Design and Development of a System for Pressure Measurement in Patients using Lower Limb Prosthetic and Orthotic Appliances

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

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Abstract

Pain and pressure sensation as parts of somatosensory system provides sense of awareness of joint position & body orientation in space. Proprioception works like a constant feedback loop where human beings are very well aware of body position and forces acting on it. Any abnormality in pressure especially for amputees would result in skin break down, joint disorders and non-compliance of prosthetic limb. In order to avoid problems related to skin & joints along with psychological satisfaction of patient, pressure mapping is performed with improved device compliance. Due to unavailability and high cost of MEMS based bubble sensors and TEKSCAN system, an effective and low-cost solution to problems related to pressure mapping before and after prosthetic fittings is introduced wherein a device capable of being incorporated within stump and prosthesis with minimal chances of breakage due to its flexibility is designed. Twelve pressure tolerant & sensitive areas of stump were marked upon silicon-based stump liner of 3mm thickness for TTP socket. FSR are attached to those specified areas and a Bluetooth module is used in PCB to send data through PLX-DAQ into MS-Excel. When a patient wears his/her prosthesis along with specially designed silicon liner having FSR and bears weight or walk, data is sent back into excel sheet recording the pressure values from 12 locations of a stump. Then adjustments can be made in prosthesis on the exact locations that showed increased pressure values so to eliminate pain and pinch and relieve the patient. Data from 7 patients during standing/ loading response of gait cycle was taken at Rehabilitation department of hospitals and required adjustments were made in prosthetic socket and alignment by the clinician/prosthetist. Comparison between means of pressure values before ($27N/m^2$) and after making adjustment in prosthesis was made which showed improved values of pressure on distal tibia ($<17N/m^2$) Data from 1 patient was obtained through all phases of his gait cycle and plotted on MS-Excel to find out exact phase of gait cycle causing more pressure on stump. The results showed significantly increased values of pressure on sensitive regions of stump during mid-stance phases of gait cycle ($>75N/m^2$). While during early stance and swing phases the pressure values were significantly low ($<28.7N/m^2$)

Key Words: *Stump, Trans-Tibial Prosthesis (TTP), FSR, Pressure sensitive & Tolerant areas, Gait cycle.*

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Table of Abbreviations

CoP	**Centre of Pressure**
GRF	**Ground Reaction Force**
TTA	**Trans-tibial Amputee**
TTP	**Trans-tibial Prosthesis**
FSR	**Force Sensitive Resistor**
BT	**Bluetooth**

2 Introduction

2.1 Background

Over a course of many years amputation has remained a topic of concern, with passage of time incidence of amputations has dramatically increased, two major causes are RTA's (Road Traffic Accidents) and Peripheral Vascular Disease mostly induced by Diabetes. (T.R Dillingham). Prosthetic satisfaction has become a subjective notion, as patients remain dissatisfied with prosthesis. The major objective of any prosthesis is to provide comfort during ambulation. While comfort mainly involves socket and residual limb interface pressure (R. Fitz Patrick). The socket fit, type of prosthetic suspension and alignment can change the interface pressure. (D.A Boone)

Although, a huge amount of research is carrying out to evaluate pressure and stress distribution at stump and prosthetic limb interface but quantitative evaluations remain inapplicable in clinical settings (P. Sewell). Henceforth, suboptimal gait pattern with an increased demand of energy and lack of satisfaction is reportedly experienced by lower limb amputees specifically (Richard E Fan et al.). The Tekscan F-scan transducer pressure mapping is utilized in prosthetics to find out dynamic pressures and compare between different socket types and fabrication techniques (Convery P). But utilization of similar procedure at clinical setups cannot be made possible due to high.

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 the prosthetic compliance and gait in amputees, mapping of pressure can be utilized as an effective source to provide feedback to the clinician to make necessary changes in alignment and fit (Sewell P).

2.2 Problem Statement

Lack of pressure mapping contributes following in Trans-Tibial amputees; asymmetric walking, skin breakdown, pain, lack of prosthetic compliance & increased falling rates (Convery P).

2.3 Objectives of Thesis

Thesis work was mainly focused around the following objectives:

i. Design & Manufacture of a wearable stump liner to map Pressure of Trans-Tibial stump.
ii. Design a commercially viable and cost-effective system for Trans-Tibial amputees
iii. Transmit, Record & Display Stump Pressure Data.
iv. Design and implement an experimental protocol for acquisition of stump pressure data

v. Validation.

2.4 Significance of Study

The main idea is to design a pressure mapping system for trans-tibial amputees ensuring the abnormal and raised pressures in order to determine its effectiveness on prosthetic compliance, proper alignment, walking balance & overall gait pattern. Socket is equipped with the pressure-sensitive stump liner & data acquired from the pressure-sensitive stump liner is recorded throughout gait cycle and during weight bearing. Data displayed into MS Excel can identify exact areas under greater pressures.

There are no such pressure mapping systems 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 properly fabricated and aligned prosthesis and pain relief. The pressurized stump liner designed for this project has a unique design. Overall pressure mapping 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.

2.5 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-tibial 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.

3 Literature Review

3.1 Introduction to Somatosensory System:

Somatosensory system is part of sensory system concerned with sensations of pain, temperature, pressure, touch, position, movement and vibration. 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). However, the neuromuscular response is different from the somatosensory response as neuromuscular response is motor response that travels from efferent to the sensory afferent organs.

3.1.1 Somatosensory Receptors

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

3.1.2 Proprioception

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

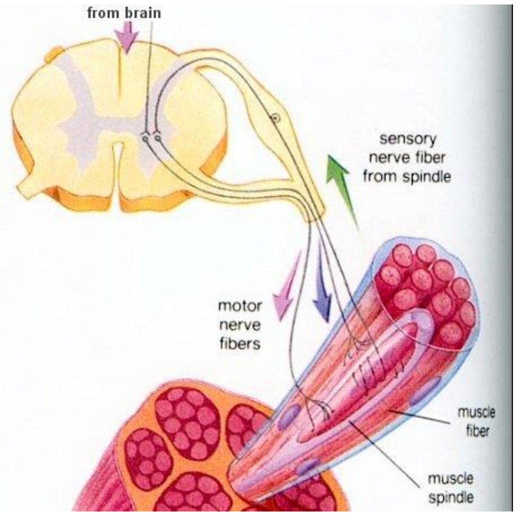


Figure 1: Working of Proprioceptors

3.2 Pressure Sensation:

Pressure sensation is the sensation of maintained distortion of skin through a stimulus, the sensation increases in a linear fashion as the skin indentation increases. The sensory receptors responsible for pressure sensation are slowly adapting cutaneous mechanoceptors. (W.D. Willis Jr) It makes 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 force and pressure sensation which can reproduce desired level of force one or more times stemming from afferent feedback of our muscle, tendons, muscle spindles and proprioceptors (Hung Y.J)

3.3 Gait cycle

A single gait cycle also known as "Stride" 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:

i. **Stride Length**: It is commonly known as measure of successive heel contact of same foot.
ii. **Step Length**: Distance which is measured from the heel strike of one foot to the heel strike of other Foot.
iii. **Cadence**: Number of steps taken per min is called cadence which is approximately 110-115/min.

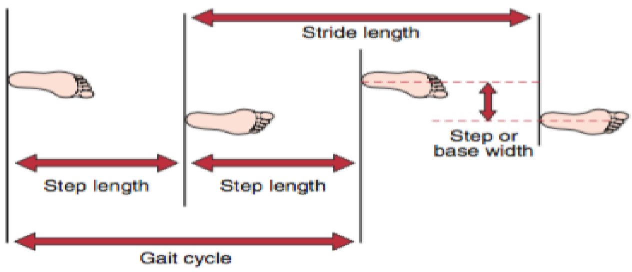


Figure 2: Step Length vs. Stride Length

3.4 Phases of Gait Cycle

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

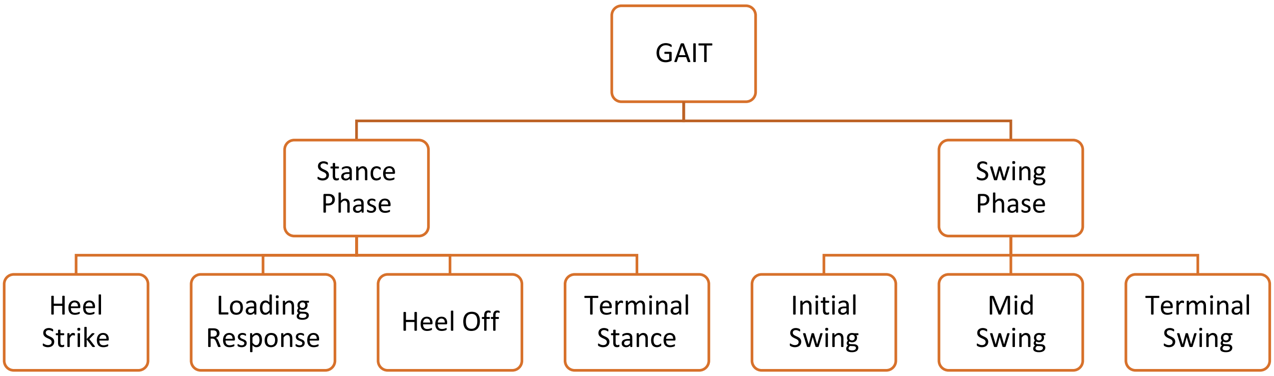


Figure 3: Schematic Representation of Gait Cycle

Stance Phase:

Stance phase initiates with the heel contact on the floor and ends when toe leaves the ground. It comprises approximately 60% of gait cycle. In this phase foot maintains its contact with ground. With reference to *Fig 1.3* sub- phases of stance phase are defined as follow:

i. **Heel Strike:** Refers to the phase when foot makes initial contact with the ground.
ii. **Loading Response:** Refers to foot-flat position on the ground.
iii. **Mid Stance:** Refers to the position where whole weight is being borne on the reference limb as the opposite limb is in swing phase.
iv. **Terminal Stance:** Refers as *Push off* phase as well, comprises heel off and then toe clearing the ground.

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, it is also known as single limb support phase. With reference to *Fig 1.3* phases of gait cycle are defined as follow:

i. **Pre-Swing:** In this phase foot begins to leave the floor.
ii. **Mid-swing:** Foot swings through air during mid- swing position.
iii. **Terminal Swing:** Heel of the foot approaches the ground.

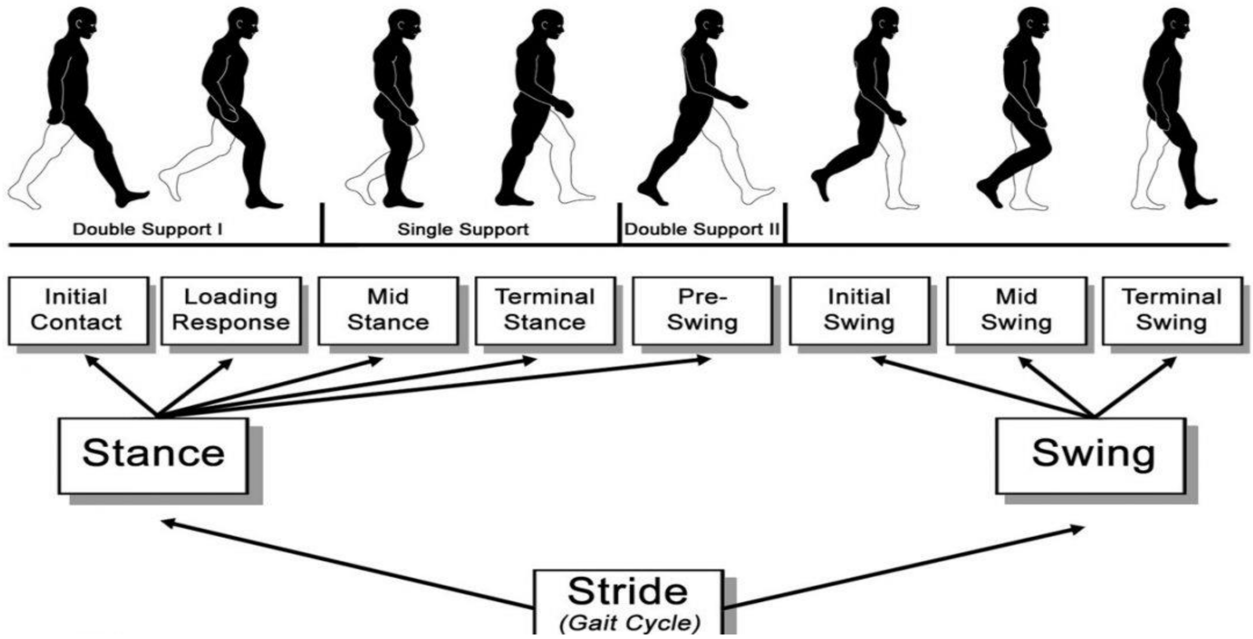


Figure 4: Phases of Gait Cycle

3.4.1 Lower Limb Joints Positioning during Gait Cycle

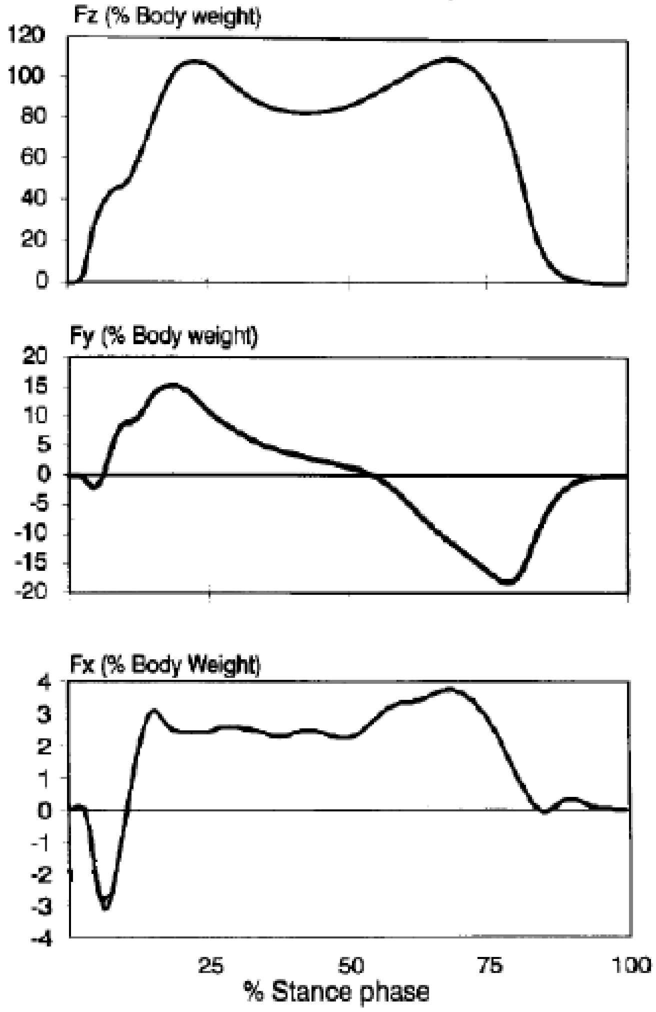
Phase	HS	LR	MS	TSt	PSw	MSw	TSw
% Gait Cycle	0%	0%-12%	13%-32%	33%-50%	51%-62%	63%-80%	80%-100%
Ankle	0◦	5◦-10◦ Planter flexion	5◦ Dorsiflexion	10◦ Dorsiflexion	15◦ Dorsiflexion	0◦	0◦
Knee	0◦-5◦ Flexion	20◦ Flexion	0◦-5◦ Flexion	0◦-5◦ Flexion	40◦-60◦ Flexion	25◦ Flexion	0◦-5◦ Flexion
Hip	20◦ Flexion	20◦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

Table 1: Lower Limb Joints Positioning during Gait Cycle

3.4.2 Ground Reaction Force

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

Figure 5: The three components of the ground reaction force



3.4.3 Pressure Sensation

Pressure is defined as the sum of forces that acts on a particular area of body (Schmid, Beltrami, Zambarbieri, & Verni, 2005). Pressure 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).

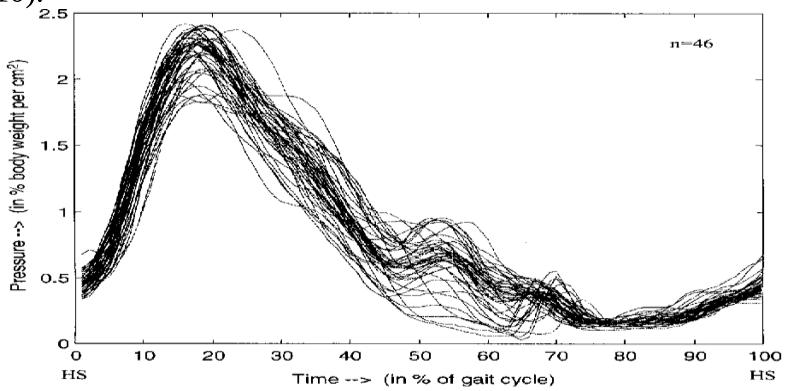


Figure 6: Pressure Characteristics at the Stump

Lower Limb prosthetic users experience pressure on stump-socket interface on daily basis however the soft tissues and skin of stump are not accustomed to pressure bearing which increases the risk of degenerative skin conditions mainly ulcers (Jia et al., 2004). The pressure when raised cause the body to sway slightly and moves center of mass forward of center of pressure which contribute to acceleration which is angular in nature. Its further results in skin problems such as contact dermatitis, hyperkeratosis and hyperplasia (N.L Dudek et al.,2008).

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.

3.4.4 Causes of Amputation

Amputation can be result of any planned surgical procedure as in case of pathological condition of limb, traumatic or congenital. So far pathological causes are mostly concerned with Peripheral Vascular Diseases and are commonest of all the other reasons as incidence of vascular amputations are approximately 8% higher than traumatic reasoning. Diabetes Miletus, tumors, frostbite injuries, neoplasms & thermal and electrical burns etc. are also major reasons behind the amputations.

3.5 Trans-Tibial Amputation

Trans-Tibial Amputation is the removal of the limb through the tibial shaft or in simpler words it is the ablation of lower limb below the knee joint. The bony resection of 12cm below the knee joint is considered functional for the prosthesis fitting for an average adult being.

The rehabilitation of Trans-Tibial amputees (TTA) 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 less oxygen and energy consumption.

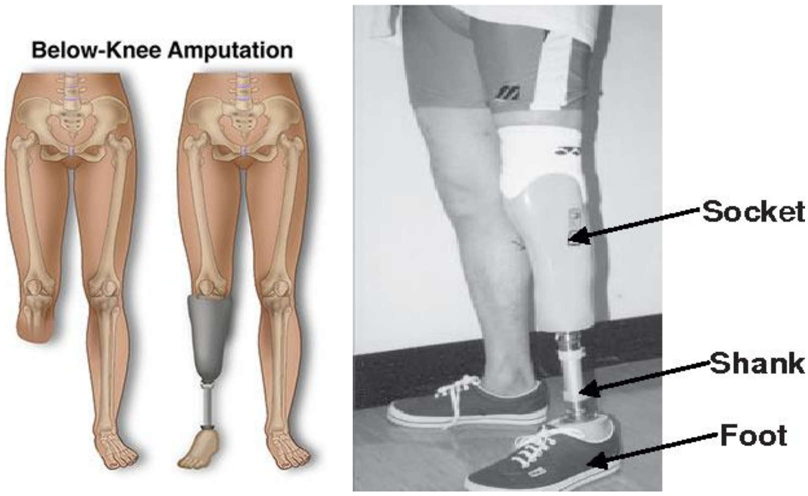


Figure7: Trans-Tibial Amputation (b)Trans-Tibial Below Knee Prosthesis

3.5.1 Gait Analysis of Trans-Tibial Amputees

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

One of the notable parameters is reduced velocity with which a TTP 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 with respect to the residual limb (Goujon-Pillet, Sapin, Fodé, & Lavaste, 2008). In another study, reported results show that TTPs exhibit an asymmetrical walking pattern (Circumduction of prosthetic limb) along with a major time during standing being spent on the sound limb hence resulting in antalgic type of gait pattern (Sonja M.H.J Jagers,MD, PhD, J.Hans Arendzen, MD Phd, Henry J. de Jongh, n.d.). More muscle activity was reported in TTPs during the swing phase of gait cycle along with an increased duration for double limb support (Eva C Wentink, Prinsen, Rietman, & Veltink, 2013).

3.5.2 Normal Prosthetic Rehabilitation Procedure

Rehabilitation program of TTPs 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:

i. Analysis of Forces
ii. Weight Bearing on Prosthetic limb
iii. Gait Training with Prosthesis/Ortho-prosthesis
iv. 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:

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

3.5.3 Lack of Pressure Mapping in TTA

A prosthetic foot lacks the normal plantar aspect & all of its proprioceptors. Thus, replication of exact Pressure pathway during gait cycle as that of a human being is not possible. As a consequence of not measuring stump-socket interface pressures there is also no quantitative assessment of biomechanical, fixative, supportive or corrective forces (MAK, AFT et al).

In a study when stability feedback during the gait cycle of prosthetic leg was found out, it was reported that Pressure pathway of prosthetic foot with respect to knee is not aligned according to normal mechanics of human gait (Martin & Gregg, 2015). Whereas in any non-amputee individual, the Pressure follows its path from heel to toes which is the most crucial variable to quantify the dynamic balance (Lugade & Kaufman, 2014). So, the lack of COP Feedback in TTA contributes a major part of asymmetric walking as no sensory clue is available (Miller, Deathe, Speechley, & Koval, 2001).

3.6 Previous Work

3.6.1 Intro to Pressure Mapping System

Restoration of sense of kinesthesia is a developing area of providing rehabilitation aid to the 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 ambulate properly is required to be filled (Zabjek & Andrysek, 2014).

The TACTILUS pressure sensing system was used to identify impact of pressure as well as pressure distribution on selected regions of TTP. Pressures were measured through the stump-liner and liner-socket interfaces. This is used as an alternative to determination of appropriateness of the socket design and fit. It was also found that the stump-liner interface showed greater pressures as compared to the liner-socket interface. It also indicates that the liner absorbs possible shocks and provide even distribution of loads. This system can be used in the designing, fabrication and application of TTP socket. Significance of this study can be applied in testing and modification of TTP Socket (Rajtukova, Hudak et al 2014)

In another study, pressure characteristics of stump-socket interface in TTA's using an adaptive prosthetic foot was done. Twelve patients using Proprio-foot (Ossur) were assessed on the basis of their gait analysis during walking, stair climbing and incline walking. Peak pressures at socket interface were compared and shown to be raised during incline walking due to maximum knee movement and pressure (Sebastian, wolf et al. 2009).

3.6.2 Intro to Pressure Mapping

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

Various designs for pressure mapping have been introduced so far for practical applications. As in development of a system for accurate pressure mapping key features or aims of designed system 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 devices and sensor systems available, each of them having some accuracies and some shortcomings depending mainly upon the positioning of pressure sensors and their linearity (Kanitthika & K, 2014). Potential applications of Pressure mapping are pressure ulcers prevention, gait analysis, performance analysis during various sports and rehabilitation (Rosenbaum & Becker, 1997).

3.6.3 Concept of Gait Phase Based Pressure Distribution

So far it is cleared that Pressures between the socket-stump interface are abnormally placed in TTA contributes difficulty in mimicking normal gait (Nolan et al., 2003). Temporal stability is also reduced due to lack of feedback from ground contributing to relative increase in vertical ground reaction force (VGRF) (Nolan et al., 2003). Henceforth, research regarding the provision of gait phase-based identification of forces and pressures is an emerging area of study.

Restoration of near to normal gait and acceptance of prosthesis among its users can be achieved if quantitative measures are available to provide an appropriate amount of pressure on the stump liner and stump socket interface (Faustini M.C, Crawford et al). In a study the effects of various TT socket settings were examined using the F-Socket (TEKSCAN) system. The effects of pressure in anterior, posterior regions of stump during 5, 0 and 10 degrees of flexion were observed and results were obtained using paired t-test to find out better outcome with flexion range (GohJ, LEE. P. et al, 2003). In another study pressures on TTP Socket during walking on plain ground and walking upstairs was also done to rule out the effects of ground surface on stump pressures (Eshraghi. Osman et al 2012).

3.7 Summary

This chapter highlights the parameters of normal gait cycle. It also elaborates that how the gait cycle of trans-tibial amputees is affected due to lack of pressure mapping before and after fabrication of prosthesis. This lack of feedback contributes increased training duration for TTA’s and thus burden over the rehabilitation clinics. Moreover, work done previously to ensure the appropriate pressure mapping from the stump-socket and stump-liner interface is discussed.

4 Research Methodology

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

4.1 Work Flow

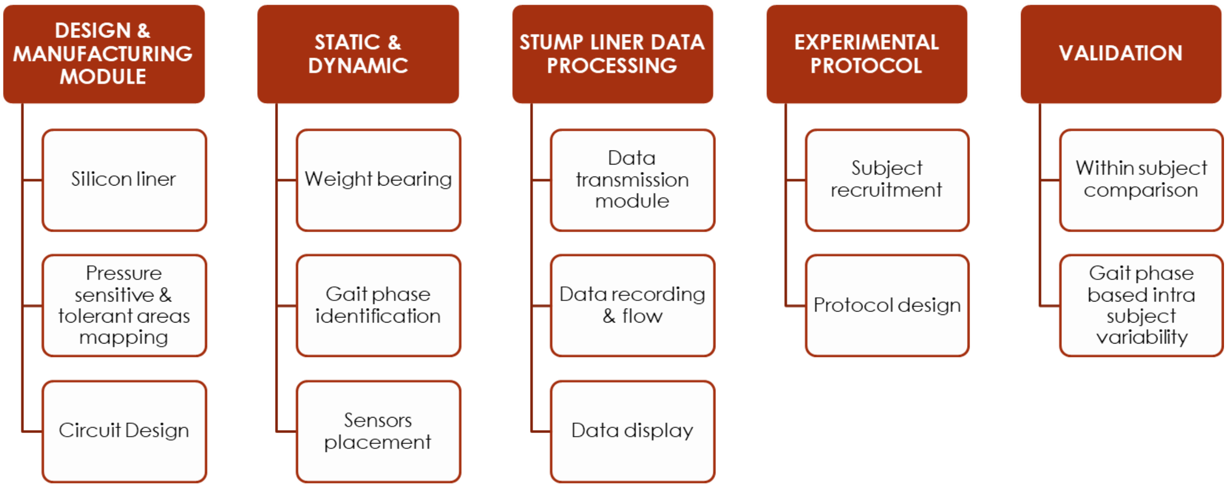


Figure 8: Work Flow

4.2 Designing & Manufacturing Modules

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

i. Stump liner Fabrication with Pressure Mapping Sensors
ii. Mapping Pressure Sensitive and Tolerant areas of stump
iii. Circuit Design

Figure 9: Concept of the Wearable Pressure Mapping System

Data from pressure sensitive stump liner is mapped through the electronic board and microcontroller housed in casing. The case is secured to thigh region by using Velcro Straps and the same electronic board operates the pressure sensors placed on the stump liner through the time discrete signal being sent through the stump liner. The pressure sensors will then generate and plot data on MS-Excel using PLX-DAQ. (Details will be explained in next Section)

4.2.1 Stump Liner Fabrication with Pressure Mapping Sensors

Pressure mapping through pressure mats, force plates, motion capture systems are opening new horizons in rehabilitation of physically disabled (Ming-Yih Lee & Yang, 2011) (Yang et al., 2012). In different studies various solutions for dynamic pressure mapping have been introduced. Force sensitive resistors (FSR) have been utilized in a numerous study 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 solutions for pressure mapping are quite accurate but the cost of them is very high so their access is an issue for physical rehabilitation centers.

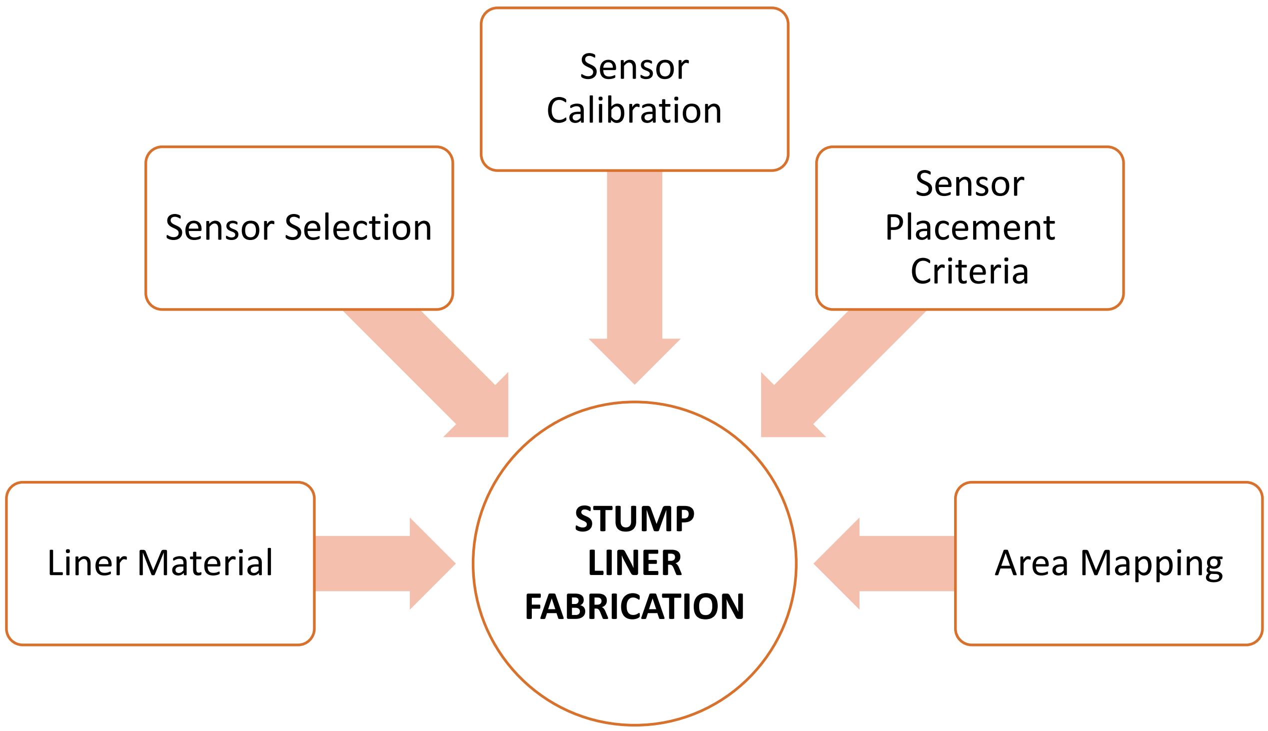


Figure 10: Steps Involve in Stump Liner Fabrication

4.2.1.1 Stump Liner Design Requirements

An ideal stump sock/liner thus designed was required to fulfill the following requirements:

i. Accurate mapping of pressure being exerted on the sensors.
ii. Allow normal walking without causing any gait abnormalities.
iii. Be comfortable.
iv. It must be light in weight (Bamberg et al., 2008).
v. Must be placed in any shape of stump without any hindrance.
vi. Wiring must not be providing any hindrance in normal walking.
vii. Withstand temperature conditions of the stump 25° C- 45°C.
viii. Power Consumption must be enough to support dynamic device design.
ix. Cost Effective.

4.2.1.2 Stump Liner Material

Stump Liner material must be comfortable, flexible and strong enough to support the amount of forces being exerted to it. For the said purpose, Silicon is selected. It is the readily available and moreover it can be molded into any shape very easily. Besides this, flexibility & comfort level provision are also the reasons of its selection. 3mm Silicon sheet is chosen, as it will allow the stump to be placed inside the socket without any interference. Sensors will be placed over the silicon stump liner.

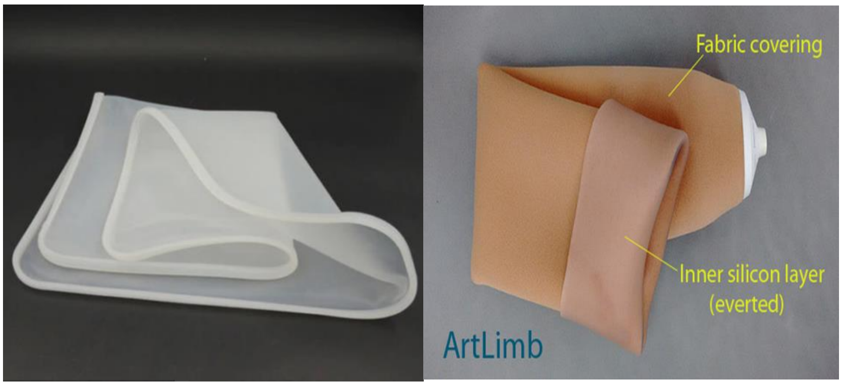


Figure 11: Silicon Sheet (b) Silicon liner

As the sensors are to be place on the upper side and wiring is to be passed from the upper side of the stump liner, a flexible bandage to cover the liner from upper sides is needed. Silicon is the ideal material. 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 stump liner is to withstand the temperature conditions. EVA Foam 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 crepe bandage of 6mm and 4mm is used to cover the upper surface of stump liner to hold the sensors and socket in place and avoid any possible risks of slipping.

Figure 12

4.2.1.3 Sensor Selection

The basic of concept of the stump liner design is to place sensors strategically on the areas where most of the body forces are being exerting during walking (Kanitthika & K, 2014) (Shu et al., 2010). (This criterion is described in detail in the following section). The pucks can be used to concentrate the force on the sensing part of the sensor. But due to adaptable nature of silicon liner pucks are necessarily required

Among many available options for force measurements, strain gauge is one of the most commonly used one. But they are not suitable for the application of stump liner primarily because of their 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 on the socket-liner interface.

FSR have been utilized in some previous studies (Lincoln & Bamberg, 2010) (Veltink, Liedtke, Droog, & vanderKooij, 2005). They measure 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 as we would need no easy breakage which is possible due to its flexible nature. But they are somehow devoid of the linearity and accuracy.

Commercially various kinds of FSR to measure force are available, but Ampere' IMS-C20B thin film resistive sensor can measure force between two surfaces and test them statistically and dynamically its 100micro meter thickness makes it able to be placed directly into test. It can measure up to 100kg. And it is cost effective as compared to other FSR commercially available.

Figure 13: FSR IMS-C20B ®

4.2.1.4 Sensor Calibration Method

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

FSR IMS C20B series is a single point piezo resistive thin film sensor which can test the forces between two surfaces statically and dynamically. 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 is 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. These sensors simply utilized an OP Amp to amplify the value of voltage being generated every time when force is applied.

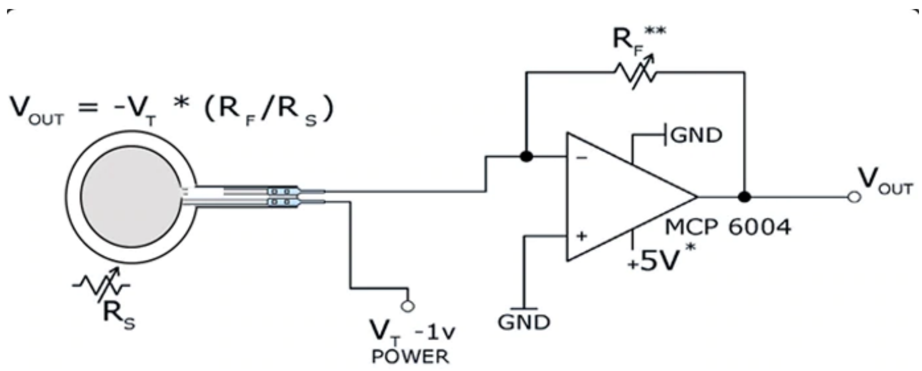


Figure 14: Circuit Diagram of Force Sensors

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

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

(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 15: Sensor Calibration Method

As shown in Figure 3.8, there is a fixed system where known loads are being applied on the sensors. 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.

$$F'' = F' x L_2 / L_1$$

(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 12 sensors is slightly different from each other. On plotting a graph between voltage and force all the sensors show approximately a linear curve. The results of output voltage of 12 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.

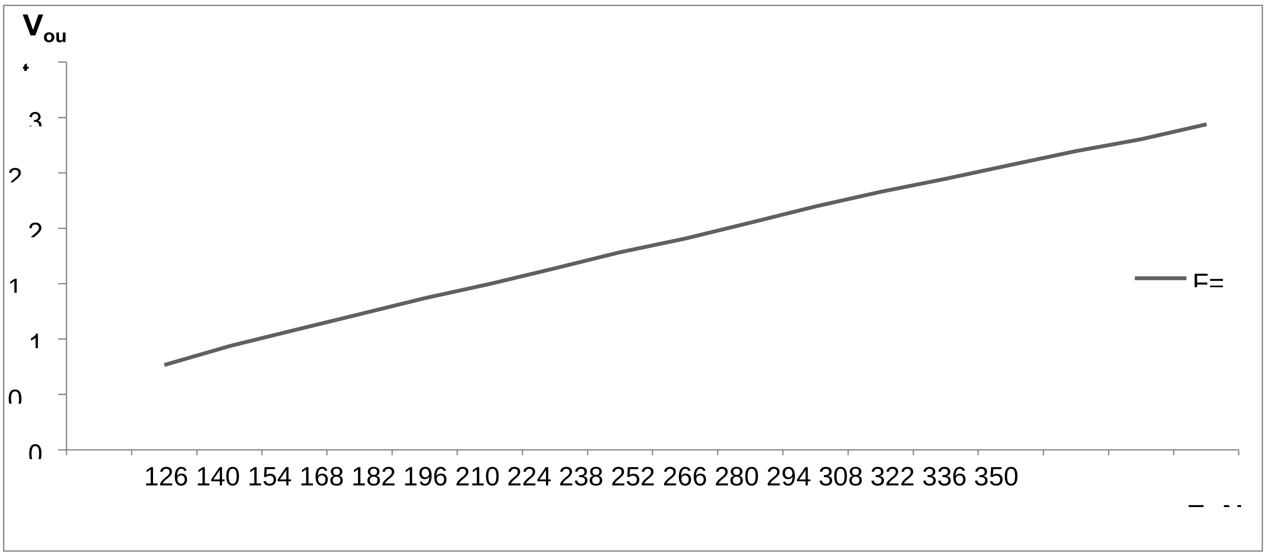


Figure 16: Force vs Output Voltage for 11x Sensors Straight line indicates the linear response of the all the sensors.

4.2.1.5 Sensor Position Criteria

The outer side of stump liner can be divided into 12 points and these points are markes as red and blue colors. These 12 points are basically representative of the anatomical pressure tolerant and sensitive areas of stump upon which loads are being borne during walking. The red points are the pressure sensitive regions which are not ideal for large pressures, while blue points are the pressure tolerant regions that are capable of bearing large loads. These points are mainly concerned with the distribution of forces with prosthesis during standing and walking. Henceforth, static as well as dynamic forces are aimed to be concentrated on these points (Lin Shu et al., 2010).

These areas are divided as (*Figure 17)* pressure sensitive areas of stump, which include all the bony prominences of stump such as patella (knee cap), lateral tibial condyle, tibial tuberosity, distal end of tibia, distal end of fibula, femoral condyle and fibular head. While pressure tolerant areas are those which are tendons or muscle regions such as patellar tendon, medial tibial flare, supracondylar area, supra patellar area medial and lateral tibial flare. These points are thus important to derive physiological, anatomical, functional & biomechanical information for limb kinetics and kinematics.

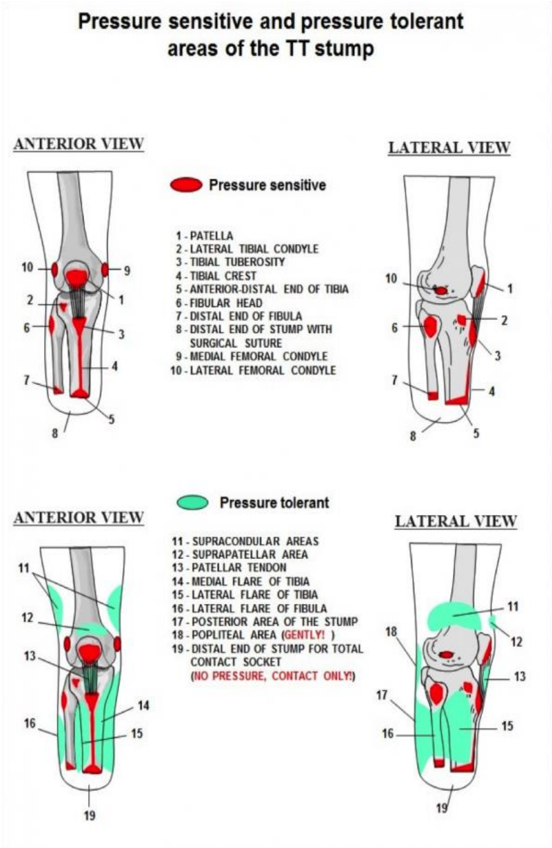


Figure 17: Sensor Placement Points

4.2.1.6 Pressure Mapping

The stump liner embeded with FSR sensors that maps the Pressure as soon as the weight bearing on the stump occurs. Static Pressure is measured during standing/ weight bearing while for dynamic pressure mapping subject has to ambulate with prosthesis. Wires are soldered to the terminal of each sensor, and are connected to circuit. The output of 12 sensors is processed and value against each sensor generated is recorded for further interpretation. The output signal from each sensor is processed through Aurdino Mega.

Figure 18: Stump Liner Embedded with FSR Sensors

4.2.2 Circuit Design

Following figure is the circuit diagram for twelve sensors is shown, similar circuit for 11 sensors is made.

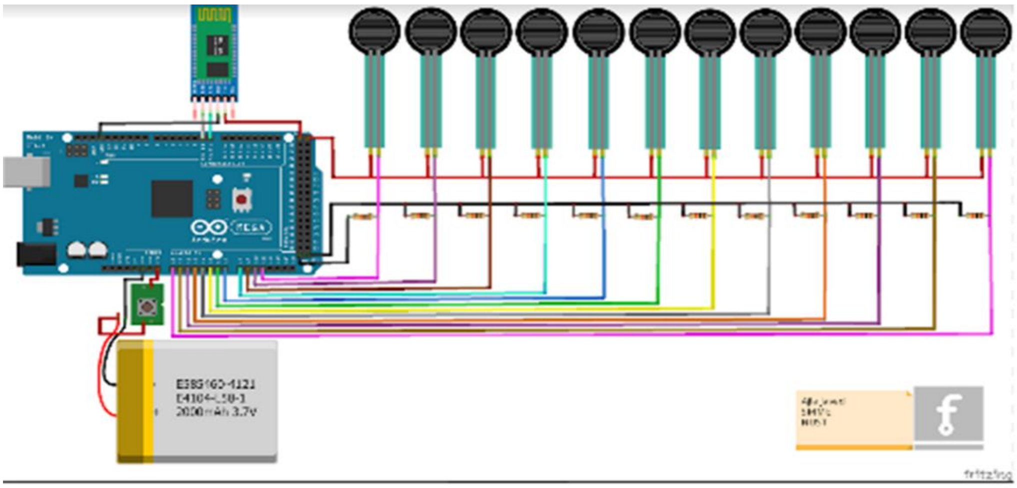


Figure 19: Circuit Diagram for twelve sensors

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 voltage regulated 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. A Bluetooth module receiving power of 5V is also connected to Arduino for serial communication of data in real time.

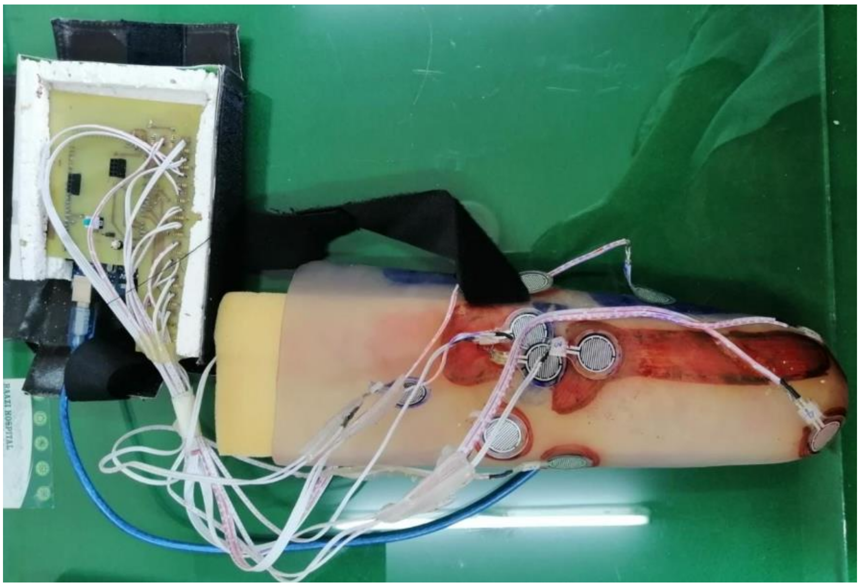


Figure 20: Silicon Stump Liner for Pressure Mapping along with the Circuit

4.3 Identification of Heel Strike Phase

During heel strike 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- tibial 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, our device along with other visual and audio clues help to identify the abnormally raised pressure through the TTP socket and manual changes in prosthetic alignment particular to that phase can be made. By audio clue we mean the feedback for the trainer & by visual clue we mean the setting of gait training room the mirrors, parallel bars etc.

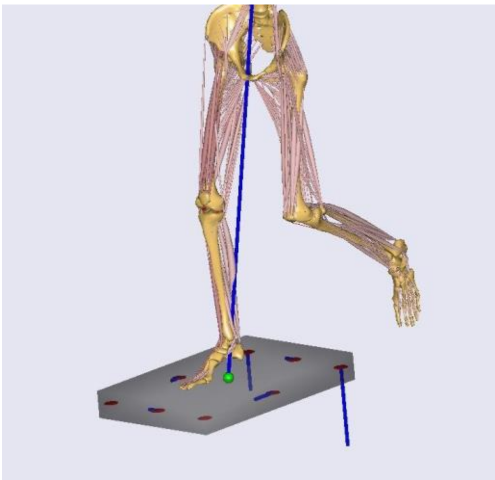


Figure 21: GRF during Heel Strike/ Initial Stance

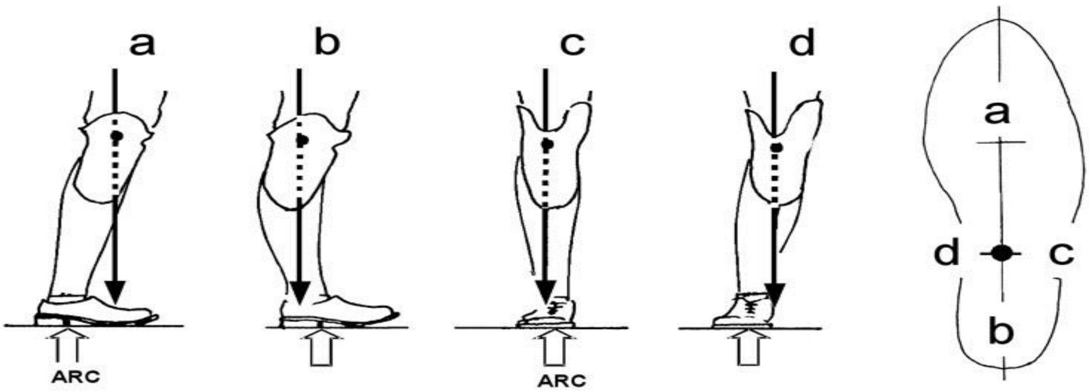


Figure 22: Effect of GRF and Prosthetic Alignment on Gait of TTP user

4.3.1 Identification 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.

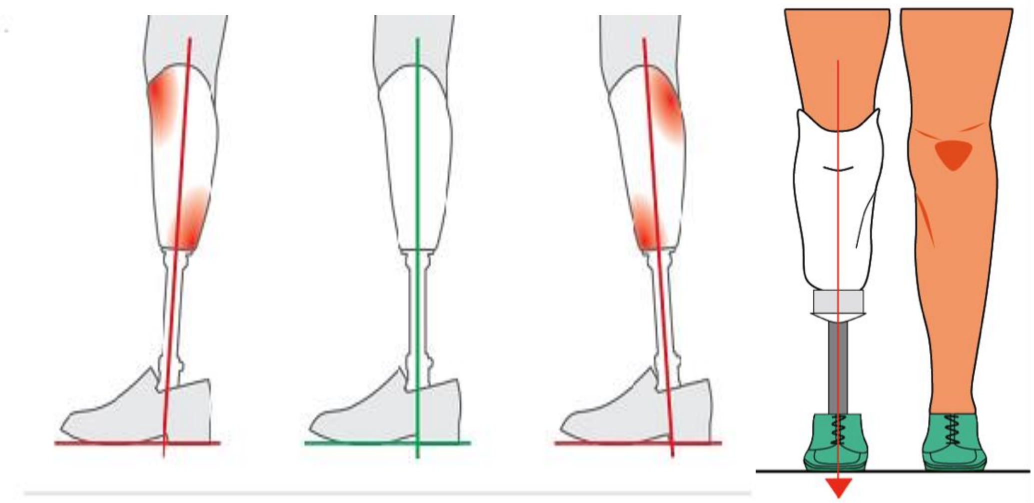


Figure 23: Malalignment Pressure points (b) GRF during mid stance

4.3.2 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. It is also known as pre-swing phase. Because the limb is preparing to enter into swing phase. It mainly involves the flexion at the knee joint. Any abnormal pressures due to alignment or poor prosthetic deign could lead to gait abnormalities of circumduction as limb itself is unable to clear the ground.

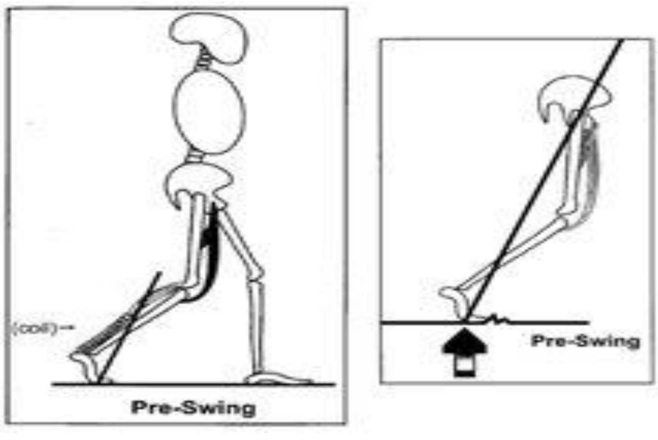


Figure 24: GRF during terminal stance phase

GRF during this phase passes through the anterior of the ankle and hip joint and posterior to the knee 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).

4.4 Stump Liner Data Processing

The data acquired from stump liner is basically the output obtained from 12 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 of an amputee.

The analogue signals from each sensor is converted to digital through a set of steps (including code mapping in Arduino) which are not only processing these signals 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/ prosthetist to have the idea of appropriate pressures on stump during the gait cycle. This section therefore, deals with the mechanism responsible for the flow of data from stump liner.

Followings are the three objectives to be obtained:

i. Data Transmission
ii. Data Recording
iii. Data Display

4.4.1 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 interaction with microcontroller and PC very easy.

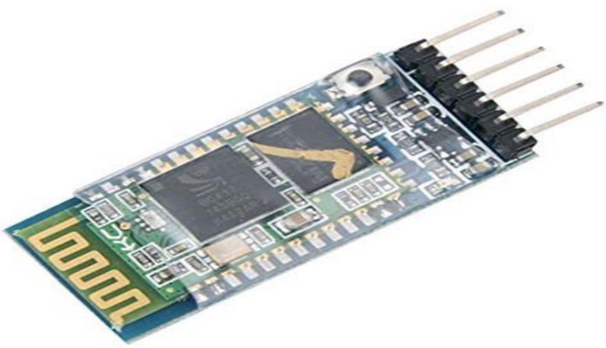


Figure 25: Bluetooth Module HC- 05

The module is connected to Tx/Rx pins of the Arduino and also with the inbuilt/ USB Bluetooth module on PC. It has simple circuitry involves which makes its utility more feasible and thus working with it is not a cumbersome task. 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 with each other.

Once the hardware is completed, the source code is made and burns in Arduino Mega to fetch data from 12 sensors of stump liner and transfer it into PC for the recording of numerical values for future interpretation.

The circuit diagram is shown as follow:

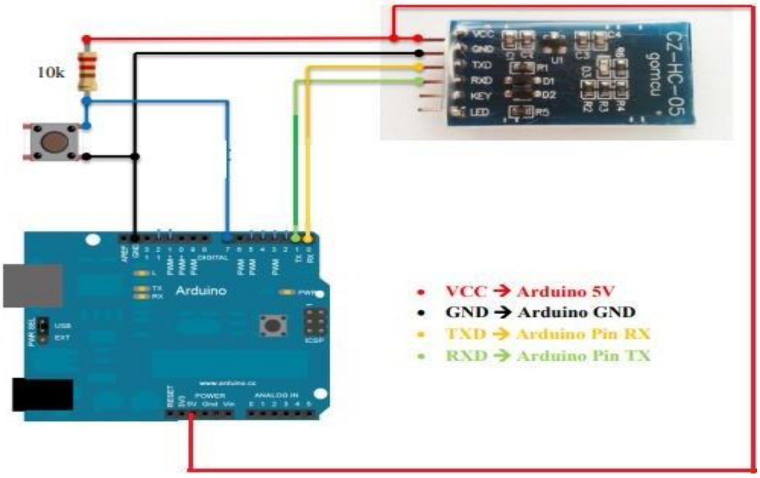


Figure 26: Bluetooth circuit Diagram

The overall flow of data is depicted as follow. Following figure shows that stump liner data is transmitted to Arduino when interaction between BT and Arduino takes place. The interaction 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 and displayed on PC as pressure values the data is recorded there as well. Here it is to be mentioned that the data being displayed on PC through PLX-DAQ into MS-Excel, takes place in real time.

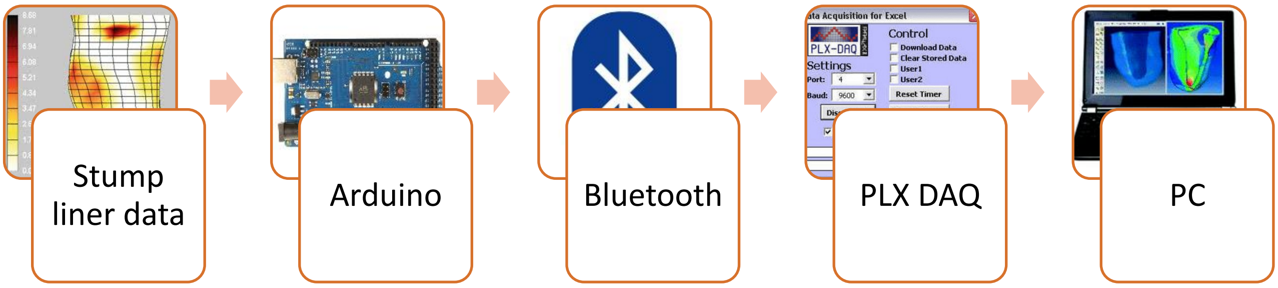


Figure 27: Data Flow

4.4.2 Data Recording

Data from each sensor is sampled at the rate of 7.5Hz which means that approximate time period is 135ms for each sample. The data recorded is compiled in .txt files and is saved in MS Excel for further processing.

4.4.3 Data Display

Data needs to be displayed in real time in order to help the clinician to have an idea about the raised pressures at specific regions at the specific instance in gait cycle. For this purpose, data from BT is transmitted to the MS Excel through PLX DAQ. The data showing pressure values from 12 sensors is displayed on Excel sheet and is averaged for further processing and plotting.

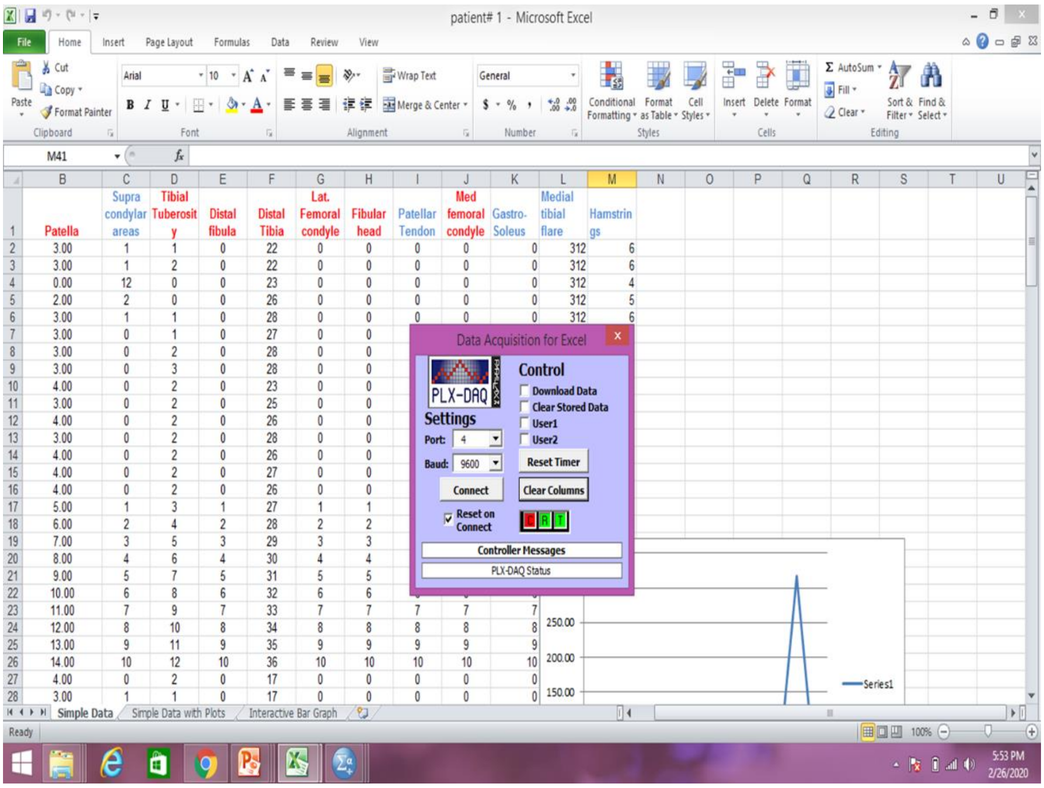


Figure 28: Data plot of 12 FSR in Excel

PLX-DAQ:

PLX-DAQ is a Parallax microcontroller data acquisition add-on tool for Microsoft Excel. Any of our microcontrollers connected to any sensor and the serial port of a PC will send data directly into Excel. It can plot or graph data as it arrives in real-time using Microsoft Excel.

DATA PROCESSING:

The averaged data is then plotted on line graphs which shows various pressure from twelve areas of stump. Gait phases of the subject are marked on the Excel sheet using visual monitoring and videography while subject is walking through all phases of gait cycle and hence plotting of dynamic data is done through which gait phase identification that which shows marked increases in pressure values and it can be correlated with the abnormalities of the stump or prosthetic alignment. While static data is plotted when the subject is in standing position or loading response phase of gait cycle. The regions marked as blue on Excel are pressure tolerant areas and raised values of pressure on them are not bothersome. While the regions marked as red are the pressure sensitive regions and raised values of pressures on them should be dealt with by making necessary adjustments in prosthetic alignment, fit, comfort and training.

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

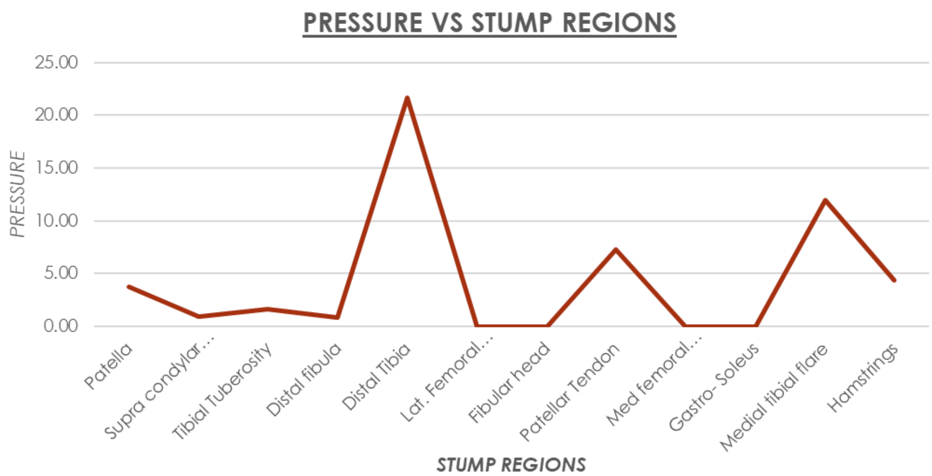


Figure 29: Test Data of Stump-Liner Interface

The display is an easy way to gather information about real time changes. Pressure 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.

4.5 Experimental Protocol

In order to validate the working of device, an experimental protocol is designed for subjects having no complications with prosthesis. The need of such experimentation is required not only to validate the device but also to create a log of data from prosthetic users having no complications with prosthesis. The collected data can be utilized for future studies.

4.5.1 Subject Recruitment Criteria

The protocol designed thus comprises 7 trans-tibial prosthetic users. Irrespective of their socket type, prosthetic components, heights, weights or gait pattern followed, they are included in the study with the criteria of being able to walk with their Trans Tibial Prosthestic limb whether first time or old prosthetic users and the ideal stump size of 12-14cm was considered for application. For optimum testing of device, random sampling from TT prosthetic user population is carried out.

Parameter	Mean	Standard Deviation
Age	35	±3.29
Height	5.8”	±2.20
Weight	80kg	± 11.7

Table 3 Parameters of Subject

4.5.2 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:

i. Each subject is asked to take off prosthetic limb.
ii. Stump liner having sensors attached on its surface is worn on the stump and then socket is placed on the stump liner.
iii. The circuit box is secured to the thigh region by Velcro straps.

4.5.3 Method of Trials

Each subject is asked to wear the device (Stump Liner) then wrap around the elastic bandage of 6mm width and then the prosthesis socket is worn on the socket liner. The subject is asked to bear weight and then walk on a straight path while wearing the device at a normal walking speed. The no. of steps each subject is asked to move are 12 in number. Per subject total no. of trials taken are 3. Videography is done to ensure the data is synced with the gait phase marked on Excel sheet.

Figure 30: Data recording

4.6 Summary

The main focus of this chapter is on the designing of a device which is capable of mapping pressure throughout gait cycle & its effective application in clinical set ups for better prosthetic compliance. The chapter discuss various parameters involved in device design. It also explains the experimental protocol performed in order to validate the device.

5 Results & Discussion

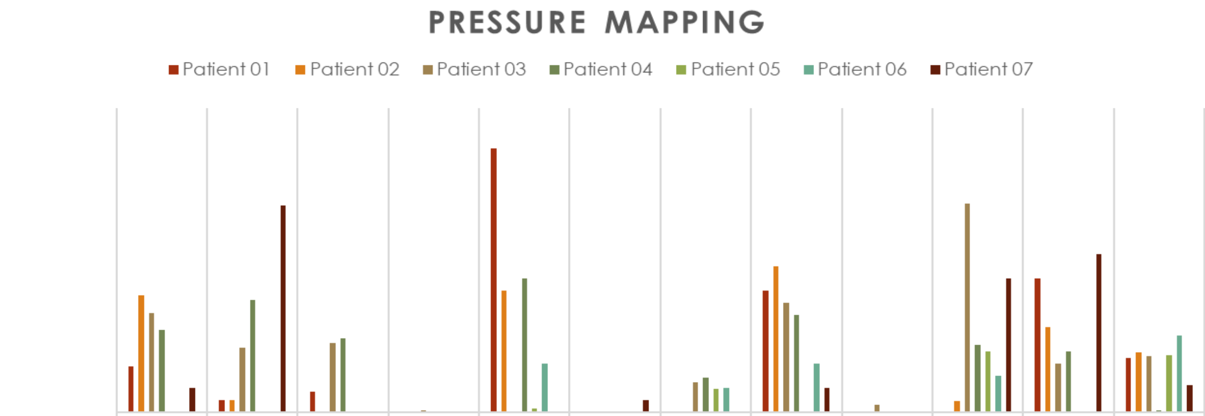
Once the device is fabricated it is required to put it through tests to analyze its working and effectiveness. Once the data from prosthetic users is acquired for multiple trials, its analysis is to be made. In order to assure the maximum working of the device and validate its functioning accordingly,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

i. Comparison of Sensor Point Pressure According to Stump Region among Subjects
ii. Intra Subject Comparison of Pressure before and after prosthetic adjustment
iii. Gait Phase Based Intra Subject Variability

5.1 Comparison of Sensor Point Pressure among Subjects

The data acquired for each step for same trial will show some variability among subjects. 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 pressure bearing during static loading can be analyzed from the data. The recorded data for individual sensor is analyzed to extract the pattern of loading and to check variation in loading mechanism in twelve different regions of stump.

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



	Patella	Supra condylar areas	Tibial Tuberosity	Distal fibula	Distal Tibia	Lat. Femoral condyle	Fibular head	Patellar Tendon	Med femoral condyle	Gastro-Soleus	Medial tibial flare	Hamstrings
Patient 01	3.74	0.94	1.66	0.00	21.63	0.00	0.00	10.00	0.00	0.00	11.00	4.40
Patient 02	9.59	1.00	0.00	0.00	10.00	0.00	0.00	12.00	0.00	0.88	7.00	4.88
Patient 03	8.09	5.25	5.66	0.16	0.00	0.00	2.41	9.00	0.59	17.16	4.00	4.59
Patient 04	6.74	9.17	6.04	0.00	11.00	0.00	2.83	8.00	0.00	5.51	5.00	0.09
Patient 05	0.00	0.00	0.00	0.00	0.24	0.00	1.91	0.00	0.00	5.00	0.00	4.69
Patient 06	0.00	0.00	0.00	0.00	4.00	0.00	2.00	4.00	0.00	3.00	0.00	6.25
Patient 07	2.00	17.00	0.00	0.00	0.00	1.00	0.00	2.00	0.00	11.00	13.00	2.21

5.1.1 Pressure Sensitive Distal Tibia Region Point Pressure analysis

During loading a prosthetic limb, the maximum pressures are observed at the distal end of stump as it is the area from which weight transmission takes place (Rajtukova, Hudak R., Zivkak 2014). It is the pressure sensitive region because it's the bony end of stump hence it is bound to have a limited pressure. Our device is being validated for the same pattern. Maximum pressure on the distal tibia portion (sensor 5 in our setting) is observed. The reason for maximum loading on distal tibia during the weight bearing phase ensures secure weight transmission and acceptance by the prosthetic limb and hence by the ground.

The results for sensors at distal tibia are plotted for seven subjects static loading for a single trial.

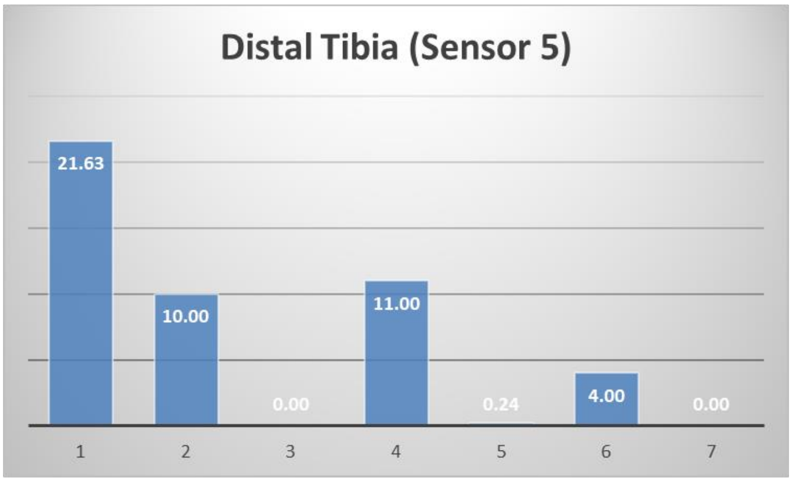
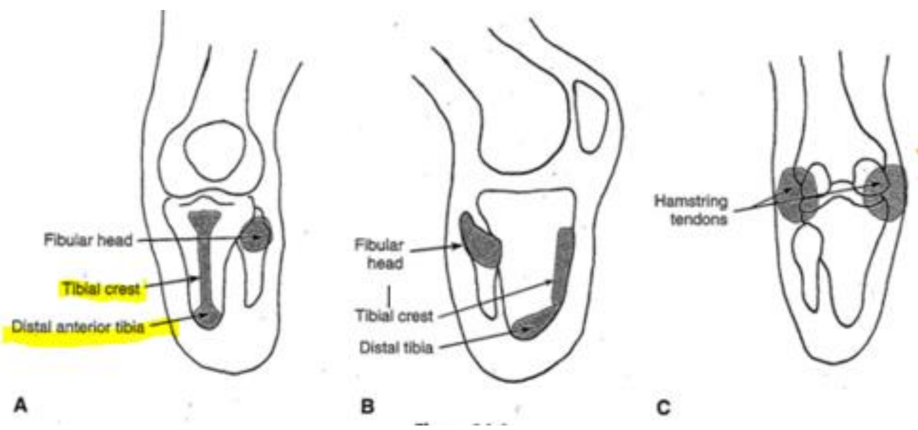


Figure 31: Individual Sensor Graph for Distal Tibia



5.1.2 Pressure Tolerant Patellar Tendon Region point Pressure Analysis:

The analysis of patellar tendon region in TTP which is also one of the pressure tolerant regions indicates that pressure on the sensor more bears more load during static loading (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 tolerant, more the body is said to be balanced.

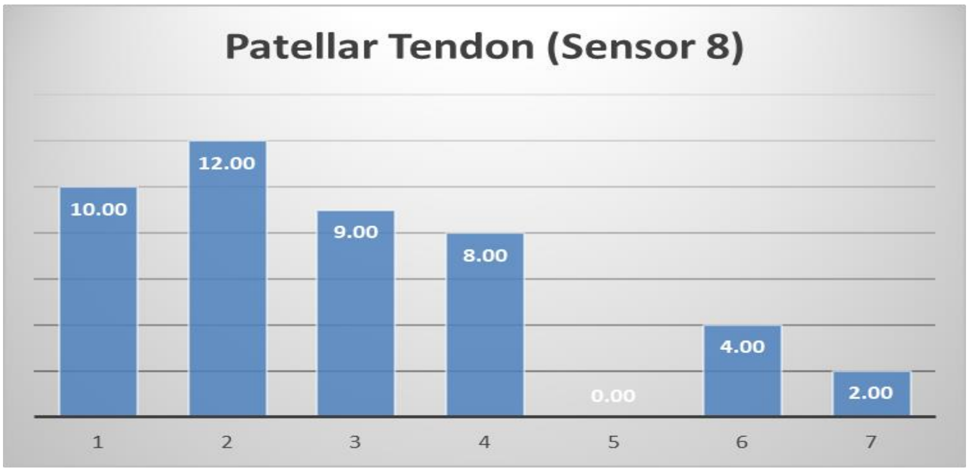


Figure 32: Individual Sensors Graphs for PT

5.1.3 Pressure Tolerant Posterior Region of Stump Pressure Analysis:

The interpretation of the data acquired from the sensors embedded in the posterior region indicates that during static loading a normal subject will try to balance its body by bearing more loads by the muscle flares and bulk regions which are mainly on the posterior surface of stump marked as blue on the device. These include the hamstrings which are the flexors of knee and extensors of hip joint. The gastro-soleus compartment and the medial tibial flare. As we know the co-activation of these muscle help in pressure tolerance by the stump which is important for forward propulsion. It is also 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).

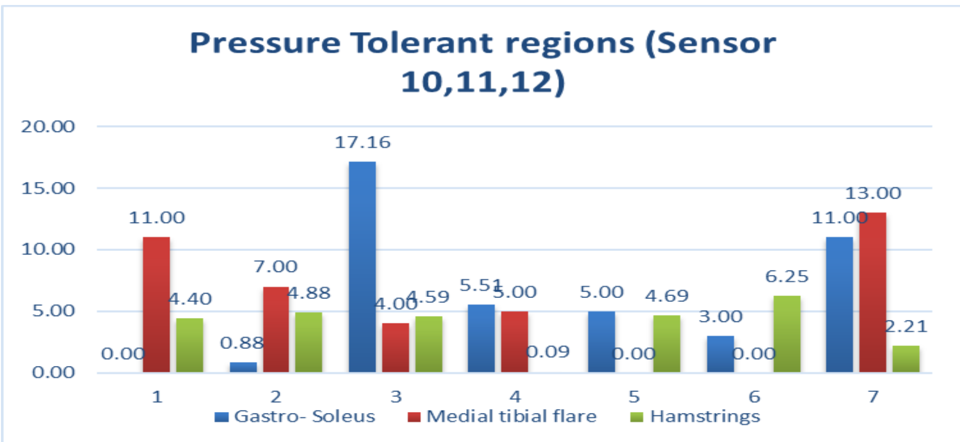
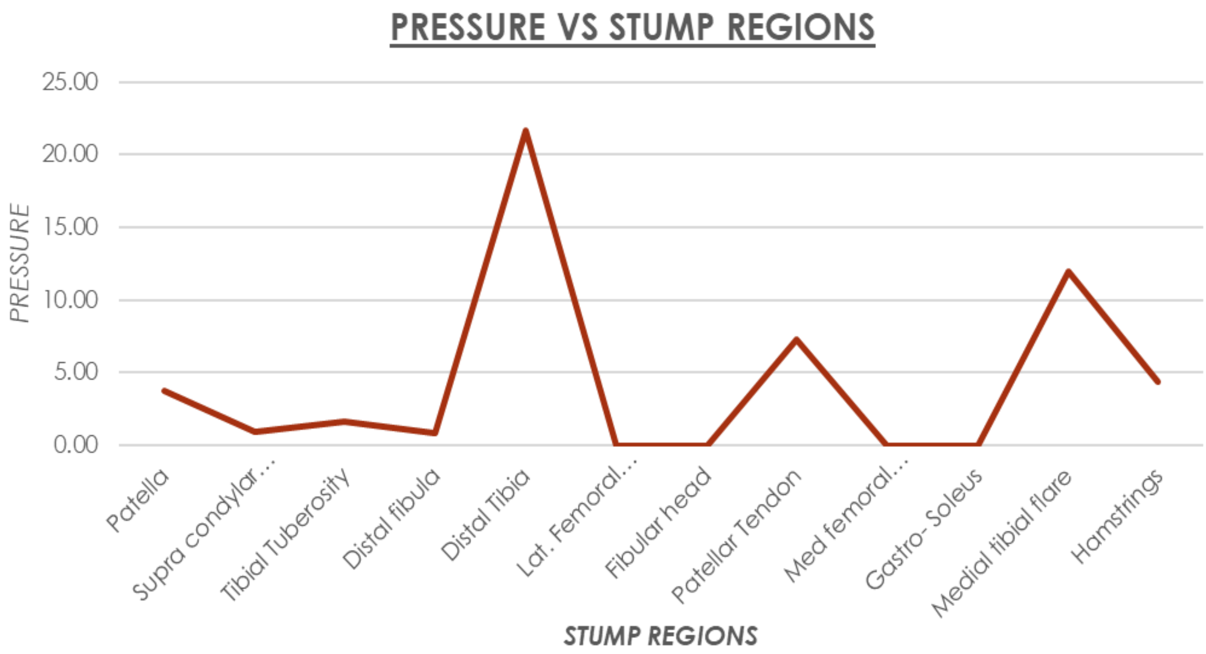


Figure 33: Individual Sensor Graphs for Fore Foot

5.1.4 Intra-Subject Pressure Value Before Prosthetic Adjustment:

Following results show intra subject variation for one trial during static loading of stump. The graph below shows pressure values of patient 1 who was also having complaints of pain at the distal most end of stump. By mapping the pressures, we found that distal tibia was having raised pressures.



5.1.5 Intra- Subject Pressure After making Prosthetic Adjustments:

The clinician made a relief window at the distal end of prosthesis due to which the distal tibia became less prone to pressure and patient felt relief in pain. It can be demonstrated by plotting the pressure again after prosthetic adjustment. At distal tibia the irritation and pain reduced as the pressure value dropped to $11N/m^2$ from $21N/m^2$ hence showing the efficacy of the device.

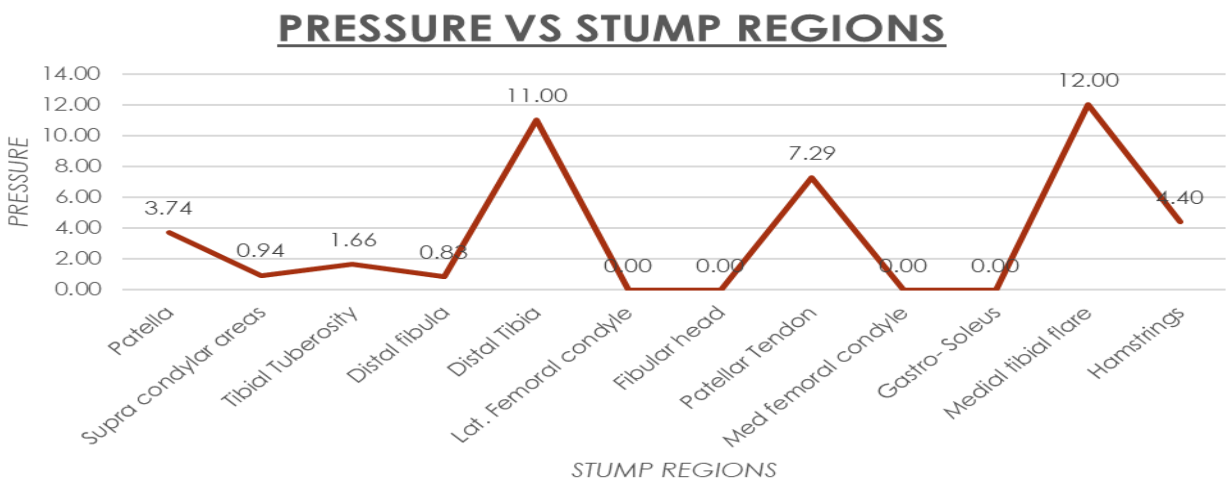


Figure 34: Pressure value on distal stump after prosthetic adjustments

5.2 Gait Cycle vs Pressure

The last step of validation is to compare pressure on stump regions through different phases of gait cycle. The graph demonstrates the values of pressures from twelve regions of stump, five pressure tolerant and seven pressure sensitive areas during two major phases and different events of gait cycle.

The pressures are observed to be higher at the Tibial tuberosity and distal tibia which are both pressure sensitive regions, during stance phase of gait cycle. Over all the stance phase which involves the weight bearing and shock absorption showed greater pressure values than the swing phase during which the limb is in air and have no ground contact.

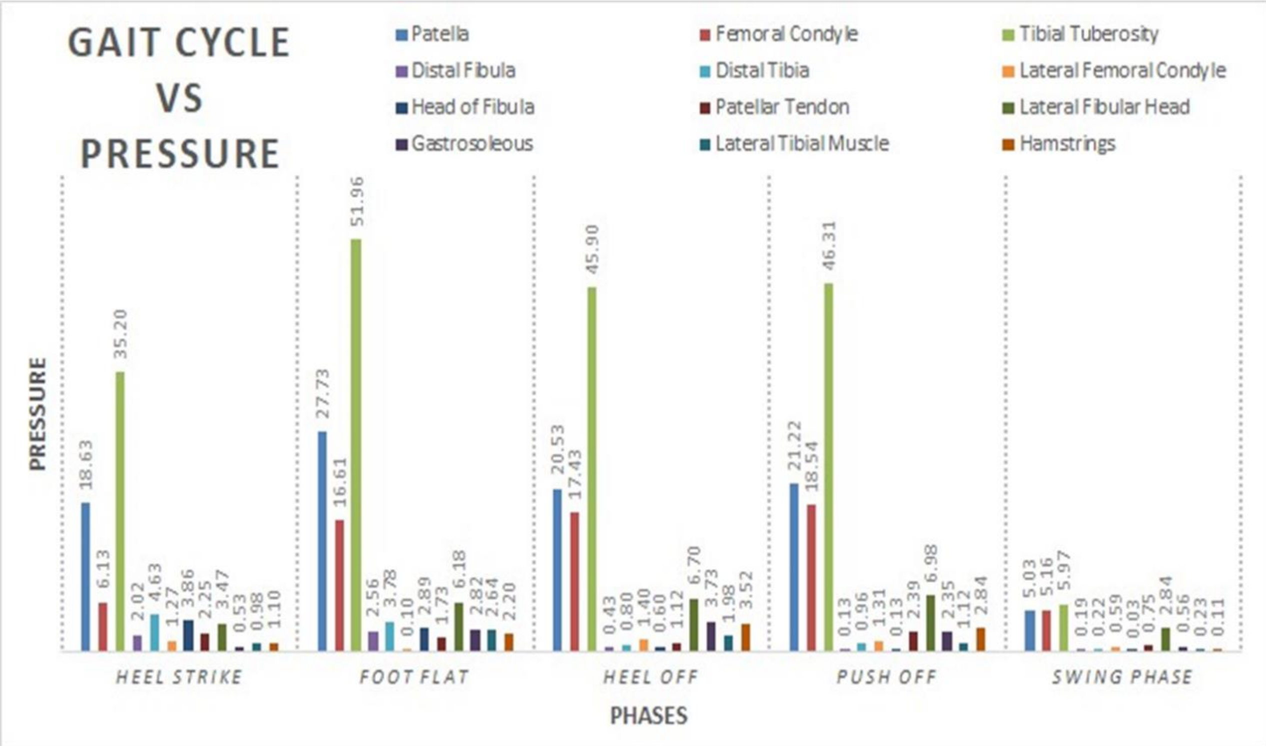


Figure 35: Pressure Distribution on TT stump Vs Gait Cycle.

5.3 Summary

The chapter elaborates three major validation methods being employed. All methods validate that stump liner for pressure mapping designed is capable enough to map the appropriate pressure points and this information in turn is applicable to provide phase-based ratio of pressure vs the stump.

6 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 prosthetic complications of pain, impingement, and pressure sores hence leading to non-compliance of device. The results from different methods validate the working of the device design and functionality.

6.1 Conclusion

The conclusion thus drawn is that a wireless device capable of mapping prosthetic pressure is developed at the end of the thesis work. The pressurized stump liner 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 specific regions of stump during gait training. Overall pressure mapping system design is user friendly and is totally hidden within the prosthetic limb. Phase based differentiation on the basis of Pressures enables to generate feedback which help to remove gait deviations in a prosthetic limb user. Such devices can act efficiently in prosthetic clinics to train amputees, as along with visual and sensory clues physical clue for prosthetic fabrication and acceptance will be available.

6.2 Limitations

The device is also having some limitations. One of which is that sensors cover only finite points on the stump. More area of stump covered; more appropriate Pressure 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. Stump conditions could vary among subjects which can influence pressure values obtained. The number of patients whose data was taken were less due to limited time and resources.

6.3 Future Works

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

i. A Graphical User Interface (GUI) can be built for pressure area mapping of Trans Tibial and Trans Femoral Prosthetic sockets.

ii. More data from healthy population can be acquired in order to evaluate the differences among parameters of normal & different pathological gaits.

iii. Extensiveresearchregardinggaitanalysisinaccordancewith Prosthetic Observational Gait Score can be conducted for TTPs.

iv. Utilization of such systems for Peripheral Neuropathies can be considered.

v. Various characters of normal gait on the basis of Pressure mapping can be explained.

vi. A study can be conducted in order to evaluate differences in orthopedic deformities before and after using orthotic & prosthetic appliances can be made.

vii. A study regarding designs of socket selection based on pressure mapping of stump can be done.

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

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