Evaluation of Socket Design by Measurement of Interfacial Socket Pressure for Below Elbow Amputees

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

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I, Maria Qubtia, certify that this research work titled **"Evaluation of Socket Design by Measurement of Interfacial Socket Pressure for Below Elbow Amputees"** is my own work. The work has not been presented elsewhere for assessment. The material that has been used from other sources has been properly acknowledged / referred.

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Copyright Statement

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Dedicated to my exceptional parents and adored siblings

For their prayer, support, advices, and encouragement

Abstract

Socket design is one of the most important factor for effective utilization of the upper limb prosthesis. Socket encircles the residual stump of amputees and interface pressure between prosthetic socket and residual stump act as direct indicator of the good socket design which is directly linked with comfort and satisfaction of the patients. Socket should be fabricated individually to exactly match with user' morphology to appropriately distribute pressure throughout whole stump. The objective of this study was to evaluate the socket design of below elbow amputees by monitoring pressure at different anatomical landmarks that prosthetist gives special consideration during fabrication of socket. A total of 6 trans-radial amputees wearing body powered prosthesis with voluntary opening device were included in this study. The flexiforce sensor was selected due to its thin flexible profile that permit socket-residual limb interface pressure measurements without any need to modify the socket. The sensors were placed at seven different anatomical landmarks on residual stump by using double sided adhesive tape. Participants performed three static poses: supination, pronation and lifting load with their prosthesis while stump-socket interface pressure was recoded accordingly to the anatomical points bearing pressure magnitude. The different pressure magnitude at different anatomical positions reveals unique characteristic in the 6 participants that can be considered in individuals socket designs. This work presents a technique that makes it very easy to quantify the interaction of socket-residual stump of upper limb amputees. This is a fundamental first step toward improving socket designs developed through informed, analytically based designed tools.

Keywords: Trans-radial amputation, Interface pressure, Residual stump, Below elbow socket, Flexiforce sensor, Pressure sensitive and tolerant areas.

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List of Abbreviations

UL	**Upper Limb**
RS	**Residual Stump**
PS	**Prosthetic Socket**
BE	**Below Elbow**
FSR	**Force Sensitive Resistor**

CHAPTER 1: INTRODUCTION

1.1 Background:

One of the foremost vital components for the effective utilization of an upper limb (UL) prosthesis is the socket design. Sockets enclose the user's residual stump (RS). The interface pressure between RS and socket is a direct indicator for the good socket design which is directly linked with comfort and satisfaction of the patients.

Although, significant research has been carried on the assessment of UL socket design, but the area of research related to analytical understanding of interaction between the RS and prosthetic socket (PS) is still scanty. Though, the contact pressure between RS and UL prosthesis socket have been evaluated to find the relationship between maximum pressure and discomfort(Daly, Voo, Rosenbaum-Chou, Arabian, & Boone, 2014). Similarly, the maximum pressure distribution at different anatomical location on RS has been evaluated(Schofield et al., 2017), but this study has limitation does not reveal the magnitude of pressure at different anatomical points.

The important factor for the satisfactory prosthesis is the design of socket. UL amputees reject their prosthesis due to socket design therefore changes in socket geometry are crucial for the success. So, the analytical study of pressure measurements and mapping of UL socket create foundational informant to help in PS designing and fabrication.

1.2 Problem statement:

The most cause of prosthesis rejection is pain, discomfort, and problems with socket fitting(E. Biddiss & T. Chau, 2007; Daly, Liming, Teri Rosenbaum, David, & David, 2010).

Commercially available UL socket display large number of problems. They do not allow client to completely flex or extend the elbow joint. They don't restrict unwanted motion between RS and PS during different tasks and these also concentrate load at distal end of the stump. This decrease stability, range of motion and exerting inappropriate pressure on different anatomical landmark make them uneasy for the client. Due to this 66% of upper limb amputees rejects their prosthesis(Kejlaa, 1993). This problem is the main intuition behind this research work. Therefore, measuring pressure on different anatomical landmarks may provide an opportunity for the redesigning and fabrication of the socket friendlier for the client.

1.3 Objectives of Thesis:

This work focus the following objectives:

1. Design a cost effective, portable, and reliable pressure monitoring device
2. Evaluate socket design by monitoring interface pressure and range of motion
3. Analytically characterize the maximum pressure occurrence between RS and PS during different tasks.
4. Evaluate the contact point of PS that decreased range of motion of RS.

1.4 Significance of Study:

The main idea of this study was to measure and map the pressure exerted by the UL socket on the stump. The study has improved the understanding of PS fitting at the very basic level and aid in improving socket design and fabrication process. Pressure sensors were placed on different anatomical location of RS of the participants and were asked to perform different tasks with their prosthesis. This is the basic first step toward novel socket designing and fabrication.

There is a lack of the quantitatively understanding of UL socket design in the literature. This work evaluates socket function and comfort during different tasks by measuring the pressure on pressure sensitive and pressure tolerant areas. The resulting pressure magnitude and location should be considered during socket designing and manufacturing to minimize the risk of tissue damage, discomfort, and skin related problem. This study results may help amputees to perform work without any hindrance.

1.5 Thesis overview:

Chapter 1 deals with introduction and explanation of problems. Chapter 2 includes the previous study that has been done on the same problem statement. Chapter 3 describes the design and operation of the fabricated pressure mapping system. Chapter 4 shows the results obtained from device and analysis of the same results and in the last Chapter 5 conclusion and future works are discussed in detail.

CHAPTER 2: LITERATURE REVIEW

2.1. Amputation:

Amputation is the complete or partial loss of limb and reduce the functioning ability of this anatomical body structure. Amputation can be result of purposefulness surgical method in case of obsessive etiology, traumatic or inherent. Trauma is the most common cause of amputation (Kim, Park, Kim, Kim, & Shin, 1996; Raichle et al., 2008; Ziegler-Graham, MacKenzie, Ephraim, Travison, & Brookmeyer, 2008). Cancer, congenital limb loss and frostbite are other cause of amputation. The excised individual is called an amputee.

2.1.1 Epidemiology and need:

Worldwide, an estimated that about 150,000 to 20,000 amputees are added each year(Molina & Faulk, 2020). Removal of body parts has a negative and unsafe effect on individuals. Loss of limb put significant impact on patient’s mobility, functioning, self-care, and body images(Bolton, Lobben, & Stern, 2010; Maguire & Parkes, 1998). Numerous amputees have a problem with their appearance and how other people view them. These feeling regularly try to hide their body imaged from others or change their appearance from other ways(Gilg, 2016). Therefore, prosthesis become essential as they provide an important backing to these patients so that they can carry out their daily activities and incorporate in the society.

UL prosthesis mainly used to replace structure and function of missing body parts. UL prosthesis consists of socket, suspension system, control system, interposing joint and terminal device. PS is a junction through which body parts directly interface with prosthesis. Socket is used to transfer the forces from stump to other parts of prosthesis. PS exerts the undesirable forces on soft tissue of stump. Soft tissue has less tolerance to bear force and mechanical load. Compression and degeneration of soft tissue leads to the motion occurred between RS and PS, leads to decrease the efficiency of prosthesis. The interface between RS and PS is varies with volume fluctuation of the stump, so that the rotation and slippage of the socket increases.

Numerous prosthetic stimulators are currently being developed that are used at clinical setup for the correct prescription of prosthesis(Chadwell et al., 2021). There is a need to design the instruments that monitor the comfortability and functionality of socket and suspension system. These self-monitoring prosthesis systems decrease the number of visits to the prosthetist. Performance of various socket design need to be evaluated before there monitoring system can designed.

2.1.2 Levels of amputation:

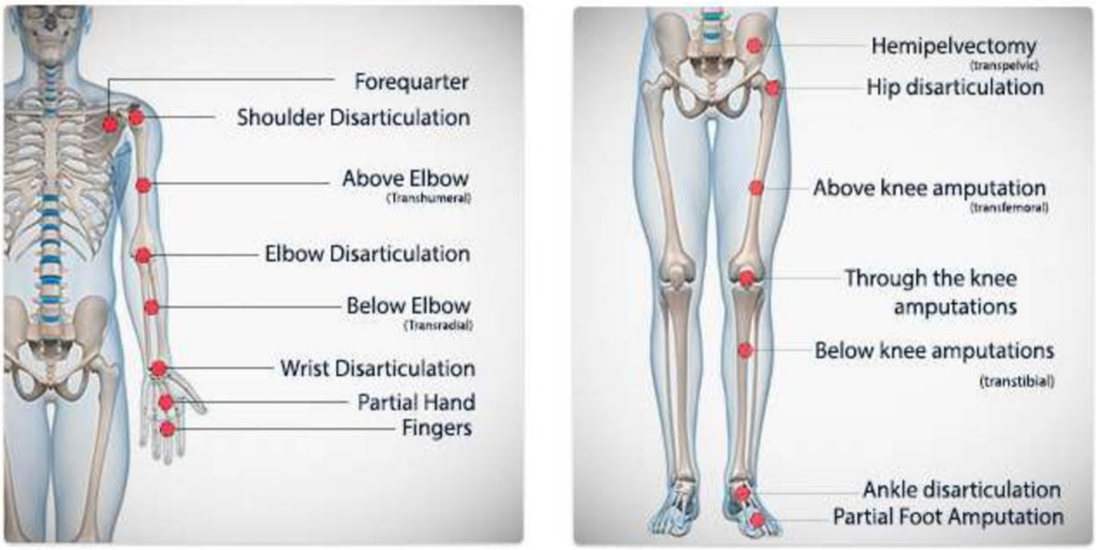


Figure 1: (a) levels of upper limb amputation (b) Levels of lower limb amputation

2.2. Prosthesis:

Prosthesis is a device that is used to replace the function and appearance of missing body parts that are lost due to trauma, injury, disease, or other medical condition. Prosthesis should be design according to patients' requirements.

2.3. Lower limb prosthesis:

Lower limb prosthesis is an artificial organ used to replace the lower extremity and provides functionality and restore appearance. After lower limb amputation prothesis serves some purpose. The main purpose is to establish the active movement of the inactive body part(Fiedler, Akins, Cooper, Munoz, & Cooper, 2014). Ambulation employing a prosthesis require expanded use as the removal level move proximally. Therefore, to reduce this increase in physical activities, prosthesis needs to be designed that facilitate movement. Additionally, well-fitting prosthesis help to prevent breakdown of delicate tissue by redistributing compressive forces amid weight bearing and minimize shearing force on the skin(Crowe et al., 2019).

The lower limb prosthesis has two essential subclasses including trans-femoral and trans-tibial. Trans-femoral prosthesis that replaces a leg loss above the knee. Transfemoral amputees can have a really worrying issue in repossession normal movement. Normally transfemoral amputees typically use about 80% more energy to walk than a normal individual(Starholm, Gjovaag, & Mengshoel, 2010). Transtibial prosthesis is an artificial device that substitute a leg loss below knee.

Transtibial prosthesis are generally able to achieve normal mobility than transfemoral amputees(Beisheim, Horne, Pohlig, & Sions, 2019). prosthesis is generally recommended based on basis of level of amputations.

Figure 2: (a) Transtibial / below knee prosthesis (b) transfemoral / above knee prosthesis

2.4. UL prosthesis:

The UL prosthesis is device that replace the lost part of UL from shoulder to fingers. UL amputees often use prosthesis for two general purpose: to improve their physical appearance and to enhancing their capability to perform daily routine task(Cordella et al., 2016). But, these two goals are usually in conflict with each other(Dewar, 1999).

It is much more difficult to restore function of UL amputees than the lower limb amputees(Kejlaa, 1993). The basic function of lower limb is to provide support, upright position, and a variety of movements(Windrich, Grimmer, Christ, Rinderknecht, & Beckerle, 2016). In contrast the UL involves not only fine movements but also more complex task such as self-care and social interaction. Hence, it is not surprising that ULamputees are less satisfied with the restoration of function provided by prosthesis than lower limb(Raichle et al., 2008).

2.5. Categories of UL prosthesis:

The UL prosthesis has four major types. Each of these differentiated by the method through which these devices are controlled.

A. Passive prosthesis:

Passive prosthesis is light in weight, are functionally active and have resemblance with natural arm.

Figure 3: Below elbow passive prosthesis.

Passive prosthesis is often used by amputees that are more conscious about their appearance than function(Maat, Smit, Plettenburg, & Breedveld, 2018). The function of passive prosthesis is limited which only provides a supportive surface for holding heavy objects.

B. Body powered prosthesis:

These prostheses allow active movement to amputees. The advantages of body powered prosthesis is that they are light weight and durable and provide feedback to client by based on tension in the control cable. The impediments are that they require tackling, and client must have the quality and ability of movement to drag the cable adequately to form the device work in all position especially overhead.

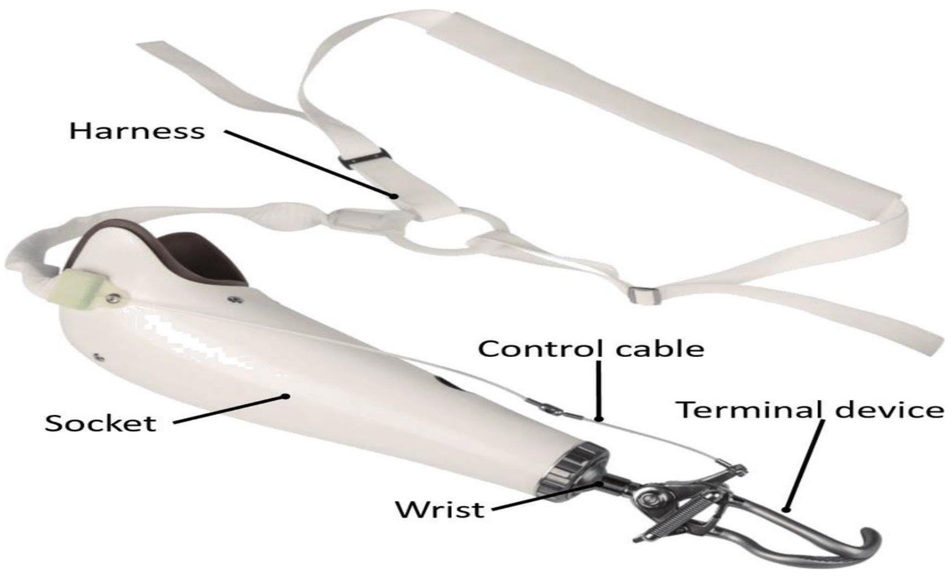


Figure 4: Below elbow body powered prosthesis.

C. Externally powered prosthesis:

These prostheses are power-driven by the batteries placed within framework. Externally powered prosthesis is controlled by the pressure sensor, switches, and electromyography (EMG) signals(Maitin & Crus, 2015). They got to be charged day by day and, require more support than body powered prosthesis, and they are most costly. Because their complexity, these are more prone to breakage and require repair(E. Biddiss & T. Chau, 2007).

D. Hybrid prosthesis:

Those prosthesis that consisting of both bodies powered and externally operated prosthesis known as hybrid prosthesis. The advantages of using hybrid prosthesis that increased grip strength is because both prostheses work simultaneously.

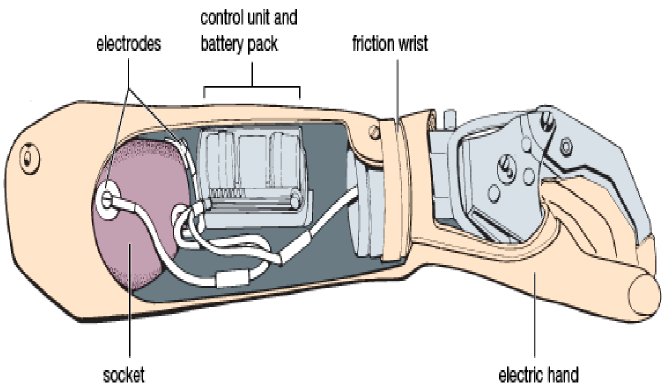


Figure 5(a): Below elbow myoelectric prosthesis (b) Trans humeral hybrid prosthesis

2.6. Body powered prosthesis:

Individuals with UL amputation prefer to use body operated prosthesis(Shaperman, Landsberger, & Setoguchi, 2003). The advantages of body powered prosthesis includes soundless activity, light weight, direct fetched, strength, infallible quality, sensory input around the terminal device and basic operational mechanism associated with certain body movement to function the intentionally opening or closing of terminal device(Millstein, Heger, & Hunter, 1986).

Overall discharge rate of body-driven prosthesis ranges from 16%(Bhaskaranand, Bhat, & Acharya, 2003) to 66 %(Kruger & Fishman, 1993). Essential points of prosthesis removal include weight of prosthesis and problem related to socket(Wright, Hagen, & Wood, 1995).

2.7. Component of below elbow (BE) body powered prosthesis:

There are following component of body powered prosthesis

1. **Terminal device**

A body powered prosthesis can be fitted with a hook, hand or both to adapt to conditions, mostly for regular cosmeceuticals or in social sitting. (Texas Assistive Devices, 2016; TRS Prosthetics 2016). This is only effective if the client has the power to use prosthesis to move arm in any position. An additional 2-inch cable needs to be rotated for a voluntary opening hook. Legitimate fitting of socket and harness is required to obtain range of motion. A proper socket fitting requires that it be fitted to the body with firmness which can causes discomfort and dislodge the physically driven hands at a rate of about 80% (Millstein et al. 1986) with 87%(Kejlaa 1993). Common complaints focusing on gradual activity, cumbersome use, hygiene and assistance problems, weight loss, inadequate hold quality and high energy requirement for work esteem, toughness, lower weight and great graspable of objects being dealt with and in general, are more worthy to clients(Millstein et al., 1986).

Figure 6. Terminal device (a) Hosmer hook (VO) (b) TRS hook (VC)
(c) Otto Bock hand (VO).

VO: voluntary opening; VC: voluntary closing.

2. **Harness system:**

The harness system is used to suspend the prosthesis on client's shoulder, so that the socket is firmly held on the remaining stump during various activities. Shoulder flexion and scapular abduction are Power source for the body-driven prosthesis. Therefore, harness system transmits the forces that run through the body to the terminal device via the cable system.

The advantages of using harness system are that it gives feedback to the amputees through cable tension. Through feedback, amputees can predict the opening and closing of the device and increased amount of stress.

There are three types of harness system used with body-driven prosthesis including figure eight harness, figure nine harness and chest strap with shoulder saddle. The figure eight harness system is the most widely used system for body driven prosthesis. Axilla loop of harness system act as a reaction point to transfer body forces to the terminal device. Anterior bolster strap and y suspensor carry the significant parcel of pilotable load.

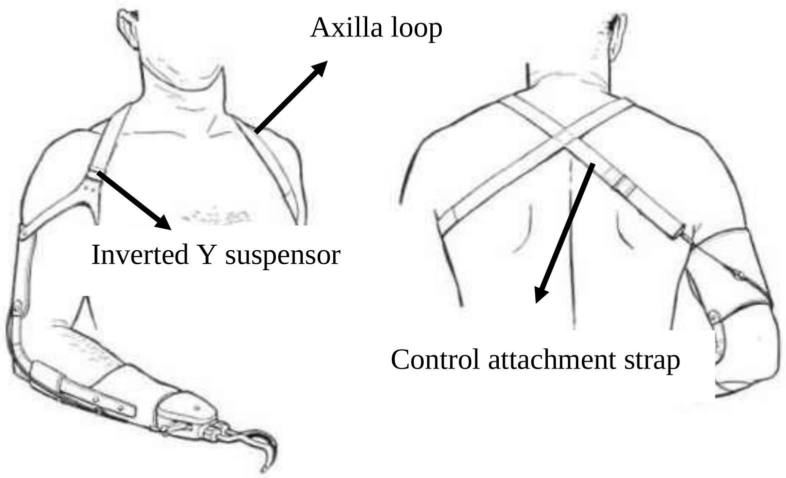


Figure 7. Below elbow prosthesis with figure-8 harness.

For patients whose axillary loop could not withstand excessive pressure they used a chest strap along the shoulder girdle.

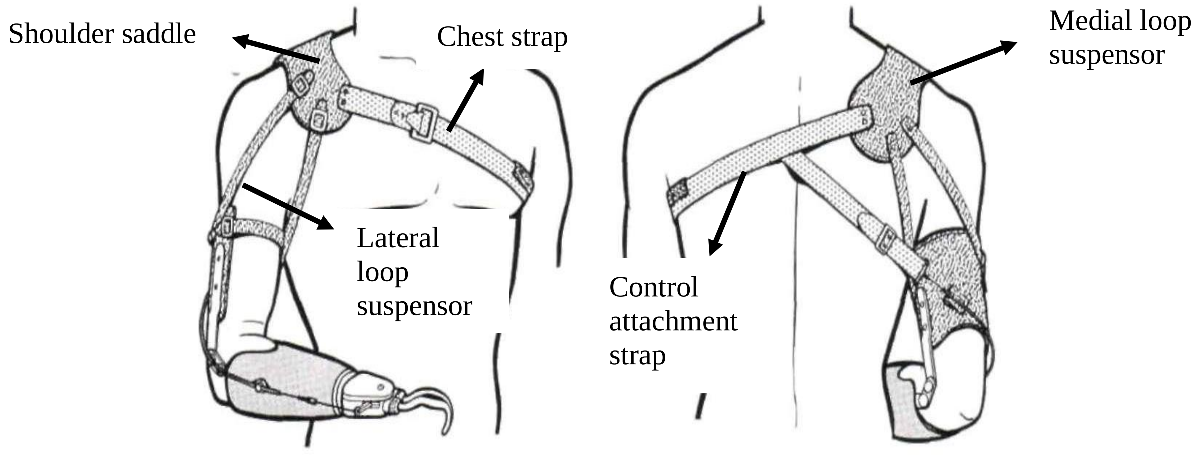


Figure 8. Below elbow prosthesis with chest-strap harness and shoulder saddle.

Figure -9 harness is most commonly used harness system(Millstein et al., 1986).

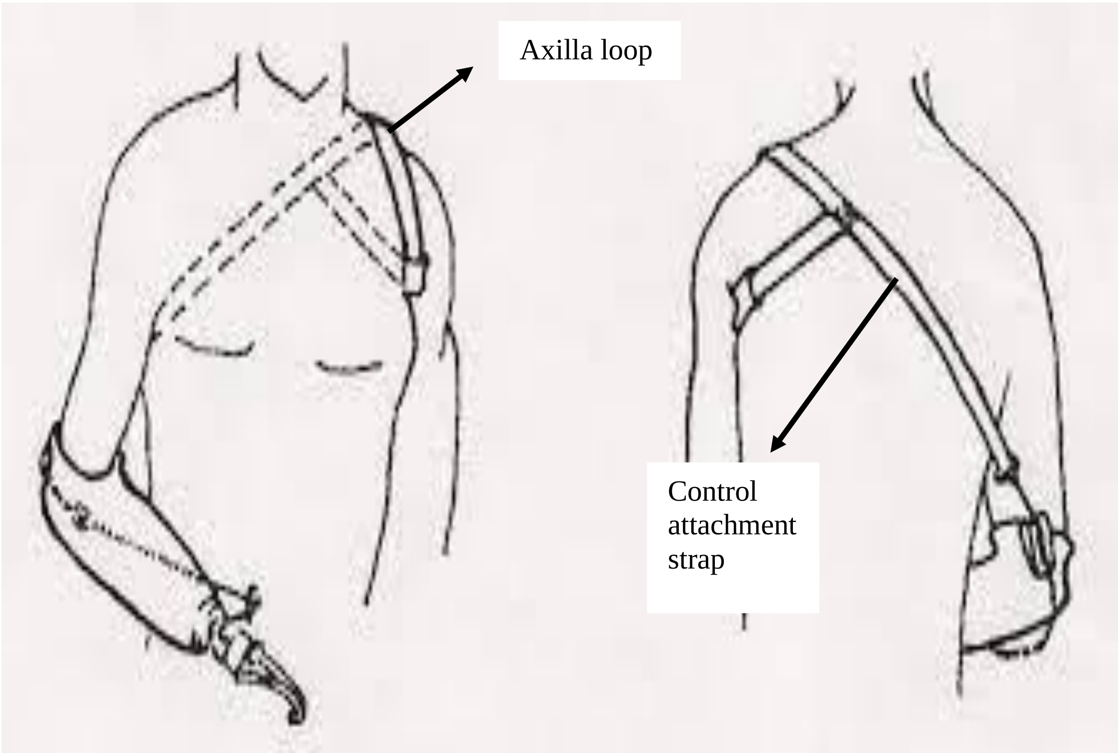


Figure 9. Below elbow prosthesis with figure-9 harness

One of the disadvantages of using control system is that it puts too much pressure causing skin disruption(Dar et al., 2014), limited range of motion ((Van Lunteren, van Lunteren-Gerritsen, Stassen, & Zuithoff, 1983)) and wearing of the dress(Kejlaa, 1993).Since accomplishing adequate squeeze strength and grab strength within the terminal device required high actuation strength(Smit & Plettenburg, 2010). When producing high process strength, the pressure and stress on skin causes discomfort in the axillary region. Therefore, excessive pressure on the arteries can increased blood flow and prolonged compression can causes neuropathy. These effects can result in sensory impairment in some parts of the arm and hand(Bromberg, 2005).

3. BE socket:

Proper fitting of PS is the determine factor of satisfaction of amputees with prosthesis. The Precise fitting of socket to RS provides strength and equally distribute the pressure throughout the whole stump. The pressure at the interface between stump and socket is important for the comfort and functionality of the amputees.

The socket surrounds the stump and act as point of connection securing the prosthetic components to the amputee. It is at this junction where the delicate tissue of stump directly interferes with the hard materials of prosthesis. Thus, the socket should be custom designed to help the individual to adjust with residual morphology, accomplish the suspension of prosthesis, and help in control by safely. This not only advances the client capacity to move and control their prosthesis, but in a framework that is something else truant of coordinate tactile criticism, may help in enhance proprioception feedback.

Following step involved in socket fabrication:

i. Stump examination, marking and measurement:

RS testing before prosthesis prescription plays an important role. It is important to differentiate between skin lesion, painful scars, scraped area so that relief can be given in PS. The prosthetist marks these areas with indelible pencil, and measure stump circumference and length. He also measures the length of contralateral arm of the amputees for accurate sizing of prosthesis.

Figure 10. Measurement of below elbow stump length

The length of RS is recorded from the olecranon. On the off chance that distal excess is obvious, the estimation ought to incorporate these excess tissues.

The length of contralateral forearm is estimated from proximal point of the olecranon to the distal point of the ulnar styloid and arm is flexed at 90-degree midway between supination and pronation.

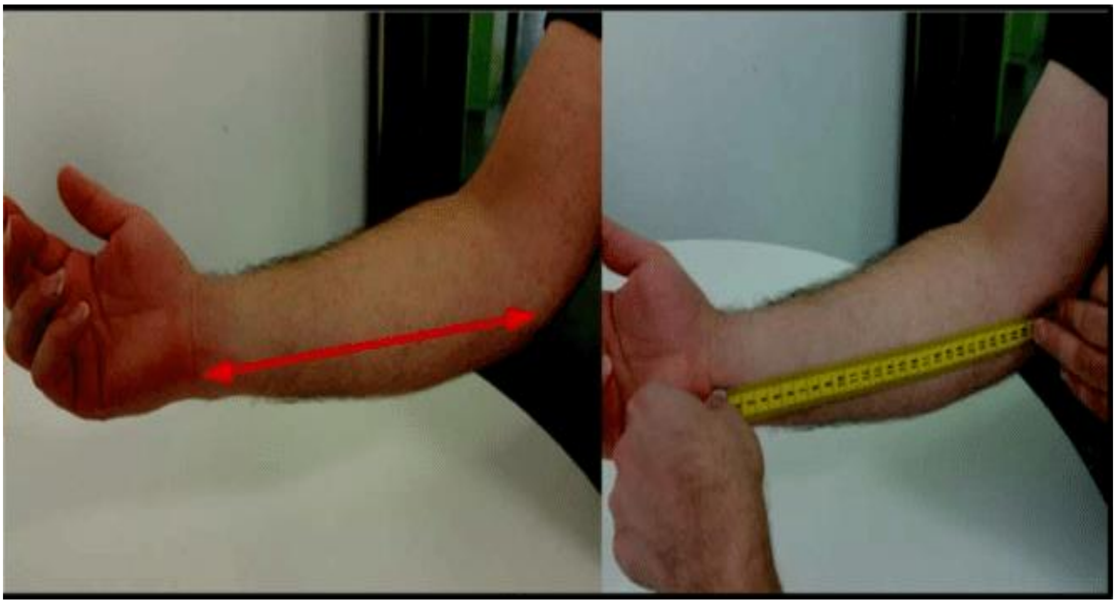


Figure 11. Measurement of contralateral forearm length

ii. **Primary cast:**

Gypsona plaster bandages are tied around the RS to form the initial cast of stumps.

Figure 12. Primary cast of residual stump

iii. Master mold:

The liquid plaster of Paris is poured into the primary cast to make model of stump. He compares the measurement of mold with recorded stump estimate, makes any rectification shown, and after that smoothest and removes grease.

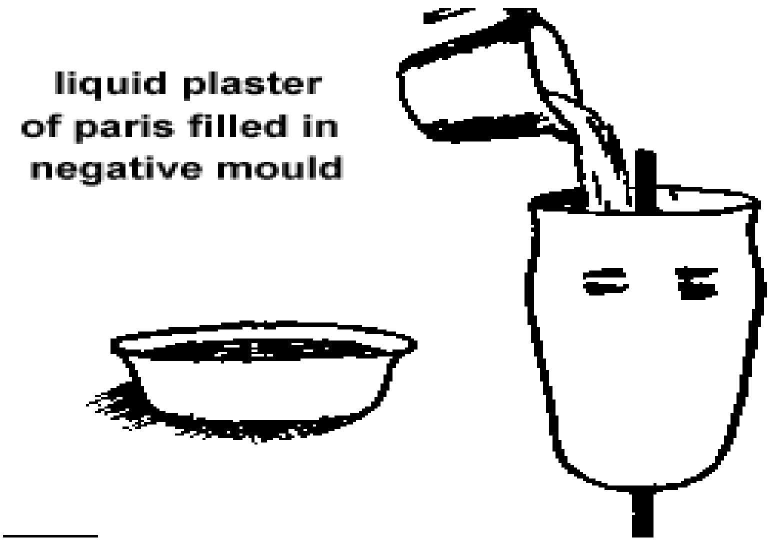


Fig 13: Formation of master mold of residual stump

iv. Check socket:

The stockinette is drag over the rectified mold and soak into wax. Wax check socket is fitted to amputees, so the prosthesis can suit any pressure touchy areas. The wax prosthesis socket also allows prosthetist to detect the pivot of elbow motion and to determine the area of trim lines for most extreme, snug lower arm portability.

Fig 14: Formation of check socket

UPPER EXTREMITY MEASUREMENT CHART

Prosthetist______________________________ Date__________

Patient's Name______________________ Amputation Date__________

Amputation Type__________ Left___ Right___ Race: Caucasian____ Negro____

Height_________ Age____ Sex: Male____ Female____

Socket: Double Wall____ Single Wall____ Split____ "Muenster" Type____

Monolith____ SD Socket____ Section Plate____ Abduction____

Other____

Hook____ Hand____ Wrist____ Elbow____ Hinge____

Harness____________________ Control System____________________

Cuff_________ If no cuff is used, indicate attachment point for housing cross bar assembly______________________________

Range of Motion of Stump: Elbow Flexion__________ Pronation________
Elbow Extension________ Supination________

Condition of Stump (irritation, abrasion, etc.): ____________________

____

Special Considerations: ______________________________

____

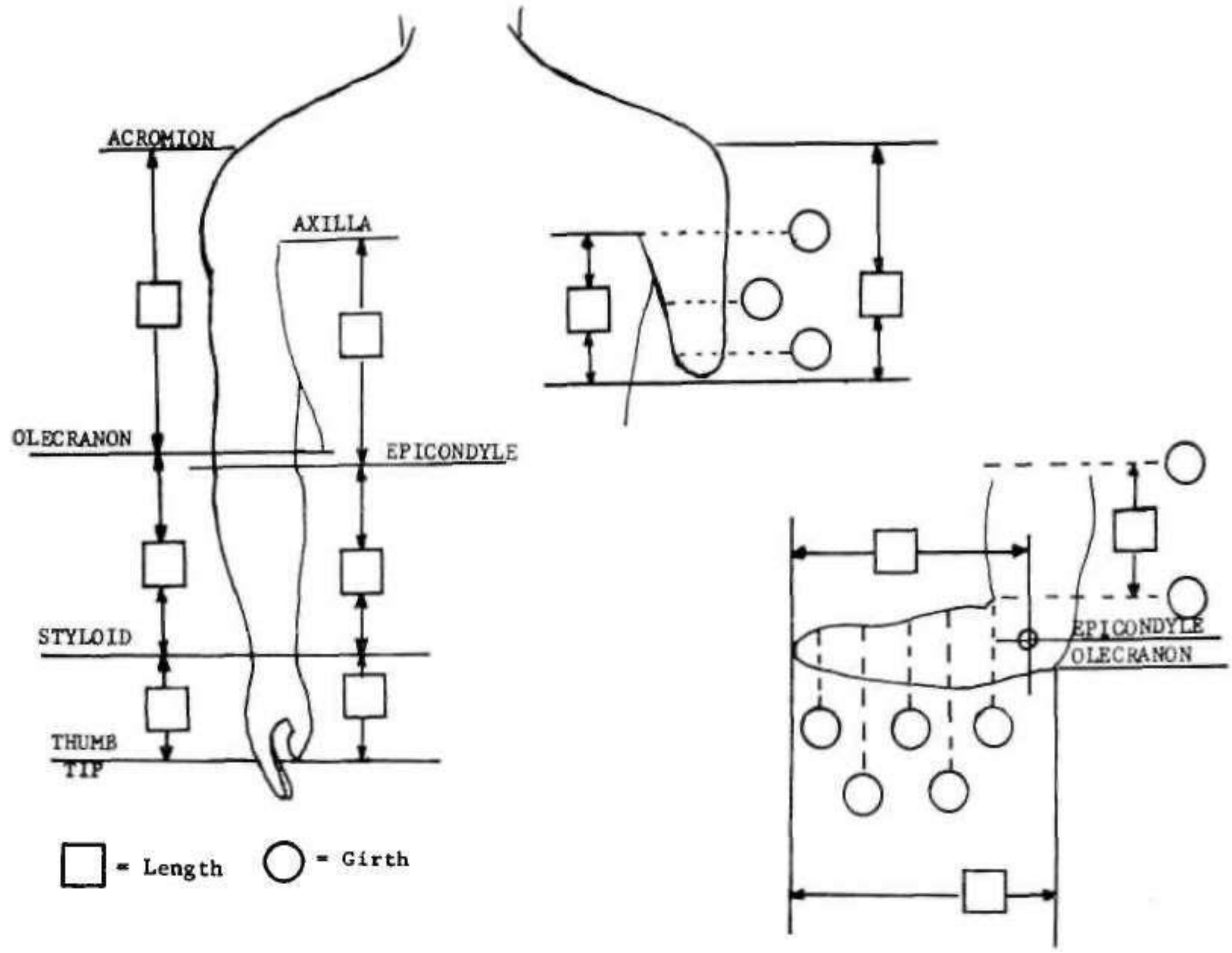


Figure 15: Measurement chart of upper extremity

v. **Lamination:**

The prosthetist spout mortar into socket. He Putin stockinette over the rectified model, so that the plastic paste cannot perforate in the plaster. PVC sheet applied over the stockinette and plastic paste is spout through mouth of PVC sheet to pervade the stockinette.

These are general aspect of prosthetics socket:

1. The lower arm is set in 35 degree of flexion with respect to humerus. Since of decreased of valuable movements, the prosthesis socket is flexed to position the terminal device within the most generally valuable area.
2. The front trim line amplified of the antecubital crease, with a channel given for the biceps muscle to maintain strategic distance from impedances between prosthesis socket and biceps muscle amid flexion.
3. The back perceptive of prosthesis socket encased the olecranon, taking benefit of this eminence quality to supply connection and steadiness to prosthesis socket. The trim line was fair over the level of epicondyles.

2.8. Previous work:

Carey and colleagues examined the compensatory movement of transradial prosthesis client by performing diverse daily routine task including lifting a box, turning a steering wheel, drinking from a cup and opening a door. They concluded that those activities that require the forearm rotation and wrist motion, amputees compensate this by bending the torso and cervical spine. This study not depicts about which portion of socket restrict valuable motion lead to compensatory motion(Carey, Highsmith, Maitland, & Dubey, 2008).

The gamut of movement of the upper appendages like performing the everyday tasks such as eating, drinking(Safaee-Rad, Shwedyk, Quanbury, & Cooper, 1990), zipping a coat(Landry, 2002),cartoon pouring(Murgia, Kyberd, Chappell, & Light, 2004) have been recorded and analyzed. Movement investigation of exercise of everyday living has been performed to decide ideal wrist arrangement of an upper appendage's prosthesis(Stavdahl, 2002).

Creating upper appendages and understanding the activity motif produce by these components can be encouraged by comparison with individuals with ordinary upper appendages where development limitations have been controlled. Ponders have inspected common one-sided tasks completion with an upper appendage by wearing a wrist brace(Mell, Childress, & Hughes, 2005); by using a body driven prosthesis test system(Weeks, Wallace, & Anderson, 2003).

An assortment of prosthesis socket plans has been depicted in writing by specialists within field. One motif is compression released prosthesis socket which employs an attachment of rotating delicate tissue compression and released zones arranged along the long pivot of inborn bone “a high level of natural bone control”(Alley, Williams, Albuquerque, & Altobelli, 2011). Clinical study revealed that, subject was less satisfied with consolation and in general utility of CRS prosthesis socket, and expressed that extra modification are required to the CRS socket design(Resnik, Patel, Cooney, Crisco, & Fantini, 2016).

Another study introduces the air splint prosthesis socket, the framework of this socket works to estimate and the changes for the fitting of the prosthesis socket required. This auto-adjustable socket is important for daily routine task to reduce discomfort and skin problem. The main aim of using air splint socket is keeping up a great fit. Disadvantages of using this framework is that cannot be connected to the amputees that have a small volume and short length of RS(Gholizadeh, Osman, Eshraghi, & Abd Razak, 2014).

Satisfaction of UL amputees regarding prosthesis during different daily routine have been evaluated by different survey-based study(E. A. Biddiss & T. T. Chau, 2007; McFarland, Hubbard Winkler, Heinemann, Jones, & Esquenazi, 2010; Østlie, Franklin, Skjeldal, Skrondal, & Magnus, 2011). These studies don’t analyse the socket design by using any sensor. So, these data are not sufficient to make any modification in prosthesis design.

Another work also depict about pressure distribution at the interface of prosthesis socket and RS by using f-socket sensor system, during different static pose condition(Schofield et al., 2017), however pressure distribution at the diverse anatomical point amid distinctive daily routine tasks have not been evaluated. This f-socket system is very expensive to use.

2.9. Summary:

This chapter briefly depict a few fundamental concepts of prosthesis components conjointly examining the causes of dismissal of body driven prosthesis. It moreover illustrates the impact of prosthesis socket design on patient’s requirements. In addition, work done already to ensure that there must be quantitatively analyzed the prosthesis socket design.

CHAPTER 3: RESEARCH METHODOLOGY

The methodology of this study comprised of following steps:

- Designing and manufacturing of device
- Data collection
- Data analysis

3.1. Designing and manufacturing of device:

There are following steps were involved in designing of device

- Selection of sensor
- Circuit design
- Calibration of sensor
- Sensor placement criteria

3.1.1. Selection of sensor:

The literature outlines some quantitative strategies, including strain gauges, piezoresistive, piezoelectric and optical sensor. Most researchers are in favor of utilizing the force sensitive resistor (FSR), due to their thin structure, easy to use, good flexibility and simple composition(Almassri et al., 2015; Hollinger & Wanderley, 2006; Schofield, Evans, Hebert, Marasco, & Carey, 2016).

Table 1: Comparison of FSR and Flexiforce A101®

Characteristic	**FSR**	**Flexiforce A101**
Range	30-100N	0-20
Linearity	Non Linear Response	±3%
Sensing area	0.3mm	3.8mm
Hysteresis	10%	4.5%
Repeatability	±2%	±2.5%
Response time	<3µsec	<5µsec
Thickness	0.35mm	0.203mm

FSR commercially available in different size and shape that are used in a variety of pressure monitoring applications. Piezoresistive sensor consists of very thin sheets, perfect for situated within PS for pressure monitoring(Yiğiter, Şener, & Bayar, 2002).

The two majors commercially available FSRs are FSR Interlink and Flexiforce Tekscan. A few researchers experimentally compared these two products and found that Flexiforce Tekscan is better in term of linearity, repeatability and accuracy (Hollinger & Wanderley, 2006; Rao, Webb, Jackson, Zhang, & Bennion, 1998).

3.1.1.1. Flexiforce:

Flexiforce sensor design by Tekscan Company. These sensors are piezoresistive in nature. The sensors are made of bilayers of polyester film and Silver is placed on each layer as a conductive material. Pressure sensitive ink define active area of the sensor. Flexiforce sensor are available in various size and length, however Flexiforce A101 was the most appropriate for the project.

Figure 16: Flexiforce sensor A101®

3.1.1.2. Puck:

Flexiforce sensors are flexible in nature and it is important to note that bending of sensitive area of sensor affect the results. To overcome this problem, researchers prescribed to use puck on sensor for precise reading (Freschi, Vecchi, Micera, Sabatini, & Dario, 2000; Geddes, 2007; Jensen, Radwin, & Webster, 1991).

According to Tekscan the area of puck should be about 68% of sensitive area of the sensor. Tekscan recommended to use puck when area of loading exceeds or smaller than the sensitive area of sensor. Either a hard or soft puck can be used and for this project hard pucks were chosen to improve the sensor performance. Pucks serve to increase performance of the sensor by evenly distributing the force through whole sensitive area of sensor and by preventing the bending of sensor from secondary load (Geddes, 2007)

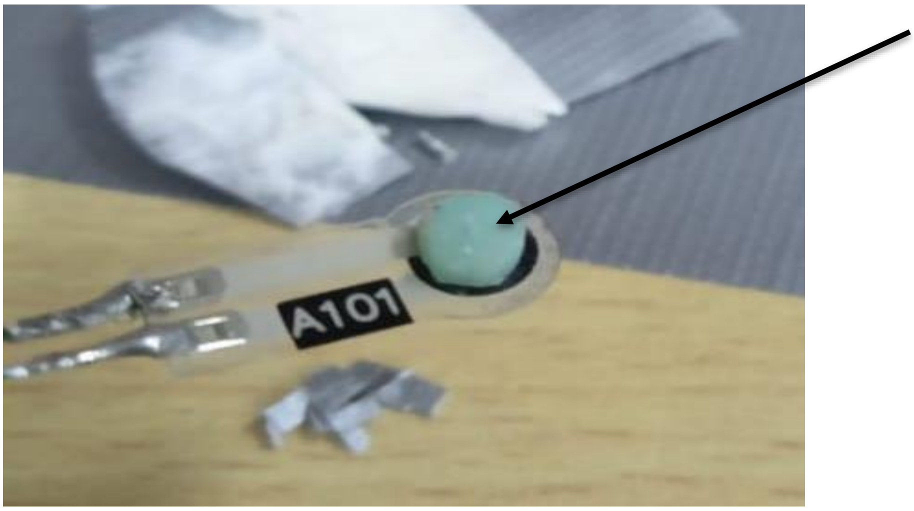


Figure 17: Puck is placed on above the sensor

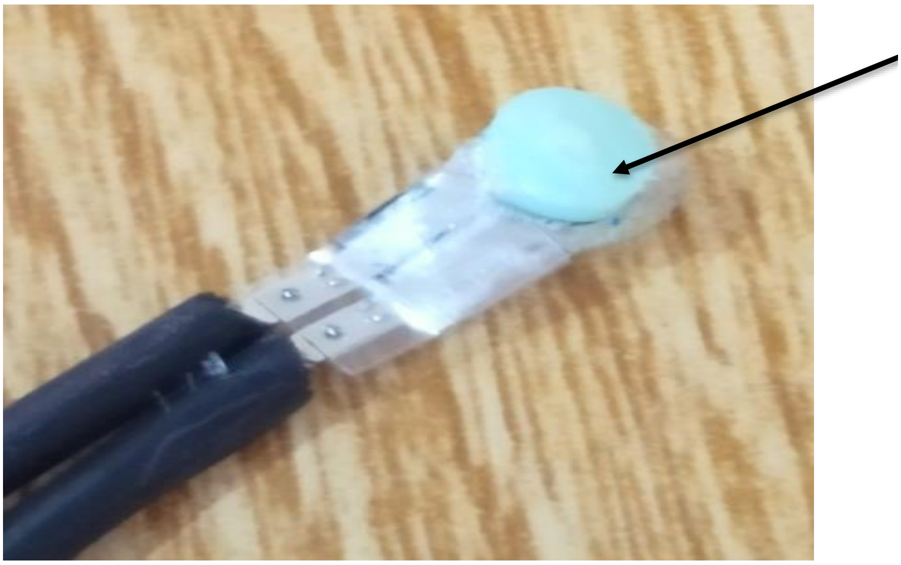


Figure 18: Puck is placed below the sensor

3.1.2. Circuit design:

A simple voltage divider circuit have been used. This circuit design is very easy to follow and make modifications. Few researchers use this sensor circuit design successfully in their research(Geddes, 2007; Jensen et al., 1991). Tekscan recommended circuit in which inverting operational amplifier is used which is very complex to follow. In this circuit seven sensors were connected in series with 10kohm resistors. Wires of sensors were connected at analog inputs channels of Arduino Mega 2560.

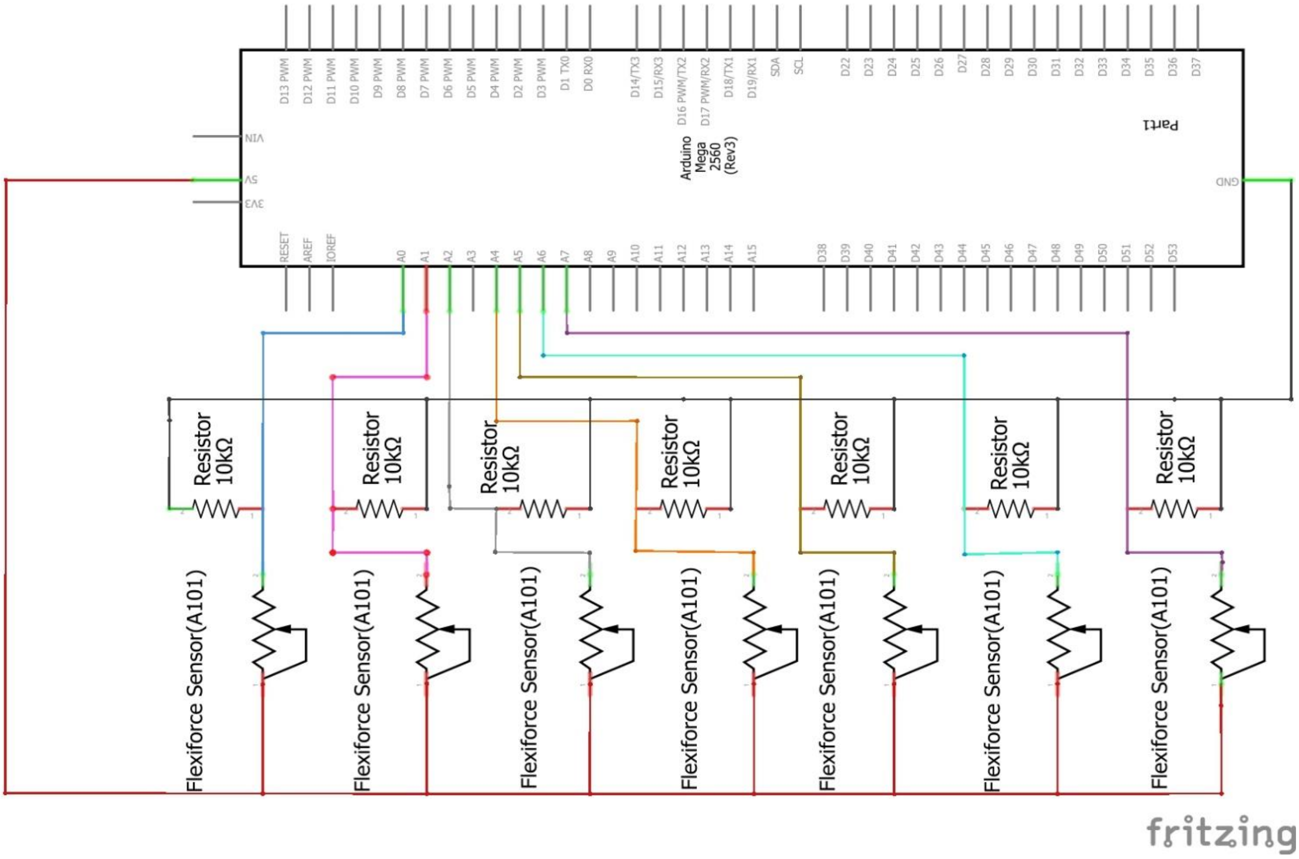


Figure 19. schematic diagram of flexiforce sensor circuit

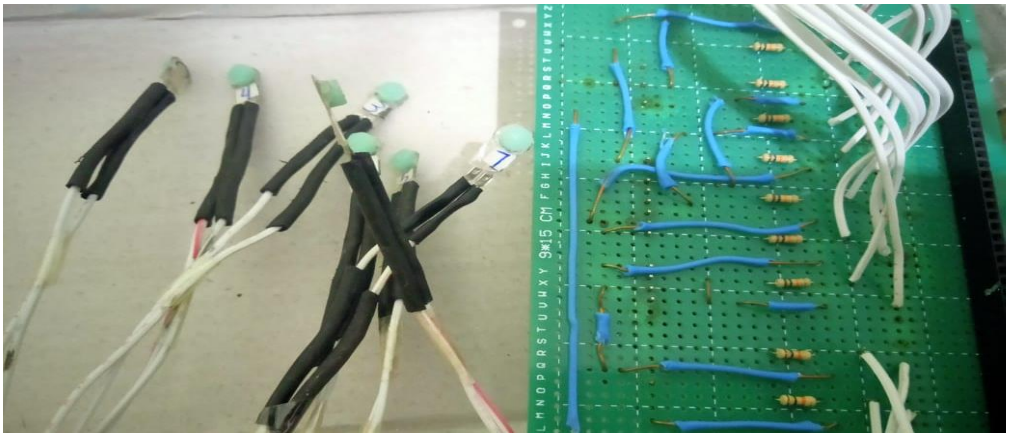


Figure 21. Pressure monitoring system

3.1.3. Calibration of sensor:

To calibrate sensors, ten discrete loads in the range between (0-20N) were applied for ten times. Mean value was taken. Each sensor was calibrated independently. Excel is used to fit linear equation to the force verses voltage. R^2 value obtained 0.983 which show the linear response of the sensor against the pressure. The average value of voltage reached 590V at the maximum force of 18N.

Figure 21. Calibration of sensors

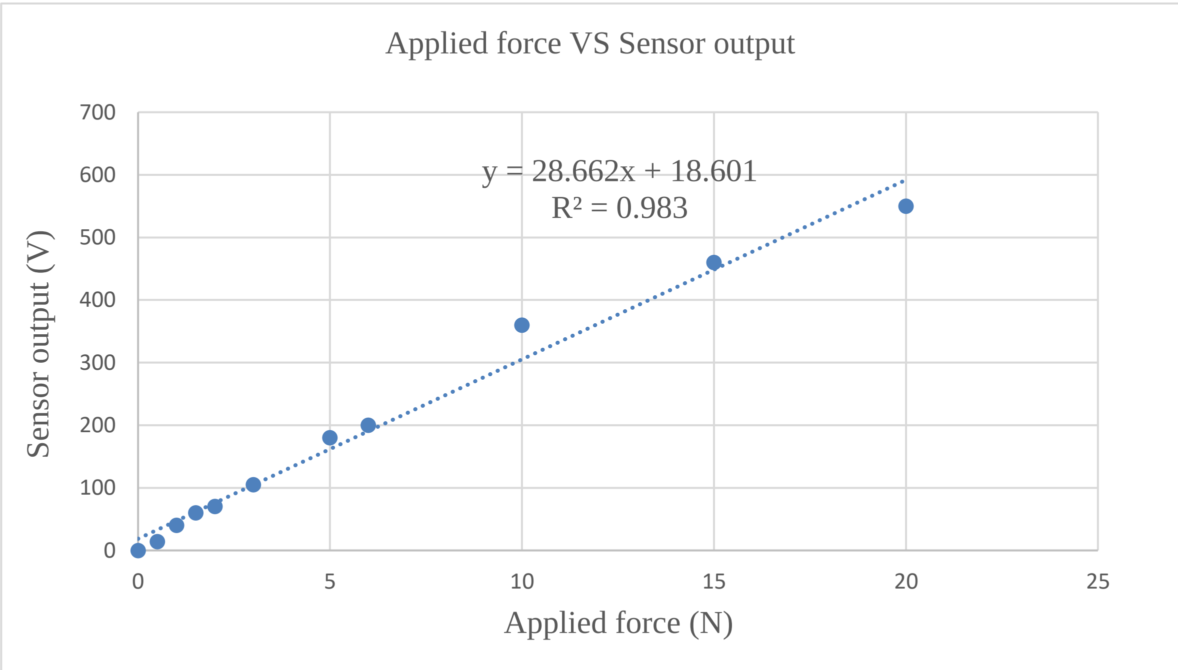


Figure 22. Regression line

3.1.4. Sensor placement criteria

Sensor were placed at different seven anatomical landmarks of BE stump. Three sensors were placed at bony prominence of elbow joint. During rectification of negative cast of traditional socket specific attention is given to these points. Medial and lateral humeral epicondyles are pressure sensitive areas, so materials are added in these points during rectification of negative cast of BE amputees to inhibit pressure on these sensitive areas. Materials are also added at olecranon region this bony prominence is also pressure sensitive region of stump (Kay, Cody, Hartmann, & Casella, 1965). The two sensors were placed on the muscle bellies of brachioradialis and flexor muscles at ulna sides of forearm. The last two sensors were placed at distal region of radial and ulna bones. According to previous study(Sang, Li, & Luo, 2016) traditional socket design concentrate more pressure at distal part of stump. During surgery nerve are cut proximally so the amputee loss sensation at distal part. Loading of distal part of stump for long duration lead to skin related problem such as ulcer (Lyon, Kulkarni, Zimersonc, Van Ross, & Beck, 2000).

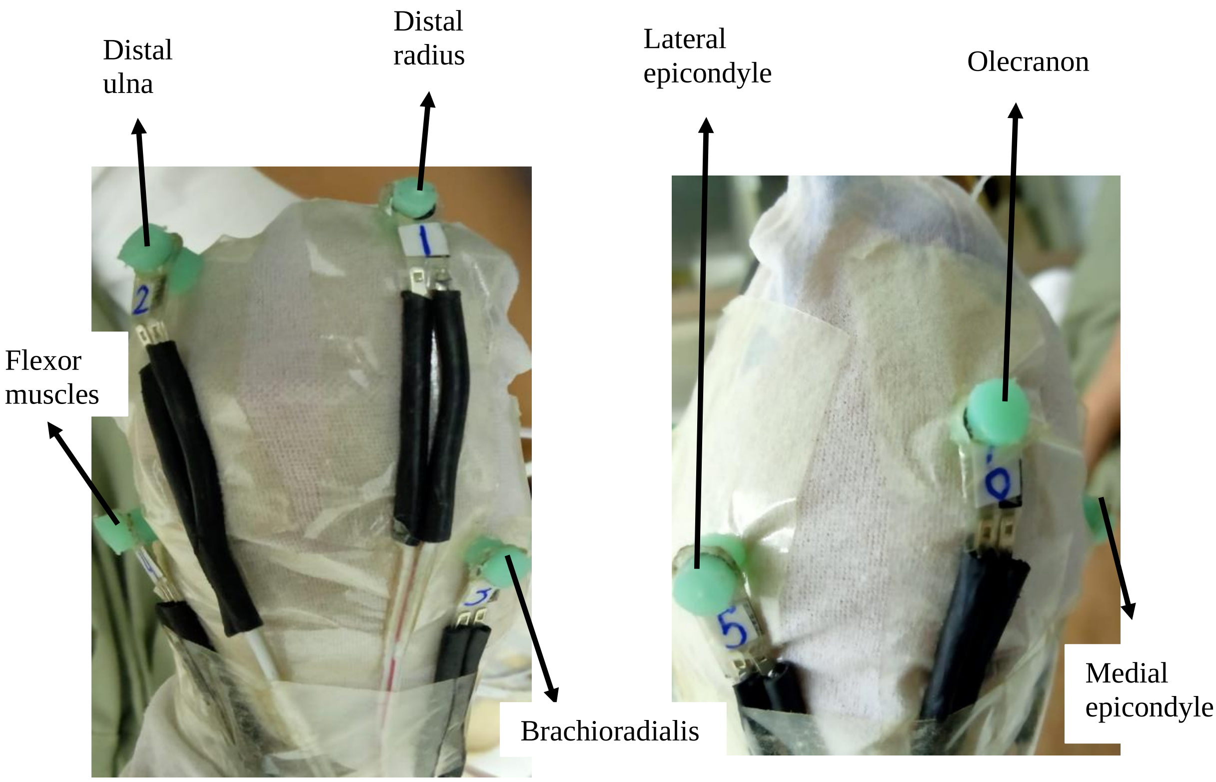


Figure 23. (a) Sensor placement at anterior forearm (b) Sensor placement at posterior forearm

3.2. Data acquisition:

Data from each sensor was taken at the rate of 15 samples per second and data was collected three times. Average value was taken, and it were matched with its corresponding anatomical points on the stump. The Arduino Mega was used to collect data from all sensors. The recorded data was compiled in .txt file and imported into MS Excel for further processing.

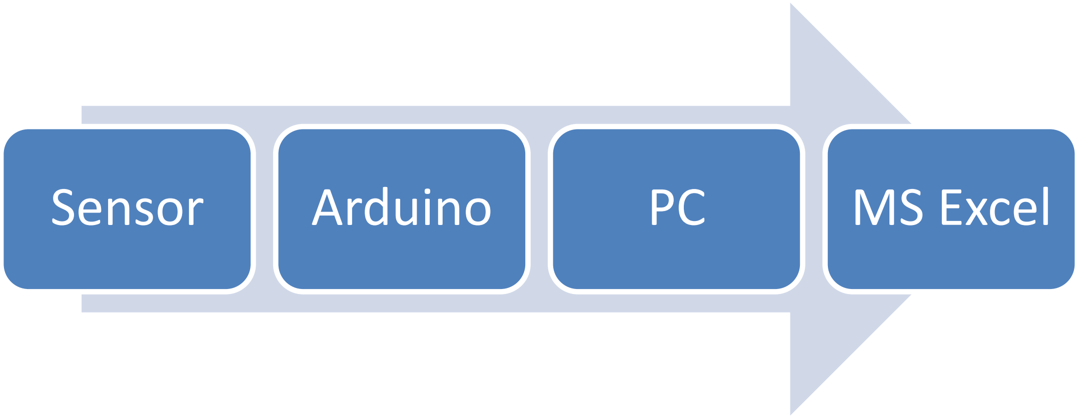


Fig 24. Data flow

3.2.1. Data collection:

A total of 6 transradial amputees were selected for this study. All the subjects wearing body powered prosthesis with using voluntary opening terminal device were recruited. Ethical approval certificate was obtained from review board of Chal Foundation Rehabilitation Center and participants were provided consent form prior to data collection. Participant's demographics and characteristics of residual stump and prosthetic components are given in Table 2.

3.2.2. Experimental protocol:

The protocol consists of the following four steps:

i. Each subject was asked to take off their prosthesis.
ii. Each subject was asked to wear thin socks on the stump. Seven of flexible sensors were attached to the stump by double-sided tape.
iii. After sensor placement subject's liner was rolled over skin and sensor. Next the socket was donned on.
iv. The subject was asked to perform some static activities like supination, pronation and lifting load.

Table 2. Participant demographics and characteristic of stump and prosthesis components

Characteristic	**Subject 1**	**Subject 2**	**Subject 3**	**Subject 4**	**Subject 5**	**Subject 6**
Gender	Male	Male	Male	Male	Female	Male
Age (year)	9	17	14	47	35	26
Weight (kg)	26	70	42	78	60	74
Height (m)	1.37	1.52	1.62	1.72	1.57	1.82
Cause of amputation	Trauma	Trauma	Trauma	Trauma	Trauma	Trauma
Amputation side	Right	Right	Right	Left	Right	Left
Time since 1st prosthesis (month)	2	24	2	48	8	38
Stump length (cm)	7	15	14	25	12.5	12
Stump shape	Cylindrica	Conical	Conical	Conical	Cylindrical	Cylindrica
Stump condition	Good	Good	Good	Good	Good	Good
Terminal device	Hand	Hand	Hand	Hand	Hand	Hand
Harness system	Shoulder strap	Shoulder strap	Shoulder strap	Shoulder strap	Shoulder strap	Shoulder strap
Socket type	Munster	Munster	Munster	Munster	Munster	Munster

3.2.3. Functional tasks:

During data collection participants were asked to perform the following static activities:

Figure 25. Supination position

Figure 26. Pronation position

Figure 27. Lifting load

3.3. Data analysis:

For statistical analysis all the collected data was imported into Microsoft Excel. Data of each participated subject was investigated separately to monitor socket design by measurement of interfacial pressure at sensitive and pressure tolerant areas of the stump. From graphical analysis of this data, it can be easily determined the cause of discomfort by the socket design. This collected data can be used for better and more comfortable socket design.

3.4. Summary:

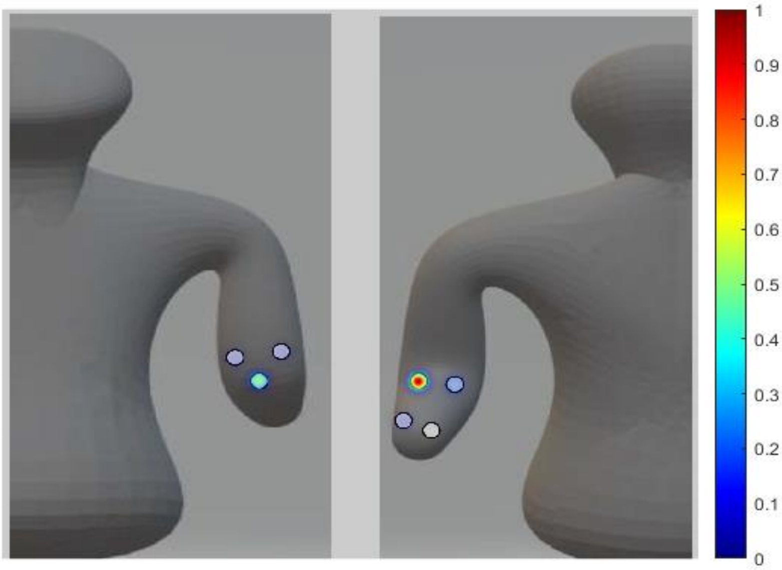
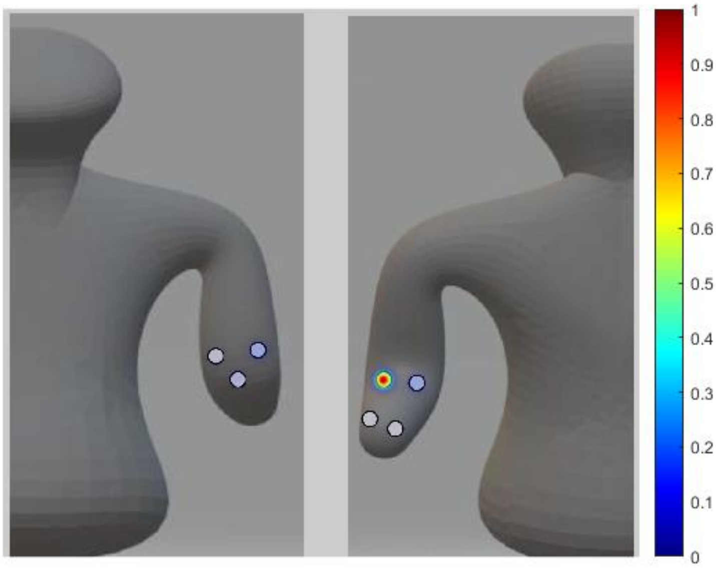
The main focus of the study to design a pressure mapping device which is capable of monitoring interface socket pressure during various tasks. The different pressure magnitude at different anatomical position reveals unique characteristic in the 6 participants that can be considered in individuals socket designs. This work presents a technique that makes it very easy to quantify the interaction of socket-residual stump of upper limb amputees.

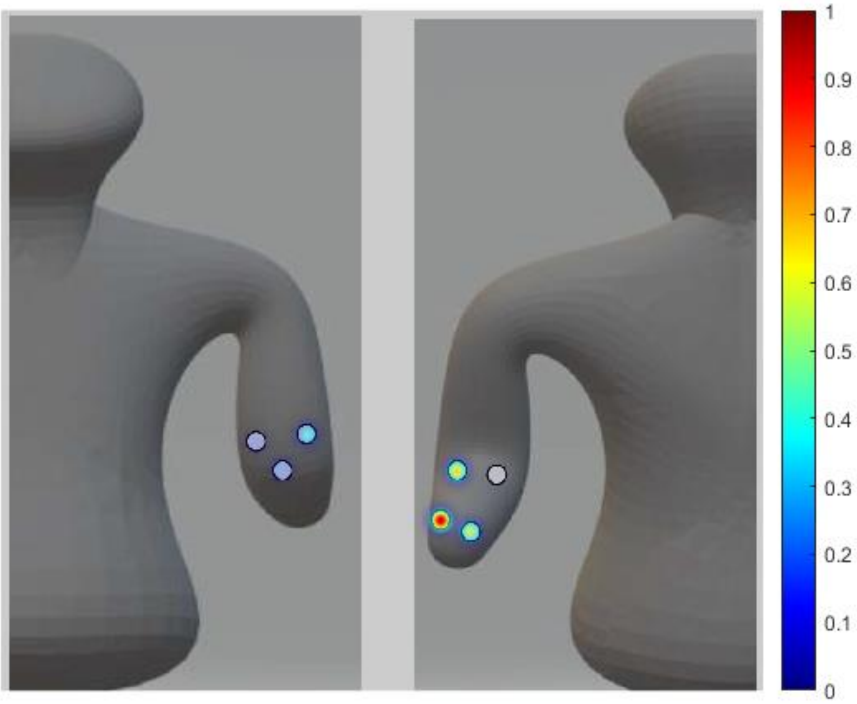
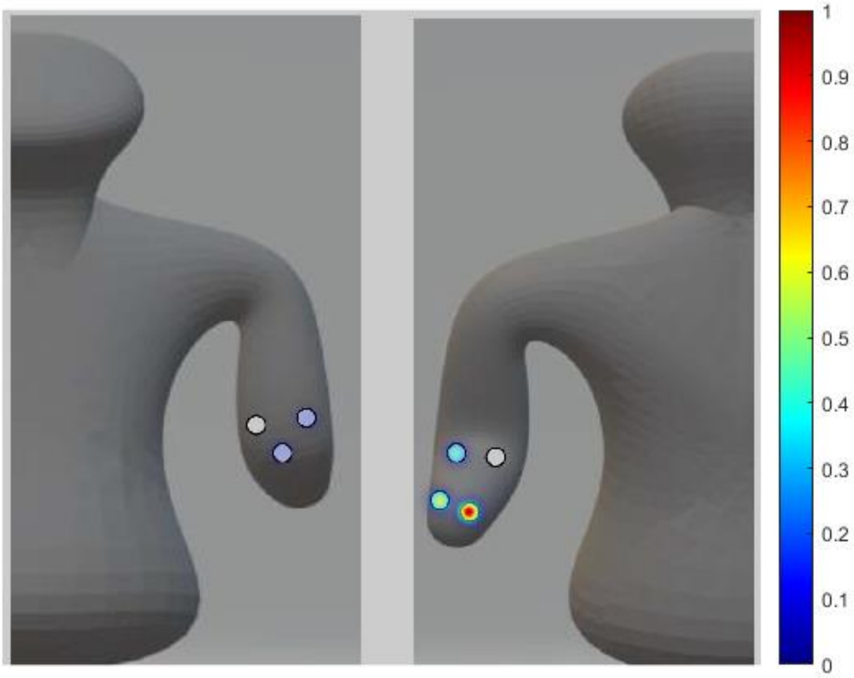
CHAPTER 4: RESULTS & DISCUSSION

Once the device was fabricated it is required to put it through the test to analyze its functioning and effectiveness. The data from prosthetic users is acquired form multiple trials, analyzed to ensure maximum functioning of the device and to verify its operation accordingly.

4.1. Results of subject 1:

Table 3: Pressure map of subject 1

Position	Functional activities	Pressure Map
1	Liner donning	
2	Supination	

3	Pronation	
4	Lifting load	

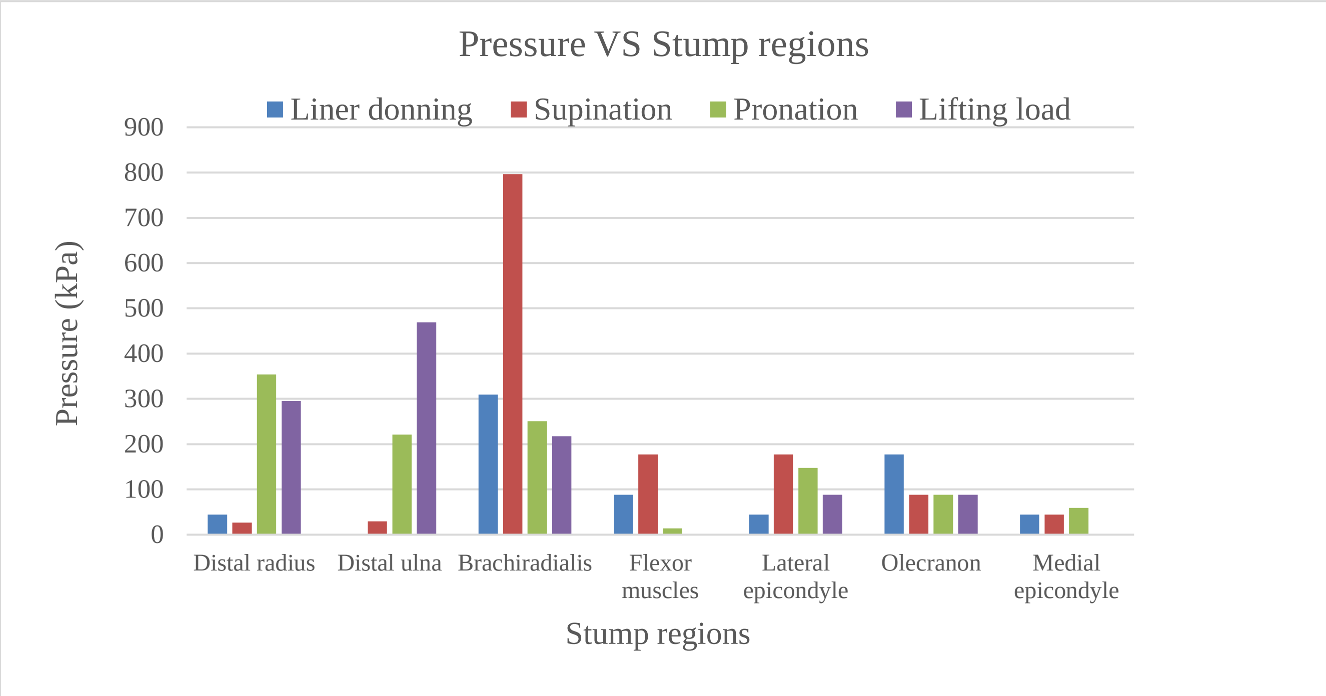


Figure28: Experiment results of subject 1

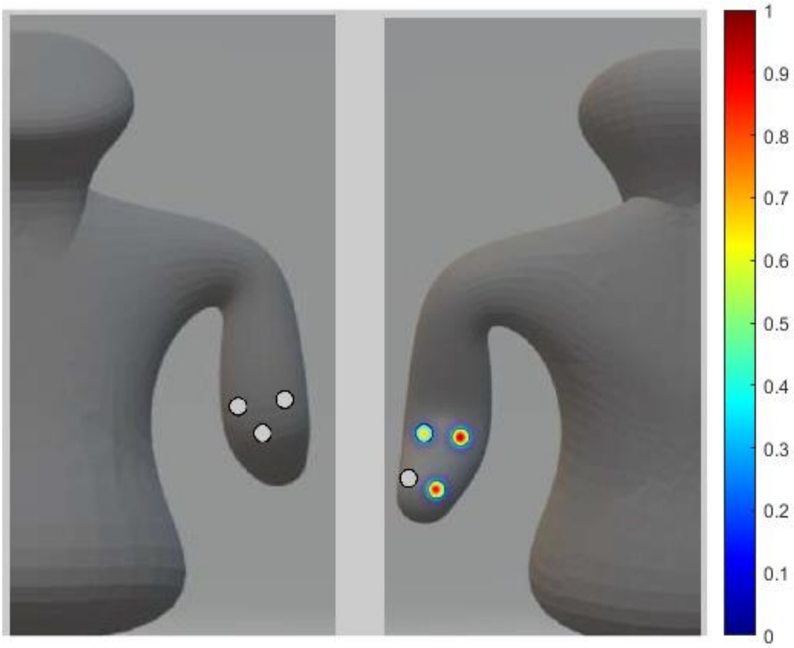
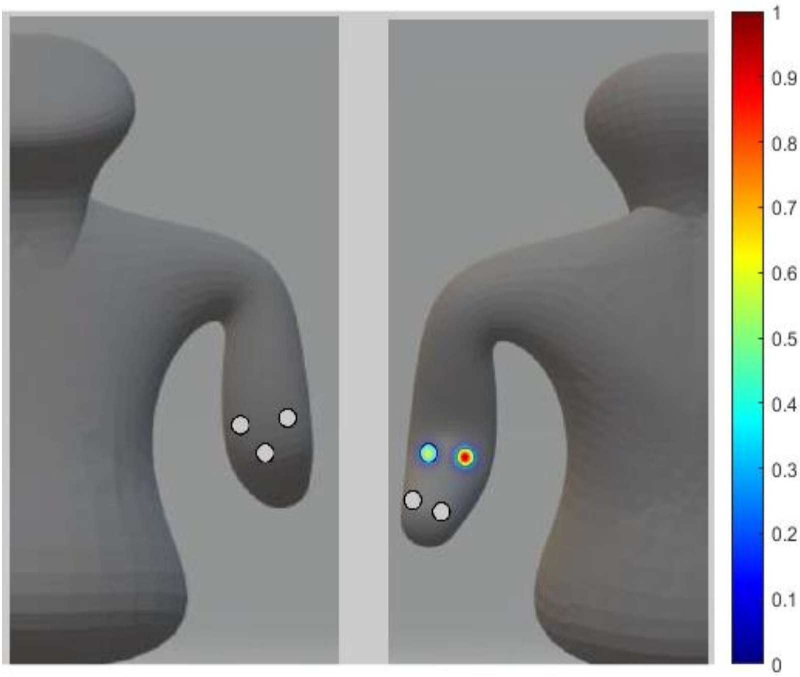
4.1.1 Subject 1:

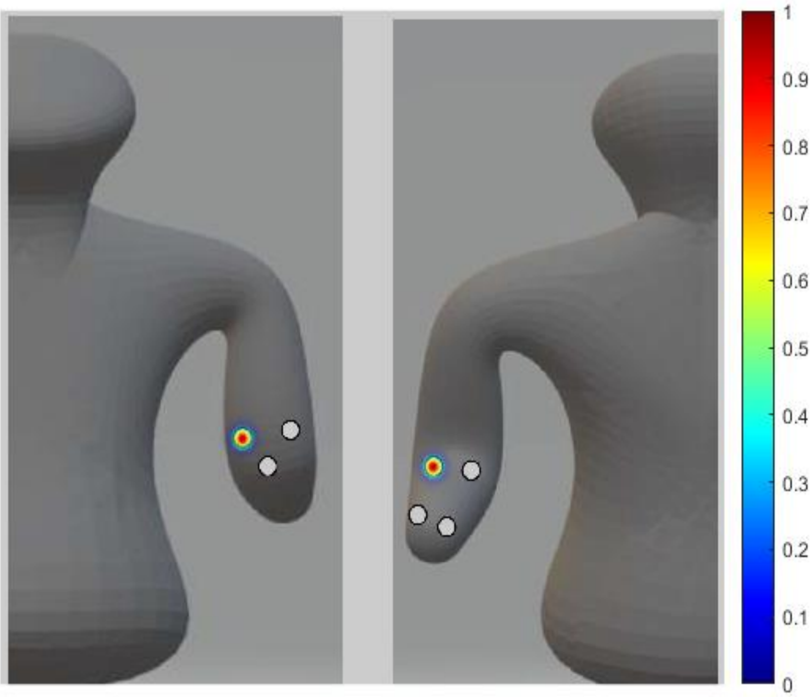
Subject 1 had a right side of transradial amputation. He was using his prosthesis with polyethylene liner from two months. The stump was good no skin complications were noted. The prosthetists evaluate socket design and subjects confirmed their satisfaction with prosthesis.

Seven pressure sensors were placed at different anatomical points. Results are highlighted in graphs and pressure maps. With liner donning bellies of brachioradialis muscle of the stump bearing maximum pressure 309.7 kPa. The magnitude of pressure increases to 796.5 kPa during supination position of arm, indicating that the soft muscle tissue is compressed. When amputees pronate his forearm and lift a load of 500 gram on its terminal device socket concentrate load at the distal radius and ulna that decreased stability and subject complaint the pressure at bony regions and was feeling uncomfortable. The disadvantage of using Muenster socket design is that it concentrates load at distal sensitive bony areas of stump. Because of this complication many amputees reject their prosthesis. The socket design of subject 1 was good. When prosthetist designs a socket, they consider area of bone to reduce pressure at these locations and maximize pressure at muscle flaps of forearm.

4.2. Results of subject 2:

Table 4: Pressure maps of subject 2

Position	Functional activities	Pressure Map
1	Supination	
2	Pronation	

3	Lifting load	

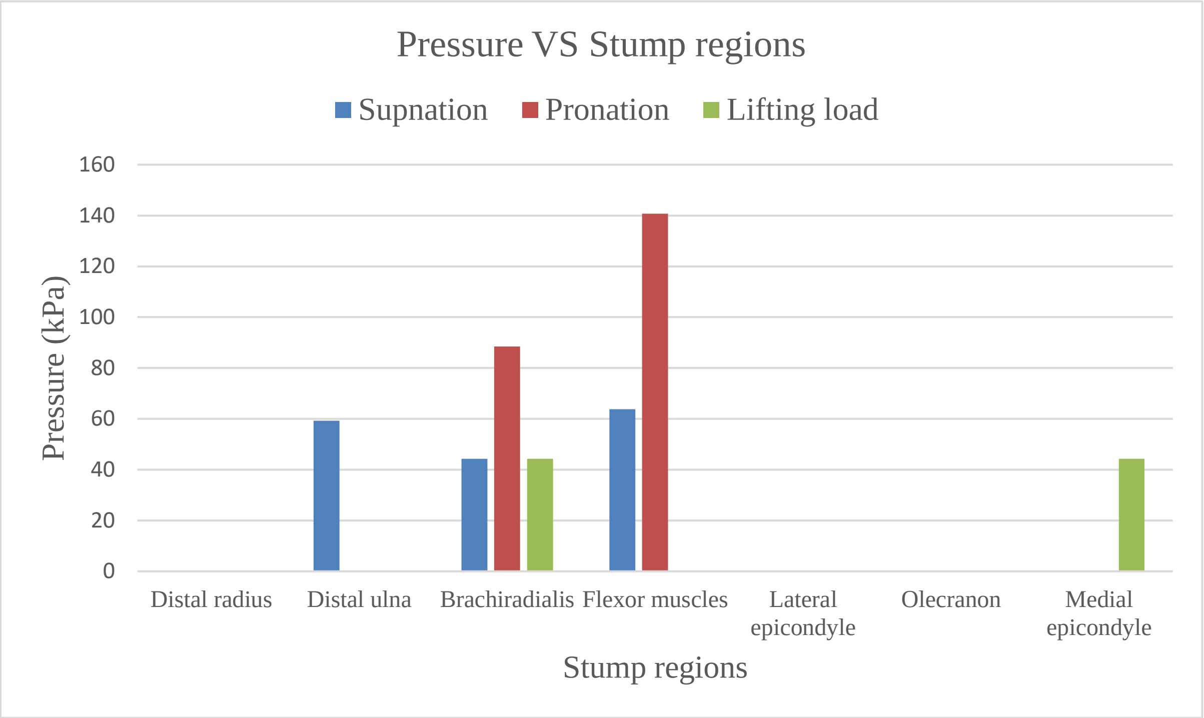


Figure 29: Experimental results of subject 2

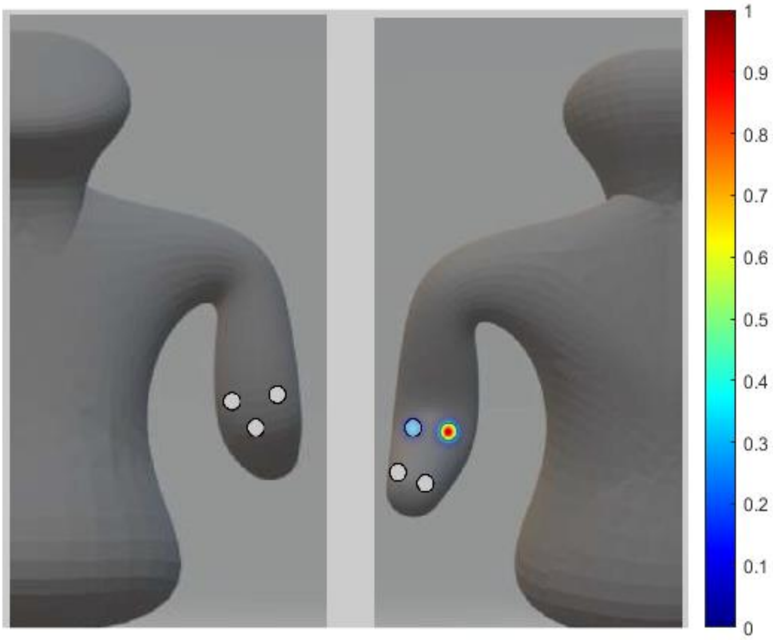
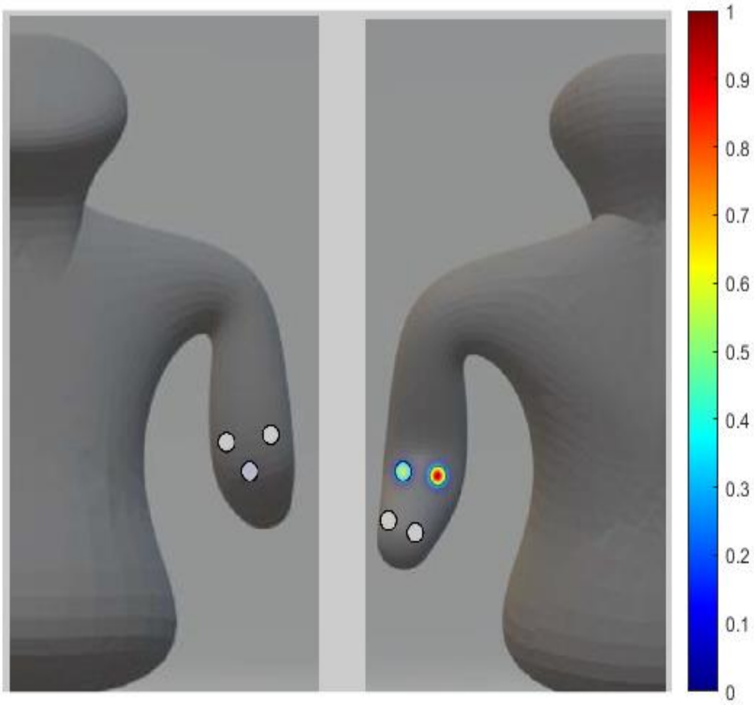
4.2.1 Subject 2:

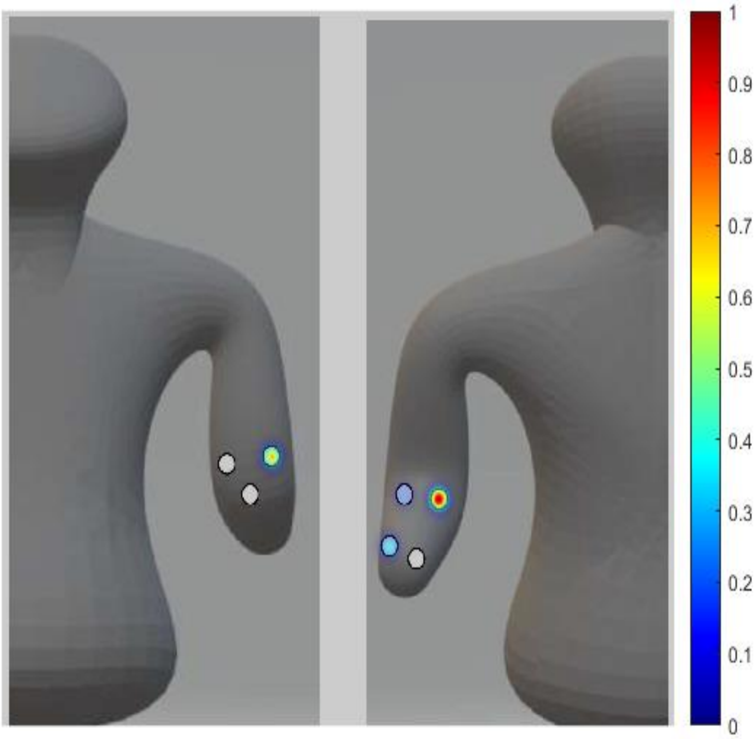
Subject 2 had a right side of transradial amputation. He was using his prosthesis with socks from 2 years. The amputees' stump was in good condition. The subject confirmed that socket was not snuggly fitted on stump.

The seven thin and flexible sensors were directly adhered at socks by double sided tape. During supination and pronation position maximum pressure was noted on flexor muscles about 63.8kPa and 140.7kPa respectively. When amputees carry a load of 500 gram with terminal device pressure, 44.3kPa was noted on two anatomical points including Brachioradialis muscle and medial condyles. The reading of other sensors was missing. This indicates that socket was not fully in contact with the stump. Unstable socket interface leads to improper distribution of pressure and it also increase the skin complications. Subject 2 was also enabled to perform any dynamic activities. This participant was using his socket from 2 years because the socket got lose due to changes in the shape and circumference of stump. Amputees do not consider replacing the socket. It is important for the amputees to monitor the changes in its stump every 7-9 months. The stable fitting of socket is essential for successful use of the prosthesis.

4.3. Results of subject 3:

Table 5. Pressure maps of Subject 3

Position	Functional activities	Pressure Map
1	Supination	
2	Pronation	

3	Lifting load	

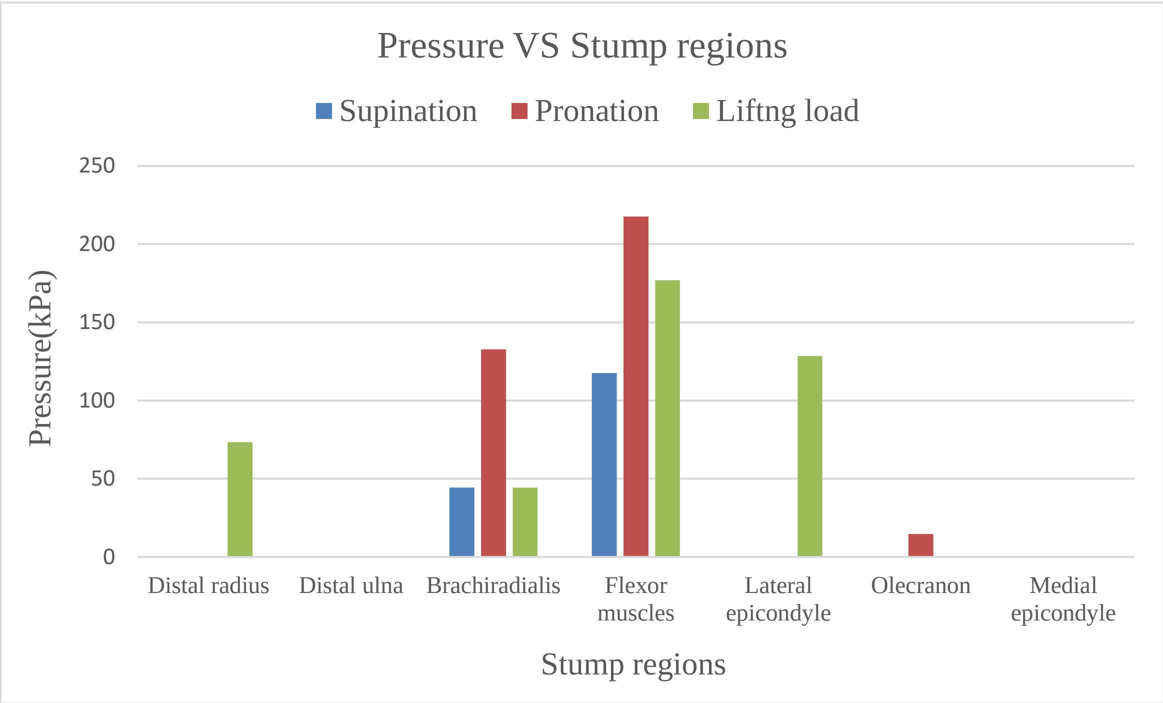


Figure 30: Experimental results of subject 3

4.3.1 Subject 3:

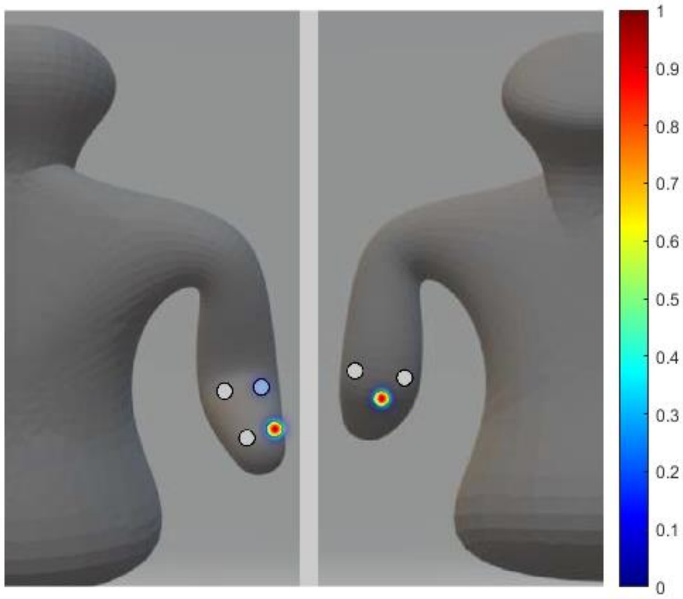
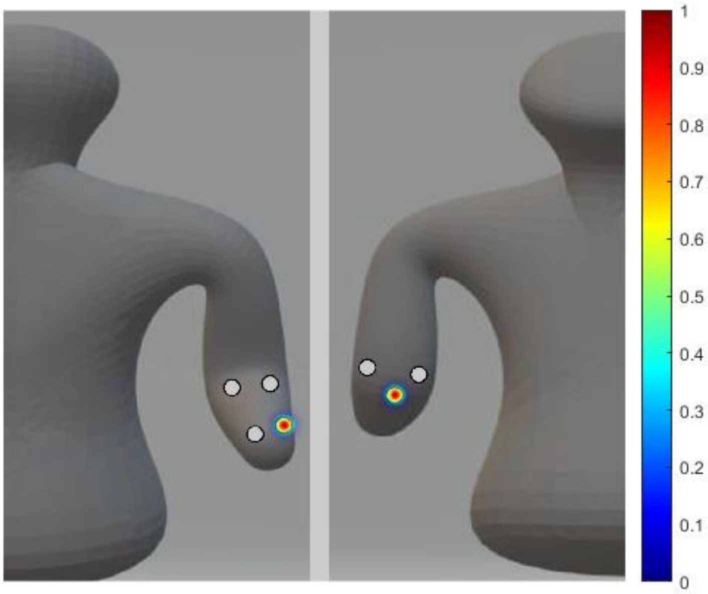
Subject 3 had a right side of transradial amputation. He was using his prosthesis with thin socks from 2 months. The Prosthetist confirmed that socket was a perfect fit for amputee. However, it was noted that the socket was not properly stabilized on stump. There was an unwanted movement between the soft tissue of stump and the hard materials of the prosthesis.

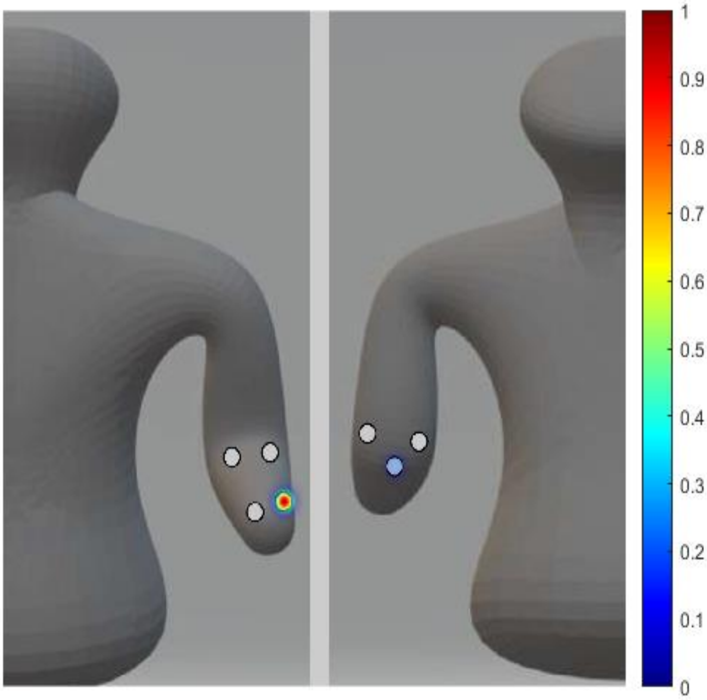
The flexiforce sensors were directly adhered to the socks with the help of double-sided tape. The maximum pressure 117.6kPa and 217.7kPa were noted on flexor muscles during supination and pronation position respectively. The bellies of flexor muscles with a pressure of 176.9kPa while lifting 500 grams with the prosthesis. There was an unevenly distribution of pressure on muscle flaps of forearm. At some points sensor readings were missing, indicating that there was no contact between the socket and stump at these locations.

This socket needs to be redesigned to match the user's morphology and increase stability and reduce discomfort. This design show that there is also a gap in technical knowledge that requires an expert prosthetist to design a socket that should be feasible to amputees so as not to further complicate and increase the rate of prosthesis rejection.

4.4. Results of subject 4:

Table 6. Pressure maps of subject 4

Position	Functional activities	Pressure Map
1	Supination	
2	Pronation	

3	Lifting load	

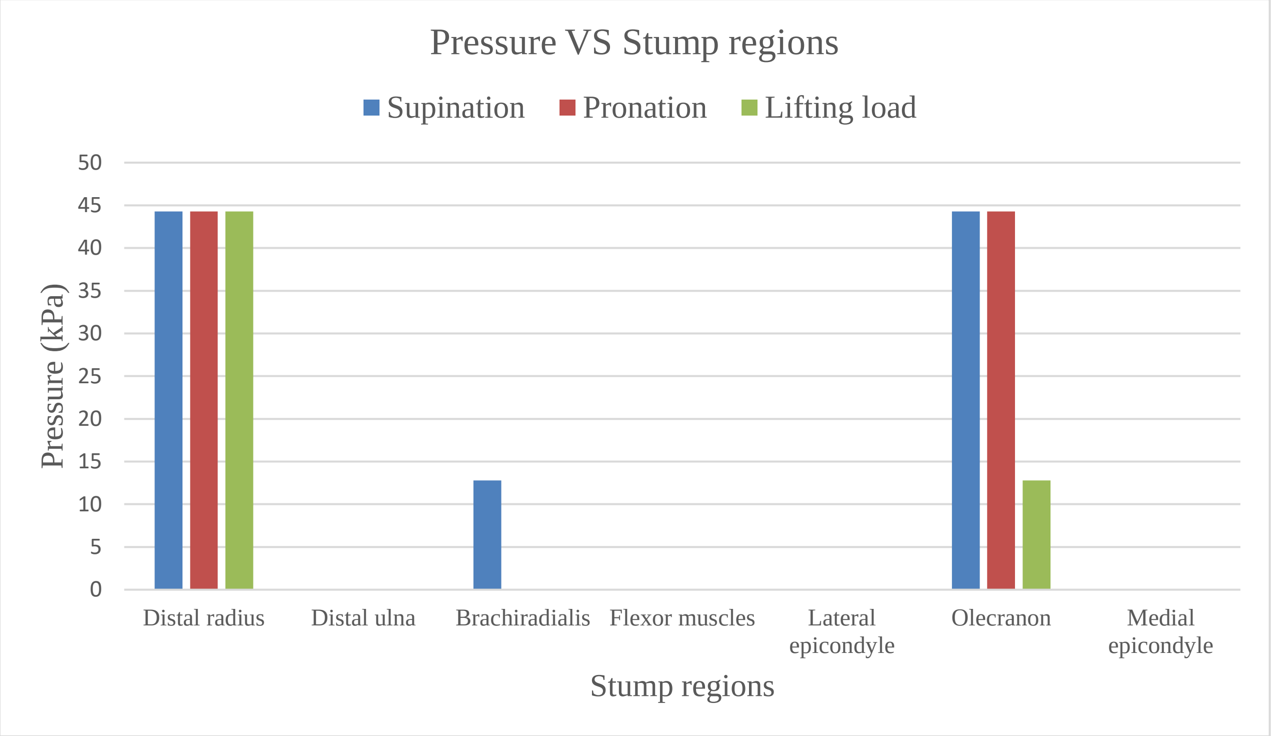


Figure 31: Experimental results of subject 4

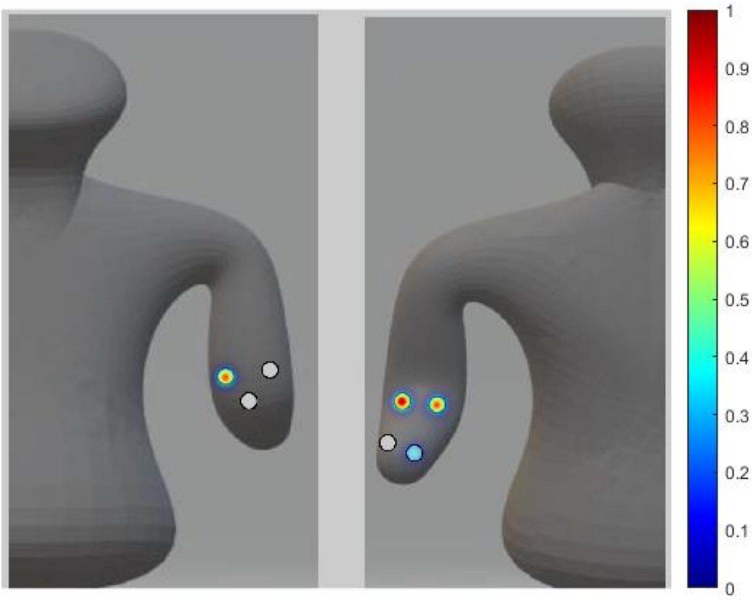
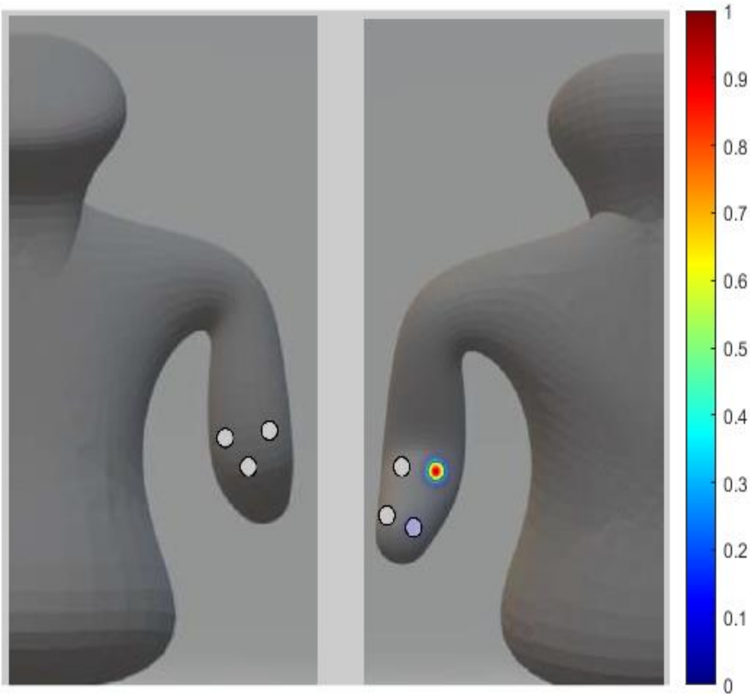
4.4.1 Subject 4:

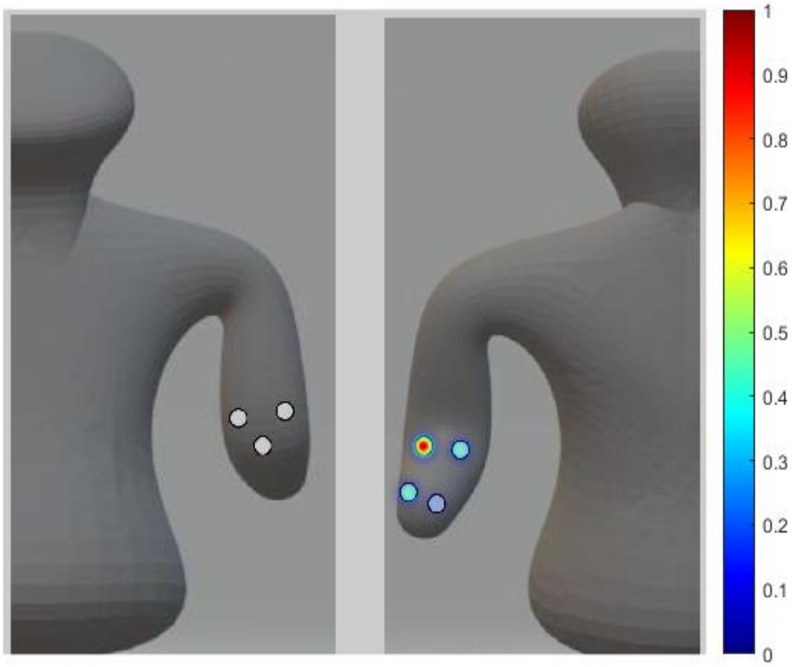
Subject 4 had a left side of transradial amputation and was using their prosthesis with socks from 4 years. The results are presented in graph and heat maps.

The seven piezo restive sensors were placed in pressure sensitive and pressure tolerant anatomical areas those prosthetist gives special considerations of when fabricates the socket. During all activities: supination, pronation and lifting load pressure values were noted at only 2 anatomical points. Radial end and olecranon bone bearing pressure at magnitude of 44.3kPa. when a prosthetist designs a socket, puts maximum pressure on the muscle’s areas. But in this case pressure in the bony areas was maximum while pressure at muscle areas was zero. This indicates a lack of instruction about prosthesis replacement and socket fitting issues. There are needs to taught amputees about functioning, stability, and fitting of prosthesis. This suggest that main reason for rejecting prosthesis is a lack of proper guidance on the device. Other factor includes high cost of prostheses, which is why many amputees do not replace their socket.

4.5. Results of subject 5:

Table 7. Pressure maps of subject 5

Position	Functional activities	Pressure Map
1	Supination	
2	Pronation	

3	Lifting load	

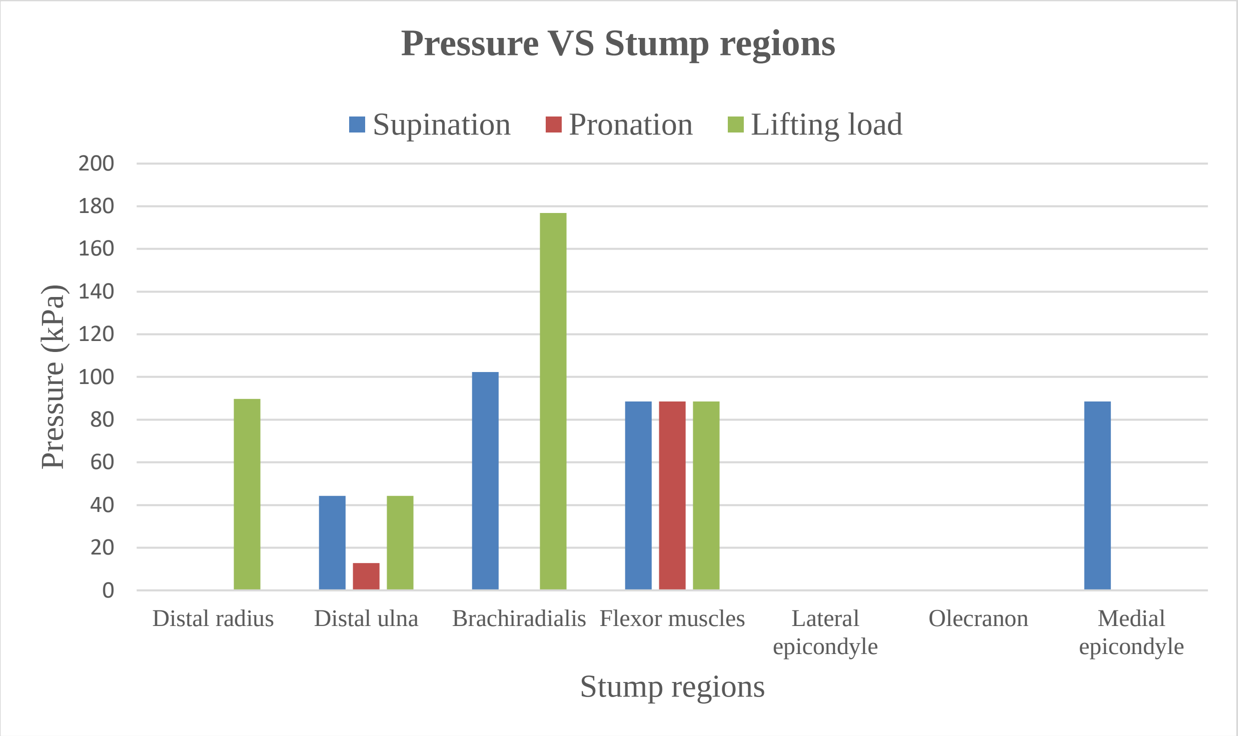


Figure 32: Experimental results of subject 5

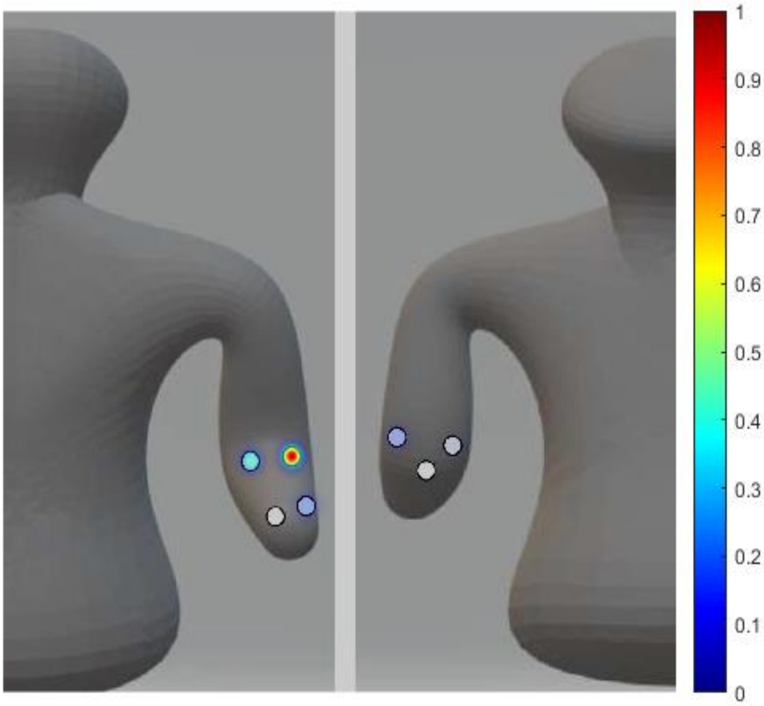
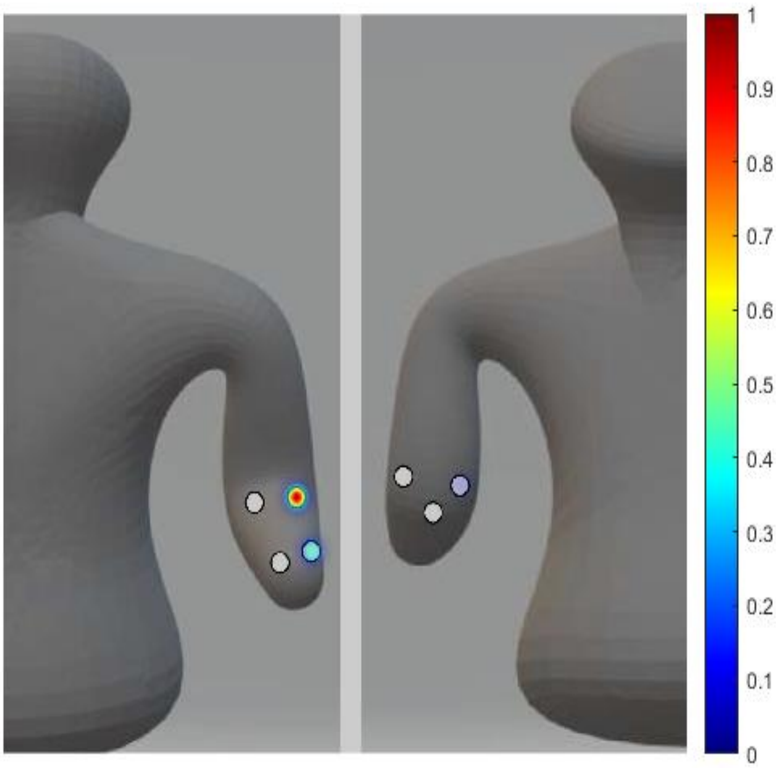
4.5.1 Subject 5:

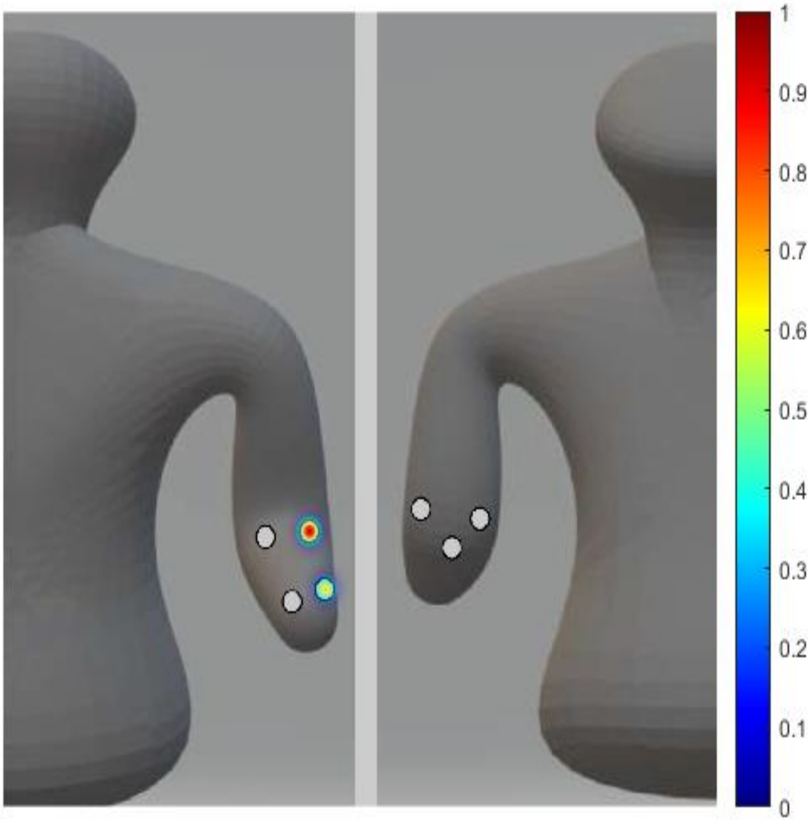
Subject 5 had a right side of transradial amputation. She was using their prosthesis with socks from 8 months. The stump was in good condition. The results were highlighted in graphs and heatmaps.

Seven thin and Flexible sensors were attached to the socks by double-sided tape. The maximum pressure of 102kPa intensity was noted on the brachioradialis muscle during supination position. The pressure magnitude on brachioradialis was 0kPa and the maximum pressure in the flexor muscle was 88.5kPa. When the amputees load of 500 grams with prosthesis, the brachioradialis and flexors muscle note 176.9kPa and 88.5kPa pressure. The pressure on radial end increased to 89.7kPa. Improper distribution of pressure due to poor socket design and this leads to skin complications and reduce functionality. In this situation Amputees was unable to do any dynamic activity so she would prefer not to use this heavy device which would not only reduce her functional dependency but also create other skin problems.

4.6. Results of subject 6:

Table 8. Pressure maps of subject 6

Position	Functional activities	Pressure Map
1	Supination	
2	Pronation	

3	Lifting load	

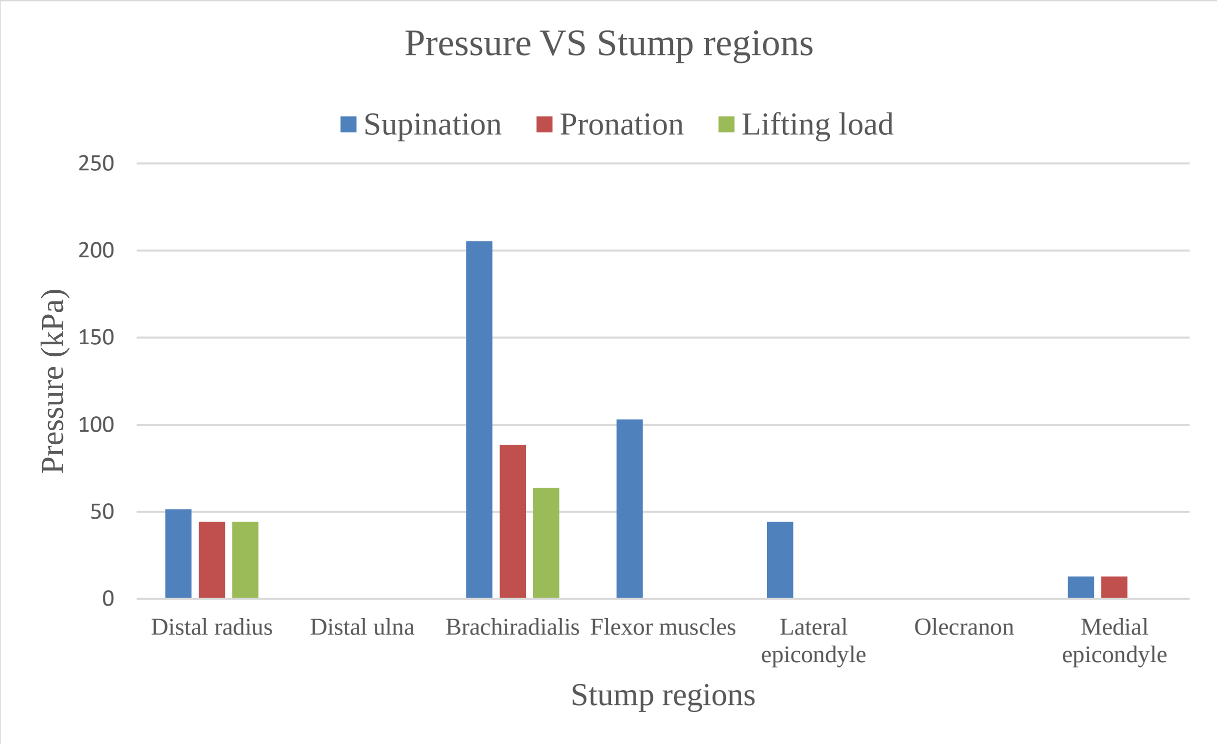


Figure 33: Experimental results of subject 6

4.6.1 Subject 6:

Subject 6 had a left side of transradial amputation and he was using their prosthesis with socks from 2.5 years. The stump was in good condition. the results were highlighted in graphs and heatmaps.

Seven flexiforce sensors were directly attached on socks with the help of double-sided tape. During supination the pressure magnitude on brachioradialis and flexor muscles was about 205.4 and 103.1 was noted respectively. Pressure magnitude at flexors muscle was 0kPa and at brachioradialis muscle was 88.5. when amputees lift loads of 500 grams with prosthesis the pressure was occurred at only wo anatomical points at radial end and brachioradialis muscles. The socket as not fully stable on stump.   this socket needs to be evaluation and redesigned.

4.7. Comparison between subjects:

This is the comparison to sensor point pressure between subjects during different activities.

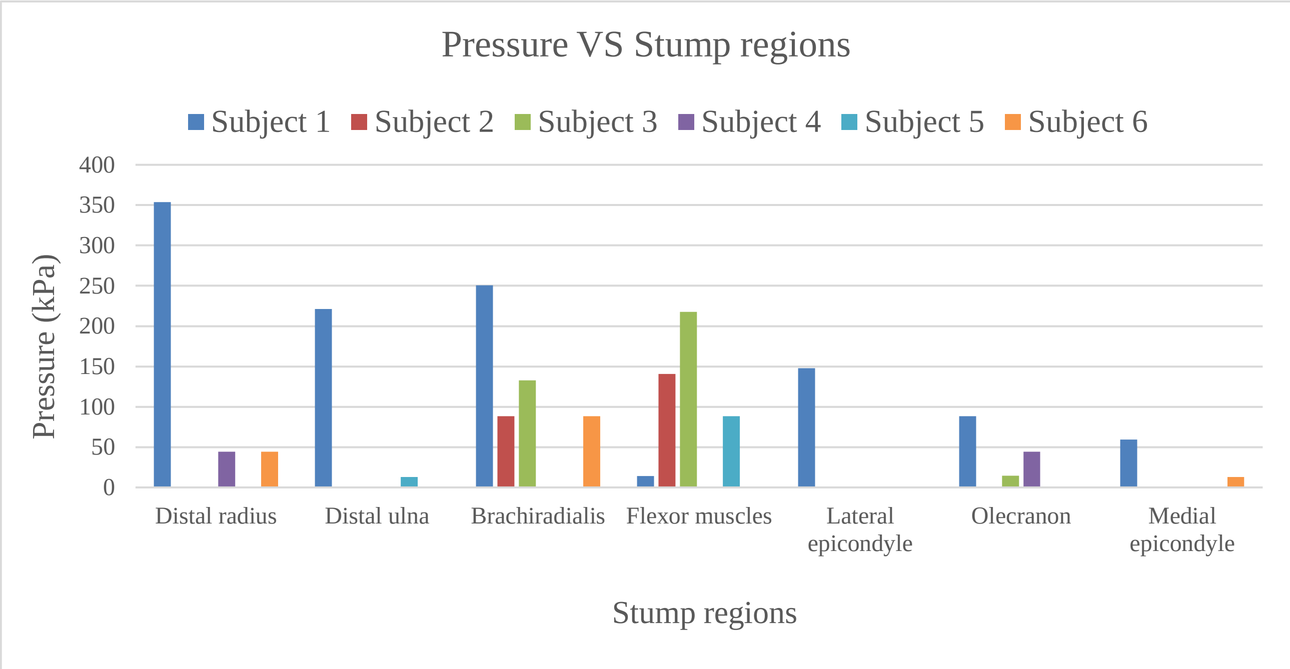


Figure 34. Pressure points comparisons between subjects during supination

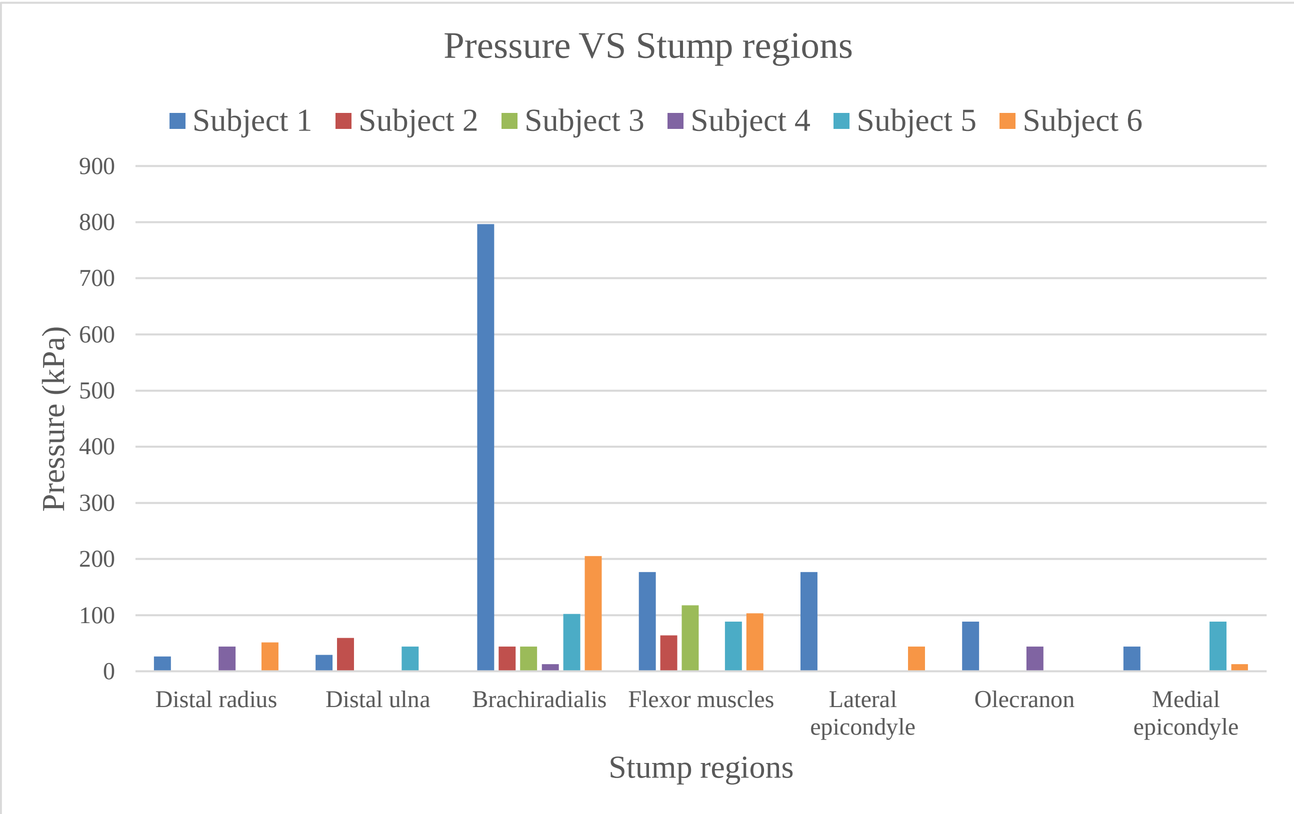


Figure 35. Pressure points comparison between subjects during pronation

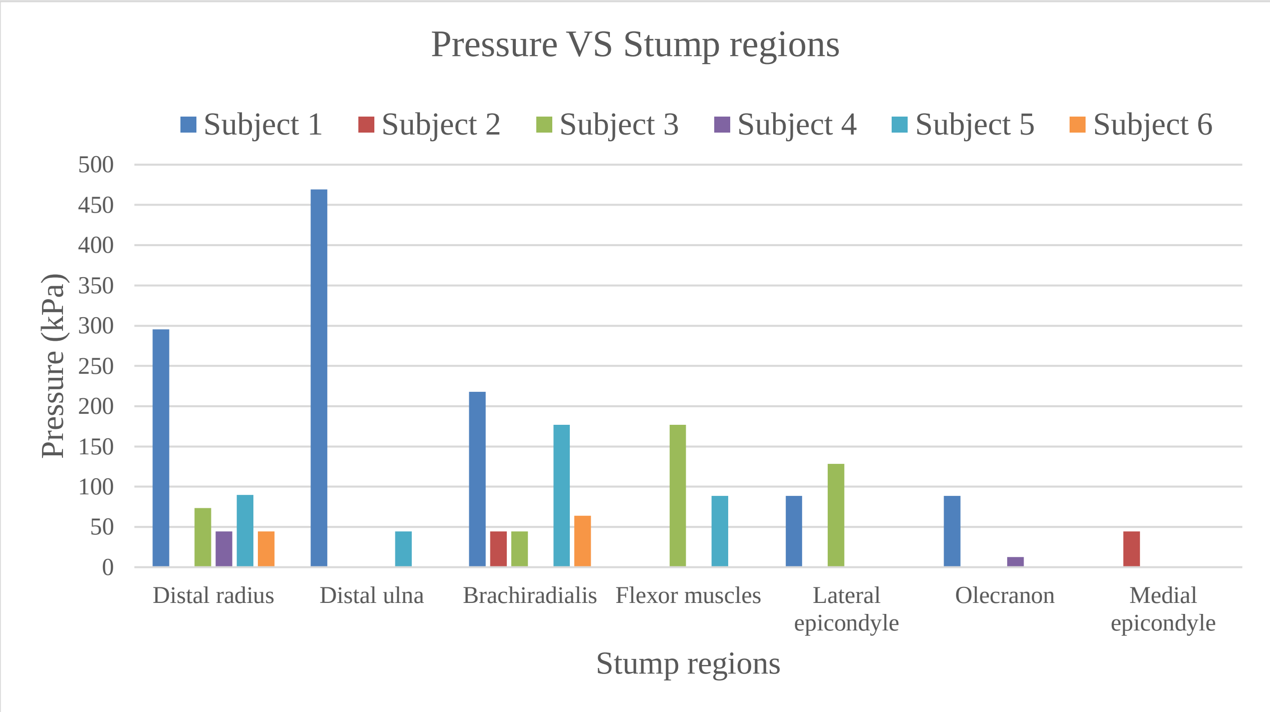


Figure 36. Pressure points comparison between subjects during lifting load

CHAPTER 5: CONCLUSION AND FUTURE PROSPECTS

This pressure monitoring device used in the study is cost effective and portable that can be provided to the rehabilitation center for evaluation of socket design at clinical setup. The results of different methods validate the efficiency and working of the device.

5.1. Conclusion:

The study revealed that the device deign has the capability to monitor the different socket design. This pressurized device is very cheap and easy to use at the clinical setup. Equipping the device to the user is not a cumbersome task. Currently, there is no such pressure mapping system available for the evaluation of socket design. Therefore, Inclusion of this monitor device will provide an effective way to devise a socket with maximum comfort for the amputees

All subjects in this study were unable to perform dynamic activities due to the uncomfortable socket design. Socket design of participants 2,3,4,5 and 6 are lose that leads to improper distribution of pressure over bony areas leading to skin breakage, injury, loss of stability and leading to the falls of prosthesis. Subject 2 has been using their prosthesis from two months. The pressure data obtained indicates that this socket design was not designed correctly. The sensors did not read the data correctly and there is lack of information in our areas of interest. This socket needs to be redesigned so that it matches with user's morphology and distribute pressure evenly.

As the participants 2,4 and 6 were using their 1st prosthesis since amputation. According to literature, changes in size of residual volumes are caused by muscle atrophy, fluid volumes changes or muscle compression. Changes in volume of stump that cause socket to be loose. There is a need to regularly monitor the stump size and socket fitting.

Before designing final socket, it is important to design a pressure monitoring system to monitor the check-socket. Reliable information extraction depends upon correct socket design. Socket should be fully stable on stump to prevent unwanted motion between soft tissue and hard material of the socket.

5.2. Future works:

The following aspects need to be addressed in the future studies:

1. The proposed device can be used for clinical trials as check-socket before designing actual socket.

2. Further work with evaluation of socket design by dynamic activity or any other static pose activity also possible.
3. The discomfort in subjects and device rejection rate can be reduced by regular evaluation of pressure monitoring points in socket.
4. Further study and design manipulation is required to use this device to validate orthosis device and spinal braces.

There are so many hypotheses that can be tried and tested by using this pressure mapping system.

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