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## Development of software to estimate pressures on the residual limbs of amputees by means of a pylon mounted transducer

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DEVELOPMENT OF SOFTWARE TO ESTIMATE PRESSURES ON THE  
RESIDUAL LIMBS OF AMPUTEES BY MEANS OF A PYLON  
MOUNTED TRANSDUCER

by

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Bachelor of Technology  
Bapatla Engineering College, India  
2007

A thesis submitted in partial fulfillment  
of the requirements for the

**Master of Science Degree in Mechanical Engineering**  
**Department of Mechanical Engineering**  
**Howard R. Hughes College of Engineering**

**Graduate College**  
**University of Nevada, Las Vegas**  
**December 2010**

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**THE GRADUATE COLLEGE**

We recommend the thesis prepared under our supervision by

**Malli kartheek Yalamanchili**

entitled

**Development of Software to Estimate Pressures on the Residual Limbs  
of Amputees by Means of a Pylon Mounted Transducer**

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**December 2010**

## ABSTRACT

### **Development of Software to Estimate Pressures on the Residual Limbs of Amputees by Means of a Pylon Mounted Transducer**

by

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The alignment of prosthesis has been recognized as one of the main factors that determine successful prosthetic outcomes for trans-tibial amputees. Alignment is defined as the relative position and orientation of the prosthetic components. Misalignment can result in changes in the position and orientation of the joints of the leg and moments experienced by them during gait, increases in energy use, and discomfort or even tissue breakdown at the socket/stump interface. Hence it is very important to align the prosthesis in correct manner. Gait analysis can be used to examine the effects of incorrect alignment of the prosthesis during gait.

Gait analysis studies involve continuous curves of data measured over a gait cycle. The data may include ground reaction force, and the kinematic and kinetic properties of the ankle, knee, and hip joints (angles, angular velocities and accelerations, moments and powers). The objective of this thesis is to develop software that allows a tri-axial transducer to be utilized in a clinical setting to measure the forces and moments that are transmitted from the foot through the pylon to the socket and the residual limb. By placing a transducer on the pylon at the base of a socket, the forces and moments that are directed into the socket can be measured. It can be hypothesized that this information can

be used to estimate the intra-socket pressures that occur between the walls of the socket and the residual limb (1). If alignment of the components is altered, then data from transducer can be used to determine if the forces, moments, loading rates, and impulse transmitted to the residual limb inside the socket change. A means would then exist for measuring the effect that different alignments might have on the residual limb.

In the thesis research, a JR3 tri-axial transducer that measures forces and moments in three dimensions at the base of the socket and Tekscan software that measures pressures inside the socket will be used for collecting data. The thesis will examine the development and validation of software and a GUI interface that facilitates the processing of the transducer and pressure sensor data. Goals are to develop a software package that 1.) Permits display of the effect of alignment on the transducer measurements and pressure transmitted to the residual limb in a manner useful in a clinical or research setting and 2.) Produces an output file of the data in a format that lends itself to analysis using standard statistical package. The development of this software involves designing a means for dividing a continuous stream of transducer and pressure data into individual gait cycles, processing the data for analysis, and displaying it by means of the software. Data on gait can be challenging to analyze since many variables vary as a function of walking speed, and different types of research questions require processing of the time domain using different techniques. Because the data consist of forces and moments about the three axes of the transducer (6 variables), and pressure sensor data (pressure or force), the GUI interface must offer the user some flexibility with respect to choice of variables for analysis while still being easy to use. The processed data also must be formatted in a manner that facilitates use in statistical analysis packages such as SPSS, SYSTAT or

options available in EXCEL. MATLAB will be used to develop a software code that can be exported out of MATLAB and installed on a laptop.

Previous research suggests that the data produced by the software can be used to estimate the pressures acting on the residual limb by means of regression analysis (1). The forces and moments constitute the independent variables, and the pressure represents the dependent variable. If this can be verified, then the effects of alignment changes on the residual limb of an amputee can be estimated.

This thesis will focus on development of the software and GUI interface. In it, 1) transducer measurements will be compared with force plate measurements using an experimental design to validate the transducer; 2) the design, development, and operation of the software will be explained, and 3) use of the software will be validated with an example. If an amputee subject can be recruited, the example will involve pressure data obtained from a residual limb and will examine the relationship between transducer measurements and pressure measurements. If an amputee subject cannot be recruited, simulated gait will be used in the example. The protocol involving amputee subjects has been approved by the IRBs of both UNLV and the US Army Medical Research and Materiel Command, who is funding the study. Should an amputee subject be recruited, Informed Consent will be administered.

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## CHAPTER 1

### INTRODUCTION AND BACKGROUND

#### 1.1 Purpose

The purpose of the following research was to develop software that allows a commercial tri-axial transducer mounted on the pylon of a trans-tibial prosthesis directly below the socket to be utilized in a clinical setting to measure the outcomes of prosthetic intervention including intra-socket pressures and; gait parameters (including peak ground reaction forces, loading rates, crossover times, and impulse) and to validate the software. One of the requirements of the software was that it must facilitate analyses to be undertaken to determine if the forces and moments occurring at the base of the socket can be used to estimate intra-socket pressures.

#### 1.2 Background

A major problem faced during war time is rehabilitating military personnel who have become amputees. Amputations are a very common consequence of modern warfare. During the Civil War and World War II the official statistics indicate that 35,905 amputations were performed, among which 13,095 were lower limb amputations. Most of them were below the knee.

Amputation is not necessarily a career ending injury, especially with the advent of new techniques in prosthetics and evolution of prosthetic devices that enable soldiers to perform at a higher level than they could in the past. The army has a rehabilitation program for soldiers who sustained traumatic amputations on the battle field. The goal of

this program is to give amputees the option to remain on or return to active duty and complete their military careers.

During World War II the United States military established five “amputation centers” (Bushnell General Hospital in Brigham City, Utah; Lawson General Hospital in Atlanta, Georgia; McCloskey General Hospital in Temple, Texas; Percy Jones General Hospital in Battle Creek, Michigan; and Walter Reed General Hospital in Washington, DC), because of the enormous number of amputees. Walter Reed General Hospital was the main center. Training of therapists, prosthetists and medical officers was pursued.

The socket is a critical component for prosthetic performance, which achieves a coupling between the prosthesis and the transtibial residual limb, and is the sole means of load transfer between the prosthesis and the residual limb. The correct fitting of prosthetic sockets is very important to achieve stability, comfort and efficient control for mobility.

### 1.3 Problem

The problems that are being examined in this research concern the utility of the pylon-mounted triaxial transducer 1) to determine the effect that different designs of the prosthetic components that occur below the socket have on the forces and moments transmitted to the socket, 2) to determine the effect that different types of activities or terrain have on the forces and moments transmitted to the socket. The main components of the trans-tibial prosthetic leg are the socket, interface between the socket and residual limb, suspension, foot and various shock absorbing devices. For the transfemoral prosthesis, all of these components are found plus knees. By examining these problems it

may be possible to determine if the triaxial transducer can be utilized to evaluate the effectiveness of alternative component designs and improve the performance of lower limb prostheses. It may be possible to better design prostheses to meet the requirements of amputees when undertaking activities in their daily lives, including a return to active military duty.

#### 1.4 Solution

Gait analysis is one of the best ways to determine the effectiveness of the prosthetic components. For analysis of gait forces and moments developed in the socket are to be measured. Research plan is to measure forces and moments directly with the use of tri-axial transducer attached to the pylon. Tri-axial transducer measures forces and moments and the measured data can be used for estimating the intra-socket pressures as a function of these forces and moments. Estimation of intra socket pressures will help in deciding the most effective component.

## CHAPTER 2

### LITERATURE REVIEW

Prosthesis is used to restore appearance and functional mobility to individuals following amputation. Prosthetics research seeks to determine characteristics that are important to the function and comfort of lower-limb prostheses. A coupling between the prosthesis and residual limb is achieved by the, which has to be designed properly to achieve satisfactory load transmission, stability, and efficient control for mobility. Improved understanding of the interaction between the prosthetic socket and the residual limb is fundamental to achieving these goals.

Surveys have shown that amputees complain about their prostheses being uncomfortable. It is not uncommon for amputees to develop skin problems on the residual limb, such as blisters, cysts, edema, skin irritation, and dermatitis. Discomfort and skin problems are usually attributed to a poor socket fit. To prevent discomfort and skin damage while maintaining daily activities, great care should be taken in the design and fitting of a prosthetic socket in order that the stresses at the residual limb/socket interface can be distributed so that they not only provide satisfactory load transmission, stability, and efficient control for mobility, but also avoid overstressing residual limb soft tissues and causing injury.

Further advancement of prosthetic fitting techniques can improve the amputee's comfort and acceptance of the prosthesis. Improved understanding of the transmission of forces and moments to the residual limb through the socket can advance the science of socket fitting. The fitting process requires obtaining data by several means, including questioning the patient to learn what he or she is experiencing and, listening to verbal

reports from the patient. As an understanding of residual limb anatomy and physiology and the bio-mechanical principles of socket-fitting evolved following World War II, improved socket designs, such as patellar tendon bearing (PTB) transtibial socket, and the quadrilateral transfemoral suction socket appeared. By the 1980's the silicon suction socket and ICEROSS liner were developed and employed the so-called "hydrostatic weight bearing principle" and the "total surface bearing (TSB)" concept.

## 2.1 Measurements using a Tri-axial Transducer

Force platforms or force plates are instruments that measure the ground reaction forces generated by a body standing on or moving across them, and are used in gait labs to quantify balance, gait and other parameters of the biomechanics of walking or movement. The most common areas of application are in medicine and sports. Applications of force plate measurements occur in clinical research, gait analysis, balance control/evaluation and sports performance evaluation.

Many researchers have used force plates to obtain a clinical evaluation of gait. Different types of gaits were classified with the help of force plate by Jacobs *et al.* (1972) who analyzed the vertical component of the forces exerted in normal walking to diagnosis pathologies of the hip joints. Yamashita and Katoh (1976) used a specially designed force plate to analyze the moving pattern of the point of application of the vertical component of the ground reaction force resultant during level walking.

With force plates, inverse dynamic methods can be used to estimate the loads experienced by the prosthetic components. Force plates have disadvantages, however. The drawbacks of using force plates are that only one or two steps of walking can usually



be measured. Targeting force-plate (aiming the foot to ensure that it lands directly on the plate) can produce an ‘un-natural’ or exaggerated gait. In addition, loads cannot be measured easily using force plates when walking on uneven terrain. Force measuring transducers mounted on the pylon of prosthesis can overcome these problems. There is no need for the subject to walk in restricted path. Joint angle goniometers may be fitted obviating the need for cameras except when forces and moments are required relative to the ground reference system, which simplifies data retrieval and processing. Also, several consecutive strides may be examined. A pylon transducer replaces part of the tubular section of the prosthesis.

Berne *et al.*, (1975) designed and built a short pylon transducer at the Bioengineering Unit, University of Strathclyde. In addition to three moments and longitudinal force, shear forces were also directly measured. To avoid non-linearity of readings, the transducer was machined as one component.

Boccardi *et al.*, (1977) suggested a technique of displaying the data from a force plate, namely the “Butterfly Diagram”, in which the resultant force vectors, displayed on a storage screen represented the projection, onto the sagittal plane, of the ground reaction force with its magnitude, inclination, and point of application clearly shown. Cunningham and Brown (1952) described the use of Force Plate and Pylon Transducers in bio mechanical analysis of gait in humans.

Frossard *et al.*, 2003 developed and tested a device for direct measurement of force and moments in the prosthetic limb of transfemoral amputees during daily activities. One female transfemoral amputee participated in the study. The prosthesis consisted an ischial containment socket, the transducer, an Otto-Bock safety knee, and a solid-ankle, cushion

heel (SACH) foot. The six-channel commercial transducer (Model 45E15A; JR3 Inc, Woodland, CA) was used along with a wireless modem to transfer data to a laptop. Results showed that the transducer is a superior technique to previously used techniques for measuring the forces and moments. The superiority of it is due to the combination of the direct measurement of the loading, the size of the transducer, and the absence of cables to transmit the data.

An experimental surgical method known as osseointegration attempts to solve a number of problems associated with conventional sockets, including insufficient length or fluctuations in volume of the residual limb. Osseo-integration is an alternative means of attaching prosthesis to the residual limb. It overcomes the problems caused by the prosthetic socket like pain in residual limb, and tissue break down, and is recognized to be well-suited for transfemoral amputees. Commercial transducers associated with wireless modems are particularly suitable for direct measurement of loads applied on socket of transfemoral amputees. Osseointegration has been found to help in reducing skin problems and pain as well as increasing the range of motion. The procedure involves surgery and rehabilitation. A common method of prosthesis fixation is to use titanium threaded implant that is inserted into the bone along with a coupling device that connects to the external components.

Lee *et al.*, (2006) studied the importance of load applied on the stem of the implanted fixation device and attempted to optimize the mechanical design of the fixation. A six-channel load transducer (Model 45E15A; JR3 Inc., Woodland, USA) and wireless modem were used to measure directly the 3-dimensional forces and moments applied to the abutment. Force and moment patterns of each gait cycle, the magnitudes and time of

occurrence of the local extrema of the loads, as well as impulses were analyzed. Loading on the abutment was measured when the amputees performed activities which included straight-line level walking, ascending and descending stairs and a ramp as well as walking around a circle. Results suggested that if level straight-line walking is considered to be the base line, the other five activities did not produce significant increase in loading when compared to the base line.

Lee *et al.*, (2007) studied the loading applied to the abutment during the rehabilitation process among the individuals with osseo-integrated prostheses. This study measured the loads acting on the abutment during level-walking among amputees fitted with an Osseo-integrated implant for over one year. A commercial six-channel transducer mounted between the abutment and the prosthetic knee was used to measure the load induced. The magnitude and the pattern of the loads and the moments were studied. The results presented in the paper showed that the load variation among the amputees was high in comparison to the step-by-step variation of every individual. This result suggested that the system should be custom designed for each amputee or the system should be applicable to a broad range of loads if the same standard is to be used for all amputees. In addition, the rehabilitation plan should be designed specifically for an amputee to provide the training for the load that will be experienced.

Since the procedure of Osseo-integration involves inserting a titanium implant and an abutment surgically, the rehabilitation process involves the application of incremental loads on the abutment to prepare the bone to tolerate the loads when the amputee walks. Studying the mechanical loads applied during the rehabilitation procedure helps to address the problems of mechanical failure of abutments and use an efficient

rehabilitation protocol. During the rehabilitation process, a set static load is applied and the stress is measured, thereby preparing the bone for tolerating the stresses likely to be generated in future during gait. An initial load of 200 N is applied initially, followed by incremental loads of 100 N per week over a period of 3 months. Lee *et al.*, (2008) used FE modeling to compare the effect of three different loading scenarios on predicted bone stresses adjacent to an Osseo-integrated implant for a trans-femoral amputee. The objective of this paper was to study the non-axial forces and moments in addition to the vertical forces that were developed. Since measurement using implanted sensors was not feasible, the study used Finite Element methods to predict the stresses in the bone adjacent to the implant. The data for the following loading cases were obtained using a pylon-mounted tri-axial transducer during independent walking- (1) forces applied on the long axis of the limb; (2) applied on the three axes corresponding to the “true” load measured simultaneously by a tri-axial load transducer; and (3) three-dimensional loads are measured by. The study reported that the first case produced relatively uniform stress distribution as compared to the second and third cases. The stresses measured in the second loading were found to be three times higher than in the first loading technique. Thus the study concludes that the rehabilitation program may be applying much higher stresses than expected. The paper suggested the use of a tri-axial load transducer to monitor three dimensional forces and moments to help improve the rehabilitation process.

Frossard *et al.*, (2010) studied the relevance of measuring the loads applied on osseo-integrated fixation during static load bearing exercises, using the load transducer. The main objective of the study was to introduce a three dimensional load and compare measurements from the transducer with those from a force plate. Previously a weigh scale

is used to measure the loads, which lacked precision, control. An alternative method of estimating loads is to use inverse dynamic methods, but the experimental results are not representative of the loads developed during the daily routine activity. Loading was directly measured with a kinetic recording system including a six-channel transducer. One trans-femoral amputee fitted with an osseo-integrated implant was asked to self-apply 10 kg, 20 kg, 40 kg and 80 kg loads on the fixation, using self-monitoring with the weighing scale. The JR3 transducer used in these studies represents a step in the evolution towards the development of sensors integrated into osseo-integration components which can be used by clinicians who are faced with the challenge of safely helping patients adapt to an osseo-integrated implant and the attached lower limb prosthesis.

## 2.2 Socket Pressure Sensors

Careful design and fitting of the prosthetic socket is necessary to prevent discomfort and skin trauma. One of the goals of socket design is to distribute pressures in a manner that the residual limb can tolerate without discomfort when the amputee goes about performing daily activities. Researchers have been working for the last 40 years to quantify the stresses at the socket-residual limb interface. A number of investigations have involved the experimental measurement of the stress and the application of finite element analysis modeling. The information gained has been used for the assessment and improvement of socket design and fitting, and has contributed to understanding the behavior of the prosthetic interface.

The clinical importance of knowing the pressures occurring at the socket interface have led to the development of a number of transducer devices that measure pressure. However, most of the devices are not suited for clinical use because they, protrude through holes drilled in the inner wall of the socket. This causes the physical displacement of flesh and also destroys the integrity of the socket. Appoldt *et al.* (1969) studied the socket pressures as a function of pressure transducer protrusion i.e the extent to which pressure measurements, presumably reflecting conditions at the residual limb-socket interface, are altered by the presence of a protruding pressure transducer. The apparatus consisted of pressure sensors capable of being mounted in either a flush or protruding configuration (Sensotec Division of Scientific Advances, Inc.; Model SA-SAM-7BW), and a second flush-mounted transducer (Microsystems Model No. 1003-0046), which was employed as an independent means of verification. Four above-knee amputees, equipped with quadrilateral total contact suction sockets were tested. Analysis of the data for level walking indicated that, generally, the protrusion gages recorded higher pressure values than those obtained from the flush gages.

Krouskop *et al.* (1987) measured the interface pressures in above knee sockets of amputee patients during the stance phase of the gait cycle. Eighteen above knee amputees were used as subjects for this study. Nine of them were fitted with rigid wall quadrilateral brim AK sockets, and five were fitted with Normal Shape Normal Alignment (NSNA) sockets without any discomfort. The remaining four subjects experienced discomfort with their prostheses. The pneumatic pressure transducers were selected in preference to a strain gauge or piezo electric devices, to measure interface pressures at multiple sites around the circumference. The pneumatic transducers were better able to isolate the

interface pressure from the total stress acting on the surface of the residual limb. Four to six arrays were attached to the inside of the socket with double faced pressure sensitive tape. Results indicated that with the quadrilateral socket, most of the loading occurred under the brim and varied around the circumference. In the NSNA socket, much of the tissue loading was in the proximal third of the socket. But the magnitudes of the pressures in well-fitting sockets of both types were similar. Thus magnitude of pressure in an above-knee socket may provide a more useful guide than distribution for predicting the fit of a socket.

Goh *et al.*, (2002) tried to evaluate the residual limb/socket interface pressure in amputees who were wearing a socket developed by a pressure casting system (PCast). The hydro static theory of socket design postulates that residual-limb/socket pressures should be uniform, or pressures profiles should show even distribution. Pascals law, the theory behind the hydrostatic socket, states that for a fluid at rest, the fluid pressure on any surface exerts a force perpendicular to that surface. In 1965 Murdoch introduced a pressure casting concept where fluid was used as a medium to apply uniform pressure around the residual limb. More traditional methods involve taking a plaster cast using no or minimal pressure applied by the hands during casting (Patellar-bearing or PTB sockets). But the traditional methods produce inconsistent results, and the sockets are sometimes unsatisfactory to the amputee. Five male unilateral transtibial amputees were research subjects for this study. The test sockets were fabricated with 16 pressure measurement sites four on each side (anterior, posterior, medial and lateral). Results showed that a hydrostatic pressure profile (i.e., uniform pressure) was not evident during standing or gait. This probably was due to the complex tissue morphology of the residual

limb (bone and soft tissue of varying stiffness), together with the variations in pressure occurring between the socket and residual limb during different phases of gait. However, despite these inconsistent pressure profiles, the PCast technique was able to produce sockets that fit comfortably for these five subjects.

Neumann *et al.*, (2005) developed a methodology for measuring and mapping of the pressures developed inside a comfortable ischial containment socket during gait. The study addressed several issues including 1) the extent to which pressures inside the socket can be measured, 2) how pressure data can be presented to facilitate comparison with psychophysical data concerning subjective pressure perception, 3) how well the pressure measurements agree with the predictions made by Radcliffe, who is considered to be the first engineer to develop a biomechanical model to explain socket pressures. The F-Socket system (Tekscan, Inc., South Boston, MA) was used for the measurement of pressures developed inside the socket. The F-socket sensor consists of 96 individual force sensing resistor (FSR) cells arranged in 16 rows and 6 columns. It is 0.28mm thick and very flexible. It can record pressure data from several consecutive steps. At least seven sequential steps at normal cadence can be recorded using older technology, and dozens of consecutive steps can be recorded with state-of-the-art systems. The sensor needs to be equilibrated and calibrated prior to collecting data. To analyze the pressure data, different areas of the sensors were windowed and average pressures over all the cells in the window were computed using the Tekscan software. Area peak and average window pressures were computed for five consecutive steps starting from the second step. Polar plots of average pressure versus location on the circumference of the residual limb were prepared using SYSTAT. The measured pressures were in general agreement with



Radcliffe's predictions. It was concluded that the pressure mapping could contribute valuable information on the distribution of pressure within an ischial containment socket. However, use of the F-Socket to measure pressure over an entire socket was relatively expensive and time consuming, and the limited number of sensor arrays that could be used at one time (two) made it impossible to measure all locations simultaneously.

Peng Dou *et al.*, (2006) studied the pressure distribution at the residual limb/socket interface in transtibial amputees during walking on stairs, slope and on non-flat surfaces such as roads which amputees encounter daily. It is very important to get the reliable quantitative data on the interface pressures that occur since they can lead to pressure ulcers and other trauma related pathologies. The authors used a portable pliance pressure distribution measuring system (Germany-Novel Electronics, Munich, Germany) that allowed dynamic, real-time (50 Hz), telemetric measurement of up to 90 pressure sites within any given prosthetic socket. Five sensor strips were used. The regions selected for pressure measurement were based on clinical interest and were chosen to produce minimal surface distortion of the sensors due to curvature of the socket. Results showed that (1) compared with normal gait on a level surface, when walking on stairs and a non-flat road the mean peak pressure (MP) and mean pressure level over 90% (MP90+) both increased at the patellar tendon. (2) The time in which pressure exceeded 90% of peak pressure (TP90+) changes remarkably during walking on stairs, slope and non-flat road relative to natural gait condition. (3) The pressure characteristics during normal gait on a level surface did not appear to be highly predictive of what occurs in the conditions of walking on stairs, slope and non-flat surfaces.

Frank *et al.* studied the local pressures experienced between residual limb and socket wall in the case of quadrilateral total contact suction sockets fitted to above knee amputees. Two types of transducer designs were utilized to measure pressure. One was commercially available semi conductor strain gage attached to a diaphragm. The other was a plunger piston-type force gage. The diaphragm design was found to have a greater range and sensitivity. Extensive testing has shown that it is under-damped and it cannot work reliably over large pressure gradient. The especially developed (piston) unit offers a readily altered pressure sensing area, mean readings independent of pressure gradient affects and appropriate (near critical) damping. Two subjects with above knee amputations were subjects in the study. Results showed that local intra-socket pressures are of limited value for use in alignment tool when the adjustments that to be made are small. Strain-gauge-type sensors were found to produce an undesirable response to point loading and piston-type sensors had to be kept clean to prevent hysteresis or jamming.

### 2.3 Tekscan

Highly reliable devices like force platforms have disadvantages because they can measure only a limited number of steps and are restricted to use in laboratory environments. They cannot be used on stairs or uneven terrain. Devices which move with the research subject and can be inserted in places like shoes or sockets offer an advantage. Force-Sensing Resistor (FSR) Sensors meet this requirement. After the development of grid-based pressure sensor technology in 1987, different sensors have been developed for a variety of industrial and medical applications. The F-scan Mobile system (Tekscan Inc., South Boston, MA, USA) has 960 different pressure-sensing

locations (sensels) and a spatial resolution of 4 sensels/cm<sup>2</sup> for studies of gait. It is placed in the insole of the shoe, or against the wall of a socket. The advantages of F-Scan are its use of multiple sensor cells for measuring the pressure distribution over an area and the dynamic response of a surface to loading.

Clinicians became increasingly interested in measuring in-shoe pressures that occur between the plantar surface of foot and shoe. McPoil *et al.* (1995) compared the reliability and validity of normal forces and pressure measurements obtained using two In-shoe plantar pressure measurement systems (EMED and F-Scan). EMED Pedar (Novel GmbH) hardware and analysis software were used to collect data from the EMED insole at a sampling rate of 50 Hz. EMED insole had 99 capacitance sensors and was 2mm thick. The F-Scan (Tekscan, Inc) hardware and analysis software, version 3.622, were used to collect data from F-Scan insole at a sampling rate of 50 Hz. For dynamic testing phase of the study four male subjects were selected. Calibration was done to both insole systems according to manufacturer's specifications before data collection. Results showed that EMED has linear response to applied loads with minimal error when compared with F-Scan insole. F-Scan demonstrated large amount of error especially for loads above 200 KPa. The EMED insole showed less creep than F-Scan insole during the application of a continuous and constant pressure. The dynamic testing conducted on EMED insole indicated high level of reliability than F-Scan insole. The results indicated that the reliability of F-Scan insole system is suspect.

Foot orthoses are used to redistribute pressure from painful regions of the plantar surface to pain-free regions of plantar surface in order to reduce the incidence of foot pain by increasing the surface area of plantar pressure distribution. Brown *et al.*, (1996)

used FSCAN sensor to determine the efficacy of pressure redistribution with Plastizote, Spenco, Cork, and a plastic foot orthosis as compared with no orthosis. It is very important to measure pressures at the shoe-foot interface when evaluating the efficacy of foot orthoses. FSCAN sensor (Tekscan, Boston, MA) was used for pressure measurement. Rose *et al.*, (1992) evaluated this system and assessed that FSCAN system “could be useful for making comparisons and evaluating changes in a well-controlled clinical study”. Ten normal subjects, three men and seven women participated in study. Subjects were asked to walk under five different conditions. The Plastizote orthoses were custom molded, Spenco, cork and plastic orthoses were appropriately sized, off-the-shelf models. Prior to collection of data subjects weight was entered into the FSCAN software to calibrate the sensors. The FSCAN software was used to calculate stance time and peak pressure for eight regions of the foot during each step of each walking trial. Results reported that foot orthoses can effectively redistribute pressure at the shoe-foot interface. The Plastizote, cork, and plastic orthoses had the potential benefit of relieving pressure at the forefoot, heel, and second through fifth metatarsal regions at the cost of increasing pressure at the midfoot region. Measurement reliability of the FSCAN sensor has to be improved.

For measuring dynamic pressures at the interface between the residual limb and socket Force Sensing resistors (FSR) have been used for. Convery *et al.* (1997) summarized both the calibration problems encountered and the techniques adopted to minimize inaccuracies. The mylar/ resistive ink F-socket transducer (9810), developed by TEKSCAN Inc. in Boston, was used for this study. It has 96 rows and 6 columns (96 cells), covering a total sensing area of 15,500 mm<sup>2</sup>. The output from the TEKSCAN FSR

considers common cell area to estimate the pressure of an individual cell in an array. The thickness, size, sensitivity, resolution and frequency response are the advantages of Tekscan sensor. Disadvantages are hysteresis, drift and temperature sensitivity. Incremental compressive loads were applied to individual cells of the sensor, using a specially developed pressure rig, so that all 96 sensors could be loaded simultaneously. The pressure system consisted of an accurately calibrated pressure regulator. The response of FSR to incremental loads was not satisfactory. Cyclic tests indicated good dynamic response between applied load and the FSR output. Results indicated that the three dimensional curved surfaces within a prosthetic socket introduced significant inaccuracies in FSR output data. Sensitivity to loading rates and hysteresis were two problems of the FSR.

Ping Luo., (1998) performed a validation study of the F-scan (Tekscan, Inc ., South Boston, MA) in-shoe sensor system under various pressures, loading speeds, and temperature conditions. The sensor insole consists of 955 individual pressure-sensing cells which are evenly distributed at an interval of 5.05mm. The F-Scan insole pressure sensor system used in this study had a uniform response to the static loading throughout all the cells ( $R^2=0.979\pm0.016$ , mean $\pm$ SD). Sensor output was recorded on a 486 computer. The experiments were performed on a servo-hydraulic material test system (MTS 810, MTS Systems Corporation, Minneapolis, MN) which is used to apply compression force to either the entire insole sensor or individual cells. Quantitative validation of the F-Scan pressure sensor suggested that it is adequate for determination of pressure distribution under contact conditions with soft materials. However, the sensor is sensitive to surface conditions, loading speeds, and temperature. Calibration was

recommended for accurate measurements in actual clinical or experimental conditions prior to use. The sensor system is not suitable for hard surface contact, such as rigid plastic sheeting.

The F-Scan in-shoe sensing system (Tekscan, Inc., Boston, MA) has many applications in clinical world. The high accuracy level of this sensor may be preferable for common clinical tests, but the specific conditions under which this high accuracy is valid was unclear. Sumiya *et al.* (1998) conducted a study to examine the characteristics and to gain a better understanding of the F-Scan system to determine its appropriate clinical application. To accomplish this sumiya et w., compared F-scan in shoe system with another system. Due to the reason that both systems were not sufficiently accurate, the study was mainly aimed at evaluating the accuracy of F-scan through investigating physical properties. F-Scan, version 3.42 and Kistler force plate to determine the vertical component of ground reaction force were used. Results showed that F-Scan's sensitivity decreased as the felt in contact with the foil increased in thickness, and stabilized at the lowest level when felt thickness exceeded 0.4mm. The F-Scan yielded a delay in the first peak time and underestimated the second peak force compared to the vertical component of the floor reaction force that was synchronously measured by the Kistler force plate. Because of these reasons rather than using F-Scan measurement to accurately obtain actual values, it should be used for relative comparisons of the plantar pressure distributions under constant conditions.

Convery *et al.* (1998) described the distribution of the pressure patterns monitored using Force Sensing Resistors (FSR) during the stance phase of gait when a transtibial prosthesis is used. The F-Socket transducer (Tekscan Inc., Boston, MA) was used for

measuring pressures. The calibration rig used for calibrating transducers consisted of a frame, a socket brim template, and a dynamic loading input generator. An accurate pre-selected pressure was applied to the inner socket wall via a pressurized gel filled sheath. A patient was fitted with a trans-tibial prosthesis incorporating an acrylic resin laminated PTB socket. The four transducers were attached to the anterior, posterior, medial and lateral walls of trans-tibial socket. A strict test protocol was adopted. Tekscan transducers provided a large amount of data (42,000 recorded pressure readings) during a single step. Statistical analysis of force plate and pressure data revealed that there was no significant difference in the ground reaction force or the average pressure of the transducers. Using Tekscan software four specific areas (patellar bar, proximal popliteal, posterior medial flare and the fibula head) with more than 100KPa were identified. This study highlighted the capability of FSR to display residual limb/socket interface pressure distribution during gait.

Polliack *et al.* (1999) conducted extensive series of trials to evaluate different aspects of performance (accuracy, hysteresis, drift and effect of curvature) of the Rincoe SFS and the F-Socket system. Rincoe SFS (Rincoe & Associates, Golden, CO) and the F-Socket system (Tekscan, South Boston, MA) were used for evaluation. An Icross silicone liner was rolled over the sensors placed at nine sites of a positive transtibial residual limb mold. The mold, attached sensors, and the silicone cover were placed into the pressure vessel for preliminary tests were conducted. Due to the ability to calibrate F-Socket sensor prior to testing, accuracy errors were less for it than for the Rincoe SFS. Both the sensors are not capable of conforming around a highly contoured site, such as patellar tendon, results in measurement errors. Large hysteresis and drift errors were reported for

both the systems. Drift errors were recorded over a 20-minute period. The F-socket's software was more user friendly than the Rincoe SFS. The Rincoe SFS was limited to recording a maximum of three frames per trial, where as F-Socket allowed a maximum of 456 frames. Of the two commercial systems F-Socket Interface pressure system was preferred over Rincoe Socket Fitting System. Results also recommended that the F-socket be used only in a static or standing environment. The system should be recalibrated after each trial due to high hysteresis and drift errors.

In gait analysis a system capable of detecting heel strike and toe off is very useful. The initial foot contact (IC) and end of foot contact (FO) represent the start of stance and swing, respectively. The software associated with the F-Scan system determines IC and FO using force measurements. However, there is conflicting information in the literature regarding the accuracy and repeatability of the system when measuring forces and researchers have suggested the possibility of a delay in the time response of the system, which would affect its ability to accurately detect gait events. Catalfamo *et al.*, (2008) evaluated the F-Scan in shoe pressure measurement system. Ten subjects (9 male and one female) were used to evaluate the reliability of the F-scan Mobile system for detecting IC and FO. Two methods were used, one was the force detection (FD) in-built algorithm used by F-Scan software and new area detection (AD) method using the loaded area during the gait cycle. Force detection method calculates the force threshold as 10% of the range (difference between maximum and minimum force). FD uses this threshold force to find stance phase when every time the force signal diminishes below it. Area detection method calculates area threshold as 5% of the range (difference between maximum contact area and minimum contact area). IC was determined whenever the area signal fell



below the threshold. The results of this study showed a significant difference between the proposed area detection algorithm and the existing force detection algorithm for both gait events.

## 2.4 Gait analysis

*Gait* is the way in which animals, including humans, move from one point to the other over a solid substrate. The walking pattern is studied as a *gait cycle*, which is defined as the movement of a single limb from heel-strike to heel-strike again. *Gait analysis* is the systematic study of locomotion of humans using the eye and the brain of observers, augmented by instrumentation for measuring body movements, body mechanics and the activity of the muscles. Gait analysis commonly involves the measurement of the movement of the body in space and the forces involved in producing these movements.

Weber brothers in Germany were the first to conduct formal biomechanical investigations during the early nineteenth century. Since that time advances in kinetics, kinematics, electromyography and mathematical engineering have contributed towards the development of gait analysis. *Kinematics* is the measurement of movement. Early kinematic studies on human walking performed in the 1870's were made using still cameras. The first major study of the kinematics of gait was undertaken during the 1940's and 1950's. *Kinetics* is largely related to measurement of the forces acting between the foot and the ground. Although most research on the kinetics of gait has concentrated on ground reaction forces, work has also been done on limb accelerations. Modern gait analysis systems provide additional kinetic information in the form of joint moments and

joint powers, based on kinematic and force platform data, and the use of engineering mathematics. Most motion capture systems record motion in 3 planes, facilitating analysis in sagittal, frontal and transverse planes. Contemporary gait analysis involves use of the method of ‘inverse dynamics’ (the Newton-Euler method) to calculate joint moments and powers using ground reaction forces and limb motion. Both motion capture data and force plate data are required.

*Electromyography* (EMG) is the measurement of the electrical activity of the muscles. The first major studies of EMG were performed in the 1940’s and 1950’s. In the 1890’s mathematics was applied for the first time to understand the mechanics of walking.

Pattern recognition methods are used for surveillance applications in which an attempt is made to identify an individual based on facial recognition. It is difficult to get good facial detail much of the time. Psychophysics research has revealed that humans have the capability to recognize a person from displays of their gait, so gait analysis can be used to identify specific individuals. Two approaches to recognizing gait are model-based and model-free. In model-based recognition the gait signature is extracted by fitting the movement of the thighs to an articulated pendulum-like model of motion. In the presence of noise, classifications made by this method may not be reliable. The model-free approach uses optical flow data to derive the motion image sequence corresponding to a walk cycle.

Huang *et al.*, (1999) used model-free approach which uses optical flow to derive the motion image sequence corresponding to a walk cycle. Kale *et al.*,(2003) used the appearance based approach to study the problem of gait recognition. The authors used

width of the outer contour of the binary model of silhouette as basic image feature. It had structural as well as dynamical aspects and compactly represented gait of the individual. Different gait features were extracted from the width vector data such as the smoothed width vectors, the velocity profile and Sequences of such temporally ordered feature vectors were used to represent a person's gait. Dynamic time warping (DTW) has been used to match so that non-linear time normalization can be used to normalize gait data across naturally occurring changes that take place when walking speed varies. The performance of different gait measurements is tested using the UMD, CMU and USF databases.

Gait analysis usually involves multiple curves obtained by conducting multiple trials on an individual subject or several subjects. Each curve often represents a single gait cycle. Three principal problems may be encountered when analyzing multiple curves obtained from one or more subjects: (i) determining the reliability of the gait curves for a single given patient, (ii) the classification of a new subject to a given population and (iii) the comparison of two populations (independent or paired). Duhamel *et al.*, 2003 presented statistical tools for solving these problems and indicated how they can be used in clinical practice. The tools are, respectively, (i) intra-class correlation coefficients, (ii) confidence bands for a population, and (iii) a combination of analysis of variance and confidence bands to examine the differences between the means of the two populations. Kinematic gait parameters were recorded using a VICON (Oxford Metrics, Oxford, United Kingdom) motion analysis system. Confidence intervals were used to determine the range of the normal values or to perform group comparisons. In the case of gait curves confidence bands are analogous to confidence intervals. Comparisons of groups

were performed by analysis of variance (ANOVA) using a mixed linear model. Results showed that it is a reliable tool for use in clinical gait analysis.

Plotting an individual subject's data along with normative values obtained from a pool of normal subjects (i.e., the mean and  $\pm 1$  S.D. for the normal pool) is a common method of visually assessing normality. This method of data interpretation is often time consuming and complex, especially when the process requires the inspection of a plethora of line graphs for numerous variables that are displayed across several report pages. Manal *et al.*, (2003) proposed an alternative method for displaying movement pattern deviations relative to normative data by color-coding the magnitude and the direction of the deviation. An advantage of this approach is that the time-history of several variables can be displayed simultaneously, in a manner that is concise, visually effective, and reduces complexity, especially for patients and family members. Impaired gait data for one patient was compared to normative data for 15 healthy subjects to demonstrate the color-coding method. Visual3D (C-Motion Inc., Rockville, MD, USA) was used to calculate sagittal plane ankle, knee and hip angles and moments during the stance phase of walking. A major drawback of this method is that useful information is lost when the data are reduced to and reported as a deviation.

The timing of heel strike (HS) and toe off (TO) is essential when analyzing gait. O'Connor *et al.*, (2006) developed an algorithm which automatically determines these times from kinematic data recorded by a motion capture system of the type, routinely used in gait analysis laboratories. The foot velocity algorithm (FVA) uses displacement time data for heel and toe markers gathered from the motion analysis system to identify HS and TO. The FVA only requires the vertical information, however, and it will work

equally well with 2D sagittal kinematics. The FVA has been verified with large and small data sets. A large data set containing 54 normal children was found to have errors of  $16 \pm 15$ ms for HS and  $9 \pm 15$ ms for TO. The algorithm also worked well when tested on a small number of children with spastic diplegia. Performance of the FVA has been compared with the force plate method. The FVA produced more accurate results and was easier to implement than the force platform method.

Inverse dynamics is most widely used method for estimating the forces and moments at different joints during walking. It requires use of a force plate. However inverse dynamics is based on assumptions that may not be valid and it is sensitive to input data. Alternatively, transducers can also be used to measure the forces and moments if they can be installed at the right locations. Dumas *et al.*, (2009) compared the forces and moments applied on a prosthetic knee as measured directly using a transducer with ones calculated by inverse dynamics computations using the ground reaction vector technique. One fully rehabilitated female transfemoral amputee participated in the study. Data from the transducer was recorded at 200 Hz. The position and orientation of the transducer was aligned with the socket. The gait data were recorded using a 6 camera Peak-Motus system (VICON, Oxford, UK) and a force plate (AMTI, Watertown, MA, USA) at 50 Hz and 500 Hz respectively. The amputee walked at 1.21 m/s. The support and swing phases represented 57% and 43% of the gait cycle, respectively. Forces and moments were calculated at different joints using 3D inverse dynamics and the 'ground reaction vector'. Results showed that the maximum root mean square errors (RMSE) between forces estimated by inverse dynamics and directly measured forces by the transducer (i.e., 56 N) and moment (i.e., 5Nm) were reasonably small. However, the application of inverse

dynamics to amputee gait demonstrated typical errors arising from the assumptions of rigid segments and ideal joints and with sensitivity to the kinematic derivatives used to estimate joint and segment velocities and accelerations.

## CHAPTER 3

### INSTRUMENTATION

This chapter describes the different instrumentation used for data collection and explains how data were captured and transmitted, and the operation of the transducer and pressure sensor.

#### 3.1 JR3 Transducer

As reported in the literature review, previous studies have successfully used the JR3 commercial transducer to directly measure the forces and moments applied to the socket of amputees during daily living activities. These studies demonstrated that direct load measurement by means of a transducer attached to the pylon directly below the socket could improve the validity of estimates of the loads transmitted to the socket and allow measurements to be taken for many consecutive walking steps. In addition, direct measurement by means of the transducer allows loadings to be measured for a wide variety type of activities and terrain.

##### 3.1.1 Specifications

The six-channel commercial transducer (Model 45E15A; JR3 Inc, Woodland, CA, 95776) was used for collecting data (Figure 3-1). It is 4.5 inches in diameter and 1.5 inches thick and weighs 2 lb. It has amplifier, signal conditioning and A/D or analog output buffer electronics integrated into the sensor body. The 45E15 is machined from a solid billet of aluminium and it uses metal foil strain gauges bonded to strain rings as the sensing element. The mechanical structure of the 45E15 produces a transducer with exceptional stiffness. Each channel was sampled at 100Hz. The accuracy of the

transducer is +/- 0.25% of full scale for all axes. The details of transducer specifications are provided in Table 3-1.



Figure 3.1: JR3 45E15 Transducer

Fx, Fy	Fz		Mx, My	Mz	
250	500	Lbs	1125	1125	In-lbs
1000	2000	N	125	125	N-m

Table 3.1: JR3 45E15 Transducer specifications

### 3.1.2 Data capture and output

The transducer was mounted on the prosthesis pylon such that the vertical axis (z) of its coordinate system was aligned with the long axis of the pylon. At an alignment acceptable to the transtibial amputee, the socket axis is typically aligned to tilt anteriorly to the pylon, which reduces the tendency for the anatomic knee to hyper-extend during stance. The two other axes of the transducer were mutually orthogonal with the X axis



extending anterior to the pylon and the Y axis extending according to the right hand rule (medially on the right leg and laterally on the left leg). Consequently, the coordinate system of the transducer was aligned approximately parallel to the local anatomical axes of the leg. A wireless modem was used to transmit data from the transducer to the nearby laptop components consisted of a transmitter and a receiver. The 200-g transmitter was connected to the transducer by a serial cable and was carried in a back pack (Figure 3-2).



Figure 3.2: Transmitter

### 3.2 Tekscan F-Socket

Tekscan's F-Socket was used to measure the pressure occurring between the socket wall and the residual limb. F-socket is based on the same hardware and software as the F-Scan in shoe pressure measurement system and is offered as an option with the F-scan (Tekscan, Inc). Pressure measurements using F-Socket can help identify socket fit problems and improve the design, fit, and function of prosthesis sockets through better knowledge of the pressure distribution within the prosthetic socket interface.

### 3.2.1 Specifications

The F-socket sensor model 9811E was used for collecting pressure data. It is an FSR type of pressure sensing device which measures pressure by detecting voltage changes that occur when an electric current is passed through an ink. The F-socket sensor is rectangular (21.5 X 7.5 cm), consists of 96 individual cells arranged in 16 rows and 6 columns, and has a lower spatial resolution than the in-shoe sensor. It is approximately 0.28mm thick and very flexible. The sensor can be trimmed to fit inside the curved surface of a prosthetic socket to minimize distortion. Cells can be removed from the end of the strip and vertical slits created between the columns of sensors. F-socket specification details are provided in Figure 3-3 and Table 3-2.

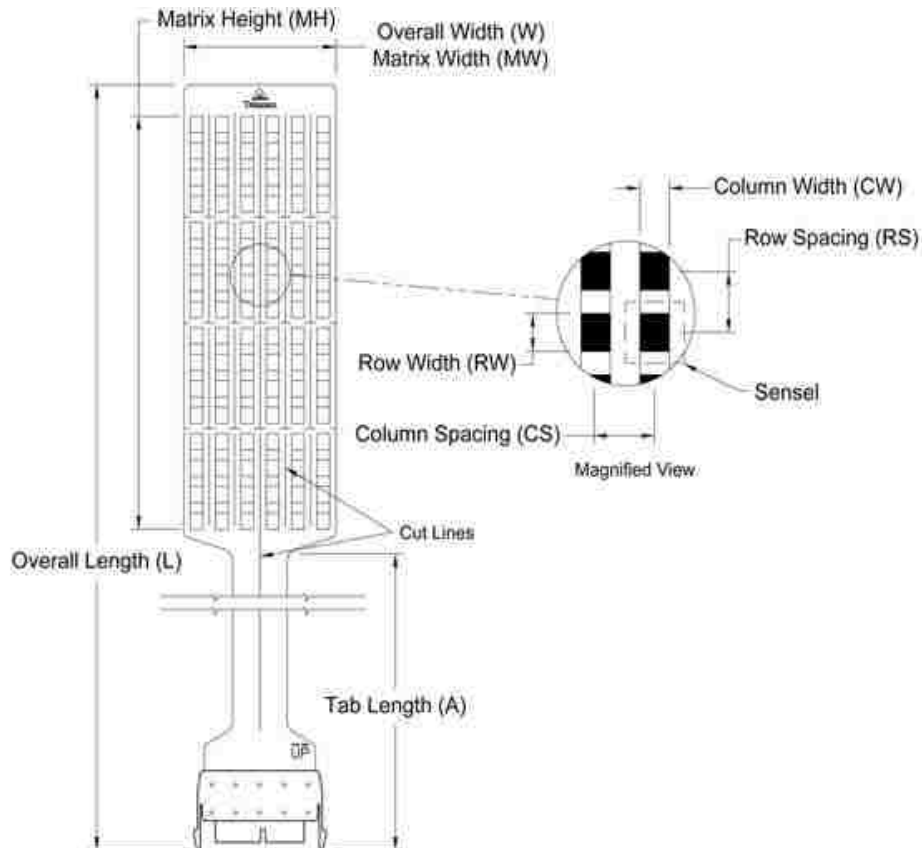


Figure 3.3: F-socket sensor 9811E

Overall length L	Overall width W	Tab Length A	Matrix Width MW	Matrix Height MH	Columns CW CS QTY			Rows RW RS QTY			Total No.of Sensels
(in) 14.48	(in) 3.00	(in) 5.61	(in) 3.00	(in) 8.00	(in) 0.25	(in) 0.5	6	(in) 0.31	(in) 0.5	16	96
(mm) 367.8	(mm) 76.2	(mm) 142.5	(mm) 76.2	(mm) 203.2	(mm) 6.4	(mm) 12.7	6	(mm) 7.9	(mm) 12.7	16	96

Table 3.2: F-Socket specifications

### 3.2.2 Data capture and output

The F-Socket sensor employs force sensing resistors for measuring the pressures developed in the socket. These force sensing resistors measure pressures based on piezoelectric ink sandwiched between two Mylar layers. As pressure increases, the contact area between ink particles increases, and resistance to current flows through the ink changes. The voltage drop across the cell changes, and when the sensor has been properly calibrated, this change in voltage can be used to estimate the pressure applied to the sensor. The calibration was performed by sandwiching the sensor between two layers of 14-mm thick Plastizote cut to the exact dimensions of the sensor to prevent possible bridging. The layers in turn were sandwiched between two layers of 9-mm thick clear copolyester to provide stiffness. A known weight was applied to the copolyester plates to perform the calibration. Data was outputted in matrix form.

## CHAPTER 4

### SOFTWARE DEVELOPMENT OBJECTIVES

This chapter discusses the development goals of the software. The subsequent chapters discuss problems faced during development of the software, the processing, steps developed for the software and corresponding flowcharts, the output and final products of the software including the GUI, and the statistical packages that can be used for analysis of the data exported from the software.

Four main steps involved in the development of software were: 1) the development of code for displaying and analyzing the data collected from the JR3 tri-axial transducer, which can measure forces and moments in three dimensions at the base of the socket; 2) the development of code for displaying and analyzing the data on pressure occurring inside the socket measured by means of the Tekscan pressure measurement system; 3) the development of code for merging data from the two previously mentioned sources in to one GUI display and, 4) developing code that allows exporting the processed data into an EXCEL file, which can be used in statistical analysis packages such as SPSS, and SYSTAT.

#### 4.1 Transducer Software

This section discusses the development and operation of software for analyzing the forces and moments data collected by the JR3 tri-axial transducer. A requirement existed for two separate methods of analyzing the transducer data: Requirement A called for normalized gait cycle which enabled steps of different duration to be compared, and

Requirement B called for analysis of the actual (non-normalized) gait cycle which enabled loading rates and impulse to be calculated.

**Requirement A:** The goals of software design for data normalized in the time domain were to:

1. Display via a GUI, the continuous stream of data produced by the transducer during one walking trial for any of the three force and three moments.
2. Convert the continuous flow of data during one walking trial into discrete gait cycles for analysis, and also display the discrete gait cycles by means of a GUI.
3. Normalize each discrete gait cycle so that gait cycles during the trial can be compared in the time domain;
  - a. Subdivide each step into 50 discrete time intervals, so that each interval represents 2% of the gait cycle
  - b. Assign sampling data points from the transducer into the correct time interval.
4. Compute the mean and standard deviation of the 50 normalized intervals for the trial and display using a GUI.
5. Compute the resultant mean force and mean moment for the trial, and the angle of the force with respect to the pylon axis.
6. Copy the processed data into an EXCEL compatible file format for export.

**Requirement B:** The goals of software design for data not normalized in the time domain were to:

1. Compute the average loading rate beginning at heel contact over the trial and display the results.

2. Compute the average impulse for three separate stance phases (heel contact to first maximum, first maximum to second maximum, and second maximum to toe off) and the total stance phase and display the results.
3. Copy the processed data into an EXCEL compatible file format for export.

To achieve these goals the following decisions were made during the design phase of software development.

- Prior to the use of transducer software and GUI, the raw data produced by the transducer should be opened and saved in an EXCEL file format. Data saved in the Excel file should then be fed into the transducer software.
- Among the various variables that could be used to identify heel strike and to-off, the vertical force parallel to the pylon (z-direction) should be used. Z-direction force data should be displayed to show the continuous stream of all the steps together.
- Individual gait cycles should be selected by inspection of the plot, rather than by an algorithm. For ease of selecting individual gait cycles, zoom in, zoom out and pointer options should be included in the window. For finding the exact heel contact and toe-off points the zoom in option should be used and for identifying those sample points the software pointer should be used. Location of the tip of the pointer over the point should provide the time of occurrence of the sample points that identify the beginning and end of the gait cycle. The end time for one gait cycle can be the start time for the next gait cycle unless it is preferred to examine only the stance phase. In this case the start and end times of stance should be determined.
- After inputting the start and end points of individual gait cycles (or stance), the transducer force and moment data associated with each step should be divided into 50

intervals. For example if there are 350 transducer sample points associated with a single step, the software should calculate that there will be 7 sample points in each interval ( $350/50$ ) and sort every 7 consecutive points into each of the 50 intervals in sequence. Then the software should compute the average force or moment value of those 7 points in each interval and the GUI should display the plots of the mean values of each of the 50 intervals for each step (gait cycle).

- After displaying the mean value of each step for each of the 50 intervals of the individual gait cycle, the software should calculate the means and standard deviations over all of the steps in the trial for each of the 50 intervals and plot them in a separate window.
- The same procedure should be followed for calculating the means, standard deviations, loading rates and impulses of remaining forces in the other two directions and the moments in all three directions. The start and finish times of each gait cycle should be automatically brought forward from the definitions supplied by the user for the Z direction force, so that the same time points are used for forces and moments along the other two dimensions.
- The resultant force and moment for the average of all the steps in the trial should be computed for each of the 50 intervals using the Pythagorean Theorem and displayed.
- The angle of resultant with the pylon should be calculated as the arctan of  $X/Z$  and  $Y/Z$  and displayed.
- After calculation of means and standard deviation, the software should calculate the loading rate and impulse using actual times rather than normalized times.

- After calculation of all these parameters, the resulting data should be exported into an Excel file format which can be used for input into statistical software such as SPSS, or SYSTAT.

#### 4.2 Software for Tekscan data

This section discusses the goals for the development and operation of the software for merging and analyzing data collected using the Tekscan F-socket software that measures pressure inside the socket. Requirements of the software interface design were to:

- Utilize analysis capabilities inherent in the Tekscan software to the extent possible
- Create a visual display that allows the user to simultaneously inspect both transducer data and Tekscan data for correlation
- Develop Tekscan output files that can be merged with transducer software output files and used in statistical regression packages where the pressure data serve as the dependent variable and the transducer data serve as the independent variables.

Decisions made during the design of the Tekscan GUI follow:

- The Tekscan F-socket data should be collected following the normal procedures that Tekscan recommends and make use of the software Tekscan supplies. Using the Tekscan software, the user should open the downloaded movie and add a box or polygon to the window to extract pressure data from the region of the sensor that is of interest and prepare a plot of pressure versus time for the box or polygon using the data analysis capability within the Tekscan software.
- Raw data from the Tekscan F-socket will be in matrix form (cell value versus time) with one entry for each cell of the sensor (92 cells in the case of the F-Socket); the raw sensor



array, cannot be used in the software to analyze pressure unless it is calibrated and windowed using the Tekscan software. However, the data from the box or polygon described above will exist as a single value versus time. This data should be saved in ASCII format and exported from the Tekscan software after plotting the window or polygon. A Tekscan feature allows this.

- This exported file should be opened in Excel and saved as an Excel file, so it can be input directly into the software.
- After the Tekscan data have been input into the GUI, the processing of it should follow the same steps used for the transducer data. For each gait cycle, the result should be 50 intervals, and the GUI should compare the means of the pressure data falling within the interval. Then the means and standard deviations of, over all the gait cycles in the trial should be computed so there are 50 means and standard deviations, one for each normalized interval.
- At the end of processing the Tekscan data, a file should be created in Excel format and contain the values of the 50 means and standard deviations computed over all the gait cycles in the trial, which can be exported from the GUI and input into statistical software for further analysis.

In order to assist the user, additional decisions were made concerning the data display options to be made available in the GUI. It was the opinion of the research team that too many display options may make the software unwieldy and the data difficult to view. This section describes decisions made with respect to some constraints that were built into the GUI.

- Curves showing the mean values of pressures inside the box or polygon should be displayed on the screen in a manner that allows the user to visually compare them to on the curves of the mean forces and moments computed over the trial. This would facilitate visual inspection of the data for potential correlations between pressure and the forces and moments.
- Depending on the plane of the residual limb in which pressure measurement was undertaken with the Tekscan equipment, the forces and moments most likely to be related to pressure variation should be displayed. For pressures acting primarily on the frontal plane of the residual limb, the most likely sources of gait-related pressures were assumed to be forces acting in the X and Z directions and moments about the Y and Z axes. For pressures acting primarily on the sagittal plane of the residual limb, the most likely sources of gait-related pressures were assumed to be forces acting in the Y and Z directions and moments about X and Z axes.
- In order to merge data from Tekscan with data from the tri-axial transducer and display both simultaneously, the pressure data should be sorted into 50 intervals following the same normalizing procedure used for the transducer data.
- The two sources of data should be merged into one combined file in EXCEL format to facilitate export into available statistical packages. Regression analysis should not be carried out within the GUI software.

Different Software packages, explained in the next chapter, were analyzed to develop a GUI for attaining the above mentioned objectives.

## CHAPTER 5

### SOFTWARE LANGUAGE

Different languages were examined to develop the software including LabVIEW, Visual Basic, Mathcad., and MATLAB. Based on compatibility and ease of operation Matlab was chosen.

#### 5.1 Lab View

LabVIEW (Laboratory Virtual Instrumentation Engineering Workbench from National Instruments, Inc) can be used as a platform and development environment for a visual programming language. It is mainly used for instrument control, data acquisition, industrial automation, analysis and signal processing, embedded design, and test automation. LabVIEW can be used for developing stand-alone executable programs, which can be distributed an unlimited number of times. This feature was considered important since a need existed to develop a stand-alone executable program; which could be loaded onto a laptop and used in prosthetic clinics with ease. But, to build stand-alone executable with LabVIEW, the Application Builder component included within the Professional Development System was required, and this would necessitate a separate purchase by the user.

#### 5.2 Mathcad

Mathcad software mainly is used for the documentation and, validation of engineering calculations. Some of the capabilities of Mathcad are finding roots of polynomials, matrix and vector operations, curve fitting, solving differential equations,

and solving systems of equations. The software is primarily intended for non-programming users. It is quite difficult to program complex projects in Mathcad as compared to MATLAB.

### 5.3 Visual Basic

Visual Basic (VB) is an integrated development environment (IDE) and third-generation event driven programming language. It was derived from BASIC and enables the rapid application development (RAD) of graphical user interface (GUI) applications. VB was designed to be easily learned and used by beginning programmers. It can be used for developing complex applications apart from allowing programmers to create simple GUI applications. Visual Basic can create executables (EXE files), ActiveX controls, or DLL files, but primarily is used to develop Windows applications and to interface database systems. The main reason for ruling out VB was because it required the manual selection of the steps needed in the software. Coding for the manual selection of steps in VB is difficult when compared with MATLAB.

### 5.4 MATLAB

MATLAB is a fourth generation programming language and numerical computing environment. MATLAB can be used for plotting functions and data, implementation of algorithms, creations of user interfaces, matrix manipulation, and interfacing with programs in other languages. It is very easy working with MATLAB executable code, which doesn't require any other separate package. A program written in MATLAB can be installed on a laptop without the need for installation of a comprehensive MATLAB

background package. This made it desirable to choose MATLAB for developing the software.

### 5.5 Problems encountered and resolved

Problems encountered during the development of the GUI software using MATLAB and described below.

- Clipping of a continuous stream of data into discrete steps: Initial plans were to develop a GUI that employed a pointer which could be positioned over a desired point on the raw data plot, and by clicking a mouse the starting and ending point of a step could be selected. In other words, the initial design concept was to develop software with which discrete steps could be selected manually (clipping) just by clicking on the desired start and end points. But restrictions in the MATLAB code prevented being able to do this, and it also was found to be impossible to use different colors to identify the curves of different individual gait cycles.

To overcome this difficulty the notion of using a pointer was retained, but the means for identifying the start and end points was designed to utilize 10 edit boxes into which the values of the graph coordinates of the start and end points of each step could be entered manually.

- Pointer: For entering the values for start and end points the user would need to know the exact values of the coordinates, which can be accomplished only by looking at the raw data plot. But it is difficult to determine exact values in a plot containing thousands of sample points just by inspecting it with the naked eye.

It took several months to find a solution to this problem. By looking at different options and asking for help on internet forums the problem was resolved successfully. To solve this problem, a pointer which displays the x and y values of the plot was incorporated into the GUI. These values are entered into the ten pairs of edit boxes described above.

- One way mapping: Initially total data from the transducer file was plotted. But once plotted, it was not able to go from the plot back into specific regions of the data file on which the plot was based. In other words, while individual gait cycles could be identified, it was not possible to pull those data out from the original transducer file and recover the values of the forces and moments recorded from the transducer. This made it impossible to further process data and plot individual gait cycles or calculate means.

To solve this problem, code was completely changed and rewritten using a different logic. Internet forum groups were called upon to help us solve this problem.

- Executable file: We faced problems in converting the .m file of Matlab into an executable file that would work as a stand-alone application without any need of the original Matlab version installed on the target system.

To solve this problem we referred to several websites, forum groups, and requested help online from MATLAB programmers.

## CHAPTER 6

### GUI DESIGN AND OPERATION – TRANSDUCER DATA

#### 6.1 Logic Chart

This chapter indicates, by means of a flowchart which is shown below, the steps involved in processing the transducer and Tekscan pressure data. The flowchart explains the step by step calculation of the various parameters obtained from the raw transducer data. The flowchart depicts the logic behind the code, and a similar logic was used to process both transducer and Tekscan pressure sensor data. This chapter also explains use of the software in terms of the sequence of steps to be followed. A sample data file is used.

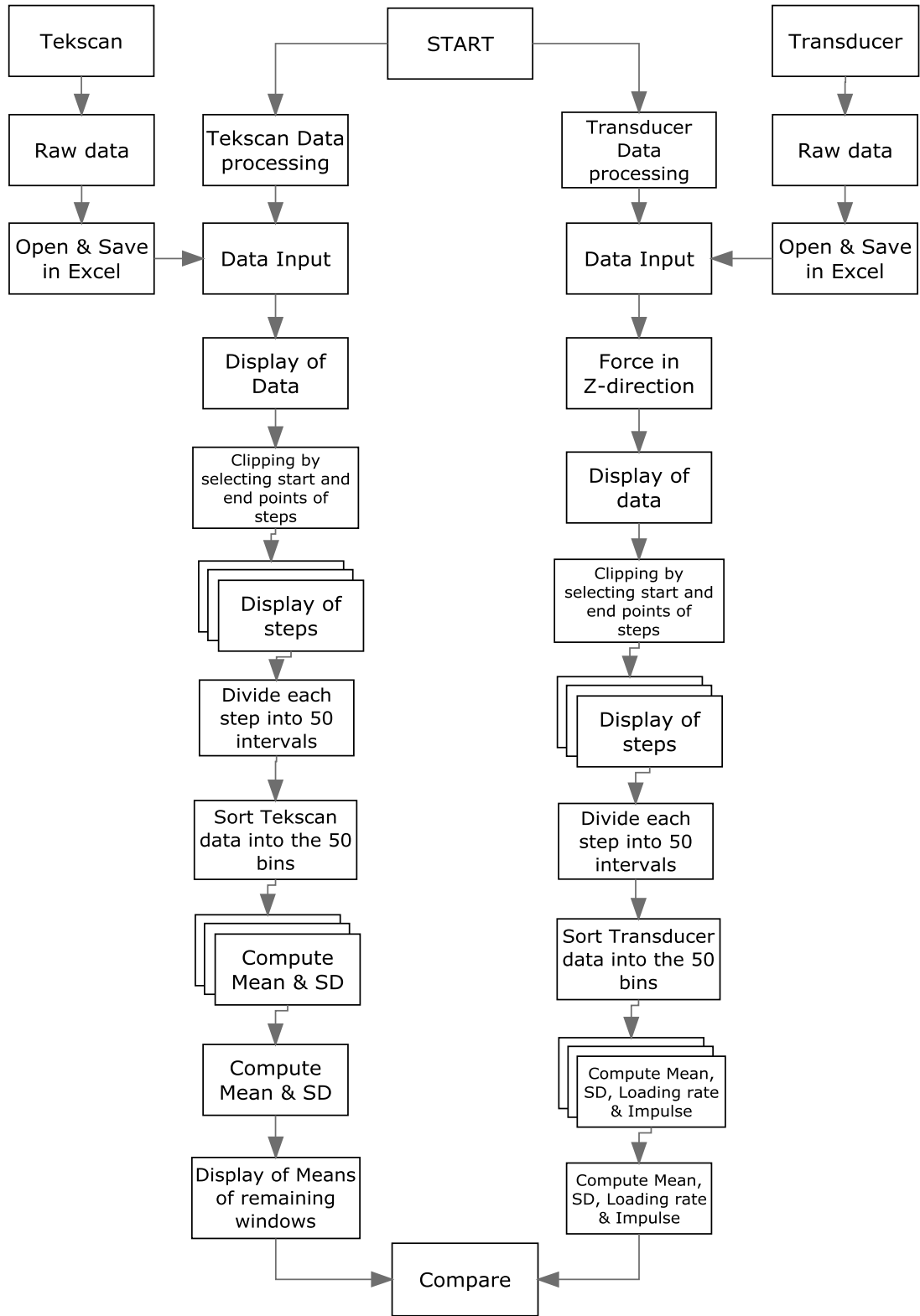


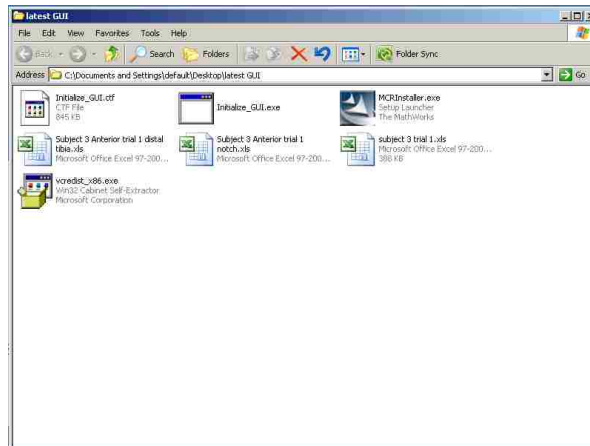
Figure 6.1: Flowchart for software



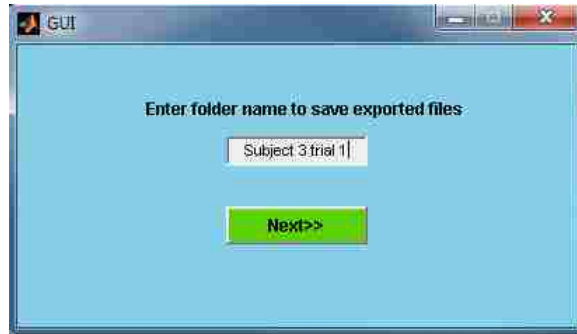
## 6.2 GUI Displays

This section explains the step by step procedure for using the software and obtaining the GUI displays. The text also explains how the various programs, imported files, and exported files are named and located.

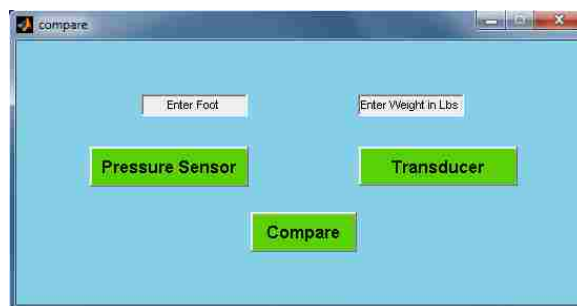
The GUI itself is inside the **GUI** folder. To use the GUI on a new installation, the first requirement is to install the **MCRInstaller.exe** on the computer in which the GUI will be used. Data files from the transducer and pressure sensors will be in a format other than Excel. For the GUI to import these data successfully, the users must convert them to Excel format and save them in Excel format. When saving the transducer files in Excel format, users have to select **delimited**, then mark **space**, then click **finish** and save it in the **GUI** folder. To get the pressure data from the socket window location the Tekscan software has to be used. This will be explained in Chapter 8 with the help of Tekscan software displays. For saving pressure sensor data files in Excel format after windowing, the user has to select **Delimited**, then **comma**, and then **finish** and save it in the **GUI** folder. After saving data files in Excel format in the **GUI** folder the display should appear as follows:



From the **GUI** folder the user has to double click on the **Initialize\_GUI.exe** to start the GUI. Then the following window will open. In this window the user has to enter the folder name into which all exported files from the GUI are to be saved.

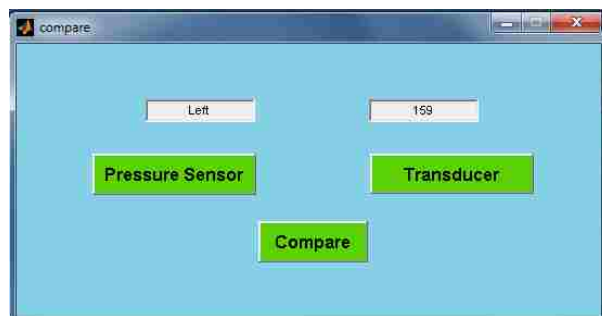


After entering the folder name user needs to click on the **Next>>** option to go onto the following window. Here the user has to enter the side on which the prosthetic foot is located (right or left) and the weight of the subject in English pounds.



This window has three more options displayed- Pressure Sensor, Transducer and Compare. The **Pressure Sensor** option will take the user to the portion of the software in which the pressure data can be analyzed, The **Transducer** option will take the user to

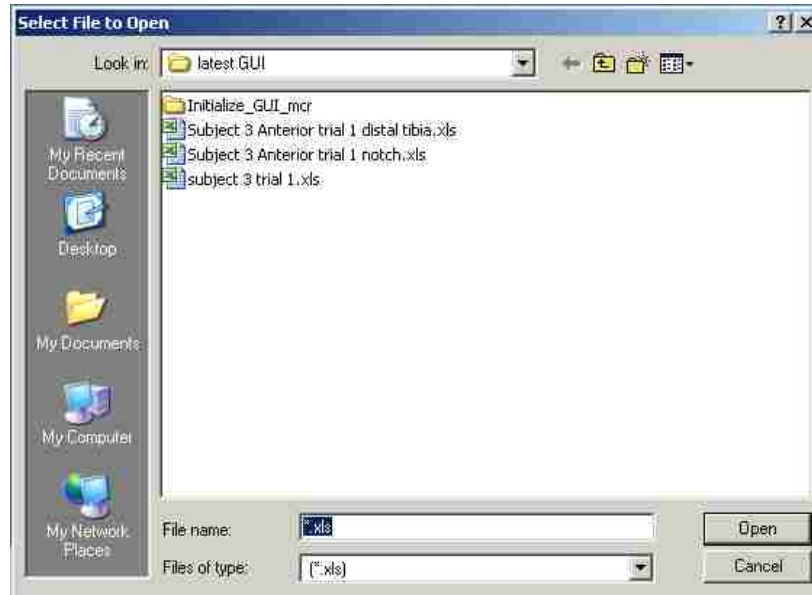
windows which can be used to analyze the transducer data, and the **Compare** option will compare both the transducer and pressure sensor data. First, the user has to select either **Pressure Sensor** or **Transducer** to analyze the corresponding data and only when both have been processed can the user select **Compare** for comparing the data from the two sources. Below is shown how the screen should appear for a subject weighing 159 lbs when the prosthetic foot is on the left leg.



When the **Transducer** option is been selected the following window then appears.



After clicking on the **Browse** button in this window, the following window will open. This window is used to select the transducer data file to be analyzed from the GUI folder.



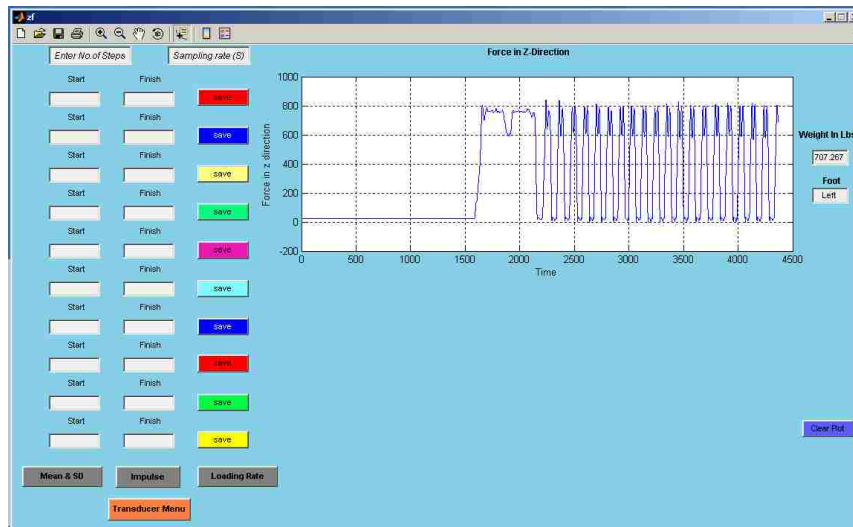
After selecting the transducer data file, “**subject 3 trial 1.xls**” in this case, the following window pops up:



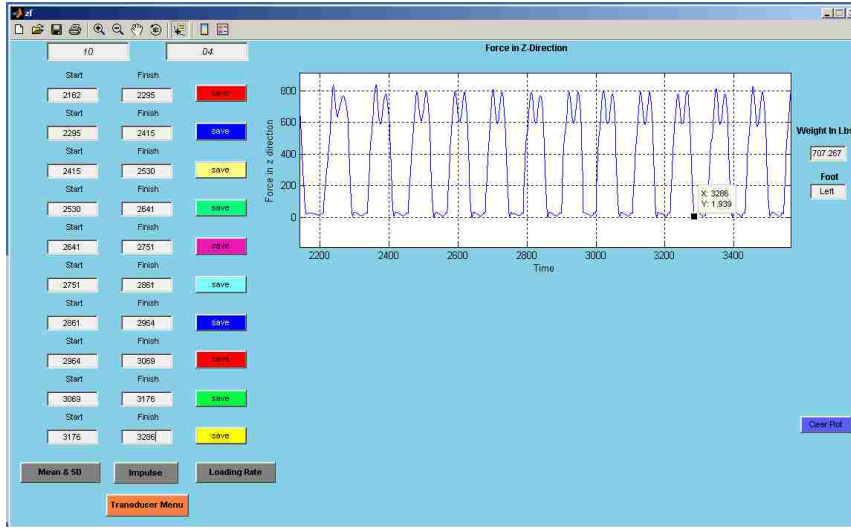
Initially the user can only select the **Z-Direction** under **Forces** to define individual steps. If the user selects other than the **Z-Direction** the GUI will ask the user to go back and select the **Z-Direction**. Selecting the **Z-Direction** will allow the user to select ten good steps to be analyzed from the trial, which frequently will consist of more than ten

steps. [It is recommended that at least fifteen steps be recorded excluding steps that are different from the intended activity, such as turning around at the end of a corridor]

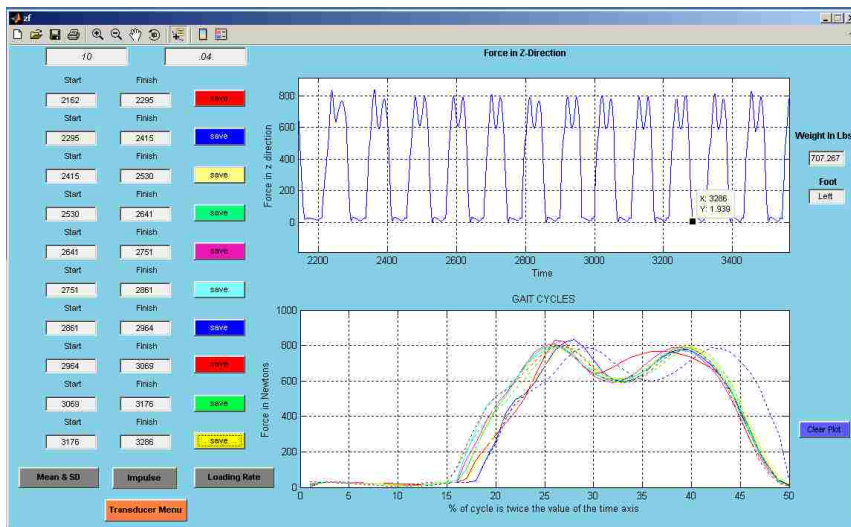
Selecting the **Z-Direction** will open the following window which is used for identification of no more than 10 good steps for analysis. In this window the user has to enter the number of steps to be analyzed and the sampling rate of the transducer in the corresponding text boxes. This window requires the user to select the start and end points of the 10 good steps by visual inspection. The user can utilize the **Zoom in** and **Zoom out** options located in the toolbar on upper left hand side of the window to place a window on the screen around the trace of the transducer data and magnify or diminish the data for inspection. The **Data cursor** option in the same tool bar can be used for finding the x-coordinates of the data. These x coordinate data are used to define to the start and end points of each of the ten steps.



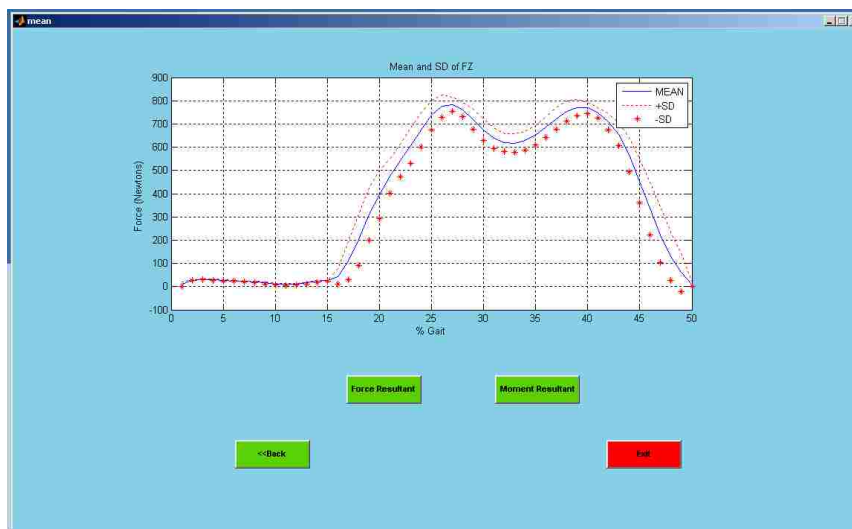
After Zooming in and using the **Data cursor**, the window can be made to look like the following display:-



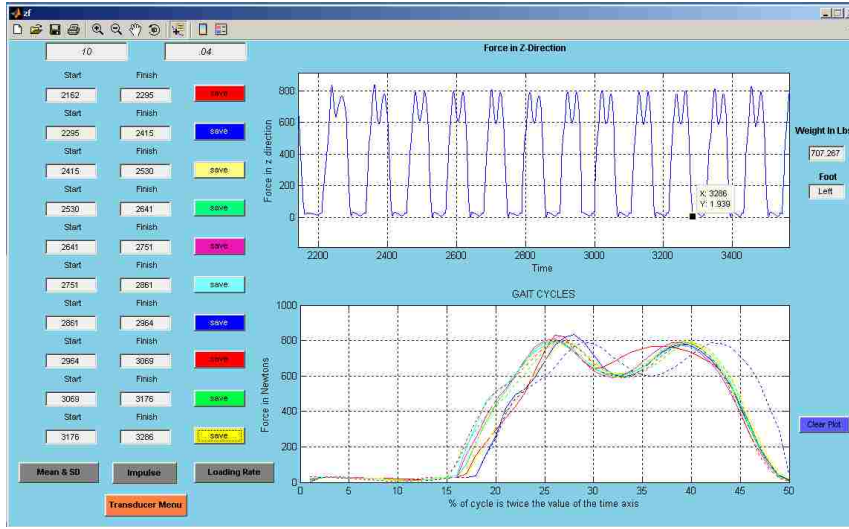
After entering the start and end points of the 10 good steps into the corresponding text boxes and clicking the respective save buttons the GUI will plot the gait cycle for the step below the main plot. The curve for each of the ten steps will be the same color as the **Save** button. The data of each single step is then sorted into 50 bins and the mean for each bin is plotted in the second plot as shown below:



For analysis of the gait cycles, the Mean and Standard Deviations for each of the 50 intervals is computed over the ten steps by the GUI. For calculation of the means and standard deviations over the steps, the user has to click on the corresponding **Mean & SD** button at the left hand bottom of the window. The following window pops up after selecting **Mean & SD**:-



The options on this window include **Force Resultant**, **Moment Resultant**, **Back** and **Exit**, each of which takes the user to the next box. **Exit** will exit the GUI, **Back** takes the user back to the previous window, **Force Resultant** will plot the resultant of forces in X,Y,Z directions and **Moment Resultant** will plot the resultant of moments in the X,Y,Z directions. Force and Moment resultants can be obtained only after analyzing all the forces and moments along three axes. So at this time, having processed only the force along the Z axis, only the **Back** button can be used. After clicking the **Back** button the following window appears:-



Now the user has to click on **Transducer Menu** to analyze the forces and moments along the other axes. By activating **Transducer Menu**, a window as shown below appears.

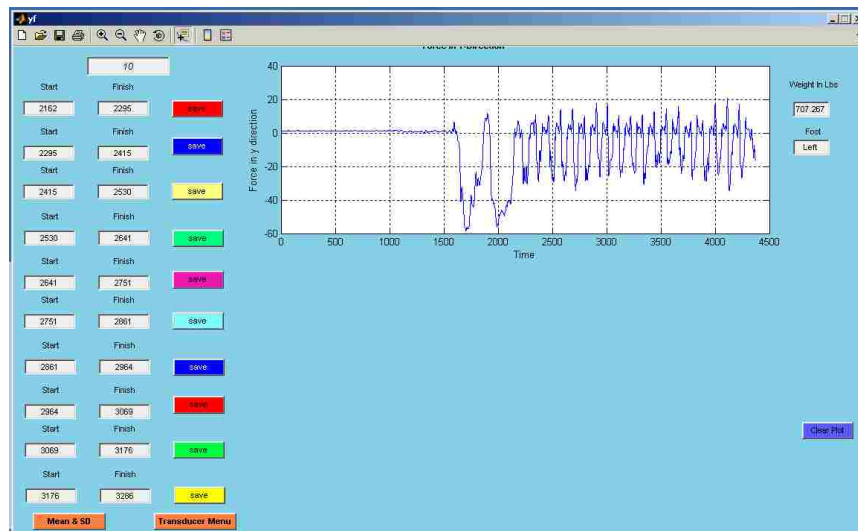


Now the user can select among the options specified in the window. All options are available to the user at this time. For explanation purposes in this chapter, the **Y-Direction** under Forces has been selected and the following window appears. The same

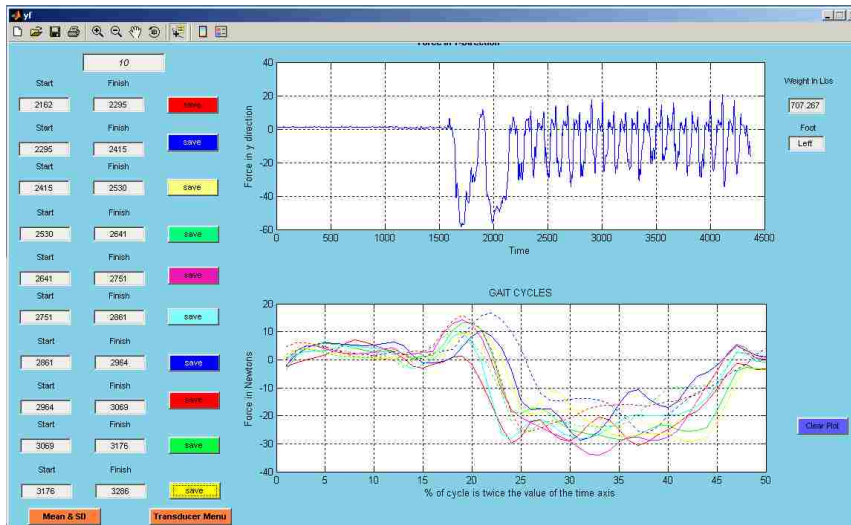


procedure followed by the user to analyze the force in Z-direction should be used here to analyze the force in Y-direction. However, the x coordinate values used to define steps in the Fz window just explained will reappear, and these same values should be used again to break the stream of data from the transducer into the same time-wise segments so data points will match across all the forces and moments. This will ensure that the beginning and ending points of the steps will agree, and all 50 intervals will span the same points in the gait cycle. To do this, only the **SAVE** buttons for the ten steps need be clicked. The x coordinate values in the boxes should not be changed.

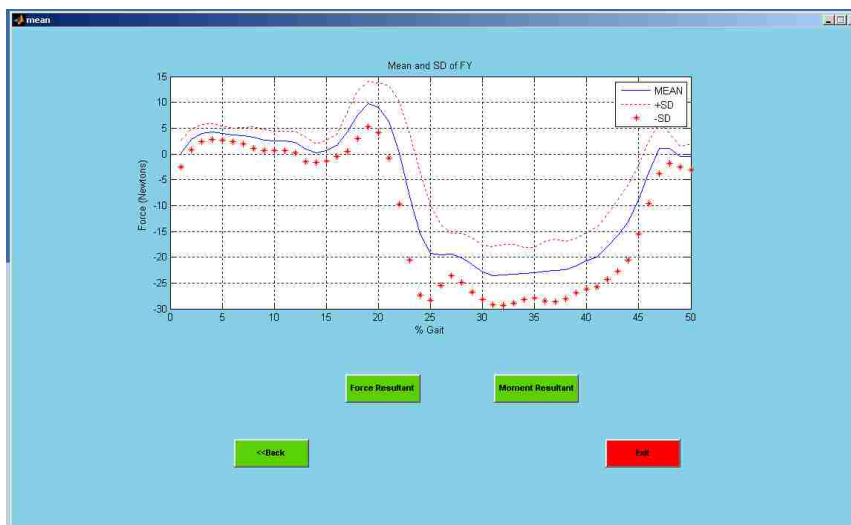
The same procedures should be followed again for the remaining forces and moments. All windows that appear in the process are shown in the discussion that follows one after the other.



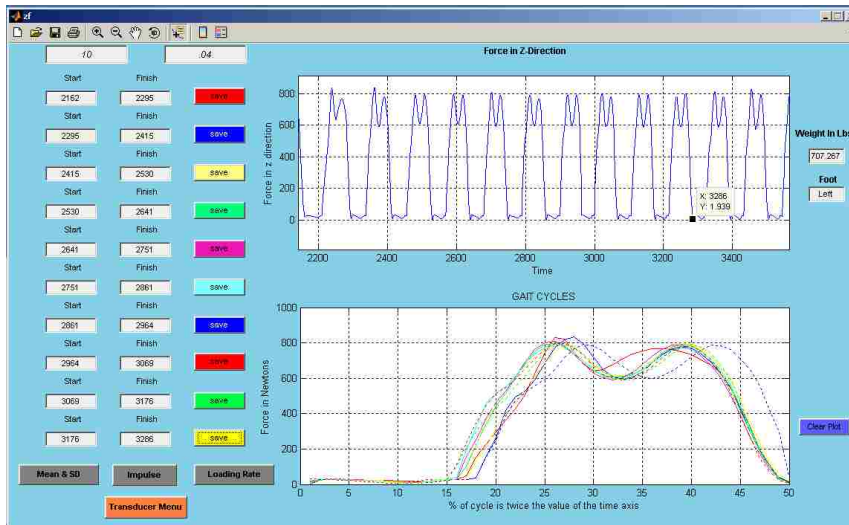
Clicking the **Save** buttons of all ten steps will produce the second plot with gait cycles.



Clicking **Mean & SD** will produce the following window with the means and standard deviations plotted.



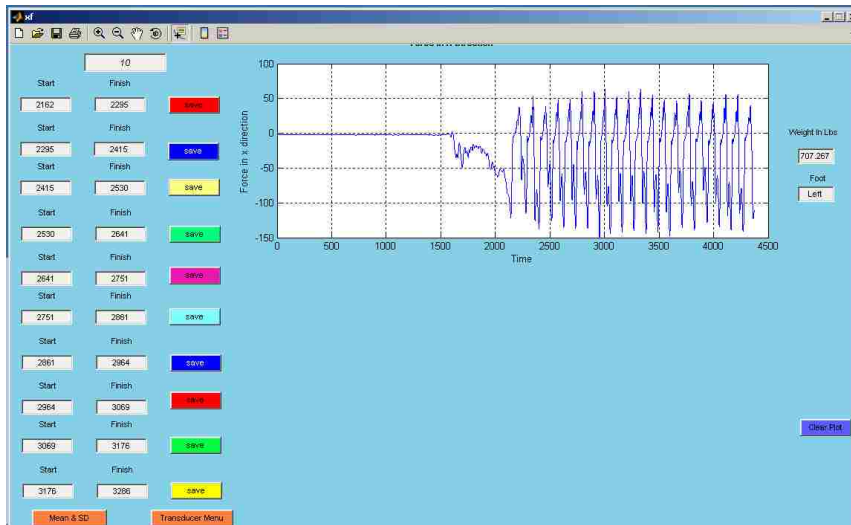
Using the **Back** button in the above screen will take the user to the Z-Direction plot window.



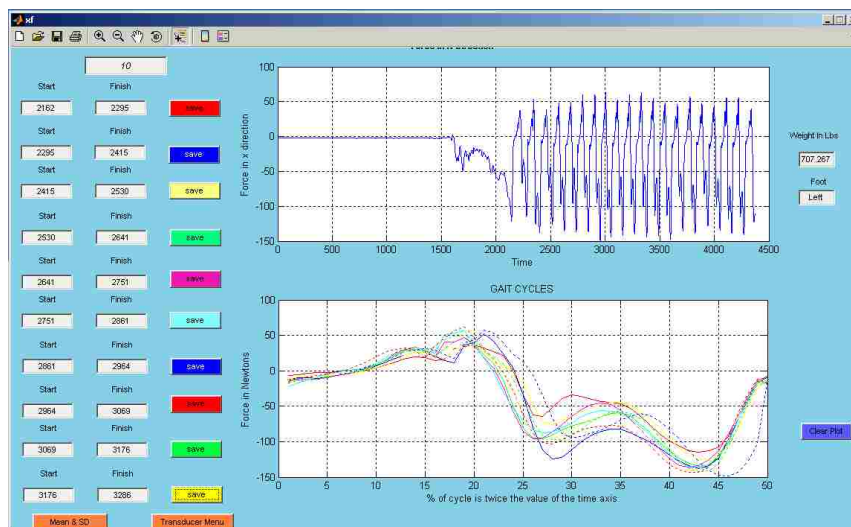
Again using the **Transducer Menu** button will let the user select the moment or force along other axes to analyze as shown below.



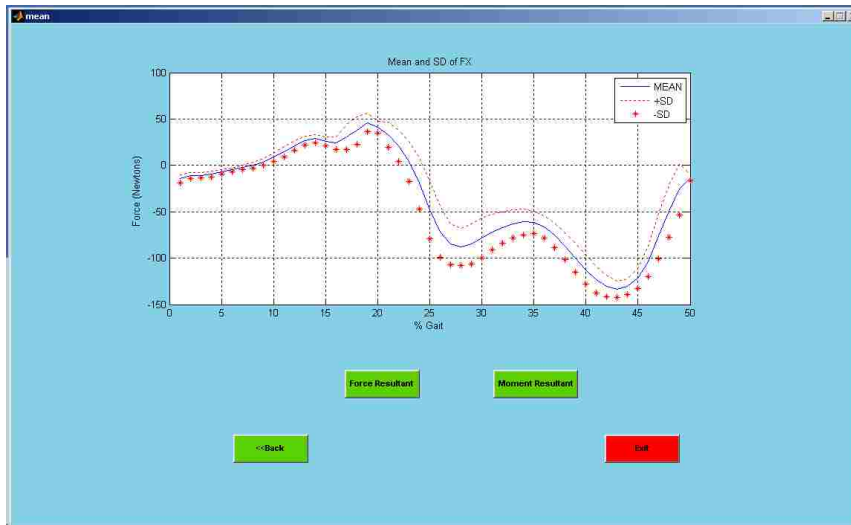
Selecting **X-Direction** under **forces** will give the user following window.



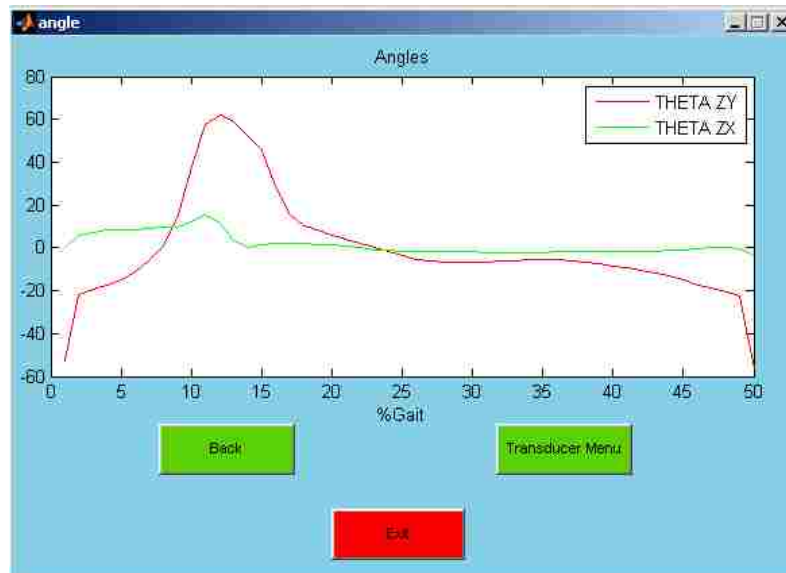
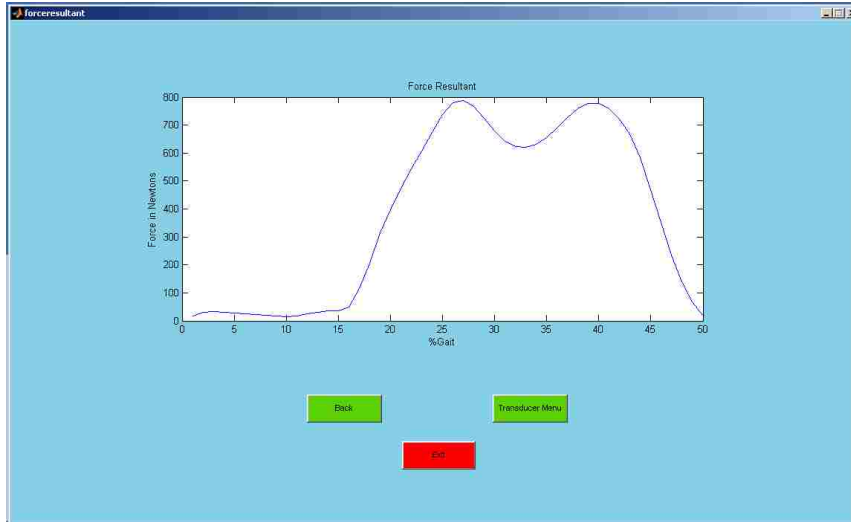
Gait cycles will be plotted as shown below in the second plot after clicking on the **Save** buttons of all ten steps.



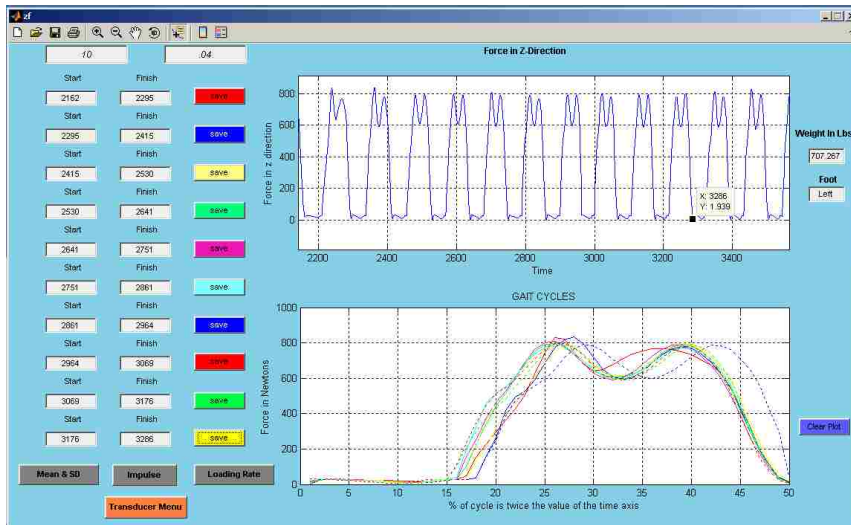
The **Mean and SD** button is used to produce the curves for the forces in the X-direction for the ten steps.



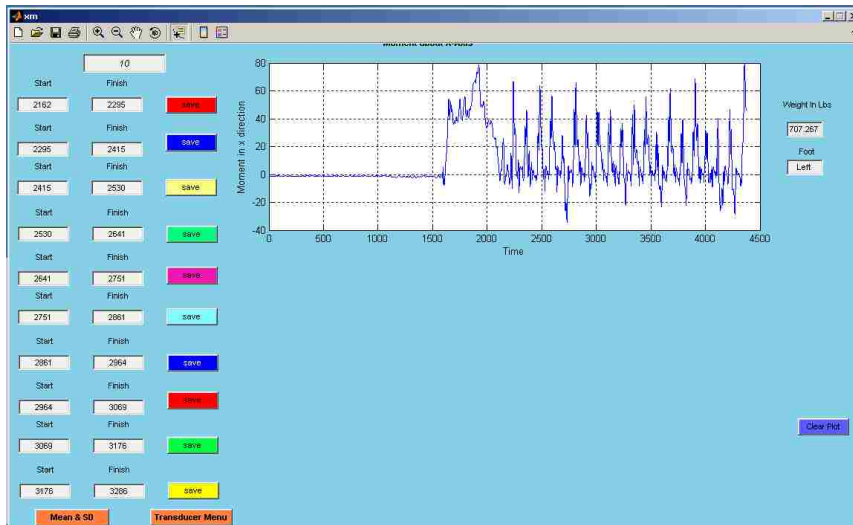
Now the user has completed processing the forces along the three axes and can use the **Force Resultant** option in the above window to obtain the following plot of the resultant force vector length computed from the magnitudes of the forces along each of the three axes. A second window indicates the angle of the resultant vector with respect to the Z axis of the transducer, which is more or less parallel to the pylon. The values shown include the projection angle of the resultant force vector with respect the Z axis in the ZX plane and ZY planes. The following two windows show how the resultant forces and its angle with the Z axis of the transducer appear.



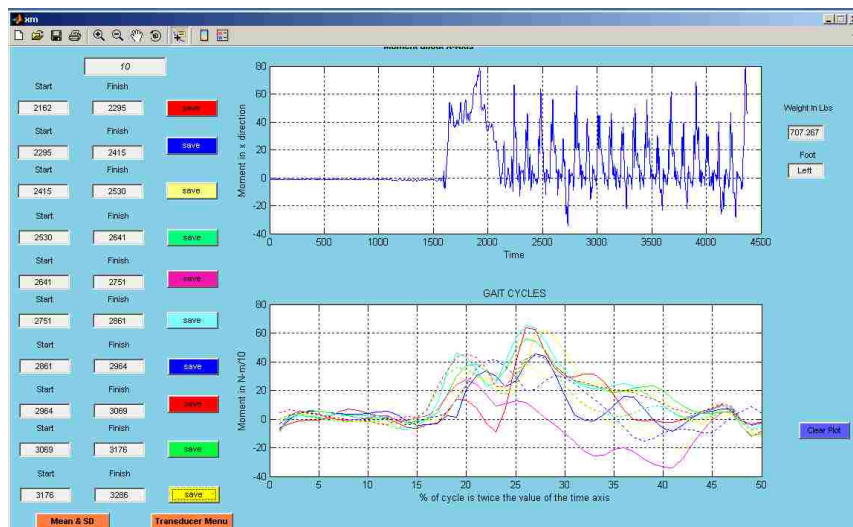
Next, to process the data for the moments about the X,Y,Z axes the same steps must be followed. Going back to Z-direction force window again will provide the following window:-



The user must analyze the moments in all three directions. For demonstration purposes the moment about the x-axis is selected from the **Transducer Menu**.

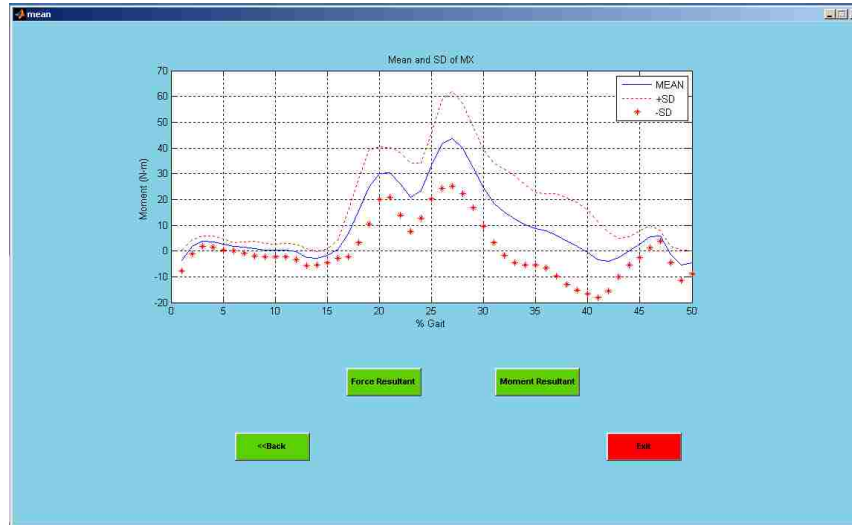


The same procedure used to analyze the force data has to be followed to analyze the moment data. However, the x coordinate (time) values defined initially for delineating individual steps for Fz have been preserved and do not need to be entered again. All windows are shown below. The first window depicts moments about the x axis.

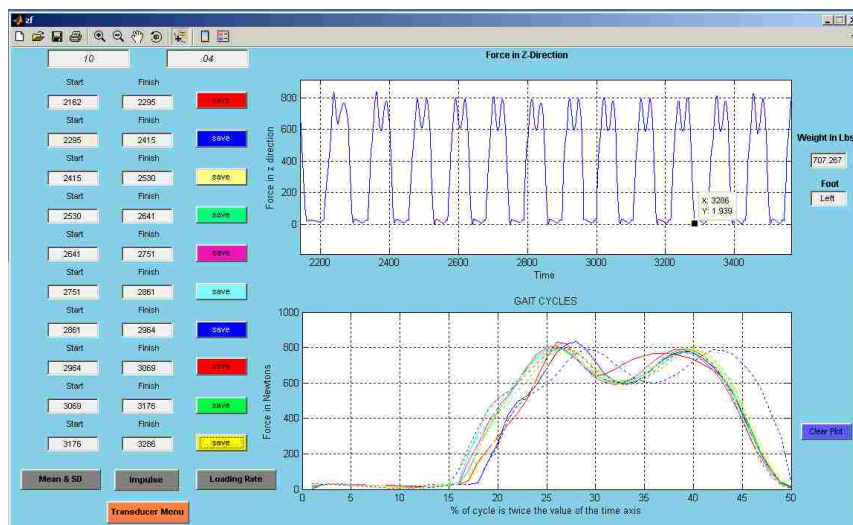




The mean and moment standard deviation of the moment about the X-axis are shown next:



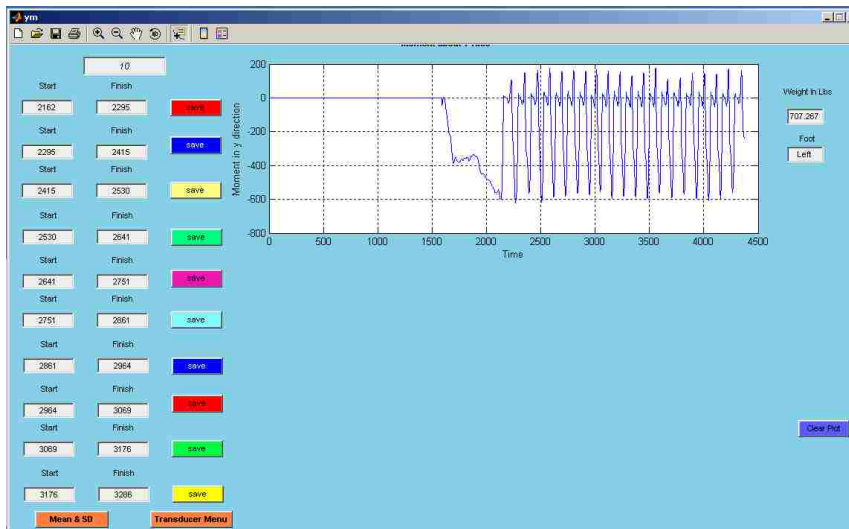
To next process the data for the moment about the Y axis, the user must go back to the original Z axis force window from the window depicting the mean and standard deviation for the moment about the X axis, and click on the **Transducer Menu** button



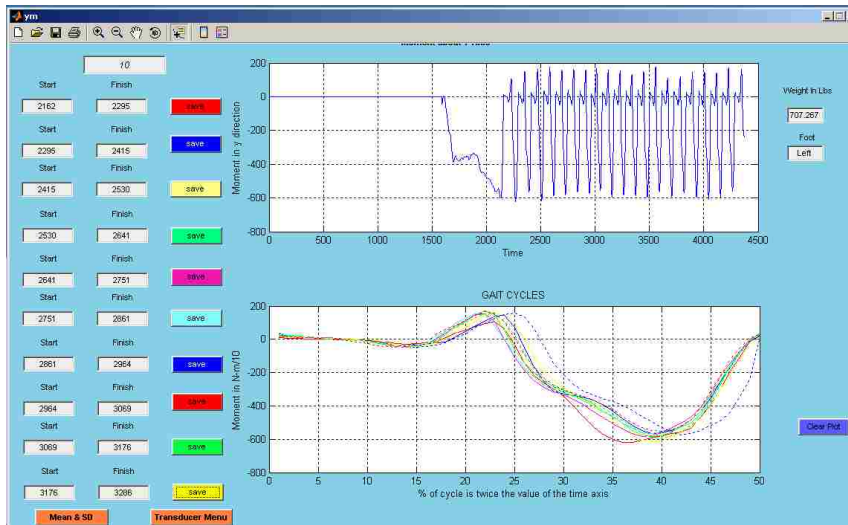
The following window shows the resulting Transducer Menu:



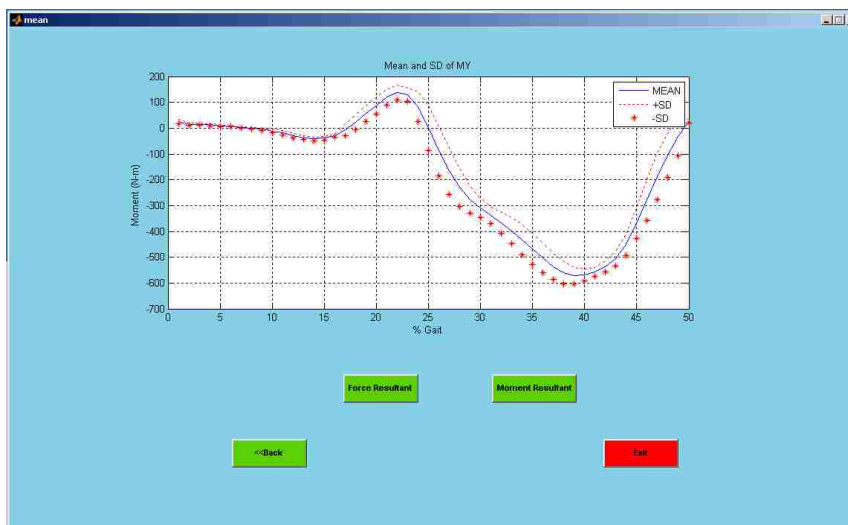
The button to analyze moments about the Y axis must be clicked:



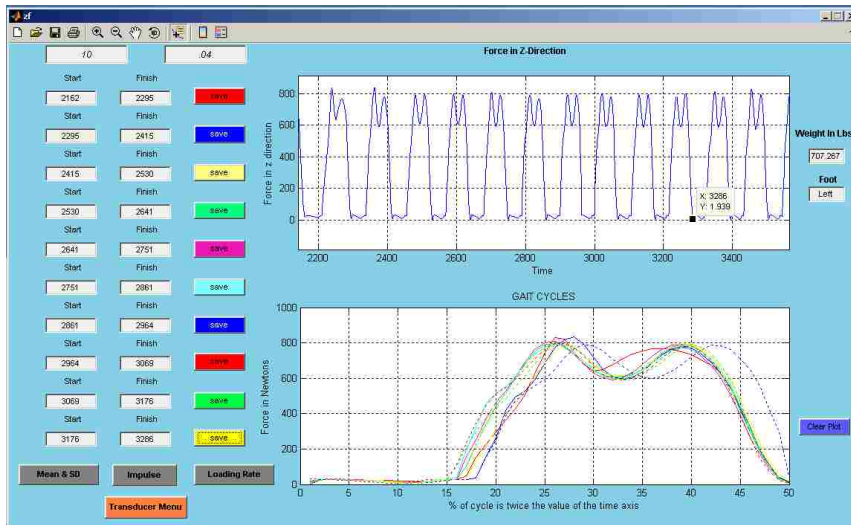
Then all the starting and ending values must be SAVED for the ten steps, which identify the gait cycles for moments about the Y axis:



The mean and standard deviations of the moments about the Y axis must then be computed:



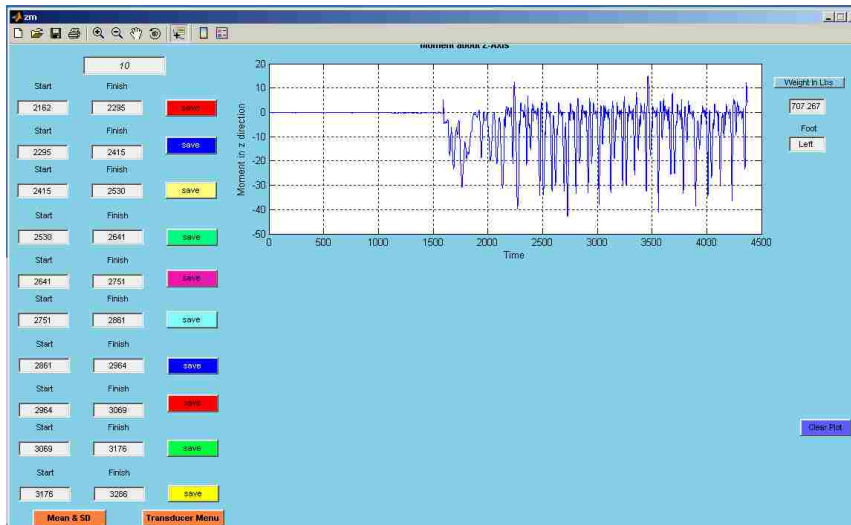
The user must then go to the original window used to first display forces in the Z direction and click on the **Transducer Menu**:



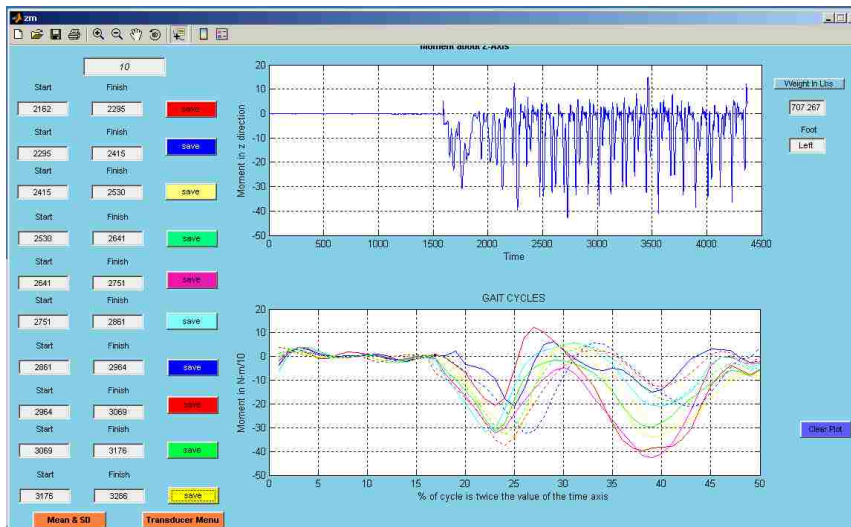
Again the Transducer Menu will appear:-



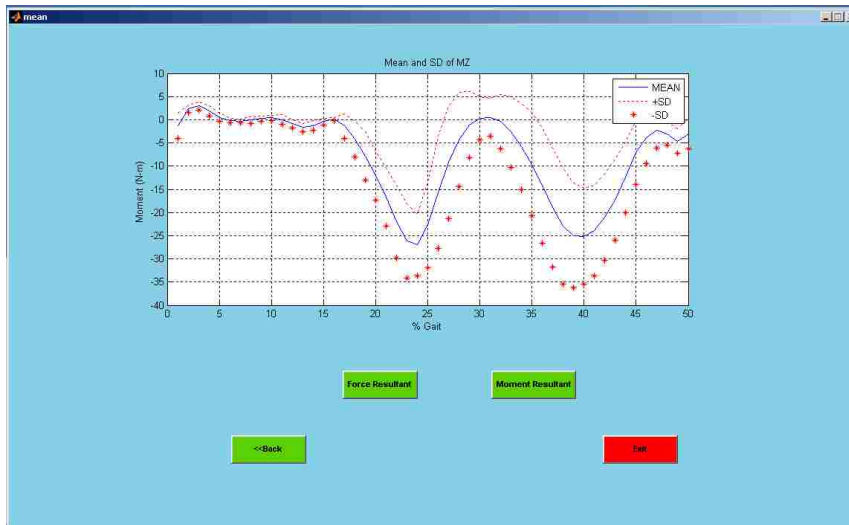
The user must request a display of moments about the Z axis:



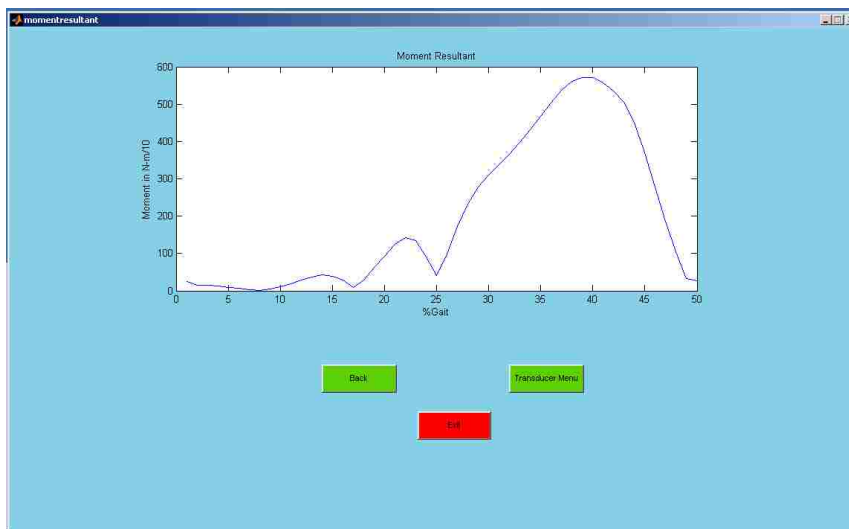
The starting and ending coordinates for the moments about the Z axis then appears:

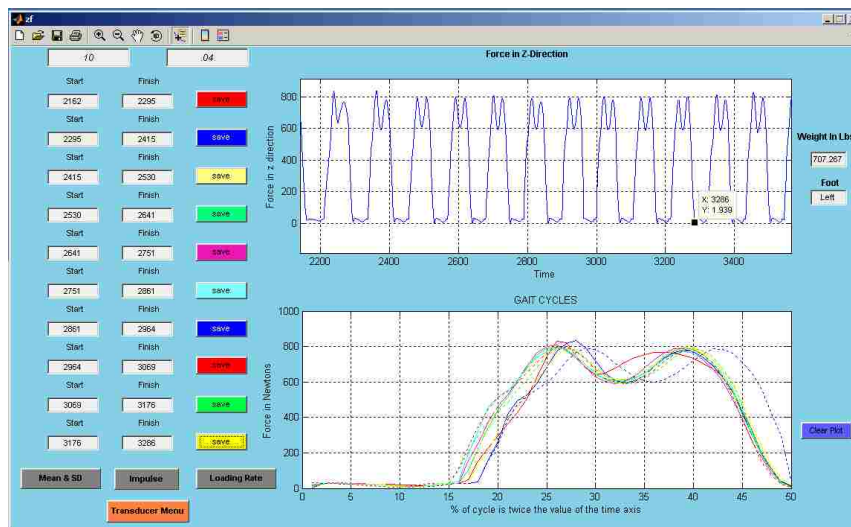
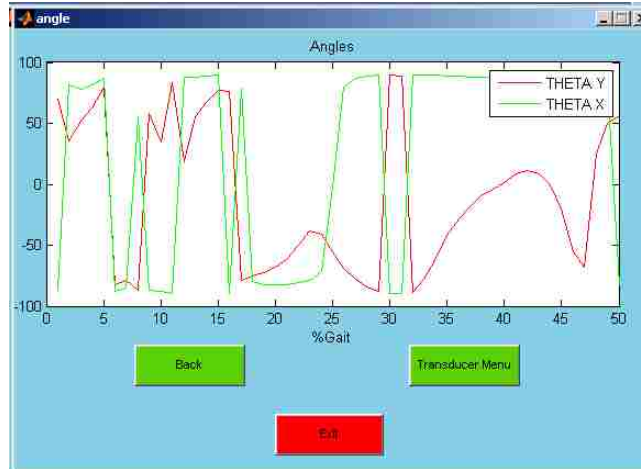


The mean and standard deviation of the moments about the Z axis are computed :



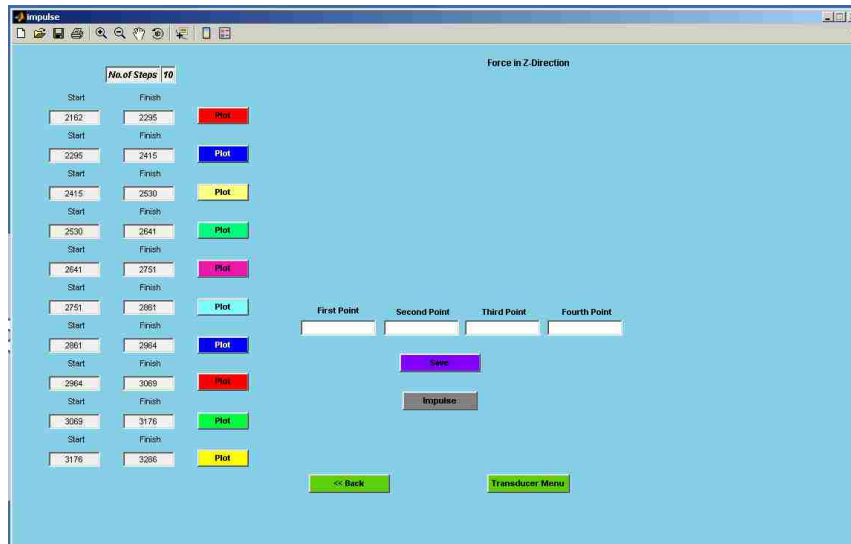
Now user can click the **Moment Resultant** button to compute the resultant of the moments about the three X, Y, Z axes since all three moments has been analyzed. Clicking on the **Moment Resultant** will produce the following windows (Resultant magnitude and resultant projection angles with respect to the Z axis in the ZX and ZY planes).



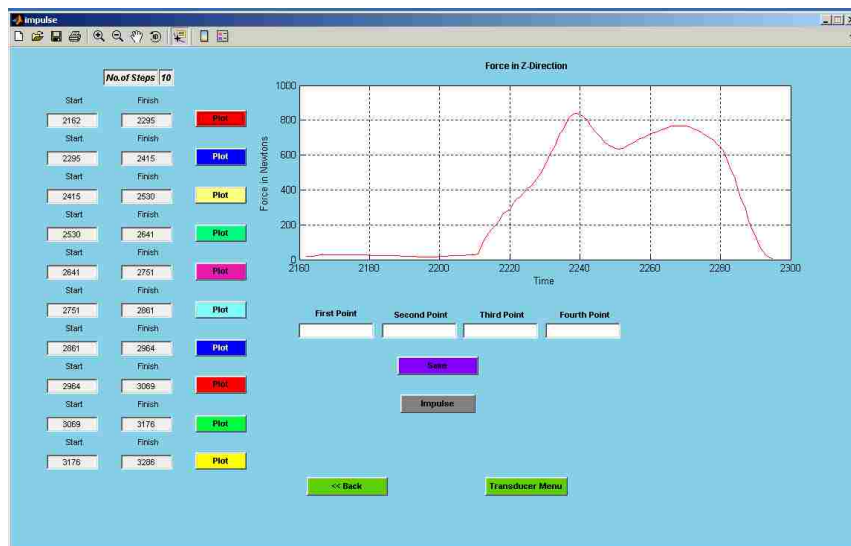


After all three forces and moments have been computed the user can calculate impulse and loading rate by using the two buttons beside **Mean & SD** button in the above window. Impulse is broken down into three phases for calculation. The first phase corresponds to foot loading, the second to midstance or rollover, and the third to the propulsive phase. For demonstration purposes the impulse for Fz has been selected. After selecting **Impulse** the following window appears in which the user has to input the x

coordinate values for the four points defining the three impulse segments. These points are obtained from the plot of the force (in this case  $F_z$ ) for each step.

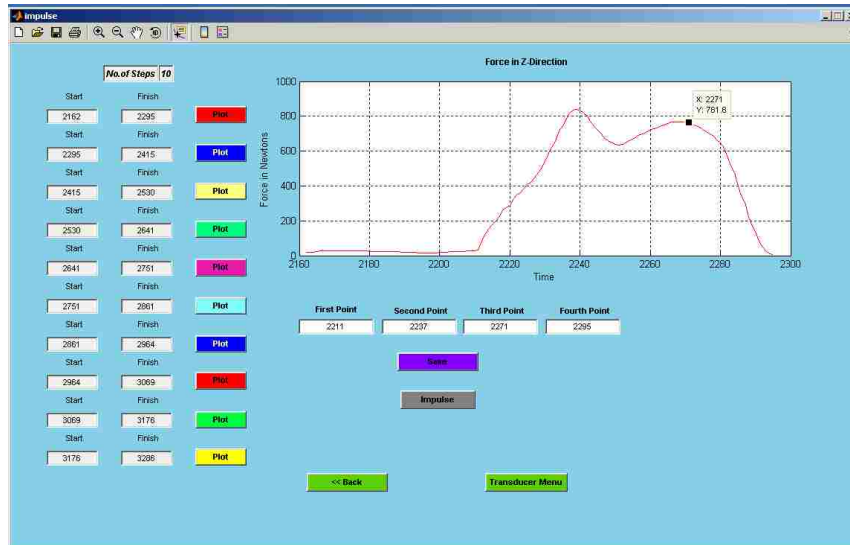


The user has to click the **Plot** button beside the start and finish buttons in the window to look at the original data for the step. With the use of zoom and data cursor the values of the four points can be entered.

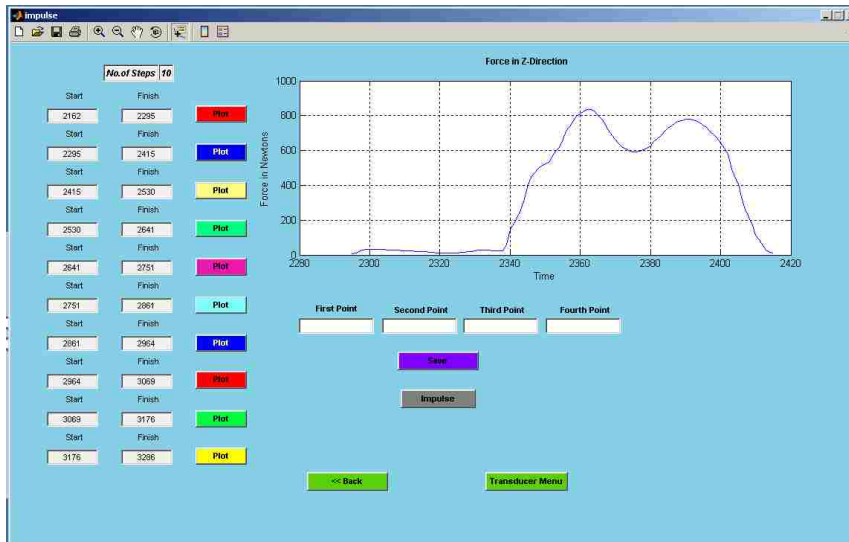




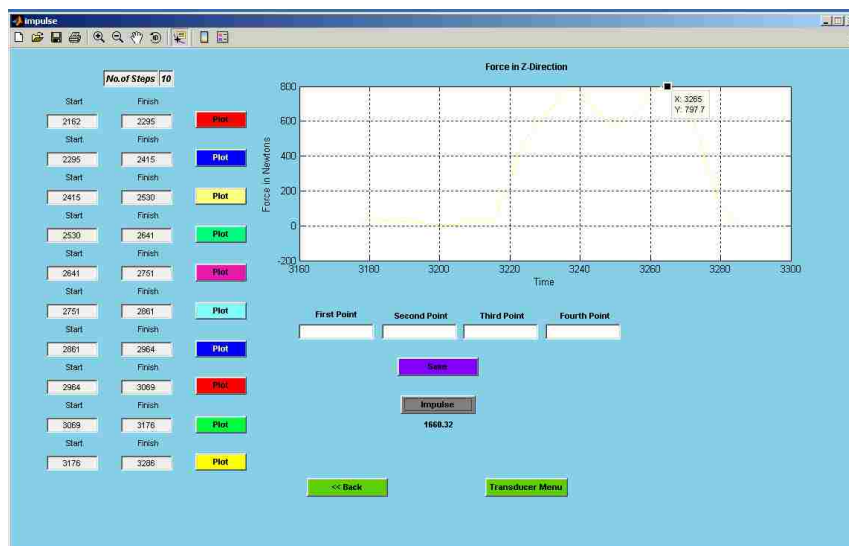
After entering the four points the user has to click the **Save** button under the four text boxes. The GUI will then calculate the three impulses and the total impulse and save it in the program for export.



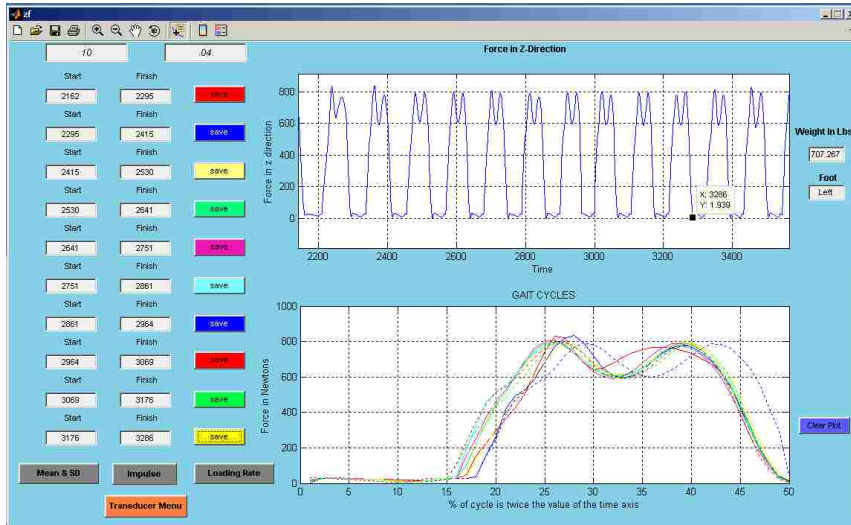
Once the user is done the **next plot** button has to be clicked to display the second step.



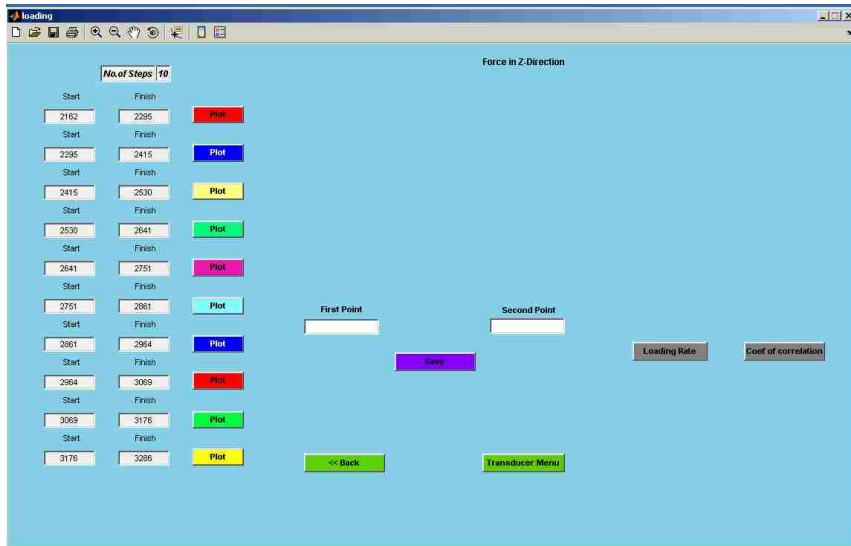
The same procedure has to be followed to calculate the impulses for the three separate phases and total impulse, and then all these steps repeated for the remaining steps. Once all 10 steps are done the user has to click on the **Impulse** button just below the **Save** button. It will display the total impulse below the **Impulse** button as shown below.



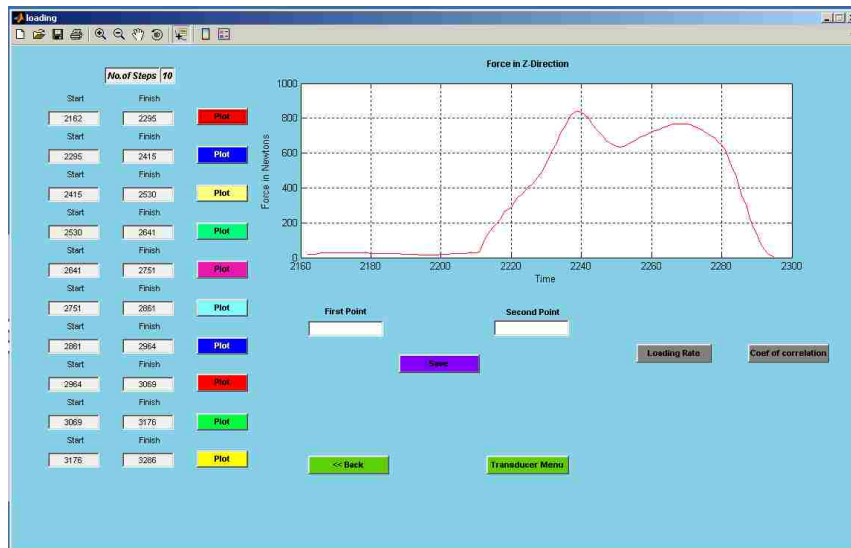
To calculate Loading Rate the user has to click on the **Back** button on the above window, which causes the following window to appear:-



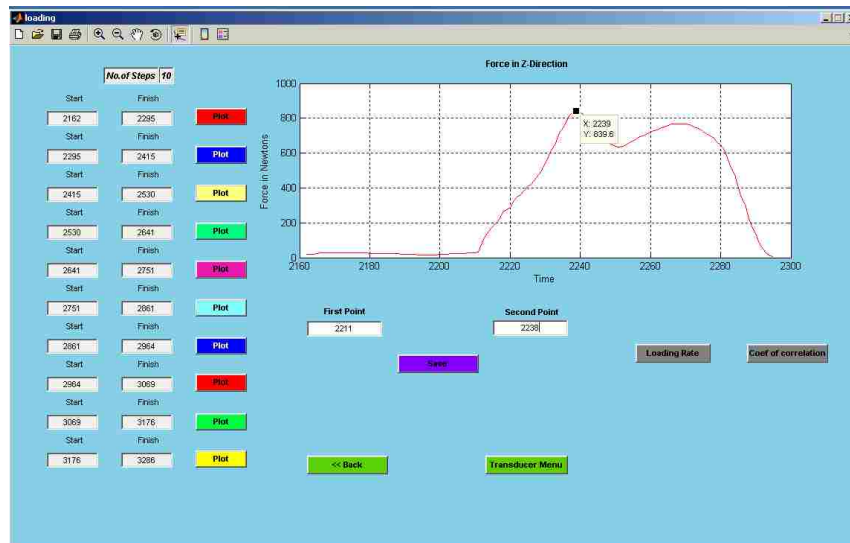
Now the user has to click on the **Loading Rate** button to bring up the loading rate window.



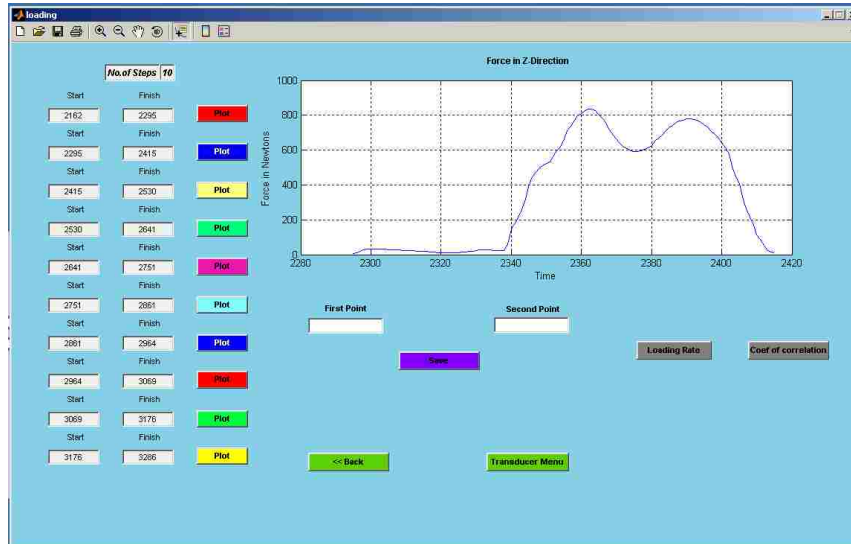
Computing the loading rate involves almost the same procedure as computing the impulse. After clicking on the **Plot** button, the following window and the corresponding step data will be displayed.



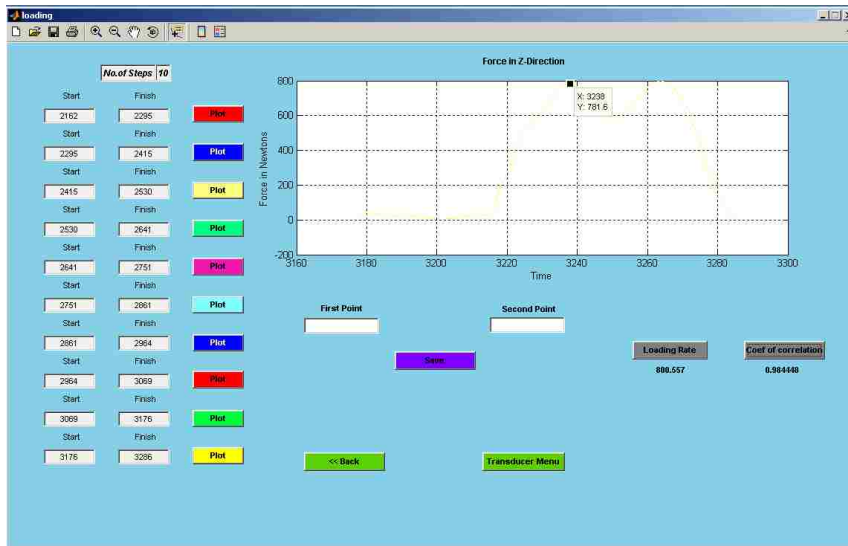
The user has to enter the two points in time to be the starting and ending points for calculating the loading rate. Then the **Save** button must be clicked as shown in the following window.



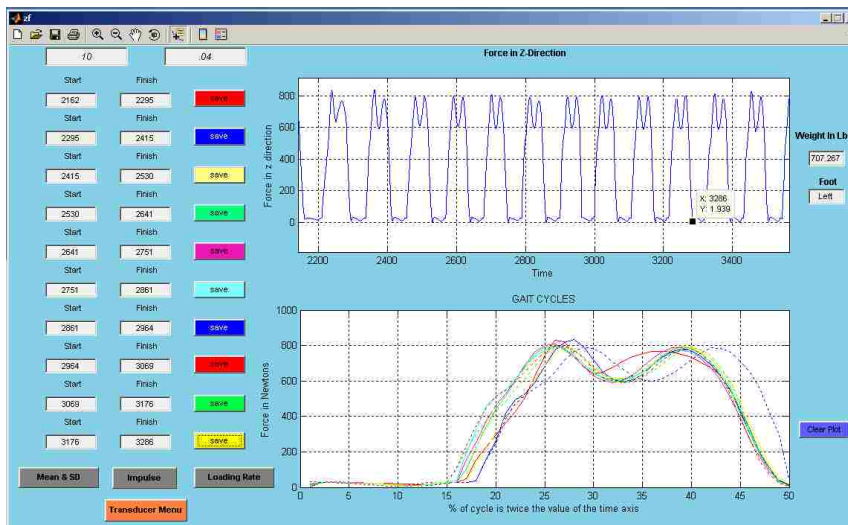
Once user is done with this first step in the sequence of steps recorded by the transducer, he or she should click the **Plot** button, which will display the second step.



The same procedure has to be followed for calculating the loading rate of the second and remaining steps. After all ten steps are entered in this manner, the user has to click on the **Loading Rate** button and the **Coeff. of Correlation** button, which will compute the mean loading rate over all ten steps as shown below:-



After the loading rate calculations are completed, the pressure sensor data can be analyzed. This is described in the next chapter



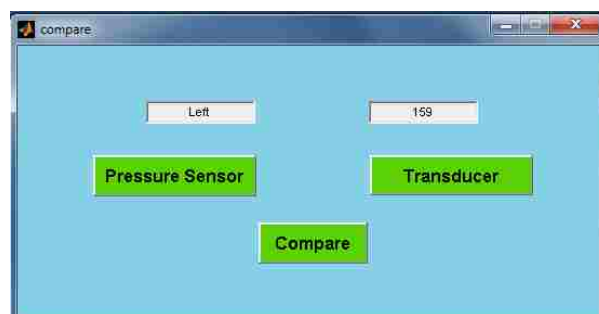
## CHAPTER 7

### GUI DESIGN AND OPERATION – PRESSURE DATA

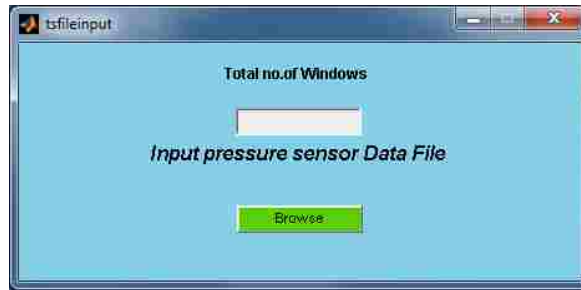
Before the Tekscan pressure data can be imported into the GUI, the pressure sensor data must be windowed. The method for doing this is explained in chapter 8. For this chapter, it is assumed that the procedures of Chapter 8 have been carried out, and a file exists within the **GUI** folder in Excel format. To integrate the socket pressure data into the GUI analysis software the user has to go to the transducer menu and from there to the **Main Menu**. The button for doing this is shown below.



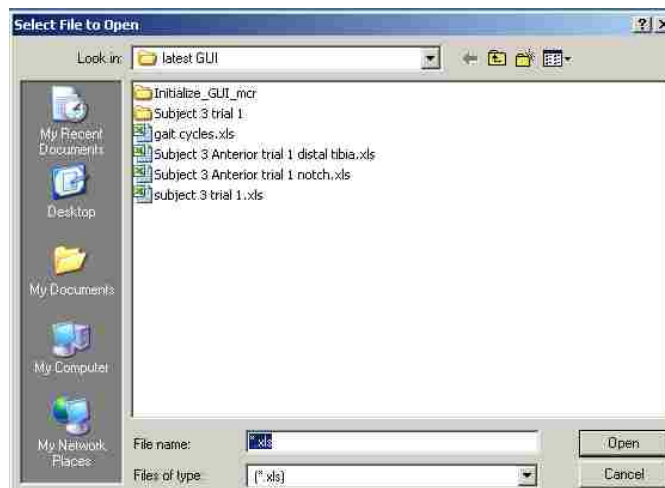
After clicking this button, the main menu will appear as shown below.



Next the user should select the **Pressure Sensor** option to analyze the pressure data. After selecting the **Pressure Sensor** option the following window appears in which the user has to enter the number of pressure windows exported using the Tekscan software. The full window for the entire array should be included as one of these.

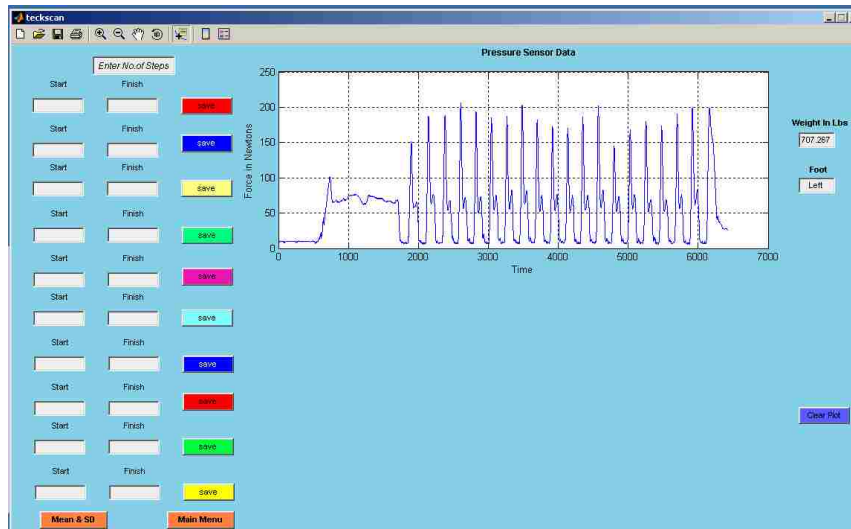


After entering number of windows, selecting the **Browse** option opens the following window and allows the user to select the pressure data file, which has all windows data from Tekscan.

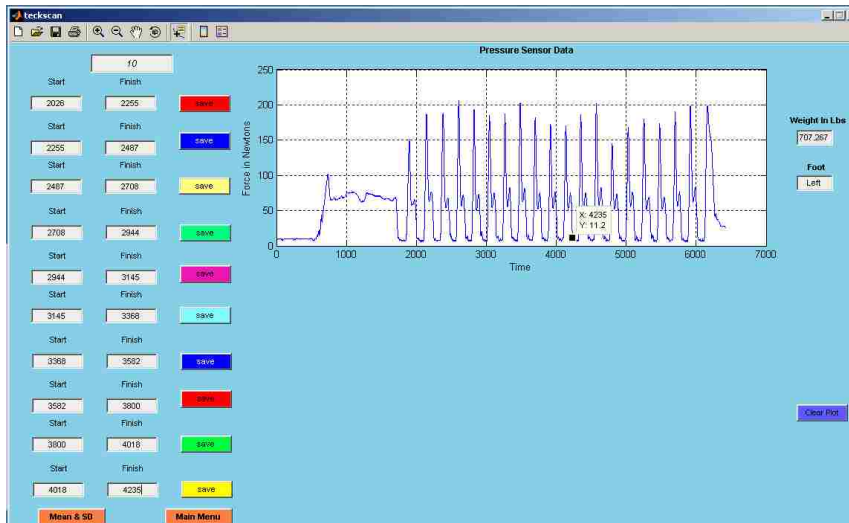




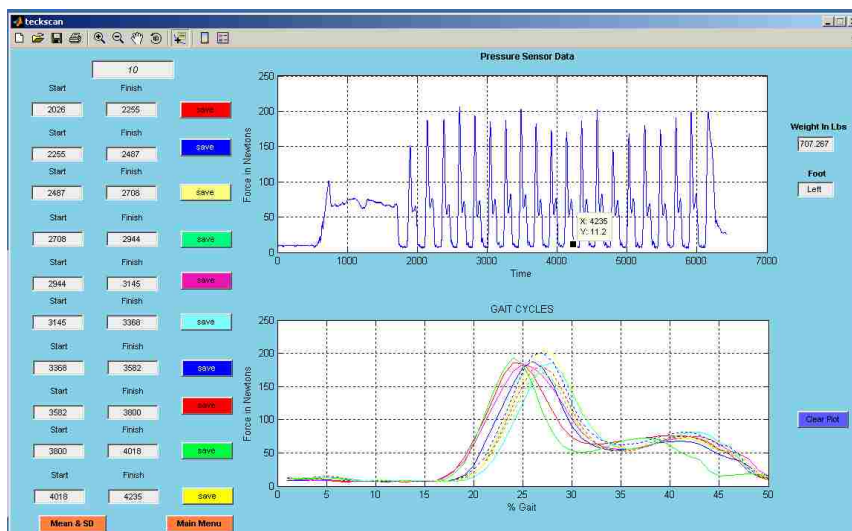
After selecting the pressure data file, the windowed pressure data will be displayed as shown below:



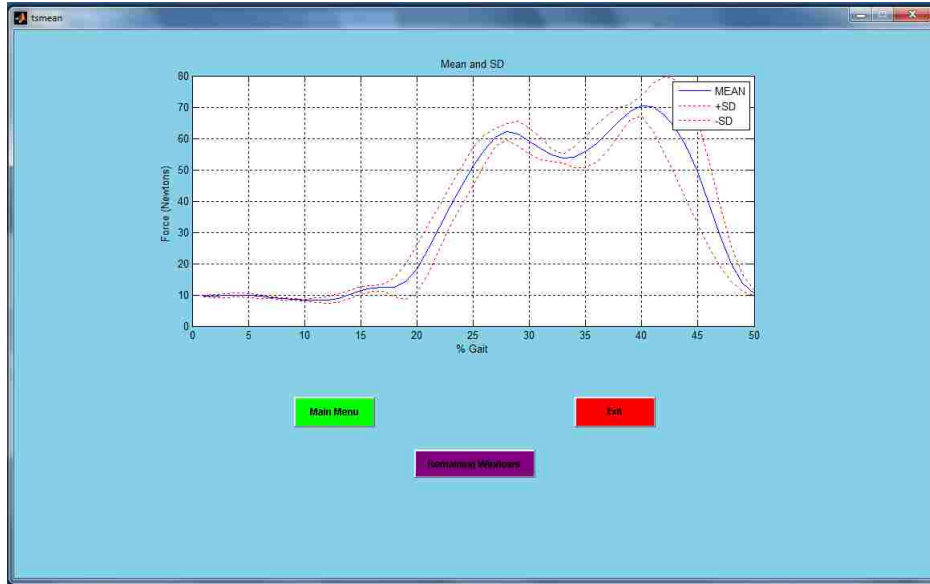
Similar to the processing of transducer data the user has to select the time domain  $x$  coordinate values of the start and end points for each step and enter them into the corresponding text boxes using the **Zoom** and **Data cursor** options from the toolbar located at the top of the window.



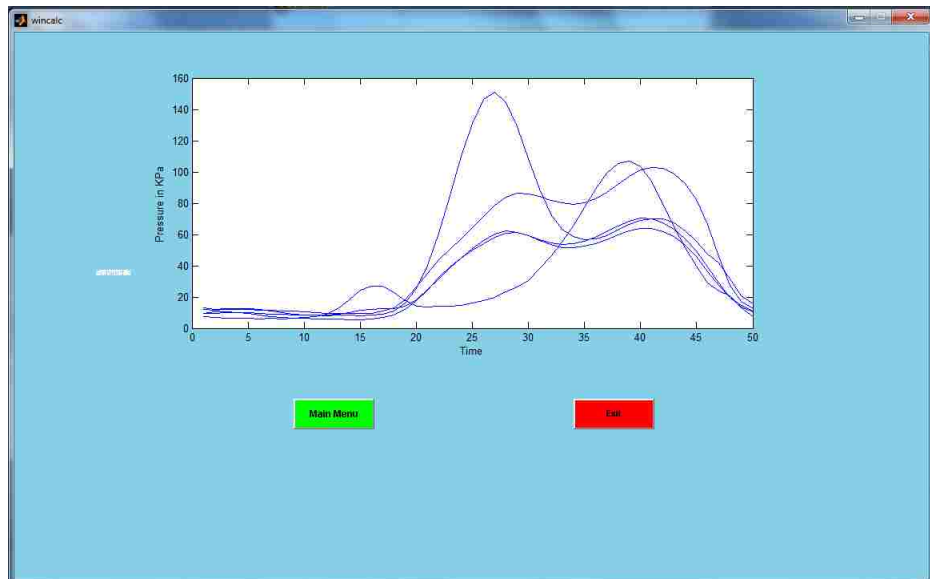
After entering the start and end points of all ten steps the user has to click on the **Save** buttons to obtain a plot that overlay all of the pressures for the ten steps, as shown in the window below:



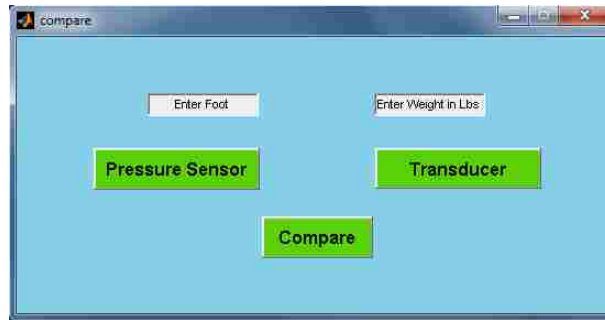
The mean and standard deviation of the ten steps can be calculated using the **Mean & SD** button in the window and the following plot will be displayed.



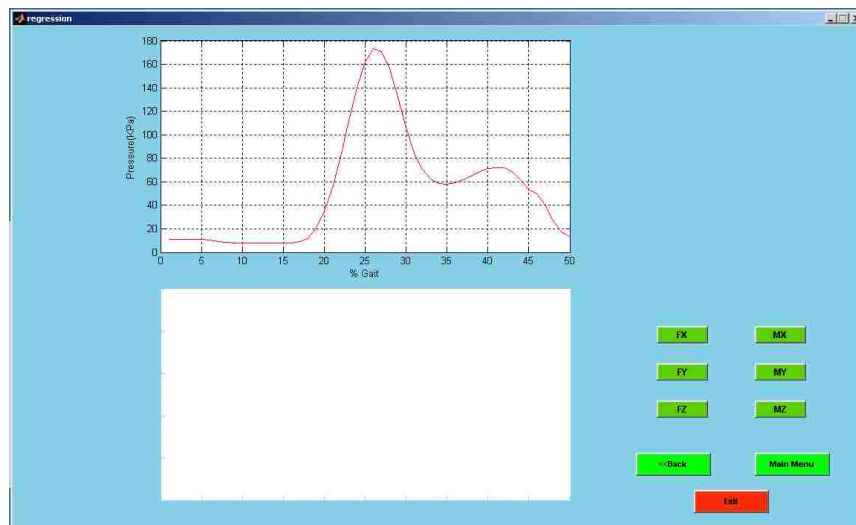
Next the user has to click on the **Remaining Windows** button to analyze the mean of remaining windows as shown in the following window.



Next the user has to go back to the **Main Menu** in order to compare the transducer data and pressure data.



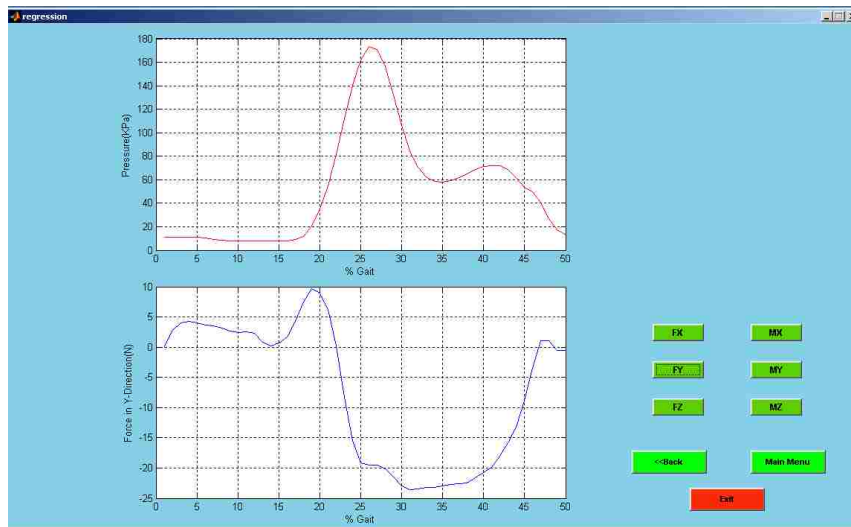
Clicking on the **Compare** button will open the following window showing the pressure data plotted in KPa and displaying buttons which allow different options for selecting the particular force or moment from the transducer data.



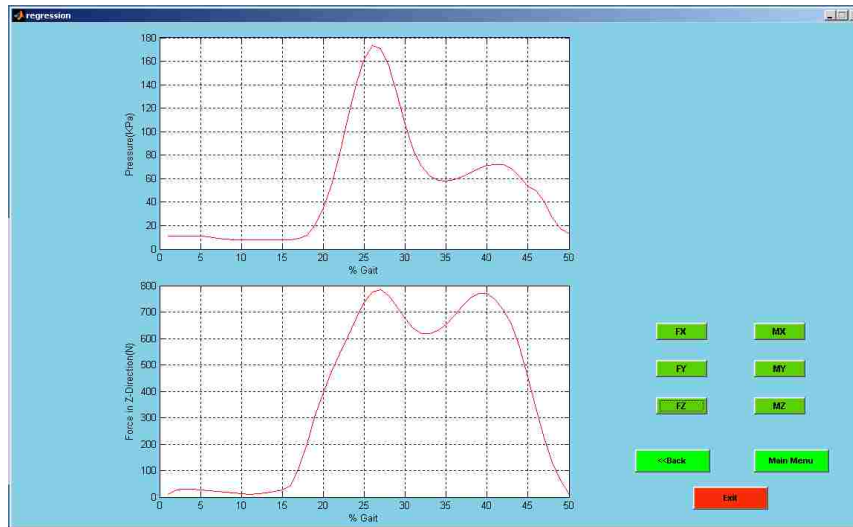
A plot of the force or moment will be displayed in the second window. If the user has selected FX, from the options provided, the plot will appear as below. [Note that in the following plots, the pressure curve displayed in the upper plot area does not change.]



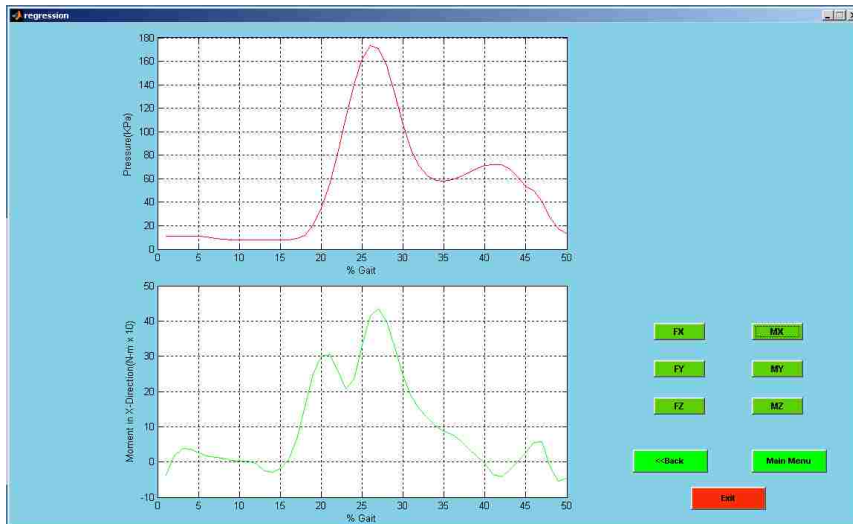
If the user selects **FY**, the following plot will be displayed in the lower plot area.



If the user selects **FZ**, the following plot will be displayed in the lower plot area.



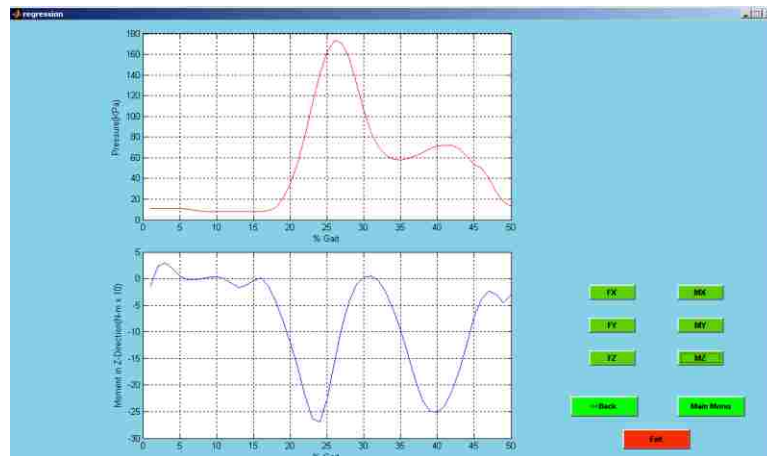
The following plot will be displayed in the lower plot area if the user selects **MX** from the options provided.



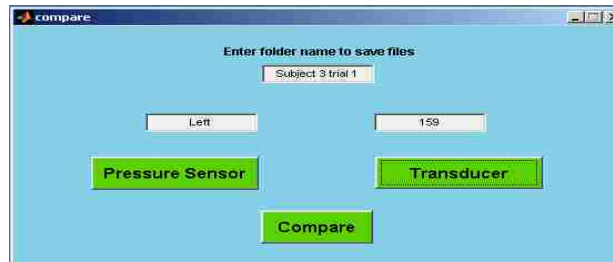
The following plot will be displayed in the lower plot area if the user selects **MY** from the options provided.



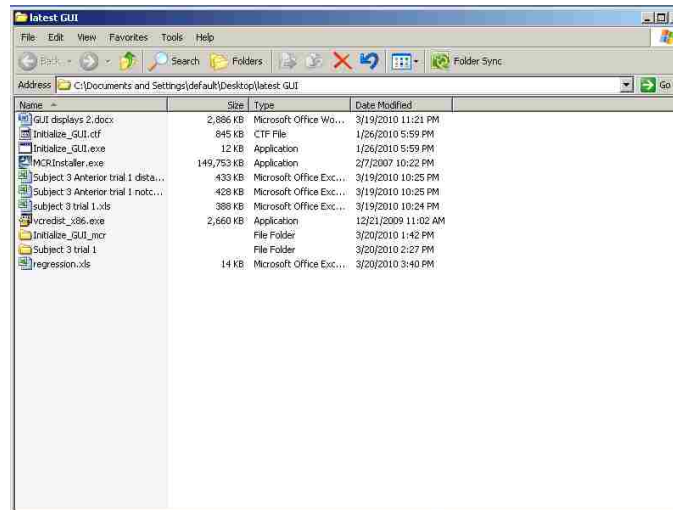
The following plot will be displayed in the lower plot area if the user selects **MZ** from the options provided.



After comparing both the transducer data and the pressure data, the user has to return to the main menu to export all the files.



After saving these files, the GUI folder will appear as follows:



Before using the Pressure sensor GUI user has to export all windows data from Tekscan software, which is explained in the next chapter.



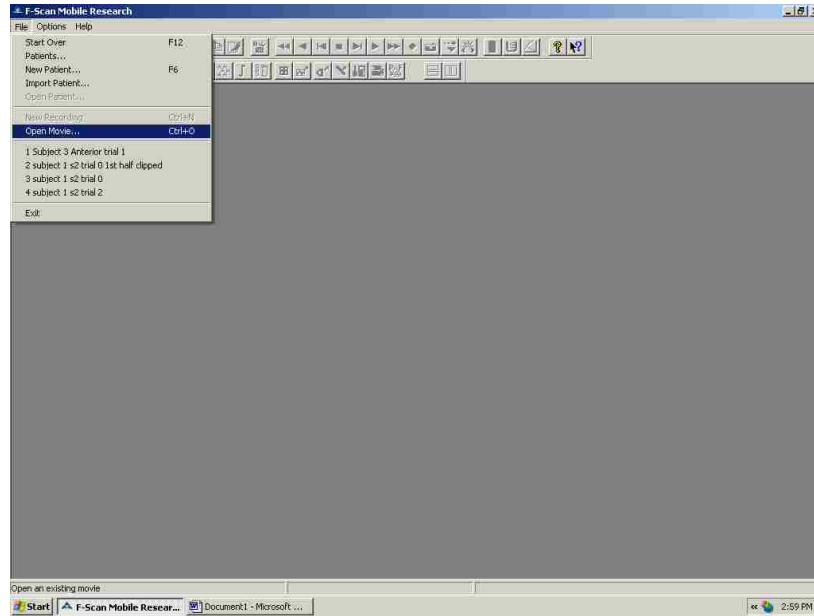
## CHAPTER 8

### WINDOWING TEKSCAN PRESSURE DATA

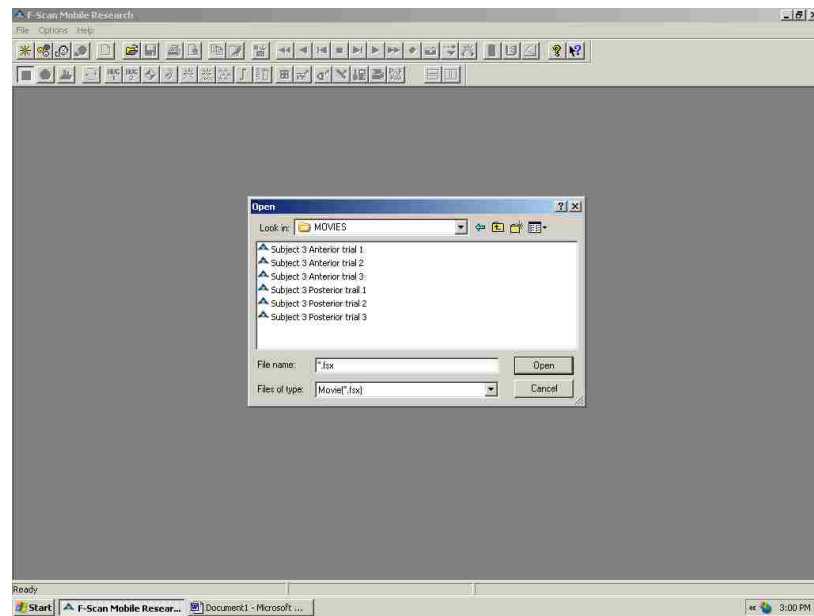
The steps in this chapter must precede those in Chapter 7. This chapter explains how the pressure data obtained and displayed using Tekscan software can be processed to produce the Excel file that must be exported from the Tekscan software in a format that allows it to be processed by the GUI. The file that is produced in Excel format must contain a time series of average pressures for the region of the prosthetic socket that is of interest.

Data from the Tekscan pressure sensor is stored in a movie format by the Tekscan software. The format displays each entire sensor array, and the movie feature plays the displays in sequence so that changes in pressures can be observed. The user has to use Tekscan software to window this data for the region of the prosthetic socket that is of interest. The following section explains, with the help of window displays, how to use the Tekscan software to produce the window for the region of the socket that is of interest and prepare the data for export.

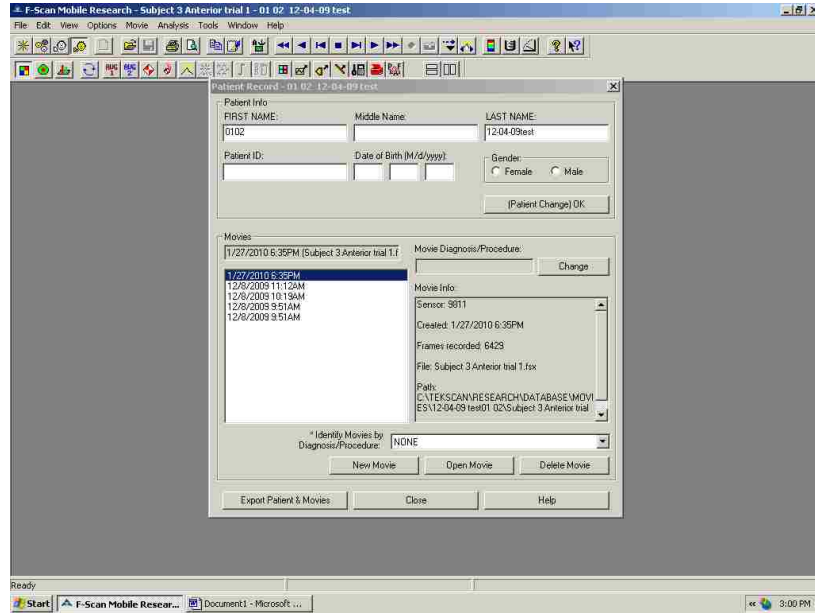
After opening the Tekscan software the user has to click on the **file** button on the top left hand side of the window to open a movie file. This will produce the screen shown below.



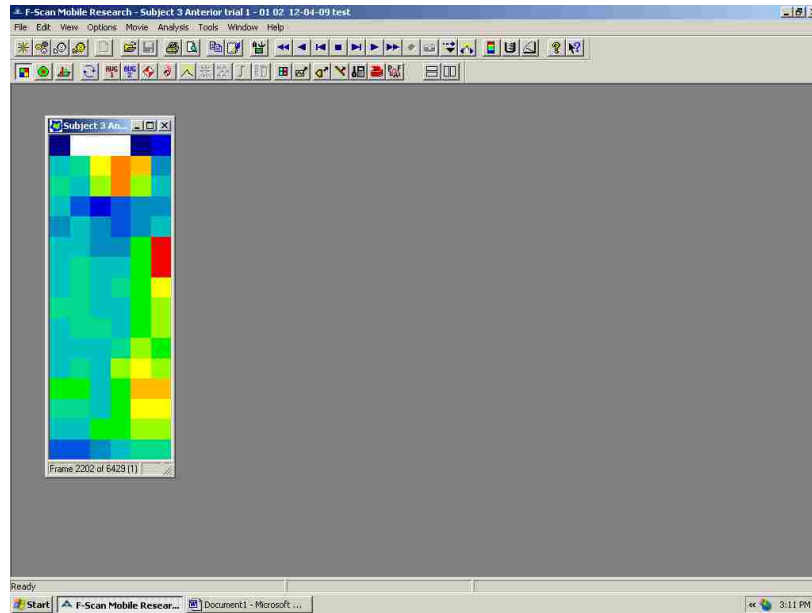
After clicking on **open movie** in the **file** option, the following window will pop up and allow the user to select the movie for the particular pressure data set of interest. The user has to go to the folder where the **Movie** files were stored and select the one that is desired for analysis. This is shown below:



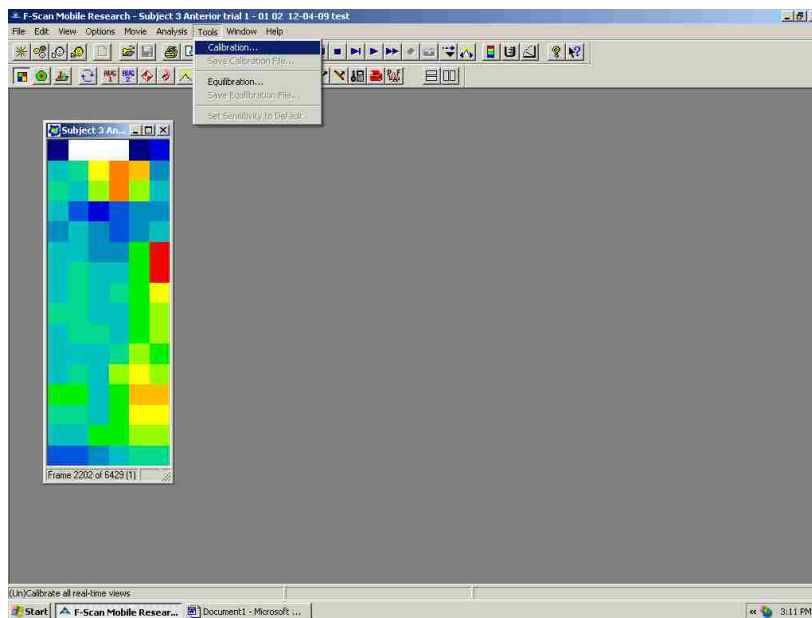
After selecting the appropriate file, the following window appears.



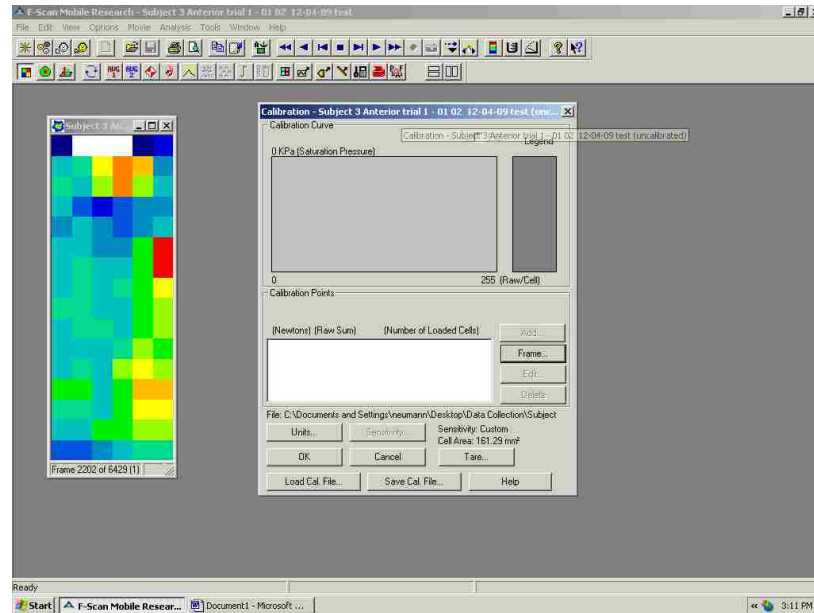
This window can be closed without any consequences at this time. After closing the above window the following window with the movie will appear.



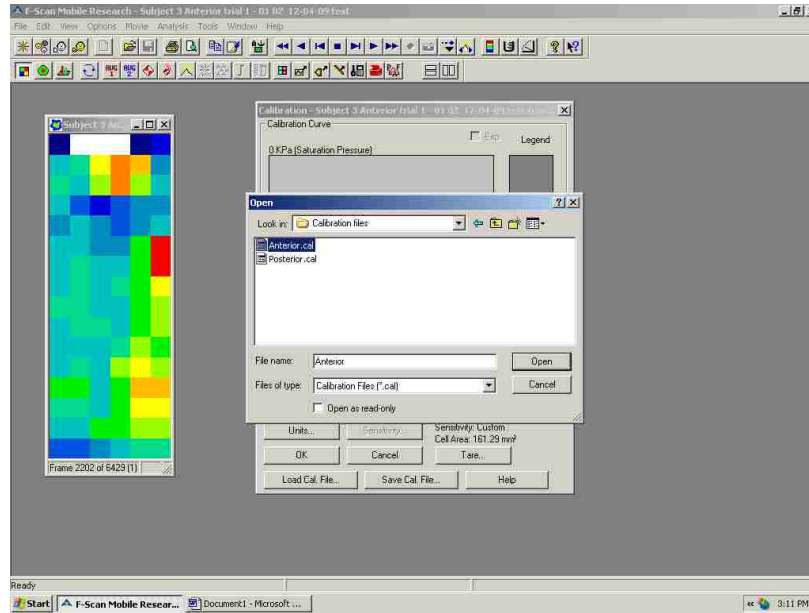
First the user has to calibrate the sensor data using a calibration file that was created prior to the actual recording of the pressure data. To do that the user has to go to **Tools --> Calibration** as shown in the window below.



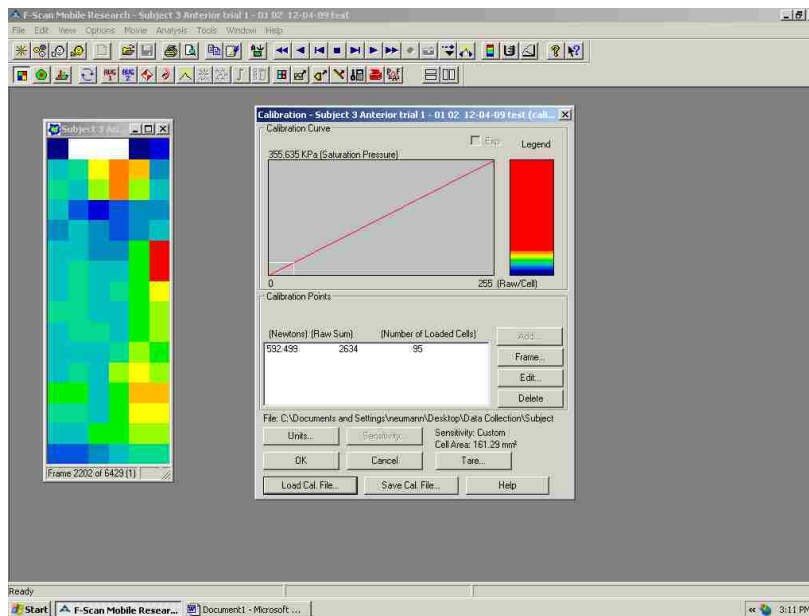
After selecting **Calibration** from the **Tools** menu, the following window will appear.



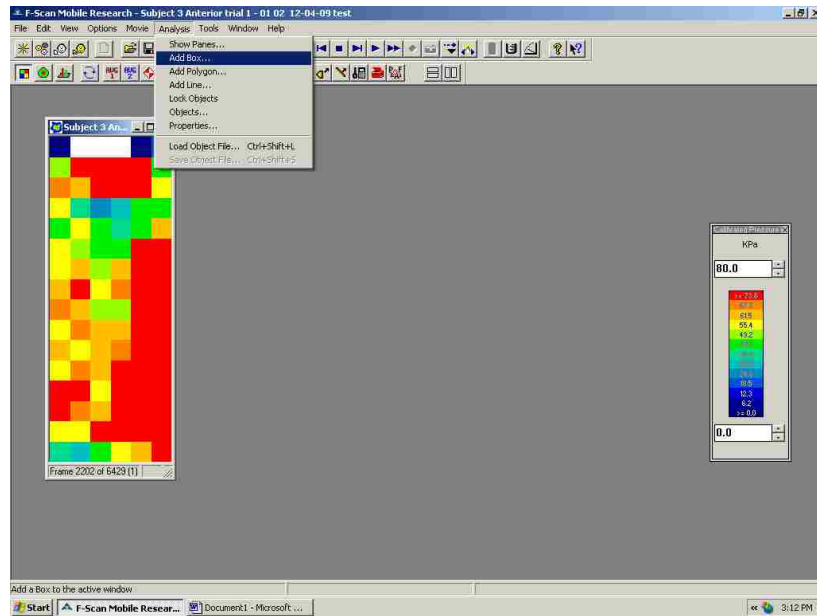
For calibrating the raw sensor data the user has to use the pre-saved calibration file. To do that the user has to load the calibration file using the **Load Cal. File** button at the bottom left corner of the window. After clicking on the **Load Cal. File**, a window with different calibration files will appear. The user has to select the appropriate calibration file.



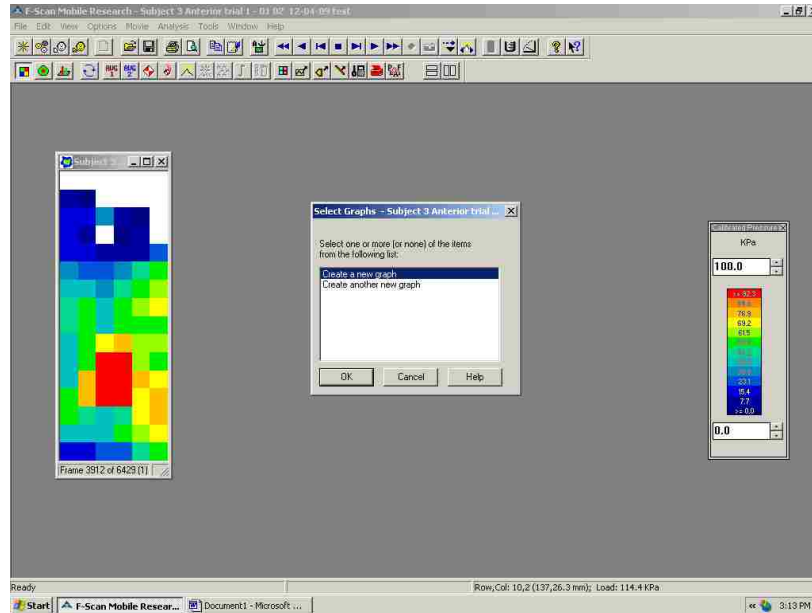
Selecting the calibration file and clicking on the **Open** button will produce the following display, which will indicate that the raw pressure data in the file have been calibrated. Then the user should click **OK**.



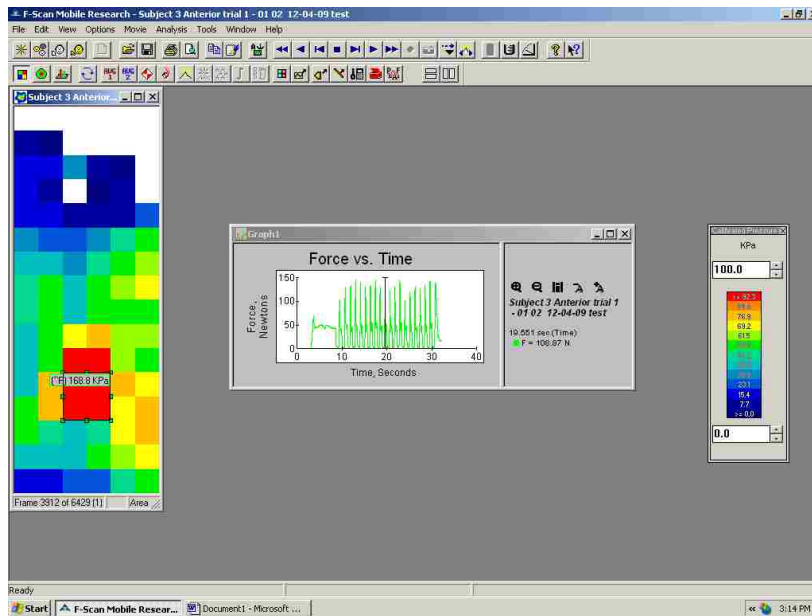
The following window will appear after clicking on the **OK** button. To window the region of the socket desired for analysis the user has to click on the **Add Box** option under **Analysis**.



After selecting the **Add Box** option, the following window will appear with two options and the user will be asked to select one of them.

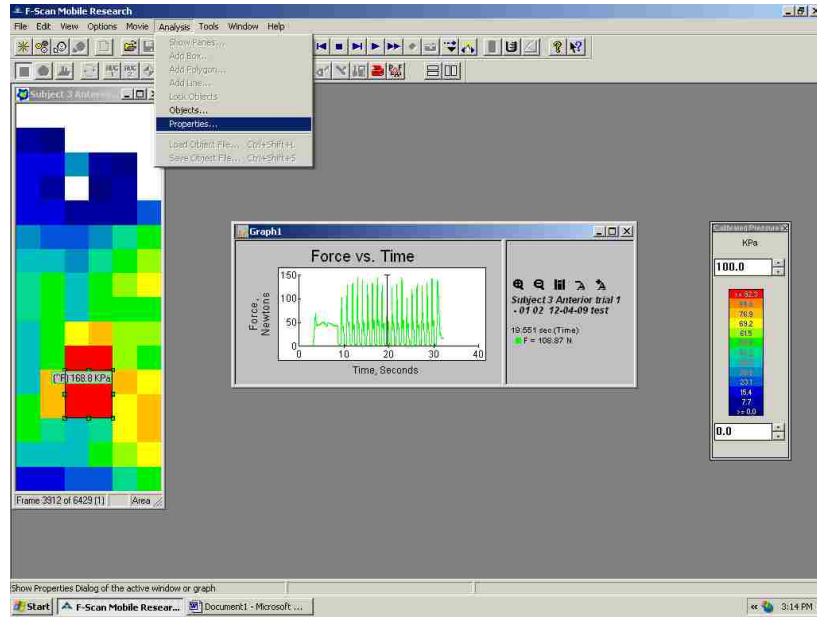


The user should select **Create a new graph** and the following plot will be displayed showing the total pressure for the entire sensor array along with a box located in the movie window. The user can modify the box and move it from one point to another to window the region of interest in the socket.

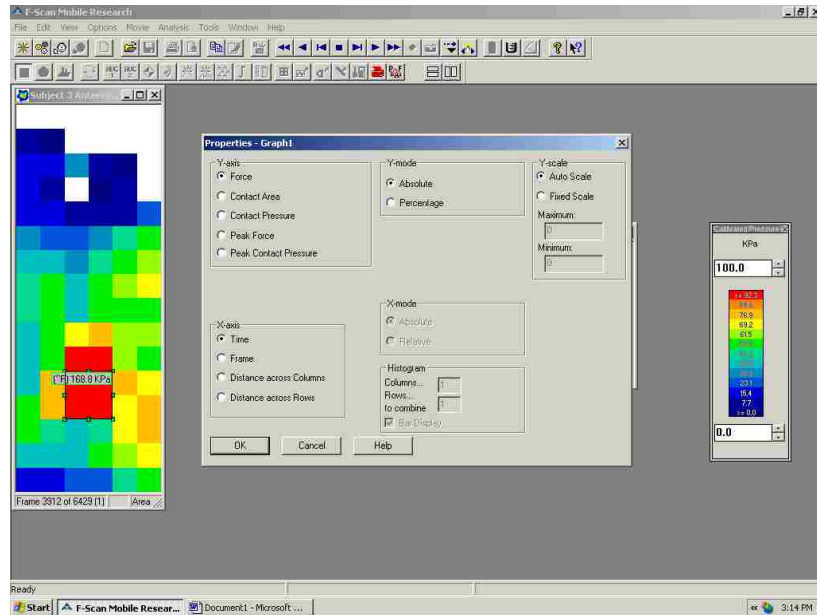




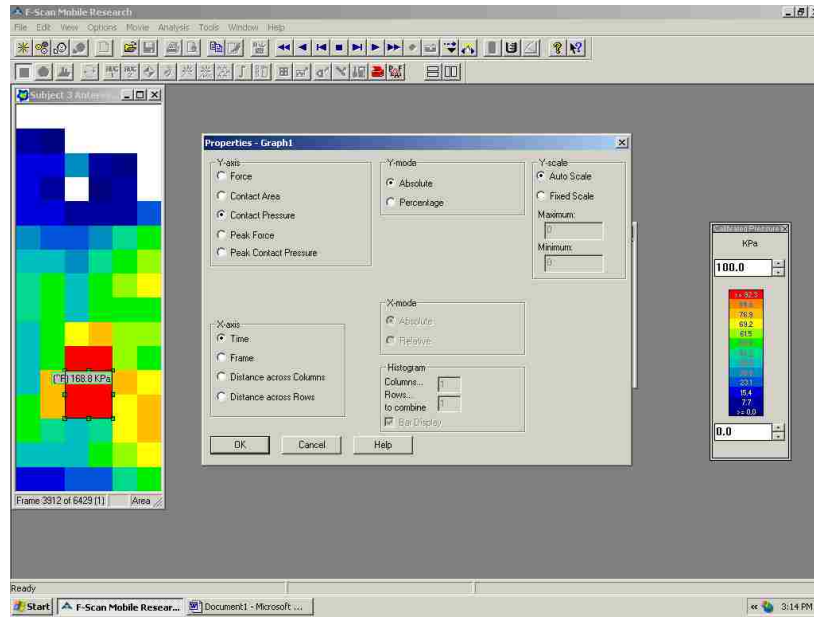
The units of the data may be in the default format, and to convert them into desired units the user has to go to Properties under Analysis. First, though, the graph window has to be selected as shown below.



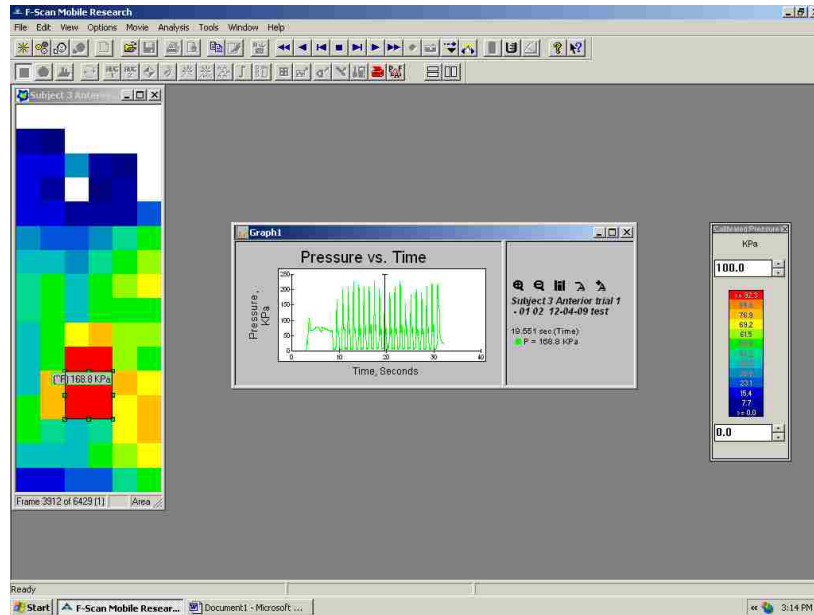
The following window will appear:



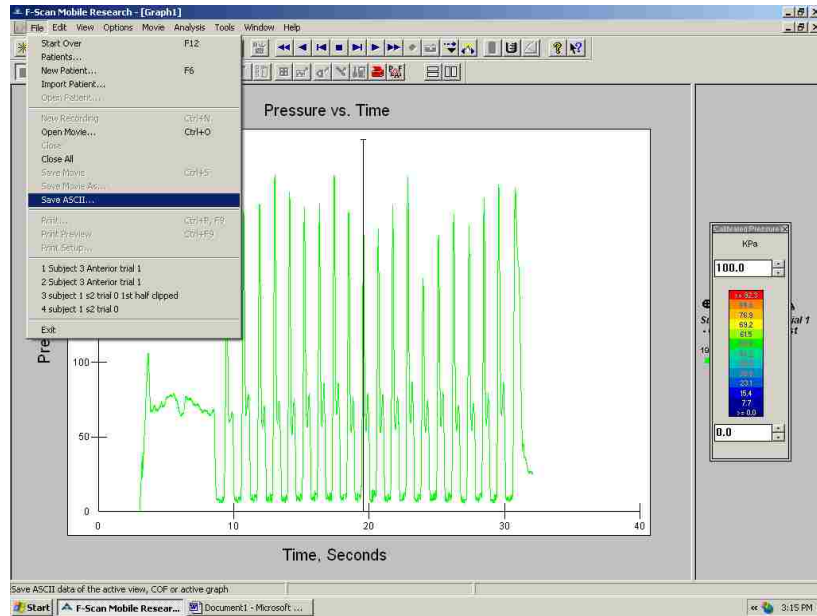
For demonstration purposes the following options have been selected from the window shown: **Contact Pressure, Time, Absolute, and Auto Scale.**



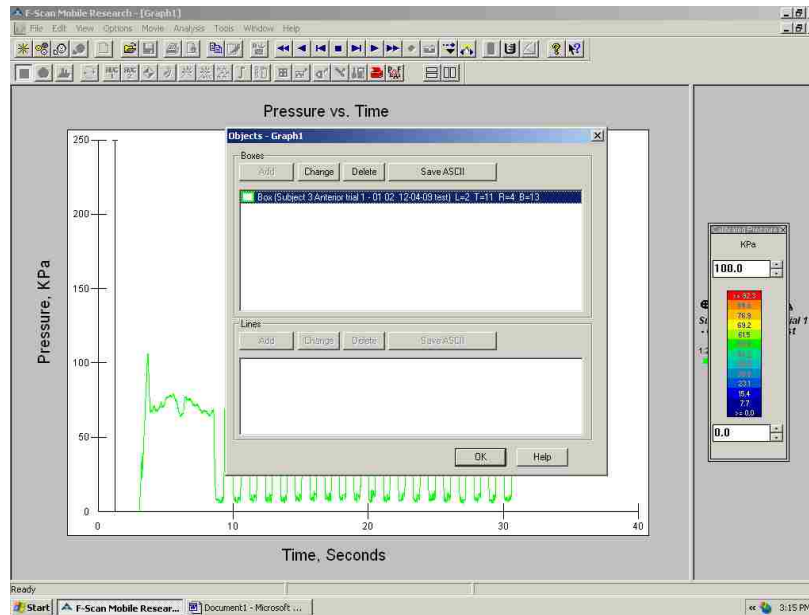
After selecting contact pressure the following window with pressure shown in KPa will appear:



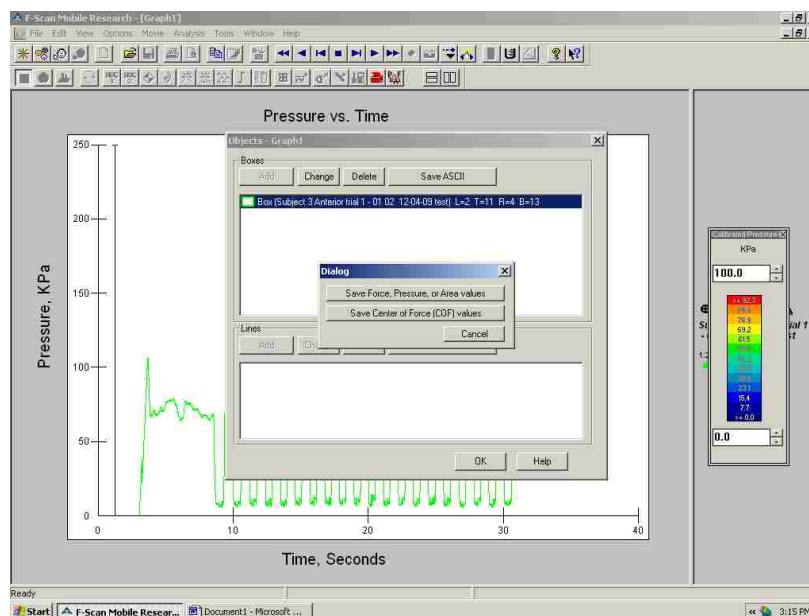
Next the user has to double click on the graph window to maximize it. For saving the data in ASCII format the user has to select **Save ASCII** under the **File** option.



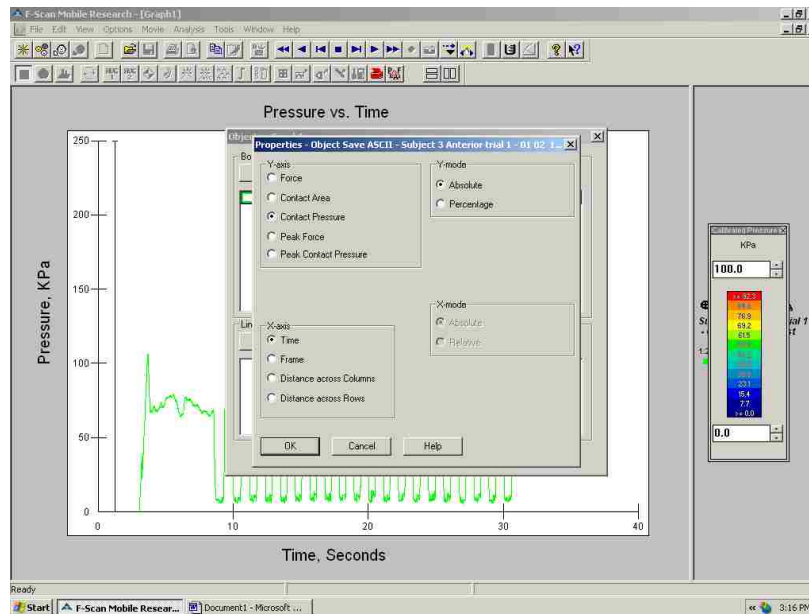
The following window will appear in which the user has to select the graph that it is desired to save in ASCII format and then click **Save ASCII** in that window.



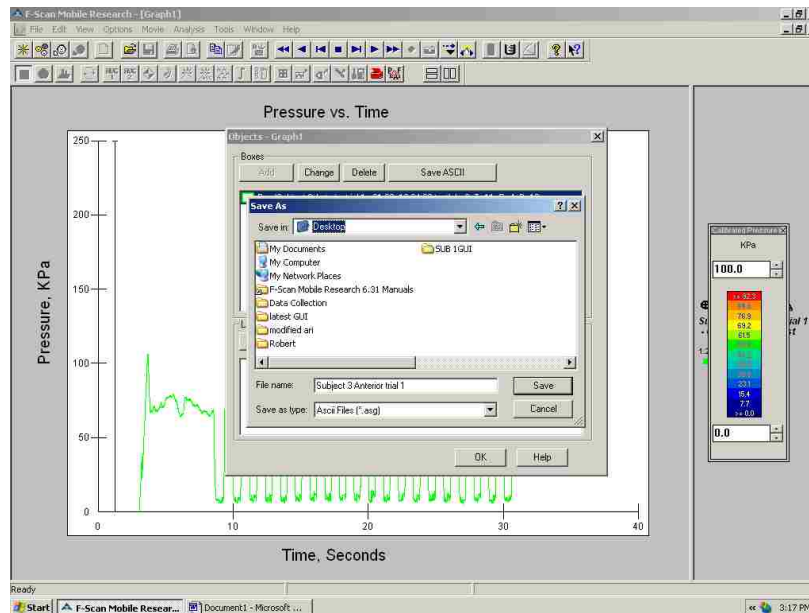
Then the Tekscan software will ask the user whether to save “**Force, pressure or Area values**” or “**Center of Force (COF) values**”. For pressure analysis the user should select the first option to save **Force, Pressure and Area values**.



After selecting the first option the following window will appear and the user should click **OK** without making any changes.



The Tekscan software will then ask the user where to save the ASCII file as shown below:



Once the file has been saved, it must be converted to Excel format so that it can be used in the GUI as desired in Chapter 7.

## CHAPTER 9

### VALIDATION OF TRANSDUCER MEASUREMENTS

This chapter enumerates the procedures used to validate the forces and moments recorded by the transducer. For validating the recorded measurements three different procedures have been followed. They included over-load calculations to determine how close the transducer came to exceeding its mechanical limits during use, weight calculations to determine whether weights self-reported by subjects were close to weights that were measured, and a comparison of transducer data with force plate data for forces and moments.

#### 9.1 Over load calculations

The transducer manufacturer, JR3 Inc, provided two equations that could be used to calculate whether over-load conditions were being approached. The equations are shown below and represent constraints that must be met to ensure that over-loading has not occurred, which could damage the transducer:

$$1) \quad FX/1700 + FY/1600 + FZ/4800 + MX/4400 + MZ/3800 \leq 1$$

$$2) \quad FX/1700 + FY/1600 + FZ/4800 + MY/4400 + MZ/3800 \leq 1$$

Numbers in the denominators are in pounds which have to be converted into Newton's when calculating. To convert Pounds into Newton's a multiplier of 4.4 and to convert in-lb's into Newton-meter's a multiplier of 0.112985 was used.

Figure 9.1 shows the values obtained by using equation 1 and Figure 9.2 shows those obtained by using equation 2. Both equations must be satisfied in order to confirm that the loading on the transducer didn't exceed the maximum limit. From figures 9.1 and 9.2

we can conclude that loading never exceeded the maximum limit as the values throughout the plot are less than 1.

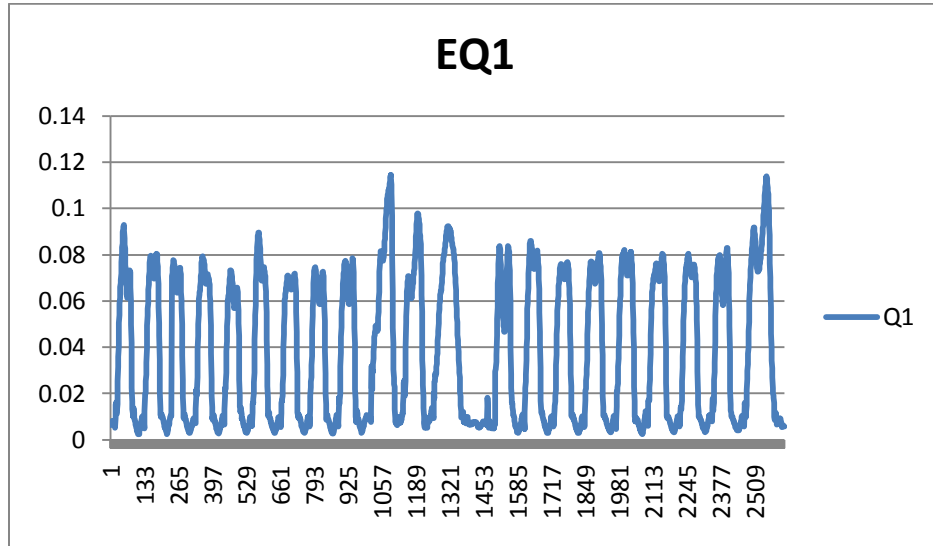


Figure 9.1: Values obtained by using first equation for over load calculations.

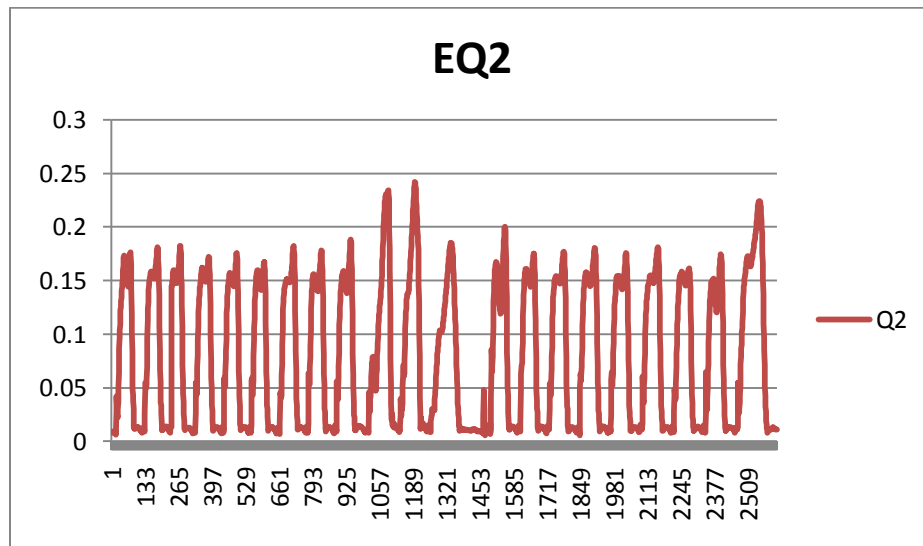


Figure 9.2: Values obtained by using second equation for over load calculations.



From these graphs we can conclude that the transducer was far from an over load condition.

## 9.2 Weight Calculations

Unfortunately, the research team did not have access to an accurate scale when data collection took place, so it was not possible to obtain an accurate record of the weight of the subjects. Collection took place on Saturdays in and around the Engineering building, and subjects were often available for only limited amounts of time. The weights of the subjects reported by the transducer were calculated from the measured data and compared with the self-reported weights of the subjects. During data collection, subjects were asked to take their anatomical foot off the ground just after the transducer was turned on, so that all their weight would be supported on the prosthetic side. Subjects were allowed to touch a wall for balance, but were asked not to transfer any support from the prosthetic side to whatever was being used for balance. The procedure followed for calculating the weights of the subjects is described below:

1. A graph of the vertical ground reaction force ( $F_z$ ) was obtained.
2. The approximate 3 second period when the subject placed all of their weight on the prosthetic side was identified. This was the duration when  $F_z$  remained approximately static near the beginning of data collection, i.e. when the curve was horizontal.
3.  $F_z$  as displayed in the cells during that time period was averaged.
4. The average was converted from Newton's to Pounds-force by dividing by 4.4.

The values obtained from the transducer data are compared to the self reported weight below.

	Self-Reported	Transducer	Difference
Subject 1	208	217	9
Subject 2	213	223	10
Subject 3	158	171	13
Subject 4	211	218	7

Table 9.1: Comparison of Self-Reported and Transducer weights.

The back pack for the transducer weighed 5lbs, and if this is subtracted from the transducer measurement the resulting weights are 212, 218, 166, 213, and the differences are 4, 5, 8, and 2 lbs respectively. Thus, the weights measured by the transducer were approximately 1.8%, 2.2%, 4.8%, and 0.93% higher than self-reported weights. Clothing worn by the subjects may have accounted for some of the difference. Also, self-reported weights may have been inaccurate. Based on this analysis of the data, it was felt that the transducer measurements were accurate enough for clinical use and the objective of the research.

### 9.3 Comparison of Transducer Data and Force Plate Data

A force plate is a measuring instrument placed in the floor of a gait lab that measures the ground reaction forces generated by a person walking across it. It is a large and expensive item of equipment that is calibrated at the factory and can be assumed to be accurate. An experiment was devised that would allow the transducer data to be compared with that of the force plate to validate the transducer data. An experimental

setup was devised that placed the transducer in between two 27 cm SACH (left and right) so as to create a mirror-like configuration. The sole of one of the feet was placed on the force plate and the heel was elevated 3/8 inch to bring the top of the foot and transducer to a level position. Figure 9.3 illustrates the experimental setup for the validation of the transducer measurements.

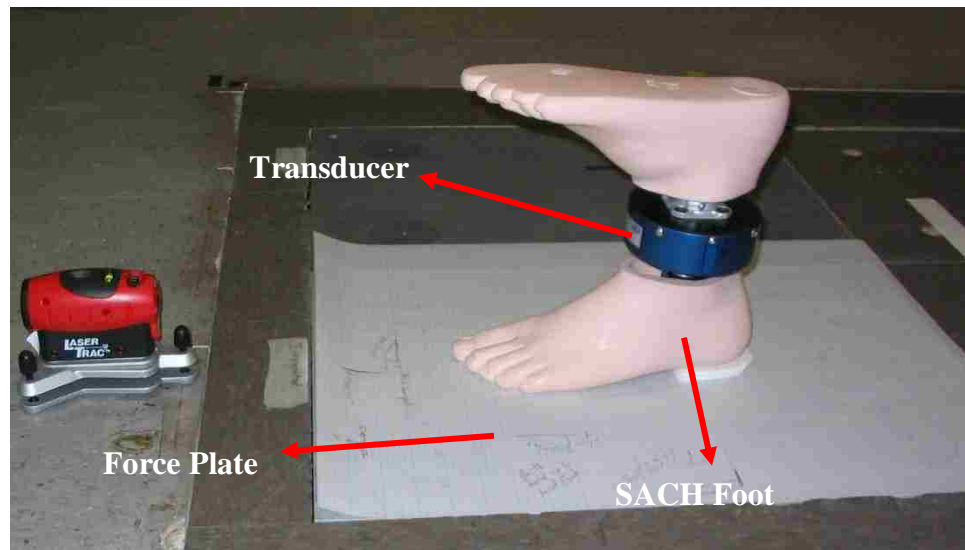


Figure 9.3: Experimental design for transducer validation

It was planned that by maintaining the transducer in a level position and applying weight to the sole of the other foot, the data recorded by the transducer should approximate the data recorded by the force plate. However, if the sole of the foot on the force plate started to compress, then the transducer would rotate slightly and values in the X, Y, and Z directions for the force plate and the transducer would not be the same since the frame of reference for the transducer is fixed with respect to its construction. The sole of the other foot was manipulated by hand to simulate a step. In the experiment loading was applied to the sole-up foot starting at the heel. The experimenter grasped both the toe

and the heel and applied his weight to the heel first. He then rolled his weight over the sole and down to toe manually using his hands. It was observed that the transducer did rotate slightly due to compression of the foot, and the amount of rotation could not be measured. Thus, it was not possible to compare forces along each of the X, Y, and Z axes. Instead, the resultant forces for the transducer and the force plate were computed and compared. Results, shown in figure 9.4 below, were highly similar. The forces in the X and Y directions could be compared when the transducer was level, which occurred around the midpoint of the period when force was applied by hand.

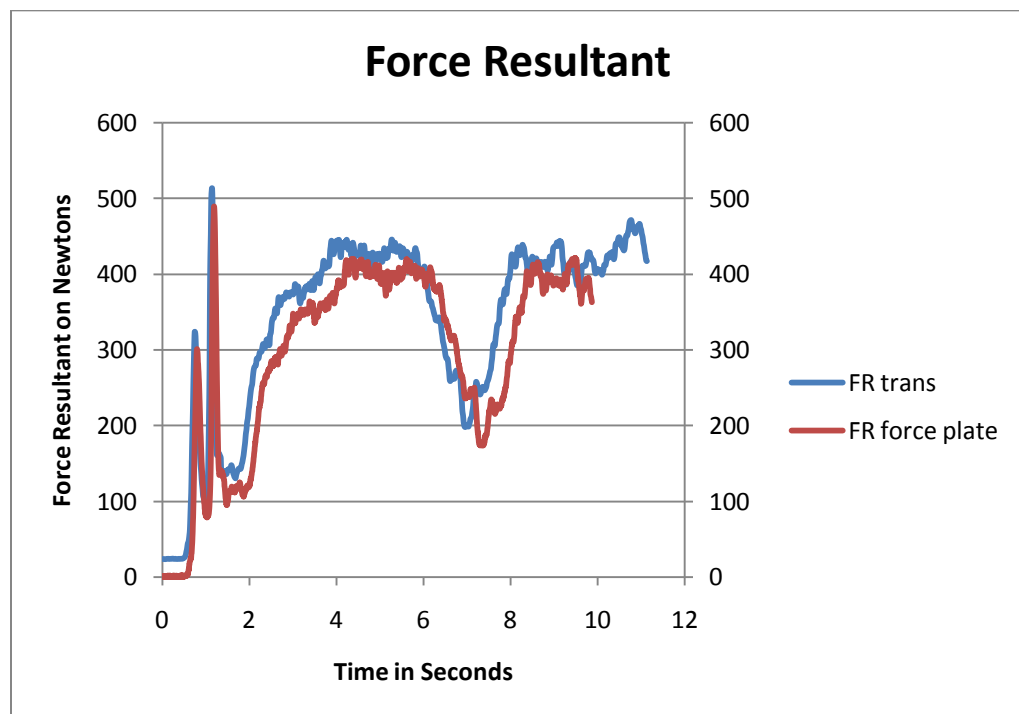


Figure 9.4: Comparison of Force plate data and transducer data.

## CHAPTER 10

### RESULTS

Description of the experimental design for use of the transducer to collect data and examples of the output files from the GUI are the main topics of the present chapter. Experimental design consists of installing the transducer onto the pylon, inserting F-Socket sensors into the socket of the subject, and collecting of data through the wireless transmitter. The EXCEL files output from the GUI can be used to plot the mean and standard deviation of each of the 50 intervals for the forces, moments, and average pressures in the Tekscan windows.

The tri-axial transducer used for data collection is a six-channel commercial type weighing 2 lb's and is manufactured by JR3 Inc, Woodland, CA. The transducer is mounted on the pylon such a way that its X axis points in the anterior direction and is approximately perpendicular to the pylon. The Y axis points medially when mounted on right leg or laterally when mounted on left leg, making the Z-axis vertical and approximately parallel to the pylon. The transducer is connected to a transmitter using a serial cable and the transmitter is kept in a backpack carried by the subject. The transmitter transmits the data to a personal computer or laptop wirelessly using the wireless modem. Figure 10.1 illustrates the transducer mounted pylon.

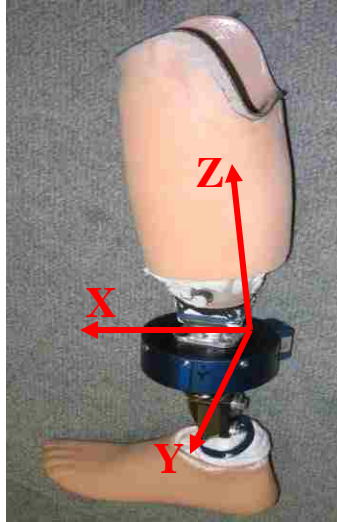


Figure 10.1: Transducer Mounted Pylon

For pressure measurement inside the socket, the Tekscan F-Socket was used, which utilizes the same hardware and software as the F-Scan in shoe pressure measurement system, also manufactured by Tekscan, Inc. Two F-Socket sensors were placed on anterior and posterior sides of the socket, one on each side, using tapes carefully to avoid putting any pressure on the sensors. Figure 10.2 illustrates the set up of transducer and F-Socket sensors in the socket.



Figure 10.2: Experimental setup of transducer and F-socket.

After setting up of the transducer and F-socket sensors, subjects were asked to walk for at least 15 steps to get at least 10 good steps. Subjects were asked to walk on different types of surfaces including slopes, stairs, ramps, walking straight on a level surface at a self-selected comfortable speed, and walking on a circle. Figures 10.3 and 10.4 illustrates a subject walking on the stairs and the set up for data collection respectively.



Figure 10.3: Subject walking on the stairs



Figure 10.4: Data collection process

The files exported from the GUI are in EXCEL format and can be used to plot the mean and standard deviations of the variables. Further statistical analyses including the t-test, ANOVA, and regression analysis can be performed on these files using statistical packages. Figures 10.5 provides an example of the 10 good steps taken by the subject and selected by the user to process forces in Z direction and figures 10.6 illustrates the 10 steps for moments about Z axis.

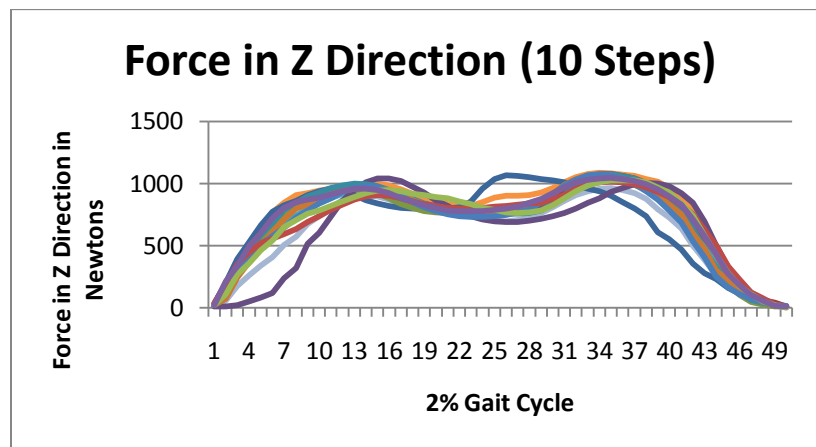


Figure 10.5: Plot of 10 steps for force in Z-Direction

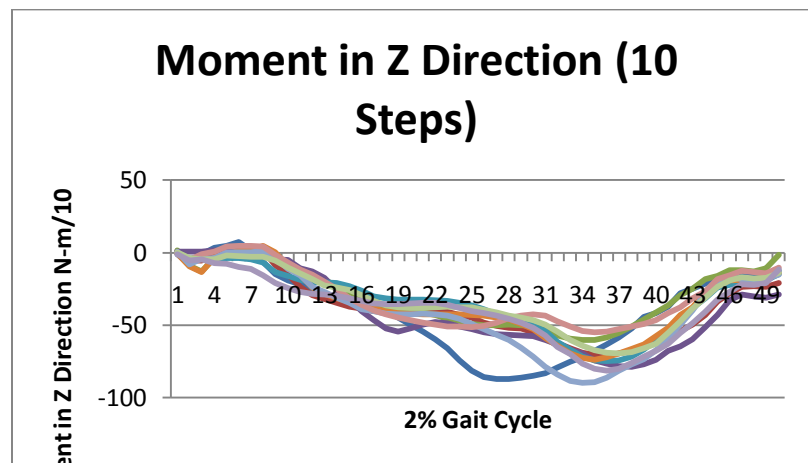


Figure 10.6: Plot of 10 steps for moment about Z-axis



The data in the exported files from the GUI can also be used to plot the means, and plus and minus one standard deviation for the force and moment variables. Figures 10.7 and 10.8 illustrates the mean, plus and minus one Standard Deviation for force and moment along the Z axis respectively. Similarly the means and SD of the forces and moments along the other axes for the 10 good steps can also be plotted using the data output by the GUI.

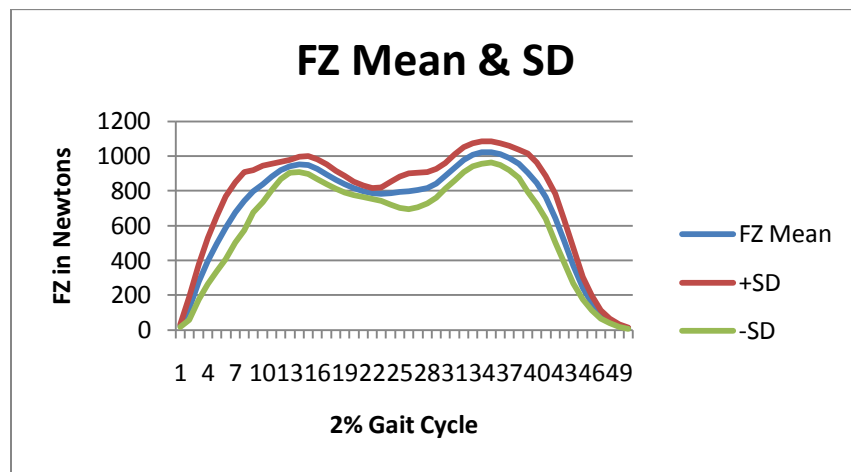


Figure 10.7: Plot of Mean and SD for force in Z-Direction

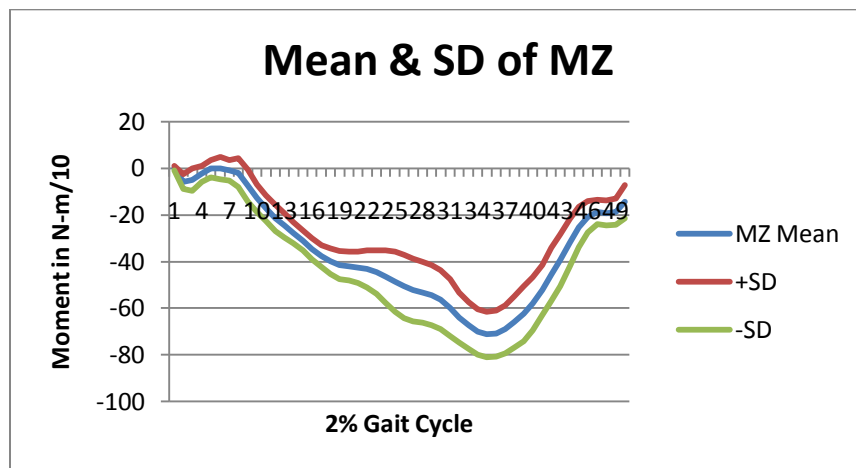


Figure 10.8: Plot of 10 steps for moment along the Z axis

## CHAPTER 11

### DISCUSSION

Knowing the relationship between the intra-socket pressures experienced by the residual limb and the selection of feet of different design is very important in the clinic. Yet, it is one of the more poorly understood phenomena, due in large part to a lack of instrumentation capable of obtaining the relevant data. The major hypothesis of this study is that intra-socket pressures can be estimated if the forces and moments at the base of the socket known because these forces and moments transmitted are generated by the residual limb during gait. The purpose of this chapter is to explain how the files generated by the researcher via the GUI can be used to examine the effect that feet of different design have on the forces and moments at the base of the socket and how this data can be used to estimate intra-socket pressures. Data were collected from four subjects who had been administered Letters of Informed Consent that were approved by the IRB at UNLV. The analyses presented in this chapter were carried out by other members of the research team but are included in this discussion to illustrate an application of the instrumentation and GUI.

#### 11.1 Interpretation of GUI exported files

Exported files have data like start and end of the 10 good steps taken by the subject and selected by the user, 10 steps divided into 50 intervals and sorted into 50 bins, means and standard deviation of the variables (Forces in three directions and moments along three directions), resultant of force and moment as well as angles made by the resultant with three axes. Figure 11.1 shows an example of the exported EXCEL file.

	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q	R	S	
1						FX (N)														
2	STEP 1	STEP 2	STEP 3	STEP 4	STEP 5	STEP 6	STEP 7	STEP 8	STEP 9	STEP 10	MEAN	SD				RESULTANT	THETA	THETA1	THETA2	
3																				
4	-29.5208	-23.2295	-23.9285	-22.3423	-25.5417	-24.1436	-25.4879	-24.6813	-25.2191	-22.3154	-24.641	2.084786				24.98459	-3.71685	80.50663	-89.3776	
5	-24.6096	-19.34	-20.8635	-19.4117	-21.1682	-21.4819	-23.2026	-22.4498	-22.7993	-19.5013	-21.4828	1.785532				30.93402	14.82557	-44.9549	-75.1521	
6	-22.6111	-18.6858	-20.998	-19.4655	-19.6805	-21.0517	-22.5036	-19.815	-21.5088	-18.6589	-20.4979	1.450415				35.30153	13.51983	-36.2609	-71.8512	
7	-17.6014	-18.6051	-20.1286	-17.7806	-17.7448	-21.9121	-22.6649	-20.2451	-20.3437	-17.9061	-19.4932	1.840291				34.52394	12.94267	-35.0668	-71.8718	
8	-14.1689	-16.9382	-17.933	-15.8358	-15.8358	-20.1645	-20.2183	-18.9546	-17.6641	-16.1316	-17.3845	1.986298				31.55314	12.10351	-34.0276	-72.3803	
9	-10.9874	-15.0382	-15.0741	-13.9538	-13.5085	-18.3094	-18.2018	-17.3146	-15.1816	-14.3571	-15.1986	2.257433				28.05624	11.25959	-33.3099	-73.145	
10	-8.03891	-13.0128	-12.8246	-12.2062	-11.5341	-15.9703	-15.7552	-15.9939	-12.8246	-12.5558	-13.0316	2.375387				25.07259	10.482892	-31.7413	-73.4306	
11	-7.36676	-11.6685	-11.077	-10.5124	-10.2704	-13.685	-13.5774	-13.443	-11.3997	-11.2204	-11.4221	1.905273				21.8648	10.10654	-31.8936	-74.0165	
12	-5.10834	-10.5931	-7.2861	-8.17334	-9.30255	-12.3138	-11.9911	-11.5879	-9.81339	-8.87238	-9.5042	2.264611				17.10911	11.30024	-34.2655	-73.6531	
13	1.156097	-6.45264	1.111287	-3.49518	-6.56018	-10.5931	-8.89926	-10.2436	-6.10312	-0.91412	-5.09938	4.395052				10.59766	15.83137	-29.7066	-63.5724	
14	8.953033	1.451843	9.652069	3.575836	-0.1882	-5.69983	-2.31219	-6.85593	1.371185	7.608734	1.755655	5.793069				5.088467	31.50292	23.2301	35.12574	
15	14.78729	7.36676	19.22348	9.275665	6.479523	0.914124	4.436188	-0.72592	9.867157	15.83585	8.746011	6.452799				9.163634	77.37223	86.08929	73.03126	
16	21.23993	16.508	26.64401	18.33624	15.43256	9.275665	16.07782	5.968689	18.25558	25.35349	17.3092	6.395096				17.51265	70.86267	87.11406	81.7342	
17	26.4827	25.1384	38.63516	26.75156	23.9823	18.68576	26.21384	15.40567	28.31094	34.22586	26.38322	6.688124				27.21924	12.163	75.49726	86.80899	
18	30.24673	33.23108	39.57617	32.55893	33.23108	27.74634	34.19897	24.25116	40.51718	40.54407	33.61017	5.440654				36.87481	3.147096	65.74129	88.58062	
19	25.27283	40.97424	30.13919	36.56494	39.8988	37.55972	41.78082	31.0802	43.90482	32.47827	35.96538	6.005701				42.44846	4.505139	57.9959	87.18089	
20	16.23914	34.68292	23.6059	29.95099	33.20419	43.09824	38.76959	36.40363	30.83823	19.73431	30.65271	8.522829				40.96713	6.844754	48.64039	83.96766	
21	8.926147	20.27203	48.60986	18.44379	20.35269	35.03244	25.75677	33.79568	16.64243	44.14679	27.19786	12.77784				61.28035	5.387826	26.44934	79.26509	
22	32.77402	29.78967	53.96017	26.42892	34.27963	21.72388	45.89438	22.74554	46.37833	49.17447	36.3149	11.66085				144.7521	3.840408	14.56069	75.50974	
23	35.32819	43.63596	61.08496	45.78683	45.38354	52.72342	54.06772	32.98911	56.37991	58.47702	48.58567	9.566118				258.5633	3.195731	10.84709	73.75438	
24	41.29688	55.22382	58.04684	59.41803	55.4389	65.0372	60.38593	48.31412	69.15076	65.62869	57.79412	8.342777				380.1961	2.70587	8.753113	72.93604	
25	39.5224	63.23584	40.92047	70.89835	63.47781	74.87747	62.83255	58.66522	70.65637	59.95575	60.50422	11.86434				488.6852	2.117937	7.116864	73.50087	
26	30.99554	58.42325	7.90448	69.55405	63.98865	78.05002	57.29404	66.27396	50.35745	43.04446	52.58899	20.73208				568.0992	1.256361	5.312749	76.72984	
27	-3.30698	36.72626	-37.6673	50.59943	49.52399	56.32614	37.69415	63.82733	14.84106	11.82983	28.0394	31.54722				643.607	0.028189	2.49694	89.35359	

Figure 11.1: Example of an exported GUI file

In Figure 11.1 first 10 columns depicts 10 good steps taken by the subject. Next two columns shows the mean and standard deviation of the 10 steps. 14th column gives the Force resultant and last three columns are for the angles made by the resultant with three axes. This matrix is for force in X direction. Similar to this one same EXCEL sheet has forces in other two directions and moments about three axes. This data can be used for plotting different variables and means and standard deviation of the 10 steps.

When installed correctly using the standard four hole bolt pattern, the transducer has an X axis pointing in the anterior direction and is approximately perpendicular to the pylon. Thus, it is pointed toward the toe and the line of progression. The Y axis is directed to the left and is approximately perpendicular to the pylon. When the transducer is mounted on the right leg, the Y axis is pointing medially. When the transducer is mounted on the left leg, the Y axis is pointing laterally. The Z axis is vertical and approximately parallel to the pylon. Forces are reported in terms of vectors in the X, Y,

and Z directions. Moments are reported with respect to these axes. A force couple in the ZY plane is reported as a moment about the X axis; a force couple in the XZ plane is reported as a moment about the Y axis; and a force couple in the XY plane is reported as a moment about the Z axis.

The transducer measures forces and moments applied to the transducer along these axes. It is assumed that these forces are produced by the socket but ultimately are created by the residual limb inside the socket. In order to relate these transducer measurements to the forces and moments applied to the residual limb, they are assumed to be in the opposite direction to the forces and moments the residual limb applies to the socket and which are measured by the transducer. To facilitate interpretation with respect to the residual limb, the GUI multiplies all the transducer measurements by -1 before displaying them. This results in the relationships shown in Table 11.1.

Table 11.1 indicates how the forces and moments displayed by the GUI can be interpreted with respect to the residual limb. It is assumed that the socket is rigid. The first column refers to variables (forces and moments) shown in the GUI display as the raw transducer data are processed. The second column indicates what the corresponding forces or moments are that the socket is transmitting to the transducer. The third column indicates how the forces and moments displayed by the GUI are experienced by the residual limb of the amputee. The fourth column identifies possible biomechanical correlates of clinical interest or engineering design relevance. The Resultant Force and Resultant Moment are the lengths of the force and moment vectors in the 3 dimensional space defined by the X, Y, Z axes as calculated by the Pythagorean Theorem, and are

always positive since all three component forces and moments become positive when squared.

<b>Reported by GUI</b>	<b>Effect from Socket</b>	<b>Effect on Residual Limb as Transmitted Through Socket Interface</b>	<b>Biomechanical Correlate</b>
<b>Force X</b>	Anterior-Posterior Force Perpendicular to Pylon	Anterior-Posterior Force on Limb	Braking and Propulsion Force on Foot
+		Pressure on Posterior	
-		Pressure on Anterior	
<b>Force Y</b>	Medial-Lateral Force Perpendicular to Pylon	Medial-Lateral Force on Limb	
+		Pressure on Right Side	
-		Pressure on Left Side	
<b>Force Z</b>	Force Parallel to Pylon	Vertical Force on Limb	Vertical Ground Reaction Force Related to Loading Response, Propulsion, and Vertical Movement of body Center of Mass, and/or linear shock absorption
+		Upward Pressure	
-		Downward Pressure	Not expected during stance
<b>Moment about X</b>	Abduction or Adduction Rotation Moment on Socket in Frontal Plane of Socket	Moment Creating a Varus or Valgus Moment at the Knee	Moment in Frontal Plane Related to Foot Inversion and Eversion Resistance and/or Foot Inset or Outset and/or Socket Abduction-Adduction
+		Pressure on Distal Right and Proximal Left	

-		Pressure on Distal Left and Proximal Right	
<b>Moment about Y</b>	Flexion or Extension Rotation Moment on Socket in Sagittal Plane of Socket	Moment Creating a Flexion or Extension Moment at the Knee	Moment in Sagittal Plane Related to Heel and Toe Resistance and/or Foot Anterior or Posterior Placement and/or Socket Flexion-Extension
+		Pressure on Distal Anterior and Proximal Posterior	
-		Pressure on Distal Posterior and Proximal Anterior	
<b>Moment about Z</b>	Internal or External Rotation Moment on Socket in Transverse Plane of Socket	Moment Creating an Inward or Outward Rotation Moment at the Knee	Moment in Transverse Plane Related to Foot Rotation Resistance or Foot Internal-External Rotation and/or torsion moment absorption
+		Pressure to Rotate Counter-Clockwise as Viewed from Above	
-		Pressure to Rotate Clockwise as Viewed from Above	

Table 11.1 Interpretation of GUI Variables

## 11.2 Comparison of different daily activities

Everyone performs different daily activities on different terrain. By using the transducer and GUI one can understand the pattern of forces and moment being transmitted to the residual limb, and this may help the clinician to select the appropriate prosthetic components to minimize the effects of the forces and moments. Feet that store

and release energy is being designed by manufacturers in a large number of different ways. Some are made from carbon fiber composites and have the appearance of the letter J. Others made from carbon fiber composites consist of a series of plates that define a heel and forefoot keel. Some featured large coiled springs that store and release energy. Still others feature elastomeric bumpers that store and release energy. No one has yet found a way to measure and compare the performance of these different feet on amputees, which leaves the clinician with a great deal of uncertainty when trying to select an appropriate foot. The transducer mounted below the socket by comparing different daily activities with the transducer, one can better understand the type of design that might be needed for stability and comfort of the amputee. Figures 11.2 and 11.3 provide examples of the type of data obtained from the transducer after it has been processed with the GUI. The figures compare the resultant moments and forces measured for a subject while walking on a ramp, going up step, walking across a slope with the prosthetic foot on the uphill side, and walking on the level at a self-selected comfortable speed (SSCS). The student t-test can be performed on the data exported from the GUI to determine if the peak forces and moments are the same for any pair of activities.

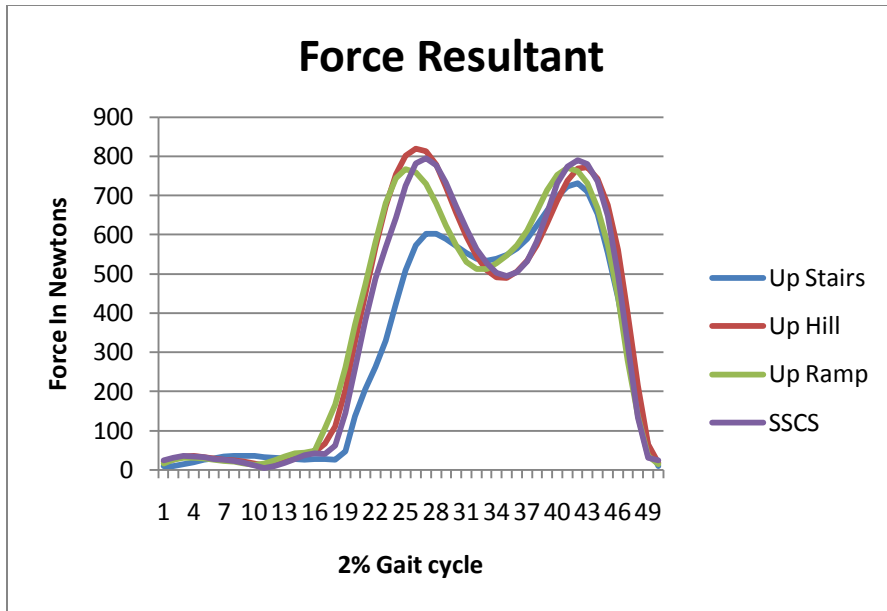


Figure 11.2: Comparison Force Resultants for different daily activities

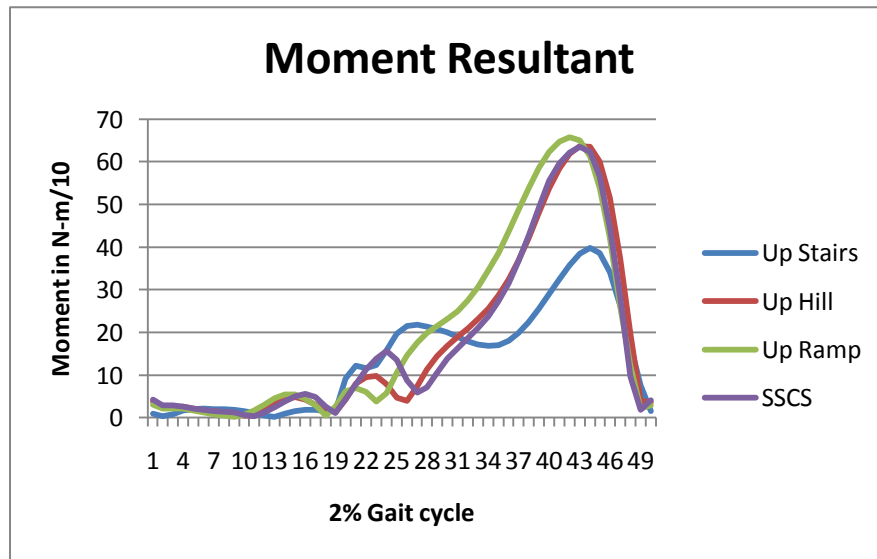


Figure 11.3: Comparison of Moment Resultants for different daily activities



### 11.3 Comparison of different feet for a given subject using GUI exported files

The files exported from the GUI include the force and moment resultants, which can be compared for different types of feet. This is shown in figures 10.4 and 10.5, for three different feet worn by the same subject. These exported files permit a statistical comparison of peak values using the t-test.

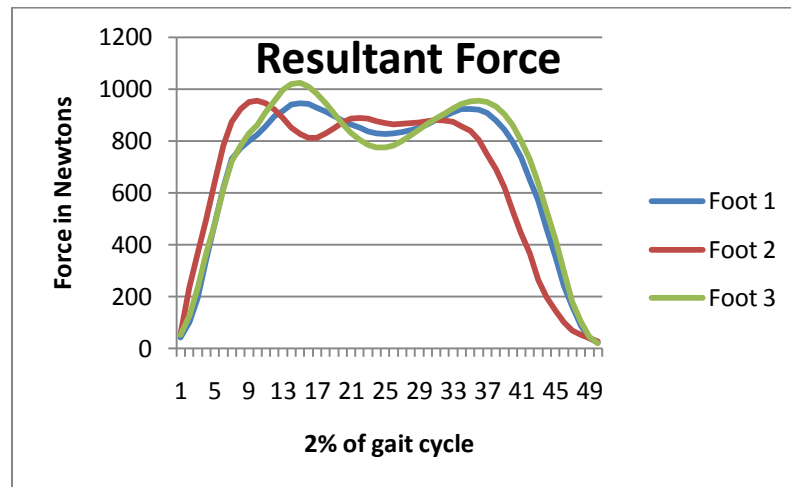


Figure 11.4: Comparison of Force Resultants of three different feet

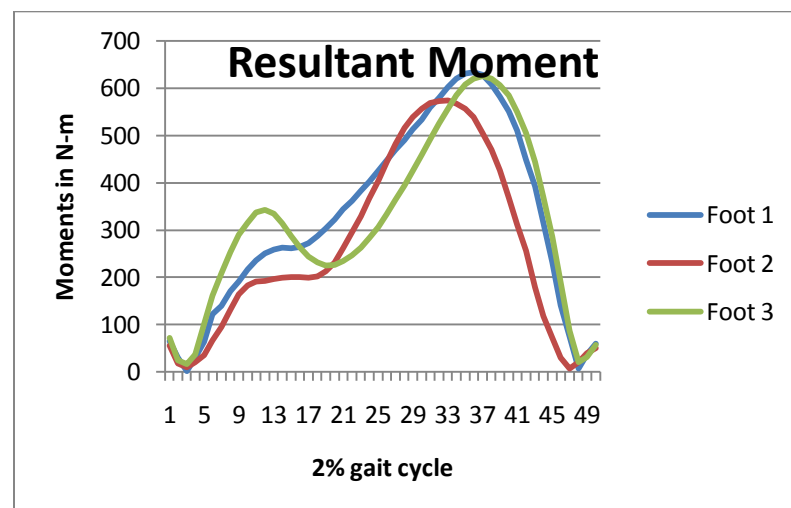


Figure 11.5: Comparison of Moment resultants of three different feet

#### 11.4 Comparison of Feet across Subjects using GUI exported files

The SACH foot was used by three of the four research subjects, which permits a demonstration of how the output from the transducer can be used to compare feet across subjects. The same design of SACH foot was used for all three subjects, and only the size, side (two left feet and one right foot), and heel plug that controls heel stiffness varied. The feet were produced by Ohio Willow Wood and were a right 27 cm with a firm heel plug (Subject 4), a left 27 cm with a medium heel plug (Subject 2), and a left 24 cm with a medium heel plug (Subject 3). In order to compare the subjects, the force and moment data from the transducer had to be normalized. Force data were divided by the subject's weight in Newton's, and moment data were divided by the subject's mass in kg. The subject's weights were obtained by having the subject stand on the prosthetic foot alone for 3 to 5 seconds following transducer initialization and prior to walking. Subjects were allowed to touch the wall to help with balance, but were monitored to ensure that they did not try to support their weight. Data for level walking at a self-selected comfortable speed were used to compare the peak forces and moments reported by the transducer along all three axes. The intervals when the maximum occurred were determined by inspection of the output from the GUI. A one-way ANOVA was used to compare each maximum of the mean value using the three subjects as groups, and the values of the ten steps as observations for each group. In order to compare the right foot of Subject 4 with the left feet of Subjects 2 and 3, forces along the Y axis and moments about the X and Z axes for Subject 4 had to be multiplied by -1.

Figure 11.6 graphs the force in Z direction and figure 11.7 graphs the moment about the Z axis versus the per cent of the stance phase for the three subjects when the data

have been normalized and the data for Subject 4 had been corrected to make the right foot comparable to the left feet of the other subjects. The graphs indicate that the force and moment curves appeared different for the different subjects, and ANOVA verified this for the peak values. Differences were evident for  $F_x$ ,  $F_y$ ,  $M_x$  and  $M_z$ . Since the feet were all of identical design, this could only be attributable to differences in either the gait patterns of the individual subjects or the alignment of the prostheses.

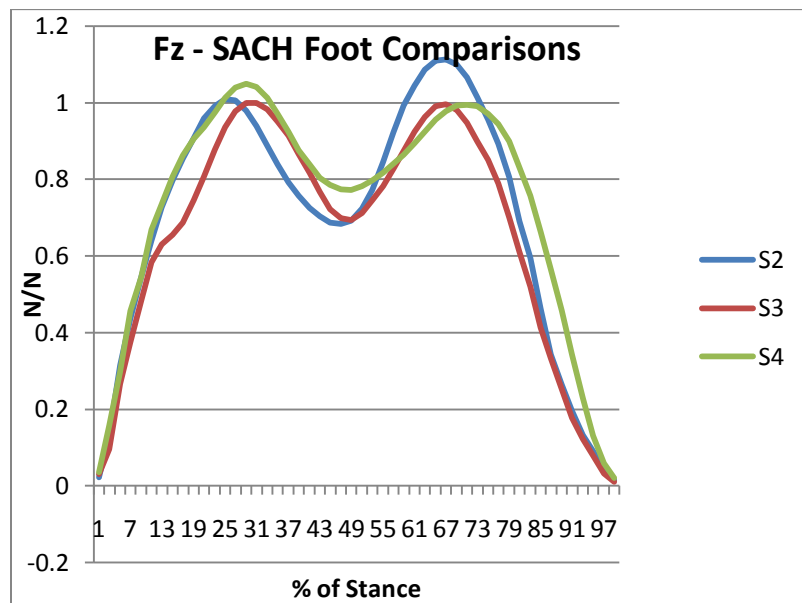


Figure 11.6:  $F_z$ - SACH Foot Comparisons

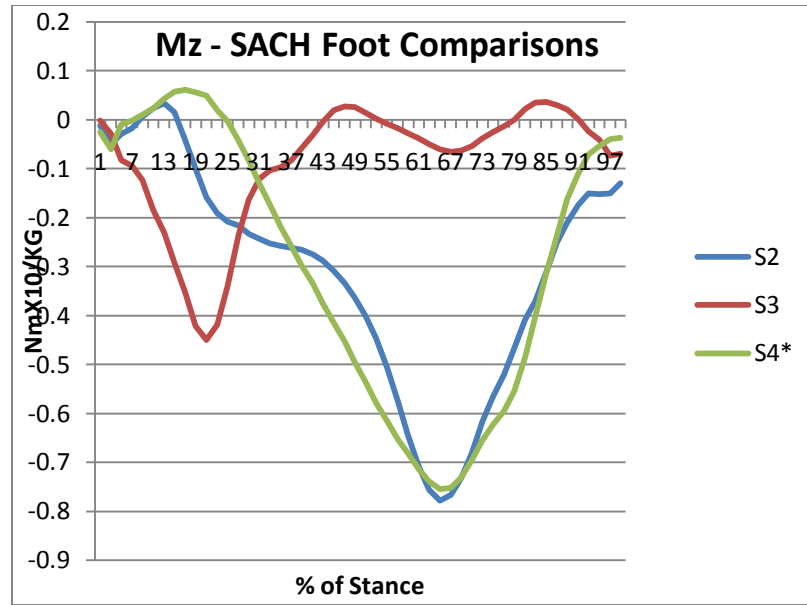


Figure 11.7: Mz-SACH Foot Comparisons

### 11.5 Estimation of Intra-Socket Pressures on the Residual Limb

One of the major hypotheses of the study is that the transducer makes it possible to examine the relationship between the forces and moments in the pylon and the pressures exerted on the residual limb inside the socket. A previous study was able to estimate the pressures inside a transtibial socket using measurements of the forces and moments in the pylon. The instrumentation used in this early study was very primitive in comparison to the transducer and Tekscan pressure measurement system used in the current study. Pressure measurement was accomplished by drilling holes into the socket and inserting force transducers. This destroyed the integrity of the socket and would be unacceptable in a clinical setting. Forces and moments at the base of the socket were measured by gluing strain gauges onto the pylon, which would also be very difficult to undertake in a clinical setting. In contrast, the transducer and Tekscan pressure measurement system used in the current study can be used easily in a clinical setting and have no effect on the

integrity of the socket because no holes have to be drilled. Tekscan's F-Socket, which employs a matrix of 96 force-sensing resistors (FSR), can be used to window multiple sites within the socket.

As part of the earlier study, alignment of the prosthesis was varied, and the sensitivity of pressures to changes in alignment was modeled as a function of the alignment changes. The models used were

$$\begin{vmatrix} \sigma_p(\theta, t) \\ \sigma_g(\theta, t) \end{vmatrix} = |W(\theta)| * \begin{vmatrix} F_z(\theta, t) \\ M_x(\theta, t) \end{vmatrix}$$

Where:

$\sigma_p(\theta, t)$  = pressure on the patellar tendon region

$\sigma_g(\theta, t)$  = pressure on the gastrocnemius region

$W(\theta)$  = matrix of coefficients that relate pylon forces and moments to socket pressures

$F_z(\theta, t)$  = axial force in the pylon

$M_x(\theta, t)$  = flexion-extension moment in the pylon

$\theta$  = socket flexion-extension perturbation with respect to an acceptable alignment

$t$  = time during the gait cycle

And

$$|W(\theta)| = \begin{vmatrix} W_{11} + \left(\frac{dW_{11}}{d\theta}\right) * \theta & W_{12} + \left(\frac{dW_{12}}{d\theta}\right) * \theta \\ W_{21} + \left(\frac{dW_{21}}{d\theta}\right) * \theta & W_{22} + \left(\frac{dW_{22}}{d\theta}\right) * \theta \end{vmatrix}$$

The model added the pressure effects created by pylon axial forces to the pressure effects created by pylon flexion-extension moments. It was calibrated using regression analysis by entering pressure as the dependent variable and force and moment and socket

alignment perturbation as the independent variables. Observations consisted of variable values sampled at uniform intervals during the gait cycle over multiple steps. The authors reported correlation R values of 0.937 in the patellar region and 0.984 in the gastrocnemius region for the first subject in the study, and values of 0.938 and 0.989 respectively for a second subject.

The forces and moments represented in the above model have been measured for the four subjects by the tri-axial transducer and Tekscan pressure measurement system. The data collected will be used to model pressures at multiple sites inside the socket and the model fitted using regression analysis.

## CHAPTER 12

### CONCLUSIONS

The socket is the sole means of load transfer between the prosthesis and the residual limb, which makes it a critical component for prosthetic performance in transtibial amputees. The socket has to be designed properly to achieve satisfactory load transmission, stability, and efficient control for mobility. Improved understanding of the interaction between the prosthetic socket and the residual limb can produce improved socket design. Estimation of pressures inside the socket is a way to understand the interaction between prosthetic socket and the residual limb. An important question is how well the forces and moments measured just below the socket can be used for estimating the pressures inside the socket. Tri-axial transducer can be used to measure the forces and moments below the socket. Although this study focused on transtibial amputees, the instrumentation can also be applied to transfemoral amputees when there is a sufficient distance between the socket and the knee.

In this study the utility of the pylon-mounted triaxial transducer was examined to determine 1) the effect of different designs of the prosthetic components that occur below the socket (feet) have on the forces and moments transmitted to the socket, 2) the effect that different types of activities or terrain have on forces and moments transmitted to the socket. This study also developed and validated a software that facilitates the processing of the transducer and pressure sensor data

Transducer measurements provided objective data on the magnitudes of forces and moments experienced in different types of activities. This could be used to evaluate and prescribe components, especially feet, and possibly develop specifications for

components designed expressly for certain activities. Measurements of the forces and moments applied at the distal end of the socket could help understand component performance.

The ability of the patient to generate and tolerate forces and moments in the residual limb during gait could be charted as rehabilitation progresses. Gait improvements are associated with the ability of the amputee to bear weight on the amputated side, which is a function of ability to tolerate pressure on the residual limb. Measurements of the forces and moments being accepted during gait would provide quantitative evidence of this, and provide physiatrists, orthopedic surgeons, and physical therapists with additional objective data on patient improvement and job-related capabilities.

Transducer measurements may offer a means of determining discomfort thresholds, and assist in determining how the forces and moments that create discomfort would need to be modified to eliminate discomfort. This knowledge could assist in identifying prosthetic strategies to reduce discomfort, or help verify that no prosthetic solution exists.

The ability to mathematically relate the forces and moments transmitted to the distal end of the socket to internal socket pressures would open the door to research on socket design and comfort. It would make it possible to study the effect of different socket designs and suspension methods on pressure distribution and discomfort. It is possible that the design of sockets for activities other than walking might require improved understanding of how moments and forces at the distal end of the socket transform into socket pressures.

The transducer and associated software developed as a part of the research has advantages over force plate and motion capture systems in the case of amputees. The



drawbacks of using force plate are that only two or three steps of walking can usually be measured, targeting the force plate can result in an un-natural or exaggerated gait and loads cannot be measured on uneven terrain. But the software along with the transducer cannot be used for analysis of the sound leg as it is not possible to mount a transducer on it. A gait lab with a motion capture system and force plate must be used to analyze the gait of the sound leg.

The user has to be careful when using the transducer for the collection of data to zero it out before the start of data collection. The user has to zero out the transducer by asking the subject to put no force or pressure on the transducer mounted leg before initializing it for the data collection. If data has been collected without zeroing it out, the values will be offset during gait making it impossible to analyze the data.

The present version of the GUI software requires manual input of the start and end of each step for defining individual steps. This is a shortcoming that was not overcome though a substantial effort was made to develop an algorithm. If one of the starting and ending points are identified or entered incorrectly, it will impact the statistical analysis of the data. One of the future enhancements in the software could be the development of an algorithm to automatically identify the beginning and end of the individual steps.

It might not be possible to use the modem for transmitting the data collected by the transducer to the laptop in locations where there is no electrical source. If one wants to use it on a ski slope or military training ground it might not be possible to find a power supply to plug it into. Development of internal memory for the storage of transducer data could be a future development for the transducer.

The present version of the software has no option for saving the data once processing has started. After initializing the GUI the user has to follow all of the steps to completion and export the files without stopping it. The user cannot close the GUI and start again from the same point. Including a save option in the GUI would make it a more user-friendly application. In the software when working on the calculation of Impulse and Loading rate, the user has to be very careful inputting the values. The user cannot change the values of x-axis points once entered into the software. Including an option for changing the values for Impulse and loading rate would be helpful for the user.

The software developed in this research may be helpful in determining the type of foot that is best for a particular subject. Even though the software could be modified as suggested above, which would make it more user friendly, the present version has the capability of providing valuable information, and is ready for use by researchers and clinicians.

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