Provision of Sensory Feedback System to the Trans-femoral Amputees on the Basis of Centre of Pressure

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A thesis submitted in partial fulfillment of the requirements of the degree of MS Biomedical Sciences

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Dedicated to the most Courageous & Inspirational Woman,
My Mother- Ms. Saima Bilal

Abstract

Somatosensory feedback provided by skin, joint and muscle's receptors play an important role to maintain gait balance and allow movements to humans. Amputation i.e., loss of limb or a part of it causes loss of the respective functions and also affects the quality of life of the amputee. Physical rehabilitation of amputees via prosthetic devices is not new but the most difficult task is to help amputees use such devices effectively.

With trans-femoral amputation there is significant loss of proprioceptors. Center of Pressure (COP) is the point of application ground reaction force acts as weighted average of all the forces acting on the body during standing and walking. COP is responsible for an appropriate balance and coordination to be maintained.

In this study, a technique has been devised to map COP in trans-femoral amputees. The COP is mapped with help of a specialized insole that houses piezo resistive sensors. The mapped COP is then transformed into a systematic haptic feedback via a control algorithm generated by microcontroller. This systematic haptic feedback controls the vibro-tactile units placed at specified regions of the stump. Vibro-tactiles units provide output stimulation to the specified region allowing the amputee to get improvised sensation of a compromised gait pattern.

A GUI for clinicians which will help him to get real time awareness of overall walking pattern of amputee and thus guide him accordingly.

In this way we are helping the amputee to get physical feedback from ground to the stump and also helping clinician to train his patient efficiently with minimal time as clinician may be able to analyze walking and standing errors in real time.

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List of Abbreviations

CoP	**Centre of Pressure**
CoG	**Centre of Gravity**
GRF	**Ground Reaction Force**
TFA	**Trans-femoral Amputee**
TFP	**Trans-femoral Prosthesis**
FSR	**Force Sensitive Resistor**
VTU	**Vibro-Tactile Unit**
BT	**Bluetooth**

1 Introduction

1.1 Background

Many people suffer from diminished sensory feedback, which in turn obstruct their everyday proprioception. By birth physiological impairments or developmental issues, traumatically induced injuries or amputations, each of them contribute to various levels of lack of proper sense of positioning as a result of lack of feedback from ground(Brose et al., 2010).

Although, a huge amount of research is carrying out to improve mechanical functionality of lower limb prosthesis but, the area of research where we need to provide the prosthetic leg user with appropriate sense of positioning, is still empty(R.E. Fan et al., 2008). Henceforth, suboptimal gait pattern with an increased demand of energy is reportedly experienced by above knee amputees specifically(Richard E Fan et al.). The utilization of functional electrical stimulation in amputations of upper limb particularly trans-radial seems to improve sensory response of the remaining limb(Patterson & Katz, 1992). But utilization of similar procedure for above knee amputations is not ye evaluated.

Such problems increase the burden over rehabilitation clinics as it requires a large number of resources and time duration to make the amputees learn the optimal use of the prosthetic leg. To improve this diminished sense of positioning in above knee amputees, mapping of centre of pressure can be utilized as an effective source to provide feedback to the amputee from ground(Han, Paik, & Im, 1999).

1.2 Problem Statement

Lack of center of pressure (COP) feedback contributes following in trans-femoral amputees wider steps than able-bodied subjects, asymmetric walking, increased variability in the medio-lateral acceleration of the trunk, inferior standing balance & increased falling rates(Martin & Gregg, 2015)(Lugade & Kaufman, 2014).

1.3 Objectives of Thesis

Thesis work was mainly focused around the following objectives:

1. Design & Manufacture a wearable insole to map pathway of Centre of Pressure (CoP)
2. Design a commercially viable and cost effective haptic feedback system for trans-femoral amputees
3. Transmit, Record & Display Plantar Pressure Data

4. Design and implement an experimental protocol for acquisition of planter pressure data
5. Validation

1.4 Significance of Study

The main idea is to design a haptic feedback system for trans-femoral amputees ensuring the restoration COP feedback in order to determine its effectiveness on standing balance, walking balance & overall gait pattern. Shoe is equipped with the pressure-sensitive insole & data acquired from the pressure-sensitive insole are coded into time-discrete stimulations by means of vibrating elements placed on the stump. The vibrating elements placed on the thigh are driven by via electronic control board.

There are no such sensory feedback systems are available for the amputee. The prosthetic leg having such feedback system will be a smart device as it shall be able to provide amputee the sensory feedback from the ground to the stump. The pressurized insole designed for this project has a unique design. Overall haptic feedback system design is user friendly and is totally hidden within the prosthetic leg; therefore, be helpful for trainers to train the subject without any hindrance.

1.5 Thesis Overview

First chapter deals with the motivation and background of the work done. In the Chapter2, there is description of normal physiological gait, trans-femoral amputation and thus identification of the key problem arising during the gait training of the amputees. The Chapter 3 deals with the methodology used to design the device and experimental protocol being employed. The Chapter 4 shows the results acquired for validation of appropriate working of device and in the last Chapter 5 conclusion and future works are discussed in detail.

2 Literature Review

2.1 Introduction to Somatosensory Feed Back

Somatosensory feedback is a varied sensory class receiving sensation from skin, mucous membranes, limbs and joints. It is also known as tactile sense, occurring on the exterior of skin and sometimes at interior as well (Sensory Functions of the Skin of Humans - Book). One should be able to differentiate that neuromuscular response is different from the somatosensory response as neuromuscular response is motor response i.e. efferent to the sensory (afferent) information.

2.1.1 Somatosensory Receptors

Receptors are defined as cells that are capable of receiving external stimuli and transmitting that particular signal to the sensory nerve. Depending on the type of signal transduces by a set of receptors somatosensory receptors are classified as mechanoreceptors, chemoreceptors, nociceptors & proprioceptors.

2.1.2 Proprioception

Proprioception is basically the sense of awareness of joint position & body orientation in space. Proprioception is working like a constant feedback loop where we are very well aware of our body position and forces acting on it(Matthews, 1988).

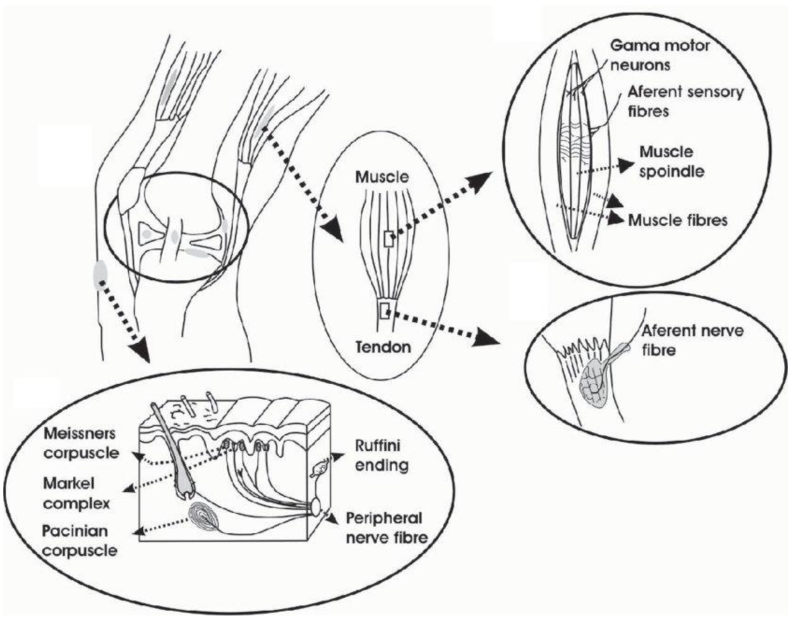


Figure 1Various Locations of Proprioceptors

Consider walking on an uneven terrain, where our foot adapts itself to walk without having a fall. The major reason for this unhindered walking is the proprioception which is created through the feedback generated when sole of feet touch the uneven ground surface and Centre of pressure thus mapped give feedback to ankle, knee and hip joints in order to have a smooth pace rather having a fall(Fukuoka, Nagata, Ishida, & Minamitani, 2001).

2.2 Gait cycle

Normal gait cycle begins with the heel strike of reference foot on the ground and subsequently when the contact of same foot comes across the ground for the second time.

Some terminologies are required to be mentioned here in order to have complete understanding of gait cycle. These terminologies are below:

A. **Stride Length**: It is commonly known as measure of successive heel contact of same foot.
B. **Step Length**: Distance which is measured from the heel strike of one foot (say Right) to the heel strike of other Foot (say Left).
C. **Cadence**: Steps per min is cadence which is approximately 110-115/min.

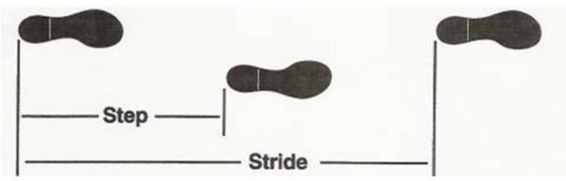


Figure 2: Step Length vs. Stride Length

2.3 Phases of Gait Cycle

Mainly gait cycle is divided into Stance and Swing phase. These phases are sub-classified as follow:

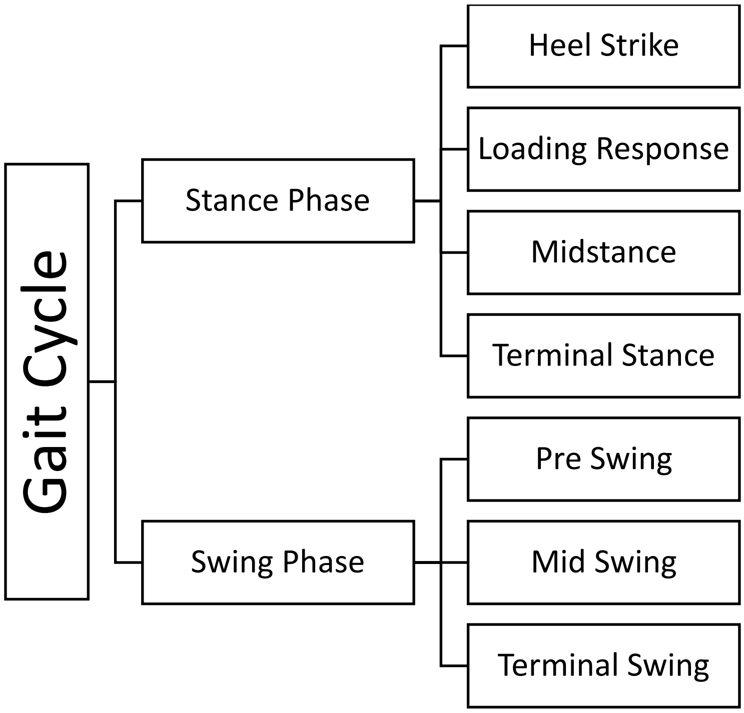


Figure 3Schematic Representation of Gait Cycle

1. **Stance Phase:**

   Stance phase initiates with the heel contact on the floor and ends when toe leaves the ground. It comprises approximately 50%-55% of gait cycle. In this phase foot maintains its contact with ground.

With reference to *Fig 1.3(A,B,C,D)* sub- phases of stance phase are defined as follow:

A. **Heel Strike (HS):** Refers to the phase when foot makes initial contact with the ground.
B. **Loading Response (LR):** Refers to foot-flat position on the ground.
C. **Mid Stance (MS):** Refers to the position where whole weight is being borne on the reference limb as the opposite limb is in swing phase.
D. **Terminal Stance (TSt):** Refers as *Push off* phase as well, comprises heel off and then toe off positions.

2. **Swing Phase:**

   Swing phase initiates right after the toes leave the ground and the reference limb swings through the air. It is non-weight bearing phase. Consider here that during mid-swing on the reference limb opposite limb is in its mid-stance phase. Henceforth, the body is said to be supported by single limb during this phase.

With reference to *Fig 1.3(E,F,G)* phases of gait cycle are defined as follow:

E. **Pre Swing (PSw):** In this phase foot begins to leave the floor.
F. **Mid-swing (MSw):** Foot swings through air during mid- swing position.
G. **Terminal Swing (TSw):** Heel of the foot approaches the ground.

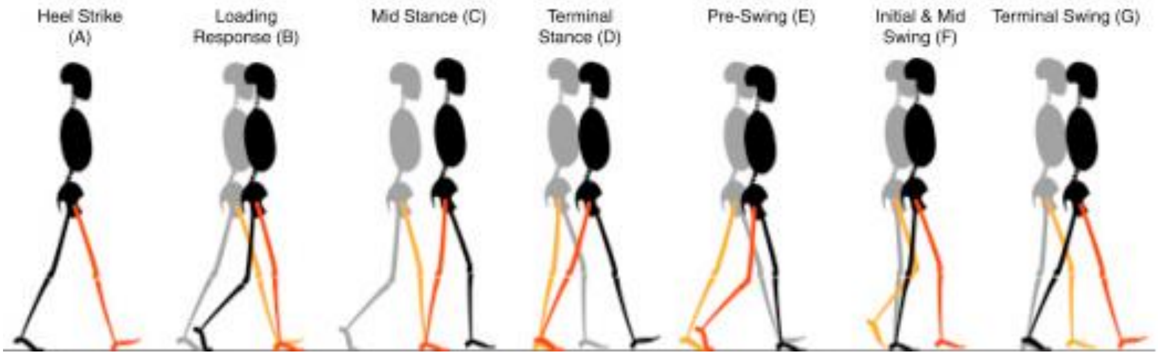


Figure 4Phases of Gait Cycle

2.3.1 Lower Limb Joints Positioning during Gait Cycle

Phase	**HS**	**LR**	**MS**	**TSt**	**PSw**	**MSw**	**TSw**
% Gait Cycle	0%	0%-12%	13%-32%	33%-50%	51%-62%	63%-80%	80%-100%
Ankle	0◦	5◦-10◦Planterflexion	5◦ Dorsiflexion	10◦ Dorsiflexion	15◦Dorsiflexion	0◦	0◦
Knee	0◦-5◦ Flexion	20◦ Flexion	0◦-5◦ Flexion	0◦-5◦ Flexion	40◦-60◦Flexion	25◦Flexion	0◦-5◦ Flexion
Hip	20◦ Flexion	20◦ Flexion	0◦ Flexion	~20◦ Hyperextension	~10◦ Hyperextension	15◦-25◦ Flexion	20◦ Flexion

Table 1: Lower Limb Joints Positioning during Gait Cycle

2.3.2 Ground Reaction Force

Normal body balance is dependent on the position of body with respect to that of supporting surface. CoG changes with the change of posture but a shift of CoP is an indirect procedure of determining total body sway. As it can be seen in *Figure 2.6* that due acceleration and then deceleration a double humped curve for ground reaction forceis plotted. The depiction of friction generated when heel touches the ground & forward pushing at the end of stance is basically due to fore aft component of force. Finally medial-lateral forces are less and most of which are directed medially(Giakas & Baltzopoulos, 1997).

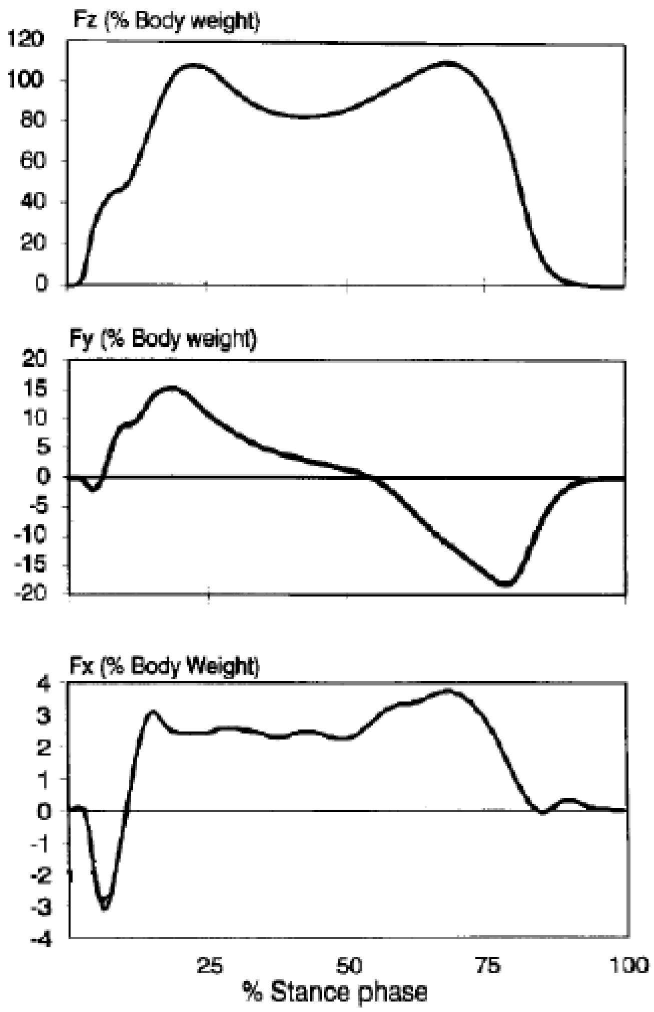


Figure 5: The three components of the ground reaction force

2.3.3 Centre of Pressure

Centre of Pressure (CoP) is defined as the point where the aggregate of pressure acts on a body, producing a force to act through that point on the body(Schmid, Beltrami, Zambarbieri, & Verni, 2005). CoP is majorly responsible for the progression of center of mass in the forward direction, whereas the center of mass is the mean position of matter in a body.

In biomechanics, CoP is the tern given to the point of application to the vector component of ground reaction force. In other words it is the position on the supporting surface where resultant vertical force would act & supporting surface in case of human body is foot(Ruhe, Fejer, & Walker, 2010).

During the gait cycle as one moves from Heel Strike (HS) i.e. beginning of stance phase to Toe Off (TO) which is making up the end stance phase and approximately 57% of the total gait cycle(Lin Shu et al., 2010).

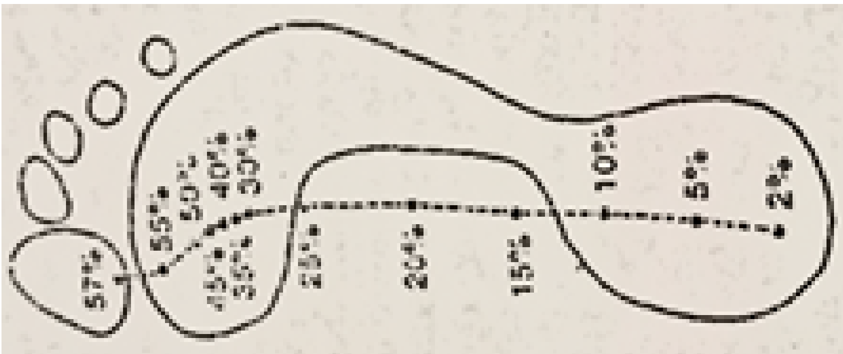


Figure 6 Progression of CoP during Gait Cycle

Body sways slightly during standing, because of this swaying center of mass (CoM) moves forward of CoP. This forward shifting will thus contribute to acceleration which is indeed angular in nature. In order to overcome this situation an individual will try to move CoP ahead of CoM. It will be helpful to revert the acceleration(Winter, 1995).

2.4 Introduction to Amputation

Amputation can be defined as the removal of a limb or a part of it and thus loss of the respective function of the anatomical structure removed.

2.4.1 Causes of Amputation

Amputation can be result of an intentional surgical procedure as in case of pathological etiology, traumatic or congenital. So far pathological causes are concerned Peripheral Vascular Diseases are commonest of all the other reasons as dyvascaular amputations are approximately 8% higher than traumatic reasoning. Diabetes Miletus, tumors, frostbite injuries, neoplasms & burns etc. are also major reasons behind the amputations.

2.5 Trans-femoral Amputation

Trans-femoral Amputation is the removal of the limb through the femoral shaft or in simpler words it is the ablation of lower limb above the knee joint. The bony resection between 12cm above the knee joint, 18cm approximately below the greater trochanter &5cm distal to lesser trochanter is considered functional for the prosthesis fitting for an average adult being.

The rehabilitation of Trans-femoral amputees (TFA) is more extensive and cumbersome in the regard of a greater loss of proprioception providing structures & henceforth requires more time period for a better rehabilitation.

By better rehabilitation here we mean the better use of prosthetic limb with far more better efficiency.

Figure 7 (a): Trans-femoral/ Above Knee Amputation (b) Trans-femoral/ Above Knee Prosthesis

2.5.1 Gait Analysis of Trans-Femoral Amputees

A lot of studies are reported so far in order to determine the kinetics and kinematics of TFA with varying types of prosthesis being used. Walking patterns in TFAs differs remarkably as compared to the normal abled being.

One of the notable parameter is reduced velocity with which a TFA walks. It is reveled in the results of a study that the reduction in walking speed is a contributor of increased angulations in the body upper to the residual limb(Goujon-Pillet, Sapin, Fodé, & Lavaste, 2008). In another study, reported results show that TFAs exhibit an asymmetrical walking pattern along with a major time during standing being spent on the sound limb(Sonja M.H.J Jagers,MD, PhD, J.Hans Arendzen, MD Phd, Henry J. de Jongh, n.d.). More muscle activity was reported in TFA during the swing phase of gait cycle along with an increased duration for double support(Eva C Wentink, Prinsen, Rietman, & Veltink, 2013).

2.5.2 Normal Prosthetic Rehabilitation Procedure

Rehabilitation program of TFA requires an elaborated knowledge of normal biomechanics. More or less each trainer has to go through followings in order to assure the maximum use of the prosthetic leg by the amputee:

1. Analysis of COG
2. Weight Bearing on Prosthesis
3. Re Educating Gait
4. Performance of Functional Tasks

The first two steps are directly linked to each other while considering the gait training of amputee. As the passage of COG is directly linked with the appropriate weight distribution on the lower limb(Robert S. Gailey, Jr., M.S.Ed. & Curtis R. Clark, n.d.).

Particular procedures significant to biomechanics involve:

1. Correct foot placement during heel strike by providing the amputee with hand rail for both sides and bearing weight on the sound limb.
2. Then transferring weight on to the prosthetic side and amputee is asked to initiate the gait cycle.
3. Lastly swing on the opposite side is being practiced by the amputee(Icrc, n.d.)(Yuen, Nelson, Peterson, Dickinson, & Dickinson, 1993).

2.5.3 Lack of COP in TFA

A prosthetic foot lacks the normal plantar aspect & all of its proprioceptors. Thus, replication of exact COP pathway during gait cycle as that of a human being is not possible. In a study when stability feedback during the gait cycle of prosthetic leg was found out, it was reported that COP pathway of prosthetic foot with respect to thigh is not aligned according to normal mechanics of human gait(Martin & Gregg, 2015). Whereas in an abled body individual, the COP follows its path from heel to toes and is the most crucial variable to quantify the dynamic balance(Lugade & Kaufman, 2014). So the lack of COP Feedback in TFA contributes a major part of asymmetric walking as no sensory clue is available(Miller, Deathe, Speechley, & Koval, 2001).

2.6 Previous Work

2.6.1 Intro to Vibro-Tactile (VT)/ Sensory Feedback System

Restoration of sense of kinesthesia is a developing area of providing rehabilitation aid to amputees. It is an established fact in literature that in current clinical practices regarding gait training of amputees the void regarding sensory clue or feedback to move is required to be filled(Zabjek & Andrysek, 2014).

A vibro tactile (VT) system generates tactile sensations on skin using the actuators sensitive to frequency on which they are being applied say for tendons ~80Hz as reported in a study when being stimulated at said frequency subjects were able to move arm at a greater range of motion(Craske, 1977). In another study pager motors were applied to upper leg and operated at different frequencies in order to check and thus analyze the effect of individual frequency and resultant outcomes in terms of stimulation(E. C. Wentink, Mulder, Rietman, & Veltink, 2011). Its effectiveness in treatment of postural stability has also been analyzed and supportive results are been reported(Rusaw, Hagberg, Nolan, & Ramstrand, 2012).

2.6.2 Intro to COP Mapping

Mapping of pressure pathway during the gait cycle is an important measure to analyses various gait parameters, temporal as well as spatial parameters(Pataky et al., 2008). Mapped COP can be a source of various applications as well(Taborri, Palermo, Rossi, & Cappa, 2016).

Various designs of insoles for pressure mapping have been introduced so far for practical applications. As in development of an insole for accurate pressure mapping key features although remain same i.e., cost effectiveness, data transfer via a wireless mode and most importantly synchronization of data in real time in order to have a fair share of analysis to be made(Ming, Konstantin, Weizman, & Woudstra, 2015).

Although commercially there are various insoles available, each of them having some accuracies and some shortcomings depending mainly upon the positioning of pressure sensors(Kanitthika & K, 2014). Potential applications of COP mapping are foot ulcers prevention, gait analysis, rehabilitation & performance analysis during various sports(Rosenbaum & Becker, 1997).

2.6.3 Concept of Gait Phase Based Stimulation of Thigh/Stump

So far it is cleared that COP travels abnormally in TFA contributes difficulty in mimicking normal gait(Nolan et al., 2003). Temporal stability also reduces due to lack of feedback from ground contributes relative increase in vertical ground reaction force(Nolan et al., 2003). Henceforth, research regarding the provision of phase based stimulation during gait cycles is an emerging area of study.

Restoration of sense of positioning i.e. proprioception, is thus, thought to be recovered to near normal when a certain computed variable relevant to COP is utilized to generate stimulations to specified region of limb/ stump(Tucker et al., 2015). Such systems are often known as haptic feedback system and such systems are been under testing to analyze the overall effect on biomechanics(M.-Y. Lee, Chang, & Ku, 2008),(Bril et al., 2016),(Femery, Moretto, Hespel, Thévenon, & Lensel, 2004).

Different designs have been introduced on the concept of mapping of COP and different studies have been carried out. In one study they have used force sensors insole and actuators on the whole thigh. Study was mainly focused on constant vs feedback in the direction of error to access the response of abled bodied subjects as they have tried to study the main kienesological parameters of gait cycle through this study(Plauch et al., 2016). The shortcoming of the design was lying in an unnecessary number of actuators around the thigh.

In another study, insole embedded with force/ pressure mapping sensors was used. Three actuators on the stump were placed and operated in accordance to phase based feedback mechanism. This system was less efficient as the actuators were remotely operated through PC rather than working via an electronic board(Crea et al., 2015).

2.7 Summary

This chapter highlights the parameters of normal gait cycle. It also elaborates that how the gait cycle of trans-femoral amputees is effected due to lack of feedback from the ground. This lack of feedback contributes increased training duration for TFAs and thus burden over the rehabilitation clinics. Moreover work done previously to ensure the appropriate pressure mapping from the planter aspect of foot and application of VTU on stump to generate tactile stimulations is discussed.

3 Research Methodology

3.1 Work Flow

The research methodology of thesis work revolves around the basic objectives, enlisted in Chapter1, Section 1.3.

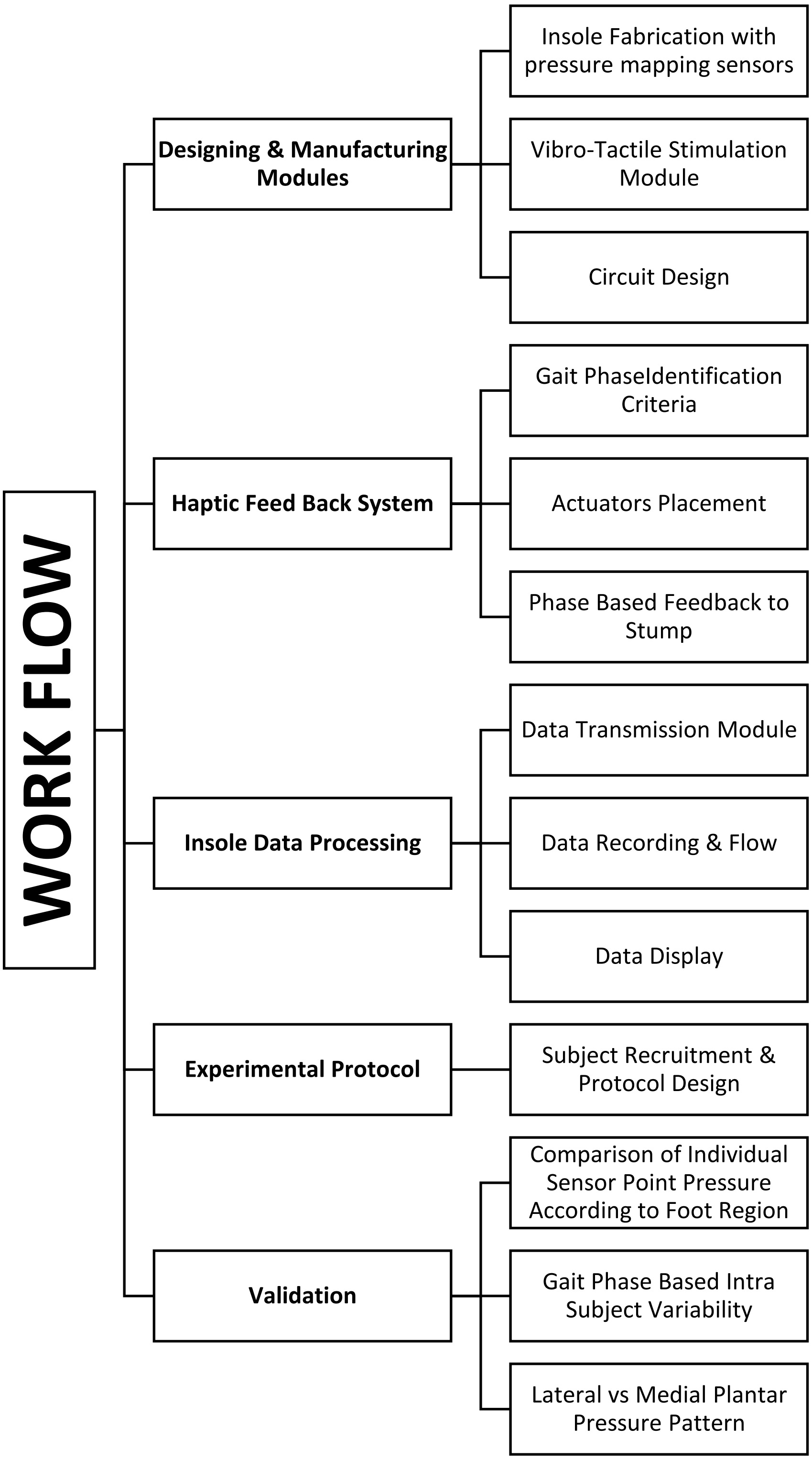


Figure 8 Work Flow

3.2 Designing & Manufacturing Modules

Designing and manufacturing of device has three basic modules as follow:

1. Insole Fabrication with Pressure Mapping Sensors
2. Vibro-Tactile Stimulation Module
3. Circuit Design

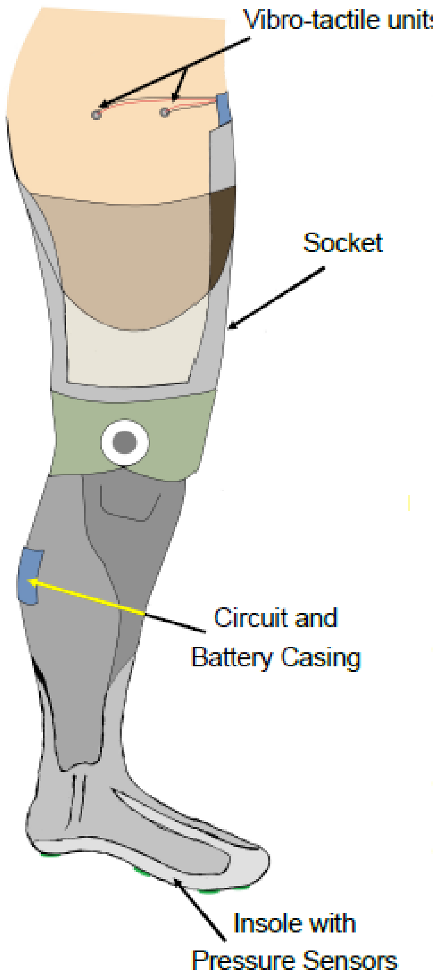


Figure 9Concept of the Wearable Feedback System

Data from pressure sensitive insole is mapped through the electronic board and microcontroller housed in casing. The case is secured to calf region by using Velcro Straps and the same electronic board operates the vibrating bodies placed on the stump through the time discrete signal being sent through the insole data. The vibrating bodies will then generate tactile stimulation on the stump region. (Details will be explained in Section-------)

3.2.1 Insole Fabrication with Pressure Mapping Sensors

CoP mapping through pressure mats, force plates, motion capture systems are opening new horizons in rehabilitative practice(Ming-Yih Lee & Yang, 2011)(Yang et al., 2012). In different studies various designs for dynamic pressure mapping have been introduced. Force sensitive resistors (FSR) have been utilized in a number of studies but somewhere accuracy regarding the calculation of vertical force has been compromised(Lincoln & Bamberg, 2010)(Bamberg, Benbasat, Scarborough, Krebs, & Paradiso, 2008)(Howell, 2012). Some commercially available insoles are quite accurate but the prices are very high.

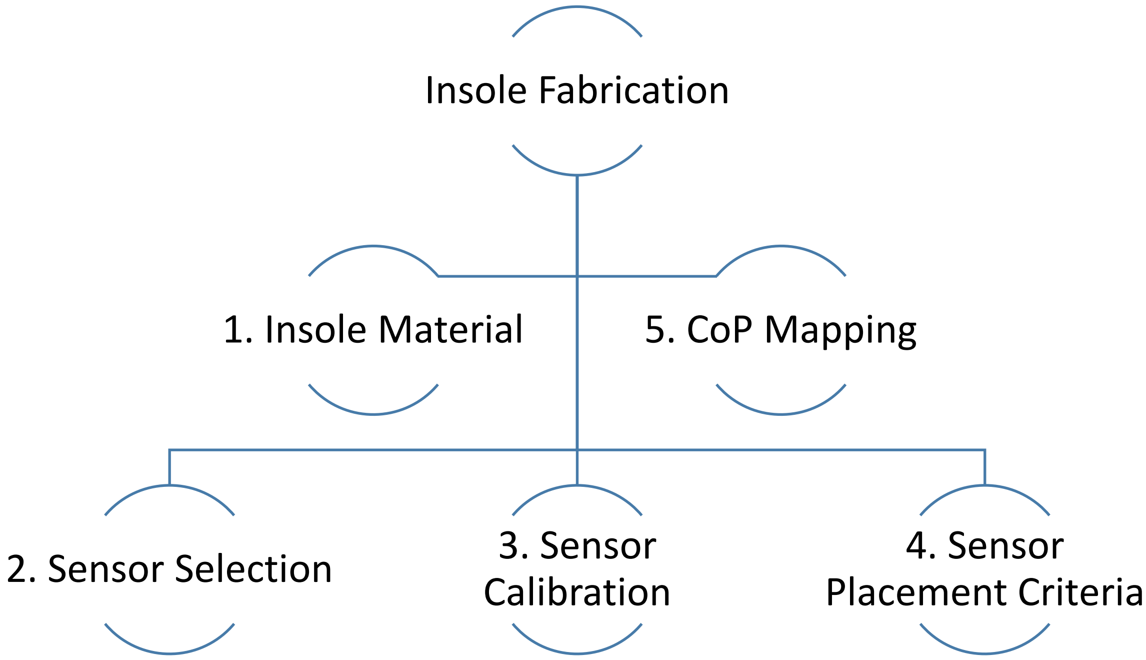


Figure 10Steps Involve in Insole Fabrication

3.2.1.1 Insole Design Requirements

An insole thus designed was required to fulfill the following requirements:

1. Accurate mapping of vertical force being exerted on the sensors.
2. Allow normal walking without any change in normal gait pattern.
3. Be comfortable.
4. It must be light in weight(Bamberg et al., 2008).
5. Must be placed in any shoes without any hindrance.
6. Wiring must not be providing any hindrance in normal walking.
7. Withstand temperature conditions within the shoes 25° C- 45° C.
8. Power Consumption must be enough to support dynamic device design.
9. Cost Effective.

3.2.1.2 Insole Material

Insole material must be comfortable, flexible and strengthen enough to support the amount of forces being exerted to it. For the said purpose, Pellite is selected. It is the readily available and moreover it can be fabricated very easily. Besides this, flexibility & comfort level provision are also the reasons of its selection. 5mm Pellite sheet is chosen, as it will allow the insole to be placed inside the shoes without any interference. Sensors will be placed over the insole being fabricated from the sheet.

Figure 11Pellite Sheet

As the sensors are to be place on the upper side and wiring is to be passed from the underside of the insole, a sheet to cover the insole from both sides is needed. Rexine Sheet is the appropriate choice. This material is labelled as high resistant to flexion, puncture and tear. Moreover it is fairly strong when it comes to tensile forces. One of the objectives while designing the insole is to withstand the temperature conditions. Rexine is the material of choice to achieve this objective as well. It allows better temperature and will not let the moisture amount to be increased above a certain level. As increased amount of moisture will cause increase chances of slipping. These properties are required to avoid any damage to sensors, the pucks of 8mm Pellite placed over sensors, and the wiring passing through underside of sensors.

It should be noted here that both of the materials utilized are very cheap and readily available in market.

Figure 12A Patch of Rexine Sheet

3.2.1.3 Sensor Selection

The basic of concept of the insole design is to place sensors strategically on the areas where most of the body forces are being exerting during walking as determined from(Kanitthika & K, 2014)(Shu et al., 2010). (This criterion is described in detail in the following section). The pucks are used to concentrate the force on the sensing part of the sensor.

Among the available options for force measurements, strain gauge is one of the most commonly used one. But they are not suitable for the application of insole primarily because of its size. Secondly, say if we somehow manage to arrange one of smaller size, still the range up to which it can measure is ~10N, which is very low to map accurately the force per unit are being exerted.

FSR have been utilized in some previous studies(Lincoln & Bamberg, 2010)(Veltink, Liedtke, Droog, & vanderKooij, 2005). They determine the force when it is applied perpendicular to their surface. They are cost effective as well as highly flexible. Their flexibility makes them suitable for the application we are concerned with. But they are devoid of the linearity and the accuracy we are also concerned with.

Commercially various kinds of FSR to measure force are available, though when comparison of FSR by Interlink Electronics and FlexiForce sensors is carried out, it’s clear that

FlexiForce sensors are much better and suitable for the application. FlexiForce sensors come in various varieties and the most appropriate for the project is FlexiForce A201®(Manual) .

Characteristic	**FSR**	**FlexiForce A201®**
Linearity	Non Linear Response	±3%
Range	0.2N-20N	0 -100 N, 440 N
Temperature	-40° C to 85° C	9° C to 60° C.
Hysteresis	10%	4.5%
Repeatability	± -2%	± -2.5%
Rise Time	< 03 microseconds	< 05 microseconds
Thickness	0.3mm	0.203mm
Senssing Area Diameter	5mm, 12.7mm	9.53mm

Table 2 Comparison of FSR and FlexiForce A201®

Figure 13FlexiForce A201®

3.2.1.4 Sensor Calibration Method

In order to get understanding of sensor calibration, a brief detail of sensor working is required to be understood.

FlexiForce A201® sensors are piezo-resistive in nature. Being ultra-thin, makes these sensors ideal for non-intrusive forces which exerts during walking. Two layer substrate of polyester film is utilized in the composition of these sensors. A conductive layer followed by pressure sensitive ink and then utilization of an adhesive to bind these two layers complete the composition of the material.

In order to map forces following circuit diagram is recommended by Tekscan. These sensors simply utilized an OP Amp to amplify the value of voltage being generated every time when force is applied.

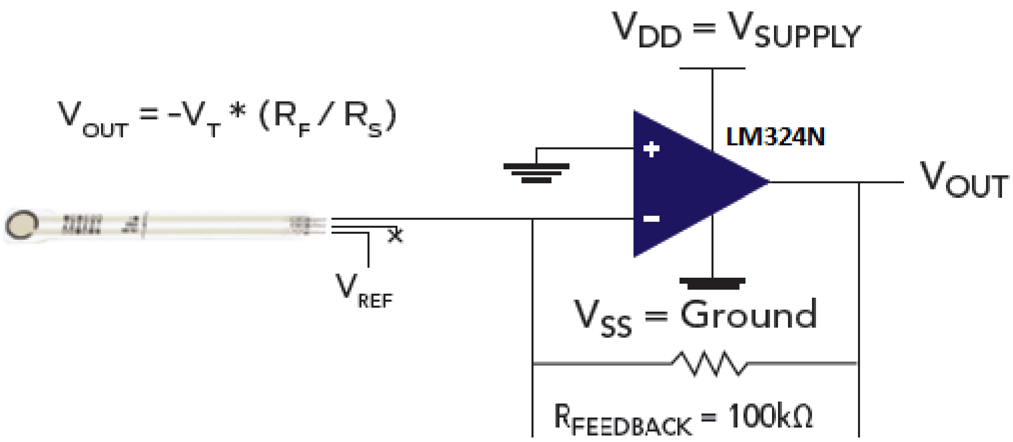


Figure 14: Circuit Diagram of Force Sensors

LM324N is a low power OP Amp and because of the low current, the voltage at the output terminal will be thus function of the change in resistance of the sensors which is given as follow:

$$V_{out} = -V_T * (R_F/R_S) \quad (3.1)$$

Where V_T *is* the driving voltage of the sensor, R_S is the resistance of the sensor. It is to be mentioned here that R_S is the function of the force being applied perpendicular to the sensing area of sensor. R_F is reference resistance against which actual force across the sensor is determined as the change in sensor's own resistance. With reference to Equation (3.1) the output voltage obtained is an amplified signal. Certain variation in $R_{F\ value}$ results in adjustment of V_{out}(Manual).

Now in order to calibrate these sensors, condition is required to be accomplished. By conditioning we mean to apply loads of known values to the sensing area of sensor and against each load respective voltage is to be determined.

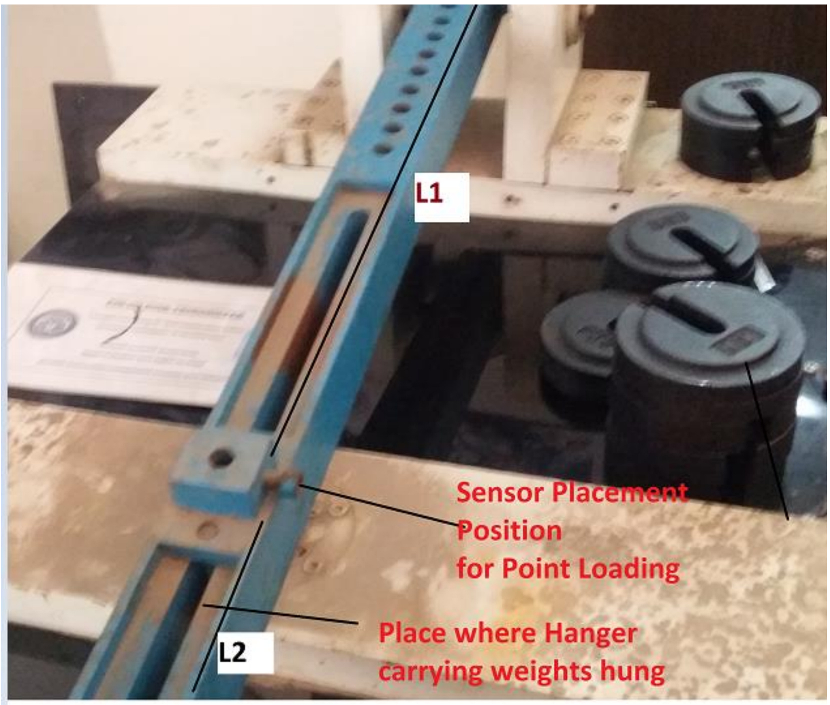


Figure 15Sensor Calibration Method

As shown in Figure 3.8, there is a rod fixed at one end and is free from the other end where loads are being applied. Sensors are placed under the part “a” of the system. This system is basically applying force through some lever arm henceforth the net force being applied on the sensor is calculated through Equation 3.2.

$$F'' = F' x L_2/L_1 \qquad (3.2)$$

Whereas F'' is the force applied through the lever arm created by L_2/L_1 and F' is the amount of force due to load applied on to the hanger. It is to be mentioned here that F'_{min}=126N & F'_{max}=350 N.

Calibration results for individual sensors are recorded for three times. The output voltage of 11 sensors is slightly different from each other. All the sensors show approximately a linear curve when a graph between force and voltage is plotted. The results of output voltage of 11 sensors are averaged out and a linear curve is obtained as a result. The average output voltage reaches to the value of 3.5V for the maximum force of 350N.

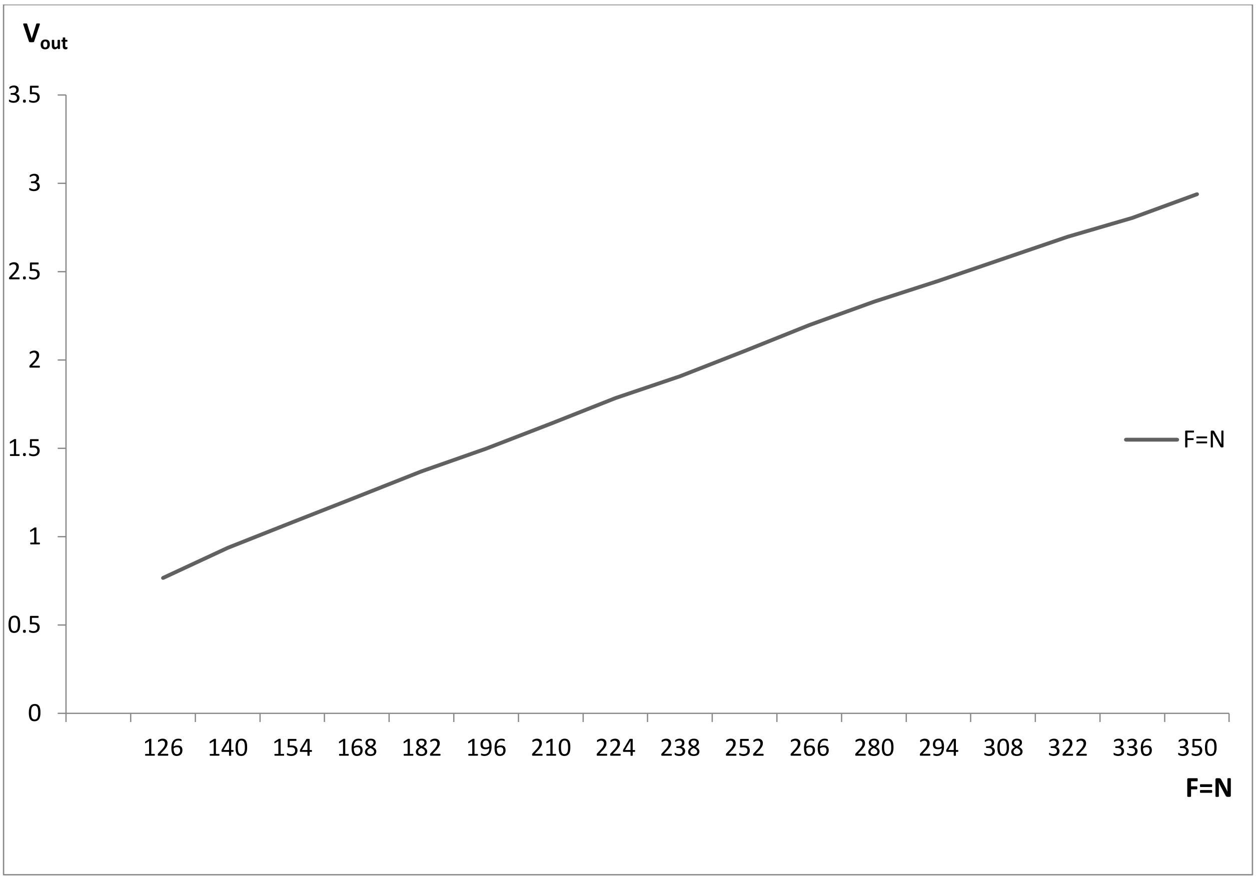


Figure 16 Force vs Output Voltage for 11x Sensors

Straight line indicates the linear response of the all the sensors.

3.2.1.5 Sensor Position Criteria

The underside of foot can be divided into 11 points. These 11 points are basically representative of the major point upon which loads are being borne during walking. These points are mainly concerned with the balance of body during standing and walking. Henceforth, static as well as dynamic forces are concentrated on these points(Lin Shu et al., 2010).

These areas are divided as (*Figure 3.10)* heel region (1-3), midfoot region (4-5), metatarsal region (6-10) & big toe (11). It is to be mentioned here that for convenience the sensors over the second toe is not placed. These points are thus important to derive physiological, anatomical, functional & biomechanical information for foot kinetics and kinematics.

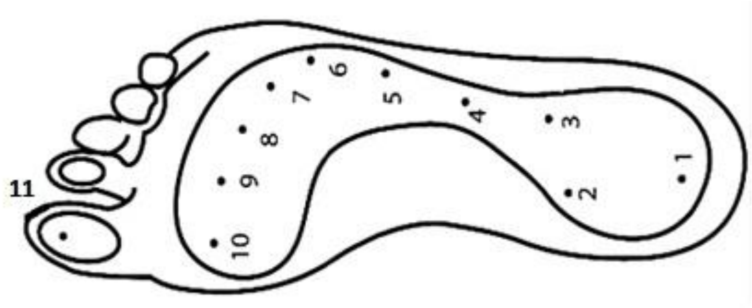


Figure 17 Sensor Placement Points

3.2.1.6 Centre of Pressure (CoP) Mapping

The insole embeded with peizo-resistive sensors maps the pathway of CoP as it travels from hind foot to fore foot throught the stance phase of gait cycle. Each sensor is equipped with the puck of 8mm Pellite. Wires are soldered to the terminal of each sensor, and are connected to circuit. The output of 11 sensors is processed and value against each sensor generated is recorded for future interpretation. The output signal from each sensor is proceesed through Aurdino Mega.

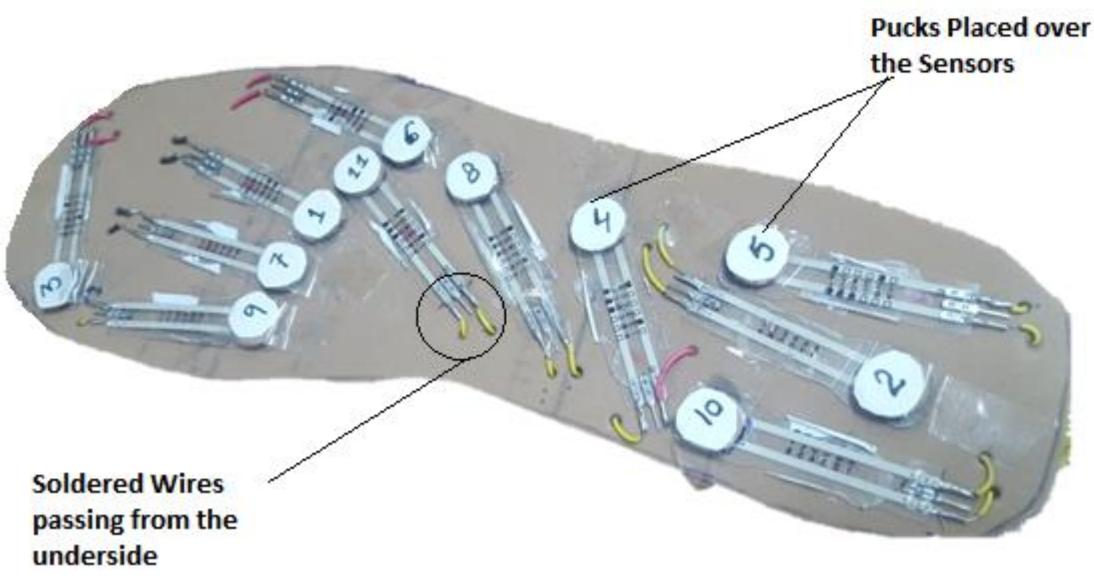


Figure 18 Insole Embedded with Piezo-resistive Sensors

3.2.2 Vibro-tactile- Stimulation Module

3.2.2.1 Vibratory Actuator

The actuator selected for stimulations over the stump is a miniature one. The selected actuator is basically a miniaturized motor also known as pancake or shaft less micro motor. They are known as "Eccentric Mass Motors" in terms of its mode of operation. The rotator has a flat plastic disc, which has a bearing in its middle being sat on a shaft. On the same disc two coils and a mass is also integrated.

Figure 19Coin Shaped Miniature Vibro- tactile Unit\

It has three layers of adhesives which thus make mounting easy, though some glue is also applied for maximum security of actuators to the band. Its height is 10.2mm and weight is 3gm. Its smaller size makes it feasible to be fitted in the thigh band. Its coin shaped configuration is perfect to apply localized stimulation over the appropriate muscles depending upon the phase of gait. Besides the ease of mounting, there is ease of functioning also available by the use of this motor.

3.2.2.2 Thigh Band Working

The vibrations generated by this rotatory unit are of frequency~ 230 Hz- 250Hz. This makes it feasible for the use of production of tactile stimulation over the stump as the same frequency range is ideal to stimulate Pacinian corpuscles.

In order to make maximum feasibility to be availed, a Velcro strap is used as a thigh band. Motors are mounted on the thigh band such that by certain adjustment they will lie on the below mentioned regions, irrespective of the stump size. The sites where 3 motors are placed are respective to bicep femoris, vastus lateralis and rectus femoris muscles.

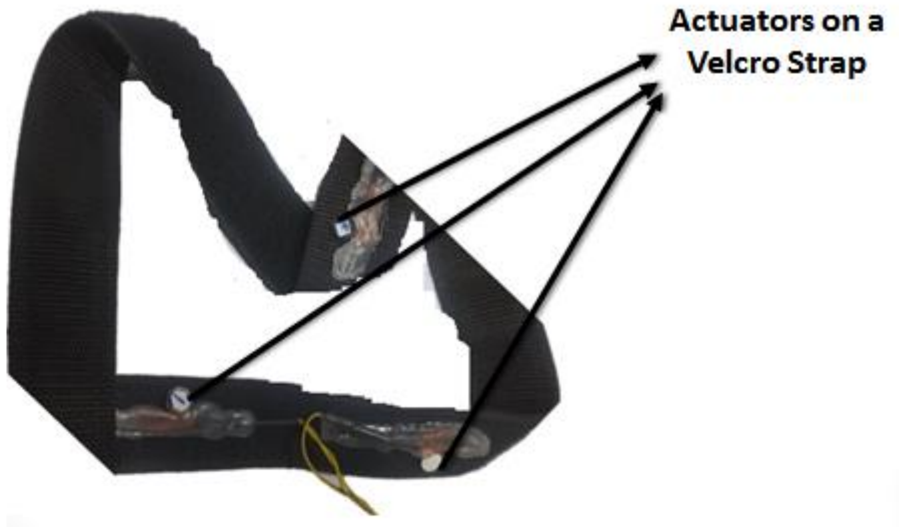


Figure 20 Thigh Band Embedded with Actuators

3.2.3 Circuit Design

Following figure is the circuit block diagram for a single sensor is shown, similar circuit for 11 sensors is made.

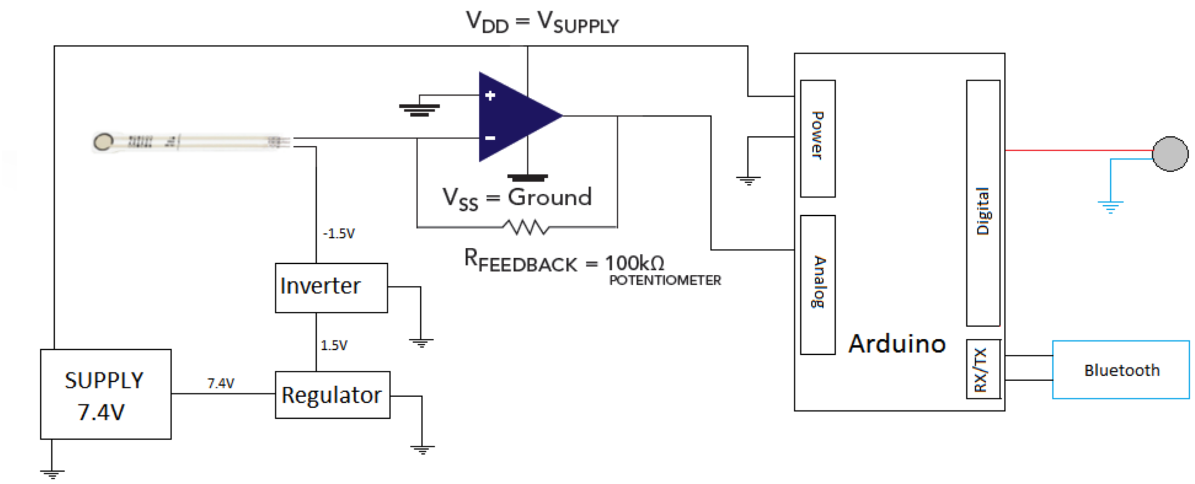


Figure 21 Circuit Block Diagram for a single Sensor

The battery of 7.4 Volts is used to operate sensors, Op Amp connected to each sensor and the Arduino Mega. The battery supply of 7.4 V is regulated at 1.5mm for optimum working of sensor. The regulated voltage is then inverted and is given to the input terminal of the sensor. The output terminal of sensor is connected to an Op Amp so that the output signal from sensor is amplified. The output is generated against the feedback resistor of 100KΩ. The output signal once amplified reaches to the analog pins of Arduino mega. The value from the sensors once above the set threshold value operates the vibro-tactile unit in a time discrete function. The actuators are receiving power from the Arduino. There is a Bluetooth module receiving power of 5V is also connected to Arduino for serial communication of data in real time.

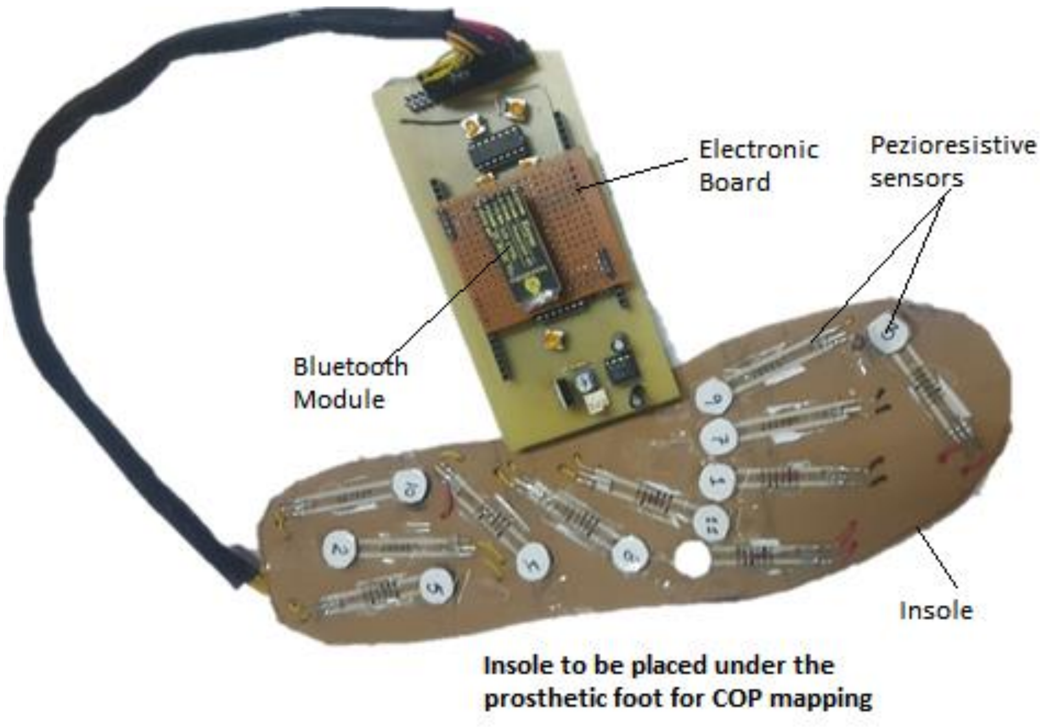


Figure 22 Insole for CoP Mapping along with the Circuit

3.3 Haptic Feedback System

The haptic feedback system works on the criteria of identification of phase of gait cycle. As per normal cycle of gait, the mapping of CoP is utilized to determine the direction of CoG in order to give stimulation of tactile nature to stump. The details of said criteria are elaborated in the following sections.

3.3.1.1 Identification of Heel Strike Phase

The identification of heel strike phase is made when the maximum load is being borne on the sensor lying in the heel region generates the value above the set threshold of 5Kg. these sensors are 2(mid heel), 5(lateral heel) and 10(medial heel) in our setting .

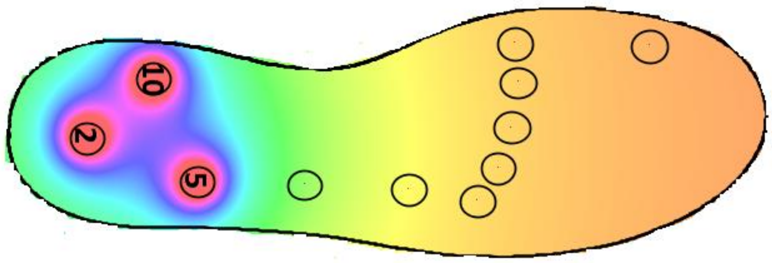


Figure 23Identification of Heel Strike Phase

During this phase the reference foot strikes the ground from heel and the opposite foot is about to leave the ground. The direction of ground reaction force in this situation passes through the posterior of knee in normal as it will help the knee joint to be extended(HERZOG, NIGG, READ, & OLSSON, 1989) .

. But in trans- femoral amputees, there is lack of identification of this phase correctly leads to the misplacement of foot. This misplacement in turn leads the GRF to pass through in the direction of error and hence the chances of stumbling or falling increases. Such scenarios increase the duration of gait training of novice prosthesis user and thus burden over rehabilitation center in terms of direct as well the overhead expenses.

In order to overcome the issue, when our device accomplishes the detection of heel strike phase, the VTU 1 over the posterior thigh i.e over the rectus femoris muscle produces stimulations with the frequency of ~230Hz-250Hz. The delay of VTU 1 activation with respect to phase identification is >3ms (the running time of four lines code). This stimulation gives the amputee a sensory clue along with the audio clue and the visual clue. By audio clue here we mean the feedback for the trainer & by visual clue we mean the setting of gait training room the mirrors, parallel bars etc.

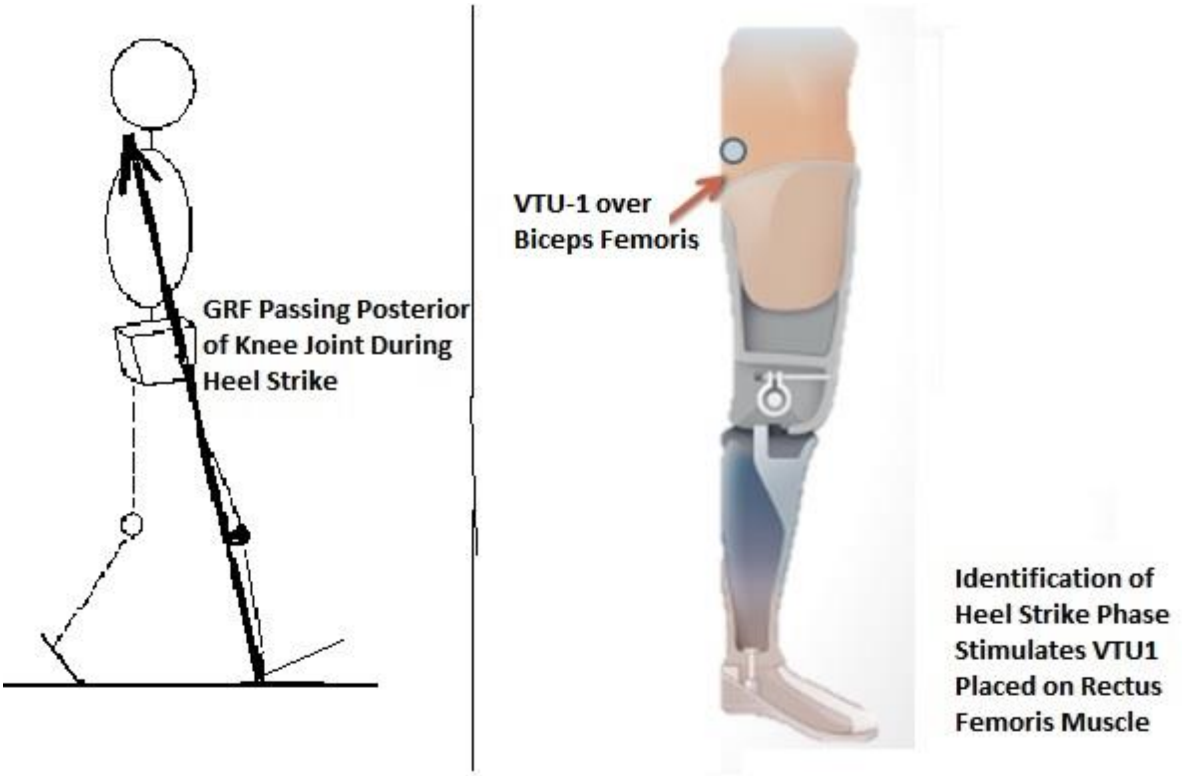


Figure 24 (a) GRF during Heel Strike (b) VTU-1 Placement

3.3.1.2 Identification of Foot Flat- Mid Stance Phase

In order to identify foo flat- mid- stance position, the sensors 8 & 4 are taken into consideration. During loading response these two sensors are maximally loaded.

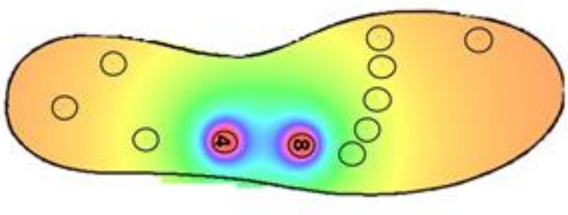


Figure 25Identifcation of Foot Flat- Mid Stance Phase

During normal gait cycle the GRF from foot flat to mid stance duration passes through the lateral side of the reference limb(HERZOG et al., 1989). The opposite limb is in swing and the reference limb needs to be strong enough to support the single limb stance. The muscles on the lateral side then stimulate in order to bear maximum body weight and thus helping opposite limb to advance forward.

Therefore, VTU-2 is placed over vastus laterlis to give TFAs sensory information about the phase of gait being identified through appropriate pressure mapping from the said sensors.

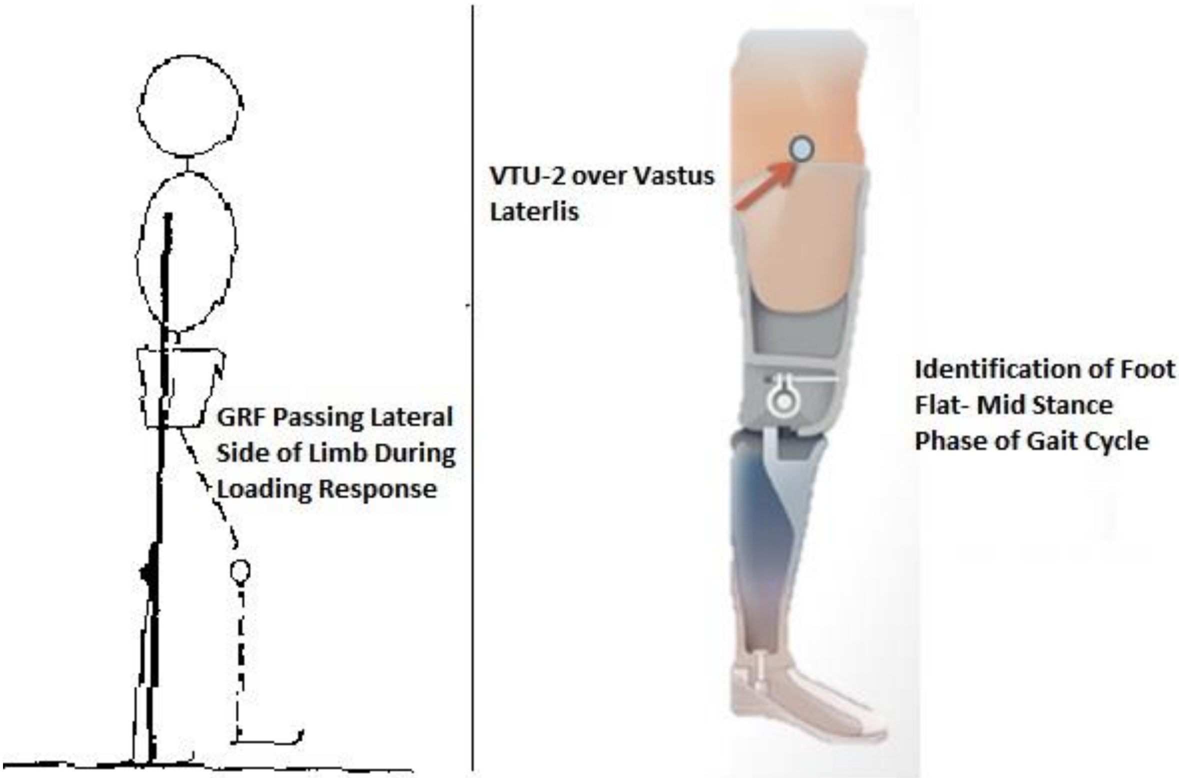


Figure 26(a) GRF during Loading Response (b) Placement of VTU-2

3.3.1.3 Identification of Terminal Stance

Terminal stance comprises the last third part of the gait cycle. The foot of reference limb is moving from mid stance to toe- off. During which the pressure points for the insole selected are shown in.

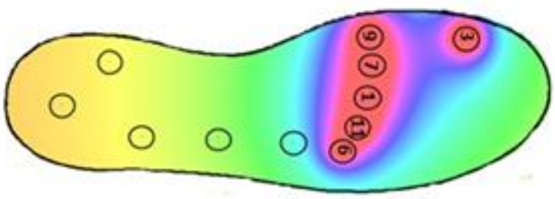


Figure 27 Identification Points of Terminal Stance

GRF during this phase passes through the anterior of the limb as it will make it then avoidable for limb to stumble. It also prepares the limb for swing phase by providing it enough support from the anterior side(HERZOG et al., 1989).

Henceforth, VTU-3 is placed on anterior side over the location of Bicep femoris to support loads as well as to help forward progression of the reference limb.

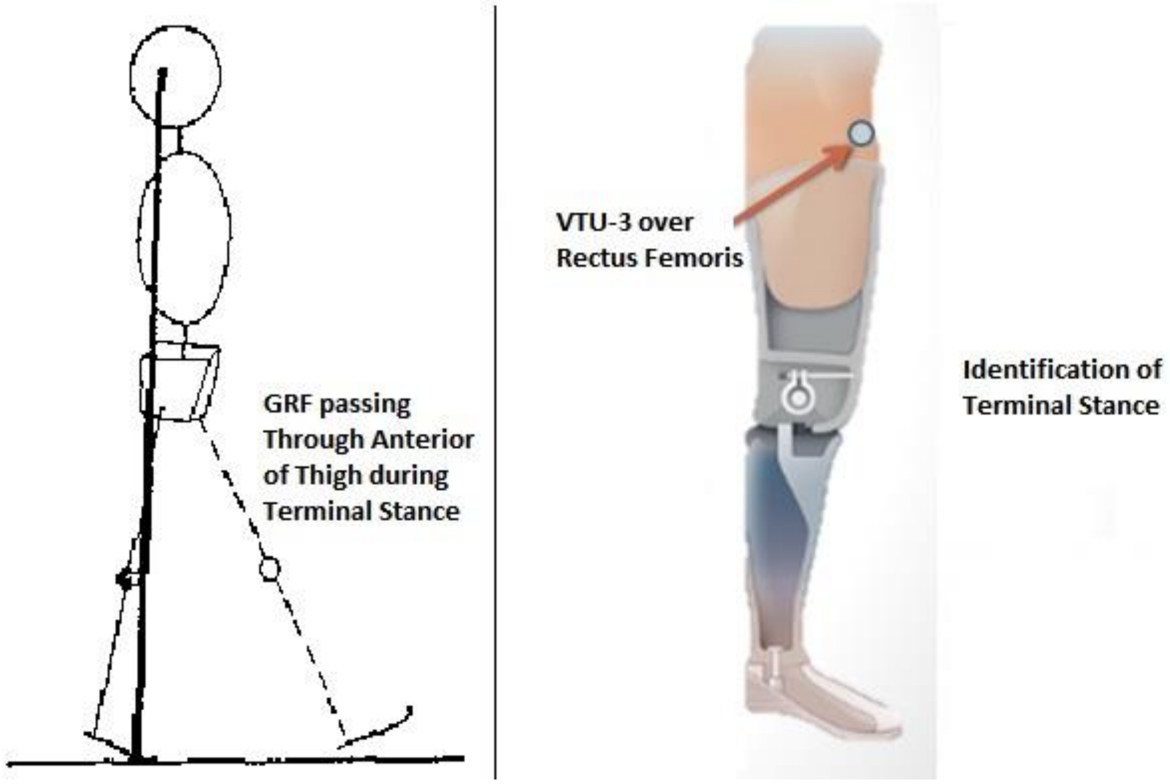


Figure 28 Figure 3 20 (a) GRF during Terminal Stance (b) VTU- 3 Placement

3.4 Insole Data Processing

The data acquired from insole is basically the output obtained from 11 sensors. This data is the most important factor to be analyzed not only for this study but also many other studies for future can be designed from this data. Therefore, the numerical value generating against each time is crucial to analyze various temporal and spatial features of gait cycle.

The analogue signals from each sensor is converted to digital through a set of steps which are not only processing these signal but also recording and storing them for future references and interpretation. The recorded data needs to be displayed in real time without any delay for clinician to have the idea of appropriate foot placement during the gait cycle. This section therefore, deals with the mechanism responsible for the flow of data from insole.

Followings are the three objectives to be obtained:

1. Data Transmission
2. Data Recording
3. Data Display

3.4.1.1 Data Transmission

The module involves in data transmission is Bluetooth (HC- 05). It is used for wireless communication. It is a user friendly device in the truest sense as it follows the serial mode of communication. This type of communication therefore makes its interfacing with microcontroller and PC very easy.

Figure 29 Bluetooth Module HC- 05

The module is connected to Tx/Rx pins of the Arduino and is also connected to inbuilt/ USB Bluetooth module on PC. It has simple circuitry involves which makes its utility more feasible and thus working with it is not that cumbersome. The model: HC-05 needs the input voltage of DC 5V. One of the most important features is that that its master and slave mode can be switched.

Once the hardware is completed, the source code is made and burns in Arduino Mega to fetch data from 11 sensors of insole and transfer it into PC for the display of GUI as well as recording of numerical values for future interpretation.

The circuit diagram is shown as follow:

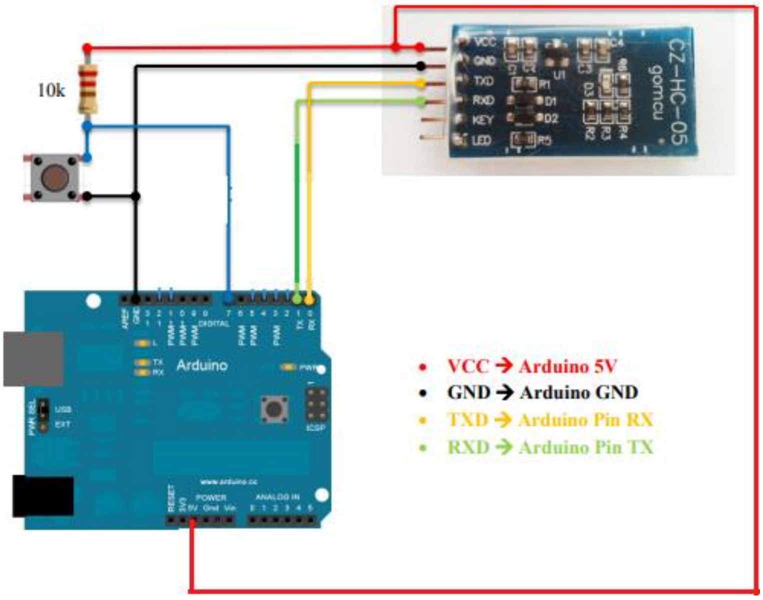


Figure 30 Bluetooth circuit Diagram

The overall flow of data is depicted as follow. Following figure shows that insole data is transmitted to Arduino when handshake between BT and Arduino takes place. The handshake is established because of the command sent from PC after the connection between the BT module of PC and the HC-05 is made. The information sent by the BT is received on PC as displays the data and recorded there as well. Here it is to be mentioned that the data being displayed on PC in the form of GUI, takes place in real time. The Arduino is also connected to VTUs embedded on thigh band.

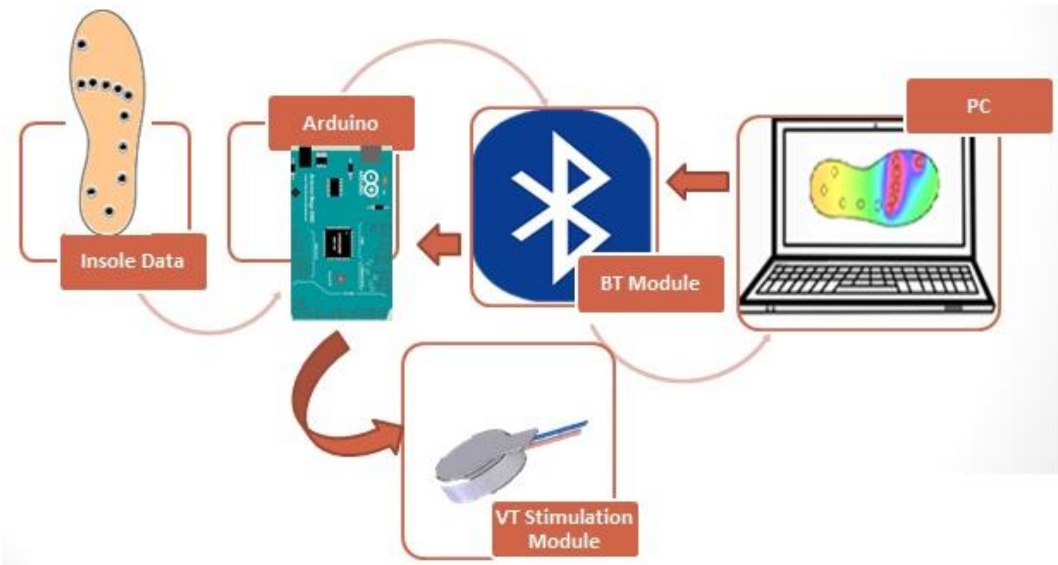


Figure 31Data Flow

3.4.1.2 Data Recording

Data from each sensor is sampled at the rate of 7.407Hz which means that approximate time period is 135ms for each sample. The data recorded is compiled in .txt files and is imported to MS Excel for further processing.

3.4.1.3 Data Display

Data needs to be displayed in real time in order to help the clinician to have an idea about the foot placement pattern being adopted by the subject. For this purpose a graphical user interface needs to be designed. The data is displayed in the Processing® Software. The contour mapping system is used to represent each sensor. Change in color is generated at each sensor position according to their respective values.

GUI with the shape of an insole created using an online SVG editor.

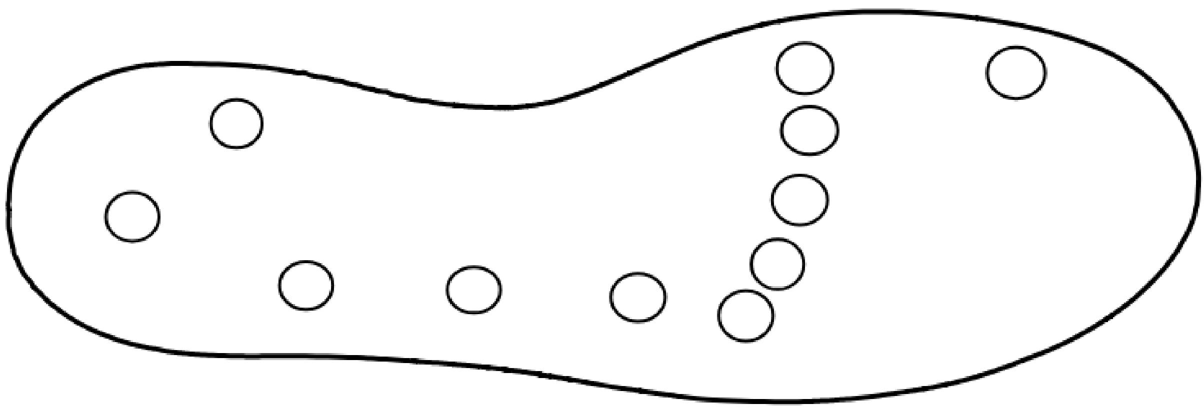


Figure 32 GUI of Insole

"Heat Mapping" type of display was selected to show a colored banding between the interacting sensors. By heat mapping here we means that when the value of a sensor is above the set threshold and is increasing there is a color changing display shown on the screen. Blue color means that sensor is minimally loaded and the red color means that sensor is being loaded on its extreme maximal ranges. If load on the sensor is continuously increasing, then the red color will spread out of the blob set for that specific sensor. If the load is moving from one to another sensor there is flow of colors between the interacting sensors is also established. The higher the signal strength the larger the red color area

Here the test data for contour mapping and interacting sensors is displayed.

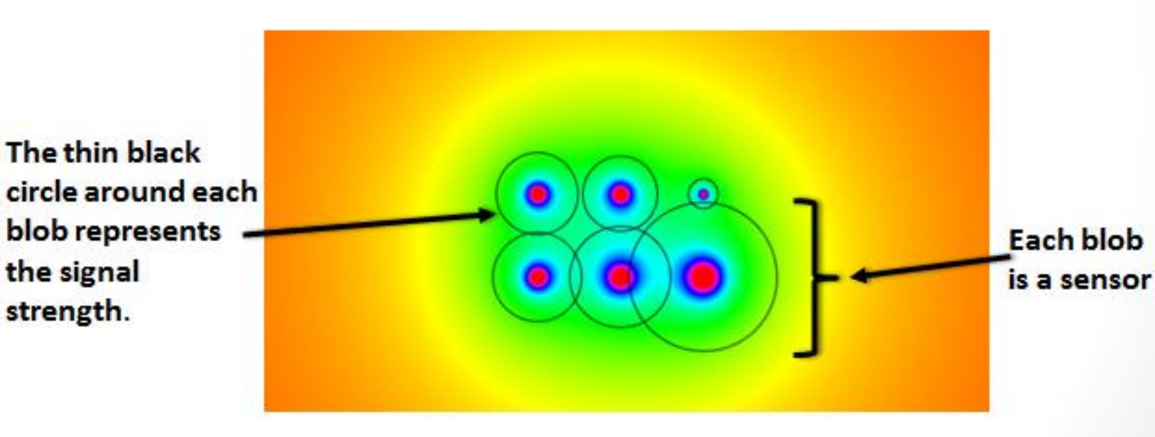


Figure 33 Test Data of Interacting Sensors

As shown in the figure above that the amount of signal strength determines the amount of circumference of the thin black circle. But during transition of load from one to another sensor the color bands blends to give an idea about the shared loading upon two sensors as depicted in the following figure:

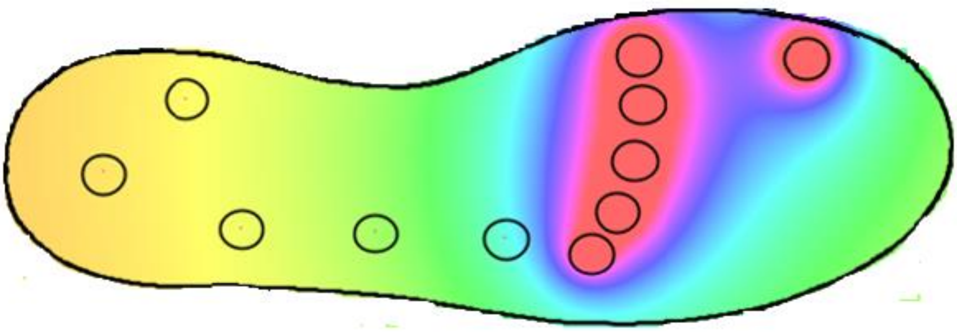


Figure 34 Final GUI (Showing CoP mapping during Heel Off)

The display is an easy way to gather information about real time changes. CoP mapping on display animation can be recorded in order to ensure that numerical data is synced. It will provide great deal of help during the analysis of numerical data and to extract useful features from the data.

3.5 Experimental Protocol

In order to validate the working of device, an experimental protocol is designed for sound subjects. The need of such experimentation is required not only to validate the device but also to create a log of data from sound population. The collected data can be utilized for future studies. Moreover, experimentation on sound subjects is pre requisite for clinical trial as well.

3.5.1.1 Subject Recruitment Criteria

The protocol designed thus comprises 21 sound subjects. There is no specific recruitment criteria opted. Irrespective of their heights, weights or gait pattern followed, they are included in the study only single criteria of being able to walk on their own. For optimum testing of device, random sampling from healthy population is carried out.

Parameter	Mean	Standard Deviation
Age	26.6	±3.29
Weight	70	± 14.7

Table 3 Parameters of Subject

3.5.1.2 Equipping the Device

One of the major objectives of the thesis work is to make this device user friendly as much as possible. Equipping the device to the user is not a cumbersome task. It comprises following simple steps:

1. Each subject is asked to take off both shoes.
2. Sensor insole is placed under the right foot and secured there by using Velcro straps.
3. The circuit box is secured to the calf region by Velcro.

3.5.1.3 Method of Trials

Each subject is asked to walk on a straight path while wearing the device at a normal walking speed. It is to be cleared here that barefoot trials are made. The no. of steps each subject is asked to move are 6 in number. Per subject total no. of trials taken are 3. Videography is done to ensure the data is synced with the steps taken w.r.t time. For more surety that data is completely synced the animation and the video of walking both are recorded in real by using screen recording feature by the help of software Camtesia®.

Figure 35Real time Screen Recording

3.6 Summary

The main focus of this chapter is on the designing of a device which is capable of mapping center of pressure throughout gait cycle & its effective application in generating feedback stimulation in response to the CoP mapped. The chapter discuss various parameters involved in device design. It also explains the experimental protocol performed in order to validate the device.

4 Results & Discussion

Once the device is fabricated it is required to put it through tests to analyze its working and effectiveness. Once the data from normal subjects is acquired for multiple trials, its analysis is to be made. In order to assure the maximum working of the device and validate its functioning accordingly, the data acquired for following validation parameters:

1. Comparison of Individual Sensor Point Pressure According to Foot Region
2. Gait Phase Based Intra Subject Variability
3. Lateral vs Medial Plantar Pressure Pattern

4.1 Comparison of Individual Sensor Point Pressure According to Foot Region

The data acquired for each step for same trial even of same subject will show some variability. Values generate against each sensor depends greatly upon the body weight, individual's walking pattern, individuals walking speed & step length etc. But overall pattern of foot placement during gait can be analyzed from the data on the basis of repeatability and synchronicity. The recorded data for individual sensor is analyzed to extract the pattern of loading and to check variation in loading mechanism in three different regions of foot i.e. hind foot, mid foot and fore foot.

The individual sensor results are shown as follow and are analyzed on the basis of anatomical division of foot.

4.1.1 Hind Foot Region Point Pressure analysis

During heel strike, maximum load over mid heel is reported in certain studies in comparison to lateral and medial side(Benocci, Rocchi, Farella, Chiari, & Benini, 2009)(Zhu, Wertsch, & Harris, 1991). Our device is being validated for the same pattern. Maximum pressure on the mid heel portion (sensor 2 in our setting) is observed. The reason for maximum loading on mid heel during the heel strike phase ensures secure landing of foot to ground. Moreover it also depicts the digging kind of action for approximate fixing of the heel in the ground.

The results for all the three sensors in the hind foot region are shown in following figure. These are graphs plotted for a single subject walks for a single trial.

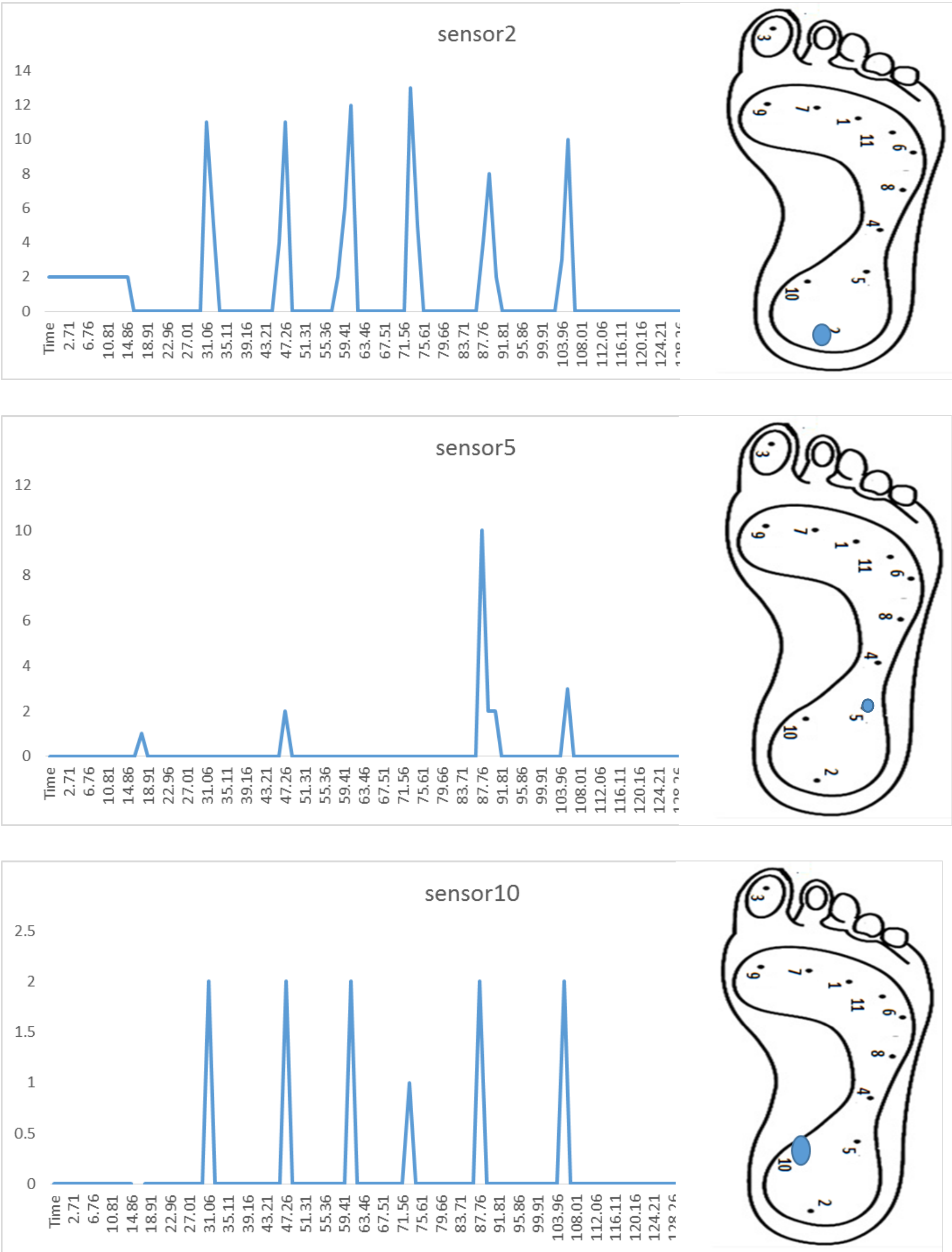


Figure 36 Individual Sensor Graphs for Hind Foot

4.1.2 Mid Foot Region

The analysis of midfoot region indicates that pressure on the sensor more toward middle region bears more load during mid-stance region(Mariani, Rouhani, Crevoisier, & Aminian, 2013). As during this phase the opposite limb is in its swing and the reference limb is trying to balance the body through single limb. More loads being shifted towards the middle region, more the body is said to be balanced.

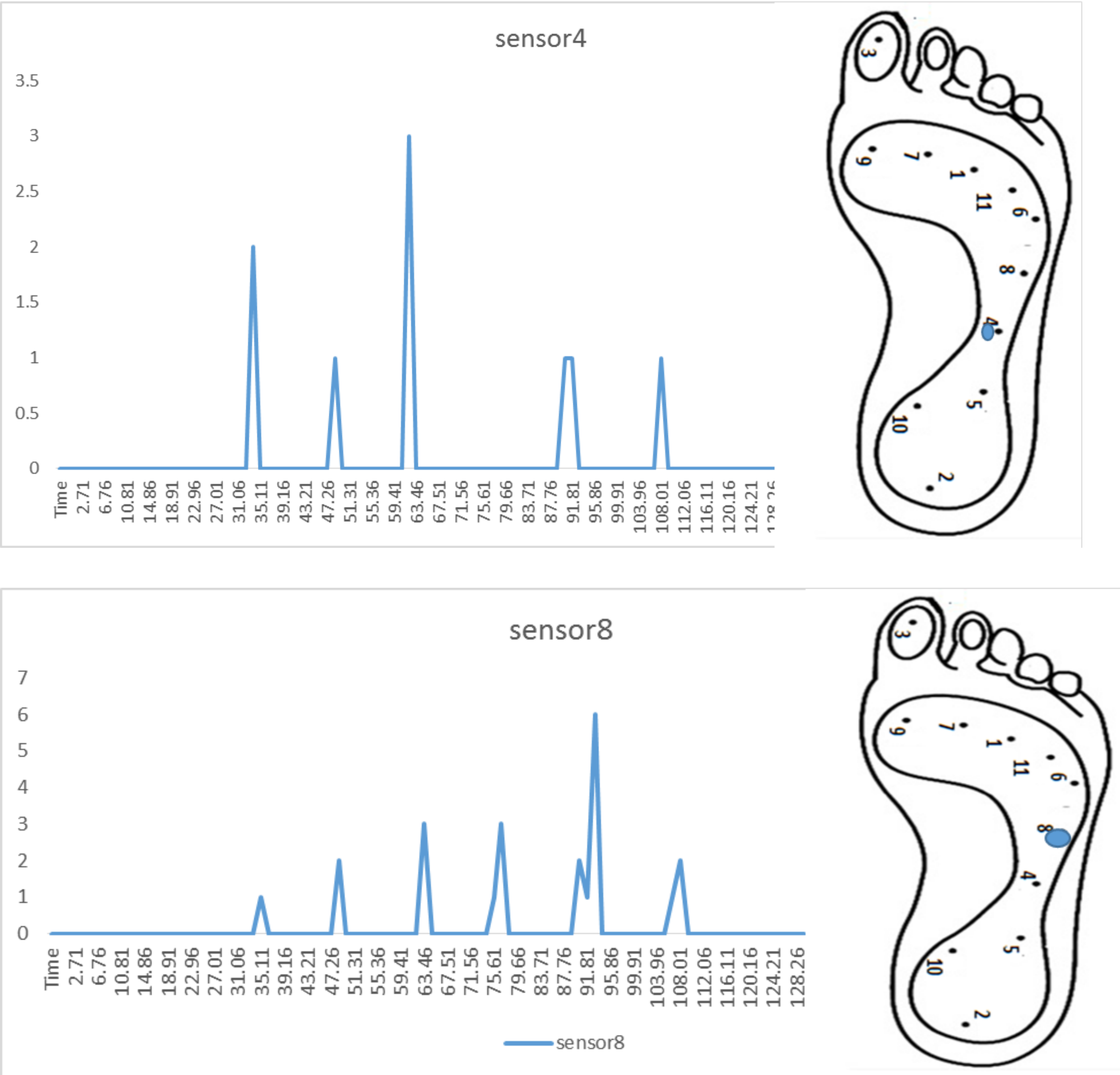
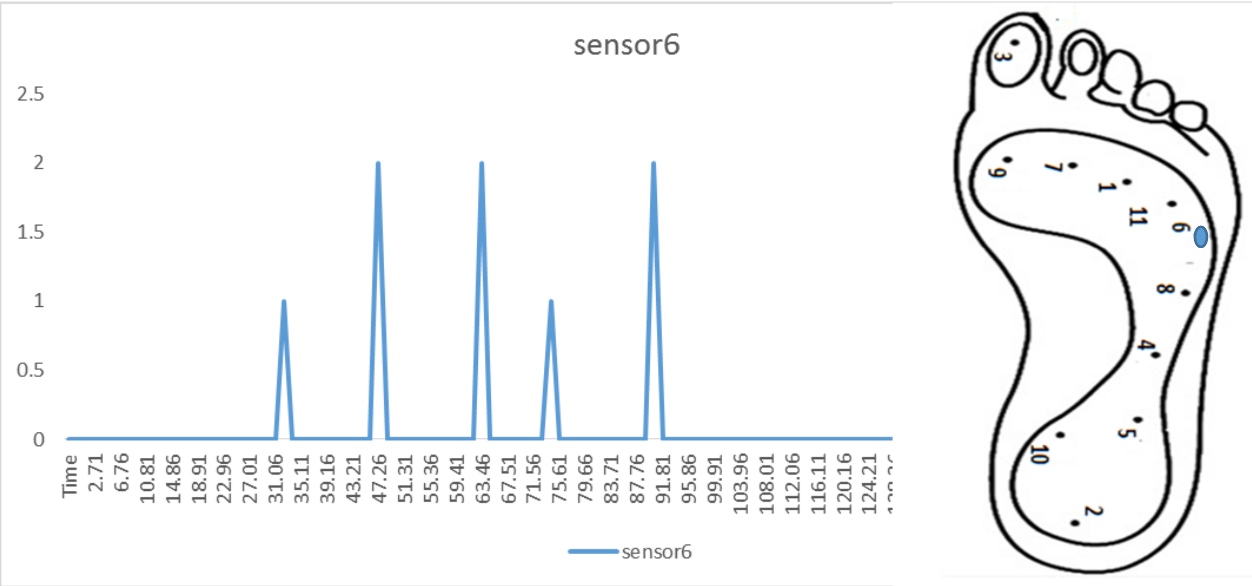
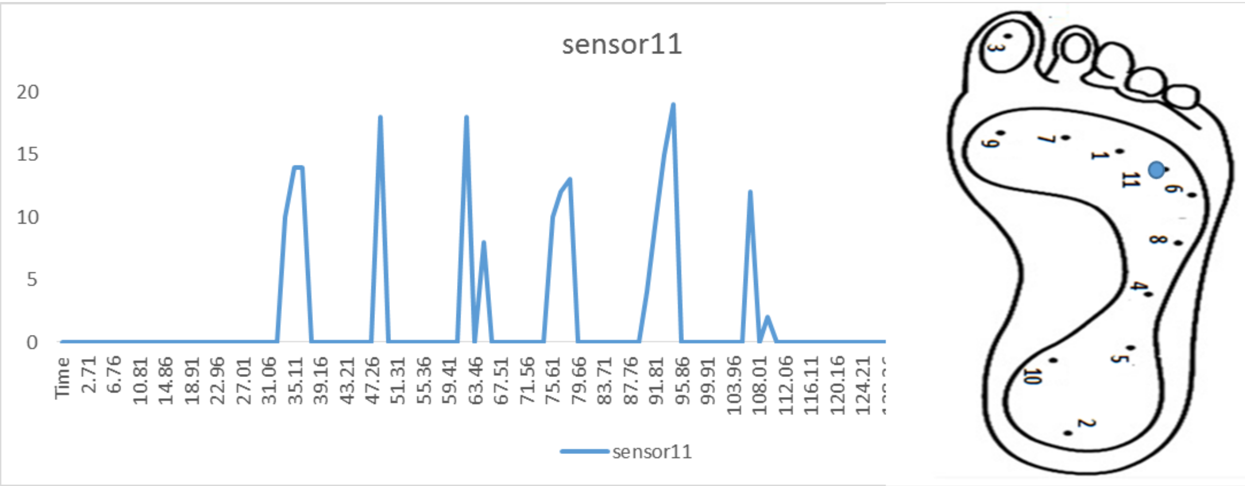


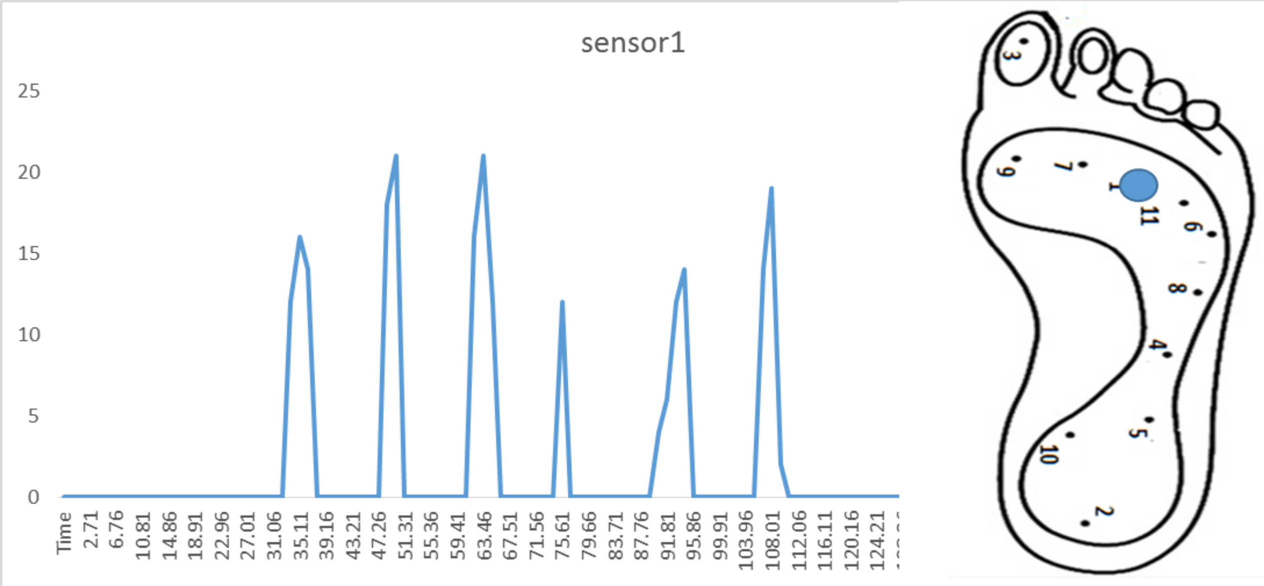
Figure 37 Individual Sensors Graphs for Mid Foot

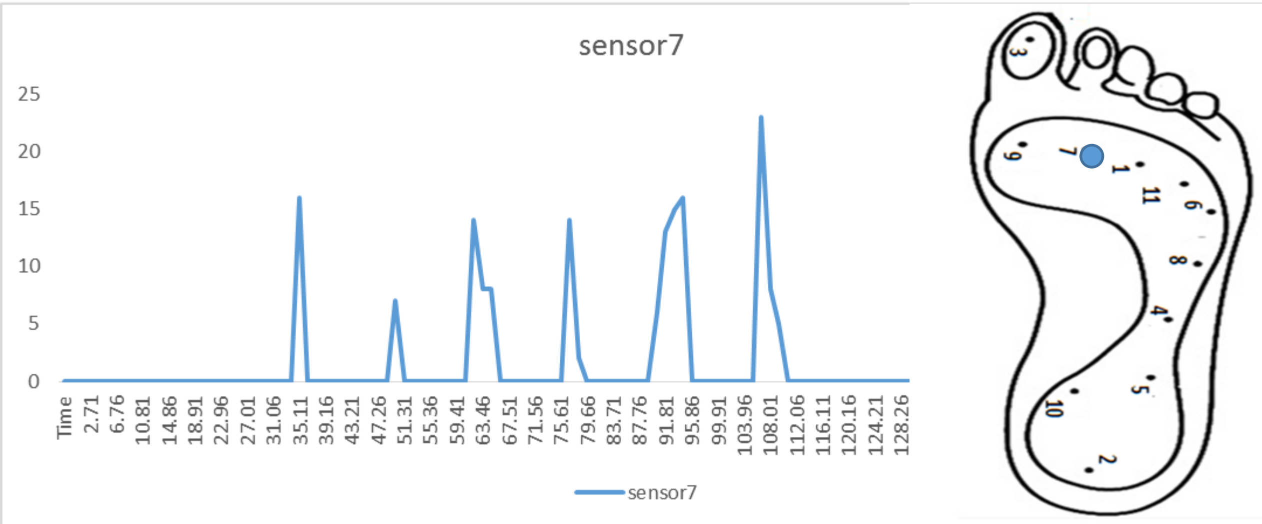
4.1.3 Fore Foot Region

The interpretation of the data acquired from the sensors embedded in the forefoot region indicates that during terminal stance phase a normal subject will try to balance its body more towards the medial side. As we know the CoG lies in the vicinity of second sacral vertebra, more the body is brought about to medial side, more is the stability assured. It is required because during the terminal stance where reference limb is about to leave the ground opposite limb is about to hit the ground, and then the reference limb will be ready to swing through the air(Diamond et al., 2018).






sensor1
25
20
15
10
5
0
Time
2.71
6.76
10.81
14.86
18.91
22.96
27.01
31.06
35.11
39.16
43.21
47.26
51.31
55.36
59.41
63.46
67.51
71.56
75.61
79.66
83.71
87.76
91.81
95.86
99.91
103.96
108.01
112.06
116.11
120.16
124.21
3
9
7
1
11
6
8
4
5
10
2


sensor7
25
20
15
10
5
0
Time
2.71
6.76
10.81
14.86
18.91
22.96
27.01
31.06
35.11
39.16
43.21
47.26
51.31
55.36
59.41
63.46
67.51
71.56
75.61
79.66
83.71
87.76
91.81
95.86
99.91
103.96
108.01
112.06
116.11
120.16
124.21
128.26
sensor7
3
9
7
1
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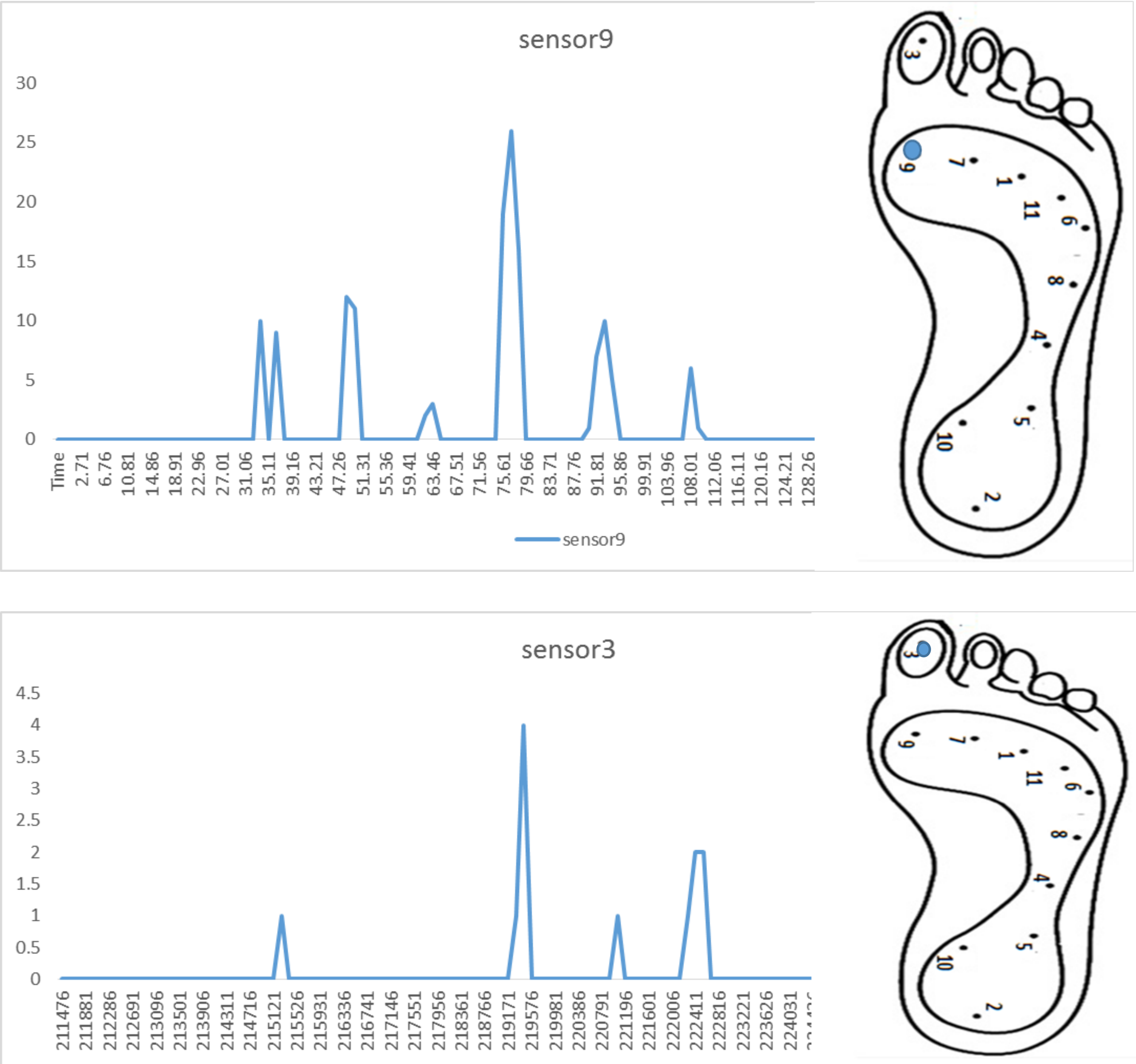


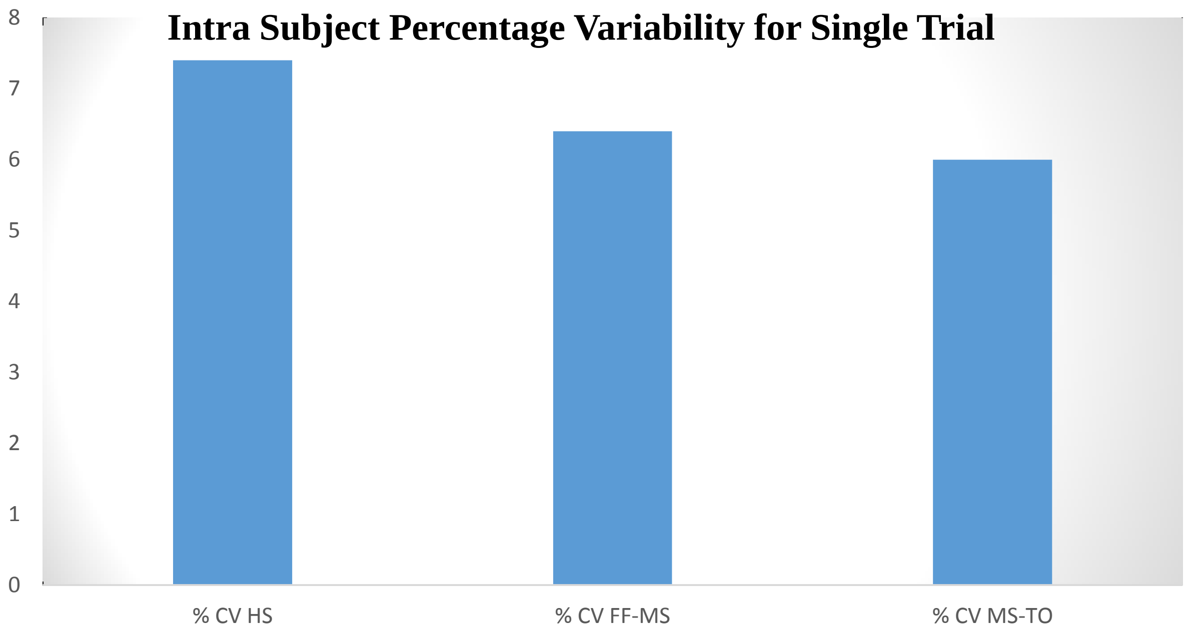
Figure 38 Individual Sensor Graphs for Fore Foot

4.2 Gait Phase Based Intra- Subject Variability

The goal of this analysis was to assure that for the same subject our device is not showing results with an increased value of standard deviation. Slight variabilities are though acceptable as the same individual will not walk every time with same pace as well as with same step length. But a huge variation will otherwise indicate the flaw in device and non-repeatability of results.

4.2.1 Intra- Subject Variability of Single Trial

Following results show intra subject variation for one trial between the three phases of gait cycle i.e. heel strike, mid- stance and toe off. These variations among the phases of gait cycle are of slight value because of some randomized error.



4.2.2 Intra- Subject Variability for Three Trials

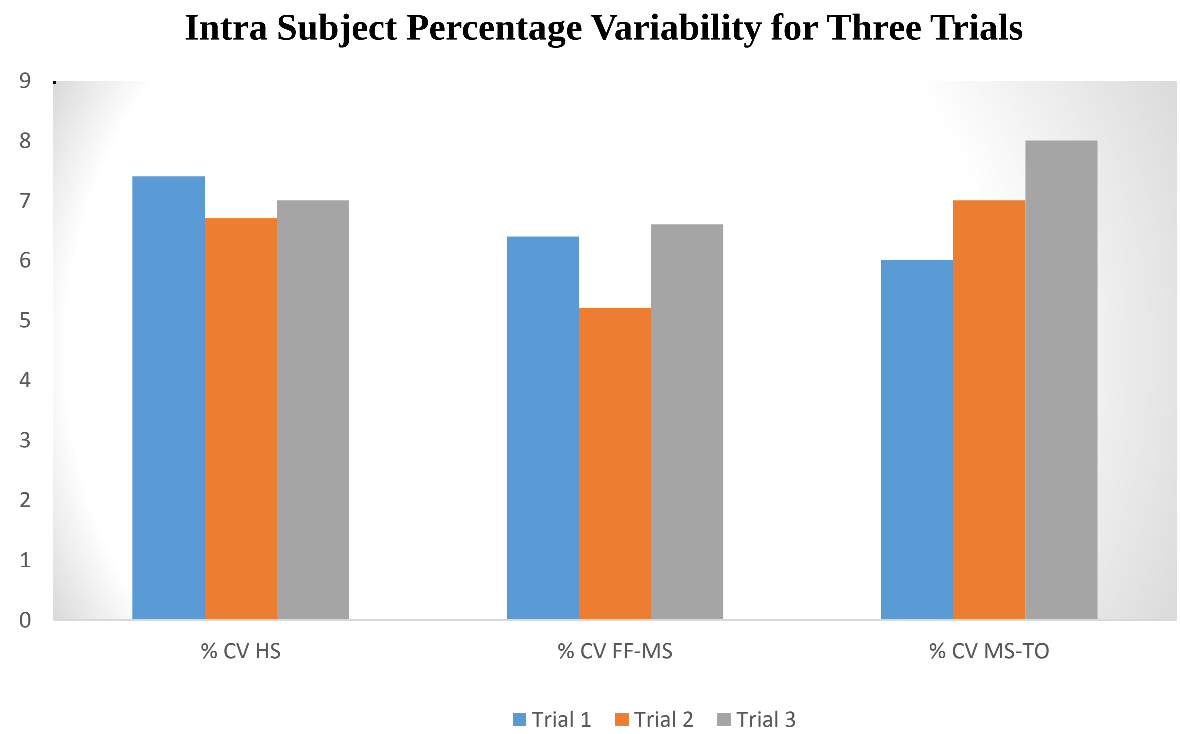
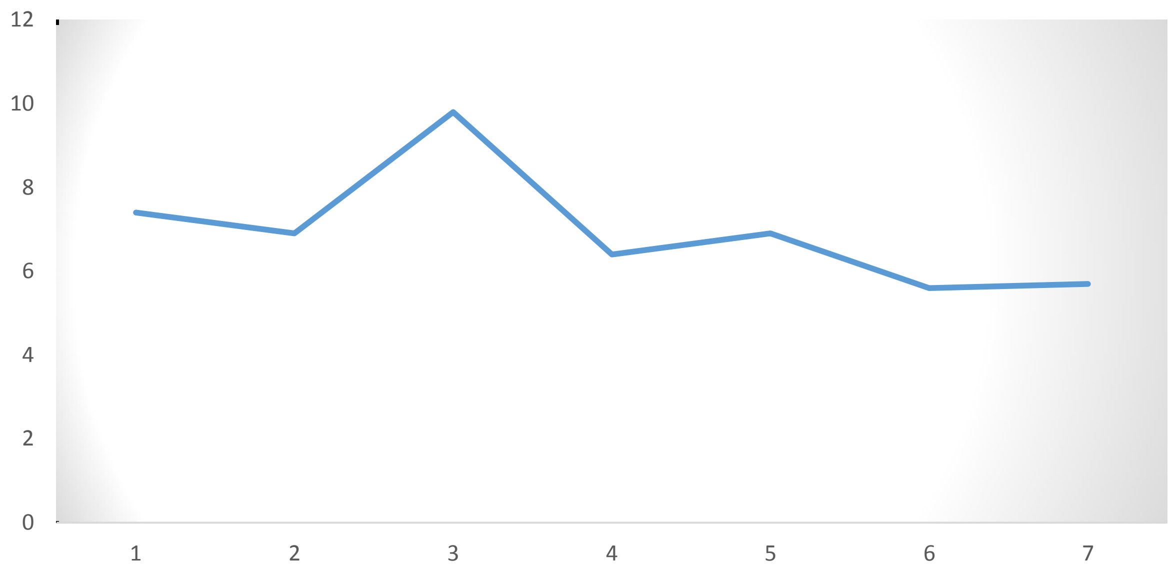


Figure 39 Intra Subject Variability for 3 Trials

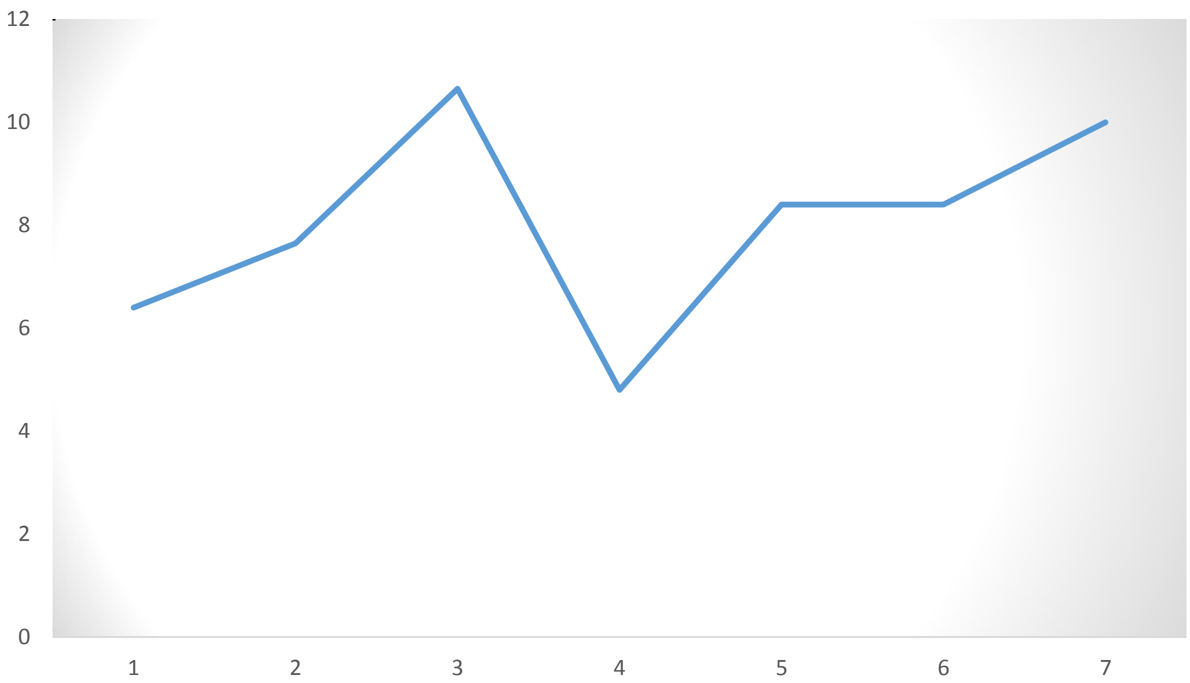
4.2.3 Percentage Variability during Phases of Gait Cycle

Following results show that percentage variability during three phases of gait cycle. These variations among the phases of gait cycle are of slight value because of some randomized error. But overall variation in percentage is ≥10%. (Here results of 7 subjects are shown).

% age Intra-subject Variability during HS



% age Intra-subject variability FF-MS



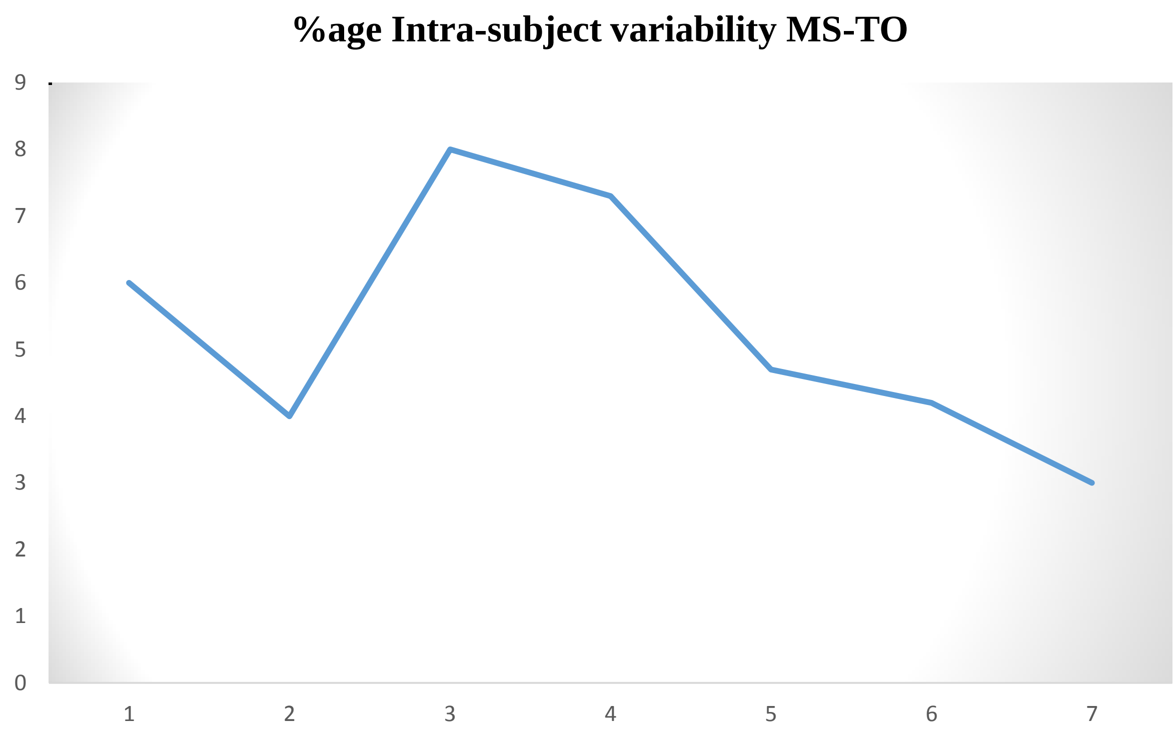


Figure 40 Results of %age Variability in Different Phases of Gait Cycle

4.3 Lateral vs Medial Plantar Pressure Pattern

The last step of validation is to compare medial vs. the lateral side of foot during heel strike and terminal stance. The results show that for a person having normal BMI the concept of loading towards the medial side is retained

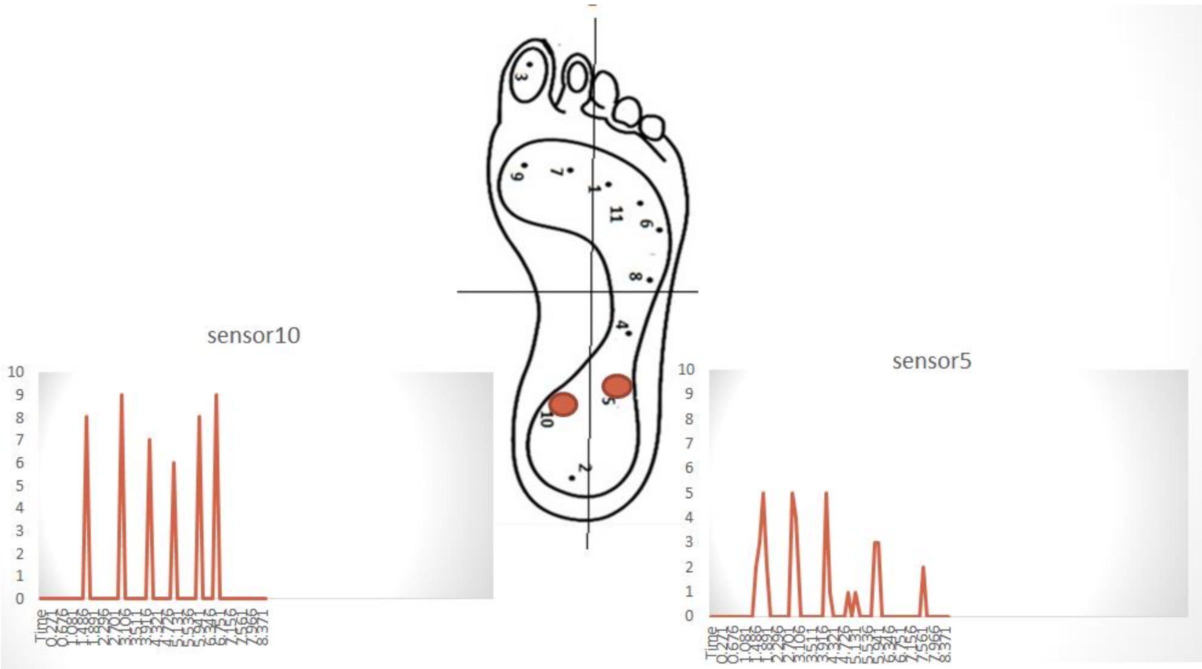


Figure 41 Medial vs. Lateral Pressure during Heel Strike

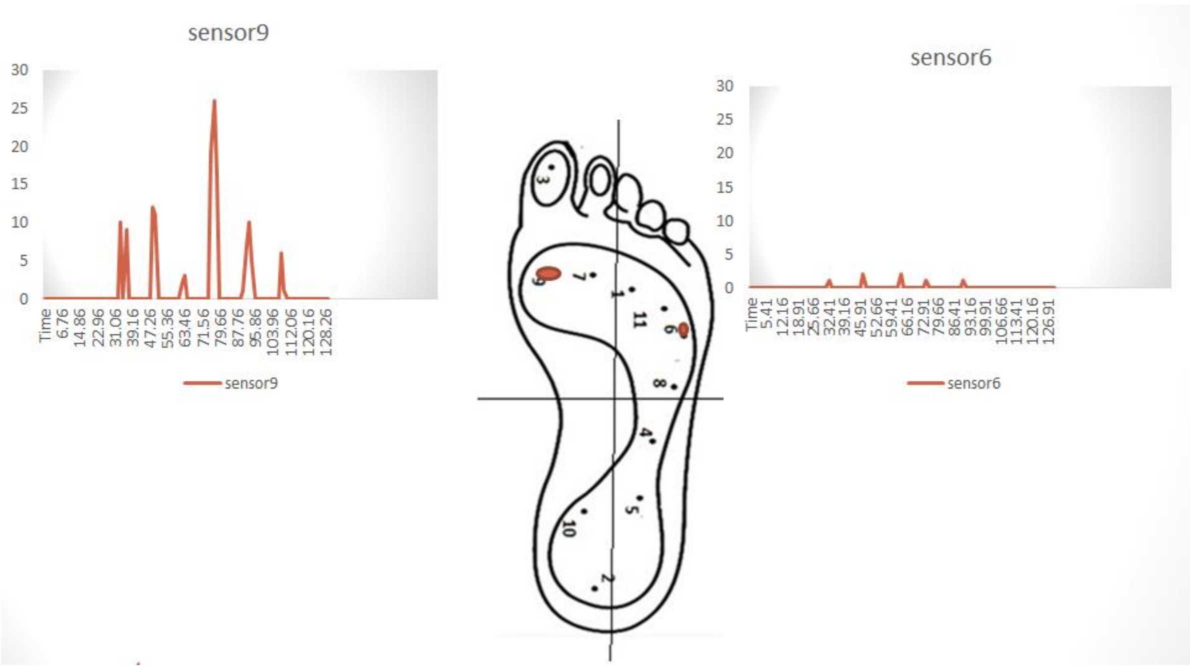


Figure 42Medial vs. Lateral Pressure during Terminal Stance

4.4 Summary

The chapter elaborates three major validation methods being employed. All three methods validate that insole for pressure mapping designed is capable enough to map the appropriate pressure points and this information in turn is applicable to provide phase based stimulation to the thigh region.

5 Conclusion and Future Works

The device design is a cost effective solution we can provide to our physical rehabilitation clinics. It is a portable solution to reduce gait training time usually taken by TFAs who are novice leg users. The results from different methods validate the working of the device design and functionality.

5.1 Conclusion

The conclusion thus drawn is that a wireless device capable of mapping COP is developed at the end of the thesis work. The pressurized insole designed for this project has a unique design. The smaller size of circuit makes this device a handy solution to trainers in gait training centers. Equipping the device to the user is not a cumbersome task. There are no such sensory feedback systems are available for the amputee.

The prosthetic leg having such feedback system will be a smart device as it shall be able to provide amputee the sensory feedback from the ground to the stump during gait training. Overall haptic feedback system design is user friendly and is totally hidden within the prosthetic leg Phase based differentiation on the basis of COP enables to generate sensory feedback through actuators. Such devices can act efficiently in prosthetic clinics to train amputees, as along with visual and sensory clues physical clue for gait training will be available.

5.2 Limitations

The device is also having some limitations. One of which is that sensors cover only finite points on the insole. More area of insole covered, more appropriate CoP mapping can be assured. Separate insole for each foot size should be available. Another limitation is caused by BT. BT has lesser range. HC- 05 is capable of transmitting data in the range of 9m. Therefore, in order to make the device work in clinical set up other data transmission wireless modules like wi-fi etc. should also be considered.

5.3 Future Works

This study is helpful to design future studies. These studies are as follow:

1. An algorithm for auto detection of temporal and spatial gait features from the insole's data is to be designed.
2. More data from healthy population can be acquired in order to evaluate the differences among parameters of normal & different pathological gaits.

3. Extensive research regarding gait analysis in accordance with Prosthetic Observational Gait Score can be conducted for TFAs.
4. Utilization of such feedback Systems for Peripheral Neuropathies can be considered.
5. Various characters of normal gait on the basis of CoP mapping can be explained.
6. A study can be conducted in order to evaluate difference in walking pattern obtained from the people of different age groups.

There are so many such hypothesis can be tried and tested by using pressure mapping device.

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