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VALIDATION OF ESENS PRESSURE SENSOR ARRAY DURING WALKING AND
RUNNING

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Bachelor of Science in Exercise Science
Cleveland State University
2018

Submitted in partial fulfillment of requirements for the degree
MASTER OF EDUCATION
at the
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RUNNING

NICHOLAS M. CHAMBERS

ABSTRACT

The eSens Pressure Sensor Array is a prototype device aimed at quantifying the spatiotemporal measurements obtained during walking or running. The objective of the present investigation was to validate the spatiotemporal measurements from the eSens against those of the PKMAS walkway.

Twenty-four adults with a mean age of 40.72 years completed the study. Mean group height and weight were 66.64in and 152.48lb respectively. Subjects performed a series of 6 locomotor conditions consisting of 3 differing walking or running speeds. Subjects were asked to walk or run at the instructed speed along a course constructed of markers at 5m or 10m before and after the PKMAS walkway. Subjects would move from one marker to the distal marker before being instructed to turn around and continue until twenty steps were taken on the mat with the foot that instrumented with the eSens.

Results showed ICC acceptance ($ICC = 0.943$) for Stride Time (SdT) during the Slow Walk (SW) condition. No other ICC values showed acceptable agreement between the eSens and PKMAS. These results led to the rejection of the initial hypothesis, that the eSens Pressure Sensor Array as implemented in this study, was a valid tool to quantify spatiotemporal gait measurements.

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CHAPTER I

INTRODUCTION

In human biomechanics, the examination of gait is a highly researched topic. In respect to human locomotion, the two major gait cycles studied are running and walking. In order to identify the unique gait characteristics of both of these movement patterns an understanding of both their kinematics and kinetics is required. As the two movement patterns have primary differences in speed, foot loading patterns and movement phases, the ability of a device to measure gait at varying movement speeds is extremely valuable.

Until recently researchers in the field of human performance have only been able to study force production during locomotion by using force plates or pressure plate treadmills (Exell, Gittoes, Irwin, & Kerwin, 2012). Force plates act as an instrument to measure units of ground reaction force production during human motion. Often times these pieces of equipment are seen in laboratory settings where athletes are asked to walk, run, or jump and land on the plates so that their force generation can be analyzed.

Being able to measure pressure output has been a well-covered topic in scientific research. Prior to finding application in human movement, particularly locomotion, these types of pressure measurements stemmed from technology known as tactile sensors. According to Sokhanvar, Packirisamy, & Dargahi (2007), tactile sensors vary in size

depending on their use, however, the basic premise entails the transfer of an electrical impulse through the completion of a pressure based circuit. Depending on how the sensor is constructed, the timing of pressure application as well as the amount of pressure placed on that circuit can be measured and put into numerical values.

As deviations in gait are a major indicator of injury in the body, force or pressure plates can also be utilized to identify underlying movement problems. This makes these types of equipment very valuable for athletic populations, clinical populations, and the general population alike. By using pressure sensors to examine the ground or collision forces resulting from repetitive motion such as that seen in running based activities, the impacts that these forces have on the rest of the body can be investigated (Hreljac, 2004). In addition to the potential application in laboratory settings, measuring repeated forces during daily human locomotion represents a valuable goal for further understanding of activities of daily life (ADLs) and general physical activity. This further expands the possible opportunities for these devices as people from the general population can become more informed of their gait and any possible deviations or deficiencies.

Despite the apparent benefits proposed to the general and athletic populations, there are some downsides to the current forms of force and pressure sensing technology. The issue with these current methods lies in the concept of testing environment, especially for long distance runners (Mooses, et al., 2015). Compared to running outdoors or on a track, long distance runners are not placed in their natural athletic environment when utilizing these pieces of equipment. Furthermore, during practical use, pressure plate measurements are often conducted in a laboratory setting with limited space, which can result in a skewed subject exhibited gait pattern.

The eSens is a modern attempt to provide an answer for the need to conduct gait and running tests in more natural environments. eSens does this by providing a mobile device to be connected to the shoe laces as well as an insole to be placed underneath the pre-existing insole that the runner would normally utilize. More work needs to be done to validate the gait metrics outputted by this device with current clinical and research technological standards. By cross comparing the measurements collected by the eSens during various walking and running speeds with standardized measurements collected by the Zeno Metrics Pressure Walkway (PKMAS), the validity of the eSens modular pressure sensor array can be determined.

Purpose

The purpose of this study is to validate the accuracy of kinematic gait measurements from the eSens Pressure Sensor Array (eSens) during various walking and running speeds by correlating the measurements gathered from the eSens with those of the previously validated Zeno Metrics Pressure Walkway.

Hypothesis

The eSens Pressure Sensor Array will provide valid and accurate measurements associated with walking and/or running.

CHAPTER II

LITERATURE REVIEW

Walking Gait

During the walking gait cycle the subject is actively catching themselves as the center of gravity is shifted forward. Once the center of gravity reaches the outer perimeter of the base of support, a step is taken to compensate and the walking cycle begins. With the heel and forefoot of both feet on the ground, this is known as double support. Whence the trailing leg is picked up to be swung through, single support begins. The process of alternating between double support and single support thus repeats on each side until locomotion ceases. This process is displayed in Figure 1, presented by Umberger (2010).

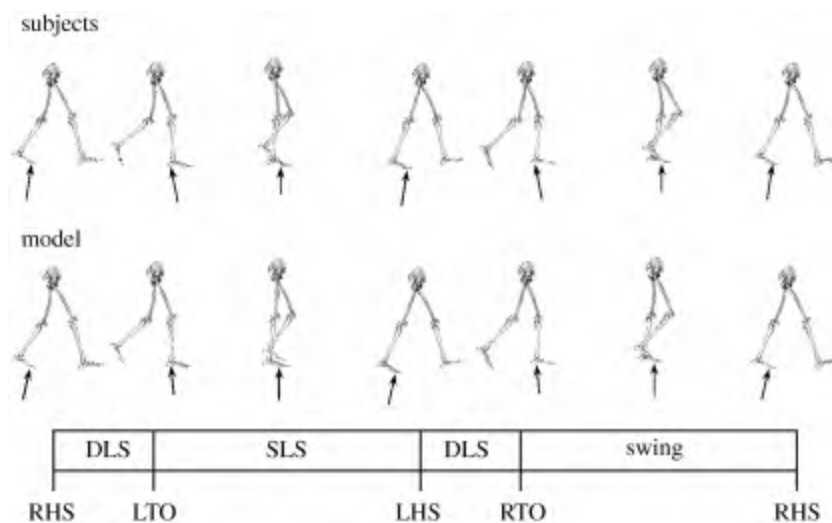


Figure 1: Walking Gait cycle in Human Subject

When looking at the primary activities of human life, locomotion ranks highly on the list. People are always moving from point to point and generally speaking, this is achieved via walking. By examining walking more closely, general parameters and population norms have been determined which help researchers to identify deviations in gait. For example, in a study by Winiarski, et al. (2019), when subjects were asked to walk at different self-determined paces, a general norm was found; that the subjects' normal pace was that which required the least amount of expended energy; or kcals. Better said, people tend to walk in a way that is easiest for them to move and which requires the least amount of calorie expenditure. As speeds changed, a normalizing action occurred which resulted in repeated trials yielding similar results in respect to spatiotemporal measurements.

The technology industry has tapped into this information in recent years by marketing products with pedometers or accelerometers which track people's steps and distance covered throughout the day. A popular product marketed today is the FitBit. This is a watch like device which uses an accelerometer to track basic activity analytics such as step count, elevation, active minutes, and estimated energy expenditure. Examined in an article by Sushames, et al. (2016), the FitBit was validated against visual analysis of activity. Within this study, the FitBit was found to be moderately accurate when compared to visual analysis. There were some deviations in distance and step count, however, this was likely due to excessive bodily movement or the swinging of the arms during locomotion.

Ultimately this extra movement is responsible for a lot of the inaccuracies for the presently marketed pedometers. For mass population activity tracking, a simple to use,

accurate, and efficient product is essential. To combat the inaccuracy caused by excessive bodily movement, collection of ambulatory measurements via the insole of a shoe is theoretically more relevant. By only collecting measurements when pressure is applied by the foot to a ground surface, gait properties can more precisely be collected using trackers such as the eSens. This is especially relevant when looking at community ambulation in which massive amount of data are recorded during the activities of daily living. In a study by Dondzila, et al. (2012), the validity of commonly marketed pedometers in step count were evaluated. The researchers found that, as speed increased in all age groups, steps were either over or under estimated more frequently. In addition, age played a factor into step count alterations as age plays a role in overall gait efficiency. The study concluded that the presently marketed pedometers such as the Omron HJ-720ITC; which has been previously validated (Silcott, et al. 2011), are suitable for daily living use. This conclusion, however, is made purely on numerical step quantity. This does not take into account any usable information such as step/stride length, timing of strides, velocity, or cadence. These additional measures above simple step count could permit deeper analyses into the fluctuations of gait throughout the day for an individual. In order to acquire this information, more sensors or equipment would need to be purchased.

Running Gait

During the running gait cycle, different from the walking gait cycle, the subject is actively causing a propulsion off of the ground with each leg to avoid the double support phase associated with walking. As explained later, the running cycle begins with an initial foot strike with the leading leg (Novacheck, 1998). The part of the foot that makes initial contact differs from person to person, as explained by Lieberman, et al (2010). In

a study by Lieberman, et al. (2010), foot strike pattern during running is described in three patterns; fore foot, mid foot, or rear foot. By examining each of these strike patterns, the differing amount of ground force contact or reaction forces put on the body can be studied. For example, in the study by Lieberman, et al. (2010), researchers found that people who are accustomed to running barefoot shared a common fore foot strike pattern, while those who run shod generally strike with their heel. This information is extremely valuable because it shows natural adaptation to impact forces.

When running barefoot, there is no cushioning between the foot and ground to displace the collision forces during running. Multiplying this force by the amount of repetition can surmount to a great deal of impact force on the body, thus by striking with the forefoot, some of this energy is displaced as the duration of this impulse is extended. This concept can further be applied to the eSens technology. By mapping multiple sensors along the base of the shoe insole, information on how a runner strikes the ground can be computed and analyzed. Thus if a runner is suffering from an overuse injury or is questioning the use of insoles/orthotics, their strike pattern and ultimately the impact forces acting on their body can be examined. Vice-versa, if a runner wishes to change their strike pattern then the eSens can be used over time to assess the changes in strike pattern.

Following foot strike, the body is pulled over-top the lead leg, whilst the trailing leg experiences flexion at the hip and knee resulting in what Clement & Taunton (1980) refer to as toe off, or take off. In an article by Clement & Taunton (1980) one of the original guides to running form is presented. Within this article the kinematics of basic running form are broken down with an emphasis on the strike pattern and toe off of the

running stride. Basic running biomechanics are described as having a support phase and a recovery phase or flight phase. Within the support phase, one leg goes from initial foot strike through to a toe off whilst during the recovery phase the same leg goes from a rear swing to and forward swing in order to complete the follow through motion. These phases are examined unilaterally as the two legs are performing the opposite phase concurrently in Figure 2.

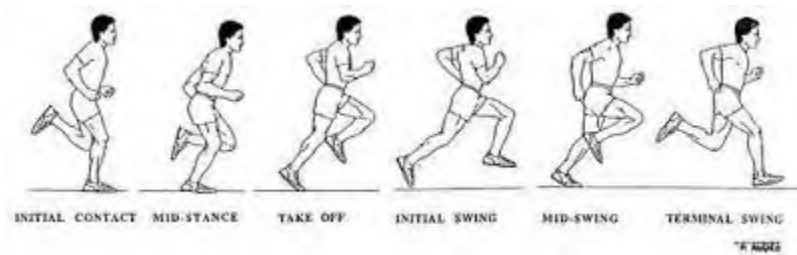


Figure 2: Running Gait Cycle in Human Subject

In addition to these basic biomechanics, the article begins to explain the impact that variant foot alignment can have on the impact forces experienced by the runner's body. Explaining characteristics such as lateral/medial forefoot post and displaying the force angles that these changes have on the ankle anatomy gives a sense of importance to proper running form.

By understanding the various loadings of the foot during running and how these play into the forces experienced by the body, the importance of the eSens insole can be ascertained. While one heel sensor is being used within this study, the final prototype will have a sensor for the heel, midfoot, and forefoot. This theoretical mapping of the sole of the foot will enable researchers or athletic coaches to understand how their athletes are performing. In addition, from a recreational sense if a runner is experiencing discomfort while running, these sensors can begin to paint a picture of what gait deviations might have led to that discomfort and help find a way to improve comfort.

Commonly seen in running populations with high millage, overuse injuries or running discomfort can be a major hindrance on performance. A recent article by Stoggl & Wunsch (2016) redefines the biomechanics of long distance running. Explained in this article, compared to when the article by Clement & Tauton (1980) was published, the total number of entries in the New York City Marathon increased from around 15,000 to over 50,000. With more than a three-fold increase in participation, it is apparent that greater efforts in running based research are warranted. Along with participation increase, the article explains that athletic performance has also been on the rise. With an average velocity of 10 km/h and around 20,000 strides being taken in a single event, runners are becoming faster, stronger, and more efficient. In addition to the positive improvements, the occurrence of injury has also risen. With 36% and 32% of injuries in males and females, respectively, occurring at the knee, the constant impact forces generated by long distance running have increased as competition in this sport as increased. The article goes on to include information on the biomechanics of running, such as that that has been previously discussed, however, the ultimate conclusion is the need to run faster. The authors close the article with the topic of breaking a 2 hour marathon. With world records being minutes shy of accomplishing this feat, it is clear that there will be no rest in sight for athletes who are training to beat this time.

By utilizing equipment such as the eSens pressure sensors during training or marathon competition, athletes can gain valuable data and information about their running performance. In terms of the article by Stoggl & Wunsch, equipment such as motion capture cameras, chase cameras, and force plates were used to collect the data utilized in the article. These pieces of equipment are often times limited by mobility, as

only sections of the runners' performance can be measured and the rest theoretically estimated. With the eSens, a full athletic performance can be recorded on the microchip and exported for analyses with ease. This opens up a higher degree of accuracy in full competition performance measurements such as those presented in this article.

In taking the understanding of kinematic changes during running a step further, the surface that a person is running on also has an impact on their running form. In an article by Dixon, Collop, & Batt (2000), this concept was tested with 6 runners who all shared a heel strike running form. The subjects were asked to run a 3 m distance in which three different running surfaces were interchanged. The researchers hypothesized that as the running surface was changed, the runners would instinctively alter their running kinematics to help increase impact absorption. Ultimately the results both supported and contradicted the initial hypothesis. While some runners altered their joint angles in a visual compensatory reaction, others did not have noticeable changes. In addition it appeared that the peak impact forces on the various materials, in fact did not share similar results. This finding suggests that the runners did not compensate much due to the altered surface but rather changed their form based off of how their perception of what was needed.

This article proves useful in supporting the use of the eSens based off of environmental changes during running. The idea that testing environment should mimic sporting environment can be supported here. While researchers attempt to bring surface material to laboratory settings such as explained in this article, this is ultimately a delimiting variable for multiple studies. By utilizing the eSens instead of a force plate, the

subject can be immersed into a natural running environment free from the typical constraints of a treadmill or laboratory.

Furthermore in an article by Mooses, et al. (2015) the concept of testing environment and running surface was examined. 13 elite distance runners were studied and the impact of treadmill running versus track running on VO2 max and running economy was examined. The subjects ran variably increasing speeds on an outdoor track. These speeds were recorded and matched when running on the treadmill. The results showed no significant differences for the VO2 max, however, running economy was significantly better when running on a track.

As running economy can affect the overall motivation and validity of performance tests, this study shows that there is justification for conducting running tests in the field. Despite no deviations in VO2 max, the kinematics of running present a valuable justification for the eSens sensors. Through measurement of swing/stance time, the various ground reaction forces, and the strike pattern of the foot, the running economy of an athlete can be determined fairly easily. Based off of the findings in the above study, if testing were to be conducted via treadmill, then validity could be put into question when examining running economy.

Injury Prevention

Beyond learning new ways to improve athletic performance and enhance the training of individuals, safety and injury prevention reign among the top priorities in exercise and sport. As touched on, injury prevention in distance running is a paramount consideration when factoring in the amount of repetitive stresses that people who engage in these activities undergo. In an article by Hreljac (2004), a meta-analysis on the current

knowledge of running and injuries was discussed. Hreljac explains that, a large majority of impact force graphs for recreational runners has two peaks. The initial peak represents the heel strike, and the second peak represents the active force that the person applies into the ground during the stance portion of the running stride. Both of these forces are vertical impact forces and send energy up through the shank into the rest of the body. Hreljac goes on to explain that the magnitude of these forces as well as the kinematic orientation of the runner's stride leads to impact or overuse injuries. They conclude that an enhanced level of pronation following initial contact with the ground could help to reduce the overall magnitude of these forces on the body by allowing more time for the foot to displace the energy of impact.

Applying this knowledge to the current study, the justification of the impact sensors in the eSens is readily understandable. By analyzing how hard the runner hits the ground with their initial foot strike, small changes can be made to help prevent overuse injury or in the event of an injury; help alleviate the complications.

Furthermore, a study by Jacobs & Berson (1986) essentially opened the door for studying injury prevention in middle-long distance runners. In this study, a sample size of 550 subjects were asked, out of around 3000-4000 race participants, to complete a survey. Of this sample, 451 runners completed the survey and were included in the study. The survey that was completed consisted of four sections which included running habits, injury information, how the runner treated the injury, and demographics. The study showed that there was a diverse population with the majority being males. There was a significant relationship determined between training volume and injury, with nearly 70% of the subjects who ran more than 30 miles per week reporting incurring injuries.

The study concluded that determinants for injury risk include training volume, non-running training participation, the number of races per year, and pre/post run stretching. In regards to the relevance of this article to the current study, it can be seen that training volume and the repetitive impact forces on the body are highly correlated with injury. By using the eSens during training or periodically throughout the training cycle, any adaptive changes in running form due to excessive force strain from training can be seen and proper action can be taken before an injury occurs.

Force Plates

Force plates have long been used in relation to human kinetics. The basic premise for force plates provides an instrument which numerically measures the electrical current resulting from a force being applied to it. Similar to tactile sensors, these pieces of equipment are usually on a larger scale and often cost a great deal to install or operate. An example of a force plate is presented in Figure 3.



Figure 3: Common Force Plate Utilized in Human Subject Testing

The basic measurements obtained from most force plates as described by Rainone, et al. (2008), include impact forces, ground reaction forces, time of contact, center of pressure and distance. With these measurements a numerical value can be placed on static and dynamic gait. The drawback to this form of gait analysis, however, lies in the immobility of the force plates as well as the limited testing environment. In the

study by Rainone, et al. (2008), these students used a manufactured force plate prototype to test the efficiency of gait. During this study, subjects were asked to walk along a 10 foot course which had a constructed ramp containing the force plate in the middle. While this enables a simulation of natural stride and gait, the unnatural environment created by this course exemplifies the downfall of modern force plate technology. In addition, the subjects were only permitted to use one, right, footfall on the plate which not only limits true data collection but does not take into account unilateral deviations in gait. These limitations are somewhat overcome by instrumented treadmills, however, these machines encompass an even greater financial burden and lack of fidelity to standard over ground locomotion.

Moving forward, similar technology has been developed into gait mats. By lining a fabricated walkway with pressure sensing circuits, the gait of individuals can be measured continuously over a longer length of space when compared to force plates. Used in the present study as a form of validation, the software for the PKMAS walkway was previously validated for its ability to detect changes in center of pressure during walking. Conducted by Lynall, et al. (2017), the study consisted of 25 subjects who were asked to complete 2 walking sessions consisting of 8 walking trails over the walkway and 8 over a course spanning 2 force plates. The results for center of pressure path and speed from the two instruments were compared and it was determined that there were no clinically significant deviations between the two devices. This indicates that, while more stringent testing requirements could result in more similar statistical data; the PKMAS walkway software is more than able to produce valid and reliable pressure data when compared to the gold standard of force plates. This study in particular, provided the basis

for the present investigation as the PKMAS walkway is being determined as a valid and comparable instrument with which to compare the eSens data to. By simultaneously collecting data on the two devices, similar statistical results were expected.

While the software for the PKMAS was validated by the previous study, previous studies conducted on the GAITRite walkway system provide validation and practicality for the use of a gait mat in the present investigation. In a study by Bilney, Morris, & Webster (2003), the validity of the GAITRite walkway's ability to measure the spatial and temporal components of gait was examined. 25 healthy subjects were tested using the GAITRite walkway system. The walkway system was comprised on a carpet which contained embedded pressure sensitive circuits. When these sensors were compressed the mat collected data about the time, direction, and amount of pressure being applied. These measurements were compared against the Clinical Stride Analyzer (CSA), which had previously been used to measure spatiotemporal components of gait. Each subject was asked to walk along the walkway at 3 different speeds; preferred, slow, and fast. The parameters relating to walking gait such as stride length, cadence, and deviation were measured. Following the study it was determined that the GAITRite system and in turn pressure sensitive walkways were valid methods of collecting spatial and temporal measurements pertaining to gait.

With these two studies acting as collective support for the usage of the PKMAS walkway as a validating instrument, the data collected by the PKMAS walkway will be viewed as the gold standard in the present study.

Tactile Sensors

Tactile sensors are an emerging field in engineering research. With the idea of circuit completion due to motion or contact with skin, this research has created a bridge between engineering and exercise/medical research. The uses for tactile sensors are bountiful and researchers have been studying how far this technology can possibly go.

In a study by Sokhanvar, Packirisamy, & Dargahi (2007), tactile sensors were studied for minimally invasive surgeries. While these sensors looked to provide a person with the sense of pressure and touch, the major emphasis in this study was the size and material makeup of these sensors. In this study, polyvinylidene fluoride or PVDF film was used to comprise the tactile sensors. When properly handled, this material creates a semi-solid polymer that can be flexed and is sensitive enough to differentiate between minimal and maximal pressures applied by the digits of the hand. The researchers propose that this new material will be able to better conduct voltages and yields the benefit of mass production through micromachinery.

This study proposes new materials for pressure based tactile sensors, much like the eSens uses. While the eSens is focused on a polymer implanted with conductive strips, the application of this study supports the tactile response desired in the eSens and its ease of fabrication.

Looking deeper into the material makeup of the eSens, a study by Hammond III, et al. (2014) proposed the usage of micro-channels embedded within a polymer. In this study, the optimization of a soft tactile sensor was explored via numerous avenues. The researchers explained that the sensor being investigated was composed of a bilayer polymer which had fluid filled channels embedded between the layers. These micro

channels were placed into a cross-bridge like pattern that created contact points to provide for taxel formation. Further explained by Hammand III, taxel is an acronym for Tactile Pixel. These types of sensor are formed when a cross hatch within a circuit allows for applied pressure to complete the circuit. By manipulating their design, the researchers were able to develop specific sensor points for the various channels that were sensitive up to 25-250mN of force.

The fabrication of these sensors, and their advancement in design helps to support the design and construction of the eSens. This study promotes the concept of cross-bridging to form taxels, similar to how the eSens utilizes crossed conductive stripes to form its taxels. Based off the study in question, through optimization, this process can yield hypersensitive tactile sensors that will be able to stand up to repeated use.

The general application of tactile sensors has been discussed in brevity pertaining to micro implants and the usage of sensor for micro-force feedback systems. The eSens aims to handle much larger, repetitive, forces that are a resultant of running or walking. A study by Vatani, Engeberg, & Choi (2014) looked to examine motion via a force application on a tactile sensor. The tactile sensors, previously discussed, all dealt with single point force application much as a touch sensor feedback system would function. When a point of contact is made, the tactile sensor measured the force at that point. This study by Vatani et al (2014), looked to analyze a tactile sensor that picked up sliding motions and was able to measure the distance of these motions, as well as, the force output during the motion. Using a similar, skin like, polymer blend as the eSens with embedded conductive strips, the tactile sensors successfully quantified the direction and force of the applied motion in this study.

Applying this knowledge to the eSens, by positioning various sensors around the insole or base of the foot, a foot-strike pattern can be painted during the subject's walking or running activity. The ability to paint this picture is an invaluable resource for anyone interested in gait during locomotion. With the ease and practicality that the eSens would have provided, its use from activities related to daily living all the way to athletics can be justified.

CHAPTER III

METHODS

Research Design

This was an experimental validity study focusing on the comparison between the measurements obtained by the eSens pod and the PKMAS gait mat. The independent variables were the eSens pressure sensor array and the PKMAS pressure gait mat. The dependent variables included Step Length (StL), Stride Length (SdL), Step Time (StT), Stride Time (SdT), Stride Velocity (SdV), Stance Time (SnT), Swing Time (SwT), Single Support (SS), Double Support (DS), Velocity (Velo), and Cadence (Cad).

Subjects

Twenty-six subjects were recruited from the Greater Cleveland Area as well as from 15:13 Fitness & Strength in Grafton, Ohio and were able to provide at least 1-2 hours of time for the study on one occasion (Appendix B). Interested subjects were given a pre-participation screening questionnaire to determine eligibility for the study. Subjects who passed the screening were given an informed consent and were knowledgeable that their participation was voluntary and that they could terminate their participation at any point in the study (Appendix A).

Inclusion/Exclusion Criteria

To participate in this study, subjects were between 18-64 years of age. Subjects completed the AHA/ACSM Pre Participation Screening Questionnaire as well as a screening survey created by the researchers (Appendix C & D). The screening survey included questions pertaining to subject gender, age, physical activity, and injury status. All subjects were physically active for at least 30 minutes, 3 times a week. In addition, subjects were free from any musculo-skeletal injuries that could have affected their gait or running performance (Appendix E).

Subjects who did not meet the age range were excluded. Subjects who completed but did not pass the AHA/ACSM Pre Participation Screening Questionnaire were excluded. Subjects who did not meet the minimum physical activity requirements were excluded. Subjects who had any current or recent (within 1 year) medical conditions or musculo-skeletal injuries that severely affected their gait were excluded.

Equipment Used

Equipment used in this study included the PKMAS Zeno Metrics Pressure Sensitive Gait Mat (Appendix G), which was used to provide a standard measurement of gait and running performance; and the eSens Sensory Array (Appendix H-K). The eSens Sensory Array measured the gait pressure variable levels based on sensor loading voltages and accelerometer data from an embedded accelerometer. Timing between the various phases of locomotion was then calculated from these values with a proprietary algorithm. A data collection sheet was used to keep record of inter testing procedures and times (Appendix F).

Procedures

Prior to the acceptance of any subject, the subjects completed the screening process, were versed on the informed consent (as well as being provided a copy), and provided written informed consent. Subjects who did not meet the any of these inclusion requirements were excluded from the study. Following the completion of these screenings, the subject's height and weight were measured, they were fitted with the eSens sensor, and were briefed on the testing process. The eSens sensor was attached to the shoe laces of their right shoe and a non-invasive sensor was placed underneath the right shoe's insole. Only one sensor in the heel was utilized in the present investigation. It should be noted that the eSens system has the capability to incorporate up to three pressure sensors in the insole. One sensor was selected for this study in the interest of minimizing device complexity for the initial validity check.

The data collection process took approximately 1-2 hours and consisted of a multi-trialed test. The subjects were brought to the Woodling Gym at Cleveland State University or to 15:13 Fitness & Strength's gym floor where the testing environment was set up. The PKMAS walkway was laid flat on the gym surface and electrical tape was placed 5m and 10m from either end of the mat in order to create a testing course (Figure 4).

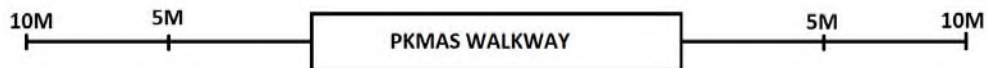


Figure 4: PKMAS Walkway Course

During the trials, the subjects were asked to begin at one of the designated tape markers. The subjects were asked to perform a total of 6 trials. These included a Normal Walk (NW), Slow Walk (SW), Fast Walk (FW), Normal Run (NR), Slow Run (SR), and Fast Run (FR). For the walking trials, the subjects began at one of the 5m tape marks and were asked to walk at the described pace across the walkway towards the distal 5m tape mark. Following a 3 second countdown, the subjects walked across the course. After a brief pause at the completion of the course, the subject turned around and waited for the next 3 second countdown. This process was repeated until a total of 20 steps with the right foot (instrumented side) were recorded on the PKMAS walkway. The same process was utilized for all walking trials with verbal queues for the different speeds being to walk slower or faster than the preferred, normal pace. For the running trials, the same outline and order of testing was followed, however, subjects were asked to start at one 10m tape mark and end at the distal 10m tape mark. This permitted a long enough acceleration zone for participants to reach preferred running speeds before and maintain those speeds across the runway. This set up was utilized to promote steady state walking and running velocities across the total length of the mat. The process was repeated until a total of 20 steps with the right foot were recorded by the gait mat, similar to the walking trials.

After all tests were conducted, the sensor was removed from the subjects' shoe and the subjects were provided the option of receiving a gait analysis from the PKMAS software.

Data Analysis

This study analyzed the validity of the eSens sensor compared to the PKMAS walkway. Data were analyzed using IBM's SPSS version 25. Intraclass correlation coefficients (ICCs) were calculated for the spatiotemporal gait parameters for each of the walking and running speeds. ICCs represent the consistency and magnitude of observations on a measurement made by multiple raters. In this instance the raters are represented by the eSens and the gold standard PKMAS walkway. Traditionally, ICCs greater than 0.700 are considered to show acceptable agreement for validity/reliability analyses. Further, the ICCs considered in this study were absolute ICCs, indicating both consistency in ordering of measures as well as magnitude of values between the two devices.

CHAPTER IV

RESULTS

Out of 26 recruited subjects, 25 participants (9 male, 16 female) completed testing. Ultimately 24 subject data sets were used in analysis (1 subject was excluded due to unreadable eSens data). The mean sample age was 40.7 years. Mean group height and weight were 169.27cm and 69.31kg respectively.

First, an analysis of PKMAS walkway data between the 3 instructed speeds for each testing condition was conducted to rule ensure that the speed instructions produced significantly different gait velocities in each condition. Separate 3x1 repeated measure ANOVAs were used to compare the average speed observed by the PKMAS walkway during the instructed speed conditions of, 'Normal', 'Slow', and 'Fast', for the two movement conditions (walking and running; NW v. SW v. FW and NR v. SR v. FR). The results showed significant statistical difference ($p < .05$) between the instructed speeds for both walking and running within the group. Condition means and 95% confidence intervals are presented in Figures 5 & 6.

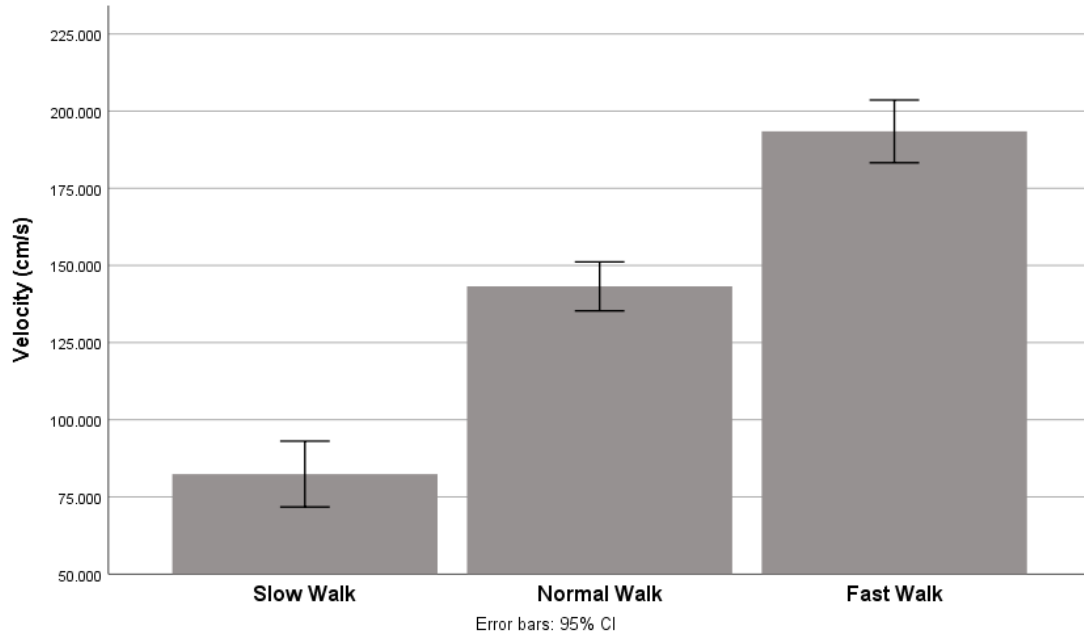


Figure 5: 3 Way ANOVA results for Walking Speed Conditions

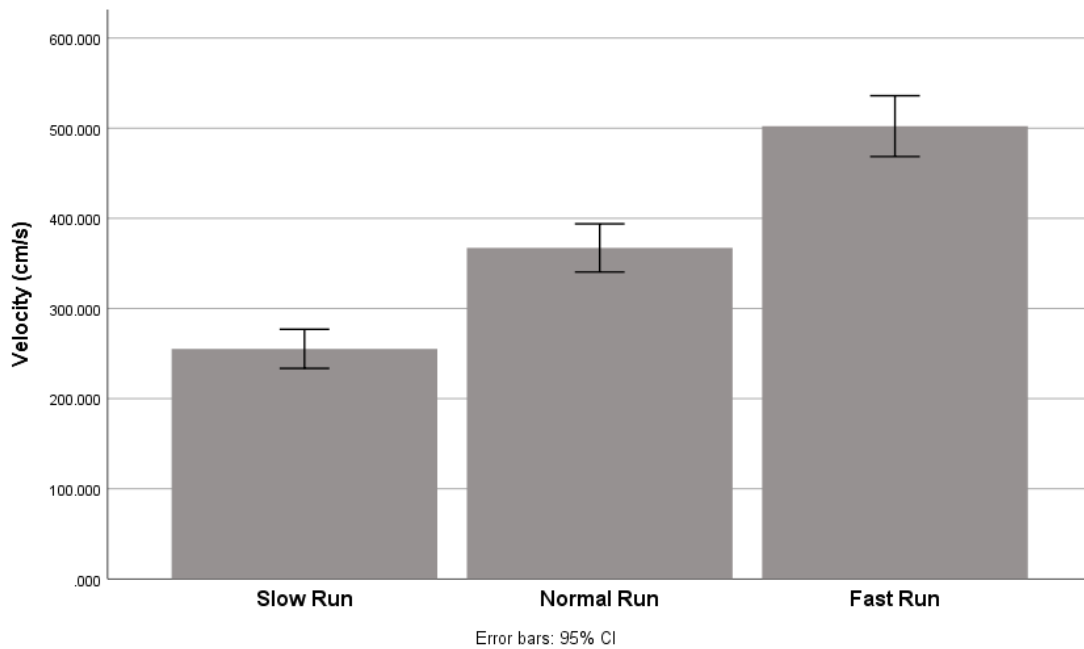


Figure 6: 3 Way ANOVA results for Running Speed Conditions.

Data for the eSens was compared to the PKMAS walkway utilizing absolute Intraclass Correlation Coefficients (ICC). Each condition was tested separately with the paired variables; Stride Length (SdL), Stride Time (SdT), Stride Velocity (SdV), Stance

Time (SnT), and Swing Time (SwT), being compared individually for each condition. All ICC values greater than 0.70 were considered acceptable for the purposes of this study; as they indicated agreement between device measurements.

Results for the Normal Walk (NW) showed no statistical validity in any of the observed variables. Investigating 95% confidence intervals for the ICC values showed that no values were close to the desired ICCs value, with some being closer to 0.00.

	Normal Walk		
Variable	ICC Absolute	95% Low	95% High
SdL	0.112	-1.216	0.632
SdT	0.239	-0.824	0.68
SdV	0.003	-1.501	0.588
SnT	0.183	-0.369	0.581
SwT	-0.234	-1.307	0.412

Table 1: NW ICC Values

Results for the Slow Walk (SW) showed correlation between the devices in Stride Time (SdT), however, no other variables were correlated. With an absolute ICC value of 0.943 ($p > 0.70$) and supporting confidence interval values, the SW SdT ICC indicated acceptable agreement between the eSens and the PKMAS walkway.

	Slow Walk		
Variable	ICC Absolute	95% Low	95% High
SdL	0.337	-0.422	0.703
SdT	0.943	0.868	0.975
SdV	0.183	-0.773	0.637
SnT	-0.22	-1.589	0.451
SwT	0.331	-0.447	0.702

Table 2: SW ICC Values

Results for the Fast Walk (FW) showed no acceptable validity in any of the observed variables. SdT showed an observable ICC value of 0.448. This did not meet the desired ICC level, however, it was among the highest observed value in the present study.

Fast Walk			
Variable	ICC Absolute	95% Low	95% High
SdL	-0.021	-1.136	0.538
SdT	0.448	-0.167	0.751
SdV	0.131	-1.005	0.624
SnT	0.216	-0.282	0.587
SwT	-0.008	-1.017	0.533

Table 3: FW ICC Values

Results for the Normal Run (NR) showed no acceptable validity in any of the observed variables. SdT showed an observable ICC value of 0.612. This did not meet the desired p value, however, it was among the highest observed value in the present study.

Normal Run			
Variable	ICC Absolute	95% Low	95% High
SdL	0.151	-1.138	0.658
SdT	0.612	-0.052	0.852
SdV	0.19	-1.122	0.679
SnT	0.017	-0.012	0.094
SwT	0.013	-0.012	0.077

Table 4: NR ICC Values

Results for the Slow Run (SR) showed no acceptable validity in any of the observed variables. Values did not approach the accepted ICC criteria.

Slow Run			
Variable	ICC Absolute	95% Low	95% High
SdL	0.311	-0.709	0.725
SdT	0.327	-0.284	0.695
SdV	0.264	-0.963	0.715
SnT	-0.02	-0.037	0.075
SwT	0.004	-0.028	0.077

Table 5: SR ICC Values

Results for the Fast Run (FR) showed no statistical correlation in any of the observed variables. Values did not reach the desired p value.

Variable	Fast Run		
	ICC Absolute	95% Low	95% High
SdL	0.232	-0.905	0.699
SdT	-0.083	-0.48	0.363
SdV	0.309	-0.815	0.735
SnT	0	-0.009	0.022
SwT	0.009	-0.073	0.172

Table 6: FR ICC Values

CHAPTER V

DISCUSSION

The purpose of the present investigation was to identify validity of the eSens system's spatiotemporal measurements against the previously validated PKMAS walkway. The results of this investigation indicate no such agreement between measurements, thus the original hypothesis is rejected. The results did show one condition with promising data (SW, SdT), however, this was not enough statistical support to establish total validity for the eSens system. Multiple limiting factors in the present study likely played roles in the resulting outcomes of testing; including method of collecting observational data, location of testing, placement of sensor within the subject's shoe, and method of computing eSens data.

Prior to testing it was expected that the most favorable results would be observed during the SW condition due to the kinematics of the slow walk. During a walking gait cycle, it has already been addressed that the heel naturally comes in contact with the ground to initiate and terminate each gait cycle. During the SW condition, it was anticipated that the slow performance of the walking gait cycle would be most favorable for the eSens sensor as there was enough time to provide for the loading and unloading of the sensor's circuit. In addition, at a slow pace, it was expected that heel contact would

almost always be present for each stride. These points, are thought to have been the factors responsible for the high ICCs of Stride Time (SdT) observed during the slow walk. Presented in figure 7 was one of the most distinguished examples of this concept.

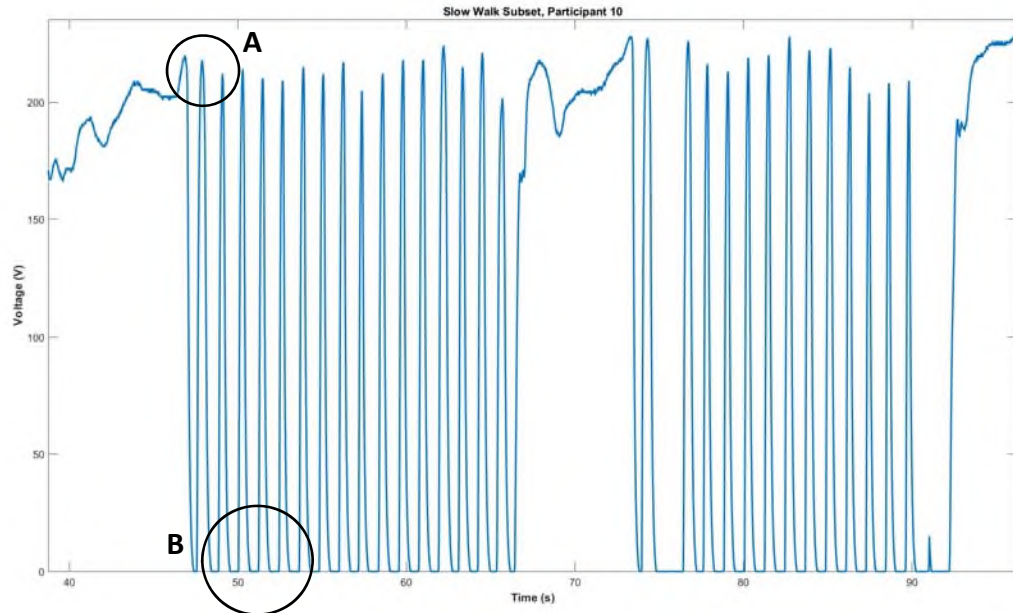


Figure 7: Slow Walk (SW) Raw Data Graphical Report

It can be seen that there was a definite loading and unloading of the sensor throughout the testing trial. After the initial stride was taken the sensor was unloaded, observable by Circle A, in which the voltage dropped to a value of 0. The gait cycle then followed a consistent pattern of loading and unloading, observable by Circle B. This pattern includes definite points of contact with the ground, shown by the point which the voltage begins to increase from 0, and points of toe off, shown by the points when the voltages dropped back to 0. The time between these two points resulted in the measured SdT for the conditions. With consistent and definite points of contact and release during the SW condition, this led to the favorable results for SdT.

While only the SW condition yielded an acceptable ICC, two other conditions presented elevated ICC values that approached but did not meet the acceptability criteria and warranted further inspection. Displayed in the following figures (8, 9, & 10), the SW, FW, and NR conditions were correlated with the PKMAS walkway based on SdT.

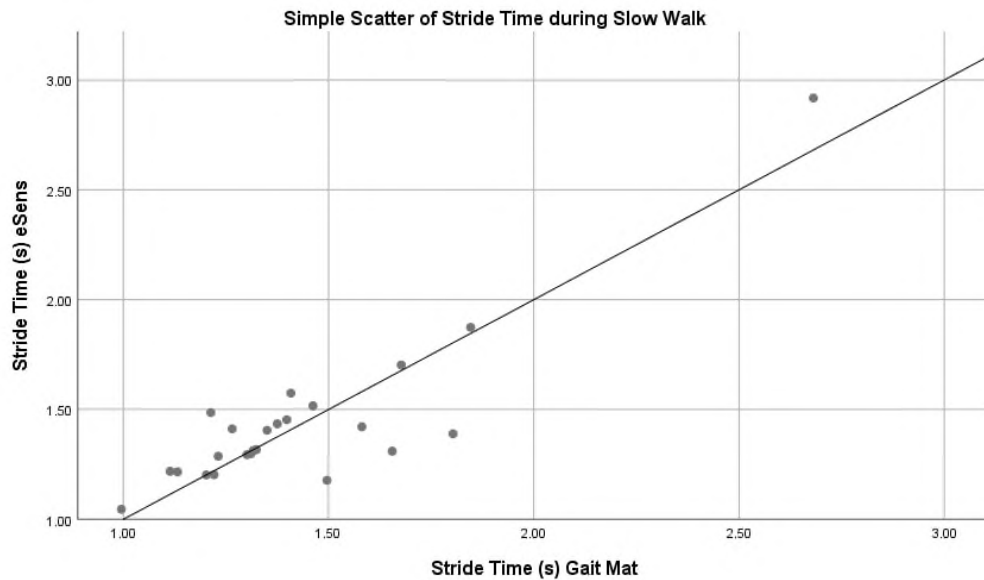


Figure 8: Slow Walk Condition Stride Time Correlation eSens vs. PKMAS Walkway

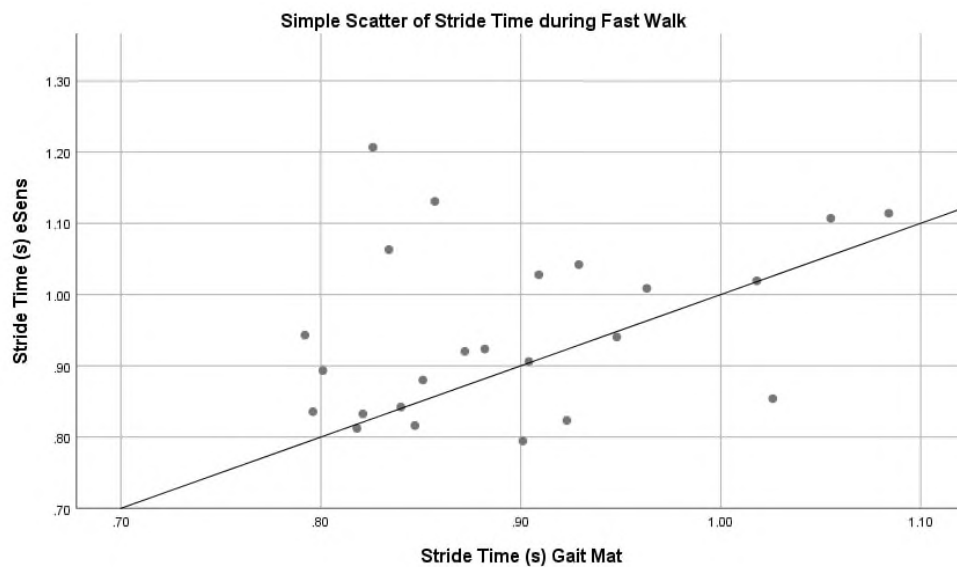


Figure 9: Fast Walk Condition Stride Time Correlation eSens vs. PKMAS Walkway

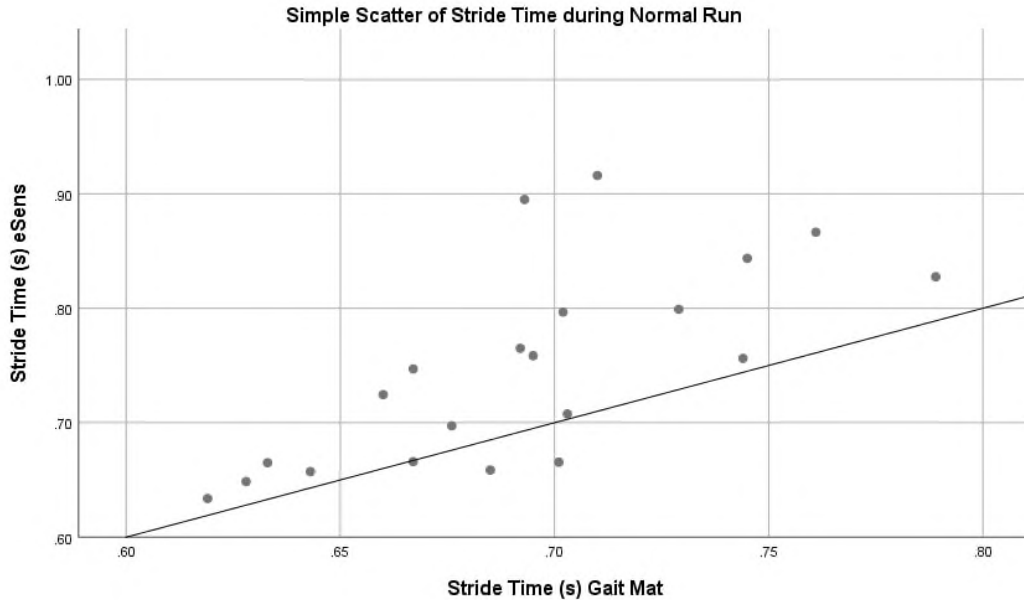


Figure 10: Normal Run Condition Stride Time Correlation eSens vs. PKMAS Walkway

From these scatter plots, a visual example of the similarity between the eSens and PKMAS walkway measurements of stride time can be seen. In the SW condition (Figure 8), which was previously explained to have had an ICC that was statistically acceptable, the plot lines up fairly orderly in a one to one ratio. In the following two figures for the FW and NR condition, however, there is no such similarity. There appears to be a trend that can be assumed for these figures (9 & 10) but not to the level of absolute agreement tested by the ICC.

During the present investigation, the method chosen to identify which recorded stride of the eSens data should be compared to the PKMAS strides was researcher observation. Appendix F shows the sheet that was utilized during each test. Once the PKMAS walkway and the eSens sensor were switched on to collect data, the researcher counted the number of right foot strikes that the subject made from the point of starting to the point of mat contact. Then the researcher proceeded to count the number of right foot strikes that were taken while the subject moved across the mat. If any error was made in

counting this was indicated for post testing review. While minimal mistakes were made with this method, as two researchers were often utilized, this did open some opportunity for human error.

Furthermore, the location of testing for the present study did change throughout the totality of the study. While both locations provided plenty of open space and a safe surface to walk or run on, the surface materials had major differences. While testing in Woodling Gym, the subjects were placed in an environment comprised of a flat, open gym floor which consisted of hardwood flooring and polishing surface wax. While testing at the 15:13 Fitness & Strength fitness facility, the subjects' environment was still an open gym setting, however, the gym floor consisted of 3/4in rubber stall mats. As seen in the study conducted by Dixon et al. (2000), running surface did have an effect on collision forces measured during testing. Thus it is thought that potentially, the eSens could have picked up on pressure forces better in one environment compared to the other. There were no analyses done to provide an answer to this question, however, this is a concern for future research. Any deviations with respect to this consideration, however, would have been ruled out as group data was averaged before analysis. Furthermore, only strides occurring on the PKMAS walkway were included for analysis and that surface was consistent in both environments.

A frequently discussed topic in locomotion, more specifically running, is the concept of toe versus heel striking. Previously discussed within the present investigation, the concept lies within which area of the foot comes into initial contact with the ground during a stride. During the present investigation, one sensor was chosen; to be placed underneath the heel portion of the subject's shoe insole. The thought with this decision

was supported by the fact that during walking, the heel naturally comes in contact with the ground. An important setback to the decision was the concept of toe striking. It was noted that at least 3 subjects were consistent toe strikers during running, in which their heels almost never came in contact with the ground except for during the turnaround at the end of the course. As the sensor was positioned in the heel of the shoe this theoretically would not allow for the circuit in the eSens system to be loaded, thus ultimately resulting in minimal or no data being recorded. This was observed in Figure 11, in which the raw eSens data showed sporadic voltage spikes, indicating that the sensor was unable to pick up all of the strides performed during the running condition for the subject. As the eSens data was filtered based off of stride number per pass, this example showed one of the obstacles encountered by researchers during computation.

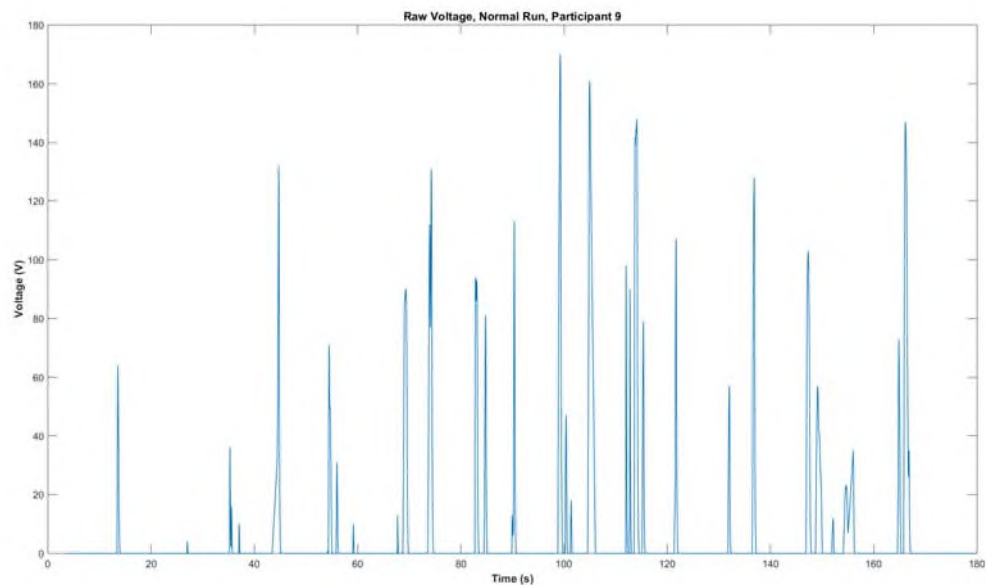


Figure 11: Raw eSens Voltage Data for Normal Running Condition

In future investigations, the use of a toe box sensor or a toe, in conjunction with heel, sensor setup would conceptually eliminate this setback.

One of the final noted limiting factors in the present investigation was the method of computing the raw data obtained from the eSens. Presented initially in a time series format with pressure and accelerometer data, the present algorithms were used to create an automated MatLab script which allowed for mass data computation. Within the algorithms, certain quantities and methods of quantification remained questionable with some values being dependent upon numerically integrated quantities. In addition, large portions of the current eSens computing process requires visual inspection of data files and identification which could have further led to the presence of human error. With these factors all being applied initially to the raw data, any error along the chain of computation would have been carried up the chain to the final outcome measures. An example of these factors applied to the present research can be seen in Figures 12 & 13 in which the raw eSens data shows initial unloading of the sensor followed by much smaller peaks (suggesting this subject was a toe striker and minimal heel contact occurred during running). The following figure presented the processed data, in which the present algorithms were unable to pick out the correct passes during the subject's trial.

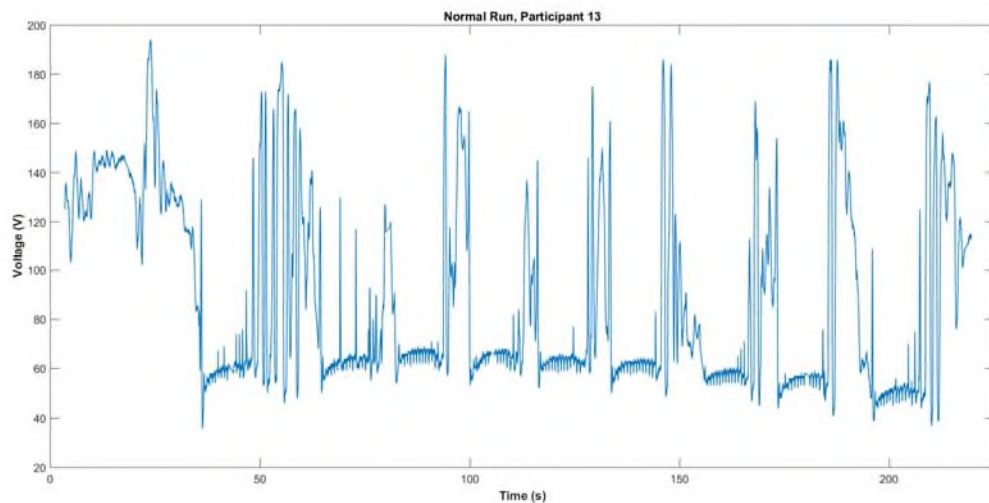


Figure 12: Raw eSens data for Normal Run Condition Showing Unreadable Passes

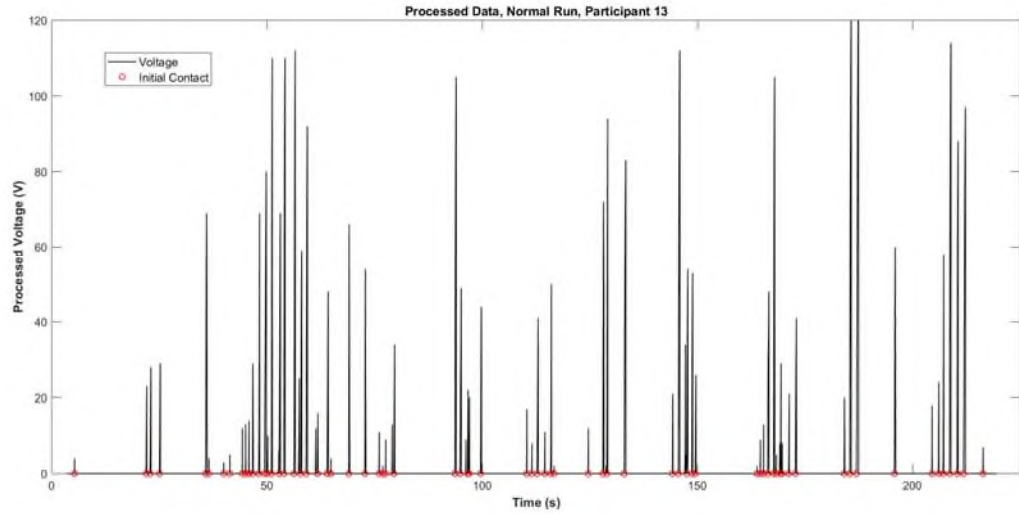


Figure 13: Processed data for Normal Run Condition Showing Uneven Pass Distribution

Future effort should be put into devising a secure, objective method for computing raw data from the eSens which accounts for mass data such as that seen in the present study. With this in effect, any human error due to visual inspection would be ruled out and future investigations can be completed on a larger scale.

CHAPTER VI

CONCLUSION

In summary, while the present investigation did not yield statistically acceptable validity results, a large amount of usable knowledge was gained which could be applied to future research. With respect to the present study, it was found that more limiting factors played a role in the results than were anticipated. The eSens sensors were able to successfully pick up on the presence of heel pressure throughout different speeds of gait cycles for walking and running. Due to the aforementioned limiting factors, however, these outcome measures could not be validated for accuracy. This showed promise for the eSens device, while also providing the researchers with greater information on ways of improving testing and data computation methods.

Recommendations for future research were centralized around the methods of data collection/testing and data computation. It was suggested that a more consistent form of intra-testing visual inspection is utilized such as a high definition camera. While a webcam, hooked up to the PKMAS walkway, was utilized in the present investigation; human error, pertaining to counting or gait analysis, could have played a role in the usability of this information. Furthermore, the usage of a dual sensor setup, with one in

the toe box and one in the heel cup of the subject's shoe was suggested to rule out the discrepancy between toe/heel strikers. Lastly, as mentioned previously, the development of a computer automated data computation program would have led to more reliable and valid results by removing the impact of human error or statistical assumption as was present in the current investigation.

REFERENCES

- Almeida, M., Saragiotto, B., Yamato, T., & Lopes, A. (2015). Is the rear foot pattern the most frequently foot strike pattern among recreational shod distance runners. *Physical Therapy in Sport, 16*, 29-33.
- Bilney, B., Morris, M., & Webster, K. (2003). Concurrent related validity of the GAITRite walkway system for quantification of the spatial and temporal parameters of gait. *Gait and Posture, 17*, 68-74.
- Bobbert, M., Yeadon, M., & Nigg, B. (1992). Mechanical analysis of the landing phase in heel-toe running. *Biomechanics, 25*(3), 223-234.
- Carrel, A. (2007). The effects of cueing on walking stability in people with Parkinson's disease. *Iowa State University*.
- Clement, D., & Taunton, J. (1980). A guide to the prevention of running injuries. *Physician, 26*, 543-548.
- Dixon, S., Collop, A., & Batt, M. (2000). Surface effects on ground reaction forces and lower extremity kinematics in running. *Med. Sci. Sports Exerc., 32*(11), 1919-1926.
- Dondzila, C., Swartz, A., Miller, N., Lenz, E., & Strath, S. (2012). Accuracy of uploadable pedometers in laboratory overground, and free-living conditions in young and older adults. *International Journal of Behavioral Nutrition and Physical Activity, 9*:143
- Exell, T., Gittoes, M., Irwin, S., & Kerwin, D. (2012). Considerations of force plate transitions on centre of pressure calculation for maximal velocity sprint running. *Sports Biomechanics, 11*(4), 532-541.

- Hammond III, F., Kramer, R., Wan, Q., Howe, R., & Wood, R. (2014). Soft tactile sensor arrays for force feedback in micromanipulation. *IEEE Sensors Journal*, *14*, 1443-1452.
- Hreljac, A. (2004). Impact and overuse injuries in runners. *Med. Sci. Sports Exerc.*, *36*(5), 845-849.
- Jacobs, S., & Berson, B. (1986). Injuries to runners: A study of entrants to a 10,000 meter race. *The American Journal of Sports Medicine*, *14*(2), 151-155.
- Lieberman, D., Venkadesan, M., Werbal, W., Daoud, A., D'Andrea, S., Davis, I., Mang'Eni, R., Pitsiladis, Y. (2010). Foot strike patterns and collision forces in habitually barefoot versus shod runners. *Nature*, *463*, 531-536.
- Lynall, R., Zukowski, L., Plummer, P., & Mihalik, J. (2017). Reliability and validity of the protokinetics movement analysis software in measuring center of pressure during walking. *Gait & Posture*, *52*, 308-311.
- Mooses, M., Tippi, B., Mooses, K., Durussel, J., & Maestu, J. (2015). Better economy in field running than on the treadmill: evidence from high-level distance runners. *Biology in Sport*, *32*(2), 155-159.
- Novacheck, T. (1998). The biomechanics of running. *Gait and Posture*, *7*, 77-95.
- Paquette, M., Peel, S., Schilling, B., Melcher, D., & Bloomer, R. (2017). Soreness-related changes in three-dimensional running biomechanics following eccentric knee extensor exercise. *European Journal of Sport Science*, *17*(5), 546-554.
- Gait Analysis Software and Assessment Systems: ProtoKinetics
<https://www.protokinetics.com/>

- Rainone, R., Gardner, B., & Frost, J. (2008) Gait efficiency analysis using three axis force plate. *Worcester Polytechnic Institute*, Project: BJS-RW08.
- Silcott, N., Bassett, D., Thomson, D., Fitzhugh, E., & Steeves, J. (2011). Evaluation of the Omron HJ-720ITC pedometer under free-living conditions. *Medicine & Science in Sports Exercise*, 43(9), 1791-1797.
- Sladek, E. & Fearing, R. (1989). The dynamic response of a tactile sensor. *UCB/ERL* M89-139
- Sokhanvar, S., Packirisamy, M., & Dargahi, J. (2007). A multifunctional PVDF-based tactile sensor for minimally invasive surgery. *Smart Mater. Struct.*, 16, 989-998.
- Stoggl, T., & Wunsch, T. (2016). Biomechanics of marathon running. *Marathon Running: Physiology, Psychology, Nutrition and Training Aspects*, 171(7), 13-45.
- Sushames, A., Edwards, A., Thompson, F., McDermott, R., & Gebel, K. (2016). Validity and reliability of FitBit Flex for step count, moderate to vigorous physical activity and activity energy expenditure. *PLoS ONE*, 11(9): e0161224.
- Umberger, B. (2010). Stance and swing phase costs in human walking. *Journal of Social Interface*, 7, 1329-1340.
- Vatani, M., Engeberg, E., & Choi, J. (2014). Detection of the position, direction and speed of sliding contact with a multi-layer compliant tactile sensor fabricated using direct-print technology. *Smart Mater. Struct.* 23, 1-11.
- Winiarski, S., Pietraszewska, J., & Pietraszewski, B. (2019). Three-dimensional human gait pattern: Reference data for young, active women walking with low, preferred, and high speeds. *International Journal of Biomedical Research*, 1-7.

APPENDIX A: INFORMED CONSENT



Informed Consent

Validation of eSens System During Walking and Running

Introduction

This study is being completed by students and faculty from Cleveland State University. The study will take place in the Human Performance Laboratory (HPL). The project is being conducted by Dr. Douglas Wajda, Dr. Kenneth Sparks, and graduate student Nicholas Chambers.

Before you decide if you would like to participate in this study, there are a few things you need to understand about the study. Please read this document carefully. Ask any questions you may have.

The purpose of this study is to validate the accuracy of the eSens system for measuring walking and running. The eSens system consists of a data logger placed on the shoe laces and a non-invasive insole placed underneath the insole of your shoe. The system senses the pressure of your steps to gather data about your walking and running.

The eSens measurements will be compared to a pressure sensitive walking mat. Confirming the validity of the system will provide researchers with a cost effective tool that can be used outside of a standard research lab.

Procedures

You will be asked to come to the HPL for one testing session. The session will last between 1-2 hours. We ask that you do not exercise for 24 hours prior to the testing date.

During the study an eSens system will be placed in your right shoe. Testing will take place on a 30 meter course. The course will be laid out on a gym floor with a gait mat placed in the center. You will be asked to walk or run at a specific pace for each trial.

You will perform 8 trials to establish normal walking and running speeds. Following that, you will complete 20 walks at speeds faster and slower than your normal pace. You will also complete 20 runs at speeds faster and slower than your normal jogging pace. You will be given time to rest between each trial.

Risks and Obstacles to Completion

Risks associated with this study are not expected to exceed those of everyday life. The testing course will be closed off from the public to accommodate privacy and safety. The researchers will make sure that the environment is free from hazards.

The primary risk of the study is a slight risk of tripping and falling. Because of a fall, the potential risks include bone fractures, torn ligaments, muscle strains, joint sprains, bruises or joint dislocations. The tests will not require an all-out effort and we expect this risk to be minimal.

Every effort will be made to minimize potential risks. Dr. Wajda has extensive experience with gait measurement and will directly supervise the research staff. The HPL practices standard emergency procedures. An Automatic External Defibrillator is available. All laboratory personnel are certified in CPR and First Aid.

Benefits

The benefit of the study is the development of a tool that can help our understanding of gait efficiency. You will also receive a gait analysis during walking and running. It may help you in knowing how to improve your performance.

Confidentiality

To protect your privacy, your name will not be used in any document of the project. A participant number will be assigned to you. Data collected may be used for a scientific purpose with your privacy maintained. Research staff will be the only witnesses of the information being presented. Data will be stored in the HPL in a locked filing cabinet.

Participation and Freedom of Consent

I understand that participation in this project is voluntary. I understand I have the right to withdraw at any time without consequences. I understand that if I have any questions about my rights as a participant, I can contact Cleveland State University’s Institutional Review Board at (216) 687-3630.

The purpose and risks of the study have been explained to me. If I have any questions about the procedures I can contact the research team. I have read the consent form, or it has been read to me, and I understand it. I acknowledge that I am at least 18 years old and agree to participate in this study. I have been given a copy of this consent form.

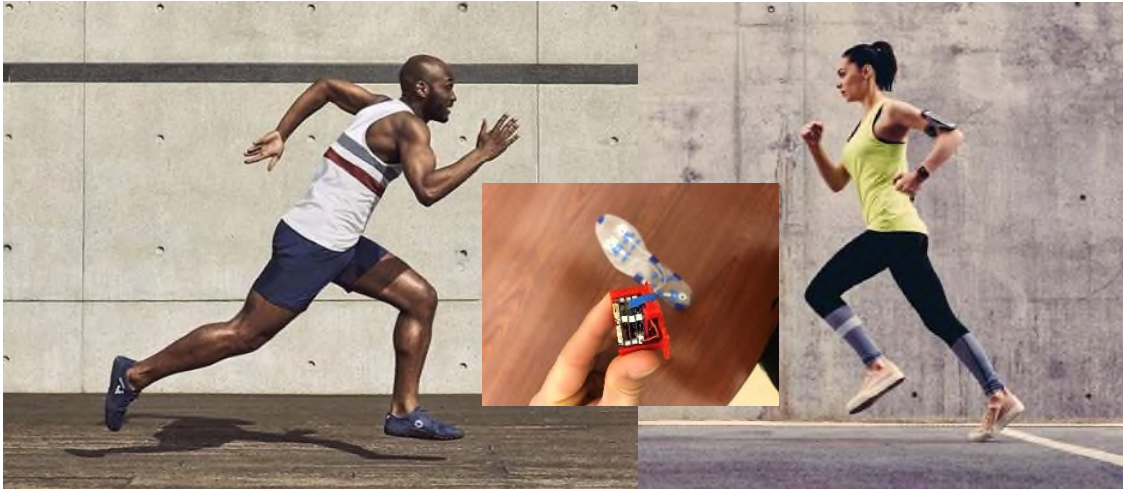
Participant Name (Please Print): _____

Signature: _____ Date: _____

Witness Name (Please Print): _____

Witness: _____ Date: _____

ATTENTION RUNNERS



The Cleveland State University Health and Human Performance Lab is Conducting a Research Study!

Our aim is to validate a potential commercial product known as eSens. This instrument will be used to analyze the form and forces acting on the body during walking or running.

Testing will be done in one, 1-2 hour session.

Participants should be between 18-64 years old and should have some experience running.

If interested in learning more or volunteering for this study please contact:

- **Nicholas Chambers: 330-416-3819 / n.m.chambers@vikes.csuohio.edu**
- **Dr. Kenneth Sparks: 216-687-3630 / k.sparks@csuohio.edu**
- **Dr. Douglas Wajda: 216-687-4873/ d.a.wajda@csuohio.edu**
- **Dr. Emily Kullman: 216-687-4854/ e.kullman@csuohio.edu**
- **Or feel free to stop by the lab at PE 60 in the basement of the PE building.**

APPENDIX C: AHA/ACSM PRE-PARTICIPATION QUESTIONNAIRE

Name _____

Date _____

AHA/ACSM Pre-participation Screening Questionnaire

Assess Your Health Needs by Marking all *true* statements

History

You have had:

- A heart attack
- Heart Surgery
- Cardiac Catheterization
- Coronary angioplasty (PTCA)
- Pacemaker/implantable cardiac
- Defibrillator/rhythm disturbance
- Heart valve disease
- Heart failure
- Heart transplantation
- Congenital heart disease

Recommendations:

If you marked any of the statements in this section, consult your healthcare provider before engaging in exercise. You may need to use a facility with a medically qualified staff.

Other health issues:

- You have musculoskeletal problems. (*Specify on back*)*
- You have concerns about the safety of exercise. (*Specify on back*)*
- You take prescription medication (s). (*Specify on back*)*
- You are pregnant

Symptoms

- You experience chest discomfort with exertion.
- You experience unreasonable breathlessness.
- You experience dizziness, fainting, blackouts
- You take heart medications. _____

Cardiovascular risk factors

- You are a man older than 45 years.
 - You are a woman older than 55 years or you have had a hysterectomy or you are postmenopausal.
 - You smoke.
 - Your blood pressure is greater than 140/90 mm Hg.
 - You don't know your blood pressure.
 - You take blood pressure medication.
 - You don't know your cholesterol level.
 - You have a blood cholesterol >240 mg/dl.
 - You have a blood relative who had a heart attack before age 55 (*father/brother*) or 65 (*mother/sister*).
 - You are diabetic or take medicine to control your blood sugar.
 - You are physically inactive (*i.e., you get less than 30 minutes of physical activity on at least 3 days/week*).
 - You are more than 20 pounds overweight.
 - None of the above is true.
- If you marked two or more of the statements in this section, you should consult your healthcare provider before engaging in exercise. You might benefit by using a facility with a professionally qualified staff to guide your exercise program.**
- You should be able to exercise safely without consultation of your healthcare provider in almost any facility that meets your needs.**

-
- Proceed with test if musculoskeletal problems are minor, concerns about safety of exercise are normal, and prescription medications are not for cardiac, pulmonary, or metabolic disease.

Risk Status (Low, Moderate, High): _____

APPENDIX D: DEMOGRAPHICS DATA SHEET

Name: _____

Date: _____

Demographics

Gender: Male ___ Female ___ Other ___

Age: _____

Anthropometrics

Height: _____ in

Weight: _____ lb

BMI: _____

APPENDIX E: PHYSICAL ACTIVITY/INJURY SCREENING

Name: _____

Date: _____

Please circle ONE of the below options that most accurately represents your current activity levels.

Definition of exercise involves cardiovascular exercise that elevates heart rate above resting.

Exercise Description

Circle One

Exercise less than 1-2 times / week for 20-30 minutes.

Sedentary

Exercise 1-3 times / week for 20-30 minutes.

Lightly Active

Exercise 3-5 times / week for 20-30 minutes.

Active

Exercise 5+ times / week for 20-30+ minutes.

Highly Active

Please mark an 'X' next to all that apply.

NORMAL DEFINITIONS

Past joint, muscle, or bone injury within the past 10 years: _____

Past joint, muscle, or bone injury within the past 5 years: _____

Past joint, muscle, or bone injury within the past year: _____

Current joint, muscle, or bone injury: _____

Current joint, muscle, or bone overuse injury: _____

OTHER

None of the above apply: _____

Joint, muscle, or bone complication does not fall into above definitions: _____

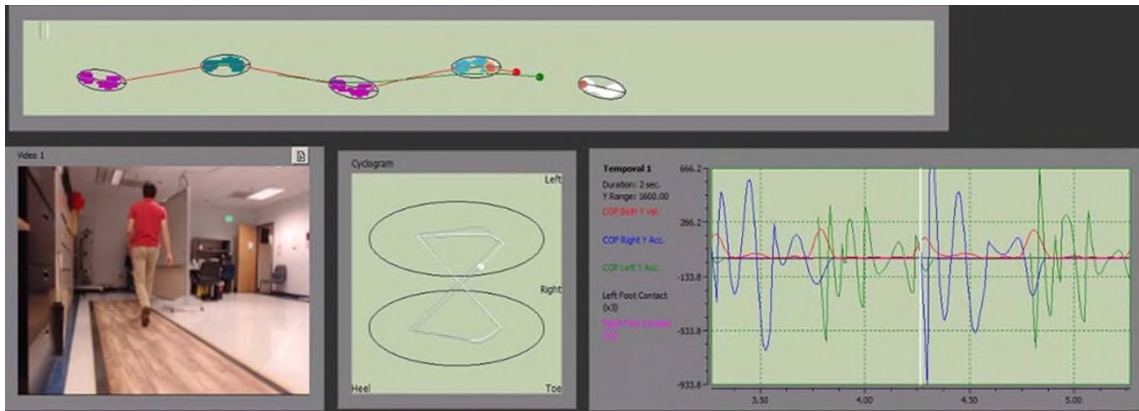
APPENDIX F: DATA COLLECTION SHEET

DATA COLLECTION SHEET

Subject ID _____ Right Leg Length _____ cm Left Leg Length _____ cm Date _____

PASS	NW		SW		FW		NR		SR		FR	
	S#	MH#	S#	MH#	S#	MH#	S#	MH#	S#	MH#	S#	MH#
1												
2												
3												
4												
5												
6												
7												
8												
9												
10												
11												
12												
13												
14												
15												

APPENDIX G: PKMAS ZENO-METRICS PRESSURE WALKWAY



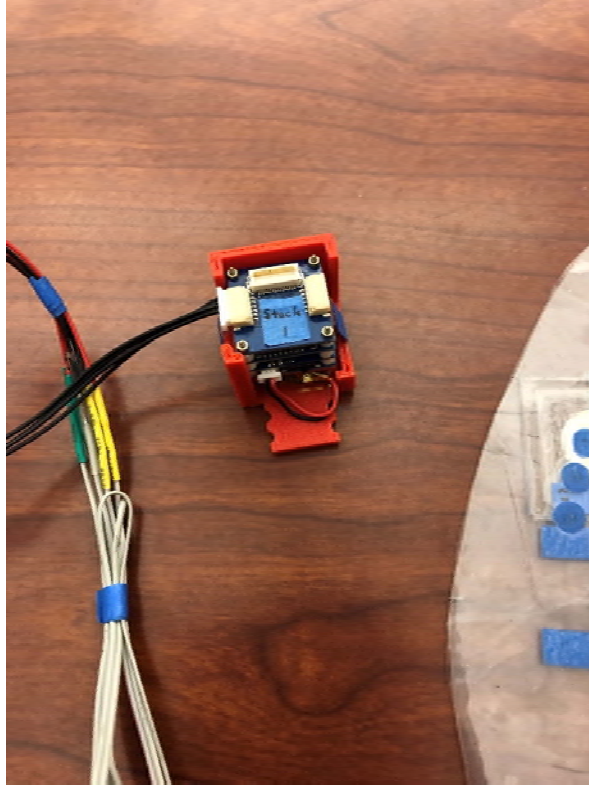
APPENDIX H: ESEN INSOLE (OUT OF SHOE)



APPENDIX I: ESENS INSOLE (IN SHOE)



APPENDIX J: ESENS SENOR HOUSING



APPENDIX K: ESENS SENSOR HOUSING (ATTACHED TO SHOE)



APPENDIX L: IRB APPROVAL FORM

From: system@cayuse424.com <system@cayuse424.com>
Sent: Tuesday, March 5, 2019 1:16 PM
To: Douglas A Wajda <d.a.wajda@csuohio.edu>; Emily S Kullman <e.kullman@csuohio.edu>; Kenneth E Sparks <k.sparks@csuohio.edu>
Cc: Cayuse IRB <cayuseirb@csuohio.edu>
Subject: IRB-FY2019-154 - Initial: IRB Approval



March 5, 2019

Dear Douglas Wajda,

IRB-FY2019-154 - Initial: IRB Approval



RE: IRB-FY2019-154
Validation of Esens Pressure Array During Walking and Running

The IRB has reviewed and approved your application for the above named project under the category noted below. Application renewal is not necessary unless indicated below.

Approval Category: Expedited Category 4
Approval Date: March 5, 2019
Expiration Date: --

By accepting this decision, you agree to notify the IRB of: (1) any additions to or changes in procedures for your study that modify the subjects' risk in any way; and (2) any events that affect that safety or well-being of subjects. Notify the IRB of any revisions to the protocol, including the addition of researchers, prior to implementation.

Thank you for your efforts to maintain compliance with the federal regulations for the protection of human subjects. Please let me know if you have any questions.

DO NOT REPLY TO THIS EMAIL. IF YOU WISH TO CONTACT US, PLEASE SEND AN EMAIL MESSAGE TO cayuseirb@csuohio.edu.

Sincerely,

Mary Jane Karpinski
IRB Analyst
Cleveland State University
Sponsored Programs and Research Services
(216) 687-3624