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Development of a Smart Insole System for Real-Time Detection of Temporal Gait Parameters and Related Deviations in Unilateral Lower-Limb Amputees

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UNIVERSITY OF MIAMI

DEVELOPMENT OF A SMART INSOLE SYSTEM FOR REAL-TIME
DETECTION OF TEMPORAL GAIT PARAMETERS AND RELATED
DEVIATIONS IN UNILATERAL LOWER-LIMB AMPUTEES

By

Monica Stalin

A THESIS

Submitted to the Faculty
of the University of Miami
in partial fulfillment of the requirements for
the degree of Master of Science

Coral Gables, Florida

December 2012

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Development of a Smart Insole System for Real-time
Detection of Temporal Gait Parameters and Related
Deviations in Unilateral Lower-limb Amputees

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Gait is a complex cycle with both between and within limb variability. It should be studied carefully using justifiable and accurate measures. Unilateral lower limb amputees often favor and stress their intact limb during most of the functional activities. This can lead to secondary comorbidities or complications like degenerative arthritis, back pain that may affect the mobility and quality of life. Symmetry is an issue in the gait of amputees because of the unnatural asymmetry imposed on the biomechanical system by the prosthesis. Current gait assessment techniques monitor the symmetry of macroscopic gait parameters like stance and swing period durations. It was anticipated that the measurement of phase duration symmetry would improve the gait assessment techniques. This research project determined the phase duration symmetry of 6 healthy non-amputees and 10 unilateral lower limb transtibial amputees (TTAs). It was found that the TTAs possess greater asymmetry in some of the phase durations although the symmetry of stance and swing period durations was found normal. A wireless smart insole system was designed and developed to address these issues and to improve and expand upon current gait analysis techniques. The appropriate sensor was selected among various currently used insole sensors and the accurate location of sensors on the insole was determined. The insole was designed for both anatomical and prosthetic foot and a

method to develop a standardized prosthetic foot insole was determined. The insole system was implemented with various algorithms that were able to detect the phases and calculates the phase duration symmetry real-time. Hence this research project established that gait assessment using wireless smart insole system that detects the phase duration symmetry could be an effective aid in the detection of certain temporal gait deviation in unilateral lower limb amputees.

DEDICATION

“Genius is 1 percent inspiration and 99 percent perspiration.”

— Thomas A. Edison

I dedicate this thesis to

My beloved parents, **Dr. P. Stalin** and **Mrs. Thilagavathy** for their great faith in me and understanding, unstinted support, constant encouragement and most of all love.

My dear sister, **Ms. Preetha Stalin** for holding hands with me and cheering me up all through my life.

My grandparents, **Mr. C. Jegadeesan** and **Mrs. Valliammal** for their enormous affection and care.

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1

INTRODUCTION

Biomechanics is the study of external and internal forces acting on a biological system and the effect of these forces on the function of neuromuscular skeletal system. It can be broadly classified as kinematics and kinetics with respect to static and dynamic characteristics. Biomechanics has a vital role in orthopedics, physical therapy and rehabilitation by characterizing function and dysfunction of the muscular skeletal system. One specific measure of biomechanics is the analysis of human gait.

Gait analysis is the quantitative measurement and assessment of human walking. It does not require any invasive study procedure and it can be studied using on-body sensors and/or some external gait measurement equipment. Conventional method of measuring the gait parameters can range from the clinician's visual observations to a computerized video analysis system within a motion laboratory, with analysis of the body segments using computer based force and optical tracking sensors. The former procedure is highly dependent on observer's judgment and the latter system requires mathematical expertise and labor intense equipment. The disadvantages of these conventional methods have been slowly eliminated by portable gait analysis systems that can be carried by the subject and allowing outdoor measurement, using the wireless wearable system that

includes a powerful microcontroller, miniature sensors, high capacity memory and small batteries.

Gait analysis technologies were not applied to the understanding of prosthetic gait until the World War II. In 1945 the National Research Council set up the Committee on Prosthetic Devices and a team of about 40 scientists was assembled at the Biomechanics Lab at the University of California at Berkeley. The team was headed by Verne T. Inman (Orthopedic Surgeon) and Howard D. Eberhart (Structural Engineer) [1]. They compared lateral stick figures of amputees to normal subjects as a means to objectively identify gait deviations in the sagittal plane. Their data documented asymmetry in the stance and swing phase times between the prosthetic and sound limb [2]. They found that malalignment of the prosthetic foot was the most crucial for gait symmetry and evaluated some of the prosthetic designs [3].

Gait is a complex cycle with both between and within limb variability. It should be studied carefully using justifiable and accurate measures. When quantifying symmetry between the limbs, the measure of appropriate gait parameters should be determined [4]. Lower limb amputees often favor and stress their intact lower limb more during everyday activities. This can lead to secondary comorbidities or complications that may affect the mobility and quality of life [5, 6]. Gait deviation in amputees should be assessed by analyzing certain “appropriate” temporal parameters using more clinically friendly equipment. The reliability of temporal gait parameters has a trade-off with accurate detection of gait events.

1.1 GAIT TERMINOLOGIES:

Gait is a series of rhythmical pattern of movements that results in the forward progression of center of gravity. A single sequence of these functions by one limb is a *gait cycle* which is also called as *stride*. Therefore a gait cycle could be defined as the period of time from one event (usually initial contact on the floor) of one foot to following occurrence of the same event with the same foot [7]. Therefore one stride includes two steps (fig 1.1) and it is divided into two periods – stance and swing. *Stance* is the entire period during which the foot is on the ground and *swing* period begins when the foot is lifted up in the air for the forward motion (fig 1.2).

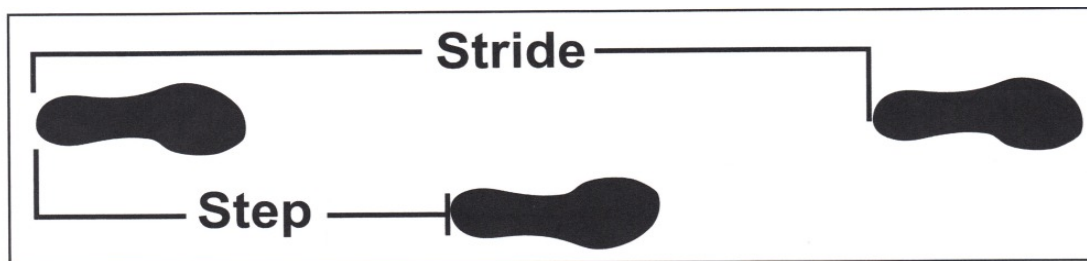


Fig 1.1: A Gait Cycle/Stride [8]

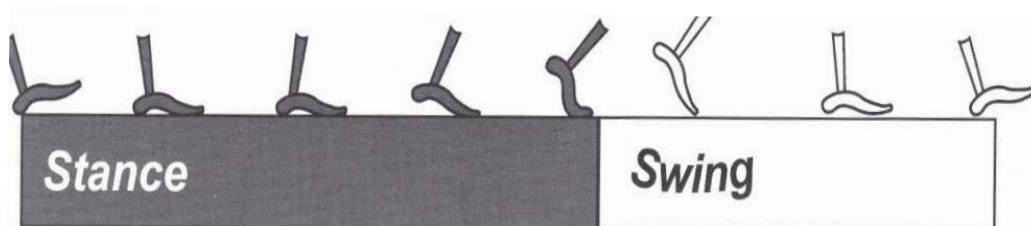


Fig 1.2: Gait Periods – Stance and Swing [8]

Jacquelin Perry subdivided these two periods into 8 phases which enables the limb to accomplish 3 tasks (fig 1.3). As mentioned earlier, stance is the entire period

during which the foot is on the ground and it begins with the initial contact (which is also named as heel strike). The initial contact is the moment when foot just touches the ground and it is followed by loading response which continues until the other foot lifted up for swing. During these phases, the body weight is transferred to this limb soon after the swing phase and this task is named as “weight acceptance”. The midstance begins when the other foot is lifted up for swing and it is followed by the terminal stance. During these phases, the total body weight is supported by only one limb and hence this task is named as “single limb support”. Pre-swing is the end of stance phase and the limb prepares itself for the limb advancement. The swing period is divided into 3 phases – initial swing, mid swing, terminal swing. The initial swing begins when the foot is lifted off from the ground, the midstance begins with the single limb support of the other limb and it is followed by the terminal swing until the foot touches the ground – “swing limb advancement task” (fig 1.4).

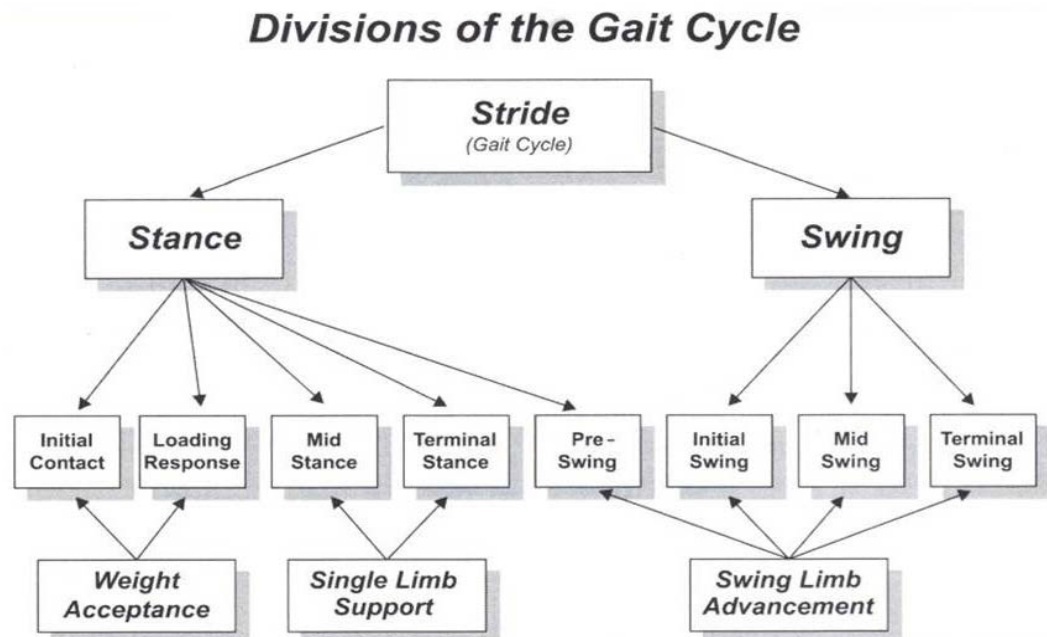


Fig 1.3: Division of the Gait Cycle [8]

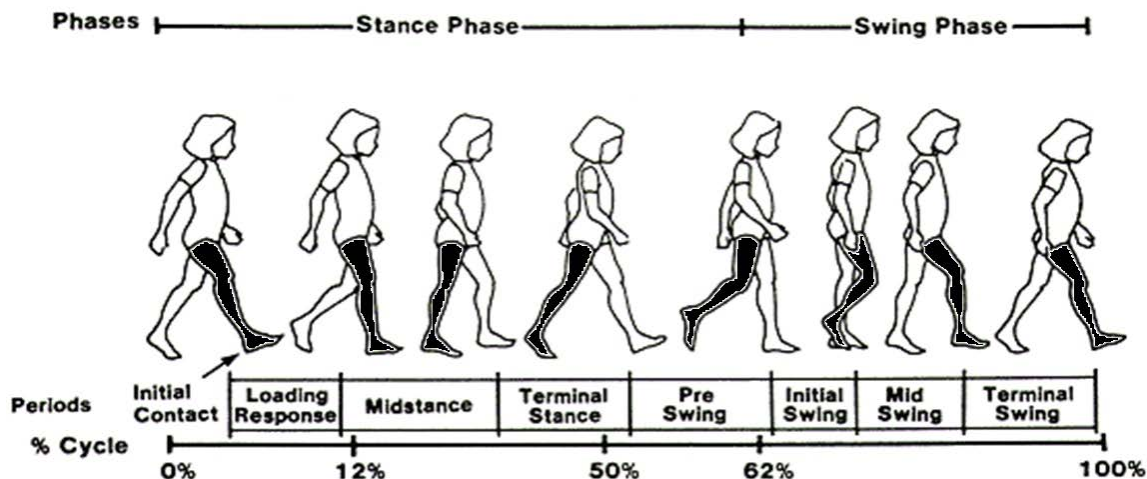


Fig 1.4: 8 Phases of the Gait [8]

Normal gait have been assumed to be symmetric on their either side, although some previous articles have reported that the limb dominance should be associated with symmetry [9, 10]. The symmetry between the limbs could be quantified using the bilateral temporal gait parameters [11]. Previous research on normal temporal gait symmetry has focused on a few macroscopic parameters like stride, stance and swing time ratios between the limbs. The inter-symmetry of gait, in each of the 8 phases (fig 1.4) defined by Perry, has not yet been analyzed.

Abnormal gait results in secondary physical complications which affects their quality of life. For example, people with lower limb amputation often favor and stress their sound limb i.e., intact limb during most of the functional activities and this results in higher incidence of certain secondary comorbidities like degenerative arthritis [5]. So in order to reduce or avoid these complications, symmetry is monitored and several gait parameters are assessed with the normative gait data during various functional activities.

1.2 OBSERVATIONAL GAIT ANALYSIS:

People have been thinking about how they walk since the earliest times. The initial works of these pioneers since the 17th century resulted in the development of clinical gait analysis and necessary equipment and devices [1]. The rapid advancement in modern computers made a drastic revolution in gait analysis. The development of clinical gait analysis was driven by Jacquelin Perry and David Sutherland who had studied under Verne T. Inman. Perry developed methodological approaches to observational gait analysis to complement it as well as instrumented methods for measuring simple temporal-spatial parameters. Sutherland continued to look for ways of obtaining three-dimensional information from cine film [1].

Observational gait analysis (OGA) is the qualitative approach of clinical gait analysis, analyzing an individual's upper and lower extremities, pelvis and trunk motion during ambulation from visual observations. OGA method is used due to the ease, rapidity, simplicity, and low cost of use when compared with instrumented gait analysis systems. This method provides clinicians identify means of identifying gait deviations and determining the possible cause of these deviations. Observational gait analysis is clinically useful with videotape slow-motion replay and freeze-frame, offering significant improvement over unaided visual observation [12].

OGA checklist requires the clinicians to make decisions about the presence of a short list of gait deficits. In the fig 1.5, the shaded regions are phases of the gait cycle during which no deficit listed could be seen. Thus, the checklist focuses your attention on the *unshaded* cells, which specify certain deficits during certain parts of the gait cycle.

This checklist was developed by the Professional Staff Association of Rancho Los Amigos Medical Center (1989).

	STANCE				SWING		
	LR	MSI	TSt	PSw	ISw	MSw	TSw
Trunk							
forward lean					■	■	■
backward lean					■	■	■
lateral lean (R/L)					■	■	■
Pelvis							
no forward rotation (R/L)		■	■				
no contralateral drop (R/L)			■	■	■	■	■
hiking (R/L)	■	■	■				
Hip							
inadequate extension	■				■	■	■
circumduction/abduction	■	■	■				
Knee							
excessive flexion			■				■
uncontrolled extension			■	■	■	■	
inadequate flexion	■	■	■				■
Ankle/Foot							
foot slap		■	■	■	■	■	■
forefoot contact		■	■	■	■	■	■
foot flat contact		■	■	■	■	■	■
late heel off	■	■	■		■	■	■
contralateral vaulting	■	■	■	■			

Fig 1.5: Observational Gait Analysis Checklist

The problem with observational gait assessment (OGA), however, is that it is relatively subjective in nature and it has been suggested that this subjectivity may lead to poor validity, reliability, sensitivity, and specificity when compared to the more objective instrumented gait analysis [13, 14, 15]. It should be noted that walking is a complex integrated activity with multiple factors interacting to the individual body segments synchronously. Hence, the clinicians are required to have excellent OGA skills for assessment of critical aspects of walking. With instrumented gait analysis, a number of research studies have presented objective, quantified analyses of amputee gait. Clinicians, however, tend to rely on observational gait analysis to provide information about prosthetic fit, alignment, and deviations from expected gait values for the individual amputee [16].

1.3 CURRENT GAIT ANALYSIS TECHNOLOGIES:

The current gait analysis systems include motion capture system, force plates, EMG, inertial measurement unit, insole plantar pressure measurement system [17].

1. Gait measurements using *motion capture system* can be done in two ways - video camera (with or without markers) or optoelectronic system (active or passive markers) [17]. Although this system is considered as a “gold standard system”, it requires cumbersome equipment and tight clothes for marker placement which may cause patients to alter their gait. Despite the functionalities of the system, such wearing devices may disturb the gait motions due to their insufficient degrees of freedom, which also reduce the accuracy of measurement. In this aspect, although camera-based method (fig 1.6) produces well-quantified and accurate results on the

joint motions of the lower extremity, the use of the camera-based method is restricted to a laboratory environment, and hard to be used in daily living.

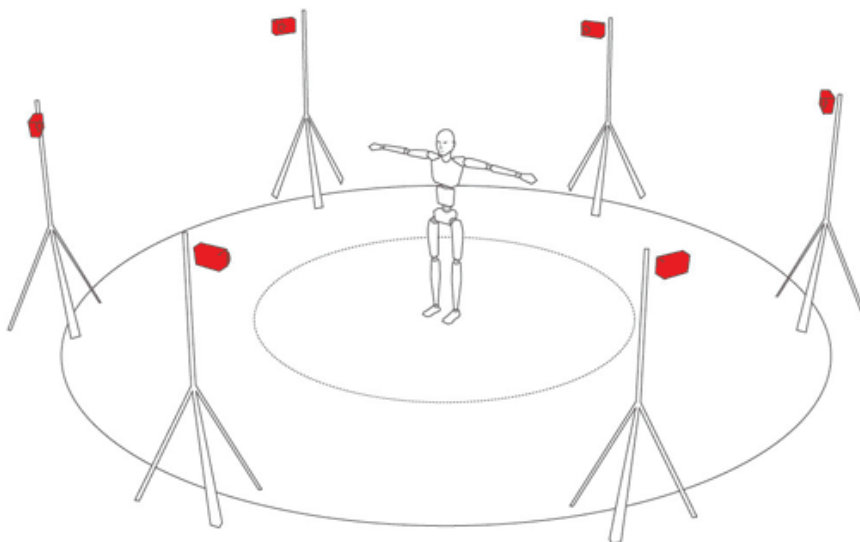


Fig 1.6: Opti Tract Arena Motion Capture System

- The first commercially available *force plate* was Kistler in 1969 [1]. Force plates typically consist of piezoelectric load cells mounted between two metal plates. It measures the three dimensional ground reaction forces generated by a body standing on or moving across them (fig 1.7). Thus the force plates provide the biomechanical measures for a “single foot-strike”. The force plates are often used along with the motion capture system.

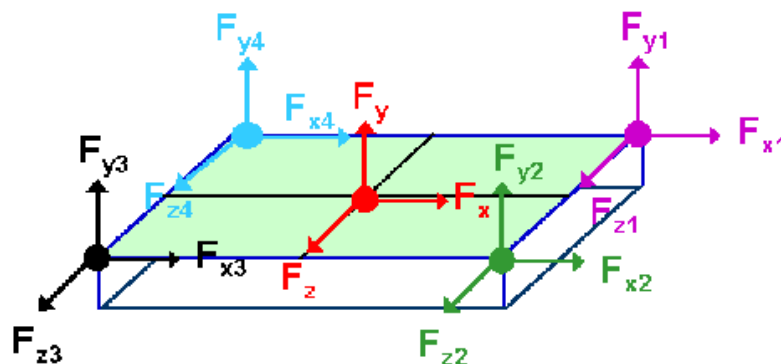


Fig 1.7: Force plates [18]

3. *Electromyography* (EMG) in gait analysis is an invasive/non-invasive procedure used to detect and measure the electrical activity of the muscles during contraction. Sensors can be placed on the skin or fine wires inserted into the muscle of interest. Placing the sensors on the skin can give erroneous readings for a specific muscle as other muscles lying around or on top can cause cross-talk in the signal [17].
4. The *insole plantar pressure measurement* system is developed to record the gait for several steps. Some of the commercially available insole systems are F-Scan and Pedar insole system. This system uses the insole embedded with hundreds of pressure sensitive sensors which records the pressure applied by the foot (fig 1.8). The spatio-temporal parameters can then be derived from the recorded gait data.

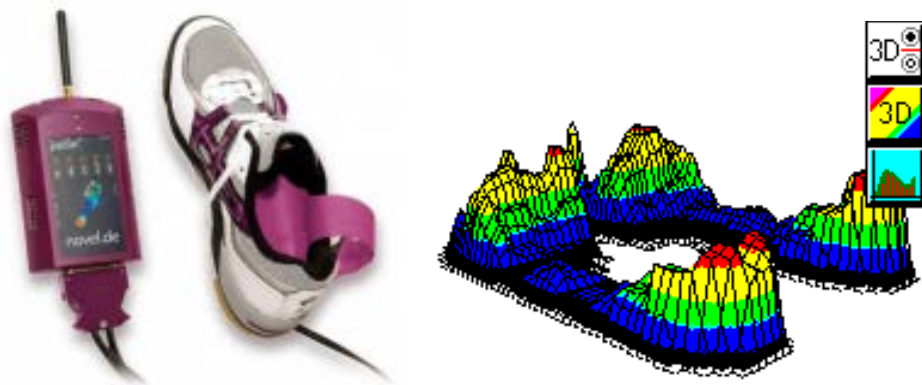


Fig 1.8: Insole Plantar Pressure Measurement System [19]

5. An *inertial measurement unit* (IMU) works on the principle of moment of inertia and consists of 3D – accelerometers, gyroscopes and magnetometers. The sensors are small, light weighted and can be attached to the any segment of the human body (fig 1.9). This system is not restricted to the laboratory and can record up to

several hours. The critical challenge with this system is to remove the motion artifacts and the data reconstruction.



Fig 1.9: Inertial Measurement Units [20]

1.4 VERTICAL GROUND REACTION FORCE (VGRF):

The average person takes 3 to 3.5 million steps per year [22]. The foot is the only anatomical structure that comes in contact with the ground during the gait cycle and also during most of the other activities. Hence, it has to withstand any impact generated as a result of the body weight and in turn the ground reaction force produced [21]. This reaction force is distributed under the plantar surface of the foot and its effect is to accelerate individual body segments and transmit force to adjacent segments [22]. These Ground Reaction Forces (GRFs) could be quantified using the force plates.

A force plate is a transducer (piezoelectric/strain gauge/load cells) that is set in the floor to measure the force applied by the foot to the ground. These devices provide measures of the three components of the resultant ground reaction force vector. Carlet in 1872 (fig 1.11) first recorded the characteristic shape of vertical component of ground

reaction force (VGRF). VGRF has an “M” shaped curve during the stance phase i.e., during foot-strike on the force plate. Perry depicted the gait phases from the “M” curve as shown in the fig 1.2.

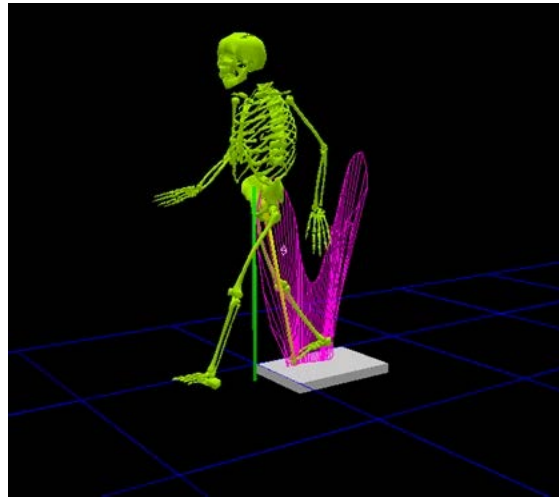


Fig 1.10: Force plate and VGRF [18]

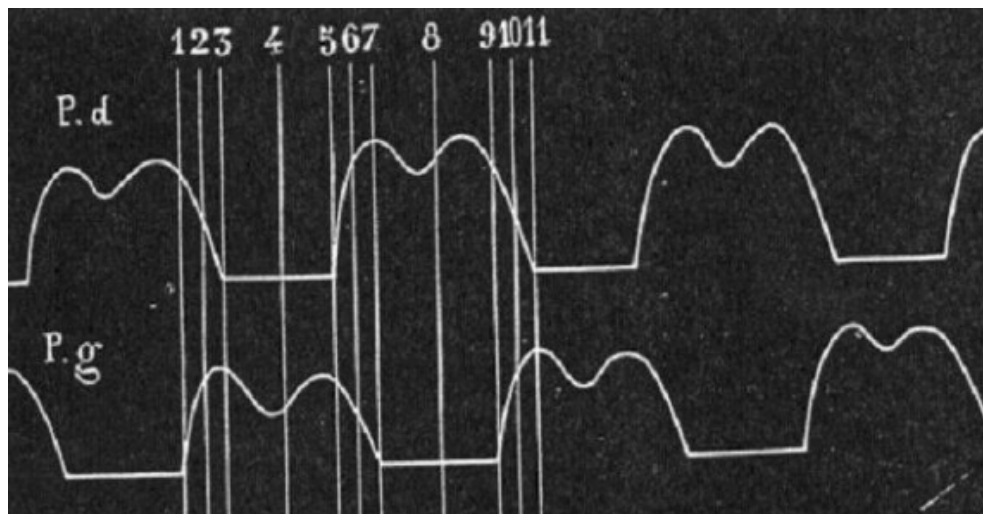


Fig 1.11: VGRF First Recorded by Carlet [1]

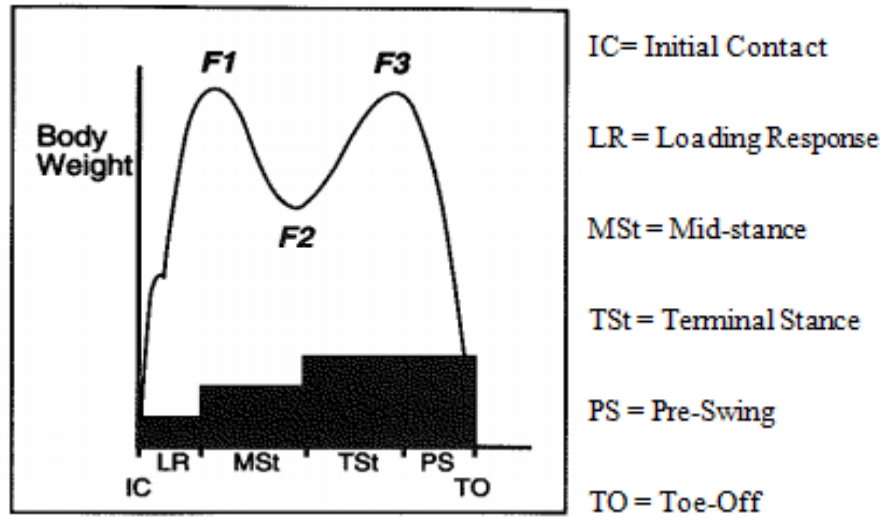


Fig 1.12: Vertical ground reaction force (VGRF) pattern and the gait phases [8]

Force plates are considered to be a “gold standard system” for the measurement of Ground Reaction Forces (GRFs). However, they are very expensive, laboratory process and it requires complex calibration process. The accurate detection of gait deviations needs several continuous gait cycles but a force plate measures only a single foot-strike (fig 1.13).

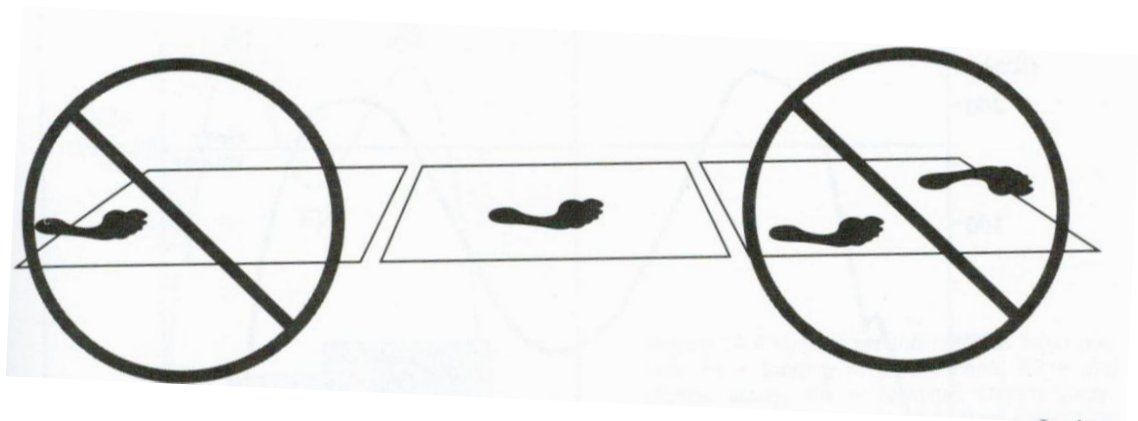


Fig 1.13: Force plates – Single Foot-Strike Measurement [8]

1.5 INSOLE PLANTAR PRESSURE MEASUREMENT SYSTEM:

The insole plantar pressure measurement system is developed to record the gait for several steps. Some of the commercially available insole systems are F-Scan and Pedar insole system. This system uses the insole embedded with hundreds of pressure sensitive sensors which records the pressure applied by the foot (fig 1.14). The spatio-temporal parameters can then be derived from the recorded gait data. The movie of foot plantar pressure pattern information during various activities could be recorded wirelessly. The F-Scan unit consists of a datalogger attached to the waist, two receivers from each insole attached to the shank.

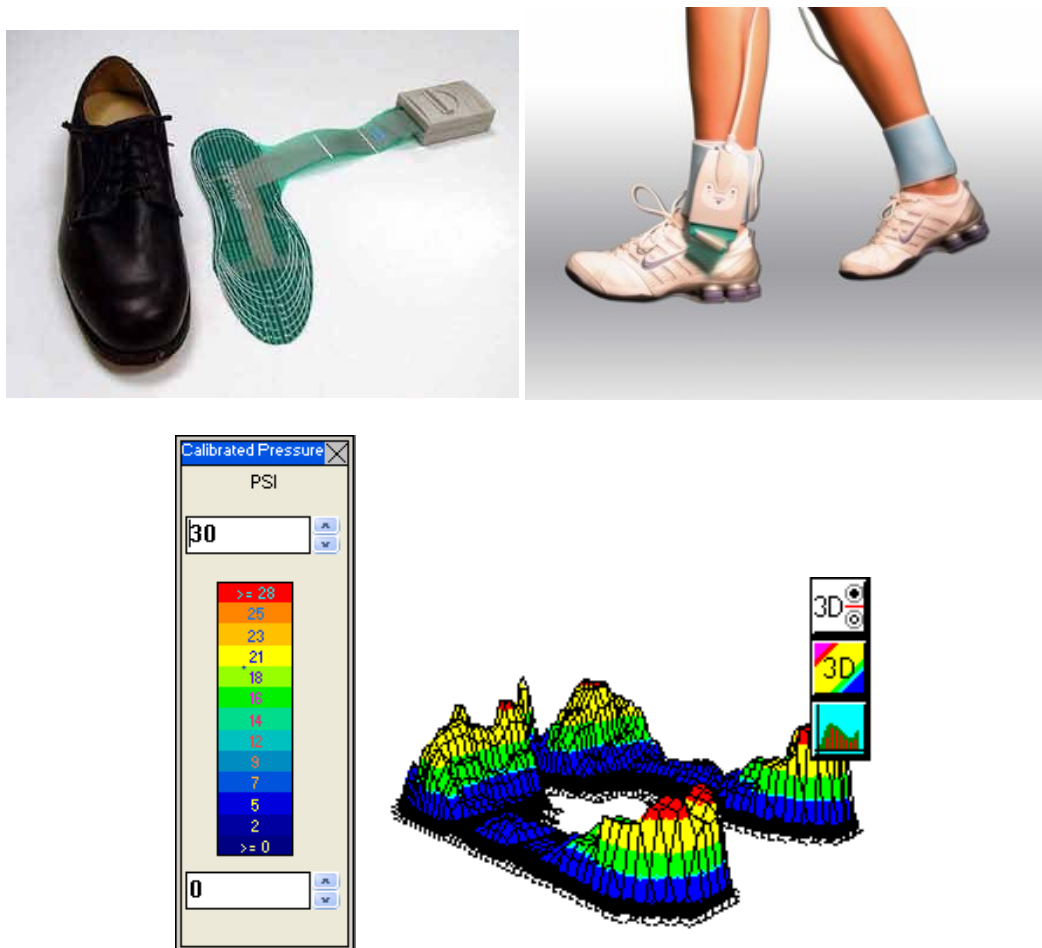


Fig 1.14: Insole Plantar Pressure Measurement System [23]

However, the insole plantar pressure measurement systems are less durable and it last only for 12 steps. The software is labor intense and doesn't directly measure most of the gait parameters. Although this system is called a portable system, it requires the subject to carry heavy datalogger and the receiver units which weigh about 4 pounds and there is a chance of affecting the natural gait.

1.6 NEED FOR INSOLE SYSTEM AND ITS CURRENT ADVANCEMENT:

The current technologies are not clinically friendly and require more resources like expensive equipment, training in the use of equipment and time to collect and/or analyze data. However, a wireless instrumented insole systems have the advantages of giving real-time information with minimal resources as well as providing real-time feedback to amputee users, which can be used to minimize gait deviations and achieve a more symmetrical gait.

The insole systems currently available for commercial use or in research laboratories vary in design and instrumentation to meet different application requirements. The key instrumentation requirements are sampling frequency, accuracy, sensitivity and calibration, miniature, lightweight, and energy efficient circuit solutions, mobility, limited wiring, low cost and low power consumption transmission device. The required key specifications for a force/pressure sensor in terms of sensor performance include linearity, minimal hysteresis, durability, repeatability, sensing size and pressure range. The most common pressure sensors are capacitive sensors, resistive sensors, piezo-electric sensor and piezo-resistive sensor.

A few research articles have discussed the development of instrumented insoles that can provide reliable foot plantar pressure information during gait. Sensor placement in the insoles plays a major role obtaining important and reliable gait information. Hence the sensors should be placed on the pressure bearing points in the foot plantar surface. This can be investigated using various foot print techniques like PressureStat film, APEX foot imprinter, microcapsule socks, Fuji Pres-sensor Mat, and Shutrack system [24]. The instrumented insole system allows gait data collection outside the clinic or laboratory and also allows the subjects to collect data by themselves. Most instrumented insoles were designed only for the human foot and have used the FSR output to detect only the temporal parameters of two gait periods i.e., stance and swing durations.

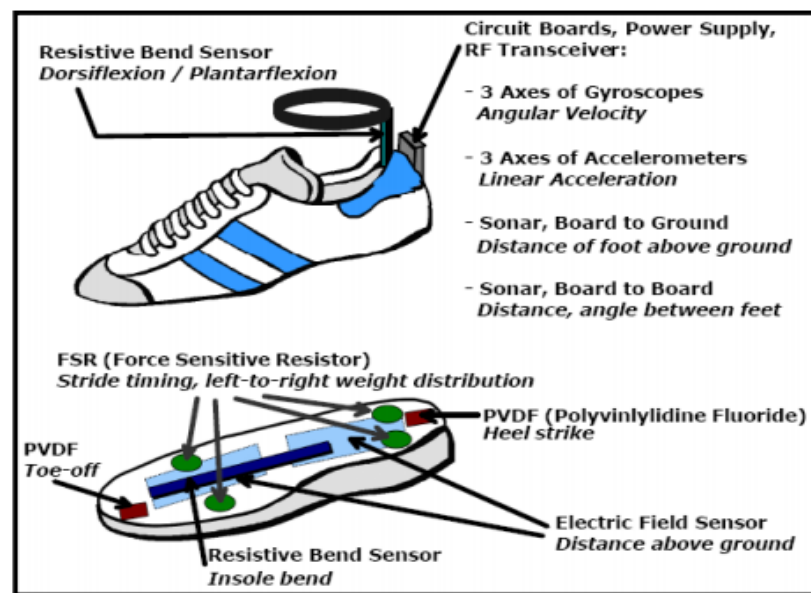


Fig 1.15: Insole System with Various Combinations of Sensors [25]

The above instrumented system (fig 1.15) generates different foot pressure values at the same time using various combinations of sensors - force sensitive resistors (FSRs), PVDF strips, bi-directional bend/ flex sensors, electric-field height sensor. Later, it was

found that the insole system may not require as many sensors as in fig 1.15 [25] and it was re-designed with only two sensors as in fig 1.16 [26]. However, this system uses only two FSRs – one on the heel and the other one on the forefoot. One sensor on the forefoot would not be able to discriminate and compare the pressure distribution on medial and lateral side of the foot which in turn hard to detect certain amputee deviations like medial and lateral whip. Moreover, it was designed only to measure the stance time and the swing time symmetry and the phase duration asymmetries are not monitored [26].

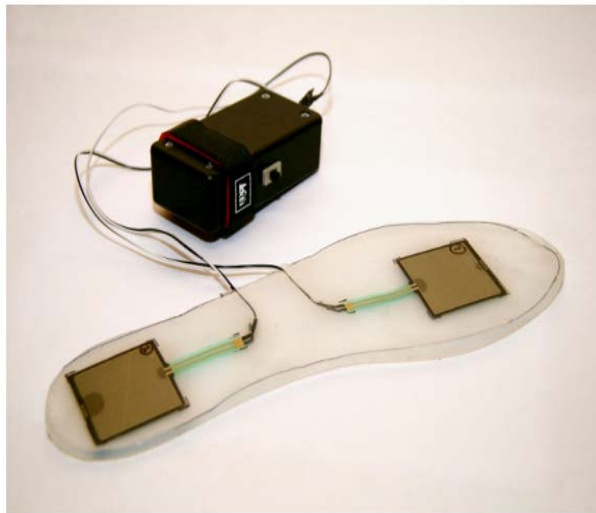


Fig 1.16: Current advancement in Insole design [26]

The selection of sensors should meet the necessary requirements as mentioned earlier and the location of sensors completely depends on the pressure bearing points on the foot plantar surface on each phase of the gait. Most currently available insole systems use Interlink Electronics force sensors which has relatively low sensing pressure range. The effectiveness in the gait analysis system could be achieved by retrieving appropriate gait data and not with the increased number of sensors. The selection and location of sensors reflects the accuracy in gait phase detection which in turn assess the temporal gait symmetry.

The insole material should be selected to make sure that it is not rigid to affect the foot plantar and dorsi flexion. Also, the insole surface must be smooth with limited wiring from the sensor. The detection of gait events including the stance sub-phases (WA, MSt, TL) using the instrumented insole system requires robust algorithms to detect the gait phases and calculate the phase durations real-time.

No research on the design of an instrumented insole system for the prosthetic foot has been published. The question, whether the insoles designed for physiologic foot can be used with prosthetic foot has not been investigated.

1.7 PROSTHETIC GAIT ASSESSMENT:

People with lower-limb amputation often favor and stress their intact lower limb more during everyday activities. This can lead to secondary physical conditions or complications that may affect the mobility and quality of life [5, 6]. Nearly sixty thousand major lower limb amputations are performed in the United States each year [27]. Symmetry is an issue in the gait of amputees because of the unnatural asymmetry imposed on the biomechanical system by the prosthesis [28]. In pathological gait, marked differences have been noted between the affected and unaffected limbs.

The most prominent asymmetries found in amputee gait have involved shortened stance times [29, 30, 31] for the prosthetic limb compared to the natural limb. Most studies in the literature have focused on the qualitative description of gait asymmetries [30], or quantitative measures based on the symmetry in gait periods and actually on the gait phases. Loss of normal neuromuscular control and proprioceptive feedback functions

have been cited as the major causes of the increased variability in gait timing between normal and amputee subjects [32].

It is even reported that with increasing walking speed, temporal asymmetry reduced and loading asymmetry increased [33]. The temporal asymmetry increase with the level of amputation i.e., trans-femoral amputees shows increased asymmetry in their stance phase than the trans-tibial amputees [34]. The common amputee gait deviations like vaulting, medial or lateral whip (fig 1.17) could be assessed with a fact that they often tend to skip/prolong few gait phases on one of the limbs which in turn results in the asymmetrical gait. Most studies on amputee gait have been done only with level walking activity whereas very few researchers have analyzed the prosthetic gait during various other functional activities like sit-to-stand, stand-to-sit, ramp incline and decline, stair ascent and descent and turns [35]. However, the temporal gait asymmetries on unilateral lower-limb amputees with respect to each gait phase - Weight Acceptance (WA), Mid-stance (Mst), Toe Load (TL), Swing (Sw) during various activities have not yet been studied. Gait training has been shown to be effective in unilateral TTAs to reduce the gait deviations [36]; however the influences of training on temporal parameters of each gait phases are unknown.

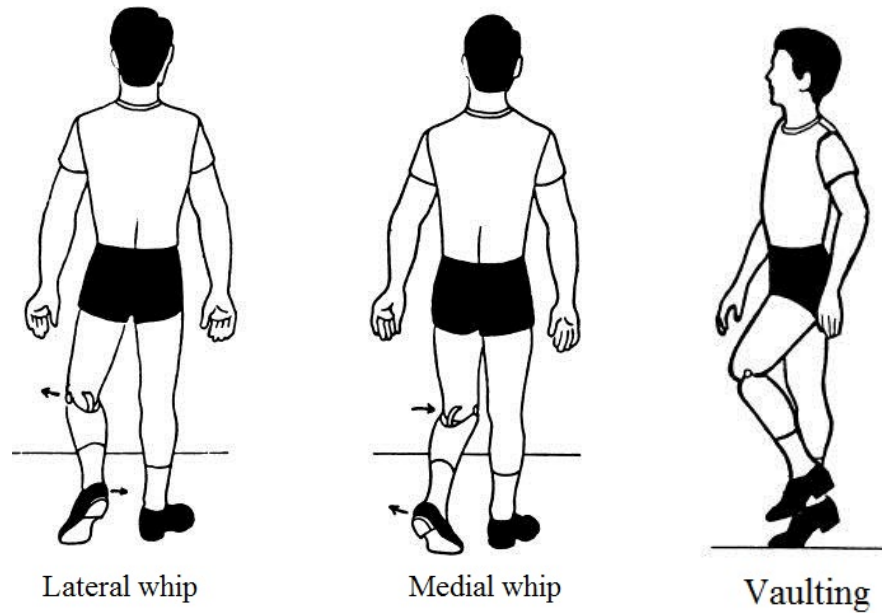


Fig 1.17: Amputee gait deviations [37]

There are often difficulties associated with standard gait analysis techniques that require subjects to perform multiple trials walking over ground and placing other feet on one or more force plates. With the current measuring techniques that monitor only the stance and swing phase symmetry, the gait deviations may not be accurately assessed. For example, the decreased stance time on the prosthetic limb does not provide better assessment of the deviation unless the phase duration symmetry (WA, MSt, TL, Sw) is monitored (fig 1.18). Some previous articles reported that the amputees face problem with the incline and decline walking more than the level ground walking. However, there is no research has been published on the phase duration symmetry in lower limb amputees during various function activities like level walking, incline and decline walking.

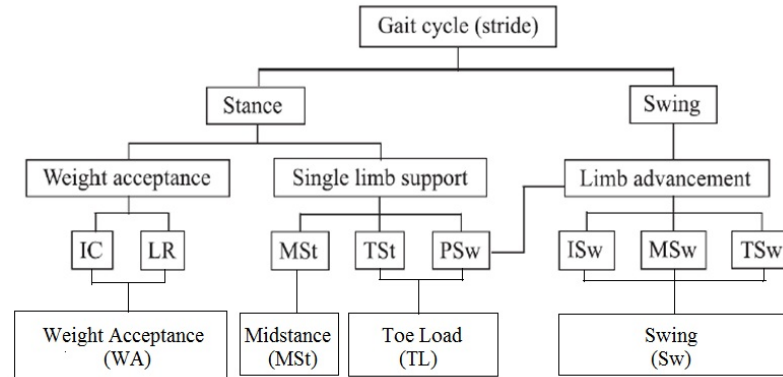


Fig 1.18: Importance of Phase Duration Asymmetry

This research project describes the development of a wireless instrumented insole system that was designed to address these issues and to improve and expand upon current gait analysis techniques. Unlike other systems, the smart insole system detects and assesses the real-time gait deviations in amputees. It was anticipated that gait assessment using the phase duration symmetry could be an effective aid in the detection of certain temporal gait deviations in unilateral lower limb amputees.

2

RESEARCH OBJECTIVES

2.1 RESEARCH PROJECT OBJECTIVES:

1. To determine the percentage of pre-determined phase durations in a gait cycle during level walking (LW), ramp incline walking (RI) and decline walking (RD) in non-amputees using existing commercially available systems.
2. To compare the symmetry index of pre-determined phase durations in a gait cycle during LW, RI and RD between non-amputees and uni-lateral transtibial amputees (TTAs).
3. To design a wireless smart insole system that detects the four pre-determined phases and can be used by both anatomical and prosthetic foot.
4. To create a decision making engine that assesses the phase duration asymmetry and determines where relative deviations occur at the plantar surface of the anatomical and prosthetic foot.

2.2 PROJECTS UNDERTAKEN TO ADDRESS OBJECTIVES:

1. *Established the percentage of 4 pre-determined phase durations in a cycle during LW, RI, RD activity.*

Several continuous gait cycles were recorded using the F-Scan insole plantar pressure measurement system and the percentages of the phase durations during

LW, RI, and RD were established using Jacqueline Perry's interpretation of phases from the VGRF 'M' curve [8].

- 2 *Compared the phase duration symmetry of the entire stance period with the pre-determined phases – WA, MSt, TL in both non-amputees and TTAs.*

The phase durations measured from the VGRF were used to calculate the symmetry between the either limbs. The symmetry was assessed using the Symmetry Index (SI) formula [35].

- 3 *Designed and developed a wireless instrumented smart insole system for both anatomical and prosthetic foot.*

A smart insole system was designed and developed for the real-time assessment of temporal gait deviations in unilateral lower-limb amputees. Force Sensitive Resistors (FSRs) embedded on the insole were instrumented with using the arduino microcontroller. The sensor data from the insole are wirelessly transmitted to the control unit (PC) using the xbee radios.

- 4 *Determined the appropriate sensors and its location on the maximum foot plantar pressure bearing points.*

The appropriate pressure sensor for the insole was selected to meet the required sensor properties. The sensors locations were determined based on the maximum foot plantar pressure bearing points and the foot anatomy. Using the F-Scan system and PressureStat film, the precise locations of the sensors on the insole were determined.

5 Developed and implemented algorithms in MATLAB to:

1.1. Detect the pre-determined phases (WA, MSt, TL, Sw).

The developed smart insole system detects each pre-determined phases real-time based on the foot plantar pressure distribution.

1.2. Calculate the phase duration asymmetry.

A trigger was set to monitor the change in phase and that takes the time stamp from MATLAB. The duration of each phase was calculated and four steps were averaged using the moving average filter at the end of each cycle. The symmetry between the either limbs were determined real-time using the SI formula for each cycle.

1.3. Implement a finite state machine that could detects the related gait deviations occur at the plantar surface of the anatomical and prosthetic foot.

Certain amputee gait deviations were assessed based on SI of each phase in a cycle.

3

IMPORTANCE OF PHASE DURATION SYMMETRY

3.1 GAIT DATA COLLECTION:

Temporal gait data during LW, RI and RD were collected from six healthy non-amputee subjects, aged 50-55 years and ten uni-lateral trans-tibial amputees using the portable F-Scan insole plantar pressure measurement system [35]. The study protocol was reviewed and approved by the Institutional Review Board (IRB) at the Miami Veterans Affairs Health Care System and informed written consent was obtained from the subject prior to study enrollment [35].

During the data collection process, subjects were given a 30 second rest period at the end of each trial. Longer rest periods were given if needed. Data collection with the F-scan system was done as follows:

- **Level Walking:** Subjects were asked to walk on a 20 meter long level path at a self-selected walking speed. Data collection began only after the subject completed three full strides. The first five complete steps from the intact side and the first five complete steps from the amputated side were used for data analysis.

- **Ramps:** Subjects were asked to walk on a 7.3 meter long ramp having a slope of 5 degrees, which conforms to the Americans with Disabilities Act (ADA) guidelines. Three to five steps, chosen during the middle portion of the ramp were used for analysis [35].

3.2 F-SCAN INSOLE SYSTEM:

The F-Scan insoles are extremely thin (0.007"/0.15 mm) and made up of 960 pressure sensitive sensels which is attached to the handle (DAQ) (fig 3.1). Insoles can be trimmed to fit shoe sizes up to 14 USA. Each sensing element in the insole uses resistive technology and can measure pressure ranges of 345-517 kPa (sensitive) to 862 kPa (standard) [23]. Wrinkles in the insoles were avoided to get rid of the clumsy gait data. Fig 3.2 gives the dimensional specifications of an F-Scan insole. A data-logger unit with a rechargeable battery was attached to the waist belt that records the movie of insole data with selected frame rate. Data collection and analysis were done using the Research Foot software version 5.9 (Tekscan Inc., Boston, USA).

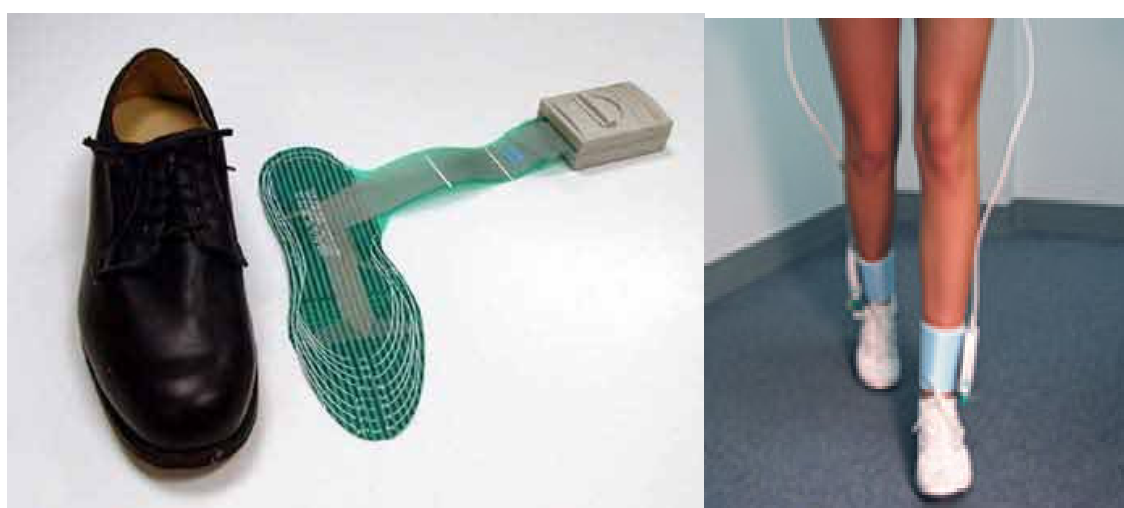
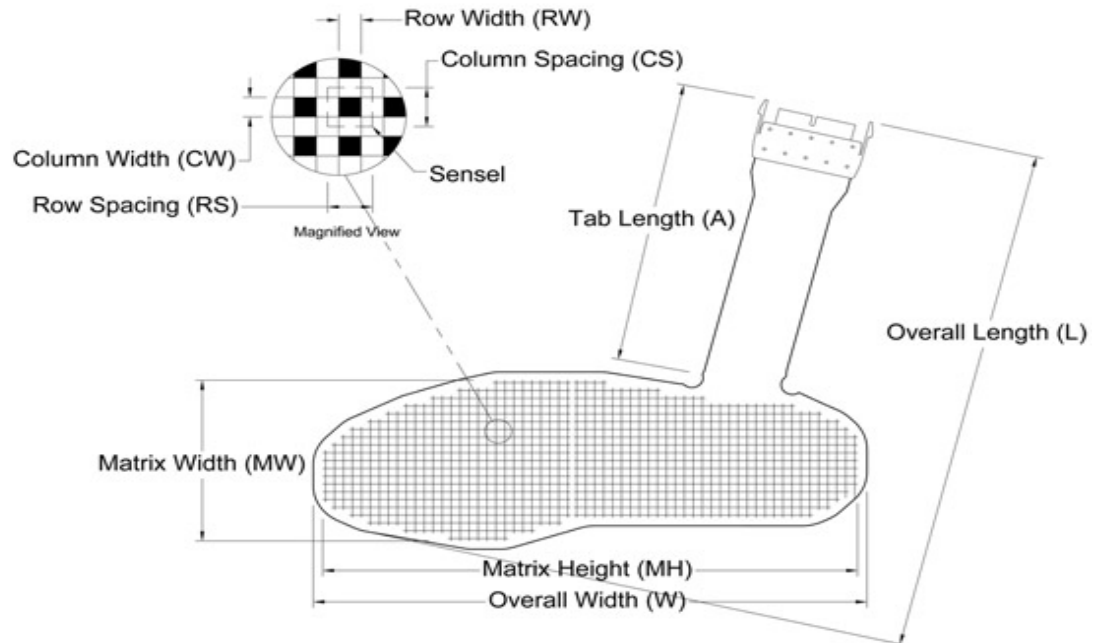


Fig 3.1: F-Scan insole plantar pressure measurement system



Overall Length L	Overall Width W	Tab Length A	Matrix Width MW	Matrix Height MH	Columns			Rows			Total No. of Sensels	Resolution Sensel Density
					CW	Pitch CS	Qty.	RW	Pitch RS	Qty.		
(in.) 18.83	(in.) 12.35	(in.) 13.20	(in.) 4.20	(in.) 12.00	(in.) 0.100	(in.) 0.200	21	(in.) 0.100	(in.) 0.200	60	954	(sensel per in. ²) 25.0
(mm) 478.3	(mm) 313.7	(mm) 335.3	(mm) 106.7	(mm) 304.8	(mm) 2.5	(mm) 5.1	21	(mm) 2.5	(mm) 5.1	60	954	(sensel per cm ²) 3.9

Fig 3.2: F-Scan Insole – Dimensional Specifications [23]

3.3 COMPUTATION OF TEMPORAL GAIT PARAMETERS:

The temporal gait parameters i.e., the duration of gait events were measured and calculated using the “M” shaped vertical ground reaction force (VGRF) curve from the F-Scan insole with respect to the two peaks and a valley as described by Perry [8] (fig 1.12). Several continuous gait cycles were recorded and the temporal parameters from the F-Scan VGRF were measured.

Fig 3.3 explains the measurement of the temporal gait parameters for one of the limbs (green) using the method provided by Perry. Several continuous steps were analyzed and the phase durations are measured from both the limbs.

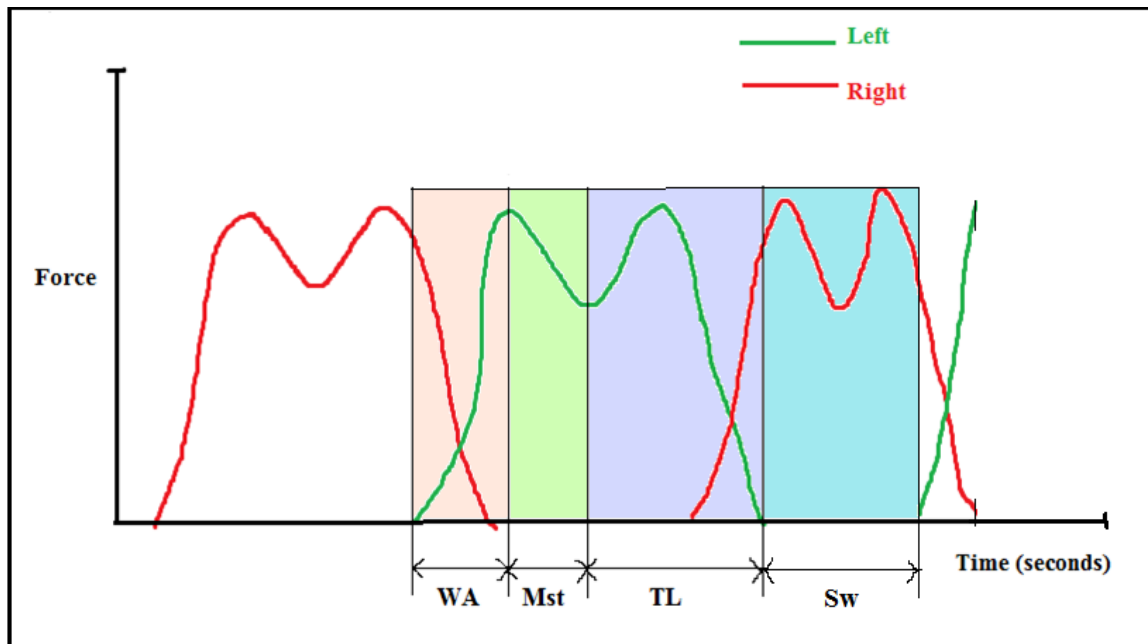


Fig 3.3: Graphical representation of vertical ground reaction forces and Calculation of Temporal Parameters obtained with F-scan sensors during two consecutive steps. WA – Weight Acceptance; Mst – Mid-stance; TL – Toe Load; Sw – Swing

The Symmetry Index from the gait phase durations can be calculated [35] as

$$\text{Symmetry Index (SI)} = 100 - \left(\frac{100 * (T_s - T_p)}{(T_s + T_p)} \right) \%$$

Where T_s = Phase duration on the sound limb

T_p = Phase duration on the prosthetic limb

The gait data were analyzed to:

- i. To determine the percentage of the four pre-determined phase durations in a gait cycle.
- ii. Compare the phase durations between level walking and ramp walking activity in both non-amputees and amputees.
- iii. To determine the phase duration symmetry in both non-amputees and unilateral lower-limb amputees.

3.4 SYMMETRY INDEX INTERPRETATION:

The symmetry index generates the value in terms of percentage. A symmetry index of 100% would mean equal amounts of time spent by the two lower limbs on the particular phase. In amputees, SI of less than 100% would denote prolonged phase durations on the intact limb and SI of greater than 100% denotes the prolonged phase durations on the prosthetic limb.

Symmetry Index may not be ideal (100%) even in healthy non-amputees due to limb dominance. Hence it was anticipated that the non-amputees possess the phase duration SI in the range of 95-105%.

3.5 PERCENTAGES OF PHASE DURATION IN A GAIT CYCLE DURING LW, RI AND RD:

The percentage of these four pre-determined phases in a cycle from five steps from each of six non-amputees have been calculated and averaged. Table 3.1 gives the percentage with the standard deviation of phases in a cycle calculated during three

different activities - level walking (LW), ramp incline (RI) walking, ramp decline (RD) walking. The variations in the percentage of gait phases have been pictorially represented in fig 3.4.

Table 3.1: Percentage of Phase Duration in a Cycle during Level Walking, Incline and Decline Walking

Activity	Non-amputees - % of Phase Durations in a Cycle Mean (SD)				
	Weight Acceptance	Midstance	Toe Load	Stance	Swing
<i>Level Walking</i>	15.41 (1.41)	16.16 (3.28)	32.23 (2.89)	63.80 (1.32)	36.20 (1.32)
<i>Incline Walking</i>	15 (1.28)	18.02 (2.13)	30.35 (2.39)	63.37 (1.02)	36.63 (1.02)
<i>Decline Walking</i>	12.65 (1.24)	20.29 (2.56)	28.25 (1.01)	61.19 (0.77)	38.81 (0.77)

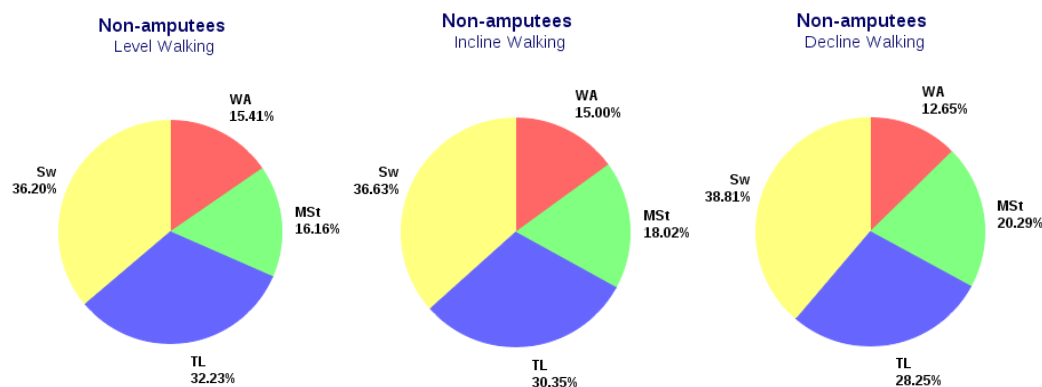


Fig 3.4: Comparison of normative percentage of gait phases of middle aged healthy non-amputee controls during LW, RI and RD

3.6 COMPARISON OF PHASE DURATIONS DURING LEVEL WALKING AND RAMPS:

Student t-tests were done to analyze the difference in the percentage of gait phases during incline and decline activity from level walking activity and a significance level of $P < 0.05$ was used. The phase durations of all the gait events but the mid-stance during decline walking were found to be significantly different from the level walking (table 3.2). But the phase durations during incline walking were not significantly different from the level walking.

Table 3.2: p-values to analyze the difference of gait phase durations of non-amputees during RI and RD from LW

Activity	T-Test - Variation in % of Gait Phases in RI and RD from LW				
	Weight Acceptance	Midstance	Toe Load	Stance	Swing
LW vs RI	0.684	0.346	0.348	0.608	0.608
LW vs RD	0.033*	0.091	0.020*	0.008*	0.008*

***Indicates significantly different**

3.6.1 Discussion:

Perry divided the gait cycle into eight phases (fig 1.4) and reported the definitive percentage of phases per gait cycle during level walking (table 3.3). From table 3.2, the percentage of phase durations during the level walking was found close to Perry's report. During gait cycle, the prolonged/shortened duration of one phase has its effect in the

duration of the consecutive phases, as the phase durations are calculated in terms of percentage. In ramp decline walking, the WA duration has been reduced (15.41 to 12.65%) with increase in the MSt duration (16.16 to 20.29%) and the decrease in TL durations (32.23 to 28.25%) followed by increase in Sw duration (36.20 to 38.81%). The duration of WA and TL phase during decline walking were found to be reduced with the increase in the MSt and Sw phase durations. This happens with the fact of increasing walking speed during the decline walking. The p-values in the table denote that the phase durations during decline walking ARE significantly different from level walking except the midstance. No significant difference was found during the incline walking.

Table 3.3: Perry's Gait Phase Duration

`GAIT PHASE	% OF GAIT CYCLE
Initial Contact	0-2
Loading Response	2-12
Mid Stance	12-31
Terminal Stance	31-50
Pre Swing	50-62
Initial Swing	62-75
Mid Swing	75-87
Terminal Swing	87-100

3.7 SYMMETRY INDEX OF HEALTHY NON-AMPUTEES:

Table 3.4: Temporal Symmetry Index of Controls

Activity	Non-amputees - Temporal Symmetry Index (%) Mean (SD)				
	Weight Acceptance	Midstance	Toe Load	Stance	Swing
<i>Level Walking</i>	100.66 (4.16)	99.65 (4.71)	102.57 (4.10)	101.44 (1.72)	97.65 (3.14)
<i>Incline Walking</i>	97.36 (2.78)	96.56 (7.07)	102.95 (4.04)	99.65 (0.91)	99.15 (1.64)
<i>Decline Walking</i>	101.92 (3.50)	97.31 (3.78)	101.18 (1.50)	100.20 (0.78)	99.87 (1.80)

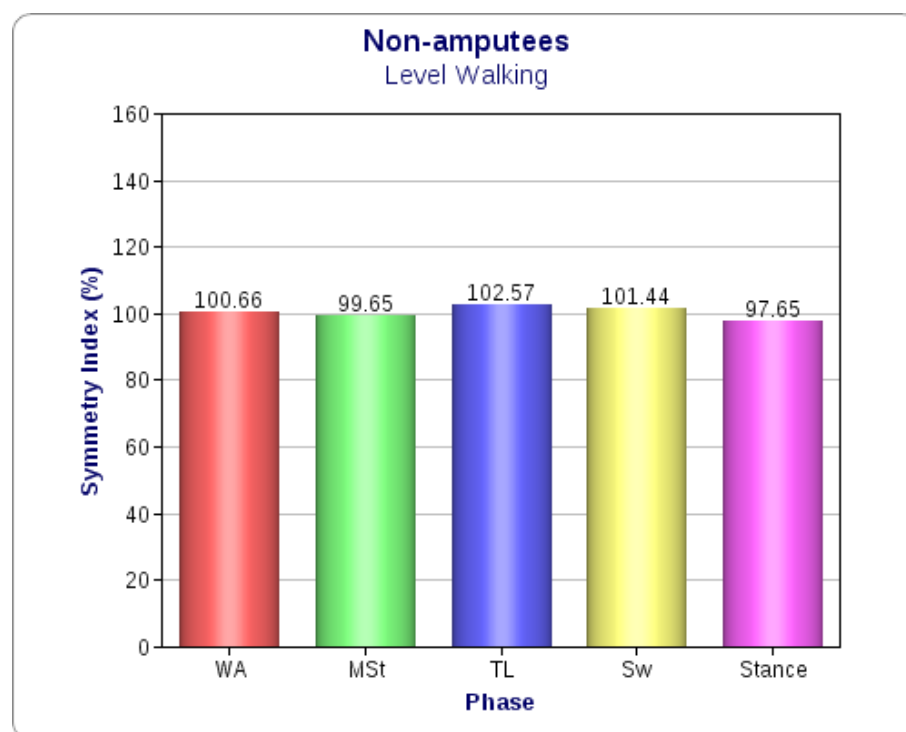


Fig 3.5: Symmetry Index of healthy non-amputees during level walking activity

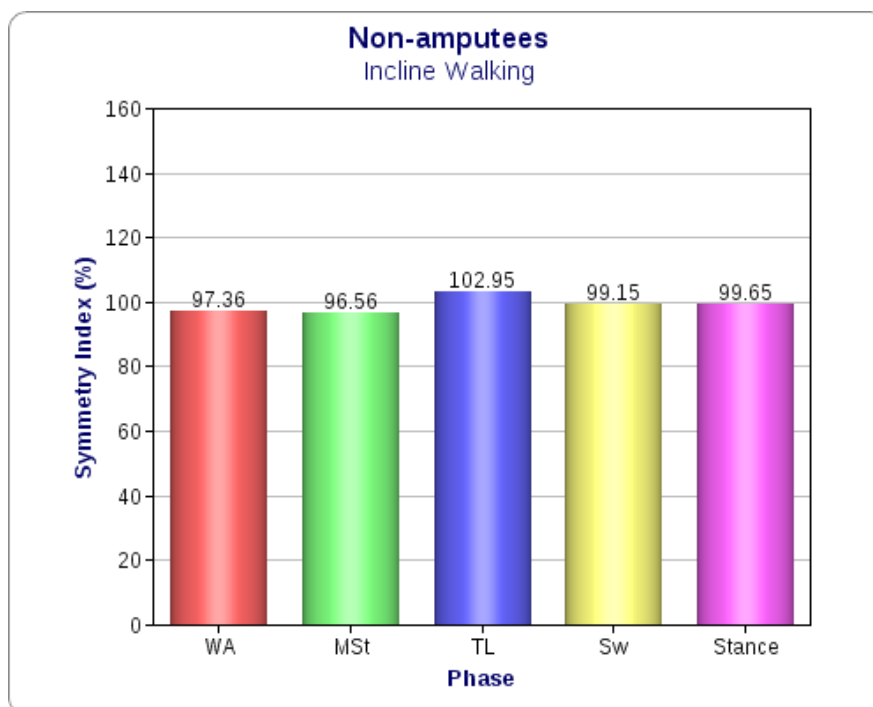


Fig 3.6: Symmetry Index of healthy non-amputees during incline walking activity

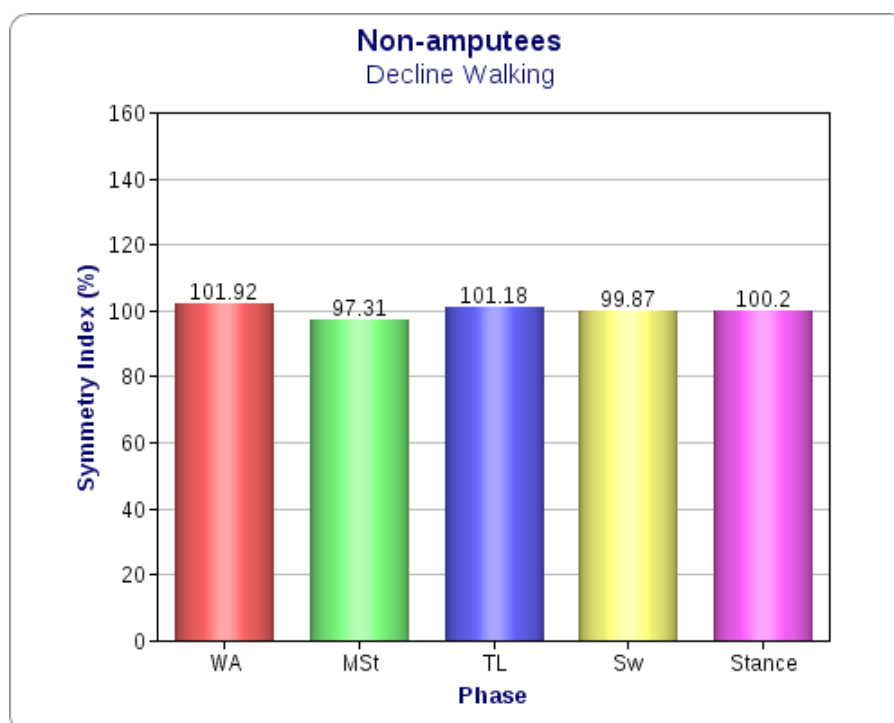


Fig 3.7: Symmetry Index of healthy non-amputees during decline walking activity

3.7.1 Discussion:

The absolute symmetry index is 100%. The symmetry index of all the gait events including the stance sub-phases (WA, Mst, TL) of all controls during all the three activities – LW, RI, RD were found to be close to 100% with minor standard deviations (Table 3.4). Hence the normative symmetry index ranges from 95-105%. Fig 3.5-7 represents graphical representation of the mean of symmetry indices of the each gait events of non-amputees during level walking, incline and decline walking. The symmetry index less than 95% implies prolonged phase durations on the dominant limb and greater than 105% implies shortened phase durations on the non-dominant limb.

3.8 PHASE DURATION SYMMETRY IN UNI-LATERAL LOWER LIMB TTA:

The symmetry index has been calculated and averaged from the gait data collected from ten uni-lateral lower-limb trans-tibial amputees during the three activities. In all three cases, the symmetry index of stance and swing phase were found to be more close to 100% with the standard deviation of 2-5% but temporal gait phase asymmetry was found (Table 8) in the gait stance sub-phases – WA , Mst, TL (fig 3.8-10). The symmetry index less than 95% indicates prolonged gait phase durations on the intact limb and greater than 105% indicates shortened gait phase durations on the prosthetic limb.

Table 3.5: Temporal Symmetry Index of Uni-lateral lower limb TTA

Activity	TTA - Temporal Symmetry Index (%) Mean (SD)				
	Weight Acceptance	Midstance	Toe Load	Stance	Swing
Level Walking	111.53* (15.02)	90.05* (18.35)	98.04 (9.62)	99.53 (2.02)	100.64 (4.08)
Incline Walking	111.58* (10.05)	79.34* (22.07)	101.46 (10.33)	99.23 (1.59)	101.41 (2.73)
Decline Walking	115.23* (14038)	99.24 (16.93)	90.73* (9.36)	99.41 (2.72)	101.47 (5.63)

*indicates the greater asymmetry

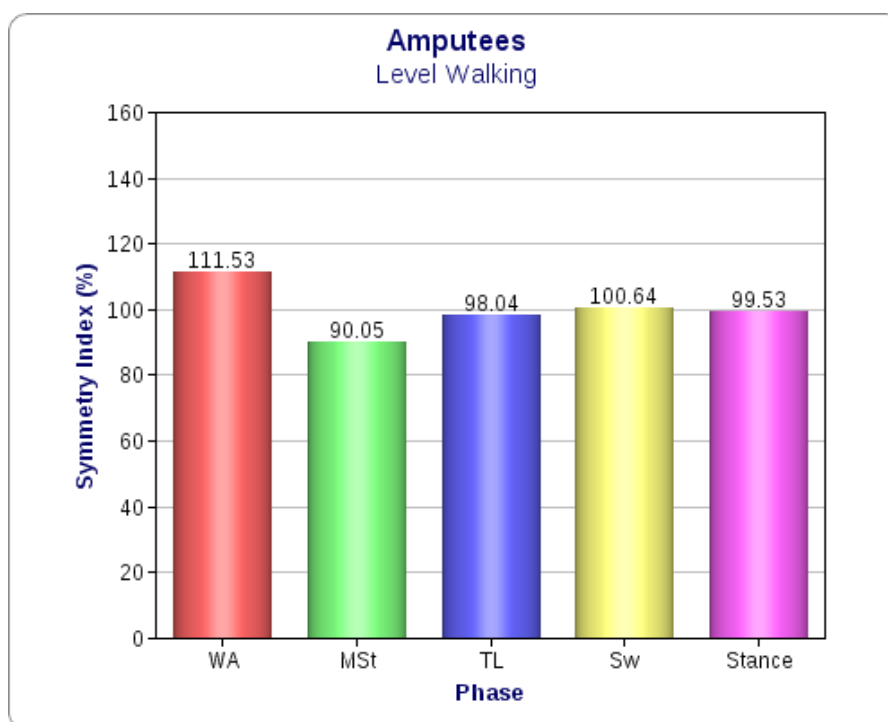


Fig 3.8: Symmetry Index of Uni-lateral TTA during level walking activity

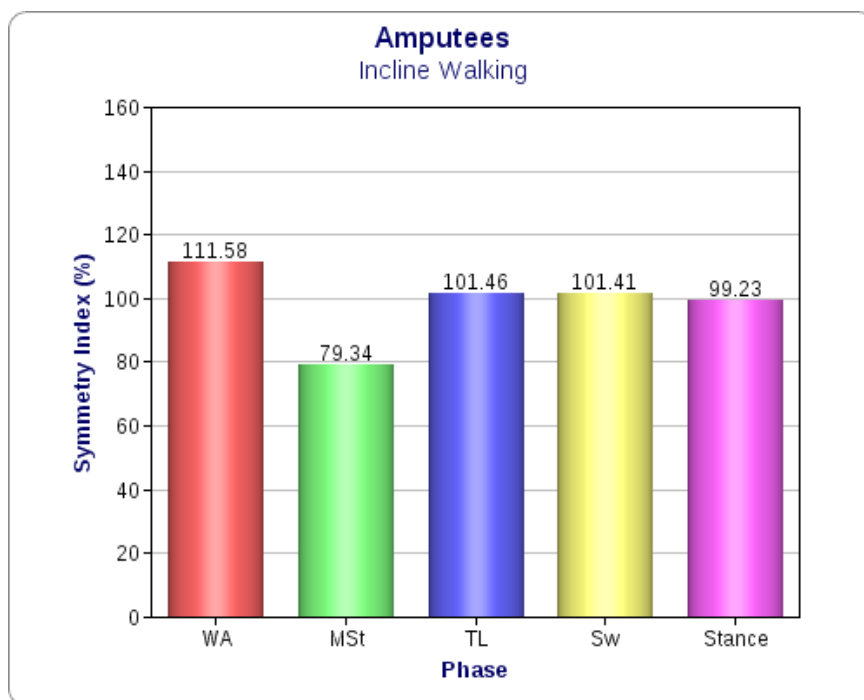


Fig 3.9: Symmetry Index of Uni-lateral TTA during incline walking activity

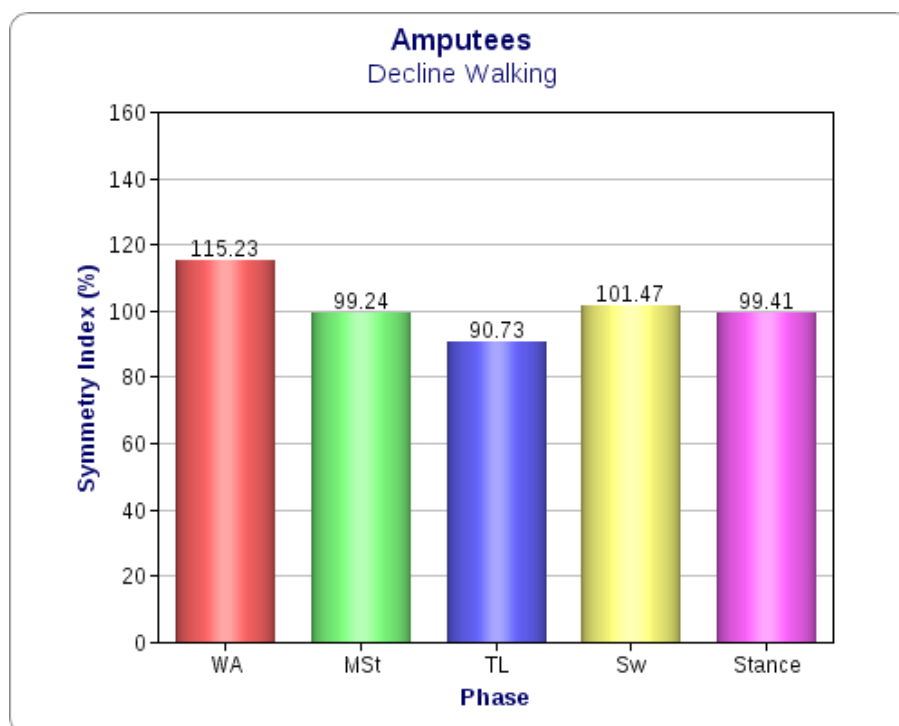


Fig 3.10: Symmetry Index of Uni-lateral TTA during decline walking activity

3.9 COMPARISON OF RAMP WALKING AND LEVEL WALKING IN UNI-LATERAL LOWER LIMB TTAs:

Table 3.6: p-values to analyze the difference of gait phase durations of uni-lateral lower limb TTAs during RI and RD from LW

Activity	T-Test - Variation in % of Gait Phases in RI and RD from LW				
	Weight Acceptance	Midstance	Toe Load	Stance	Swing
LW vs RI	0.992	0.254	0.453	0.717	0.625
LW vs RD	0.580	0.260	0.102	0.914	0.710

The statistical difference during incline and decline walking from level walking of uni-lateral lower limb TTAs were analyzed (table 9) using T-tests and a significance level of $P < 0.05$ was used. The gait phase durations during both incline and decline walking were not significantly different from the level walking.

3.9.1 Discussion:

Current research assess the temporal parameters in amputee using macroscopic parameters like stance time, swing time, stride time, double limb support time and single limb support time [40]. This research project analyzed the symmetry of gait sub-phases such as weight acceptance (WA), midstance (MSt), toe load (TL) and swing (Sw). As seen in table 8, the stance phase and swing phase symmetry ratio were found to be close to 100% but the stance sub-phases – WA, MSt, TL were found to be asymmetric during all three activities. The common amputee gait deviations like vaulting, medial or lateral

whip could be assessed with a fact that they often tend to skip/prolong few gait phases which in turn results in the asymmetrical gait. Hence the macroscopic symmetry measures (stance and swing time) may not be consistent in gait deviation assessment.

The symmetry index less than 95% indicate that the amputee is spending more time on the intact limb and greater than 105% indicate that the amputee is spending more time on the prosthetic limb. Hence the most of the amputee gait deviations could be simple assessed by the temporal symmetry measures of stance sub-phases. For example, decreased stance time in the prosthetic limb could be assessed using the asymmetries found during the WA, Mst, TL. In table 3.5, during level walking, SI of 111.53% (WA) 90.05% (MSt) implies that TTAs are spending more time on the WA on the intact limb and MSt on the prosthetic limb. This result interprets that the amputees take longer time to balance their prosthetic foot which causes greater phase duration asymmetry.

The phase durations during both ramp walking were not significantly different from the level walking in TTAs (table 3.5). This implies that the amputees tend to control their speed on ramps due to many factors like fear of falling, poor balance.

4

WIRELESS SMART INSOLE SYSTEM

A microcontroller based wireless instrumented insole system was designed and tested with both human and prosthetic foot. The insole design, sensor selection and placement were determined to achieve the accurate phase detection and the computation of phase duration symmetry (fig 4.1).

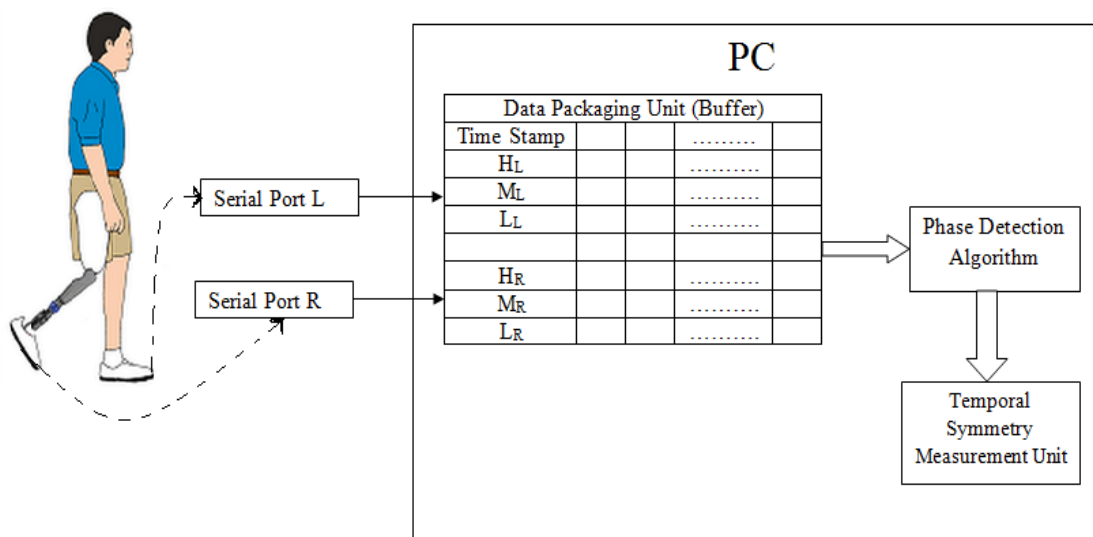


Fig 4.1: Block diagram of the Smart Insole System

4.1 SELECTION OF SENSORS:

A variety of sensors are used to measure the foot plantar force and pressure distribution. The sensors were selected according to the different application requirements. The most commonly used sensors in research are force sensitive resistors (FSRs), PVDF strips, air pressure sensors, bi-directional bend/ flex sensors, electric-field height sensor. Each sensor has its own advantages and disadvantages.

i. PVDF Strips:

The important characteristics of PVDF includes: piezoelectric, versatile, low density, low mechanical impedance, easy fabrication Ferro-electric material. A couple of square films of PVDF is placed one against the other with a frothy material between them. This material offers resistance to the pressure. In the base another part of frothy material was placed as a protection surface as shown in the fig 4.2. Electric contacts were placed between on every PVDF film using conductive tape in order to measure the change in voltage with respect to the applied pressure.

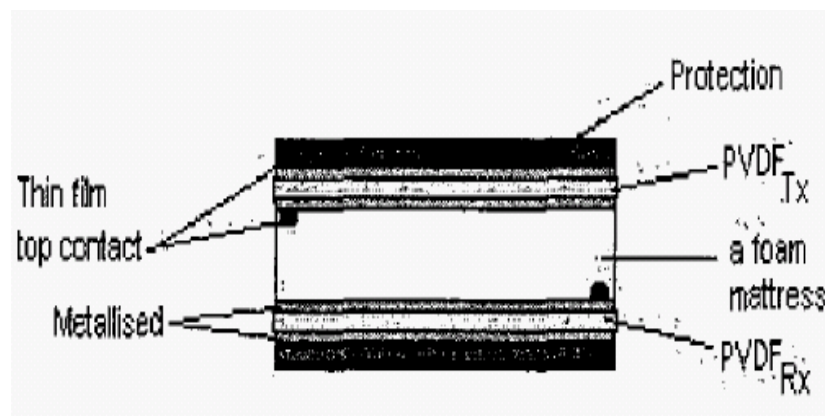


Fig 4.2: PVDF Pressure Sensor

ii. Air Pressure Sensor:

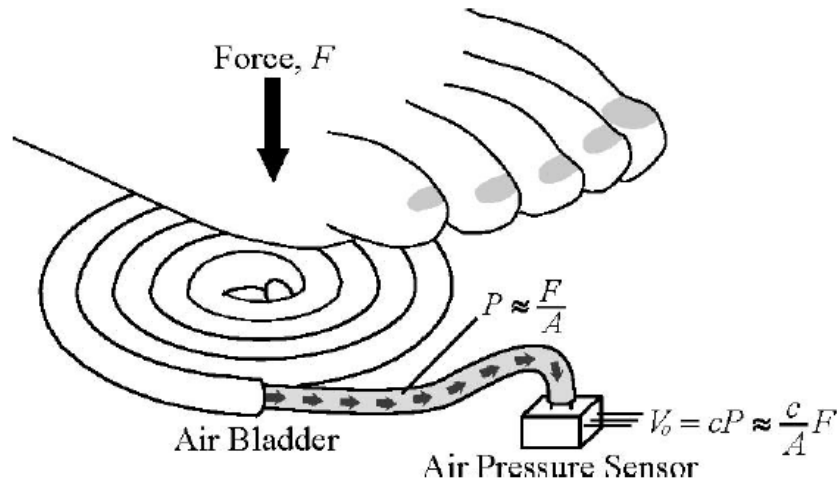


Fig 4.3: Air Pressure Sensor [39]

Air pressure sensors are used to replace the force sensitive resistors, as it is comparatively more durable and suitable for measuring Ground Reaction forces (GRFs). When the foot presses the air bladder (fig 4.3), it deforms and the change in pressure which is proportional to the external force.

iii. Bi-Directional Bend/ Flex Sensors:

Flex sensors are sensors that change in resistance depending on the amount of bend on the sensor. They convert the change in bend to electrical resistance – the more the bend, the more the resistance value. They are usually in the form of a thin strip from 1” – 5” long that vary in resistance. They can be made uni-directional or bi-directional. The flex sensors embedded on the insole is used to measure the plantar flexion and dorsi flexion angle.

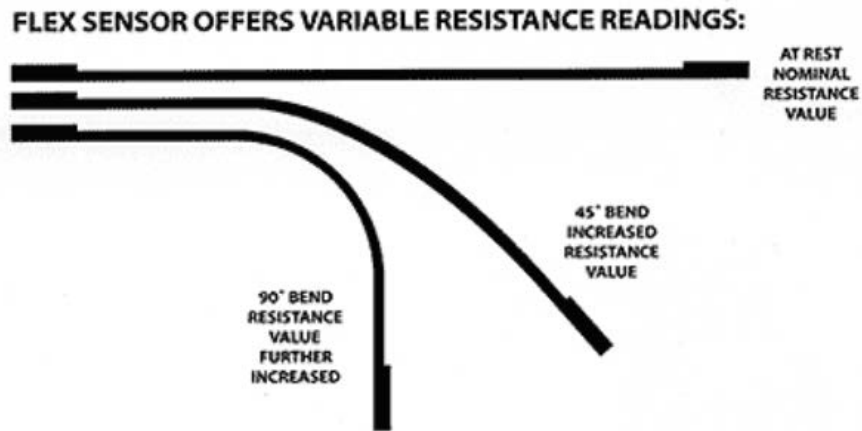


Fig 4.4: Flex Sensors

iv. Electric-Field Height Sensor:

Electric-field height sensors are basically capacitive sensors which act as a parallel plate capacitor. It is used to measure the height of the foot above the floor. The capacitance of a parallel plate capacitor is proportional to the surface area A and inversely proportional to the distance, d between the two plates (in this case, ground and the foot).

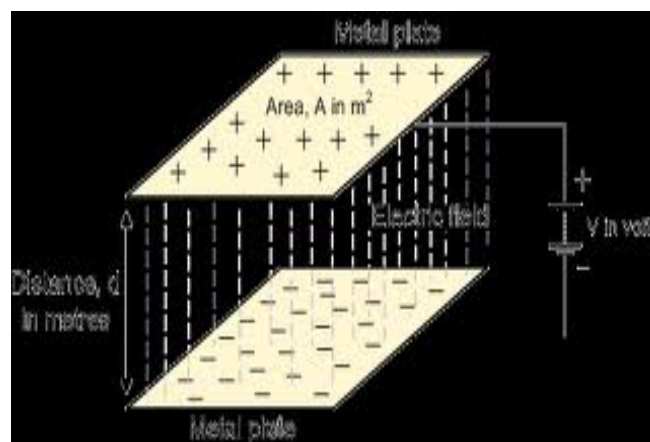


Fig 4.5: Parallel Plate Capacitor

v. Force Sensitive Resistors (FSRs):

FSR uses variable resistance to measure pressure applied to a sensor cell. This technology is very reliable and can be incorporated in thin and flexible applications. FSR also allows a high degree of design freedom and adapts to a simple electronic interface. FSRs are sensors that detect the physical pressure, squeezing and weight. They are simple to use and low cost.

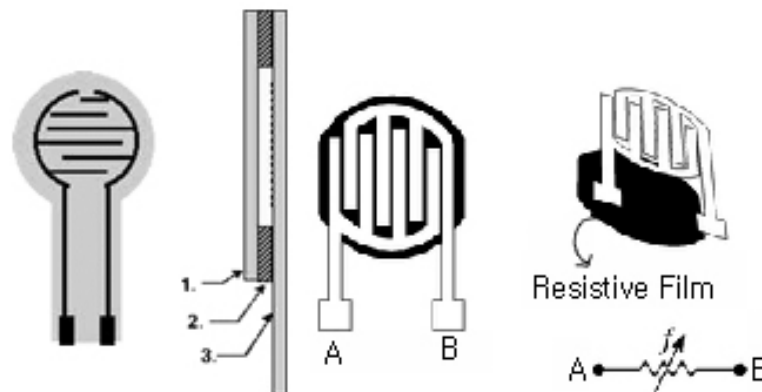


Fig 4.6: Force Sensitive Resistors [38]

The Tekscan custom made FSR with the active region of 1 inch diameter (fig 4.7) was found to be appropriate for this study compared to PVDF sensor, bend sensor and other Interlink's FSR because it can sense up to 127 psi and is comparatively more durable (up to million steps). The high pressure rating is desirable as these sensors could potentially be used for functional activities, such as jumping, running etc.



Fig 4.7: Tekscan Custom Flexi-force Sensor

4.2 DETERMINATION OF SENSOR PLACEMENT:

For the measurement of temporal gait parameters, the smart insole is instrumented with *Force Sensitive Resistors* (FSRs) placed on the maximum pressure bearing points on the plantar surface of the foot. Fig 4.8 gives the maximum pressure bearing points – Heel and the meta-tarsal heads which could be obtained from the color legend provided by F-Scan software.

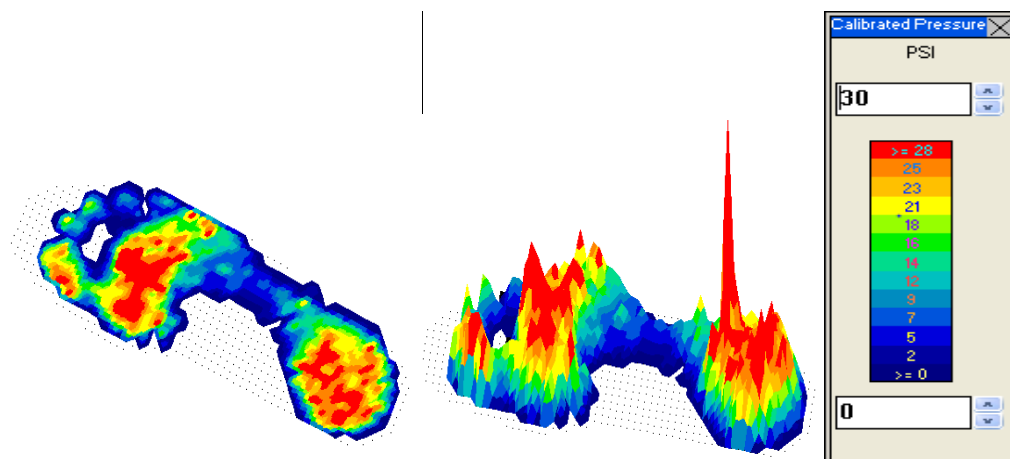


Fig 4.8: Detection of maximum pressure bearing points using F-Scan insole plantar pressure measurement system



Fig 4.9: PressureStat Device

The insole design and the location of the sensors is highly dependent on various foot anatomy like flat or high arched foot, clubfoot and extra toe, as this may alter the pressure bearing points. The insole designed for physiologic foot would not be same for the prosthetic foot because of differences in designs of the feet. In order to get the precise footprint, the subjects were asked to walk over the PressureStat film during a normal stride. The pressure sensitive chemicals in the multi-layered film of the device produced an exact replica of a subject's footprint (fig 4.9). Darkened areas reflect points of high pressure in the patient's foot. Hence the sensor locations in smart insole system were determined based on the maximum pressure bearing points as reflected by the PressureStat film and the requirements to meet the accurate gait phase detection. The

sensors in the smart insole system were placed on Heel, first Metatarsal head (Medial) and the fifth Metatarsal head (Lateral) (fig 4.10).

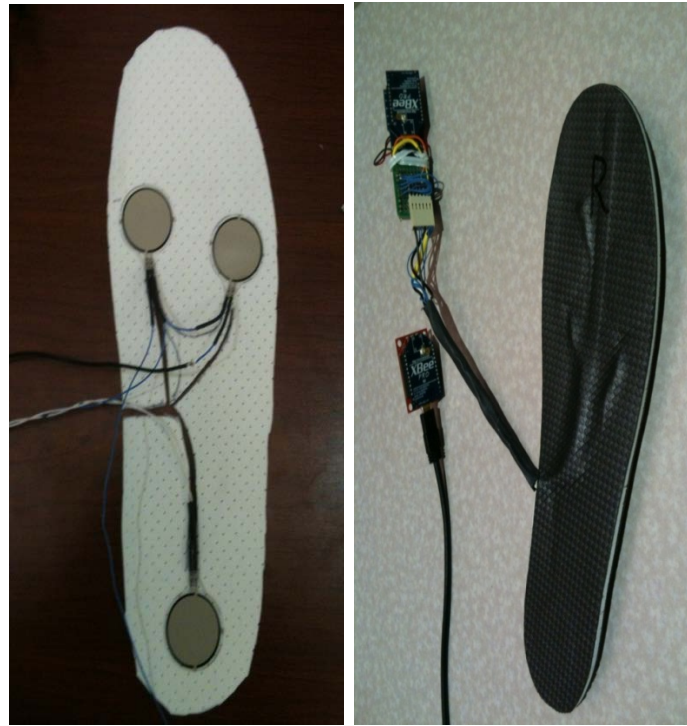


Fig 4.10: Smart Insole System

The insole material was selected to make sure that it is not rigid to affect the foot plantar flexion and dorsi flexion. Also, the insole surface must be smooth with limited wiring from the sensor. Hence the wires from each sensor were pushed into grooves on the insole to obtain smooth surface.

4.3 INSOLE INSTRUMENTATION:

4.3.1 VOLTAGE DIVIDER CIRCUIT:

In order to get the output in terms of engineering units, these variable resistive sensors were built into the voltage divider circuit (fig 4.11) with the pull-down resistor, R of $1M\Omega$. The pull down resistor R has its effect in the sensitivity of the digital output.

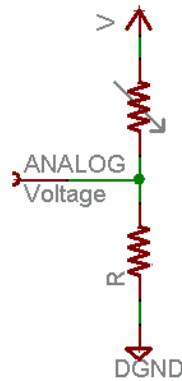


Fig 4.11: Voltage divider circuit

4.3.2 FIRMWARE DESIGN:

The voltage divider circuit from each sensor was connected to the Arduino Fio board for the wireless transmission of sensor voltage output to the processing unit (Fig 4.12). The circuit board is powered with an external rechargeable battery of 3.3V. The battery can be recharged using the mini-USB cable.

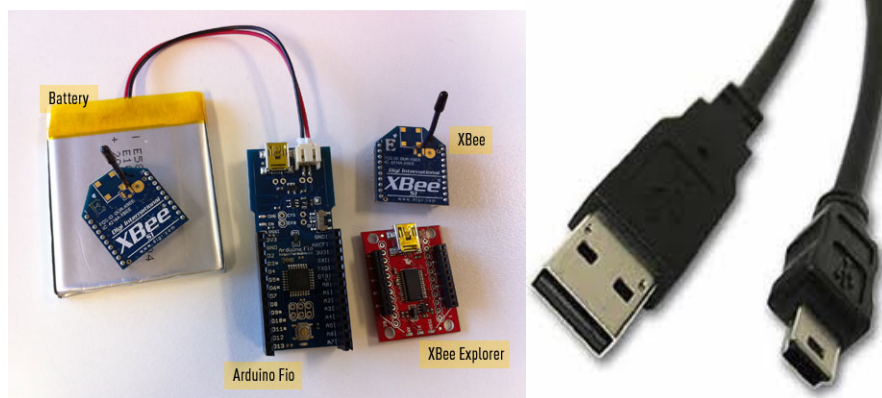


Fig 4.12: Arduino Kit

Arduino Fio was used due to its size and its compatibility with Xbee radios. It has 8 analog input pins in total. The wires from the sensors were connected to the arduino board using a 6 pin polarized female connector (Fig 4.13). The pin numbers were

standardized as *Lateral, Medial and Heel* from pin 3 through 5. The pin 6 has the combined wire from all the sensors which goes to the input voltage (3.3 V) port of arduino board (fig 4.14).



Fig 4.13: 6 pin polarized female connector

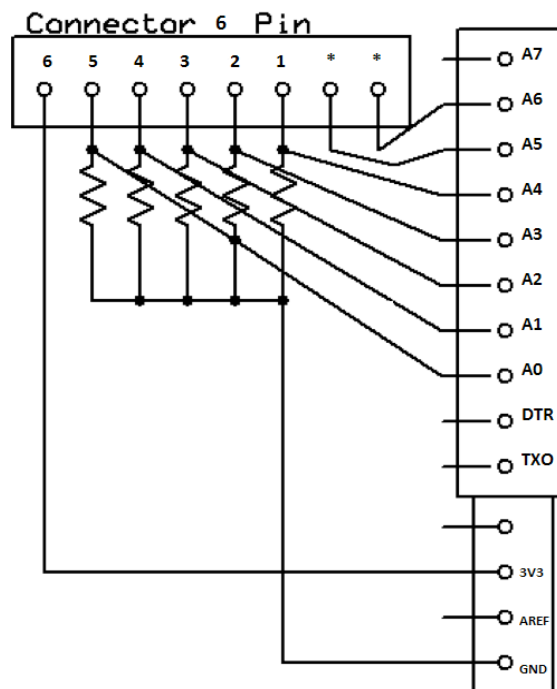


Fig 4.14: Insole PCB sketch

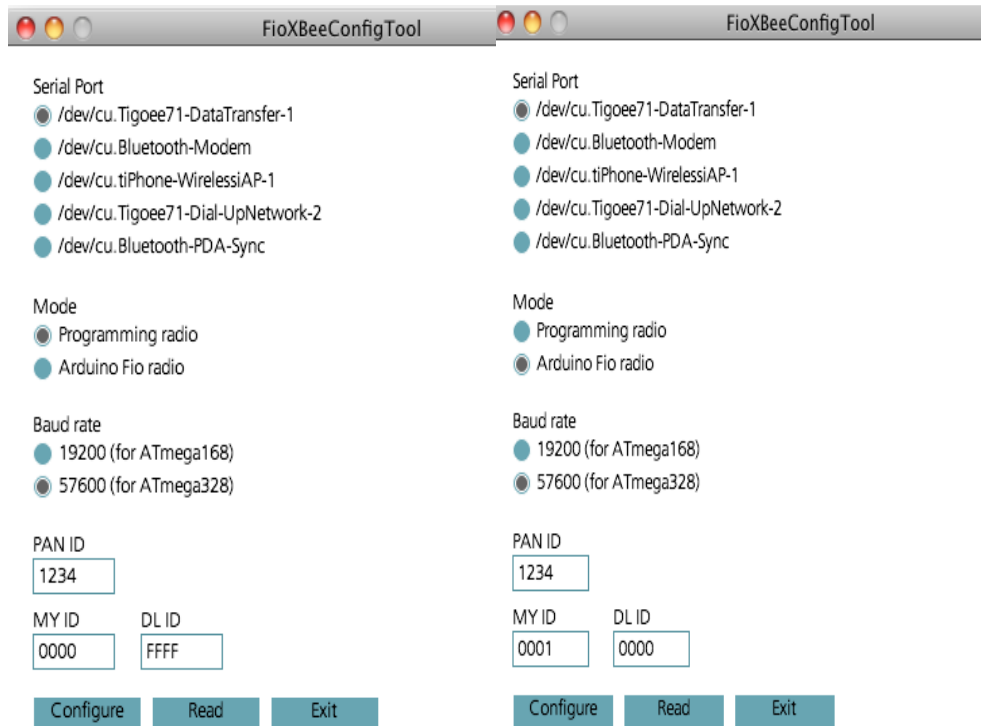


Fig 4.15: Fio Xbee Config Tool

The wireless transmission unit in arduino was designed with xbee pro radios. Each insole system needs two xbee radios, one for PC (programming radio) and other for the arduino board. The xbees were paired up using FioConfigTool (fig 4.15) by specifying same PAN ID and baud rate. The programming radio was connected to t9he PC through sparkfun xbee explorer via mini-USB cable.

4.3.3 FIRMWARE CODE:

The firmware code was flashed to the arduino board using the xbee radios. The baud rate was set to 57600bps and the input analog ports were specified. The transmitted signal from the each sensor was smoothened using weighted moving average filter and printed to the serial monitor (fig 4.16).

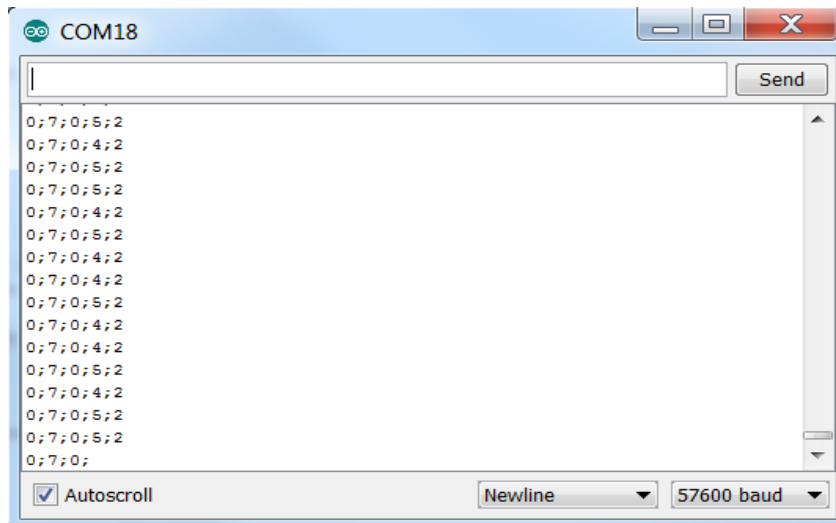


Fig 4.16: Arduino serial monitor

4.3.4 FSR CALIBRATION:

The FSR is a non-linear sensor and its response to the force was analyzed using Tekscan equilibration and calibration device (model: PB100E) (fig 4.17) at Max Biedermann Biomedical Research inst. at Mount Sinai hospital in Miami Beach.

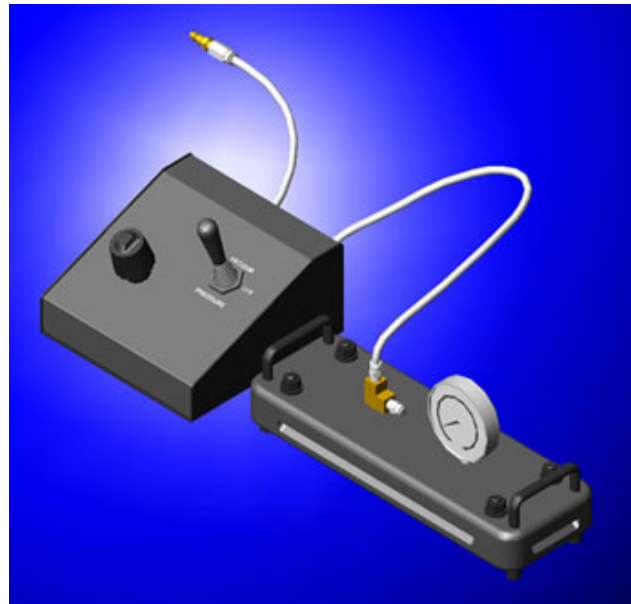


Fig 4.17: Tekscan equilibration and calibration device (model: PB100E)

As the resistance of the FSR is inversely proportional to the applied force, the conductance (inverse of resistance) was calculated which has an approximate linear relationship with the applied force (fig 4.18). The input voltage of 3.3 V was applied to the voltage divider circuit. The output voltage was measured using the arduino sketch. The arduino microcontroller has an inbuilt 10 bit ADC.

Therefore the output analog voltage from the microcontroller ranges from 0 to 1023 V. The corresponding voltage output in the range of 0 to 3.3V could be calculated as,

$$\text{Resolution} = 3.3/1024 = 3.2 \text{ mV}$$

$$\text{FSR_Voltage}_{(0-3.3V)} = \text{Arduino output voltage}_{(0-1023V)} * \text{Resolution}$$

The change in resistance of the sensor in turn could be derived as

$$\text{FSR_Voltage} = (\text{Input voltage} * R) / (R + \text{FSR_Resistance})$$

$$\text{FSR_Resistance} = ((\text{Input voltage} - \text{FSR_voltage}) * R) / \text{FSR_Voltage}$$

$$\text{FSR_Conductance} = 1/\text{FSR_Resistance}$$

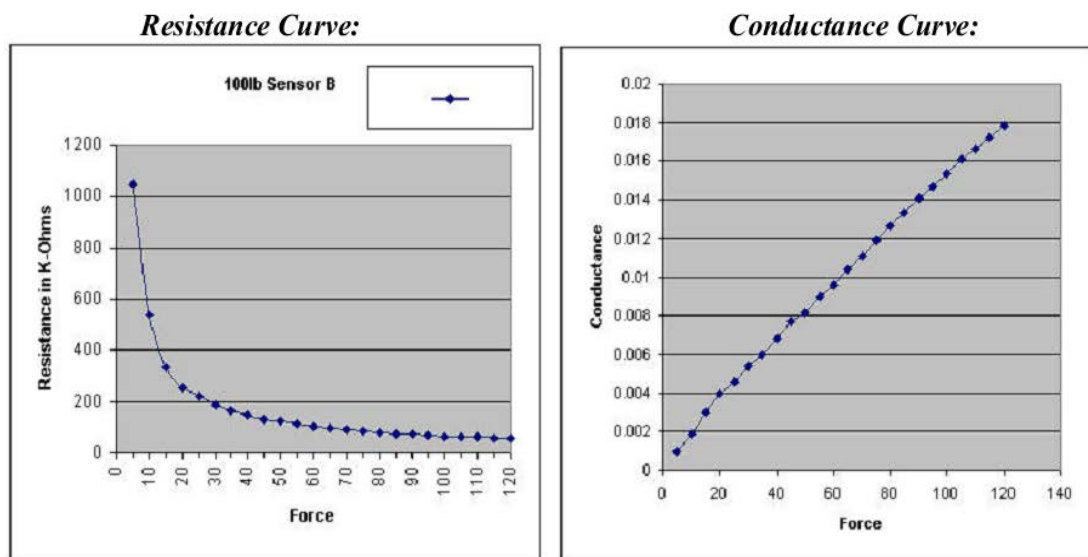


Fig 4.18: FSR Response [30]

The threshold calibration was done to detect the gait phases accurately. The threshold for each FSR (onset and offset) was set to 20% of the maximum FSR voltage output, initially. The software was later modified to adjust the thresholds automatically, for each test subject depending on the patient anthropometrics. The subject was asked to lean back and forth to get the voltage range of each sensor and it is used to detect the thresholds automatically as 20% of maximum and minimum sensor voltage output range. This procedure is desirable because the sensor output varies with each person's body weight.

4.3.5 INSOLE DATALOGGER:

Openlog sparkfun datalogger was attached to each insole system to record and compare the efficiency of xbee transmission line (fig 4.19). Openlog is simple to use and simple to change. It records the entire data that is written on the serial monitor. It can log to low-cost microSD FAT16/32 cards up to 16GB and configured to various baud rates. Once the openlog is powered up, the SD card looks for CONFIG.TXT file or else it will create the default config file [31]. The blinking blue LED indicates the logging of data. Openlog creates a new text file (LOG##.TXT) every time the arduino board was turned ON. The default config file has one line (9600, **26**, **3**, **0**). Each value is separated by a comma:

- **9600**: The communication baud rate. 9600bps by default. Acceptable values are 2400, 4800, 19200, 38400, 57600, 115200.
- **26**: The [ASCII](<http://www.asciitable.com>) value (in decimal form) for the escape character. 26 is ctrl+z. 36 is '\$'.

- **3**: The number of escape characters required. By default it is three so you must hit ctrl+z three time to drop to command mode.
- **0**: System mode. OpenLog starts in newlog mode ('0') by default. Acceptable values are 0 = New Log, 1 = Sequential Log, or 2 = Command mode.

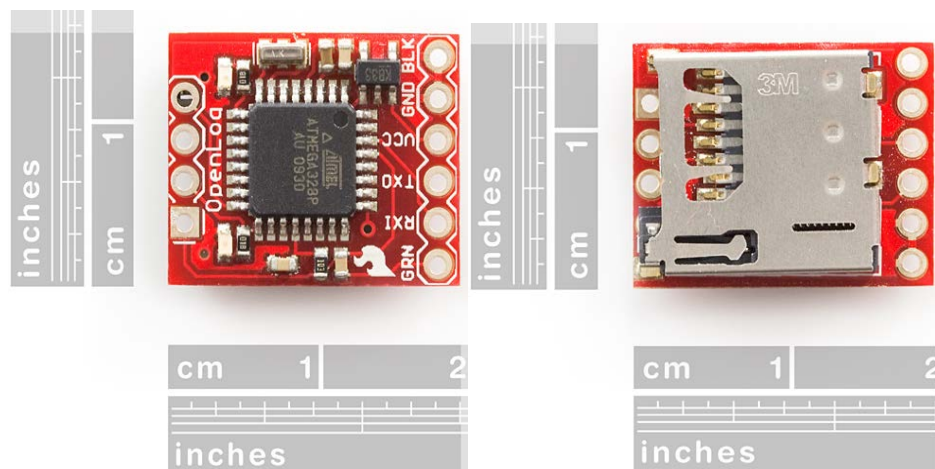


FIG 4.19: Sparkfun Openlog open source datalogger [31]

4.4 ALGORITHMS TO DETERMINE TEMPORAL GAIT ASYMMETRY:

4.4.1 FUZZY INTERFERENCE GAIT PHASE DETECTION ALGORITHM:

The F-Scan insoles have approximately 960 sensors which could record and generate the “M” shaped vertical ground reaction force (VGRF) curve whereas the smart insoles were designed with only three FSRs by considering certain factors like latency, low power consumption transmission device. Moreover, the FSRs in H, M and L were found to be sufficient to detect the four gait phases. Hence using the F-Scan system, the force versus time curve on the FSR locations (H, M and L) were compared and analyzed with the VGRF (fig 4.20). With reference to the fig 4.21, the fuzzy logic gait phase

detection algorithm examines the load on the Heel FSR and the forefoot (T) (average of M and L) FSR. Figure represents the force on the FSRs (H and T) per gait cycle.

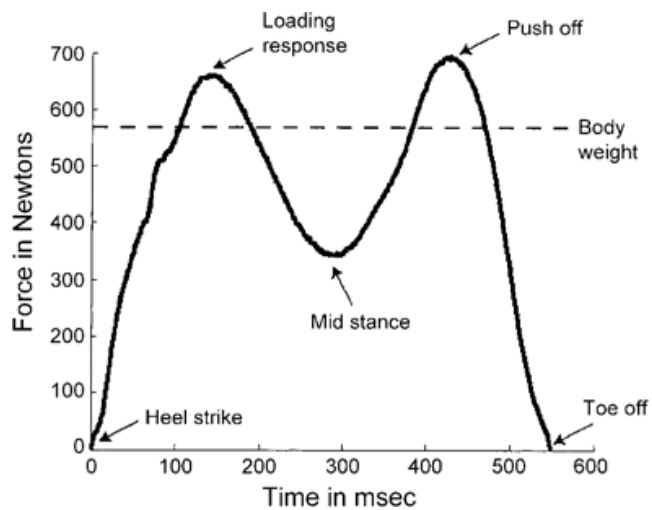


Fig 4.20: Detection of gait phases using “M” curve

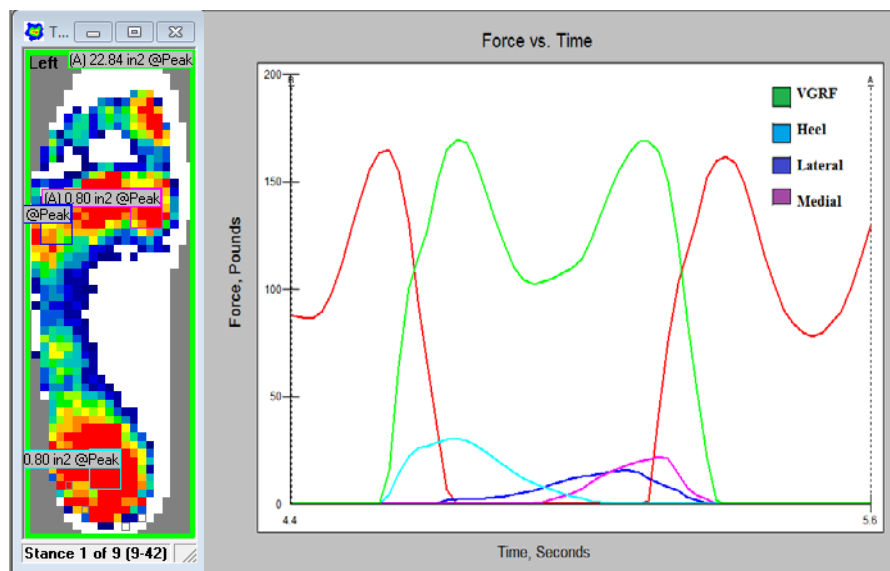


Fig 4.21: Comparison of F-Scan VGRF and force on H, M and L

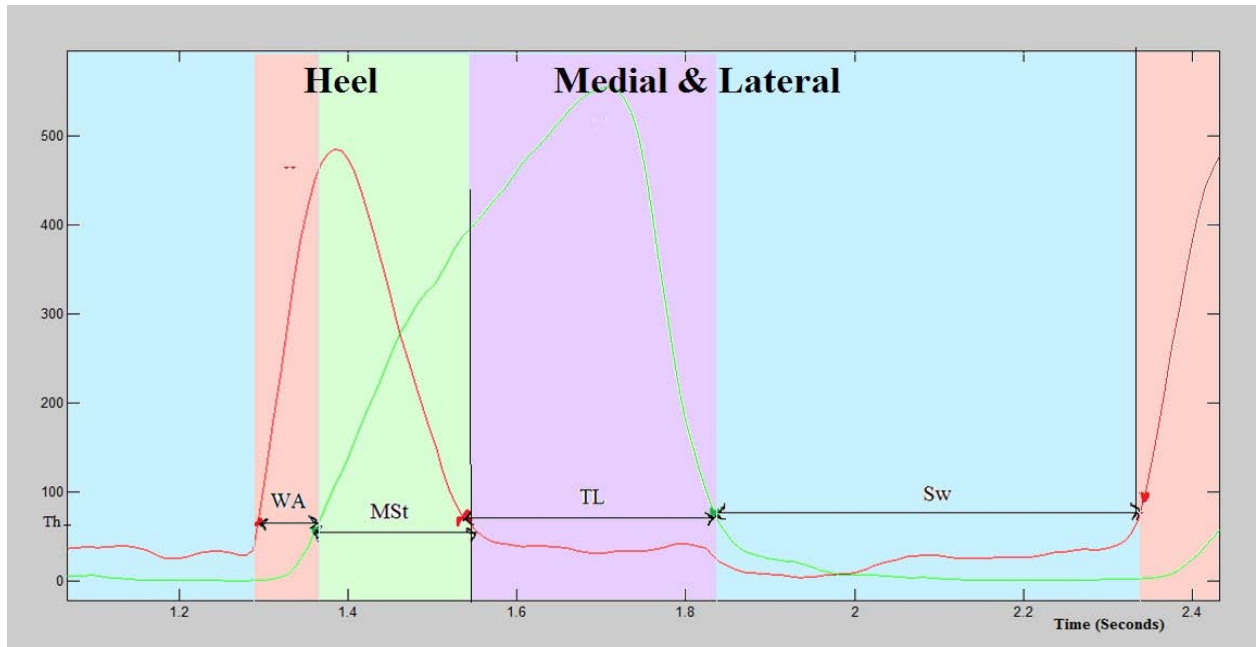


Fig 4.22: Detection of gait phases using smart insole.
X-axis: Time (seconds), Y-axis: Arbitrary digital voltage output

The fuzzy logic gait phase detection algorithm (fig 4.2) was developed based on the foot plantar pressure bearing points during different gait phases. As explained in section 4.2, the FSRs were placed on Heel, Meta-tarsal 1 (medial) and Meta-tarsal 5 (lateral). Based on fig 4.23, the fuzzy logic system was developed depending on the load on each FSR during the four phases of the gait.

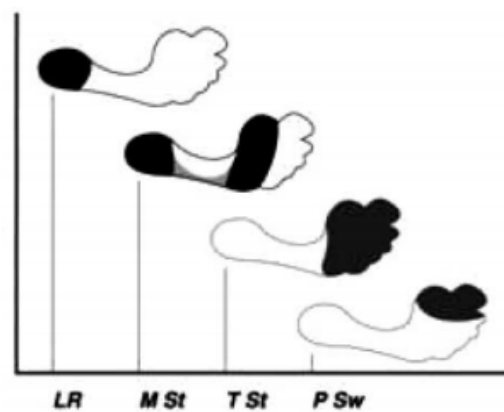














Fig 4.23: Gait phase vs pressure bearing points

The smart insole system was programmed to detect four phases (WA, Mst, TL, Sw) – three stance phases and a swing phase (table 4.1).

Table 4.1: Insole gait phases

GAIT PHASE	Insole Gait Phases
Initial Contact	Weight Acceptance (WA)
Loading Response	
Mid Stance	Mst
Terminal Stance	Toe Load (TL)
Pre Swing	
Initial Swing	Swing (Sw)
Mid Swing	
Terminal Swing	

Table 4.2: Fuzzy Interference System for Gait Phase Detection
* Black Circle (3rd row) represents loading on the FSR

Perry's Gait Phase				
Gait (Prosthetic Limb)				
Load on FSRs*				
[H M L]	[1 0 0]	[1 1 1]	[0 1 1]	[0 0 0]
Insole Gait Phases	WA	MSt	TL	Sw

4.4.2 CALCULATION OF PHASE DURATIONS:

The fuzzy interference phase detection algorithm detects the four phases and the output is sent to the phase duration calculation algorithm. The MATLAB takes the timestamp at every change in phase and it calculates the duration of each phase (fig 4.24). Using the moving average filter, the phase durations of four steps are averaged at the end of each gait cycle. The algorithm calculates the phase durations of both the limbs simultaneously and the symmetry index of each phase at the end of a cycle is monitored real-time.

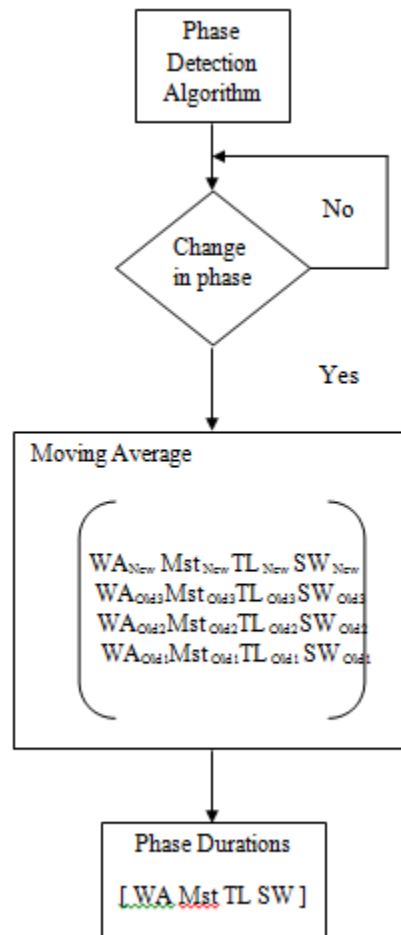


Fig 4.24: Phase duration calculation algorithm

4.5 STATE DIAGRAM FOR GAIT DEVIATION DETECTION

Gait deviations exhibited by unilateral lower-limb amputees are numerous and certain deviations could be detected by the pattern of each gait cycle. The normal gait cycle goes through all four phases of the gait (fig 4.25, black line). Table 4.3 identifies some of the gait deviations with respect to the progression of gait phases. The phase duration asymmetry in any of the gait phases was found to assist the gait deviation detection. For example, greater asymmetry in TL implies the insufficient or prolonged time spent on the Toe Load. Therefore, using the GUI display, the related deviations could be assessed.

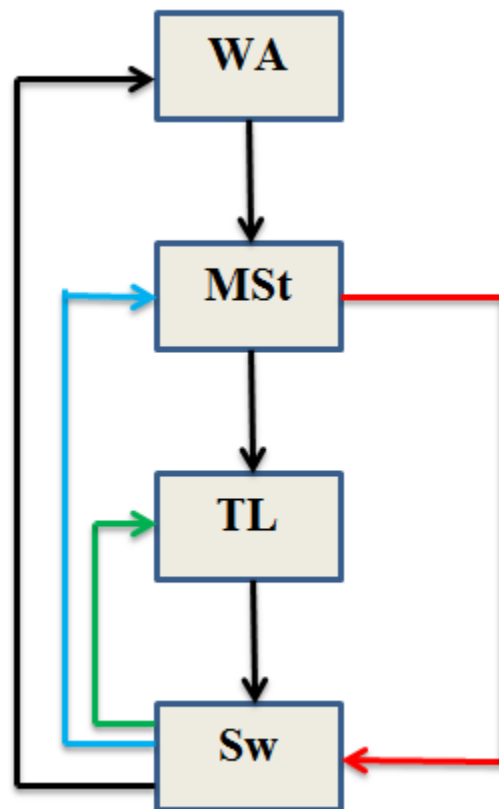


Fig 4.25: Algorithm to Detect Gait Deviation

Table 4.3: Gait deviation detection

Progression of Gait Phases	Gait Assessment
WA → MSt → TL → Sw → WA	Normal (Black line)
WA → MSt → Sw → WA	Not enough load on the toe – Heel Walker (Red line)
TL → Sw → TL	Toe walker (Green line)
MSt → TL → Sw → MSt	Vaulting on the other limb (Blue line)

4.6 INSOLE QUALITY ASSURANCE TEST:

Here is a list of typical malfunctions that were witnessed during the production or testing of the insole systems:

- Sensor values that “float” at approximately 1.65 V (or around 512 digital).
 - This is most likely due to a sensor that is disconnected from its pull-down resistor, which grounds the output when the FSR is at maximum resistance (no load).
- Saturating sensor values was experienced under three conditions.
 - The FSR substrate is damaged due to excessive loading
 - The FSR is directly sprayed with an adhesive
 - A soldering iron was applied (a) too close to the FSR, or (b) for too long to the FSR, thus damaging the FSR substrate

In either case, the FSR should be replaced

- The FSR is reporting 0V regardless of loading
 - Sometimes the 3.3V pin on the Arduino Fio does not actually provide 3.3V, in which case it should be shorted to Aref
- When one FSR is loaded, more than one FSR responds, this is most certainly a short.

Check the following:

- Make sure that the solder joints on the resistors and on the connector aren't accidentally shorted together
- Ensure that the wires from the FSRs in the insole aren't shorted together. This can happen when either (a) hot glue is applied to the wires, or (b) the heat gun is applied to the shrink tubing for a prolonged period. In either case, the surrounding plastic sheath can melt, thus shorting the internal wires.
- The data rate is slow or stops
 - This can happen if there is poor RF communication between the insole Tx and the computer Rx radios. Ensure that both radios have ceramic antennas attached, and that there is a line of sight between the radios.
 - Check the battery of the Rx radio

4.7 INSOLE TEST ON CONTROLS AND UNI-LATERAL TFA:

The developed insoles were tested with a healthy non-amputee and a uni-lateral transfemoral amputee (TFA). Gait data were collected simultaneously from both F-Scan system and the smart insole system to determine the validity of in-soles in accurately detecting the temporal parameters. The F-Scan insole sensors were placed inside the shoe and it was ensured that there were no wrinkles in the F-Scan insole. The smart insoles

were placed on top of the F-scan sensors. Subjects were then asked to walk along a level walkway of 30 feet, and ascend and descend a 24 feet long wooden ramp inclined at 5 degrees. The temporal gait parameters measured and computed from these systems were compared and analyzed. The phase detection algorithm was found to give erroneous output with the amputee gait. Upon troubleshooting procedure, the problem was found to be with the misplacement of sensors in prosthetic insole. The appropriate location of sensors on the prosthetic foot could be determined only by analyzing its maximum pressure bearing points during each phase of the gait. The prosthetic foot used for this study was Re-Flex VSP foot which is inserted in the foot shell (fig 4.26). The selection locations in prosthetic insole determined using PressureStat may not be appropriate because the pressure bearing points were reflected by the prosthetic foot and not the foot shell.



Fig 4.26: Re-Flex VSP foot with Foot Shell

4.8 DESIGN USING F-SCAN DATA WITH PROPRIO FEET:

The maximum pressure bearing points are different for different prosthetic foot designs. For this study, the Re-Flex VSP foot was used. F-scan data from 10 TTAs (fig 4.27(b)) using the Proprio foot was used to estimate the location of maximum plantar pressure areas during gait. The Proprio foot was used as its foot plate is similar in design to the Re-Flex VSP foot (fig 4.27(a)).



Fig 4.27 (a): Proprio foot and Re-Flex VSP Foot

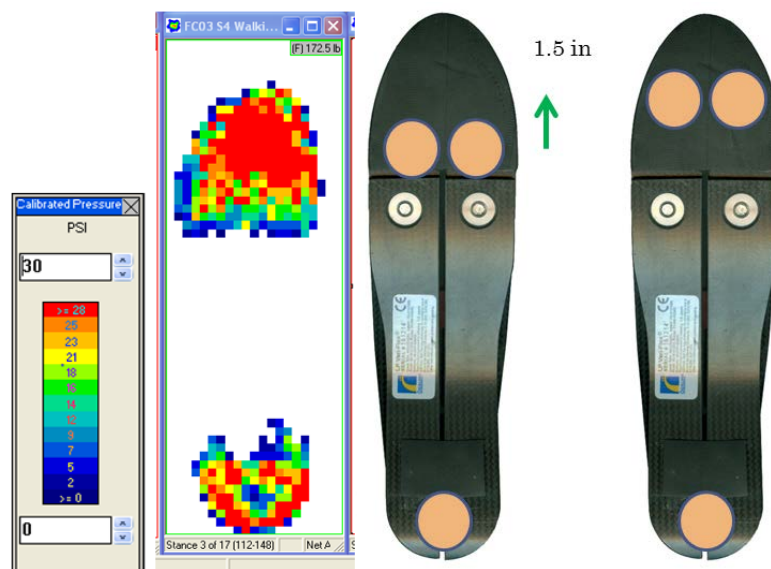


Fig 4.27 (b): F-Scan representation of pressure bearing points on the prosthetic foot

The F-Scan gait data representation is shown in fig 4.27(b). Red color denotes the maximum pressure and blue denotes the minimum pressure. The dimension of each sensel including the row and column spacing was found to be 0.2 in x 0.2 in. Using the dimensions of each sensel (fig 3.2) in the F-Scan insole and the subjects' foot size, the locations of the sensors in the prosthetic foot were determined. As a result, the medial and lateral sensors in the prosthetic insole were found to be off by 1.5 inches vertically and they were placed horizontally side by side.



Fig 4.28: Simulator boots

4.9 GAIT ASSESSMENT USING SMART INSOLE SYSTEM

The wireless instrumented smart insole system was tested and temporal gait parameters were calculated (table 4.4, 4.5) with a healthy non-amputee and another non-

amputee using simulator boots to mimic bilateral TTA gait (simulator boots fig 4.28). The insole was compared with the F-Scan data and the error percentage was calculated using the formula:

$$\% \text{ Error} = [(\text{Insole data} - \text{FScan data}) / \text{F-Scan} * 100]$$

Table 4.4: % Error of Insole data from F-Scan data – Non-amputees

Activity	Healthy Non-Amputee % ERROR [(Insole-Fscan)/Fscan*100]			
	WA_L	MST_L	TST_L	SW_L
LW	6.84	8.22	-5.09	-6.14
RI	-2.11	18.18	-8.25	4.91
RD	63.08	68.57	32.08	6.28

Table 4.5: % Error of Insole data from F-Scan data – Simulator boots

Activity	Simulator boots % ERROR [(Insole-Fscan)/Fscan*100]			
	WA_L	MST_L	TST_L	SW_L
LW	-4.66	19.09	-92.17	-61.63
RI	-84.88	-16.62	-60.66	-39.97
RD	-61.22	-16.19	-56.08	-37.26

4.10 DISCUSSION:

4.10.1 NEED FOR INSOLE SYSTEM

The conventional motion capture system, force plates, insole plantar pressure measurement system provides accurate temporal gait measures with the expense of cumbersome equipment, labor-intense user interface and heavy on-body sensors. Perhaps several different wireless instrumented insole systems were designed to be clinically

friendly, ease of use of equipment at the expense of accuracy. This ambulatory insole system can be carried by the subject and allows self-data collection. The symmetry measures using the insole system requires more accurate and robust gait phase detection algorithm which in turn provides the accurate gait phase durations.

Unlike other systems, the smart insole is more user-friendly and the temporal gait symmetry could be assessed real-time. The common amputee gait deviations like vaulting, medial or lateral whip could be assessed with a fact that they often tend to skip/prolong few gait phases on one of the limbs which in turn results in the asymmetrical gait. The assessment and correction of amputee gait requires data on several continuous gait cycles. The smart insole system allows the clinician to assess the temporal symmetry on each phase of the gait real-time.

DISCUSSION:

4.10.2 CHALLENGES IN INSOLE DESIGN

Upon analysis of insole data from non-amputees, the appropriate locations of sensor in human foot were found as – Heel, Meta-tarsal 1 and Meta-tarsal 5. As the anatomy and size of human foot is highly variable, it is challenging to design a standard insole for specific shoe size. For this research project, the insoles were custom designed for each subject based on foot print obtained from PressureStat film. However, the insole design for amputated limb could be standardized depending on the design of prosthetic feet. The sensors locations in the prosthetic foot could be accurately determined by the analyzing the maximum pressure bearing points during each gait phase using insole foot plantar pressure measurement system such as F-Scan system and Pedar system.

The key sensor requirements include - linearity, minimal hysteresis, durability, repeatability, sensing size and pressure range. Most currently designed insoles use Interlink Electronics sensors which are comparatively less durable and have lower pressure sensing range. The insoles sensors should atleast be sensitive up to 100 lbs (50% of body weight in average).

Calibration of FSRs is another challenging task. FSRs are non-linear sensors and the estimation of applied force could be studied by the conductance-force relationship as the conductance has approximate linear relationship with the applied force. For dynamic pressure study, it is important to condition the sensors as mentioned in datasheet/manual. It helps to reduce the effect of drift and hysteresis. All new sensors are conditioned by placing 110% of the test weight on the sensor which allow the sensor to stabilize, and then remove the weight. The interface between the sensor and the test subject material should be the same during conditioning as during calibration and actual testing.

The applications of sensors in which they are subjected to severe conditions, such as against sharp edges, or shear forces affects the sensor life. The insole sensors should atleast be durable for about 1 million steps. After each insole design, visually inspection of the sensors for physical damage was done. It is also important to keep the sensing area of the sensor clean. Any deposits on this area will create uneven loading, and will cause saturation to occur at lower applied forces.

The key requirements of the insole instrumentation (microcontroller with the circuit board and a radio) includes small, light weighted, cased, limited wired. The radios in the microcontroller should have a good antenna for the better transmission of data. The pull-down resistor R, in the voltage divider circuit determined the sensitivity of the digital

voltage output. The value of R could be best determined by using the potentiometer (variable resistor) to obtain good sensitivity.

The accuracy of phase detection algorithm has its importance in the appropriate determination of threshold values. The real-time adaptive thresholds based on the sensor output could improve the robustness of the phase detection algorithm. In this research project, the thresholds were set to 20% of max –min sensor output on maximum applied force.

Arduino Fio was used in the smart insole system due to its size and its compatibility with Xbee radios. The firmware code could be flashed to the arduino fio using programming radio. The data from arduino radio is transmitted to the programming radio as long as it is connected to the PC and this may cause trouble which flashing the new firmware code. Hence the arduino boards should to reset at the moment of uploading the firmware code.

The temporal gait measurement using the insole system could provide sufficient data on the stance phase and not the swing phase. Hence the assessment of swing phase could be done by knee angle measurements. The addition of knee angle information to the insole data could also improve the accuracy of phase detection algorithm. Moreover, the knee angle data is necessary to study the various other activities like sit-to-stand, stand-to-sit, stairs ascend and descend. The bilateral temporal symmetry measures require the synchronization of more than one system/sensor output.

The detection of gait events/phases is the key to the measurement of temporal gait parameters and the symmetry index. In this research project, the phase detection algorithm requires four thresholds – Heel_{ON}, Heel_{OFF}, Toe_{ON} and Toe_{OFF}. As seen in

table 14 and 15, the error percentage of insole data from the F-scan data in certain gait phases/activities. This error percentage could be reduced by setting adaptive thresholds or using the detecting peaks and the intersection points between heel and toe sensor output.

5

CONCLUSION & FUTURE WORK

5.1 CONCLUSION:

Gait phase duration symmetry should be monitored in the unilateral lower limb amputees for the accurate detection of certain gait deviations. Healthy non-amputees are found to be more symmetric in the phase durations between their either limbs. In amputees greater symmetry was found in some of the phases however the stance and swing periods were found to be symmetric. Previous method of gait analyzing techniques assessed only the stance and swing symmetry which does not provide enough information on the prosthetic gait. Hence the phase duration asymmetry should be monitored real-time. Current technologies on the foot plantar pressure measurement mainly include force plates and certain labor intense insole system. But in this research project, a wireless smart insole system was developed using the arduino microcontrollers. The selection of appropriate sensor for the study and location of Force Sensitive Resistors (FSRs) on the insole was accurately determined. The difference in the design of insole for prosthetic foot from the anatomical foot was analyzed and methods to obtain a standard prosthetic foot design were developed. The signals from each FSRs was wirelessly transmitted to the computer using xbee radios. The computer acts as the control unit in

which the phase detection algorithm and algorithms to assess the phase duration symmetry and detect the related deviations were implemented using the MATLAB software. Hence the gait assessment on unilateral lower-limb amputees could be done real-time using the developed wireless instrumented insole system.

5.2 FUTURE WORK:

The possible future work include

1. Development of an on-body control unit implemented with the phase detection and phase duration symmetry calculation algorithm which would enable the real-time feedback given to amputees.
2. Set adaptive thresholds for the gait phase detection.
3. Derive the conversion factor to determine the pressure applied on the FSR proportional to the voltage output.
4. The developed smart insole system provides information on kinetic data (parameters based on foot plantar pressure distribution). Motion analysis requires kinematic data from several body segments which could be obtained from Inertial Measurement Units (IMUs). It consists of triple axis accelerometer, gyroscopes and magnetometer.
5. Inertial Measurement Units (IMUs) should be used along in synchronization with the insole sensors to analyze the swing phase and to detect certain gait deviations that occur due to trunk rotation, external limb rotations etc., as insole system alone is unable to detect those deviations.

6. Implementation of artificial intelligence, neural networks towards the development of robust and reliable gait correction model.
7. The real-time instrumented gait feedback should be able to discriminate the amputee gait deviation versus mal-alignment of prosthetic fit. The portable gait analysis system should be built with its own artificial intelligence such that it should not require any kind of clinician's visual observation.
8. Obtaining normative sensor data during various functional activities and various temporal and spatial parameters.
9. Determination of calibration or conversion factor between the gait parameter and sensor data.

6

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