a 90 degree angle. The participants will stand looking straight ahead and hold as still as possible.

*C. Tandem stance:* Participants will be asked to place their dominant foot forward and place the toes of their other foot to the heel of the dominant foot. The participants will stand looking straight ahead and hold as still as possible.

Once the data are collected, calculations of center of mass displacement (in cm), the variability of displacement and area ($cm^2$), and the peak speed of displacement (cm per second) will be determined. These values will provide insight about direction of sway and how quickly sway occurs during these three balance conditions.

***Walking Gait.*** Two types of gait tests will be used to comprehensively characterize the gait patterns, motion and foot pressures that occur during walking: a force-plated treadmill and a GaitRite© gait mat. First, kinematic and kinetic measures will be captured using 3-dimensional (3D) motion capture techniques. High-speed filming will also be used to record a video reference of each condition (Edgertronic Inc, San Jose, CA; frame rate=498 frames per second).Once completed, each participant will walk across a gait mat to obtain relative foot pressure patterns. The total time to complete all the gait tests is approximately 15-20 minutes.

***3D Instrumented Motion Analysis on Force Plated Treadmill:*** To determine ground reaction forces (GRFs) during walking, dynamic assessments of these forces and force patterns (kinetics) will be collected during a 10 second sample period with participants walking a self-selected speed and a standardized speed on a force-plated treadmill (AMTI, Watertown, MA USA). Each participant will first be acclimated to the treadmill, then allowed to walk for three minutes at a self-selected pace. Participants' walking motion (kinematics) will be captured by using a high-speed 7-camera optical motion analysis system (Motion Analysis Corp, Santa Rosa, CA, USA). Then participants will be asked to walk at standardized speed of (3.2 mph), a speed at which corresponds to an average preferred walking speed of healthy adults in the age range we will use here (Van Uden and Besser, 2004).


Kinematics and kinetics will be derived from the marker data using standard rigid body mechanics equations implemented within commercially available software (Cole et al. 1993). During the last minute, a sample of walking data will be captured and written to disc for offline processing. The following measures will be obtained in the sagittal plane for the ankle, knee, hip and pelvis joint: joint angles at foot contact, peak angles at mid-stance and excursion (range of motion per joint). These data will be processed using Visual 3D software. The peak GRFs in each of the three planes (sagittal, frontal and transverse) will be determined. Knee moments and the rate of force development after foot contact will be calculated for each leg (DeLeva et al. 1996). Moments will be adjusted for body weight X height. The picture above left shows the instrumented treadmill setup. The vertical displacement of the center of mass (COM) will be calculated as the difference in the maximal and minimal vertical height of the estimated COM during an average gait cycle. The stance time was determined as the percent of the gait cycle during which the foot made contact with the treadmill. Cadence, COM vertical displacement, step length, step width will also be calculated.

***GaitRite© Gait Mat Measures*:** Participants will be asked to walk across the 26' long gait mat and their self-selected speed to capture the foot pressure patterns. The pressures are color

mapped, where higher pressures are brighter reds and blues, where areas of low pressure are represented by grey or light blue. Temporalspatial parameters will also be captured (cadence, speed, step lengths, step width, toe out angle, stance and swing time and variability about these measures). A total of six trials will be captured and averaged to determine the typical loading pressure pattern. The change in peak foot pressure location will be documented from a 12-square grid generated from the plantar surface on the mat. In each of the 12 squares, averaged pressures will be automatically calculated by the software. If the location of the peak pressure square on the grid changes from the initial baseline measure to week one shifts from an unfavorable location to the expected healthy locations (heel, lateral metarsals and hallus), this will be coded as positive change. The peak pressure values will also be captured and recorded at each time point. Walking gait mats such as these are widely used to track changes in gait with different interventions and are sensitive to changes in temporalspatial parameters and relative foot pressure patterns (Nandikolla et al. 2017). Previous research has established the test–retest reliability of temporospatial parameters derived from the GAITRite system, with reports of good to excellent reliability, both within and between-days, in healthy adults (Van Uden and Besser, 2004). The picture above left shows the GaitRite gait mat in use during a typical walking trial.

**Foot Device and Prescription for Use**

The foot device is similar to a shoe insert (see image below). The devices are pre-sized to fit a variety of shoe sizes for men and women. Participants will be instructed to wear the device in one pair of their own personal shoes for one hour each day for days one and two. On each subsequent day until day seven, the time for use will increase by one hour per day. This is nearly identical to wear progressions in other foot orthotic-shoe devices prescriptions (Hamlyn et al. 2012), and is expected to be well-tolerated and safe. These same shoes will be worn for the initial and final testing sessions in the lab to reduce biomechanical variability of measures, and to replicate what the use of the device would be like for the general population on a daily basis. Image A below shows the shape of the foam-based device and the surface area that will make contact with the foot, and Image B shows a close up of the textured rubberized material will be that will make contact with the foot. These inserts weigh approximately 1.5 ounces.

A. B.

## Statistics

**Sample size:**

Because there are no directly comparable data from which to construct a matched sample size estimate, we have used the study with the closest match in aims and population (Hamlyn et al. 2012). For the matched pairs design, this study would require a sample size of 14 people to achieve a power of 80% and a level of significance of 5% (two sided), for detecting a mean of the differences of 17 $cm^2$ of postural sway area between pairs, assuming the standard deviation of the differences to be 20 $cm^2$.

**Analysis for the Specific Aims:**

Descriptive statistics (means and standard deviations for continuous variables, frequencies and percents for categorical variables) will be calculated on all study variables and demographics. Normality of the data will first be confirmed using Shapiro-Wilk tests.

***Aim 1: Determine the effect of an experimental foot device on static balance and center of mass displacement (sway) during standing.*** We will use repeated measures analysis of variance (ANOVA) to determine whether significant improvements in the functional outcomes occurred. The dependent variables will be the key functional task outcomes for balance (center of mass displacement, variability of displacement and area, and the peak speed of displacement) and the independent variable will be time (initial assessment, week one). Covariates to the models will be body weight and sex. The one-week change scores in the functional task outcomes will be calculated, and effect sizes of the foot device will be determined using Cohen's *d*. For these described statistical tests an $\alpha$ level of 0.05 will be established as significant.

***Aim 2: Determine the effect of an experimental foot device on walking gait temporalspatial parameters, ground reaction force patterns and joint forces, and relative foot pressure patterns.*** Similar to Aim 1, repeated measures ANOVAs will be used to determine whether significant improvements in the dependent variables for walking gait occurred. The dependent variables will be the kinematics in sagittal plane, temporalspatial parameters, ground reaction forces, impact loading rate and foot pressure change. The independent variable will be time (initial assessment, week one). The one-week change scores in the functional task outcomes will be calculated, and effect sizes of the foot device will be determined using Cohen's *d*. To determine whether any statistically significant shifts in the peak pressures on the plantar surface occurred, Chi Square ($\chi^2$) tests will be used. An $\alpha$ level of 0.05 will be established as significant.

***Data Management:*** Data will be collected and saved in Microsoft Excel®. The electronic files will be de-identified and saved on the departmental, firewalled encrypted server. Data will be reviewed before analysis and cleaned to ensure that all numbers are within expected limits. Once data collection is complete, statistical analyses will be performed using the Statistical Package for the Social Sciences (SPSS version 24; IBM Chicago, IL).

## Possible Discomforts and Risks, Protections against Risks

There are minor potential risks and discomforts associated with this study. All precautions will be put into place to minimize these risks.

***Foot Device and Study Measures.*** The risks to participating in this study are minimal. A potential discomfort may be related to wearing the foot device during the one week period. The devices are purposefully designed to stimulate the plantar surface of the foot and may feel

slightly unstable. Adjusting to the slight instability might initially feel uncomfortable for some people when they first wear the foot device. This discomfort is expected to improve over time as the participant becomes comfortable wearing them each day. A second anticipated discomfort is the development of mild muscle soreness in the lower extremities from wearing the foot device. As occurs with the start of any new shoe or shoe device where muscles engage in unaccustomed activity, muscle soreness may develop. This may appear in the muscles of the feet, lower leg, upper leg or gluteal muscles. This soreness is transient and is expected to dissipate within 48-72 hours.

With any treadmill or walking tests, there is the very small possibility of injury. We take all precautions to reduce this risk of falling or injury by familiarizing the participant with the treadmill, coaching them through all the processes of the treadmill use and having spotters next to the treadmill.

***Informed Consent.*** Written informed consent will be obtained after explanation to subjects about all procedures and time commitments. The study coordinator will explain to prospective participants the purpose, methods and extent of the study. Potential participants will be asked to read the informed consent form and to ask questions. The form will be written in simple, easy-to-understand language. We require the coordinator to review all key aspects of the study verbally. They will then question potential participants to ascertain whether they have understood the information. A copy of the signed and dated consent form will be given to participants, and the original document will be placed in subjects' individual study files, which will be stored in a locked, secure location in the OSMI.

***Confidentiality.*** Data will be used only in aggregate and no identifying characteristics of individuals will be published or presented. Confidentiality of data will be maintained by using research identification numbers that uniquely identify each individual. Safeguards will be established to ensure the security and privacy of participants' study records. Appropriate measures will be taken to prevent unauthorized use of study information. Data other than demographic information do not use names as an identifier. The research ID number will be used. The research records will be kept in a locked room in the OSMI. The files matching participants' names and demographic information with research ID numbers will be kept in a separate room and will be stored in a locked file that uses a different key from that of all other files. Only the study team members will have access to these files. After the study is completed, local data will be stored with other completed research studies in the OSMI records room.

***Data Safety and Monitoring Plan*****.** Although the risk for an untoward event occurring due to participation in the study is extremely low, we will put all data safety and monitoring procedures into place. A Data and Safety Monitoring Plan (DSMP) will be implemented to ensure the safety of all participants involved in the study and to ensure the validity and integrity of the data. The study team will monitor all aspects of safety. The Study Coordinator will meet monthly to review all Serious, Unexpected and On-site adverse events and will make recommendations to the PI and Co-investigators. Study safety personnel will be notified of all Serious and on-site events within 24 hrs of initial confirmation. The PI will complete an Event notification and Evaluation form which will be reviewed by the IRB. A summary of non-serious events will be reported to the PI and IRB.A structured safety monitoring system will be established in order to both assure real-time participant care and unbiased monitoring of adverse outcomes. For ongoing participant safety, events will be assessed by the PI, physician, and Co-investigators to determine if they are Serious, Unexpected or On-site, as defined below. If so, an event evaluation form will be completed that will include a description of the event, a classification of seriousness, assessment of potential relationship to the study, assessment of need for change in the consent or the study activities, a summary of known prior health issues, event outcome

and a classification of the main organ system involved. The classification of potential relationship to the intervention is as follows:

| | |
|---|---|
| Definite | Temporal pattern + Known or expected AE response pattern |
| Probable | Temporal pattern + Known or expected AE response pattern + Could not be explained by participant's clinical state |
| Possible | Temporal pattern + Known or expected AE response pattern + Could have been produced by a number of other factors |
| Unknown | Relationship for which no evaluation can be made. |
| Not related | AE for which sufficient information exists to indicate that the cause is unrelated to the study intervention |

The study PI and Co-investigators will notify the IRB of any serious adverse events that result in death or on site events that result in medical care within 24 hrs of being made aware of the serious adverse event.

**Participant Compensation for Time and Travel:**
The participants in this study are partners in this research. We will provide each participant with a stipend of $125.00 funds to defray cost of travelling time investment during a work week, and parking at the OSMI.

**Possible Benefits:**
The study participants may gain some insight into their own gait and balance abilities, as each participant will receive a copy of their normal walking gait report without the foot device after they are done participating in the study.

**Analyze the risk-benefit ratio:**
This study provides little risks to individuals. It poses a very low risk of breach of PHI. The risk-benefit ratio is acceptable.

**Conflict of Interest:**
This study is being sponsored by Villency Design Group, LLC. to determine the proof of action of their foot device design.

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Statistics description:
All statistics were performed on SPSS v 25.0. Descriptive statistics were performed on participant characteristics and opinions of orthotics on foot motion and health (means and standard deviations or % of the group). Repeated measures analysis of variance were used to determine whether significant improvements in the main functional outcomes (temporalspatial parameters of gait, ground reaction forces, loading rate and joint moments, foot pressure patterns, balance assessments [amount of center of mass sway in antero-posterior and medial-lateral directions and velocities of sway in different directions) occurred over time point (baseline, week 1). Effect sizes of the foot device on the key functional variables was determined using Cohen's *d*. Safety measures of lower extremity muscle soreness and pain were reported as means for each day of the study. Significance was established in advance for all tests at $p<0.05$.