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Trans-Tibial prosthetic system design and benefits for the amputee, service providers and society: An evidence based clinical study

By

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List of Abbreviations

ADL	Activities of Daily Living
ANOVA	Analysis of Variance Analysis
CNC	Computer Numerically Controlled
CSA	Cross Sectional Area
FEA	Finite Element Analysis
FSR	Force Sensing Resistor
ICC	Intraclass Correlation Coefficient
kPa	Kilo Pascal
NHS	National Health Service
PEQ	Prosthesis Evaluation Questionnaire
POP	Plaster of Paris
PTB	Patella Tendon Bearing
PVD	Peripheral Vascular Disease
SPSS	Statistical Package for the Social Sciences
TSB	Total Surface Bearing
VAS	Visual Analogue Scale
WESTMARC	West of Scotland Mobility and Rehabilitation Centre

Abstract

Two trans-tibial socket concepts are in regular use in prosthetic clinics. These may be categorised as the "hands-on" (hand casting) concept and "hands-off" (pressure casting) concept which, in addition to the distinctive casting methods, require different liner materials and components to create the desired loading distribution. Amputees have stated that quality of fit of the prosthetic socket is of highest importance, but, although pressure distribution has long been regarded as important, there is no general consensus regarding socket fit criteria. Furthermore, the casting process is carried out with the limb stationary. During walking the pressure distribution will change constantly throughout the gait cycle. The quality of fit of the prosthesis remains very subjective with little quantitative information regarding the pressure distribution within the socket. The aim of this study was to investigate and to compare the dynamic interface pressure distribution of the two socket concepts for a trans-tibial amputee population. In addition, the impact of the two socket concepts on their daily living activities was assessed. The objective was to relate measured pressure distribution to activity level and patient acceptance and thus increase understanding of what constitutes a good socket fit. The dynamic interface pressure distribution inside the socket of 48 patient's own prosthesis was recorded, using a validated pressure measurement system. The dynamic pressures recorded between the residual limb and the prosthetic socket showed similar distributions between the different casting concepts, although overall the hands-off sockets showed higher pressures than the hands-on group. The results from the questionnaire indicated that the quality of fit of the prosthetic socket had a strong correlation with user satisfaction. Results of this study have shown that the impacts of the two distinct prosthetic socket concepts have on the life of the amputee are very similar. Most of the participants used their prosthetic device regularly, and responded in similar ways regardless of the type of socket worn.

1 Thesis Summary

The thesis consists of fourteen chapters, which can be subdivided into four sections, plus references and appendices. The first of these sections includes the initial four chapters of the thesis which provide an overview of the thesis (Thesis Summary) and introduce the background behind the study (Introduction) and the factors considered before investigation (Residual Limb and Prosthetic Socket). The second section of the thesis outlines the outcome measures implemented within the investigation (Pressure Measurement, Activity Monitoring and Patient Feedback) these are described in chapters four, five and six. The third section of the thesis, containing chapters seven, eight and nine, indicates the experimental phases of the investigation, detailing the methodology used and subsequent results (Preliminary Studies, Methodology and Results). The results are discussed and conclusions drawn in the forth section, chapters ten and eleven (Discussion and Conclusions).

1.1 Section 1: Introduction, Residual Limb and Prosthetic Socket

Chapter 1: Introduction

Amputees have stated that quality of fit of the prosthetic socket is of highest importance, but, although pressure distribution has long been regarded as important in creating good socket fit, there is no general consensus regarding socket fit criteria. Two trans-tibial socket concepts are in regular use in prosthetic clinics. These may be categorised as the "hands-on" (hand casting) concept and "hands-off" (pressure casting) concept which, in addition to the distinctive casting methods, require different liner materials and components to create the desired loading distribution. The quality of fit of the prosthesis remains very subjective with little quantitative information regarding the pressure distribution within the socket. The introduction chapter presents the rational behind providing a good prosthetic rehabilitation service and defines the aims of this study, which was to investigate and to compare the dynamic interface pressure distribution of the two socket concepts for a trans-tibial amputee population. In addition to the interface pressure, the impact of the two socket concepts on patient's daily living activities was assessed. The objective was to relate measured pressure distribution to activity level and patient acceptance and thus increase understanding of what constitutes a good socket fit.

Chapter 2: Residual Limb

The residual limb and prosthetic socket are the two interfaces which the prosthesis and human body are connected. To understand what constitutes a good socket fit an understanding of these two elements is required. The second chapter describes the key factors that must be addressed when fitting a prosthesis to a patient. These key factors are the transfer of load between prosthesis and skeletal structure, and tissue mechanics of the residual limb. The blood supply, nutrition, temperature, and limb volume changes are also described, as these intrinsic influences can affect the fitting process. In addition to these, extrinsic factors such as the mental health and age of the patient may also determine the success of prosthetic fitting.

Chapter 3: Prosthetic Socket

The third chapter details the second interface in the system, the prosthetic socket. The transfer of load from the socket to the residual limb is dependant upon the design of the prosthetic socket. The process of capturing the shape of the residual limb is described and details of the two main prosthetic socket concept are described, namely the hands-on and hands off concepts. These two concepts require different components and suspension systems to be utilised when fabricating a prosthesis, the differences are described and the benefits of each outlined.

1.2 Section 2: Pressure Measurement, Activity Monitoring and Patient Feedback

Chapter 4: Pressure Measurement

Chapter four describes the pressure measurement principles and defines two main areas of interface pressure measurement within the prosthetic environment. These two principles define the placement of the transducers within the prosthetic socket. Transducers can either be classed as those which are placed through the socket wall, or transducers which are placed inside the prosthetic socket. The need for a non invasive transducer is explained and the F-Scan pressure transducer is chosen as the method used for pressure measurement in this study. This system is described in detail.

Chapter 5: Activity Monitoring

The second outcome measure implemented in this study is described in chapter five. Activity Monitoring is a useful clinical tool in assessing prosthesis use. Evaluating patient gait is critical to determine if the prosthetic socket is fitting well. The pattern of gait is described including the extrinsic factors that can influence ambulation. Various monitor types are in use in both research and clinical settings; however a monitor that can determine the time and duration of activity would be most useful in a clinical context. The ActivPAL activity monitor is described and is the monitor chosen for this investigation.

Chapter 6: Patient Feedback

Patient Feedback is the third outcome measure used in this study and is described in chapter six. Feedback is vital in improving patient care, as patient and prosthetists expectations may differ. The physical and psychological issues of patient treatment are discussed. It is important that an accurate method of measuring patient satisfaction is used in a research context. A number of questionnaires have been developed and reported on. The main questionnaires used in the healthcare industry are summarised and the Prosthesis Evaluation Questionnaire (PEQ) is defined as the outcome measure used in this study.

1.3 Section 3: Preliminary Studies, Methodology and Results

Chapter 7: Preliminary Studies

Three preliminary studies were conducted during the course of the investigation. These were designed to supplement and define the protocols used within the main investigation. The first of these preliminary studies was investigating the load transmission through a silicone liner. This would be important in deciding on the placement of transducers inside the prosthetic socket. The F-Scan pressure measurement system was placed on either sides of a sample of silicone liner and subjected to a loading pattern similar to that experienced in human gait. Results indicated that small differences in interface measurements recorded by the F-scan on either side of the silicone were due to errors in the system rather than the placement of the transducer and silicone in relation to the applied force.

The second preliminary study involved the development of a calibration procedure for the F-Scan socket transducers. This comprised designing and building a platform which was capable of housing trans-tibial prostheses of different shapes and sizes whilst the socket transducers were calibrated. The platform used a series of inflatable balloons to apply a known dynamic pressure pattern to the pressure transducers which were placed inside the prosthetic socket. Results show that the platform was capable of accurately calibrating and equilibrating the socket transducers.

The final preliminary study investigated the reliability of the activity monitors used in the investigation. Previous literature had indicated that the ActivPAL monitor was accurate and reliable over small time periods, no information was found for reliability over 24 hours. The preliminary study showed that the monitors used were reliable over this longer period and would provide accurate data.

Chapter 8: Methodology

Chapter eight describes the methodology utilised in this investigation. The chapter is divided into three main sections, experimental design, display of results and finally analysis of results.

The experimental design section describes the three outcome measures i.e. F-Scan pressure measurement system, ActivPAL and PEQ. The time required to introduce the subject to the study, instrument their prosthesis, calibrate the transducers, complete the PEQ and perform the pressure data collection took approximately 45 minutes. Six pressure transducers were used on each subject; four socket pressure transducers recorded the interface pressure at the prosthetic socket/residual limb interface. The remaining two transducers were foot transducers which recorded the subject's foot force, which were later be used to determine step timings. A detailed description of the equipment used and protocol followed is given, in addition to the calibration procedure utilised to ensure consistency between subjects. A description of the ActivPAL monitor is presented, including the placement of the monitor. The monitor was placed on the subject's prosthesis and not on the thigh as directed by the manufacture. Therefore only stepping activity was obtained, and differentiating between sitting/lying down and standing was not possible. The PEQ was given to each subject to complete, whilst their prosthesis was being instrumented and calibrated. A detailed description of each of the sub-groups within the PEQ is given in this chapter. Responses to the questions asked within the questionnaire were recorded on a visual analogue scale. Each subject was given the questionnaire and an instruction sheet.

The next section within the methodology chapter is the display of results. This section indicates how the data collected was converted into a form that could be statistically analysed. Particular reference is given to the data obtained from the F-Scan transducers. An individual step was selected for each subject, from the series recorded in the clinic room using the F-Scan foot transducers and video analysis. Maximum average and peak interface pressures were taken in three points during the gait cycle for each of the four transducer arrays inside the prosthetic socket. Activity monitors were connected to the computer and the data uploaded. Daily step counts and the timings of ambulation were collected from the activity monitors. Each response score from the PEQ visual analogue scale was measured and the distance recorded. A number of the questions could be classified as a sub group, and an average score for the complete group could be calculated.

Having converted all the data into a format which could be analysed, statistical methods were used to investigate the influence of the socket design on the three outcome measures. Descriptive analysis was initially made on the demographics of the two sample groups. A three way repeated measure ANOVA model was used to determine the distribution and magnitude of interface pressure data throughout stance phase. Differences between the two groups further analysed using a Tukey post hoc test and an independent sample test. Differences between the two groups for activity and questionnaire response scores were checked using an independent sample test.

Chapter 9: Results

The following chapter, chapter nine presents the results of the statistical analysis. Both subject groups were shown to exhibit similar demographics, allowing comparisons to be drawn between the two groups. The average dynamic interface pressure distribution measured in both subject groups was shown to be similar, despite the different casting techniques used to shape the prosthetic socket. Magnitudes of average and peak interface pressure were higher for the group wearing the hands off socket concept. The daily step count for both groups showed no statistical difference between the groups, and the distribution of walking activity identified that the subjects wore their prosthesis for over eight hours every day. PEQ scores indicated that both subject groups were highly satisfied with their prostheses. Only three questions from the 82 asked showed a significant difference between the two groups.

1.4 Section 4: Discussion and Conclusion

Chapter 10: Discussion

The dynamic pressures recorded between the residual limb and the prosthetic socket showed similar distributions between the different casting concepts, although overall the hands-off sockets showed higher pressures than the hands-on group. The results from the questionnaire indicated that the quality of fit of the prosthetic socket had a strong correlation with user satisfaction. Results of this study have shown that the impacts of the two distinct prosthetic socket concepts have on the life of the amputee are very similar. Most of the participants used their prosthetic device regularly, and responded in similar ways regardless of the type of socket worn.

Chapter 11: Conclusion

In conclusion, dynamic interface pressure distribution is not dependant upon the method of casting; however the magnitudes of pressure are dependant. Patients wearing the hands-on sockets preferred lower interface pressures. Those wearing the hands-off concepts preferred higher interface pressures. Despite these differences the satisfaction of both groups was similar and the activity recorded by the subjects indicated that ambulation levels were similar to those of the non amputation persons, of a similar age.

2 Introduction

2.1 Chapter Introduction

The introduction chapter outlines the changing face of healthcare, and in particular the way in which the prosthetic service is delivered. The two main concepts for prosthetic socket design are outlined and the rational for investigating and measuring the interface pressure between the residual limb and prosthetic socket is described. The main aims and objectives of the study are highlighted and the three outcome measurers used are summarised. An investigation hypothesis is given and the project layout presented.

2.2 General

"The fact that an opinion has been widely held is no evidence whatever that it is not utterly absurd; indeed in view of the silliness of the majority of mankind, a widespread belief is more likely to be foolish than sensible" *Marriage and Morals chapter 5* (Russell, 1929)

In the past, clinical experience was seen as the method of determining the best course of action with regard to lower limb prosthetic care. Subjective assessment criteria were used and the prosthetists experience was the foundation to achieve a good socket fit. Successful fitting of the prosthetic socket was the result of the prosthetists ability to transfer experience with previous fittings and adapt the prosthesis to an individual through alignment procedures (Krouskop et al., 1987).

2.2.1 Subjective to Objective Assessment

The concept for evidence-based health care has become the routine in continuously improving patient treatment. This type of procedure removes the emphasis on clinical experience, personal intuition and non systematic methods for decision making. It encourages the need for the examination of evidence from clinical research.

Many of the procedures in modern prosthetic treatments were developed during the 18th and 19th centuries. Names like Symes, Lister and Gritti changed the way in which medicine and lower limb amputation surgery was performed. These methods were developed from subjective experience. Early amputations usually resulted in death from shock caused by blood loss. Those who did survive surgery usually died in early postoperative period due to infection. The two world wars brought with them great numbers of casualties, many suffering limb loss. Advances in life saving medicines meant that many of those who, traditionally would have died from their wounds were now surviving, these included amputees. Large numbers of service personnel requiring rehabilitation after lower limb loss resulted in major advances in prosthetic treatment and care.

The majority of lower limb prosthetic users have below the knee amputations, and wear trans-tibial prostheses. Early trans-tibial prosthetic sockets were carved out of wood, a procedure requiring a great deal of skill and time. Little thought was given to the biomechanical principles between device and user. Sockets were no more than a receptacle in which to place the residual limb. The use of plaster of Paris to create socket configurations was only occasionally used until the 1950's when Radcliffe introduced the Patella Tendon Bearing (PTB) concept, a new method of coupling the prosthetic socket to the limb (Radcliffe and Foort, 1961). Until this time, load was transmitted from the body to the prosthesis via a thigh corset which off loaded some of the force from the residual limb. The PTB dispensed with the need of this appendage by using the theory of a total contact socket, where all areas of the residual limb transferred weight. This was combined with a loading pattern which permitted pressure tolerant areas of the stump to carry a greater proportion of the body weight, whilst offloading those areas which were deemed to be pressure sensitive.

In the late 1960's an alternative concept for pressure distribution within the prosthetic socket was developed. This method involved hydrostatic casting, in which a plaster cast of the residual limb is created whilst a uniform distributed pressure is applied (Murdoch, 1968). This method of uniform pressure distribution creates a socket whose entire surface of the socket transmits an even load.

With little published evidence as to the benefits of other trans-tibial socket designs, the PTB became the accepted method of socket design. Technological advances in components and synthetic materials such as thermosetting resins, thermoplastics, composite and flexible materials have paved the way for lighter, stronger more cosmetic and less intrusive devices. The application of these materials has the potential to offer the user a more energy efficient gait. In the 1980's and 1990's the use of liners became increasingly popular, Fillauer describes the silicone suspension socket (Fillauer et al., 1989). Kristinsson developed the Iceross procedure, which utilises the uniform pressure concept first introduced by Murdoch (Kristinsson, 1993). Air is used as a pressure medium instead of water. This development in prosthetic technology has seen the increase in use of the pressure cast socket as a regular alternative to the PTB design. Today both the hand cast PTB and pressure cast trans-tibial socket designs are being used in providing prostheses for amputees.

In addition of the two casting methods which are implemented to create the desired loading distribution, the concepts utilise different interface liners and components. The terms "hands-on" and "hands-off" will be used within this manuscript to differentiate between the two prosthetic concepts. These terms are used to describe the combined effects of casting technique, interface material, alignment and components. Hands-on sockets have been hand cast and rectified by the prosthetist using the PTB pressure distribution theory as described by Radcliffe (Radcliffe and Foort, 1961). Subjects normally wear a PE-Lite interface liner between residual limb and prosthetic socket. Hands-off sockets have been cast by means of a pressure casting technique employing a loading condition via an air bladder (Kristinsson, 1993). A uniform pressure is applied during the casting process with little rectification required. Although the pressure distribution is assumed to be uniform, it may be different over different areas of the residual limb. Silicone liners are worn over the residual limb and utilise a ratchet pin attachment for suspension to the prosthetic device.

2.2.2 Problem Statement

It can be stated that the advances in prosthetic rehabilitation evolved from the demand created as a result of limb trauma. Today the need for prostheses is mainly driven from amputations resulting from vascular disease (NASDAB, 2005). The aim of the clinical team should be to deliver the best service possible. However the change in patient population may require a change in prosthesis prescription.

It is estimated that there are around 5,500 people in the UK who are referred to prosthetic centres requiring lower limb prosthetic treatment each year, and of these 75% of patients are older than 65 years (NASDAB, 2005). In the UK as with much of the western world, Peripheral Vascular Disease (PVD) generally caused by atherosclerosis and a loss of viable blood supply in the limb, accounts for the greatest number of lower limb amputations, approximately 85%. Due to associated medical problems and poor general health, it is estimated that the life expectancy after amputation for those suffering from PVD is less than four years (Ng et al., 1996). Trauma, infections, congenital absences and tumours attribute to the remaining causes for amputations (NASDAB, 2005). Although there are no exact numbers of amputees within the British population, estimates based on clinical populations and large scale monitoring groups suggest a figure of 1 in 1,500. (LLIC, 2006). Figures published by the Amputee Statistical Database for the UK in 2005, indicate that numbers of lower limb amputations has remained at a consistent level over the past 7 years. Trans-tibial amputations account for over half of the total amputations. Inconsistencies between prosthetic centres with registering amputee numbers means that the number of patients undergoing an amputation but not proceeding to limb fitting may be much higher than records indicate.

PVD is a systemic disease, bringing with it challenges to successful fitting, due to reduced blood supply, poor tissue quality and impaired sensation. If these are attributed with diabetes visual impairment may also be a result. The disease often results in patients presenting with other health conditions, which is why over half will not become users of prostheses. The onset of PVD is a relatively slow process;

patients prior to amputation may have had a period of inactivity, which may have led to a further decrease in general health and therefore limiting the use of the limb to those who are prescribed prostheses.

2.2.3 Clinical Team

The emergence of a multidisciplinary team has dramatically improved the rehabilitation prospects of the amputee. The team usually consists of a prosthetist, surgeon, physiotherapist, occupational therapist, nurse, social worker, and increasingly, a clinical psychologist. Patients are referred to the physiotherapist after only a short post operative period, usually a matter of days. Evidence suggests that the quicker a patient is fitted with a prosthesis, the better the long term outcome will be (Lilja and Oberg, 1997, Munin et al., 2001). Early mobilisation is important to the likelihood of joint contractures, muscle weakness, maintenance of general health and can enhance the level of rehabilitation achieved by the patient.

2.2.4 Compliance

Pain is a natural deterrent; most people will try and avoid the producers of pain in an attempt to reduce discomfort. If the prosthesis is causing irritation then the patient may be reluctant, even refuse to wear it. There are many reasons why someone may not use their prosthesis once fitted, including a reduction in health which limits the energy a person can expend. However the quality of fit of the prosthetic socket has been shown to be of highest importance for prosthetic wearers (Legro et al., 1999). Sores, blisters and irritation attributed to skin friction are very painful and dangerous to those with impaired sensation and reduced blood flow. A survey of amputees found that nearly 60% reported moderate to severe pain most of the time whilst wearing their prosthesis (Nielsen, 1991).

Movement of the socket over the residual limb occurs when the effects of inertia and gravity during swing will tend to move the prosthesis distally. Upon heel strike the socket will move back up the residual limb. Movement can also occur during stance phase during loading and off loading.

Whilst advances have been made to prosthetic components and socket materials, understanding of socket fit remains an area of limited knowledge. Material technology and the best components are of little use if the prosthesis is not comfortable, or the patient does not have the confidence to use it. The starting point in producing a successful prosthetic limb for a patient is the socket. Without a good fitting socket, inaccuracies often develop more distally. A socket that is too tight will lead to difficulties donning the prosthesis, too loose and the prosthesis may not be secure during gait. A loose socket may also make any attempts of dynamic alignment very difficult.

The quality of fit of the prosthesis remains subjective with little quantitative information regarding the pressure distribution within the socket. A combination of the prosthetists skill and experience together with the patient's proproceptive feedback is required for a successful outcome. For the experienced prosthetist this can be an effective tool, however, for the less experienced prosthetist assessment of socket fit remains a difficult task.

2.2.5 Confidence

It does not matter about the length of time someone has worn a prosthetic limb, the effects of a new socket are the same. A new prosthesis is met with an air of expectation and trepidation. The unknown is a strong barrier to break through. A period of settling in and becoming accustomed to the new device is a common experience. This variability impacts on the patient's experience of prosthetic limb fitting, an experience that will be different every time they have a new socket fitted. If the period of adjustment after socket fitting can be reduced, subsequent prosthetic fitting will be less stressful for the amputee. There have been changes to the methods of fitting prostheses in recent years. With the recent advances in technology, it is now possible to extend the boundary of knowledge of what makes a good fitting socket.

2.2.6 Possible Solution

If a method of creating a socket with reduced differences from the previous limb could be produced the patient would in fact become accustomed to the use of their new prosthesis in a shorter time period. A reduction in such a conversion period would be both beneficial to patient and prosthetist. The patient would experience less stress and anxiety before a new limb is fitted. The prosthetist would benefit from a reduced number of return visits by the patient, thus freeing up more clinical time to spend with each patient.

The question of alignment will make any prosthesis fitting a unique one, no matter how similar the socket. The alignment process has the potential to determine the eventual fit of the limb. A socket which fits well should be comfortable, a well fitting socket should function well, and a well functioning socket should be utilised more frequently. The converse is also true; a comfortable, well fitting socket on a badly aligned prosthesis may also cause pain and eventually lead to removal of the prosthesis.

The process of fabricating a prosthesis can be long and difficult. Patients can be left frustrated and with a prosthesis that is uncomfortable. The most likely problem is in the fitting of the socket. However there is no general consensus regarding the socket fit criteria. Traditionally the process of making a socket begins with a hand cast of the residual limb, to create a negative mould. The problem is that every prosthetist performs hand casting differently. Sockets created by the same prosthetist on the same patient may also differ. A study has shown that even under controlled conditions the shape of a plaster mould cannot be accurately reproduced by the same prosthetist in consecutive trials (Buis et al., 2003). This means that every socket is going to fit differently depending upon the tension of the plaster bandage during casting, and the amount of plaster added or removed during rectification.

In order for a patient to accurately provide feedback on the fit of a prosthetic socket they must first build their own knowledge and experience of the prosthesis in every day activities. This can only be gained after long term experience of the prosthesis they are wearing. Despite this, much of the research investigating socket fit has incorporated specially fabricated prosthetic sockets. It is difficult to provide reliable information as to the quality of socket fit if the socket in question is at most only a few hours old. What is being measured in these situations may be well controlled, but these conditions do not reflect the day to day application in which they will be utilised.

The information gained when the prosthetic user provides feedback about their experience using the prosthesis supplements information obtained from other more controlled environments. The dialogue also creates links between the prosthetic user and the researcher. This leads to areas of knowledge, which when shared serves to build and reinforce overall prosthetic care.

2.2.7 Summary

Two different philosophies in shaping the trans-tibial prosthetic socket are prescribed in clinics, the PTB hand cast and Pressure cast socket. A more scientific approach is required to establish if a difference exists between the two concepts. This is to create their strengths and provide a good socket solution for a particular residual limb and patient. Any approach must provide quantifiable evidence to the service provider, patient and society, in order that an accurate evaluation can be made and comparisons be drawn.

To this end, the project will combine scientific evidence from dynamic stump/socket interface pressure distribution data and relate this to quantitative data gained as a result of feedback from the amputee. This knowledge will be used to determine what makes a good socket fit. Socket fit and function can only be accurately and reliably evaluated using scientific methods. These processes provide a platform on which differences in function can be measured.

2.3 Investigation Aims

The aim of this project is to increase knowledge and understanding about the differences between the hands-on and hands-off concepts of casting the trans-tibial prosthetic socket and provide information to prosthetists to facilitate improved patient care. The prosthetic socket plays a critical role within the prosthesis. The socket/stump interface serves as the coupling between skeleton and artificial limb. Lower-limb amputees have identified comfort and mobility as the two most important characteristics of a prosthesis (Klute et al., 2001). Success can be measured in terms of scientific evaluation and, maybe more importantly, in terms of patient response.

This study will measure the interface pressure distribution between residual limb and prosthetic socket and combine the results with responses from the prosthetic wearer. Previous interface pressure measurement studies tend to be limited in the number of subjects recruited as prostheses instrumented are fabricated for the specific purpose of the investigation. This confines the prosthesis to using experimental sockets, limiting the patient's response to an intervention due to the restricted time the prosthesis has been worn in the clinic or laboratory.

Scientific evaluation of the prosthetic socket will be obtained via the measurement of the interface pressure inside the socket using Tekscan's F-Scan® system, a validated pressure measurement system. Patient responses to the prosthesis can be gained using a validated questionnaire and an activity monitor. Activity monitors manufactured by Pal Technologies Ltd will be utilised in this study. Monitors have been shown to estimate successfully patient's activity levels during the day and provide quantifiable activity changes (Kriska, 2000). However the authors suggested that the information monitors provide should be supplemented with questionnaires in assessing activity in large population studies. A combination of the two methods of activity assessments would work best. Attention should be given to the interpretation of the results if different patient assessments are used (Sager et al., 1992).

To gain a reliable patient response to the prosthetic socket design the patient's own prosthesis will be required during this investigation. It is important that subjects recruited will have been prescribed and used their prosthesis for regular daily activities at least six months prior to their participation in the project. Prostheses fitted will have been delivered during regular clinical practice, by experienced prosthetists, and are not issued with respect to this study. In order that the patients own prosthesis can be used, a non invasive pressure measurement technique was required.

These aims can be summarised as follows:

- Investigate and compare the dynamic interface pressure distribution of a hands-off prosthetic system and a hands-on prosthetic system for a trans-tibial amputee population by means of pressure mapping.
- Assess the impact of socket comfort on daily living activities.
- Present evidence to clinicians to facilitate appropriate prosthetic system prescription for trans-tibial amputees.
- Provide evidence for future innovation in trans-tibial socket designs.

The objectives of this study are:

- Measure the interface pressure between residual limb and trans-tibial prosthetic socket to determine the dynamic profile and magnitude of the pressure.
- Obtain feedback from the prosthetic wearer as to the satisfaction of their prosthesis.
- Measure the motion of the prosthetic wearer during their activities of daily living.
- Determine if a relationship exists between interface pressure, satisfaction and daily activity.

2.4 Prosthetic Interface Pressure

Persons with lower limb amputations are required to transmit large loads through soft tissue, not designed for such conditions. Patients often experience discomfort in their residual limb. One method for quantifying this discomfort is by measuring the interface pressure created at the stump/socket interface. Results from a study of trans-femoral amputees, found that wearers who wore "uncomfortable" sockets generated higher interface pressures (Krouskop et al., 1987). Two studies designed to investigate the pressure distributions recorded during prosthetic stance of a trans-tibial amputee have been undertaken (Convery and Buis, 1998, Convery and Buis, 1999). Each study was conducted on a different design of prosthetic socket. In the first study a subject wore a hand cast socket. The second study the subject wore a socket cast using the hands-off hydrostatic casting concept. Both studies implemented Force Sensing Resistors to measure the dynamic stump/socket interface pressures during gait. A distinct pressure pattern was seen when examining the distribution of interface pressure within the hand cast socket. A ring of increased pressure at the patella bar level, with no major distal end pressure. It was also seen that interface pressure at the patella bar increased towards late stance to a value of 244kPa (Convery and Buis, 1998). The same patient was cast using the hydro cast technique of shaping the stump during casting in the second study. When comparing this data to that of the hand cast socket, it was clear that the pressure within the hydro cast socket was greatly reduced, and the distribution more evenly spread. Although it should be noted that the results described by Convery and Buis were recorded without interface liners. Despite this difference both sockets were deemed satisfactory by the patient and prosthetist. Only one subject was used in each of the studies. A larger study is required to achieve a better understanding regarding the pattern and magnitude of interface pressure within the trans-tibial prosthetic socket.

2.5 Patient Feedback

The amputee has to make many permanent changes to many areas of their life including behaviour, social and emotional (Gallagher, 1999). Interface pressure measurement is one way to gain information regarding socket fit. The data is capable of determining the profile and magnitude of normal pressure within the prosthetic socket, information which will increase understanding about the influence different socket designs have on the residual limb. Patient satisfaction may also be influenced by the manner in which the prosthetic service is delivered. Successful fitting of a prosthesis has much to do with the attitude of the amputee as it does with the prosthetist. A prosthesis may fit perfectly, be the best shape and aligned in the most optimal position possible. However, if the patient has had negative experiences during the fitting process, this may reduce the effectiveness of any device delivered. The implementation of a patient questionnaire would provide a quantifiable feedback. One which is specifically designed to gather information on both the overall performance of the prosthetic limb as well as information on specific areas of daily living and prosthetic care. This study will utilise information gained from a questionnaire in conjunction with the interface pressure measurements to produce a holistic assessment of prosthetic fitting.

2.6 Project Hypothesis

The hypothesis is devised on the theory that the casting methods used in the two trans-tibial socket concepts will lead to considerable differences between the two concepts, in terms of the dynamic stump/socket interface pressures. This will be seen by a more uniform pressure distribution with lower and fewer peak pressures during weight-bearing for the hands-off prosthetic socket system compared to those wearing a hands-on prosthetic socket system. The importance of lower and fewer peak pressures can be expressed as a comfort indicator by the amputee.

Using the recorded pressure distribution, activity monitor output and satisfaction scores from the PEQ, the following hypothesis were produced:

- There is a difference between the distribution of dynamic interface pressures. The hands-on (PTB) socket concept will show a greater number of areas of peak pressure than sockets of the hands-off (IceCast) socket concept.

- The magnitude of dynamic interface pressure recorded at the residual limb/prosthetic socket interface is different between the two socket concepts. The magnitude will be greater in the hands on socket concept.
- The distinction in interface pressure expected between the two socket concepts will result in a difference in the activity of those wearing the two socket concepts. The activity of subjects wearing the hands off socket concept will be greater than the activity of those wearing the hands on sockets.
- Subjects will express a higher satisfaction with their prosthesis when lower interface pressures are recorded at the limb/socket interface.

2.7 Chapter Summary

It has been shown that prosthetic care is more than just physical. Emotions have just as big an impact in the lives of the prosthetic wearer as the prosthesis itself. Increasing patient satisfaction should be the ultimate aim of any prosthetist. Evidence based practice is important in the provision of the best possible care and the enhancement of quality of life for the lower limb amputee, however, the evidence available is limited. The aim of this study is to investigate and to compare the dynamic interface pressure distribution of two different socket concepts, the hands on, PTB socket and the Hands off, pressure cast socket. This information will be related to patient feedback and activity level. Data gained will contribute to socket prescription and design for trans-tibial amputees.

The following two chapters described the two most important elements to a successful coupling between human body and prosthesis, i.e. the residual limb and the prosthetic socket. Each chapter will identify the central points within both of these elements and discuss the implications in the context of prosthetic fitting.

3 Residual Limb

3.1 Chapter Introduction

The residual limb provides the primary interface between human body and prosthesis. Understanding the tissue mechanics and structure of the limb is vital if a successful fitting socket is to be achieved. This chapter focuses on the main influencing factors to limb health when fitting a prosthesis to the residual limb i.e. the transfer of load between prosthesis and skeletal structure, tissue mechanics of the limb, blood supply and nutrition to the limb, temperature and volume changes of the limb and the mental health and age of the amputee.

3.2 Transfer of Load

Load transfer is accomplished through the skeletal structure, through the heel pad and plantar surface of the foot. The skin coverage over the residual limb was not originally intended to be subjected to the same forces as it is subjected to when a prosthesis is fitted. It does not have the same weight bearing characteristics as the heel and plantar surface of the foot. The primary function of the prosthetic socket is to transfer the forces from the prosthesis to the skeletal system. As the primary interface between patient and ground, the socket should achieve optimal distribution of interface loads, whilst providing a stable and energy efficient coupling between the residual limb and the prosthesis. An ideal fitting socket will be one which the distribution of interface pressure is optimised throughout the gait cycle. However there is no general consensus on what is the optimal distribution over the residual limb (Mak et al., 2001).

3.3 Tissue Mechanics

The mechanical properties of skin are important on many different levels. The skin is not only the largest organ; it is the physical boundary with the surrounding environment (Tortora and Grabowski, 1998). Skin integrity is of great importance to the maintenance of good dermatological health. Skin which has lost its normal elasticity and resilience can become bruised and cracked, which may produce a difficult platform on which to act as an interface with the prosthesis. Residual limb soft tissues within the prosthetic socket are subjected to a special environment. The skin of the residual limb is not physiologically designed to endure the enclosed micro climate environment and variety of pressures inherent in the wearing of an artificial limb. Patients often express that their prosthesis is uncomfortable, common causes of under-use are skin breakdown and painful walking (Lyon et al., 2000). Discomfort is usually associated with skin complaints such as rashes, blisters, or other skin irritations.

The condition of the skin of the residual limb is of extreme importance to an amputee's ability to use a prosthesis. If the normal skin condition cannot be maintained, the prosthesis may not be worn, even if the fit of the socket is accurate. This results in the patient not only having a physical impairment but also impacts on them mentally, socially, and economically. Lower limb amputees are frequently troubled by skin problems (Lyon et al., 2000). Maintaining stump hygiene is of paramount importance in preventing infectious or traumatic skin problems in the future of the amputee.

The skin acts as the body's first line of defence against its surroundings. Over the course of time a person's skin will undergo changes, sometimes these skin changes are visible, such as wrinkles, blemishes or rashes. In other cases, the changes may not be easily identified. Skin adaptation of the residual limb will take place as cells in the epidermis and deeper in the dermis repair or protect damaged tissue. (Tortora and Grabowski, 1998). Some amputees may experience problems due to the close-fitting interface of the socket. Most trans-tibial prostheses have a close-fitting socket in which air cannot easily circulate and which may trap perspiration. The liner is the primary interface for weight bearing and uneven loading may cause stress or friction on localised areas of the stump skin and deeper tissue (internal shear).

Usually, the supply and removal of fluid in the body are well balanced (Campbell, 1993). However after amputation this balance is disturbed. The normal pattern of blood and lymph channels and the relationship of pressures, both inside the vessels and in the surrounding tissues of the stump are impaired which causes changes in skin properties.

When amputees first begin to wear a prosthesis, the skin of the residual limb must adapt to the entirely new environment. The amputee can expect oedema and redness resulting from prior capillary bleeding. Some abnormal swelling can be partially prevented by gradual compression of the stump tissues with an elastic bandage, or shrinker sock, either before the use of the prosthesis or during times when the artificial limb is not being used.

Tissue breakdown is more likely to occur if the area has been subjected to repeated injury. Friction has both positive and negative effects on the residual limb. It has an important role in achieving good suspension and load support, but contributes to the heat build up within the socket and produces stresses on the surface of the soft tissue that can be damaging. The shear forces on the surface may also cause stresses in underlying tissue.

Surface breakdown may occur from repeated shear forces. Deep tissue distortion due to shear forces is also another major contributing factor. Other contributing factors to skin breakdown include the loss of sensation which can cause reduced nutrition and oxygen perfusion. Pressure tolerance guidelines indicate that acceptable continuous pressure is time dependant, with acceptable pressures reducing quickly after one hour (Kosiak, 1961). Tissue was tested using pressures of between 0 and 700 mmHg (90kPa). These values are much lower than the peak pressures, and even the average pressures measured in the prosthetic socket. However, with the prosthetic socket the cyclic action of the gait cycle results in variable pressure. The cyclic pattern of pressure applied to the surface of the skin results in far less alteration of mechanical properties than when the skin was subjected to static pressure (Edsberg et al., 1999). In a different study, the same authors reported that tissue surrounding a pressure ulcer has undergone significant remodelling (Edsberg et al., 2000). These changes could have vast implications to the residual limb environment when controlling and distributing interface pressures.

Pressure management within the prosthetic socket can therefore be seen as an important factor in achieving a good socket fit and comfort. Pressure measurement will provide an objective measurement which can be used to evaluate a prosthetic socket design. It must also be noted that in addition to interface pressure, a number of other factors can compromise the condition of the residual limb and may cause tissue breakdown. Factors include blood supply, temperature, nutrition, mental health, the age of the person and residual limb volume changes. Many of these are the predisposing elements which resulted in the amputation in the first place and are still present post operatively.

3.4 Blood Supply

Human tissue requires oxygen and nutrients to maintain a level of repair. Anything that causes poor circulation thereby reducing the flow of blood to the skin will compromise the mechanics of tissue. Factors such as smoking, diabetes, high blood pressure or high cholesterol can all compromise blood flow. Oedema causes skin to be malnourished, and, eventually to get thinner making the skin more susceptible to injury and breakdown (Tortora and Grabowski, 1998). People with diabetes have numerous skin problems that require the combined contributions of the prosthetist, medical specialist, and dermatologist. Skin breakdown is caused mainly by the duration and intensity of pressure and by the degree of tissue tolerance (Brand et al., 1976). It can be defined as localised areas of cell death that develop when soft tissue is compressed between a bone prominence and a hard surface for a prolonged period of time.

Skin may breakdown as a result of unrelieved pressure occurring by sitting or lying in one position for long periods of time, or by shear forces and friction. Damaged skin will initially turn red at the area under the pressure and if care is not taken to protect it from further damage, may break into an open sore.

3.5 Temperature

A residual limb contained inside a prosthetic socket is likely to experience an increase in temperature depending upon activity and ambient temperatures (Peery et al., 2005). An increase in temperature may lead to an increase in perspiration, which could increase the risk of tissue breakdown, if the skin becomes moist. The non porous materials of the socket increase the risk of a build up of moisture, which thin socks and liners worn over the residual limb are designed to remove. Temperature increase can also be attributed by friction between limb and socket wall (Sanders, 2000).

3.6 Nutrition

The person's diet can also lead to compromised tissue integrity. Poor nutrition promotes swelling and compromises the process that gets oxygen to cells throughout the body. Proteins maintain the skin's elasticity, and help in wound healing. Carbohydrates provide energy and nourishment (Tortora and Grabowski, 1998). Without enough carbohydrates, the body will use proteins instead, which will make them unavailable for their wound-healing job. Zinc is crucial for skin repair because it helps metabolise carbohydrates, fats and proteins. Vitamins A and C increase the skin's strength (Campbell, 1993). Fluids are important to be maintained as more than a litre of water each day can be lost as part of the healing process.

Physical Health can also impact on tissue mechanics; fevers can change the body's metabolism, alter skin tolerance, and lower the body's resistance. In addition, fevers shunt the body's disease-fighting resources to areas where they're most needed, which is likely not to be the skin.

3.7 Mental Health

Mental Health also affects skin. If a person is stressed or depressed, they may not pay as close attention to skin care, putting the skin at risk. Stress and depression can also change the body's immune system. The body's ability to fight off viruses can be decreased by stress, and the healing process is slowed down (Ader et al., 1995).

3.8 Age

Over time, skin gets weaker, thinner, stiffer, and less elastic. Knocks, injuries and pressures that at one time had no impact at all may now lead to bruises, discolorations, and breakdowns. At the same time, the small blood vessels that take oxygen and nutrition to the skin cells also age and degenerate, making them less able to keep the skin nourished (Carrino et al., 2000).

3.9 Volume Changes in the Residual Limb

During the day the volume and shape of the residual limb is likely to change, depending upon the activities of the amputee. Studies of trans-tibial vacuum sockets have shown that they can reduce volume loss during gait by improving the balance of fluid transfer at the residual limb with changes to the positive and negative pressures during stance and swing. (Beil et al., 2002, Board et al., 2001). Upon removal of the trans-tibial prosthetic socket, the residual limb can also increase in volume, as fluid expelled by walking, and the restriction of the socket, returns to the residual limb. This change usually occurs immediately after removal and after a few minutes stabilises. Changes to the volume to the residual limb over longer periods of time tend to be smaller than these initial increases (Zachariah et al., 2004).

3.10 Chapter Summary

In this chapter the key elements to observe when fitting a prosthetic limb have been discussed. Knowledge of the underlying structure of the residual limb and the factors that can disrupt the homeostasis of tissue influence the design of the prosthetic socket. In the following chapter, the design of the prosthetic socket is described, with these factors in mind.

4 Prosthetic Socket

4.1 Chapter Introduction

The prosthetic socket is the most important element within the prosthesis and the fit of prosthesis can define quality of life for the patient. It acts as the interface between human and device, the shape capture of the two main socket designs and their suspension methods are discussed in this chapter.

4.2 Load Transfer

The socket is designed to fit the skeletal structure, allowing for changes in the musculature, whilst maintaining comfort and function. A total contact fit is required to transfer body weight from the skeleton to the prosthetic limb, and provide the broadest distribution of pressure possible, whilst minimising shear forces (Hachisuka et al., 1998, Sonck et al., 1970). The skin and the underlying soft tissues of the residual limb are not designed to tolerate the high pressures, shear stress, abrasive relative motions, and the other physical irritations encountered at the prosthetic socket interface. In order to design a good socket fit with optimal mechanical load distributions, it is critical to understand how the residual limb tissues respond to the external loads and other physical phenomena at the interface. Two principles of load distribution are generally followed when taking a cast for a prosthetic socket. The load is either distributed over specific areas of the residual limb, according to the underlying anatomy (Radcliffe and Foort, 1961) known as the Patella Tendon Bearing (PTB) prosthetic socket concept. The second concept is to distribute the load uniformly over the entire limb. This is achieved by using a pressure cast technique.

With the absence of the normal leg, the prosthetic socket must provide stability and transfer load from body to ground in a static and dynamic loading condition during the stance phase, whilst transferring the angular moments to create acceleration throughout the gait cycle. In addition to this transfer of load, the socket must also maintain its position when the leg is in swing phase. These factors, static and dynamic load transfer and suspension, are what dictate the design of the prosthetic socket.

4.3 Shape Capture

The first stage in producing a prosthetic socket typically begins with a negative plaster cast of the residual limb. The plaster is applied to the residual limb in the form of plaster impregnated bandage. Once wet, the plaster bandage is wrapped around the residual limb. When dry, the plaster bandage hardens and a negative shape of the limb is produced. It is during this hardening period the plaster is subjected to pressure. The difference in design theory dictates the method of applying this pressure. The cast produced provides a rigid, static copy of the residual limb in one set position. With a hard cast, it is impossible to address the shape changes of bone and soft tissue that occur while an amputee walks with a prosthesis. Just as the skin and soft tissue on the bottom of a foot is moulded and shaped in a well fitting shoe, the shape of the residual limb changes while compressed in a prosthesis. As a patient walks, pressure points on the limb vary with the body's shifting weight.

The use of plaster of Paris as a method of capturing the shape of the residual limb to create a prosthetic socket has changed little over the last fifty years. In one study sand replaced liquid plaster as a means of producing a positive model (Wu et al., 2003). It was shown that sand could reduce the fabrication times in producing a prosthetic socket, and could be useful in developing nations where cheaper alternatives are required. Other methods have been used recently including laser scanning, CAD/CAM, vacuum casting and direct contact fabrication, such as ICEX (Ossur, Iceland). All these processes have each been shown to exhibit their own advantages over more traditional methods. One of the aims of these methods is to reduce the inaccuracies between shape capture and definitive socket fitting. However plaster of Paris still remains the most common method in daily use in the clinic.

Hands-On Concept (PTB)

The aim during the casting and rectification of a hands-on socket is to provide pressure relief on pressure sensitive areas such as bony prominences, blood vessels and nerves. Whilst plaster sets the cast is modified by applying pressure with the fingers over weight-bearing points e.g. patella tendon, The positive mould is rectified by applying plaster to pressure vulnerable areas and removing plaster from pressure tolerant areas.

Hands-Off Concept (Pressure Cast)

Hands-off sockets rely on an assumed uniform pressure distribution. Therefore the wet plaster is subjected to a uniform pressure whilst the shape is obtained. The most common method for this is by using air or water.

4.4 Consistency of Shape Capture

Humans are creatures of habit; any changes to the "norm" can bring fear and anxiety. Anyone who has recently been through a life changing experience, such as losing a limb, the fear of the unknown and what lies ahead may bring significant stress to that individual. Even those patients who have many years and countless appointments with a prosthetist may be unsure of what to expect if they are prescribed a replacement limb. Maybe the limb they are currently wearing had been used for many years, and the prospect of changing to a new prosthesis increases their anxiety. This fear may be greater if the patient has experienced difficult periods adjusting to prostheses in the past. Clinical experience suggests that most patients take time to adjust to a new prosthesis, even experienced users. This adjustment period will vary from patient to patient and prosthesis to prosthesis. Consistency of fit is important to maintain on a day to day basis, but also each time a new prosthesis is delivered. If, at the time of fitting an accurate and reproducible method could be implemented to fit a new prosthesis the experience of the patient would be improved. This improvement would last beyond the time of fitting, and serve to reduce the anxiety of the anticipation of subsequent fitting appointments.

The consistency of rectification of hands-on style sockets has been investigated (Convery et al., 2003). The study highlights the variations between different prosthetists, and also indicates variations between rectifications from the same prosthetist. The same group also compared the consistency of shape capture of the hands-on and hands-off sockets. Results indicated that casts taken using the hands-off system produced more consistent results than the hands-on system (Buis et al., 2003). Although both of these studies only involved a small number of subjects, the results indicate that there is far less variation in the shape of the casts produced by a "hands off" approach.

4.5 Socket Designs

Patella Tendon Bearing Socket (Hands-on)

The Patella Tendon Bearing (PTB) socket has been a successful method of designing prosthetic sockets since its introduction in the 1960's. The socket is based on the biomechanical theory developed by Radcliffe and Fort (Radcliffe and Foort, 1961). The PTB socket design incorporates selective loading areas of the residual limb on structures designated as those which can tolerate greater magnitudes of pressure. This creates smaller areas to tolerate larger forces. Whilst reducing the loading of sensitive areas. In doing so the residual limb is loaded proportionally to the underlying soft tissue and bony structures. Subsequently the volume of the prosthetic socket is different from the volume of the residual limb.

The name of the PTB socket is given due to the area of greatest loading, the Patellar Tendon, Figure 1.

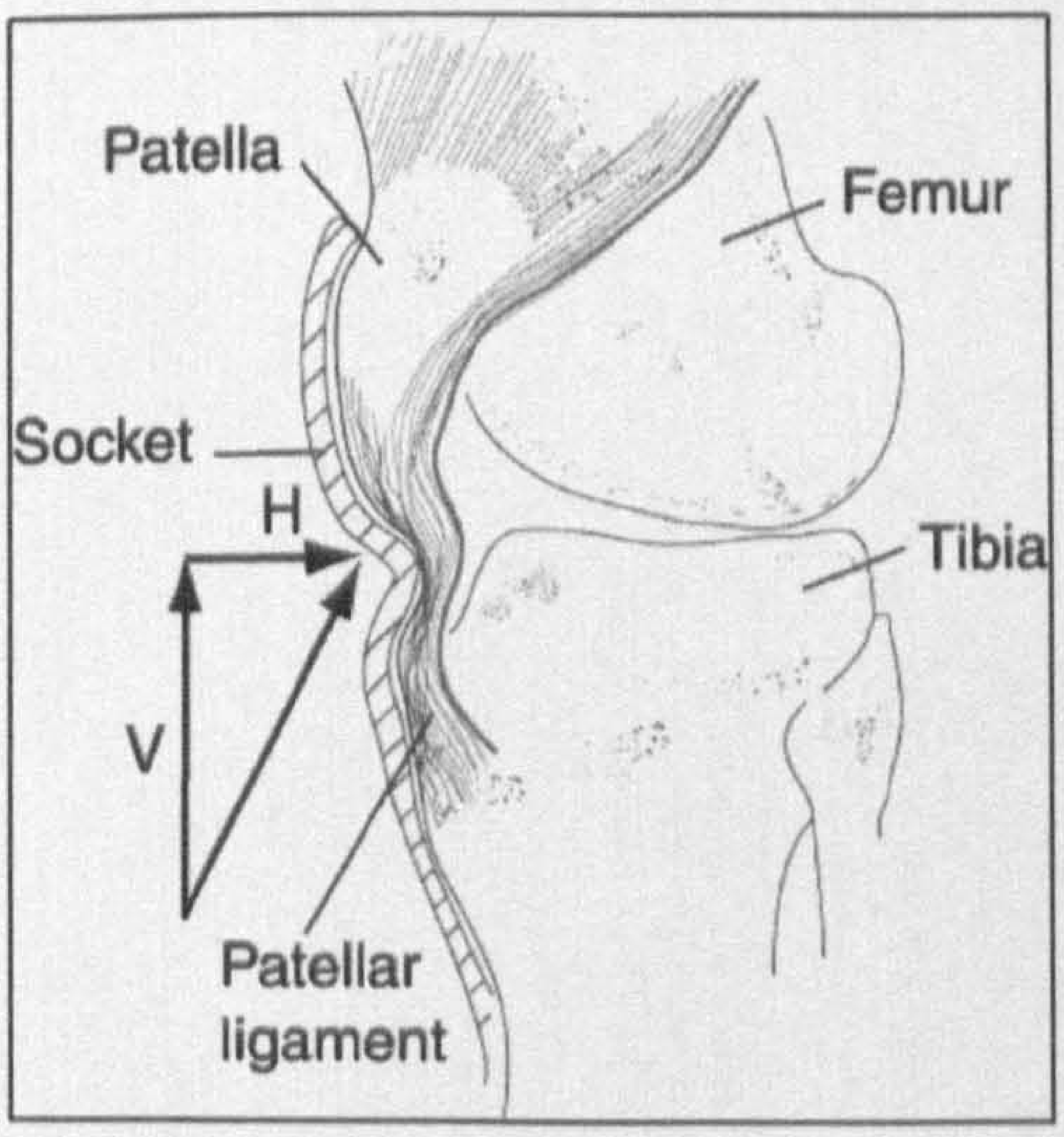

Figure 1: Loading of the Patella Tendon

Pressure tolerant areas over the residual limb include the patellar ligament, anterior compartment, and medial flare of the tibia, shaft of the fibula, gastrocnemius and popliteal fossa. Tissue at these areas is compressed by the socket, reducing the movement of the skeleton. Load is transferred to these areas from the anterior distal tibia, fibular head, crest of tibia, peroneal nerve, distal cut fibula and the lateral tibial condyle. These areas are seen as pressure sensitive sites on the residual limb. Until the introduction of the PTB, thigh corsets were used to assist in the loading of the prosthesis. The prosthetist has to rely on patient feedback to determine how much pressure can be tolerated in different regions over the residual limb. The effects of depth of patella tendon rectification have been investigated (Kim et al., 2003). They found that by loading the patella tendon the pressures in other areas of the socket are reduced. However a compromise between pressure applied by the patella bar and pressure around the stump needs to be met. Subjective assessment found that a patella tendon bar depth of 4mm produced the most comfortable sockets.

The trim lines of the socket are dependent upon the position of the areas for load transfer, in particular the patella tendon and the reactive force at the popliteal area of the knee. These trim lines can restrict the motion of the knee. Accurate marking of the residual limb is required, in order to identify those pre-selected regions of pressure tolerant and sensitive areas. Accurate casting of the limb is difficult as the stump is wrapped using Plaster of Paris bandage. The tension and shape of a cast will be dependant upon the prosthetist taking the cast and the experience of the prosthetist. Careful rectification is required in order to replicate the transfer regions determined by the assessment of the residual limb. It is difficult to repeat and be consistent when using this type of cast method.

Pressure Cast Socket (Hands-off)

In the 1960's the "Dundee socket" was developed (Murdoch, 1968). It was created using a hydro cast method. The socket was designed in order to remove some of the inconsistencies that the more traditional wrap cast introduced. One of these inconsistencies was the variation of training and manual dexterity of the prosthetist.

The amputee's residual limb is covered with plaster of Paris bandage (POP), whilst still wet the limb is placed into a tank of water. A membrane separates the limb and water. The system is sealed enabling weight transfer through the residual limb whilst placed in the tank. By adjusting the level of water, the position of the limb can be adjusted. The pressure produced around the limb is uniform, thus creating a different shape than that of the hands-on design. This principle of load transfer has been described in terms of volume matching (Klasson, 1995). Volume matching refers to the volume of the residual limb under load contained by the same volume in the socket. The hydrostatic theory has a number of limitations such as the principle of uniform pressure distribution (Pascal's principle). This principle is based on a fluid at rest; the fluid in the residual limb is not at rest during the gait cycle and so shear forces may also be present (Goh et al., 2004). Another limitation is that the theory assumes that the limb is a closed system, which it is not (Schuch, 1988).

The ICEROSS® casting system introduced in the 1990's (Kristinsson, 1993) followed the concept of uniform pressure distribution. Instead of using water as a medium to create the pressure, the ICEROSS technique uses air. The system was developed in response to the "ineffective" and "uncomfortable" PTB design. An air filled bladder is inflated around the patient's residual limb, which has been wrapped with plaster of Paris. A number of studies have recommended various levels of pressure which should be applied during casting ranging from 13kPa to 34kPa (Kristinsson, 1993). A forerunner to the ICEROSS system was a pneumatic pressure sleeve introduced in the 1960's (Gardner, 1968). The authors recommended that the sleeve be inflated to 100mm Hg (14kPa). The pressure during casting will influence this as an increased internal pressure results in increased stiffness of coupling. A study concluded that to achieve a stiff coupling the residual limb muscles should be relaxed, thus reducing the cross sectional area of the limb (Lilya et al., 1999). Although the study was conducted on hand cast sockets, it does highlight the need to increase the stiffness of the system to improve the function of the socket. Pressure casting accomplishes this by creating a volume and surface match between limb and socket (Klasson, 1995).

There are many variations on the pressure cast socket concept; however all incorporate the principle of uniform pressure distribution over the entire surface of the residual limb (Cluitmans et al., 1994, Datta et al., 1996, Hachisuka et al., 1998, Kristinsson, 1993, Narita et al., 1997). This method creates an evenly distributed pressure over the entire surface of the residual limb, irrespective of the underlying tissue. The theory of uniform casting pressure is based on Pascal's principle of fluid dynamics and states that the external pressure applied on a fluid is transmitted uniformly throughout the entire body of that fluid. The pressure on any surface exerts a force perpendicular to that surface (Myers, 2006). When a fluid/semi-fluid is trapped in a volume matched container it becomes able to transfer loads. Soft tissue within the residual limb can be described as a semi-fluid, which when enclosed within a prosthetic socket is able to transfer the force from the skeleton. The bony areas of the residual limb can be protected using silicone pads incorporated into the walls of the prosthetic socket. The flowing characteristics of the silicone interface liner means that the shape of socket is constantly changing in response to the forces created during the gait cycle. This decreases peak pressures in the prosthetic socket and increases blood circulation to and around the residual limb.

4.6 Benefits to the Patients

Most patients wearing a pressure cast socket also wear a silicone liner as an interface between limb and socket. A silicone liner provides an adaptive interface between residual limb and hard outer socket wall. No modifications are made to the shape or volume of the cast during and after the casting process, therefore the socket has the same volume as the residual limb. The proximal areas of the stump do not have the same high demand for the transfer of forces as in the PTB design; therefore the proximal trim lines are not required to be as high. This permits an increased range of movement at the knee joint. Advances in suspension methods permit ever changing trim line styles, which permit better knee flexion when sitting (Soderberg, 2002). The intimate fit of the pressure cast socket aids in blood circulation, and helps prevent oedema. The greater surface area over which the residual limb can take loads means that the pressures are reduced and the total contact nature of the socket increases sensory feedback and aids in improved proprioception. The liner transfers the shear forces from the skin interface to the outside of the liner.

A study of trans-tibial amputees cited increased range of motion and perceived reduction of weight as advantages over the PTB style socket (Kahle, 1999). The proximal trim of the supracondylar suspension PTB socket incorporates the femoral condyles, and is consequently much higher than a socket using auxiliary suspension methods such as thigh corset or knee strap. One reason for the increase in range of motion at the knee is due to the reduction in the level of the trim lines. The reduction of the proximal trim line also improves the appearance of the limb (Cluitmans et al., 1994, Hachisuka et al., 1998). However these authors also indicate that patients' may sometimes experience problems with the creasing of the liner during knee flexion.

Many of the studies examining the two design concepts indicate the hands-off having an advantage over the traditional hands-on style. The interface between residual limb and prosthetic socket is one area which has been investigated by a number of researchers. Pressure studies have shown that the hands-off casting technique produces less problems of tissue breakdown resulting from the interface pressure (Cluitmans et al., 1994, Datta et al., 1996, Hachisuka et al., 1998). Whereas the Hands-on PTB style socket principle creates uneven pressure distributions over the surface of the limb. (Convery and Buis, 1998, Radcliffe, 1961, Radcliffe and Foort, 1961). Problems with skin abrasion caused by the stretch effect, as the PTB prosthesis is donned have been reported.

Some users have experienced problems when using the prosthetic interface liners. Skin irritation is one area that is widely reported (Cluitmans et al., 1994, Datta et al., 1996), with itching and excessive perspiration cited as the main areas of concern. The studies indicate that these skin problems reduce after a short period of wearing the liner, as the residual limb tissue becomes accustomed to the environment (Datta et al., 1996). The study also concludes that despite the advantages of the pressure cast system, users of both systems walked on average the same distances.

The use of silicone liners with integrated locking devices improves the cosmetic appearance of the hands-off prosthesis, with the removal of external suspension methods. In addition to the improved cosmesis, the studies show an improvement to the suspension of the prosthesis (Cluitmans et al., 1994, Datta et al., 1996, Hachisuka et al., 1998, Yigiter et al., 2002). Also an improvement in the ability to walk up and down stairs due to the increase in knee flexion and less pistoning because of the improved suspension and function of the design is reported. Pistioning can create a shear force which in turn produces a stretch effect in the tissue of the residual limb, which can cause skin abrasion.

4.7 Liners and Socks

Prosthetic socks and liners provide shock absorption and a method of adjusting the volume of the socket. Prosthetic socks are available in several materials including wool, cotton and synthetics. They help absorb perspiration and allow ventilation. To accommodate for the volume changes patients can adjust the thickness of the prosthetic socks, Figure 2.

Figure 2: Prosthetic Socket Socks

Socket liners can be custom made, usually formed during the manufacture of the prosthetic socket and made from materials such as Pe-Lite, a dense flexible foam.

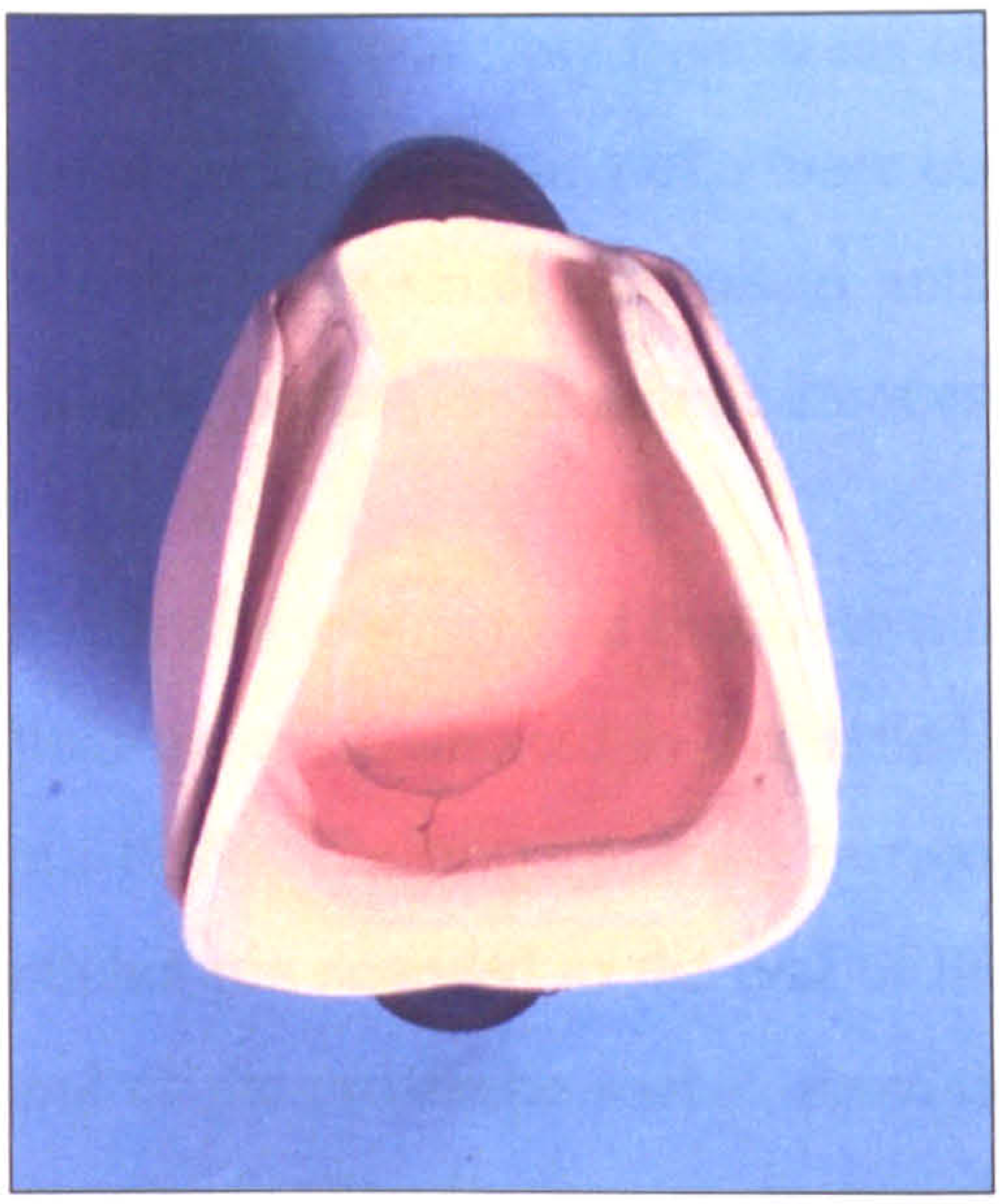

Figure 3: Prosthetic Socket with a soft Pe-Lite liner

Stock liners are also used; these are usually available in silicone, urethane and may incorporate impregnated oil which can be designed to resist bacteria and fungus growth for skin health and odour reduction. Usually the silicone is attached or sandwiched between fabrics, and provide cushioning, pressure distribution and reduced friction, Figure 4.

Figure 4: Typical interface liners, silicone liner (left) and Pe-Lite Liner (right)

Silicone tends to flow from areas of high pressure to areas of lower pressure within the socket, maintaining of a more even pressure distribution. The softer interface can accommodate small changes in limb shape within the socket. All of these liners are airtight so that perspiration cannot escape.

Studies have suggested that over time the skin tends to sweat less within the airtight liner once accustomed to the sealed environment (Cluitmans et al., 1994, Fillauer et al., 1989). The liners primary purpose is suspension of the prosthesis. An attachment ratchet pin screwed to the end of the liner attaches to a locking device in the distal end of the prosthetic socket, providing a secure coupling of the residual limb to the prosthesis. The liners also protect the skin against shear forces because movement occurs between the outside of the liner and the adjacent material (Emrich and Slater, 1998).

Liners can offer protection against friction and dynamic pressure distribution resulting from the flow characteristics of the materials. Suspension of the prosthesis is achieved when fitted with a distal socket attachment. However these types of prosthetic liners are required to be washed daily, carefully following the manufacturer's recommendations. It therefore may be an unsuitable prescription for some patients. Liners are generally much softer than the socket and are not rigid enough to support the amputee's weight without the support of the socket.

When fitting a prosthetic interface liner to a patient, the size of the liner is important. The distal end of the liner can create tissue damage to the distal end of the residual limb if the wrong size of liner is selected. Too small and the liner may create excessive pressure over the distal skin. Too large and an air pocket may result at the distal end, causing oedema of the residual limb. In a study of ratchet pin suspension and suction suspension systems it was found that the pin suspension system may cause an increase in suction at the distal end, causing daily and chronic skin changes (Beil et al., 2002).

The silicone liner brings with it both advantages and disadvantages to the prosthetic system. Patients have reported it to be lighter and reduce the overall volume of the prosthetic limb (Yigiter et al., 2002). Also experiencing difficulties in donning and doffing the liners, which fit intimately to the residual limb, and require a degree of precision when fitting (Hachisuka et al., 1998). This intimate fit of the liners can create hygiene problems for the user (Kristinsson, 1993). Some of the hygiene problems are due to the increase in sweating that occurs.

4.8 Suspension to the Residual Limb

As with load transfer, the suspension of the prosthesis also has two main design principles, with many variations within these designs. The two principles are self suspension, systems which do not require any visible suspension methods and auxiliary suspension, those which rely on belts or knee cuffs for suspension. The method of suspending the prosthesis will usually be dictated by the design chosen for load transfer. Psychological implications of prosthetic rehabilitation are becoming increasingly used in improving treatment. The sense of improved body image that a prosthesis offers the amputee can be just as important as the ability to walk. Thus the cosmetic appearance of the prosthesis may have a major role in determining if the limb will be worn or not. Recent years have led to the rise in self suspending methods of the prosthesis, removing the need for straps, buckles and corsets. A prosthesis that has good suspension feels much lighter and allows the amputee to ambulate with more confidence (Edwards, 2000). Secure suspension reduces the movement between limb and socket, thus minimising the shear forces between the two surfaces.

Both systems of suspension have advantages and disadvantages. As self suspending methods remove the requirement for external straps, belts or thigh corsets, so the cosmesis of these sockets is improved. However some patients prefer the additional assurance that these straps offer. Self suspending methods are becoming the most common method for attaching the prosthesis to the residual limb. These generally bring increased freedom of additional movement at the knee joint due to the removal of knee straps and buckles whilst the use of the quadriceps muscles is maintained. When describing pin attachments, they have been classified as self suspending suspension methods. This is because they do not require the use of visible straps and belts. A study of trans-tibial sockets used x-ray and cineradiography measurements to investigate the suspension effects of both the PTB and silicone liner ratchet locks (Narita et al., 1997). It concluded that the suspension effects of the silicone liners were superior to the PTB and that the angle change between tibia and socket was significantly smaller when using silicone liners with locking devices.

Auxiliary Suspension

Thigh corset with side joints

Few amputees wear this type of prosthesis; in general those that do either have knee instability, or their skin on the residual limb cannot tolerate applied pressure. The thigh corset increases the loading area of the prosthesis and is therefore sometimes used for short residual limbs, Figure 5.

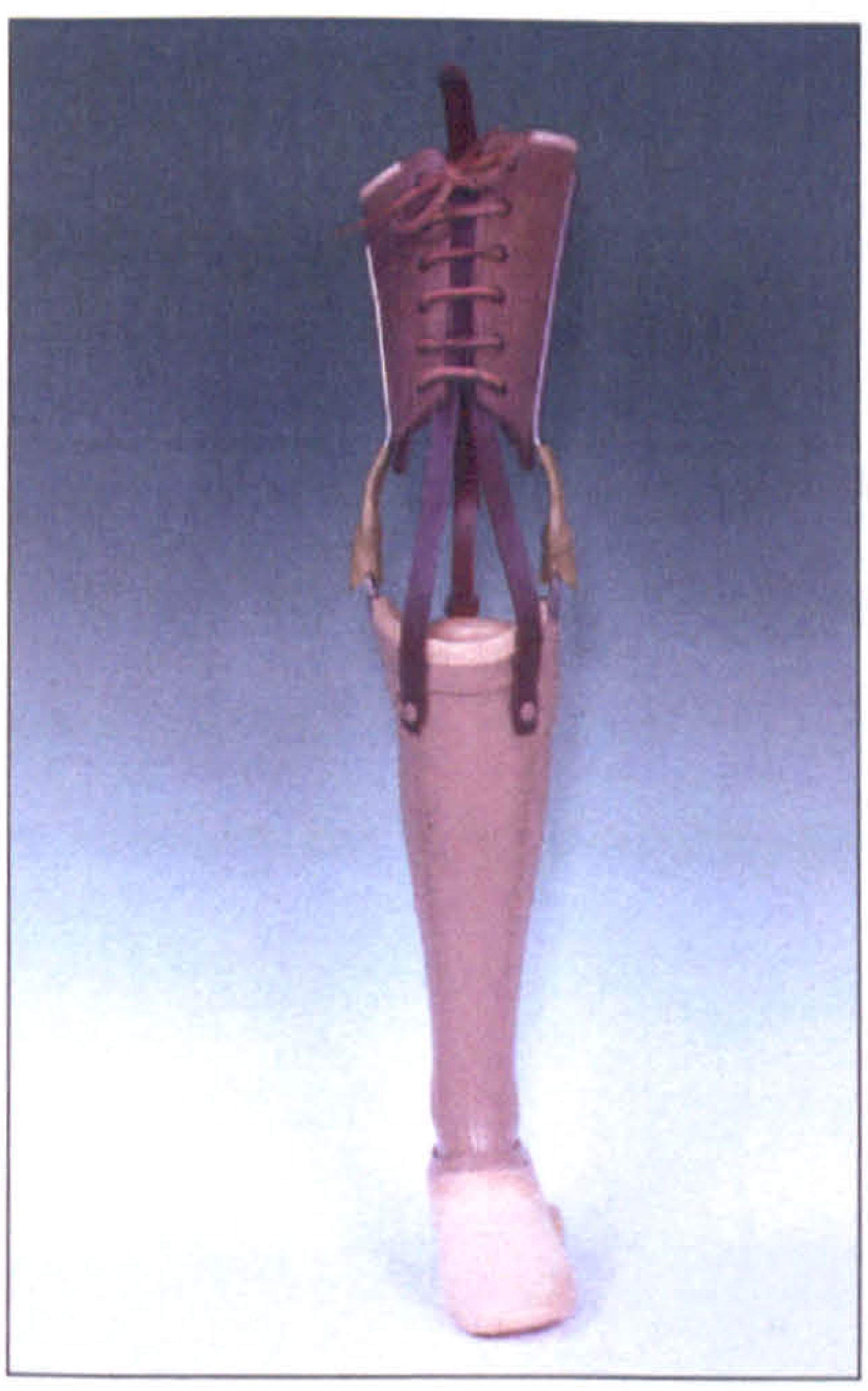

Figure 5: Prosthesis with Thigh Lacer and Side Joints

Some patients may have been prescribed this type of device in the past and are reluctant to change. A study into the effectiveness of the thigh corset concluded that the interface pressure between limb and socket could be reduced by 19% if the thigh corset was used (Shem et al., 1998). It is known that the thigh corset does cause thigh muscle atrophy and the additional weight and size reduce the cosmesis and increases fabrication time.

Supracondylar Cuff

The cuff is attached to the medial and lateral walls of the prosthetic socket, and rotates on its attachment points as the knee flexes. The fully adjustable strap passes above the patella, Figure 6.

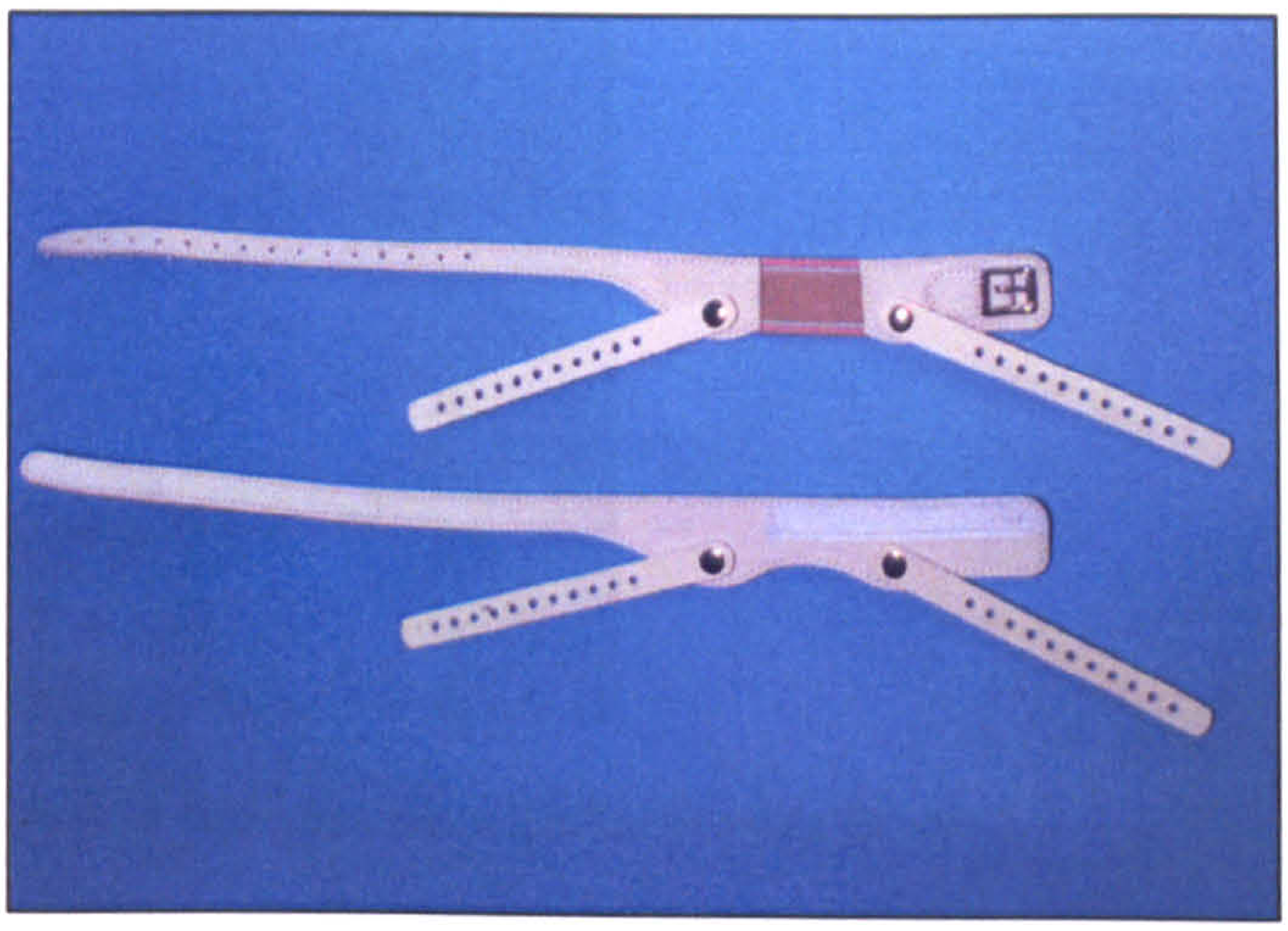

Figure 6: Cuff Suspension

The cuff works best if the patella is prominent. The trim lines used in conjunction with the cuff are lower than the supracondylar self suspending design, which reduces the stability of the socket. Therefore knee stability and good muscle strength is necessary for this design to be used.

Suspension Sleeve

The sleeve is placed over the prosthetic socket and rolled up over the knee. The sleeve is made from a material that has a high coefficient of friction, usually latex, neoprene or silicone, Figure 7.

Figure 7: Prosthesis with Suspension Sleeve

This minimises the displacement relative to the residual limb. These liners suspend the limb because they form an airtight seal next to the skin. This prevents sweat escaping, however the skin tends to sweat less in an airtight liner once accustomed to the sealed environment. These materials do occasionally result in skin reactions, and cause heat build up and induce sweating. Because the sleeve is pulled up over the proximal trim line, it conceals the shape of the socket, improving the contour between socket and limb. It improves movement (reduced pistioning) and eliminates the need for straps. Strength and hand dexterity of the patient is required as these sleeves fit tightly around the socket and thigh. The sleeve can also be used in conjunction with self suspending methods in order to assist in the suspension or provide a visual assurance to the patient.

Self Suspension

Supracondylar

The supracondylar design is the most common method for self suspending a PTB, KMB, PTK and PTS socket design, Figure 8.

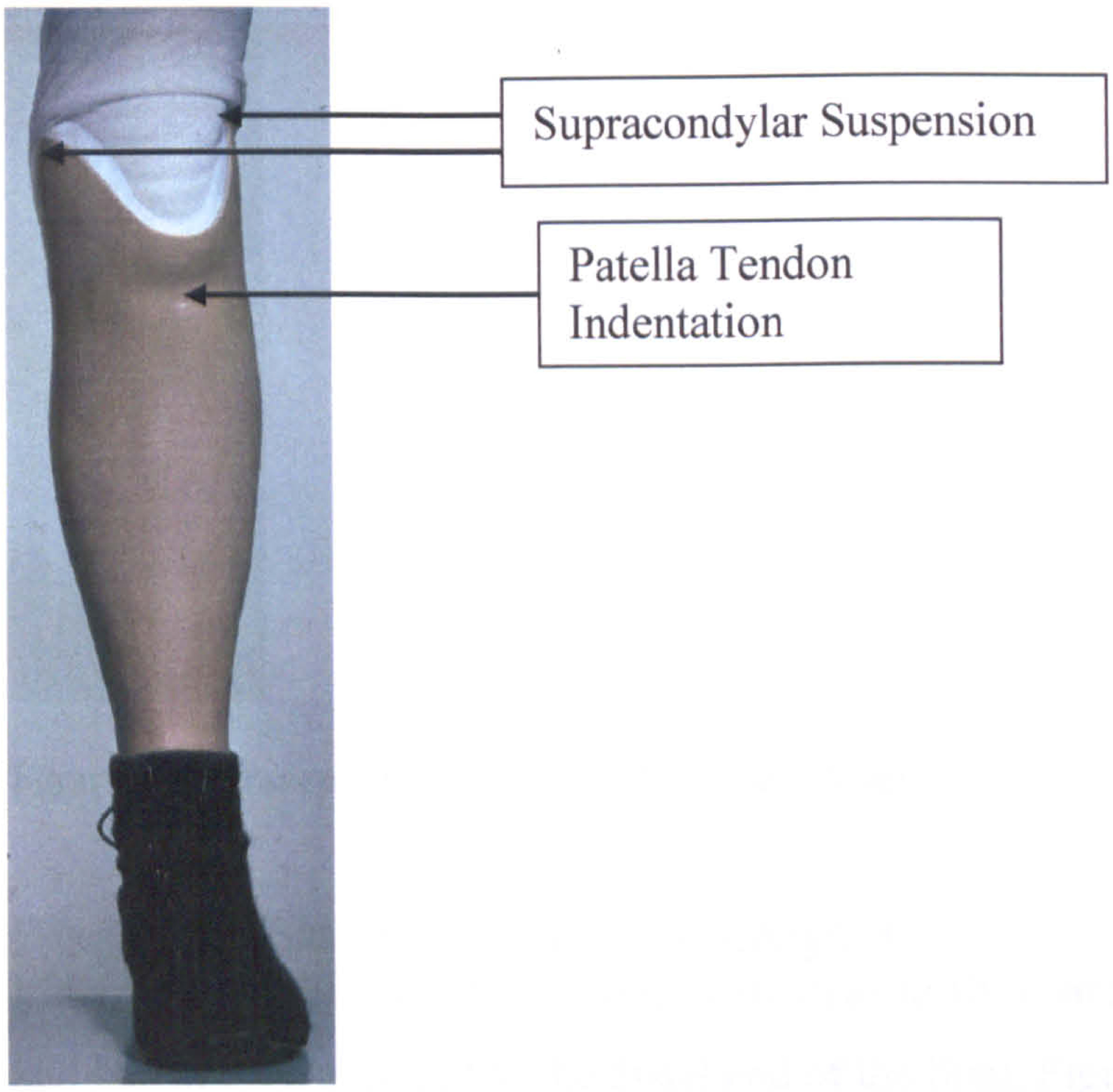

Figure 8: PTB Prosthesis, showing PTB indentation and Supracondylar suspension

The proximal trim lines enclose the condyles of the femur and have a high anterior wall enclosing the distal half of the patella. The medial and lateral walls are indented above the condyles. The trim line provides more support anteriorly and aids improved stability at the knee. The higher anterior trim can also act as a hyperextension stop. However it does present a restriction in sitting and the higher trim lines may generate a poor cosmesis.

Supracondylar, Suprapatellar

A similar design to the supracondylar socket, this design also utilises the femoral condyles. The difference in this design is that the trim line encapsulates the entire patella. This shape increases the medial-lateral stability of the socket and the trim line proximal to the patella acts as an assist to prevent hyper extension of the knee, Figure 9.

Figure 9: Supracondylar, Suprapatellar socket design

Silicone (or Similar) liner with Pin/Lanyard

Liners are manufactured in a number of sizes to fit most residual limbs. Both the pin and lanyard are attached to the distal end of the liner, Figure 10.

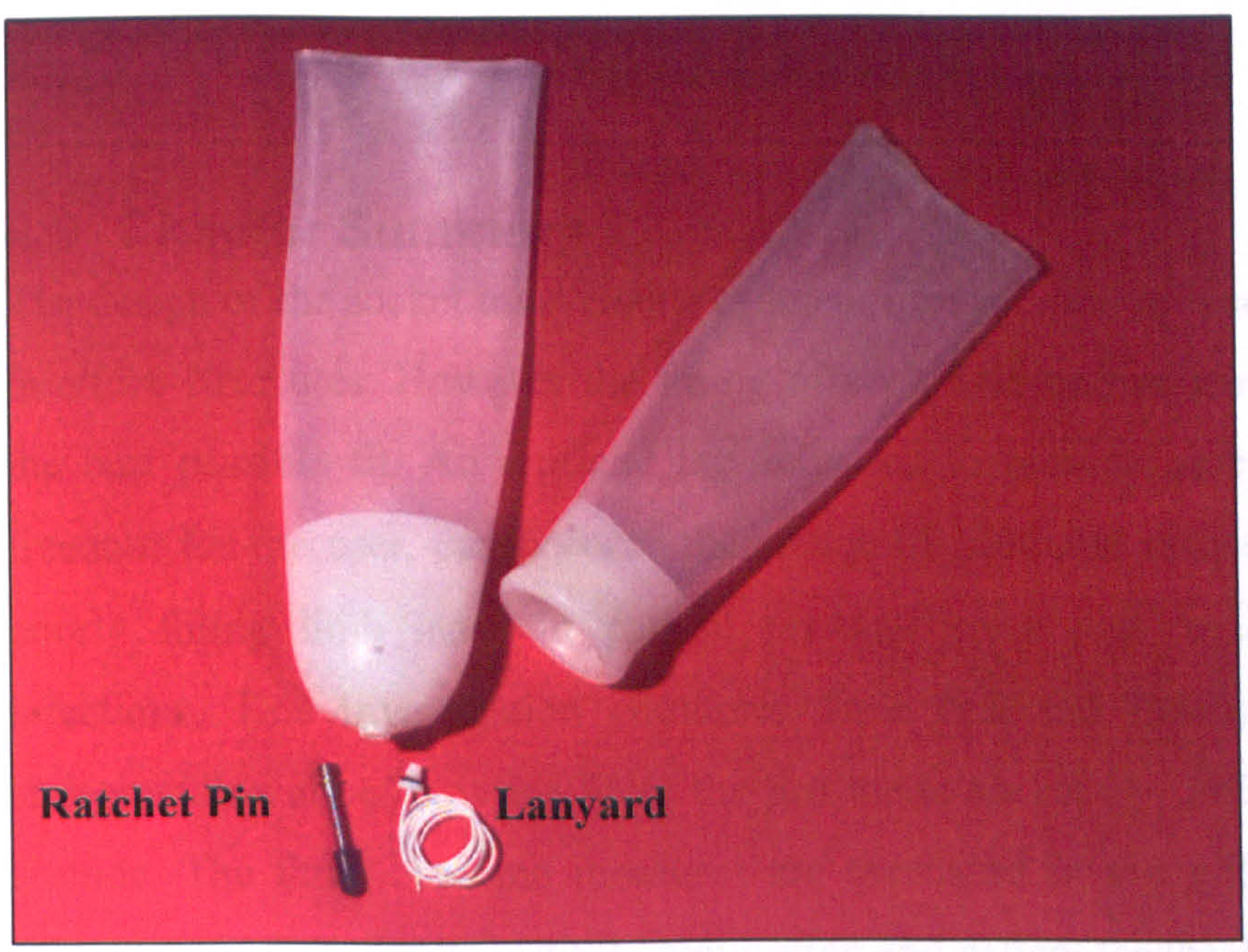

Figure 10: Silicone Liner, showing ratchet Pin and Lanyard

The liner is rolled onto the limb and remains on the limb due to the high coefficient of friction between liner and skin. Liners worn next to the skin can reduce the friction and offer a dynamic pressure distribution because of their flow-like characteristics. The pin engages into a ratchet locking mechanism at the bottom of the socket when the patient pushes their limb into the socket. The ratchet pin can only be removed by pressing a release button or turning of a screw. The lanyard is more common for use in trans-femoral sockets; however it can be used in trans-tibial socket design. The lanyard cord passes through the distal end of the socket, and is attached to the outside of the socket wall.

Suction Socket

Designed to remove the need for auxiliary suspension methods, and so improve the cosmetic appearance, and function of the limb. By establishing a negative pressure at the interface between socket and limb during swing the socket remains in position. A valve at the distal end of the socket permits expulsion of air from the socket but prohibits flow into the socket. During the development of a suction socket it was found that patients using the system had an increased range of movement at the knee owing to the reduced trim line and absence of auxiliary suspension methods (Fillauer et al., 1989).

4.9 Chapter Summary

The design of the socket must enable efficient transmission of loads between the two interface structures. However the fitting of such devices frequently fails to provide the best possible fit. An artificial leg delivered to provide mobility and increased freedom for the user, can become the source of profound discomfort. For some, a poorly fitting limb leads to painful pressure sores and troublesome, recurrent infections. This investigation combines three outcome measures to provide an understanding about how the fit of the prosthetic socket can influence the wearer's attitude. The three outcome measures are discussed in the follow three chapters, namely pressure measure, activity monitoring and patient feedback.

5 Pressure Measurement

5.1 Chapter Introduction

The prosthetist does not have any quantitative information to measure the pressure or distribution throughout the socket in a clinical setting. Experience and feedback from the patient are the only methods which can be used to asses if the socket fit is adequate. The measurement of dynamic socket interface pressures remains a research tool, rather than a tool used routinely in the clinic. This chapter introduces the techniques used to measure interface pressure within the prosthetic socket and explores the rational behind the choices made for the methodology of pressure measurement in this investigation.

5.2 Techniques of Measuring Pressure

Transparent check sockets could be made prior to definitive socket fitting; this enables the prosthetist to view areas of skin blanching, giving a visual indication of interface load. However this assessment can only indicate static load, and does not provide a tool for measuring dynamic load distribution, or a quantifiable measure of pressure. The last twenty years has seen a number of investigations of pressure measurement for factors relating to lower limb prosthetics. With the emergence of smaller transducers, and more powerful, portable computers a large amount of information has been collected.

The aim of this investigation is to measure the dynamic interface pressure of the patients own prosthesis, however there are methods of calculating interface pressure which do not involve the physical presence of the interface being measured, one of these is using Finite Element Analysis (FEA).

5.3 Finite Element Analysis

The use of physical devices in the measurement of the interface between residual limb and prosthetic socket will have inherent difficulties. Computer modelling has emerged which in part may overcome some of the physical constraints. It is not limited to just estimating the interface pressure at the stump/socket interface, Finite element analysis (FEA) has the potential to provide information relating to deeper layers of tissue. FEA analysis computer models can provide data relating to the interface pressures, stresses and movement of the limb within the socket.

A complex structure can be divided into a number of sections called "elements". These elements are defined by a number of points (nodes) which create the geometry of the object being represented. The response of each element can then be calculated, which forms the behaviour of the structure. Models can be designed in various ways, using a combination of boundary conditions. These boundary conditions are defined according to material properties. Linear or non-linear conditions can be implemented depending upon the required outcome. In terms of prosthetic analysis, dynamic models combine the effects of material properties with the addition of inertial effects of gait, although dynamic analysis is relatively limited. A recent study (Jia et al., 2004) investigated the effects of inertia on the FEA model. They calculated the forces and moments with and without the effects of inertia and concluded that the interface pressures and shear stresses are considerably different between the two loading conditions. They recommended that future models be designed with kinematic information of the limb. Although the properties of bone and socket material can be modelled with a high accuracy, the challenge for FEA modelling comes when representing human tissue. Boundary conditions are required within the computer model in order to simulate friction between tissue and socket. Researchers have investigated this problem (Zhang et al., 1996), however analysis is still based on estimates of physical properties. A review of techniques used to model the prosthetic socket suggested that the representation of tissue properties and the interface condition were two limitations of FE analysis (Silver-Thorn et al., 1996, Sewell et al., 2000).

5.4 Physical Measurement

In the case of this investigation, it is the pressure distribution at the interface of the subjects own trans-tibial prosthetic socket which is to be captured. Analysis of the pressure from each socket will be compared, and conclusions drawn between two socket designs. This means that a system which can provide, accurate, reliable and permanent data needs to be used. The interface pressure throughout gait is required to be captured; therefore a system capable of measuring the dynamic condition is required.

The distribution of underlying anatomy at the residual limb is uneven. This is due to the fact that the residual limb is a combination of bone, soft muscle, skin and fatty tissue, which all carry different tissue properties and characteristics. The measure of interface pressure over the residual limb is one way in which to gain more objective information in the manner in which the skeleton is coupled to the prosthetic socket. It is important to know what is required to be measured. This will enable the correct choice of transducer to be made. Interface pressure is the result of the forces present at the interface and the area on which these forces act. Forces at the interface act in combination of those acting parallel to the interface (shear force) and those perpendicular to the interface (normal force).

Shear Force

The coupling between residual limb and prosthetic socket is an important aspect for socket fit. The coupling is affected by the shear forces which generate when there is movement between limb and socket. Both normal force and shear force are present in the prosthetic socket and a compromise between the two has to be made. The tightness of the socket will affect the movement between the socket and the limb. A loose fit will reduce interface pressure, however shear forces will increase reducing stability. Whereas a tight fit will increase the interface pressure, and reduce the shear forces, increasing stability. Friction is one element that can be used to influence the coupling between limb and socket. To create movement within the socket, shear forces have to overcome friction, which in some circumstance can cause tissue damage. Some degree of friction is required to support the residual limb inside the socket during stance and assist in suspension during swing.

Tri-axial transducers used in trans-tibial sockets have been developed (Sanders et al., 1992, Williams et al., 1992). This design is capable of measuring the shear forces in two directions and normal force. These all require special sockets to be manufactured, and protrude out of the socket which may impede the subject when walking. In one study placement of transducers on the medial aspect of the prosthetic socket was avoided due to interference by the contra lateral limb (Sanders et al., 1993). Measuring at specific locations within the socket may enable highly accurate, sensitive transducers to be mounted (Sanders and Daly, 1993), but the position of these devices remains vital to the interpretation of the data gained.

Movement between limb and socket has also been investigated by using x-ray (Narita et al., 1997). This data only provided a static measurement, but they did indicate that the tibia moves a considerable amount between the two loading conditions.

Interface Pressure

The purpose of instrumenting the prosthetic socket in this investigation was to measure the direct pressure between residual limb and prosthetic socket. The interface pressure is defined as force per unit area applied on a surface in a direction perpendicular to that surface, i.e. pressure (P) is a function of force (F) and area (A) P = F/A. The SI unit for pressure is the Pascal (N/m^2) (Myers, 2006). When measuring pressure at the interface between residual limb and prosthetic socket kilo Pascal will be used (kPa). There are three types of pressure measurements, each have a different point to which the measured pressure is referenced. These are absolute, differential and gauge pressure. Absolute pressure measurement is measured relative to a vacuum. Differential pressure measurements are taken with respect to a specific reference pressure. Gauge pressure is measured relative to ambient atmospheric pressure.

5.5 Pressure Transducers

The most fundamental component to any measurement system is the transducer. In this investigation the transducer should be capable of converting the force at the stump/socket interface to a pressure, and presenting this information in a manner that can be analysed in relation to the other subjects in the study. The transducer must not disrupt the interface being measured and should conform to the contours of the prosthetic socket (Lee et al., 1997). It should be capable of measuring pressure in a dynamic situation, at a resolution and frequency suitable for capturing gait activities. This narrows the type of transducer available, as many of the simple mechanical instruments are not suited for this application. The measurable voltage signal obtained via the transducer is converted to actual units of pressure.

Due to the vast number of applications which pressure is measured there are many different methods of pressure sensors or transducers available. Sensors usually convert pressure into an output, typically a voltage which can be measured. The three most commonly used pressure transducers of this form are the *Strain gauged device*; a change in pressure causes a strain gauged diaphragm to deflect leading to a change in resistance and therefore voltage difference, which can be measured by a Data Acquisition System. Resistive strain gauged devices have a large pressure range, typically up to 100MPa, with an accuracy of between 0.1-1 percent of span, and respond fast in a dynamic situation. The *Capacitance transducer*; the capacitance between two metals plates changes if the distance between these two plates changes. *Piezoelectric transducers*; implement the electrical properties of crystals such as quartz. These crystals generate an electrical charge when they are strained.

Criteria for Transducer selection

Nine key points to use when deciding upon the most suitable transducer have been outlined, these are the range, sensitivity, frequency response, mass, accuracy, hysteresis, linearity, cost and environmental conditions (Havey et al., 1996). A description of these points are given below, with specific details relating to this investigation. Although the perfect transducer would have ideal qualities in all of these categories, a compromise would be expected for any application.

Range

The transducer used must be capable of measuring the full scale of interface pressure expected with the prosthetic socket. An adequate allowance should remain at the upper end of the transducer's range so that the transducer will not be damaged if an unexpected pressure is recorded. In previous studies of interface pressure, the highest maximum peak values have been recorded at between 300 and 400 kPa (Jia et al., 2004, Sanders et al., 2005, Zhang et al., 1998, Convery and Buis, 1998, Convery and Buis, 1999). Although a typical interface pressure would be at about 100kPa. Based on this evidence, the transducer used should be capable of recording up to 500kPa so that all eventualities would be covered.

Sensitivity

Sensitivity is closely related to the range of the transducer. As the range of the transducer increases, so the sensitivity decreases. Therefore the range chosen should not far exceed the maximum pressure expected. Sensitivity is the ratio of the output signal to the corresponding input signal (Busch-Vishniac, 1999). As with range, the sensitivity of a transducer must be matched to the expected levels of signal.

Frequency Response

The range and reproduction accuracy of a frequency which the transducer is capable of measuring is called the frequency response.

Mass and Dimensions

A transducer chosen for use in the prosthetic socket is required to be as light, small and thin as possible. The subject will be required to walk using their prosthesis whilst the transducers are attached to the socket. The transducer should not impede or affect the gait of the subject due to its size or weight.

Accuracy

The accuracy of the transducer relates to how close the output of the transducer is to the actual value being measured.

Hysteresis

When a transducer is taken from zero to full load and back to zero the output for a given load value may be slightly different when the load is rising to when the load is decreasing. The area between the two output curves is used to calculate the hysteresis. Normally quoted as a percentage of full load. Hysteresis is an important factor when deciding upon a transducer for use in gait application, owing to the cyclic pattern.

Linearity

Linearity is defined as the closeness of a calibration curve to a specified straight line. It is expressed as the maximum deviation of any calibration point on a specified straight line during any one calibration cycle.

Cost

The cost of a transducer may dictate the level of the characteristics mentioned above. However cost should not be seen as the most important factor.

Environmental Conditions

When compared to other conditions in which transducers are used, the interface between residual limb and prosthetic socket may be considered less harsh. However the environment in which the transducer will be used should be considered. It is known that the temperature within the prosthetic socket increases during use (Peery et al., 2005) therefore any transducer used should be temperature stable.

The interface between residual limb and prosthetic socket is not a smooth flat surface. The transducer chosen will have to conform to the contours of the socket. If placed inside the prosthetic socket, the transducers should not interfere with the volume or suspension between limb and prosthesis. The unique shape and curvature of each residual limb will make the placement and sensing area of the transducer an important consideration.

5.6 Transducer Types

The most common application for transducers is measuring force and pressure at the stump/socket interface. Interface pressure measurement systems are currently limited to research use due to the cost and adaptations required to the prosthesis. Although current technology limits the use of pressure measurement as a clinical tool, the implementation of regular pressure measurement techniques has the potential to improve patient satisfaction and increase efficiency within the clinic. A recent study summarised the benefits of pressure measurement in the clinic (Polliack et al., 2002). The study suggested that by identifying areas for cast modification following check socket fitting, the number of follow-up visits can be reduced. Quantifying the fit and documenting this information can improve fitting of subsequent sockets by providing more accurate and objective outcome measures. There are many designs of transducer; each has a unique combination of characteristics that determines its performance profile. The choice of sensor is determined by the principle of matching the performance profile and measurement task (Urry, 1999).

Strain Gauge

When external forces are applied to a stationary object, stress and strain are the result. Strain is defined as the amount of deformation per unit length of an object when a load is applied. Strain may be compressive or tensile and is typically measured by strain gauges. All strain gauges are designed to convert mechanical deformation into an electric signal. A change in capacitance, inductance, or resistance is proportional to the strain experienced by the sensor. If a wire is held under tension, it gets slightly longer and its cross-sectional area is reduced. This changes its resistance in proportion to the strain sensitivity of the wire's resistance. The most widely used characteristic that varies in proportion to strain is electrical resistance. Although capacitance and inductance-based strain gauges have been constructed, their sensitivity to vibration, mounting requirements, and circuit complexity has limited their application.

The strain gauge is used to measure the displacement of an elastic diaphragm due to a difference in pressure across the diaphragm. These devices can detect gauge pressure if the low pressure port is left open to the atmosphere or differential pressure if connected to two process pressures. If the low pressure side is a sealed vacuum reference, the transmitter will act as an absolute pressure transmitter.

Diaphragm transducers were used in early attempts to evaluate socket interface pressure (Burgess and Moore, 1977, Pearson et al., 1974, Rae and Cockrell, 1971, Appoldt and Bennett, 1967). One manufacturer, Kulite, adapted transducers originally designed for use in the aviation industry for use in prosthetics (Burgess and Moore, 1977, Pearson et al., 1974, Sonck et al., 1970). A diaphragm to which were attached strain gauges were also used in a study investigating the pressure distribution of trans-tibial amputees (Goh et al., 2003a). Their findings were compared to the theoretical distributions that Radcliffe (1961) proposed when the PTB socket was designed.

Capacitive

One type of capacitive transducer performs in a similar way as the diaphragm strain gauge. The capacitance change results from the movement of a diaphragm element. The deflection of the diaphragm causes a change in capacitance that is detected by a bridge circuit. The diaphragm is usually metal or metal-coated quartz and is exposed to the process pressure on one side and to the reference pressure on the other.

Depending on the type of pressure, the capacitive transducer can be either an absolute, gauge, or differential pressure transducer. Compared with strain gage transducers, they do not drift as much. Tests performed using capacitance transducer showed that it performed well in all categories it was subjected to (Polliack et al., 2002).

Piezoelectric

Dynamic forces can be measured using a piezoelectric force transducer. Surface charge on the piezoelectric material is proportional to the magnitude and orientation of stress induced. Resonant piezoelectric pressure sensors measure the variation in resonant frequency of quartz crystals under an applied force. An in-shoe foot pressure measurement system has been designed and developed to measure the absolute pressure values at discrete predefined anatomical site. Piezoelectric copolymer film transducers have been integrated into an insole system which incorporates eight transducers for measurement of multiple consecutive footsteps (Nevill et al., 1995).

Pneumatic

These sensors are flexible and are capable of conforming to the contours of the prosthetic socket. They are preferred to a strain gauge or piezoelectric device as they can isolate the interface pressure from the total stress (Krouskop et al., 1987). The strain gauge and piezoelectric transducer both react to normal and shear stresses. Although work with this type of transducer is limited within the field of prosthetics as they do not have sufficiently quick response time to react to the dynamic nature of gait.

Hydraulic

A prototype hydraulic transducer was developed for above knee prosthetics to measure the pressure without the need to fabricate an experimental prosthesis. (Naeff and van Pijkeren, 1980, Van Pijkeren et al., 1980). A small plastic bag containing oil is placed inside the socket. This bag is connected to a tube which passes from within the socket, to an external processing unit. The oil filled sensor is sensitive to changes in temperature and is difficult to calibrate.

Force Sensitive Resistor (FSR)

A few studies have used FSR technology to investigate the dynamic loading pattern of the trans-tibial amputee (Maurer et al., 2003, Sanders, 1995, Sumiya et al., 1998, Convery and Buis, 1998, Convery and Buis, 1999). A FSR transducer is capable of sensing an applied force. Transforming the physical pressure into a corresponding electrical response. Changes in pressure are converted into changes in electrical resistance. Increased pressure produces an associated change in resistance which can be used to control circuits.

When external force is applied to the sensor, the resistive element is deformed against the substrate. Air from the spacer opening is pushed through the air vent, and the conductive material on the substrate comes into contact with parts of the active area. The more of the active area that touches the conductive element, the lower the resistance. Operationally, an FSR is similar to a strain gauge, the main difference being that a strain gauge's backing deforms with the resistive element, while an FSR's does not. This fact is important to consider when mounting an FSR against a support within the prosthetic socket.

Because the FSR's operation is dependent on the deformation of a continuous spacer between two conductive elements, it works best when affixed to a support that is firm, flat, and smooth. Mounting to a curved surface, (as is often the case when placing sensors on the body or clothing) reduces measurement range and resistance drift. One solution is to use a sensor with a smaller active area, since less of the sensing area will be deformed by the contours of the body.

5.7 Placement of Transducer

The design of the transducer to a large extent determines its placement on the prosthetic socket in order to record interface pressure. Studies can be broadly divided into two categories, those measuring pressure by placing transducers through the prosthetic socket wall (Appoldt and Bennett, 1967, Goh et al., 2004, Sanders et al., 1992, Sanders et al., 1993, Williams et al., 1992, Zhang et al., 1998), those studies that mounted thin transducers onto the inside of the socket wall (Appoldt and Bennett, 1967, Convery and Buis, 1999, Convery and Buis, 1998, Krouskop et al., 1987, Naeff and van Pijkeren, 1980, Shem et al., 1998, Van Pijkeren et al., 1980, Zhang et al., 1996, Springer and Engsberg, 1993). Earlier studies instead attached the transducers directly to the patient's skin. (Appoldt and Bennett, 1967, Burgess and Moore, 1977, Rae and Cockrell, 1971, Sonck et al., 1970).

Transducers are mounted through the socket wall if the dimensions of the transducer thickness necessitates. Positioning the transducer in this manner requires holes to be drilled through the socket, or special sockets to be fabricated with provision for transducer mounting. These transducers therefore can not be used in conjunction with the patients own prosthesis, confining this method as a research tool, rather than a clinical tool. This technique is expensive as it permanently alters the prosthesis, and the proportion of the socket measured is limited. The amount of the socket which is measured can be increased if the number of transducers is increased, but this introduces other problems. Additional weight produced when these transducers are attached may alter the gait pattern of the subject. An increase in the number of transducers will result in a decrease in socket material, altering the strength and mechanics of the prosthetic socket. Pressure gradients in surrounding tissue will not be measured. Small variations in the position of residual limb inside the socket will alter the pressures recorded. Critical sites such as the tibal crest, patella tendon and fibula head have to be avoided due to their high curvatures (Sanders et al., 1993). Sockets have been created by duplicating a patients own socket to create an experimental socket (Appoldt and Bennett, 1967). This enabled wall mounted transducers to be used in a socket with which the subject was more familiar.

If the transducer is to be positioned inside the prosthetic socket, thin sensors are required. This type of transducer can be positioned quickly, and does not interfere with the construction of the prosthetic socket and no socket modifications are required. Transducers of this kind include fluid filled cells, pneumatic transducers and printed circuit designs. Transducers placed inside the socket may create stress concentrations due to their finite thickness or variation to compressibility in relation to the interface material.

Positioning the transducer between socket wall and residual limb increases the area which can be measured. By increasing the number of pressure cells inside the socket an array can be created enabling pressure distribution to be measured. Attempts to produce a transducer array in order to increase the coverage over the residual limb began in the early 1970's (Rae and Cockrell, 1971) . Single cell silicone diaphragm transducers were designed. Five of these were arranged in an array which could be placed on the residual limb. These transducers were durable and sensitive enough to be placed at the stump/socket interface to provide graphical representation of the pressure generated. Although technology at the time limited the display of the data, this did push forward the boundaries of prosthetic pressure measurement.

5.8 Pressure Distribution over the Residual Limb

Studies investigating pressure distribution over the residual limb suggest that interface pressure is high at the popliteal region (Zhang et al., 1998). Other studies confirm this finding and also suggest that the patella tendon and the anterior distal area are other areas of constant high pressure during walking when wearing a PTB socket (Pearson et al., 1974, Sonck et al., 1970). These results seem to be in line with the pressure profiles that Radcliffe suggested in his theory of biomechanics of below knee prosthetics (Radcliffe, 1961). Using the Ground reaction vector, these biomechanical profiles were examined by Goh (Goh et al., 2003a, Goh et al., 2003b). These studies compared the theoretical distributions with results obtained using strain gauge pressure transducers attached to the prosthetic socket. The results of this study showed that none of the subjects pressure profiles measured followed those described by Radcliffe. They noted that each subject exhibited a different pressure profile, and the profiles were not determined solely by the ground reaction force, which Radcliffe had suggested. Results of the study in which the hydro cast was worn showed that the pressure profile did not exhibit a hydrostatic pressure profile.

Deformation of the residual limb may be caused by high interface pressures. An accurate image-based method of visualising these limb changes within the socket was developed (Commean et al., 1998). The system uses X-ray tomography imaging to produce a 3D map of the residual limb. This restricts the clinical application, but does provide a sound research tool with potential for assisting in quantifying what makes a good fitting socket.

5.9 Prosthetic Pressure Measurement Systems

Pressure-mapping systems can be used to evaluate the performance of design concepts and demonstrate the efficacy of these concepts for clinicians. Many of the pressure measurement systems used to assess socket fit are confined to research tools and are not appropriate for clinical use. A few systems have been specifically designed for use inside prosthetic sockets. These devices are extremely thin, flexible and cause minimum interference to the prosthetic socket, or patient. These properties make them suitable for use with the patients own prosthesis, removing the need for new experimental socket to be fabricated.

Rincoe Socket Fitting System

The Rincoe Socket Fitting System (R.G. Rincoe and Associates, Golden, CO), comprises of force sensitive resistors (FSR) surrounded by a polyvenilidyne fluoride coating with a total thickness of 0.36mm. The array incorporates 60 individual cells arranged in 6 thin rows containing 10 cells. Individual cells are separated by 2.3mm (Polliack et al., 2000). Calibration of these transducers can not be performed by the user, tables are provided for use with the software. Although the device is capable of recording in both static and dynamic conditions (three points during gait), it is limited to recording a maximum pressure of 83kPa. This device has been used to evaluate static interface pressures within the prosthetic socket (Shem et al., 1998). However due to the limited maximum recording range of the transducers, dynamic recording was not possible.

Tekscan F-Socket Pressure Measurement System

The F-Scan in-shoe measurement system has been adapted for use within the prosthetic socket. These transducers incorporate Mylar/resistive ink and utilise FSR technology. The 9811 F-socket transducer specially designed for prosthetic sockets has an array of 16 x 6 transducers giving a total sensing area of 15,150 mm^2. Transducers are 0.17mm thick which makes them flexible and ideal to record pressures within the prosthetic socket without interference of volume.

A comparison of the two pressure measurement systems has been performed (Polliack et al., 2000). The accuracy, hysteresis, drift and effect of curvature on the transducers were tested. It was found that the F-Scan system had an increased accuracy in both flat and curved orientation. However errors in hysteresis for both systems were high. They concluded that the F-Scan measurement system had more favourable results over the Rincoe system. They do recommend that both systems be used with caution.

Novel Pliance System

Unlike the two previous measurement systems, the Novel Pliance System incorporates capacitance sensors. It comprises of a 4×4 matrix with 1-mm thickness.

The system can perform using up to 16 sensor pads at once. However, with a thickness of 1mm, this system may interfere with the volume of the prosthetic socket.

5.10 F-Scan Prosthetic Socket Transducers

The pressure measurement system selected for the application of measuring interface pressure distribution within the prosthetic sockets in this investigation is the F-Scan system manufactured by Tekscan, Inc. (Boston, MA, USA). The system is capable of measuring pressure at the interface and does not interfere with the prosthetic socket volume integrity. This is vital as the subjects own prostheses can be used when measuring interface pressure.

Development of F-Scan System

Tekscan specialises in producing pressure measurement systems for biomedical applications. A forerunner to the prosthetic socket pressure measurement system was the in-shoe transducer. Limitations experienced in the use of the foot sensors led to adaptations being made to the application of the socket transducers.

Dynamic pressure measurement systems were developed to overcome the limitations that static measurement systems produced and provided a more comprehensive indication of the interface pressure generated throughout stance. Due to the limited and hostile environment within the shoe, many early systems failed, or prevented the wearer from walking in a natural pattern. The F-Scan in-shoe pressure measurement system was one solution to these problems, as it provided an unobtrusive method of obtaining dynamic data. Measures can be made of repeated foot steps, thus reducing the possibility of the subject targeting a force plate or pressure mat which is laid on the floor. The F-Scan in shoe system was utilised in this study to identify the initiation and end of stance phase.

The in-shoe system comprises of a matrix of cells embedded in a Mylar coating. Each cell is spaced at 5mm intervals. This forms a "pressure mat" which lies inside the shoe. This system overcame problems of discrete sensors placed at specific locations within the shoe which could only provide limited information about the interface. These discrete devices also tend to move within the shoe during gait.

The F-Scan matrix can be cut to the shape of the foot, thus reducing migration within the shoe. The resistance at each cell is inversely proportional to the pressure applied on its surface. As the pressure applied to the transducers varies, so the resistance changes proportionally. The in-shoe transducer has been used in a number of applications, with various degrees of success.

Calibration of the in-shoe transducer is performed "in situ" by loading each array with the total weight of the patient. This is achieved by having the patient stand on one leg during the calibration procedure. The system has a facility for the weight of the patient to be inputted, thus each array can be individually calibrated. Results from a study investigating the peak pressures recorded by the system indicated the pressures were highly correlated with force platform measures. Strictly following calibration as indicated by the manufacture is adequate for clinical purposes. Providing a reliable tool in the management of pressure related foot conditions (Mueller and Strube, 1996, Randolph et al., 2000). However the reliability of this process has been questioned because the application of the F-Scan transducers in many cases involves patients with impaired or compromised balance. Causing an error of up to 14% in some cases (Woodburn and Helliwell, 1996). Users of the F-Scan system can improve the utility of the data by regularly changing the insoles and by calibrating using an air pressure bladder (Quesada et al., 1997, Rose, 1992). As with the inaccuracies of in-shoe contours, the problem of calibration has been address with the socket transducers, by using an air filled compliant membrane to calibrate the transducers.

Calibration of the transducers remains one of the most critical procedures in producing accurate, reliable results. By recognising the limitations of the system and putting in place procedures which take into account these issues, a reliable outcome can be achieved (Buis and Convery, 1997). The F-Scan pressure measurement system has been used in several investigations into socket design. Various methods of calibrating and application of the transducer are seen in the literature. Many of the limitations are not recognised in studies using the system.

Concern has been expressed as to the accuracy of the in shoe F-Scan transducers when subjected to the curvature of the contours of the shoe. A comparison between two matrix devices, the F-Scan and EMED system, questions the ability of the F-Scan system to accurately measure plantar pressures (McPoil et al., 1995). These concerns have been addressed in the application of the prosthetic socket transducers within this study by implementing equilibration and calibration in situ within the prosthetic socket.

The curvature of the prosthetic socket can introduce inaccuracies to the data. It has been shown that placing the socket transducers in situ before calibration increases accuracy by reducing the effects of bending (Buis and Convery, 1997). A comparison study of a compliant feature socket used the F-Scan equipment to measure the interface pressure in various designs of socket (Faustini et al., 2005). In their study the transducers were calibrated using a pressurised flatbed bladder device, then placed on the subject's limb. Transducers were secured on the limb in order that different sockets could be interchanged and comparisons drawn. This technique introduces calibration inaccuracies as the position of the individual cells during calibration and equilibration is different to the profile when recording pressure. Comparisons may be drawn between sockets as only one subject was used in this study. It can be assumed that inaccuracies measuring all socket designs were consistent when measuring the different designs. Although this technique does highlight the difficulty in producing consistent calibration if multiple subjects are used and absolute measures are required.

Sites of cast modification were the focus of one study implementing the F-Scan system (Springer and Engsberg, 1993). They suggest that this type of transducer could be used to quantitatively evaluate the fit and comfort of new prosthetic sockets. In order to identify the points of modification, the pressure transducers were placed directly on the residual limb. It is not clear how the system was calibrated, and therefore the validity of the results can not be established. However their results were similar to those of another study (Houston et al., 1994).

A study investigating the effects of interface friction on the interface pressure within the prosthetic socket has been conducted (Zhang et al., 1996). The findings indicated that interface pressures increase with the decrease in friction. F-Scan foot transducers were placed in the prosthetic socket. Calibration of foot transducers was performed by standing the subject on the prosthesis with their entire weight passing through the transducer. This is possible when the sensors are in the shoe, as the line of force is perpendicular to the sensor and so the shear element is minimal. However when the transducer is placed in a near vertical position, as in the prosthetic socket a different calibration approach is required in order to apply a perpendicular force to the transducer.

5.11 Chapter Summary

It has been shown that the pressure transducers used in this investigation allow the patients own prosthesis to be worn during data collection. This also enables a recording to be obtained of the patient's activity on a daily basis in activities of daily living. The technique of activity monitoring is given in the next chapter.

6 Activity Monitoring

6.1 Chapter Introduction

Regular physical activity and fitness are important for the health and well being of people of all ages and abilities. Assessments of mobility can be used as a clinical assessment tool. This chapter identifies methods used to assess human gait and the influencing factors that may affect ambulation. Different activity monitor types are highlighted and the selection of the activity monitor used in this investigation is presented.

6.2 Gait Analysis

Prosthetists are able to observe the individual walking into or around the clinic room. However assessment of activities of daily living such as walking on uneven ground, or climbing stairs are more difficult to assess. Alternatively, patients are sometimes asked to report on themselves by filling out a questionnaire or responding to interview questions. Although these methods are quick and inexpensive, they only provide subjective measurements and can be difficult to categorise, the accuracy of such subjective measures may sometimes be limited (Sager et al., 1992, Smith et al., 2004).

Gait laboratories can provide comprehensive analysis on how an individual walks. Aspects of gait, such as kinematics, ground reaction forces and energy requirements during walking could provide quantitative information. However, the mechanical and physiological details of how people walk are not the only concern. Gait laboratory testing does not show how much a subject can actually walk. An approach complementary to traditional testing methods is to monitor activity as the person goes about normal daily life. Studies have shown that continuous monitoring over several days provides a clearer indication into many clinical areas. Armstrong et al (2001) monitored persons at high risk of amputation due to diabetes and concluded that the ability to continuously monitor patients may assist clinicians in prescribing activity just as they prescribe drugs (Armstrong et al., 2001). Although the study was focused on providing care for those at risk of amputation, it does highlight the importance of assessing patients in a day to day environment, one that can supplement clinical activity. In order to gain objective measurements to the effects of prosthetic fitting and quantify physical activity under normal living conditions a valid, accurate and cost-effective technique of human movement, analysis and monitoring is required. The extent to which a person is able and willing to move about is often a strong indicator of their condition (Coleman et al., 1999).

The Prosthesis & Gait

The function of the prosthesis is to replicate the role of the amputated (or missing) anatomical limb, to make standing and ambulation possible. An early study into prosthetic gait found that patients were able to achieve a "good gait", for the duration of the walking cycle. This "good gait" was similar to that of normal subjects (Leavitt et al., 1972). In order to achieve this "good gait" throughout the gait cycle, the prosthesis must accomplish three different tasks (Fish 1993). The first is the successful connection between limb and prosthesis, via the prosthetic socket. As has been previously described, the socket is the interface between prosthesis and skeleton and is required to transfer the axial and transverse forces generated during stance between the two. The second task is weight acceptance, the most demanding task in the gait cycle. Weight acceptance involves the transfer of body weight onto the prosthesis during stance. In this position the knee is ahead of the ground reaction force, thereby producing a flexion moment at the knee creating an unstable alignment. Shock absorption and the maintenance of a forward progression are also important components of this phase. Therefore the correct component choice and alignment for the individual patient is important. During mid stance there is a period of single limb support. During this time the prosthesis must support the entire body weight and provide upper body stability while progression must be continued. The final task of the prosthesis in the gait cycle is limb advancement. This requires foot clearance from the floor, as the prosthesis swings through to its destination in front of the body. Foot clearance is performed by small adjustments in foot angle, however the proprioception which would normally provide this feedback is missing on the amputation side. The interface between prosthetic socket and residual limb must therefore provide suspension between residual limb and prosthesis to ensure ground clearance.

In order to gain a better understanding of the three functions of gait described above, it is important to appreciate the dynamics of the gait cycle and how these three tasks fit into it. Normal gait is driven by the proper functioning of the musculoskeletal system and the nervous system. The nervous system is responsible for both motor output and sensory input. In humans there is more than one group of muscles responsible for propulsion. As a result it is possible for an amputee to compensate for a defect in muscle control. Although locomotion is still possible using alternative muscle groups, stride length and velocity are often compromised as a result.

Phases of Gait

The gait cycle can be divided into two phases, these being stance and swing. The period during which the foot is on the ground is the stance phase. The swing phase begins when the foot is lifted from the floor until the heel is placed down. During normal walking stance phase lasts for approximately 60% of the gait cycle, and swing occupies the remaining 40% (Whittle, 2001). Both phases are important in the successful fitting of a prosthetic limb. Stance phase is of particular importance in prosthetic fitting, as during this period the interface between residual limb and prosthesis is subjected to the greatest load. Stance phase can be further divided into smaller periods, dependant upon the location of the leg. During the measurement of the prosthetic socket interface pressure, these sub phases of stance phase will be utilised.

Biomechanics of Amputee Gait

The biomechanical principles and pressure profiles of amputees were first discussed by Radcliffe (Radcliffe, 1961). He based the Patella Tendon Bearing (PTB) prosthetic socket design on the assumption that trans-tibial amputees walk in the same manner as a non amputee. During initial contact the ground reaction force acts anterior to the knee. This causes the knee to extend, with the hamstrings preventing any hyperextension. The action of the hamstrings would cause increased pressure concentration at the patella tendon and distal region of the posterior aspect. Reaching mid stance, the ground reaction force would now be posterior to the knee, and so produce a flexion moment. This tendency would be resisted by the quadriceps, and extension of the hip. This action would produce a high concentration of pressure along the anterior aspect of the limb with a tendency of the anterior distal region to experience the highest pressure. The popliteal region would again experience a high pressure and at this point in the gait cycle the pressure would be highest in a more proximal area. At the end of stance, between heel off and toe off, the line of ground reaction force would remain behind the knee, thus the same pressure profile would remain as was expected at mid stance.

Abnormal Gait

When pain or tissue damage occurs at the residual limb, abnormal gait is often the result. If a prosthetist is confronted with an abnormal gait they must have sound understanding of the characteristics of normal gait to enable them to accurately detect and interpret deviations from the normal gait pattern. However, each amputee may display certain variations from the norm which are superimposed on the normal pattern of walking. The prosthesis serves two roles in terms of gait. Firstly, it should enable the user to hold an upright posture in order to maintain balance. Secondly, it must be securely fitted in order that the wearer has the ability to initiate and maintain rhythmic stepping, whilst walking.

Other factors are also attributed to achieving normal gait such as the musculoskeletal system. This must provide enough support and control for the remaining intact bones and well functioning joints as well as adequate muscle strength. Muscle tone must be high enough to resist gravity, but low enough to allow sufficient movement of the lower limb. Vision is also vital to normal walking, particularly important when other sensory inputs are reduced as in the case of an amputation, where propreoception is compromised due to the loss of the foot. Vision and inner ear balance give information about the movement and position of the head and body relative to the surroundings and is important for the automatic coordination and balance responses to changes in surface conditions via the vestibular system. (Whittle, 2001).

Elderly Amputee Gait

In the UK, the majority of trans-tibial amputees are elderly, 55+ years (NASDAB, 2005). In addition to gait deviations caused by the prosthesis, the elderly amputee may also experience gait deviations due to their age. The prosthetist must be able to distinguish the normal gait changes that occur with age from the abnormal gait changes that occur due to incorrect prosthetic alignment or fitting. Elderly people tend to have decreased muscle bulk, strength, and flexibility, as well as some loss of hearing and vision. The major changes in gait are a reduction in the overall velocity and reduction in the step/stride length (Judge et al., 1996). In general, when increasing their velocity, the elderly tend to take more steps instead of increasing their stride length. The elderly tend to have more trouble walking in situations that require speed e.g. crossing the street, agility e.g. walking on uneven surfaces or in crowds, or in the dark. There is also decreased arm swing, decreased rotation of the pelvis, and a more flat foot approach to both heel strike and push off.

6.3 Patient Activity

It is known that increased physical activity can decrease the risk of obesity, coronary heart disease, respiratory disease and diabetes. Based on the wealth of benefits provided by regular exercise, health professionals recommend that patients increase their level of physical activity. However, the factors that regulate an individual's average daily activity level may be beyond the control of the individual. People are classed as "sedentary" if they walk under 5000 steps per day. "Low Active" if they walk 5,000-7,500 steps per day and "somewhat active" if they walk between 7,500 and 10,000 steps per day (Physical-Activity-Task-Force, 2003). Government targets recommend that people achieve at least 10,000 steps per day.

Comfort

If the amputee deems the prosthesis they are wearing uncomfortable, this may limit their activity. Therefore it may be expected that the activity of the patient would be an indicator of the comfort of the prostheses. However this theory is difficult to put into practice, as no two people have the same lifestyle. For instance, two subjects may have what they would classify as a good fitting socket, the socket may not be causing any medical concern and pressures in both are at the same level. However if one subject's lifestyle demands a higher level of activity than the other, the measurement of activity between these two individuals would suggest the more active person to have the better socket, which may not be the case. Discomfort may limit activity, however the opposite is not true, a comfortable prosthesis may not always increase activity.

6.4 Monitor Types

There are a wide range of different measures for activity, including those based on body acceleration, energy expenditure and heart rate monitoring. Subjective monitoring includes the use of log books, diaries, observation and questionnaires. The complexity and diverse nature of human activity means that it is likely that no one method for recording human activity will provide all the answers. As devices become smaller and more accurate it may be possible to incorporate many aspects of monitoring into a single device. The method of choice will depend upon how the measurement will be used and why it is being performed (Schutz et al., 2001). The study recommends that if patterns and intensity of activity are needed, an accelerometer may be better suited. This echoes the findings by an earlier study which found that activity monitoring are reliable and valid measurement tools for measurement during daily life (Bussmann et al., 1998).

Assessing patient use of the prosthesis is important, particularly in post operative situations. Increased information may help target resources to areas which will help increase rehabilitation. As in all health care professions it is becoming increasingly important to provide evidence to support treatment provided. Patients in this study have been fitted with an accelerometer based activity monitor, small in size, non-invasive, and causes minimal intrusion to the subject movements during daily activities. The duration, frequency, and intensity of activity are measurable using this monitor. This information will enable any differences between the patients activity to be highlighted.

The number of accelerometers is extensive and continually growing. With the Nation's health high on the agenda of government, the promotion of an increase in daily activity has seen many companies promoting activity monitors. There is also an increase in public demand for accountability in health care (Hoxie, 1995). Attention is now being drawn to methods of assessing treatment beyond the clinic room.

Monitors have been investigated by many researchers; It is increasingly becoming more important to not only provide the number of steps performed, but the time and duration of this activity (Zhang et al., 2003). The Step Activity Monitor (Brandes and Rosenbaum, 2004, Hartsell et al., 2002, Silva et al., 2002, Smith et al., 2004, Boone and Coleman, 2006a) provides useful, accurate records of physical activity. The Sportbrain (Sportsbrain, Campbell, California) and Biotrainer Pro (IM Systems, Baltimore, MD) also record the time and steps. These monitors are worn strapped to the waist (Holtz-Neiderer and Armstrong, 2004). Problems with the inaccurate recording of the numbers of steps when using waist worn monitors have been reported, particularly in heavy and obese people (Silva et al., 2002). The monitors are activated by movements at the pelvis, and small movements of the lower limbs may not be recorded. The Ossur Patient Activity monitor, a lightweight design which fits around the ankle of the user has been described as a potential tool to measure amputee activity (Karason, 2005). The monitor can calculate the speed and distance of each step. Other devices can detect if the user is sitting, standing or walking (Walker et al., 1997) and require sensors to be positioned on the patients body in order to detect its orientation. A commercial example of this is the Dynaport ADL Monitor (Brandes and Rosenbaum, 2004). This device utilises three accelerometers and is placed at the waist and thigh.

This study recruited subjects at regular intervals throughout the year as seasonal effects of activity have been studied and have indicated that activity increases during spring and summer (Pivarnik et al., 2003). A study by Stewart (1998) reported that the activity of patients reduced following amputation, with an increased use of additional walking aids (Stewart, 1998). Armstrong monitored diabetic related subjects at high risk of amputation, using a log book and activity monitor (Sportsbrain.com, Sunnyvalem California) (Armstrong et al., 2001). The average age of the subjects was 64.6 ± 1.8 years and the study found that the subjects took on average 4548 steps ± 779.3 per day. In a study of patients with a total hip arthroplasties, Silva reported that the subjects walked close to 2 million cycles per year (4 million steps per year or 11000 steps per day (Silva et al., 2002).

In a recent study, several inexpensive monitors were tested for reliability and validity (De Cocker et al., 2006). Results show that many of the monitors gave inaccurate records of daily activity, making them inappropriate for measuring physical activity. These monitors were tested against a Yamax Digiwalker which has been shown to provide reliable information when assessing daily physical activity patterns (Welk et al., 2000). The study highlights the difficulty in accurately measuring daily activity.

The monitor selected for this study was the ActivPAL professional activity monitor (PAL Technologies, Glasgow). The small, lightweight and discrete design makes it ideal for the application intended in this investigation. Each monitor uses algorithms to calculate the movements of the monitor on a second by second basis. A detailed description of the activity monitor is described in section 9.2.3.

6.5 Chapter Summary

The gait pattern of an amputee and the importance of understanding deviations to ambulation have been described. Activity monitors have been shown to be one tool that can extend clinical assessment of prosthetic use beyond the clinic room. The use of an activity monitor in this investigation enables quantifiable information to be gained regarding the subject's use of their prosthesis. Subjective assessment of the use of the prosthesis can be gained by questioning a patient. Patient feedback is discussed in the following chapter.

7 Patient Feedback

7.1 Chapter Introduction

The expectation of the prosthetist and the patient may differ when it comes to the satisfaction with a prosthesis. It is not only the physical condition that is being treated; psychological care is also vital to any successful rehabilitation programme. This chapter describes the physical and psychological care required in prosthetic treatment and methods employed to gain patient feedback. A literature review on assessment techniques is presented, and the selection of the questionnaire used in this investigation is outlined.

7.2 Quality of Care

The quality of care is the most important aspect of providing a patient with a prosthesis. The aim of the clinical team is to deliver a high quality service. A service that is able to create an environment in which the patient is comfortable, both physically and psychologically. Satisfactory delivery of a prosthesis is the ultimate goal of any prosthetist. However for the patient the final delivery of the limb may not be as important as the process, and subsequent visits to the clinic. The less trouble a patient experiences with the prosthesis, the fewer emotional problems will be exhibited (Ham and Cotton, 1991).

7.3 Psychological Care

Pawar (2005) outlines several key points important in building patient satisfaction and compliance (Pawar, 2005). Although the points made relate to healthcare in general they serve as a good framework for prosthetic practice. They may go some way to improving the experience patients face when adjusting to a new prosthesis or prosthetist. Firstly, and probably most important of all, Pawar states that a sense of trust should be built between the clinician (prosthetist) and patient. This is essential in enabling any message to be received by the patient successfully. Trust must be established so that future treatment or advice can be effectively communicated (Goleman et al., 2002). Many amputees attending the clinic for the first time will be anxious about the unknown. Patients who have received poor treatment in the past may also have an increased state of fear. In order to deliver a successful service to the patient, prosthetists must listen to their patients in order to provide insights into the lives of those being treated. This will enable the prosthetist to understand the patient's values, goals and challenges.

The second point Pawar outlines is that it is vital to uncover the needs of the patient. The most important aspect to good conversation, involves asking questions with interest and with a goal of trying to understand how the patient sees the world around them. The relationship between patient and prosthetist may last several years. Prosthetists have to establish themselves as trusted medical professionals in order to lay the foundation for the long term care which will be provided. Establishing a good level of communication and finding out the patients needs at the beginning of any treatment plan may facilitate a reduction in patient dissatisfaction.

If a patient attends the clinic and proceeds to complain about the treatment they are receiving or function of their limb, the prosthetist should not immediately respond with a solution upon hearing the complaints. Instead the prosthetist should explore the reasons for the complaint and make a connection with every patient. It is important to find out how their problems affect the patient's day-to-day lives, or how they have approached the problem and what their results have been. Only after the patient has finished speaking should the prosthetist address other options and ask the patient how these other options sound in the context of their overall goals.

When a person looses a limb, it is not only the physical loss that a person has to cope with. The loss may have psychological implications that a prosthesis will never really replace. Sigmund Freud's says in *Civilization and Its Discontents*, "Man has, as it were, become a kind of prosthetic god. When he puts on all his auxiliary organs he is truly magnificent; but those organs have not grown on to him and they still give him much trouble at times." Freud was referring to the car as our prosthetic legs, or glasses as our prosthetic eyes. However it remains true that for amputees, the aim of the prosthesis is to restore function after the loss of a limb, but this can bring with it a great deal of pain. Freud had experienced pain from a prosthesis. During the writing of the book, he wore a prosthesis in the roof of his mouth as a result of throat cancer (Peters, 1999).

Some people relate to their prosthesis in a way that they give it a name, they think of it as part of themselves, something to look after. In the same way that people treat their glasses, amputees may need to keep the prosthesis near by in order to put it on quickly when required. They may also have a feeling of freedom when taking it off. There is also a more philosophical problem of where the self begins and ends. The perception of body image has been found to be an important factor in determining psychosocial well-being (Breakley, 1997). The amputees may feel their old body and get the feelings through the artificial leg even though the prosthesis is a mechanical device and their body is not connected to it. Prosthetists should be aware of the psychological issues that may influence the rehabilitation of their patients (Desmond and MacLachlan, 2002). After delivery of a prosthesis to a patient, the prosthesis still remains the property of the government; people who have had limbs for a long time can still regard it as something they have to give back. When an amputee begins to get used to a prosthesis the prospect of having a prosthesis replaced is more terrifying than losing the limb the first time.

Losing a limb and then being fitted with a prosthesis is as much an emotional loss as it is a physical loss. There is a large variability in how people respond. Some people will react as though it was a lost person and others will treat it with little emotional response. The prosthesis can become a part of the patient, either functionally in helping them to ambulate. Or it can also become a part of them emotionally in a positive sense. This is a battle for some people in that the prosthesis is not a friend that they have chosen and it is often an annoying object in the sense that it does not have the capability, the movement, or the flexibility of the original leg. In fact it's actually an object that can be the subject of much annoyance. The response to a prosthesis can also vary amongst patients. Some may come home after weeks of fitting and developing the right prosthesis and throw it in a cupboard and never use it again, whereas for others it can become a close part of them.

7.4 Physical Care

The number of older adults living with lower limb amputations is increasing because of the aging population and the increased incidence of Peripheral Vascular Disease with age (NASDAB, 2005). Amputation is usually seen as the last resort to PVD after other treatments have failed. This makes it particularly difficult outcome for older adults and their families. The prospect of lifelong rehabilitation can seem vast. It is the responsibility of the healthcare professionals to encourage these patients and to help them adjusted to limb loss and encourage patients that their lifestyle can be restored.

A patient with vascular disease often has other chronic medical problems. Close attention to wound healing after amputation is vital to assure infection is controlled. Successful rehabilitation is complicated because of the normal physiological effects of ageing, decreases in muscle strength, bone density and oxygen consumption and other medical conditions associated with age. One of the most important factors affecting rehabilitation outcomes is the increased energy expenditure needed for prosthetic use. Research findings state that the trans-tibial amputee requires up to 20% more energy (Mensch and Ellis, 1986) and this coupled with other age related changes such as the decrease in cardiopulmonary reserve and muscle mass loss make successful prosthetic rehabilitation a major challenge.

Another common occurrence following lower-limb amputation is the loss of usual muscle strength, decrease in endurance, and the changes in biomechanics of lower-limb function. Flexion contractures are especially dangerous to the elderly, since they heighten the threat of falling and fracturing the head of femur. Hip flexion contractures increase the risk of falling, due to the patient's centre of gravity now being behind the knee axis. Younger people typically can recover from a fall; older people often do not. Prosthetists have to be especially careful about component selection, fitting, and training of their geriatric patients.

A number of steps can be performed to promote successful prosthetic use, function, and mobility for older amputees. The process starts with patient assessment; having the necessary strength, cognitive function, and balance skills necessary to don and doff a prostheses is important. If trans-tibial amputees are able to stand with the aid of a walker or crutches then they can usually be fitted with a prosthesis.

Decreased mental function that inhibits the ability to learn the new skills required for prosthetic use is also common with the elderly population. It is important for the prosthetist to understand the decisions a patient is going through. Many of the trans-tibial amputees who have lost a limb as a result of diabetes may have spent time at home in a wheelchair, losing strength and cardiovascular fitness, prior to amputation. The ideal goal of successful rehabilitation is achieving the level of function the amputee had before the onset of the medical condition leading to the amputation. There have been major advances in prosthetic components such as dynamically responsive and multi-axis feet, more comfortable socket designs, improved skin/socket interface materials and suspension techniques. But just providing these technically advanced components does not substitute for the appropriate therapeutic training of residual muscles and improving the ability of the heart and lungs to respond to the increased energy demands required with prosthetic use.

Beginning rehabilitation as soon as possible after amputation surgery is generally highly beneficial to amputees, and can often prevent contractures (Cutson et al., 1994). When a patient develops a flexion contracture, they will require physiotherapy and advice. It is possible to prevent flexion contractures of the legs by mobilising the amputee out of the wheelchair and bed as soon as possible after the amputation. Patients kept in a wheelchair for periods of time either before or after the amputation will be more prone to developing flexion contractures of the hips and knees that may preclude successful prosthetic function.

Developing a multidisciplinary care team from the start, including the patient and patient's family provides the most useful strategy for rehabilitation management. A prosthetist should be included in the preoperative consultation. At this stage the prosthetist can provide information into how the residual limb will interface with the socket of the prosthetic limb.

Immediately postoperatively, a stump shrinker should be fitted over the bandages. It is essential that the bandages are wrapped evenly as to ensure an even distribution of pressure over the residual limb. This covering creates a safe environment for the residual limb, protecting it from additional trauma and promoting healing. The limb protector helps reduce oedema, increasing venous return, and reducing the risk for infection. These factors can often result in early patient discharge. The stump shrinker should be worn during the patients stay in hospital and after the patient's returns home. The implementation of immediate postoperative prosthetic fitting encourages early ambulation. This in turn promotes the healing of the limb and can be valuable to the patient's mental outlook. After 6-7 days post amputation, the patient will begin gait training using a temporary prosthesis or other mobility aid.

Amputation is a difficult outcome for older adults, their families, and the medical care delivery system. With early prosthetic management, however, older adult amputees can benefit from faster recoveries, earlier discharges, and increased rehabilitation potential and independence. Advances in prosthetic design have resulted in greater comfort for the vascular amputee and a reduced incidence of injury or infection in the residual limb. In the managed care environment, where the focus is on cost constraint, these techniques deliver the best long-range outcomes for older adult amputees as well as for the care providers. Appropriate medical and rehabilitative care can have a positive effect on the functional outcome for an elderly lower limb amputee (Coletta, 2000).

7.5 Measuring Patient Satisfaction

Comfort

The term comfort is often used when describing the performance or experience of a prosthetic limb. However comfort may mean different things to a prosthetist as it does to a patient. The prosthetist will usually attribute a comfortable prosthetic limb as one with the optimal fit and alignment of the device. Whereas the patient may be experiencing many other factors that make up the comfort of the limb, these have been mentioned during the description of physiological implications of wearing a prosthesis. Therefore comfort may be seen as the combination and interaction of physical and psychological elements.

Pain

Pain is not straightforward; experience of pain can vary widely, from person to person particularly in special circumstances. Identical injuries can produce widely varying experiences of pain. In some cultures people will intentionally scar their bodies to provide decorative incisions in the skin. Their pain tolerance seems to be unusually high, compared to most western cultures, in which every minor headache seems to require an immediate painkiller. What about pain felt; for which there is not even any flesh in which to experience it, i.e. phantom limb sensations or pain? Pain may be seen as a state of mind rather than a state of the body. One of the most common complaints that the prosthetic user mentions is in relation to pain

(Chadderton, 1978). Amputees may express concern that their prosthesis is uncomfortable, in many cases this expression of discomfort can be attributed to the fit of the prosthesis.

Subjectively, the painful experience is related to conceptions about pain and pain management (knowledge, beliefs and attitudes) acquired through previous experience (Koyama et al., 2005). These result in individual behaviours, meanings, and expectations about the pain itself and its development. Cognitive aspects have a decisive influence on the appreciation and expression of and tolerance to pain. The evaluation of the damage caused by pain permits the assessment of its impact on daily life activities. The identification of significant impairment, especially to movement and walking functions, as well as to other functions, such as sleep and the ability to establish social relationships, is important since this impairment might represent a risk factor for complications mainly related to psychological and social aspects (Eccleston, 2001). The fear and anxiety may have profoundly different effects on a person's ability to feel pain.

Fear and anxiety have different effects on pain stimulus in humans. Fear reduces pain, whereas anxiety has an enhancing effect. Fear mobilises a person to take action, commonly known as the fight or flight response. Anxiety leads to scanning of the environment and body, resulting in increased sensory input. Confronted with life-threatening situations, which would elicit fear, the body reacts by shutting off the pain response because feeling pain might get in the way of survival. Alternatively, during times of low threat, times likely to produce a state of anxiety rather than fear, the chance of survival is increased if pain is enhanced so that behavioural responses can occur to minimize tissue damage (Wilkinson, 1986).

From a clinical perspective, a patient who has had negative experiences from first fitting of a previous new prosthesis may be anticipating a threatening event, thus achieve a higher degree of anxiety. This raised level of anxiety may cause the patient to experience enhanced perception of pain. Therefore using pain as an indicator of biological damage may not be an accurate measure to socket fit. If each new socket fitted to a patient had a more consistent feel, the patient would be in a reduced state of anxiety, therefore a reduced perception of pain making the delivery and subsequent acceptance of the prosthesis more successful for both prosthetist and patient.

Lower back pain and arthritis of the knee are secondary disabilities that pose serious problems for large percentages of amputees and can lead to significant loss of function. Various studies show that as many as three-quarters of lower-limb amputees suffer lower back pain. In a recent paper, back pain was suggested to be surprisingly common in persons with lower-limb amputations and, for some who experience it, may greatly interfere with function (Kulkarni et al., 2005).

Phantom Limb Sensation and Pain

Phantom pain can take many different forms, often more than one pain occurs in the same person, the most common descriptions are of crushing and burning. Suffering pain from the absent limb means that the patient can find it difficult to communicate the distress of phantom pain to others and can lead to greater frustration and suffering. The loss the limb, from accident or disease is compounded with the agony of the phantom pain. Phantom pain can be controlled by coping mechanisms which the amputee develops to control the pain or sensation (Whyte and Niven, 2001).

Cosmetic Appearance

The prosthetic limb main function is to transfer ground reaction forces from the ground to the body. However the prosthesis also provides a cosmetic replacement of the missing body part. The main focus of this investigation is to understand more about the fit of the prosthetic socket in order to provide prosthetists with more information when designing the prosthesis for a patient. However, the cosmetic appearance of the prosthesis is just as important, if not more important for some patients. The introduction of the NHS National framework agreement published in 2004 emphasis's the need to increase the provision of silicone covers to prostheses. Consideration must therefore be given to the appearance of the limb in order to improve the service and care to the amputee.

An aesthetic, acceptable limb can increase the level of self-esteem and can motivate a patient, enabling a quicker and sometimes more successful rehabilitation. Developments in silicone and PVC covers have helped to attain a more realistic effect. In some situations patients are unable to rehabilitate successfully after their amputation. This group of patient tend to be much older and have other associated conditions. Many are of limited mobility or even non-ambulatory before the operation. For these cases, wheelchair or cosmetic limbs can be provided. These are usually little more than shaped blocks of foam with a soft socket attachment and cosmetic cover to finish. Although functionless in the ambulatory sense they provide the wheelchair-bound patient with the appearance of a limb.

7.6 Patient Feedback

Patient surveys are an instrumental component in monitoring the quality of care, this is particularly important when dealing with prosthetic use. In a dynamic healthcare industry, prosthetists are faced with maintaining high quality services but also continually becoming more efficient. Patients and prosthetists are examining the delivery of prosthesis from both a quality and post delivery perspective. The need for evidence-based practice in all areas of the health service is driving forward the requirement to measure the outcome of an intervention. This is of particular relevance in the area of prosthetic rehabilitation, where traditionally methods and practices have been based on professional experience. As a result of this increase in the need to provide evidence for clinical decisions, there has been an increase in patient questionnaires designed to gain patients feedback, and thus measure the outcome.

Activities of daily living

Activities of daily living (ADL) refer to the basic tasks of everyday life, such as eating, washing, dressing, toileting, and transferring. If someone is unable to perform these activities, they need help in order to cope, either from other human beings or mechanical devices or both. Patient Satisfaction Surveys provide the improvement in knowledge that impacts positive patient relations in many ways, including understanding and identify the principle drivers to patient satisfaction, as well as the factors that lead to patient dissatisfaction. By understanding patient expectations, they can be correlated in relation to the goals, objectives, and strategies of the prosthetic department. As a result of patient feedback, quality improvement programs can be developed around patient satisfaction results, strengthening the quality of patient services and improve the level of prosthetic care. The amount of training and the time it takes for a patient to receive a new prosthesis were two factors that were found to affect the long-term use of the prosthetic limb when patients were asked in a study assessing the predisposing factors related to prosthetic use (Gauthier-Gagnon et al., 1998). A long term outcome study of traumatic lower limb amputees reported that although almost all use a prosthesis, the majority are not satisfied with prosthetic comfort (Dillingham et al., 2001). Amputees have also been shown to have a reduced sense of self confidence as a result of their amputation (Nicholas et al., 1993). This study also identifies that depression is negatively correlated with time since amputation. Although correlations were weak, the information is useful in quantifying the holistic care of the patient. The finding that "time is a healer" should represent a challenge to the prosthetist. The prosthetist has a critical role in reducing this time of healing by providing the best possible prosthetic care from the first instant of rehabilitation. This is not just the provision of a prosthesis, but providing clear information on all aspects of patient care. The results of a recent survey of trans-tibial amputees confirm this (Trantowski-Farrell and Pinzur, 2003). They conclude that rehabilitation efforts should be specifically designed to the patient. Not simply directed to prosthetic fitting and independent walking.

Outcome Measures

Many outcome measures are available in the medical field; however few are specific to the area of prosthetics. In a review of literature, twenty five outcome measures were examined (Condie et al., 2006). The study concluded that no single measure emerged as being universally appropriate, and it is unlikely that prosthetists will be able to use the findings from the studies to make informed choice on outcome measures because of the complex design of each study. An earlier study also examined scales used in lower limb amputations, with particular focus on mobility (Rommers et al., 2001). They too failed to find any consensus amongst the literature, and major failings in the studies undertaken.

Several outcome scales for use with the amputee population have been designed and tested. Each has unique features and scores in determining patient satisfaction. A brief outline of the more common scales are given below, all of which have been assessed for validity and reliable. They vary in application style, and complexity of analysis, but each one enables assessment of the lower limb amputee in terms of quality of life.

Ambulatory skills of amputees wearing a prosthesis can be measured before and after amputation using the Locomotor Capabilities Index (LCI). It contains 14 questions with a 4 point answer ordinal scoring scale. It can be divided into two sub scales, each comprising of 7 questions, one scale covering basic activities and more advanced activities. The test shows good internal consistency and is recommended for clinical use (Franchignoni et al., 2004). Trinity Amputation and Prosthesis Experience Scales (TAPES) comprises of 39 items relating to areas such as pain, health and prosthetic use. Each question is rated on an ordinal scale, of either 3 or 5. The amputee Mobility Predictor with Prosthesis (AMPPro) comprises of a simple scoring system containing twenty one items to objectively measure function in amputees before and after amputation (Gailey et al., 2002) tested the AMPPro and found it to be a valid and reliable tool for assessing prosthetic function. The Prosthetic Profile of the Amputee (PPA) consists of 44 questions, grouped into 6 sections, including behaviour, prosthetic use and motivation. It is a reliable instrument, enabling the understanding of prosthetic use (Gauthier-Gagnon and Grise, 2006). The Special Interest Group in Amputee Medicine (SIGAM) utilises an algorithm to plot responses to a questionnaire. Patients can be allocated to one of six grades, dependant upon their answers (Ryall et al., 2003). The Amputee Activity Score (AAS) is an older system, it has eight scales, with 20 items, in tests the AAS was deemed to be reliable (Panesar et al., 2001). The Functional Measure for Amputees (FMA) measures the function of amputees; it is similar to the PPA and consists of 13 questions, with the use of a guide to the scoring. The quality of life of amputees was the focus of the Attitude to Artificial Limb Questionnaire (AALQ). It comprises of 10 items, scored on an ordinal scale, and is a simple device for assessing amputee's attitude to prosthetic use (Fisher and Hanspal, 1998). A simplified scale was also validated by the same team. Patients responded to a 10 point scale, where 0 and 10 represented the most uncomfortable and the most comfortable socket. Results showed high correlations with prosthetists own view of socket fit (Hanspal et al., 2003).

7.7 Prosthetic Evaluation Questionnaire (PEQ)

In order for the subjects participating in this investigation to provide quantitative feedback, a questionnaire was implemented. This resource would mean that responses from the subject could be compared to the data obtained from an activity monitor and pressure measurements of the prosthetic socket. A validated Prosthetic Evaluation Questionnaire (PEQ) developed by the Prosthetics Research Study group in 1997 was applied (Legro et al., 1998). Validation of the questionnaire was tested using the short form 36 questionnaire (SF-36). The sub scales within the questionnaire demonstrated high internal consistency. The questions examine health-related quality of life by means of a self reported questionnaire and are specific to persons with lower limb amputations. Questions relate to both the physical and psychological influences of prosthetic wearing and provide an indication as to patient satisfaction of their prosthesis.

The PEQ is designed specifically for persons wearing a lower limb prosthesis and has been used to report prosthesis related issues and recreational activities from a diverse group of amputees (Legro et al., 1999, Legro et al., 2001). The questionnaire comprises of 82 individual questions. Subjects mark a visual analogue scale (VAS) which can be measured to create a quantitative value for patient feedback. At the ends of the scale are two extreme responses, i.e. at one end would be "can not do it" at the other "no problem". The PEQ was one of three self reporting mobility scales used in assessing prosthetic use which were investigated for reliability and validity (Miller et al., 2001). They found that all three showed acceptable validity and reliability. They did, however alter the VAS to a numeric scale 0-10 because they deemed it to be unfamiliar and not easily understood by participants. This evidence was based on a small pilot study. For the purposes of our study no alterations were made to the questionnaire, as validity and reliability have been shown in its original form (Legro et al., 1998).

Despite the difficulties in applying outcome measures in the field of prosthetic rehabilitation, there is a need to increase evidence based practice. However any device must be user friendly and quick to administer if it is to be of any use (Uellendahl, 2006).

7.8 Chapter Summary

Understanding a patient's perception of their prosthesis is crucial in providing a high standard of care to the patient. This chapter described the important issues surrounding the physical and psychological aspect of prosthetic care and identified the PEQ as the outcome measure used in this investigation to gain feedback from patients enrolled in this study.

8 Preliminary Studies

8.1 Chapter Introduction

During the planning of the project, a number of preliminary studies were conducted. These were undertaken during development of the overall test protocol to facilitate efficient and accurate testing methodology.

The first study investigated the placement of the pressure transducers in relation to the silicone liner. It was necessary to determine if the position of the pressure transducers could accurately measure residual limb interface pressure when placed on the outside of the silicone liner. This would be essential when measuring the pressure cast sockets.

Having been instrumented, each prosthetic socket requires to be calibrated before measurement can be taken. A custom made platform on which to calibrate prosthetic sockets was required for the project. The second preliminary investigation involved designing, building and testing the calibration platform.

A number of activity monitors were used throughout the project. The third study measured the reliability of these monitors over a period of one day. Evidence from this study would benefit the overall evaluation of the subject's activity.

8.2 Load Transmission Through a Silicone Liner

Calibration of the F-Scan prosthetic socket transducers requires the transducers to be placed in situ with an air filled bladder applying a known uniform loading. The transducers have to be placed between the silicone liner and the socket wall, rather than next to the patient's skin as the patient is unable to wear their prosthesis at the time of calibration. The transducers cannot be placed between the residual limb and liner, since the silicone sleeve forms a total surface coupling with the stump. As a result, the elastic behaviour creates an initial tension which produces an additional unknown pressure that can not be replicated during the calibration procedure and would also create signal drift of the F-Scan equipment. The PTB sockets permit the transducer to be placed at the liner and limb interface. A detailed description of the F-scan equipment and calibration process is given in section 9.2.2. The purpose of this preliminary study was to determine whether a silicone liner would directly transfer load generated on one side to the other. This would be of benefit to the overall investigation as it will assist in the placement of transducers that will measure the stump/socket interface pressure in a silicone liner.

The outcome of this preliminary study will increase the understanding of silicone liner behaviour by determining whether F-Scan transducers placed between socket wall and liner record the same pressure distribution as if they were placed between skin and the liner. However, this method of data capture limits the results of the study since the transducers employed have some minor limitations, which have already been described. In spite of this, the outcomes from this investigation will form the basis of future research into socket pressures when using silicone liner interfaces.

8.2.1 Methodology

This study investigated the load transmission through a commercially available silicone liner as used in trans-tibial prosthetic sockets. Tekscan F-Scan prosthetic socket transducers were utilised to capture the pressures generated within purpose designed test platforms. The same test sample of silicone liner was used throughout all tests, and was cut from a 5mm thick prosthetic liner to a size of 100mm x 60mm. The utilised socket transducers were trimmed to a length of 150mm and subsequently equilibrated and calibrated according to a validated protocol. A length of 150mm was used to represent the typical length of a residual limb. The F-Scan foot transducers were cut to a rectangular section of 45mm x 97mm and calibrated using a pressure of 100kPa in a flatbed calibration device as described by (Buis and Convery, 1997).

Test Platforms

Two test platforms were designed and constructed to evaluate the anticipated effect that curvature might have on pressure distribution. The first design was a flat test platform, comprised of two metal plates (140mm x 77mm x 15mm) connected with four bolts, each with a diameter of 10mm. The screws passed through holes drilled wide enough to allow the two plates free vertical movement during the tests, See Figure 11.

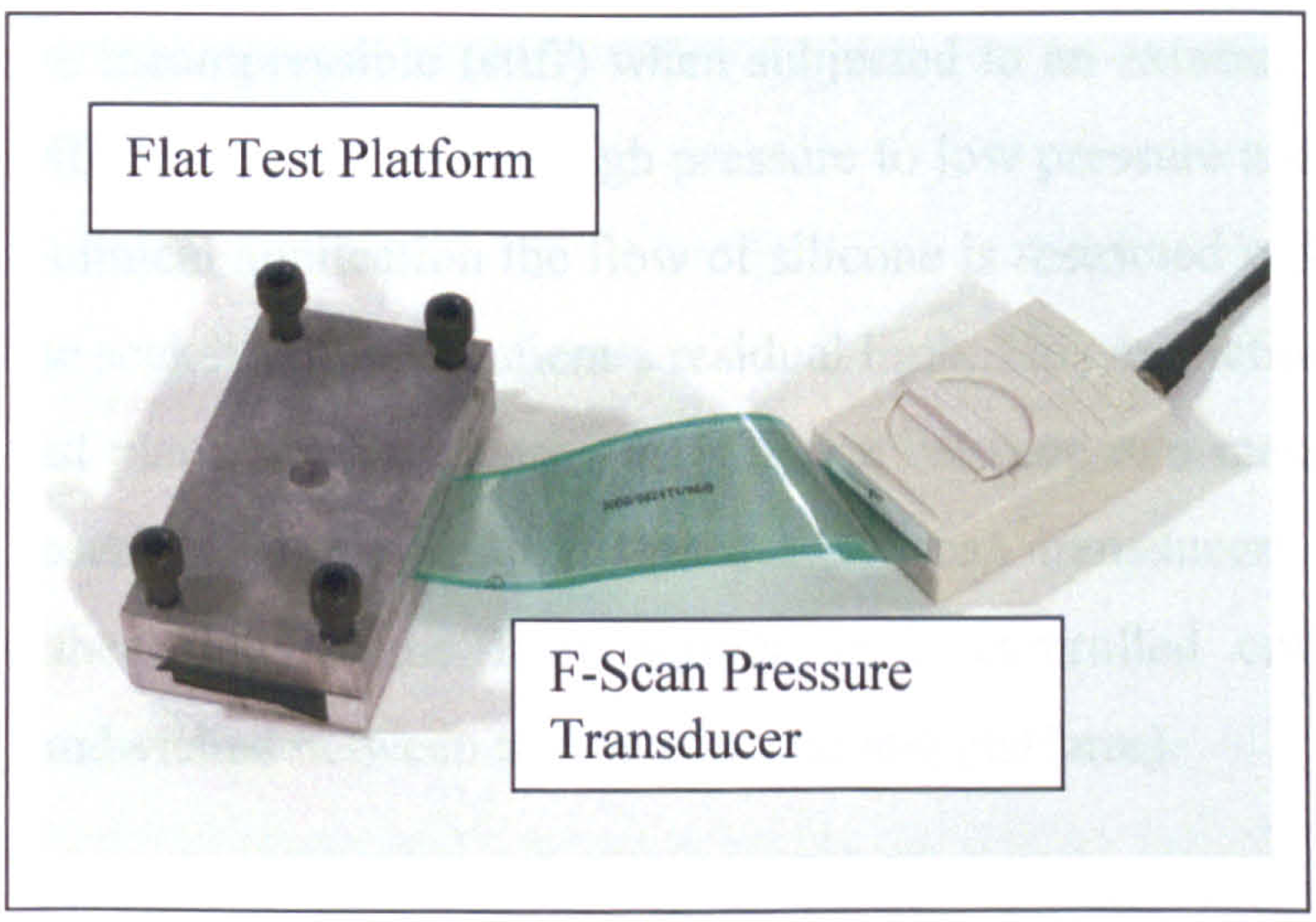

Figure 11: Flat Test Platform

The second test platform involved a curved base, 245mm long with an 80mm diameter. The diameter of 80mm was chosen to represent the typical diameter at the mid point down the residual limb. Held above this was a steel bar of length 265mm and 75mm in diameter. Springs placed under the steel bar prevented the weight of the bar compressing the F-Scan transducers until the loading device compressed the test platform. Two running guides 25mm wide ensured that the steel bar was permitted to move in the vertical plane and prevented rotation, see Figure 12

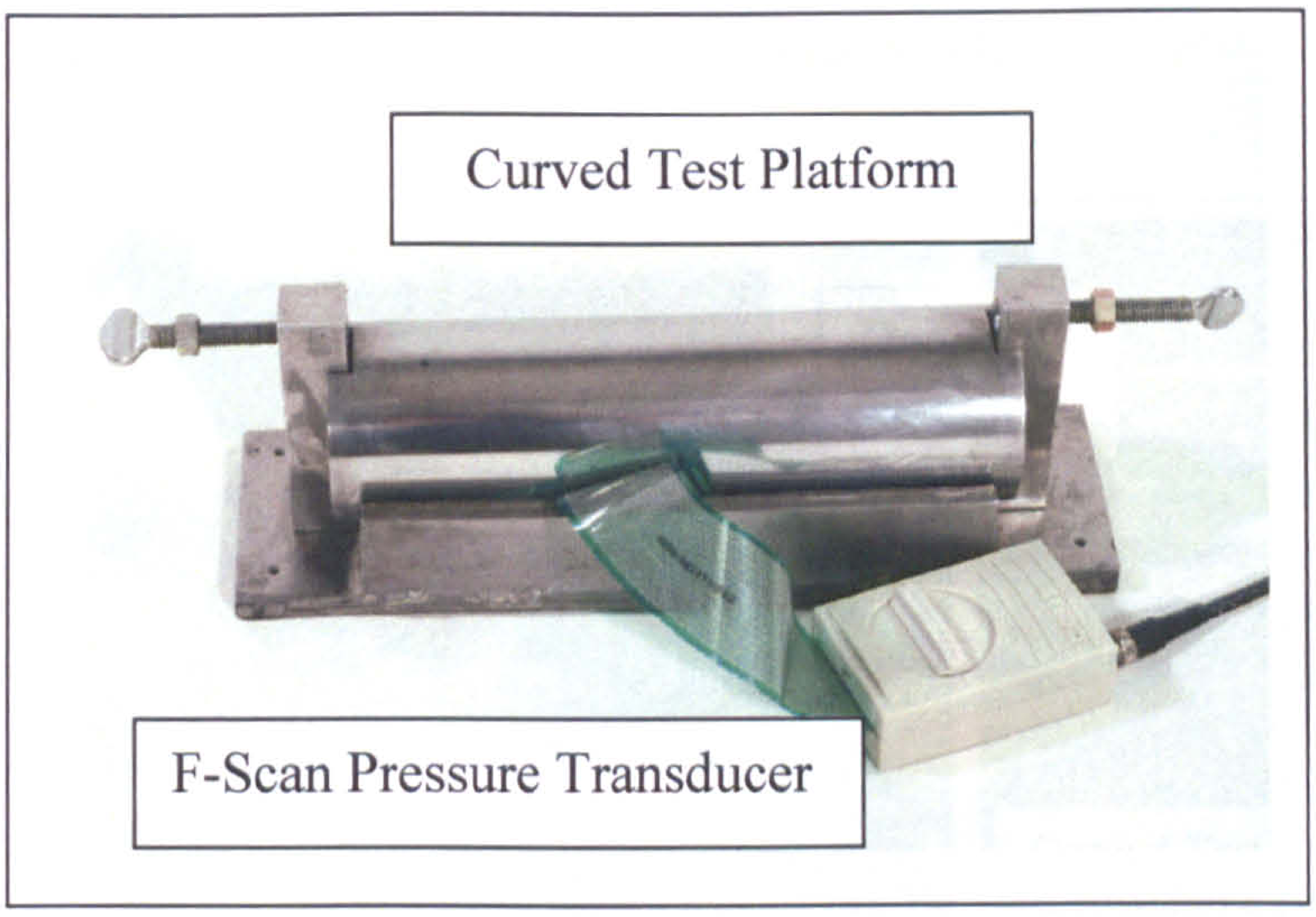

Figure 12: Curved Test Platform

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The characteristic behaviour of silicone can be compared with that of a liquid. Both are incompressible (stiff) when subjected to an external loading condition and both will flow from areas of high pressure to low pressure areas with constant volume. In a clinical application the flow of silicone is restricted within the prosthetic socket by the socket wall and patient's residual limb. This restriction of flow is simulated in the test platforms by locating the silicone between two metal plates. The test platforms described above ensured that the Tekscan transducers were accurately placed on either side of the liner surface in a controlled environment. (The liner was sandwiched between transducers and test platform).

Test Procedure

The silicone liner, including the sensors, was exposed to a dynamic loading environment. Reproducible and accurate loading conditions were applied by using a programmable computer numerically controlled (CNC) Deckel FP4NC milling machine. This machine has previously been tested for accuracy and validity (Buis et al., 2003) and shown to have an accuracy of 0.005mm. Gradual force was applied to compress the platform via a 10mm steel rod attached to the chuck of the Deckle machine, surrounded by a stiff spring with outside diameter 15mm. The spring prevented damage to either the test platform or the Deckle machine. A CNC program moved the head of the milling machine in a vertical plane to a displacement of 15mm in the at a frequency of 1 Hz, see Figure 13.

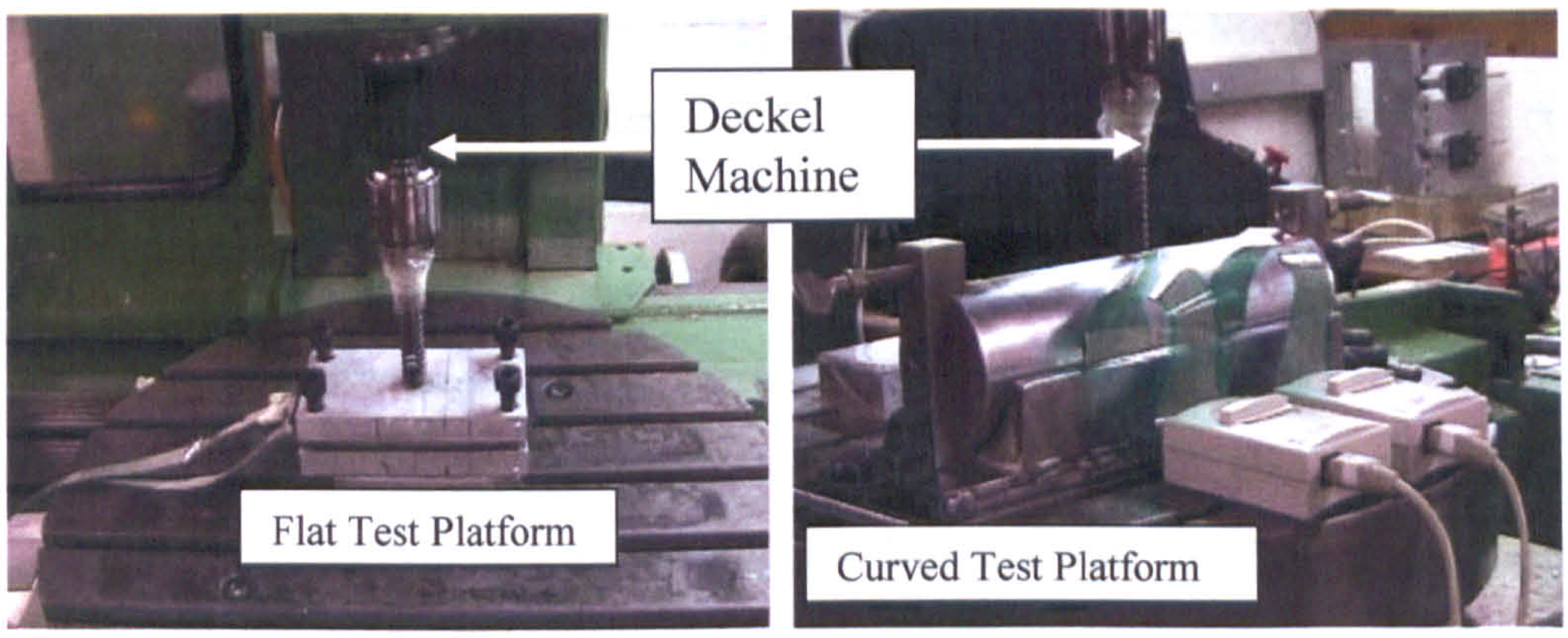


Figure 13: Test Platforms located on Deckel Machine

Five trials were performed to examine the consistency of data obtained from the transducers. The trials were carried out with one minute intervals in between in order to allow the transducers to recover. The platforms were clamped onto the Deckel machine, preventing movement during and between trials. The accuracy and consistency of the Deckel milling machine enabled us to compare the pressures applied to the silicone during each trial.

Different configurations of F-Scan transducers were examined in order to reduce the effects of transducer variances within the results. Initially one F-Scan foot transducer was placed on the upper surface of the silicone in the flat test platform. After five trials the platform was turned over and another five trials were carried out. In this way the transducers were not moved in relation to one another, only their positions with respect to the applied load and the silicone were altered.

Further tests were carried out using F-scan 9811 socket transducers. The single transducer array was split along the midline with one half placed on the underside of the silicone and the other on the upper surface. A simultaneous pressure measurement could then be obtained on both surfaces. These two areas were divided and identified using the F-Scan software. As with the foot transducers, the rig was turned over and the process repeated after a set of five trials.

The curved platform was used to examine the effects of curvature on the transducer. Following the same procedure as for the flat test platform, a F-Socket transducer was divided in two, half placed on either side of the silicone and then placed in the curved platform (position 1). The position of the transducer was recorded so as to ensure identical placement when the two halves were swapped over for the repeat trials (position 2). The five trials where carried out in position 1, then each half of the transducer was removed and placed on the opposite surface of the silicone, position 2. This procedure provided two sets of data for each half of the F-Socket sensor, namely above and below the silicone.

8.2.2 Results

Five trials were carried out for each of the transducer positions and test platforms. The consistency of the Deckel Machine allows us to concentrate on the average of each set of five trials rather than the five individual measurements.

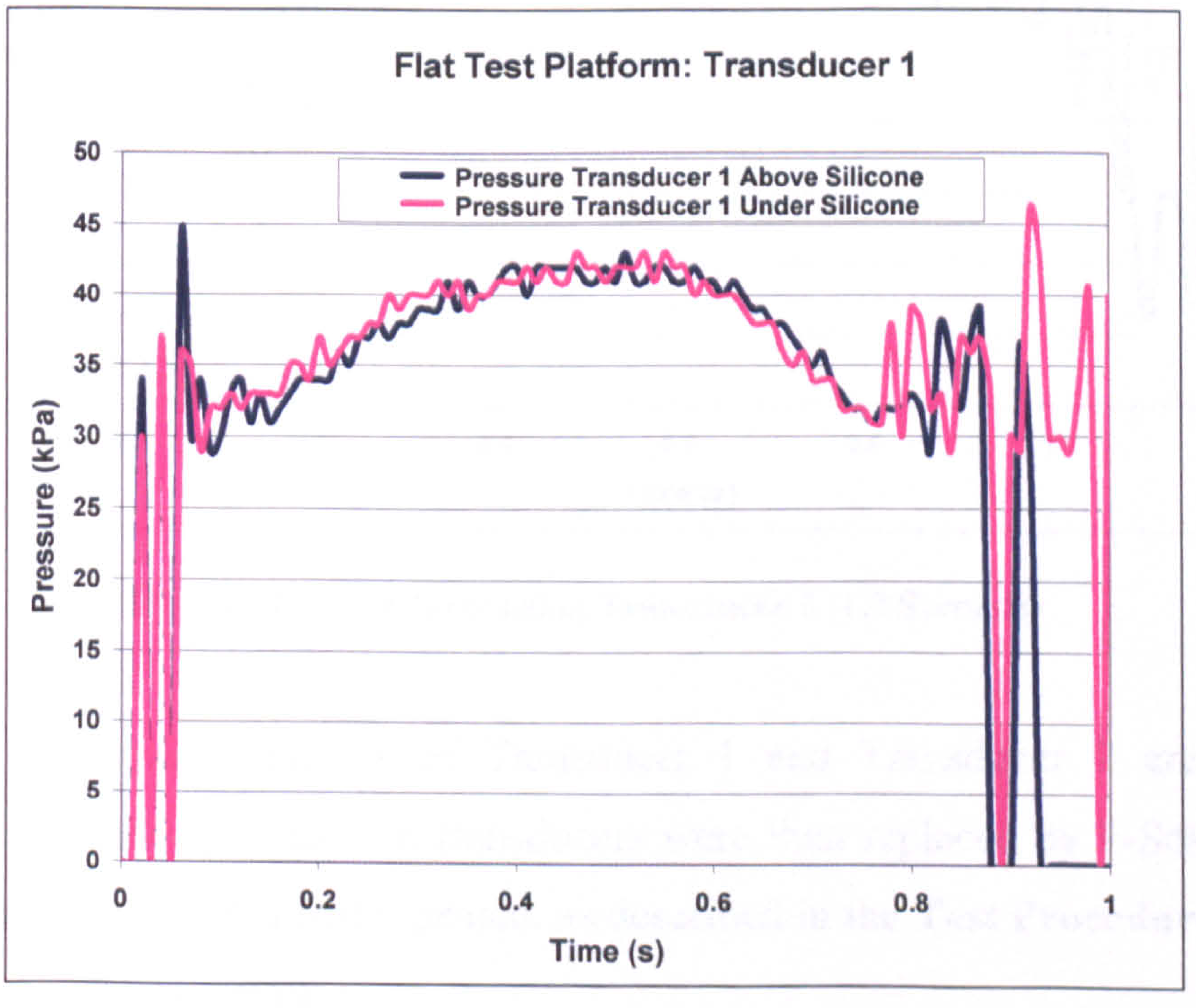


Figure 14: Flat Test Platform using Transducer 1 (1 Second)

Figure 14 indicates the pressure measured using the foot sensors and the flat test platform. Each trial lasted for 1 minute with cyclic pressures of 1Hz, although for the purposes of clarity only a 1 second sample of data has been displayed. It can be seen that when the transducer was moved from one surface of the silicone to the opposite surface (changing the position of the transducer with respect to the applied pressure) there was very little effect on the pressure recorded by Transducer 1. The test was repeated using a different transducer and the results are presented in Figure 15. These show that a small difference is observed when the position of the transducer is changed from one side to the other. These differences are of the order of 2kPa (0.8% of maximum pressure).

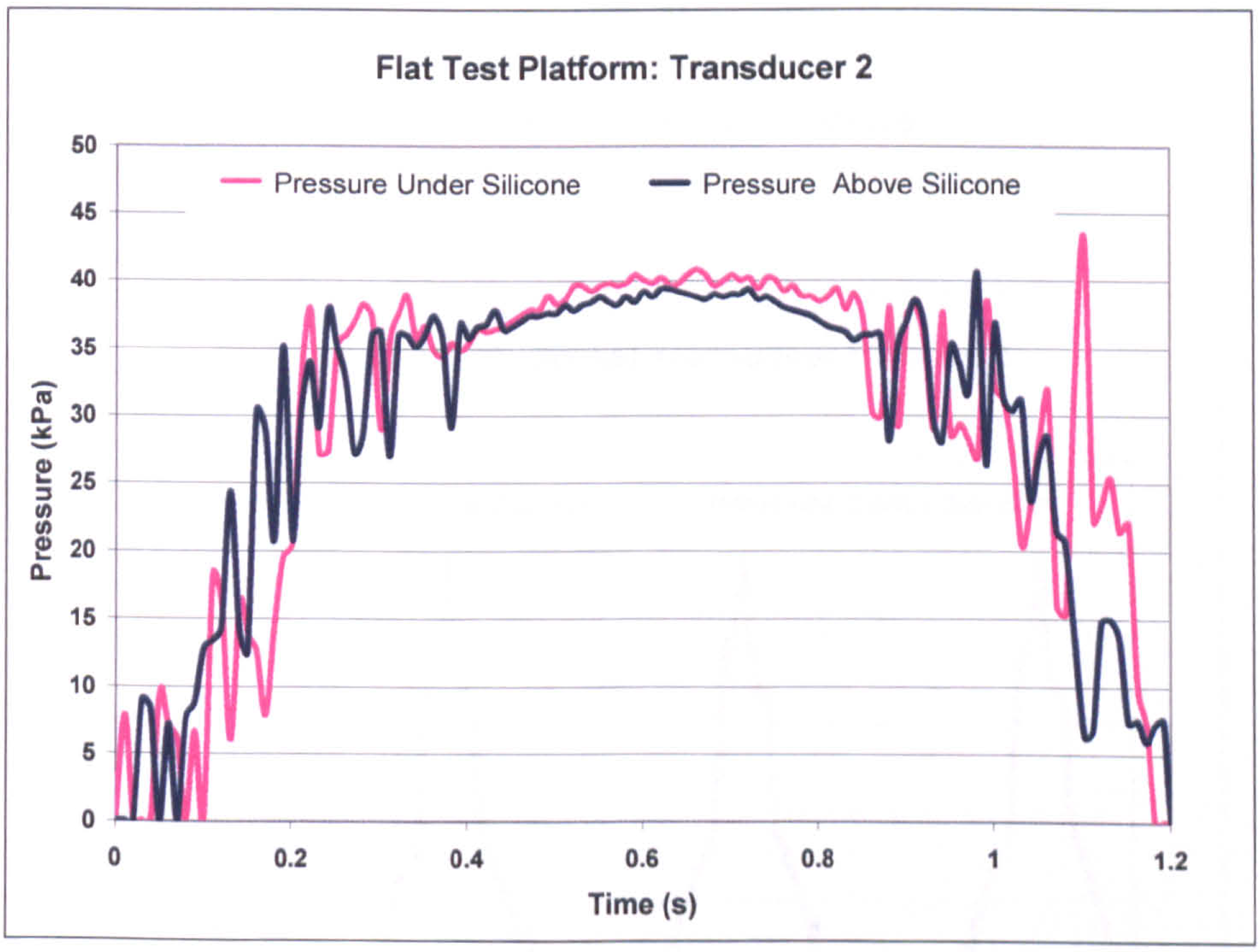


Figure 15: Flat Test Platform using Transducer 2 (1.2 Seconds)

The peak pressures of Transducer 1 and Transducer 2 are 42kPa and 40kPa, respectively. The foot transducers were then replaced by F-Scan socket transducers and the experiment repeated, as described in the **Test Procedure** section. The results are shown below.

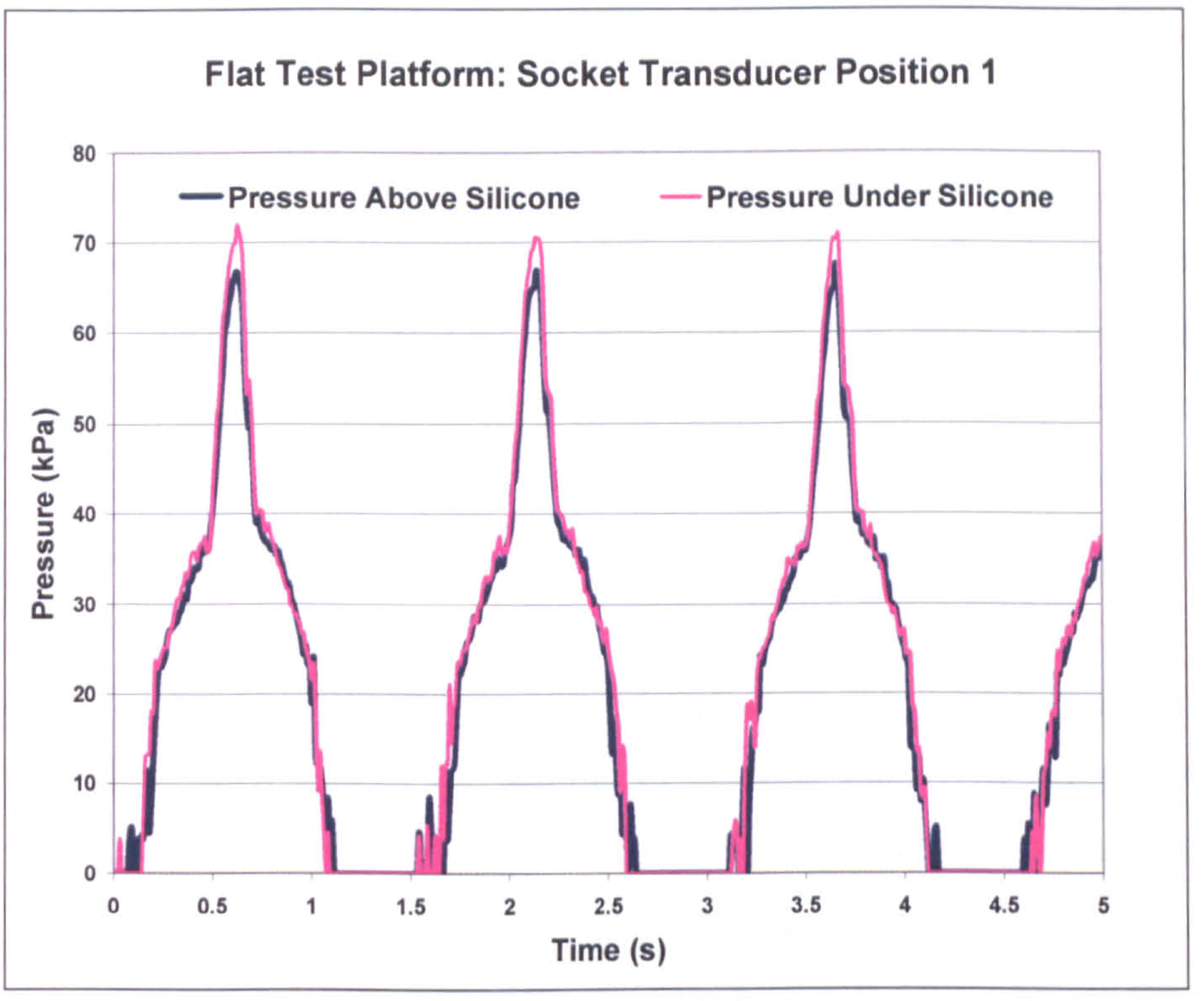


Figure 16: Flat Test Platform: Socket Transducer Position 1

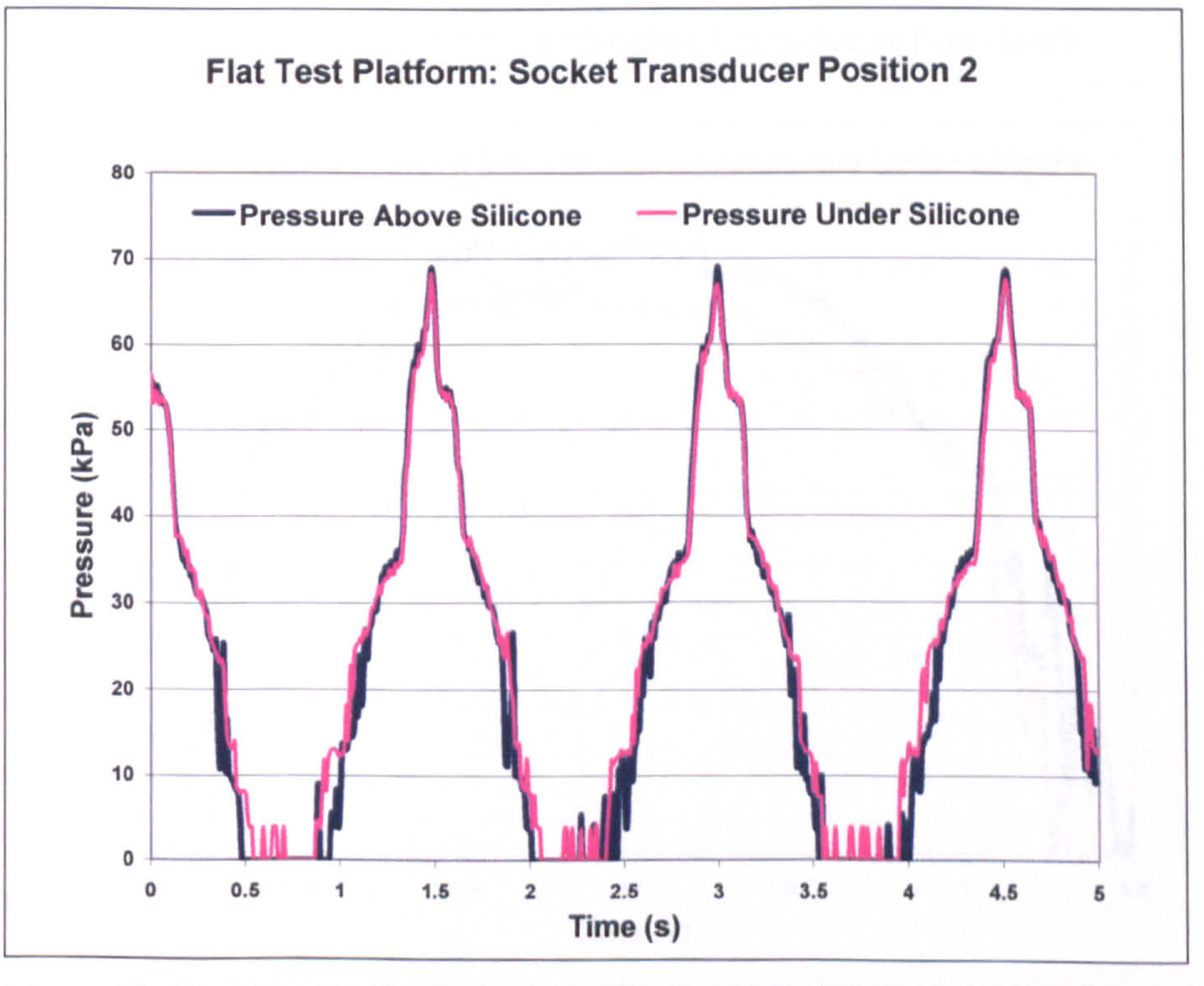


Figure 17: Flat Test Platform: Socket Transducer Position 2

Figure 16 and Figure 17, display five seconds samples of the recordings of a 1 minute trial. The shape of the graphs shows the gradual increase in pressure as the spring was compressed, and then a sharper increase as the head of the milling machine continued it's downwards movement onto the test platform. In the first configuration there is a small difference in the peak pressure between the two halves of the transducer array, indicating a difference above and below the silicone. When the rig was turned over to position 2, no pressure variation between above and below could be observed.

Next, a curved platform was utilised and again the F-Scan socket transducers were placed on each side of the sample of silicone liner. The same test procedure was carried out, and the displacement of the milling machine was reset to 15mm. Figure 18 shows the pressures for 1 loading cycle above and below the silicone in position 1, while Figure 19 illustrates the pressures after the transducers have been swapped over, position 2.

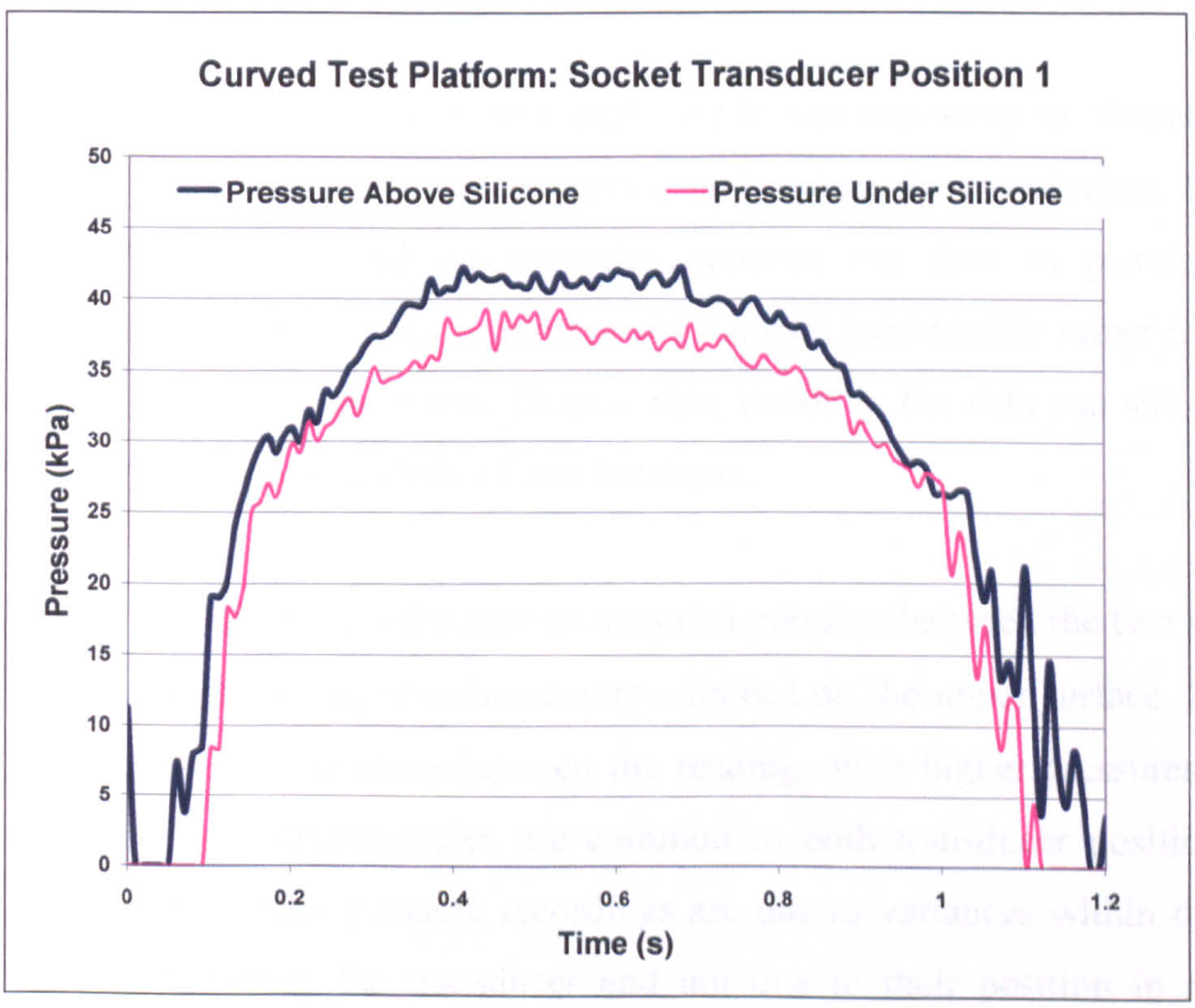


Figure 18: Curved Test Platform using Socket Transducer (Position 1, 1.2.seconds)

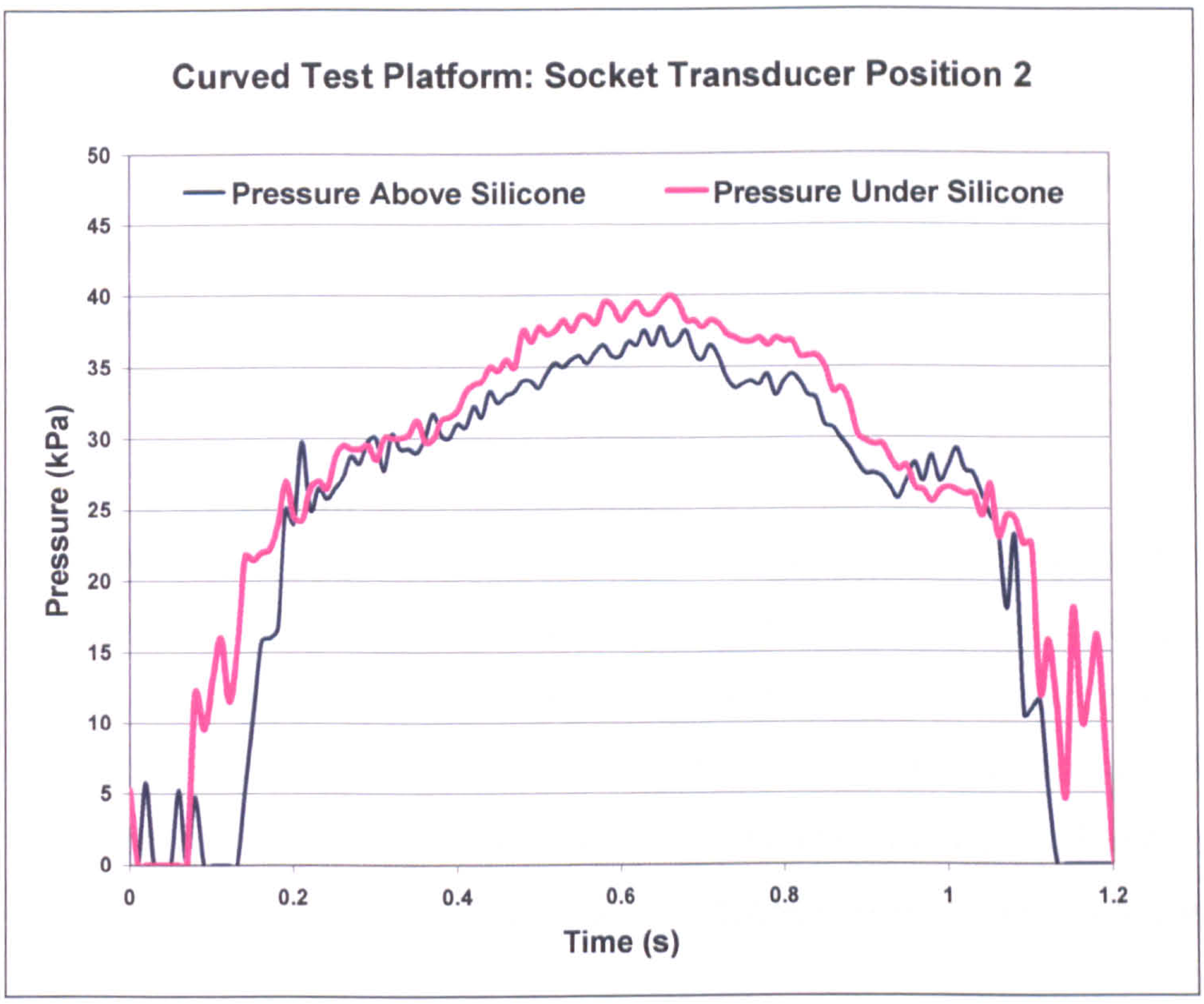


Figure 19: Curved Test Platform using Socket Transducer (Position 2, 1.2 seconds)

When the transducers were swapped over it was necessary to dismantle partly the curved test platform in order to remove and replace the transducers. This procedure could have introduced discrepancies between the data in positions 1 and 2. Therefore, the data for each position is examined individually rather than comparing results for the two positions. Despite this, trends in the data can still be compared, thereby justifying our study of two locations.

Figure 18 indicates a difference in recorded pressure between the two surfaces of the silicone, with the larger measurement obtained on the upper surface. Figure 19 also indicate a small variation between the readings with higher pressures on the under surface. These discrepancies are common to both transducer positions. Therefore differences in peak pressure recordings are due to variances within the response of the two halves of the transducer and not due to their position in relation to the silicone.

Figure 14 to Figure 19 above, as mentioned earlier, represent the average pressure from each of five trials performed. This reduces the quantity of data displayed (as each trial comprised of over 6000 samples) and allows easier comparison of pressure measurements. Due to the Deckel machine introducing noise into the results, several of the trials show inconsistent peaks.

8.2.3 Discussion

The aim of this study was to investigate the load transmission pathway through a silicone liner. The main objective was to investigate pressure measured on one surface of a silicone liner and compare it to that obtained on the opposite surface (the skin boundary and socket boundary), when subjected to a controlled loading condition. Understanding the behaviour of silicone will help facilitate the placement of transducers in a study of stump/socket interface pressures in silicone liners.

Experiments have been carried out using platforms that simulate the conditions expected within a prosthetic socket, whilst maintaining a consistent and reproducible environment in which to carry out tests. The results obtained from this study indicate that there is a small variation in the interface pressure measured on either side of the silicone liner using Tekscan F-Scan pressure transducers. However differences measured show no relationship to the orientation of the transducer placement. Results should not be seen as conclusive for silicone behaviour. Further work will be needed to investigate if the data obtained using the F-Scan system is consistent with other pressure measuring devices. However, the aim of this preliminary study has been achieved in determining the suitability of the F-Scan transducer placement for future studies.

Limitations

The test platforms used have only uniform surfaces and do not accurately reproduce the complex contours of the prosthetic socket. The recording provided information about the transfer of pressure through the silicone liner, however an additional interface pressure will be measured at the surface of the residual limb, created by the compression of the silicone liner once rolled over the residual limb. Therefore the pressure measured on the outside of the limb is an underestimate of the pressure at the limb/liner interface. The milling machine used as a consistent and reproducible pressure generator itself introduced problems as it generated an amount of noise that disrupted the F-scan system output. Despite these boundaries, it is the authors' opinion that the results obtained will enable further studies into the interface pressure of the prosthetic socket.

8.2.4 Conclusion

This pilot study has examined variations in peak pressure readings when measuring pressure at different locations on a silicone liner using the F-Scan system. It was shown that small measured pressure differences on either side can be attributed to variations in the individual transducer responses rather than influences from the silicone. This preliminary study demonstrates that stump interface pressures generated in patients wearing silicone liners can be obtained by placing the sensors between the socket wall and the liner. Most importantly, measuring pressures in this way will cause no disruption or impairment to the suspension of the prosthesis.

8.3 Calibration Platform Validation

Prior to inviting subjects to participate in the study, a strict protocol was devised to produce a reliable method of recording the interface pressure at the stump/socket interface. Preconditioning, Equilibration and Calibration produce the most accurate response from the transducer if they are performed when the transducer is placed in situ. To undertake these procedures a platform was designed and built which enabled a controlled sequence to be undertaken. Several requirements were needed for a successful device to be made. The tool also needs to produce a repeatable procedure for any trans-tibial socket and be able to house a prostheses of any size without the need to interfere with the alignment or shape of the prosthesis. The system would also be used whilst the patient was waiting in the clinic, therefore the procedure needed to be quick and reliable.

8.3.1 Calibration Platform

The calibration platform shown in Figure 20 was constructed with these factors in mind. The tubular steel frame creates a rigid basis for applying air pressure to the socket.

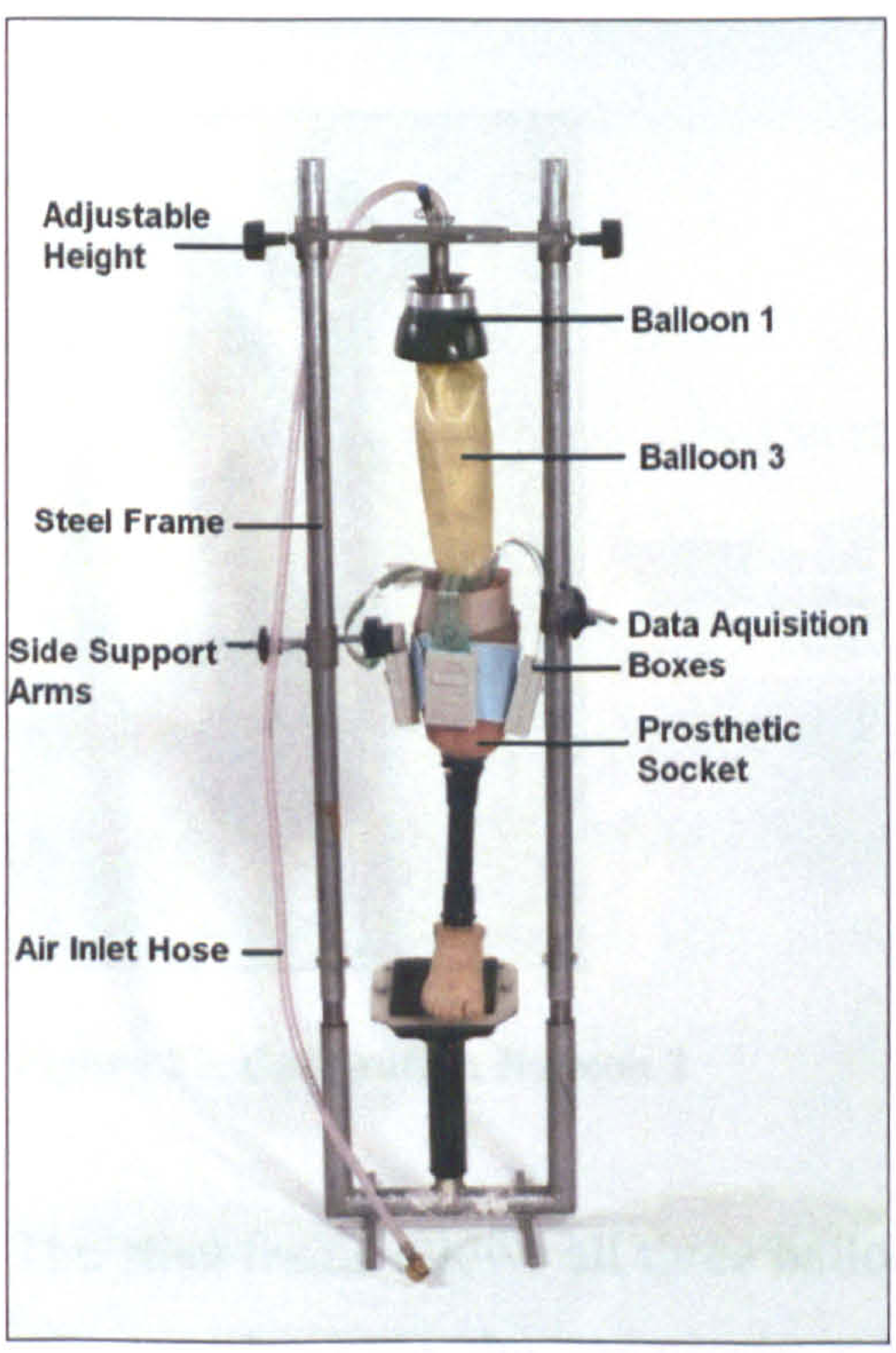


Figure 20: Calibration platform with prosthesis in situ

Three air filled balloons are used during calibration. Balloon 1, Figure 21 and balloon 2, Figure 22, minimise the volume of the socket, a third is inflated to generate the required pressure for preconditioning, equilibration, and calibration. A regulator provides timed air pulses to inflate the outer balloon at a known pressure. The balloons enable a uniformly distributed pressure to be administered over the socket wall.

Figure 21: Calibration Balloons

Figure 22: Calibration Balloon 2

The steel frame allows all three balloons to be moved down inside the prosthesis and is secured within the prosthetic socket, Figure 23. A webbing strap is wrapped around the proximal end of the socket to minimise any deflection caused by the increase in pressure within the socket. Adjustable side arms on the frame reduce deflection of the socket and stabilise the prosthesis.

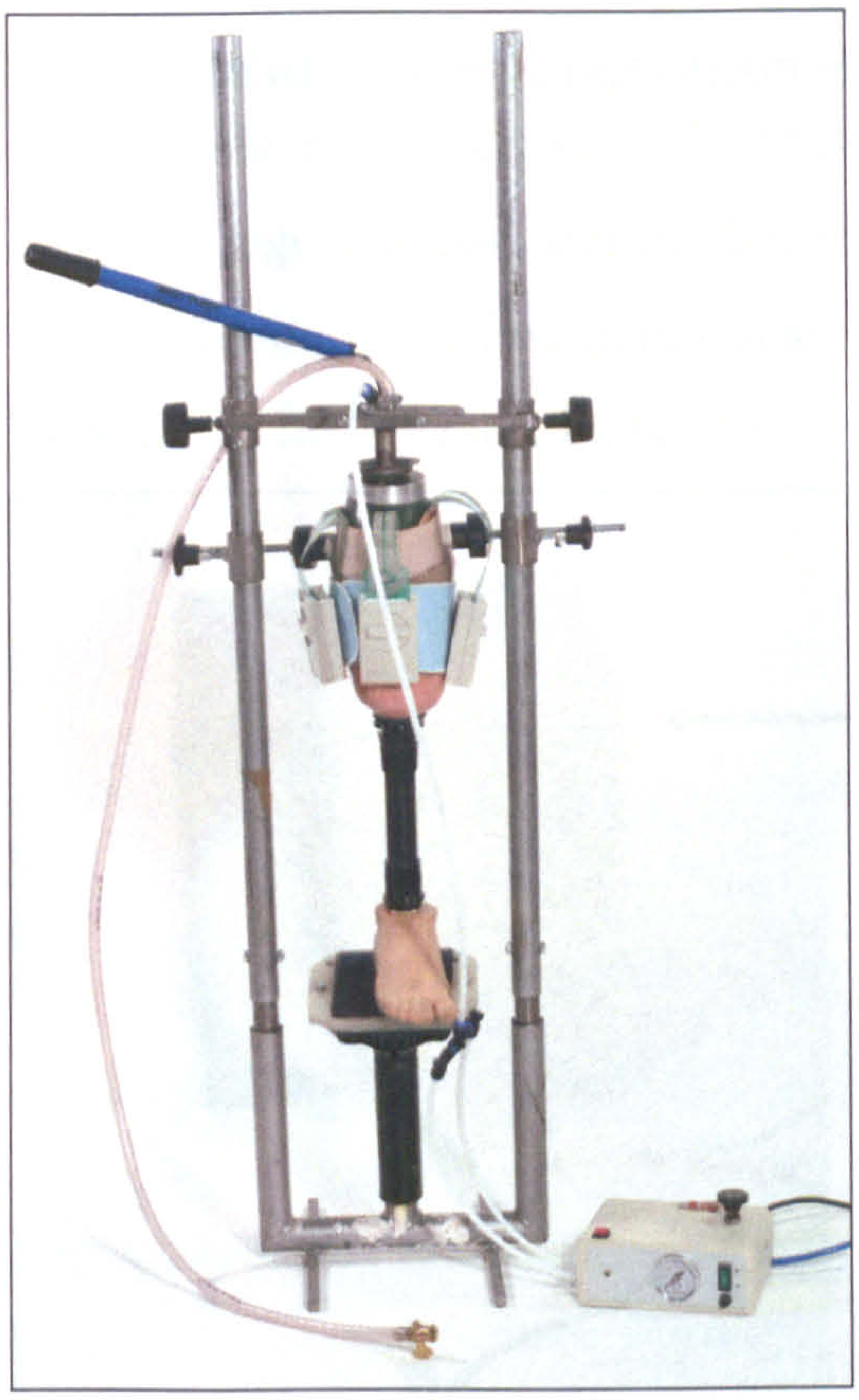


Figure 23: Calibration platform during calibration

Balloon 1, Figure 21, fits around inside of the proximal opening of the socket. This balloon is inflated by a bicycle pump and forms a rigid seal, reducing the movement of the calibration device when the other balloons are inflated. Balloon 2, Figure 22, is situated inside balloon 3. This smaller balloon is an adjustable spacer, capable of being inflated to reduce the volume inside the prosthetic socket. Using a tap within the air line the volume of this balloon can be adjusted to fill the volume within the socket, but not creating any pressure on the socket walls. Using the F-Scan transducer outputs the pressure can be adjusted until no contact pressure is recorded.

Balloon 3, Figure 21, is filled with air using a high pressure air line. When inflated the balloon creates a pressure inside the socket. The air line is regulated via an electronic timing box so the inlet pressure can be measured and delivered in a dynamic pattern for preconditioning of the transducers.

8.3.2 Validation of Calibration Bladder

An Entran® transducer, model ELFM-B1-25N was used in order to check the output of the air regulator box, and validate the output response of F-Scan within the socket after calibration. The Entran transducer is connected to LabVIEW software produced by National Instruments, Figure 24.

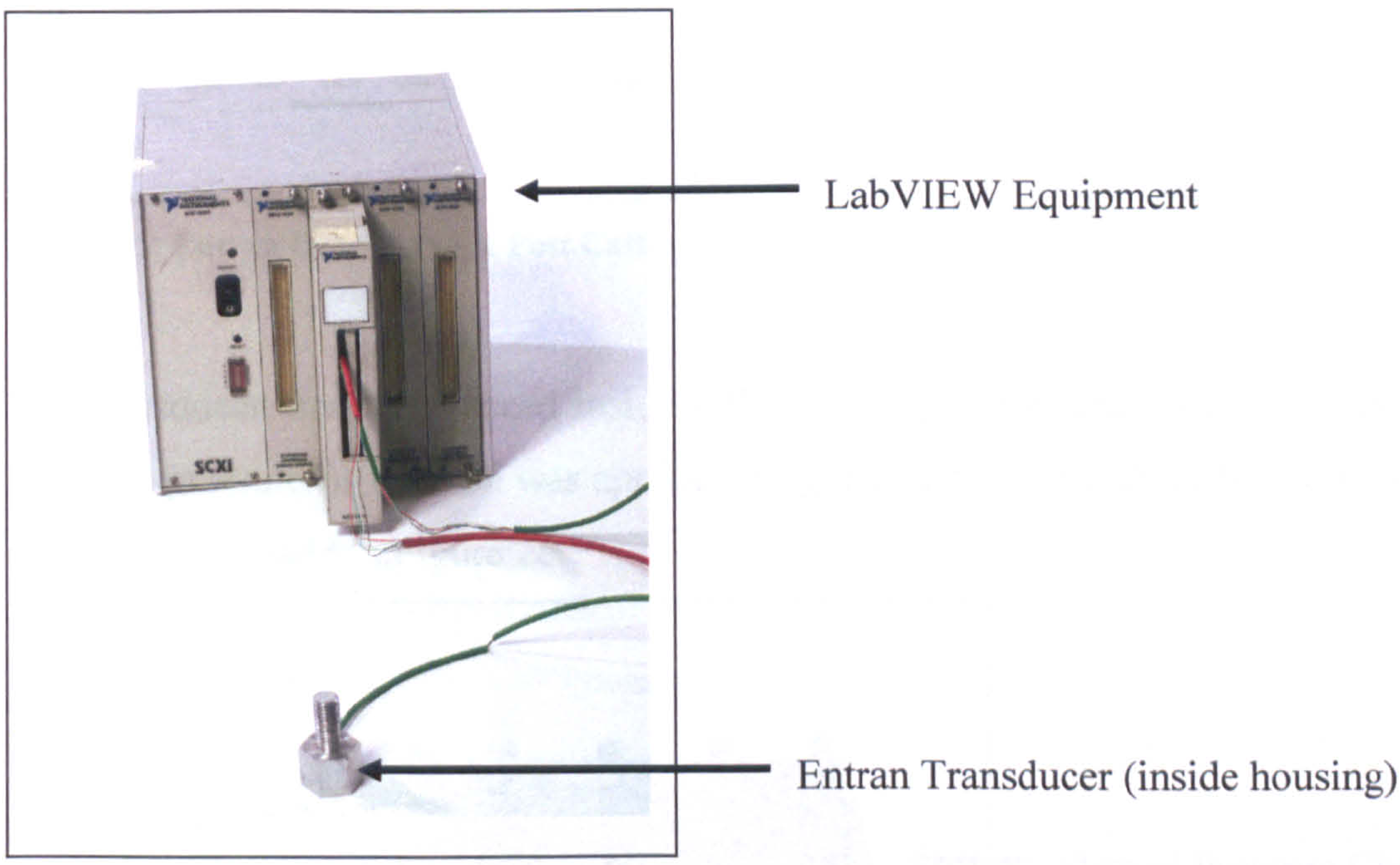


Figure 24: LabVIEW Equipment and Entran Pressure Transducer

This was performed to attain confidence in the readings obtained during patient trials. Normal controlled conditions using a flatbed air chamber could not be used as the F-Scan transducers were placed in situ. So validation was sort implementing Entran pressure transducers.

8.3.3 Calibration of the Entran Transducer

The Entran pressure transducer was calibrated independently using known weights. The voltage output from the Entran transducer was recorded. Having completed the pre calibration procedure, the data obtained from the graph was added to the processing software to calibrate the transducer. A second graph was then plotted, which shows the pressure output for the known applied weights, Figure 25.

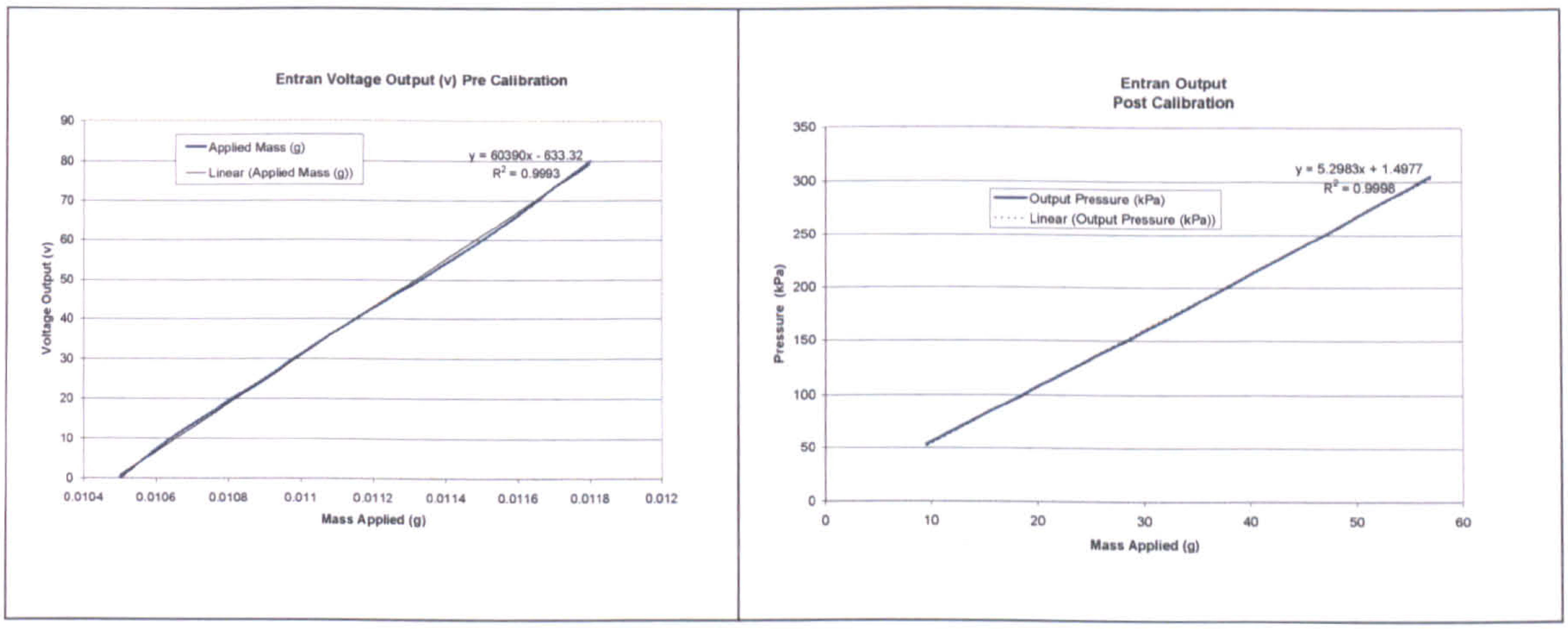


Figure 25: Entran Output Pre & Post Calibration

The transducer was then placed inside a flatbed air pressure chamber and a known dynamic pressure of 100 kPa was applied using the same air regulator box as used to inflate the air bladder, Figure 26.

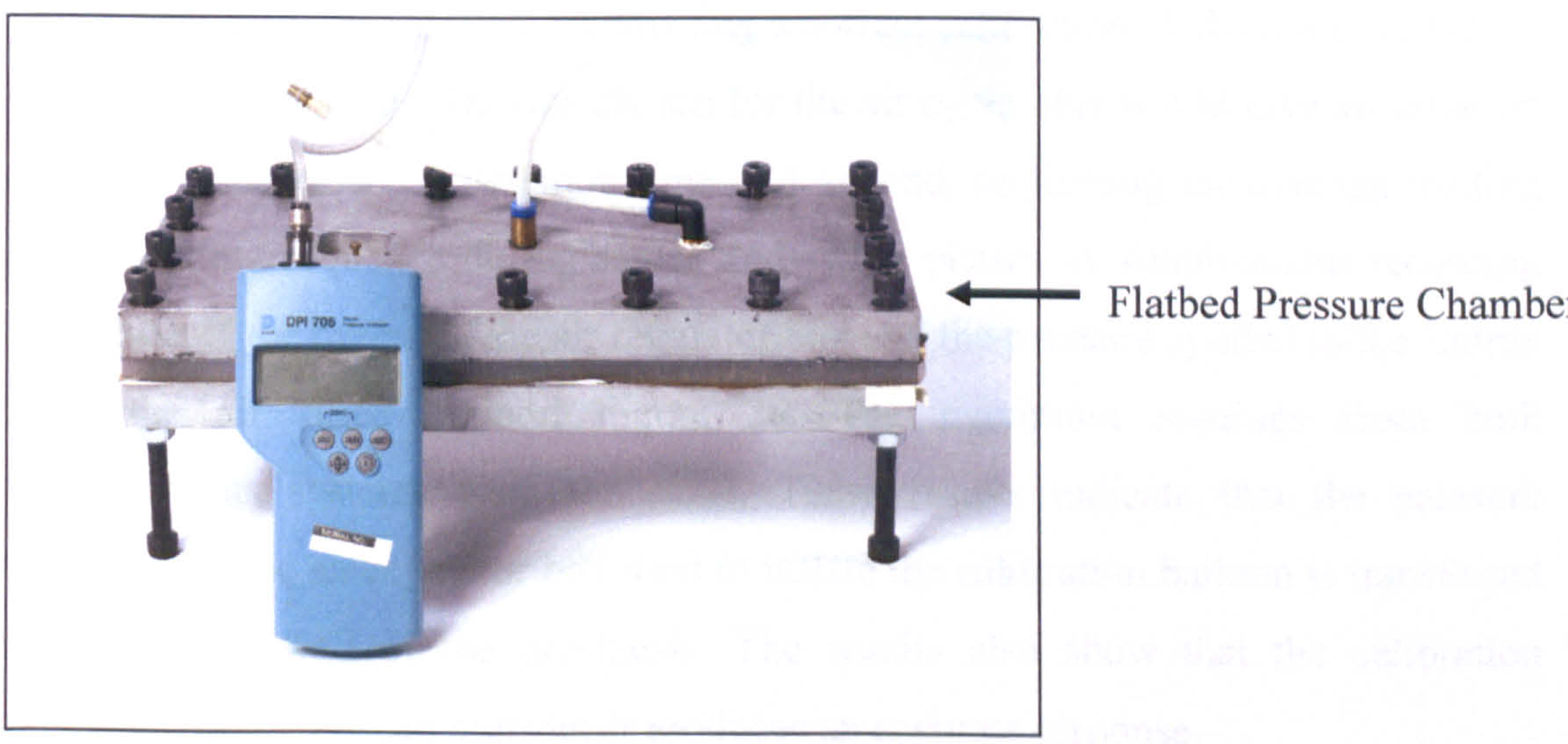


Figure 26: Flatbed Pressure Chamber

Figure 27 shows the pressure readings obtained from the flatbed, identifying consistent readings to those obtained from the air regulator box.

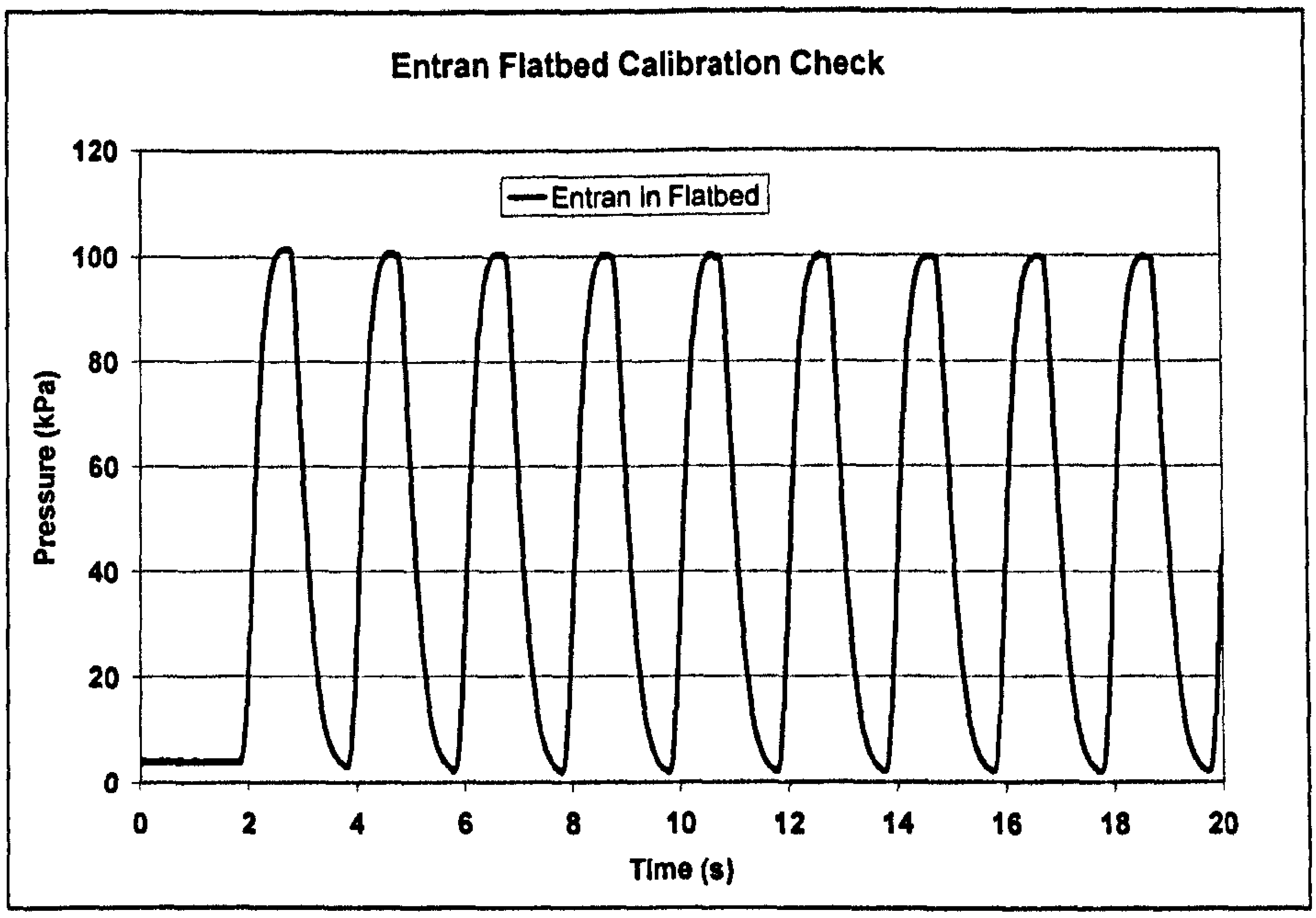


Figure 27: Entran Output inside Flatbed

8.3.4 In Socket Validation

Mounting holes were made on the experimental prosthesis socket through which the transducers were placed after establishing a correct calibration. A dynamic air supply with a frequency of 0.5 Hz was chosen for the air cycle, this would give an inflation time of 1 second, and a deflation time of 1 second, replicating the average loading and unloading sequence during stance and swing phase. A simultaneous recording was made of the output of the air regulator box and the pressure applied to the Entran from the air filled balloon Figure 28. The maximum readings from both measurements systems were the same. These results indicate that the pressure produced by the air regulator box used to inflate the calibration balloon is transferred to the socket wall of the prosthesis. The results also show that the calibration procedure of the F-Scan transducer produces an accurate response.

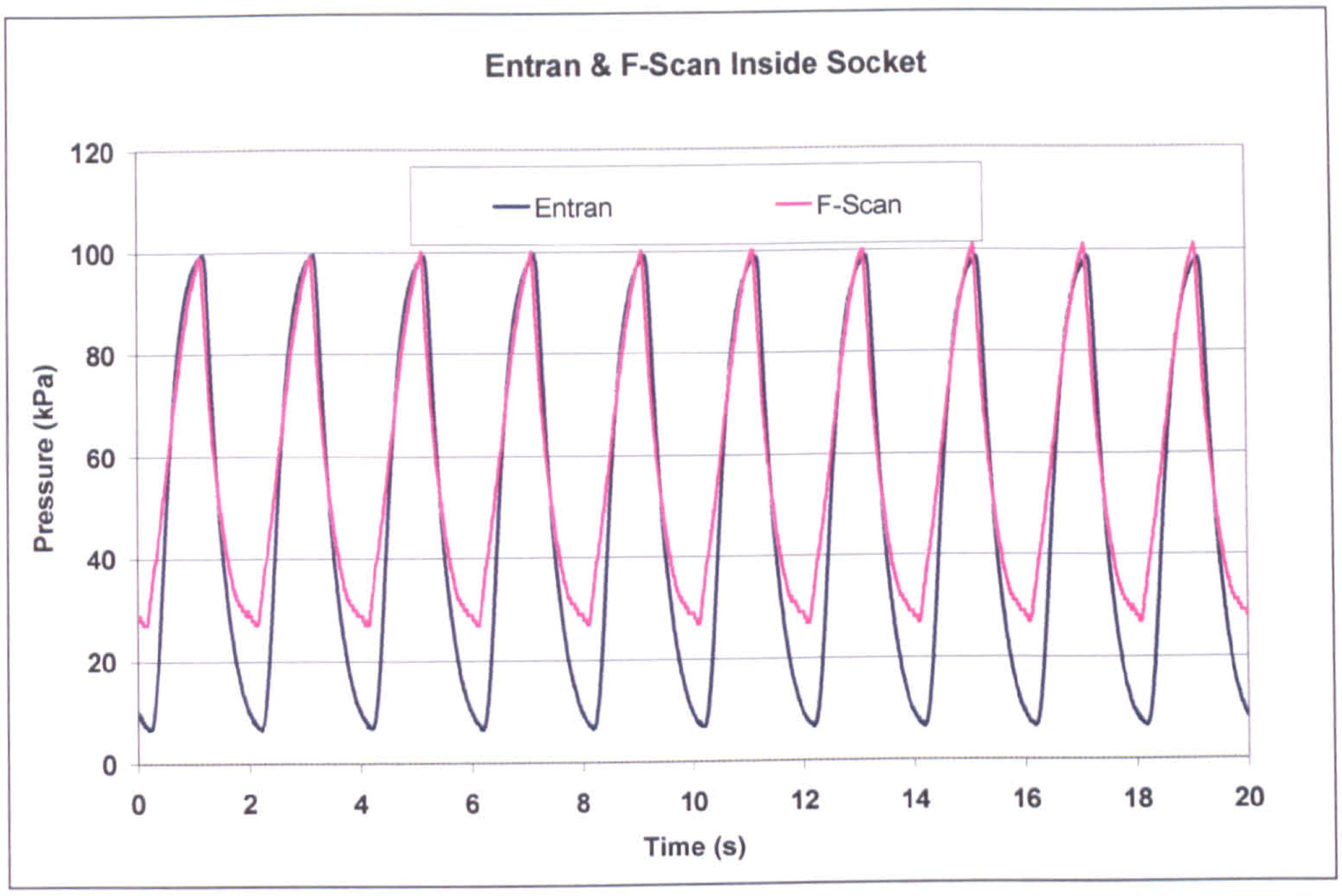


Figure 28: Simultaneous Recording of Entran & F-Scan Transducer

It can be seen that the minimum pressure for both systems does not reach zero. The frequency of inflation resulted in the balloon re-inflating before the interface pressure reduced to zero. It can also be seen that the F-Scan readings are 20kPa higher than the Entran transducer when a minimum recording is reached. This was due to an inherent error within the data acquisition stem which consistently recorded a interface pressure of 20kPa on one of the cells. Although this error affects the minimum interface pressure recorded, it did not interfere with the maximum pressure recordings. This showed that the applied pressure at the air regulator box was being transferred to the socket wall by the air filled bladder. Using this information calibration of the prosthetic socket transducers could proceed.

8.3.5 Summary

The calibration platform designed for this investigation allows accurate calibration of the F-scan socket transducers to trans-tibial prosthesis of different sizes. The steel frame construction enables a uniform dynamic interface pressure to be applied to the F-Scan socket transducers whilst the transducers are in situ within the prosthetic socket. The calibration protocol was checked using Entran pressure transducers mounted inside a flatbed chamber. The Entran pressure transducers were also used to ensure that the interface pressure applied via the inflated calibration balloon was accurate. The results indicate that the calibration procedure for the pressure transducers is reliable and accurate. Using this procedure to calibrate the F-Scan pressure transducers in situ will increase the accuracy and reliability of the interface pressure measurements recorded as the subjects walk on their prostheses.

8.4 Activity Monitor Comparison

Eight ActivPAL activity monitors were used during this study enabling several subjects to participate in the project simultaneously. Details of these monitors can be found in section 9.2.3 on page 128. Monitors were selected at random, and given to each subject over the course of the project. The reliability of each monitor needs to be tested to ensure that the monitor selection does not affect the calculated activity of the subject. Studies have been performed to determine the reliability and validity of the ActivPAL monitors. These have shown excellent interdevice reliability (Grant et al., 2006). These tests were performed over a relatively short time period (mean duration 38.7 minutes). Another study involved subjects walking on a treadmill at predetermined walking speeds for approximately 5 minutes and over a 500 meter course (Ryan et al., 2006). These studies were designed to investigate the monitors' reliability when compared to external monitoring methods. Results were encouraging for the period in which the devices were used. Intraclass correlation coefficient (ICC 2,1) of between 0.78 and 0.99 indicated that a good reliability exists between monitors. However these studies have not shown that the monitors are accurate when recording over a longer time period, which will be required in this current investigation.

To allow for a daily activity recording of each subject in this study, the monitors will be required to record data over a 24 hour time period. One 24 hour period will be selected from a recording period of one week. By recording activity over one week the daily fluctuations in activity will be seen and permit a representative daily activity level to be analysed. This preliminary investigation was designed to provide information as to the reliability of the monitors over a longer period than has previously been investigated. It was the purpose of this investigation to determine the inter device reliability, not the accuracy of the device in recording the leg movements. Accuracy has previously been reported.

8.4.1 Method

A normal subject was chosen to wear the monitors in each trial. The same statistical analysis methods were performed on the results of this study as were performed on the earlier studies by Grant and Ryan. This enabled comparisons to be drawn.

During this preliminary investigation all eight monitors used in the larger project were randomly paired together before each trial. These monitors were placed in a specially designed neoprene cuff manufactured to fit around the lower leg at a position just above the ankle. Each cuff had space to securely accommodate a pair of monitors. One monitor was placed on top of the other. In this orientation both monitors would be at identical heights from the ground, and both would face in the same direction. The monitors were programmed and switched on and placed in the cuffs. The subject wore each pair of monitors for 24 hours whilst performing normal daily activities.

8.4.2 Results

The subjects wore the randomly selected pairs of monitors in the ankle cuffs. A total of 20 successful trials were completed. Intraclass correlation coefficient (ICC 2,1) analysis was performed to determine the inter-device reliability of the monitors. Reliability for the 24 hour time period was excellent (0.997).

8.4.3 Discussion

Longer term reliability between the ActivPAL monitors was required for the purposes of this investigation. Analysis of the data obtained from the monitors suggested a high degree of consistency between the monitors. The results confirm the shorter term results measured by Grant that ranged from 0.78-0.99 (Grant et al., 2006). This reliability would be important when comparing recordings from several subjects over a 24 hour period.

8.5 Chapter Summary

The three preliminary studies described in this chapter supplement the investigation methodology by providing information which has influenced the development and subsequent analysis of data collection. Using information gained from these studies the following study methodology was formulated.

9 Methodology

9.1 Methodology Introduction

The methodology chapter is subdivided into three sections, **Experimental Design, Display of Results** and **Analysis of Results**. Experimental design refers to the protocol set out whilst conducting the investigation. The Display of Results section outlines the processes in place to transform the data captured by the three outcome measures and physical measures taken from the subject. The final section is the Analysis of Results, statistical methods for interpreting the outcome measures are detailed in this section.

9.2 Experimental Design

The investigation was implemented following funding from Action Medical Research (AMR) and ethical approval granted by the Local Regional Ethics Committee and University Ethics Committees (Ref EC/03/S/66). Subjects from the West of Scotland Mobility and Rehabilitation Centre (WESTMARC), based at the Southern General Hospital situated in Glasgow, were invited to participate in this study. The participants recruited had established unilateral amputation of at least one year and had been wearing their current prosthesis on a daily basis for considered normal activities of living for at least 6 months. The use of the subjects existing socket is possible because the pressure sensors will not interfere with the socket configuration.

Two subject groups were created, dependant upon the prosthetic socket intervention used on the subjects own prosthesis. Half of the selected subjects had been using trans-tibial prostheses with a "hands off" design. The other half of the selected subjects had been using prostheses with a socket with a "hands on" concept.

9.2.1 Preparations for Subject Trials

Before the experimental trials took place, preparations were made to ensure that the time each subject spent in the clinic was used as efficiently as possible. Each subject was assigned a trial identity number unique to this study. During subject trials a patient documentation pack consisting of:

1. An **Information Sheet,** outlining the procedures performed and the reasons for investigation, Appendix 1 .
2. A **Consent Form** for agreement to participate in the study and a video image consent form was also included, Appendix 2.
3. A **Patient Information Sheet** was prepared in order that correct and consistent information be sought from each subject. The data asked in this sheet included general demographics and measurements taken of subjects residual limb.
4. **Transducer Configuration Sheet.** Each socket transducer was required to be trimmed to an individual shape to fit the unique shape of the subject's prosthetic socket. A record of this shape is noted for future reference, Appendix 4.
5. An **Activity Monitor** is placed in the pack, along with a record of the monitor's reference number.
6. A **Special Postal Delivery Envelope** is included in the pack; enabling each subject to return the activity monitor in a safe and reliable manner.
7. The **PEQ** is also included in the pack.

This pack ensured all documents were available during the subject trials.

The six F-Scan transducers required for use with the subject were allocated. Equilibration was performed on the foot transducers in the flatbed air chamber prior to contact with the subject. A note was taken of the activity monitor so that data could be traced in future analysis.

Information and Consent

A reliable and repeatable test protocol was created and rigidly followed so that data from the different subjects could be compared.

The letter sent to subjects, inviting them to attend the investigation provides a brief outline of the research area. The subject was requested to bring a spare prosthesis or stump shrinker for use whilst their prosthesis was taken away for instrumentation. This reduced the likelihood of swelling of the residual limb, thus compromising the pressure study.

Upon arrival at the clinic the subject was introduced to the project. It was explained about the need for a large population study into the effects of socket comfort with possible implications to both the patient and to the Health Service. The subject received the introduction sheet outlining the three main areas, from which data will be gained, Appendix 1. These were the pressure study, attachment of an activity monitor and the questionnaire. Time was spent explaining these three areas before the subject signed the consent form, Appendix 2. Each subject was given the opportunity to express any concerns and have questions answered regarding the study. University expense forms were given to the subject enabling them to be reimbursed for any travelling expense incurred.

Preparing the Subject for Investigation

Having given consent, each subject was asked to remove their prosthesis. Measurements of their residual limb were taken and information gathered with regard to the cause and time since amputation. This information was used to determine subject demographics of each group during analysis of the results. The residual limb measures are used to calculate surface area, and volume of the stump.

Residual Limb Measurement

Circumferential measures were taken of the residual limb at two levels by the researcher. The proximal measure was taken at the level of the patella tendon. The second measure was taken at a point towards the distal end of the limb, see Figure 29.

Figure 29: Location of circumferential measures

The distance between the two circumferential measurement points and overall length of the residual limb was also measured using a residual limb measuring stick. Using these measurements the surface area and volume of the residual limb was estimated.

Placement of the ActivPAL Activity Monitor

The activity monitor was attached onto the outside of the prosthesis using adhesive tape which can easily be removed. The use of the monitor was explained to the subject, including that the monitor will record all movements of the leg whilst they are wearing the device. In most cases the subject was given a special postal delivery envelope in order that they could return the activity monitor after a period of one week. These envelopes provided a reliable and secure method of retrieving the activity monitors without the need to bring the subjects back to the clinic.

Completion of Subject Demographic Information

In addition to placing F-Scan socket transducers inside the prosthetic socket, F-Scan foot transducers were placed in each of the subjects shoes to record the foot position during the gait cycle. At this stage the subject's weight and shoe size was confirmed, this data was needed for the calibration procedure of the foot transducers. Obtaining the information at this point meant preparations could be made for the pressure study. The foot sensors were trimmed to fit the subject's shoe shape.

Prosthesis Evaluation Questionnaire

The patient was instructed to sit at a desk to complete the Prosthetic Evaluation Questionnaire (PEQ). A list of the questions can be found in Appendix 3. A wheelchair was made available for each subject to use during the time they were not wearing their prosthesis. Each subject filled in the questionnaire themselves. This insured no influencing factors made upon the placement of the response check marks. Whilst the subject was completing the PEQ, their prosthesis was taken to be instrumented and transducers calibrated.

Subject Trials

After finishing the calibration procedure, the prosthesis was returned to the subject. Whilst the subject donned the prosthesis, the two foot transducers were connected to the computer and the video camera set up. Each of the six channels from the F-Scan data processing box were connected to their corresponding transducers and data acquisition boxes positioned to allow ease of walking by the subject.

Walkway

A predetermined walkway was created in the clinic room; this was identical for all subjects. Markers placed on the ground identified the area in which the video camera recorded the foot position. It has been shown that it takes approximately two steps to initiate and terminate gait (Miff et al., 2005). Therefore the walkway was flat and 15m in length to allow several steady state cycles to be recorded. Reproducing a "typical" walking environment within the clinical setting is not possible. The effects of the clinical environment were minimised by allowing the subject to be relaxed, reassured and familiar with the environment. Before undertaking any recording in this study, subjects were asked to walk several lengths of the walk way in order to establish a comfortable walking pattern and become accustomed to the instrumented prosthesis. It was important when measuring interface pressure between prosthetic socket and residual limb that the subjects gait is as close to a regular pattern as possible. Therefore all subjects were instructed to walk along the walkway at a self select walking speed which was similar to that experienced in normal activities.

The clinical facility in which experiments were conducted was familiar to all subjects attending the research investigation. The walkways were located in clinic rooms where the subjects attend for their prosthetic treatment.

A video camera attached to the F-Scan system provided a visual recording of the leg and foot movements of the subject as they moved along the walkway. The video and pressure recordings could be synchronised, enabling improved analysis of the interface pressure data.

Capturing Socket Interface Pressure Information

The F-Scan equipment was set to record 10 seconds of information. This enabled multiple steps to be captured, reducing the chances of "targeting". Targeting can be a problem if the subject alters their walking pattern so that they can strike a platform or hit a particular point on the walkway. During the recording of interface pressure within the prosthetic socket, the subject's foot position was also recorded by video camera. Data from each of the six transducer arrays and video were saved using a predetermined coding system. Upon completion of the trial, the subject was instructed to sit and rest before being asked to complete an identical second trial.

Upon completion of the two trials, the prosthesis was removed from the subject. All transducers were removed. Before returning the prosthesis to the subject the residual limb was examined to ensure it was in the same condition as before the trials began.

9.2.2 F-Scan Pressure Transducer System

The Tekscan F-Scan software system available during this project was version 5.24 (later updated to version 5.83). The pressure measurement system comprises of four main devices; the transducer array, cuff unit, signal processing box and host computer. The computer used to run the F-Scan software incorporates an AMD Athlon XP2400+ microprocessor operating at 518MHz. The computer has a 30 GB of hard drive space and 192MB of RAM. An external hard drive of 250GB disk space provided permanent secure source of data backup.

Transducers

Two types of transducer array were used, F-Scan foot sensors (Model 3000) and Prosthetic socket sensors (9811). Four socket transducers are placed inside the prosthetic socket to capture the interface pressure. Two foot transducers are placed in the shoes of the subject to capture the foot interface pressure, and provide information to the timing and position of the foot during gait. Both of these transducer arrays are constructed from a matrix of force sensing resistors arranged in rows and columns. The F-Scan transducer is an extremely thin, matrix-based sensor created by a printing process. Layers of a conductive element and a pressure-sensitive ink are printed onto two thin, flexible, Mylar sheets with rows printed onto one substrate and a column pattern on the other, one sheet is positioned on top of the other creating a sensor which is 0.17 mm thick. Before assembly, a thin semi-conductive coating of ink is applied as an intermediate layer between the rows and columns. This ink provides the electrical resistance change at each of the intersecting points. When the two sheets are placed on top of each other, a grid pattern is formed, creating a sensing location at each intersection. This construction makes the transducers ideal to record pressures within the prosthetic socket or within the shoe without interference with volume.

Measuring the changes in voltage at each intersection point, the applied force (or pressure) distribution pattern can be measured and displayed on the computer screen. The resistance of each cell is inversely proportional to applied surface pressure. As a force is applied to the transducer the properties of the resistive ink layer change, therefore altering the output signals. The greater the force the better the connection between the contacts, hence the conductivity is increased and resistance decreases. The F-Scan transducers can accept pressure ranges as low as 1 kPa or as high as 175 MPa. Areas of high pressure are displayed as colour changes and peaks on a 2D or 3D image. When hot spots or high pressure points are observed, it can be symptomatic of a poor fit.

The particles making up the layers are of the order of fraction of microns, and are formulated to reduce the temperature dependence, improve mechanical properties and increase surface durability. As with all resistive based sensors, the force sensitive resistor requires a relatively simple interface and can operate satisfactorily in moderately hostile environments.

Transducer Array

Figure 30 indicates the main elements of the F-Scan transducer. It shows the F-Scan transducer **Array,** which consists of 96 independent **Cells.** These cells are positioned into 6 columns. The columns can be divided by cutting in-between the columns. Splitting the array in this fashion greatly increases it's flexibility to adjust to the contours of the prosthetic socket. Each of the six columns of cells can be further trimmed to differing lengths dependant upon the area to be covered. This enables the array to be trimmed to fit the individual prosthetic socket. The 6 columns and 16 rows giving a total sensing area of 15,150 mm^2. The foot transducers also comprise of a Mylar-ink construction, comprising of a total of 960 individual cells. These transducer arrays can be trimmed to fit individual foot shapes.

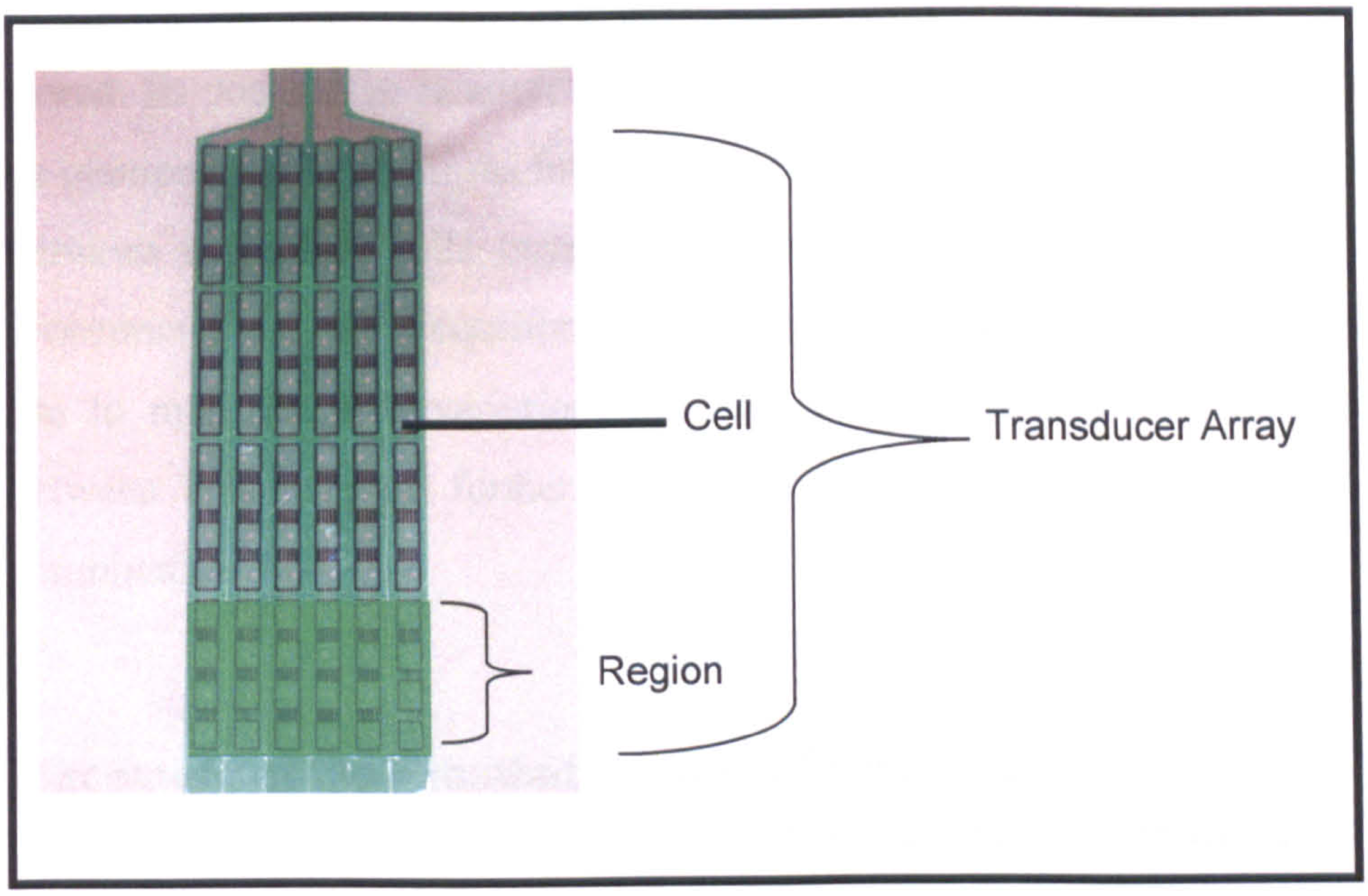


Figure 30: Make up of F-Scan Pressure Transducer

When analysing the output from each array, the array can be divided into groups of cells called **Regions.** These regions can be set to any position, containing any number of individual cells. Four arrays are positioned into the prosthetic socket, Figure 31. Each array will then measure the interface pressure at the four **Aspects** of the socket, i.e. Anterior, Medial, Posterior and Lateral.

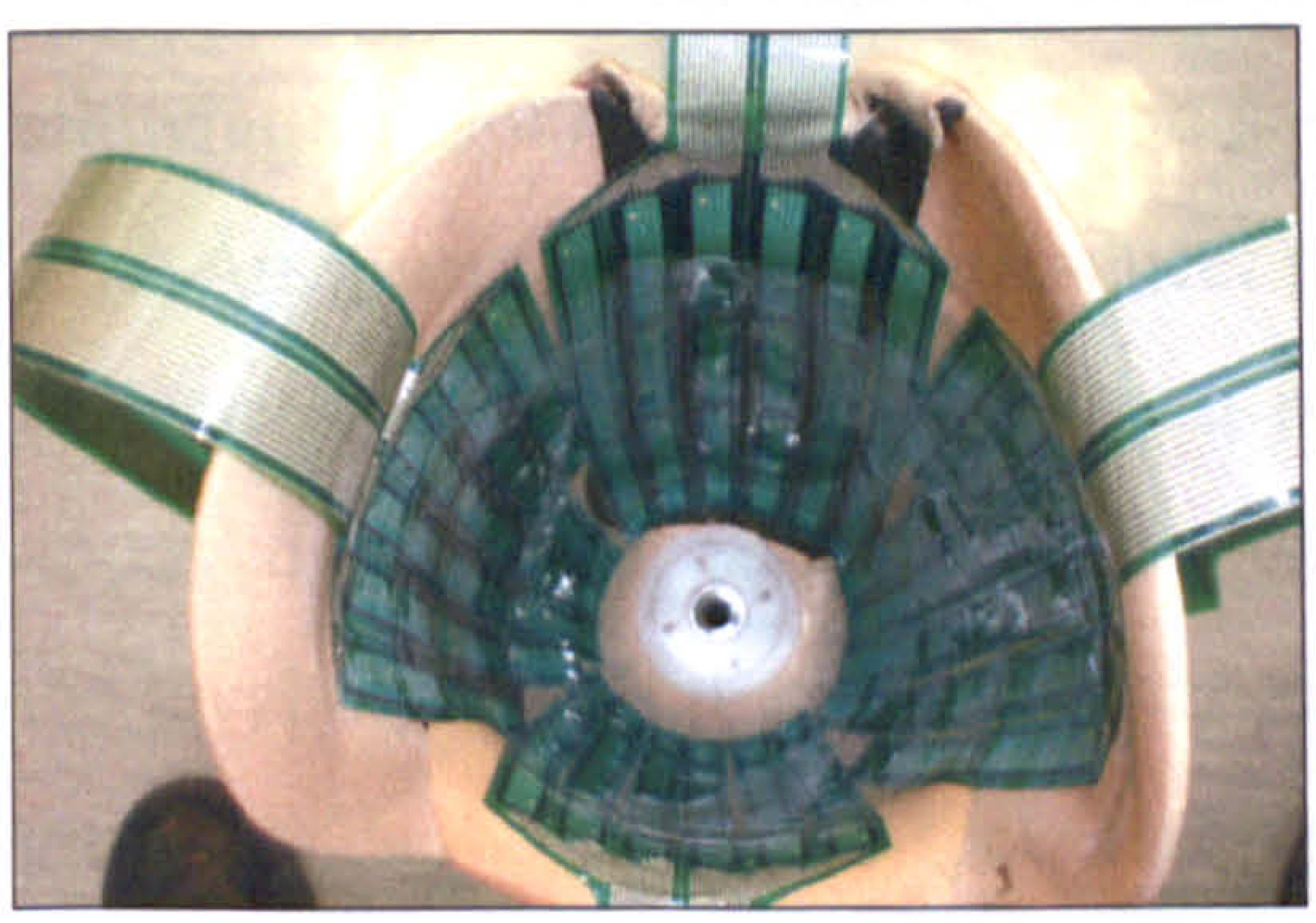


Figure 31: View inside prosthetic socket

In order to understand the results gained from these transducers it is important to appreciate how the F-Scan transducer is constructed and how the unit processes the information received from the transducers. The construction of each transducer array means that, during the collection of data, information from each cell is independently stored. Its position in relation to the other cells is recorded. This enables the data to be manipulated into various forms dependant upon the required format. Inaccuracies between individual cells have been highlighted (Buis and Convery, 1997). It is recommended that the equilibration software be used on the transducer arrays before use to minimise this variation. In addition to equilibration, individual variations between cells can be further reduced if a collection of cells are considered in combination.

Placement of the Prosthetic Socket Transducers

The F-Scan system in use was a six channel data acquisition device. This allowed one channel per foot, and four channels for the prosthetic socket at the anterior, medial, posterior and lateral aspects. Each channel has a predetermined letter assigned by the manufacturer this being A,B,E,F,G,H. The same channel is designated to the various locations being measured and these remain constant between all subjects. Channels A and B are assigned to the left and right foot respectively. Channels E,F,G and H allocated to Anterior, Medial, Posterior and Lateral aspects around the prosthetic socket.

Each array can be individually cut to fit the complex contours of a prosthetic socket, allowing over 90% coverage of the socket, without overlapping the array on either side. An illustration of the transducer configuration was made to aid analysis of the information, Appendix 4. The distal patella boarder provides the boundary for the upper edge of the array. The lower boarder of the transducers was positioned above the level of the distal end cup of the silicone liner. The four socket transducers are glued inside the prosthetic socket using non-volatile spray glue, Figure 31, page 118. Transducers are placed inside the socket in the same order. Firstly the anterior array is positioned, followed by the posterior, then medial and finally lateral. Transducers are placed into socket so the words "This side up" face into the socket, the view of pressure distribution on the computer screen then displays the pressure profile as if looking at the socket wall from the stump. Although all six channels are identical, the procedure for attaching the transducers to the data acquisition device remains constant for all subjects simplifying future analysis.

The two prosthetic socket designs warrant two different approaches to be applied to the position of the transducers during this investigation, see Figure 32.

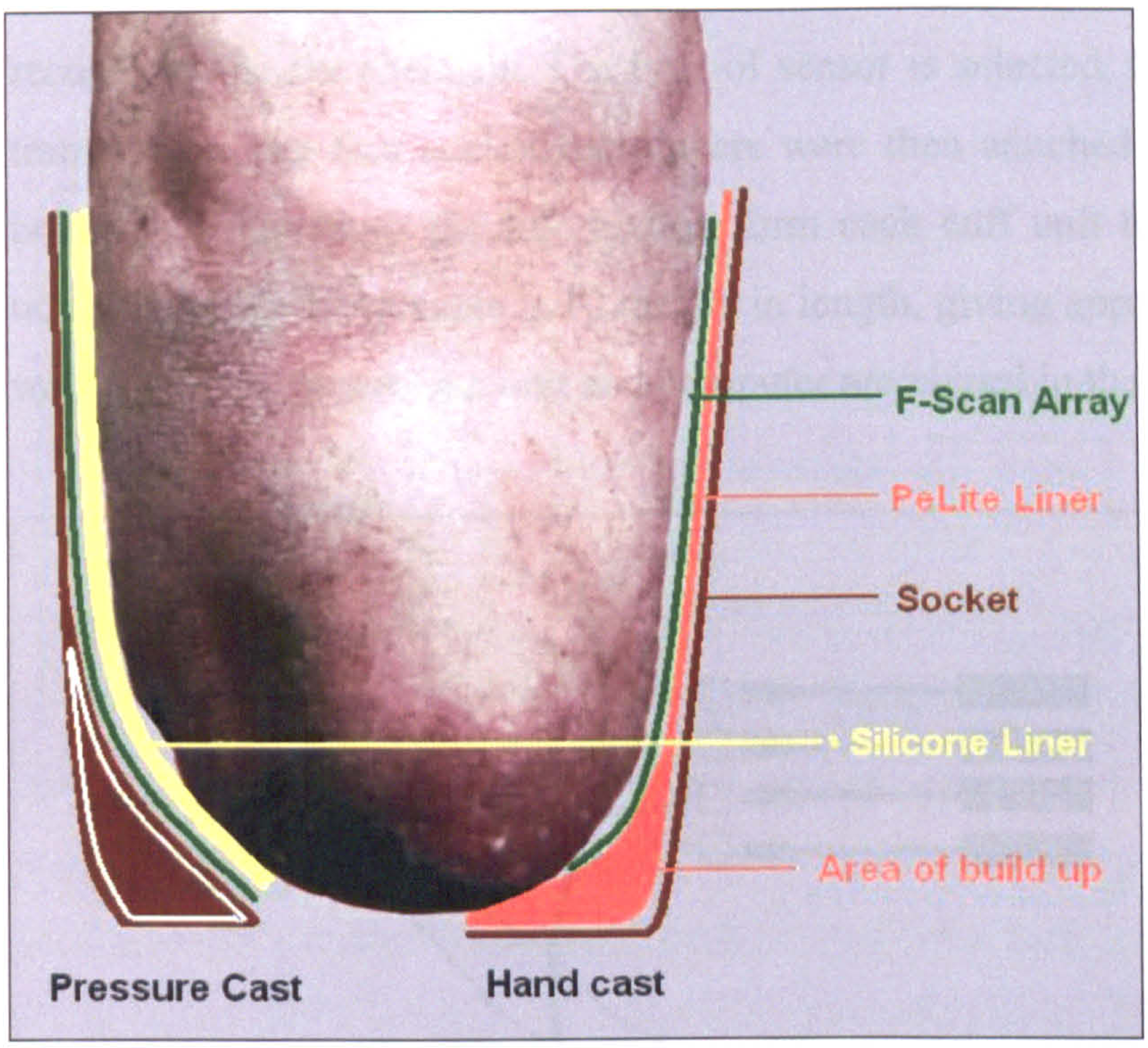


Figure 32: Placement of Socket Transducers

Transducers inside pressure cast sockets have to be placed between the silicone liner and the socket wall. They cannot be placed next to the subject's skin as the subject is unable to wear their prosthesis at the time of calibration. The transducers cannot be placed between the residual limb and liner, since the silicone sleeve forms a total surface coupling with the stump. As a result, the elastic behaviour creates an initial tension which produces an additional unknown pressure that cannot be replicated during the calibration procedure. The elastic behaviour would also create signal drift of the F-Scan equipment. During preliminary investigations using the F-Scan system it has been shown that the transducers cannot detect a difference in interface pressure when recording at either side of the silicone liner. It should be noted that this initial unknown pressure created by the liner can not be recorded when placing the transducers on the outside of the liner. Recorded pressures outside the liner may be lower than those experienced at the limb interface. It can therefore be deduced that in PTB sockets the transducer can be placed at the liner and limb interface.

Transferring the Information

After the computer is switched on and the F-Scan programme started, the system recognises the six channels. The type of sensor is selected, this being 9811 (socket transducer). The four socket transducers were then attached to the data acquisition boxes. A cable sends the information form each cuff unit to the signal processing unit, Figure 33. Each cable is 10 meters in length, giving approximately 20 meters of walkway if the processing unit and computer are placed in the middle of the path.

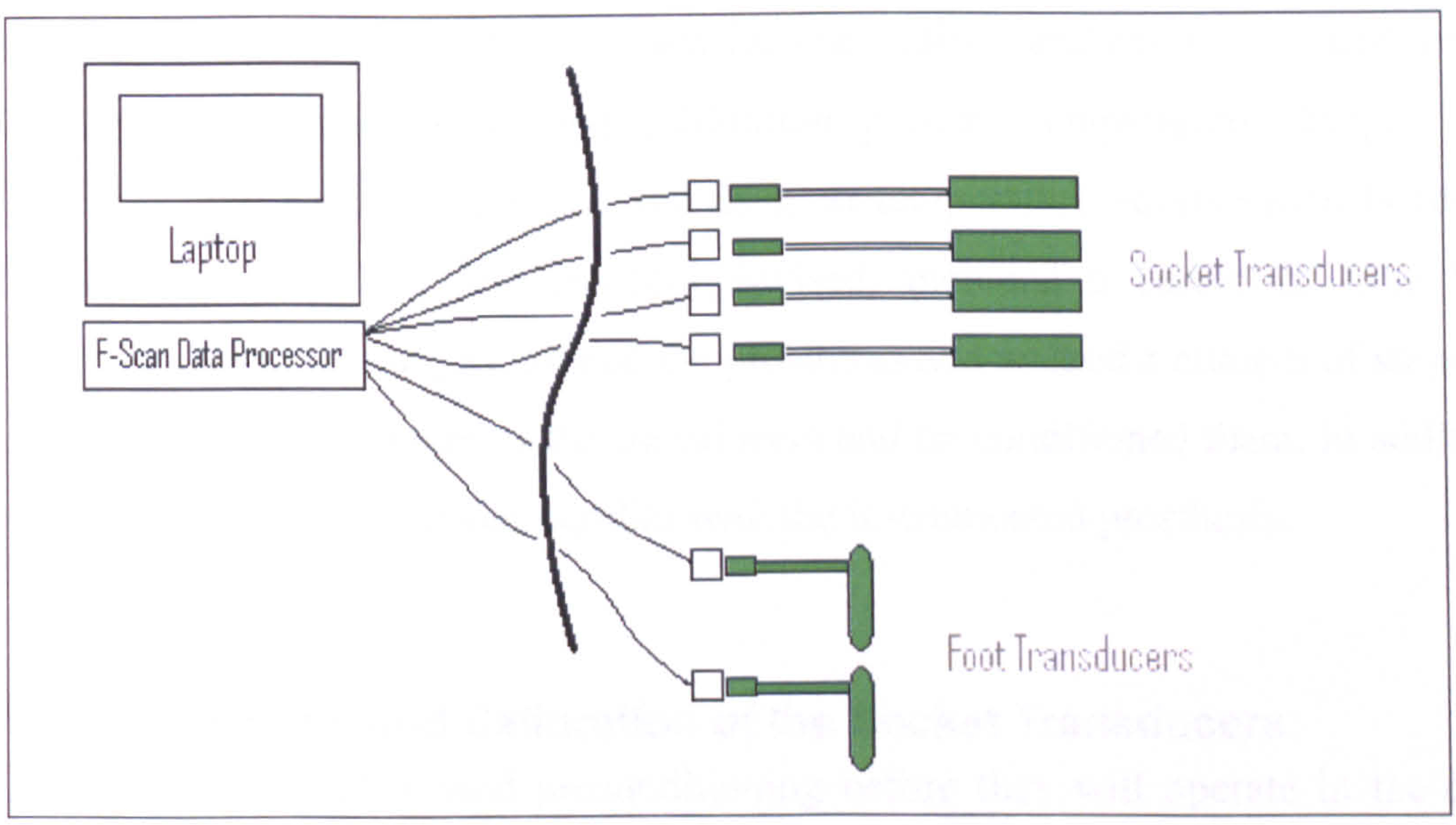


Figure 33: Schematic of system set up

Velcro bands and a waist belt secured the cuff boxes and cables during each walking trial, minimising the interference to the subject. As force is applied to the matrix, the data acquisition box measures the change in resistance from each cell to determine the magnitude, location, distribution, and timing of the pressure exerted. Each cell is effectively a variable resistor whose value is high when no force is applied to it.

The F-Scan signal processing box is connected to the computer via a PC interface board inserted into the expansion slot of the Laptop computer. The interface board accepts transducer data into the computer, making it available for the software. The sensor is read sequentially by applying a known voltage to one of the rows and measuring current-to-ground on one of the columns. The microprocessor selects the row and column to be read by identifying the proper address for each cell. The data acquisition parameters are set for a 10 second recording at a frequency of 127 Hz and the noise threshold set to its lowest limit, this being 3.

Understanding the Limitations of the System

Several problems exist when using the F-Scan transducers. Methods have been implemented within the protocol to reduce these occurring. The possibility of mechanical breakdown is reduced by attaching the array to the socket, preventing movement. Transducers are only used for one subject, and can be checked for error during the preconditioning and calibration period. Temperature changes at the interface may have an affect on the data, so temperature equilibration is required before any recording. The protocol devised, included a period of time before recording when the subject donned the prosthesis and walked a number of steps. This increased the temperature of the transducers and preconditioned them, in addition to ensuring the subject became familiar with the instrumented prosthesis.

Preconditioning and Calibration of the Socket Transducers

The Transducers also need preconditioning before they will operate in the correct manner. A specially designed platform was constructed which enabled a repeatable dynamic loading pattern to be performed on the pressure transducers whilst they were in situ within the prosthetic socket. A 30 cycle program at 100 kPa was performed before equilibration and calibration. The active area of each transducer was recorded during preconditioning, and used to calculate the force on the transducers. The platform provided a stable base in which trans-tibial prostheses of differing sizes could be calibrated in an identical manner. This was important when comparing the large number of subjects.

Two different F-Scan transducers are used during this study, in shoe foot and prosthetic socket pressure transducers. These two designs require different methods of equilibration and calibration.

Preconditioning of the transducers is important for achieving accurate response. During evaluation of the transducers, it was found that a good dynamic response was seen between the applied load and the transducer output after an initial "breaking in" period. The response stabilised after 10 cycles (Buis and Convery, 1997).

A 10 cycle preconditioning sequence at 100 KPa was performed using the dynamic air pressure applied by the calibration bladder. The bladder provides a repeatable dynamic loading pattern on the F-Scan socket transducers. This preconditioning was performed because it takes several loading cycles for the F-Scan transducers to become stable, Figure 34.

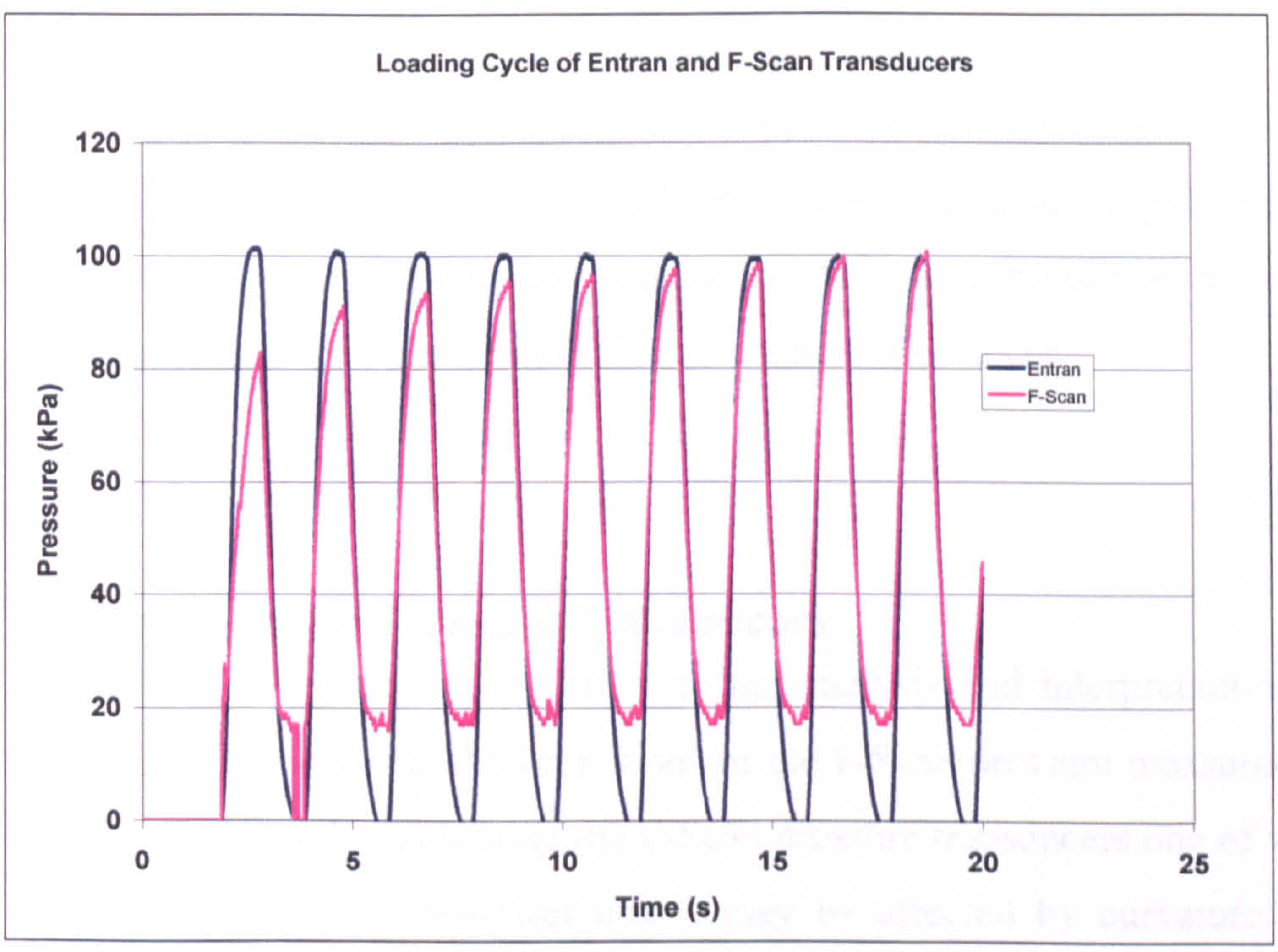


Figure 34: Loading Cycle of Entran & F-Scan Transducer

Equilibration of the Pressure Transducers

Each transducer array comprises of many separate cells, during the manufacturing process it is possible for discrepancies to exist in the sensitivity of individual cells. The equilibration process is performed to compensate for any variation between the individual cells and their response to an applied load. The flexibility of the transducer array makes them ideal for use in confined spaces such as the shoe and prosthetic socket. This flexibility does however introduce possible problems due to the effects of curvature on the response of the transducers. To minimise the effects of curvature the transducers were equilibrated in situ, within the prosthetic socket using a specially designed platform as described in section 8.3.1, page 99. A known uniform pressure is applied by an air filled inflatable bladder inserted into the prosthetic socket. In situ equilibration is not possible with the in-shoe transducers owing to the confined space within the shoe. The equilibration process requires a uniform distributed pressure to be applied over the entire surface of the array. This is performed inside a flatbed air chamber before the application of the transducer to the shoe.

After the 10 preconditioning cycles the air pressure remains static for a delay of five seconds and each transducer is equilibrated during this delay. Equilibration files are saved for each of the six socket transducers. After each transducer was equilibrated the files were saved before proceeding to the next transducer.

Calibration of the Pressure Transducers

Calibration of transducers is critical to the analysis and interpretation of the data recorded. Understanding the limitations of the F-Scan pressure measurement system is vital in accurately calibrating the F-Scan pressure transducers one of which is that the responses of the transducer arrays may be affected by curvature. In order to address the limitations and maintain accuracy, the transducers are placed in situ before performing equilibration and calibration. Calibration refers to the process of determining the relation between the output of a measuring instrument and the value of the input quantity. In general terms, calibration is often regarded as including the process of adjusting the output or indication on a measurement instrument to agree with value of the applied standard, within a specified accuracy. In terms of the F-Scan system, calibration of the transducers converts the raw data into pressure units, using the patient's body weight, or a known load as a reference to which the raw data is compared. The near vertical position of the prosthetic socket transducers around the prosthetic socket necessitates a different method of calibration as is used for in-shoe foot transducers. Having placed the transducers inside the prosthetic socket for equilibration, the same process is used for calibration. A known load is applied to the transducers using the inflatable bladder.

Calibration follows a one minute recovery time after the equilibration process. A 10 cycle loading pattern is performed on the transducers before calibration. It is known that the transducers are prone to drift; therefore calibration is performed at the point when the maximum pressure (100kPa) is applied. The pressure is held at 100kPa and the transducers are calibrated immediately. This procedure was followed for all transducers, and all subjects. The active area of each transducer was recorded and used in the calibration formula, shown below. The value of force calculated is inputted into the F-Scan software for calibration of the transducers.

$$\frac{\text{Total Sensor Area (mm}^2\text{)}}{1000} \times \text{Applied Pressure (kPa)} = \text{Force used for Calibration}$$

After each transducer was calibrated the files are saved before proceeding to the next transducer. A 10 second recording was taken after completion of the calibration procedure to examine the transducer response.

Calibration of the Foot Transducers

Once the subject's shoe size and shape is determined, the two foot transducers are trimmed to fit inside the shoe. Equilibration is performed inside a flatbed air chamber, which delivers a known uniform pressure to the entire surface of the transducer. The equilibration files are saved so to be loaded later once the transducers are fitted. Calibration takes place having fitted the transducers inside the subject's shoe. As with the socket transducers, the Foot transducers are required to be preconditioned before calibration. For this reason the subject is requested to walk for 30 steps to precondition the transducers. This also provides time for the subject to become accustomed to the instrumentation of the prosthesis. The subject's own body weight is used during the calibration process. When body weight is inputted into the system for calibration the weight is required to be converted into a force in Newton's. For consistency of converting body weight, a table was produced which enabled body weight given in imperial or metric to be easily converted into Newton's. The subject stands still on one leg causing the vertical force to pass through the transducer.

F-Scan Data Saving

Due to the large quantity of data processed during the study a large number of files were created. In order that information can be readily accessed a file saving protocol had to be developed to standardise the naming of these files. Each subject in the study had a designated folder with their respective identification number. These folders have sub folders containing paths for the main areas within the study, i.e. the subject's details, pressure study, activity monitor and questionnaire.

Information collected from the F-Scan pressure recordings contains a large numbers of files. Each of the files starts with the two letters representing the position of the transducer (or the word video for the video recording). Followed by the subject's identification number inside brackets (**), then the trial number.

AS(**)trial 1	Anterior Socket
MS(**)trial 1	Medial Socket
PS(**)trial 1	Posterior Socket
LS(**)trial 1	Lateral Socket
LF (**)trial 1	Left Foot
RF(**)trial 1	Right Foot
Video(**)trial 1	Video Recording

During data collection, each transducer required a separate equilibration (equ), calibration (cal), and pressure recording (fsx) to be created. To simplify identification, each file type will use the same file name as shown above. For example a recording made using the anterior socket transducer will have the following file names:

AS(**)trial 1.equ	for the equilibration file
AS(**)trial 1.cal	for the calibration file
AS(**)trial 1.fsx	for the movie file
Video(**)trial 1	for the video recording.

(One file will be created for the video and used for all the transducers)

During the calibration procedure a recording was made of the dynamic loading pattern for the socket transducers in order to check the output of each transducer. The recording was saved using the same notation as above, with trial 1 replaced with calibration 1.

9.2.3 ActivPAL™

The ActivPAL™ activity monitor is a small, lightweight and discrete monitor. The acceleration of the leg is recorded at a sampling rate of the monitors is 10 Hz. The monitors are extremely lightweight, weighing about 20g including the battery making them ideal for placement on the subject's prosthesis, where weight considerations are important. The small size of the monitors means that they do not interfere with daily activities and are not obtrusive through clothing. Each monitor is approximately 53mm long, 35mm wide and 7mm thick, Figure 35. Operation of the monitor is conducted via a 3V lithium Ion battery providing sufficient power for the recording period. The memory capacity of the monitor is capable of recording daily activity for periods of over a week. Subjects wore the monitor for one week during the investigation, therefore the memory was sufficient for the requirements of this study.

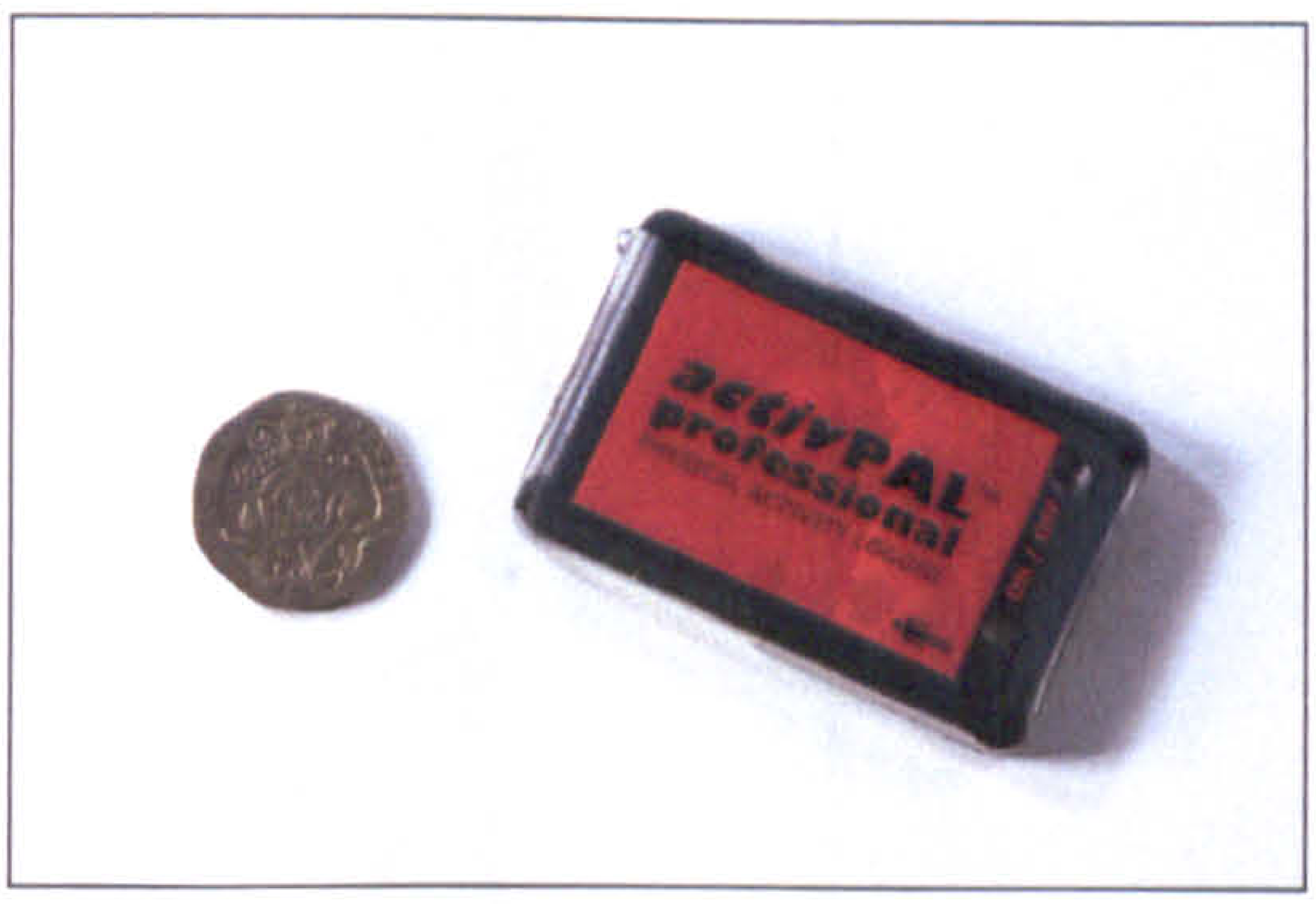


Figure 35: ActivPAL™ Activity Monitor

Position of the ActivPAL

Guidelines supplied by PAL Technologies indicate the monitor should be placed on the thigh facing in the anterior direction. In this position the monitor's orientation will determine the position of the person wearing it. Activities are divided into three categories, walking, standing and sitting. These periods are displayed in coloured lines of differing length dependant upon the energy expenditure needed to perform the tasks. If the monitor is in the vertical position, and stationary, the monitor records that the subject is standing. If the monitor is vertical, but experiencing horizontal acceleration the subject is walking. If the monitor is in the horizontal position, the subject is either sitting, or lying down. The company suggest attaching the monitor to the subject using either specially formulated sticking strip which allows safe, painless removal of the monitor. Other methods suggested include neoprene strap or medical grade adhesive tape. The monitor must be in a stable position to accurately measure activity. The device has been quantified against a diary and pedometer and found to be highly accurate (Ryan et al., 2006). Studies conducted on the accuracy of the monitor show that it has a high inter-device reliability (ICC 2,1) of 0.97 (Grant et al., 2006).

During this investigation the monitor was not attached to the subject's thigh, but to their prosthesis by the researcher. The monitor was positioned at the level of the ankle, on the anterior aspect of the prosthesis, securely attached using strong tape, Figure 36.

Figure 36: Position of Activity Monitor

The small size and light weight of the monitors makes this a suitable position for placement on the prosthesis. Once placed in position and switched on by the researcher and remained on, the monitor could be left in this location, with no need for the subject to touch it for the duration of the recording. The monitor was attached below the sock level, therefore was disguised in most applications.

Locating the monitor at the ankle presented benefits for the subject and for the reliability of the data. The subject would not continually be reminded of the monitor, visually by the position on the thigh or by having to remove the monitor each time they bathed. The reliability of the data could be maintained as the monitor would remain in the same location for the duration of the recording. This position could be checked by the researcher before the trial began, and a consistency throughout each trial and between subjects could be established. If placed on the thigh, the placement of the monitor is left to the subject to determine, introducing a risk that the monitor may not be worn correctly during the study. This repeated removal and reapplication of the monitor would also introduce small changes in the position of the monitor at each application. The subject may also forget to replace it after bathing or sleeping, resulting in data being lost. Fastening the monitor to the prosthesis using adhesive tape allowed the monitor to be securely attached to the prosthesis. It also facilitates the easy removal of the monitor by the subject at the end of the recording period. This permitted the activity monitor to be returned to the researcher, without an additional appointment. However in this position the time spent standing and sitting could not be used due to the position of the monitors on the prosthesis as seen in Figure 36.

Activation and Use

A small recessed button located on the front of the monitor permits an easy method of activating the monitor, but prevents accidental switching off during its recording. An LED light next to the on/off switch flashed when the monitor is switched on and recording.

Having attached the monitor to the subject's prosthesis, the position of the monitor was checked, and monitor switched on. At this stage the LED light was observed for several seconds to confirm that the monitor was working and functioning correctly.

Each subject fitted with the monitor wore it from the day of participation in the study until one week after their appointment. During this time the monitor will record their daily activity. Each subject was asked to remove the monitor from their prosthesis after one week and return it using a prepaid, pre addressed special delivery postal envelope.

Monitors are connected to the PC via a USB connection cable providing fast download and uploading performance. Once connected, monitors are synchronised to the computers clock, enabling accurate evaluation of time based activities.

9.2.4 Prosthesis Evaluation Questionnaire

The PEQ is one of the few instruments for measuring prosthesis-related quality of life and functional outcomes (Boone and Coleman, 2006b) and is the outcome measure chosen for this study. It comprises of a total of 82 questions, contained within 18 subscales (9 validated, 9 independent) see Appendix 3. Legro concluded that the PEQ was a useful tool in evaluating prosthetic care (Legro et al., 1998). The scales have been validated for internal consistency and temporal stability. A number of studies have been conducted using the PEQ, summarized by (Boone and Coleman, 2006b). The review found that the PEQ is a relatively simple to use instrument that can be used to answer a wide variety of questions relating to the functional outcomes of lower limb prostheses.

Visual Analogue Scale

Most of the questions within the questionnaire are in a visual analogue scale (VAS) format. Each visual analogue scale is scored as a continuous numerical variable. Measured as the distance in millimetres from the left end point of the line to the point at which the subjects mark crosses the line. Each line is 100mm long and is always measured from the left (0-100). Each questionnaire has a patient instruction sheet which indicates the correct way in which to mark their response. All questions are worded so that higher scores demonstrate a more positive response; negative responses return a lower score. Some of the questions have a check mark which the subject can mark if the question does not apply to them. These questions are then scored either as 100 or as no response (nr). Validated scales are calculated by calculating the mean score from within subscale; the calculation is adjusted, excluding any missing responses.

Validated Sub-Scales

The questionnaire is divided into groups of similar issues, the nine validated groups comprise of questions relating to the ambulation of a subject, the appearance of the prosthesis, frustration caused by the prosthesis and the general utility of the prosthesis. As well as the perceived response from friends and family, the social burden the subject feels, and the sounds the limb makes. Residual limb health and general well being are also included as groups. Each validated subscale is independent of each other; therefore the questionnaire can be adjusted to a particular requirement. All questions refer to the use of the prosthetic limb over the four weeks preceding the application of the questionnaire. The questions within these groups have been shown to correlate strongly with each other, therefore can be grouped together and assessed as one (Legro et al., 1998). A single response score can be gained for each of the nine groups. The remaining questions are classified as individual questions and are scored independently, but are divided into groups within the questionnaire. These include satisfaction with the prosthesis and the pain the prosthesis creates, transferring, prosthetic care and self efficiency.

PEQ Question Codes

All questions are coded; a separate code book defines the questions and the scale used in recording the answer. Several questions use a seven point ordinal scale (0-6) when asking subjects to indicate the usage or experience in a particular issue. One question is not coded, and is not scored, it simply asks the applicant to name two family members, in which to relate the following questions to.

Reliability of the Visual Analogue Scale

It is important that all subjects have identical questionnaires on which to mark their responses. In order to ensure the highest consistency between questionnaires one copy of the original PEQ was printed and the lengths of all scales measured to confirm an accurate reproduction. Further copies of the questionnaire were photocopied in one batch. Enough versions of the questionnaire were made and included in the information pack provide to each subject. Selections of these copies were taken and response lines again measured. Measurements showed no significant variation between copies. Further precautions to introducing inaccuracies into the measurements were put in place. The same person measured all the response lines for all subjects. The same ruler was also used for all measurements.

9.3 Display of Results

Each outcome measure and measurement taken from the subject requires different visualisation methods. The data gained from the three outcome measures are displayed in terms of the subjects' group i.e. Hands-on (PTB), or Hands-off (Pressure cast). Results are further displayed in terms of other subscales where necessity dictates.

9.3.1 Residual Limb Surface Area and Volume

Measurements taken from the residual limb were used to create a model of the residual limb. If the circumference of the residual limb is assumed to be the shape of a cone, a simplified model of the residual limb can be produced, Figure 37. These calculations are used to provide an estimate the volume and surface area of the residual limb.

Section 1 can be considered an open ended cone, section 2 as a half sphere. Considering these two shapes the volume and surface area can be calculated.

Limb Model

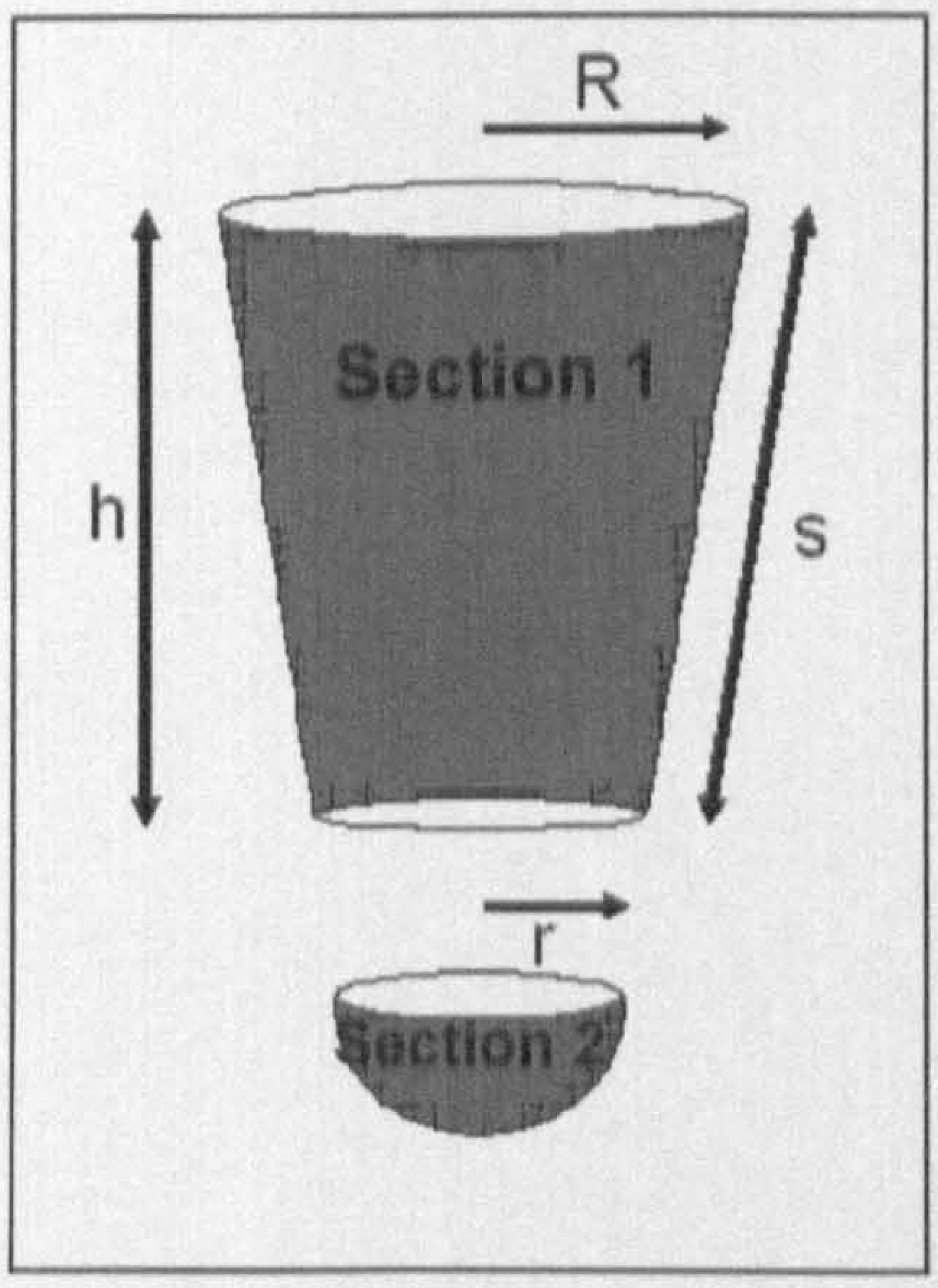


Figure 37: Simplified limb shape

Where: R = Radius at the level of the patella tendon

h = distance between the two measures

r = distal radius measure

s = the slant height

The slant height (s) is expressed as: $\sqrt{(R-r)^2+h^2}$

The radius measures can be calculated using the circumferential measures taken from the residual limb (Figure 29). Circumference (C) is expressed as: $2\pi r$.

Therefore: $r = C/2\pi$.

Volume of the Residual Limb

The total volume of the residual limb shape is the sum of the volume of the open ended cone and the half sphere. The volume of the open ended cone is expressed as: $h\pi/3 * (R^2+Rr+r^2)$. Volume of half a sphere is expressed as: $2/3*\pi*r^3$

Surface Area of the Residual Limb

The surface area of an open ended cone (not including either end) is expressed as: $\pi*s*(R+r)$. The surface area of half a sphere (not including flat surface) is expressed as: $2\pi r^2$.

Other Subject Measurements

Descriptive analysis is given for the other measurements taken during the initial subject meeting. These are displayed in terms of the socket type worn.

9.3.2 F-Scan Output Display

The software displays the interface pressure in real time on the computer screen in coloured 2D or 3D images. Subject information can be recorded, stored and played back for analysis. The software allows multiple windows to be opened and pressure information to be analysed in defined areas of interest, or as a complete transducer array,

Figure 38. Force and pressure changes can be observed, measured, recorded and analysed throughout the test. The output from the anterior, medial, posterior and lateral prosthetic transducers is displayed in separate rectangular windows. Owing to the tapered shape of the prosthetic socket, several of the distal cells are removed. The posterior positioned transducer is positioned lower in the socket due to the lower height of the posterior socket wall.

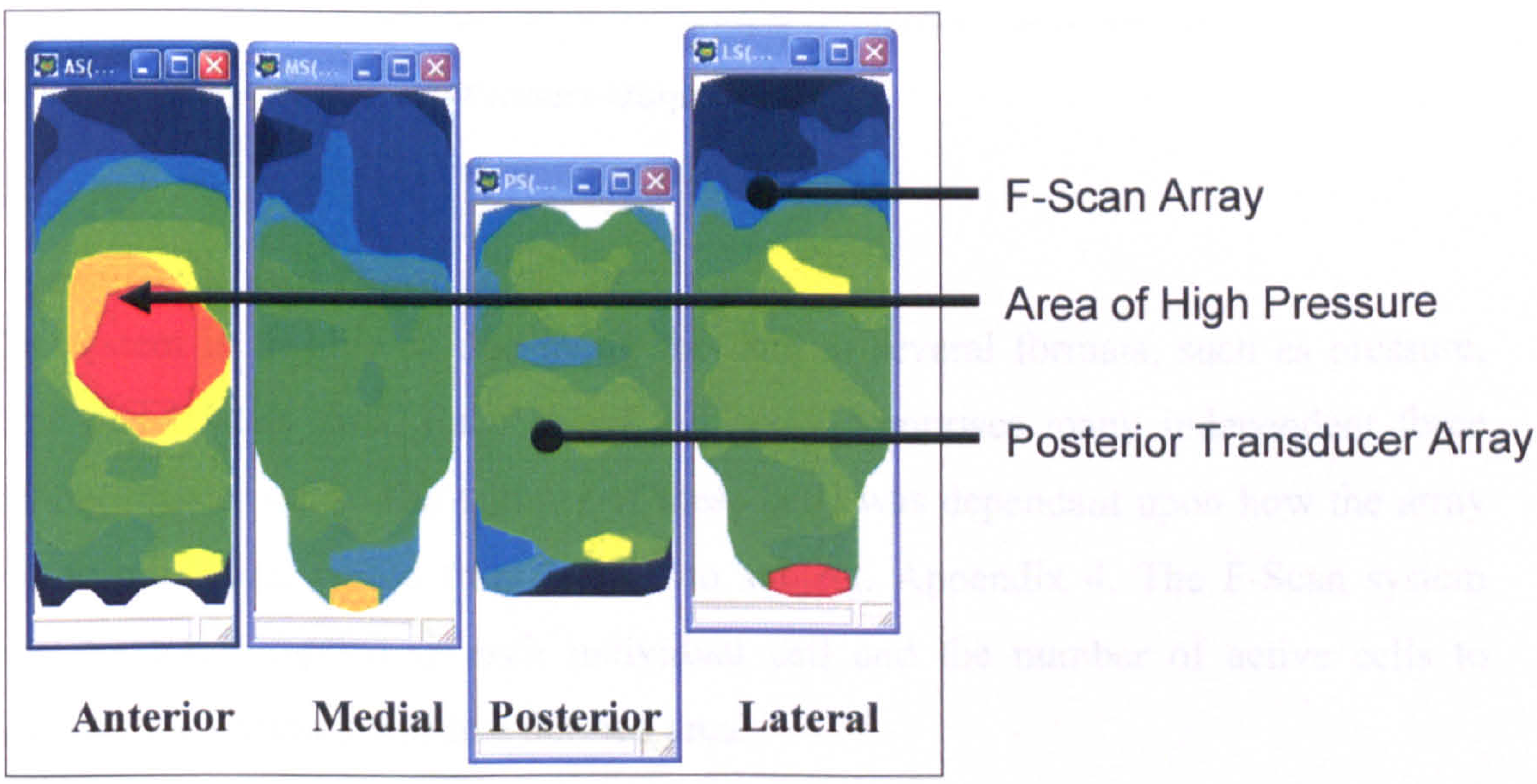


Figure 38: F-Scan Output of Socket Transducer

The software enables the location of areas of interest, and display temporal, force, and pressure characteristics on-screen. Various plots of Force, Pressure, and Time are available. Mathematical operations, including peak pressure distribution, average and centre of force can be shown. Graphical information can be exported to other software packages such as MatLab or Excel for further manipulation by using the ASCII transfer function. The processing box has six individual channels, each capable of independently receiving signals. Four of these channels were designated for receiving socket transducer signals, the remaining two were allocated to the left and right foot. Using computer modelling, the four individual transducer outputs can be connected and the information seen as a seamless image, Figure 39.

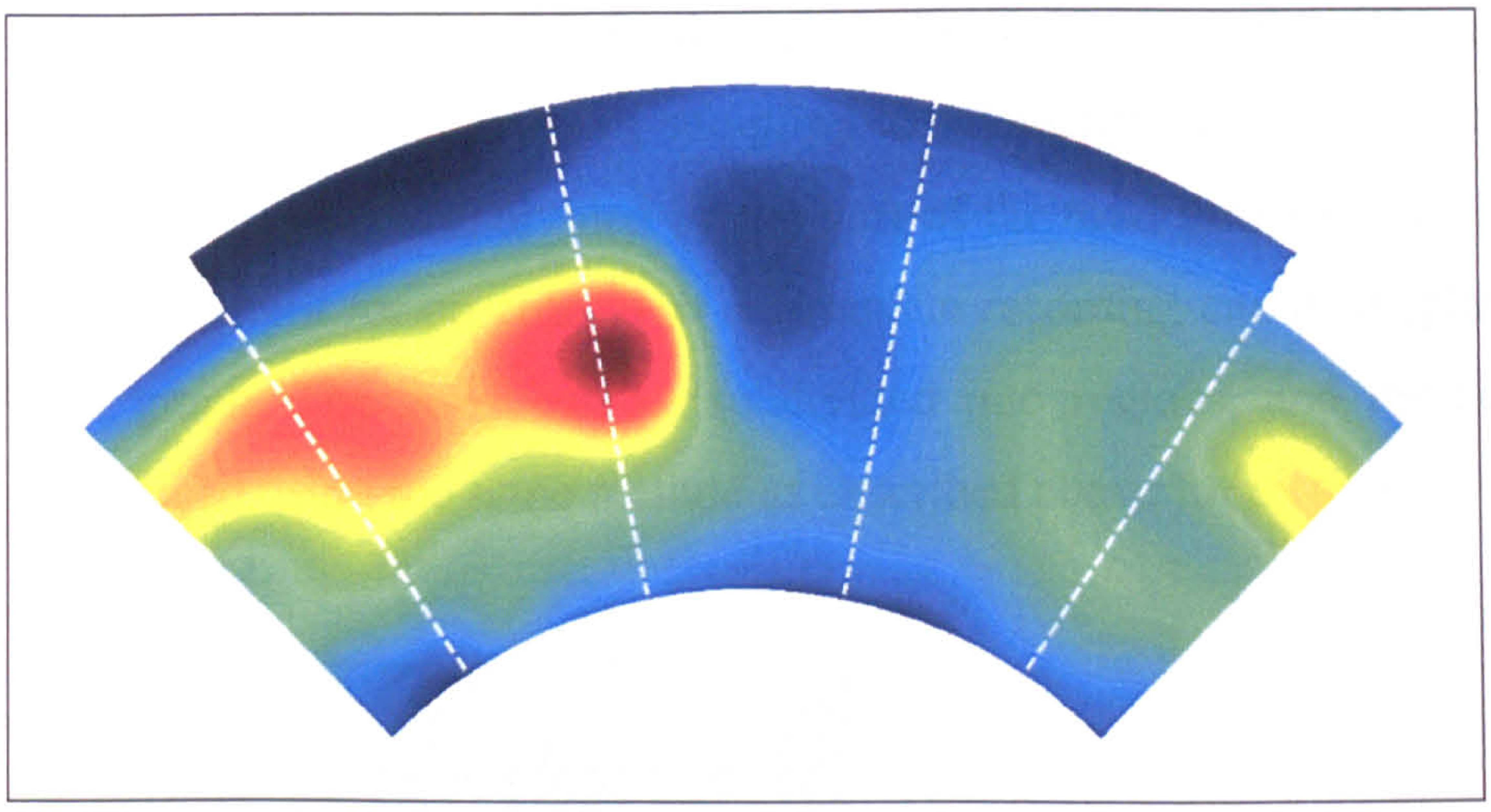


Figure 39: Computer image of Pressure Output

Pressure Output Display

The system is capable of displaying the data in several formats, such as pressure, force and contact area. Each transducer array comprises many independent force sensing resistor cells. The number of these cells was dependant upon how the array was trimmed and varied from subject to subject, Appendix 4. The F-Scan system uses the force applied to each individual cell and the number of active cells to calculate the pressure within a defined area.

To analyse the pressure magnitude and distribution within a prosthetic socket the information was calculated in two ways. The average pressure over a defined area and the peak pressure within a defined area. A defined area may be the entire array, or a smaller region within the array.

Average Area Array pressure

The software displays the average (mean) of all individual active cells contained within each region (or entire array) for every sampling point throughout the recording, see Figure 40. An active cell is defined as a cell subjected to at least 7kPa of pressure, minimum threshold. Every time the system samples data, the force applied to each individual cell is captured. If the force output from the cell is above a pre-selected threshold of 7kPa the cell is deemed to be active. The average pressure of an array at each instant of sampling is calculated by using the sum of the force across all active cells, divided by the area of the total number of active cells. In this way the output for an array over a complete recording can be displayed by one line on a graph. The array can be subdivided into regions, and the average pressure determined using the same method as described above for an array.

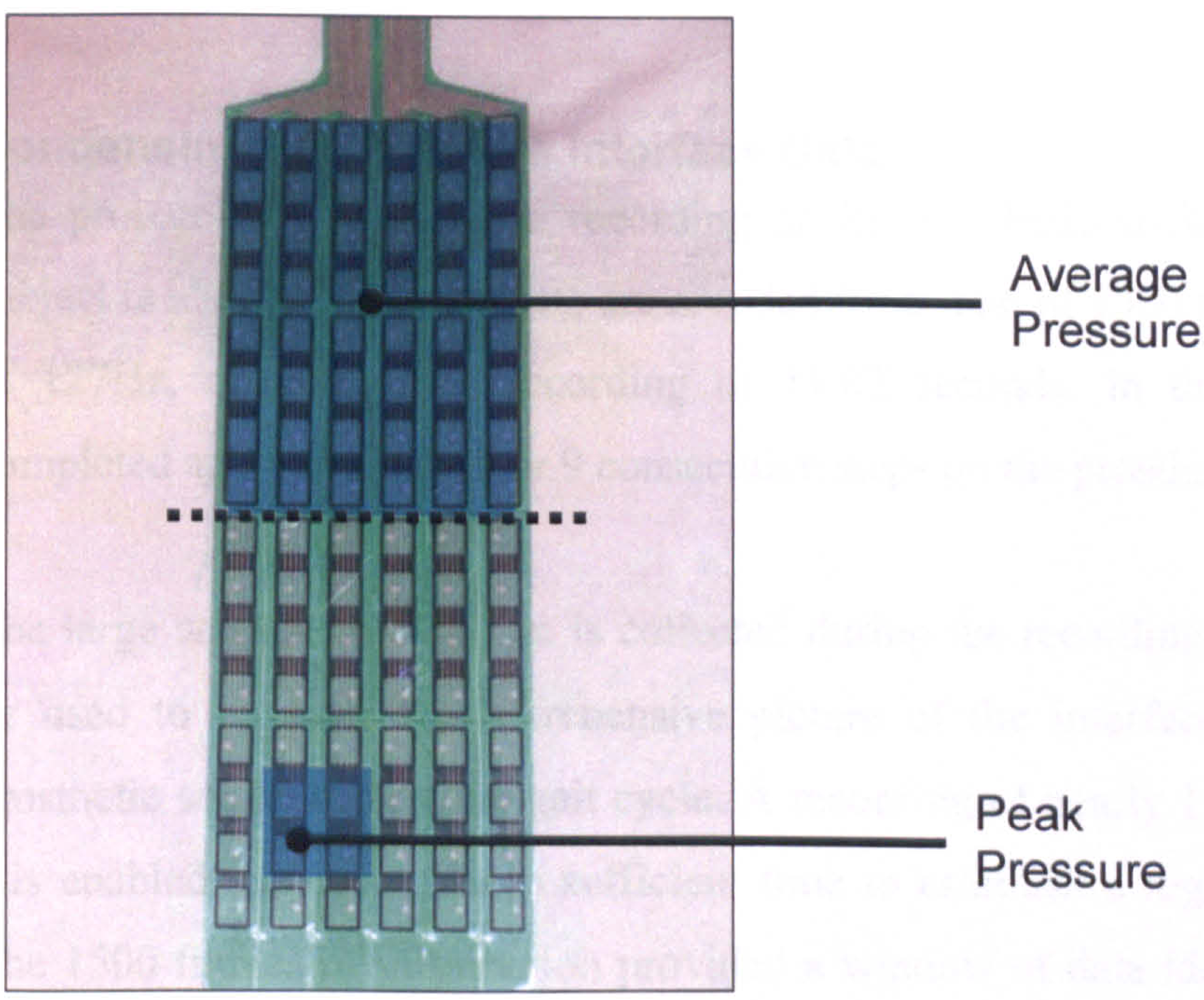


Figure 40: Cells used for Average and Peak Pressure Calculations

Peak Pressure

The peak pressure of each array can be displayed. In this case the four adjacent cells subjected to the highest pressure at each point in the recording are used with the average (mean) of these four cells being displayed, see Figure 40. The average of four cells is used instead of just the individual cell with the highest pressure, as a defective cell may produce an incorrect result.

Percentage increase in Peak pressure

The difference between the average and peak pressure can be expressed as a percentage difference, removing the absolute pressure scale.

$$\text{Peak \% Increase} = \frac{\text{Peak Pressure (kPa)} - \text{Average Pressure (kPa)}}{\text{Average Pressure (kPa)}} \times 100$$

This information will show how the peak pressures within the socket relate to the average pressure throughout the socket.

Condensing the Pressure Interface Data

The protocol for obtaining a recording at the prosthetic socket interface for each subject is identical. All subjects are recoded for a total of 1500 frames at a frequency of 127Hz, resulting in a recording of 11.82 seconds. In this time the subjects completed approximately 8 or 9 consecutive steps on the prosthesis.

The large amount of data that is collected during the recording of each subject may be used to produce a comprehensive picture of the interface pressures within a prosthetic socket during the gait cycle. A recording of nearly 12 seconds was made, this enabled subjects to have sufficient time to establish a regular walking pattern. The 1500 frames of information provided a window of data identifying consecutive steps along the walkway. This walkway was outlined for the subject and located within a prosthetic fitting room, with a smooth, flat floor covering.

Single Step

When the subjects had walked on their prosthesis for a few steps, the pattern of interface pressure data for each step becomes consistent. This can be seen in Figure 41. These findings have previously been documented (Sanders et al., 1993). Once the recording was taken and the data was examined, a single step from those captured was selected for further analysis. The step selected was one which represented a typical pattern of the entire collection of recorded steps. Figure 41 shows an output from a subject, the graph indicates the interface pressure measurements of all four transducer arrays, located on the anterior, medial, posterior and lateral aspects of the prosthetic socket respectively. Subjects were, on average, able to take 12 steps (6 on the prosthetic side) before turning and walking back along the walkway.

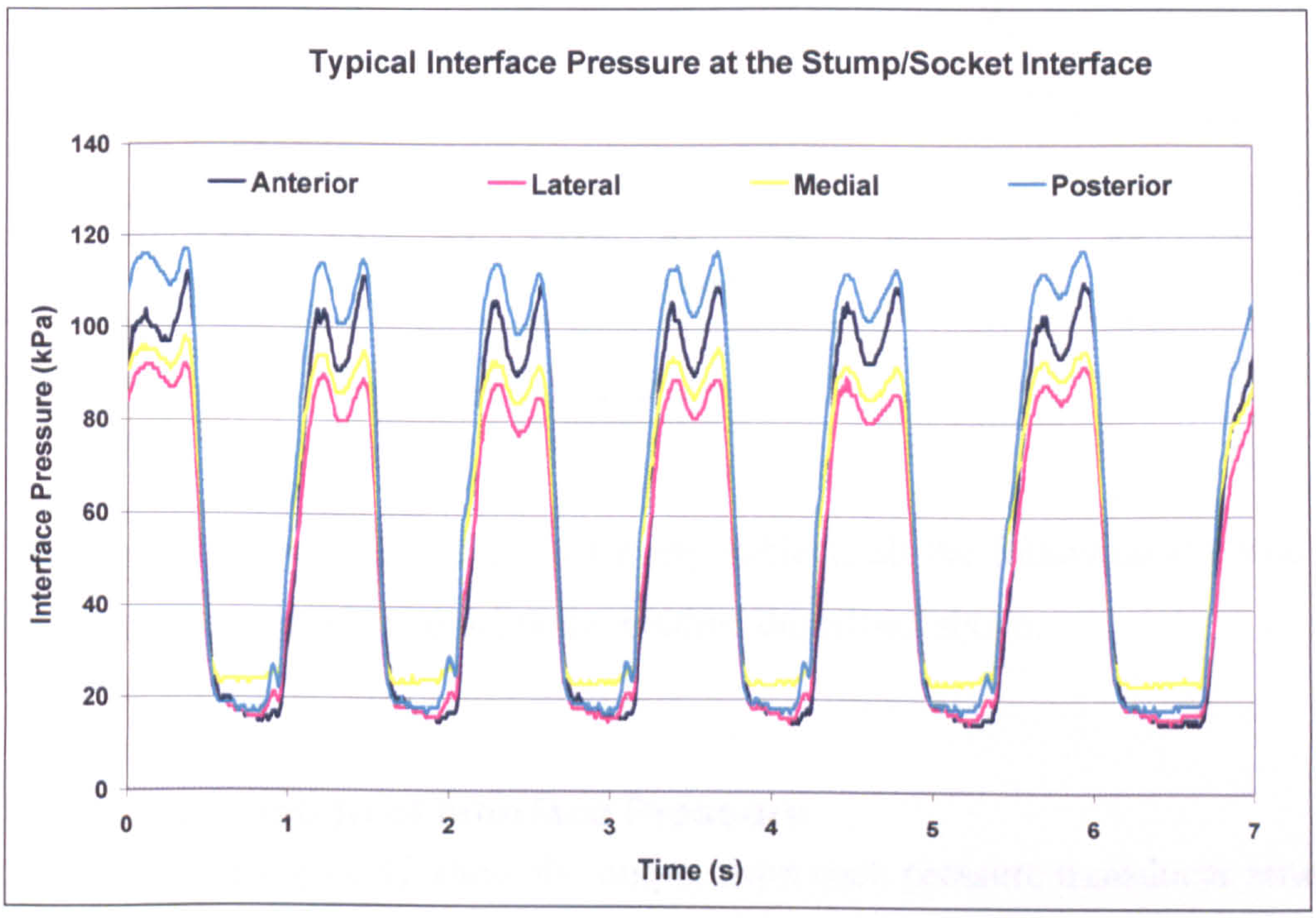


Figure 41: Typical pressure output during level walking at the residual limb/prosthetic socket interface

Having chosen one step using the prosthetic socket interface data, the specific duration for the step was obtained using the information from the prosthetic foot transducer. This was made possible by synchronisation of the foot and socket sensors during data capture. The point at which the number of cells at the heel became active was taken as heel strike. The point at which the cell activity ceased was taken as toe off, and the end of stance. A step lasted approximately 1 second, although this was depended upon the walking speed of the subject (Figure 42).

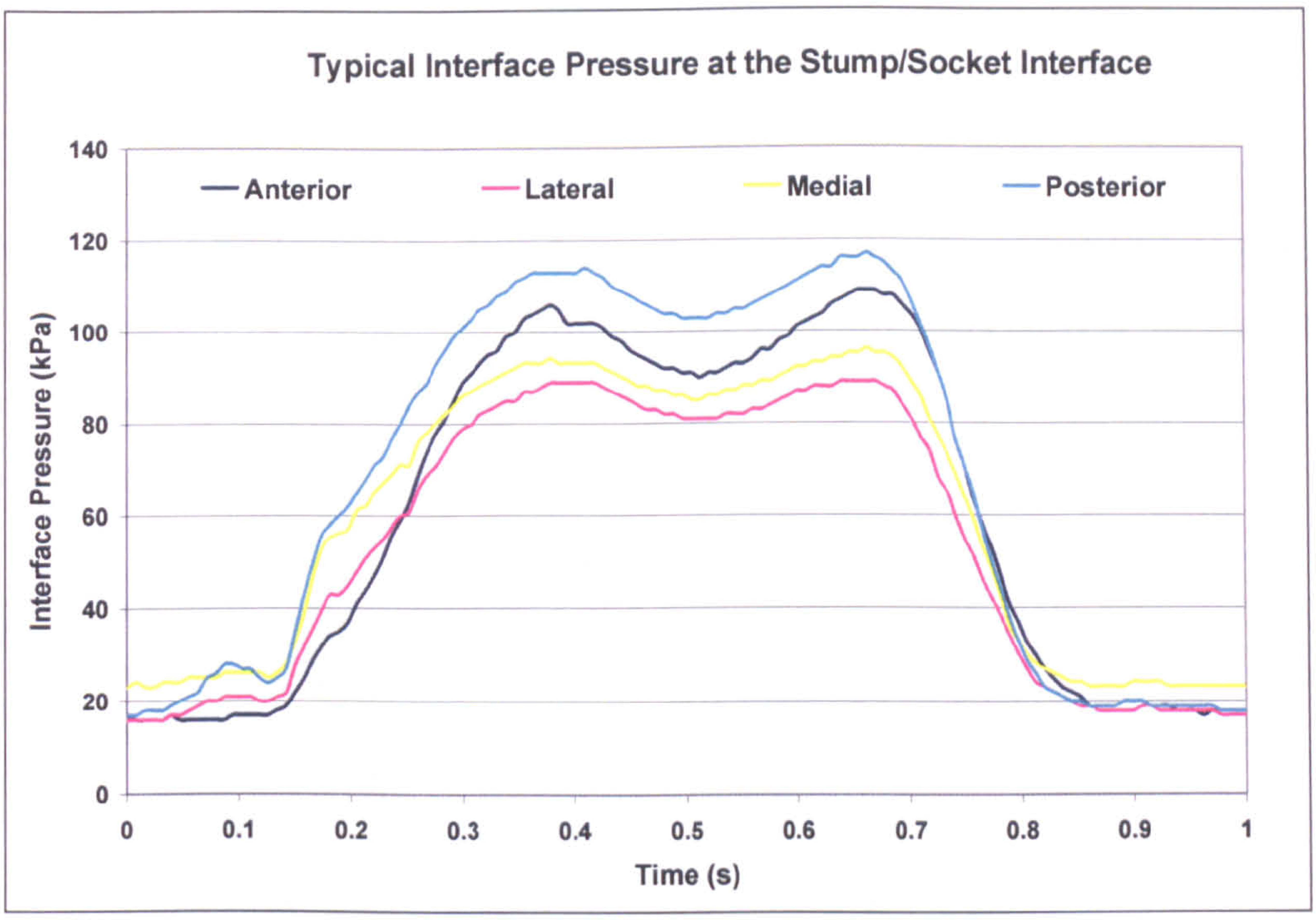


Figure 42: One step chosen for further analysis

This procedure was carried out for every subject; all the following analysis is based on the single step selected using the method described above.

Visual Description of Interface Pressure

Figure 41 and Figure 42 show the output from each pressure transducer array. Using this information a visual description of the results will be given, before any statistical analysis is performed.

Selecting Specific Points within Stance

The pressure output in its original form is displayed in continuous form, in terms of time. The time of stance phase varies from subject to subject, making data unsuitable for comparison between subjects.

The purpose of this investigation is to compare the maximum levels of interface pressure between subjects wearing the two different types of prosthetic socket. The peaks in interface pressure within stance phase are important because it has been shown that increases in pressure on the tissue surface can lead to blood occlusion and possible tissue damage (Edsberg et al., 1999). The exact point within stance phase at which they occur is not required for this investigation.

Upon examination of the interface pressure output, the prosthetic socket interface pressures follow similar waveform to those typically associated at the foot. There are three points of interest during stance phase; Weight acceptance, Stance and Forward Progression (Fish and Nielsen, 1993).

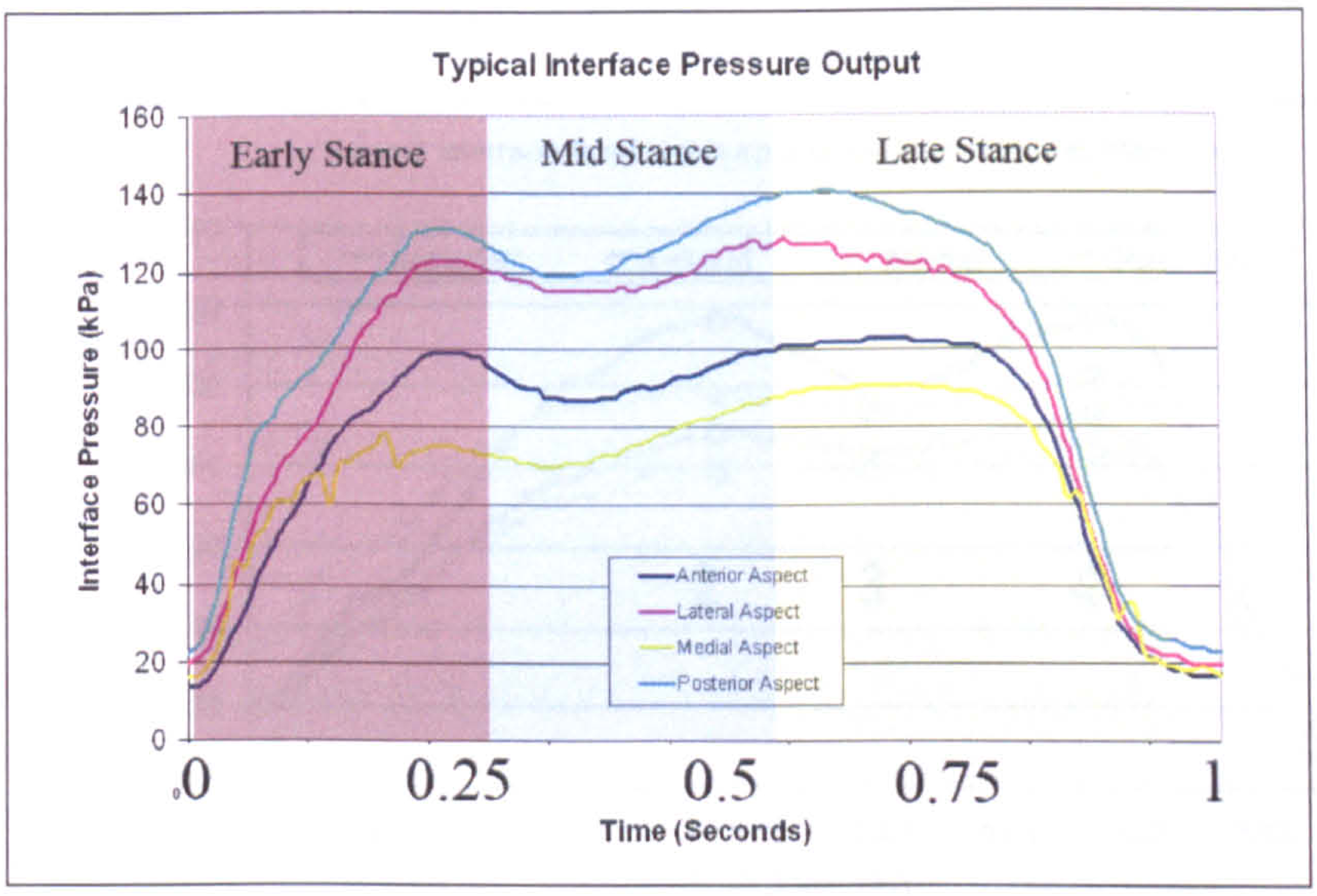


Figure 43: Typical Pressure Output. Showing the Three Sub-Phases

Weight acceptance portion of the stance phase includes initial contact and loading response. The middle phase, Stance, includes mid stance, and terminal stance. The final portion of stance phase, Forward progression, encompasses terminal stance and pre-swing. These three phases can be seen in Figure 43. The first phase is during loading response, when the interface pressure increases to the first peak. The second phases cover the mid stance period, when the interface pressure is more stable, maybe reducing slightly at the mid point of stance. The final phase indicates the period of late stance, after reaching a peak, the interface pressure reduces as the prosthesis moves towards swing phase and body weight is transferred to the sound limb. After recording three points are selected within the selected step. Two of these are given by the two peaks seen in the output waveform. The third by the mid point between the two peaks.

The peak in interface pressure during early stance, late stance and the low point at mid stance have been identified in Figure 44 as points 2, 4 & 3 respectively. If the stance phase interface pressure for each is considered using readings from these three points, the time each phase takes can be eliminated. As stated earlier, the period of stance phase was determined using the foot transducers. Initial contact, point 1 and at final contact, point 5 are also shown in Figure 44.

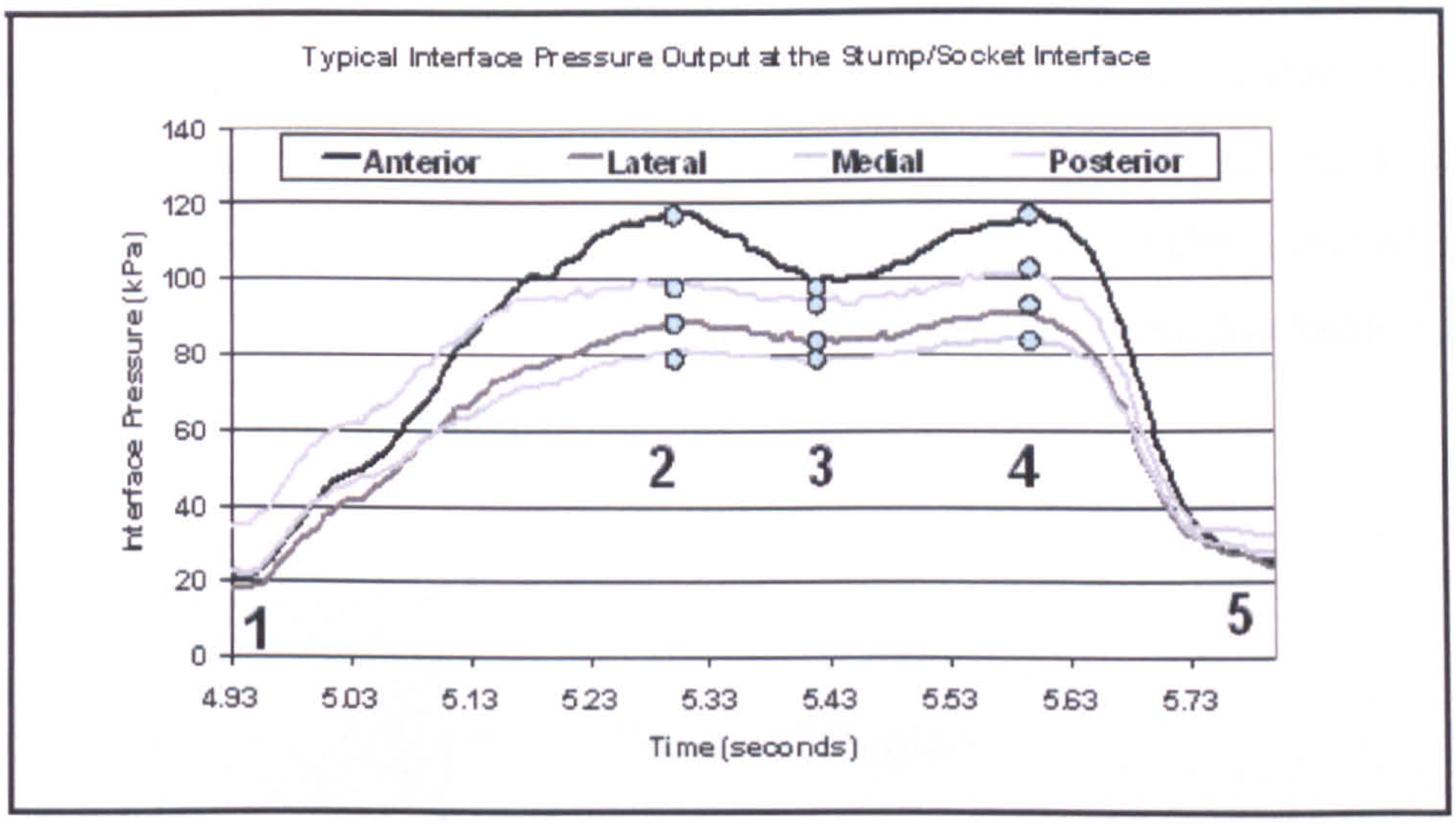


Figure 44: Points selected at peak values

Describing Different Pressures

The description of the interface pressure over a region is given using two methods. Firstly the **Average Area Interface Pressure**, this term denotes the average (mean) pressure for a collection of individual cells. The second method of displaying pressure is the **Peak Interface Pressure**. The term Peak Pressure refers to the interface pressure at a specific point within the region.

Displaying Pressures

Two methods of displaying the interface pressures are shown. The absolute pressure, average and peak are given in terms of Kilopascals (kPa). The peak pressure is also given in terms of a percentage increase from the average pressure.

Dividing the Transducer Array into Regions

During stance phase the interface pressure between residual limb and prosthetic socket will change dependant upon many factors. These include prosthetic alignment, walking pattern and walking speed. Moments and couples acting on the prosthesis during stance result in the location of peak pressures changing as the position of the socket changes with respect to the prosthetic foot. To determine how the pressure migrates over the prosthetic socket during stance, the interface will be divided into smaller regions. The four arrays within the prosthetic socket were divided into two sections, in half, transversely, this producing a total of eight proximal and distal regions. Each transducer array was divided into two areas, Figure 45. When sub-dividing the array into smaller areas, the name given to these sections is called **Regions**.

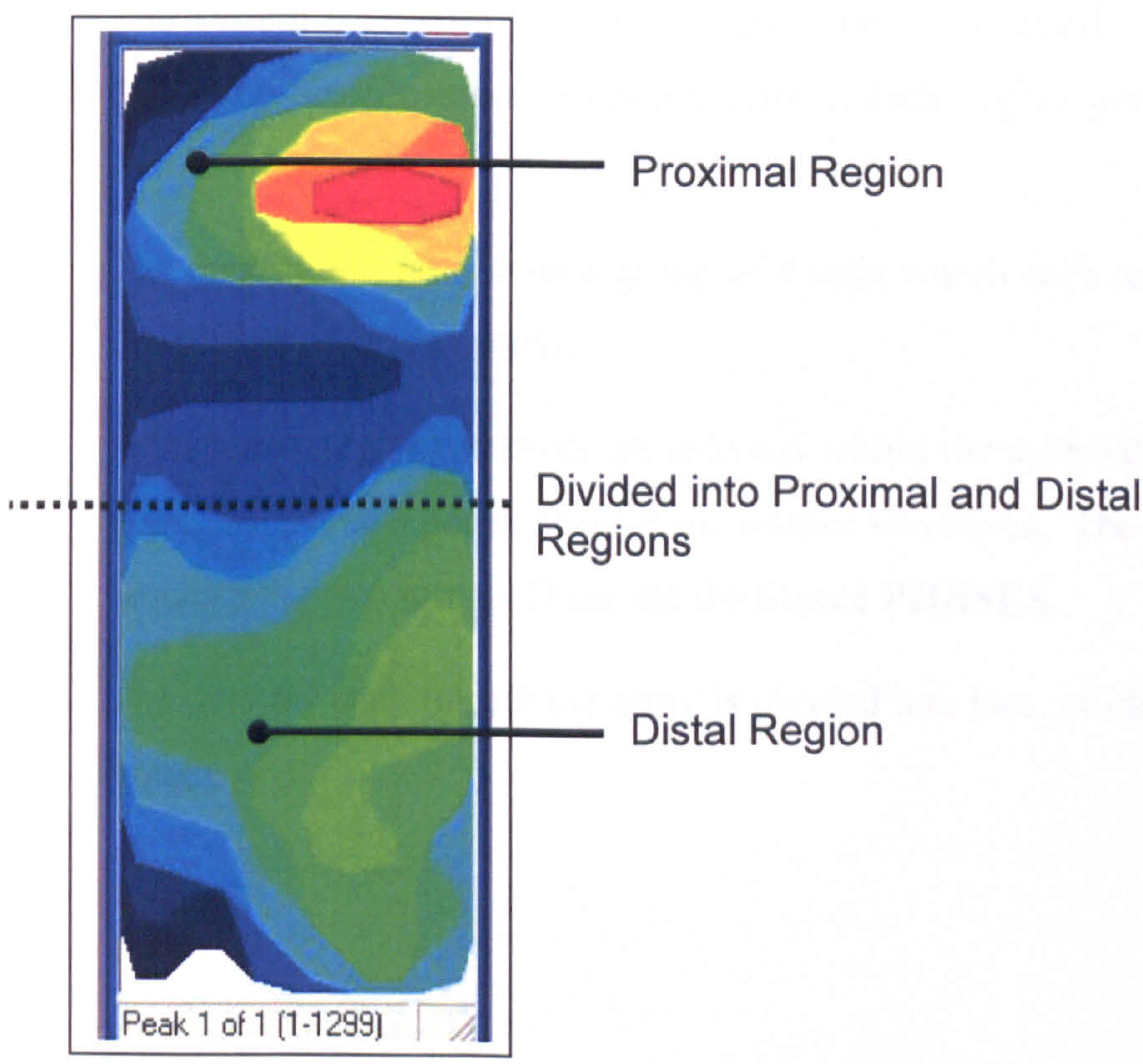


Figure 45: F-Scan Socket Transducer Divided into Regions

Summary of F-Scan Pressure Data Display

It has been shown how the data which is recorded is used and managed into a form which can be analysed. This is a brief summary of the methodology and includes the terminology derived from the processes.

- F-Scan socket transducers contain a number of **CELLS,** which make up a transducer **ARRAY.**
- Four arrays are positioned inside each prosthetic socket. These are the socket **ASPECTS.**
- The system records the interface pressure while the subject walks for 12 seconds. During this time a number of steps are captured.
- One step is selected. The duration of it is determined using the F-Scan in shoe foot transducers.

The system calculates the mean output over all selected cells for every frame of data. The mean pressure over the cells in each region produces the **AVERAGE** pressure output.

The maximum pressure on a group of 4 cells within each region for every frame is the **PEAK** pressure output.

After recording three points are selected within the selected step. Two of these are given by the two peaks seen in the output waveform. The third by the mid point between the two peaks. These are the Stance **PHASES.**

The data for each transducer array is divided into two, producing 2 **REGIONS** per aspect.

9.3.3 ActivPAL Output

The ActivPAL monitors provide information regarding the number of steps taken each day, the cadence and the time of day the activity was performed.

Number of Steps Taken

The ActivPAL software displays the recording output in various forms. Outputs can be displayed either as a summary of daily activities or by hourly activity. The summary of daily activity shows activity on an hour by hour basis, indicating the proportion of each of the three forms of usage, i.e. walking, standing or sitting, Figure 46. However, due to the position of the monitor in this study, only the stepping activity is used, as the orientation of the monitor could not detect weather the subject was sitting or standing.

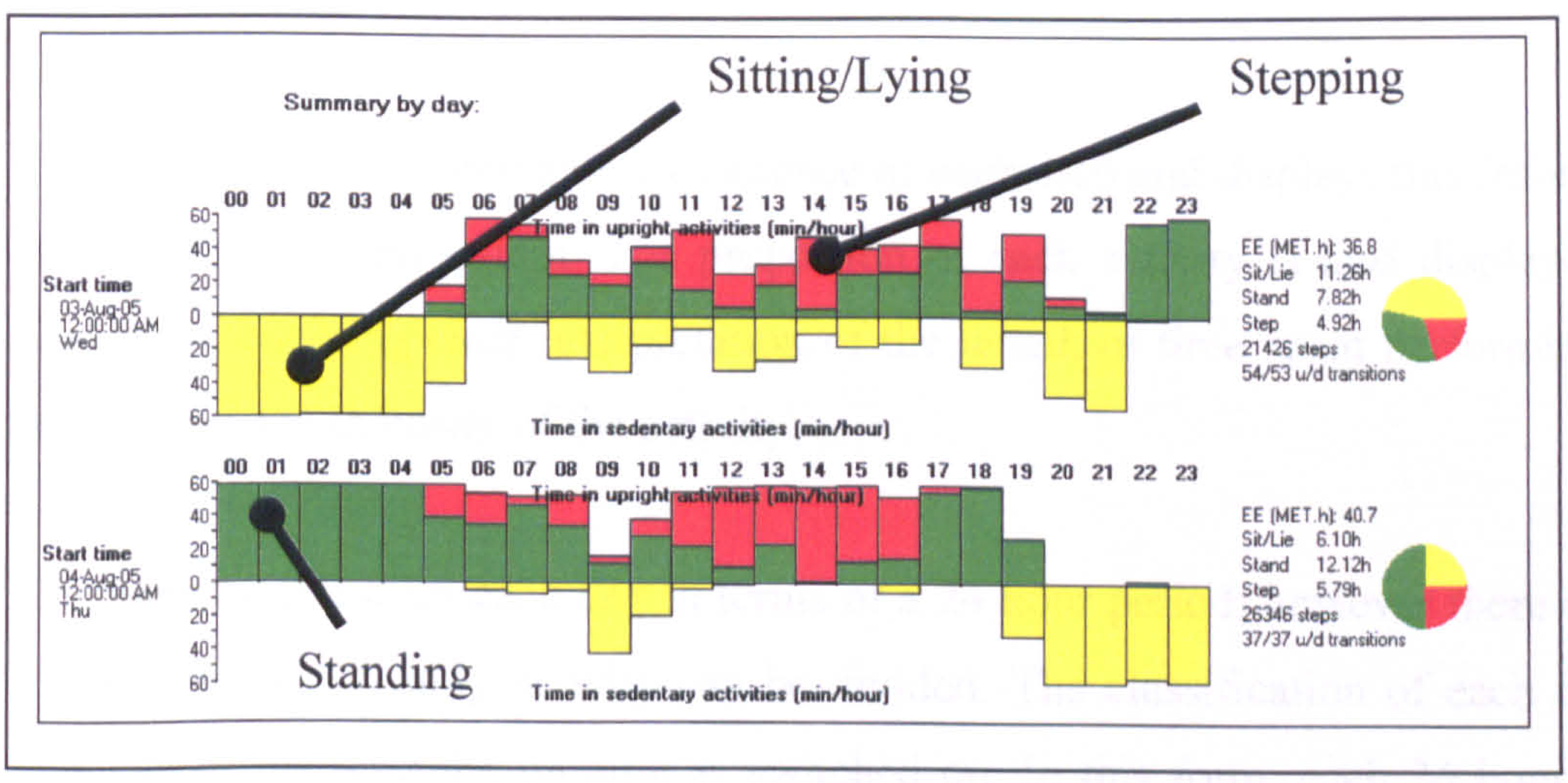


Figure 46: Activity Summary by Day

Hourly summaries show activity every 15 second period is displayed. As was the case for the daily display, the different forms of activity are shown using the same different coloured lines, Figure 47.

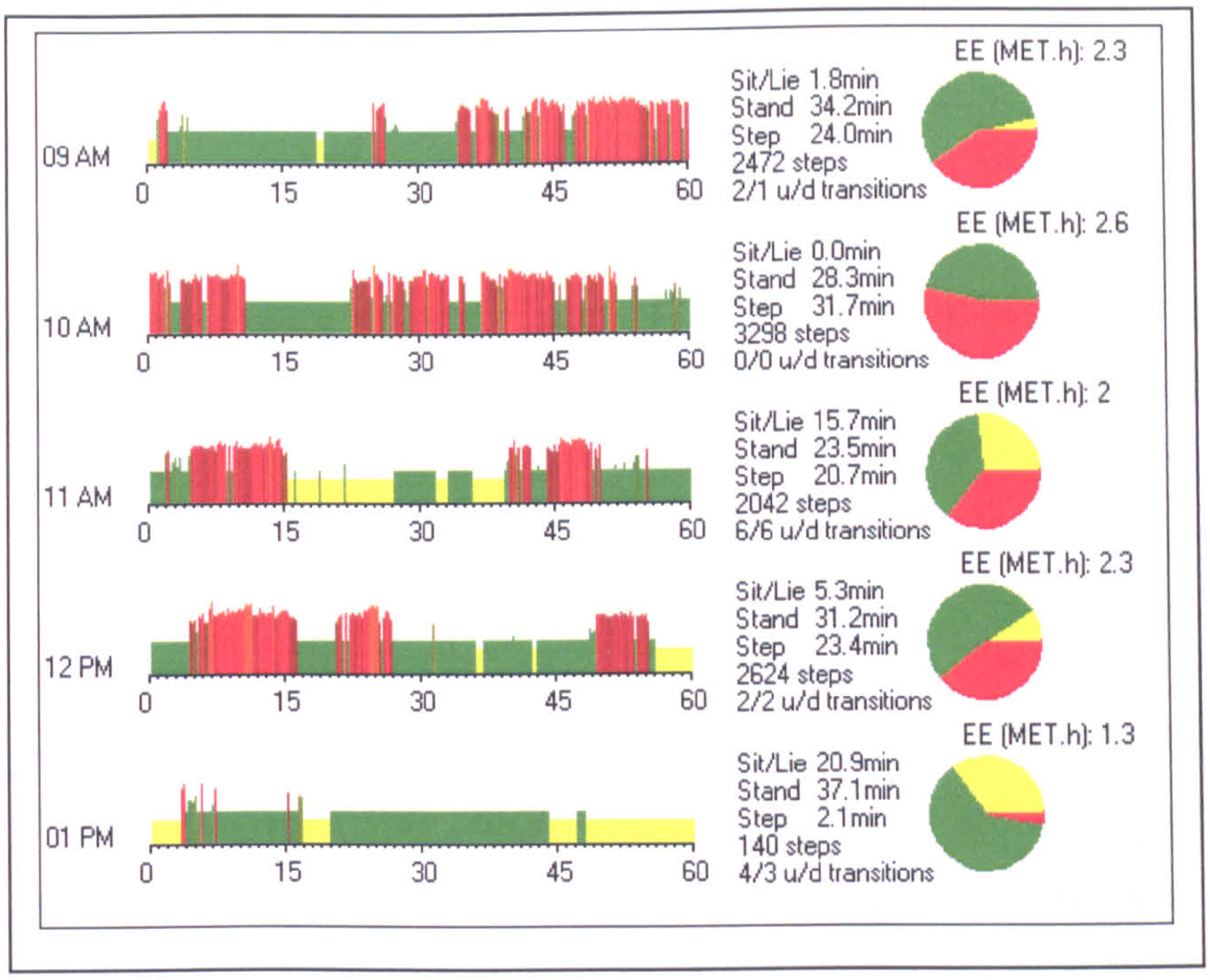


Figure 47: Activity Summary by Hour

The daily summary calculates the cadence of each step and displays this information in the form of a histogram. The proportion of each activity is also displayed as a histogram, enabling clear interpretation of the length of time spent performing each activity and the intensity of the activity.

The monitor classifies each day in terms of a 24 hour period; however there are two methods in which daily activity can be divided. The classification of each day can begin from the time the monitor is switched on. In this form, each 24 hour period begins and ends at an arbitrary time, determined by the activation time of the monitor.

The other format, and the one chosen to determine daily activity for the purposes of this study is by classifying each day from mid night (12am). Regardless of the activation time of the monitor, each daily interval is at mid night. The first day and last day of monitoring contain less than 24 hours, and are therefore disregarded when analysing the data. Once the monitor was switched on by the researcher at the beginning of the study, the monitor remained on until being returned after a one week period.

Percentage of Time spent Walking

In addition to the number of steps taken each day, the total time spent walking is given, see Figure 46 and Figure 47. The time (in hours) for each subject will be converted into a percentage of the total time in order that the subjects can be compared.

Cadence

The cadence (steps per minute) of each step is also recorded by the monitor. The monitor provides this information in the form of a histogram. The histogram indicates the total number of steps taken at a particular cadence. The number of steps taken at each cadence was converted into a percentage of the total number of steps taken in the day. This enabled subjects with differing number of recorded daily steps to be compared. The average cadence of both groups will be displayed.

Time of Day of Activity

The on board clock within the activity monitor enables the time of day of activities to be recorded.

Transferring Data

Once returned, the information is uploaded and saved. All information displayed, can be saved and exported into Microsoft Excel spreadsheets, making further interpretation of the data possible. Once data is successfully transferred, the monitor is reprogrammed. This process erases all data held and re synchronises the monitors on board clock with the computer clock.

9.3.4 PEQ Output

The majority of questions contained in the PEQ resulted in a numerical value representing the level of agreement the subject gave to each statement. All lines are 100mm long, recorded as a number of between 0 and 100. Values of 0.5 were given to any response which fell between two 1mm intervals. Six of the questions within the PEQ are in the form of a seven point Likert scale. Each question is given an individual code, these codes and the corresponding results for each subject group are given in the results chapter, and Appendix 3.

PEQ Categories

For the most part, the categories to which the questions are attributed are grouped together within the questionnaire. The heading of these groups are not shown within the PEQ, however the questions are divided into seven specific groupings according to the type of question being asked. Outlined below is a description of each of the groups.

PEQ Validated Scales

The description of the seven groups below can be classed as either independent or validated scales. Forty one of the eighty two questions (50%) within the PEQ are classified within nine validated sub-scales. The average score from the responses in each of these nine "validated" sub-scales can be reported. These validated scales are used when comparing the PEQ responses to the interface pressure data. The responses from the "independent" questions cannot be grouped together.

Group 1: Questions relating specifically to the prosthesis:

Satisfaction (Independent): The subject's satisfaction regarding their prosthesis and their ability to walk using the prosthesis.

Utility (Validated): Subjects are asked to rate different aspects of their prosthetic limb, including the fit and weight and the comfort in various activities. The ease of donning and doffing limb as well as the energy used when walking are also included.

Appearance (Validated): As well as the outward appearance of the limb, subjects are asked about the ability to wear different clothes and shoes and to rate any damage caused by their prosthetic limb.

Residual Limb Health (Validated): General questions relating to the skin tissue of the limb, including amount of sweating and smells created by wearing the socket. Limb swelling, development of rashes, pimples and sores caused by the prosthesis are also covered.

Sounds (Validated): Any noises created by the prosthesis are rated and how these noises impacted the wearer is included in this category.

Group 2: Questions about Specific Bodily Sensations

Pain (Independent): This category covers the largest collection of questions within the PEQ. Several of the questions within the pain grouping are in the format of a Likert scale, requiring the reader to rate particular aspects of pain into one of 7 codes. Questions include phantom limb sensations and pain, other painful sensations in the residual limb, other leg and foot and back pain. As well as rating the pain the subject is asked to rate the impact these feelings have had on them.

Group 3: Questions about Social and Emotional Aspects of Using a Prosthesis

Perceived Response (Validated): These questions refer to the attitude the prosthetic wearer has to those around them, and any frustration the subject has experienced. Questions relate to the partner or family members of the subject, and their response to the prosthesis.

Social Burden (Validated): The ability to look after someone else and the burden the prosthesis has had on the wearer is included in this group as is information about how the prosthesis has hindered the wearer.

Group 4: Questions about the Ability to Move around

Ambulation (Validated): The ability of the subject to walk with their prosthesis in various environments such as up and down stairs and hills are included, as is different surfaces.

Transfer (Independent): The ability to transfer from chairs, toilet and showers are questioned in this category.

Group 5: Questions about Satisfaction with Particular Situations

Satisfaction (Independent): Previously described.

Well Being (Validated): Questions relating to life after amputation and the quality of life are asked within this grouping.

Prosthetic Care (Independent): The prosthetist and prosthetic care the subject has received during their treatment is rated.

Group 6: Questions about Abilities to do Daily Activities under Difficult Conditions

Self Efficacy (Independent): These questions refer to the subject's ability to achieve routine tasks if the comfort or fit of the prosthesis is poor.

Group 7: Questions about the Importance of Different Aspects of Experience with the Prosthesis

Importance (Independent): These questions all begin with "How important..." They ask the subject to rate the importance of many of the previous questions covered in other categories.

9.4 Analysis of Results

During the analysis of the data, the three outcome measures were analysed as individual items. Following this a comparison of the outcome measures was made. All analysis was performed using two statistical packages; these were Minitab version 14 (Minitab Inc, State College, PA) and SPSS version 14 (SPSS Inc, Chicago, IL). Levels of significance was be set at 5%, unless otherwise stated. The purpose of the data analysis was to determine the differences which exist between the two different prosthetic socket designs using the three outcome measures described. During the description of the analysis the term "Group" was be used to describe the collection of subjects who wore the same design of prosthetic socket.

9.4.1 Analysis of Subject Demographic

In the first instance descriptive statistics are provided for the general questions gained from each subject, such as the height, gender, age and reason for amputation. Residual limb measurements are also shown in this form to provide a clear understanding about the subjects participating in the study.

The normality of results for each group was determined using the Anderson-Darling test for Normality. Normality was gained if the p-value is greater than 5%. If data in both groups is normally distributed a 2 sample independent t-test will be used to determine how well matched the two groups are. The Mann Whitney independent sample test will be used if data from one or both groups is not normally distributed.

9.4.2 Analysis of Interface Pressure

Analysis was performed using the three outputs detailed i.e. average interface pressure, peak pressure and peak percentage increase. For each of the three measures the same analysis was completed.

It was shown in the output section of this chapter that a number of processes have been performed to create manageable data. Each subject has four transducers, which are divided into two. This produces eight regions. Three phases are selected for a particular stance phase and the interface pressure taken at the **eight** regions. Therefore a total of **twenty four** data points are produced for each of the pressure outputs for each subject. This data is provided in Appendix 5 and Appendix 6.

Statistical Analysis of Interface Pressure

During the analysis three terms were used to describe the location of the interface pressure, namely **Groups, Regions** and **Phases.** Sockets were either of a hands on, or hands off design, this establishes two **Groups.** Eight positions on the limb were defined, **Regions,** and the point during the gait cycle and which the interface pressure was recorded, **Phases.** To determine the interaction of interface pressure throughout the socket and between the two socket designs a three factor, repeated measure analysis of variance (ANOVA) was used. The three factors are **Group, Phase** and **Region.**

If any significant interactions between the two groups occurred, a 2 sided Tukey Post Hoc test was used to identify the specific areas for further investigation. Independent sample tests were used to determine the level of significance of any differences found.

9.4.3 Analysis of Activity Monitor Data

The monitors are capable of displaying daily activity in terms of a 24 hour period or by day. The 24 hour period classifies data into 24 hour periods from the point at which the monitor is switched on. Display by day utilises mid night (0.00) as the interval between each day's activity. For the purposes of this project the activity recorded per day was used in this way so that all subjects' activity would be categorised at the same point. Only daily step count and percentage of time spent in walking activity was used in this study.

Each subject wore the monitor for one week; however the actual time recorded varied. Only complete day recordings were used for analysis. This reduced the total number of days used, as the first and last day of recording were omitted due to incomplete data. The average (mean) of the daily number of steps was used in the analysis of the subject's activity. Normality and differences between the two groups were determined using the same methods as described for the subject demographic data i.e. Anderson Darling test for normality and Independent sample tests, results shown in Appendix 11.

9.4.4 Analysis of PEQ Information

Each PEQ visual analogue scale was measured and the result recorded. Due to the large amount of data created the individual measures are given in Appendix 12. The average responses to the individual questions contained within the PEQ was found in terms of the two subject groups and the distribution tested using the Anderson Darling test for normality. Differences between subject responses were determined using independent sample tests. If responses from both group followed a normal distribution then an independent sample t-test was the statistical method to check for differences. If either or both of the group's responses were not normally distributed then the Mann Whitney test was used, Appendix 13.

Scores from the nine validated sub-scales were analysed using the same method as the individual questions.

9.4.5 Comparing the Outcome Measures

Having analysed the three outcome measures (Interface Pressure, Activity Monitor and PEQ) independently, information from each measure was correlated against each of the other two measures to determine if a relationship existed between the three outcome measures. The Pearson correlation was the test used in all cases.

PEQ and ActivPAL

The response scores from all of the questions using the visual analogue scale within the PEQ were correlated against the daily step count from each subject, Appendix 14.

ActivPAL and Interface Pressure

The daily step count from each subject was correlated with the average and peak interface pressure from each of the eight regions within the prosthetic socket, Appendix 15 .

PEQ and Interface Pressure

The response scores from the nine validated scales were correlated with the interface pressure measurements taken within the prosthetic socket, Appendix 16.

9.5 Chapter Summary

The processes of designing the investigation, displaying the results and methodology of analysing the results obtained have been described in this chapter. The experimental design identifies and described the three outcome measures, i.e. the Tekscan, F-Scan pressure mapping equipment, PAL Technologies ActivPAL activity monitor and the Prosthesis Evaluation Questionnaire. In addition to the three outcome measures the experimental design also describes the protocol developed for obtaining the data. The methodology of displaying the results pays particular attention to the F-Scan data. A detailed process of condensing and displaying the large amount of data gained from the F-Scan recordings is given. Different statistical methods are described which were used to analyse the three outcome measures. The results of the data collection and subsequent statistical analysis are given in the following chapter.

10 Results

10.1 Chapter Introduction

The data in this chapter is divided into four sections. Firstly the demographic of the subjects who participated in the study are examined. Secondly, data gained using the foot transducers is analysed in order to develop an understanding as to the variations between the two subject groups in terms of gait patterns. Thirdly the data from three outcome measures is analysed. Results from the three outcome measures are independently analysed and finally the results from the three outcome measures are compared.

10.2 Subjects

10.2.1 Subject Demographic

A total of 48 subjects were randomly selected and invited to participate in this study from 79 people who responded positively and invited to attend for the study from a total of 133 patients attending the West of Scotland Mobility and Rehabilitation Centre (WESTMARC), based at the Southern General Hospital situated in Glasgow. The participants recruited had established unilateral amputation of at least one year and had been wearing their current prosthesis on a daily basis for considered normal activities of living for at least 6 months.

Two groups of 24 subjects (wearing two kinds of prosthetic socket in their own prosthesis) were then. Half of the subjects (n=24) had been using trans-tibial prostheses with the pressure cast prosthetic socket concept. The other subjects (n=24) had been using prostheses with a hand cast socket of the Patellar Tendon Bearing (PTB) design. The group sample size of 24 subjects was selected to achieve a statistical power of 80%. The group sample size (n=24) was based on the pilot studies described in the introduction (Convery and Buis, 1998, Convery and Buis, 1999) and allowed detection of a clinical difference of 10 kPa between the paired average peak pressures for both sockets with a 5% level of significance. The demographic of these subjects are shown in Table 1. Before any measurements were taken informed consent was obtained and information regarding the project conveyed to each subject.

Table 1: Descriptive Statistics for Subjects

Variable	Group	Number of Subjects	
Subject	Hands Off	24	
	Hands On	24	
Gender (Male/Female)	Hands Off	20/4	
	Hands On	20/4	
Side of Amputation (Left/Right)	Hands Off	14/10	
	Hands On	12/12	
Reason for Amputation (PVD/Other)	Hands Off	4/20	
	Hands On	8/16	
Variable	**Group**	**Mean ± St Dev**	**Range**
Age (years)	Hands Off	50.04±11.89	25-69
	Hands On	60.54±14.85	29-89
Height (m)	Hands Off	1.74±0.095	1.5-1.85
	Hands On	1.72± 0.071	1.63-1.83
Mass (kg)	Hands Off	83.99±16.84	60-116
	Hands On	82.96±15.44	57.17-104.8
Body Mass Index	Hands Off	27.63±4.99	17.92-36.44
	Hands On	28.52±5.44	20.26-38.59

It can be seen from Table 1 that both groups were well matched in terms of sample size. The majority of subjects were male (83%), and subjects with non PVD reasons for amputation made up the largest proportion of subjects (75%). Despite this uneven distribution, the number of Male and Female subjects is the same between groups, and both groups have a disproportionate number of non PVD subjects.

The distribution for normality was checked using the Anderson Darling test, results given in Table 2. Where tests for normality indicated that both groups followed a normal distribution the independent sample t-test was used. In cases where variables from either or both subject groups did not follow a normal distribution the Mann Whitney independent sample test was used. In all cases significance was taken where the p-value was 0.05.

Table 2: Tests for Normality and Independence

Variable	Socket Type	Test for Normal Distribution	Independent Sample Test (p value)
Age (years)	Hands Off	0.485	**0.010**
	Hands On	0.779	
Height (m)	Hands Off	**0.009**	0.679*
	Hands On	**0.028**	
Mass (kg)	Hands Off	0.164	0.826
	Hands On	0.083	
Body Mass Index	Hands Off	0.818	0.573
	Hands On	0.252	

*denotes Mann Whitney test.

Bold- Significant response

No significant difference exists between the two groups in terms of subject height, body weight, or Body Mass Index. A significant difference was seen between the two subject groups in terms of age. Table 1 shows that the age of the subjects wearing the pressure cast sockets are 10 years younger than those wearing the hands on sockets. Although this result does show a significant difference between groups, it reflects the clinical population from which the sample was taken.

10.2.2 Residual Limb Measurements

As described in the methodology section, several measurements were taken from the subject's residual limb. Using these measurements, further calculations can be made to determine the residual limb surface area and volume. These measurements are shown in Table 3. Results followed the same statistical analysis as described for Table 2.

Table 3: Residual Limb Measurements

	Socket Type	Mean ± St Dev (m)	Range (m)	Test for Normal Distribution (p value)	Independent Sample Test (p value)
Circumference at Patella Tendon (m)	Hands Off	0.334 ± 0.033	0.285-0.4	0.205	0.434
	Hands On	0.327 ± 0.031	0.26-0.375	0.587	
Residual Limb Length (m)	Hands Off	0.141 ± 0.019	0.105-0.175	0.610	**0.013**
	Hands On	0.123 ± 0.025	0.07-0.18	0.250	
CSA at Level of Patella Tendon (m^2)	Hands Off	0.009 ± 0.002	0.006-0.013	0.088	0.445
	Hands On	0.008 ± 0.001	0.005-0.011	0.721	
Surface Area of Residual Limb (m^2)	Hands Off	0.042 ± 0.011	0.029-0.076	**0.007**	0.673*
	Hands On	0.039 ± 0.001	0.021-0.057	0.507	
Volume of Residual Limb (m^3)	Hands Off	0.031 ± 0.008	0.019-0.056	0.098	0.392
	Hands On	0.027 ± 0.008	0.014-0.043	0.282	

CSA- Cross Section Area

*** Mann Whitney Independent Sample Test**

A significant difference can be seen between the residual limb lengths of the two groups (p=0.013). Despite the difference in residual limb length, the surface area and volume of the residual limbs do not show a significant difference.

10.2.3 Interface Pressure Influencing Factors

Interface pressure can be influenced by a number of factors. Those which have been measured include the residual limb surface area and the weight of the subject. Table 2 and Table 3 show both sample groups are well matched in terms of these variables. No significant difference is seen between the two groups when tested as independent variables. This finding is important as it means that differences between the two groups in terms of interface pressure are not from the residual limb measures or subjects' weight.

It is possible that the interaction of body weight and limb size creates variation between the two sample groups. This difference could influence the interface pressure readings. To determine if a difference exists between the two groups, the variables have been tested in combination.

For these calculations body weight has been converted into body mass. Three calculations were performed, body mass was divided by the residual limb surface area (BM/SA) and the cross sectional area at the patella tendon level (BM/CSA). These two calculations provide a theoretical pressure measurement. It does not take into account the influence of alignment and walking speed, however it does include the measured subject variables. Body mass was also divided by the volume of the residual limb (BM/Vol). Table 4 displays the results of these calculations.

Table 4: Combining Variables

	Socket Type	Test for Normal Distribution	Independent Sample Test (p value)
Body Mass/CSA	Hands Off	0.398	0.473
	Hands On	0.256	
Body Mass/SA	Hands Off	**0.036**	0.805*
	Hands On	**<0.005**	
Body Mass/ Vol	Hands Off	**0.013**	0.232*
	Hands On	**0.027**	

*** Mann-Whitney Test**

CSA-Cross Section Area, SA-Surface Area, Vol-Volume

The results in Table 4 show that no significant difference exists between the two sample groups when combination of body mass and residual limb size is examined.

10.3 Foot Transducers

Data from the foot transducers and video enabled a specific step recorded during the trial to be selected for analysis. The first and last steps recorded were removed, the remaining steps were examined and a "typical" step output was chosen. Using this information the timing of the selected step could be made and the cadence calculated. The information in Table 5 shows the Timings (in seconds) of the stance and swing phase for both the prosthetic side and the sound side. In addition the percentage of stance and swing is also shown for comparison between groups.

Table 5: Foot Timings

Socket Concept	Hands Off		Hands On	
	Mean (seconds, except*)	Std. Deviation	Mean (seconds, except*)	Std. Deviation
Prosthetic Stance Phase	0.84	0.10	0.89	0.14
Sound Side Stance Phase	0.91	0.13	0.91	0.13
Prosthetic Swing Phase	0.47	0.09	0.44	0.07
Sound Side Swing Phase	0.41	0.06	0.43	0.07
Total Prosthetic Side	1.31	0.13	1.33	0.13
Total Sound Side	1.32	0.16	1.33	0.12
Percent Prosthetic Stance Phase (%)	63.98*	5.48	66.45*	6.26
Percent Prosthetic Swing Phase (%)	36.02*	5.48	33.56*	6.26
Percent Sound Side Stance Phase (%)	68.65*	3.27	67.95*	5.35
Percent Sound Side Swing Phase (%)	31.35*	3.27	32.05*	5.35
Percent Difference (%)	4.67*	7.24	1.51*	8.37

10.4 Prosthetic Socket Interface Pressure

It has been shown in the methodology section how the interface pressure measurement data will be displayed and analysed. Three different formats were described. The first two formats, average interface pressure over each region and peak pressure within each region were in terms of the absolute pressure, this being kPa. The third format, peak interface pressure was displayed as a percentage increase from the average interface pressure for each region.

Output of the four socket transducers

As a precursor to the examination the different regions within the prosthetic socket a visual description of the output will be given for the four aspects of the prosthetic socket. The methodology section described how the interface pressure is displayed using the F-Scan socket transducers. The graph in Figure 48 shows the interface pressure output for one subject during a single stance phase. The four lines represent the average interface pressure over the four pressure transducer arrays.

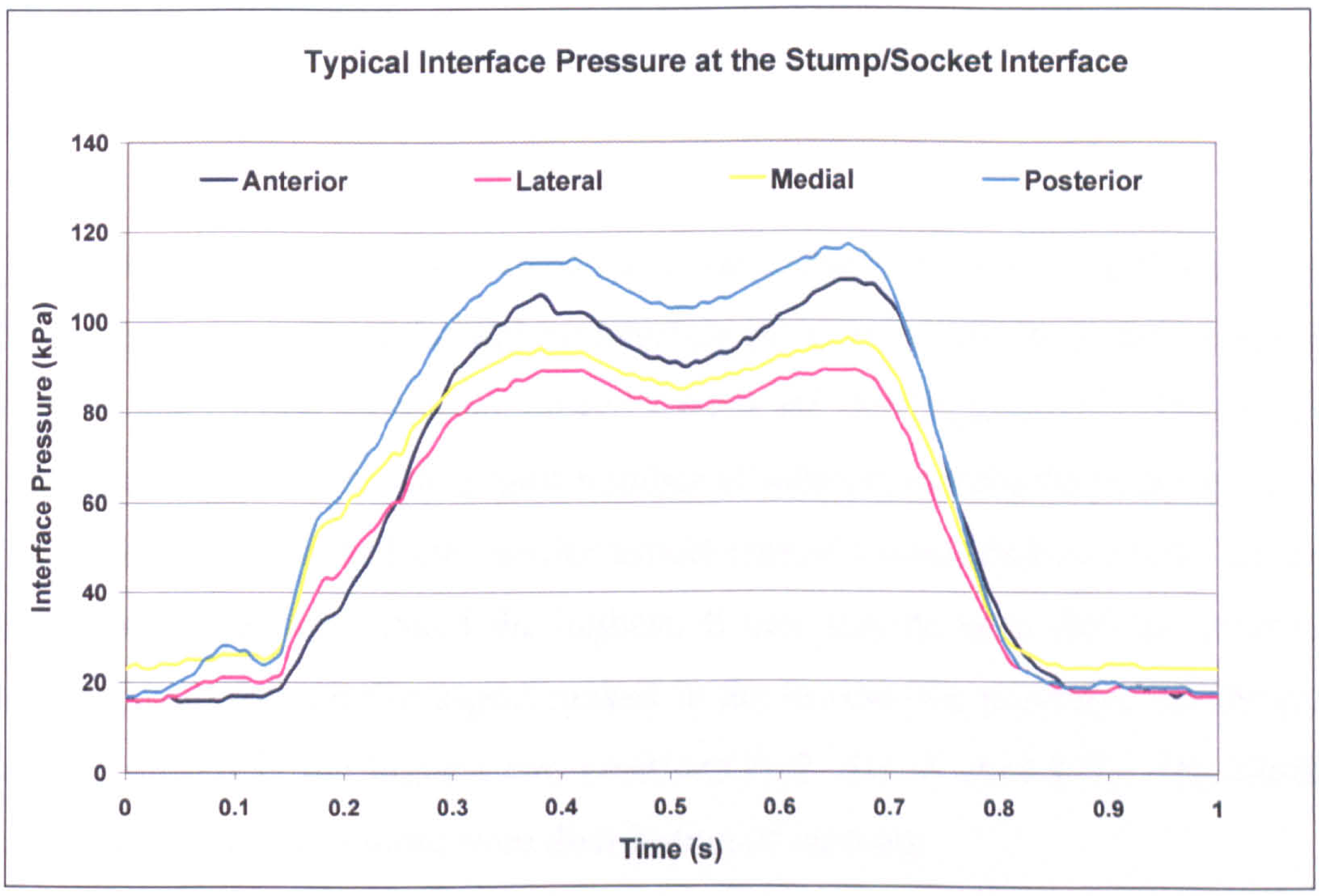


Figure 48: Typical Socket Transducer Output

It can be seen from the graph in Figure 48 that the magnitude of interface pressure at each aspect remains constant with respect to the other transducers through stance. This pattern was experienced by most subjects, Table 6 shows the number of subjects with the same aspect ranking, (and the percentage of the total group). An aspect with the highest interface pressure is ranked 1, lowest interface pressure ranked 4.

Table 6: Socket aspect ranked in terms of interface pressure

Rank	Anterior	Medial	Posterior	Lateral
1	3(6.25)	3(6.25)	**30(62.5)**	12(25)
2	3(6.25)	15(31.25)	11(22.91)	**17(35.42)**
3	17(35.4)	**19(39.58)**	4(8.33)	9(17.75)
4	**25(52.08)**	11(22.91)	3(6.25)	10(8.33)

(%) Percentage of total number of subjects ranking at that position.

Table 6 indicates the socket aspect with, on average the lowest interface pressure is the anterior aspect, and the highest interface pressure is over the posterior aspect. The Lateral and Medial aspects are ranked second and third respectively. The anterior and posterior aspects show the largest number of subjects ranking them in their positions. 52.08% of subjects had the anterior aspect ranked lowest, and 62.5% of subjects had the posterior aspect ranked the highest. It can also be seen that the proportion of sockets with the anterior aspect ranked in the lowest two positions and the posterior aspect ranked in the highest two positions both rise to over 87%. The Medial and Lateral aspects had a more even distribution of ranking.

These results provide an indication as to the pattern of interface pressure over an entire aspect throughout the prosthetic socket during the gait cycle. Further analysis using validated statistical methods will be implemented on subdivided socket aspects at specific points within the gait cycle. The analysis will examine patterns and magnitudes of interface pressure within each aspect and investigate differences between socket concepts.

Interface Pressure Data Handling

It has been shown that the amount of data captured during recording of each subject is too great to display. The methodology chapter identifies the process of condensing this data into a manageable format. The description of selecting particular points within the gait cycle was given. The output of this data selection is given in Appendix 5 and Appendix 6. Data for interface pressure given in this chapter refer to these data points, although they are not shown.

10.4.1 Average Interface Pressure

Interface pressure values identified in this section refer to the average interface pressure over each region as described in the methodology chapter.

Fitting the data to the Model

Each interface pressure recording was identified for each of the eight regions and at the three phases of stance. A three way repeated measure ANOVA model of statistical analysis was used to determine if differences in interface pressure exist between the two subject groups.

The data measured by the F-Scan pressure measurement system was tested to determine if it would fit the ANOVA model. A probability plot of the residual values was produced to determine the normality of the data, with a confidence level of 95%, Figure 49. In addition plots of the residual and fit values were produced to determine the homogeneity of the data, Figure 50.

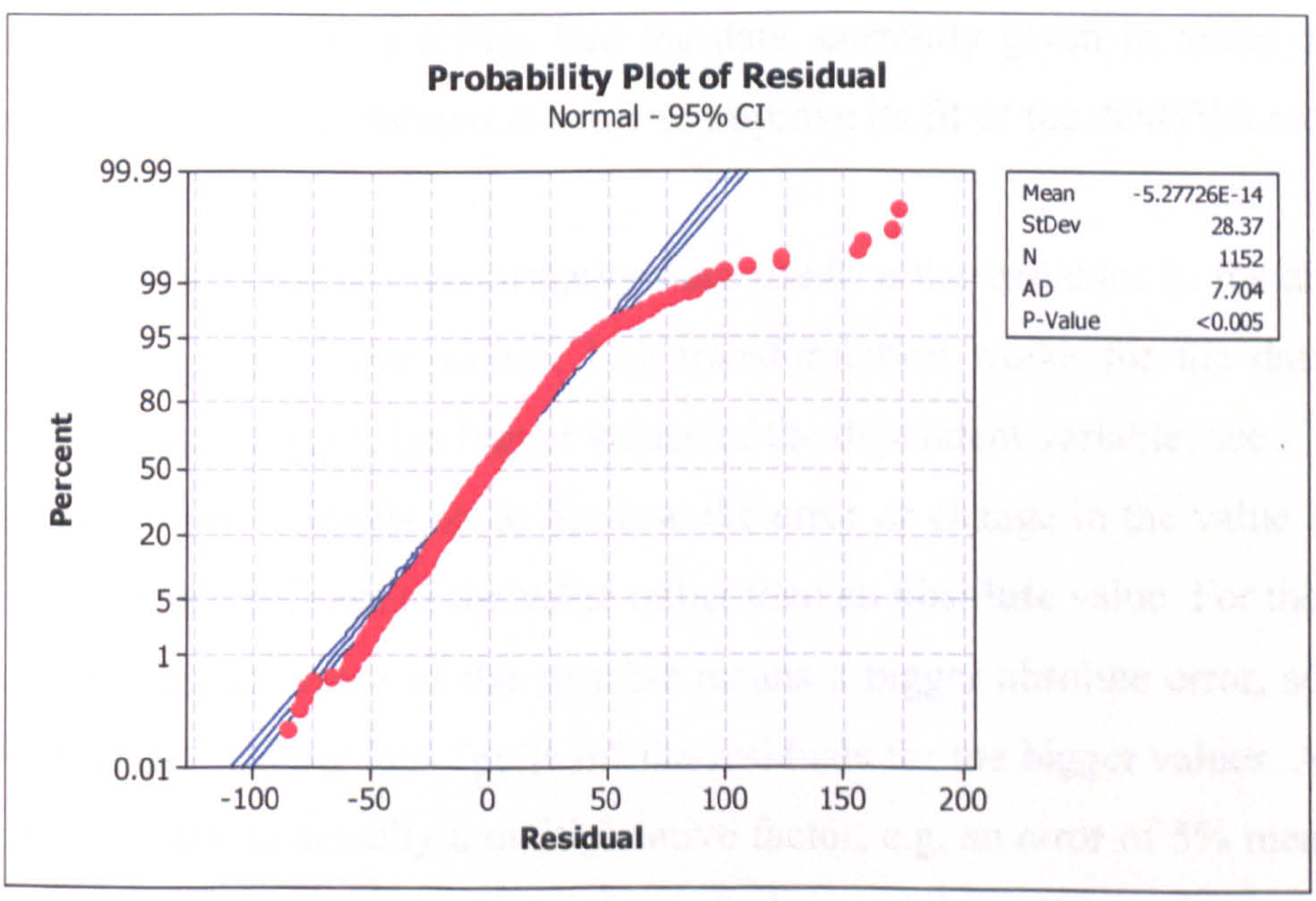


Figure 49: Probability Plot of Residual Average Interface Pressure Values

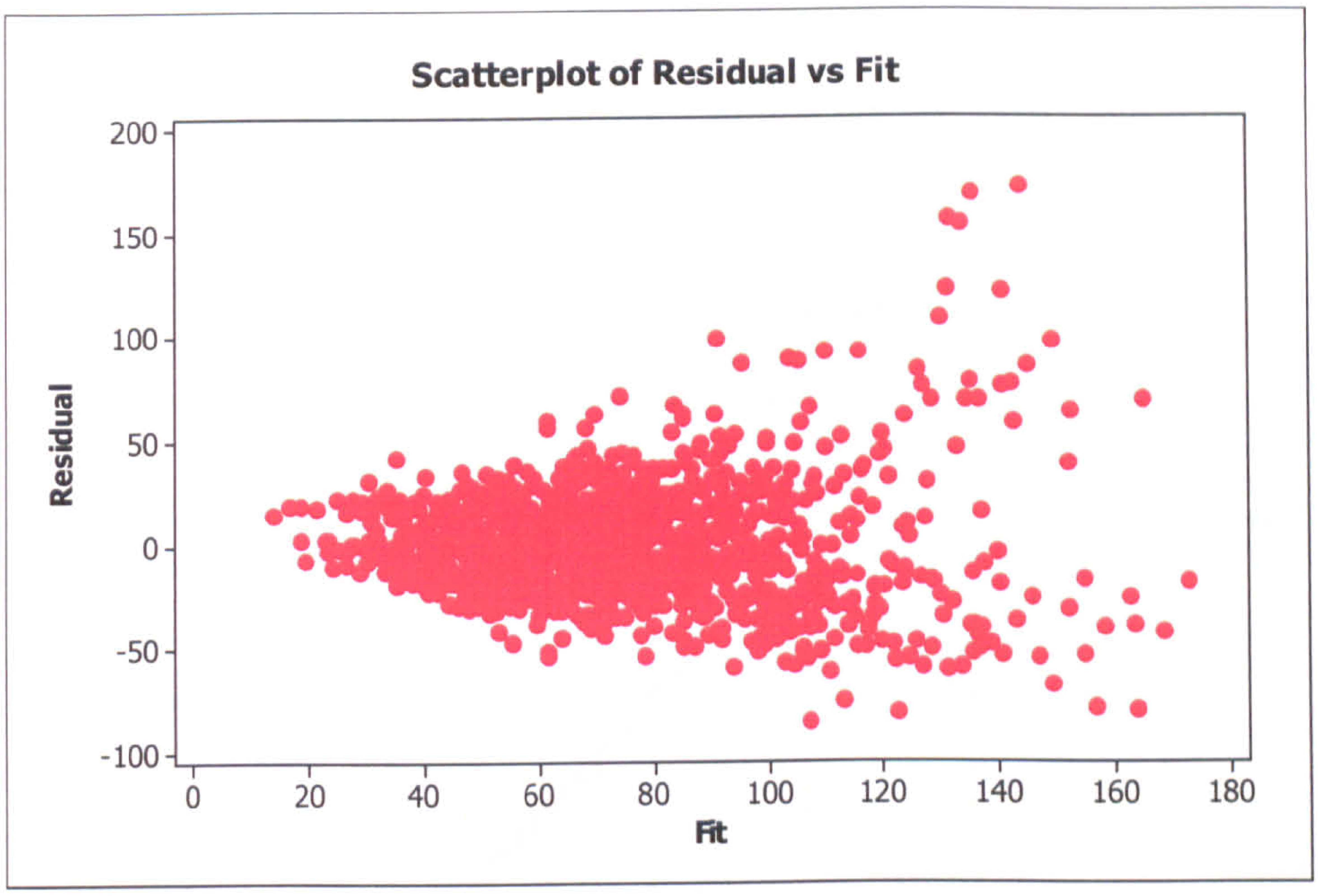


Figure 50: Plot of Residual vs. Fit for Average Interface Pressure Values

It can be seen in Figure 49 that the data does not follow a normal distribution ($p<0.005$). The scatter plot in Figure 50 also shows that the data has poor homogeneity, seen by the wider dispersal of plots as the value of fits increases. The results of these plots means that the data, currently given in terms of kPa will be required to be transformed in order to improve its fit of the ANOVA model.

Natural logarithmic transformations are used on the variables in the analyses, rather than the original raw values. Log transformation works for the data because the residuals get bigger, for bigger values of the dependent variable, see Figure 50. Such trends in the residuals occur because the error or change in the value of an outcome variable is a **percent** of the value rather than an **absolute** value. For the same percent error, a bigger value of the variable means a bigger absolute error, so residuals are bigger too. Taking logs "pulls in" the residuals for the bigger values. A percent error in a variable is actually a multiplicative factor, e.g. an error of 5% means the error is typically 5/100 times the value of the variable. When logs are taken, the multiplicative factor becomes an additive factor, i.e. log(Y*error) = log(Y) + log(error). The percent error therefore becomes the same additive error, regardless of the value of Y. Therefore non-uniform residuals become uniform.

Transforming the data into its natural log (Ln) improved the distribution of the data, Figure 51, although it still does not follow a normal distribution (p<0.005). However the homogeneity of the data is vastly improved, Figure 52.

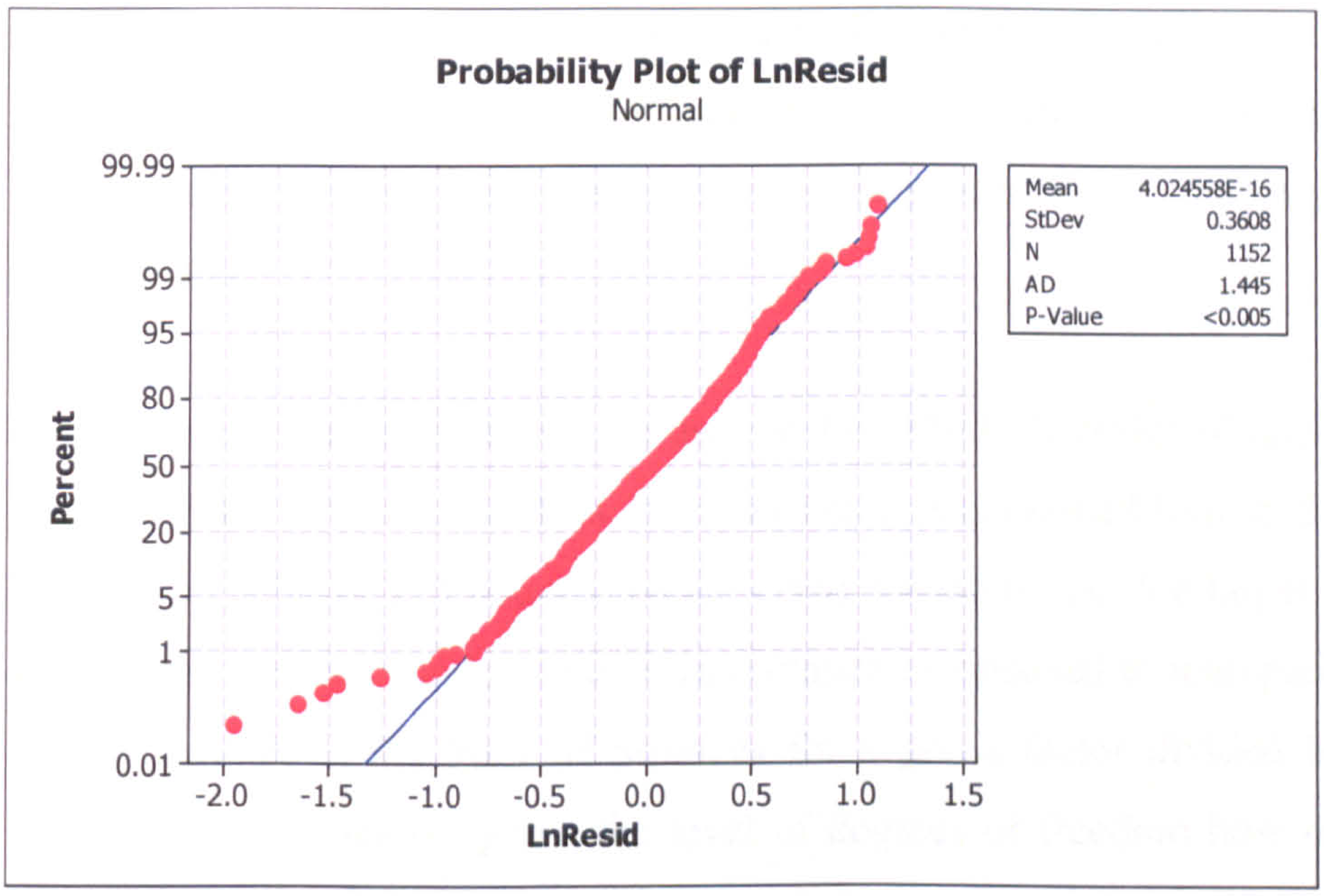


Figure 51: Distribution of Residuals, Using Natural Log (Ln) Transformation

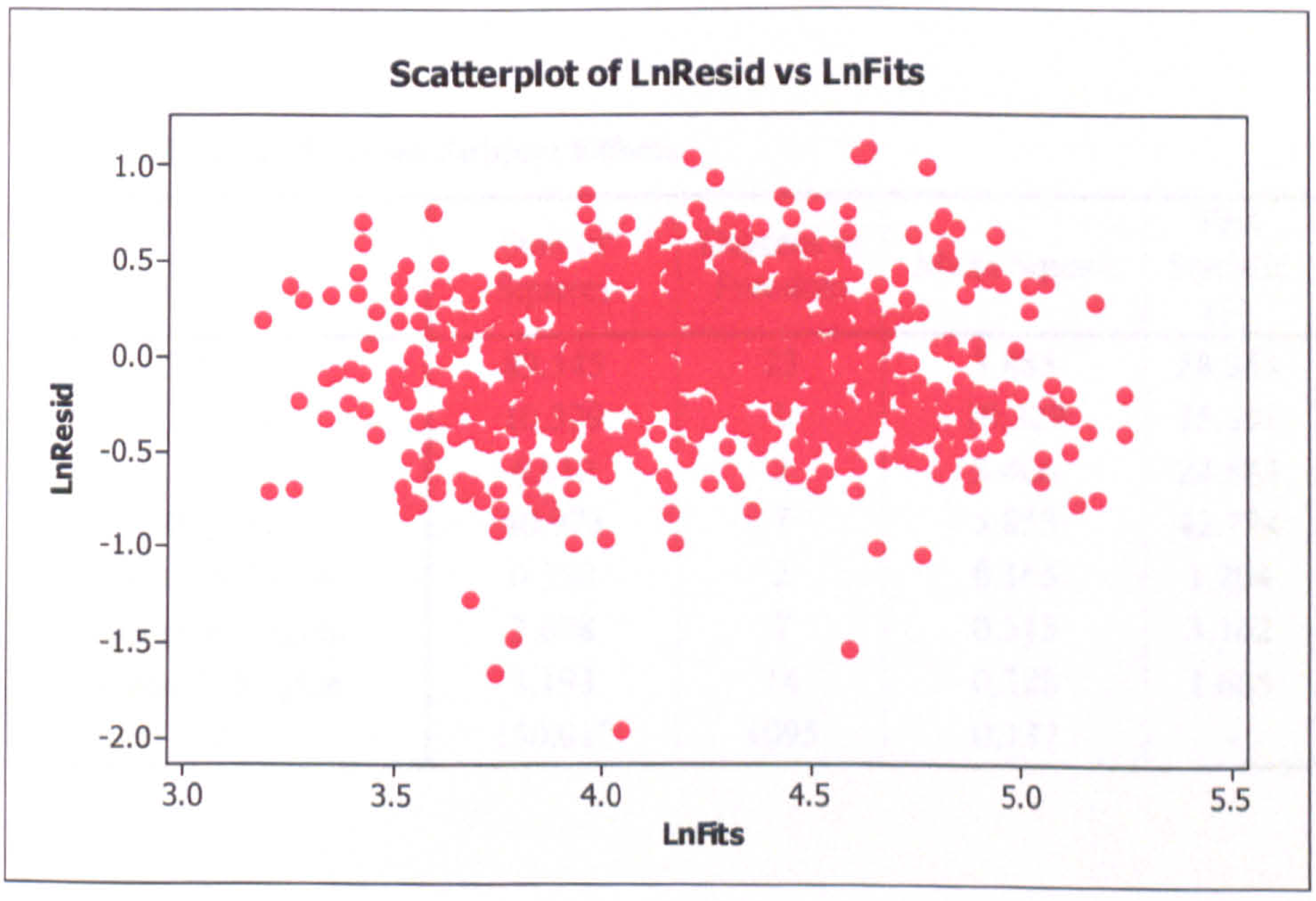


Figure 52: Plot of Residual vs. Fits for Transformed Data

Analysing the Data

Having transformed the data for the average interface pressure data, and establishing an improved fit of the model the data could be analysed. The data was inputted into a univariate general linear ANOVA model. The output is shown in Table 7. All statistical analysis is performed using data in its transformed state. For ease of interpretation however, the graphs shown are plotted using the original interface pressure data.

The following terms **(in bold)** are used in the ANOVA tables of analysis. The **test statistic (F)** is a measure of how much variation is explained from a given **factor** [or interaction] relative to the unexplained **error** variation. i.e. the larger F is the more **significant** the factor is in terms of importance as opposed to unexplained variation. **Means Square** is the **Sum of Squares** for a given factor divided by that factors **degrees of freedom** i.e. given the level of degrees of freedom how much variation [sum of squares] is present. Degrees of freedom are a measure of how much independent information is used to obtain the estimate – (n-1) i.e. if sample of 24, then 23 degrees of freedom.

Table 7: Tests of Between Subject Effects

Factor	Sum of Squares	Degrees of Freedom	Mean Square	Test Statistic (F)	Significance (p)
Subject	89.345	23	3.885	28.354	<0.001
Group	10.329	1	10.329	75.391	<0.001
Phase	6.812	2	3.406	24.863	<0.001
Region	40.973	7	5.853	42.724	<0.001
Group & Phase	0.330	2	0.165	1.204	0.300
Group & Region	3.608	7	0.515	3.762	<0.001
Phase & Region	3.193	14	0.228	1.665	0.057
Error	150.017	1095	0.137	-	-

Table 7 displays all of the interface pressure data in terms of the independent variables subject, group, phase and the region. It can be seen that there is significant interaction within each of these four variables, ($p<0.001$). These results only identify the differences in interface pressure for one variable at a time and do not make a distinction between the various regions within the socket, nor the phase during the gait cycle. The combination of Group and Region identifies a difference between the two variables. It can be seen that there is a significant difference ($p<0.001$) between the region within the socket and the type of socket worn (Group).

Difference between each Phase of Stance

In order to identify the significant difference occurring within the phases of stance during the gait cycle a 2 sided Tukey post hoc test was conducted on the data in terms of phase, Table 8.

Table 8: Tukey Post Hoc Test on Phase

Comparisons between Phases

(I) Phase	(J) Phase	Mean Difference (I-J)	Significance
Early Stance	Mid Stance	0.0348	p = 0.393
	Late Stance	- 0.1429	p < 0.001
Mid Stance	Late Stance	- 0.1777	p < 0.001

The results of the post hoc test identify that the changes in interface pressure do not have a significant difference during early stance ($p=0.393$) but show a significant difference towards the end of stance, ($p<0.001$ between mid & late stance).

Difference between the Regions within the Socket

The difference between the regions within the prosthetic socket shown in Table 7 also identified a significant relationship. Following a 2 sided Tukey post hoc test it could be seen that significant differences exist between most of the regions within the socket. Table of results is displayed in Appendix 7 due to the large amount of data.

Interaction between Region and Phase

Table 7 identified the difference between Region and Phase as not significant (p=0.057). However in order to summarise the results of the findings for Region and Phase, the graph in Figure 53 shows the difference of each region within the prosthetic socket at each of the three phases within stance. The graph identifies the significant difference seen in the distribution within the prosthetic socket at the end of stance and the significant difference seen throughout the socket.

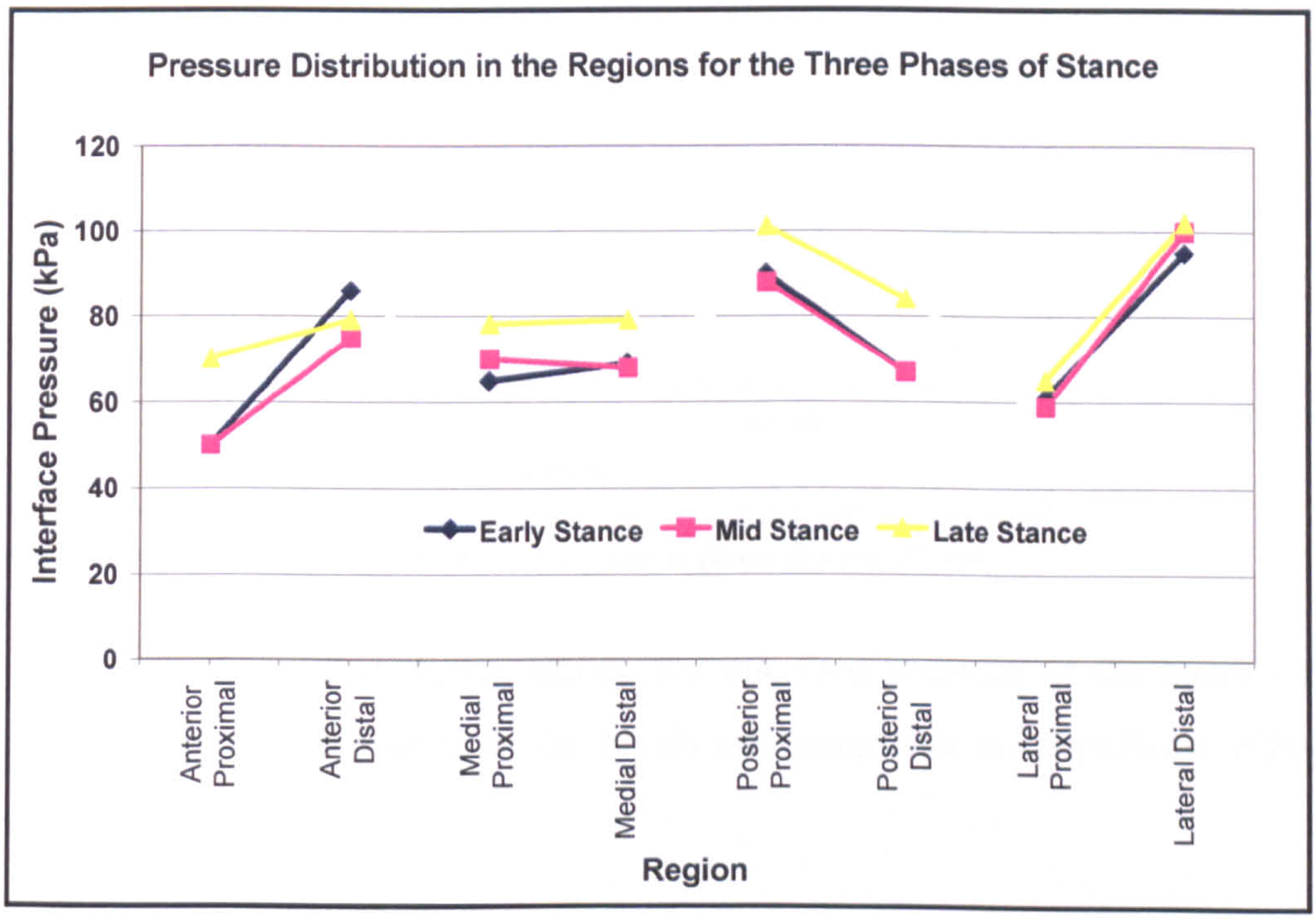


Figure 53: Distribution throughout the Prosthetic Socket at each Phase

Differences between Groups

The analysis above showed that significant differences are present within the prosthetic socket throughout stance phase. However these results are based on the entire sample, and do not take into account the socket design worn.

It was seen in Table 7 that no significant interaction was present between the two groups in terms of phase (p=0.300). The graph in Figure 54 provides a visual indication of this result.

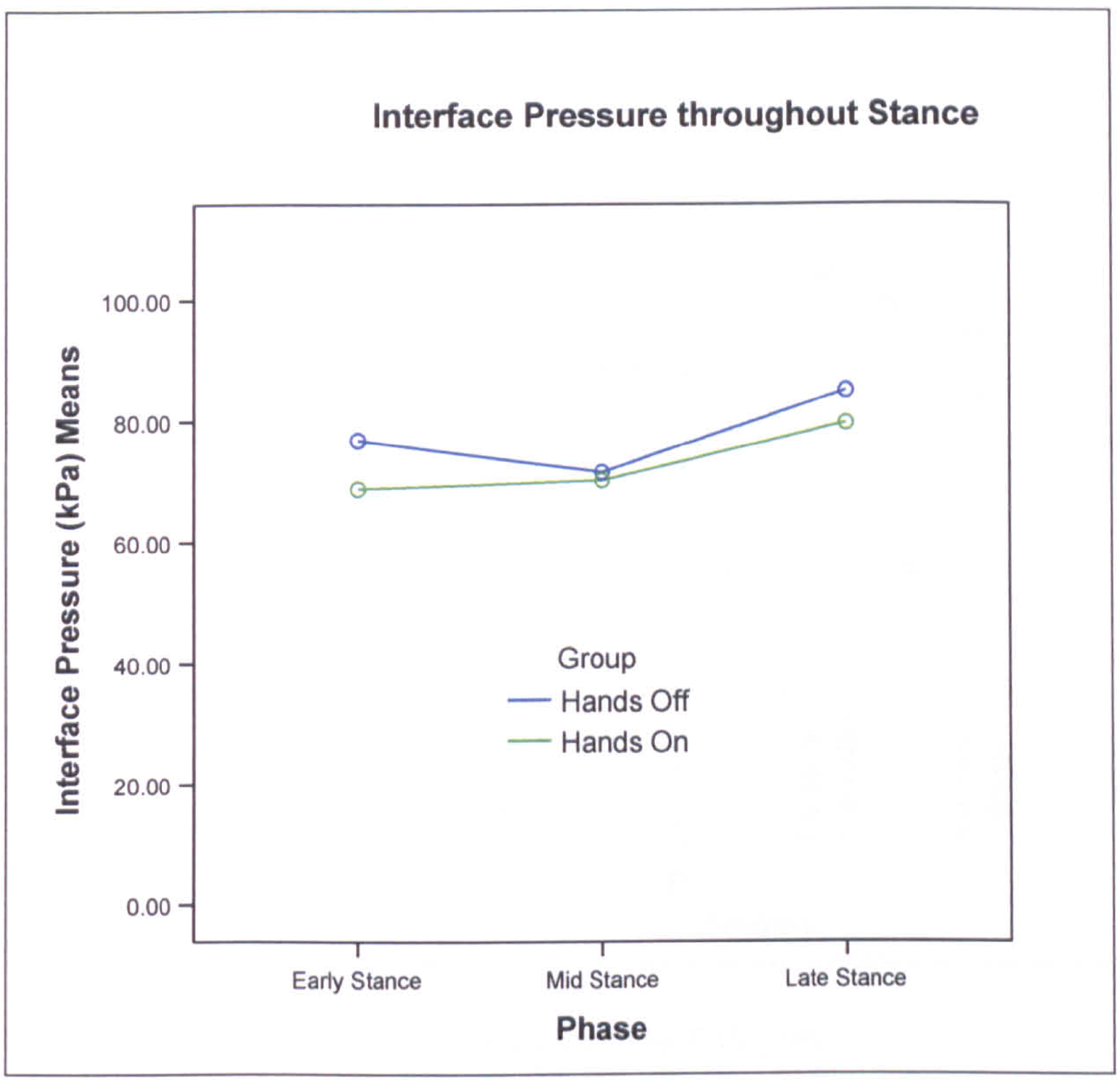


Figure 54: Interface Pressure by Group throughout Stance Phase

The graph shows that during stance the interface pressure of the hands off socket concept group is higher than the hands on group, but no significant difference is present.

Interface Pressure by Group and Region

A significant difference between group and region was seen in Table 7 ($p<0.001$). The graph shown in Figure 55 indicates the location throughout the socket where these differences occur.

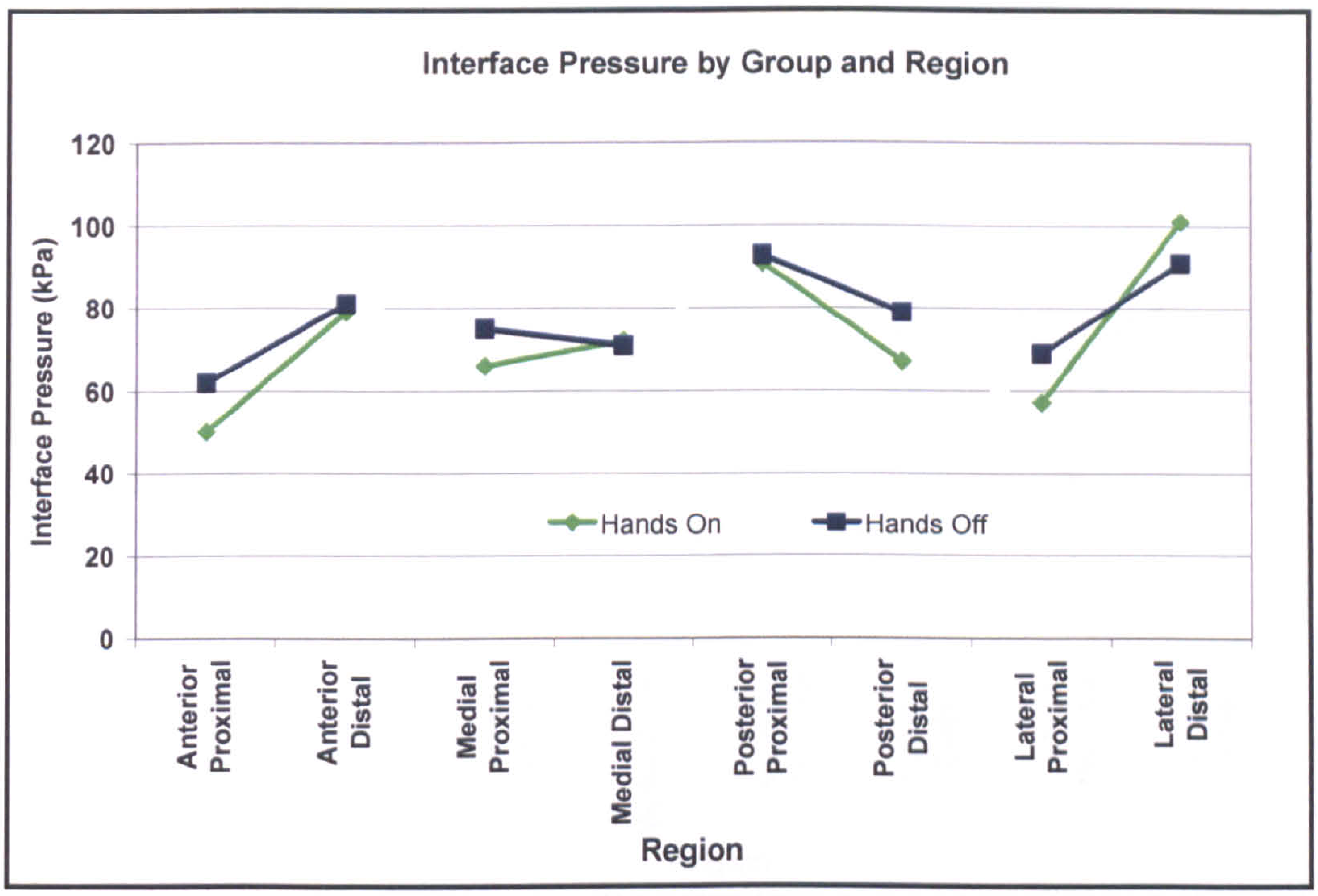
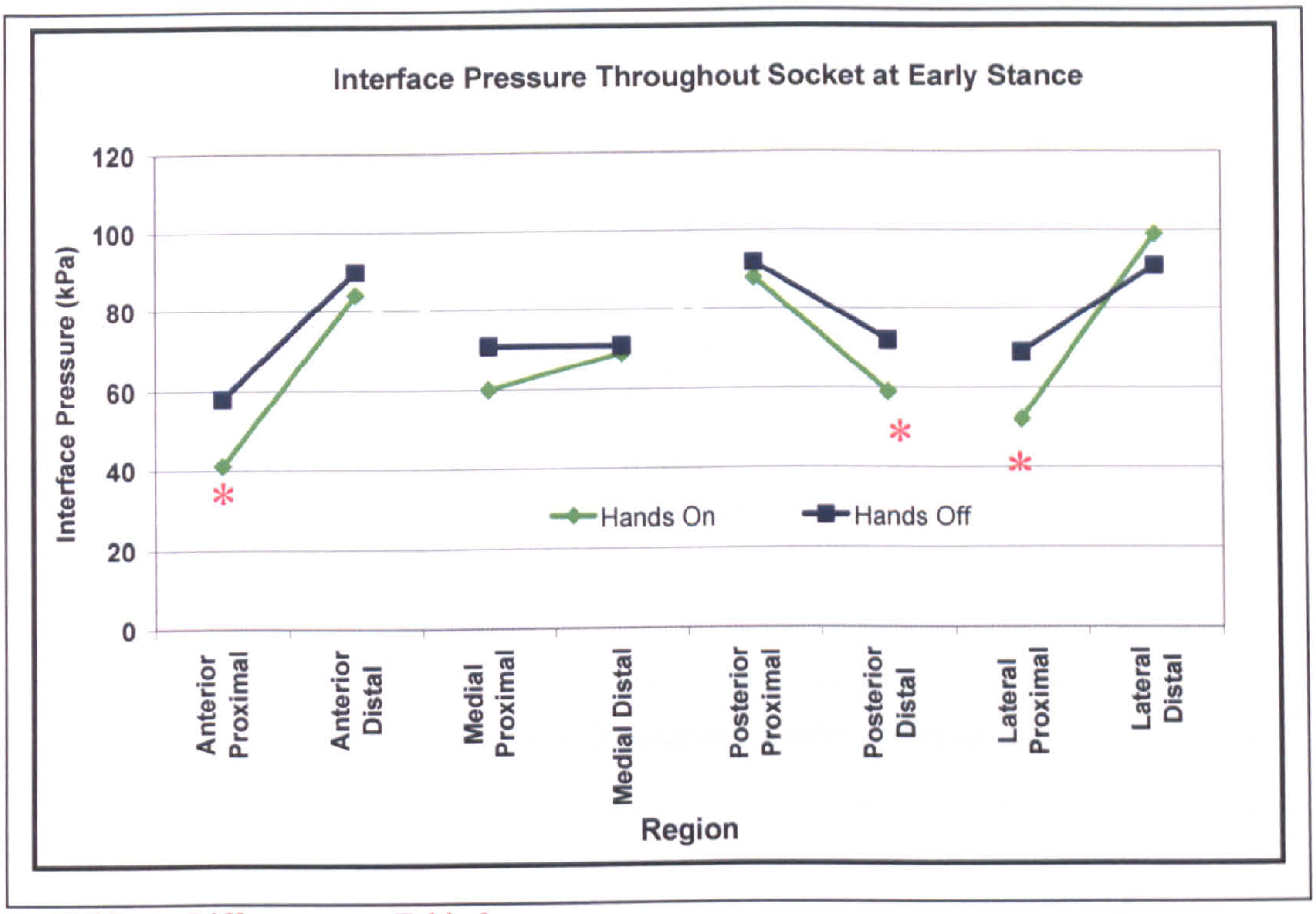


Figure 55: Interface Pressure by Group and Region

The graph suggests that significant differences exist at the proximal region of the anterior, medial and lateral aspects. These are in addition to the distal region of the posterior and lateral aspect. This graph combines the interface pressure for the three phases within stance. It was shown that a significant difference exists between the three phases. The next three graphs display the same information as shown in Figure 55, but for each phase individually.



* Significant Difference, see Table 9

Figure 56: Interface throughout the Socket (Early Stance)

The interface pressure for both socket concepts shows a similar pattern throughout the prosthetic socket at early stance, Figure 56. The hands off socket show the higher interface pressures. When early stance is viewed in isolation, the same places within the prosthetic socket appear to show larger differences in interface pressure when comparing the two socket designs.

In order to statistically determine if there is a significant difference in interface pressure between the two socket concepts at these locations for each of the three phases a Mann Whitney independent sample test was performed. The level of alpha was reduced by a factor of 3 from 0.05 to 0.017 for these tests in accordance with the Bonferroni correction factor (Bland, 2000). A parametric independent sample test was deemed inappropriate due to the distribution of the data.

Results from the Mann Whitney test are shown in Table 9. It can be seen that with alpha reduced to 0.017 the proximal regions of the anterior and lateral aspects and distal region of the posterior socket show significant differences between groups.

Table 9: Significant Differences between Groups at Early Stance

Region within Prosthetic Socket	**P-value**
Anterior Proximal	**0.003***
Lateral Proximal	**0.017***
Posterior Distal	**0.004***

***Significant difference when p≤0.017**

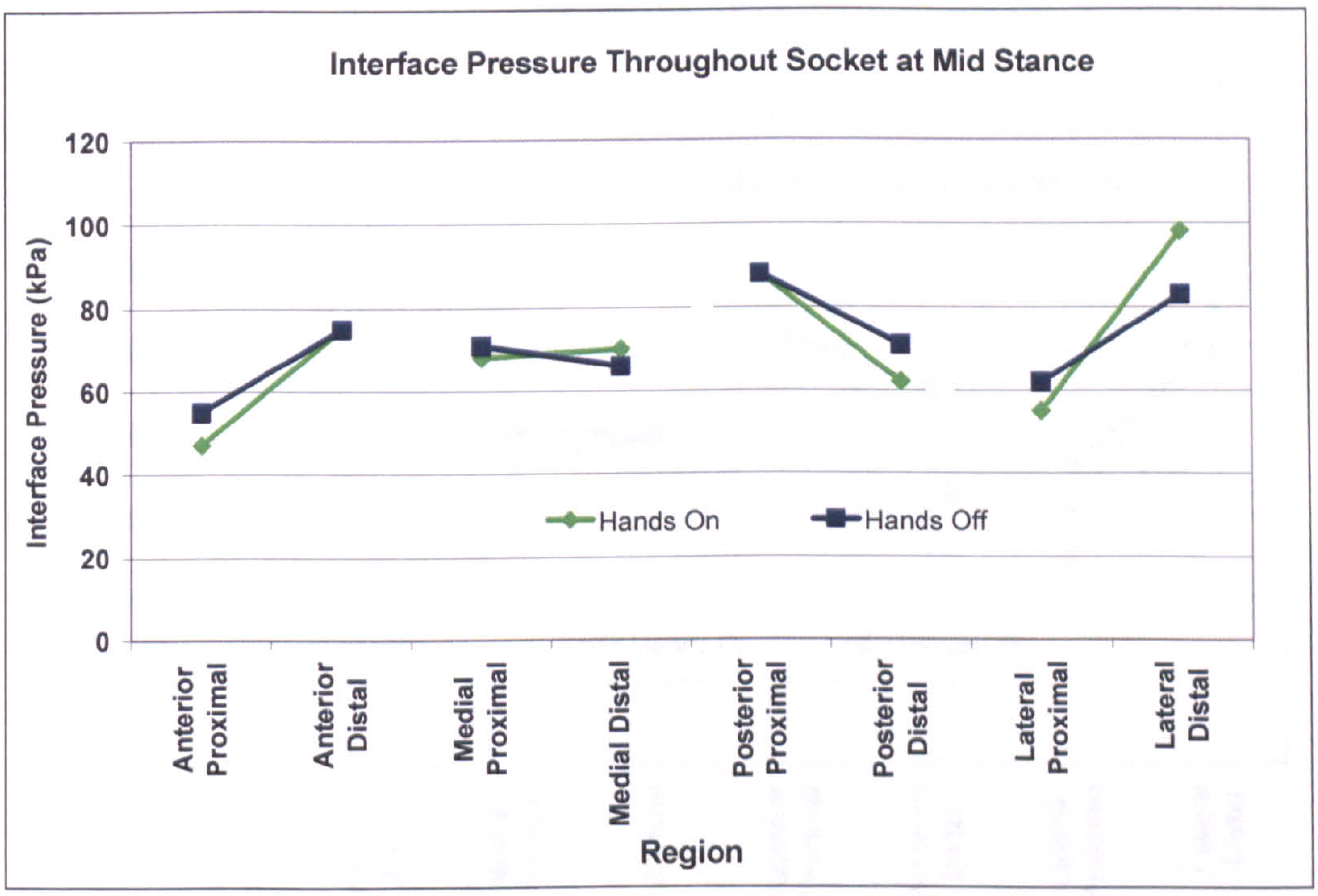


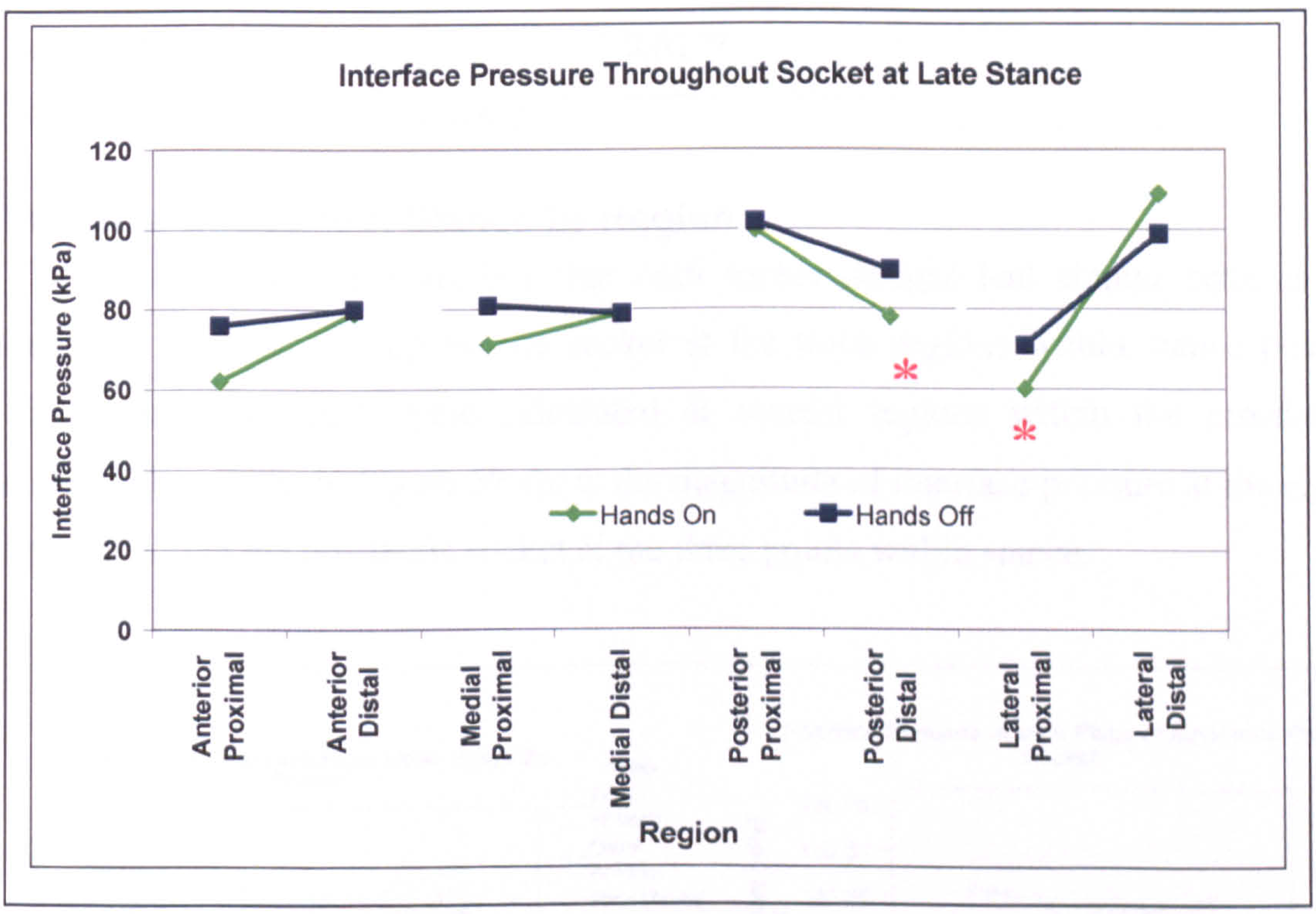
Figure 57: Interface Pressure throughout Socket (Mid Stance)

The graph, Figure 57, shows that the pattern of interface pressure throughout both prosthetic socket concepts is again similar between socket concepts at mid stance. However the differences look much smaller than at early stance. The same points within the socket show larger differences, therefore the same statistical analysis was performed and results shown in Table 10.

Table 10: Significant Differences between Groups at Mid Stance

Region within Prosthetic Socket	P-value
Anterior Proximal	0.115
Lateral Proximal	0.045
Posterior Distal	0.034

Table 10 shows that at mid stance the differences seen at early stance are no longer present. No significant differences are recorded between the two socket groups.



* Significant Difference, see Table 11

Figure 58: Interface Pressure throughout Socket (Late Stance)

A similar pattern of interface pressure is seen at late stance, Figure 58, as was seen at early stance, Figure 56. Again the interface pressures of the hands-off socket design are greater than in the hands-on socket for most regions within the socket. The distal region of the lateral aspect shows a reversal in this trend.

The four regions within the socket were again tested using the Mann Whitney test; the results can be seen in Table 11. Significant differences between the sockets can be seen at the proximal region of the lateral aspect and the distal region of the posterior aspect.

Table 11: Significant Differences between Groups at Late Stance

Region within Prosthetic Socket	**P-value**
Anterior Proximal	0.071
Lateral Proximal	**0.009***
Posterior Distal	**0.017***

***Significant difference when p≤0.017**

Interface throughout Stance by Region

The previous analysis identified that both socket designs had similar patterns of interface pressure throughout the socket at the three regions within stance phase. Significant differences were calculated at several regions within the prosthetic socket. The graphs in Figure 59 show the magnitude of interface pressure at the eight regions within the prosthetic socket at the three points within stance.

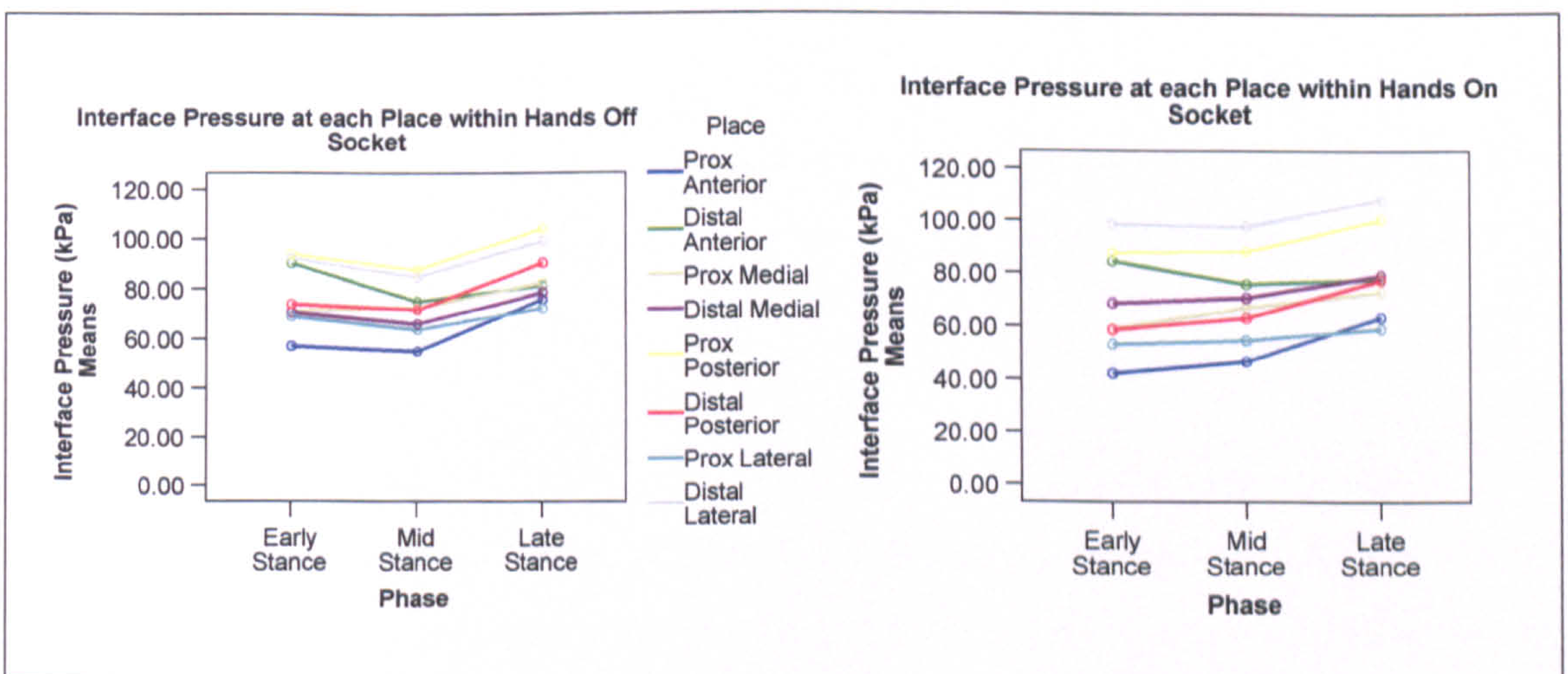


Figure 59: Interface Pressure throughout Stance by Region

It was seen in Figure 56 to Figure 58 that the pattern of interface pressure throughout the prosthetic socket was similar for both socket concepts. The graphs in Figure 59 also show this similarity. Regions with higher interface pressures in the hands off sockets also have the higher pressures in the hands on sockets. In addition to this Figure 59 also illustrates that the interface pressures at each region within the hands off socket are much closer together than for the hands on socket. This identifies smaller differences in interface pressure between each region within the pressure cast socket. A statistical difference in interface pressure was seen when comparing the pressures at late stance with early and mid stance in both subject groups. This difference can also be seen in Figure 59.

10.4.2 Peak Interface Pressure

The previous calculations of interface pressure were performed on the average pressures over each region. The following analysis will use the peak interface pressure measured within each region. The difference in calculating the average and peak interface pressure can be found in the methodology section.

Fitting the data to the Model

An identical method to that implemented during analysis of the average pressures was used in determining the best ANOVA model to use for the peak pressures. A probability plot of the residual values was produced to determine the normality of the data. Homogeneity was determined by plotting the residual and fit values, see Appendix 8.

A similar pattern is seen in both plots for the peak interface pressure as was seen in Figure 49 and Figure 50 when examining the average pressures. It can be seen in that the data for peak pressure does not follow a normal distribution ($p<0.005$). The plot of residual and fit data points has poor homogeneity. The results of these plots means that the data, currently given in terms of kPa will also be required to be transformed in order to improve its fit of the ANOVA model, as was the case when using the average interface pressures.

A natural log (Ln) transformation improved the distribution of the data, Appendix 8, although it still does not follow a normal distribution ($p<0.005$). The results show that the homogeneity of the data has been improved by transforming the data using natural logs.

Analysing the Data

The transformed data was inputted into a univariate general linear ANOVA model for analysis. Table 12 presents the results of this analysis. As was described when using the average pressures, statistical analysis of the peak pressures is performed using data in its transformed state and graphs will be plotted using the original interface pressure data. For details of the content of the table see description for Table 7, page 171.

Table 12: Tests of Between-Subjects Effects for Peak Pressure

Factor	Sum of Squares	Degrees of Freedom	Mean Square	Test Statistic (F)	Significance (p)
Subject	78.777	23	3.425	22.648	0.001
Group	9.922	1	9.922	65.611	0.001
Phase	4.851	2	2.425	16.037	0.001
Region	28.045	7	4.006	26.492	0.001
Group & Phase	0.647	2	0.323	2.139	0.118
Group & Region	7.431	7	1.062	7.020	0.001
Phase & Region	4.443	14	0.317	2.099	0.010
Error	165.596	1095	0.151	-	-

It can be seen from Table 12 that there is significant differences within each of the individual variables, in all cases $p<0.001$. Comparing Group with Region and Phase and Region identifies a significant difference between the region within the socket and the type of socket worn (Group) $p<0.001$. There is also a significant difference between the phase and the region within the socket $p=0.010$.

Difference between each Phase of Stance

The locations of significant differences between the phases of stance during the gait cycle were identified using a 2 sided Tukey post hoc test. Results of this test are given in Table 13.

Table 13: Post Hoc Test on Phase

Comparisons between Phases

(I) Phase	(J) Phase	Mean Difference (I-J)	Significance
Early Stance	Mid Stance	0.054	p=0.132
	Late Stance	-0.102	p<0.001
Mid Stance	Late Stance	-0.157	p<0.001

The results of the post hoc test identify that the changes in peak interface pressure do not have a significant difference during early stance (p=0.132) but show a significant difference towards the end of stance, (p<0.001 between mid & late stance).

Difference between Regions

The difference between the regions within the prosthetic socket shown in Table 12 also identified a significant relationship. Following a 2 sided Tukey post hoc test it can be seen that significant differences exist between most of the regions within the socket. Table of results is displayed in Appendix 9, due to the large amount of data.

Difference between Region and Phase

Significant differences were seen in Table 12 between the region and phase. These differences can be seen in the graph, in order to summarise the results of the findings for region and phase the graph in Figure 60 shows the interaction of each place within the prosthetic socket at each of the three phases within stance. The graph identifies the significant difference seen in the distribution within the prosthetic socket at the end of stance and the significant difference seen throughout the socket.

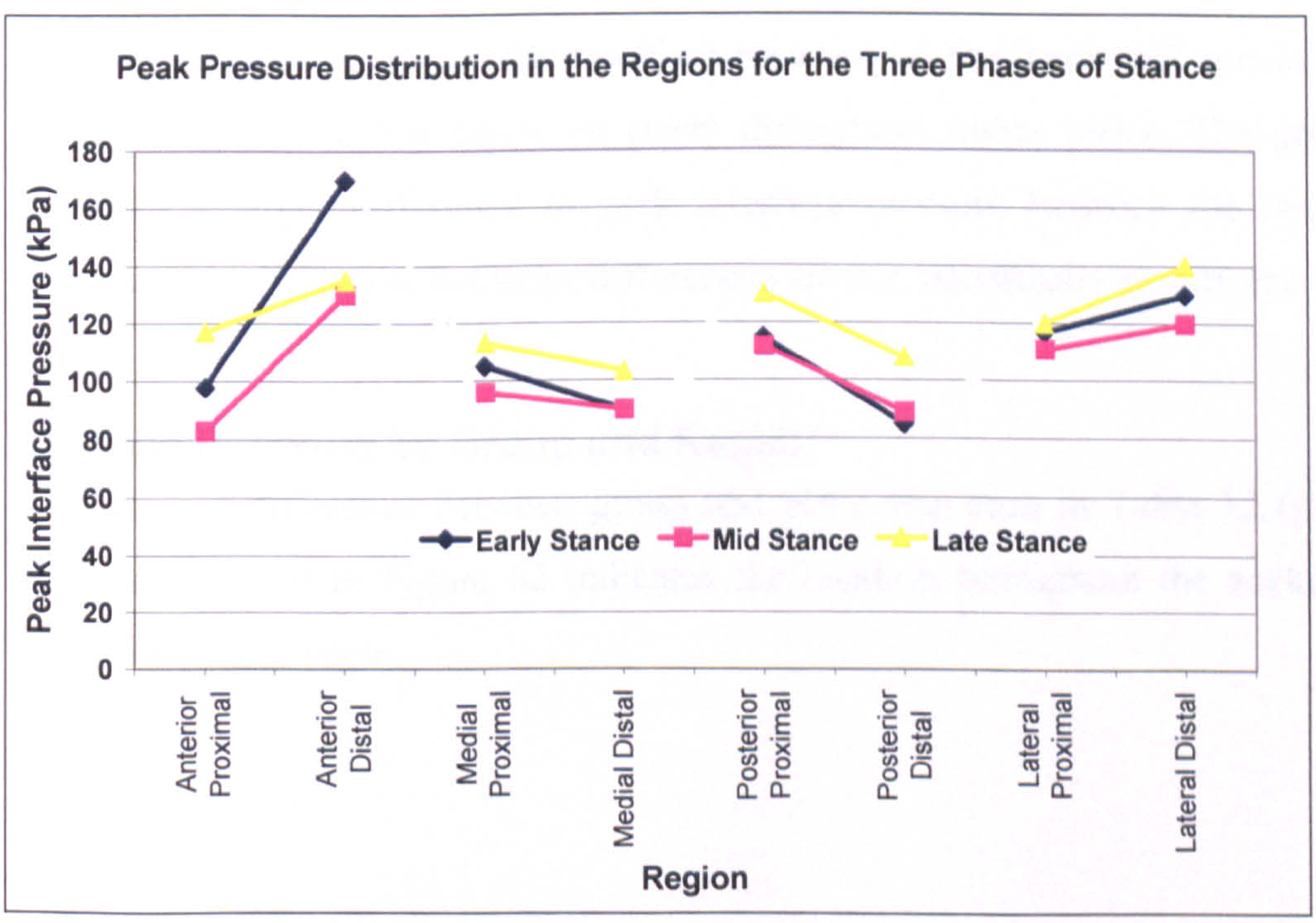


Figure 60: Peak Pressure Distribution throughout Prosthetic Socket at each Phase

Differences between Groups

It was seen in Table 12 that no significant interaction was present between the two groups in terms of phase (p=0.118). The graph in Figure 61 provides a visual indication of this result.

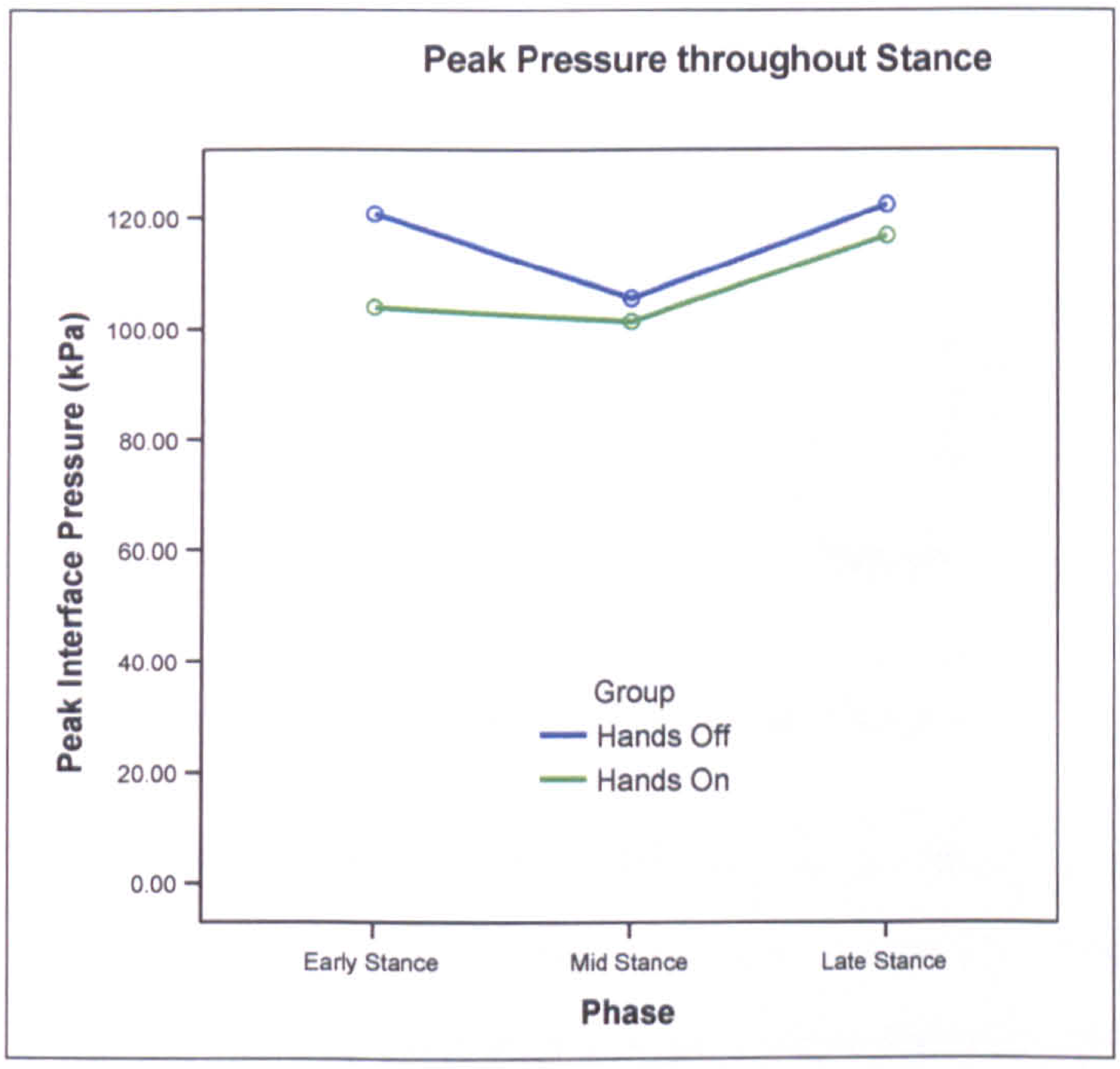


Figure 61: Peak Interface Pressure by Group throughout Stance Phase

It shows that during stance the interface pressure of the hands off socket concept group is higher than the hands on group throughout stance phase. The graph also illustrates a larger difference in peak interface pressure between the two socket concepts at early stance, but these differences are not statistically significant.

Interface Pressure by Group and Region

A significant difference between group and place was seen in Table 12 ($p<0.001$). The graph shown in Figure 62 indicates the location throughout the socket where these differences occur.

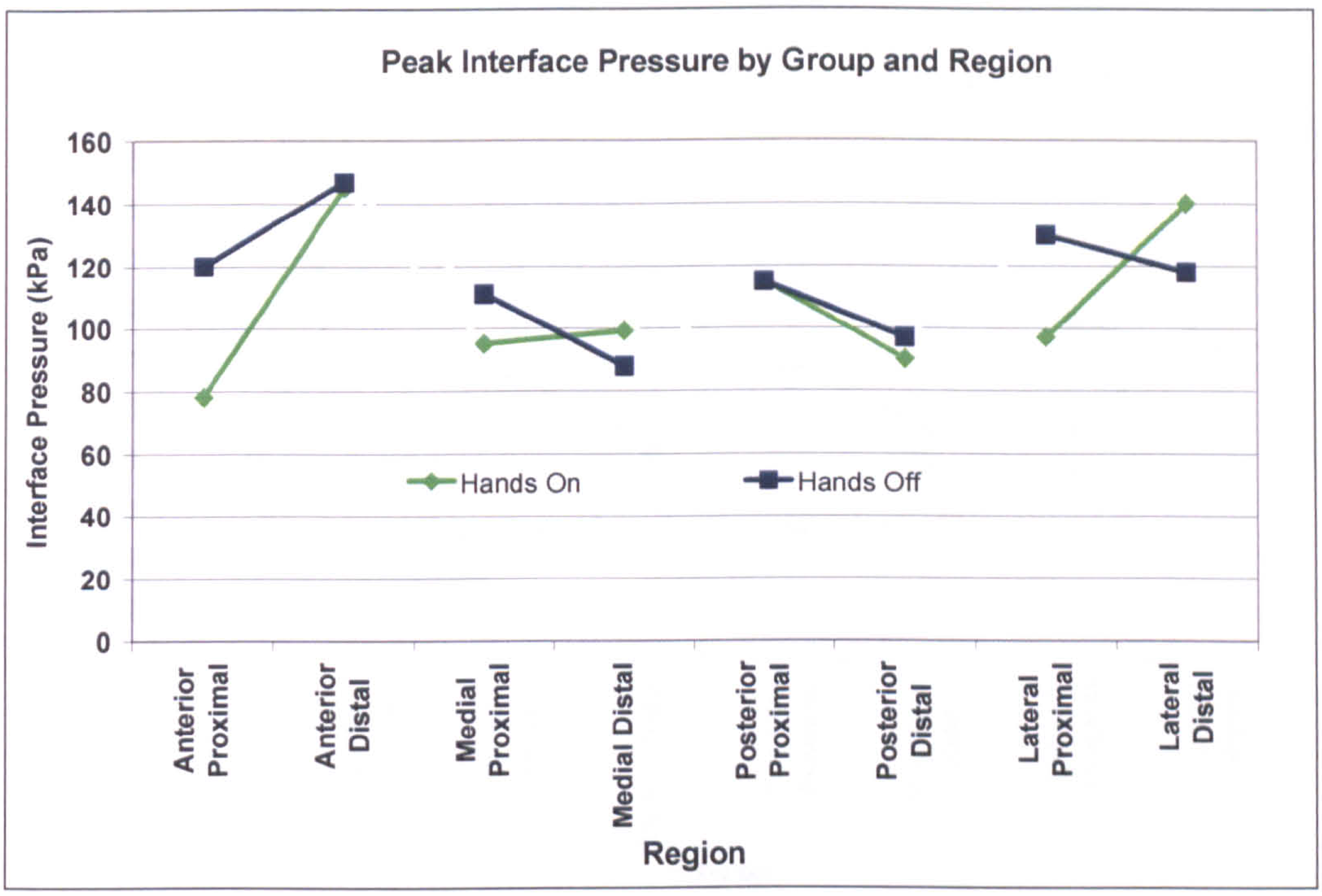
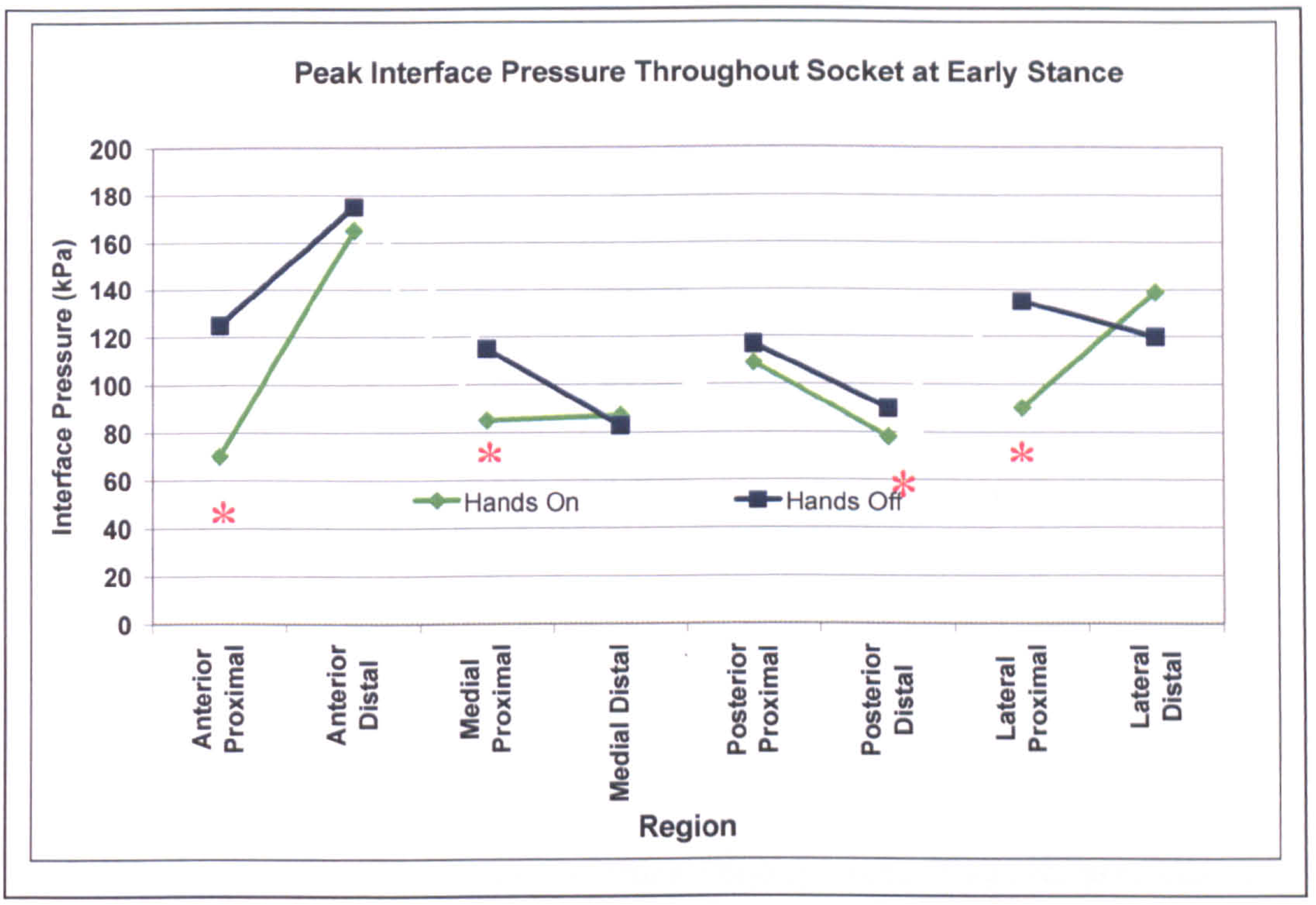


Figure 62: Interface Pressure by Group and Region

The graph suggests that differences in peak pressure between the two socket concepts exist at the same regions as for the average interface pressures. These locations are the proximal region of the anterior, medial and lateral aspects, and the distal region of the posterior aspect. This graph combines the interface pressure for the three phases within stance. The next three graphs display the same information as shown in Figure 62, but for each phase individually.



* Significant Difference, see Table 14

Figure 63: Peak Interface throughout the Socket (Early Stance)

The interface pressure for both socket concepts shows a similar pattern throughout the prosthetic socket at early stance, Figure 63. The hands off socket show the higher interface pressures. It can also be seen that the anterior proximal region of the hands off socket shows a large difference in peak pressures at early stance.

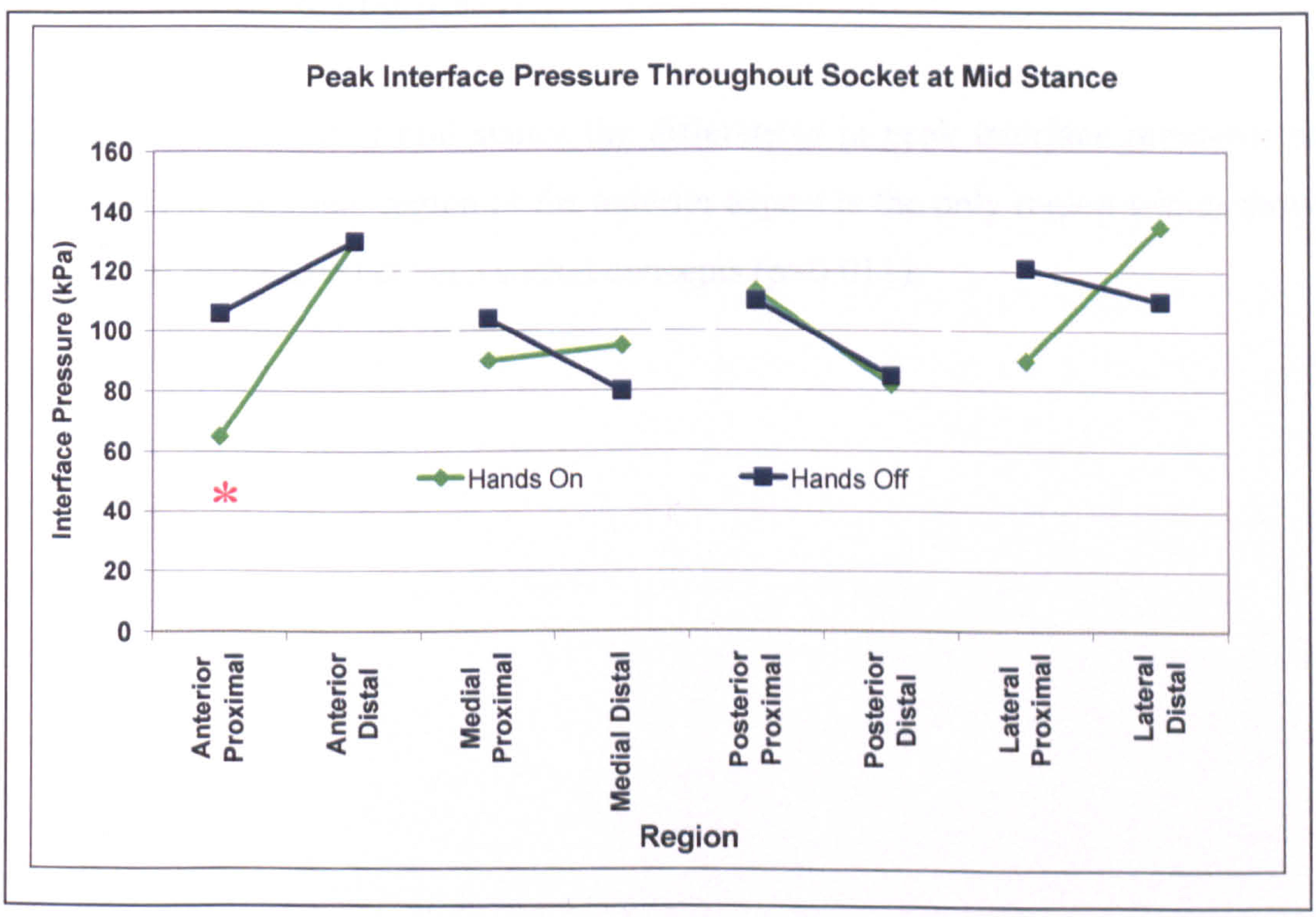
The differences in peak interface pressure between the two socket concepts can still be seen when viewing just early stance. These differences are checked statistically to determine if there represent a significant change. A Mann Whitney independent sample test was performed. As was described during testing of the average interface pressures, the level of alpha was reduced from 0.05 to 0.017 for these tests in accordance with the Bonferroni correction factor (Bland, 2000).

Table 14: Significant Differences between Groups at Early Stance

Region within Prosthetic Socket	**P-value**
Anterior Proximal	**<0.001***
Medial Proximal	**0.003***
Lateral Proximal	**0.008***
Posterior Distal	**0.016***

***Significant difference when p≤0.017**

Table 14 shows the results from the Mann Whitney test. It can be seen that the four regions did produce a statistically significant difference in peak pressure.



* Significant Difference, see Table 15

Figure 64: Peak Interface Pressure throughout Socket (Mid Stance)

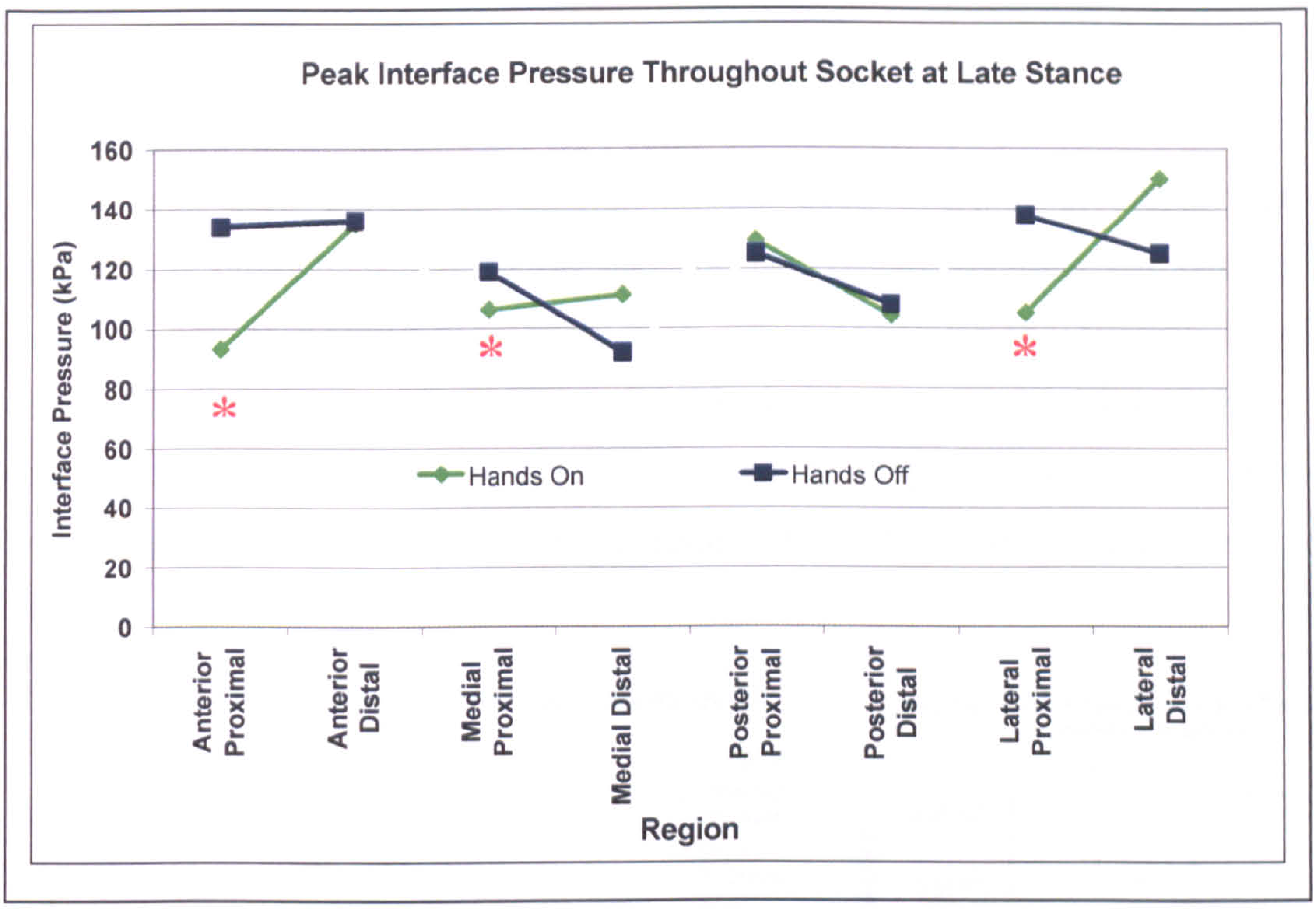
The graph in Figure 64 demonstrates that the pattern of interface pressure throughout both prosthetic socket concepts is again similar. As was the case for the average interface pressure the differences are much smaller than at early stance. The same four regions will be subjected to the identical statistical analysis, results shown in Table 15.

Table 15: Significant Differences between Groups at Mid Stance

Region within Prosthetic Socket	P-value
Anterior Proximal	**0.011***
Medial Proximal	0.037
Lateral Proximal	0.032
Posterior Distal	0.056

***Significant difference when p≤0.017**

Table 15 shows that at mid stance the differences in peak interface pressures have reduced. The proximal region of the anterior aspect is the only region which shows a significant difference between socket concepts (p=0.011).



* Significant Difference, see Table 16

Figure 65: Interface Pressure throughout Socket (Late Stance)

A similar pattern of peak interface pressure is seen at late stance as was seen at mid stance. There is less of a distinction between the two socket concepts throughout the socket. The four regions within the socket were again tested using the Mann Whitney test; the results can be seen in Table 16. Significant differences between the sockets can be seen at the three proximal regions but not at the distal region of the posterior aspect.

Table 16: Significant Differences between Groups at Late Stance

Region within Prosthetic Socket	P-value
Anterior Proximal	**0.011***
Medial Proximal	**0.006***
Lateral Proximal	**0.011***
Posterior Distal	0.051

***Significant difference when p≤0.017**

Interface throughout Stance by Place

It has been seen during the analysis of the peak interface pressures that the distribution throughout the socket and the differences between the two socket concepts has been similar to those seen when analysing the average interface pressures. Significant differences were calculated at several regions within the prosthetic socket. The graphs in Figure 66 show the magnitude of interface pressure at the eight regions within the prosthetic socket at the three points within stance.

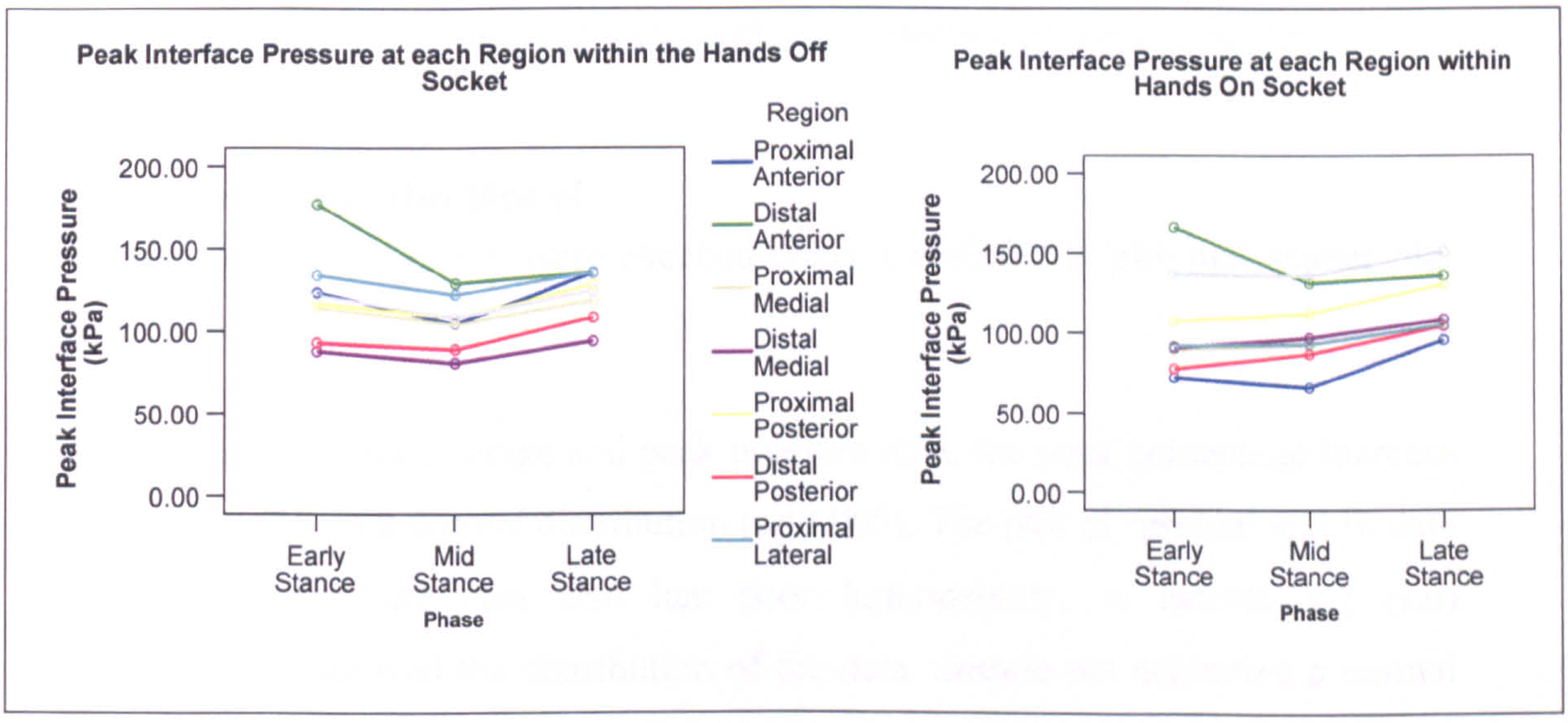


Figure 66: Peak Pressure Distribution at each Region throughout Stance

The graphs in Figure 66 show that the regions with higher interface pressures in the hands off socket also experience the higher pressures in the hands on socket. In addition to this Figure 66 illustrates that the interface pressures at each region within the hands off socket are closer together than for the hands on socket. This was also the case for the average interface pressures, and identifies smaller differences in interface pressure between each region within the hands off socket.

10.4.3 Peak Interface Pressure Percentage Increase

The average interface pressure over each region and the peak interface pressure within each region have been measured in the previous two sections. In this section the increase in peak pressure in terms of a percentage increase from the average pressure will be investigated.

The calculation for the peak pressure percentage increase from the average interface pressure is given in the methodology chapter. During the analysis of the percentage peak pressure increase the methodology used will be identical to that implemented during analysis of the average pressures and peak interface pressure analysis.

Fitting the data to the Model

Normality and homogeneity were checked using a probability plot and scatter plot respectively.

As in the case with the average and peak pressure data, the peak percentage increase data does not follow a normal distribution ($p<0.005$). The plot of residual and fit data points shows that the data also has poor homogeneity. A natural log (Ln) transformation improved the distribution of the data, despite not achieving a normal distribution ($p<0.005$). Homogeneity of the data has been improved by transforming the data using natural logs.

Analysing the Data

The transformed data was inputted into a univariate general linear ANOVA model for analysis. Table 17 presents the results of this analysis. Statistical analysis of the peak percentage increase is performed using data in its transformed state and graphs will be plotted using the original percentage increase values. For details of the content of the table see description for Table 7, page 171.

Table 17: Tests of Between-Subjects Effects for Peak Percentage Increase

Factor	Sum of Squares	Degrees of Freedom	Mean Square	Test Statistic (F)	Significance (p)
Subject	122.273	23	5.316	10.064	<0.001
Group	.695	1	0.695	1.316	0.252
Phase	5.212	2	2.606	4.934	0.007
Region	229.140	7	32.734	61.969	<0.001
Group & Phase	.448	2	0.224	0.425	0.654
Group & Region	19.627	7	2.804	5.308	<0.001
Phase & Region	6.259	14	0.447	0.846	0.618
Error	577.891	1094	0.528	-	-

It can be seen from Table 17 that a significant difference occurs for subject, phase and region. A significant difference also exists between region and group ($p<0.001$).

Differences between each Phase of Stance

The locations of significant differences between the phases of stance during the gait cycle were identified using a 2 sided Tukey post hoc test. Results of this test are given in Table 18.

Table 18: Tukey Post Hoc Test on Phases

Comparisons between Phases

(I) Phase	(J) Phase	Mean Difference (I-J)	Significance	(I) Phase
Early Stance	Mid Stance	0.114	0.053	p=0.077
	Late Stance	0.167	.0525	p=0.004
Mid Stance	Late Stance	0.053	0.0525	p=0.575

The results of the post hoc test identify that the percentage increase in peak pressure show a significant difference between early and late stance, ($p<0.004$).

Differences between Regions

The information in Table 17 identifies a significant difference between the regions within the prosthetic socket. Following a 2 sided Tukey post hoc test it can be seen that significant differences exist between most of the regions within the socket. Table of results is displayed in Appendix 10, due to the large amount of data.

Differences between Region and Phase

There are no significant differences between the region and phase. The differences for region and phase are shown in the graph, Figure 67. It shows the difference of each region within the prosthetic socket at each of the three phases within stance.

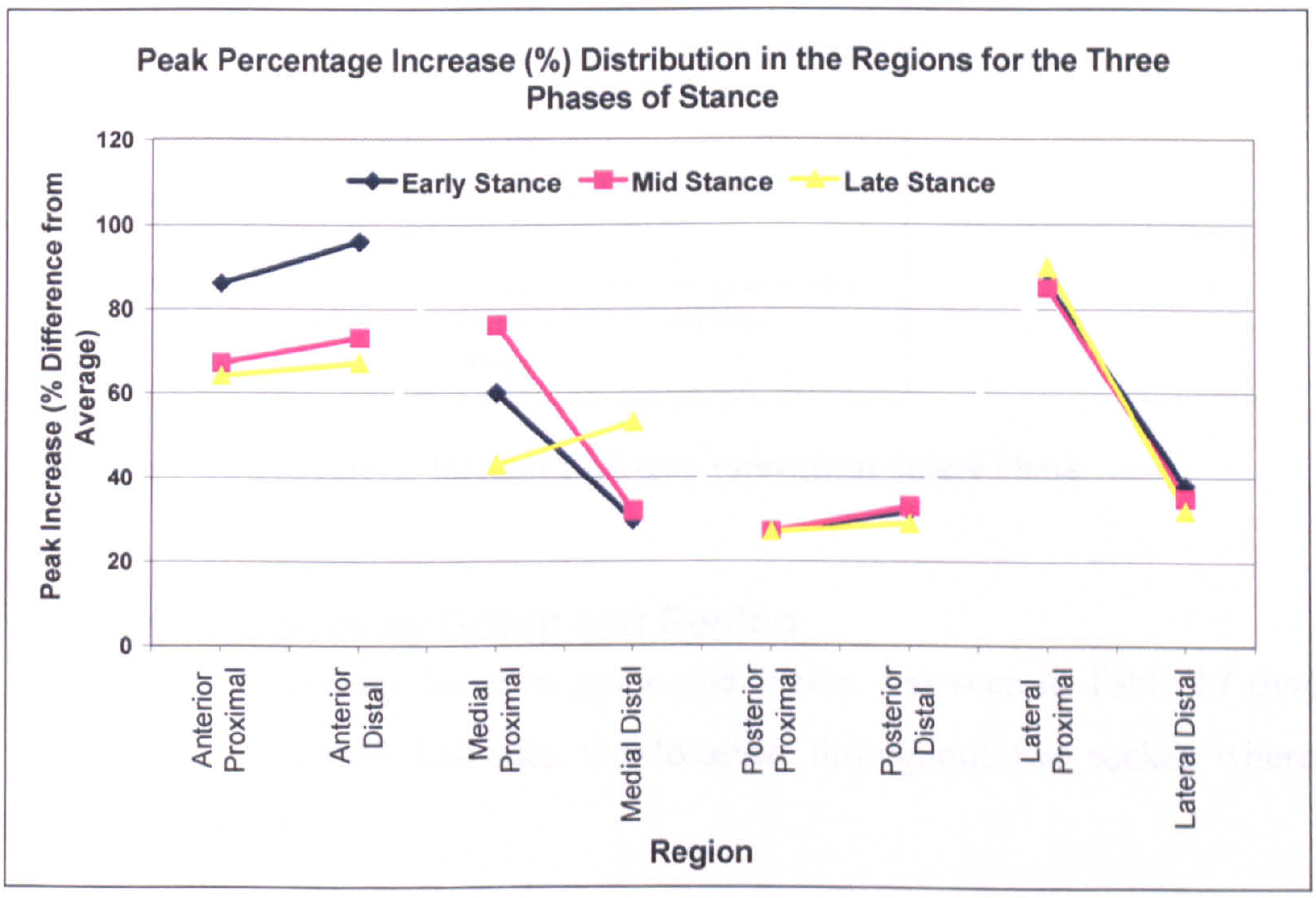


Figure 67: Peak Pressure Increase throughout Prosthetic Socket at each Phase

It can be seen that the posterior and lateral aspects of the socket show similar distributions in all three phases. The anterior and medial aspects have different distributions in each of the phases, although the pattern of distribution is similar.

Differences between Groups

It was seen in Table 17 that no significant difference was present between the two groups in terms of phase (p=0.654). The graph in Figure 68 provides a visual indication of this result.

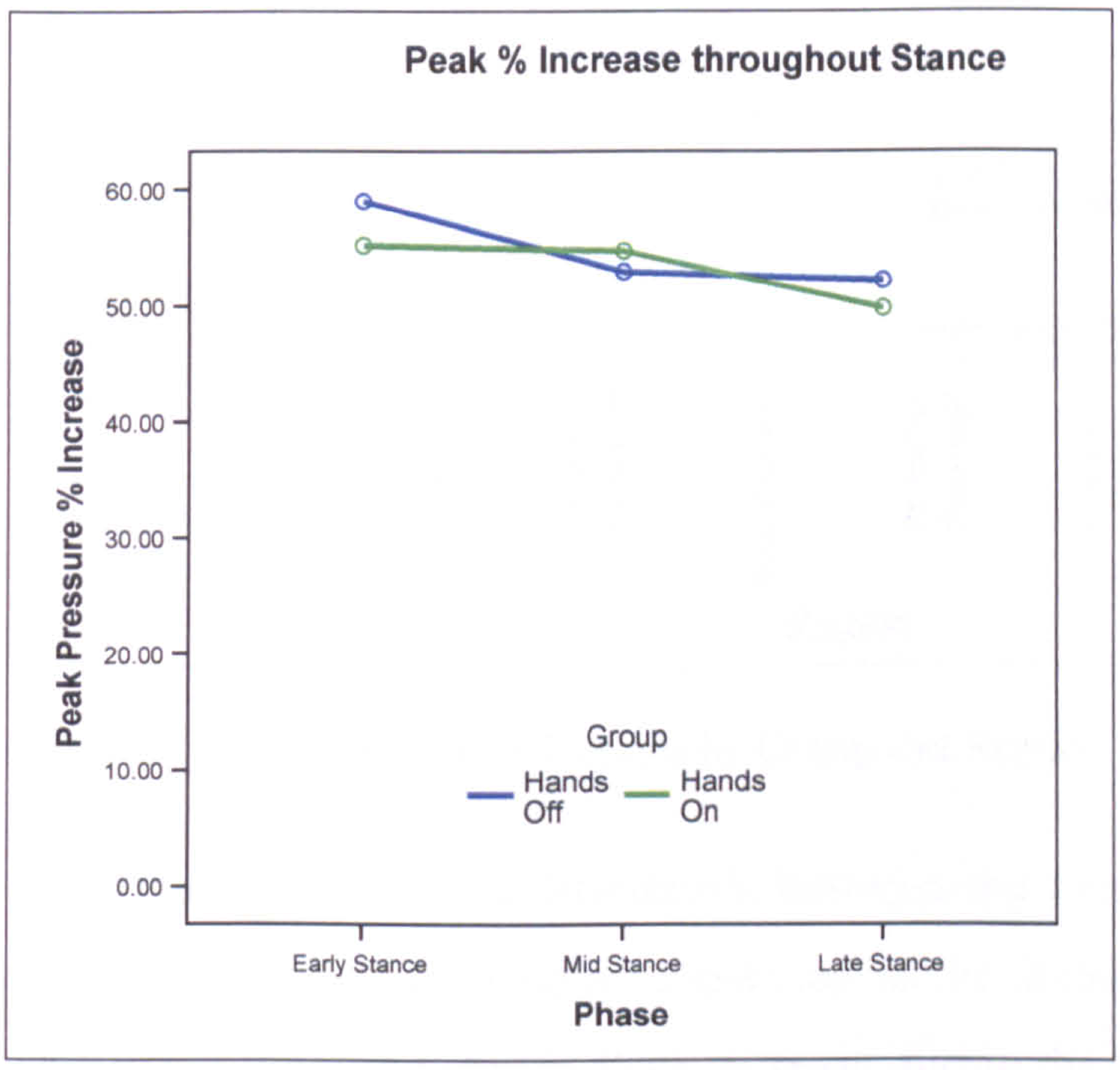


Figure 68: Peak Pressure % Increase by Group throughout Stance Phase

Interface Pressure by Group and Region

A significant difference between group and region was seen in Table 17 (p<0.001). The graph, Figure 69 indicates the location throughout the socket where these differences occur.

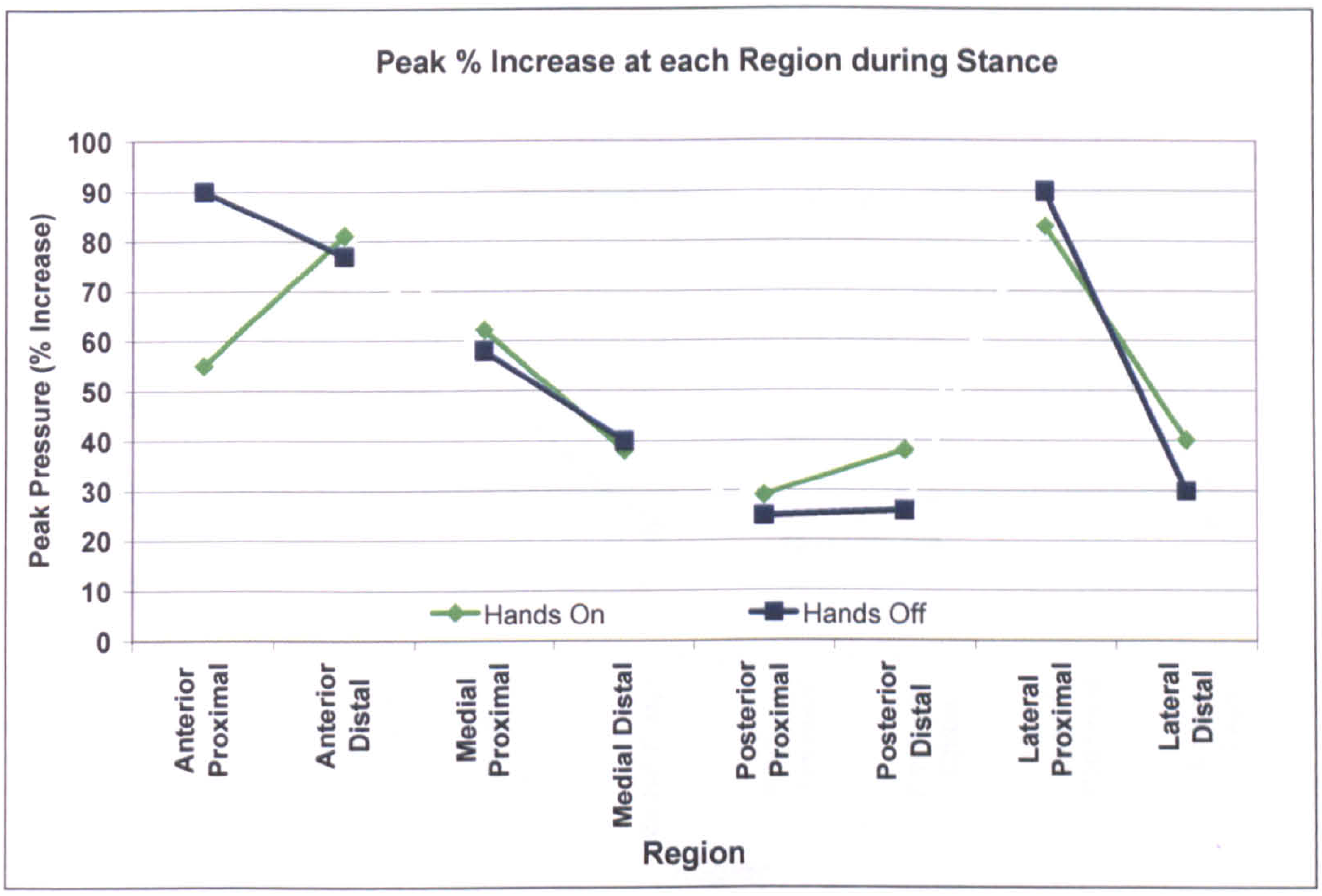
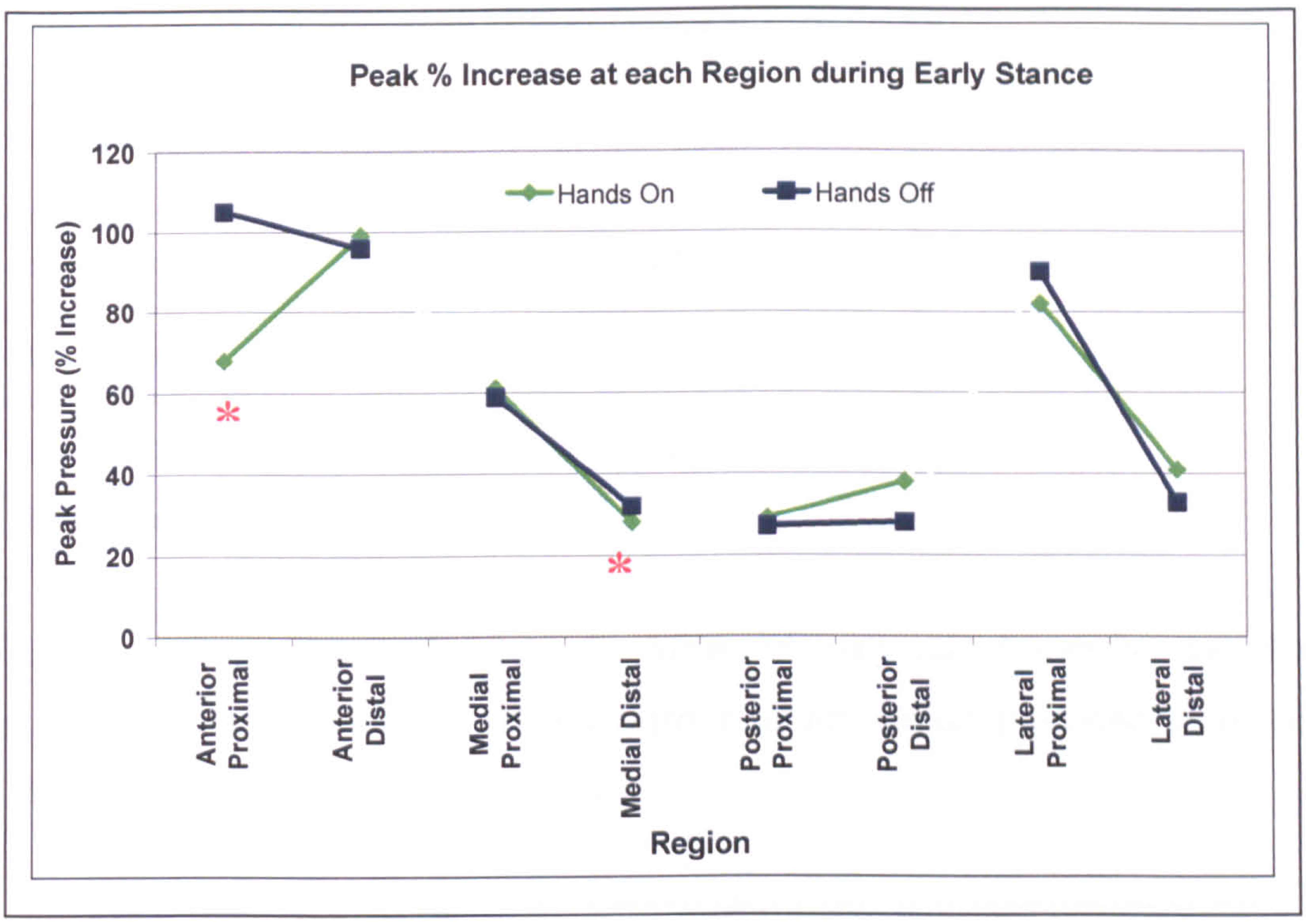


Figure 69: Peak Pressure % Increase by Group and Region

The graph suggests that differences between the two socket concepts occur at the proximal region of the anterior aspect and at the distal region of the posterior aspect. This graph represents the % Peak increase during the whole of the stance phase. The next three graphs display the same information as shown in Figure 69, but for each phase individually.



* Significant Difference, see Table 19

Figure 70: Peak Interface throughout the Socket (Early Stance)

The interface pressure for both socket concepts shows a similar pattern throughout the prosthetic socket at early stance, Figure 70. The hands off socket show a higher interface pressure at the proximal region of the anterior aspect and at the distal region of the medial aspect. Whereas, the hands-on socket concept has a higher interface pressure at the distal region of the posterior aspect. These regions are checked statistically to determine if the differences are significant. A Mann Whitney independent sample test was performed. As has been described previously the level of alpha was reduced from 0.05 to 0.017 for these tests in accordance with Bonferroni correction factor (Bland, 2000).

Table 19: Significant Differences between Groups at Early Stance

Region within Prosthetic Socket	P-value
Anterior Proximal	**0.003***
Medial Distal	**0.005***
Posterior Distal	0.025

***Significant difference when p≤0.017**

Table 19 shows the results from the Mann Whitney test. It can be seen that the regions in the anterior and medial aspects of the socket produced a statistically significant difference.

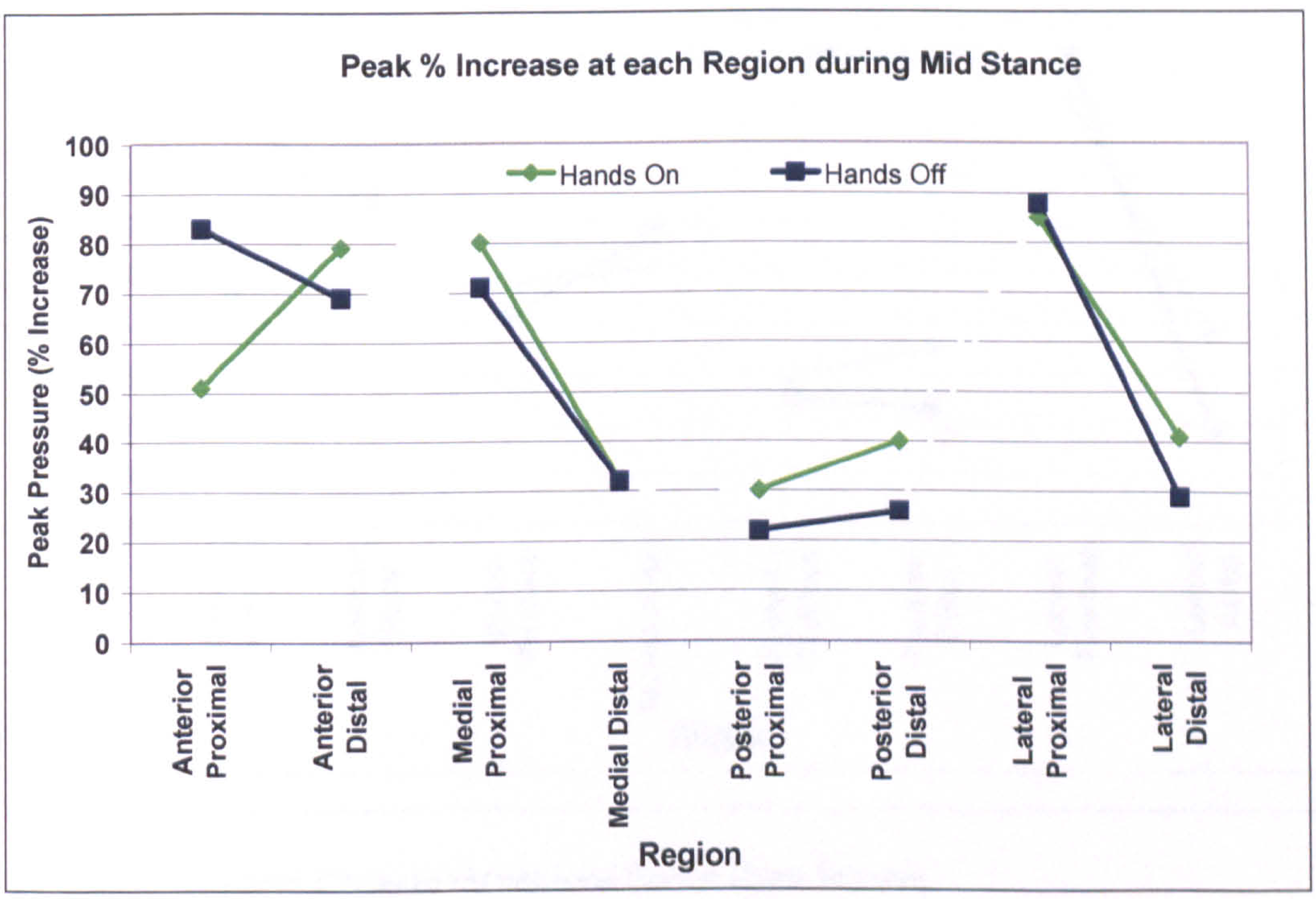


Figure 71: Peak Interface Pressure throughout Socket (Mid Stance)

Figure 71 demonstrates the pattern of interface pressure throughout both prosthetic socket concepts at mid stance. The same three regions will be subjected to the identical statistical analysis, results shown in Table 20.

Table 20: Significant Differences between Groups at Mid Stance

Region within Prosthetic Socket	P-value
Anterior Proximal	0.081
Medial Distal	0.490
Posterior Distal	0.127

Table 20 shows that at mid stance the differences in peak interface pressures have reduced. No significant differences are seen within the socket.

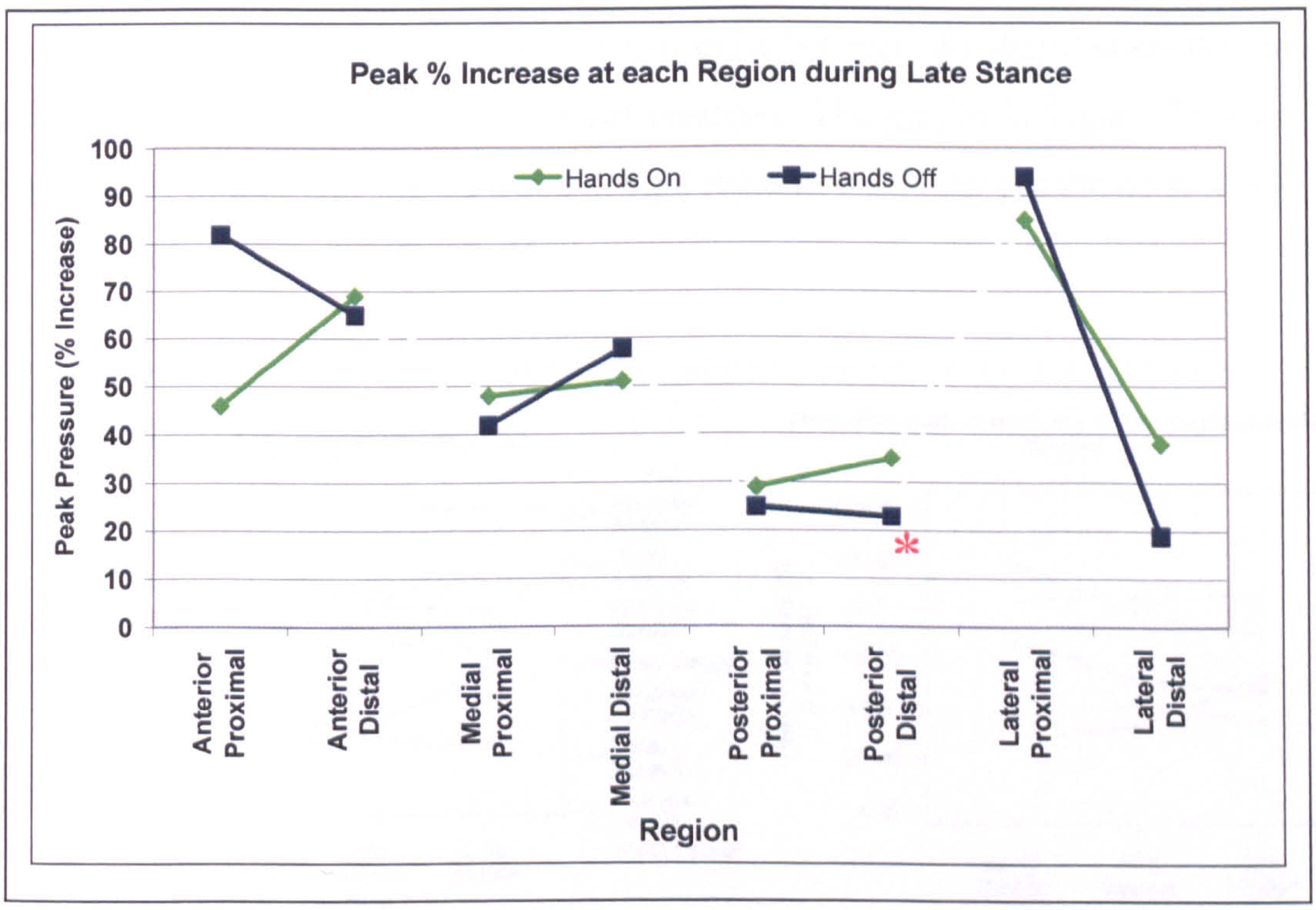


Figure 72: Interface Pressure throughout Socket (Late Stance)

The three regions within the socket were again tested using the Mann Whitney test; the results can be seen in Table 21. Significant differences between the sockets can only be seen at the distal region of the posterior aspect.

Table 21: Significant Differences between Groups at Late Stance

Region within Prosthetic Socket	P-value
Anterior Proximal	0.078
Medial Distal	0.022
Posterior Distal	**0.012***

*Significant difference when p<0.017

Interface throughout Stance by Region

It has been seen during the analysis of the peak interface pressure percentage increase that fewer significant differences exist between the distribution throughout the socket and between the two socket concepts. The graphs in Figure 73 show the magnitude of interface pressure at the eight regions within the prosthetic socket at the three points within stance.

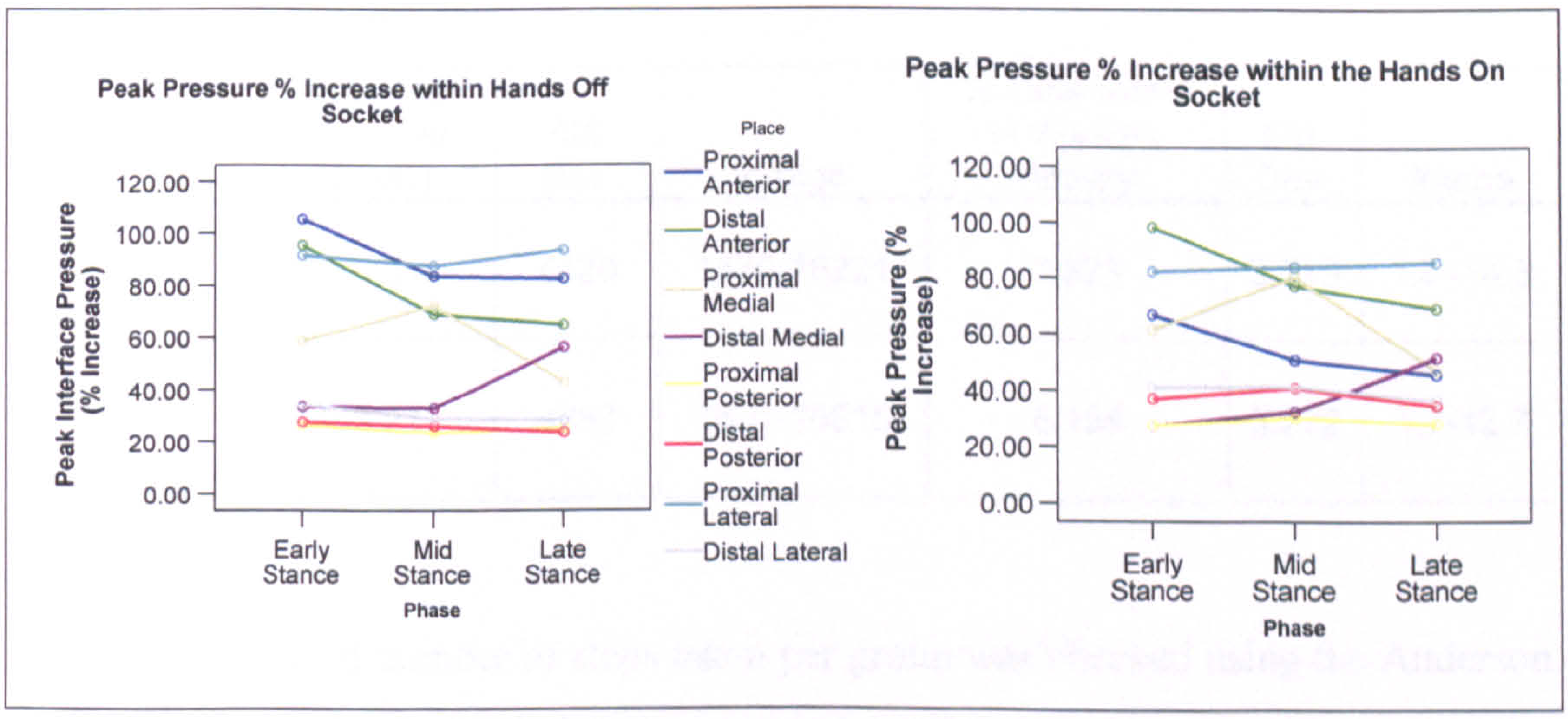


Figure 73: Peak Pressure Increase throughout Stance

The graphs in Figure 73 show that the regions with the higher percentage increase in peak interface pressures are similar for both socket concepts. In addition Figure 73 also illustrates that the percentage increases are similar for both socket concepts.

10.5 Activity Monitor Results

Each subject wore an ActivPAL monitor for a period of one week. During this time the movements of the prosthesis were recorded. The monitors were positioned on the anterior aspect of the shank of the prosthesis, at the level of the ankle. Reasons for this placement are described in the methodology chapter. The daily step count and percentage of time spent in walking activity was taken from each subject.

10.5.1 Number of Steps Taken

Each subject had a maximum of six days (complete 24 hour periods) of continuous activity. The daily activity and percentage of time spent in walking activity for each subject is given in Appendix 11. The average (mean) of all daily number of steps taken and percentage time spent walking was calculated and used for the purposes of analysis, Table 22.

Table 22: Daily Activity

Socket Concept	Number of Steps Taken (per Day)	Std. Dev.	Range	% Time Spent in Walking Activity	Std. Dev.	Range
Hands Off	9130.024	4420	1570-16221	7.525	3.719	1.5 -14.3
Hands On	7383.21	4383	1601-16815	6.154	3.272	1.7-12.7

The distribution of number of steps taken per group was checked using the Anderson Darling test. This enabled the correct choice of independent sample test to be implemented in order to determine if a significant difference exists in the average number of steps taken per group. Results of the normality test indicate that both the hands off group and the hands on group have normal distributed outputs ($p=0.386$ & $p=0.448$ respectively). Table 22 shows that subjects wearing the hands off prosthesis walked on average 9130 (SD 4420) steps per day and the group wearing the hands on group walked on average 7383 (SD 4383) steps. There was a wide variation in the number of steps between the subjects which can be seen when examining the standard deviation of the two groups.

Results from the test for normality indicated that the data was normally distributed (hands off $p=0.386$, hands on $p=0.448$). Therefore a two sample independent t-tests was used to check the difference in daily steps taken between the two groups. Results of this test show that there is no significant difference in the steps taken between the two casting groups ($p=0.173$).

Although no significant difference exists between the two groups in terms of number of steps taken per day, it can be seen that on average the group wearing the hands off sockets take more steps than those using the hands on sockets. One factor which may cause this difference could be the age of the subjects. In the analysis of the sample groups it was seen that the average age of the two groups showed a significant difference. For this reason a correlation between age and number of steps was taken for each group to determine if the age of the subject has any relationship to the number of steps taken.

A Pearson Correlation test was performed on both groups. The results of this test showed no significant relationship between age and steps taken (Hands Off group $p=0.409$ $r=-0.177$, Hands On group $p=0.879$ $r=-0.033$).

10.5.2 Time Spent in Walking Activity

In addition to the average number of steps taken each day, the activity monitors provide the total time spent stepping. This is displayed in terms of hours, and percentage of total time. For comparison, the percentage of time spent walking is used. Table 22 shows the results.

The distribution of both groups were normal (hands off $p=0.220$, hands on $p=0.250$). An independent sample t-test indicated that there was no significant difference between casting groups in terms of time spent walking ($p=0.182$).

10.5.3 Steps per Minute

In addition to the number of steps, the cadence, (steps per minute) is given by the activity monitors. The results are seen in the graph in Figure 74.

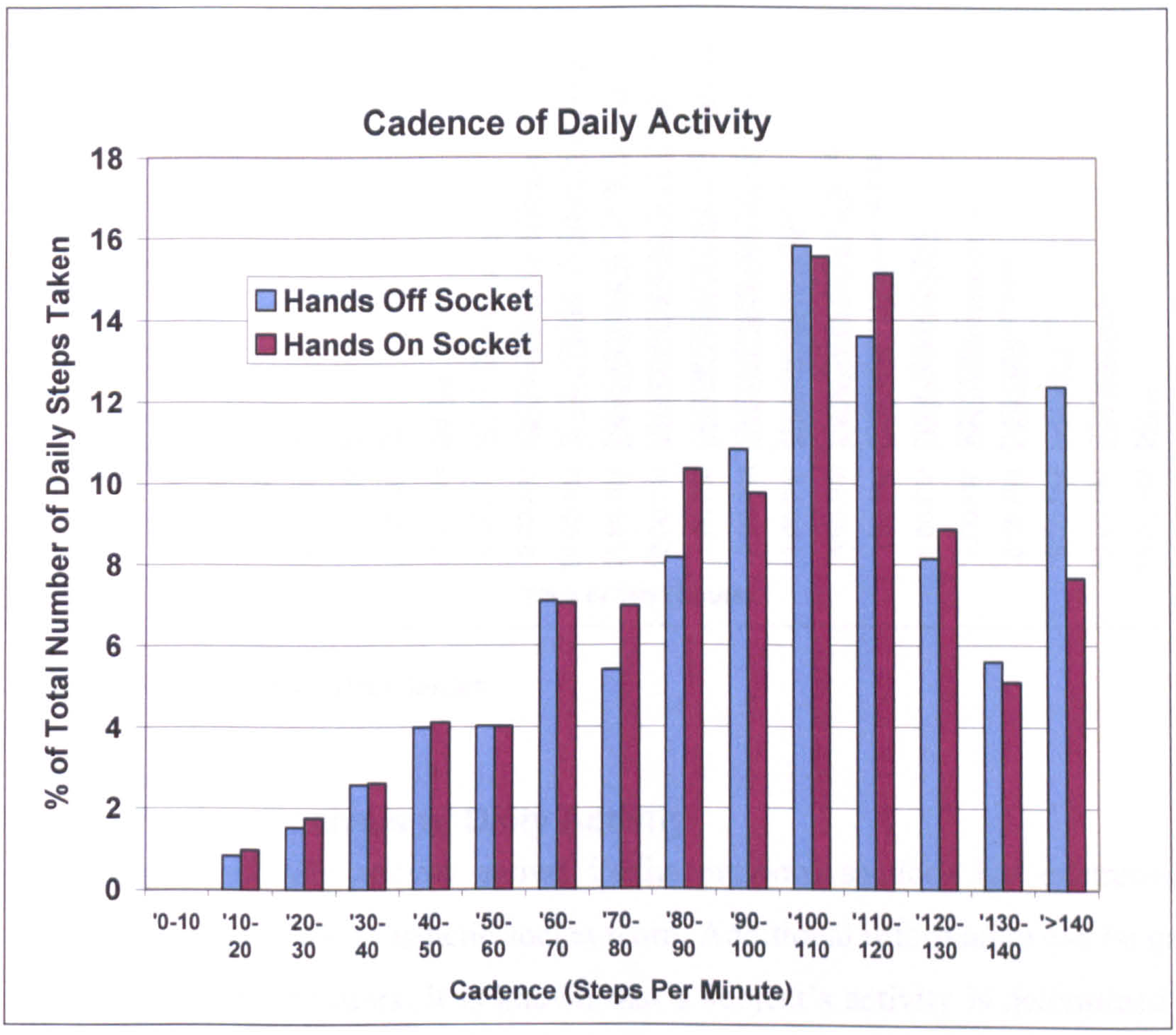


Figure 74: Cadence of Daily Walking

10.5.4 Time of day of Activity

The activity of each group is shown in Figure 75. The graph combines the number of steps taken each hour and displays the combined total in one hour categories.

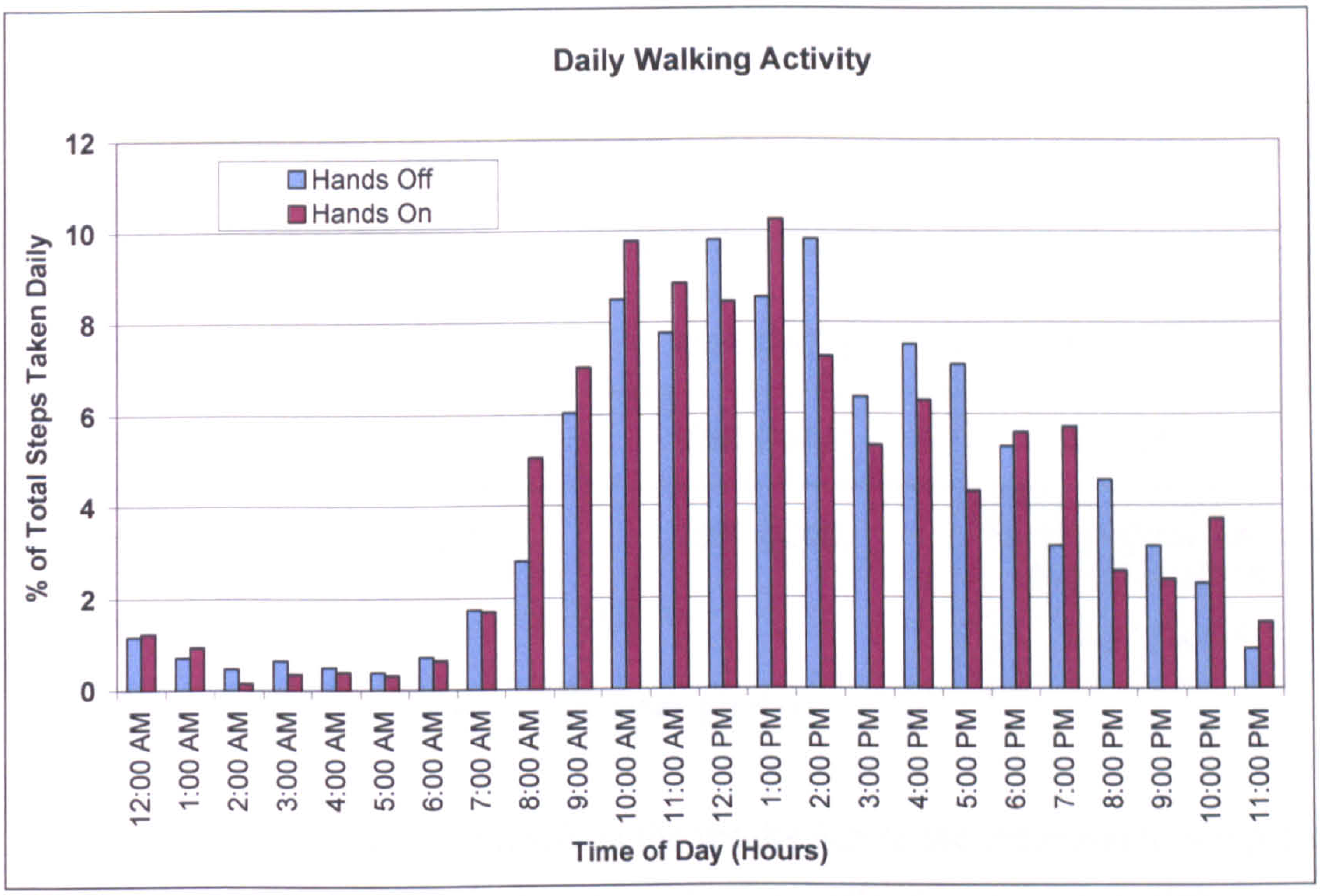


Figure 75: Daily Waking Distribution

10.5.5 Further Analysis of Daily Activity

The analysis of daily activity shown in the previous sections has examined the subjects in terms of the prosthetic socket worn. Additional information can be gained using the activity monitors. It is known that a subject's activity is determined by a wide combination of factors. Many of which are not recorded within this study. Studies have shown that the reason for amputation has a strong influencing factor on the activity of the prosthetic user. During the description of the demographic of subjects within both groups, it was shown that the groups were well matched in terms of subjects with and without PVD.

To indicate the effects of pathology on the activity of subjects within this study, subjects in the hands on and Hands off groups were sub divided into those who had an amputation as a result of PVD and those with other reasons for amputation, resulting in four sample groups. Table 23 shows the average (mean) results of these four sub groups.

Table 23: Daily activity, in terms of Number of Steps per Day given with Respect to Socket Design and Pathology

Pathology	Socket Concept Group		Activity by Pathology (Both Socket Concepts)
	Hands Off (Std Dev)	Hands on (Std Dev)	
PVD	7406 (5123)	4386 (2821)	5392 (3799)
Non PVD	9475 (4331)	8881 (4202)	9211(4223)
Activity by Socket Concept	9130 (4420)	7383 (4316)	**Average Daily Activity for All Subjects** **8257 (4410)**

Results shown in terms of number of steps taken per day

Statistical analysis is not performed on the results due to the reduction in sample size in each group. However the table does give an indication as to the differences in daily activity between the two socket concepts and pathology. The average number of steps taken for the entire study sample is 8257 steps per day.

10.6 Results from the PEQ

Due to the large amount of data produced from the PEQ responses, the individual scores from each subject are not included in the results chapter. These can be found in Appendix 12. All scores are out of 100, where 100 is the maximum agreement to a question, and 0 the lowest. The higher the number for any question, the higher the satisfaction of the subject. It should be noted that where subjects reported no response (nr) on questions their score is either recorded as a 0 or 100. No response would be given if a particular question was not applicable to the subject i.e. if a question referred to phantom pain and the subject did not suffer any phantom pain the result would be recorded as no response. The score given for "nr" questions was dictated by the PEQ instruction booklet. It is therefore possible that a subject may have several 100 or 0 scores when viewing the results.

10.6.1 Responses from the Individual Questions

Subject responses to all individual PEQ questions were divided into two groups according to the prosthetic socket concept worn. The distribution of this data was checked using the Anderson-Darling test for normality, and according to its result, the corresponding tests were used to establish statistical significance. The results from these tests are also shown in Appendix 13 due to the amount of data generated. Significant responses from the tests are shown in Table 24.

Table 24: Significant Difference Responses for PEQ Questions

Group/ Question	Question Name	Hands Off Mean	Std. Dev.	Hands On Mean	Std. Dev.	p value
1N	Damage to Covering	90.275	14.352	79.813	23.062	0.049
1V	Residual Limb Health	56.146	41.116	84.958	21.026	0.035
2O	Intensity of Back Pain	53.867	27.786	30.500	25.054	0.048

10.6.2 Responses from the Validated Scales

No significant differences exist between the two subject groups in terms of the nine validated scales within the PEQ. The graph in Figure 76 shows the group average scores for these nine scales.

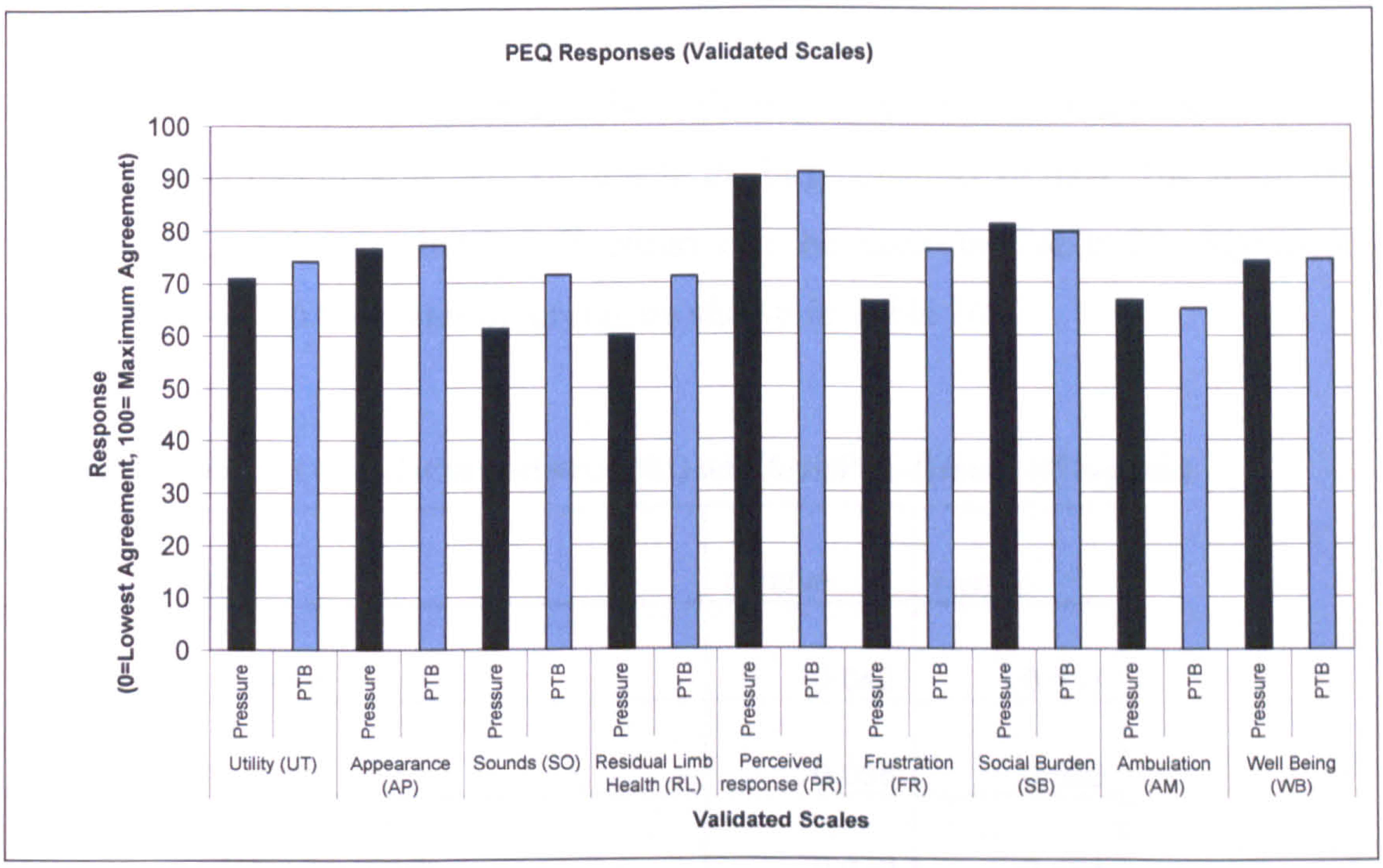


Figure 76: Responses from the Validated Scales

10.7 Combined Results from Outcome Measures

The relationship between the three outcome measures will be tested using Pearson correlation.

10.7.1 PEQ and ActivPAL

Results of the correlations between the daily step count and the responses from the PEQ can be found in Appendix 14, due to the large quantity of data. The significant correlations within the hands off group can be seen in Table 25. Significant correlations within the hands on group are shown in Table 26.

Table 25: Significant Correlations between PEQ and ActivPAL (Hands off Sockets)

Hands off Group	p-value	r-value
Weight of Prosthesis	0.043	0.417
Ability to Walk uphill	0.008	0.525
Importance of walking uphill	0.016	0.485

Table 26: Significant Correlations between PEQ and ActivPAL (Hands on Sockets)

Hands on Group	p-value	r-value
Ability to Stand	0.035	0.432
Ability to Don	0.040	0.422
Care giving to others	0.020	0.529
Ability to walk	0.011	0.510
Ability to go up stairs	0.017	0.483
Transfer to lo chair	0.021	0.469
Transfer to toilet	0.042	0.418
Well being since amputation	0.032	0.439
Utility	0.030	0.444
Well being	0.046	0.411

10.7.2 ActivPAL and Interface Pressure

Pearson correlations were performed on all areas within the prosthetic socket and the daily activity of each subject. The results are provided in Appendix 15.

No significant correlations exist between the interface pressure and daily activity within the group wearing the hands off prosthetic sockets. During late stance a significant negative correlation exists between daily activity and the average ($p=0.044$, $r=-0.414$) and peak ($p=0.049$, $r=-0.415$) interface pressure at the distal end of the anterior aspect of the hands on socket.

10.7.3 PEQ and Interface Pressure

The table of correlations between the eight regions within the prosthetic socket and the nine PEQ validated sub scales can be found in Appendix 16. Correlations were carried out on the average and peak interface pressures for both groups of subjects.

A number of significant correlations were seen for both socket groups and for average and peak interface pressures. Significant positive correlations are shown in bold. Whilst negative correlations are shown using a red font.

It can be seen that significant correlations between interface pressure and PEQ responses for hands off sockets have a **positive** relationship. The significant correlations between interface pressure and PEQ responses for hands on sockets have a **negative** relationship.

10.8 Chapter Summary

The results were divided into four sections. Firstly the demographic of the subjects were analysed. A number of physical measurements were made on the subjects in both groups. Results showed that the two subject groups were similar in make up. Analysis of the foot transducers indicated that both groups had an uneven gait pattern, walking with a larger proportion of time on the sound limb.

Interface pressure measurements taken at the limb/socket interface indicated that the when comparing the two intervention (socket prescription) groups, the dynamic pressure distributions at the limb/socket interface were similar. A significant difference was present in the magnitude of interface pressure between the two socket concepts at a number of regions within the prosthetic socket. The interface pressures recorded in the hands-off sockets were higher than those seen in the hands-on concept.

Despite the differences in interface pressure, the level of satisfaction with the sockets when measured by the PEQ was shown to be similar between subject groups. Self reported scores indicated high satisfaction relating to each prosthesis type for the questions asked. Notably, no statistical difference was seen between the two socket concepts for over 90% of the question responses. Differences were observed with regard to residual limb health ($p=0.035$), back pain ($p=0.048$) and intensity of phantom limb sensations ($p=0.046$). Despite two very different trans-tibial prosthetic socket concepts worn by persons with trans-tibial amputation, participants were seen to exhibit similar responses to the sockets.

Results from the activity monitor indicated that both subject groups were active throughout the day, walking on average over 8000 steps. No statistically significant difference in daily stepping activity was seen between the two groups. Despite differences in prosthetic socket concept the daily activity profiles of both subject groups were similar. Furthermore, the activity level of both groups was within the normal range for able-bodied people of similar age.

The results analysed in this chapter are discussed further in the following chapter, and conclusions drawn.

11 Discussion

11.1 Chapter Introduction

This chapter follows the structure of the results chapter, namely that the demographic of the subjects who participated in this study are discussed, followed by the three outcome measures. The similarities of distribution of interface pressure are investigated, followed by a discussion regarding the magnitude of pressure levels and the implications these have on the fit of the prosthetic socket.

The daily number of steps taken by both groups was explored, in addition to the cadence and foot timings from each subject. Responses from the PEQ which indicated a significant difference between the two groups are discussed, and the nine sub-scales within the PEQ are explained. Finally the combinations of the outcomes are discussed.

11.2 Subject Sample

In accordance with the study criteria, all subjects participating in this investigation had suffered a unilateral trans-tibial amputation. Each subject wore a prosthesis for regular daily activities. The prosthesis worn had been used for at least six months prior to this investigation. The study sample comprised of two groups each containing 24 subjects. All references to amputee statistics for the general population are made using figures from the NHS National Amputee Statistical Database (NASDAB) for year 2004/5 (NASDAB, 2005).

As outlined in the introduction the causes of amputation can be defined in terms of disease, traumatic incident and congenital absence. In the UK, the majority of amputations are performed as a result of disease, in particular peripheral vascular disease (PVD). The most common level for amputation is below the knee, or trans-tibial amputation. The most common level of amputation is at the trans-tibial level and consequently this was the population of patients investigated in order that the outcomes would benefit the widest number of people.

The primary focus of this investigation was to investigate the interface pressure of two commonly prescribed trans-tibial prosthetic socket concepts. Subjects recruited to the study had a number of different causes of amputation. To facilitate analysis of the results, the specific reasons for amputation were divided into two categories. Amputations resulting from vascular disease i.e. peripheral vascular disorder and diabetes were classified as PVD. The remaining cases of amputation in the sample were categorised as "other". This group contained reasons for amputation including traumatic injuries, cancer and amputations as a consequence of congenital deformations of the foot. No subjects recruited in this investigation wore a prosthesis as a result of a congenital limb absence.

The demographic statistics for this investigation shows that the majority of subjects participating have suffered amputation as a result of non disease related incidences (75%). Thus the sample does not reflect the population from which it was taken. One reason for this difference is due to the criteria for subject participation. This included that subjects must not be suffering from any other serious illness which may cause a danger to themselves whilst undertaking the study trials. Subjects were also required to be able to walk several lengths of the clinic room in order to gain enough data for the interface pressure measurements and be able to complete the questionnaire. These criteria resulted in a reduced number of PVD patients, many of whom suffer other conditions associated with the disease, making their participation in the study inappropriate.

NASDAB data shows that patients, who undergo traumatic limb amputation, are generally working-age adults (16-54 years old). Patients with amputations resulting from dyvascular disease are older (55 and above). The higher number of subjects with traumatic amputations participating in this study attributed to the lower average age of subject in this study sample when compared to amputee population. The average age of subjects in this study was 55 years, (range 25 to 89).

It can also be seen from the demographic statistics of this investigation that the number of male subjects is far greater than the females (80% male). However the discrepancy between the genders is similar to the national amputee population. According to recent national statistics 72% of trans-tibial amputees are male, thus the sample size of the study reflects the national population.

Despite the limitations to the sample demographic, both groups showed a similar ratio of subjects with PVD to traumatic related amputations. The ratio of male to female subjects was also consistent between groups. Both sample groups were well matched and comparisons can be drawn between them. The method of amputation may have an affect on the subject's perception and response to their prosthesis. Therefore two well matched groups were important when comparing the results of the questionnaire and activity monitor.

The primary reason for using the subjects own prosthesis during this investigation was to collect data which relates to the prosthetic socket used for everyday experiences of the amputee population. No familiarisation or adjustment period was required for the subject to become accustomed to the prosthesis. In addition to this the subjects walked as close to their normal gait pattern as possible during the collection of the interface pressure data. All subjects were instructed to walk along the walkway at a self select walking speed.

Interface pressure at the prosthetic socket, residual limb interface can be influenced by a number of elements, including the physical size and weight of the subject, the alignment and design of the prosthesis. It was important when comparing the two subject groups that as many of these factors were similar between groups. A number of physical measurements were taken at the time of recording the interface pressure within the prosthetic socket. These included subject's height, weight and a number of residual limb measurements. When the two subject groups were compared no significant differences existed in terms of these measures. The combinations of these influencing factors were also examined and found not to exhibit a difference between the two groups.

It was important to establish well matched baseline measures between both groups in order that comparisons of interface pressure measurements could be made.

11.3 Interface Pressure distribution

Quality of fit remains a subjective process in the clinic room, there is currently no consensus as to a fitting and assessment protocol (Mak et al., 2001). One method for assessing socket fit in a research context is by measuring interface pressure distribution.

The two prosthetic socket concepts used to produce the sockets for use in this investigation involve two different pressure distribution concepts during casting, therefore two different shapes of prosthetic socket. Despite this difference in pressure distribution during casting the profiles of the dynamic pressure distribution at the limb/socket interface are similar when comparing the two subject groups. However a difference can be seen in the magnitudes of interface pressure when the two groups are compared.

The interface profile over the interface between residual limb and prosthetic socket remains consistent throughout stance phase. When examining the average pressure over each aspect of the socket, the interface pressures measured are seen to remain consistent with respect to the other socket aspects during stance. In other words, if the lateral aspect recorded the highest pressure at the early part of stance, it would remain the highest throughout stance. If the medial aspect showed the lowest pressure at the beginning of stance, it would remain the lowest. The results of the interface pressure measurement within the prosthetic socket have indicated that the distribution of dynamic pressure throughout the socket during gait is similar between both socket concepts.

On average the magnitude of interface pressure at each aspect of the prosthetic socket remains consistent with respect to the other aspects throughout the gait cycle. It was seen that the posterior aspect showed the highest average interface pressure, with the anterior aspect having the lowest interface pressures of the four aspects. The average interface pressures at the posterior aspect of the socket were recorded as the highest within the socket for 62.55% of all the subjects. The anterior aspect was seen to be the aspect with the lowest average interface pressure during the gait cycle, in 52% of all subjects. This profile can also be seen when examining the proximal and distal regions of each socket aspect.

When identifying the force patterns expected between the residual limb and the prosthesis, Radcliffe described a dynamic force pattern which was shown to be influenced by the alignment of the prosthesis, muscle action and the angular position of the residual limb with respect to the ground reaction force (Radcliffe, 1961). The pressure profile explained by Radcliffe was based on normal gait, at heel strike the ground reaction force would pass anterior to the knee creating an extension moment. He said that this extension moment would then create higher interface pressures at the anterior proximal and posterior distal regions of the stump/socket interface. His description of biomechanical forces indicates that the greatest change in the pattern of force occurs immediately after heel strike, when the ground reaction force passes from anterior of the knee joint to a location posterior to the knee. This change in location changes the initial extension moment about the knee joint to a flexion moment. He describes how during the early part of stance the higher forces in the sagittal plane are shown to move from the distal posterior region to the proximal region and proximal anterior region to the distal anterior region. This change in interface pressure pattern remains constant for the rest of stance as the reaction force remains behind the knee joint.

The change in distribution over the anterior and posterior aspects of the residual limb described by Radcliffe is not seen in the results of this investigation. The interface pressure measured within the prosthetic socket showed the greatest change towards the end of stance. However the distribution throughout the socket remained consistent for all three sub phases of stance phase.

Statistical analysis using ANOVA did indicate a significant interaction between the regions during the three sub phases of stance. However Tukey post-hoc analysis shows that significant difference in interface pressure does not occur between early and mid stance ($p=0.393$). A significant change to interface pressure was seen when comparing late stance to mid stance, ($p<0.001$).

Even though there is a significant change in the magnitude of interface pressure towards the end of stance, the dynamic profile within the socket remains consistent throughout all of the gait cycle. At all three points during stance, the interface pressure at the proximal region on the anterior aspect of the socket remains lower than the pressure recorded at the distal region of the anterior aspect. This profile suggests that at heel strike the ground reaction force is already passing behind the knee creating a flexion moment. At late stance the interface pressure at the proximal region of the anterior aspect increases, creating a more even distribution of interface pressure over the anterior aspect. This increase in proximal anterior pressure has also been shown in a recent study of the pressure profile of PTB and pressure cast sockets (Goh et al., 2004, Goh et al., 2003b). However the profiles seen in the sockets in their study indicated a large difference in the distribution of pressure over the anterior aspect at late stance, which was not seen in this study.

In a comparative study of the PTB and pressure cast trans-tibial sockets the profile of the posterior aspect has been shown to be similar (Goh et al., 2004). The profile seen in their study identified the distal region of the posterior aspect as showing the higher interface pressures. This profile also contradicts the profiles described by Radcliffe, who stated that the proximal region of the posterior aspect would experience the higher pressure after heel strike. The interface pressures recorded in our study showed that on average, both groups had higher pressures at the proximal region; no significant difference was seen between the two groups in this region of the posterior aspect. The distal region experienced much lower interface pressures throughout stance compared to the proximal region. Significant differences were seen in the interface pressures between groups in this region. The hands-off sockets experienced higher pressures.

These results were also seen in a study of different walking conditions (Dou et al., 2006) They found that the maximum interface pressures occurred at the proximal posterior region and at the distal anterior region. For control purposes they recorded the interface pressure of normal, flat walking before investigating slopes and uneven ground.

Radcliffe describes the alignment of the prosthetic foot to the body centre of mass as creating a medially orientated ground reaction force. This in turn creates an adduction moment which generates higher interface pressures at the proximal medial region and at the distal lateral region of the residual limb. Although the distal lateral region of both groups in this study experienced higher interface pressures, the medial aspect did not show differences in interface pressure between proximal and distal regions. The distribution of pressure from proximal to distal regions within the lateral aspect of the socket showed the greatest difference of all the four aspects.

It should be noted that the pressure profiles described by Radcliffe were based on normal walking patterns, and the profiles given by Goh were recorded when the subjects were not wearing an interface liner. It can also be seen in Goh's studies that there was a wide variation in the distribution of interface pressure between the four subjects recorded. Despite this variation between subjects, the distribution within the socket remained similar for each subject when both sockets are compared. It is therefore not surprising to see that the distribution through the prosthetic sockets worn by the subjects in our study do not show a difference when comparing the two socket concepts. The variation experienced by Goh is also seen in this study, when looking at the interface pressure results. When the interface pressures for all regions is examined it can be seen that the range for the hands-off prosthetic sockets was smaller than those for the hands-on sockets. This result indicates that the variation in interface pressure seen in the group wearing the hands-off sockets is smaller than for the hands-on concept. A smaller variation in interface pressure could mean that the hands-off concept is a more consistent method of casting for prosthetic sockets. This is expected, as the variation in manual dexterity of the prosthetists casting and rectification technique is removed (Convery et al., 2003). Despite these variations, all subjects reported that they were happy walking on their prosthesis, which was also evident when examining the feedback gained from the PEQ.

Measuring the interface pressures of both concepts of prosthetic socket has revealed that the dynamic distribution of pressure throughout both types of prosthetic socket is similar. When the magnitudes of interface pressure are examined differences can be seen. The hypothesis set in this investigation stated that a difference would be seen in the levels of pressure recorded in the two socket concepts. Based on previous studies the interface pressures recorded in the hands-off sockets was expected to be lower than those seen in the hands-on sockets. Significant differences between the two prosthetic socket concepts were seen in this investigation; however the outcome was not as expected.

When examining the average interface pressure for the entire socket, statistical analysis reveals that no significant difference is observed between the two groups, although the interface pressures seen within the hands-off sockets were, on average, higher than those in the hands-on socket. This is contrary to the expected results.

It can be seen that differences in interface pressure between the two groups occur at the two peaks in interface pressure during stance phase, these being during early stance and late stance. During the "dip" in interface pressure at mid stance the differences between the two socket concepts is reduced and no significant difference can be seen when comparing the two socket concepts.

Despite the indentation of the patella bar at the proximal region of the hands-on prosthetic sockets, the interface pressure is seen to be greater in those subjects wearing the hands-off sockets, with no indentation. In fact, at early stance the interface pressure at the proximal region of the anterior aspect of the hands-off group is on average significantly higher than for the group wearing the hands-on sockets ($p=0.003$). Although there are differences between the two socket concepts, the pressures at the anterior proximal region have been shown to be one of the lowest of any region for both socket concepts.

The distal region of the posterior aspect of the prosthetic socket, which traditionally is compressed during the casting and rectification of the PTB socket, does experience high interface pressure throughout stance. However it can be seen that the hands-off casting method, also produces sockets with high distal region pressure at the posterior aspect. On average, the hands-off prosthetic sockets have higher interface pressures recorded in this region at both early and late stance ($p=0.004$ early stance, $p=0.017$ late stance).

The poplitial fossa is found at the proximal region of the posterior aspect of the residual limb. During casting and rectification of the PTB socket this area is indented to act as a counter force to the patella tendon bar. The principle of hands-off casting using uniform pressure results in this region receiving a less aggressive depression as in the hand-cast method. The interface pressure recorded at this site for both concepts is seen to be much higher than the distal region. However both casting concepts have produced similar interface pressure, no significant difference occurs, despite the different shaping techniques.

The proximal region on the lateral aspect of the socket also experiences significant differences in interface pressure between the two socket concepts at early and late stance ($p=0.004$ at early stance, $p=0.009$ at late stance). In general, the hands-off sockets have the higher pressures. As with the posterior aspect these significant differences occurred in the region with the lower pressure. At this region, the hands-on casting concept does have higher interface pressures than those seen in the hands-off concept. The distal region of the lateral aspect experiences the highest pressures recorded within the prosthetic socket, but both socket concepts have similar recorded interface pressures.

Zachariah investigated interface pressure in the trans-tibial prosthetic socket (Zachariah, 2001). The aim of their study was to determine the differences in pressure between standing and walking, however their results do show a similar pattern to the results gained in this investigation. They found that the interface pressures showed a regional dependence with the maximum interface pressure occurring at the anterior distal region. The pressures reported are average peak pressures recorded during a number of steps, and the timing of these peaks is not indicated. Their results also highlight the variation in interface pressure between subjects, although general trends could be seen between the two subjects, the variation in interface pressure was great. Sanders (1997) used 13 tri-axial transducers to record the interface pressure and shear stresses in trans-tibial sockets (Sanders et al., 1997). Although no transducers were placed on the medial aspect of the socket the results from the other aspects also indicate similar results to ours. At the first peak in interface pressure, the anterior distal and posterior proximal regions exhibited much higher pressure than the anterior proximal and posterior distal regions. This pattern contradicts the pattern given by Radcliffe. At the second peak the same pattern is seen, supporting again our results.

When viewing the interface pressures for all regions within the prosthetic socket during all three points within stance it can be seen that the interface pressures within the hands-off concept are more closely distributed. This indicates that the distribution of pressure throughout the hands-off socket is more even compared to the hands-on concept. This would be expected as the casting technique of the hands-off method applies a uniform pressure over the residual limb, whereas the hands-on concept influences the pressure distribution according to underlying tissue.

11.4 Interface Pressure Levels

The residual limb consists of areas of thin tissue coverage, over bony prominences and areas of thicker tissue. This difference in tissue properties is how the idea of PTB casting and rectification was devised (Radcliffe and Foort, 1961). The principle is to permit a greater deformation of the softer tissues whilst reducing the deformation of the more bony areas. Results from a recent study support the theory of tissue tolerance that Radcliffe discussed when designing the PTB socket (Zhang and Lee, 2006). Their results showed that the patella tendon was the best pressure tolerant region with the fibula head having the lowest ability to tolerate pressure.

Areas of thicker tissue coverage could be compressed a greater amount before the force increased to a point where pain was detected. However the areas of greatest compression may not necessarily be the areas with the highest pain tolerance. The study also showed that the areas of greatest compression such as the popliteal region had a lower tolerance to pain. A small indenter tool was used to apply a force to the tissue; this application is not consistent to the forces applied by the prosthetic socket. The indenter applies localised force which in turn may produce a shear force in the underlying soft tissue as it is compressed. Although not measured, it may have been the shear force creating the pain in the thicker tissue areas and not the application of the interface force. However this does illustrate that some of the more bony areas such as the tibial tuberosity and mid-tibial crest could tolerate higher pressures than softer tissues such as the popliteal muscle, with thicker tissue coverage.

The interface pressures described in the previous section relate to the average interface pressure recorded over each region for each of the three points in stance. The peak pressure, i.e. the highest pressures recorded within each region is discussed below.

11.4.1 Peak Interface Pressures

The peak pressures recorded between the residual limb and the prosthetic socket showed similar distributions to those of the average pressure. The hands-off sockets showed higher peak pressures than the hands-on group. This result is surprising when previous literature suggests that the uniform pressure distribution created by the hands-off concept produces lower peak pressures (Convery and Buis, 1999). In the same way as was seen for the average interface pressure, significant differences were seen between the two groups in terms of peak pressures at several regions at the beginning of stance and end of stance, mid stance showing fewer differences. In particular the proximal regions had significant differences in interface pressure in all regions except the posterior aspect. A significant difference was seen at the posterior aspect, but over the distal region at early stance. A significant difference was seen at the proximal region of the anterior aspect throughout stance.

The same pattern of peak pressure was observed as was seen for the average pressure, in that pressures increase at late stance. The anterior distal region was the only exception to this, the peak pressures at this region decrease throughout stance. This finding is inconsistent with the biomechanical theory proposed by Radcliffe which identified the distal region of the anterior aspect as incurring higher interface pressures from mid stance to end of stance (Radcliffe, 1961). However it does suggest that the ground reaction force was passing behind of the knee joint at heel strike, creating a flexion moment which caused the peak pressures seen at the anterior distal region. This region is also the area where the cut end of tibia is located. Despite the differences in peak pressures, the pattern of peak pressure distribution throughout the prosthetic socket is similar between both socket concepts. On average, the peak pressure values in each region are approximately 150kPa, and even the distal region of the anterior aspect which experiences the highest peak pressure does not exceed 175kPa.

These findings suggest that although the casting concept used to create the prosthetic sockets is based on two different philosophies the distribution of interface pressure is similar. The hypothesis stated that the hands-off concept would produce a prosthetic socket with lower and fewer peak pressures, due to the uniform pressure casting method used. This has not been seen in this investigation. The interface pressures recorded in the hands-off sockets are higher than those seen in the hands-on concept. Despite the differences in interface pressure the satisfaction of the sockets are similar between subject groups.

11.4.2 Percentage Increase in Peak Pressure

When examining the average and peak interface pressures it was shown that the distribution throughout the socket during stance remained similar for both socket concepts, and that late stance showed the greatest increase in pressure. A different pattern emerges when examining the percentage increase in peak pressure. Two distinct patterns appear within the prosthetic socket when the percentage increase in peak pressure is viewed at each phase within stance. At regions on the posterior and lateral aspects, the increases are seen to be identical throughout stance phase. At the anterior and medial aspects, each point in stance phase produces a different increase. In addition to this, although the average and peak pressures increased towards the end of stance, it can be seen that the percentage difference between average and peak pressure reduces during stance.

The graphs of the distribution of increase in peak pressure also indicate that the areas of thinner and bony tissue such as the fibula head and tibial tuberosity are the areas which experience the largest increase from average to peak pressure. The areas of softer, thicker tissue such as the posterior aspect show much smaller peak pressure increases. The percentage differences throughout the prosthetic socket are similar when comparing both socket concepts. Again this is surprising, as many of the claims made by interface liner manufactures suggests that the silicone liner used in the hands-off concept can reduce the peak pressures and distribute the pressures more evenly. It has been shown that dynamic interface pressure distributions and magnitudes for both socket concepts are similar between groups.

A difference between the two socket concepts is seen in the increase of peak pressure at the anterior region. At all points during stance, the proximal region of the hands-off concept exhibits a higher increase than the distal. The distal region has a larger increase than the proximal region for those wearing the hands-on concept. This difference may be explained due to the fact that the hands-on concept involves pressure relief at the tibial tubercle and crest of tibia. This offloading may reduce the peak pressure increase seen at the proximal anterior region.

Despite several areas within the prosthetic socket experiencing higher peak pressure increases compared to others, all increases are within 100% of the average interface pressure.

11.5 Activity Monitor

Health and well being can be improved by including moderate amounts of physical activity in daily life. Health benefits from regular physical activity are widely reported and even small increases are beneficial. There is increasing evidence that physical activity need not be of a great intensity to improve health. The amount rather than the intensity of physical activity enables people to select physical activity which suits their daily lives and abilities. In 2003 the Scottish physical task force set out a strategic plan to highlight the benefits and promote the health of the nation. In the report they list some of the benefits of increased physical activity including that it reduces the risk of premature coronary heart disease, hypertension, colon cancer, and diabetes mellitus. Physical activity also improves mental health and is important for the health of muscles, bones, and joints (Physical-Activity-Task-Force, 2003). Maintaining physical activity after amputation can be seen as an important goal to improve the health of amputees. Monitors were attached to the prostheses of subjects participating in the study to record their daily activity.

11.5.1 Daily Activity

Results form the activity monitor indicated that on average, the number of steps taken on a daily basis by subjects wearing the "hands-off" sockets is 9130. The group wearing the "hands-on" sockets walked on average 7383 steps. These results suggest that the group wearing the "hands-off" sockets are more active than those wearing the "hands-on" sockets. Despite the difference in activity, there is no statistical difference between the two groups ($p=0.173$). The range of daily activity of both groups was similar with the lowest daily activity at around 1500 steps, whereas the highest average daily activity was nearly 17000 steps. These results indicate that the design of prosthetic socket seems not to have an effect on the daily activity of a user. In addition, despite the use of a prosthesis, many of the subjects remain highly active. The results of 30 studies which implemented monitors to determine the activity of subjects were summarised in a paper offering methodological considerations to persons measuring activity (Tudor-Locke and Myers, 2001). They concluded that healthy younger adults could be expected to walk between 7000 and 13000 steps, with activity falling slightly for older adults to value of between 6000 and 8500 steps. In studies examining older subjects with chronic illnesses and disabilities the study concluded that activity of between 3500 and 5500 steps could be expected. These findings are from a number of studies, with several different monitor types and methodologies, although general age ranges are given, it only serves as a guide and are useful in establishing a general consensus of daily physical activity. However the results do offer some guidance to compare the results form the study. It is clear from the activity given in the review and the number of steps taken in the study that, on average, the samples were relatively active for the age group measured. As described in the sample description, many of the subjects recruited in this study had suffered amputation as a result of trauma. Other than the amputation, many of the subjects did not suffer from other health conditions. It is therefore not surprising that the activity of the group is comparable to able bodied subjects of the same age group.

The results comparing the two prosthetic socket concepts have indicated that small differences in activity exist between the two sample groups, but these are not statistically significant. It is known that a subject's activity is determined by a wide combination of factors which are not attributed to the prosthesis. Factors such as working environment, social activities or general health all influence physical activity. The contributing factors which lead to amputation as a result of vascular disease also reduce the physical capability of this population. To indicate the effects of pathology on the activity of subjects within this study, subjects were also divided into those who had an amputation as a result of PVD and those with other reasons for amputation.

The average daily activity of subjects suffering an amputation as a result of vascular disease was 5392 steps. In contrast those with other reasons for amputation had a daily activity level of 9211 steps. This value for daily activity falls within the range of 3500 and 5500 given for older subjects with disabilities and chronic illness (Tudor-Locke and Myers, 2001). The time walking per day equated to 7.29% for those without vascular disease. Subjects suffering from amputations as a result of vascular disease spent 4.75% of the day in walking activity. This result compares closely to the findings of a recent study of physical activity in people with PVD related trans-tibial amputations (Bussmann et al., 2004) They found that the time spent walking was 4.3% of the day. These results highlight the reduction in the activity level of patients with vascular disease and associated health implications.

The length of step was not measured during this study, but an approximate distance for daily activity can be calculated. It is stated that the average person takes approximately 1250 steps per km (Ainsworth et al., 1993). Using this figure as a basis for calculation it can be seen that the amputee sample within this study walk between 1 km and over 13 km per day with an average of approximately 6.5 km. Although these figures are only intended as a guide and cannot be used to draw conclusions regarding the distance walked, they do provide encouraging evidence that the prostheses delivered are being utilised to undertake daily activity at levels similar to those of the normal population.

On average, as a group, the percentage of time spent walking on the prosthesis was shown to be nearly 7% of the day. No significant difference exists between the two socket concepts for the length of time spent walking (p=0.182). The profile for walking seen from the activity monitors shows that daily activity was similar for both groups. Walking activity was spread throughout the day, with most activity around late morning and early afternoon. The output from the activity monitors indicates that although subjects only spend around 100 minutes per day in walking activity, the prostheses is in use for more than 8 hours daily.

It should be noted that a prerequisite for inclusion to this study, subjects had been using their prosthesis for at least six months for daily activities, with no residual limb health incidence. The subject groups also included a high proportion of subjects with traumatic amputation. This may account for the relatively high daily activity levels recorded in this study. Daily activity prior to amputation has not been recorded; however the study does provide encouraging evidence that a high level of daily activity can be maintained after amputation.

11.5.2 Cadence

Both subject groups have a similar cadence profile. The results from the monitors show that subjects are capable, of achieving a "normal" walking speed. The most common cadence recorded is between 100 and 110 and is performed during 16% of all steps taken. Rates of this level suggest that the subjects are walking at a speed of approximately 3 mph (Ainsworth et al., 1993). The distribution of cadence also shows that the subjects were able to maintain these speeds for a large proportion of their daily activity, with a cadence of over 80 steps per minute accounting for over 70% of the daily activity.

The activity monitor is attached to one leg; therefore the total number of steps recorded is the product of the steps recorded on one leg multiplied by two. When examining the cadence values this refers to the total number of steps for both legs, i.e. a cadence of 100 is equal to each leg performing 50 steps per minute, or each step lasting 1.2 seconds.

Using information from the foot transducers it was possible to determine the cadence of the subject when walking in the clinic room. The results from the transducers showed that on average, the group wearing the "hands-on" socket concept took 1.33 seconds between successive footfall positions and those wearing the "hands-off" concept had 1.3 seconds between heel strikes. The timings indicate that during the recording of the interface pressure measurement the subjects in the "hands-on" group were achieving a cadence of 90 and those wearing the "hands-off" socket concepts had a cadence of 92. The cadence recorded in the clinic room can be seen to equate to a cadence seen during 10% of the daily activities performed by the subject.

These results show that subjects walking in the clinic room walked with a slower cadence than the most frequent cadence seen during activities of daily living. All subjects had walked in the instrumented prosthesis before recording began to become accustomed to the wires, acquisition boxes and walkway. All subjects reported that they were comfortable with the instrumented prosthesis and were walking with an unimpeded gait pattern. Despite these precautions against gait deviations, the constraints of the clinic room and wiring arrangement meant that the subject could not perform more than twenty metres before turning direction. This restriction may have resulted in the subject selecting a slightly slower cadence than seen in an open, unrestricted environment.

11.5.3 Symmetry of Gait

It has been shown that gait asymmetry is greater for prosthetic wearers than those of the normal population (Dingwell et al., 1996, Mattes et al., 2000). Observing the symmetry of a persons gait may provide information as to the comfort of the prosthesis. Asymmetry can be caused when the amputee prolongs the stance phase on the sound limb, whist reducing stance on the prosthetic side. Several reasons can be attributed to this unequal timing, including a habit that has formed over time due to insecurity of the prosthesis. Pain or an unstable prosthesis may also cause the amputee to try and move through the prosthetic stance phase more quickly, whilst prolonging the sound side stance phase.

It was possible to calculate the percentage of time spent in each phase of the gait cycle and the differences seen between sound and prosthetic side. The timings gained by the F-scan foot transducers were converted into percentage of total gait cycle and used determine the pattern of stance and swing phase timings.

Stance phase accounts for approximately 60% of the gait cycle, with swing phase lasting 40% in the normal population. The results of this study show that stance phase lasts for over 60% of the gait cycle for both the prosthetic and sound side. Both subject groups spent a smaller proportion of time in stance on the prosthetic side than that spent in stance on the sound side. Those wearing the "hands-on" prosthetic socket concept had a more symmetrical division between sound side and prosthetic side: The "hands-on" group spent 1.51% longer in stance on the sound side, whereas those wearing the "hands-off" concept spent 4.67% additional time on the sound side.

In order to better evaluate how the prosthesis is functioning there is a need to examine patients outside the confines of the clinic room, activity monitors are a simple way of achieving this. The results from this study suggest that activity is not influenced by the prosthesis concept worn ($p=0.173$). The difference in activity may be as a result of the other influencing factors that the disease has on their overall health.

Increased use of the prosthesis due to improved socket comfort may lead to an increased risk of problems. As highlighted in a review of ICEROSS fittings (Datta et al., 1996). Patients therefore may reduce the use of their prosthesis to limit the use of their prosthesis to limit the damage they perceive may be caused. Much of these feelings can be attributed to previous experiences. However it has been shown that exercise may help to reduce pain (Bruce et al., 2005). In fact the pain threshold and the tolerance to pain in the residual limb has been shown to increase as the number of walking steps increased (Zhang and Lee, 2006). They showed that pain tolerance after 2000 steps was 13.4% greater than the values recorded before the trials.

It is important that, after an amputation, regular physical activity is maintained. Exercise is often cited as the best way to maintain a healthy lifestyle. If a patient has lost a limb due to vascular disease then exercise can help reduce the effects of secondary conditions such as diabetes or heart disease. Traumatic amputees should maintain regular exercise to reduce the onset of vascular disease and maintain overall health. Maintaining the strength of other areas of the body is also important. The upper body in particular will often compensate for the loss of the leg, in such activities as rising from a chair.

Keeping active and improving strength not only improves muscle strength which in turn improves balance, the act of performing daily physical activity improves the confidence of the amputee and helps build social links and support of those around them (Kelley, 2006).

11.6 Prosthesis Evaluation Questionnaire

The visual analogue scale provides a continuous sliding scale on which subjects mark their response to a particular question. It should be remembered that questions and responses are worded so that a response with a high value is always more favourable than one with a low value. For example a high value reported for intensity of pain (90) represents low intensity of pain, and a high score for comfort (91) represents increased comfort.

For the purposes of discussion, the scale was divided into three to distinguish between levels of response to each question. This method was used by Legro when investigating the recreational activities of amputees (Legro et al., 2001). PEQ scores of between 0 and 33 rated as low, 34 to 66 medium, and above 67 as high. These categories are only used to facilitate discussion and no statistical methods of analysis were used to support the results. All participating subjects in the study completed the PEQ; all responses were marked by the subject.

11.6.1 PEQ Responses

Two different casting techniques used to produce the trans-tibial prosthetic socket are prescribed in clinics. Any approach must provide quantifiable evidence of benefit to the service provider, patient and society in general. However prosthetists should also be aware of the psychological issues that may influence the rehabilitation of their patients (Desmond and MacLachlan, 2002).

The average (mean) score for all questions implementing the visual analogue scale was 68.6. This indicates that, in general the satisfaction from subjects was good. Figure 76 on page 206, illustrates the average scores for the nine validated scales within the PEQ. It can be seen that responses from both subject groups are similar. In addition, of the 75 VAS questions, only responses from four questions indicated a significant difference between groups. These questions are discussed below.

11.6.2 Significant differences between sample groups

Damage to Prosthesis Covering

A small but significant difference in the self reported level of damage caused to the prosthesis covering was seen between concepts (p=0.049). Those wearing the hand cast PTB sockets indicated that more damage is caused to the covering of their prosthesis than those wearing the pressure cast socket. Despite the difference, the values of both groups still showed a high level of satisfaction overall (90.2 for pressure cast group, 79.8 for PTB group).

There is no direct reason why the concept worn would have an effect on the reported damage to the covering. However the two socket designs incorporate different interface liners between residual limb and socket. The covering of the prosthesis was not specified in the question and therefore it is possible that the subjects included the interface liner as part of the covering. The Pe-Lite liner worn as an interface liner in the hand cast PTB sockets can become torn or dirty over time. This may result in subjects reporting lower satisfaction scores than those wearing the pressure cast sockets with a more durable silicone liner. These assumptions are only speculative; however the socket design does have an influence on the materials used to fabricate the definitive prosthesis. If this difference in reported damage is as a result of the different liner materials used then patient satisfaction can be improved if a more durable material is utilised as an interface liner.

Condition of the skin at the Residual Limb

Subjects wearing the pressure cast prosthetic sockets reported significantly lower scores (higher incidence) when asked to rate the sores, blisters and rashes on their residual limb (p=0.035). This group had an average score of 56.15 compared to 84.96 for those wearing a hand cast socket. Although the question did not specify the dermatological irritation, the responses support the results of previous literature which show that silicone liners can cause skin changes (Cluitmans et al., 1994, Datta et al., 1996, Hachisuka et al., 1998). These problems were also reported in a study which investigated the ICEROSS© system (Cluitmans et al., 1994). They concluded that the skin problems in the form of itching and perspiration reduced after a few weeks, when the skin became accustomed to the environment. However it can be seen in our results that patients wearing silicone liners are still experiencing skin problems after more than six months of use. Despite the difference in skin conditions, both subject groups reported similar problems with perspiration ($p=0.877$) rating it poorly with a score of 39.9. This finding indicates that although differences in perspiration seen between silicone and PE-Lite liners may reduce over time, wearers experience from the problem of perspiration within the prosthetic socket regardless of socket concept.

It has been shown that the suspension of the prosthesis is improved when a silicone liner is used (Fillauer et al., 1989, Narita et al., 1997, Tanner and Berke, 2001). Improved suspension reduces the movement of the residual limb inside the prosthetic socket, reducing the incidence of shear force. A reduction of shear would therefore reduce the relative movement on the skin surface, the cause of abrasions. A review by Cochrane et al., (2001) also concluded that the liners worn in conjunction with the pressure cast sockets offer improved suspension (Cochrane et al., 2001). However, the study highlights the increased risk of residual limb skin problems, in particular for the more active wearers.

In a recent review of literature concerning the advantages of silicone liners in trans-tibial prosthetics, researchers concluded that there is little clinical evidence to support the positive qualities of silicone liners (Baars and Geertzen, 2005). However they also point to the improved suspension that the silicone liner brings, although improved suspension may come from the attachment of the liner to the socket rather than the silicone itself.

Subjects wearing the pressure cast sockets in this study were more active, taking on average 2000 steps more than those wearing the hand cast socket. Although the daily activity did not show a significant difference between the two subject groups the result supports the findings by Cochrane, that more active wearers experience greater skin disorders. In addition to the activity, subjects wearing the pressure cast sockets were more frustrated with their prosthesis than those wearing the hand cast sockets.

Increase in residual limb skin complaints would then create increased frustration by the user.

These connections have not, and cannot be statistically shown as the PEQ does not specify the causes of frustration, or residual limb sores. However the skin problems associated with increased use of the prosthesis may be a potential reason to explain the increase in frustration seen in those wearing the pressure cast sockets. If the activity of the user has the capability of reducing the health of the residual limb, the user will become more frustrated by the prosthesis and the limitations it puts on daily activity. Patients therefore may reduce their use of the prosthesis to limit the damage that they perceive may be caused to their limb. Much of these feelings may be attributed to previous experiences. This problem was highlighted in a review of ICEROSS fitting (Datta et al., 1996).

Back Pain

The third statistically significant difference in the responses between the two subject groups relates to back pain. Subjects wearing the hand cast prosthetic sockets reported, on average a higher intensity of back pain ($p=0.048$). The average score for the group wearing the hand cast sockets was the lowest for any of the questions within the PEQ at 30.5.

Back pain has been shown to be common amongst lower limb amputees, occurring most days, although not always interfering with lifestyle (Kulkarni et al., 2005). Changes to the gait pattern whilst wearing a prosthesis can lead to associated back pain. The PEQ results showed that the subjects who reported back pain in the PTB group experienced back pain "fairly often" at between 4-6 times a week. Whereas those wearing the pressure cast prosthetic sockets reported incidence of back pain less frequently at 2-4 times per week. Subjects wearing the PTB prosthetic sockets reported, on average, a higher intensity of back pain ($p=0.048$), with an average score of 30.5. This was the lowest satisfaction score of all responses within the PEQ. One reason cited for incidence of back pain amongst amputees, is the asymmetry in gait caused by the incorrect length of the prosthesis (Friberg, 1984). Their results showed that the incidence of back pain correlated with errors in prosthesis length. The effective length of the prosthesis can be increased during swing if there is insufficient suspension between the residual limb and prosthetic socket. The weight of the prosthesis and the inertia caused by the movement of the leg during swing phase has the potential to move the prosthesis distally on the residual limb, thus effectively increasing the overall length of the prosthesis. The increased length is compensated for by gait deviations such as pelvic tilt and increased hip flexion. These additional movements create asymmetrical gait. A review of literature concerning the advantages of silicone liners in trans-tibial prosthetics point to the improved suspension that the silicone liner brings (Baars and Geertzen, 2005). They conclude that the improved suspension may come from the attachment of the liner to the socket rather than the silicone itself. Although this study did not establish a direct link between suspension and back pain, the improved suspension provided by the silicone liner can be seen to correlate with a reduced intensity of back pain in the subject group wearing the pressure cast sockets.

11.6.3 Other findings from in the PEQ

Phantom limb Sensations

Phantom limb sensations and pain in the residual limb are common occurrences for the lower limb amputee (Flor, 2002). Of the 48 who completed our study, 39 subjects (81%) reported that they had experienced some form of phantom limb sensation or pain. Incidences were similar between subject groups. Of these 39 subjects, 32 (82%) experienced phantom sensations and phantom pain, whereas 4 (10%) subjects experienced phantom sensations only and 3 subjects (8%) experienced phantom pain only. Although similar numbers of subjects from both groups reported phantom pain, the results did indicate a significant difference in intensity of phantom sensations ($p=0.046$) between the groups. Those wearing the pressure cast sockets reported higher intensity of phantom sensation (41.417) compared to the group wearing the hand cast socket (62.194). These findings suggest two points. Firstly, that the incidence of phantom pain is common amongst amputees, even established patients, supporting previous knowledge (Jensen et al., 1985). Secondly, that the design of the prosthetic socket does not influence the presence of phantom limb sensation.

However, it was evident that prosthetic socket design can influence the intensity in phantom sensation.

Groups

Satisfaction and Well-being

Despite differences seen in several responses, there was no statistical significance between the two groups when asked to rate how happy they were in respect to their own prosthesis ($p=0.390$). The rating of happiness with the prosthesis is strongly correlated with the satisfaction with their prosthetist (pressure cast group $p<0.001$ $r=0.732$, PTB group $p<0.001$ $r=0.765$). The self reported happiness is also strongly associated with the rating of prosthetic socket fit (pressure cast $p<0.001$ $r=0.688$, PTB $p<0.001$ $r=0.860$). These results confirm that socket fit is important to the happiness of the user and in turn impacts on their satisfaction of the prosthetist and prosthetic service. The overall satisfaction score from subjects showed no significant difference between socket concept ($p=0.710$). Indicating that despite differences in casting method, interface liner material and components used for the two prosthetic socket concepts, the satisfaction of subjects wearing the devices is similar. The similarity in results can also be seen in the responses to the quality of life questions. No significant difference occurs between results and the ratings of both groups which are high, at over 70.

Utility

No significant difference was seen between groups for questions relating to the use and function of the prosthesis. Both groups reported high scores for the function of their prosthesis. Our results support the results of a recent study which implemented the PEQ to compare the two socket designs in terms of the functional outcomes and cost efficiency (Selles et al., 2005). They found that no significant differences exist between the two groups in terms of function. The study concluded that both concepts performed equally, and each concept had their own advantages; the hands-off concept in terms of a lower manufacturing time, the hands-on in terms of cost.

Appearance

The use of a silicone liner with locking pin system removes the need for traditional belts and buckles used to suspend the trans-tibial prosthetic sockets. This has improved the cosmetic appearance of the limb, and is often one reason given for choosing the hands-off prosthetic socket concept. All the subjects in our study who wore the hands-on prosthetic socket concept wore sockets with supracondylar suspension, and required no belts, straps or buckles for suspension. Without these auxiliary suspension methods the improvement in cosmetic appearance the silicone liner offers is reduced. The similarity in appearance can be seen in the scores given by both group when rating the appearance of the prosthesis. Both groups responded with similar high scores when asked to rate the cosmetic appearance of their prosthesis ($p=0.489$).

One limitation of most prostheses is the fact that it can only be fitted with one type of footwear with a specific heel height. A question within the PEQ relates specifically to this. The results show that on average, as a group, subjects rated this lower than many of the other questions at 58.8, indicating a response mid way between no problem with shoe style and an inability to change the style of the shoe. Eight of the forty-eight subjects (16%) reported scores of 0, meaning they did not have the ability to change shoes. Despite only eight female subjects participating in this investigation, five of the eight subjects reporting scores of 0 were female. This result may be expected as the style and height of heel offered to females is far greater than those available to males. Styles of male shoes are similar, making the ability to change between styles easier. This may be the reason males reported less of a problem with choice.

The ability to wear shoes of choice and not be limited in the selection available may increase the wearer's satisfaction of the prosthesis. Correlating the responses to the ability to change shoe styles and how happy the wearer was with their prosthesis revealed that a significant correlation exists between the two ($p<0.001$, $r=0.563$).

The PEQ also highlights the social and emotional aspects of using a prosthesis in relation to situations with family and friends. It can be seen from the sample groups that the responses from the subjects were not influenced by the type of socket worn. No significant differences exist between groups. Scores within the perceived response category contain some of the highest responses seen within the PEQ. Many of these questions refer to the subject's family and family member's reactions. The high scores seen here indicate that the amputees perceive their families as being a strong psychological support.

The ability of increased knee flexion due to the reduction in trim lines has been shown (Cluitmans et al., 1994, Hachisuka et al., 1998). The studies suggested that walking up and down hill, and sitting in low chairs, would be easier when wearing a silicone liner "hands-off" prosthetic socket system. These findings are not reflected in this study, the socket concept utilised does not have an effect on the ability to ambulate or transfer. Both subject groups have similar scores for such questions. It can be seen that those wearing the "hands-off" sockets have reported slightly higher scores when referring to the ability to transfer to low and high chairs, however the scores do not show a significant difference to those reported by the "hands-on" group. It should also be noted that the scores for walking up and down hills is much lower than the scores for other types of terrain.

Subjects from both groups responded with similar scores when asked to rate their ability to get things done when their prosthetic socket is not fitting well. A medium rating to the question was given, indicating that despite the fit of the prosthetic socket being poor, the amputee continues to perform a few daily activities. Although this can be seen as a good achievement by the user to continue to wear the prosthesis, it also highlights the fact that amputees rely on their prostheses. Continuing to use a prosthesis that is not fitting well can increase the threat of tissue damage. In addition to this immediate danger, the amputee may become accustomed to the poor fit and accept it as normal. If this happens the quality of care provided reduces, resulting in a socket that was once regarded as poor becoming seen as satisfactory by the wearer. This may result in a decline in ambulation, and function of the prosthesis. However these results also highlight how important the prosthesis is to the wearer. When asked to rate how much work they could do without their prosthesis, both groups presented with low scores, indicating the importance of the prosthesis to the amputee. These findings show that wearing a prosthesis, even when poorly fitting enables amputees to achieve more activities of daily living.

A number of questions asked the subjects to rate the importance of issues faced when wearing their prosthesis. The ease of donning the prosthesis was rated the highest importance by both groups. The other responses all showed a high level of importance. These questions included the appearance of the prosthesis, a durable covering and has been described previously, the ability to wear different shoe heights and styles. The results from the question about sweating indicate that most subjects find it extremely annoying when they sweat inside their socket.

PEQ Summary

The results of the PEQ specified many different aspects of daily life for the amputee. Although two distinct prosthetic socket concepts are used in clinics, the results of this survey has shown that the implication these sockets have on the life of the amputee are similar. Most subjects used a prosthetic device regularly, and responded in similar ways regardless of the socket design worn. Despite encouraging results from this study as to the overall satisfaction of the prosthetic wearers, the findings also show that there is room for improvement. An average score of 70 out of 100 still means that satisfaction can be improved. In particular, sweating inside the prosthetic socket and pain in other parts of the body have been highlighted as areas of concern by the amputee. Pain experience detrimentally affects prosthesis use and satisfaction, some of this pain may be unavoidable, or attributed to other physiological factors. By improving the users satisfaction of the prosthesis the overall service may be improved.

11.7 ActivPAL and Interface Pressure

During the analysis of interface pressure it was seen that the interface pressures increased towards the end of stance. The results of correlating interface pressure and the daily activity of subjects indicated that during late stance a significant negative correlation exists between daily activity and the average and peak interface pressure at the distal end of the anterior aspect of the hands-on socket ($p=0.044$, $r=-0.414$, & $p=0.049$, $r=-0.415$ respectively). The negative correlation between the two variables indicates that subjects with higher interface pressures at this region used their prosthesis less than those with lower interface pressures. This suggests that pressure at the distal end of the tibia causes amputees to reduce the amount of walking. However this was the only region within the prosthetic socket which indicated a significant correlation between activity and interface pressure, which means that higher interface pressures may not necessarily reduce the activity of the prosthetic user.

No correlations were observed within the hands-off group, despite this, the interface pressures recorded within this group were higher than those of the hands-on group. Therefore magnitude of interface pressure alone cannot be the contributing factor in influencing physical activity.

11.8 Activity Monitor and PEQ

It can be seen from the results of the PEQ that subjects were, on average highly satisfied with their prosthesis in all aspects covered by the questionnaire. The subjects own rating of how happy they were with their prosthesis did not correlate with the daily activity recorded by the subject (hands-on $p=0.081$, $r=0.363$, hands-off $p=0.407$, $r=0.177$). Frustration with the prosthesis does not appear to influence the activity of the subject (hands-on $p=0.732$, $r=-0.073$, hands-off $p=0.965$, $r=0.009$). These results would suggest that differences in activity performed by the subject are less associated with the personal satisfaction with the prosthesis and more associated with other factors such as the requirements of daily living including social activities and employment. Correlations between the ActivPal and the PEQ indicate that for most of the PEQ responses the subjects own reported satisfaction scores are not associated with their daily activity. The lack of correlation between satisfaction and activity indicates that subjects, who were inactive or extremely active, showed no difference in their rating of satisfaction of the prosthesis. However the results only show the association between the two variables, they do not indicate cause and effect.

The potential activity a subject would like to achieve, but is unable to, is not measured; therefore it is unclear what influence the prosthesis has on the subject in terms of daily activity. However it could be expected that if the prosthesis worn is uncomfortable or limiting mobility in any way, then the subjects would record that they are less happy with the limb, or would be more frustrated. This was not the case in this investigation.

A small number of responses did correlate significantly with the activity of the subject. The significant correlations seen in each subject group differed between the two groups. The weight of the prosthesis and the ability to walk up hills were significantly correlated with the subject's activity for subjects wearing the hands-off socket concept. Those who had higher activity levels also reported higher satisfaction with the weight of their prosthesis and rated the ability and importance of being able to walk uphill. The activity of those wearing the hands-on prosthetic sockets showed significant correlations with more fundamental activities of daily living such as the ability to stand, walk, sit and walk up stairs.

The satisfaction scores relate to a subjects response to the prosthesis ability to fulfil a need, or for the prosthesis to be dependable in a given situation. These needs and situations will differ for each person. The subjective satisfaction rating will also differ amongst each individual. Despite the results from the activity monitor indicating a large spread of activity amongst subjects, satisfaction was high. It is widely known that physical activity is important in maintaining or restoring physical health. However activity cannot simply be an indicator of prosthetic satisfaction. A more beneficial method of using activity to establish satisfaction would be to determine if the prosthesis is fulfilling the requirements desired by the user.

11.9 PEQ & Pressure

Correlations were carried out between the PEQ responses and the average and peak interface pressures for both groups of subjects. A distinct pattern can be seen from the results. Significant correlations between interface pressure and PEQ responses for the hands-off cast sockets have a positive relationship. Negative relationships were seen in the significant correlations between interface pressure and PEQ responses for the hands-on sockets. These results suggest that the two prosthetic socket casting processes exhibit different outcomes in terms of patient experience of interface pressure. Those wearing the hands-on concept expressed higher satisfaction scores when the interface pressure was lower. Those wearing the hands-off concept preferred higher interface pressures.

These results are consistent with the earlier findings that on average satisfaction scores for both groups are the same, despite those wearing the hands-off sockets experiencing higher interface pressures over most of the stump/socket interface.

These results could be explained by the fact that the two concepts utilises different pressure distribution techniques. The hands-off concept uses a uniform pressure distribution during the casting process, with a silicone interface liner between residual limb and prosthetic socket. The hands-on concept utilises the underlying anatomy of the residual limb to dictate the loading pattern. If the interface pressure is increased, this would reduce the shear force seen at the interface. By reducing shear, movement between socket and limb is reduced. This may increase the comfort and reduce tissue damage, leading to an increase in satisfaction of prosthetic fit. The increase in interface pressure may be possible when a uniform pressure distribution is applied to the prosthetic socket, however when the load is applied and distributed in a non uniform manner, such as in the case with the hands-on concept any increase in interface pressure will be concentrated in smaller locations.

It is seen that those wearing the hands-off concept, which incorporate the silicone liner interface expressed a higher satisfaction when the interface pressures were higher.

11.10 Chapter Summary

The similar demographics seen by the two subject groups enabled clear comparisons to be made between the groups. Despite different casting concepts being used to create the prosthetic socket, the distribution of interface pressure measured between the two groups was similar. Both subject groups expressed high satisfaction scores with their prosthesis; however the magnitude of pressure measured in the hands-off sockets was greater than those in the hands-on sockets. The high step count recorded by the subjects is an encouragement that trans-tibial amputees can achieve a daily activity similar to that seen by their peers.

12 Conclusions

12.1 Chapter Introduction

Conclusions drawn are divided into the three outcome measures described; finally conclusions are made using the combination of outcome measure results.

12.2 Pressure Study

Newer and sometimes more expensive techniques do not always improve the fit of the prosthetic socket. Previous findings have stated that, due to the uniform pressure casting method, certain hands-off concepts will produce a prosthetic socket with lower and fewer peak pressures. However, this has not been confirmed in this investigation. The interface pressures recorded between the residual limb and the prosthetic socket showed consistent distributions between prosthetic socket groups, despite different casting concepts. The results also showed that the recorded peak interface pressures were highest for the hands-off concept and not, as expected, in the hands on sockets. Although a similarity in pressure profile was seen between the two concepts, a smaller variation in interface pressures was measured in the hands-off subject group. A smaller variation in interface pressure may lead to a more consistently fitting socket for the patient, improving the regularity of fit of subsequent prosthetic sockets. This in turn may improve the overall standard of care provided to the prosthetic user.

12.3 Activity Monitoring

In order to better evaluate how the prosthesis is functioning there is a need to examine users outside the confines of the clinic room. Activity monitors have been shown to be a simple and reliable way of measuring outcomes of prosthetic intervention without interfering with activities of daily living.

The two socket concepts used in this study would be expected to interact differently with the residual limb in terms of pressure distribution and stability. However, the results of the analysis indicate that the differences in design do not result in significant differences in the activity of persons with amputation.

Furthermore, the mean activity level for each design is within the range of normality for the age group concerned. This would suggest that both methods of manufacturing a prosthetic socket can provide a satisfactory outcome in terms of activity level. It further emphasises that persons with a trans-tibial amputation and wearing a well fitting socket can maintain activity levels of their peer group.

12.4 Patient Feedback

The results of the PEQ specified different aspects of daily life for the amputee. The quality of fit of the prosthetic socket has been shown to have a strong influence on how happy the patient is with their prosthesis. Two distinct prosthetic socket concepts are used in the clinic, with many advantages and disadvantages cited for both. However results of this study have shown that the implications these sockets have on the life of the amputee are very similar. Most subjects used a prosthetic device regularly, and responded in similar ways regardless of the socket concept worn. Newer and sometimes more expensive techniques do not always improve the fit of the prosthetic socket. Our findings support those found in a study which also compared the satisfaction scores of established unilateral amputees using the PEQ (Selles et al., 2005). They concluded that both concepts performed equally, and each concept had their own advantages; the pressure cast concept in terms of a lower manufacturing time, the PTB in terms of cost.

Despite encouraging results from this study in relation to the overall satisfaction of the prosthetic wearers, the findings also show that there is room for improvement. In particular, sweating inside the prosthetic socket and pain in other parts of the body have been highlighted as areas of concern by the amputee. Pain experienced detrimentally affects prosthetic use and satisfaction. Some of this pain may be unavoidable, or attributed to other physiological factors. Intensity of back pain has been shown to be lower in subjects wearing silicone liners. This indicates a reduction in gait deviations occurring from the improved suspension that the liner brings. The intimate fit of the liner may improve suspension but this causes a higher incidence in dermatological problems.

Making sure that the patient is aware of the potential problems before they occur should improve the satisfaction of the patient with their prosthesis. Satisfactory delivery of a prosthesis is the ultimate goal of any prosthetist. But for the patient the final delivery of the limb may not be as important as the process, and subsequent visits to the clinic.

12.5 Interface Pressure, Patient Satisfaction and Activity

Stump/socket interface pressure has been cited as an important consideration for assessing user comfort. Although differences are seen in the casting technique and subsequent prescription of prosthesis the results from this investigation indicate that the dynamic pressure distributions at the limb/socket interface were similar for the two concepts. Despite this, the magnitude of interface pressures was seen to be different between the two groups. However the resulting satisfaction scores and activity of the subjects indicate that no differences exist in the way in which the prostheses are used and perceived by the wearer. Preferences were seen to be different when examining the interface pressures. This further emphasises that using interface pressure measurements as an indicator of socket comfort should not be the only outcome measure used in the assessment of prosthetic fit.

Identifying and understanding concerns from the patient's perspective should be an essential part of any quality improvement programme. Patient satisfaction is increasingly viewed as a key indicator of performance. However assessing satisfaction is not a regular part of the clinical routine and is an imprecise concept which can be measured in many different ways. There is no consensus on which domains should be included or which are most important.

The attitudes of a person following amputation are influenced by many factors, including the media, other amputee's and by the person's interaction with their prosthetist and other health professionals. Separating the effect of expectations, experience and satisfaction is a major problem when identifying areas to improve the service given by the prosthetist.

12.6 Future Work

The transducers used in this study were chosen for their ability to be used in conjunction with the subjects own prosthesis, the focus of the study was to investigate the interface pressure distribution within the prosthetic socket. Subjects tested in this study tolerated the relatively high interface pressures measured for the hands off concept. It should also be remembered that the pressure at the interface between liner and limb will likely be higher than the pressures recorded by the transducers placed outside the liner, further dividing the magnitude of interface pressures between groups seen in this report. This could indicate that interface pressure seems not to be the main concern in socket evaluation. It is acknowledged that shear forces present between the residual limb and prosthetic socket could not be measured with this type of transducer. It is most likely that interface shear as well as internal soft tissue shear, including boundary shear, are the main areas of concern, as suggested by Sanders (Sanders et al., 2006). The philosophy described by Klasson (Klasson, 1995), whereby the "stiffest" path principle is implemented for the load transfer from socket to the weight bearing structure (the skeleton), more than likely results in higher pressures but with considerably reduced shear effects. This should be investigated further in depth.

Despite differences in interface pressure levels between the two groups, all prosthetic sockets instrumented had been in daily use for at least six months, without the user experiencing residual limb health problems. Further work should be conducted to determine if those experiencing discomfort when wearing their prosthetic limbs have interface pressures with distributions and levels out with those described in this report.

This study used prosthetic dynamic socket interface pressure mappings as an indicator in order to investigate aspects of socket concepts. Certain elements of the results came as a surprise to the investigators. However, it should be emphasised that it is impossible to claim specific merits for any socket concept due to the fact that the socket is only one item within the prosthetic system. Alignment, prosthetic foot characteristics, and compliance of materials, as well as the socket shape and dimensional aspects, to name a few, will influence normal pressure distribution. As a consequence, it is not possible to distinguish between a pressure reading originating from axial loading or one generated by couples and moments.

Future work should concentrate on interface shear mapping and the investigation of other hands-off casting concepts, including the use of a liquid loading medium instead of a gas based casting device.

12.7 Chapter Summary

The prosthetic sockets instrumented have been in daily use for at least six months, with no residual limb health problems. Despite the differences in interface pressure, the level of satisfaction with the sockets is similar between subject groups. Both pressure casting and hand casting produced satisfactory results according to reported patient satisfaction. Skin Problems were more frequent in pressure cast sockets and this may be related to the use of a silicone liner. Back pain was more intense in the PTB socket, perhaps due to less effective suspension. The ActivPAL activity monitor is a reliable, simple and unobtrusive tool for recording activity. The activity level of both groups was within the normal range for able-bodied people of similar age.

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14 Appendices

Appendix 1:Patient Information Leaflet

UNIVERSITY OF STRATHCLYDE
IN GLASGOW

NATIONAL CENTRE for TRAINING and EDUCATION in PROSTHETICS and ORTHOTICS
WHO Collaborating Centre for Research and Training in Prosthetics, Orthotics and Orthopaedic Technology

Patient Information Leaflet

RESEARCH PROJECT: Trans-tibial prosthetic system design and benefits for the amputee, service providers and society, an evidence based clinical study.

Thank you for your interest in this research project. Should you agree to take part in the project you will be required to attend the West of Scotland Mobility and Rehabilitation Centre (WESTMARC) for two appointments.

Our research project is interested in finding out about 3 things:

1. **How you use your prosthetic leg**
2. **The pressure (force) inside your socket**
3. **What you think about your prosthetic leg**

1. **How you use your prosthetic leg**
   This project is interested in finding out about how you use your prosthetic leg over the period of a week. A small activity monitor will be placed by the researcher in the shin of your prosthetic limb for a week. This device is called an ActivPAL Activity monitor and is about the size of a match box. Inside the outer casing is a device called an accelerometer which reads the movements of your leg and saves this data over the period of a week. This ActivPal is lightweight and won't affect the way your prosthesis works or the way you walk. We will then arrange a suitable time to call you back to recover the ActivPAL Activity Monitor and proceed with Steps 2 and 3

2. **The pressure (force) inside your socket**
   The prosthetic leg you are currently using will be used for this project. A new generation of pressure measuring sensors means that these can be used to measure pressure between your skin and prosthetic leg during walking without affecting your prosthetic socket.

See over

The installation of this pressure measurement system will take approximately 1 hour. After installation you will be asked to walk for a short period before socket pressure is recorded. When measurements have been completed, the pressure sensors will be removed and your prosthetic leg will be exactly as it was when you arrived. The removal of the pressure measurement system will take approximately 10 minutes.

3. **What you think about your prosthetic leg**
During the time your prosthetic leg is being set up for pressure measurement we would like to ask you some questions in relation to the use and comfort of your prosthetic leg. This will take approximately 45 minutes.

If you have any concerns about this project please speak or write to:

Mr Tim Dumbleton
Research Assistant/State Registered Prosthetist/Orthotist
National Centre for Training and Education in Prosthetics and Orthotics
University of Strathclyde
Curran Building, 131 St James Road
Glasgow G4 OLS

Tel 0141 548 3930
Fax 0141 552 1283
Email: t.dumbleton@strath.ac.uk

Appendix 2: Patient Consent Form

NHS
Greater Glasgow

SOUTHERN GENERAL HOSPITAL

CONSENT FORM

RESEARCH PROJECT: Trans-tibial prosthetic system design and benefits for the amputee, service providers and society, an evidence based clinical study.

PATIENT NAME... DATE OF BIRTH................

To be completed by the Patient

Please Initial

Yes No

. Have you read the Patient Information Sheet (version number and date)?

. Have you had an opportunity to ask questions and discuss this study?

. Have you received satisfactory answers to all your questions?

. Have you received enough information about the study?

Who have you spoken to?
Dr/Mr/Ms____

Do you understand that you are free to withdraw from the study –

- at any time
- without having to give a reason
- and without affecting your future medical care?

Do you agree to take part in this study?

Do you have any reason to believe you are or may be pregnant?
YES, I may be pregnant NO, I am not pregnant

Signed... Date.........................

Name in Block Letters...

Signature of Witness.. Date........................

Name in Block Letters...

Version 1 Nov 04

Appendix 3: PEQ Questions

Question Number	Variable Name	Description
1A	SAhapypros	How happy are you with your prosthesis
1B	UTfit	Rate the fit of your prosthesis
1C	UTweight	Rate the weight of your prosthesis
1D	UTstand	Rate your comfort whilst standing
2E	UTsit	Rate your comfort whilst sitting
2F	UTbalance	Rate how often you felt off balance
2G	UTenergy	Rate how much energy it took to use your prosthesis
2H	UTfeel	Rate how your prosthesis feels (temperature, texture)
2I	UTdon	Rate the ease of putting on your prosthesis
3J	APproslook	Rate how your prosthesis has looked
3K	SOfreqsoun	Rate how often your prosthesis made speaking sounds
3L	SObotsoun	How bothersome were these sounds
3M	APdamagclo	Rate the damage to your clothing made by the prosthesis
3N	APdamagcov	Rate the damage to your prosthesis cover
4O	APshoechoi	Rate your ability to wear the shoes you prefer
4P	APclothchoi	Rate how limited your choice of clothing
4Q	RLsweat	Rate how much you sweat inside your prosthesis
4R	RLsmell	Rate how smelly your prosthesis was
4S	RLswollen	Rate how much time your limb was swollen
5T	RLrash	Rate any rashes that you got on you residual limb
5U	RLhair	Rate any ingrown hairs on your residual limb
5V	RLsore	Rate any blisters or sores on your residual limb
6A	PAfrephsen	Rate occurrence non painful sensations on phantom limb
6B	PAintphsen	How intense were they
6C	PAbotphsen	How bothersome were these sensations
7D	PAfrephpa	Rate occurrence of pain in phantom limb
7E	PAdurphpa	How long does the pain last
7F	PAintphpa	How intense was the pain
7G	PAbotphpa	How bothersome was the pain
8H	PAfrerlpa	Occurrence of pain in residual limb
8I	PAintrlpa	How intense was the pain
8J	PAbotrlpa	How bothersome was the pain
8K	PAfreolpa	Occurrence of pain in other leg or foot
9L	PAintolpa	How intense was the pain
9M	PAbotolpa	How bothersome was the pain
9N	PAfrebapa	Occurrence of back pain
9O	PAintbapa	How intense was the back pain
10P	PAbotbapa	How bothersome was the back pain
10A	PRavoidoth	How often have you avoided strangers
10B	FRfreqfrus	Rate frequency of frustration with prosthesis
10C	FRmostfrus	Rate how frustrated you felt
11D	PRpartresp	How has your partner responded to your prosthesis
11E	PRrelafct	How has it affected your relationship
11F		Names of two members of your family
11G	PRfam1res	How has family member 1 responded
12H	PRfam2res	How has family member 2 responded
12I	SBpartburd	Burden of prosthesis on partner/family member

12J	SBsochind	Rate the hindrance your prosthesis has made
12K	SBcaregive	Rate ability to care for someone else
13A	AMwalk	Rate ability to walk
13B	AMclose	Rate ability to walk in close spaces
13C	AMupstair	Rate ability to walk up stairs
13D	AMdwnstair	Rate ability to walk downstairs
14E	AMuphill	Rate ability to walk uphill
14F	AMdownhill	Rate ability to walk downhill
14G	AMsidewalk	Rate ability to walk on the street/path
14H	AMslip	Rate ability to walk on slippery surfaces
14I	TRcar	Rate ability to transfer in and out of the car
15J	TRhichair	Rate ability to sit & get up from a high chair
15K	TRlochiar	Rate ability to sit & get up from a low chair
15L	TRtoilet	Rate ability to sit & get up from the toilet
15M	TRbath	Rate ability to shower or bathe safely
16A	SAsatpros	Rate how satisfied you have been with your prosthesis
16B	SAsatwalk	Rate how satisfied you have been walking
16C	WBsincamp	Rate how things have worked out since you're amputation
16D	WBqol	Rate your quality of life
17E	PCprostist	How satisfied are you with the prosthetist
17F	PCcurtrain	How satisfied are you with the training you received
17G	PCalltrain	How satisfied are you with the gait training you received
18A	SEfitpoor	When the fit of my prosthesis is poor I get...
18B	SEcomfpor	When the comfort of my prosthesis is poor I get...
18C	SEnopros	Without my prosthesis I get .... done
18A	IMimpwt	How important is the weight of your prosthesis
19B	IMimpdon	How important is the ease of donning your prosthesis
19C	IMimpapear	How important is the appearance of your prosthesis
19D	IMimpshoe	How important is it to wear different shoes
19E	IMimpcover	How important is it that the cover is durable
19F	IMsweatbot	How bothersome is it when you sweat inside prosthesis
20G	IMswellbot	How bothersome is swelling in your residual limb
20H	IMnohair	How important is it to avoid any in growing hairs
20I	IMlookubot	How bothersome to see people looking at your prosthesis
20J	IMimpuphil	How important is being able to walk up a steep hill

Appendix 4:Transducer Configuration

Transducer Configuration

Anterior

	1	2	3	4	5	6
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
12						
13						
14						
15						
16						

Total Anterior Cells

Area mm^2 0

Total Number of Cells 0

Total Socket Area 0

Medial

	1	2	3	4	5	6
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
12						
13						
14						
15						
16						

Total Medial Cells

Area mm^2 0

Posterior

	1	2	3	4	5	6
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
12						
13						
14						
15						
16						

Total Posterior Cells

Area mm^2 0

Lateral

	1	2	3	4	5	6	
1							1
2							2
3							3
4							4
5							5
6							6
7							7
8							8
9							9
10							10
11							11
12							12
13							13
14							14
15							15
16							16

Total Lateral Cells

Area mm^2 0

Patient Number:__________ Date:____________________ Side: Left / Right

Appendix 5: Average Interface Pressures (kPa)

Average Interface Pressure (kPa)													
		Anterior Aspect			Medial Aspect			Posterior Aspect			Lateral Aspect		
Subject	Region	Early Stance	Mid Stance	Late Stance	Early Stance	Mid Stance	Late Stance	Early Stance	Mid Stance	Late Stance	Early Stance	Mid Stance	Late Stance
1	Proximal	25	28	34	34	32	52	45	45	54	25	19	20
1	Distal	34	30	49	20	19	26	26	29	38	57	48	55
2	Proximal	55	58	71	68	67	76	79	75	82	67	66	68
2	Distal	81	76	76	85	82	88	83	80	88	86	85	94
3	Proximal	76	70	81	61	60	66	97	90	97	61	57	63
3	Distal	151	125	146	96	91	99	105	99	106	108	102	110
4	Proximal	108	87	146	103	97	135	124	106	146	91	76	96
4	Distal	150	100	109	100	88	117	107	101	132	121	102	133
5	Proximal	52	53	71	60	64	74	79	73	88	60	64	76
5	Distal	97	60	77	61	63	73	48	48	65	67	67	83
6	Proximal	28	41	62	40	41	57	66	63	79	19	17	21
6	Distal	34	29	40	33	34	48	39	40	58	51	49	55
7	Proximal	54	60	89	50	54	67	90	86	91	31	32	35
7	Distal	34	36	38	49	51	62	51	49	61	72	72	76
8	Proximal	21	20	31	32	28	34	35	36	51	29	28	33
8	Distal	52	36	29	27	25	30	15	22	35	74	73	73
9	Proximal	34	27	64	63	42	72	92	60	94	73	48	75
9	Distal	99	39	57	59	31	70	48	26	65	74	40	64
10	Proximal	60	27	46	43	47	60	100	85	105	58	57	53
10	Distal	28	69	65	28	22	21	64	53	74	93	80	102
11	Proximal	62	63	71	72	67	75	114	100	110	51	50	52
11	Distal	134	107	137	107	96	108	105	96	112	127	113	127
12	Proximal	12	13	18	48	51	51	72	64	66	62	55	54
12	Distal	10	11	8	16	20	26	40	40	49	116	100	125
13	Proximal	26	28	43	52	52	57	79	80	85	48	48	53
13	Distal	38	39	38	31	32	39	42	44	47	102	106	106
14	Proximal	54	42	77	76	62	88	80	63	91	74	49	70
14	Distal	89	63	78	79	65	90	76	61	86	82	65	89
15	Proximal	40	46	52	56	55	52	68	75	75	39	45	44
15	Distal	34	43	37	63	74	70	44	53	52	33	38	39
16	Proximal	16	17	41	38	44	53	40	44	50	21	20	25
16	Distal	60	63	54	30	30	45	31	37	54	58	72	86
17	Proximal	27	32	32	58	59	55	87	86	84	41	45	46
17	Distal	143	137	148	70	74	78	48	58	61	56	64	66
18	Proximal	19	19	33	40	39	50	78	71	86	22	24	25
18	Distal	93	70	84	81	76	94	78	75	95	116	104	125
19	Proximal	36	39	58	56	56	77	70	64	86	50	50	60
19	Distal	33	35	46	30	32	47	20	22	37	62	55	64
20	Proximal	70	68	88	74	82	97	75	86	105	110	118	133
20	Distal	96	87	91	72	77	94	60	67	83	93	97	109
21	Proximal	29	37	77	42	41	57	57	53	83	47	42	46

21	Distal	41	44	41	31	33	48	33	30	53	103	85	103
22	Proximal	63	67	82	87	89	109	87	92	110	76	75	82
22	Distal	70	71	74	55	55	58	74	76	90	94	99	114
23	Proximal	47	36	45	49	49	66	88	75	88	69	52	56
23	Distal	99	81	67	55	54	55	68	62	76	98	81	93
24	Proximal	46	43	60	55	60	81	93	90	103	49	51	62
24	Distal	58	48	54	79	76	8	69	69	81	70	72	87
25	Proximal	85	79	116	101	91	111	123	107	137	86	75	92
25	Distal	77	60	75	69	58	85	53	49	73	76	67	87
26	Proximal	26	26	50	52	54	68	78	72	92	53	49	56
26	Distal	73	58	65	61	55	68	33	33	50	70	60	79
27	Proximal	35	33	39	48	53	67	61	68	80	55	53	49
27	Distal	69	49	60	38	42	48	34	35	44	54	54	62
28	Proximal	57	60	67	76	76	84	131	122	132	83	82	86
28	Distal	123	102	117	80	75	86	62	64	73	91	87	95
29	Proximal	23	21	33	58	52	66	55	57	65	33	27	27
29	Distal	102	69	63	34	32	41	31	32	45	102	86	94
30	Proximal	47	50	51	56	61	67	85	84	81	38	44	35
30	Distal	52	63	91	52	52	59	43	40	40	93	98	102
31	Proximal	45	59	70	66	76	87	79	88	96	71	72	79
31	Distal	41	21	38	46	46	49	54	61	66	70	67	71
32	Proximal	66	81	100	71	84	98	105	110	121	78	77	80
32	Distal	67	66	78	69	68	80	93	100	110	110	113	121
33	Proximal	52	49	63	67	61	71	111	100	117	64	56	64
33	Distal	96	85	102	101	92	110	103	93	109	124	110	129
34	Proximal	109	94	120	108	100	114	173	165	179	111	102	106
34	Distal	154	140	157	127	121	139	190	182	202	254	239	263
35	Proximal	74	72	87	83	84	92	118	120	126	74	78	86
35	Distal	137	135	120	96	96	106	90	92	101	78	81	84
36	Proximal	93	80	95	88	76	84	134	128	152	83	84	95
36	Distal	153	122	118	193	174	208	97	89	128	214	204	231
37	Proximal	66	49	83	75	62	87	85	68	106	75	59	79
37	Distal	82	53	62	79	61	82	86	68	98	89	66	90
38	Proximal	39	40	73	70	68	85	111	100	104	50	46	64
38	Distal	97	90	97	63	60	85	58	55	83	100	100	140
39	Proximal	35	44	76	52	53	61	85	84	101	32	31	35
39	Distal	67	55	47	44	46	59	47	56	78	77	83	94
40	Proximal	52	81	111	112	122	128	191	217	235	136	163	186
40	Distal	247	217	201	289	305	317	131	158	219	124	136	154
41	Proximal	46	57	66	64	82	80	71	90	97	57	58	58
41	Distal	91	86	61	56	78	87	50	91	104	98	114	108
42	Proximal	52	68	120	88	94	114	138	152	198	69	68	70
42	Distal	165	139	110	125	124	136	118	136	164	203	210	206
43	Proximal	83	121	114	82	97	101	94	115	126	91	102	101
43	Distal	126	154	144	77	100	110	82	115	127	84	97	104
44	Proximal	52	45	60	110	103	120	83	76	89	84	81	96
44	Distal	79	61	69	71	67	78	68	64	76	67	62	74
45	Proximal	73	67	88	71	67	86	147	133	153	109	102	104

45	Distal	121	105	118	82	77	99	119	109	132	140	130	148
46	Proximal	37	48	54	52	54	58	55	57	62	39	41	43
46	Distal	48	51	52	30	34	41	21	19	24	51	54	57
47	Proximal	23	27	48	41	40	52	46	41	55	40	47	48
47	Distal	55	37	40	25	33	45	35	44	60	65	63	70
48	Proximal	42	57	74	57	64	66	75	74	71	35	39	50
48	Distal	97	88	71	63	68	58	94	95	104	120	115	120

Appendix 6:Peak Interface Pressures (kPa)

Peak Interface Pressure (kPa)													
		Anterior Aspect			Medial Aspect			Posterior Aspect			Lateral Aspect		
Subject	Region	Early Stance	Mid Stance	Late Stance	Early Stance	Mid Stance	Late Stance	Early Stance	Mid Stance	Late Stance	Early Stance	Mid Stance	Late Stance
1	Proximal	50	48	47	84	62	90	57	57	67	41	28	25
1	Distal	64	51	95	43	41	49	44	48	59	77	69	78
2	Proximal	73	68	112	81	77	85	94	89	99	92	91	91
2	Distal	105	106	109	95	92	99	94	93	106	96	95	103
3	Proximal	171	152	181	109	105	111	114	106	111	125	118	128
3	Distal	357	284	347	103	100	105	117	113	118	130	120	123
4	Proximal	331	130	220	169	151	211	141	115	167	143	121	172
4	Distal	419	117	128	118	116	144	120	111	153	148	132	187
5	Proximal	71	69	86	73	73	88	116	98	112	106	105	109
5	Distal	186	77	90	67	70	80	57	58	83	83	76	97
6	Proximal	40	42	85	70	67	83	95	83	98	32	29	33
6	Distal	88	47	63	40	43	60	47	51	73	72	70	78
7	Proximal	85	92	131	92	96	120	105	103	114	57	52	72
7	Distal	59	64	62	78	77	92	90	85	97	90	90	94
8	Proximal	36	38	54	55	51	41	52	45	78	52	54	57
8	Distal	130	106	55	36	32	38	20	25	48	129	106	96
9	Proximal	82	42	92	91	55	98	109	78	121	158	106	207
9	Distal	297	106	62	82	51	92	76	42	83	96	54	87
10	Proximal	52	53	82	105	97	120	105	95	113	102	95	84
10	Distal	90	120	102	38	38	35	78	68	93	108	91	111
11	Proximal	97	91	107	100	91	100	124	112	127	102	97	106
11	Distal	238	176	241	113	107	116	118	110	125	135	121	134
12	Proximal	16	23	33	76	76	67	100	84	79	164	140	132
12	Distal	13	17	9	28	36	43	53	50	64	251	178	286
13	Proximal	33	37	59	70	67	80	107	106	113	96	93	103
13	Distal	82	81	71	45	46	57	58	60	64	130	133	134
14	Proximal	136	78	111	116	89	115	90	88	109	188	122	145
14	Distal	176	93	134	89	82	96	86	78	96	109	96	116
15	Proximal	81	85	104	151	152	133	97	101	106	52	59	58
15	Distal	67	83	52	81	95	87	58	71	73	62	69	70
16	Proximal	22	35	48	89	95	100	51	63	63	41	40	54
16	Distal	158	81	74	35	49	55	42	62	64	104	129	108
17	Proximal	41	45	49	95	99	96	108	108	106	92	95	101
17	Distal	385	355	396	88	90	95	71	82	87	77	87	88
18	Proximal	24	29	37	71	64	85	91	88	108	46	51	55
18	Distal	169	104	139	124	96	118	95	95	114	145	121	143
19	Proximal	49	49	67	74	73	96	98	92	114	104	96	92
19	Distal	54	54	64	41	40	65	26	29	53	85	76	77
20	Proximal	154	125	116	151	129	138	91	104	137	193	203	278
20	Distal	174	118	112	80	84	104	80	94	116	114	119	137
21	Proximal	56	51	111	90	65	83	68	65	102	88	77	119
21	Distal	93	57	56	51	49	68	60	60	94	214	173	194
22	Proximal	150	138	170	109	112	169	109	115	143	135	155	206
22	Distal	104	96	104	67	68	72	82	84	105	117	120	138

23	Proximal	136	82	90	99	68	91	124	108	119	136	106	113
23	Distal	213	187	147	70	71	70	77	78	85	110	94	102
24	Proximal	75	55	101	76	79	99	106	102	120	80	85	103
24	Distal	73	59	81	94	94	110	89	87	106	82	84	105
25	Proximal	289	121	201	178	126	137	176	141	191	141	102	117
25	Distal	174	100	108	102	99	117	79	80	100	102	95	110
26	Proximal	58	63	76	76	72	85	96	92	110	100	105	123
26	Distal	115	94	90	73	65	80	45	45	71	126	90	107
27	Proximal	71	63	77	58	63	96	77	87	106	99	87	125
27	Distal	107	66	105	33	44	53	43	46	51	55	57	66
28	Proximal	74	76	87	98	104	115	163	145	155	107	107	109
28	Distal	164	159	177	118	122	139	84	88	98	109	107	115
29	Proximal	37	39	45	129	85	75	79	73	81	62	60	66
29	Distal	334	160	189	43	44	62	39	46	68	189	125	116
30	Proximal	52	67	63	72	90	103	45	100	101	83	93	65
30	Distal	110	114	274	79	80	89	97	53	47	158	175	156
31	Proximal	109	104	221	81	89	102	88	95	110	125	106	125
31	Distal	69	59	72	57	56	60	76	81	91	86	91	103
32	Proximal	98	129	156	83	114	133	136	144	154	232	223	220
32	Distal	83	86	110	87	91	106	113	134	143	154	160	161
33	Proximal	94	79	99	99	88	106	134	122	141	132	128	172
33	Distal	160	144	178	115	103	123	115	105	126	139	126	148
34	Proximal	224	210	295	133	127	143	232	234	260	181	159	172
34	Distal	288	263	299	151	146	163	292	285	314	335	309	357
35	Proximal	222	201	145	103	113	112	128	128	138	127	146	134
35	Distal	348	298	158	110	111	122	126	130	138	134	122	118
36	Proximal	181	146	145	124	110	126	157	150	180	151	142	151
36	Distal	229	215	215	228	203	236	137	129	176	280	255	277
37	Proximal	113	61	145	91	76	107	115	98	140	118	104	126
37	Distal	125	67	87	94	73	101	117	97	134	109	85	115
38	Proximal	60	62	90	101	98	100	165	145	154	102	87	101
38	Distal	234	197	163	85	79	101	80	76	106	144	176	210
39	Proximal	49	77	191	67	66	81	118	115	135	67	69	86
39	Distal	160	126	80	67	67	79	52	72	94	108	105	108
40	Proximal	76	116	155	262	282	282	232	287	298	195	234	269
40	Distal	441	387	368	515	530	526	180	235	269	169	185	214
41	Proximal	70	61	123	84	126	110	92	85	130	103	96	108
41	Distal	174	104	89	68	78	98	51	83	116	133	151	158
42	Proximal	70	102	178	135	152	157	174	198	287	106	130	137
42	Distal	252	236	213	141	143	167	154	172	197	238	276	327
43	Proximal	69	121	111	76	97	100	89	115	126	87	102	91
43	Distal	109	153	144	74	100	104	72	115	126	80	96	97
44	Proximal	87	66	98	207	203	242	98	88	93	189	175	179
44	Distal	145	92	121	81	80	83	75	72	75	78	77	86
45	Proximal	364	269	316	103	98	114	167	161	172	277	268	172
45	Distal	249	186	213	96	99	111	132	123	140	173	159	254
46	Proximal	50	60	73	70	75	79	75	74	80	70	75	76
46	Distal	64	83	120	46	46	59	30	24	33	91	83	84
47	Proximal	36	35	62	48	41	49	60	64	82	67	69	79
47	Distal	107	55	47	28	36	50	44	59	86	76	74	78

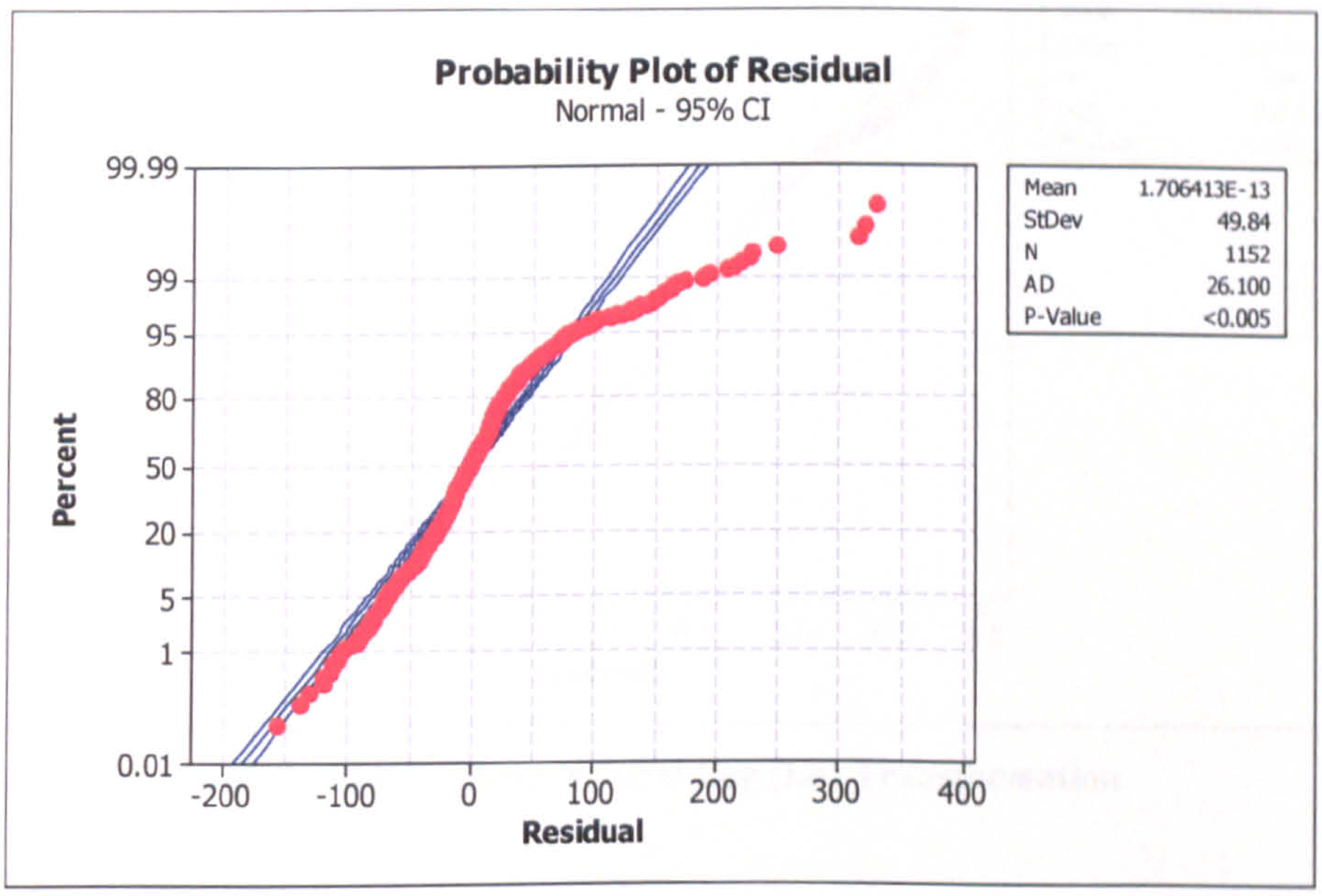
48	Proximal	71	80	92	98	99	101	101	105	110	60	67	120
48	Distal	167	137	98	75	89	63	106	111	124	160	147	148

Appendix 7:Tukey Post Hoc Test, Average Interface Pressure Difference Between Regions

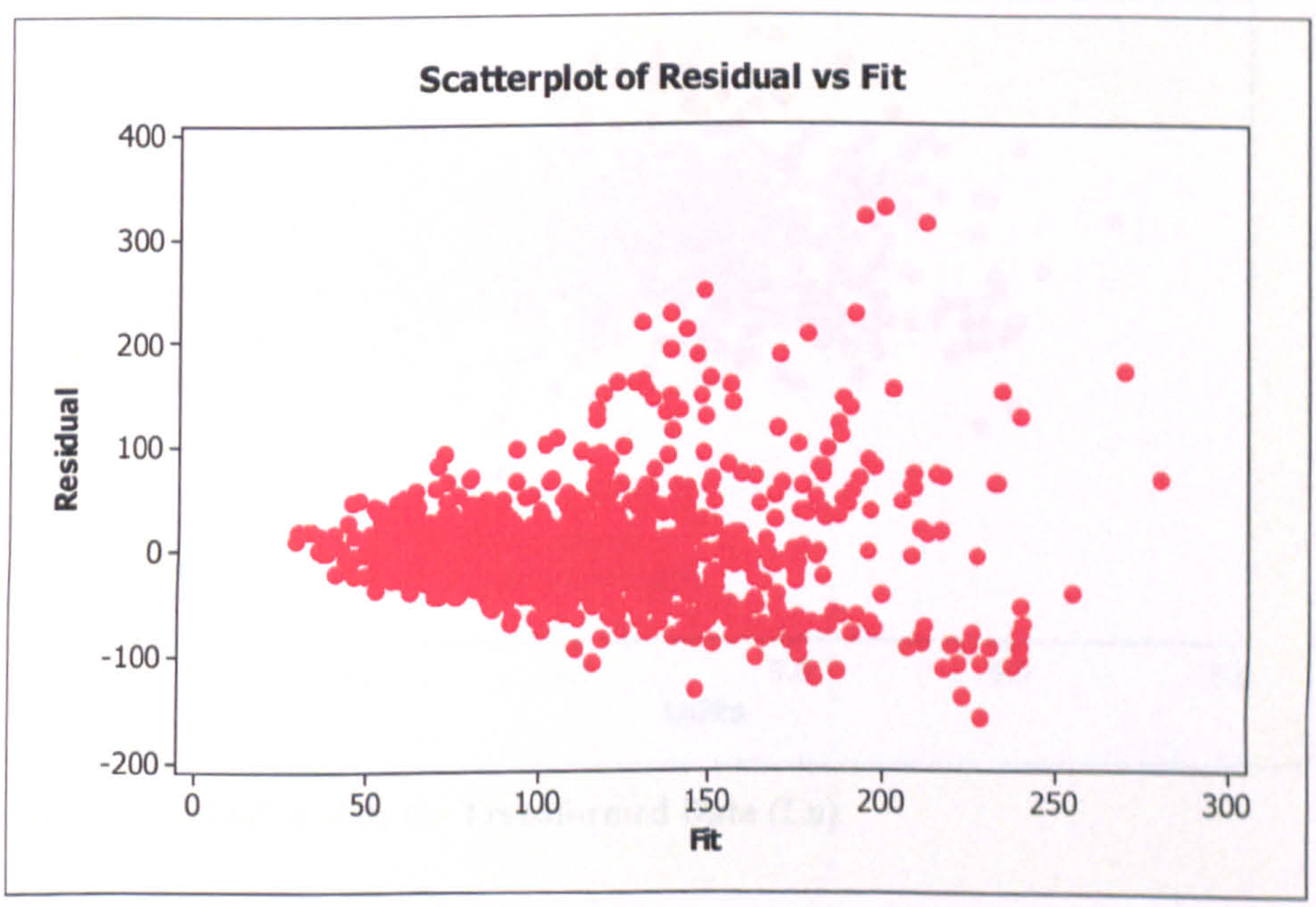
(I) Region	(J) Region	Mean Difference (I-J)	Significance (p)
Proximal Anterior	Distal Anterior	-0.323	< 0.001
	Proximal Medial	-0.247	<0.001
	Distal Medial	-0.190	< 0.001
	Proximal Posterior	-0.5515	< 0.001
	Distal Posterior	-0.230	< 0.001
	Proximal Lateral	-0.098	0.313
	Distal Lateral	-0.573	< 0.001
Distal Anterior	Proximal Anterior	.0323	< 0.001
	Proximal Medial	0.075	0.663
	Distal Medial	0.132	0.049
	Proximal Posterior	-0.228	< 0.001
	Distal Posterior	0.092	0.397
	Proximal Lateral	0.224	< 0.001
	Distal Lateral	-0.250	< 0.001
Proximal Medial	Proximal Anterior	.0247	< 0.001
	Distal Anterior	-0.075	0.663
	Distal Medial	0.057	0.897
	Proximal Posterior	-0.304	< 0.001
	Distal Posterior	0.017	1.000
	Proximal Lateral	0.148	0.016
	Distal Lateral	-0.326	< 0.001
Distal Medial	Proximal Anterior	0.190	< 0.001
	Distal Anterior	-0.132	0.049
	Proximal Medial	-0.057	0.897
	Proximal Posterior	-0.361	< 0.001
	Distal Posterior	-0.039	0.985
	Proximal Lateral	0.091	0.416
	Distal Lateral	-0.383	< 0.001
Proximal Posterior	Proximal Anterior	0.551	< 0.001
	Distal Anterior	0.228	< 0.001
	Proximal Medial	0.304	< 0.001
	Distal Medial	0.361	< 0.001
	Distal Posterior	0.321	< 0.001
	Proximal Lateral	0.452	< 0.001
	Distal Lateral	-0.022	1.000
Distal Posterior	Proximal Anterior	0.230	< 0.001
	Distal Anterior	-0.092	0.397
	Proximal Medial	-0.017	1.000
	Distal Medial	0.039	0.985
	Proximal Posterior	-0.321	<0.001
	Proximal Lateral	0.131	0.054
	Distal Lateral	-0.343	<0.001

Proximal Lateral	Proximal Anterior	0.098	0.313
	Distal Anterior	-0.224	<0.001
	Proximal Medial	-0.148	0.016
	Distal Medial	-.091	0.416
	Proximal Posterior	-0.452	<0.001
	Distal Posterior	-.0131	<0.054
	Distal Lateral	-0.474	<0.001
Distal Lateral	Proximal Anterior	0.573	<0.001
	Distal Anterior	0.250	<0.001
	Proximal Medial	0.326	<0.001
	Distal Medial	0.383	<0.001
	Proximal Posterior	0.022	1.000
	Distal Posterior	0.343	<0.001
	Proximal Lateral	0.474	<0.001

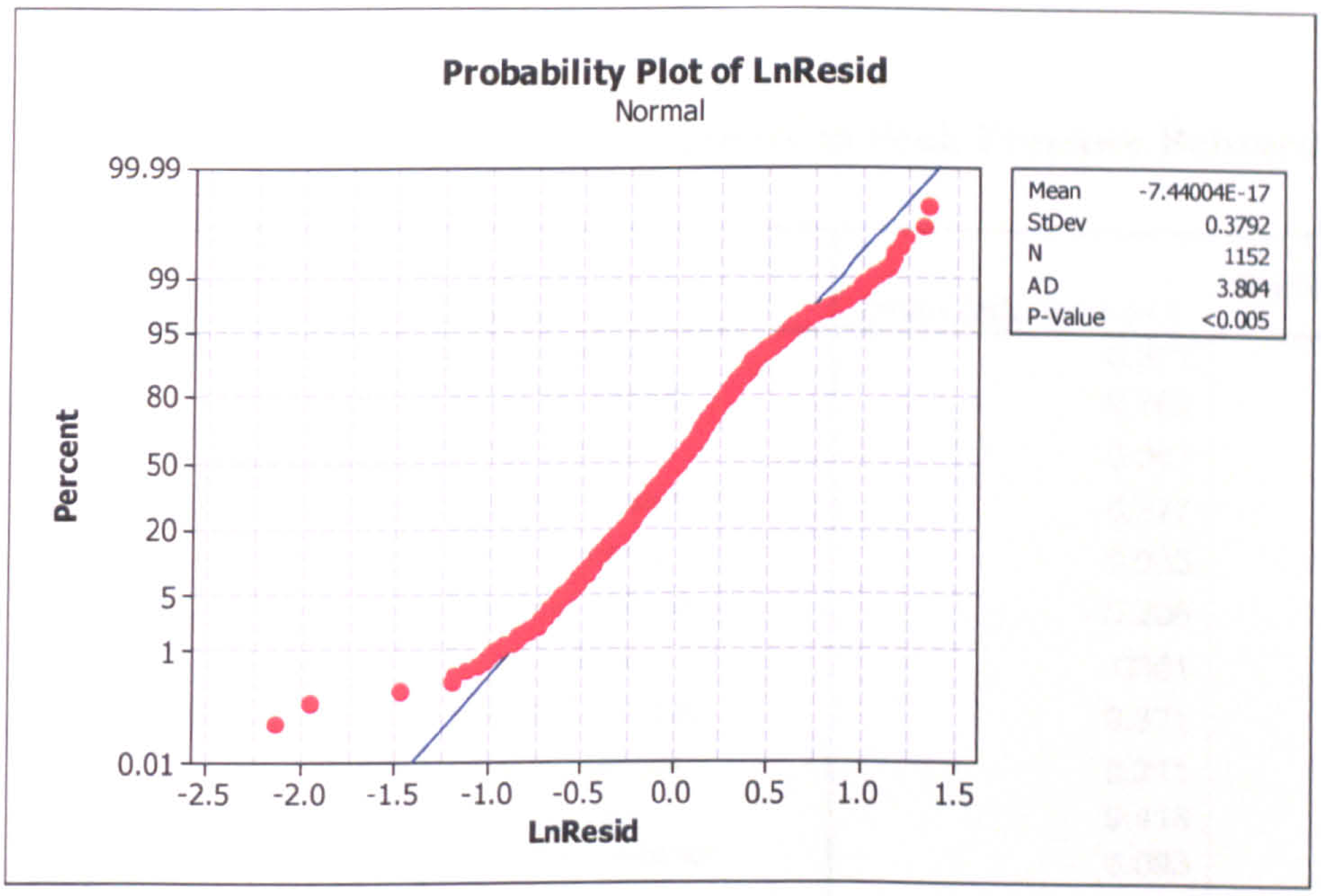
Appendix 8:Peak Pressure Transformation



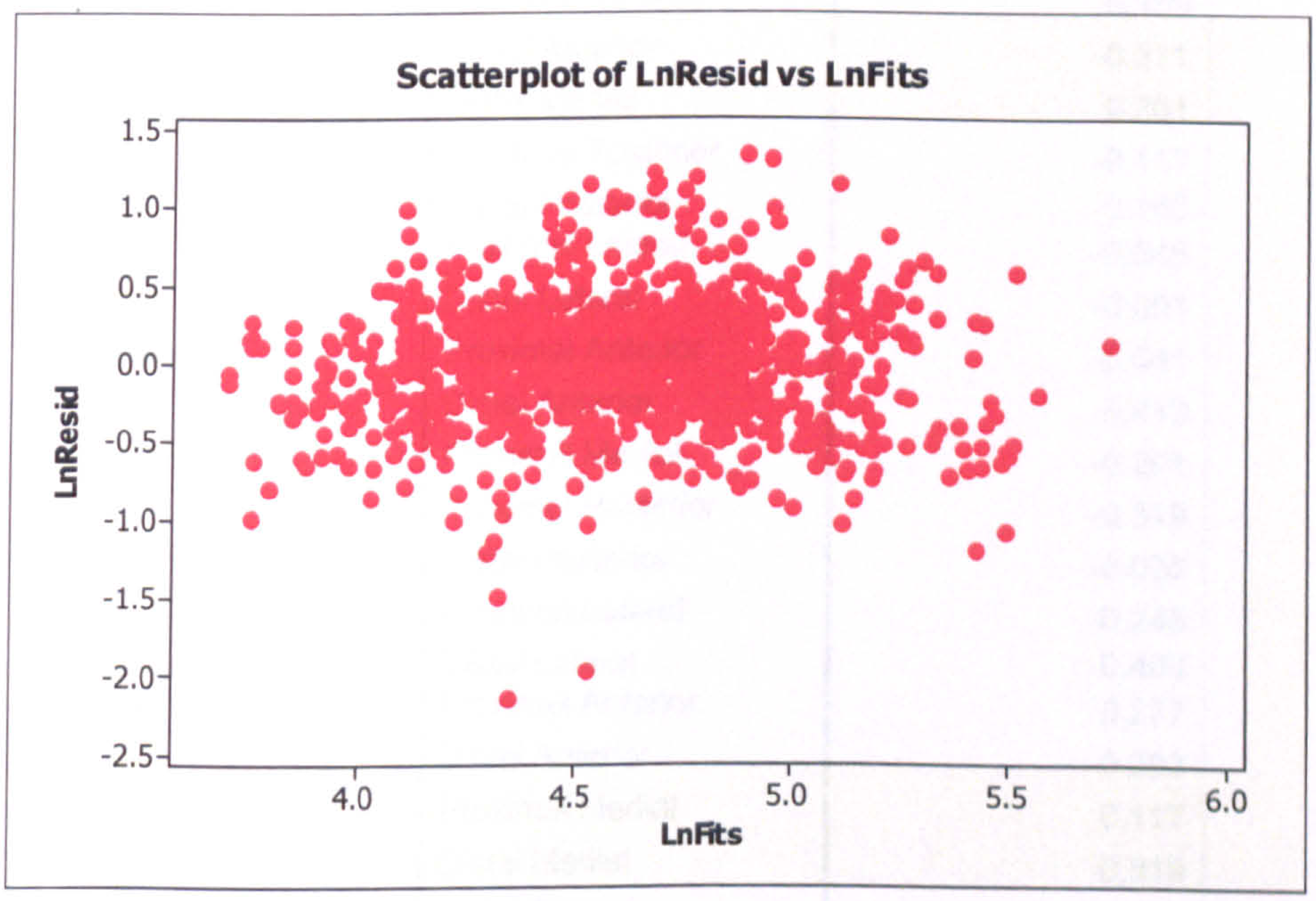
Probability Plot of Residual Peak Interface Pressure Values (kPa)



Plot of Residual vs. Fit for Peak Interface Pressure Values (kPa)



Distribution of Residuals, Using Natural Log (Ln) Transformation



Plot of Residual vs. Fits for Transformed Data (Ln)

Appendix 9:Post Hoc Test for Difference in Peak Pressure Between Regions

(I) Region	(J) Region	Mean Difference (I-J)	Significance (p)
Proximal Anterior	Distal Anterior	-0.371	<0.001
	Proximal Medial	-0.159	0.012
	Distal Medial	0.041	0.985
	Proximal Posterior	-0.277	<0.001
	Distal Posterior	0.005	1.000
	Proximal Lateral	-0.206	<0.001
	Distal Lateral	-.0361	<0.001
Distal Anterior	Proximal Anterior	0.371	<0.001
	Proximal Medial	0.211	<0.001
	Distal Medial	0.413	<0.001
	Proximal Posterior	0.093	0.449
	Distal Posterior	0.377	<0.001
	Proximal Lateral	0.165	0.008
	Distal Lateral	0.010	1.000
Proximal Medial	Proximal Anterior	0.159	0.012
	Distal Anterior	-0.211	<0.001
	Distal Medial	0.201	<0.001
	Proximal Posterior	-0.117	0.167
	Distal Posterior	0.165	0.008
	Proximal Lateral	-0.046	0.972
	Distal Lateral	-0.201	<0.001
Distal Medial	Proximal Anterior	-0.041	0.985
	Distal Anterior	-0.413	<0.001
	Proximal Medial	-0.201	<0.001
	Proximal Posterior	-0.319	<0.001
	Distal Posterior	-0.036	0.994
	Proximal Lateral	-0.248	<0.001
	Distal Lateral	-0.403	<0.001
Proximal Posterior	Proximal Anterior	0.277	<0.001
	Distal Anterior	-0.093	0.449
	Proximal Medial	0.117	0.167
	Distal Medial	0.319	<0.001
	Distal Posterior	0.283	<0.001
	Proximal Lateral	0.071	0.778
	Distal Lateral	-0.083	0.606
Distal Posterior	Proximal Anterior	-0.005	1.000
	Distal Anterior	-0.377	<0.001
	Proximal Medial	-0.165	0.008
	Distal Medial	0.036	0.994
	Proximal Posterior	-0.283	<0.001
	Proximal Lateral	-0.212	<0.001
	Distal Lateral	-0.366	<0.001
Proximal Lateral	Proximal Anterior	0.206	<0.001
	Distal Anterior	-0.165	0.008

	Proximal Medial	0.046	0.972
	Distal Medial	0.248	<0.001
	Proximal Posterior	-0.071	0.778
	Distal Posterior	0.212	<0.001
	Distal Lateral	-0.154	0.017
Distal Lateral	Proximal Anterior	0.361	<0.001
	Distal Anterior	-0.010	1.000
	Proximal Medial	0.201	<0.001
	Distal Medial	0.403	<0.001
	Proximal Posterior	0.083	0.606
	Distal Posterior	0.366	<0.001
	Proximal Lateral	0.154	0.017

Appendix 10:Post Hoc for Percentage Pressure Increase Between Regions

(I) Region	(J) Region	Mean Difference (I-J)	Significance (p)
Proximal Anterior	Distal Anterior	-0.141	0.722
	Proximal Medial	0.284	0.021
	Distal Medial	0.822	<0.001
	Proximal Posterior	0.844	<0.001
	Distal Posterior	0.759	<0.001
	Proximal Lateral	-0.339	0.002
	Distal Lateral	0.677	<0.001
Distal Anterior	Proximal Anterior	0.141	0.722
	Proximal Medial	0.425	<0.001
	Distal Medial	0.963	<0.001
	Proximal Posterior	0.985	<0.001
	Distal Posterior	0.900	<0.001
	Proximal Lateral	-0.198	0.284
	Distal Lateral	0.818	<0.001
Proximal Medial	Proximal Anterior	-0.284	0.021
	Distal Anterior	-0.425	<0.001
	Distal Medial	0.537	<0.001
	Proximal Posterior	0.560	<0.001
	Distal Posterior	0.475	<0.001
	Proximal Lateral	-0.624	<0.001
	Distal Lateral	.0393	<0.001
Distal Medial	Proximal Anterior	-0.822	<0.001
	Distal Anterior	-0.963	<0.001
	Proximal Medial	-0.537	<0.001
	Proximal Posterior	0.022	1.000
	Distal Posterior	-0.062	0.996
	Proximal Lateral	-1.161	<0.001
	Distal Lateral	-0.144	0.697
Proximal Posterior	Proximal Anterior	-0.844	<0.001
	Distal Anterior	-0.985	<0.001
	Proximal Medial	-0.560	<0.001
	Distal Medial	-0.022	1.000
	Distal Posterior	-0.085	0.976
	Proximal Lateral	-1.184	<0.001
	Distal Lateral	-0.166	0.522
Distal Posterior	Proximal Anterior	-.0759	<0.001
	Distal Anterior	-0.900	<0.001
	Proximal Medial	-0.475	<0.001
	Distal Medial	0.062	0.996
	Proximal Posterior	0.085	0.976
	Proximal Lateral	-1.099	<0.001
	Distal Lateral	-0.081	0.981
Proximal Lateral	Proximal Anterior	0.339	0.002
	Distal Anterior	0.198	0.284

	Proximal Medial	0.624	<0.001
	Distal Medial	1.161	<0.001
	Proximal Posterior	1.184	<0.001
	Distal Posterior	1.099	<0.001
	Distal Lateral	1.017	<0.001
Distal Lateral	Proximal Anterior	-0.677	<0.001
	Distal Anterior	-0.818	<0.001
	Proximal Medial	-0.393	<0.001
	Distal Medial	0.144	0.697
	Proximal Posterior	0.166	0.522
	Distal Posterior	0.081	0.981
	Proximal Lateral	-1.017	<0.001

Appendix 11: Daily Steps Taken

Subject Number	Socket Type	No. of 24h Periods	No. of Steps_1	No. of Steps_2	No. of Steps_3	No. of Steps_4	No. of Steps_5	No. of Steps_6	Average Daily Steps	% of Day Spent Walking
1	Hands On	4	10610	9982	9896	9760	*	*	10062	11.1
2	Hands Off	5	10008	10962	8970	10668	8014	*	9724.4	7.5
3	Hands Off	6	11792	11296	12760	8914	10450	15800	11835.3	8.2
4	Hands Off	6	20246	16112	17300	9178	8344	13138	14053	14.3
5	Hands Off	6	6478	6186	7228	8072	6192	7216	6895.3	7.9
6	Hands On	4	6766	7464	12598	7110	*	*	8484.5	6.4
7	Hands On	6	6316	4964	6142	4290	3446	5904	5177	3.9
8	Hands On	4	6988	9718	11806	8714	*	*	9306.5	6.5
9	Hands Off	4	14036	10660	12012	8838	*	*	11386.5	8.8
10	Hands Off	6	14486	10776	15610	10718	9902	9514	11834.3	7.3
11	Hands Off	6	1066	1514	1736	1232	1756	2170	1579	1.5
12	Hands On	4	12470	8670	8059	12532	*	*	10432.8	6
13	Hands On	6	10056	17910	21512	15558	8700	15120	14809.3	12.7
14	Hands Off	6	10854	9618	9700	5402	5280	7610	8077.3	5.7
15	Hands Off	6	21426	26346	5556	17348	8900	7064	14440	13.7
16	Hands Off	5	3226	2456	5518	1908	4754	*	3572.4	3.5
17	Hands On	4	1770	1774	1634	1226	*	*	1601	2.1
18	Hands On	4	3082	3228	2174	1898	*	*	2595.5	3
19	Hands On	6	4542	9828	5598	8498	4810	6658	6655.7	5.7
20	Hands Off	6	14022	19262	8956	16408	9350	13006	13500.7	10.6
21	Hands On	4	12112	14636	10806	9506	*	*	11765	9.4
22	Hands Off	5	11634	11554	14840	9964	4928	*	10584	7.3
23	Hands Off	6	16242	12514	12054	18908	14978	19792	15748	14.3
24	Hands Off	6	4764	7020	2258	2364	2504	5660	4095	3.4
25	Hands Off	3	6168	6934	6908	*	*	*	6670	6.4
26	Hands On	5	10520	1832	10190	5684	2784	*	6202	4
27	Hands On	6	3658	4816	4270	3746	6254	3858	4433.7	3.4
28	Hands On	6	9020	15606	11124	8240	4844	13166	10333.3	10.9
29	Hands On	6	6886	8136	4046	9240	4344	9402	7009	5
30	Hands On	6	3588	1306	1236	2480	2470	2084	2194	2.6
31	Hands Off	2	7046	3208	*	*	*	*	5127	5.6
32	Hands Off	6	16312	13766	14770	12884	21576	18020	16221.3	13.5
33	Hands Off	6	16948	9042	12938	13164	20420	14360	14478.7	10
34	Hands On	6	8370	8014	9000	7834	6426	10812	8409.3	6.3
35	Hands Off	4	5060	3526	2956	3094	*	*	3659	2.9
36	Hands On	6	10748	16506	8662	18256	11940	14900	13502	9.3
37	Hands Off	3	6416	5352	9832	*	*	*	7200	5.1
38	Hands Off	6	8792	12640	12640	12888	7964	13600	11420.7	8.3
39	Hands On	6	9130	6480	8282	6544	7118	8766	7720	6.3
40	Hands On	5	8290	1764	1328	900	1402	*	2736.8	6.4
41	Hands On	6	22406	15894	16668	16138	9968	19814	16814.7	10.9
42	Hands On	6	2532	2254	2134	1246	1194	1658	1836.3	1.7
43	Hands On	6	1474	2446	2408	2498	2426	2166	2236.3	1.9
44	Hands Off	3	4360	11200	10876	*	*	*	8812	7.2
45	Hands Off	6	2742	2146	5144	4046	1888	2638	3100.7	3.1
46	Hands On	6	3898	3380	2900	4196	4296	2568	3539.7	2.8
47	Hands On	6	8244	5162	8222	12068	13242	9106	9340.7	7.4
48	Hands Off	6	4816	6162	4398	6668	4930	3662	5106	4.5

Appendix 12:PEQ Responses

	1A	1B	1C	1D	1E	1F	1G	1H	1I	1J	1K	1L
Subject	SAhapypros	UTfit	UTweight	UTstand	UTsit	UTbalance	UTenergy	UTfed	UTdon	APproslook	SOfrequous	SObotsous
1	93	94	95	95	95	93.5	93.5	94	95	94	94	95
2	60	70.5	50.5	83.5	78.5	3.5	77	71.5	78	86.5	100	100
3	30.5	73	83	70	85.5	85.5	85.5	86	73	98	76.5	82.5
4	96.5	97	95.5	95	97	94	71.5	72.5	96.5	51	40	67
5	100	100	100	100	100	84	100	87	100	100	78.5	100
6	43	73	100	37	39	70	100	56.5	83	43.5	0	2
7	68	81.5	88.5	28.5	47.5	20	22.5	56	96	31	14	97
8	100	100	100	100	75	100	100	100	100	100	62	100
9	100	100	76	100	100	100	91	100	72	100	100	100
10	71	72	79	54.5	24	65	51	75	92	44	18	29
11	47	73	83.5	16	74	25.5	100	30	100	75	100	100
12	55	44	56	48	50	54	66	58	71.5	70	81	92
13	96	100	100	77	83.5	100	77	81.5	100	100	100	100
14	71	81.5	77	82	60	98	97	73	75	58	30.5	20
15	71	82	96.5	52	48	77	61	67	78	94	77.5	82
16	50	59	63	56	50	27	37	26	78	35	41	32
17	85.5	94.5	31.5	49.5	76	54	75	77	73	78	74	86
18	100	51	60	72.5	74	100	93	63	97	58	96	100
19	71	85	77.5	62.5	84	56	47.5	44.5	90	80	65	32
20	83	86	83.5	82.5	41	83	86	42	82.5	60	39	37
21	75	81.5	82	82	54	99	86	76	98	86	93.5	95
22	48	67	78	20	45	20	37	28	60	82	22	12
23	82.5	85.5	97	97	99	82	91	95	98	75.5	50	3
24	93.5	81	66	66	68	70	79	68.5	86	76	48	78
25	72	61	67	55	72	82	58	64	87.5	89	66	60
26	53	54	50	62	39	85	70.5	62	61	36	18.5	25
27	99	100	100	100	100	100	100	100	100	100	70	100
28	91.5	47.5	77	84.5	77.5	82	83	75	81	57	95	100
29	53	57	58	52	58	72	86	71.5	90	86	50	49
30	49	68	100	45	49	73.5	29	80	79	83	100	100
31	15	3	6	5	2	2	15	14	2	1	7	2
32	36.5	50	72.5	43.5	37	44.5	42.5	39.5	66	37	32	34
33	100	100	48	100	85	100	30	100	76	90	70	0
34	88	89	81	79	83	65	24	75	96	53.5	27.5	*
35	50	52.5	34	75.5	95	82	38	85	88.5	75	78	81
36	87	89	92	92	63	92.5	92	90	90	80	92	92
37	90.5	90	74	85	62	96.5	92.5	90.5	90	90	90.5	41
38	81	91.5	67.5	93	94	100	100	91	100	95	69	100
39	77	50	88	82	80	13	86	42	72	76	92	93
40	72.5	87.5	100	83	47.5	100	82	82	100	100	86.5	83
41	90.5	92.5	72	93	78	75	94.5	94	95.5	93	95.5	100
42	58	56.5	47	47	29	67.5	59	53.5	57	68	49	75

43	64	98	83.5	81	97	81.5	14	95	26	35	60	97
44	87.5	93	92	95.5	95	85	96	90	94.5	94	92	100
45	98	97	66	97	97	98	97	98	96	97	98	98
46	48.5	38	50	53	67.5	43	79	72	76	31	12	20
47	98	59.5	94	93	61.5	97	91	11	96	57.5	81.5	62
48	48.5	32	38	17	13	51	25	7	78	79	74.5	82

	1M	1N	1O	1P	1Q	1R	1S	1T	1U	1V
Subject	APdamagclo	APdamagcov	APshoechoi	APclothchoi	RLsweat	RLsmell	RLswollen	RLrash	RLhair	RLsore
1	96	96	95	95	94	7	94	94	93	95
2	100	*	97.5	87.5	29	58	47.5	43	100	50.5
3	98	99	92	98.5	8	19	90.5	64.5	95	18.5
4	74	79	91.5	94	43	39	93	100	100	100
5	100	100	100	100	53	53	100	68	82	100
6	100	100	2	99	1	2	16.5	48	95	100
7	98	98	98	98	64.5	4	93	31	66.5	98
8	100	100	100	100	100	100	100	48	52	100
9	100	*	0	100	53.5	100	100	100	100	100
10	29	98	42	81	19	45	27	11.5	90	5
11	100	100	0	38	0	26	100	49.5	100	21.5
12	100	83	13	89	3	3	100	13	100	54.5
13	100	100	100	100	0	49	48	83.5	100	100
14	40	98	2	97	45	73	98	100	100	3
15	97	97	9	96	30.5	90	91.5	95	100	100
16	19	100	0	100	0	0	100	100	100	100
17	84	89.5	59	84.5	67.5	67	94	88	88	86.5
18	93.5	90	92	93.5	22	57.5	95	100	100	100
19	80	64.5	76	94	4	5	70	25	29.5	74
20	87	85	83	86	41	85	83	38	85	55
21	94	68	11	79	8	51	79	86.5	87.5	85
22	100	100	26.5	32.5	7.5	0	90	44	100	9
23	98	69	85	94	26.5	28.5	92	97	96	97.5
24	52.5	72	70	90	23.5	70	55	59	43.5	58.5
25	100	100	94	94	97	93.5	57.5	100	100	100
26	50.5	55	34	32	35	39	67	65.5	30	32
27	100	91	100	100	61	100	100	100	100	100
28	75.5	95	94	94	48	83	72	100	82	80
29	92	90	19	83	26	25	89	87	89	89
30	100	75	0	100	46.5	84.5	100	100	77.5	25
31	76.5	47	22	19.5	10	2	2	21	15	4
32	100	100	15	100	15	0	20	18.5	9.5	13.5
33	85	78.5	100	45	11.5	0	28	100	14.5	10
34	27	43	20	100	11.5	13.5	95	84	94.5	94
35	96	92	43	95	51	56.5	75	20.5	89	20
36	93	92	34	92	5	92	92	100	92	90
37	98	96	90	93.5	26	75	92	63	36.5	67.5
38	33	100	64	100	37	0	100	100	100	100
39	83	19	49	62	14.5	40	71	85	89	87
40	100	100	85	100	91	87.5	100	100	100	79
41	96	80	97	95.5	93	66	91	100	100	70
42	73	72	68.5	70	69	76.5	52.5	100	100	100

43	96	28	96	96	82	95	67	100	100	100
44	94	95	95	94.5	61	90 5	90	83	100	100
45	99	*	98	97	98	97	98	99	99	98
46	92	90	19	27	26	85	89 5	100	100	100
47	95	96 5	95	95	15	16 5	94	100	100	100
48	66	*	47	45	100	100	26	8	26 5	16

	2A	2B	2C	2D	2E	2F	2G	2H	2I	2J	2K	2L	2M	2N	2O	2P
Subject	PAfrephsen	PAintphsen	PAbotphsen	PAfrephpa	PAdurphpa	PAintphpa	PAbotphpa	PAfrelpa	PAintrlpa	PAbotrlpa	PAfreolpa	PAintolpa	PAbotolpa	PAfrebapa	PAintbapa	PAbotbapa
1	1	96	95	1	2	94	95	1	94	94	0	*	94.5	0	*	*
2	1	64	*	3	3	48	73	0	98	84	1	33	25.5	1	25	20
3	0	*	*	0	0	*	*	0	*	*	0	*	*	1	85.5	65
4	1	94	91.5	0	1	94	95	1	89.5	87.5	0	*	*	5	47	50
5	5	32	100	1	4	44	76	1	68	61.5	3	41	36	2	55	54
6	3	60	13	4	3	3	8	3	3	5	3	42.5	41	0	*	*
7	2	50	45	2	1	24	50	5	40	30	5	59	53	0	*	100
8	1	100	100	1	2	100	100	1	70	65	4	51	48	0	*	*
9	2	36	13	2	1	42.5	46	0	*	*	0	*	*	0	*	*
10	1	55	89	1	1	11	72	3	12.5	14	1	45	41	1	81.5	90
11	1	*	*	0	0	*	*	0	*	*	0	*	*	2	29.5	34
12	2	53	52	1	2	7	6	0	*	*	0	*	*	0	*	*
13	4	78	84.5	2	1	2	7.5	3	47	45	3	51	55	2	46.5	82
14	2	20	97	1	1	53	77	0	*	*	0	*	*	0	*	*
15	0	*	*	4	2	67	65	4	38	22.5	4	39.5	22.5	3	62	25.5
16	5	18	45	5	3	48.5	42	0	*	*	6	16	12.5	0	*	*
17	3	75.5	66	4	1	57	65	1	72	77	2	75	64	0	*	*
18	0	*	*	0	0	*	*	2	63	28.5	0	*	*	0	*	*
19	5	12	12.5	5	3	2	2	4	18.5	12	6	1	2	6	2	2
20	3	19	52	3	2	47	47	3	57	39	0	*	*	0	*	*
21	5	51	83	0	0	*	*	0	*	*	4	16.5	15	0	*	*
22	5	25	21.5	4	2	60	81.5	6	18	19	4	60	57	3	31.5	40
23	3	42	36	4	2	30	37.5	3	73	60	0	*	*	2	*	*
24	1	76	90	1	1	55	59.5	1	74.5	84.5	6	41.5	44	6	57	51
25	0	*	*	0	0	*	*	1	94.5	74	0	*	*	0	*	*
26	2	55	70	3	3	44.5	41	3	37	33	5	32.5	22.5	5	30.5	28
27	3	100	100	0	0	*	*	1	93	98	5	70	89	0	*	*
28	0	*	*	0	0	*	*	2	74	71	2	81	83	0	*	*
29	5	34	58.5	4	2	73.5	73	1	76	73	1	72	76	5	61	59.5
30	4	47	25	4	2	71	68.5	3	60	61	3	62	64	2	64	66
31	5	16	26	5	3	27	32	5	27.5	30	5	32.5	31	5	31	33.5
32	6	14	93.5	2	2	88.5	89	6	6.5	0	3	25	20.5	1	78	64
33	6	0	0	4	3	0	0	0	*	*	0	*	*	5	0	0
34	0	*	*	0	0	*	*	3	22	23.5	6	8	8.5	7	4	9
35	6	35.5	75	4	2	27	32	1	*	*	0	*	*	5	42	27
36	2	90.5	90	2	2	92.5	95	2	91	86	2	88	77	2	*	*
37	0	*	*	0	0	*	*	2	63.5	83	1	83	89	1	89	84.5
38	6	100	100	4	3	3	100	6	13	98	0	*	*	0	*	*
39	1	88	85	1	3	59.5	58	1	87	84	6	19.5	22	1	22	29
40	0	*	*	3	3	43	40	4	18	20	5	12.5	15	6	0	0
41	0	*	*	0	0	*	*	0	*	*	0	*	*	5	44.5	49
42	3	40.5	40	3	2	46	46.5	3	37	37	1	34	41.5	0	*	*

43	3	73	98	0	0	*	*	0	*	*	0	*	*	0	*	*
44	2	*	*	1	2	97	98	1	97	96 5	0	*	*	0	*	*
45	0	99	99	0	0	*	*	0	*	*	0	*	*	0	*	*
46	5	16	42	3	1	33	39	3	44	37	6	30	29	0	*	*
47	0	*	*	0	0	*	*	0	*	*	0	*	*	0	*	*
48	6	0	0	6	6	0	0	6	0	0	3	80	72	1	94	100

	3C	3D	3E	3G	3H	3I	3J	3K	4A	4B	4C	4D
Subject	FRmostfrus	PRpartresp	PRrelafct	PRfam1res	PRfam2res	SBpartburd	SBsochind	SBcaregive	AMwalk	AMclose	AMupstair	AMdwnstair
1	93	94	94	94	94	94	95	*	94	94	95	94.5
2	30.5	63.5	58	100	90	44	59	85	87	44	100	100
3	27	*	*	*	*	*	91	*	96.5	89.5	96.5	96.5
4	75	94.5	92.5	95.5	93.5	94.5	95	95	95	95.5	75	69.5
5	68	100	100	100	100	100	85.5	86	100	100	91	87
6	90	100	100	72	100	100	38	100	100	100	43	47
7	98	98	98	97	97	95	40	95	51	95	97	95
8	100	100	100	100	100	100	100	100	100	100	100	100
9	100	100	100	100	100	100	100	100	100	100	100	100
10	12	85	52.5	75	53	90	30	*	41.5	48	4	47
11	90	100	100	100	100	100	87	*	82	40	100	100
12	20	27.5	26.5	100	100	61	100	100	72	63	39.5	44.5
13	100	*	*	100	100	100	100	100	100	100	100	100
14	100	*	*	98	99	100	100	100	100	100	98	99
15	100	92	94	*	*	*	41	35.5	68	46	42.5	45
16	13	100	100	100	100	100	100	0	44	33	23	28
17	100	97	96	97	*	96	24	43.5	41.5	42	20	19.5
18	100	97	92	94	93	95	95	95	94	91	90	90
19	2	95	94.5	95	95	91	89	93	70	71	71	71
20	100	85	84	*	*	83	84	81	81	81	83	79
21	20.5	100	100	100	100	100	99	99	63.5	95	95	39
22	29	*	*	30	46	26	100	*	12.5	20	5	5
23	29	100	99	100	100	100	100	100	97	99	98	90
24	100	*	*	100	100	100	55	*	65.5	83	54.5	70.5
25	100	*	*	*	*	*	100	*	94	96	92	87
26	24.5	*	*	74.5	56	86.5	18.5	*	57.5	45	58	65.5
27	100	100	100	100	100	100	100	100	100	100	100	100
28	36	*	*	97.5	96.5	95	47.5	93.5	92	82	94.5	82.5
29	80	90	89	90	89	88.5	87	87	65	84	47	51
30	100	100	100	100	100	100	100	30	53.5	74	44	41
31	3	81	43	74	63	22	20	40	43	23	33	15
32	16.5	100	100	100	100	100	71	100	100	100	73.5	79
33	0	*	*	100	100	100	100	47.5	100	100	100	100
34	43.5	*	*	97	100	11.5	14	81	29	92	30.5	28.5
35	93.5	96.5	97.5	95.5	96	95	95	93	92.5	93	78	88
36	92	88	91	87.5	79	89	92.5	89	83	86	90	88
37	84.5	92	91	93.5	96	97	87	96	88	91	92.5	92.5
38	100	100	100	100	*	100	100	100	100	100	100	100
39	82	90	84	93	94	92	69	40	60	50	75	67
40	92	100	100	100	100	100	45	79.5	43.5	84	81	81
41	42	*	*	*	*	*	79	*	96.5	95	95	95
42	90.5	94.5	93.5	93.5	95	96	88	*	60	68	64	68
43	*	*	*	96	95	95	18	6	36	36	20	44

44	100	*	*	100	100	100	100	100	100	100	65	66 5
45	100	*	*	99	99	97	98	*	97	98	98	99
46	35	88	88	89 5	88	87.5	15	88	82 5	85	34	30
47	100	97	97	97	99	98	99	*	99	99	99	99
48	0	100	100	100	100	65	17	*	26	9 5	21 5	49

Question Number	4G	4H	4I	4J	4K	4L	4M	5A	5B	5C	5D	5E	5F	5G
Subject	AMsidewalk	AMslip	TRcar	TRhichair	TRlochiar	TRtoilet	TRbath	SAsstpros	SAsstwalk	WBsincamp	WBqol	PCprostist	PCcurtrain	PCalltrain
1	95	95	94	94	94	94.5	94.5	94	95	94	93	94	94	95
2	79	85	100	100	100	100	100	79.5	70.5	71	73	70.5	63.5	62.5
3	98	58	84.5	98	96.5	97	96.5	73.5	96.5	95.5	77.5	97	97.5	95.5
4	95	42	93	93.5	94	95.5	93.5	96.5	85.5	92	70	92	96	95
5	100	33	100	100	100	100	77	100	87.5	100	100	100	100	100
6	43	9	100	100	100	100	46	74	75	79	100	100	100	93.5
7	47	2	98	35	7	95	43	95	7	43	79	92	96	97
8	100	100	100	100	58	100	100	100	100	100	100	100	100	•
9	100	35.5	100	100	76.5	100	100	100	100	100	100	100	100	100
10	60	4	34	73.5	24	79	37	46	28	75	65.5	83.5	41.5	73
11	48	51	100	100	24	100	100	28	64	78	71	100	100	100
12	69	18	36	57	45	64	59	37	41	56	50	56	45	33.5
13	100	46	100	100	51.5	100	100	100	100	100	100	100	100	100
14	99	99	98	99	98	98	99	82	84	97	96	99	98	98
15	53	18	62	88	65	80.5	47	88	65	87.5	80.5	93	90.5	86.5
16	67.5	17	27	65	31	33	53	73	51	61	44	84	87	87
17	46	23	49	58	22.5	46	29	74	40.5	48	73	82	73	70.5
18	94	49	93	95	39	92	92.5	93	90	93	92	89	96	94
19	89	28	79	77	79	81	25	89	69	80	81	96	97	97
20	83	34	83	84	80	83	78	40	45	43	60	77	72	73
21	97	23	96.5	97	74	97	96	85	87.5	87	86	68	90	92
22	12.5	0	20.5	34	21	18	60	45	30	28	36	74	•	•
23	99	94.5	99	85	84	98	42.5	96.5	98	97	99	100	99	98
24	75.5	28	67	79	64	100	51	76	61.5	62.5	68	100	•	•
25	93	95	83.5	100	100	100	98	52	51	47	77.5	61.5	67.5	66.5
26	64	48.5	62	80	78.5	75.5	33	42	42.5	47.5	43	73.5	81	72
27	100	100	100	100	100	100	100	100	100	100	100	100	100	100
28	89	74.5	89	90	89	89	79	86.5	74	79	82.5	89.5	89.5	87.5
29	84	16	63	84	32	86	8	16.5	49	54	78.5	48	76	63.5
30	57	19	65	86.5	0	70	100	60	56.5	56	36.5	84	•	•
31	49.5	18.5	29.5	36	28	37	11	8	11	5	35	82	86	90.5
32	100	79	95	100	100	100	100	40	89	100	94	100	100	100
33	100	8	48.5	50	50	51	12	100	100	100	74	100	100	100
34	22.5	4	48	51.5	50	79	10	87	48	93	26	89	89	52
35	84	72	87	93.5	80	91	91	79.5	78.5	69.5	85.5	92	90	82
36	90	92	90	51	85	90	90	83	90	86	89	78	87	92
37	97	65.5	73	83.5	83.5	87.5	89	90	92	90	94	95	96	96
38	100	75	100	100	100	100	100	100	100	79.5	100	100	100	100
39	56	35	56	54	22	49	44	78	80	79	66	88	81	84
40	100	63.5	100	77	83.5	81	82.5	84	86	46.5	45	100	100	100
41	95	64	70	88	88	91	75	83.5	82	82	63	97	•	•
42	68.5	45	62.5	60	59	61	63	58	60	64.5	72	62	67	65
43	27	4	18	60	14	94	56	74.5	65	94.5	66	97	96	90

44	60	52	62	66	41	51	52	98	96	96	80.5	98	99	93
45	98	28	98	98	97	98	98	96	97	98	64.5	97	•	•
46	82.5	75.5	46.5	63	32.5	64	53.5	60	59.5	51	47	47	56.5	58.5
47	97.5	31	97.5	96	96	97.5	97	97	78	97.5	98	98	95	93.5
48	31	1	33	23.5	24	18	0	19.5	19	0	42.5	45.5	•	•

Question Number	6C	7A	7B	7C	7D	7E	7F	7G	7H	7I	7J
Subject	SEnopros	IMimpwt	IMimpdon	IMimpapear	IMimpshoe	IMimpcover	IMsweatbot	IMswellbot	IMnohair	IMlookubot	IMimpuphil
1	7	91	93	93.5	93.5	•	94.5	94	5	92.5	93.5
2	15	54	66.5	54	14	23	40	44	15	98	82
3	18	97	97	85	97	72	7.5	27	90.5	96	89.5
4	2	94	91	44	34	33	14	75.5	89	68.5	95
5	0	84	100	100	100	100	52	89	87	32	12
6	22.5	45	79	100	0	0	0	0	0	0	0
7	15	90	97	84	43	39	36	93	1	95	95
8	100	100	100	0	100	100	100	100	100	100	100
9	16	22	43	0	0	0	26.5	0	100	100	90
10	9	70	80	49.5	70	52.5	21	72.5	78	78	76
11	0	100	100	100	100	100	0	0	100	15	0
12	7	64	68	48	64	63	11.5	38	28	100	79
13	100	100	93.5	92	100	100	3	49	100	100	100
14	54	49	99	50	97	46	98	100	20	95	97
15	91.5	93.5	93	49	51	15	13.5	54	83	93	72.5
16	4	96	90.5	86	85	83	7	92	88	19	85
17	2	11.5	72	85	72	62	88	78.5	65.5	93	82
18	23	94	9	6	5	20	32	93	6	96	4.5
19	18	96	95	98	97	97	2	29	95.5	92	88
20	73	78	79	79	77	74	11	85	86	85	82
21	38	97	98	43	66	95	47	51	90	97	84
22	0	100	100	48	70.5	69	0	60.5	78	100	30
23	1	99	99	99	99	100	1	2	87.5	1	98
24	0	64	100	65.5	42	43.5	21	45	66	73	29.5
25	70	91.5	70	0	76	74	20	54	71	84	90
26	10	87	84.5	39.5	80.5	27.5	49	81	93	10	90.5
27	20.5	65	76.5	22	0	0	66	30.5	85	100	75.5
28	4	82	87	70	72	71	9.5	3	92	42.5	89
29	19	63	58	40	22	40	23	79	83	82	78
30	32	59	100	50	0	81	37	89	86	100	60.5
31	20	88.5	84	81	79	86	7	25	29	27.5	81
32	21	100	100	83	80	78.5	37	0	89	100	85
33	0	100	100	100	0	100	0	0	100	0	100
34	1	63.5	80	53	80	47	14	49	91.5	91	56
35	17.5	90.5	71	89.5	84.5	80.5	74	75	55	89	65
36	89	94	92	93	90	89	7	77	86	88	89
37	14	92	93	92.5	71	68	16.5	34	72	22.5	87
38	88	0	100	0	0	0	0	88	100	100	100
39	15	85	83	67	79	86	33	23	82	86	67
40	0	100	100	100	100	100	50	45	100	100	100
41	13.5	44	18	11	50	73	93	95	15	92	13
42	77	76	70	75	56	68.5	58.5	35	69	79	60
43	2	96	97	21	5	96	94	95	96	96	95

44	1	95	96 5	53 5	2	95	40	100	58	100	54
45	2	97	97	34	46	*	97	97	97	98	51
46	5	85 5	77	81	78	77	24	80	82	86	87
47	4	98	99	99	99	98	2 5	97	96	72	68 5
48	39	100	100	100	100	*	0	0	16	25 5	100

Appendix 13:PEQ Statistical Tests

Normal Distribution	t-test used

Question Number	Variable Name	Socket Concept	Mean	Test for Normality p-value	Independent Sample Test
1A	SAhapypros	Hands Off	70.125	0.092	0.390
		Hands On	75.646	0.108	
1B	UTfit	Hands Off	74.896	0.029	0.820
		Hands On	74.625	0.038	
1C	UTweight	Hands Off	70.563	0.084	0.179
		Hands On	78.458	0.020	
1D	UTstand	Hands Off	68.375	0.009	0.710
		Hands On	70.771	0.094	
2E	UTsit	Hands Off	67.583	0.005	0.621
		Hands On	67.000	0.530	
2F	UTbalance	Hands Off	68.979	0.005	0.725
		Hands On	74.729	0.040	
2G	UTenergy	Hands Off	69.083	0.005	0.820
		Hands On	72.938	0.005	
2H	UTfeel	Hands Off	66.688	0.014	0.820
		Hands On	71.229	0.285	
2I	UTdon	Hands Off	81.146	0.005	0.457
		Hands On	84.292	0.005	
3J	APproslook	Hands Off	74.250	0.005	0.489
		Hands On	70.688	0.121	
3K	SOfreqsoun	Hands Off	62.417	0.194	0.522
		Hands On	67.042	0.005	
3L	SObotsoun	Hands Off	60.104	0.007	0.111
		Hands On	78.043	0.005	
3M	APdamagclo	Hands Off	80.917	0.005	0.867
		Hands On	88.271	0.005	
3N	APdamagcov	Hands Off	90.275	0.005	0.049
		Hands On	79.813	0.005	
4O	APshoechoi	Hands Off	56.938	0.005	0.563
		Hands On	60.688	0.005	
4P	APclothchoi	Hands Off	82.417	0.005	0.740
		Hands On	86.604	0.005	
4Q	RLsweat	Hands Off	36.917	0.158	0.877
		Hands On	41.146	0.016	
4R	RLsmell	Hands Off	50.042	0.024	0.733
		Hands On	52.042	0.062	

4S	RLswollen	Hands Off	73.167	0.005	0.521
		Hands On	82.063	0.005	
5T	RLrash	Hands Off	65.938	0.005	0.110
		Hands On	80.771	0.005	
5U	RLhair	Hands Off	78.396	0.005	0.948
		Hands On	86.063	0.005	
5V	RLsore	Hands Off	56.146	0.005	0.035
		Hands On	84.958	0.005	
6A	PAfrephsen	Hands Off	2.792	NA	NA
		Hands On	2.250		
6B	PAintphsen	Hands Off	41.417	0.020	0.054
		Hands On	62.194	0.518	
6C	PAbotphsen	Hands Off	60.500	0.025	0.947
		Hands On	64.417	0.108	
7D	PAfrephpa	Hands Off	2.292	NA	NA
		Hands On	1.792		
7E	PAdurphpa	Hands Off	1.833	NA	NA
		Hands On	1.375		
7F	PAintphpa	Hands Off	44.342	0.435	0.805
		Hands On	47.000	0.373	
7G	PAbotphpa	Hands Off	59.079	0.562	0.381
		Hands On	49.656	0.362	
8H	PAfrerlpa	Hands Off	2.083	NA	NA
		Hands On	1.917		
8I	PAintrlpa	Hands Off	51.906	0.262	0.769
		Hands On	55.079	0.384	
8J	PAbotrlpa	Hands Off	53.344	0.136	0.872
		Hands On	51.579	0.199	
8K	PAfreolpa	Hands Off	1.542	NA	NA
		Hands On	2.875		
9L	PAintolpa	Hands Off	45.136	0.204	0.968
		Hands On	44.750	0.845	
9M	PAbotolpa	Hands Off	41.000	0.167	0.576
		Hands On	47.368	0.688	
9N	PAfrebapa	Hands Off	1.833	NA	NA
		Hands On	1.708		
9O	PAintbapa	Hands Off	53.867	0.780	0.048
		Hands On	30.500	0.581	
10P	PAbotbapa	Hands Off	49.233	0.940	0.593
		Hands On	42.450	0.613	
10A	PRavoidoth	Hands Off	82.958	0.005	0.792
		Hands On	88.438	0.005	

10B	FRfreqfrus	Hands Off	71.667	0.005	0.469
		Hands On	80.958	0.005	
10C	FRmostfrus	Hands Off	61.292	0.005	0.529
		Hands On	71.348	0.005	
11D	PRpartresp	Hands Off	93.094	0.005	0.872
		Hands On	92.000	0.005	
11E	PRrelafct	Hands Off	88.219	0.005	0.817
		Hands On	91.306	0.005	
11F		Hands Off			
		Hands On			
11G	PRfam1res	Hands Off	93.025	0.005	0.095
		Hands On	94.109	0.005	
12H	PRfam2res	Hands Off	91.342	0.005	0.563
		Hands On	94.114	0.005	
12I	SBpartburd	Hands Off	86.357	0.005	0.380
		Hands On	90.043	0.005	
12J	SBsochind	Hands Off	79.813	0.005	0.214
		Hands On	68.854	0.005	
12K	SBcaregive	Hands Off	78.688	0.005	0.801
		Hands On	79.974	0.005	
13A	AMwalk	Hands Off	79.604	0.005	0.206
		Hands On	72.646	0.043	
13B	AMclose	Hands Off	74.563	0.005	0.836
		Hands On	80.458	0.005	
13C	AMupstair	Hands Off	71.833	0.005	0.591
		Hands On	70.104	0.005	
13D	AMdwnstair	Hands Off	74.688	0.005	0.321
		Hands On	68.375	0.034	
14E	AMuphill	Hands Off	58.458	0.091	0.864
		Hands On	56.833	0.096	
14F	AMdownhill	Hands Off	50.479	0.797	0.778
		Hands On	52.875	0.262	
14G	AMsidewalk	Hands Off	78.417	0.005	0.482
		Hands On	75.542	0.007	
14H	AMslip	Hands Off	45.542	0.426	0.900
		Hands On	44.375	0.083	
14I	TRcar	Hands Off	74.063	0.005	0.950
		Hands On	75.542	0.007	
15J	TRhichair	Hands Off	81.229	0.005	0.300
		Hands On	77.250	0.038	
15K	TRlochiar	Hands Off	69.229	0.005	0.183
		Hands On	58.313	0.125	

15L	TRtoilet	Hands Off	79.813	0.005	0.424
		Hands On	83.188	0.017	
15M	TRbath	Hands Off	70.229	0.005	0.508
		Hands On	65.667	0.045	
16A	SAsatpros	Hands Off	71.125	0.005	0.710
		Hands On	77.125	0.012	
16B	SAsatwalk	Hands Off	70.833	0.018	0.628
		Hands On	69.813	0.387	
16C	WBsincamp	Hands Off	73.854	0.005	0.718
		Hands On	75.438	0.014	
16D	WBqol	Hands Off	74.500	0.119	0.885
		Hands On	73.604	0.170	
17E	PCprostist	Hands Off	89.208	0.005	0.248
		Hands On	84.500	0.005	
17F	PCcurtrain	Hands Off	89.175	0.005	0.334
		Hands On	86.864	0.005	
17G	PCalltrain	Hands Off	89.825	0.005	0.132
		Hands On	82.405	0.005	
18A	SEfitpoor	Hands Off	48.667	0.258	0.487
		Hands On	54.854	0.060	
18B	SEcomfpor	Hands Off	48.583	0.375	0.571
		Hands On	54.896	0.011	
18C	SEnopros	Hands Off	23.167	0.005	0.342
		Hands On	26.021	0.005	
18A	IMimpwt	Hands Off	81.458	0.005	0.321
		Hands On	78.604	0.006	
19B	IMimpdon	Hands Off	89.563	0.005	0.079
		Hands On	80.271	0.005	
19C	IMimpapear	Hands Off	64.271	0.025	0.665
		Hands On	61.292	0.092	
19D	IMimpshoe	Hands Off	61.458	0.008	0.975
		Hands On	60.500	0.005	
19E	IMimpcover	Hands Off	63.318	0.023	0.785
		Hands On	66.522	0.049	
19F	IMsweatbot	Hands Off	25.167	0.005	0.081
		Hands On	40.604	0.028	
20G	IMswellbot	Hands Off	50.813	0.063	0.231
		Hands On	62.667	0.015	
20H	IMnohair	Hands Off	73.125	0.005	0.951
		Hands On	68.646	0.005	
20I	IMlookubot	Hands Off	66.667	0.005	0.233
		Hands On	82.917	0.005	

20J	IMimpuphil	Hands Off	72.979	0.005	0.942
		Hands On	73.125	0.005	
Validated Sub-Scales					
	Utility (UT)	Hands Off	70.910	0.029	0.902
		Hands On	74.260	0.542	
	Appearance (AP)	Hands Off	76.660	0.180	0.908
		Hands On	77.210	0.621	
	Sounds (SO)	Hands Off	61.260	0.086	0.270
		Hands On	71.490	0.005	
	Residual Limb Health (RL)	Hands Off	60.100	0.465	0.070
		Hands On	71.170	0.064	
	Perceived response (PR)	Hands Off	90.250	0.005	0.515
		Hands On	91.010	0.005	
	Frustration (FR)	Hands Off	66.480	0.005	0.535
		Hands On	76.370	0.005	
	Social Burden (SB)	Hands Off	81.120	0.005	0.488
		Hands On	79.700	0.047	
	Ambulation (AM)	Hands Off	66.690	0.006	0.650
		Hands On	65.150	0.400	
	Well Being (WB)	Hands Off	74.180	0.021	0.749
		Hands On	74.520	0.286	

Appendix 14:Correlations between PEQ and Activity Monitor

Correlations		Hands Off	Hands On
SAhapypro	Pearson Correlation	0.177	0.363
	Sig. (2-tailed)	0.407	0.081
UTfit	Pearson Correlation	0.313	0.197
	Sig. (2-tailed)	0.137	0.357
UTweight	Pearson Correlation	**0.417**	0.308
	Sig. (2-tailed)	**0.043**	0.143
UTstand	Pearson Correlation	0.312	**0.432**
	Sig. (2-tailed)	0.138	**0.035**
UTsit	Pearson Correlation	0.059	0.162
	Sig. (2-tailed)	0.786	0.449
UTbalance	Pearson Correlation	0.268	0.215
	Sig. (2-tailed)	0.205	0.312
UTenergy	Pearson Correlation	0.010	0.390
	Sig. (2-tailed)	0.961	0.060
UTfeel	Pearson Correlation	0.274	0.113
	Sig. (2-tailed)	0.195	0.600
UTdon	Pearson Correlation	0.008	**0.422**
	Sig. (2-tailed)	0.971	**0.040**
APproslook	Pearson Correlation	0.033	0.326
	Sig. (2-tailed)	0.877	0.120
SOfreqsoun	Pearson Correlation	-0.241	0.309
	Sig. (2-tailed)	0.256	0.141
SObotsoun	Pearson Correlation	-0.320	0.158
	Sig. (2-tailed)	0.128	0.470
APdamagclo	Pearson Correlation	0.138	0.072
	Sig. (2-tailed)	0.519	0.739
APdamagcov	Pearson Correlation	-0.028	0.161
	Sig. (2-tailed)	0.906	0.452
APshoechoi	Pearson Correlation	0.141	0.044
	Sig. (2-tailed)	0.512	0.837
APclothchoi	Pearson Correlation	0.208	0.206
	Sig. (2-tailed)	0.329	0.334
RLsweat	Pearson Correlation	-0.235	-0.250
	Sig. (2-tailed)	0.269	0.238
RLsmell	Pearson Correlation	-0.207	-0.231
	Sig. (2-tailed)	0.331	0.277
RLswollen	Pearson Correlation	-0.074	-0.105
	Sig. (2-tailed)	0.730	0.625
RLrash	Pearson Correlation	0.151	-0.119
	Sig. (2-tailed)	0.481	0.581
RLhair	Pearson Correlation	-0.025	0.055
	Sig. (2-tailed)	0.909	0.798
RLsore	Pearson Correlation	0.046	0.020
	Sig. (2-tailed)	0.832	0.927
PAfrephsen	Pearson Correlation	0.042	-0.181
	Sig. (2-tailed)	0.845	0.397

PAintphsen	Pearson Correlation	-0.060	0.319
	Sig. (2-tailed)	0.814	0.197
PAbotphsen	Pearson Correlation	-0.089	0.325
	Sig. (2-tailed)	0.734	0.188
PAfrephpa	Pearson Correlation	0.091	-0.360
	Sig. (2-tailed)	0.674	0.084
PAdurphpa	Pearson Correlation	0.033	-0.124
	Sig. (2-tailed)	0.880	0.564
PAintphpa	Pearson Correlation	0.192	-0.011
	Sig. (2-tailed)	0.432	0.968
PAbotphpa	Pearson Correlation	0.245	-0.021
	Sig. (2-tailed)	0.312	0.939
PAfrerlpa	Pearson Correlation	0.299	-0.320
	Sig. (2-tailed)	0.156	0.127
PAintrlpa	Pearson Correlation	-0.120	0.195
	Sig. (2-tailed)	0.659	0.423
PAbotrlpa	Pearson Correlation	-0.199	0.217
	Sig. (2-tailed)	0.460	0.373
PAfreolpa	Pearson Correlation	-0.246	-0.170
	Sig. (2-tailed)	0.247	0.428
PAintolpa	Pearson Correlation	-0.146	0.105
	Sig. (2-tailed)	0.669	0.679
PAbotolpa	Pearson Correlation	-0.253	0.129
	Sig. (2-tailed)	0.454	0.600
PAfrebapa	Pearson Correlation	-0.025	0.129
	Sig. (2-tailed)	0.907	0.549
PAintbapa	Pearson Correlation	0.053	0.202
	Sig. (2-tailed)	0.851	0.603
PAbotbapa	Pearson Correlation	-0.083	0.209
	Sig. (2-tailed)	0.768	0.563
PRavoidoth	Pearson Correlation	0.060	-0.068
	Sig. (2-tailed)	0.780	0.751
FRfreqfrus	Pearson Correlation	0.009	-0.074
	Sig. (2-tailed)	0.965	0.732
FRmostfrus	Pearson Correlation	-0.197	-0.256
	Sig. (2-tailed)	0.357	0.239
PRpartresp	Pearson Correlation	-0.068	-0.300
	Sig. (2-tailed)	0.802	0.226
PRrelafct	Pearson Correlation	0.018	-0.259
	Sig. (2-tailed)	0.949	0.299
PRfam1res	Pearson Correlation	-0.078	-0.016
	Sig. (2-tailed)	0.744	0.942
PRfam2res	Pearson Correlation	-0.117	0.024
	Sig. (2-tailed)	0.633	0.916
SBpartburd	Pearson Correlation	0.071	-0.139
	Sig. (2-tailed)	0.761	0.527
SBsochind	Pearson Correlation	0.080	0.359
	Sig. (2-tailed)	0.709	0.085
SBcaregive	Pearson Correlation	0.267	**0.529**
	Sig. (2-tailed)	0.318	**0.020**
AMwalk	Pearson Correlation	0.238	**0.510**

	Sig. (2-tailed)	0.263	0.011
AMclose	Pearson Correlation	0.295	0.448
	Sig. (2-tailed)	0.162	0.028
AMupstair	Pearson Correlation	0.099	0.483
	Sig. (2-tailed)	0.645	0.017
AMdwnstair	Pearson Correlation	0.073	0.366
	Sig. (2-tailed)	0.735	0.079
AMuphill	Pearson Correlation	0.525	0.225
	Sig. (2-tailed)	0.008	0.290
AMdownhill	Pearson Correlation	0.376	0.168
	Sig. (2-tailed)	0.070	0.433
Amsidewalk	Pearson Correlation	0.275	0.380
	Sig. (2-tailed)	0.194	0.067
AMslip	Pearson Correlation	0.104	0.224
	Sig. (2-tailed)	0.630	0.293
TRcar	Pearson Correlation	0.124	0.309
	Sig. (2-tailed)	0.564	0.142
TRhichair	Pearson Correlation	0.104	0.267
	Sig. (2-tailed)	0.628	0.206
TRlochair	Pearson Correlation	0.276	0.469
	Sig. (2-tailed)	0.191	0.021
TRtoilet	Pearson Correlation	0.139	0.418
	Sig. (2-tailed)	0.518	0.042
TRbath	Pearson Correlation	-0.023	0.244
	Sig. (2-tailed)	0.914	0.251
SAsatpros	Pearson Correlation	0.239	0.220
	Sig. (2-tailed)	0.261	0.302
SAsatwalk	Pearson Correlation	0.289	0.371
	Sig. (2-tailed)	0.171	0.074
WBsincamp	Pearson Correlation	0.351	0.439
	Sig. (2-tailed)	0.093	0.032
WBqol	Pearson Correlation	0.328	0.295
	Sig. (2-tailed)	0.118	0.161
PCprostist	Pearson Correlation	0.179	0.142
	Sig. (2-tailed)	0.403	0.509
PCcurtrain	Pearson Correlation	0.026	0.137
	Sig. (2-tailed)	0.912	0.542
PCalltrain	Pearson Correlation	0.106	0.096
	Sig. (2-tailed)	0.655	0.680
SEfitpoor	Pearson Correlation	0.386	0.270
	Sig. (2-tailed)	0.063	0.202
SEcomfpor	Pearson Correlation	0.127	0.240
	Sig. (2-tailed)	0.554	0.259
SEnopros	Pearson Correlation	0.221	0.316
	Sig. (2-tailed)	0.298	0.133
IMimpwt	Pearson Correlation	-0.090	0.111
	Sig. (2-tailed)	0.675	0.606
IMimpdon	Pearson Correlation	-0.005	-0.044
	Sig. (2-tailed)	0.981	0.838
IMpapear	Pearson Correlation	-0.118	0.020
	Sig. (2-tailed)	0.584	0.925

IMimpshoe	Pearson Correlation	-0.272	0.388
	Sig. (2-tailed)	0.199	0.061
IMimpcover	Pearson Correlation	-0.240	0.233
	Sig. (2-tailed)	0.282	0.284
IMsweatbot	Pearson Correlation	-0.290	-0.193
	Sig. (2-tailed)	0.170	0.367
IMswellbot	Pearson Correlation	-0.197	-0.074
	Sig. (2-tailed)	0.356	0.732
IMnohair	Pearson Correlation	0.303	-0.082
	Sig. (2-tailed)	0.150	0.703
IMlookubot	Pearson Correlation	0.191	-0.056
	Sig. (2-tailed)	0.371	0.795
IMimpuphil	Pearson Correlation	**0.485**	-0.043
	Sig. (2-tailed)	**0.016**	0.841
Utility	Pearson Correlation	0.252	**0.444**
	Sig. (2-tailed)	0.234	**0.030**
Appearance	Pearson Correlation	0.182	0.225
	Sig. (2-tailed)	0.396	0.290
Sounds	Pearson Correlation	-0.304	0.236
	Sig. (2-tailed)	0.149	0.266
Residual Limb Health	Pearson Correlation	-0.075	-0.211
	Sig. (2-tailed)	0.729	0.323
Perceived Response	Pearson Correlation	-0.057	-0.164
	Sig. (2-tailed)	0.790	0.444
Frustration	Pearson Correlation	-0.111	-0.206
	Sig. (2-tailed)	0.606	0.334
Social Burden	Pearson Correlation	0.070	0.348
	Sig. (2-tailed)	0.744	0.096
Ambulation	Pearson Correlation	0.286	**0.417**
	Sig. (2-tailed)	0.176	**0.043**
Well Being	Pearson Correlation	0.361	**0.411**
	Sig. (2-tailed)	0.083	**0.046**

Appendix 15:Correlations between Pressure and Activity

Hands On					
		Average Pressure		Peak Pressure	
	Region	p	r	p	r
Phase 1	Anterior Proximal	0.933	-0.018	0.463	0.161
	Anterior Distal	0.153	-0.301	0.422	-0.176
	Medial Proximal	0.470	-0.155	0.976	0.007
	Medial Distal	0.350	-0.199	0.911	-0.025
	Posterior Proximal	0.393	-0.183	0.735	0.075
	Posterior Distal	0.444	-0.164	0.721	-0.079
	Lateral Proximal	0.839	-0.044	0.268	0.241
	Lateral Distal	0.565	0.124	0.279	0.235
Phase 2	Anterior Proximal	0.420	-0.172	0.842	-0.044
	Anterior Distal	0.094	-0.349	0.190	-0.283
	Medial Proximal	0.350	-0.199	0.747	-0.071
	Medial Distal	0.315	-0.214	0.840	-0.045
	Posterior Proximal	0.309	-0.217	0.589	-0.119
	Posterior Distal	0.456	-0.160	0.825	-0.049
	Lateral Proximal	0.559	-0.126	0.704	0.084
	Lateral Distal	0.703	0.082	0.469	0.159
Phase 3	Anterior Proximal	0.508	-0.142	0.755	0.069
	Anterior Distal	**0.044**	**-0.414**	**0.049**	**-0.415**
	Medial Proximal	0.280	-0.230	0.498	-0.149
	Medial Distal	0.388	-0.185	0.990	-0.003
	Posterior Proximal	0.347	-0.201	0.754	-0.069
	Posterior Distal	0.500	-0.145	0.833	0.047
	Lateral Proximal	0.653	-0.097	0.417	0.178
	Lateral Distal	0.691	0.086	0.450	0.166
Hands Off					
		Average Pressure		Peak Pressure	
		p	r	p	r
Phase 1	Anterior Proximal	0.533	0.134	0.754	-0.068
	Anterior Distal	0.688	-0.086	0.981	-0.005
	Medial Proximal	0.969	0.008	0.293	0.224
	Medial Distal	0.799	-0.055	0.937	0.017
	Posterior Proximal	0.892	-0.029	0.650	0.098
	Posterior Distal	0.871	-0.035	0.678	-0.089
	Lateral Proximal	0.372	0.191	0.427	0.170
	Lateral Distal	0.838	0.044	0.969	-0.008
Phase 2	Anterior Proximal	0.849	0.041	0.525	-0.136
	Anterior Distal	0.797	-0.055	0.913	-0.024
	Medial Proximal	0.799	-0.055	0.395	0.182
	Medial Distal	0.864	-0.037	0.892	-0.029
	Posterior Proximal	0.847	-0.042	0.751	0.068
	Posterior Distal	0.893	-0.029	0.760	-0.066

	Lateral Proximal	0.602	0.112	0.542	0.131
	Lateral Distal	0.933	-0.018	0.959	-0.011
Phase 3	Anterior Proximal	0.714	0.079	0.523	-0.137
	Anterior Distal	0.695	-0.084	0.867	-0.036
	Medial Proximal	0.763	0.065	0.235	0.252
	Medial Distal	0.581	0.119	0.822	0.048
	Posterior Proximal	0.882	0.032	0.522	0.137
	Posterior Distal	0.914	-0.023	0.994	0.002
	Lateral Proximal	0.617	0.108	0.100	0.343
	Lateral Distal	0.893	0.029	0.902	-0.027

Appendix 16:Correlations between Pressure and PEQ

Hands Off (Average Interface Pressure & PEQ)											
	Correlations:		Utility	Appearance	Sounds	Residual Limb Health	Perceived Response	Frustration	Social Burden	Ambulation	Well Being
Phase 1	Anterior Proximal	r	0.204	0.4	0.016	0.054	-0.002	0.196	0.367	0.31	0.102
		p	0.339	0.053	0.942	0.804	0.993	0.359	0.078	0.14	0.635
	Anterior Distal	r	**0.438**	**0.413**	**0.434**	0.261	0.398	0.294	**0.598**	**0.405**	0.293
		p	**0.032**	**0.045**	**0.034**	0.218	0.054	0.163	**0.002**	**0.05**	0.165
	Medial Proximal	r	0.187	0.343	0.163	0.26	0.068	0.358	**0.407**	0.26	0.054
		p	0.38	0.101	0.447	0.22	0.754	0.086	**0.048**	0.221	0.802
	Medial Distal	r	0.341	**0.427**	**0.422**	0.055	0.392	**0.409**	**0.438**	**0.468**	0.318
		p	0.103	**0.037**	**0.04**	0.798	0.058	**0.047**	**0.032**	**0.021**	0.13
	Posterior Proximal	r	0.328	0.349	0.24	0.111	0.258	0.342	**0.502**	**0.409**	0.272
		p	0.117	0.095	0.259	0.606	0.223	0.101	**0.013**	**0.047**	0.198
	Posterior Distal	r	0.112	0.232	0.184	-0.207	0.083	-0.026	0.258	0.208	0.119
		p	0.603	0.275	0.39	0.333	0.698	0.903	0.223	0.33	0.579
	Lateral Proximal	r	0.296	0.402	-0.049	0.214	-0.067	0.331	**0.444**	**0.417**	0.15
		p	0.16	0.052	0.819	0.316	0.757	0.114	**0.03**	**0.042**	0.484
	Lateral Distal	r	0.087	0.093	0.037	-0.199	0.038	-0.162	0.292	0.153	0.015
		p	0.687	0.665	0.864	0.35	0.861	0.45	0.166	0.474	0.945
Phase 2	Anterior Proximal	r	-0.134	0.271	0.058	-0.138	-0.047	0.011	0.123	0.14	-0.142
		p	0.532	0.2	0.789	0.521	0.829	0.96	0.567	0.514	0.508
	Anterior Distal	r	0.254	0.316	0.287	0.032	0.248	0.104	0.382	0.18	0.126
		p	0.231	0.132	0.175	0.881	0.243	0.629	0.065	0.401	0.558
	Medial Proximal	r	0.341	**0.427**	**0.422**	0.055	0.392	**0.409**	**0.438**	**0.468**	0.318
		p	0.103	**0.037**	**0.04**	0.798	0.058	**0.047**	**0.032**	**0.021**	0.13
	Medial Distal	r	0.196	0.396	0.37	-0.031	0.311	0.296	0.224	0.295	0.159
		p	0.358	0.056	0.075	0.886	0.139	0.16	0.292	0.162	0.458
	Posterior	r	0.046	0.237	0.101	-0.112	0.106	0.167	0.244	0.188	0.014

	Proximal	p	0.831	0.264	0.639	0.601	0.622	0.436	0.25	0.379	0.948
	Posterior Distal	r	-0.081	0.152	0.104	-0.324	0.018	-0.153	0.075	0.05	-0.058
		p	0.706	0.477	0.628	0.123	0.933	0.475	0.728	0.815	0.788
	Lateral Proximal	r	0.11	0.365	-0.017	0.066	-0.151	0.23	0.216	0.188	-0.058
		p	0.61	0.079	0.939	0.758	0.481	0.279	0.312	0.38	0.787
	Lateral Distal	r	-0.101	0.035	-0.019	-0.317	-0.009	-0.294	0.118	-0.031	-0.177
		p	0.64	0.871	0.932	0.131	0.967	0.164	0.584	0.886	0.409
Phase 3	Anterior Proximal	r	0.073	0.253	0.042	0.105	0.087	0.146	0.325	0.292	-0.003
		p	0.735	0.233	0.846	0.624	0.684	0.497	0.122	0.166	0.988
	Anterior Distal	r	0.316	0.354	0.335	0.024	0.337	0.206	**0.515**	0.324	0.236
		p	0.132	0.09	0.109	0.912	0.107	0.334	**0.01**	0.122	0.267
	Medial Proximal	r	0.109	0.201	-0.065	0.137	-0.039	0.217	0.378	0.2	-0.036
		p	0.612	0.346	0.763	0.524	0.855	0.309	0.069	0.35	0.869
	Medial Distal	r	0.354	**0.431**	0.346	0.216	0.353	0.32	**0.482**	**0.492**	0.354
		p	0.09	**0.036**	0.097	0.31	0.09	0.127	**0.017**	**0.015**	0.089
	Posterior Proximal	r	0.246	0.313	0.026	0.06	0.116	0.297	**0.456**	0.357	0.165
		p	0.247	0.137	0.904	0.78	0.588	0.158	**0.025**	0.087	0.442
	Posterior Distal	r	0.135	0.215	0.149	-0.142	0.123	-0.004	0.332	0.22	0.094
		p	0.529	0.313	0.488	0.509	0.566	0.987	0.113	0.303	0.662
	Lateral Proximal	r	0.227	0.388	0.027	0.203	-0.051	0.36	0.362	0.315	0.012
		p	0.286	0.061	0.899	0.342	0.814	0.084	0.082	0.134	0.955
	Lateral Distal	r	0.094	0.078	-0.007	-0.169	0.071	-0.153	0.295	0.108	-0.035
		p	0.662	0.717	0.976	0.428	0.741	0.474	0.161	0.616	0.872

Hands On (Average Interface Pressure & PEQ)											
	Correlations:		Utility	Appearance	Sounds	Residual Limb Health	Perceived Response	Frustration	Social Burden	Ambulation	Well Being
Phase 1	Anterior Proximal	r	0.011	-0.242	-0.078	0.252	0.067	0.029	**-0.53**	-0.264	-0.167
		p	0.958	0.254	0.717	0.235	0.755	0.895	**0.008**	0.213	0.434
	Anterior Distal	r	0.064	0.012	0.084	**0.539**	0.071	0.149	-0.357	-0.053	-0.277
		p	0.767	0.956	0.695	**0.007**	0.742	0.488	0.087	0.805	0.19
	Medial Proximal	r	-0.082	-0.171	-0.038	0.296	-0.025	-0.078	**-0.483**	-0.244	**-0.409**
		p	0.702	0.423	0.859	0.16	0.909	0.717	**0.017**	0.251	**0.047**
	Medial Distal	r	0.103	0.054	0.095	0.385	0.064	0.151	-0.225	0.059	-0.3
		p	0.633	0.802	0.657	0.063	0.768	0.482	0.291	0.784	0.154
	Posterior Proximal	r	-0.114	-0.139	0.011	0.201	-0.029	-0.003	**-0.41**	-0.185	-0.398
		p	0.597	0.518	0.959	0.347	0.894	0.99	**0.047**	0.386	0.054
	Posterior Distal	r	-0.056	-0.185	-0.047	0.258	0.079	0.082	**-0.432**	-0.234	-0.253
		p	0.796	0.386	0.828	0.224	0.713	0.704	**0.035**	0.271	0.233
	Lateral Proximal	r	0.097	-0.058	0.071	0.292	-0.091	-0.196	-0.394	-0.117	-0.317
		p	0.651	0.79	0.741	0.166	0.673	0.358	0.057	0.587	0.131
	Lateral Distal	r	-0.042	-0.214	0.036	0.111	-0.027	0.001	-0.145	-0.097	-0.146
		p	0.846	0.315	0.867	0.607	0.9	0.995	0.498	0.653	0.496
Phase 2	Anterior Proximal	r	-0.058	-0.193	-0.059	0.352	0.146	0.047	**-0.577**	-0.342	-0.219
		p	0.787	0.367	0.784	0.092	0.496	0.827	**0.003**	0.101	0.304
	Anterior Distal	r	0.014	-0.034	0.091	**0.543**	0.112	0.106	**-0.484**	-0.208	-0.333
		p	0.948	0.875	0.671	**0.006**	0.603	0.622	**0.017**	0.33	0.112
	Medial Proximal	r	0.103	0.054	0.095	0.385	0.064	0.151	-0.225	0.059	-0.3
		p	0.633	0.802	0.657	0.063	0.768	0.482	0.291	0.784	0.154
	Medial Distal	r	0.106	0.086	0.113	**0.424**	0.095	0.138	-0.252	0.034	-0.314
		p	0.621	0.691	0.6	**0.039**	0.658	0.52	0.235	0.874	0.135
	Posterior	r	-0.062	-0.062	0.047	0.322	0.037	0.039	**-0.405**	-0.163	-0.395

	Proximal	p	0.775	0.773	0.827	0.125	0.862	0.855	**0.05**	0.446	0.056
	Posterior Distal	r	-0.023	-0.094	0.022	0.366	0.103	0.074	**-0.45**	-0.219	-0.25
		p	0.914	0.662	0.918	0.079	0.632	0.73	**0.027**	0.304	0.239
	Lateral Proximal	r	0.106	0.019	0.11	0.357	-0.006	-0.107	-0.375	-0.097	-0.324
		p	0.622	0.928	0.609	0.087	0.977	0.619	0.071	0.653	0.123
	Lateral Distal	r	-0.039	-0.169	0.071	0.208	0.029	0.05	-0.192	-0.109	-0.172
		p	0.858	0.431	0.741	0.329	0.892	0.818	0.368	0.611	0.423
Phase 3	Anterior Proximal	r	-0.158	-0.264	-0.143	0.203	0.143	0.06	**-0.427**	-0.252	-0.218
		p	0.461	0.212	0.506	0.341	0.504	0.779	**0.037**	0.235	0.307
	Anterior Distal	r	0.029	-0.065	0.067	**0.494**	0.116	0.128	**-0.536**	-0.254	-0.337
		p	0.892	0.763	0.754	**0.014**	0.588	0.552	**0.007**	0.23	0.107
	Medial Proximal	r	-0.113	-0.154	-0.093	0.261	0.001	-0.068	**-0.428**	-0.211	-0.375
		p	0.6	0.473	0.664	0.218	0.995	0.752	**0.037**	0.322	0.071
	Medial Distal	r	0.106	0.06	0.101	0.393	0.081	0.135	-0.242	0.046	-0.289
		p	0.624	0.78	0.638	0.058	0.706	0.531	0.255	0.832	0.171
	Posterior Proximal	r	-0.063	-0.094	0.014	0.288	0.03	0.039	-0.32	-0.096	-0.316
		p	0.771	0.664	0.948	0.173	0.889	0.856	0.128	0.656	0.132
	Posterior Distal	r	0.011	-0.07	0.022	0.347	0.1	0.09	-0.371	-0.131	-0.237
		p	0.958	0.747	0.918	0.096	0.641	0.676	0.075	0.542	0.265
	Lateral Proximal	r	0.121	0.032	0.079	0.31	-0.016	-0.11	-0.341	-0.048	-0.307
		p	0.572	0.883	0.712	0.14	0.943	0.61	0.103	0.822	0.145
	Lateral Distal	r	-0.038	-0.214	0.063	0.151	-0.029	0.003	-0.203	-0.115	-0.186
		p	0.861	0.315	0.769	0.482	0.893	0.991	0.341	0.591	0.383

Hands Off (Peak Interface Pressure & PEQ)											
	Correlations:		Utility	Appearance	Sounds	Residual Limb Health	Perceived Response	Frustration	Social Burden	Ambulation	Well Being
Phase 1	Anterior Proximal	r	0.239	0.37	0.071	0.363	0.112	0.295	0.375	0.282	0.04
		p	0.26	0.076	0.74	0.082	0.602	0.162	0.071	0.183	0.854
	Anterior Distal	r	**0.467**	0.302	0.361	0.381	**0.408**	0.308	**0.562**	0.355	0.316
		p	**0.021**	0.151	0.083	0.066	**0.048**	0.143	**0.004**	0.089	0.132
	Medial Proximal	r	0.255	0.284	0.09	**0.483**	0.174	0.376	0.203	0.096	0.033
		p	0.23	0.179	0.675	**0.017**	0.415	0.07	0.341	0.655	0.879
	Medial Distal	r	0.375	**0.471**	**0.427**	0.145	**0.433**	**0.481**	**0.488**	**0.551**	0.352
		p	0.071	**0.02**	**0.037**	0.499	**0.035**	**0.017**	**0.015**	**0.005**	0.092
	Posterior Proximal	r	0.391	**0.485**	0.261	0.231	0.312	0.358	**0.528**	**0.501**	0.327
		p	0.059	**0.016**	0.218	0.278	0.138	0.085	**0.008**	**0.013**	0.119
	Posterior Distal	r	0.096	0.231	0.213	-0.214	0.107	0.071	0.304	0.279	0.129
		p	0.656	0.279	0.318	0.315	0.617	0.742	0.149	0.186	0.549
	Lateral Proximal	r	0.286	0.284	-0.044	0.144	0.154	0.259	**0.52**	**0.46**	0.304
		p	0.176	0.179	0.837	0.503	0.472	0.222	**0.009**	**0.024**	0.149
	Lateral Distal	r	0.006	0.017	0.038	-0.163	0.144	-0.181	0.27	0.11	-0.019
		p	0.978	0.937	0.86	0.446	0.502	0.398	0.203	0.608	0.93
Phase 2	Anterior Proximal	r	0.276	0.088	0.068	0.008	0.116	0.18	0.088	-0.064	-0.219
		p	0.193	0.683	0.754	0.969	0.589	0.4	0.682	0.765	0.304
	Anterior Distal	r	0.272	0.294	0.035	0.227	0.15	0.342	0.234	0.193	-0.333
		p	0.198	0.163	0.869	0.286	0.485	0.102	0.27	0.367	0.112
	Medial Proximal	r	0.16	0.071	0.217	0.111	0.17	-0.003	-0.115	-0.071	-0.3
		p	0.455	0.743	0.307	0.606	0.427	0.987	0.591	0.743	0.154
	Medial Distal	r	**0.407**	0.374	0.108	**0.419**	0.349	0.284	0.345	0.162	-0.314
		p	**0.048**	0.072	0.616	**0.041**	0.095	0.179	0.099	0.45	0.135
	Posterior	r	0.326	0.104	0.004	0.188	0.183	0.32	0.306	0.114	-0.395

	Proximal	p	0.12	0.63	0.987	0.379	0.392	0.128	0.146	0.596	0.056
	Posterior Distal	r	0.12	0.052	-0.363	0.074	-0.119	0.109	0.121	-0.061	-0.25
		p	0.577	0.81	0.081	0.73	0.581	0.613	0.575	0.776	0.239
	Lateral Proximal	r	0.312	-0.016	0.019	0.059	0.162	0.38	0.272	0.159	-0.324
		p	0.138	0.94	0.931	0.785	0.449	0.067	0.199	0.459	0.123
	Lateral Distal	r	-0.09	-0.057	-0.224	0.117	-0.256	0.108	-0.018	-0.162	-0.172
		p	0.675	0.79	0.292	0.586	0.227	0.614	0.935	0.451	0.423
Phase 3	Anterior Proximal	r	0.184	-0.014	0.058	-0.15	0.044	0.081	0.099	-0.141	-0.218
		p	0.39	0.949	0.789	0.483	0.839	0.707	0.645	0.511	0.307
	Anterior Distal	r	0.312	0.246	-0.041	0.272	0.109	0.411	0.315	0.239	-0.337
		p	0.138	0.246	0.848	0.199	0.611	0.046	0.134	0.261	0.107
	Medial Proximal	r	0.147	-0.052	0.219	-0.014	0.121	0.15	-0.083	-0.017	-0.375
		p	0.492	0.81	0.304	0.949	0.574	0.484	0.701	0.939	0.071
	Medial Distal	r	0.465	0.354	0.218	0.518	0.53	0.563	0.594	0.38	-0.289
		p	0.022	0.09	0.307	0.01	0.008	0.004	0.002	0.067	0.171
	Posterior Proximal	r	0.342	0.019	0.13	0.112	0.288	0.424	0.377	0.116	-0.316
		p	0.102	0.928	0.544	0.602	0.173	0.039	0.069	0.59	0.132
	Posterior Distal	r	0.175	0.08	-0.255	0.062	0.005	0.258	0.23	0.034	-0.237
		p	0.413	0.711	0.228	0.774	0.983	0.223	0.279	0.873	0.265
	Lateral Proximal	r	0.131	-0.155	-0.043	-0.043	0.076	0.323	0.183	0.019	-0.307
		p	0.541	0.469	0.843	0.843	0.725	0.124	0.392	0.932	0.145
	Lateral Distal	r	0.102	0.07	0.041	0.134	0.015	0.268	0.138	0	-0.186
		p	0.635	0.744	0.849	0.532	0.944	0.205	0.521	0.999	0.383

Hands On (Peak Interface Pressure & PEQ)											
	Correlations:		Utility	Appearance	Sounds	Residual Limb Health	Perceived Response	Frustration	Social Burden	Ambulation	Well Being
Phase 1	Anterior Proximal	r	0.121	-0.26	-0.155	0.133	-0.02	-0.017	**-0.404**	-0.102	-0.124
		p	0.573	0.22	0.468	0.536	0.926	0.938	**0.05**	0.635	0.562
	Anterior Distal	r	0.047	0.037	0.042	**0.42**	0.144	0.204	-0.276	-0.099	-0.301
		p	0.829	0.863	0.845	**0.041**	0.502	0.338	0.192	0.644	0.153
	Medial Proximal	r	0.012	0.061	0.005	0.271	0.081	0.053	-0.171	-0.033	**-0.433**
		p	0.956	0.776	0.981	0.2	0.706	0.804	0.424	0.877	**0.035**
	Medial Distal	r	0.122	0.134	0.131	0.357	0.1	0.146	-0.16	0.101	-0.338
		p	0.57	0.534	0.541	0.087	0.641	0.497	0.456	0.639	0.107
	Posterior Proximal	r	-0.093	-0.146	-0.103	0.105	-0.087	-0.094	-0.362	-0.119	-0.316
		p	0.667	0.497	0.633	0.626	0.686	0.661	0.082	0.58	0.132
	Posterior Distal	r	-0.068	-0.207	-0.063	0.186	0.103	0.09	-0.401	-0.246	-0.316
		p	0.752	0.331	0.77	0.384	0.631	0.674	0.052	0.246	0.132
	Lateral Proximal	r	0.014	-0.107	0.096	0.058	-0.218	-0.363	-0.269	-0.122	**-0.421**
		p	0.947	0.617	0.654	0.787	0.307	0.081	0.203	0.57	**0.041**
	Lateral Distal	r	-0.11	-0.313	0.026	-0.065	-0.156	-0.195	-0.079	-0.158	-0.276
		p	0.609	0.136	0.904	0.764	0.467	0.362	0.715	0.459	0.191
Phase 2	Anterior Proximal	r	-0.023	-0.317	-0.155	0.227	0.03	0.025	**-0.566**	-0.278	-0.269
		p	0.915	0.132	0.47	0.287	0.889	0.908	**0.004**	0.188	0.204
	Anterior Distal	r	-0.016	-0.02	0.06	**0.455**	0.143	0.161	**-0.429**	-0.222	**-0.377**
		p	0.94	0.924	0.782	**0.025**	0.504	0.452	**0.037**	0.298	**0.07**
	Medial Proximal	r	-0.023	0.097	0.058	0.361	0.079	0.008	-0.26	-0.059	**-0.49**
		p	0.915	0.653	0.788	0.083	0.715	0.97	0.22	0.784	**0.015**
	Medial Distal	r	0.119	0.148	0.132	0.377	0.116	0.136	-0.183	0.069	-0.351
		p	0.581	0.49	0.538	0.07	0.59	0.528	0.391	0.748	0.093
	Posterior	r	-0.086	-0.099	-0.03	0.233	0.051	0.042	-0.374	-0.167	-0.399

	Proximal	p	0.691	0.647	0.889	0.273	0.812	0.847	0.072	0.437	0.054
	Posterior Distal	r	-0.015	-0.122	-0.029	0.285	0.124	0.09	**-0.423**	-0.21	-0.279
		p	0.944	0.569	0.891	0.177	0.564	0.675	**0.039**	0.325	0.187
	Lateral Proximal	r	-0.033	-0.078	0.102	0.182	-0.152	-0.249	-0.294	-0.121	**-0.481**
		p	0.88	0.719	0.635	0.394	0.478	0.241	0.163	0.573	**0.017**
	Lateral Distal	r	-0.099	-0.236	0.083	0.106	-0.006	-0.059	-0.131	-0.159	-0.283
		p	0.646	0.267	0.699	0.622	0.978	0.784	0.543	0.457	0.18
Phase 3	Anterior Proximal	r	-0.104	-0.367	-0.174	0.103	0.065	-0.016	**-0.465**	-0.239	-0.233
		p	0.629	0.078	0.416	0.633	0.764	0.943	**0.022**	0.261	0.274
	Anterior Distal	r	-0.048	-0.064	0.056	**0.436**	0.185	0.194	**-0.44**	-0.303	**-0.451**
		p	0.823	0.766	0.794	**0.033**	0.386	0.363	**0.031**	0.149	**0.027**
	Medial Proximal	r	0.016	0.095	0.049	0.322	0.128	0.081	-0.228	-0.013	**-0.42**
		p	0.942	0.658	0.821	0.126	0.55	0.706	0.283	0.953	**0.041**
	Medial Distal	r	0.11	0.132	0.121	0.359	0.103	0.127	-0.167	0.088	-0.339
		p	0.61	0.537	0.572	0.085	0.631	0.555	0.434	0.684	0.105
	Posterior Proximal	r	-0.071	-0.094	-0.029	0.264	0.068	0.056	-0.266	-0.065	-0.297
		p	0.742	0.662	0.892	0.213	0.752	0.795	0.209	0.762	0.159
	Posterior Distal	r	0.011	-0.132	-0.048	0.251	0.087	0.055	-0.376	-0.146	-0.244
		p	0.957	0.538	0.825	0.238	0.687	0.799	0.07	0.495	0.251
	Lateral Proximal	r	0.067	-0.036	0.092	0.208	-0.109	-0.206	-0.216	0.01	-0.39
		p	0.757	0.868	0.67	0.33	0.613	0.333	0.31	0.962	0.059
	Lateral Distal	r	-0.161	-0.255	0.063	0.023	-0.116	-0.181	-0.112	-0.177	-0.304
		p	0.453	0.23	0.771	0.915	0.588	0.398	0.601	0.408	0.148