DYNAMIC INTERFACE PRESSURE MEASUREMENT - COMPARING TWO TRANS-TIBIAL SOCKET CONCEPTS

BY

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ABSTRACT

The aim of this study was to compare two socket designs for the trans-tibial prosthetic case. Pressure distribution studies, comfort and functionality are potential methods of assessing and distinguishing the conceptual differences. This study investigated pressure distribution at the stump-socket interface, using a technique able to give precision over most of the area.

Two socket designs were studied, the worldwide accepted "conventional" hand casted socket incorporating Patella Tendon Bearing (PTB) and a "hands off" pressure casting method represented by the University of Strathclyde Hydrocast socket. The sockets used in this study differed in how pressure was applied during casting (uniform pressure versus localized pressure).

Investigations of the stump-socket interface conducted in the past were limited due to an inability to accurately monitor interface pressure during gait. There were no transducers that could measure pressure distribution over large areas or identify local pressures in socket regions with localised changes of curvature.

The Tekscan pressure measurement system, based on force sensing resistor (FSR) technology was selected for this study due to the following system characteristics:

- A complete commercially available pressure measurement system, which incorporates transducers suitable for stump-socket pressure investigations.
- The high degree of flexibility of the 0.017 mm thick transducer.
- The resolution and sensing surface of a single transducer array (96 individual sensors, covering a total sensing area of 15.500 mm^2).
- Relative cheapness of the system and replacement transducers.

The accuracy and reliability of similar Tekscan systems has been questioned by researchers using them in insole applications. Although the Tekscan system represents an innovative method of multi-point pressure measurement, a number of potential inaccuracies, typical for FSR technology, were investigated in this thesis and evaluated to confirm the reliability of this technology. The main areas of concern were:

- non linearity.
- drift.
- temperature sensitivity.
- dynamic response.
- response to shear.
- hysteresis.
- crosstalk.
- sensor wear.
- repeatability.
- calibration.

A series of dynamic and static tests were performed to investigate the main areas of concern. Static tests were discontinued due to unacceptably high drift. Dynamic tests, however, indicated a high degree of repeatability after a preconditioning period of approximately 10 loading and unloading cycles.

Equipment and test methods were developed and used to identify the limitations of the selected pressure measurement system. Tests varied from single cell pressure testing by means of indentors to full transducer testing by means of a dynamic pressure rig. Compressive loads were applied to individual sensors of a transducer, using an Instron testing instrument. System behaviour was tested for repeatability, response to curvature, drift, dynamic response and hysteresis. A shear rig was used to investigate the response of the transducer to a variety of shear loads. The dynamic pressure rig developed in this work, was used to calibrate and test the transducers for repeatability and validity.

A typical hysteresis error of 18% was noted as well as inaccuracies due to shear (15%) and 3 dimensional curvated areas (50%). Sensor wear and 3D curvature effects were minimised by bonding the transducers to the rigid inner socket wall and calibrating the transducers "in-situ". A gel filled "condom" was fitted into the socket, the brim of which was sealed, and the gel pressurised according to a predetermined dynamic loading sequence. The transducers, when calibrated, demonstrated consistent pressure output irrespective of socket curvature. This developed technique provided acceptable output validity, when subjected to a pressure range between 25 and 200 kPa. An average variation of ±2% and a maximum variation of ±10% for any individual sensor in the transducer array was observed.

It was confirmed that the inaccuracies of FSR technology must be recognised if fidelity is required. By selective application and by adopting strict test protocols it was possible to minimise inaccuracies to such a level that a satisfactory pressure distribution pattern was monitored.

Transducers were attached to the anterior, posterior, medial and lateral walls of both socket designs, with some sensors located at the distal end of each socket. These 4 transducers provided approximately 350 individual sensing cells covering 90% of the load bearing socket area. The 350 sensors were sampled at 150 Hz. for approximately 0.8 seconds of prosthetic stance providing 42,000 pressure results for a single prosthetic step.

Gait studies investigated the consistency of the subject's walking performance. This was essential because only two transducers per socket could be recorded for a particular walk.

The trans-tibial amputee's preferred walking speed and consistency with his existing prosthesis was verified with respect to walking speed and the ground reaction force (GRF). The GRF was monitored with a force plate located in a 9 metre walkway. The statistical analysis of 15 constitutive walks, with and without a metronome, indicated a highly consistent gait. Similar studies were repeated with both socket designs. Similar statistical results were noted. The test subject's preference for assistance from a metronome, together with an anticipated velocity difference between the two socket designs, supported the recommendation that future test protocol for this subject adopt metronome assisted walking speeds. This pre-determined walking speed, should match the subjects preferred walking speed with his existing prosthesis.

A strict pressure study protocol was adopted to optimise accuracy and reliability of the recorded pressure data. Simultaneous data of walking velocity, GRF and pressure data of a maximum of 2 transducers were recorded. This procedure was repeated 15 times monitoring the two transducers attached to the anterior/posterior aspects of the sockets and 15 times monitoring the two transducers attached to the medial/lateral aspects of the sockets.

Statistical analysis of both force plate and pressure data revealed that they were highly correlated. As a consequence, pressure data obtained from a walk with the transducers placed in the anterior\posterior socket region was combined with pressure data from another walk with the transducers placed in the medial/lateral socket region. This created a complete picture of socket pressure distribution during gait.

A 3D computer model was developed which enabled the output from all four transducers, and hence the pressure distribution within the socket, to be displayed at any instant of gait. The computer model also illustrated the line of action of the GRF relative to the socket.

Significant differences in pressure distribution and peak pressures were observed for both socket designs. The "Hydrocast" pressure casting concept indicated a 30% reduction in measured pressure compared with the PTB concept. Lower peak pressures were monitored in the pressure cast socket during gait (143 kPa versus 417 kPa. for the PTB socket); fewer localised pressure zones were noted within the Hydrocast socket. A greater number of subjects must be investigated to confirm the apparent effectiveness of the socket designs.

The 3D computer model enabled the mass of pressure data to be easily observed. A wide range of future pressure studies may be undertaken using the developed system, equipment, methods and protocols described in this study.

- The effects of alignment modifications on socket pressure may be re-investigated now that the total socket may be studied rather than "selected" locations.
- The variation of socket pressure with respect to time may be studied in conjunction with patient's stump volumes.

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DEDICATION

To my parents

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TEST RESULTS AND INTERPRETATION

GLOSSARY

Abbreviations:

PTB.	Patellar Tendon Bearing.
GRF.	Ground Reaction Force.
POP.	Plaster of Paris.
FSR.	Force Sensing Resistor.
CASD.	Computer Added Socket Design.
2D.	Two dimensional.
3D.	Three dimensional.
A/P.	Anterior/Posterior.
M/L.	Medial/Lateral.
A/D.	Analogue to Digital.
HS.	Heel-Strike.
TO.	Toe-Off.
N.	Force in Newton.
kPa.	kilo Pascal.
SACH.	Solid Ankle Cushion Heel.
ANOVA.	One way analysis of variance test.
RAM.	Random access Memory.
MB.	Mega bite.

CHAPTER 1

GENERAL INTRODUCTION AND OBJECTIVES

It is estimated that 3 to 4 million people in the developing world require a lower extremity prosthesis, of which 70% are trans-tibial amputees. To supply the need for prostheses is not an easy task. This situation is caused by several factors. A currently worldwide accepted practice is to hand cast a PTB type of prosthetic socket. The skill and experience required to produce an acceptable prosthesis were reasons to explore alternative socket designs.

A major problem in prosthetic socket design is that there is no precise agreement on how this should be done. The lack of quality criteria, as well as the limited knowledge about load transfer between the prosthetic socket and skeleton with respect to acceptable normal and shear stresses, contribute to an inability to design prosthetic sockets to specific standards.

Stump-socket interface pressure distribution studies are one of the potential methods of assessing conceptual differences. Investigations of interface pressure distribution conducted in the past were limited due to an inability to accurately monitor interface pressures during gait. However, in this project the tested, validated and calibrated Tekscan pressure measurement system was used, to investigate the conceptual differences between: The hand casted PTB socket and the pressure cast socket, presented in the University of Strathclyde Hydrocast socket.

The motive behind this work is to create a socket design and production system which takes account of the special circumstances in developing countries. The following objectives were identified:

- Validate the Tekscan FSR pressure measurement system under static and dynamic conditions.

- Compare interface pressures obtained from two socket designs in limited trans-tibial amputee testing. One socket design to be the PTB approach and the second socket design produced by a pressure casting approach.

- Utilise computer graphic visualisation of the instantaneous interface pressures, the ground reaction force and socket geometry to aid interpretation.

CHAPTER 2

BACKGROUND

2.1 Rehabilitation in developing countries

This section is a review of the circumstances and problems encountered in developing countries and discusses potential options to reduce the existing backlog of trans-tibial prosthetic care.

The concerns expressed by health care providers dealing with rehabilitation and particularly prosthetic issues in developing countries, reflect the need for discussion, research and agreement. Political and financial differences, as well as variances such as climate, population distribution, transportation, communication, medical infrastructures and educational systems, limit developing countries' abilities to develop and provide prosthetic care. At the heart of most literature is the dilemma of how to provide and implement appropriate prosthetic-orthotic care in the developing world, where at least 80% of those needing such care are urban and rural poor who cannot afford it. Much of the available literature emphasises "appropriate" technology, but there is often disagreement about what is considered truly appropriate. (Cummings, 1996). The suggested definition of "appropriate" prosthetic technology is as follows: *"Appropriate technology is a system providing proper fit and alignment based on sound biomechanical principles which suits the needs of the individual and can be sustained by a country at an affordable and economical price".* (The suggested definition of "appropriate" prosthetic technology was based on the results from conclusions and recommendations outlined in the consensus conference report held in Phnom Penh, Kingdom of Cambodia, 5 - 10 June 1995).

2.1.1 Incident situation

The cause of amputation in the developing world depends on the country's stage of development and can be divided into 3 major groups:

(1) countries which are at war and in decline.
(2) countries which are in post war development.
(3) countries which are at peace (Staats, 1996).

In war zones and post-war zones, the greatest number of amputations are often a direct result of fighting and landmine explosions. Landmine explosions are the main cause of lower extremity amputation and leave a deadly legacy that continues for decades after the war. In other countries, traffic accidents combined with overloaded public transport are the main incident factors for amputation. Other indirect causes of amputation includes diseases such as leprosy and tumours. Diabetes and peripheral vascular disease, which are the main causes in the western world, are of negligible significance in developing countries.

It is estimated that 3 to 4 million people in the developing world require lower extremity prostheses (Murdoch, 1990). This implies that, to fulfill this requirement with existing technology, a number of 50,000 to 100,000 prosthetists must be trained and equipped. It is predicted that by the year 2000 the combined population of Africa, Asia and Latin America will be about 0.4 billion (Poetsma, 1994). This implies there will be about 6.5 million amputees who will need a new prosthesis approximately every 3 years.

The overwhelming incidence of lower limb amputations can be divided into trans-tibial amputations, estimated at 70%, and trans-femoral amputations, estimated 30%. These figures are verified by many authors who also contributed to the ISPO congress held in Phnom Penh (1995).

2.1.2 Training and education in developing countries

Building a team of trained amputee rehabilitation personnel is a goal of many organisations and governments, which could result in sustainable programmes after the departure of non-governmental organisations (Staats,1995). A literature review highlights the following problems:

- An enormous number of qualified rehabilitation personnel is instantly needed (Murdoch, 1990; Poetsma, 1994; Shangali, 1995).
- Inconsistency in education and accepted educational standards (Cummings. 1996; Hughes, 1996). Education can vary from simple training of local craftsman to structured three year courses within an academic and clinical environment. In actual practice, this is not contributing to the overall raising of standards.
- Lack of educational materials where they are needed (Cummings, 1996). Comprehensive educational packages of text and illustrations designed for training in developing countries do exist, but are often not available at the place where they are needed.
- Prosthetic centres are often situated in the capital or other large cities (Kaphingst; Heim, 1985). In rural areas most care is sub-standard and offered by unqualified staff. Therefore it seems that most care is not given where it is most needed.
- Use of Western technology (Kaphingst, Heim, 1985). Most prosthetic centres are largely staffed by prosthetists trained abroad, employing techniques and using materials acquired abroad, which are not always appropriate.

2.1.3 Current situation of clinical trans-tibial prosthetic practice in developing countries.

In developing countries, landmine explosions dictate the majority of the level of amputations. The choice of fitting and fabrication technique depends on the availability of needed materials, but also on the education level of the care suppliers. (A prosthesis produced by an employee with a panel beating background will be different than one produced with a pottery background; but both can be perfectly appropriate).

The current practice of trans-tibial prosthetic care is to supply a hand casted PTB prosthesis. The socket is produced by making a plaster wrap cast (negative model) of which a positive model is made and rectified. Subsequently a plastic PTB socket is fabricated. In general all sockets are supplied with a suspension strap or suspension sleeve. The final prosthesis is assembled with the PTB socket and additional components which are appropriate for the country in question.

2.1.4 Discussion of rehabilitation in developing countries

A multitude of factors contribute to the diversity in quality of rehabilitation care in developing countries. It has been found that the main ambition of providers is focused on how to meet the demand for trans-tibial prostheses. This is presently approached by the following means:

- improving educational standards.
- boosting the output of qualified personnel.
- improving production techniques.
- investigating suitable production materials.
- enhancing component durability.

There is no need to discuss the relevance of the described points but the practicality of some can be debated. It is not realistic to meet the enormous demand for trans-tibial prostheses by training the estimated 100,000 additional qualified technicians. Neither the capacity of the existing training centres nor the educational resources and financial means are available.

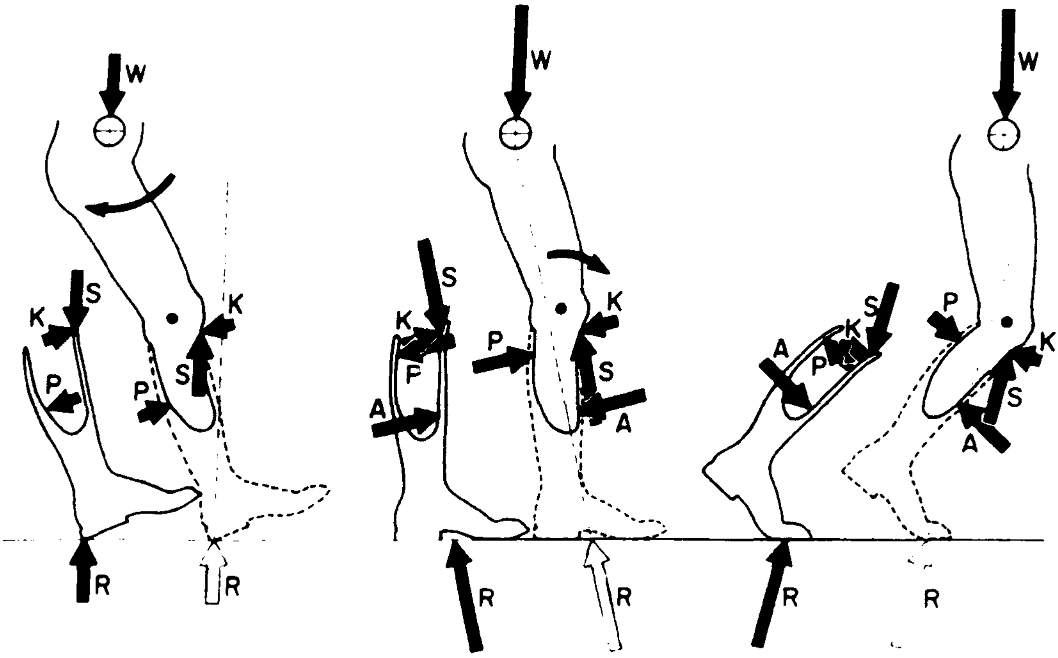

Fig. 2.1.4 (Reproduced from Radcliffe, 1961).

A lower extremity prosthesis is, biomechanically, an extension device to restore the missing limb in order to make standing and walking possible. The prosthesis design concept can basically be divided in two major components:

- structural component.
- biomechanical component.

The majority of research, and development in the field of prosthetic design is related to structural components or materials. The popularity of this line of research can be explained by the fact that the results are straight forward and directly justifiable to aid and money supplying governments, agencies and organisations.

The biomechanical component is more complicated. This is caused by a lack of a good definition of what is "biomechanically sound". A principal factor restricting the level of understanding of biomechanical effects occurring during amputee gait, is the inability of obtaining accurate quantitative assessment of stump-socket interface pressure distribution during gait.

This problem was bypassed by Radcliffe and Foort (1961) by "educated guesses" which resulted in (a) a PTB prosthesis concept. and (b) a biomechanical explanation for load transfer and force interactions between the stump and the socket during trans-tibial amputee gait. Most of the conclusions and explanations used are based on educated guesses. This results in the anteroposterior force diagram for a PTB prosthesis, Fig. 2.1.4. The diagram was based on the assumed line of action of the GRF and the substantial load transfer capabilities of the patellar tendon during gait.

Of course there is nothing "wrong" with the PTB concept, because it has proven its value over the years. But the success of the PTB concept can also be a result of the adaptability and tolerance level of the user. Although it has been successful, there are some limitations with the PTB concept:

- to produce a PTB socket requires a great amount of time, skill and experience. These are often not available in the developing world.
- the PTB concept is based on western technology and therefore not necessarily appropriate for the developing world.

Is it possible to design and evaluate a trans-tibial socket concept that will reduce the skill level needed to produce an acceptable socket fit ?

Socket design studies have been an under-developed or even a neglected area of research, compared to component and material related studies. This is caused by the complexity and lack of understanding of tissue behaviour in general and by lack of consensus of what is considered a good socket fit. This situation has already been described by Murphy (1954). Four decades later, little has changed and the main debate in socket design is still about the relative merits of high localized pressure versus uniform pressure (Hulshof, 1994). The problems mentioned above indicate the complexity of socket design and fit.

To be able to design and develop alternative socket concepts, assessment and evaluation methods are needed. Socket fit comfort, functionality and stump-socket interface pressure distribution are potential methods of assessing and evaluating socket fit, but the value of a socket design can only be evaluated if socket fit criteria exist. As a result, two "need" areas of interest are identified:

- Investigation of stump-socket interface pressure measurement systems that are able to accurately measure pressure distribution over large areas.
- What knowledge and information are necessary to specify, design and evaluate acceptable socket fit ?

2.2 Pressure measurement system investigation

Measurements of trans-tibial stump-socket interface stresses during gait are of particular interest to clinicians and researchers. Especially so in the field of assessing and analysing the difference in specific features and biomechanical characteristics, typical for different lower limb socket designs. This field of study has been investigated by many researchers, utilising different sensing devices and a variety of methods.

The principal factor restricting the level of understanding of biomechanical effects occurring during amputee gait, is the inability to accurately measure stump-socket interface pressure distribution. The investigations of interface pressures conducted in the past have been limited in this respect. This is due to the lack of transducers that could measure pressure distribution over larger areas and identify local pressures in socket regions with small and even medium radii of curvature.

Transducers are devices for the conversion of one energy form into another. The term is applied to devices for converting mechanical variables such as force, pressure, displacement, etc. into corresponding proportional electrical changes. The ideal transducer should be sensitive only to the physical quantity which it is intended to measure. In real life, all transducers are influenced by a variety of variables to a greater or lesser degree, depending on their type.

One particular commercial system which raised interest is the FSR technology based pressure measurement system developed by Tekscan[2]. The following system characteristics are identified:

- A complete commercially available pressure measurement system, that incorporates transducers suitable for stump-socket pressure investigations.

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[2] TEKSCAN, Inc., 307 W. First street, Boston, MA 02210. USA

- The high degree of flexibility of the 0.017 mm thick transducer.
- The resolution and sensing surface of a single sensor array (96 individual sensors, covering a total sensing area of 15,500 mm^2).
- Relative cheapness of the system and replacement transducers.

FSR transducer technology can be based on a variety of resistive compounds such as carbon fibres, conductive rubbers and various specially developed media impregnated with conductive ink. Although all resistive compounds exhibit the required property of a change in resistance in response to applied force, the ink impregnated type of transducer has achieved the highest popularity because of the superior reliability and validity. The Tekscan system is based on this category, utilising special ink as conductive dopant. The manufacturers claim that the system allows accurate, reliable and cost effective pressure measurements over large curvated areas and with negligible protrusion interference.

The Tekscan system has been primarily developed for in-shoe pressure measurements. A wide choice of transducer configurations, based on the same FSR technology, is available. This allows utilisation of the system in different fields of study such as dentistry, wheelchair seating and prosthetic socket investigation. More recently, the accuracy and reliability of the system has come under closer scrutiny (Rose, 1992; Cavanagh, 1992; McPoil, 1995; Brown,1996; Cobb,1995; Fleming, 1988; Sanders,1995 and Woodburn, 1996). Although the Tekscan technology represents an innovative method of multi-point pressure measurement, a multitude of potential inaccuracies, typical for FSR technology must be investigated for the technology to be considered reliable and suitable for stump-socket interface pressure studies. The following areas of concern are identified:

- non linearity.
- drift.
- hysteresis.
- crosstalk.

- temperature sensitivity.
- sensor wear.
- repeatability.
- calibration.
- dynamic response.
- response to shear.

2.3 Socket fit

A major problem in socket design is that there is no precise agreement on what is considered a good socket fit. The value of a socket design can only be investigated if socket fit criteria exist. This section is an approach to identify fit criteria as follows: What knowledge and information are necessary to specify, design and evaluate an acceptable socket fit ?

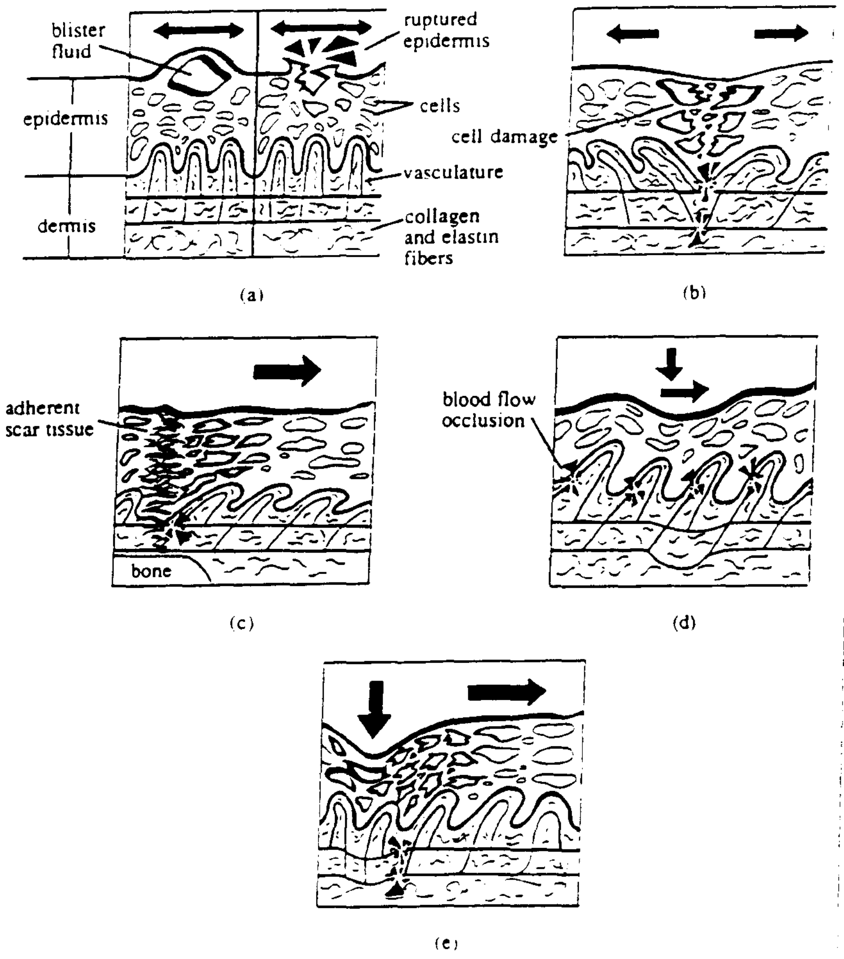
This question can be divided into 3 components:

- what is an acceptable socket fit ?
- which procedures have the potential to produce an acceptable fit ?
- what evaluation concepts can be used ?

2.3.1 What is an acceptable socket fit

The aim of a socket is to provide a coupling between the skeleton and the rigid structure of the prosthesis. This coupling transfers the ground reaction force and control forces to the skeleton. It is important to consider what determines the quality of that coupling (Klasson, 1995). It is suggested that the quality of the coupling can be defined by its stiffness. The stiffness of the coupling is influenced by the response behaviour of soft tissue during the application of forces and moments developed inside the socket during normal use. The purpose of the coupling stiffness can be divided in two components:

- protection of soft tissue from damage by avoiding or limiting displacements caused by pistoning, shift and rotation.
- enforcing stability which will result in better control of the prosthesis (Proprioception).



(a) Cyclic shear stress can cause a blister to form within the epidermis (left) or it can create an abrasion on the skin surface (right). *(b)* Shear stresses in opposite directions put the intermediate skin in tension, which can cause blanching and possible cell failure. *(c)* Shear stress adjacent to scar tissue adherent to bone puts the intermediate skin in tension. *(d)* Static shear stress reduced the normal stress necessary to cause blood flow occlusion. *(e)* A normal stress adjacent to a shear stress puts the intermediate skin in tension.

Fig. 2.3.1.1 (Reproduced from Sanders, 1992).

2.3.1.1 What is in relation to tissue an acceptable socket fit?

Abnormal loading of skin unaccustomed to bearing large forces can result in tissue breakdown. The main tissue risks may be listed as:

- Tissue breakdown from restricted blood flow as a result of abnormal stresses that are normal to the surface.
- Tissue breakdown from interface shear stresses. (Sanders,1992) See also Fig 2.3.1.1.

2.3.1.2 What knowledge and information is necessary to specify and design an acceptable socket fit ?

Little is known about how support forces are transferred from the socket to the skeleton. It must be noted that the stump tissue between skin and bone is not homogeneous. This soft tissue mass consists of several different layers, mainly skin, muscle and connective tissue, all with different behavioural properties when subjected to load.

The mechanical response characteristics of soft tissues under load are function and time dependent. Function dependent due to mechanical changes as a result of muscle contractions. Time dependant due to migration of fluid through the lymphatic and venous system. Tissue alteration of shape, volume and mechanical characteristics will take place over a prolonged period of time (weeks or months), due to internal and biological influences and external loading patterns (Hulshof, 1994). These factors make it extremely difficult to predict the mechanical response characteristics of the stump tissues.

The end result of socket fit quality depends upon the combined effect of the diverse properties of soft tissue and socket (Klasson, 1995) and accordingly lists different load transmission factors which are probably available:

- Elastic unidirectional compression of thin layers of soft tissue between the socket wall and the skeleton. The nature of elastic force transmission through thin layers of flesh is that there is a relation between stress and strain, which is the deformation in relation to the thickness of the tissue. No Shear stresses are developed in the tissue.

- Quasi-hydrostatics. Hydrostatic weight bearing means that no shear stresses are developed in the soft tissues. As a result of the multidirectional fibre composition of the various tissues, hydrostatic behaviour is not possible, therefore this load transmission component is called Quasi-hydrostatic. (Klasson,1995).
- Tissue tension (stretching of the skin covering the stump).
- Tissue shear (internal shear stresses).
- Friction.
- Energy absorbing transmission (viscosity, plasticity).
- Muscle activity.

It must be clear that the elements listed above interact with each other, but there is no agreement to their relative importance or their interaction in the load transferring medium.

2.3.1.3 What knowledge and information are necessary to implement and evaluate an acceptable socket fit ?

Socket fit criteria are essential to assess and evaluate socket fit. Three fit criteria were specified by Klasson.

- the stiffest realistic coupling between skeleton and socket.
- no tissue damage.
- minimum discomfort.

When a prosthetist produces a cast with a conventional hand casting technique, he or she strives during cast rectification to redistribute the forces over the largest possible areas to obtain acceptable local pressures. This is achieved by force redistribution from the so called "pressure sensitive" to the "pressure tolerant" areas. However, Sangeorzan et al (1989) investigated the tolerance of skin to mechanical loading over the tibia and the tibialis anterior muscle in 12 normal subjects. After having reported the obvious fact, that indentation of skin over bone was much less than skin over muscle, they report: "However, the subcutaneous pressure at which the $TcPo_2$ became zero was not significantly different in the skin overlying bone than skin overlaying muscle". This study implies that the concept of pressure tolerant and pressure sensitive areas may be a myth. When conventional hand casting is practised, the following problems may occur:

- the conventional casting may result in local pressures which are too high.
- bony prominences moving within the socket during weight bearing can cause excessive localized pressures.

These problems are solved by making modifications, resulting in total pressure relief in those areas. Of course, the effective load transfer area is reduced and therefore pressure on the remaining areas must be increased and often results in high localized pressures.

The main purpose of the following assumption is to make sure that local pressure peaks are avoided or minimized.

- The ideal pressure distribution over a selected bony area of the stump is a uniform pressure distribution.

An even pressure distribution throughout the gait cycle is of course not possible because of the variation of external forces and moments. During the gait cycle some periods are more critical than others; especially when the GRF magnitude exceeds body weight due to acceleration effects during gait. It is important to ensure that, during those critical periods the peak pressures generated inside the socket are as low as possible or without exceeding a specific tissue pressure tolerance level.

To assure tissue safety, the following tools are designed to define, implement and evaluate an "acceptable" socket fit: (Klasson, 1995)

- surface matching.
- volume matching.

2.3.1.4 Surface matching

The primary purpose of surface matching is to avoid localised pressure peaks over bony areas, avoiding tissue damage. The secondary purpose is to minimise further tissue deformation as full load is applied, hence providing stiffness. The soft tissues are then supposed to change shape at constant volume. If the tissues are stabilised as far as shape changes are concerned load transmission will be stiff. (Klasson, 1995)

A uniform pressure distribution, transmitting the force to the bone at full load over a limited area, will result in reduced pressure peaks within that area. Therefore, the local pressures and the tissue stresses are minimized at a given load. Consequently:

- the highest loads can be transferred through a given area without locally exceeding the pressure tolerance threshold.
- there is no need for deliberate pressure reliefs e.g. protecting tissues over prominences.

It is then presumed that so called sensitive areas are as sensitive to load as other areas, unless there is a pathological situation.

This results in the following conclusion: An ideal surface matching is represented by such a socket wall shape, that an even pressure distribution is developed when maximum load is transmitted from the socket wall to underlying tissue.

2.3.1.5 Volume matching

Volume matching has a hydromechanical background. The purpose of volume matching is to determine the appropriate socket volume permitting load transmission by using the soft tissues as a hydrostatic medium. Hydrostatic tissue behaviour implies no shear is present inside the tissues, therefore avoiding shear-related tissue damage. Another advantage of hydrostatic behaviour is that it stiffens under applied pressure. Hydrostatic tissue behaviour (no shear) is probably not possible because of the limited ranges and/ or directions of the fibre composition of the different soft tissues of the stump.

2.3.2 Socket shaping methods available

Several criteria based on engineering principles to specify and design an "acceptable" socket fit are listed by Klasson (1995):

- The stiffest realistic possible coupling between skeleton and socket.
- No tissue damage.
- Minimum discomfort.

Implementation tools:

- Surface matching.
- Volume matching.

Note that these criteria are only an attempt to define socket fit and are not necessarily "the" ideal fit criteria. To meet the developed specifications the following factors must be investigated:

- Which trans-tibial socket shaping techniques are available ?
- Which of those procedures have the potential to produce an acceptable socket fit ?

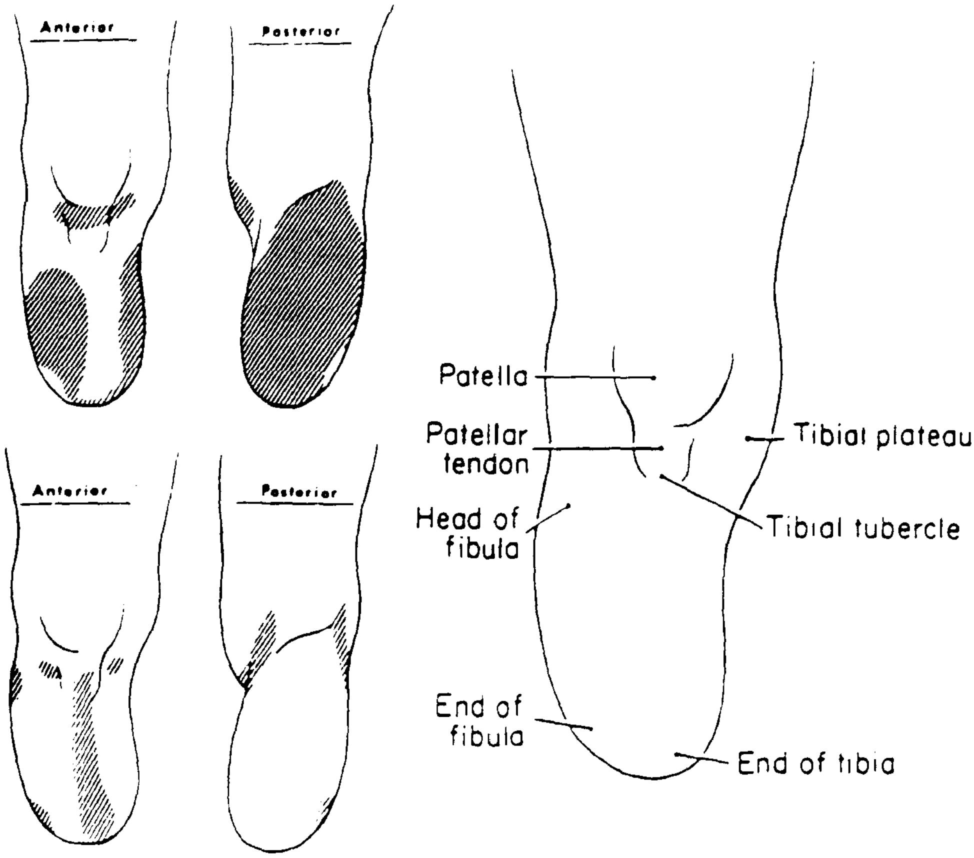

Anterior
Posterior
Anterior
Posterior
Patella
Patellar tendon
Head of fibula
Tibial plateau
Tibial tubercle
End of fibula
End of tibia

Fig. 2.3.2.1

2.3.2.1 Hand casting

The socket for a PTB prosthesis is intended to remain at all times in intimate contact with the entire surface of the trans-tibial stump. During the casting procedure, use of plaster of Paris (POP) bandage offers among other things, the opportunity of regulating the tightness of the cast by controlling the tension applied to the bandage while it is being wrapped. The prosthetist must identify and outline the bony prominences and other landmarks, this requires build-up on the positive model, in order to give relief in the socket. The areas especially well adapted to weight - bearing, those requiring reduction on the positive model, particularly the patellar tendon, is utilised to full extent. When the cast is taken, the prosthetist's intention is not to produce a "weight bearing shape" but to emphasize the special points of weight-bearing to be anticipated in a PTB socket. See Fig 2.3.2.1.

Ideal surface and volume matching is almost certainly beyond the capability of a hand casting method, although it is possible to avoid obvious mistakes that could ruin the surface matching. (Klasson, 1995). Hand casting and rectification requires knowledge, skill and experience. It is not possible to reproduce the full load bearing situation during casting. All casts produced are likely to vary between individual prosthetists. It is also doubtful that a prosthetist is able to reproduce 2 identical casts for the same subject. Exactly the same can be said for rectification related matters. This implies that hand-casting can probably not support the "ideal" socket fit criteria. Therefore hand-casting is very likely not the right direction to pursue if consistent excellence is required. In locations where trained experts are not available, such as the developing countries this is certainly true.

2.3.2.2 Shape sensing

The use of CASD concepts as a trans-tibial shaping technique to diminish the backlog in developing countries is raising interest (Cummings 1996), but is CASD a design concept or a tool ?

Current CASD concepts represent ways to computerise the socket design process, but in a more reproducible way. The stump information is gathered by digitising a hand made wrap cast or by direct laser scanning of the unloaded stump. When the stump information is gathered by digitising a hand made wrap cast, the same procedure as hand casting will be the result with similar limitations. When the stump information is gathered by direct laser scanning the only information available is the external shape or dimensions of the stump. Laser scanning can not give information about how the tissues will deform, when full load is applied.

The use of CASD systems in developing countries is not questioned in this study. CASD has the potential to be very successful, for instance, in active war areas were fabrication of orthopaedic devices is hindered as a result of the obvious war related problems (e.g. data could be sent to prosthetic centres in safer areas). Not the use, but the concept of CASD in relation to the "ideal" socket fit is questioned, resulting in the conclusion that CASD is only a tool and not a design concept.

2.3.2.3 Pressurised casting

Pressure casting concepts have been explored and used for a long time. This casting approach can be divided into two main groups: (a) a loading condition with a fluid medium (Hydrostatic principle) or (b) loading conditions with air as a loading medium. One of the earliest pressure casting concepts has been described by Murdoch (1965) where fluid was used as a loading medium. Initially the concept was described as an attempt to eliminate all errors related

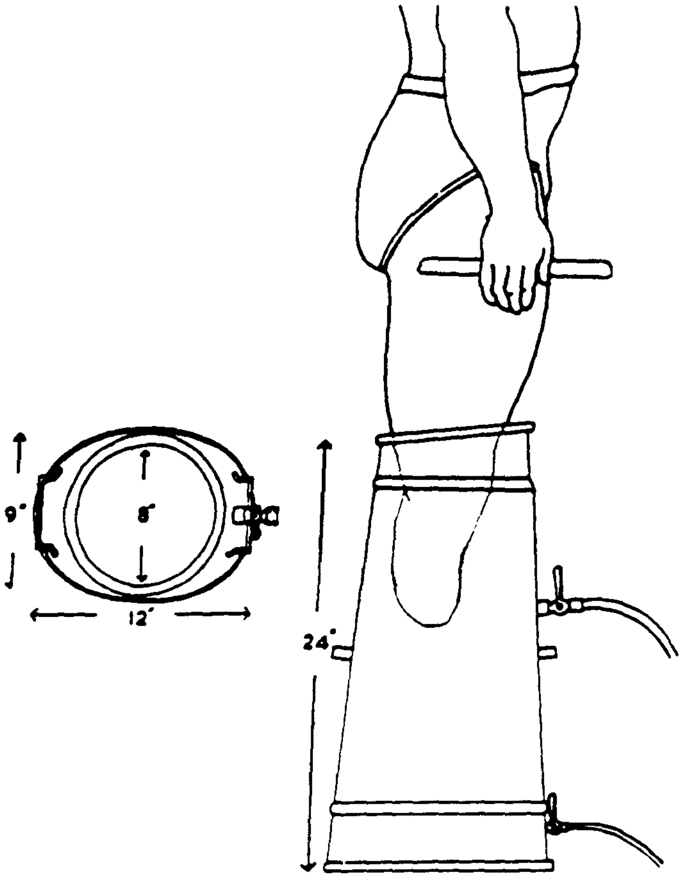


Fig. 2.3.2.3 (Reproduced from Murdoch, 1965)

to manual dexterity during the casting process. This was in relation to difficulties experienced in producing consistently satisfactory sockets. In this method, a hydrostatic tank was sealed at the top with a double nylon membrane, see Fig. 2.3.2.3. Air was bled out and water was introduced into the tank to a level that would still permit the acceptance of the volume of the stump and the lower thigh. The subject's stump was covered with socks impregnated with POP. The subject was asked to stand, with the stump in the tank. The body weight was evenly distributed between the affected and sound legs until the POP was cured. Weight distribution was monitored with bathroom scales. Pressures quoted were in the range of 14 to 41 kPa.

A number of casting methods have been described where air was used as loading medium. Gardener (1968) used ridged distal caps and latex inserts to redistribute pressure at the patella and popliteal areas. The pressure sleeve was a double-walled open end fustrum of a cone of small taper, large enough to fit over the knee. Kristinsson (Össur HF manual, 1996) leaves the distal end open in the Icecast 1 version and applies tension to the skin in a distal direction in the version of Icecast 2. None of these methods aim at a completely uniform pressure distribution as mentioned by Murdoch (1965).

Pressure casting has the potential to develop a uniform pressure distribution during casting, with the philosophy of letting nature dictate the most realistic and achievable pressure distribution. The reasons for seeking a uniform pressure distribution are described in *volume matching and surface matching.* During the casting process, manual dexterity and inter-prosthetist variances are eliminated. There is no need for rectification if certain conditions are satisfied.

2.4 Summary

It is not realistic to meet the enormous demand for trans-tibial prosthesis by training the estimated 100,000 additional qualified technicians needed in developing countries. Neither the capacity of the existing training centres nor the educational resources and financial means are available.

The current practice of trans-tibial prosthetic care (PTB socket) requires a great amount of skill and experience. It is desirable to design and evaluate a trans-tibial socket concept that will reduce the skill level needed to produce an acceptable socket. This would be valuable in developed and developing countries.

Socket design studies are hampered by the complexity and lack of understanding of tissue behaviour in general and the lack of consensus what is considered a good socket fit. The debate is still about high localised pressures versus uniform pressures.

Klasson described the following socket fit criteria:

- The stiffest realistic coupling between skeleton and socket.
- No tissue damage.
- Minimum discomfort.

Implementation tools:

- Surface matching.
- Volume matching.

According to Klasson's criteria a pressure cast concept has the best potential to meet these criteria.

Pressure distribution, comfort and functionality are potential methods to evaluate socket design differences. Investigations of stump-socket interface pressures conducted in the past were limited due to lack of suitable transducers that could measure large curvated areas. The Tekscan pressure measurement system is an innovative multi-point pressure measurement system with suitable transducers, capable to measure large curvated areas. This FSR based technology must be investigated and evaluated for the technology to be accepted.

Two areas of interest are identified for this project:

- Investigation of the Tekscan pressure measurement system.
- To investigate 2 different socket designs by means of stump-socket interface pressure distribution. ("Conventional" PTB socket versus a Pressure cast socket).

CHAPTER 3

INVESTIGATION OF THE PRESSURE MEASUREMENT SYSTEM

3.1 Relevance

The objective of this chapter is to report on the test and evaluation of the selected Tekscan system and outline its limitations. The limited documentation about the Tekscan system, as well as the many potential inaccuracies, reflect the need for indepth system behaviour investigation. The difference in suggested applications of the pressure measurement system, (prosthetic socket interface pressure measurements versus the more commonly used in-shoe pressure measurements), contributes to the need for external calibration. External calibration is described later.

3.2 The Tekscan 9810 transducer

The 9810 Tekscan transducer is a typical example of a matrix system, where 96 individual FSR sensors are arranged in an array of 16 rows and 6 columns. The transducer is a sandwich construction of two Mylar printed metal circuits, separated by a specially designed conductive ink layer. The application of force to the transducer changes the properties of the resistive ink-layer hence altering the output signal of the circuits. The greater the force the lower the resistance. The overall thickness of the transducers is 0.017 mm and the active area of an individual cell is 40 mm^2.

The transducers are made from a compliant plastic material (Mylar). Therefore, time dependent characteristics, such as creep and hysteresis, are of prime importance. Viscoelastic materials will exhibit stress relaxation, i.e. a decreasing load at constant deformation, that may or may not stabilize according to whether the material is a solid or a fluid. As viscoelastic materials display such phenomena as creep and hysteresis, any force measuring system dependant upon the stress/strain relationship of such materials is also liable to produce similar phenomena on the output data. Such systems should only be used with extreme caution.

The Tekscan transducer is a semiconductor device and is liable to be influenced by temperature changes. Therefore, it is of importance that the transducer data output is not seriously altered, after placement inside a prosthetic socket. The transducer sensitivity to ionic fluids (sweat), heat and humidity (micro climate inside the socket) must also be taken into account. Although the transducers are individually calibrated in the factory, they do behave differently. It is therefore impossible, without a good calibration method to perform extended tests like hysteresis, drift, temperature sensitivity etc. This calibration method is described later in this chapter.

According to the Tekscan manual the following transducer behaviour claims were made: drift occurs up to 5% in 10 seconds and the time factor increases by a factor of 10, i.e., the next increase up to 5% would be in 100 sec., then 1000 sec., 10,000 sec, etc. The data output changes by 1% per degree Celsius. Tekscan transducers operate best over a pressure range 15:1. The transducer used for this study (F-scan 9810) has a maximum pressure of 520 kPa and a recommended use of 340 kPa. The best expected operating range is between 34 kPa. and 340 kPa.

3.3 Tekscan hardware

The computer used in this work utilised a 486-66 DX microprocessor operating at 120 MHz. The computer provides a hard disk space of 750 MB and a RAM of 8 MB. Other Tekscan requirements of the host computer system includes, one 3.5" floppy disk drive, one IBM compatible 16-bit expansion slot, VGA monitor and graphics adapter, Microsoft-compatible mouse and 100% Microsoft compatible mouse driver, DOS 5.0 or higher operating system and a colour printer (if printouts are desired).

The Tekscan system has been delivered with one interface board which is inserted in one of the 16-bit expansion slots of the host computer. The interface board has two cable receptacles and can accept two data recordings simultaneously. The dual interface board accepts transducer data into the computer, making it available for the Tekscan software.

The signal processing unit functions as a connection interface between transducer and computer. The unit gathers data from the transducer and provides pre-amplification and signal conditioning, making it easy to send data to the computer by cable. One end of the 10 metre co-axial cable is inserted in one of the two signal processing units, and the other end is inserted in one of the two receptacles of the interface board. The trailing cables are held out of the subject's way by a Velcro waist belt. By placing the computer in the middle of the walkway the patient has approximately of 18 meters of free walking space available.

3.4 Tekscan software

The Tekscan software is based on the convention principles established by Microsoft Windows. This includes mouse operation, screen controls and pull down menus. The Tekscan program must be started from DOS, to eliminate operational conflicts when running under Microsoft Windows.

The Tekscan system used a RAM size of 8 MB. This RAM size dictates the sampling rate and the number of frames of a single data recording. This resulted in a single data recording being limited to a maximum sample rate of 165 Hz. and a frame count of 750 frames.

```
DATA_TYPE MOVIE
VERSION Tekscan Sensor Presentation Software:  Version  3.845F
SENSOR_TYPE 9810
ROWS 16
COLS 6
UNITS kPa
CALIBRATION_FILE C:\Transducer 1
ROW_SPACING 1.27 cm
COL_SPACING 1.27 cm
SENSEL_AREA 1.6129 cm²
NOISE_THRESHOLD 3
SCALE_FACTOR 2.01601
SECONDS_PER_FRAME 0.009996
MOVIE_FILENAME C:\Transducer 1
ASCII_DATA @@
82.7, 80.6, 103, 84.7, 76.6, 82.7
92.7, 84.7, 78.6, 92.7, 88.7, 78.6
82.7, 86.7, 84.7, 86.7, 82.7, 90.7
80.6, 80.6, 90.7, 84.7, 84.7, 82.7
82.7, 82.7, 88.7, 80.6, 80.6, 76.6
78.6, 80.6, 82.7, 84.7, 78.6, 78.6
90.7, 84.7, 78.6, 80.6, 76.6, 78.6
82.7, 84.7, 94.8, 82.7, 80.6, 78.6
84.7, 78.6, 84.7, 78.6, 80.6, 80.6
80.6, 80.6, 84.7, 82.7, 82.7, 86.7
80.6, 86.7, 82.7, 84.7, 88.7, 86.7
84.7, 86.7, 92.7, 74.6, 92.7, 84.7
0, 0, 0, 0, 0, 0
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0, 0, 0, 0, 0, 0
0, 0, 0, 0, 0, 0
```

Fig. 3.4.1

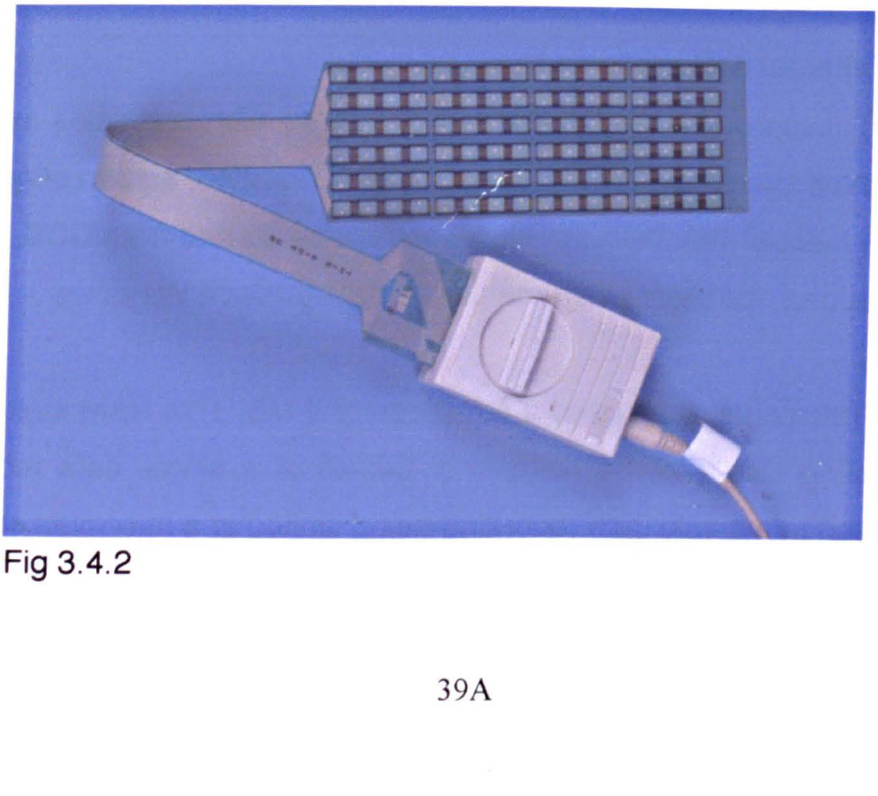


Fig 3.4.2

Capabilities of the system were as follows:

- the software allows the user to take a movie type of recording.
- pressure units can be selected by user preference.
- sampling frequency settings can be selected.
- individual transducers can be calibrated.
- recorded data can be analysed with different graph options.
- two dimensional and three dimensional view options.
- two dimensional contour view option.
- specific areas of interest can be analysed.
- direct comparison of a maximum of 2 transducer results.
- the possibility of exporting ASCII data.

When the recorded data is displayed on the computer monitor, pressure magnitude is represented in a pre-defined colour (13 colour levels). Each colour level represents a pressure range between pre-set magnitude values. This is not ideal for scientific purposes, because the pre-set magnitude range of colour levels were found to be too great. However, it is possible to export the accurate ASCII file in question to a spreadsheet program for further analysis. The user can directly choose between a variety of analysis "pull down" menu options. Those options vary from selecting different graphs; pressure versus time, force versus time, or selecting specific areas of interest or selecting the output units (kPa, N\m^2, Pounds\ inch^2 ,etc.) The only limitation of selection possibilities is the optional unit choice. The unit selection option only works when the transducers have been calibrated. Otherwise the user is limited to raw units. This calibration is established by physically applying a known weight on the transducer. The normalized data section (ASCII) contains pressure distribution information that has been gathered from the transducer. Each transducer is composed of individual sensing cells which are arrayed in a matrix of rows and columns, (see ASCII example, Fig 3.4.1). For example, an Tekscan transducer has a 96 cell configuration displayed in 16 rows and 6 columns, see Fig 3.4.2. The output values are displayed in the ASCII file in Fig 3.4.1 in 16 rows and 6 columns as well. The Tekscan system is a ready for use measuring system. This results in a situation in which it is not directly known what is happening during the analogue to digital conversion in the signal processing unit, as well as in the interface board. This "black box" situation is mainly caused by the complexity and inaccessibility of the system electronics and purpose designed software program. As a result it is assumed that the A/D conversion and signal conditioning are as accurate as possible.

3.5 The testing procedures

Introduction

The Tekscan system and a number of 9810 transducers were purchased in March/April 1995. The software program available at that time was version 3.62. During the course of the experimental tests, the software was upgraded to version 3.845 in July 1996. This change in software made some of the earlier behaviour tests and developed solutions (between April 1995 and July 1996) obsolete. The main difference between the software versions is the added equilibration option. Equilibration is a method to reduce or minimise inter-cell variation encountered on any given Tekscan transducer. This will be described in detail later.

The presentation of the data is subdivided into the time frames in which the experimental tests were performed; Period 1 being the period between April 1995 and July 1996, and Period 2 being the period after July 1996.

The experimental tests have been performed with the use of 3 different types of hardware:

- Instron 4500 series universal testing instrument and indentors.
  The Instron universal testing machine was used for testing the transducers for dynamic characteristics, repeatability and response to curvature.
- Dynamic pressure rig .

The dynamic pressure rig was used to investigate repeatability, dynamic characteristics and calibration related experiments.

- Shear rig.

  The shear rig was used to investigate the transducer output effects to shear loads.

Summary of potential system inaccuracies:

- repeatability, validity and reliability.
- dynamic characteristics (frequency response and step response).
- static and dynamic characteristics.
- hysteresis.
- linearity.
- noise.
- drift/output stability.
- thermal stability.
- transducer ware.
- response to curvature.
- sensitivity.
- inter-cell output variation.
- calibration.

3.6 INSTRON system

The Instron universal testing instrument was selected because of its accuracy, controllability and ability to create reproducible loading conditions. These characteristics made the Instron very suitable for experimental transducer behaviour tests. The Instron was capable of applying a defined loading condition to a single transducer cell by means of a purpose designed Indentor.

The Instron 4500 series universal testing instrument consisted of four separate hardware units:

- Testing machine .
- Computer.
- Front control panel.
- Chart recorder.

The testing machine incorporated two major systems:

- Crosshead drive and control system, which was able to apply compressive loads to a test specimen.
- A highly sensitive load sensing system (load cell), which measured the loading condition of the specimen.

Both of the systems were fully digital in operation and under microprocessor control.

The computer and the front panel of the instrument provided digital control, data acquisition and data readout functions for a defined loading condition.

Simultaneous data recordings, interlinking the Instron and Tekscan system, was were not possible due to limited external triggering capabilities. Therefore experimental Instron data results were recorded and displayed by means of a chart plotter. Recorded Tekscan data was recorded with the existing software. Both recordings could be directly compared and analysed.

3.6.1 Experimental Instron indentor tests

The experimental tests conducted with the Instron could be divided into 2 main groups:

- semi-static indentor tests.
- dynamic indentor tests.

The following transducer behaviour aspects were investigated;

- Transducer behaviour under different loading conditions. (semi-static and dynamic).
- Transducer behaviour response to curvature (cylindrical and spherical curvature of the loading surfaces).
- Repeatability
- Calibration possibilities.

To investigate transducer behaviour under a variety of loading conditions, it was necessary to program the Instron to execute the required loading sequence.

To be able to realise experimental behaviour tests under different loading conditions and under a variety of curvatures, three types of aluminium indentors were fabricated;

- Flat indentor with a surface area of 40.3 x 10^{-3} m^2.
- Cylindrical indentor with a diameter of 45 mm and a effective load transfer surface equal to the flat indentor.
- Spherical indentor with a radius of 13 mm and a effective surface area equal to the flat and cylindrical indentor.

Note: cylindrical and spherical indentors were pressing on matching cylindrical and spherical base plates.

The Instron testing machine was a mechanical driven machine, therefore performance limitations existed. It was very difficult for the Instron to control the applied loading sequence due to :

- loading sequences were relatively small (maximum of 8 N.).
- the increasing stiffness of the transducer material when loads above 4 N. were applied.

The Instron data results showed an over shoot spike for every incremental load applied. Attempts were made to reduce and improve this over shoot by

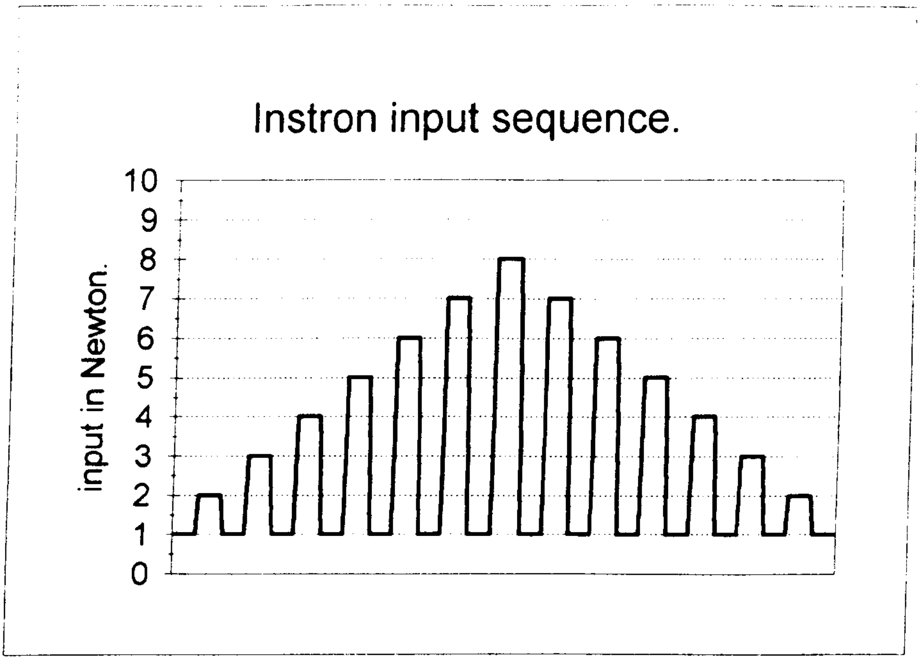


Fig 3.6.2.1

resetting the gain control. When the results were acceptable in the low region (0-4 N.) the over shoot reappeared in the higher range (4-8 N.). When the higher range was acceptable the overshoot re-appeared in the lower range. It was decided to compromise the gain setting. As consequence of this spikes were not reduced, but the signal stabilized quite soon after the load was applied.

3.6.2 Semi static tests

The following Instron programme was adopted: step loads with increments of 1N. until a maximum of 8 N. was reached. It was decided to start with an 1N. compressive load because the Instron was unable to cope with zero load. The first load, 2 N. was applied for 10 seconds, then the system reset to 1N. and held there for 10 seconds. Then the second load of 3 N. was applied and so on. This test was similar to that described by McPoil et al (1995) but lower loads and different shapes of indentors were used.

The following tests were performed:

Test 1: flat indentor with the flat area applied to 6 random cells.

Test 2: cylindrical indentor applied to the same 6 cells as in test 1.

Test 3: spherical indentor applied only to two of the same 6 cells, because of the damaging nature of this type of test to the transducer.

The flat indentor was attached to the load cell. The load cell was calibrated and reset to zero reading, to eliminate the weight of the indentor. The cell of interest was placed on the flat base of the crosshead beam of the machine. The crosshead was manually raised until the load cell output indicated contact. The Instron program was activated and the loading sequence executed. Load cell recordings were recorded with the chart plotter, see Fig. 3.6.2.1. Despite shielding the transducers, the proximity of the Instron machine induced some noise.

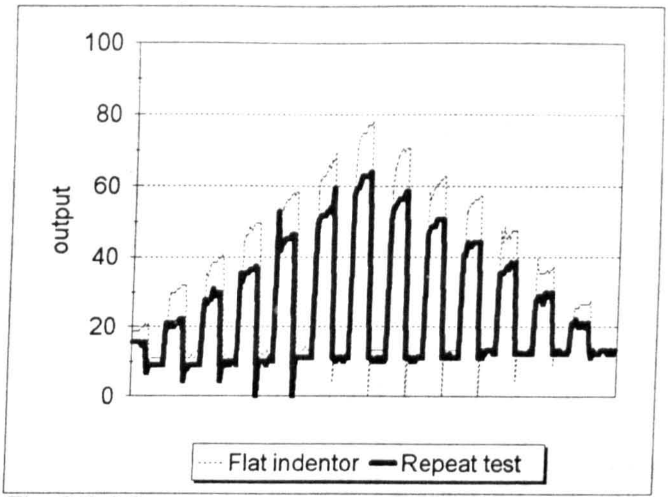


Fig. 3.6.2.2

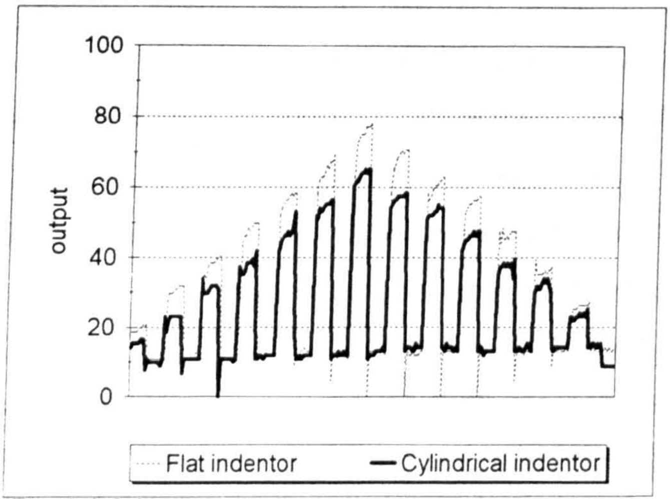


Fig. 3.6.2.3

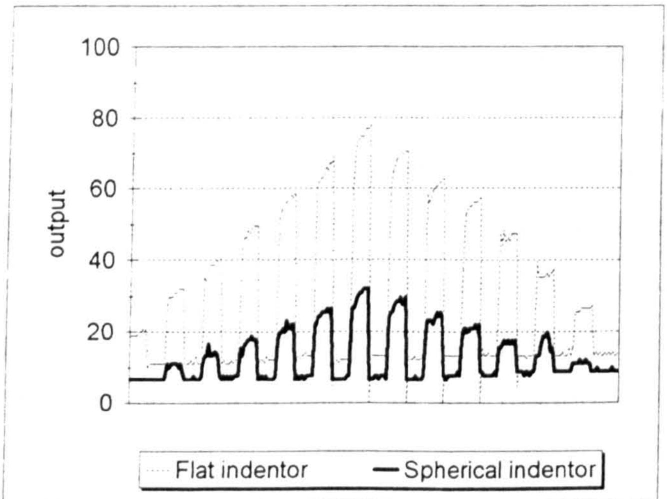


Fig 3.6.2.4

The result of a considered "typical" output representation of the flat indentor tests is illustrated in Fig. 3.6.2.2. together with the "typical" result of a repeat test. It was very clear that the repeatability of the sensor output, when the same protocol was followed, was better for one cell than for another, but the average repeatability results were poor. Fig. 3.6.2.3 compares the "typical" results of the flat indentor with that of the cylindrical indentor. The pure cylindrical curves did not have a dramatic effect on the data output. The "typical" results presented in Fig. 3.6.2.4. compared the spherical indentor with the flat indentor. Spherical indentor results demonstrate a 70% decrease in output results relative to the flat indentor results. During the test it was clear that the transducer material was creasing when the indentor was loaded. This creasing or wrinkling of the material altered the properties and resistance of the conductive ink. Output was significantly influenced.

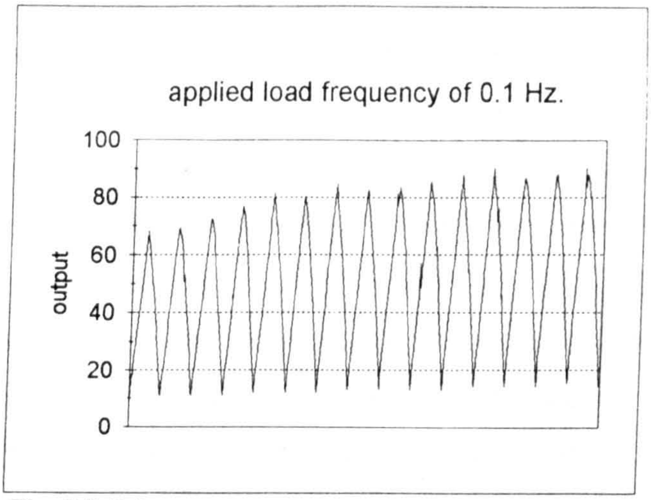


Fig. 3.6.3.1

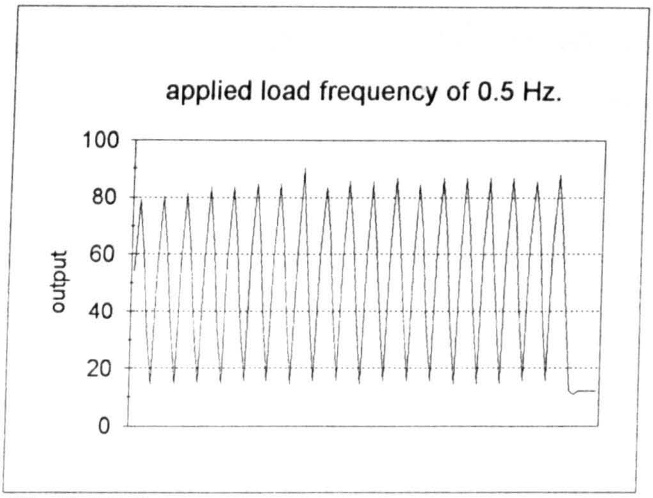


Fig. 3.6.3.2

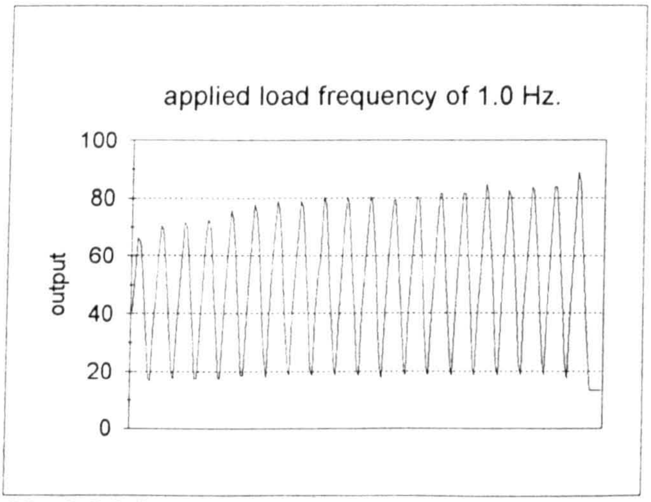


Fig. 3.6.3.3

3.6.3 Dynamic Instron tests

The sampling rate of the Tekscan system was 5 Hz. This relative low sampling frequency was chosen to be able to monitor and record data results over a substantial period of time. All described dynamic tests were executed with the flat indentor described previously. It was assumed that curvature would have the same effect on these dynamic tests.

The first dynamic tests involved output repeatability. A single cell of the transducer array was placed between indentor and base. The Instron was programmed with 20 cycles of load ranging from 1 to 8 N. and at a frequency of 0.1 Hz. This was repeated for 4 different cells. This procedure was repeated at 0.5 Hz and 1 Hz. Although the noise had its effect on the output, the signal stabilized and was very repeatable after approximate 10 cycles as illustrated in Fig. 3.6.3.1, 3.6.3.2. and 3.6.3.3. These figures illustrate a "typical" cell output. At this moment in time validity was not yet questioned. Observation was restricted to repeatability only. The first 10 cycles exhibited a very clear pre-conditioning effect. A comparison of the three graphs indicates that the change in frequency has no dramatic effect on repeatability. Although the same behaviour was exhibited in all cells tested, the output magnitude varied.
This may be due to:

- The control loop of the Instron may be inconsistent at the higher frequencies because 1 Hz. is close to the cycling limit of the Instron instrument.
- At frequency ≤ 1 Hz. the cycling time duration may have an effect on the transducer output.
- The behaviour characteristics of individual cells varies.

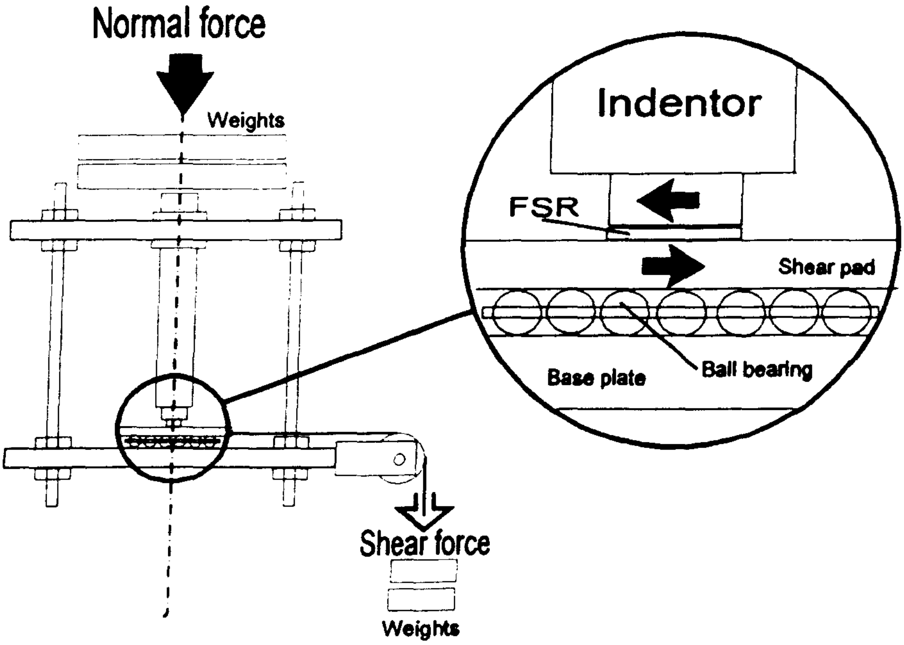

Normal force
Weights
Indentor
FSR
Shear pad
Ball bearing
Base plate
Shear force
Weights

Fig. 3.7

3.6.4 Loading range tests

The aim of this test was to investigate how the transducer output was responding to a variety of load ranges. The following load ranges were introduced:

- 4 N. to 6 N. (middle range expected inside prosthetic sockets).
- 2 N. to 4 N.
- 2 N. to 5 N.
- 2 N. to 6 N.
- 2 N. to 7 N.
- 2 N. to 8 N.

The validity of the results were very difficult to analyse due to the generated noise and control problems encountered. For instance, the Instron load cell output showed different readings from those programmed. This is probably due to the control problems of the Instron described previously. It may be concluded that dynamic testing was very repeatable even when noise was generated. Validity of the pressure data results was impossible to analyse.

3.7 Shear rig

A shear rig was used to apply a constant axial load and a number of horizontal shear forces to a single transducer cell, Fig 3.7. An axial sliding member and flat indentor (same indentor as specified previously) were mounted in the centre of the top plate and were able to slide, almost friction free, up and down. This resulted in the axial loading condition.

A caged ball-bearing was placed on top of the smooth polished surface of the base plate. The base plate was polished to reduce the friction of the bearing. A polished shear pad was positioned on top of the ball-bearing. Eight incremental shear forces were applied to the shear pad by applying weights to a pulley system. The cell in question was secured in position between the indentor and the shear pad with double sided tape.

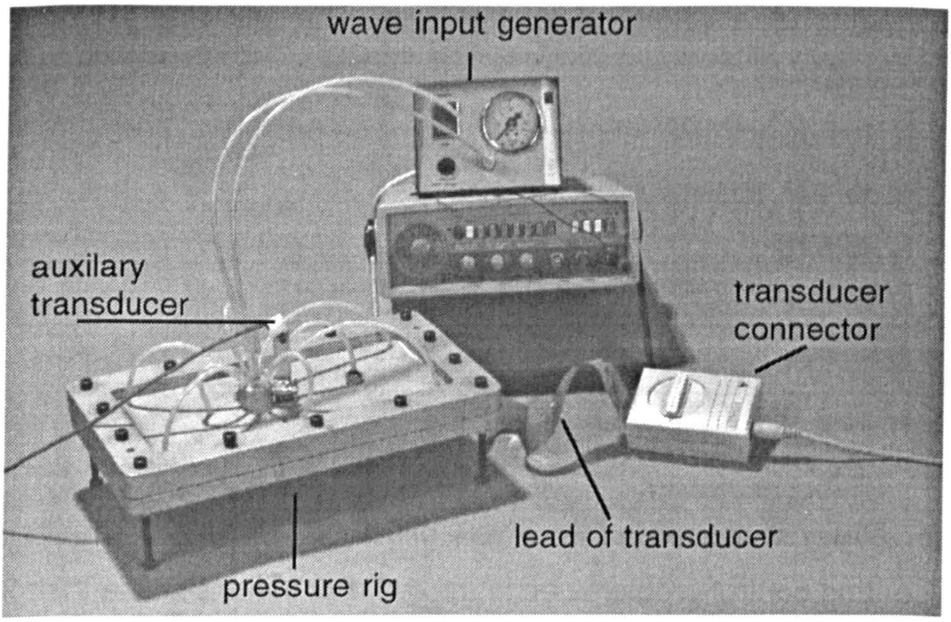


Fig 3.8.1

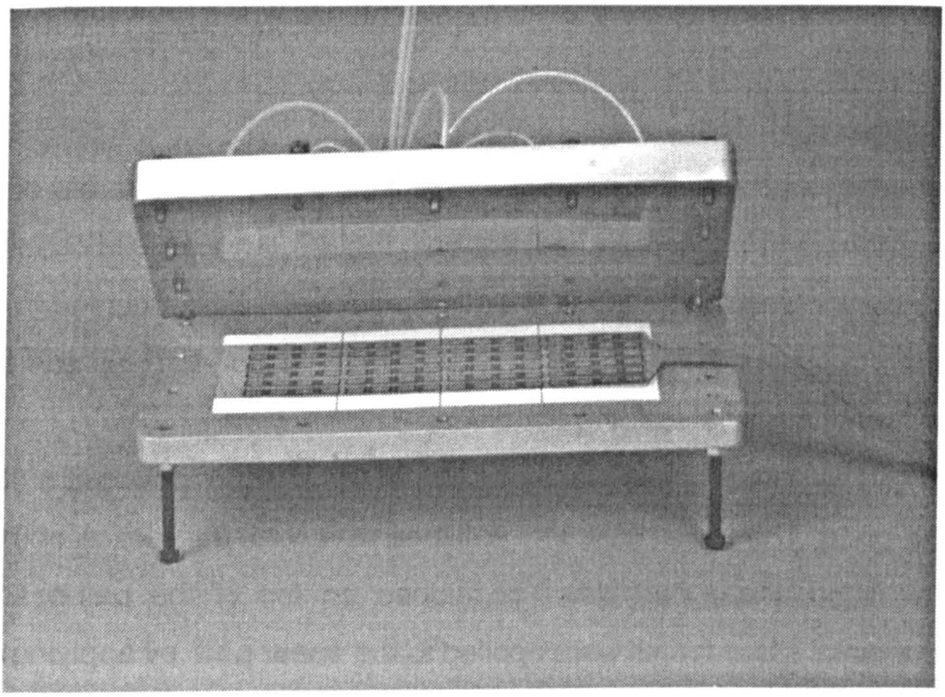


Fig 3.8.2

3.7.1 Testing for response to shear

A single static axial load of 3.7 N. was placed on the individual transducer cell for 10 seconds, no shear load was applied. A data recording was taken. The axial load was not removed and the first of 8 shear forces (0.93 N.) was applied and a recording of the cell output was noted. The shear load was removed and again the output was noted for an axial load without shear; this was done to compensate for output drift.

This sequence, with and without shear loads, was followed until all 8 shear loads (0.93 N. - 6.5 N.) were recorded. In total, 4 randomly chosen cells out of 96 cells were tested as described above. It was found that the Tekscan output increased during the first 4 shear loads. Output decreased from the 5th shear load. The increase and decrease of Tekscan output was not proportional to the applied shear load.

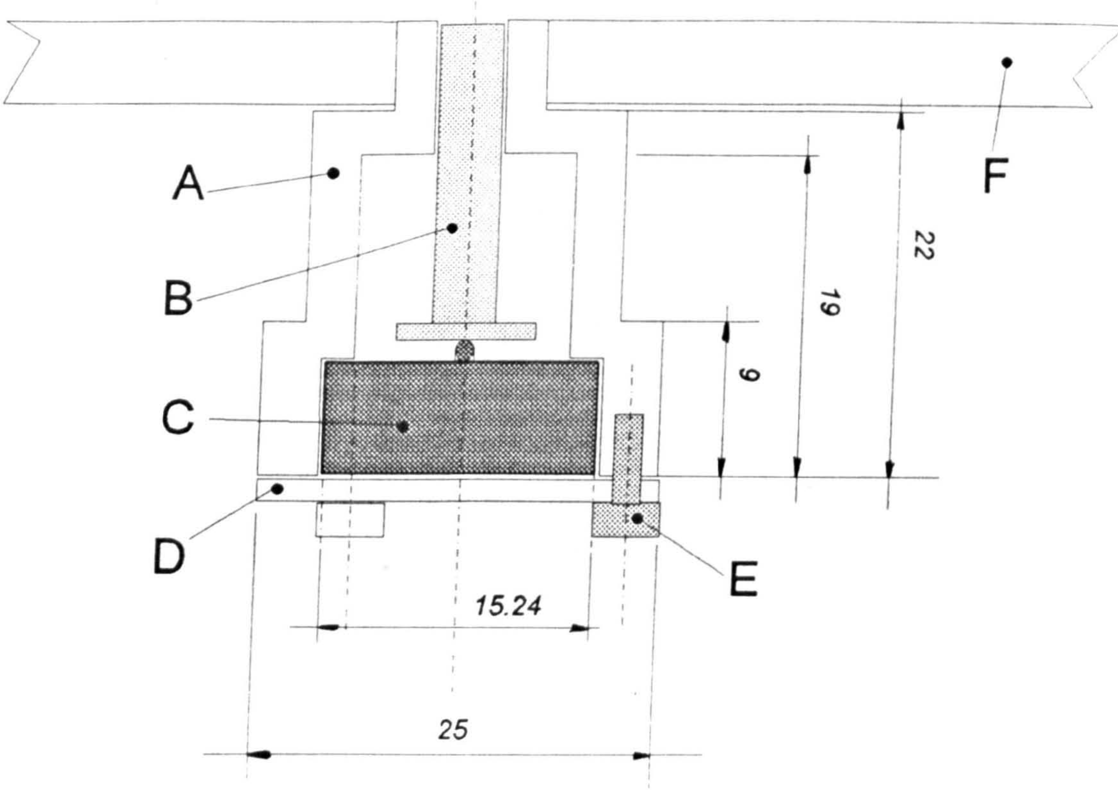
3.8 Dynamic pressure rig

The dynamic pressure rig was designed and developed as a direct result of the need identified for external calibration of the Tekscan system. The pressure rig evolved from a simple static device to the more advanced dynamic device. Air was chosen as the loading medium due to its availability, controllability and cleanness.

The complete system consisted of the following components: Fig. 3.8.1

- pressure rig
- wave impulse generator.
- one auxiliary air pressure transducer
- two Entran transducers.

The pressure rig, illustrated in Fig. 3.8.2. consists of an aluminium alloy base plate (300 mm * 170 mm * 10 mm) perforated with 1 mm holes, spaced 10 mm centre to centre.



A) Transducer housing,
B) Solid cylindrical piston,
C) Load cell,
D) Housing cover,
E) Allen screw,
F) Base plate of the Dynamic pressure rig.

(all dimensions in mm)

Fig 3.8.3 (based on work described by Torres-Moreno,1991)

The aluminium alloy top plate (300 mm * 170 mm * 20 mm) incorporates a central milled chamber of 240 mm * 120 mm * 1 mm. on the underside of the plate. The chamber was covered and sealed with a 0.2 mm thick Mylar membrane. Eight air inlet holes of 5 mm diameter were directly connected with the created chamber.

The dynamic air impulse generator was assembled from the following components:

- precision air regulator and micro filter.
- two micro valves which were solenoid operated.
- electrical signal wave input generator.

A calibrated linear auxiliary pressure transducer was placed in-line with the air inlet of the pressure chamber. Two calibrated Entran transducers were mounted flush with the bottom plate of the pressure rig, as shown in Fig. 3.8.3 One was arbitrary placed at the edge of the chamber and the other at the centre. The transducer output was monitored and recorded with an Amplicon DASH 300 data acquisition software, hosted in an external computer.

The F-scan transducer was positioned on the centre of the aluminium base plate. The top plate with chamber and Mylar membrane was placed on top of the base plate and bolted together. The transducer connector extended outside the rig, allowing connection with the Tekscan computer. The transducer was pressurised by a defined uniform air impulse via the membrane. The perforated holes in the base plate of the rig eliminated the assumed effect of air pressure build-up between the membrane and the base plate. To eliminate possible protrusion of the transducer through the holes, a paper sheet was placed between transducer and base plate, to allow air bleeding but eliminate protrusion.

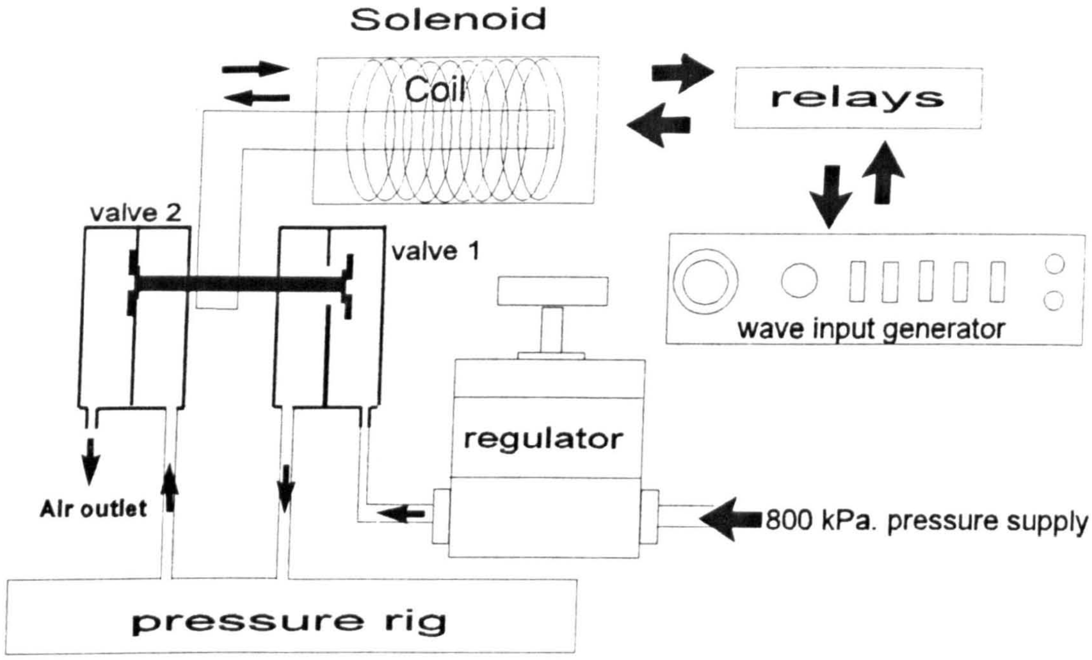

Solenoid
Coil
relays
valve 2
valve 1
wave input generator
regulator
Air outlet
800 kPa. pressure supply
pressure rig

Fig. 3.8.1.1

Before it was possible to conduct experiments with the Tekscan transducer, it was necessary to prove that the pressure rig functioned accurately. The following check methods were executed. A single transducer cell was placed at 8 random locations in the pressure chamber. A consistent loading protocol was followed. It was found that consistent output signals were produced. This method was repeated with 2 Entran transducers, known for their linearity and accuracy. One was placed at the edge of the chamber on the base plate and the other was placed in the centre of the chamber. It was found that there was no difference in output signals. This result, combined with the results obtained with the single cell, indicated that the pressure rig functioned satisfactorily.

3.8.1 Air impulse generating method

The air impulse system is illustrated in Fig. 3.8.1.1.

A constant air pressure of 800 kPa was applied to an adjustable air pressure regulator. The air pressure regulator was selected for its accuracy, repeatability and response. The regulator output could be set to any pressure range between 0 and 800 kPa. Any desired output load range and frequency could be applied to the pressure rig by opening and closing a purpose designed valve system. The opening and closing of the valves was achieved as follows:

- the solenoid was activated by the electrical wave input generator and opened the air inlet valve.
- this resulted in the rig chamber being loaded with the desired air pressure.
- then the solenoid was released and the spring pulled the thrust rod back, closing the air inlet and opening the air outlet.

The air pressure introduced to the chamber was distributed by eight inlet points, six points evenly distributed along the four sides of the chamber and two placed at the centre line. Evenly distributed load introduction points, were created to eliminate a shock wave effect, experienced when only one central inlet was

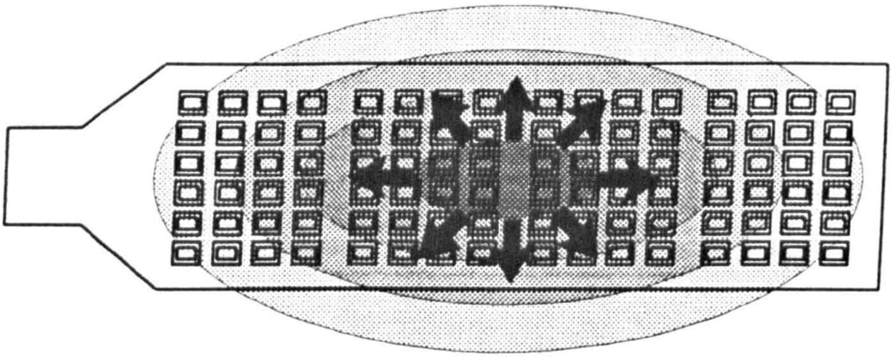


Fig 3.8.1.2.

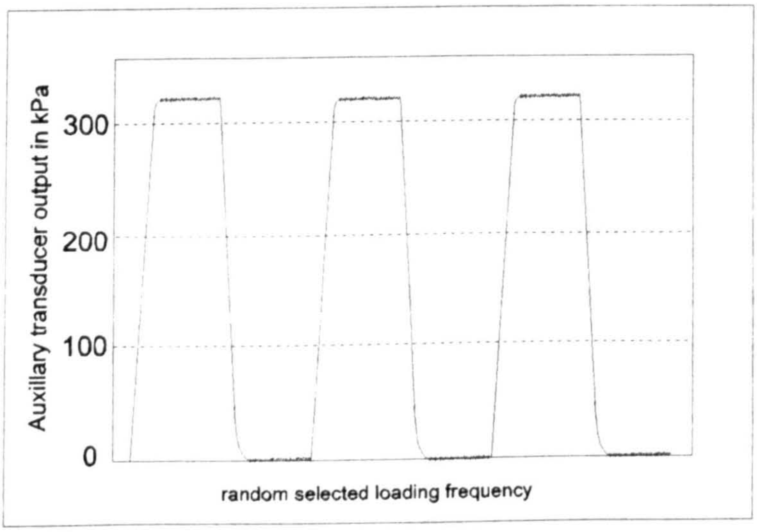


Fig. 3.8.1.3.

used, as shown in Fig. 3.8.1.2.

An dynamic air load of 325 kPa was introduced to the pressure rig with a random selected frequency. The generated impulse was observed and recorded with the auxiliary pressure transducer. This resulted in output Fig. 3.8.1.3. which displayed almost instantaneous step impulse. The last 8% of the output range showed a small deviation which was a pure pressure regulator effect. Although the selected regulator was very accurate and the response time acceptable, it showed some minor problems when the pre-set load was almost reached. This effect was also displayed when the load was released. In this case it was not caused by the regulator but the non linear air flow resistance.

3.8.2 Experimental pressure rig/ Tekscan tests

The first experiments (Period 1) included repeatability tests.

An Tekscan transducer was placed in the pressure rig and connected to the Tekscan hardware. The wave input generator was set to 1 Hz. and the pressure regulator was set to 100 kPa. The system was started and allowed to cycle for 10 cycles to overcome the pre-conditioning effect. Data was then recorded as shown in Fig. 3.8.2.1.

Data obtained was very reproducible. The graph showed that the pressure did not return to zero load. This was due to the average recording and inter-cell differences. When a single cell was selected the load returned to zero. Three quarters of the ascending load graph showed linearity then a rounded curve appeared. This reversed in the descending graph. This behaviour may be compared with the air pressure results obtained from the auxiliary pressure gauge, see Fig. 3.8.2.2.

The auxiliary air pressure data showed the same behaviour, but the curve was much smaller. A more or less similar behaviour was expected because of the behaviour of the air as a medium and the difficulties of the regulator when the maximum pre-set load was almost reached. Although the frequency was relatively high, the Tekscan transducer showed a delay in response. The importance of this consistent delay must be investigated.

3.8.3 Equilibration

Equilibration is a method to reduce inter-cell variation as experienced in the tests executed in period 1. The following method was adopted.

According to Tekscan it is very important that a uniform pressure is applied to the transducer during the equilibration process. In order to determine the correct pressure for equilibrating, it is necessary to have an indication of the pressure distribution the transducer will experience during its application. Once the desired load has been found, this pressure may be applied and allowed to

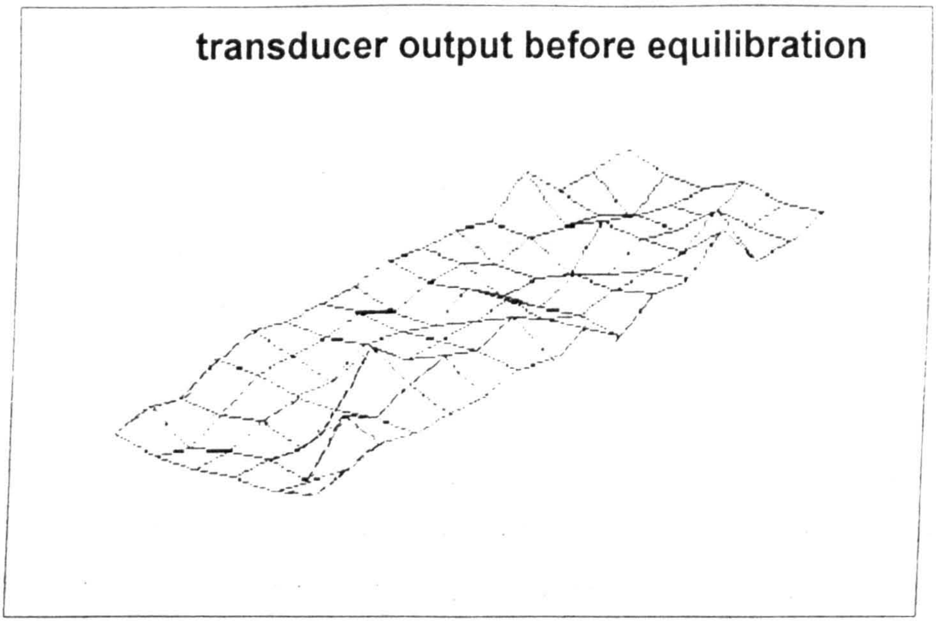


Fig 3.8.3.1

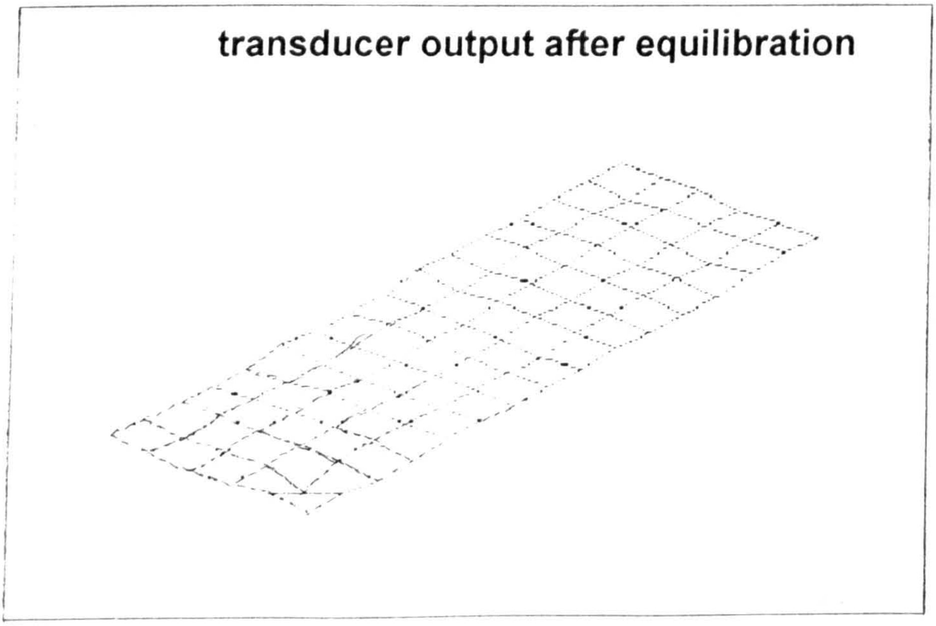


Fig 3.8.3.2

stabilize for 5-10 seconds before equilibrating. Unlike calibration, timing is not important for this process. Equilibration was performed after 10 seconds of application of a static pressure of 100 kPa. This pressure value was chosen because it was the average pressure expected during interface studies. The difference in output pre and post equilibration are displayed in Fig 3.8.3.1. and 3.8.3.2.

3.8.4 Calibration tests

Unlike equilibration, timing is of major importance for this process. The most accurate way to calibrate the system is after a pre-conditioning period of at least 10 dynamic cycles. A pre-conditioning 30 cycles with a frequency of 1 Hz. was chosen because during stump-socket interface studies the subject walked 30 steps with the instrumented prosthesis prior to data recording at step frequency of 1 Hz. A working pressure of 100 kPa was used for the same reasons as described previously.

After 10 seconds of static loading with 100 kPa, the equilibration was performed. After a pre-conditioning of 30 cycles, the pressure was maintained at 100 kPa for 5 seconds and the calibration procedure was performed. Then the pressure was released and the system was allowed to recover. The unique calibration file which was created was saved for later recall purposes.

After a recovery time of 2 minutes the transducer was again pressurised for 30 cycles with the same pressure condition. A recording was taken. The average output was compared with the applied pressure value of 100 kPa. as a double check.

The transducer was calibrated for a frequency of 1 Hz, and a load of 100 kPa. It was therefore important to know how this calibration influenced the input output relation if different loading ranges were used.

A series of 7 different pressures were applied, as shown in Table 3.8.4. The test protocol followed was the same as the protocol described during the calibration.

Input in kPa	average output in kPa	% error
50	50.1	0.2 %
75	76.3	1.7 %
100	98.7	1.3 %
125	123	1.6 %
150	145	3.3 %
200	189	5.5 %
100	102	2.0 %

Table 3.8.4

All output results were within an acceptable error margin. The higher load ranges showed a slightly higher error percentage.

3.9 Discussion of the tests

3.9.1 Repeatability, validity and reliability of the 9810 transducer

Repeatability of a measurement system can be defined as the consistency of output results when any arbitrary and repeated measured condition is applied, regardless of frequency, duration and load range of the measured conditions. The usefulness of any measurement system must be seriously questioned if the output is not repeatable to an acceptable degree. Many researchers (Rose, 1992; Cavanagh, 1992; Brown,1996 and Woodburn 1996) report significant repeatability problems between Tekscan transducers and within Tekscan transducers. The problems, encountered with repeatability described above, could be the consequence of a "inappropriate" application of FSR technology.

(see also, *transducer wear and response to curvature).* Experimental Instron indentor tests in relation to repeatability (period 1) indicated that tests performed by means of step input loading result in poor repeatability. Dynamic Instron indentor tests improved tests results dramatically. The tests showed that after a pre-conditioning period of ± 10 loading cycles, results were very repeatable over a selected number of loading ranges and frequencies. As a result, it was decided to restrict experimental tests to dynamic tests only. Transducer repeatability was also tested by means of the purpose designed "pressure rig". It was demonstrated that output results were extremely repeatable.

Validity of any measurement system can be defined as, the accuracy of the system in relation to input and output. The origin of accuracy and reliability related problems may be for simplicity divided in to two groups:

- Hardware related inaccuracies (FSR transducer behaviour related).
- Software related aspects.

FSR behaviour related inaccuracies can be a result of the following factors:

- Hysteresis effects as a consequence of FSR material compliance, loading range and loading rate.
- Transducer damage due to bending to accommodate socket curvature.
- Unsuitable application of the transducer system.

The encountered hysteresis effects can not be solved easily. However, it is possible to compensate for inaccuracies by means of specialised computer programs. Transducer damage and wear effects may be reduced or even stabilised, by avoiding active bending and creasing of the transducer during pressure recording.

Software related problems:

The tested transducer consists of a matrix configuration of 96 cells placed in 6 columns and 16 rows. One of the earlier versions of the software program had not been able to compensate for the encountered inter-cell variation of ± 25% (period 1). Therefore, inter-cell variation contributed significantly to the accuracy and reliability problems encountered by many earlier researchers. The calibration method and procedure described in the Tekscan manual has not contributed to accuracy and reliability either. (described in 3.10 "calibration").

During the first experimental tests (period 1) output validity was not fully tested due to encountered inter-cell variation and calibration problems. As a solution, raw, proportional output signals were mainly used to analyse test results. To be able to use the transducer system in the stump-socket interface study, inter-cell variance and calibrational aspects had to be solved to enable the project to progress. After the development of the "Dynamic pressure rig" and the upgrading of the software program to version 3.845, progress was made to investigate accuracy and validity (period 2). It was now possible to equilibrate and calibrate the transducer in a controlled way, for the first time. This resulted in a series of tests in which the average transducer output accuracy was of the order of an acceptable ± 2%. This has been obtained over a variety of load ranges starting from 50 to 200 kPa with 25 kPa increments. The inter-cell variation error experienced is in the order of a maximum of ± 10 %, but with the majority of the cells 90% ≤ 5%.error. The best way to overcome curvature and calibration related aspects, is to equilibrate and to calibrate transducers "in situ", i.e. placing transducers inside the prosthetic socket. A method and a protocol was developed to accomplish "in situ equilibration and calibration". As a result the same output variation was showed as the output results described above.

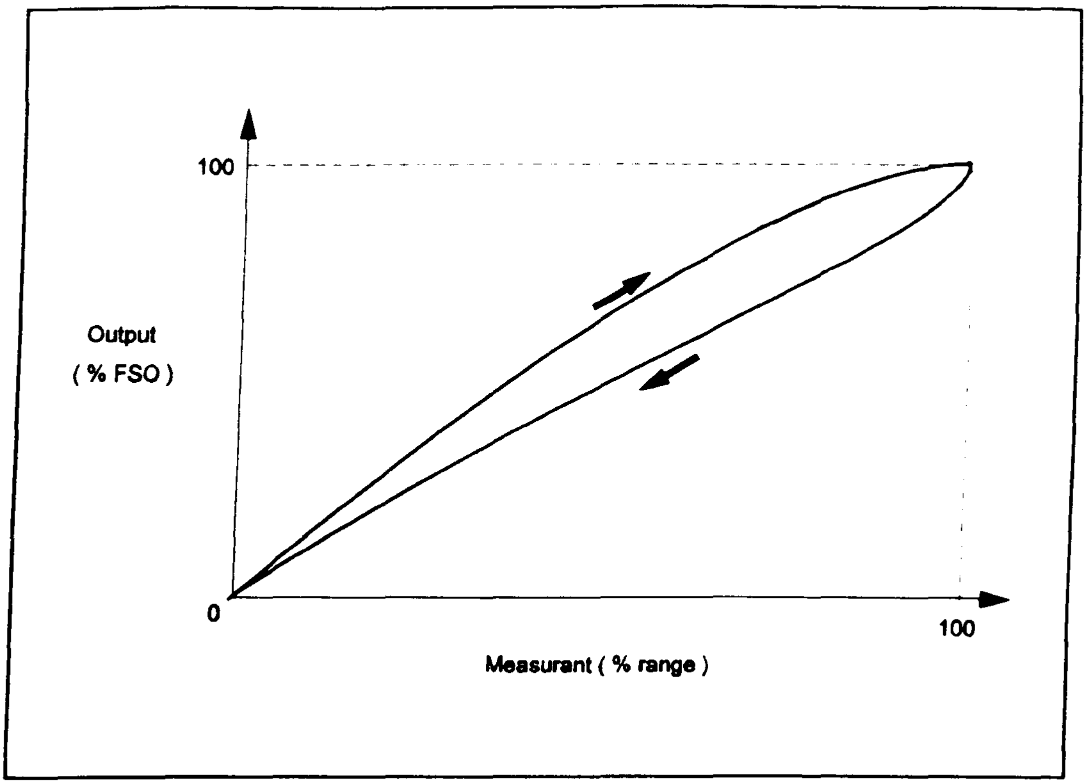


Fig 3.9.3 (Reproduced from Ruocco, 1987)

3.9.2 Dynamic characteristics

Dynamic characteristics relate the response of the transducer to variations of the applied force with respect to time. Important dynamic characteristics are the frequency response and the step response.(Ruocco, 1987).

Frequency response is a measurement of the ability of a system to respond accurately to time varying inputs over a range of frequencies. Three distinctive loading frequencies (0.1, 0.5, and 1 Hz) have been used to test frequency response (period 1). No difference in input/output relation with respect to time has been discovered. This has been confirmed when transducers were tested with a known dynamic load and load duration by means of the pressure rig (period 2).

Step response can be defined as the variation in the output value given a step change in the applied input load. The time required for the output to reach a specified percentage of the final output for each step is called the response time. Step loads were applied to the transducer with an incremental step loading sequence and a defined loading and relaxing time (period 1). This resulted in an unsatisfactory output. The output was susceptible to noise generated by the Instron and control problems encountered during operation of the Instron testing machine. The nature of the tests can, in retrospect, be questioned due to the fact that FSR technology has been found to be unsuitable for static or semi static applications (see heading *drift).*

3.9.3 Hysteresis (period 1)

Hysteresis can be defined as the maximum difference in the output values during a sequence of loading and unloading, see Fig 3.9.3.

FSR technology is very sensitive to certain variables like, load range, loading rate (frequency) and time dependency of the FSR materials i.e. transducer

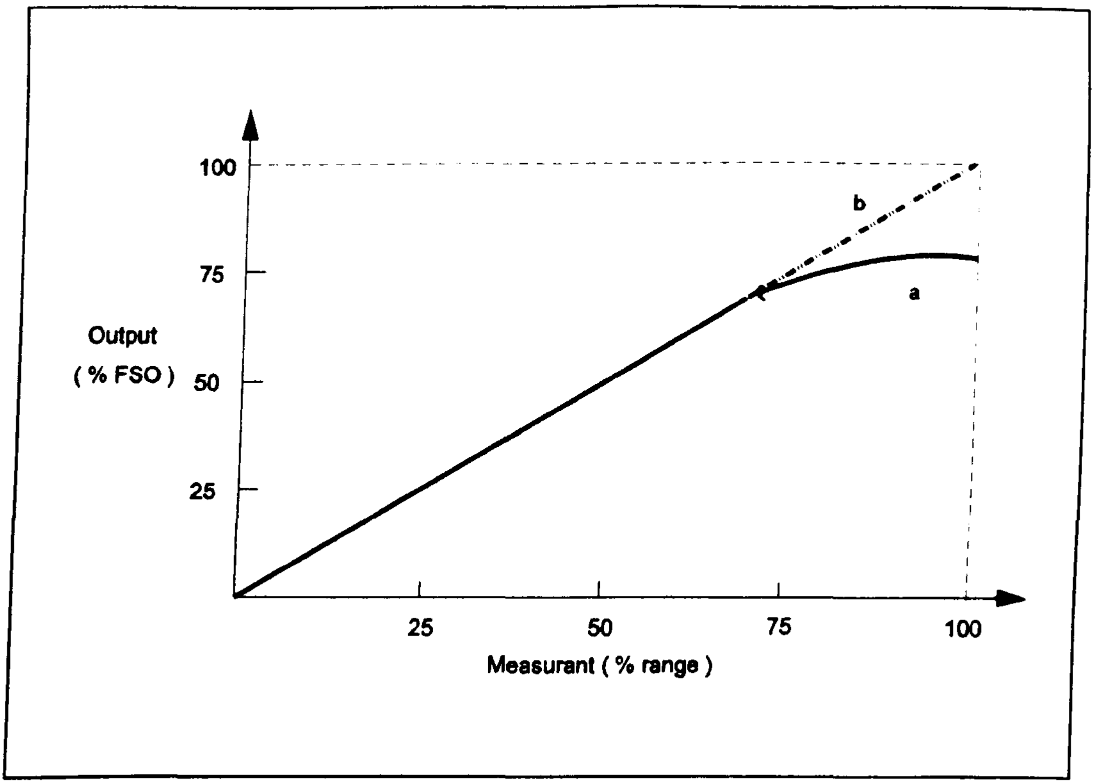


Fig 3.9.4 (Reproduced from Ruocco, 1987)

recovery time. As a consequence, transducer output has been affected in greater or lesser degree inducing hysteresis.

Test data were obtained by dynamic loading of a single cell.

It has been found that for a typical result a maximum error of 18% can be expected. i.e. For a particular applied load the vertical height between the ascending and descending graph corresponded to 18% of the output signal.

3.9.4 Linearity

Linearity can be defined as the variation in the constant of proportionality between an input physical quantity and the output signal. A transducer is said to be linear when the graph, relating input to output, is a straight line. For example, in figure 3.9.4 line "**b**" shows the theoretical straight line of perfect linearity within the measurand range. Curve "**a**" shows a transducer which is linear up to 70 % of the measurand range and then exhibits increasing deviation from the straight line. This behaviour is often known as "output saturation" and affects most transducers. (Ruocco, 1987).

The F-scan 9810 transducer has been affected as well by "output saturation". For each individual transducer the saturation level is specified in one of the pull-down menus of the Tekscan software. Levels varied between 510 kPa and 540 kPa. The maximum anticipated peak pressure we were likely to encounter during interface application was in the order of ≤ 250 kPa (Hulshof,1994; Sanders 1995, 1996.) The 250 kPa. level is significantly below the saturation level of the transducers, before the linearity is affected. During the experimental tests linearity problems did not occur.

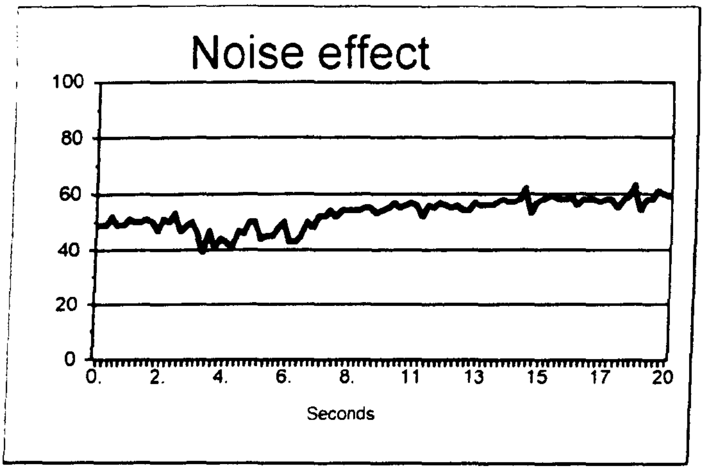


Fig 3.9.5.1

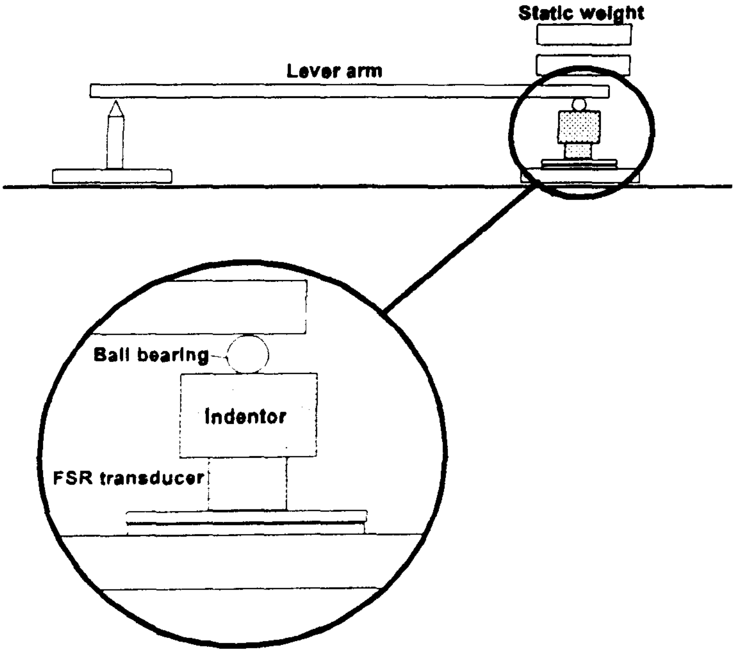


Fig.3.9.5.2

3.9.5 Noise (period 1)

Noise can be defined as the level of any signal appearing at the output of the transducer due to any cause other than the applied physical input. During the first experiments, considerable noise was demonstrated on the output Fig 3.9.5.1 This occurred when a static load was applied by means of a known load and a metal "indentor rig" Fig.3.9.5.2. It has been known that transducers based on FSR technology are liable to be influenced by certain factors, like electrical magnetic fields, ferrous metals and crosstalk (Ruocco, 1987). The maximum noise level (noise margin) that can be tolerated by the transducer before it has any significant effect on the signal output is, for the Tekscan system, a threshold of "3". Although the units of threshold "3" has not been specified any further in the manual, it could be used as a reference base. Tests have been conducted to investigate the possibility to eliminate or to reduce the excess noise effects above the Tekscan quoted threshold value of 3. As a result of the tests, it can be concluded that electrical fields as well as ferrous metals have a disturbance effect on the signal output; although the effects of electrical fields have less significance than the effect of direct contact with ferrous metals. This knowledge was taken into account for all further tests. No noise effects were noted during pressure studies with the amputee.

3.9.6 Drift/output stability (period 1)

Drift/output stability can be defined as the variation in the output of the transducer with respect to time when a constant load is applied. According to F-scan specifications, drift occurs up to 5% in 10 seconds and the time factor increases by a factor of 10. It has not been stated if these drift specifications are under static or dynamic conditions. The tests show that drift errors occur under static conditions.

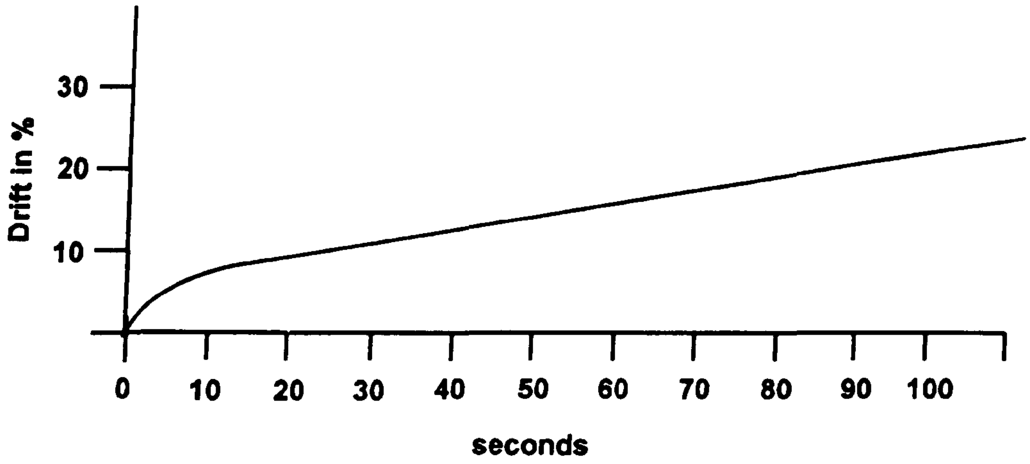


Fig. 3.9.6.

After 10 seconds an average error was measured of 8% and after 100 seconds an average of 23% was noted see Fig. 3.9.6. It can be concluded that those time dependent errors during static loading are not acceptable. Therefore, static tests with different loads range were not continued. This results in the statement that the Tekscan system can not be accurately used under static conditions. Although the Tekscan failed under static conditions, dynamic loading improved drift errors dramatically. It was found that after a pre-conditioning period of approximately 10 cycles of a triangular wave input load, the output signal stabilised.

3.9.7 Thermal stability

The inside of a trans-tibial socket can be considered a "micro climate" environment where temperature and ionic humidity exist. Measurement systems which are sensitive to temperature and humidity must take account of those effects. Although temperature and humidity are regarded as very important considerations for micro climate environments, they were not investigated further due to problems encountered in simulating temperature and ionic humidity during experimental tests. Careful consideration of these output influence factors must be given in the design of the test protocol. Recommendations for the stump-socket interface pressure study included a standardised test protocol for the time that a instrumented socket was used and the number of steps taken by a subject during data collection.

3.9.8 Transducer wear

Transducer wear or damage is significant when the Tekscan system is used for in-shoe pressure measurements. The output values drop significantly after ± 30 gait cycles (Rose, 1992; Woodburn, 1996). This transducer damage can probably be explained as more of an application problem of FSR technology, than FSR technology in itself. The conditions that the FSR technology is subjected to during an in-shoe application, are not under control and many variables exist. For instance, it is known that FSR technology is liable to damage during active bending of the transducer. (Rose,1992; Woodburn,1996; Cavanagh,1992). Eliminate active bending and life expectancy of the transducer is dramatically prolonged. Recommendations for the Tekscan 9810 transducer for stump-socket interface experiments include

- permanent placing of the transducer onto a rigid surface by means of a non aggressive glue.
- avoiding any kind of creasing of the transducer.

3.9.9 Response to curvature

One of the first findings during system familiarisation was the fact that an output was produced when a transducer is manually bent. Output readings occur on sensors where no obvious physical force was applied, (Rose,1992; Woodburn, 1996). It was also reported that transducer behaviour was influenced when similar FSR technology is used for in-shoe pressure measurements (Rose, 1992). Altered output occurs at places where active continuous bending and spherical curvature (cylindrical and spherical) is noted, primarily at the heel and metatarsal head areas. In the field of stump-socket interface pressure investigation, it is of importance to define the error occurring in relation to curvature; especially in the light of the diversity of three dimensional curvature existing in trans-tibial sockets. Due to the fact that the transducers are glued inside the socket, active bending related effects can be ignored. The first experimental curvature tests were performed in December 1995 (period 1). The Instron universal testing machine, fitted with purpose designed indentors, was used to test for curvature effects. Two types of curvature were tested:

- cylindrical curvature with a diameter of 45 mm.

- spherical curvature with a radius of 13 mm.

Both the cylindrical and spherical indentors approached the limitations specified by the Tekscan manual. These indentor dimensions are not uncommon in anatomical stump dimensions and in trans-tibial socket designs. Although noise and input control problems were experienced in relation to the Instron machine, useful data were obtained. It was found that cylindrical curvature shows the same variation in cell behaviour and magnitude as the output of a flat "reference" indentor. The results of the spherical indentor showed output inaccuracies of 50% less output. This made recorded data validity suspicious when transducers were used on curvated areas. The indentor tests described previously, were to be found obsolete in the period after July 1996. The "in situ" equilibration and calibration method eliminated the problems encountered with curvature aspects.

3.9.10 Transducer response to shear

At the time when the experimental tests took place, FSR technology was only capable of measuring normal physical loading conditions, i.e. loading conditions perpendicular to the transducer. In the suggested application of the transducer for stump-socket interface pressure studies, shear between skin and socket wall were present. Therefore transducers placed between skin and socket wall are subjected to an unknown quantity of shear. It is important to know to what extent data output are affected by this interface shear.

Experimental shear tests were conducted in period 1. A number of randomly selected transducer cells were subjected to a single axial load of 3.7 N. and 8 horizontal shear force loads with increments of 0.8 N. applied in a cumulative sequence. The test results with no shear load showed an error of $\geq$ 9% and $\leq$ 31% and with a shear load an error of $\leq$ 15%.

3.10 Calibration

The Tekscan system has primarily been developed for in-shoe pressure measurements. Transducer calibration was established by a protocol, described in the Tekscan manual, and by applying the subjects' weight on the transducer. The first software version (period 1) did not take inter-cell variation into account. As a consequence, output validity was found to be unacceptable. The upgraded software version (period 2) was able to compensate for inter-cell variation (equilibration). This was accomplished by applying a known uniform pressure to the transducer by means of an external pressure device. After equilibration was performed the transducer was removed from the pressure device and inserted in the shoe (Tekscan recommendation for insole transducers). Although the inter-cell variation was reduced, bending and curvature still existed.

Calibration as described above was not possible for stump-socket interface studies. The main reason for this is the fact that:

- more than 1 transducer was used to scan one socket (4 in total).
- Only 90% of the socket weight bearing surface was covered by the 4 transducers. This resulted in an unknown relation of applied force to a single transducer and applied body weight. Therefore, an external calibration method was developed where each individual transducer may be calibrated.

Again, experimental equipment and tests can be divided in the two time frame groups. At the time the first experimental tests started, documentation did not exist in relation to Tekscan transducer and system behaviour aspects. The beauty of a pressure rig is the possibility it gives to apply a defined uniform dynamic or static loading condition over the whole transducer by means of pressurised air. This has been the first time that tests could be performed under a controlled condition. The pressure rig, developed during the first experimental tests, was tested for functionality and validity and found to be acceptable after a number of minor modifications. The dynamic loading conditions were applied by a purpose designed and built input generator, which allowed change in loading range and frequency. It was found that transducer output was very repeatable under dynamic conditions when tested with the pressure rig.

The first experiments included repeatability and experimental calibration tests. It was discovered that acceptable calibration can only be achieved when all 96 cells are individual calibrated. This also eliminates inter-cell variation. The individual calibration curves of all 96 cells were transferred and stored in an external spreadsheet template. This template was subsequently used to scale all future data results obtained from stump-socket interface tests. This proved to be unrealistic because of the labour and complexity involved due to the enormity of data expected.

Fortunately, the Tekscan software has been upgraded with an up-dated program where inter-cell variation is dramatically reduced. This is achieved by applying equilibration, (Period 2). Tekscan claims that equilibration is a method by which output variations (inter-cell variations) are minimised. This is accomplished by applying a highly uniform pressure across the transducer. Each individual cell within the transducer should produce a nearly uniform output. When this is not the case, the software will take into account the variations between individual cells and compensate for them. This made the calibration method as described above obsolete.

Output reliability and accuracy was tested by a strict calibration and equilibration protocol as follows: The transducer in question was placed inside the pressure rig. After a preconditioning of 30 cycles of 1 Hz. and a load range from 0 to 200 kPa., the transducer was equilibrated and then calibrated. The specifically created calibration file was saved for recall purposes. After calibration, 7 different load ranges were introduced to test for reliability and

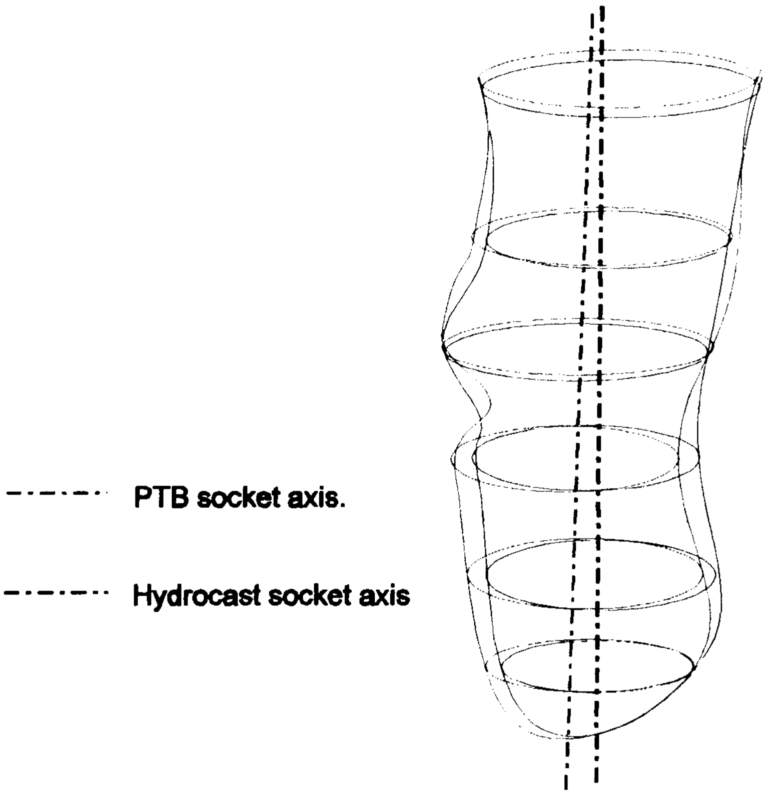


Fig 3.10.1

PTB socket axis illustrated in red, supplemented with the corresponding red socket model.

Hydrocast socket axis illustrated in black, supplemented with the corresponding black socket model.

accuracy. As a result an average error of 2% has been noted.

3.10.1 Pressure transducer positioning and placing method

It must be stated that the longitudinal "socket axis" of the two sockets (PTB and Hydrocast) are not coincident, as illustrated in Fig 3.10.1 The socket dimensions (volume and shape) are not identical. The reason for those differences can be illustrated as follows: during the hand casting process the soft tissues are manually manipulated and distorted by means of applying localized pressure on pre-defined pressure "tolerant" areas. This is exaggerated or modified during the rectification process. During the pressure casting process an equal pressure is applied, hence tissue distortion is regulated by nature.

Those dissimilarities in casting procedures will result in a variety of differences with respect to dimension, volume and shape. One of the more obvious effects is the difference of socket shape in the transverse plane, resulting in a more triangular shape for the PTB method and a more circular shape for the pressure cast method.

Because of the difference in socket dimension, volume and shape it is evident that the socket axis changes accordingly. As a result it was very difficult to establish an identical reference grid for sensor positioning in both sockets. It was not practical to establish an reference grid on the stump and place sensors directly onto the stump. This procedure would create more problems that it solves, due to:

- Transducers impossible to calibrate and equilibrate in situ.
- uncontrollable sensor position during donning due to loose or movable skin.
- uncontrollable wrinkling of the sensors, therefore unreliable test results.

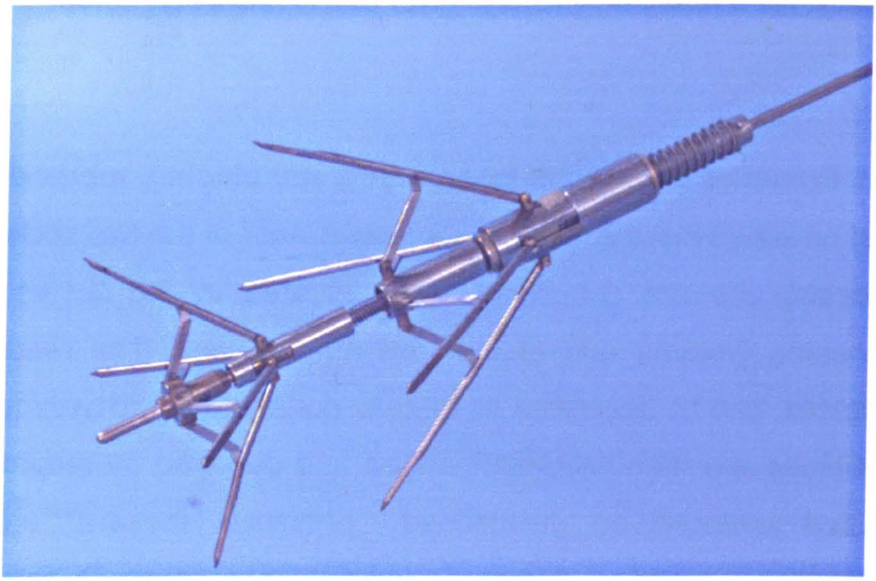


Fig 3.10.2.1

Fig 3.10.2.2

3.10.2 The centre line positioner device

The centre-line positioner was designed, tested and evaluated by Szulc J.A (1988) under the name of Szulc Socket Axis Locator (SSAL) Fig 3.10.2.1. This axis position tool consists of two separate sub-units placed on a central axis.

Each unit has two pairs of independently operating legs allowing both pairs a degree of independent movement. The cylinder sections of the units are allowed to translate causing the four legs to move like an umbrella. This outward movement action is controlled by two standard compression springs. Each spring controls one pair of legs allowing them a degree of independent movement. Both units are prevented from rotating by means of a key system placed along the central axis. The leg arrangement permits the device to be placed inside a trans-tibial prosthesis socket, subsequently the individual socket axis is defined.

The SSAL device was designed to be self aligning. After 10 successive placements of the device in a uniform cylinder, it was found that the average centre line offset is of the order of ± 0.75 mm. (Szulc,1988). The relatively small error of ± 0.75 mm. can be confidently ignored in the establishment of an sensor reference grid. This is because of the relatively large active area of the 96 cells of a single F-scan sensor. Therefore consistent sensor positioning in both socket types is not critical. The situation is different when small transducer areas (0.02 cm^2) are used. Then identical positioning of the small area transducer is very critical. Therefore it is in reality not unlikely to have 2 different measuring points in either socket. As a result, comparison between those points is useless. This is different with the distribution over a larger area rather than specifically at any particular location. The device was placed inside the selected socket, as shown in Fig 3.10.2.2. One of the leg pointers was then positioned on a pre-selected mark in the socket. In this work the mark was placed at mid-patella because of its clarity as a locatable landmark. The

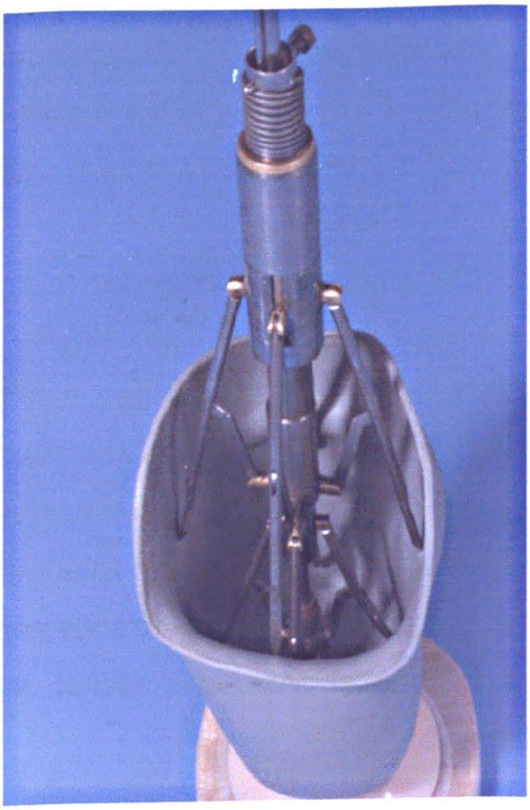


Fig 3.10.2.3

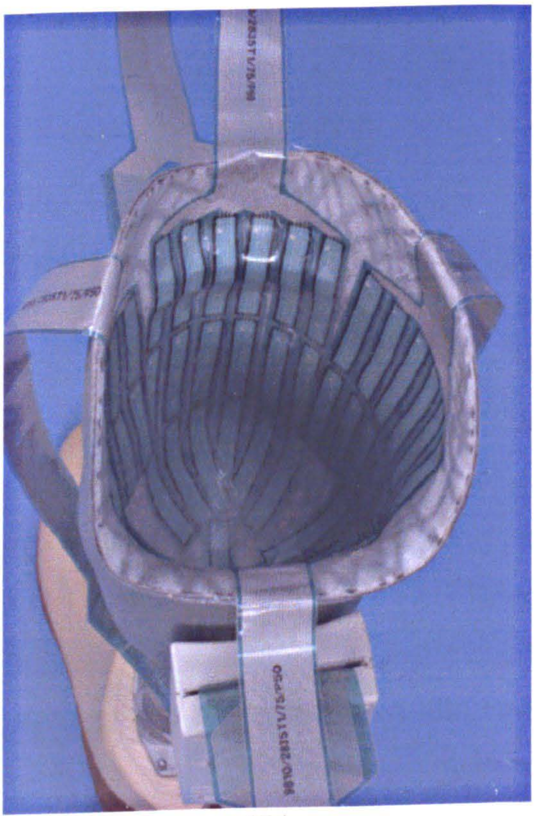


Fig 3.10.2.4

preceding step was to allow the legs to spring into place so that the device takes up its own position within the socket. Once it attained its position, the socket was marked at each leg tip, see Fig 3.10.2.3.

The marks produced with the SALL device were used to produce four axial reference lines at the following sites: Anterior, Posterior, Medial and Lateral. For creating a horizontal reference line, a marker adjustable in height was used with the bottom centre of the socket as base point.

Positioning and placement of the transducers was executed as follows: The longitudinal reference lines were used as centre line for the transducers and the horizontal reference line used to position the proximal side of the transducers. Transducers were fixed with a non aggressive spray glue which allows re-positioning, Fig 3.10.2.4.

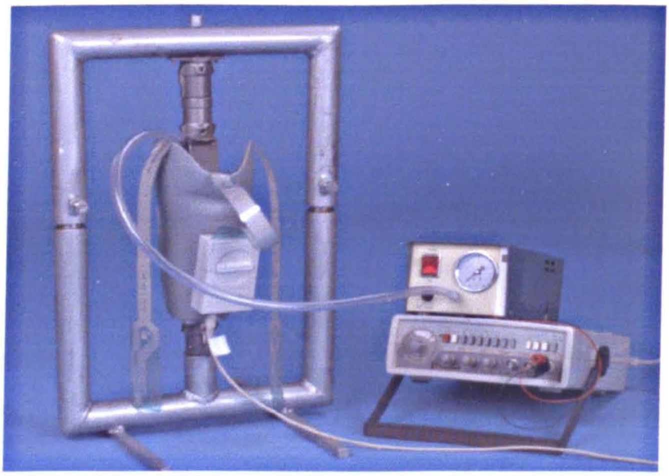


Fig 3.10.3.1

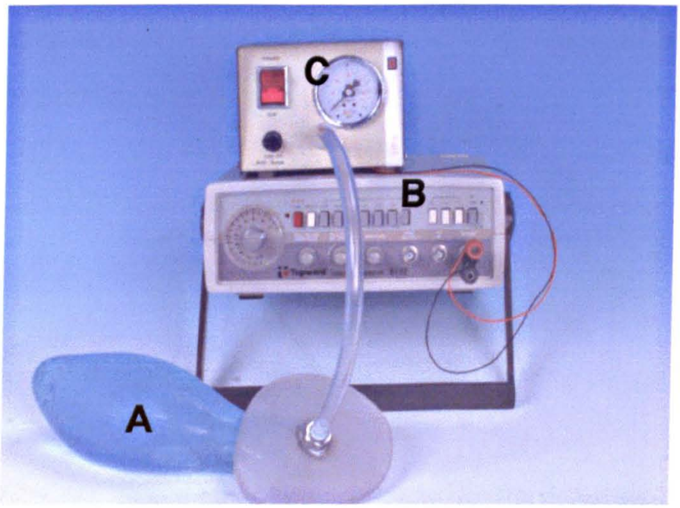


Fig 3.10.3.2A/B/C

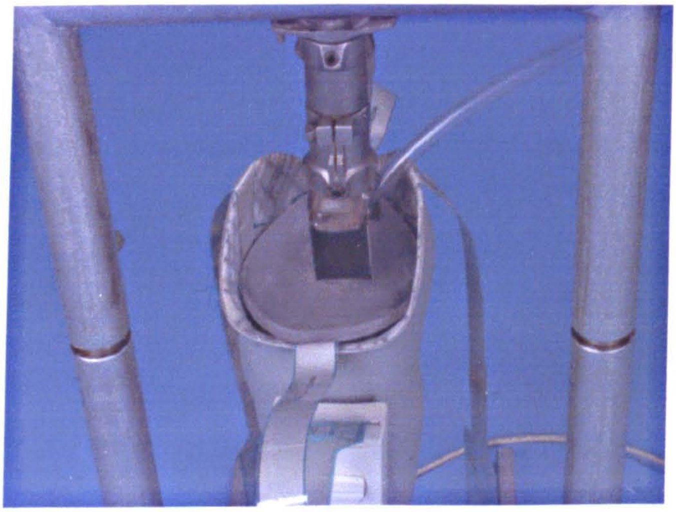


Fig 3.10.3.3

3.10.3 "In situ" equilibration and calibration

In situ calibration is obviously essential for FSR technology, because it reduces one of the main potential output errors, the curvature related aspects. A device for in situ calibration purposes was developed, as shown in Fig 3.10.3.1. This device consists of:

- a uniform loading condition transfer medium, namely a gel filled condom, Fig 3.10.3.2A.
- a closing template necessary for assuring controlled loading conditions, Fig 3.10.3.2B.
- a dynamic loading input generator, Fig 3.10.3.2C.
- a ridged calibration frame which can resist the loading conditions of 100 kPa, Fig 3.10.3.1.

The instrumented socket in question was separated from the shank pylon and placed in the calibration frame. The socket was perforated at the bottom to allow excessive air to escape during loading of the medium. This was necessary to eliminate air building up between the medium and the sensors during loading, which could threaten uniform loading conditions, essential for calibration. The condom with gel was lowered inside the socket. Subsequently, the socket is closed with the template and held in place with the adjustable top of the calibration frame. Fig. 3.10.3.3.

Exactly the same procedure as described in 3.10 was executed for calibration. (calibration after pre-conditioning of 30 cycles of 100 kPa at 1 Hz.). This calibration has a great impact on the trial protocol because the subject needed to walk 30 steps before a recording could be taken. This is described in the trial condition section.

3.11 Conclusions

The Tekscan pressure measurement system enabled almost the total load transfer surface of the trans-tibial socket to be investigated for the first time rather than "selected" locations. This meant that it is possible to investigate time varying pressure distribution patterns and pressure gradients during trans-tibial gait.

The Tekscan pressure transducers are capable of monitoring interface pressures over large areas and are able to identify localised pressures in socket regions with small and medium radii of curvature. The essential transducer characteristics include: Large sensing surface (15,500 mm^2), high sensor resolution (96 individual sensors placed in a defined matrix of 6 columns and 16 rows) and transducer flexibility.

The Tekscan software is user friendly which made monitoring and analysis of pressure data straight forward. Data recordings can be exported to external computer programs by ASCII files.

The development of calibration techniques and a test protocol ensured the accuracy and repeatability of the Tekscan system to acceptable levels. The greatest impact in relation to system output accuracy was the development of an "in-situ" equilibration and calibration method. Curvature related inaccuracies and inter-sensor variations were minimised by use of an equilibration software programme. This was achieved by applying a uniform pressure to the 4 transducer array by means of a socket fitted gel filled and pressurised "condom".

Static applications of the Tekscan system are not recommended due to the uncontrollable drift that was experienced.

Dynamic drift related inaccuracies were minimised by performing calibration after pre-conditioning of 30 dynamic loading cycles of 1 Hz. between 0 and 100 kPa. Dynamic loading conditions were generated by an load input generator. When subjected to a pressure range between 25 and 200 kPa, an average variation of ±2% and a maximum variation of ±10% for any individual sensor in the transducer array was experienced. It is essential that this same pre-conditioning of 30 load cycles is conducted prior to recording pressure data during future clinical studies of trans-tibial gait.

No difference in input/output relation with respect to time was discovered when three distinctive loading frequencies (0.1, 0.5 and 1 Hz.) were applied.

Bonding the transducers to the rigid inner socket wall enhanced transducer life and eliminated inaccuracies as a result of sensor wear due to bending and creasing.

Although the validity and repeatability of the pressure data were dramatically enhanced, inaccuracies typical for FSR technology must be taken into account. Absolute data results are doubtful because of the remaining inaccuracies due to experienced hysteresis and shear. However, adopting the developed calibration techniques, investigation of pressure patterns and pressure gradients between different socket designs may be possible.

CHAPTER 4

METHODOLOGY OF THE PILOT AND COMPARISON TESTS

4.1 Introduction

The aim of this project was to compare two socket designs by means of pressure distribution patterns studies during gait. The design variations studied were between localised pressure (PTB socket) and uniform pressure (Hydrocast socket). The commissioned Tekscan pressure measurement system was used to monitor stump-socket interface pressure distribution. Four "in-situ" calibrated transducers were placed inside the socket covering 90% of the weight bearing surface area.

Four prostheses were fabricated, two based on the PTB concept and two based on the pressure cast concept. Both PTB sockets were fabricated from the same common "master" cast and aligned similarly. Likewise with the two Hydrocast sockets. Only one socket for each design was instrumented with 4 calibrated pressure transducers. The other socket was used as a familiarisation prosthesis. This was done to minimise pressure measurement inaccuracies as described in chapter 3 and save the transducers for controlled trial conditions.

A 3D computer model was developed which enabled the data results from all four transducers and hence the pressure distribution within the sockets to be displayed at any instant of gait. The model also illustrated the line of action of the GRF relative to the socket position for any instant in time.

The clinical value of the Tekscan pressure measurement system was tested and evaluated. The effects of localised pressure versus uniform pressure in relation to pressure magnitude and distribution was investigated.

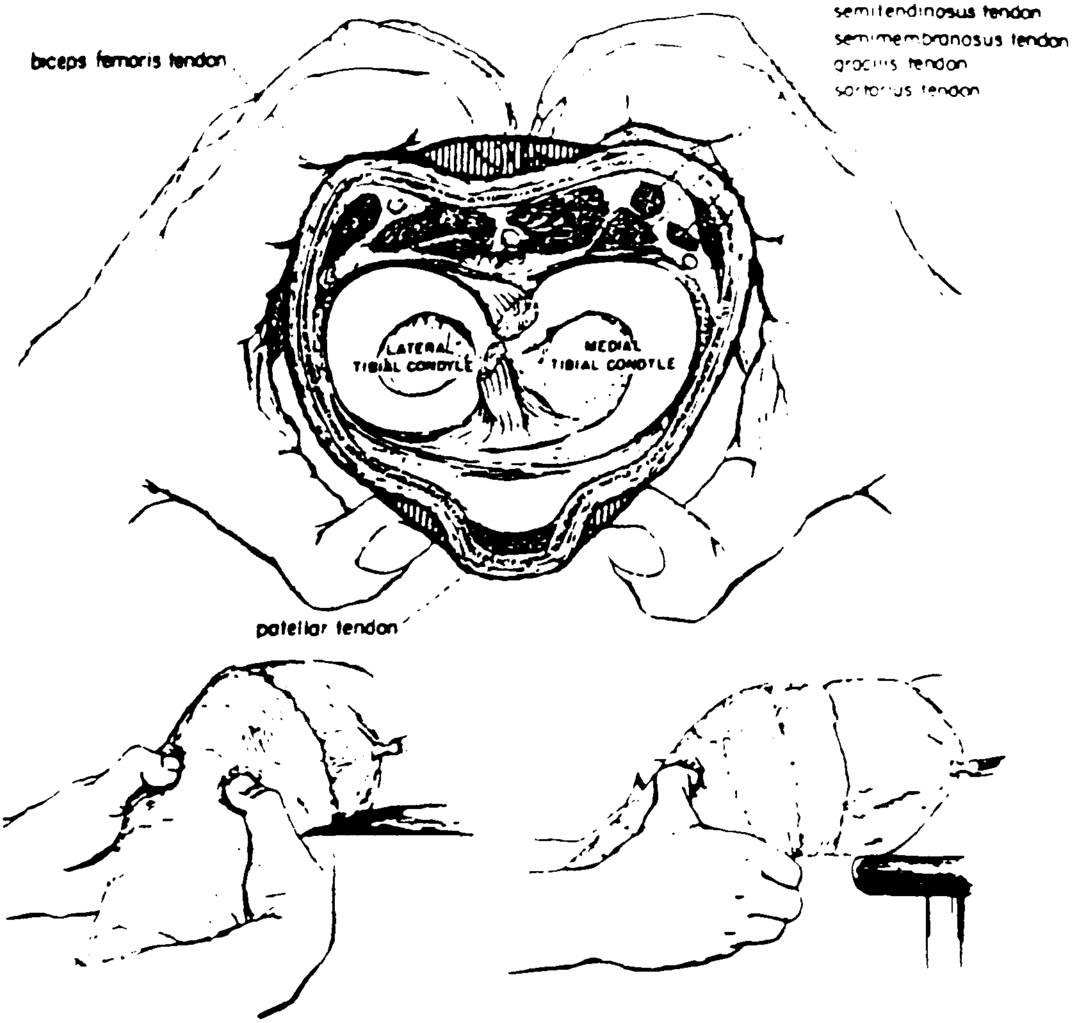


Fig 4.2.1 (Reproduced from Foort, 1991)

4.2 Test socket design and casting methods

It was decided to use hard shell sockets made from carbon fibre reinforced acrylic laminate. No liner material was used. The hardness of the socket material ensured that there were no sudden chances in socket wall characteristics that could influence Tekscan transducer accuracy and pressure patterns during gait.

4.2.1 Hand casting (PTB socket)

The patient was asked to be seated on a bench. His amputated leg was hanging over the edge which was supported by the bench at thigh level and the knee positioned in 20 deg. flexion angle. While the patient was seated with relaxed musculature, a wrap cast was taken. After the POP bandage was applied the soft cast was smoothed and worked around the prominences and depressions by hand, until the POP began to harden. At this point the fingers and thumbs of the prosthetist were used to outline the patellar tendon and to compress the popliteal tissues, as shown in Fig 4.2.1. Considerable experience and judgement is required to establish how much pressure should be applied. Both patient and prosthetist attempted to remain as motionless as possible, whilst the POP hardened beyond the possibility of permanent deformation. The hardened wrap shell (negative) was removed from the stump and filled with POP. After setting of the POP, the negative shell was removed resulting in a solid positive model.

The casting procedure and rectification of the positive model were performed according the National Centre for Training and Education in Prosthetics and Orthotics (NCTEPO) University of Strathclyde manuals.

4.2.2 Pressure casting (Hydrocast)

One of the uncertainties of pressure casting in general has been to determine the pressure magnitude and duration needed to produce a good socket fit. Gardner (1969) described that applied pressures of 13 kPa gave the best results for his pressure device. Kristinsson (1993) reported that applied pressure values of 23 to 34 kPa were needed to produce a satisfactory end result. Pressures lower than 23 kPa often resulted in too loose a fit. The difference in applied pressure values, used and recommended, have not contributed to clarification of the matter. Casting time has not been mentioned. It is possible that higher pressure values for a short time give the same results as lower pressures over a longer time. This has to do with the possibility of volume change of the stump. If it is agreed that tissue on itself is not compressible (Krouskop,1987) this implies that the only medium that is able to migrate from the stump with constant pressure would be the tissue fluids. As a result, change in stump volume depends on the magnitude and duration of the applied pressure, the viscosity of that fluid, and pathological influences if existent.

For this work it was decided that full body weight of a patient would be used to produce a pressure cast. The duration of casting was fixed by the time needed to cure the POP beyond deformation. The reason for full body weight was to simulate the pressure distribution at full load situations during gait.

4.2.2.1 Pressure casting equipment

To be able to produce the Hydrocast socket cast under full body weight the following requirements had to be fulfilled:

- The subject must be able to balance and stabilise the stump in the casting equipment. Balance may be maintained with the aid of hand supports.

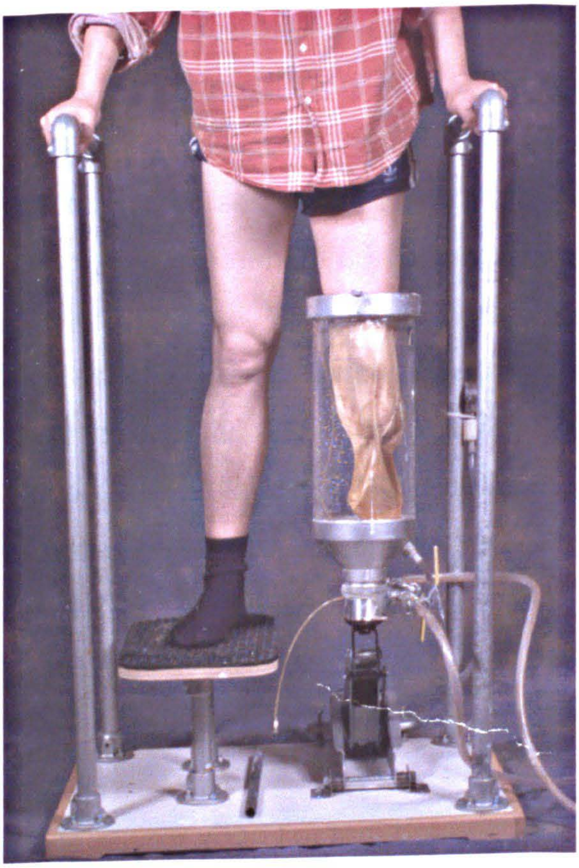


Fig 4.2.2.1

- Body weight must be fully supported by counter action of the hydrostatic medium.
- The insertion depth of stump must be variable, to accustom a variety of stump configurations.
- No tension must exist in the membrane which acts as a barrier between stump and medium.
- After curing of the plaster the subject is not able to bend the knee joint.
- The pressure cast equipment must be designed in such a way that the stump can be ejected from the equipment.

The Icecast pressurised casting instrument[1] developed by Össur Kristinsson was used as a starting basis for the development of casting equipment required for this study. The Icecast casting instrument was chosen due to the fact that it was operational and clinically proven. With adaptations it was easy to convert the Icecast casting instrument to a pressure casting system which fulfilled the previously stated requirements. This resulted in the Hydrocast system, Fig 4.2.2.1.

To ensure that the weight bearing of the subject was as uniform and hydrostatic as possible, it had to be confirmed that the subject was not hanging in the membrane during casting. The reason for this was to eliminate tension that could result in shear and to eliminate a situation in which the weight of the subject was partly supported by a upwards force as a result of ballooning of the latex membrane bag. This was solved by introducing an aluminium spacer ring. The closer the ring to the stump surface, the less tension there was and the existence of a upwards force component provided by the membrane would not create a shear problem.

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[1] Icecast, Össur HF, Hverfisgötu 105. P.O. Box 5288,125 Reykjavik, Iceland.

4.2.2.3 Hydrocast casting method and protocol

The Hydrocast pressure tank was lowered and almost completely drained of water. As a result the membrane would cling to the tank wall, creating a more accessible tank for insertion and positioning of the stump. The subject was asked to be seated, relax, and let the stump hang naturally over the edge of the support (in this case a casting chair). First one of the three aluminium closing templates was selected. This selection was established by the tightest template fit, approximately 10 cm above the knee joint. The selected template was not removed at this stage. A previously prepared polyester fabric sleeve was wetted with water and whilst tensionless pulled over the stump. A bowl of smooth POP was placed under the stump and the fabric sleeve was subsequently impregnated with POP by hand. In addition, three other fabric sleeves were first impregnated with plaster and then pulled over the stump, leaving a POP cast body of four fabric sleeves. The length of the fabric sleeve depends on the type of suspension system required (leather strap, ICEROSS or supra condylar suspension). Directly after application of the sleeves the patient was transferred to the pressure device. The stump was inserted and the height of the pressure tank was raised until the selected template met the top of the pressure tank. The template was then fixed to the top of the tank. The next step was to fill the pressure tank with hand warm water until the affected leg was lifted marginally out of the template. This was an indication that body weight was not supported by the template. The subject was asked to transfer his whole body weight to the affected leg by lifting his sound leg and maintain this position by placing his hands on the available hand bars. This position was held for the period required to cure the POP beyond deformation. After the POP was set, the amputee transferred his body weight back to the sound side. The aluminium template was released and the whole pressure tank lowered, creating easy exit for the subject without bending of the knee. (the knee was immobilised by the height of the now ridged cast). The negative cast was carefully removed and filled with POP. After the POP was set the negative was removed leaving a positive model. This model was not rectified at all and was used directly for socket production.

4.3 Fitting procedure

All the prostheses were checked using only one SACH foot, which was transferred from prosthesis to prosthesis. The reason for the use of one foot was to eliminate the behaviour characteristics exhibited between feet. All prostheses were aligned until the optimum dynamic alignment was reached. This optimum alignment was established by consensus of a team consisting of the subject and 2 senior prosthetists.

4.3.1 Fitting results

During a normal check out procedure none of the prosthetic sockets had to be modified. All sockets were worn with one towelling sock. The alignments between the 2 PTB prosthesis were identical. The alignment between the 2 Hydrocast prostheses was identical as well. The subject's opinion of the different sockets was not evaluated in a "formal" sense as he wore the prostheses for a short period. He was able to walk on both socket designs without discomfort. After visual inspection of the stump, following a familiarisation period with the two sockets, the following results were found:

- Discoloration of the stump after the use of the PTB socket at the following sites: patellar tendon, medial and lateral flare of the tibia and popliteal area just below the posterior rim.
- No significant discoloration of the skin was found after the use of the Hydrocast socket.

4.4 Subject selection and characteristics

The subject selected for this project was a male, 37 years old, whose left trans-tibial amputation was a result of an accident 10 years ago. His state of health was good and he was an very active user. His weight was 79 kg. and his height was 1.81 metre. The subjects stump was in good condition, but relatively short; a length of 12 cm measured from the tibia plateau. An abrasion, a result of a fall during showering, was located at the end of the tibia but was not uncomfortable or painful. The subject was used to wearing a PTB prosthesis supplemented with an ICEROSS silicone liner which acted also as a suspension system.

4.5 Test protocols

4.5.1 Trial walk consistency: Normal and trans-tibial subject.

Socket interface pressure is generated during typical trans-tibial amputee gait. The socket pressure during stance phase is primarily a result of the GRF and its line of action relative to the individual socket position. In order to compare the interface pressure distributions of two socket designs, the walking conditions within and between both prostheses must be acceptable and repeatable over at least a limited period of time. Walk consistency is also needed due to the fact that only 2 transducer arrays can be recorded during a single trial walk. As a consequence, pressure data from 2 walks must be combined to create a full pressure distribution pattern for a prosthetic socket.

There may be a comfort and functional difference between two socket designs. Therefore it is likely that the preferred walking speed for each prosthesis design may differ. Due to the enormous amount of data generated by the pressure measurement system, (42,000 pressure results during 1 prosthetic step) it is very difficult to normalise the recorded data to walking speed/ body weight. The normalisation (expressed in a percentage) can be used to directly compare the results of 2 different walk conditions.

It is therefore of major importance to ensure the same step to step conditions for both prostheses. This overcomes anticipated differences due to velocity variations and consequently, the difference in impetus applied by the body on the force plate. The expected differences in walking velocity were controlled by "regulating" the walking speed by means of a metronome. Not only walk consistency between both prostheses but also walk consistency with and without metronome were investigated.

The following parameters were studied:

- walk consistency.
- difference between metronome assisted walks and without metronome

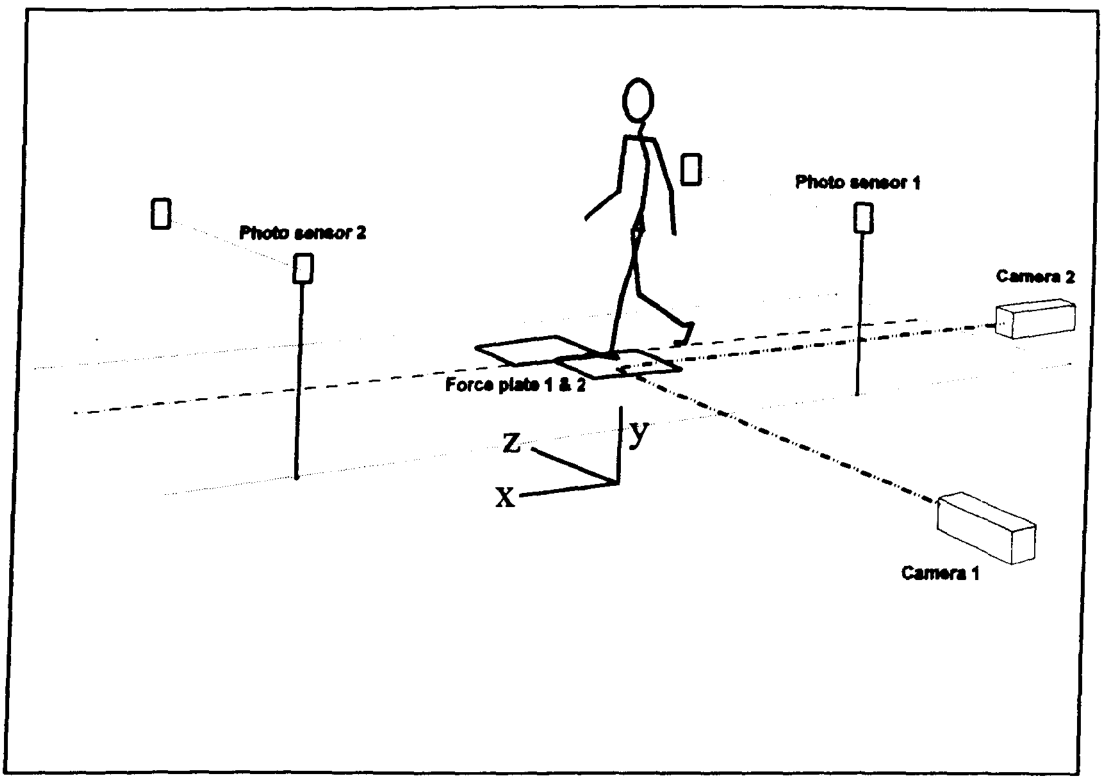
Photo sensor 2
Photo sensor 1
Camera 2
Force plate 1 & 2
z
y
x
Camera 1

Fig 4.5.1.2

assisted walks.

- difference between walking velocities.

The experimental pilot test was initially undertaken with a normal able bodied subject. This was done to investigate how feasible walk consistency is and what variation could be expected, when at least 15 successive walks were monitored and recorded. The same test was performed with an experienced trans-tibial amputee, using his previously prescribed 3 year old PTB prosthesis.

4.5.1.2 Method

The GRF was monitored with a Kistler force plate located in a 9 metre walkway. The force plate signals were recorded with BioWare software. All data files were exported to a spreadsheet for further analysis. The sample rate for the step tests was 150 Hz. This sample rate was chosen because of the maximum sampling rate of the pressure measurement system of 165 Hz., which will be used in later experiments. The Tekscan pressure measurement system was not used in this exercise but it was consistent to use the same sampling settings for possible later comparison reasons. Walking velocity was measured with a purpose built system. The system consisted of a timer with precision to 3 decimal places and two photo sensitive sensors. The first sensor started the timer when the beam was broken and the second sensor stopped the timer. The first sensor was placed one metre ahead of the force plate so that the subject had achieved his steady walking speed when the first beam was broken. The second sensor was placed an additional four meters along the walkway. The height of both sensors was at shoulder level to eliminate premature triggering due to moving extremities, see Fig 4.5.1.2.

4.5.1.3 Walking protocol

A line grid was painted on the walkway to mask the position of the force plate and the subject was not told where the plate was situated. A focus point was placed on the wall on the end of the walkway. The subject was asked to look only at the focusing point during the walk. This was done to create as much a controlled walking condition as possible. A starting point was established for ensuring that the subject hit the force plate during the successive data collection walks. At least 15 sets of force plate data were recorded to ensure statistical significance.

The subject walked at his preferred walking speed and stride length along the walkway. The force plate output and matching velocities were recorded for 15 walks. A metronome beat was matched with the subject's preferred cadence. The subject was asked to walk to match the beat and again 15 walks and walking velocities were recorded following the same procedure as described above.

4.5.2 Walk to walk pressure variability

4.5.2.1 Trial protocol

Both socket designs were tested on two separate dates 1 day apart. A familiarisation period of one morning was conducted with the non instrumented, but identical, prosthesis. The subject was allocated the morning to get accustomed to the prosthesis and trial protocol for the afternoon session. The familiarisation prosthesis was also used to spare the pressure transducers for controlled trials. This was done to reduce the potential errors experienced during the pressure system investigations. Controlled trials with the instrumented prosthesis were performed in the afternoon session. Controlled trials included; metronome assisted walks to enhance walk consistency and walking velocity, between and within socket designs. A pre-conditioning sequence taking approximately 30 steps was adopted before simultaneous data recording of the Tekscan system and the force plate. This protocol was adopted to obtain the most accurate recording condition with the Tekscan system in relation to the calibration procedure described in Chapter 3. After the data was recorded, the subject was asked to be seated for at least 3 minutes. This allowed the Tekscan transducers to recover before the next trial started with 30 steps of preconditioning followed by the test data recording.

4.5.2.2 Simultaneous recordings and equipment of F-scan/force plate systems

The complete data collection system consisted of three components:

- GRF system; two Kistler force plates, two amplifiers and BioWare software.
- Tekscan system; two Transducers, two connecting cuffs, 2 umbilical cables of ten metre length and Tekscan software.
- walking velocity measuring system; 2 photo sensitive sensors plus reflectors and a three digit timer.

Note the trials were repeated for a different combination of two Tekscan transducers.

The aim of the overall study was to investigate and to analyse the socket designs (conventional PTB socket and the Hydrocast socket), with respect to socket pressure distribution and magnitude. Generated socket pressures are a result of the GRF vector magnitude and its position in relation to the socket during the stance phase. It was therefore necessary to capture the GRF data from the force plate as well as the pressures generated in the socket at the same time.

4.5.2.3 Method

The Kistler software was capable of producing a triggering signal. This signal was produced in the form of a high to low voltage transition and was activated by footfall of the subject on the force plate. The Tekscan system was capable of receiving this high to low voltage transition via a data link and was accordingly activated. This resulted in a simultaneous recording of GRF data and Tekscan data. It was decided to use a round figure sampling rate of 150 Hz. to make later analysis of the results more convenient. The frequency used was high enough to suppress aliasing. Aliasing may occur when a too low sample rate is used, which might result in measurements being taken just before or after the peak pressure has occurred.

4.5.2.4 Data collection

The GRF was monitored with the Kistler force plate and recorded with BioWare software. The normal socket interface pressure was monitored and recorded with the Tekscan pressure measurement system. For each walk, measurements of GRF, walking velocity and 2 identified Tekscan transducers were taken simultaneously. For each of the socket designs the following data were recorded; 15 force plate steps with two transducers placed at the A/P regions of the socket and 15 force plate steps with two transducers placed at the M/L regions of the socket.

4.5.3 Tekscan data reduction

In first instance it was decided to reduce the enormity of Tekscan results to a more convenient method of repeatability assessment. The average pressure of 96 cells in a transducer was used to represent the step to step pressure variation.

Fig 4.5.4.1

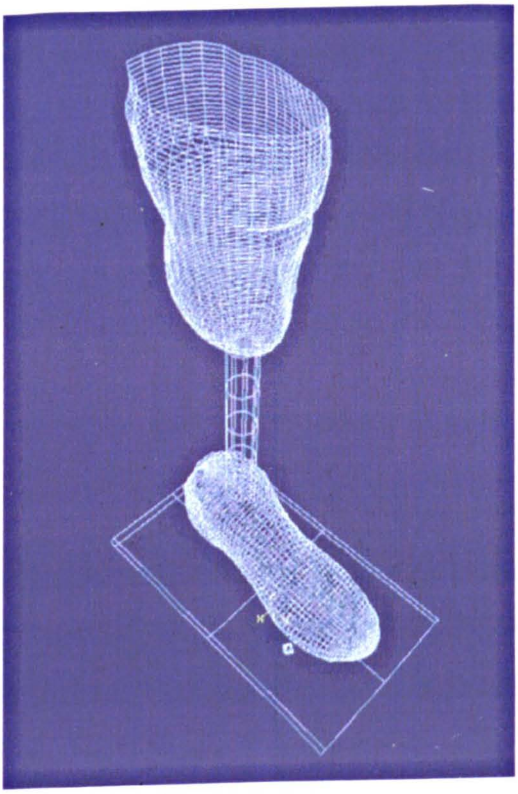

Fig 4.5.4.2

4.5.4 The 3D computer model

Introduction

The Tekscan software was limited to show no more than two transducer data results at the same time. The difficulty of relating the GRF to the socket position in time; and to the pressure distribution results directly to an anatomical reference location inside the socket, suggest the need for the development of a tool that can assist with these problems. A 3D computer model has been constructed. The enormous amount of data available, suggested data reduction. The aim of data reduction was to arrive at sets of data, which were representative of the different socket designs. This created the opportunity to monitor and analyse all four sensor results and the GRF in relation to the following parameters:

- time .
- position of the GRF vector relative to the socket.
- anatomic reference for each individual pressure sensor cell.

See Fig. 4.5.4.1 and Fig. 4.5.4.2.

4.5.4.1 Data reduction

During a typical experimental walk trial, data were recorded. The GRF was used as a starting point because of its known accuracy and the fact that ground reaction forces initiate socket interface pressure recording. The transducers used were always placed opposite each other, see also Chapter 3 (transducer positioning). This resulted in two transducers placed in the A/P region of the socket and two transducers placed in the M/L region of the socket. The following data were obtained:

- 15 GRF results recorded with BioWare and matching pressure data results obtained from the anterior transducer and 15 pressure results from the posterior transducer.
- 15 GRF results recorded with BioWare and matching pressure data results

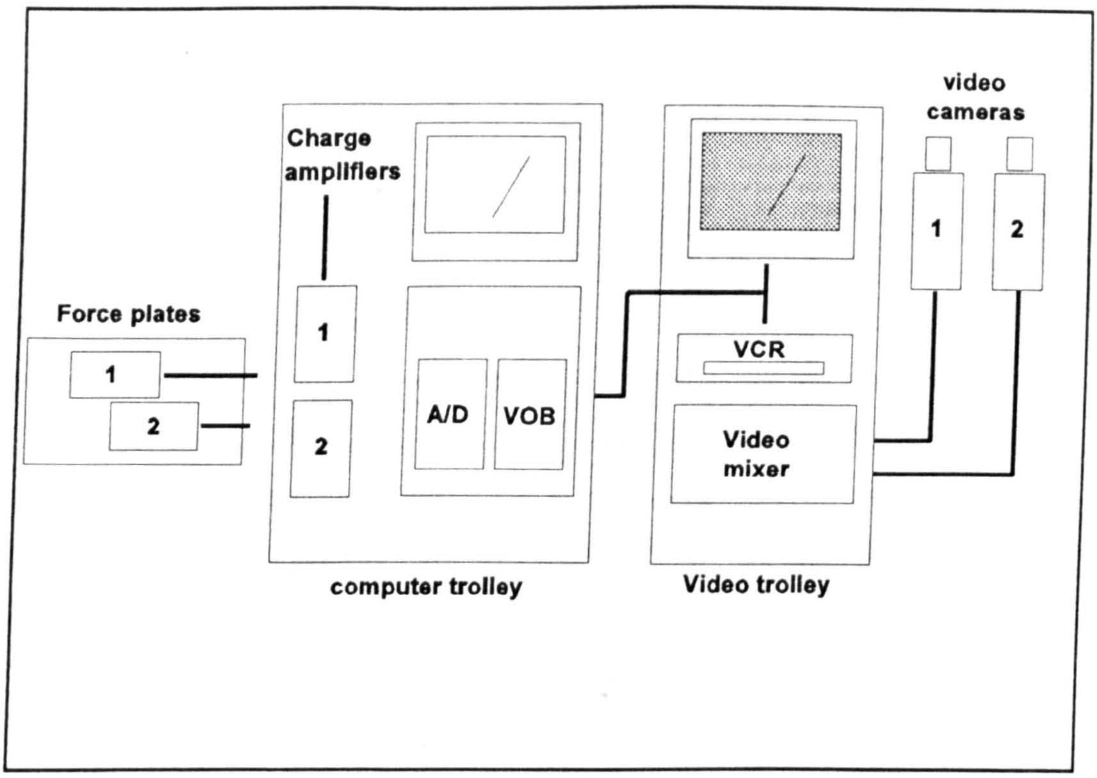
video
cameras
Charge
amplifiers
1
2
Force plates
1
2
1
2
A/D
VOB
VCR
Video
mixer
computer trolley
Video trolley

Fig 4.5.4.2

obtained from the medial transducer and 15 pressure results from the lateral transducer.

Data reduction and step selection was performed in several stages:
The first stage was to export the GRF data results from both sockets to a spread sheet; 15 steps recorded in the A/P direction and 15 steps recorded in the M/L direction, 30 recordings in total for either socket. The next stage was to calculate the average of those 30 steps. The following stage was to explore which of the recorded GRF results was showing the closest fit relative to the average.

For the PTB socket, GRF step M/L walk 2 and A/P walk 4 were the closest fit and for the Hydrocast step M/L walk 7 and A/P walk 12 were selected. The final stage was to investigate how the pressure results for the selected GRF steps deviate from the pressure average. For each sensor position for each socket design, anterior, posterior, medial and lateral, the closest fit relative to its average was confirmed.

4.5.4.2 Experimental video/ GRF data recording procedure

For both the PTB and the Hydrocast prosthesis an interlaced video recording was taken. Those video results were used to compose the transition of the 3D computer model prosthesis during gait.

The various hardware elements and data paths are symbolised in Fig 4.5.4.2. Each Kistler force plate was directly connected to its own charge amplifier. The amplifiers produced output voltages representative of both the force plate activity and the current gain settings for each channel. The computer which hosts the video vector software has two additional boards, A/D converter and a video output board.

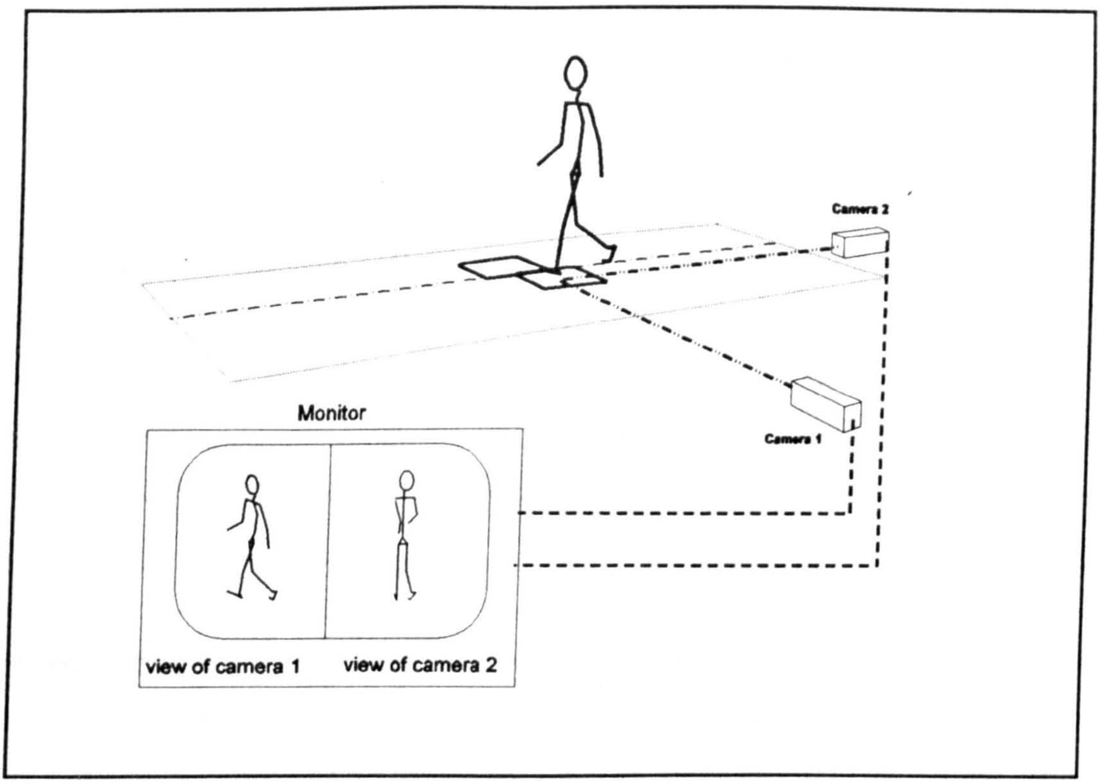

Fig 4.5.3.3.

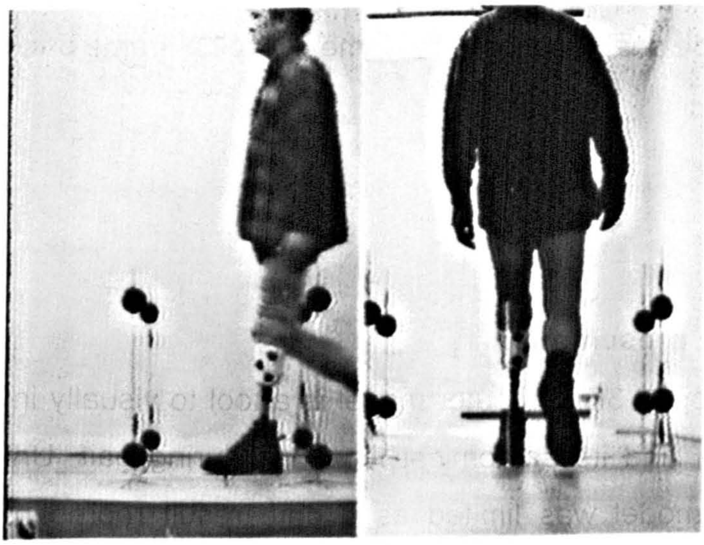

Fig 4.5.4.4.

The A/D converted output from the force plate, together with the video vector software, produced a "real time" GRF vector on the computer monitor.

The software was set in a split screen configuration. Hence 2 GRF vectors were produced on the computer monitor. On the left side of the screen the sagittal view of the GRF vector relative to the subject's walking progression, and on the right side the GRF vector front view relative to the subject's line of progression.

The video output board received 2 main input signals, the first is the GRF vectors produced by the force plate and video vector software, as described above. The second signal is produced by 2 mixed video camera views, as symbolised in Fig 4.5.4.3. Camera **1** monitored the sagittal view and is displayed on the left side of the screen. Camera **2** produced a posterior view and is displayed on the right side of the screen.

Subsequently those two main signals were interlaced on a normal television screen. This configuration enabled monitoring and recording of a subject's gait and GRF vectors, viewed from different positions. The video recorder sampled the recording with a 50 Hz. frequency. Therefore, recorded results (subject's gait) could be analysed frame by frame. A typical frame output is shown in Fig. 4.5.4.4.

4.5.5 Data presentation.

The developed 3D computer model is a tool to visually investigate pressure distribution and its anatomical location during gait. Unfortunately the 3D computer model was limited as a data result representation tool for this document. This limitation was mainly caused by the following facts:

- the interactive nature of the computer program.

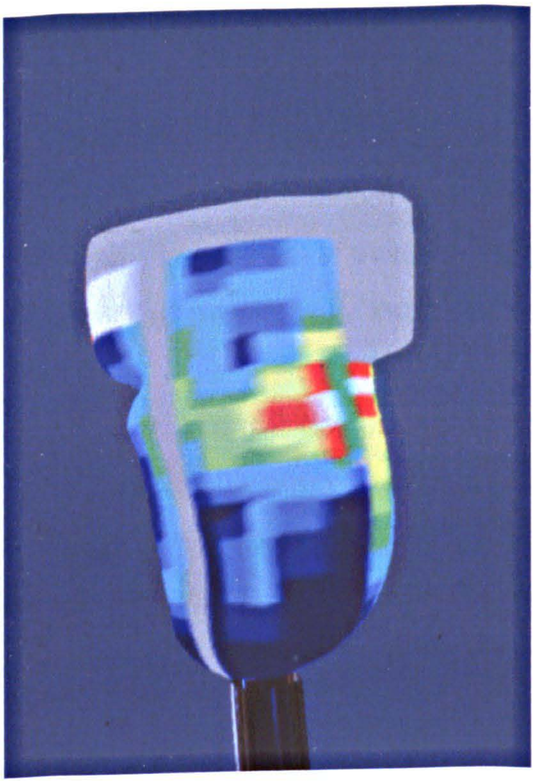

Fig 4.5.5.1

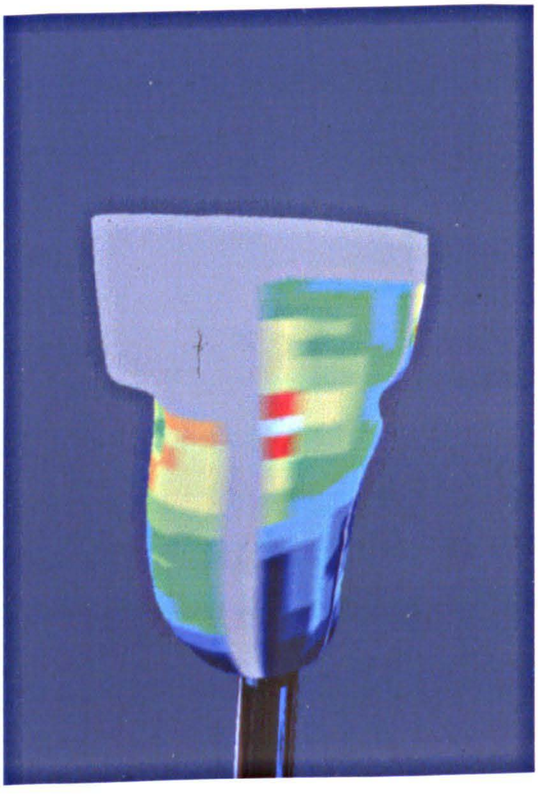

Fig 4.5.5.2

- the maximum surface area which can be displayed at any instance in time is the equivalent of the surface area of 2 transducers, see Fig. 4.5.5.1 and 4.5.5.2.
- the enormous amount of data from one single stance phase.

In order to be able to present data results throughout a single prosthetic step 8 pre-selected frames were chosen for either prosthesis. Those 8 time frames consisted of pressure data from the four pressure transducers, the GRF and its position relative to the socket for that specific time frame. Both the time frames and the 3D computer model were used to describe and interpretate the data results.

4.5.5.1 Frame selection.

Eight time frames at regular intervals were selected between HS and TO. This resulted in two sets of data results; Set 1 where the scaled magnitude and position of the GRF relative to the actual prosthesis alignment is displayed, and set 2 where the corresponding stump-socket interface pressure distribution is displayed.

4.5.5.2 Construction of data set 1. (GRF position relative to the prosthesis).

Eight distinct time frames for one prosthetic step were identified from the video recording. For each of the 8 frames the position of the socket in space was established with the aid of a fixed reference grid as displayed in Fig 4.5.4.4 (page 85).

4.5.5.3 Construction of data set 2. (stump-socket interface data).

For each selected frame the pressure output of all 4 transducers was displayed in a 2D configuration, a typical display for a selected frame is illustrated in

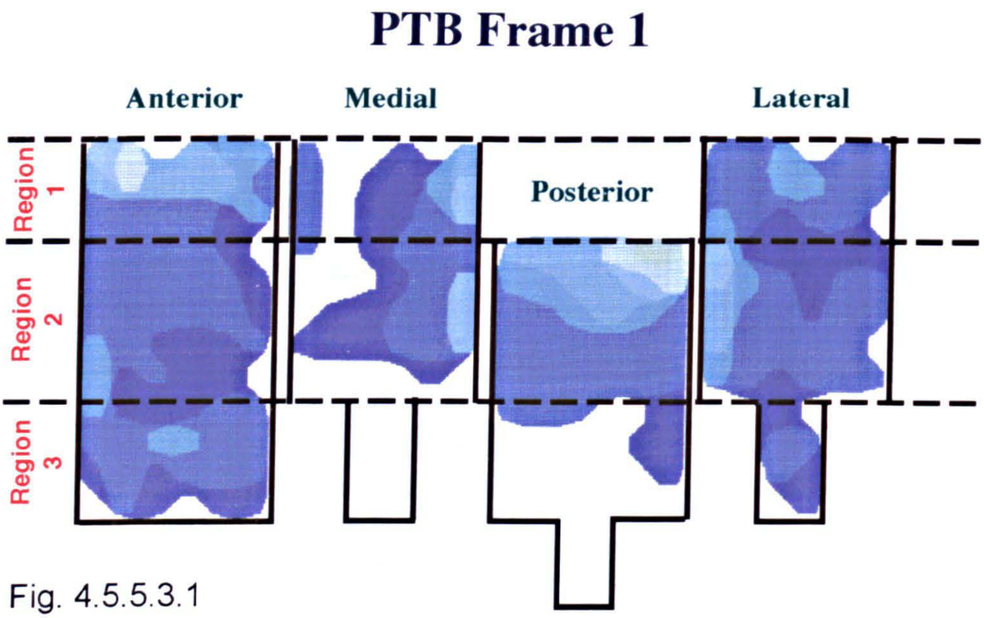

Fig. 4.5.5.3.1

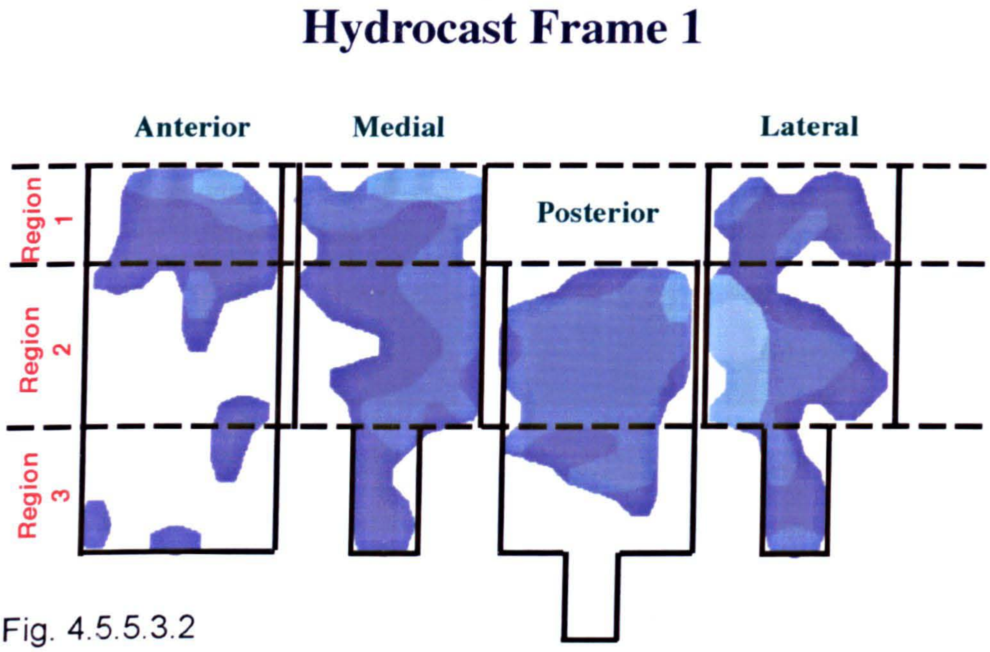

Fig. 4.5.5.3.2

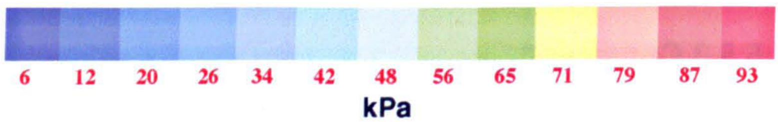

Fig 4.5.5.3.1 for the PTB prosthesis and Fig 4.5.5.3.2 for the Hydrocast prosthesis.

From left to right this figure shows, anterior, medial, posterior and lateral pressure data results. The physical outline of each transducer is marked with a black boundary line. This line is only created for frame No.1. All areas which are displayed as "white" and are situated inside the boundary, indicate pressures below the minimum measurable threshold of 4 kPa. (system limitation) This does not infer that there is no tissue contact on those areas.

For the purpose of referring 2D sensor output to a height position in the socket, 3 distinct regions are specified, see Fig. 4.5.5.3.3.

- Region 1, all pressure data results above the posterior brim (includes the Patella tendon bar for the PTB prosthesis. obviously no pressures will be noted posteriorly in this region).
- Region 2, all pressure data results in the so called " cone shaped" part of the socket.
- Region 3, all data results in the distal or spherical area of the socket.

The 3D computer model was used for identifying the specific anatomical locations during data interpretation.

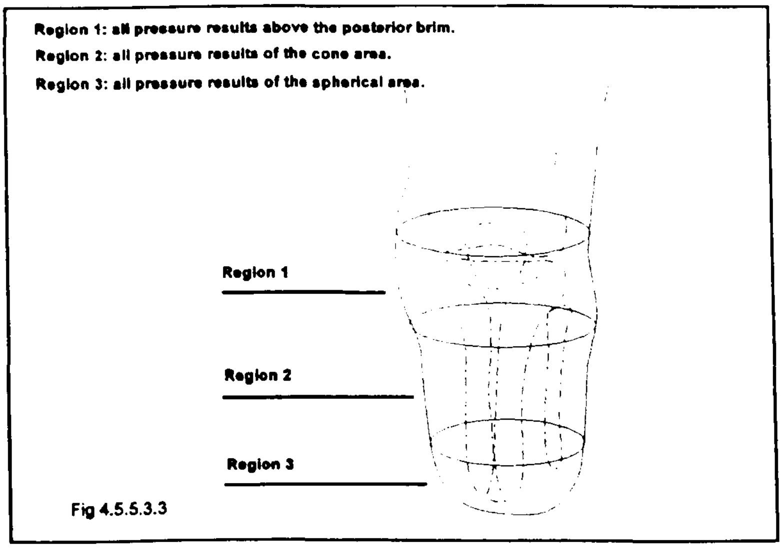

Fig 4.5.5.3.3

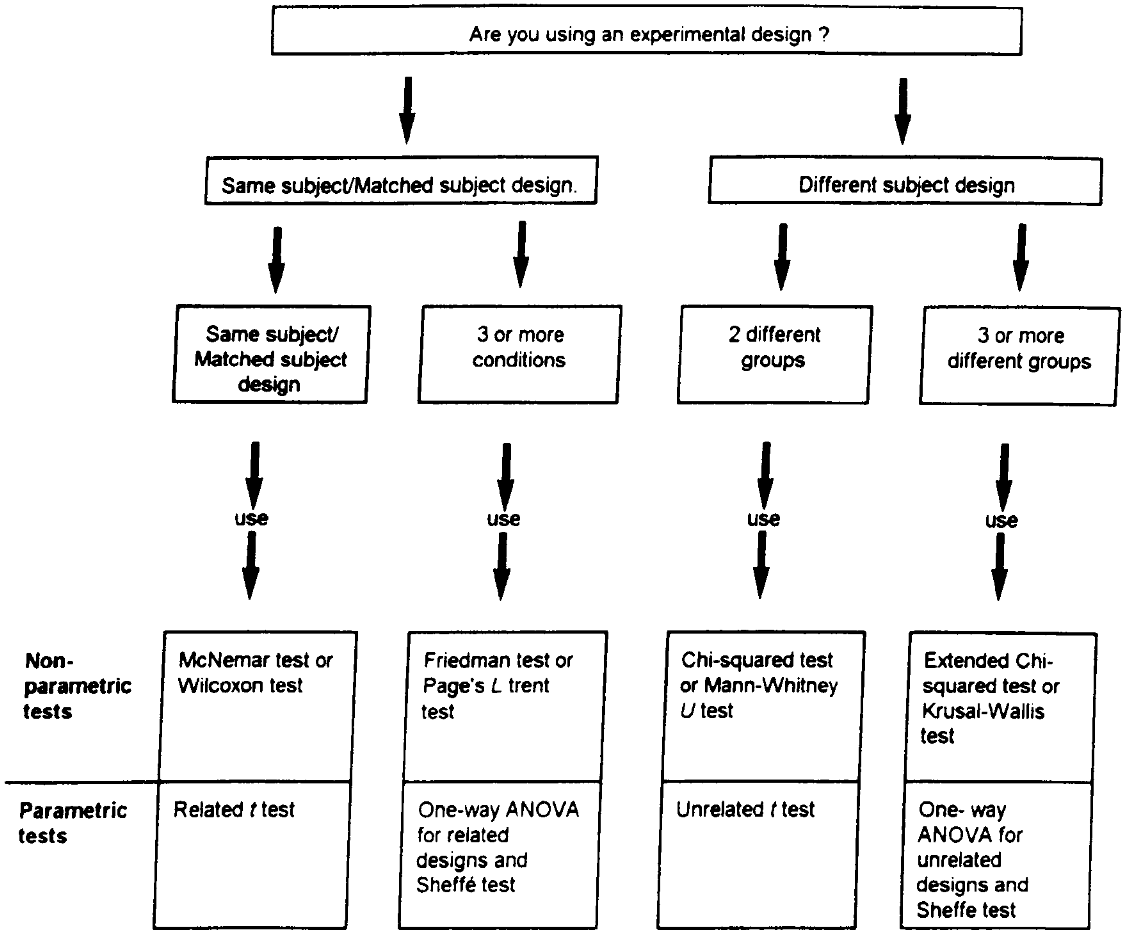

Fig 4.6 (Reproduced from Hicks, 1988)

4.5.6 Differences in prosthetic alignment

The optimum alignment of the 2 sockets was measured to investigate differences in alignment and were obtained as follows: The SSAL device, as described in Chapter 3, was used to establish the socket axis. Subsequently the angle of this axis was measured with the ground as reference base. This resulted in 2 angles, one measured in the sagittal plane and one measured in the frontal plane. Accordingly the axis was projected to the ground. Again two measurements were taken; one in the sagittal plane and one in the frontal plane. The distance in the sagittal plane was measured from the middle of the foot to the point where the socket axis intersected with the ground.

The distance in the frontal plane was measured from the centre line of the foot to the intersection of the axis in the frontal plane. Those measurements were taken for both prostheses.

4.6 Data analysis

The one way analysis of variance test (ANOVA) was used to analyse walk data obtained from the force plate and pressure data from the Tekscan system. The ANOVA test was used because one subject with more than three matching conditions at a time was studied. The results from these conditions were compared. (see also justification schedule, Fig 4.6).

The ANOVA tool determines how similar two or more samples are by calculating the F-statistic; the ratio of the mean variance between samples to the mean variance within samples. If there is no sample variability, the F ratio must be small. If the F ratio is large, greater than the F-critical value, this verifies that there is a significant difference between and within the samples. The P value predicts the probability that the results from the F test experiments are due to random error or change. If the P value is close to 1 (Maximum P=1) this means that there is a very small margin of error in the results, hence it can be concluded that the results not significant. If results obtained, indicate that the P value is relative big. It can be concluded that there is no significant variability and no significant difference between sample conditions.

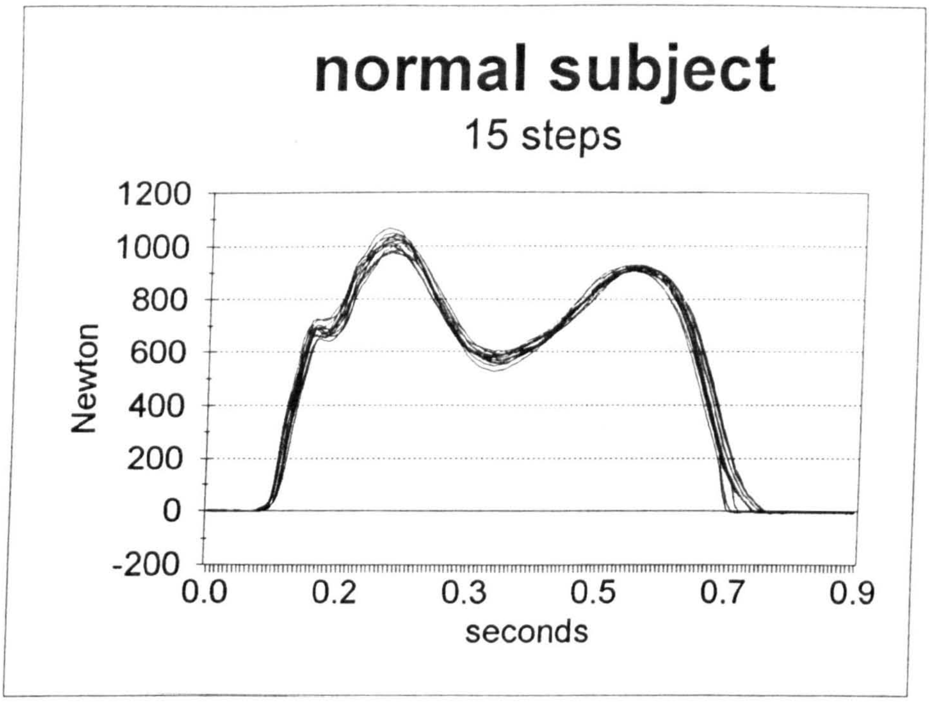

Fig 5.1.1.

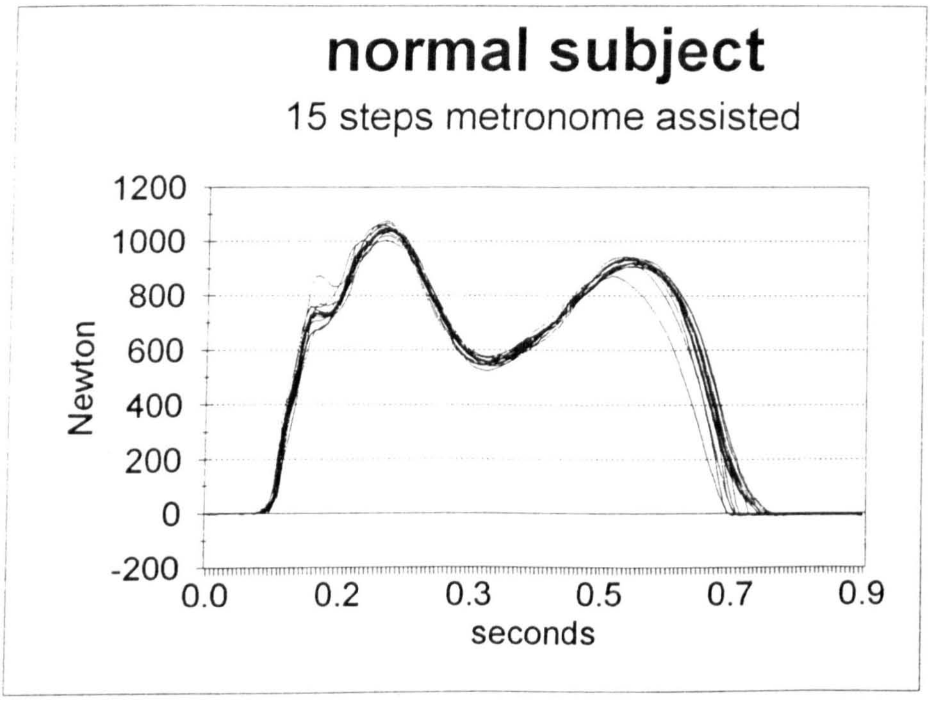

Fig 5.1.2.

CHAPTER 5

TEST RESULTS AND INTERPRETATION

5.1 Experimental data results; able bodied subject

Fifteen prosthetic steps were recorded with the Kistler force plate equipment. The vertical component of the recorded ground reaction force (Fy) was used to test the step results for variability. Fifteen steps were recorded with the subject's preferred walking speed, see Fig. 5.1.1. and 15 steps were recorded with the assistance of a metronome beat, matched to the subject's preferred walking speed, see Fig. 5.1.2.

For each of the recorded prosthetic steps simultaneous walking velocities were recorded. The following average results are noted:

Able bodied subject

average velocity of 15 steps :	84.5 m.min^{-1}
average velocity of 15 steps metronome assisted:	85.7 m.min^{-1}

5.1.1 Statistical results

The ANOVA test was used to test the recorded Fy component of the GRF for variability.

Able bodied subject; 15 prosthetic steps unassisted.

source of variation	F	F-crit	P-value
Between groups	0.04576	1.696	0.99999

Able bodied subject; 15 steps, metronome assisted.

source of variation	F	F-crit	P-value
Between groups	0.11859	1.696	0.99973

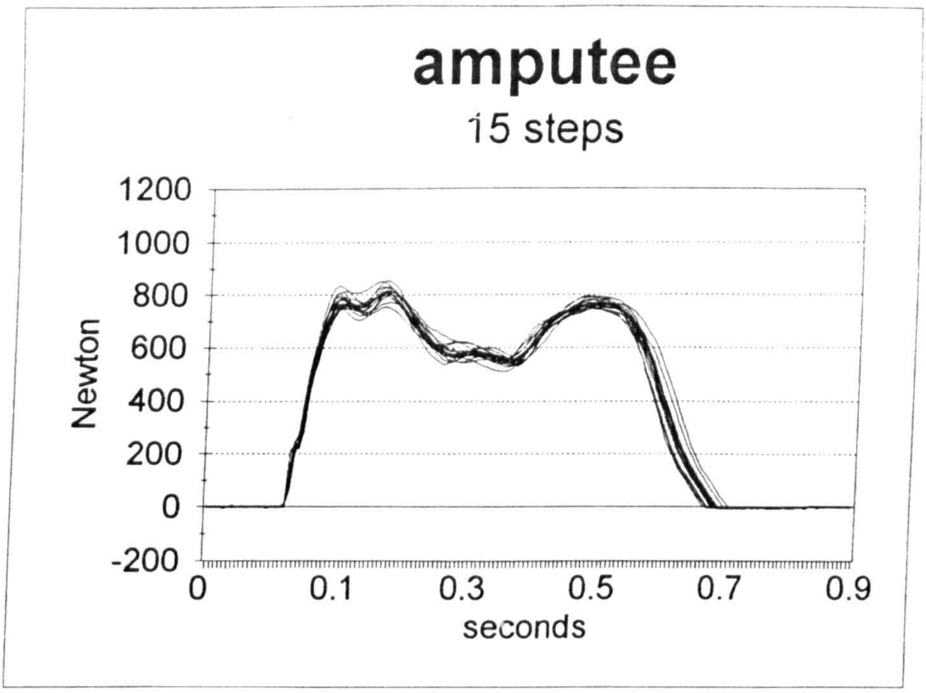

Fig 5.2.1.

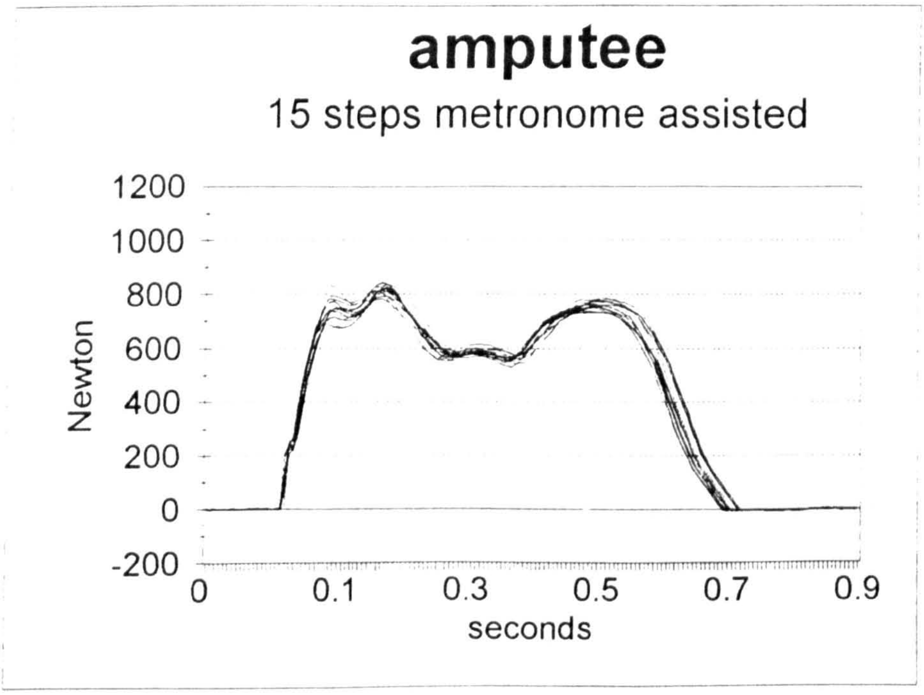

Fig 5.2.2.

5.1.2 Interpretation of the statistical results; Able bodied subject.

The F ratio for both the metronome assisted steps and unassisted steps is below the F-critical value, although the step consistency for unassisted steps is marginally better. The P value confirms that there is a very small random error in the results. There was no significant difference in average walking velocity between preferred steps and metronome assisted steps.

5.1.3 Conclusion of the walk consistency of an able bodied subject

No statistically significant walk variability was found in the recorded force plate data results. No significant differences were found between walks with and without metronome. Although walks performed without metronome indicate a marginally higher consistency (smaller F-value) it was decided to use a metronome because of the preference of the subject. The average velocity difference measured is not significant. It can be concluded that an able bodied subject can perform consistently when a trial protocol is maintained.

5.2 Experimental data results; trans-tibial amputee

The same procedure as described by the experimental results of the normal subject was used for this test. The unassisted steps are illustrated in Fig. 5.2.1 and the metronome assisted steps in Fig. 5.2.2.

For each of the recorded prosthetic steps simultaneous walking velocities were recorded. The following average results are noted:

Trans-tibial amputee

average velocity of 15 steps :	90.0 $m.min^{-1}$
average velocity of 15 steps metronome assisted:	89.5 $m.min^{-1}$

5.2.1 Statistical results

The ANOVA test was used to test the recorded Fy component of the GRF for variability.

Trans-tibial amputee; 15 steps

source of variation	F	F-crit	P-value
Between groups	0.08948	1.696	0.999996

Trans-tibial amputee; 15 steps, metronome assisted.

source of variation	F	F-crit	P-value
Between groups	0.08665	1.696	0.999996

5.2.2 Interpretation of the statistical results; trans-tibial amputee.

The F ratio for both the metronome assisted steps and unassisted steps is below the F-critical value. The P value confirms that there is a very small random error in the results. There was no significant difference in average walking velocity between preferred steps and metronome assisted steps, although the average walking velocities would be considered fast for a trans-tibial amputee.

5.2.3. Conclusion of the walk consistency of an Trans-tibial amputee

No significant walk and velocity variabilities were found. The subject indicated a preference for metronome assisted conditions.

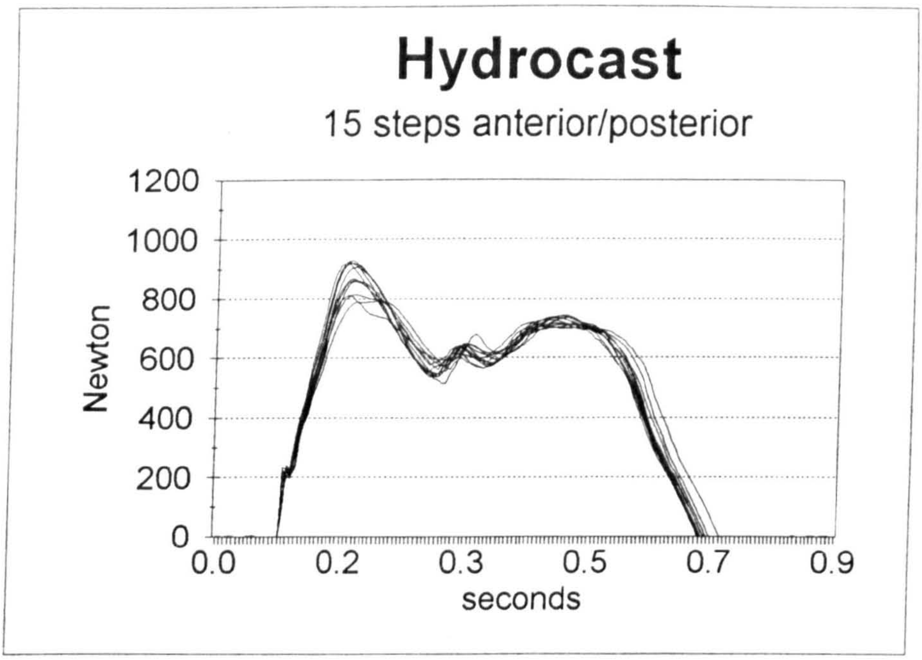

Fig. 5.3.1.

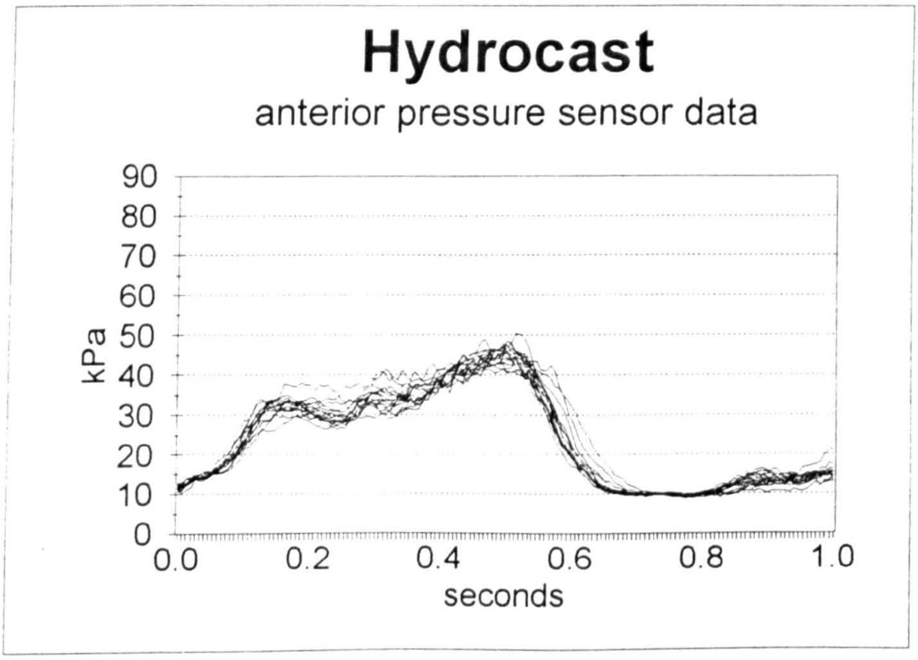

Fig. 5.3.2.

5.3 Experimental data results for the PTB and Hydrocast socket designs (step and pressure data consistency)

Introduction

For each of the socket designs the GRF and matching pressure data of 30 metronome assisted steps were recorded; 15 steps with two Tekscan transducers positioned at the A/P region of the socket and 15 steps with the transducers positioned at the M/L region of the socket. The GRF results were used to investigate repeatability of the steps. The matching pressure data were used to investigate the transducers for repeatability.

The GRF results of 15 Hydrocast steps with the transducers positioned at the A/P region is illustrated in Fig. 5.3.1. The matching pressure data of the anterior transducer is illustrated in Fig. 5.3.2. (a listing of all GRF and pressure data results for the PTB and Hydrocast sockets are presented in Appendix.5.3.)

5.3.1 Velocity results for the PTB and Hydrocast socket

For each of the recorded steps simultaneous walking velocities were recorded. The following average results were noted:

PTB socket steps

average velocity of all steps : 80.0 m. min^{-1}

Hydro cast steps

average velocity of all steps : 92.3 m. min^{-1}

5.3.2 Statistical step variability results

The GRF results of a total of 30 steps were recorded for both sockets. Again the ANOVA test was used to test the Fy component of the GRF for variability.

PTB all steps (30):

source of variation	F	F-crit	P-value
Between groups	0.13144	1.52	0.9999

Hydro cast all steps (30):

source of variation	F	F-crit	P-value
Between groups	0.14845	1.52	0.9999

5.3.3 Interpretation of the statistical GRF results and walking velocities for both socket designs

The F ratios for both the sockets were below the F-critical value. The P value confirms that there is a very small random error in the results.

There was a difference between the average walking velocity of the PTB prosthesis in relation to the Hydrocast prosthesis. This was of the order of 11%. There was no significant difference in stance phase time recorded for both socket designs. The metronome settings were similar, hence swing phase duration must be similar. The step cadence was identical (velocity = cadence * step length). Therefore, the only parameter liable to change was the step length.

5.3.4 Transducer output consistency

The average pressure results recorded for the anterior, posterior, medial and lateral socket regions were tested for output consistency. The ANOVA test was used to investigate repeatability of average transducer output.

PTB pressure results

PTB anterior pressure results:

source of variation	F	F-crit	P-value
Between groups	1.0052	1.6983	0.4449

PTB posterior pressure results:

source of variation	F	F-crit	P-value
Between groups	1.1196	1.7939	0.3411

PTB medial pressure results:

source of variation	F	F-crit	P-value
Between groups	1.1451	1.7248	0.3153

PTB lateral pressure results:

source of variation	F	F-crit	P-value
Between groups	1.1863	1.7248	0.2826

Hydrocast results

Hydro anterior pressure results:

source of variation	F	F-crit	P-value
Between groups	0.5742	1.6961	0.8868

Hydro posterior pressure results:

source of variation	F	F-crit	P-value
Between groups	1.3853	1.7939	0.1729

Hydro medial pressure results:

source of variation	F	F-crit	P-value
Between groups	1.0986	1.7939	0.3533

Hydro lateral pressure results:

source of variation	F	F-crit	P-value
Between groups	0.6102	1.6961	0.8587

5.3.5 Conclusion of the transducer output consistency

Some of the transducers showed better repeatability, but substantiated correlation between location of the transducers and repeatability could not be made.

5.4 Conclusion of the experimental data results for the PTB and Hydrocast socket designs

There was a difference in walking velocity between the two sockets but this was not significantly reflected in the recorded stance period. The difference in velocity was anticipated and the use of a metronome minimised difference in pressure record periods. It is unknown if the difference in velocity has its origin in comfort, socket design or alignment. The recorded data sets can be used for data analysis due to the following facts:

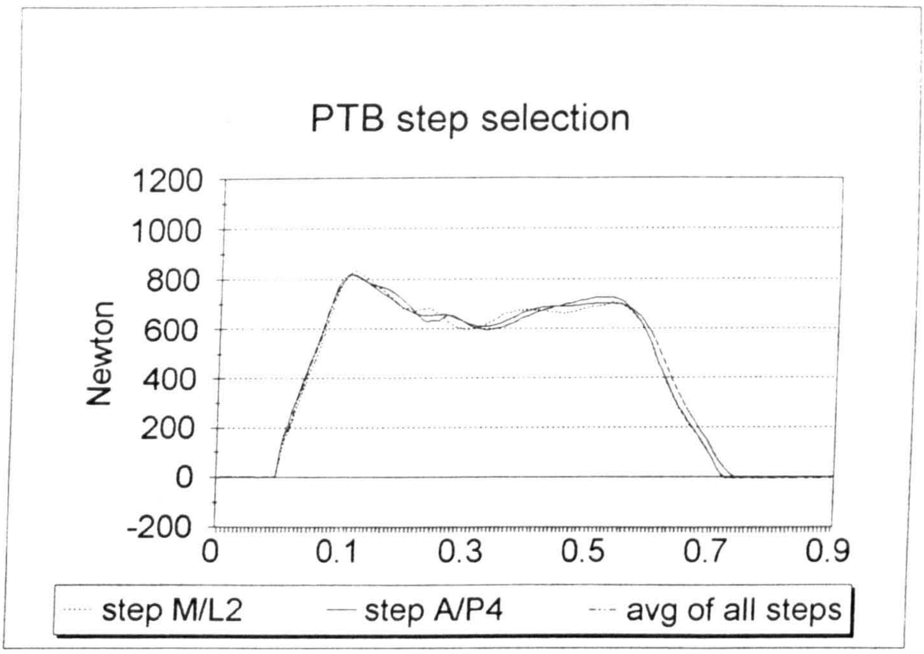

Fig 5.5.1.

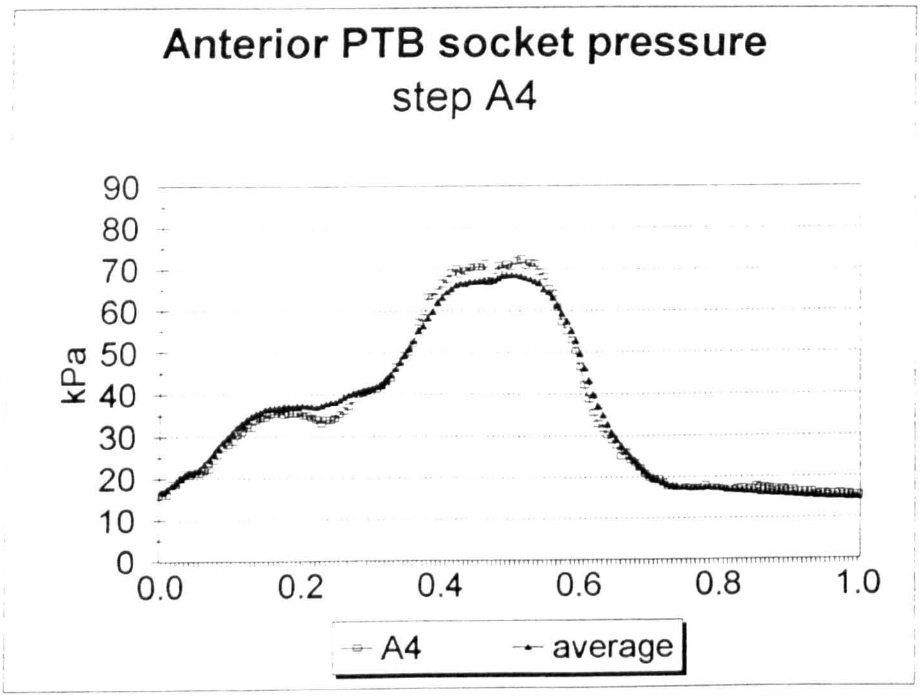

Fig 5.5.2

- no significant difference of ground reaction force within the same subject.
- no significant difference in step time within the same subject.
- no significant difference in average pressure data is experienced within the same subject.

5.5 Data selection for the 3D computer model

The aim of data selection was to arrive at sets of GRF and pressure distribution data, representative of both socket designs. An average result was calculated from the force plate data of the 30 recorded steps. The best fitting recorded result to the average was selected, as illustrated for the PTB prosthesis in Fig. 5.5.1. This procedure was repeated for each of the 4 transducers, as illustrated for the anterior transducer of the PTB socket in Fig 5.5.2. (a listing of all GRF and pressure data selection results for the PTB and Hydrocast sockets are presented in Appendix. 5.5.)

The following combinations for the 3D model were selected:

For the PTB socket:

- GRF data results from step A/P 4.
- Pressure data from M/L transducers step ML2.
- Pressure data from A/P transducer step AP4.

For the Hydrocast socket:

- GRF data results from step A/P 12.
- Pressure data from M/L transducers step ML7.
- Pressure data from A/P transducer step AP12.

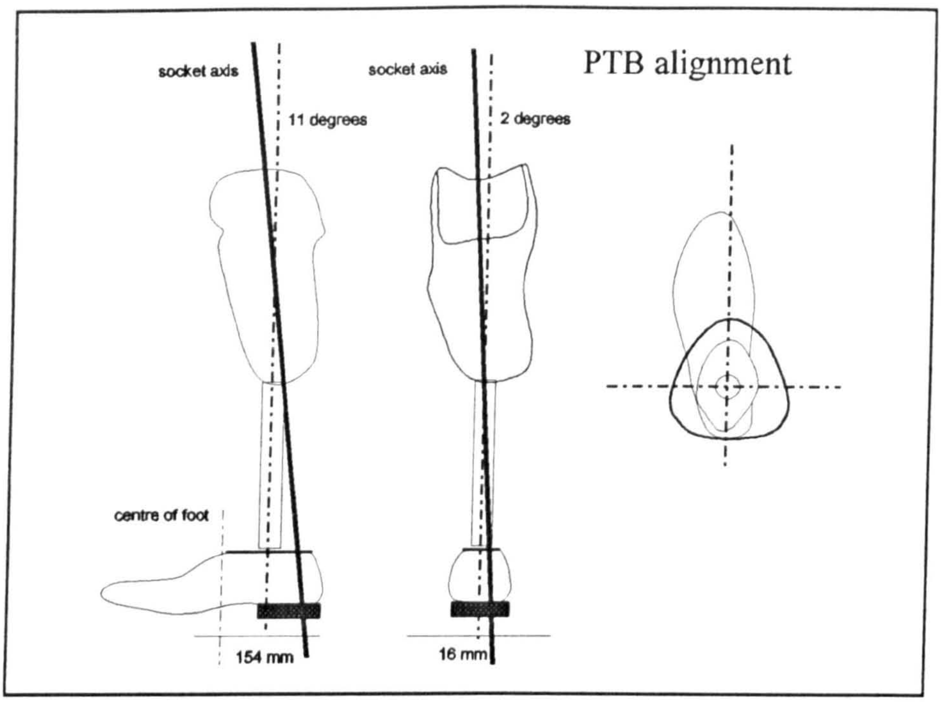

Fig. 5.6.1

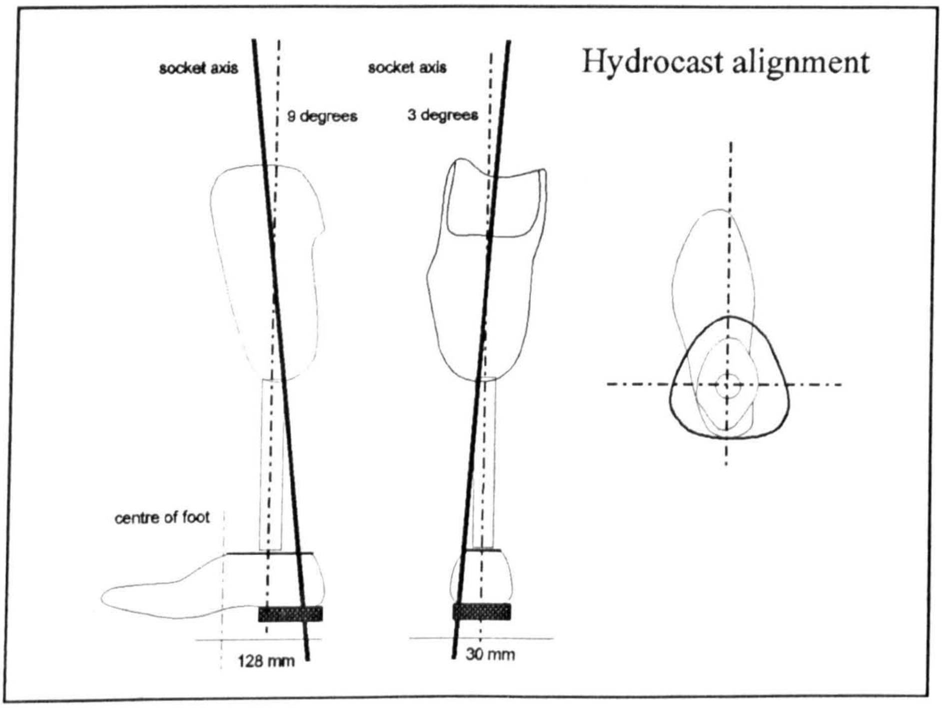

Fig. 5.6.2

5.6 Alignment results

The optimum alignment of the 2 sockets was measured to investigate differences in alignment. The angle of the socket axis was measured with a spirit level as a reference base. This resulted in 2 angles, one measured in the sagittal plane and one measured in the frontal plane. Accordingly the axis was projected to the ground. Again 2 measurements were taken; one in the sagittal plane and one in the frontal plane. The distance in the sagittal plane was measured from the middle of the foot to the point where the socket axis intersected with the ground. The distance in the frontal plane was measured from the centre line of the foot to the intersection of the axis in the frontal plane. Those measurements were taken for both prosthesis, illustrated in Fig. 4.6.1 and 4.6.2

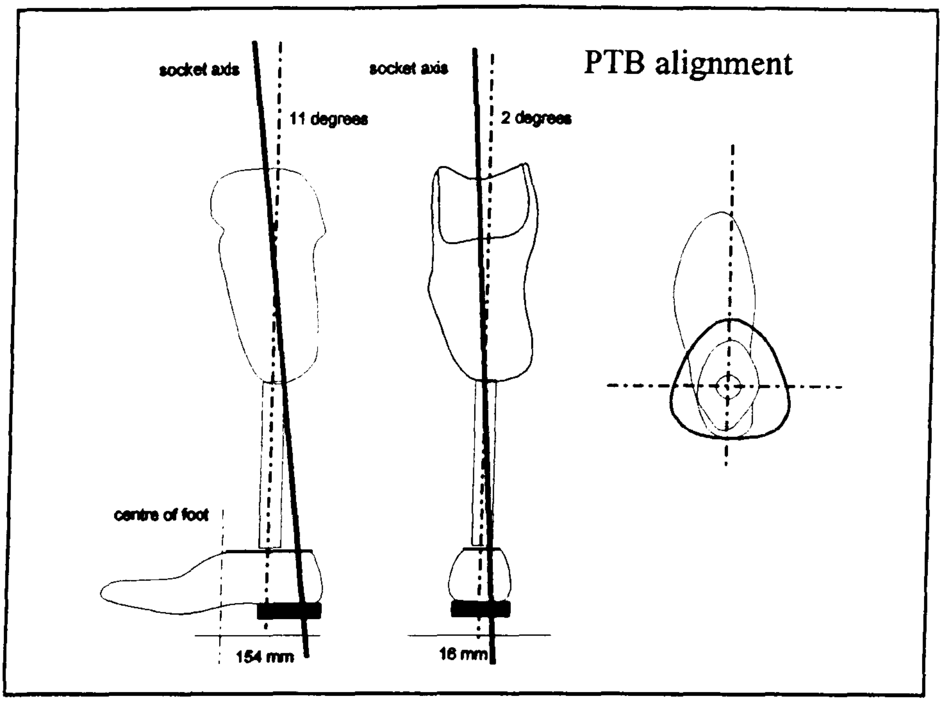

Fig. 5.6.1

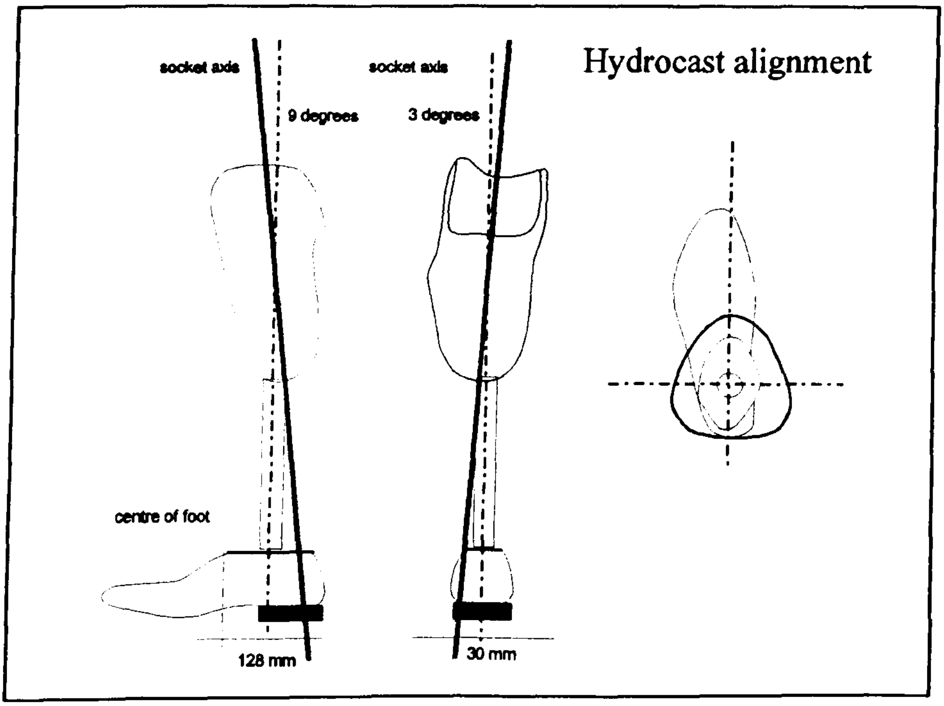

Fig. 5.6.2

5.6 Alignment results

The optimum alignment of the 2 sockets was measured to investigate differences in alignment. The angle of the socket axis was measured with a spirit level as a reference base. This resulted in 2 angles, one measured in the sagittal plane and one measured in the frontal plane. Accordingly the axis was projected to the ground. Again 2 measurements were taken; one in the sagittal plane and one in the frontal plane. The distance in the sagittal plane was measured from the middle of the foot to the point where the socket axis intersected with the ground. The distance in the frontal plane was measured from the centre line of the foot to the intersection of the axis in the frontal plane. Those measurements were taken for both prosthesis, illustrated in Fig. 4.6.1 and 4.6.2

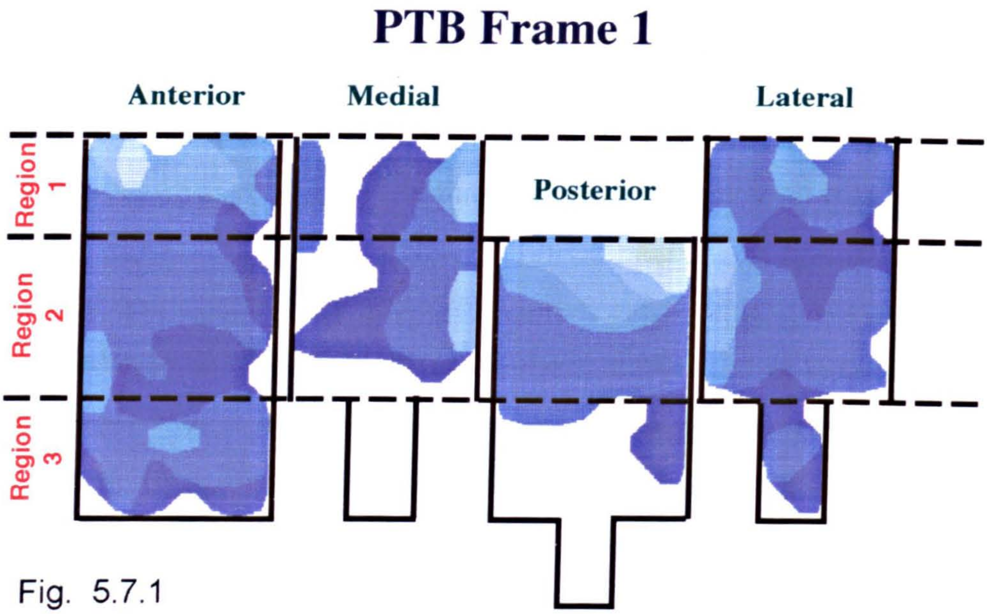

Fig. 5.7.1

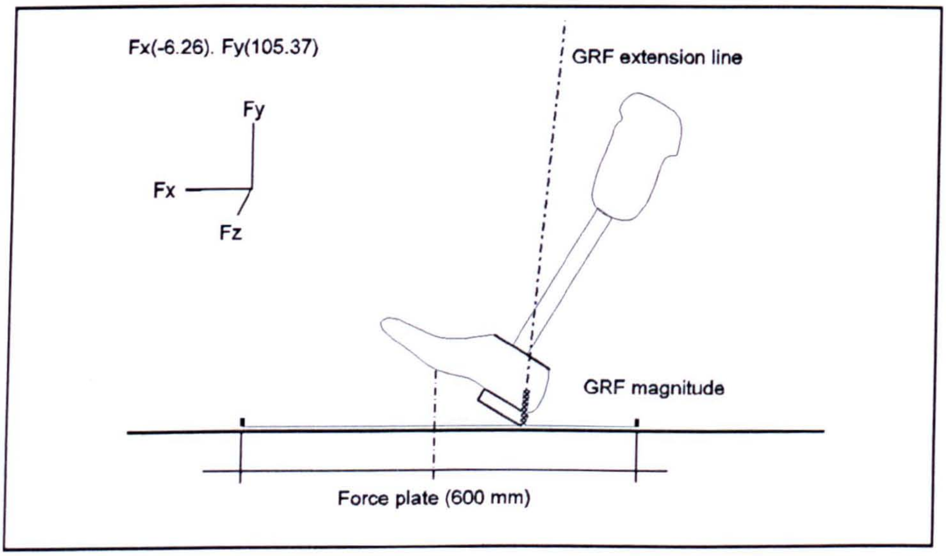

Fig. 5.7.2.

5.7 Pressure distribution results

Eight pre-selected time frames were chosen for either prosthesis. Those frames consisted of pressure distribution data from the four transducers, the GRF and its position relative to the socket for that specific frame.

Fig 5.7.1 illustrates interface pressure results of frame 1 for the PTB socket and Fig 5.7.2 displays the scaled magnitude and position of the GRF for that time frame. (a listing of all interface pressure data results and GRF results for the PTB and Hydrocast sockets are presented in Appendix. 5.7.)

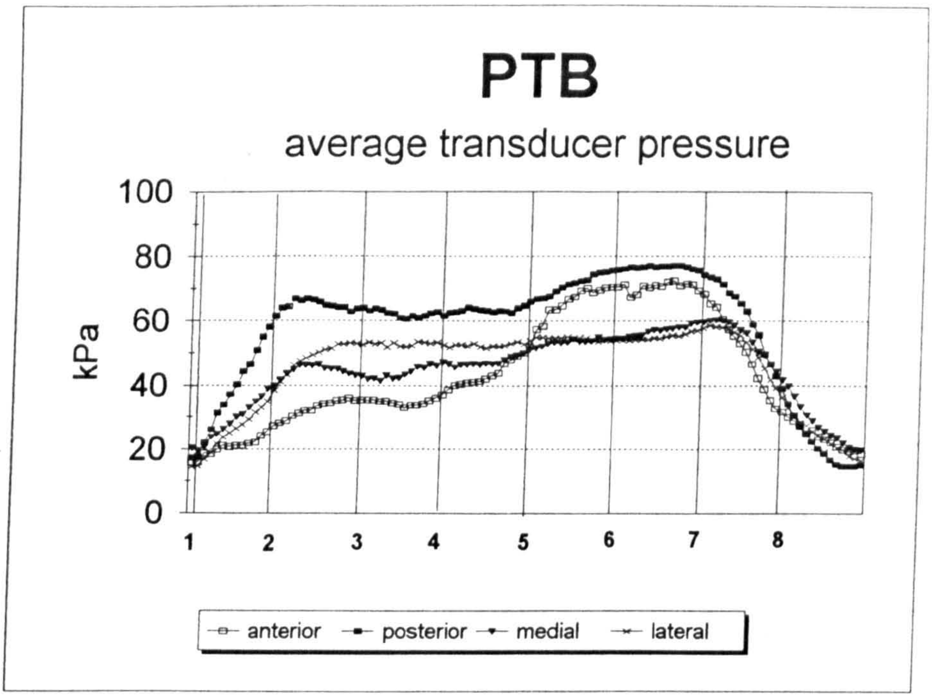

Fig. 6.2.1.

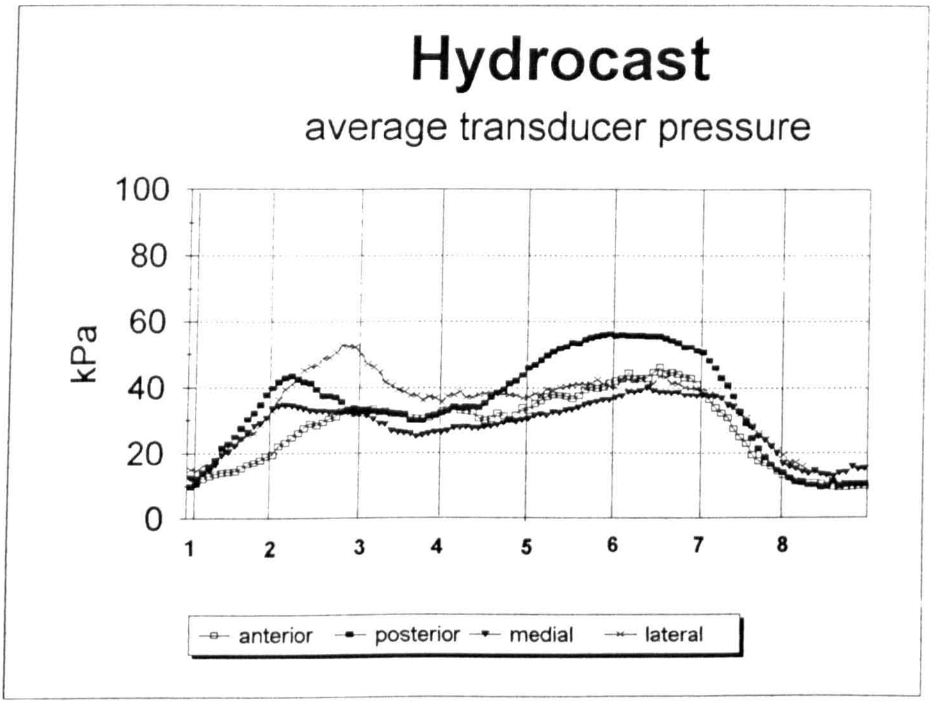

Fig. 6.2.2.

CHAPTER 6

INTERPRETATION AND DISCUSSION OF THE PRESSURE DISTRIBUTION RESULTS

6.1 Introduction

Significant differences in pressure magnitude and pressure distributions were measured during gait for both prosthetic designs. Differences in alignment of the tested prosthesis and the position of the GRF relative to the socket were also noticed. It is known that alignment and position of the GRF have an effect on the pressure distribution. However, it is not believed to be a full explanation for the difference in measured pressures. The average pressures measured within the Hydrocast socket were approximate 30% lower, compared with the PTB socket.

6.2 Observation of pressure distribution results

Significant differences in pressure magnitude and pressure distribution were noted between the two socket concepts during gait.
Stump-socket interface pressure magnitude and pressure distribution was reflected in the specific colour patterns as showed in Appendix 5.7.

This was also reflected in the the average pressure level results, Fig. 6.2.1. and 6.2.2. (where the x axis represented the 8 time frames selected during gait). Two pressure peaks can be identified during a single step, a peak just after heel strike and a peak just after mid stance.

The PTB socket had significantly more locations where the pressure levels were above 100 kpa (red colours) than the Hydrocast prosthesis.
The average pressure results of the Hydrocast prosthesis were 30% lower than the PTB prosthesis.

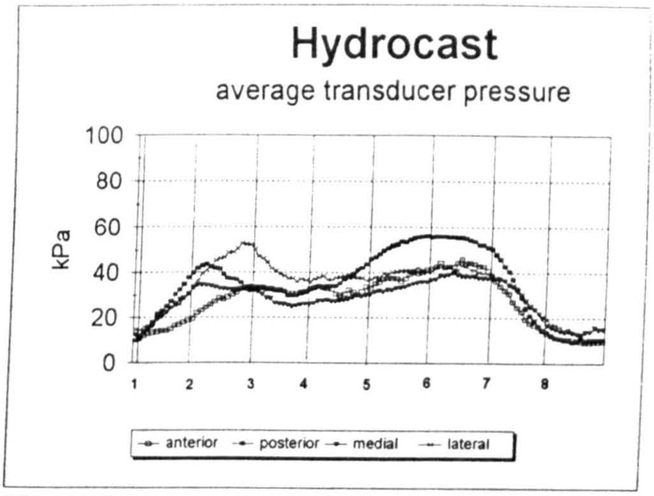

Fig. 6.2.3.

legend	No. of sensors cells used in selected area	Average pressure over the following selected areas.	Highest pressure value within the selected areas.
PTB	12	Patella bar area.	417 kPa.
PP	8	Proximal popliteal area.	132 kPa.
PMF	10	Posterior medial flare.	114 kPa.
FH	9	Fibula head area.	168 kPa.

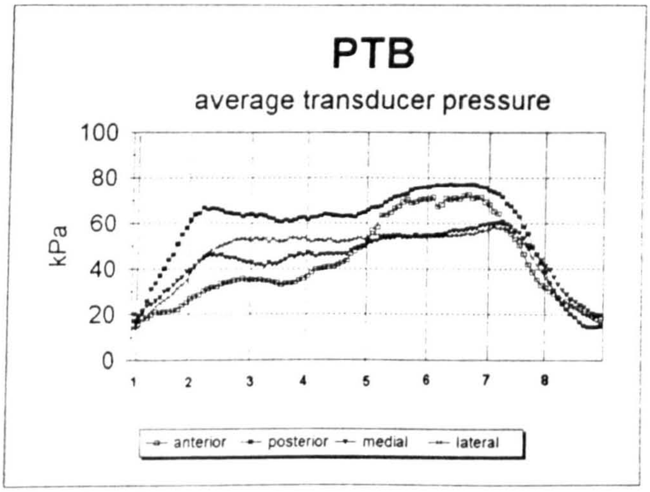

Fig. 6.2.4.

legend	No. of sensors cells used in selected area	Average pressure over the following selected areas	Highest pressure value within the selected area
MK	12	Medial knee (mid knee level).	111 kPa.
FH	9	Fibula head.	143 kPa.

Two distinct patterns regarding pressure distribution can be seen during gait:

- a ring pressure at patella bar level in the PTB socket, indicated as a red colour (≥100 kPa).
- distal pressure in the Hydrocast prosthesis, indicated mainly in green and yellow colours (between 50 kPa and 80 kPa).

A greater variation in pressure gradient was found for the PTB prosthesis. There was also an indication that the average pressure results of the 4 transducers were closer together for the Hydrocast than the PTB prosthesis. The highest average pressure levels during gait were observed between event 5 and 7. This was confirmed with the pressure distribution results of both prostheses. If peak pressures above a threshold of 100 kPa are considered potentially dangerous, then these "hot spot" areas are identified for both sockets. The average pressure did not reflect the location or the magnitude of considered dangerous peak pressures. With the aid of the Tekscan software, those identified areas were selected and resulted in the data displayed in Fig. 6.2.3. - 6.2.4. and their associated tables. The average pressure over the selected area and the highest pressure value within that selected area are listed. The only common pressure area for both prosthesis is the fibula head area. The average pressure over the fibula head area for the Hydrocast was a fraction higher than for the PTB, but the highest pressure within the selected area is higher for the PTB socket. The same patterns of pressure area results at the patellar bar and fibula head for PTB sockets were displayed in the work of Engsberg et al (1992).

6.3 Observation of the GRF during trans-tibial gait

The GRF results were very similar in magnitude but the position of the force vector in relation to both sockets was significantly different. The GRF for the Hydrocast was positioned more to the centre of the knee, whereas for the PTB

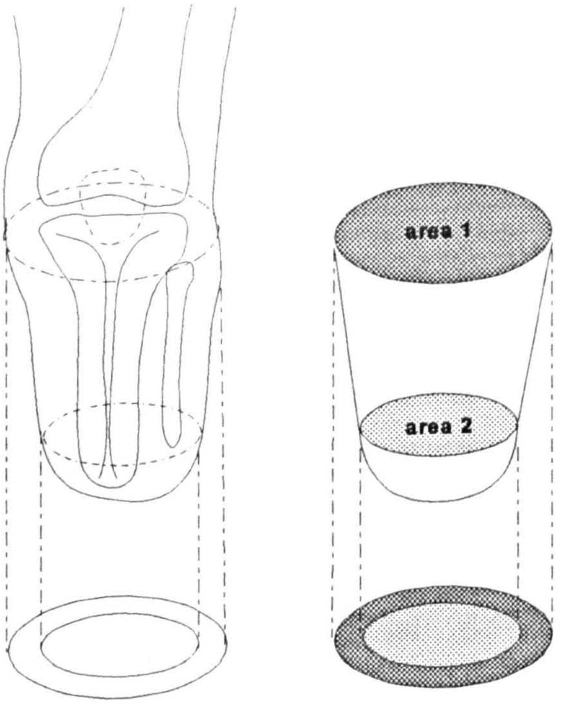

Fig. 6.4.1.

socket the GRF was positioned in front of the knee. For both socket concepts the line of action of the GRF during gait always passed in front of the knee joint, inducing a continuous extension moment of the knee. This was due to the typical gait of the tested subject

6.4 Interpretation of differences in measured pressure levels

When the amputee is in single leg stance on the prosthetic site, his body weight can be supported by an equal and opposite vertical force. The body weight is therefore supported by the greatest cross sectional area or projected area of the stump. With trans-tibial amputees this cross sectional area is often just below mid knee, see Fig. 6.4.1.

To explain the origin of the measured differences of 30% in interface pressure the following assumptions must be made:

- The stump socket can be represented as a perfect cone and half a sphere as in Fig 6.4.1.
- For simplicity the cone and sphere are taken in isolation, each with their specific projected areas (Fig. 6.4.1, area 1 and 2).
- The average measured supporting pressure acting perpendicular to the cone surface can be split into a horizontal and a vertical component. The sum of the vertical components is equal to the supporting component of the projected cone area.
- The measured pressure at the sphere area is acting in the opposite direction to the applied body weight.

Average interface pressure data from four transducers for either socket design were selected; for the cone data, region 2 was used and for the spherical area, data located at region 3 was used. As a result of the dynamic character of the measurements, interface data from key event 4 was selected. Event 4 was

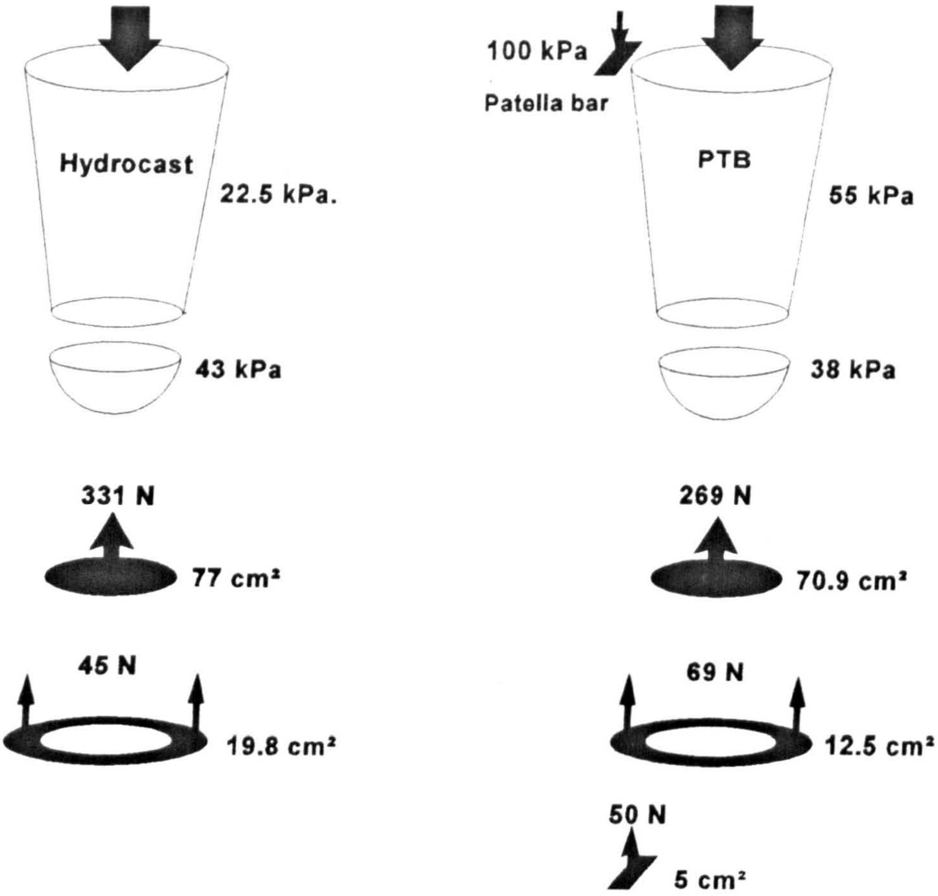

Fig 6.4.2.

Dynamic results	% weight transfer over the cone area	% weight transfer over the spherical area	% weight transfer over the patella bar area.
PTB prosthesis	18 %	69 %	13 %
Hydrocast prosthesis	12 %	88 %	N.A

Table. 6.4.2.

selected due to the fact that at this frame the stump-socket interface pressure results were considered dynamic effect free.

Table 6.4.1. lists the measured interface pressures of both socket designs for event 4.

		average dynamic pressure in kPa.
PTB	cone region	55
	sphere region	38
Hydrocast	cone region	22.5
	sphere region	43

Table 6.4.1.

The projected areas of the cone and sphere for both prostheses were measured and listed in Fig. 6.4.2. Table 6.4.2 presents the cone and sphere pressure results of both sockets for the dynamic condition.

A significant difference in average pressure levels of 30 % was experienced between PTB and Hydrocast sockets.

The results of table 6.4.1. as well as the pressure distribution results highlight those differences.

A relatively small difference of 6 % more weight transfer over the cone area was estimated for the PTB socket (table 6.4.1). This small difference in weight transfer resulted in a significant increase in pressure levels over the cone area of the PTB socket. (55 kPa) relative to the Hydrocast socket (22,5 kPa).

A difference of 19% less weight transfer was estimated for the PTB socket over the spherical area. This resulted only in a decrease in pressure over the spherical area of the PTB prosthesis (38 kPa) relative to the Hydrocast (43 kPa).

It can be concluded that if a substantial part of the body weight is transferred over the distal end, the result will be dramatically lower pressures over the inclined areas. The question; "Is this desirable or not ?" is probably an obvious one.

Summary of approximated results:

	pressure over the spherical area	Percentage of load transfer.
PTB	38 kPa.	69%
Hydrocast	43 kPa.	88%

	pressure over the conical area	Percentage of load transfer.
PTB	55 kPa	18%
Hydrocast	22.5 kPa	12%

An increase of 5 kPa in average pressure on the distal end, results in an average of 32.5 kPa reduction at the cone area. The effects of the Patella bar are not taken into account.

The question: Is it worthwhile to increase pressure levels dramatically at the cone and patella bar area to get a very small reduction in pressure at the distal end ? is likely an obvious one. Although the described estimation was based on a single stump configuration, it is probably not worthwhile to increase the pressure dramatically for the sake of minimal distal end reliefs. This was supported by the fact that the measured average pressure data for the Hydrocast socket was significantly lower than for the PTB socket, although 88% of the measured load was transferred over the distal end. No excessive pressures (≥ 100 kPa) were experienced in the distal end region of the Hydrocast socket during gait.

The approximation model, as described above, was based on the stump configuration of a single subject and was likely influenced to by the following factors;

- not all of the weight transferring surface area of the socket was covered by the four transducers.
- inability of the Tekscan transducers to detect interface shear.

6.5 Differences in pressure location and gradients

The reason for more "hot spot" areas located at the cone and patella bar area for the PTB prosthesis is likely a direct result of the hand casting concept. When a hand cast is taken the prosthetist's intention is not to produce a "weight bearing shape" but to emphasize the special areas of weight bearing to be anticipated in a PTB socket. By doing this, the prosthetist attempts to control pressure distribution. The results of our tests and approach suggest otherwise. Although prosthetists are of opinion that they are doing the right thing, in reality the effect is reversed. Typical example; The fibula head of a PTB prosthesis is normally relieved from excessive pressure by modifying the plaster model accordingly. During analysis of the results it was discovered that although a relief was made, significant pressures were found.

6.6 Correlation of pressure results with previous research

To correlate or to compare the stump-socket interface pressure results obtained in this study, with previous undertaken research in this field, has been found to be very difficult. This was caused by a number of factors:

- If it is agreed that the handcast concept is not under control and the prosthetist is not able to produce the same socket twice it is likely that interface pressure results pressure results will vary accordingly.
- Different liner materials were used in the various studies, varying in material compliance and liner thickness. Therefore results are liable to uncontrollable inaccuracies.
- Different socket materials and fabrication procedures were used. This may

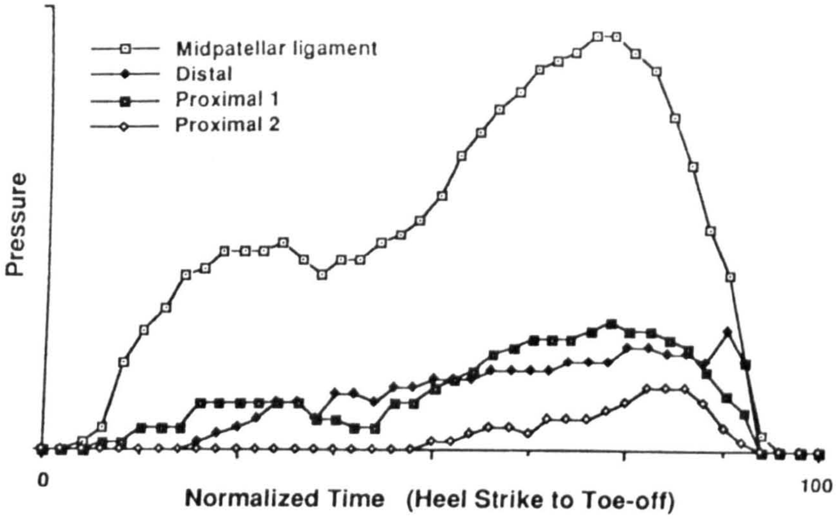

Fig. 6.6.1. (Reproduced from Engsberg, 1992).

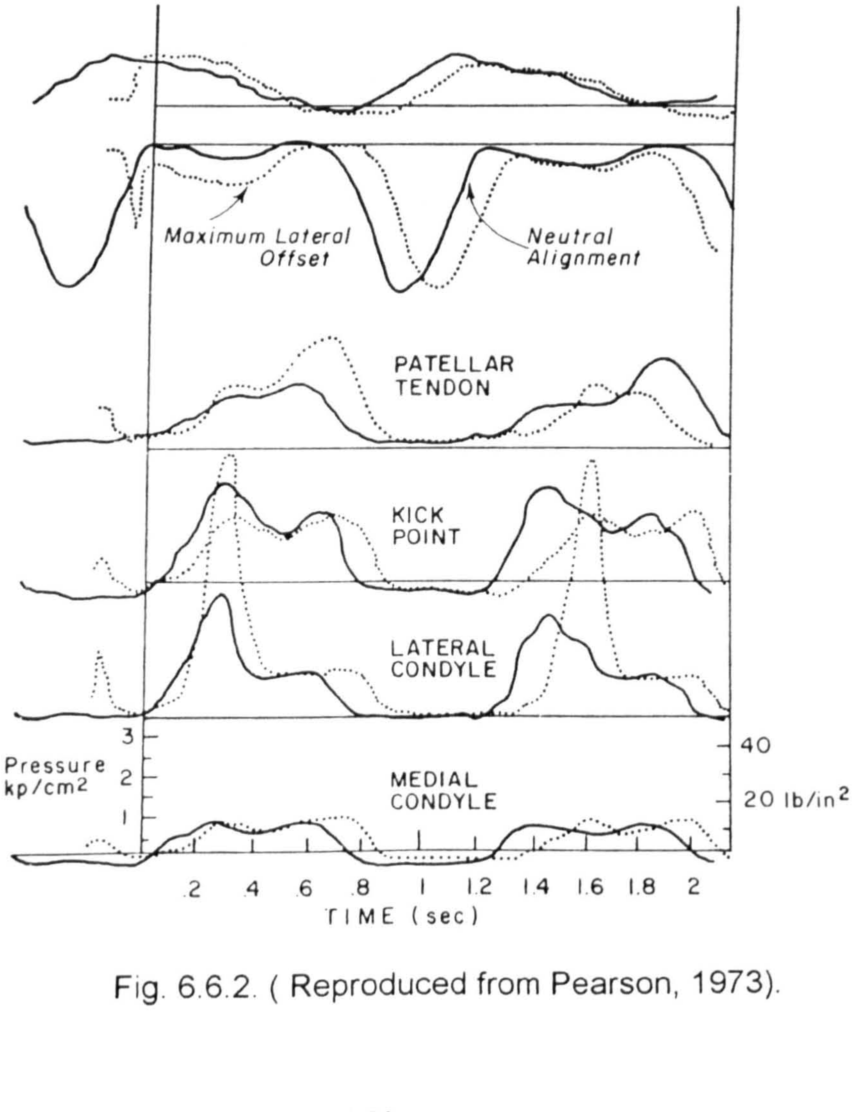

Fig. 6.6.2. (Reproduced from Pearson, 1973).

result in sudden changes in socket wall characteristics influencing the interface pressure patterns.

- The exact location of the transducers is not clearly specified. An indication that fibular head and patellar tendon as transducer location were used is not enough.
- The multitude of transducer types used, each with their own behaviour and limitation characteristics, makes direct comparison or correlation very difficult.

Although a number of problems with correlating data results exist, a global pressure pattern could be identified and correlated with the documented work of Engsberg (1992) and Pearson (1973).see Fig 6.6.1- 6.6.2.

The factors as described above are a reflection of the problems involved with correlating or comparing data with that from other sources. Therefore the data presented and analysed in this document are considered unique.

6.7 Correlation of data results, with educated biomechanical guesses in relation to socket pressure and location during normal gait

Researchers have been trying to find biomechanical explanations for load transfer and force interactions between the stump and the socket during trans-tibial amputee gait, especially Radcliffe and Foort (1961). A principal factor restricting the level of understanding of biomechanical effects occurring during gait, was the inability to obtain accurate quantitative assessment of stump-socket interface stresses at that time.

At the moment it is possible, within limitations, to monitor and record all components needed to analyse gait:

- pressure distribution and magnitude.

- position of the GRF in relation to the prosthetic socket.

This would be a opportunity to test the biomechanical model created by Radcliffe. However, the particular amputees' gait used for this study, was not typical for trans-tibial gait, since the GRF always passed ahead of the amputees' knee joint. As a result of the non typical gait it would not be expected that pressure studies would correlate with Radcliffes' biomechanical model.

CHAPTER 7

CONCLUSIONS AND RECOMMENDATIONS

The Tekscan pressure measurement system enabled almost the total load transfer surface of the trans-tibial socket to be investigated for the first time rather than "selected" locations. This meant that it was possible to investigate time varying pressure distribution patterns and pressure gradients during trans-tibial gait.

The Tekscan pressure transducers are capable of monitoring interface pressures over large areas and are able to identify localised pressures in socket regions with small and medium radii of curvature. The essential transducer characteristics include: Large sensing surface (15,500 mm^2), high sensor resolution (96 individual sensors placed in a defined matrix of 6 columns and 16 rows) and transducer flexibility.

The Tekscan software was user friendly which made monitoring and analysis of pressure data straight forward. Data recordings can be exported to external computer programs by ASCII files.

The development of calibration techniques and a test protocol ensured the accuracy and repeatability of the Tekscan system to acceptable levels. The greatest impact in relation to system output accuracy was the development of an "in-situ" equilibration and calibration method. Curvature related inaccuracies and inter-sensor variations were minimised by use of an equilibration software programme. This was achieved by applying a uniform pressure to the 4 transducer array by means of a socket fitted gel filled and pressurised "condom".

Static applications of the Tekscan system are not recommended due to the uncontrollable drift that was experienced.

Dynamic drift related inaccuracies were minimised by performing calibration after pre-conditioning of 30 dynamic loading cycles of 1 Hz. between 0 and 100 kPa. Dynamic loading conditions were generated by an load input generator. When subjected to a pressure range between 25 and 200 kPa, an average variation of ±2% and a maximum variation of ±10% for any individual sensor in the transducer array was experienced.

It is essential that this same pre-conditioning of 30 load cycles was conducted prior to recording pressure data during gait.

No difference in input/output relation with respect to time was discovered when three distinctive loading frequencies (0.1, 0.5 and 1 Hz.) were applied.

Bonding the transducers to the rigid inner socket wall enhanced transducer life and eliminated inaccuracies as a result of sensor wear due to bending and creasing.

Although the validity and repeatability of the pressure data were dramatically enhanced, inaccuracies typical for FSR technology must be taken into account. Absolute data results are doubtful because of the remaining inaccuracies due to hysteresis and shear. However, adopting the developed calibration techniques and test protocol, investigation of pressure patterns and pressure gradients between socket design concepts was possible.

The Tekscan system was incapable of monitoring and recording more than 2 transducers during a single prosthetic step. This was a major factor in ensuring controlled walk conditions.
Gait studies monitoring force plate data of 30 steps combined with statistical analysis confirmed that a normal subject, as well as a trans-tibial subject, were able to perform a consistent and repeatable gait. Stump-socket interface

pressure data, simultaneously taken during the gait studies showed the same degree of consistency and repeatability after statistical analysis. As a result interface data and force plate data for 2 steps for either socket concept could be combined to form a complete interface pressure distribution pattern. A 3D computer model was developed which displayed the combined output of 4 transducers for either socket concept as well as the simultaneously recorded GRF data and socket position in space. This proved to be an valuable tool in analysing pressure distribution patterns at any instant of gait.

Differences in the magnitude of interface pressure and pressure distribution were noted between the two tested socket concepts. Distinct pressure patterns were demonstrated. A ring of pressure at the patella bar level in the PTB socket (100 kPa.) was noted with no major distal end pressure. A more uniform pressure was noted for the pressure cast socket during gait. Significant distal end pressure, but less than 100 kPa. and no major peak pressures at the remainder of the socket were also observed.

No substantiated conclusions regarding socket concept philosophy may be made. This was a result of the following factors:

- Only 2 sockets within one subject were clinical tested. A significant number of clinical trials with a variety of trans-tibial amputation levels and stump configurations are needed to substantiate the effectiveness of a socket design concept.
- During prosthetic stance the line of action of the GRF always passed ahead of the trans-tibial amputee's knee joint and hence anterior to the socket axis. This induced a continuous extension of the knee. This was not a "typical" trans-tibial gait.
- Profound differences in optimum alignment for both prostheses were confirmed. Explanations for this difference could not be established.

The Tekscan pressure measurement system proved to be an innovative multi-point pressure measurement system for research purposes. The system is capable of monitoring differences in interface pressure distribution patterns during gait between 2 dissimilar socket concepts.
It is essential that the techniques and methods developed in this project are stringently followed to optimise output accuracy and reliability.

Following the recommended procedure, a wide range of future pressure studies may be undertaken such as:

- The effect of alignment modifications on socket pressure may be re-investigated now that the total socket may be studied rather than "selected and based on educated guessed " locations.
- The variation of socket pressure with respect to time may be studied in conjunction with subject stump volumes.

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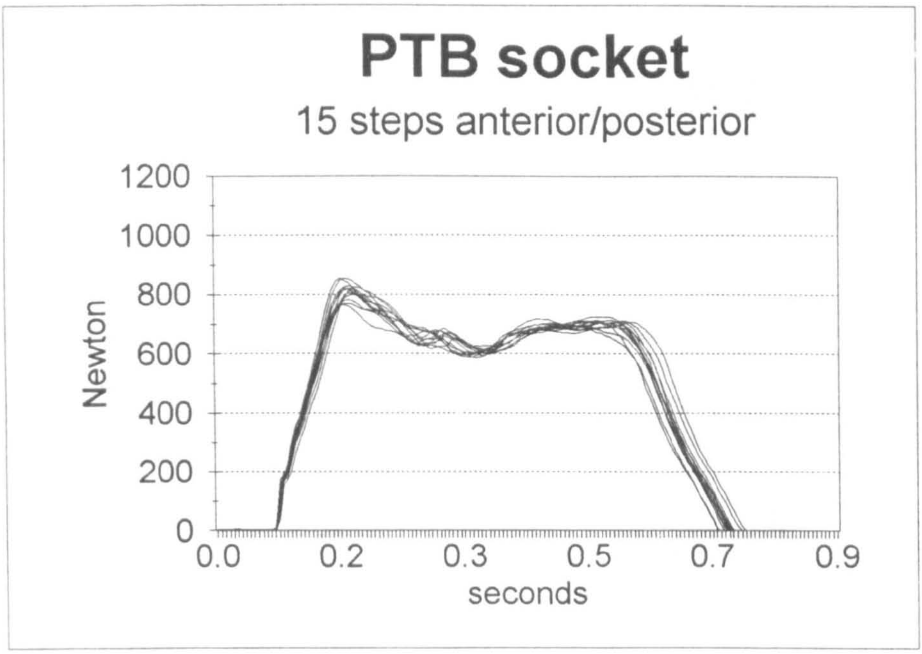
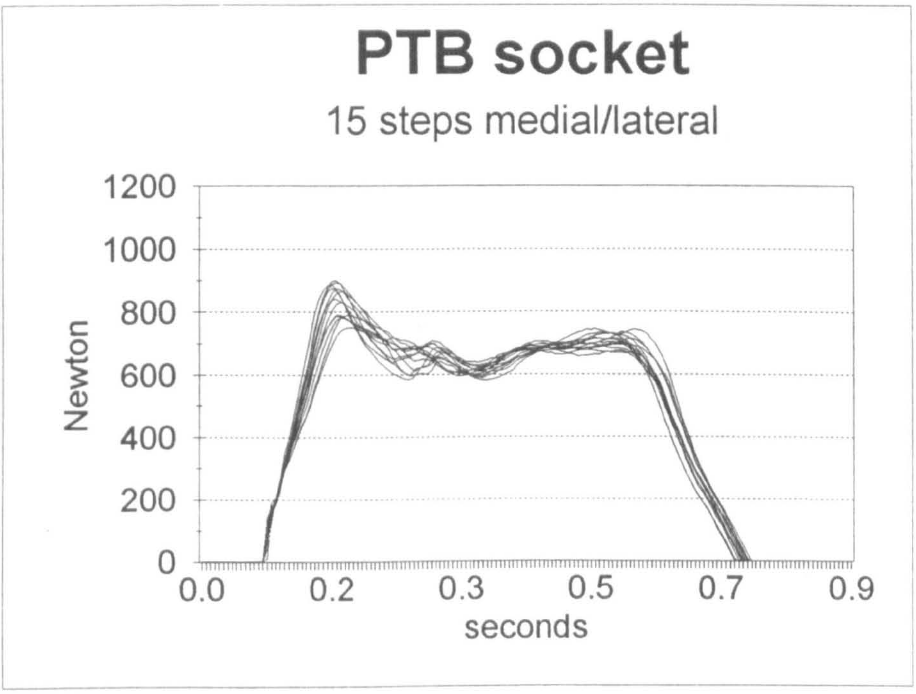
APPENDIX

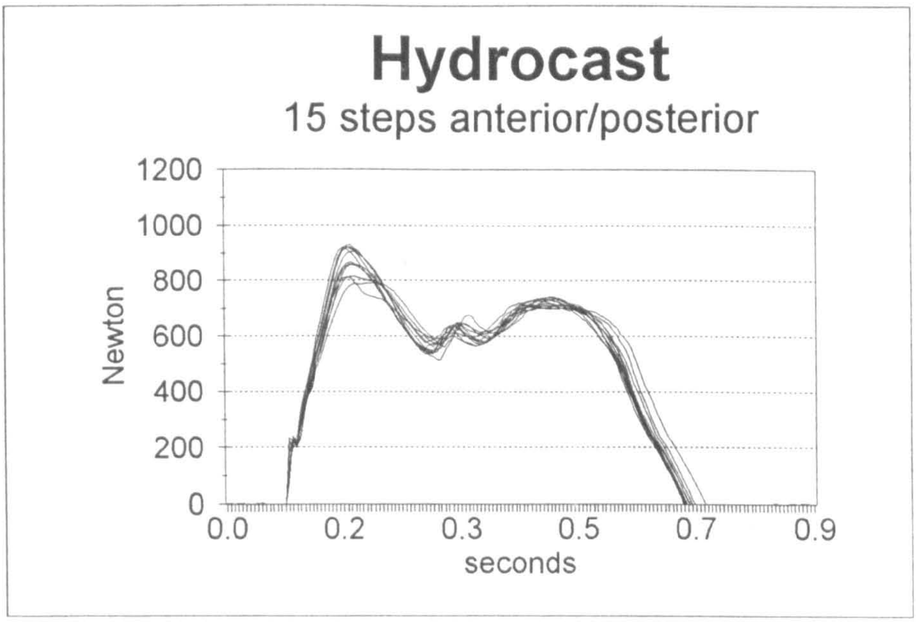
The appendices have been given the numbers of the sections they are connected with.

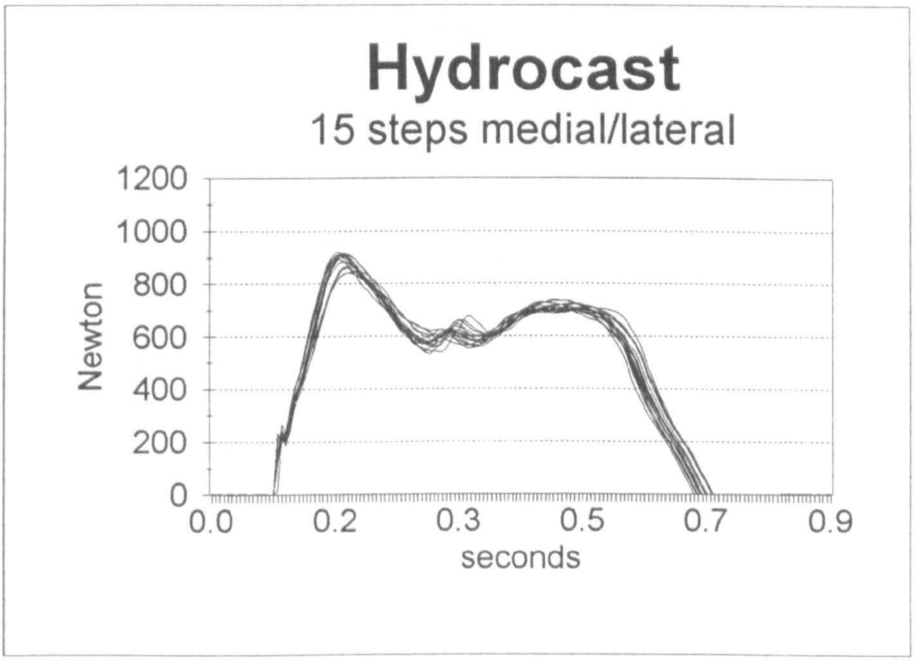
Appendix 5.3.

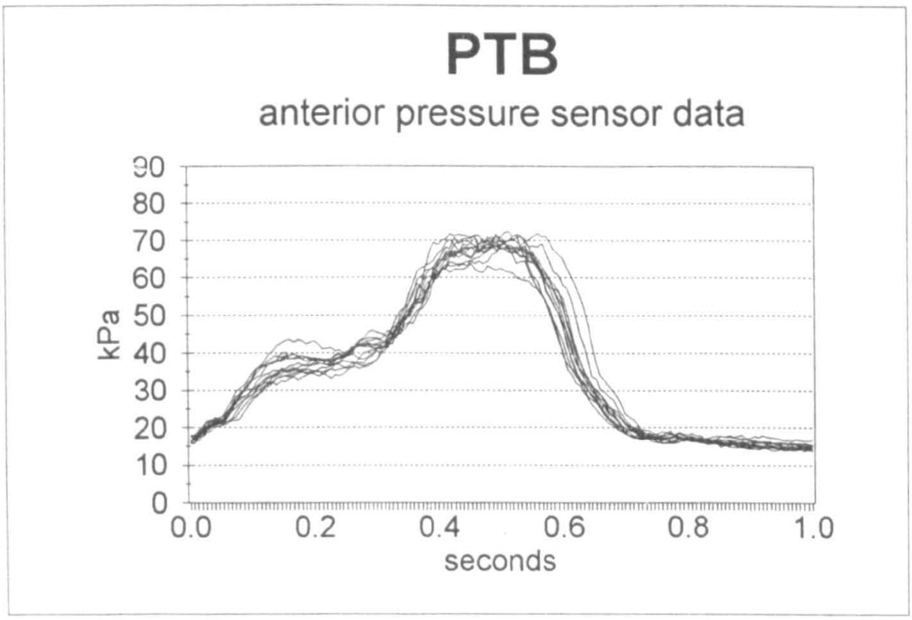
Force plate results (GRF) and average pressure results.

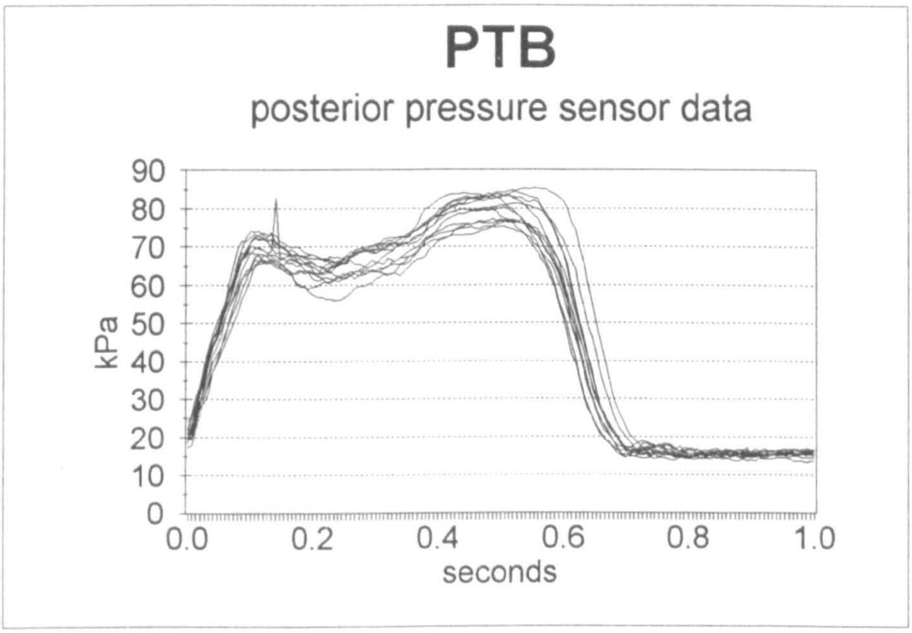

PTB socket
15 steps anterior/posterior
1200
1000
800
600
400
200
0
Newton
0.0
0.2
0.3
0.5
0.7
0.9
seconds

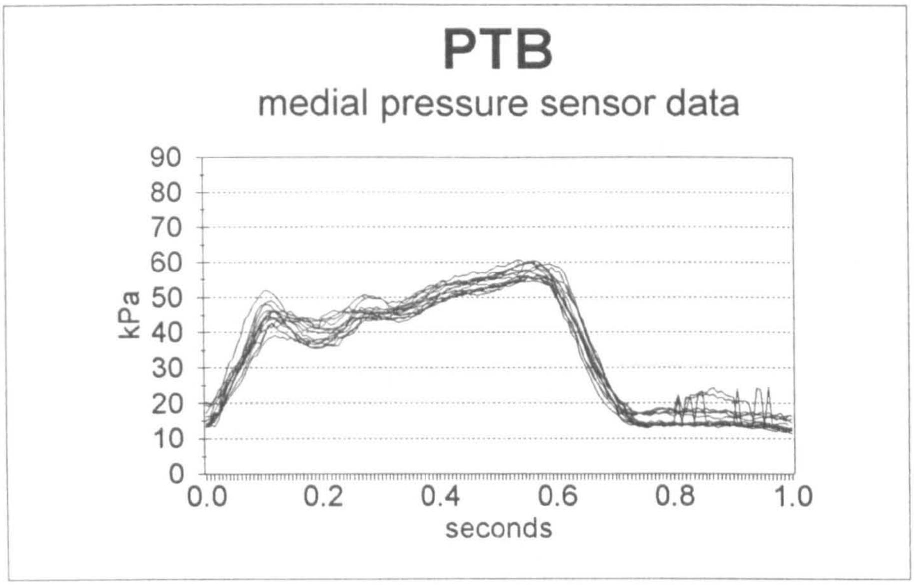

PTB socket
15 steps medial/lateral
1200
1000
800
600
400
200
0
Newton
0.0
0.2
0.3
0.5
0.7
0.9
seconds

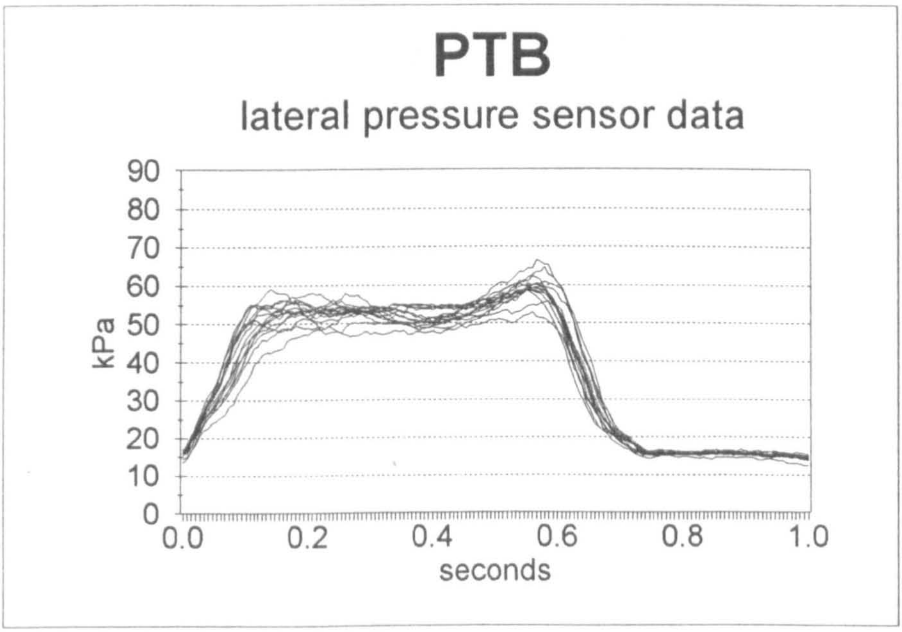

Hydrocast
15 steps anterior/posterior

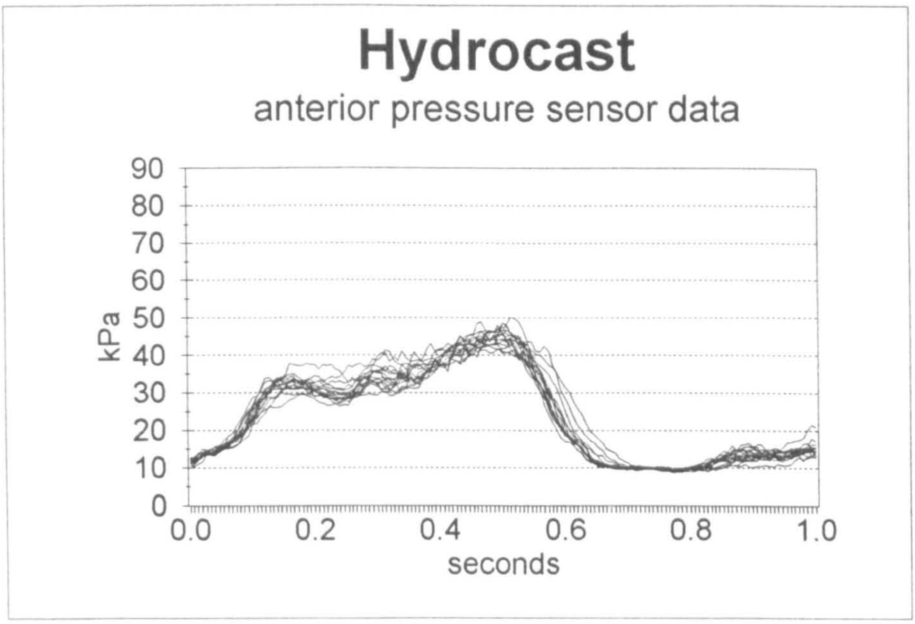

Hydrocast
15 steps medial/lateral

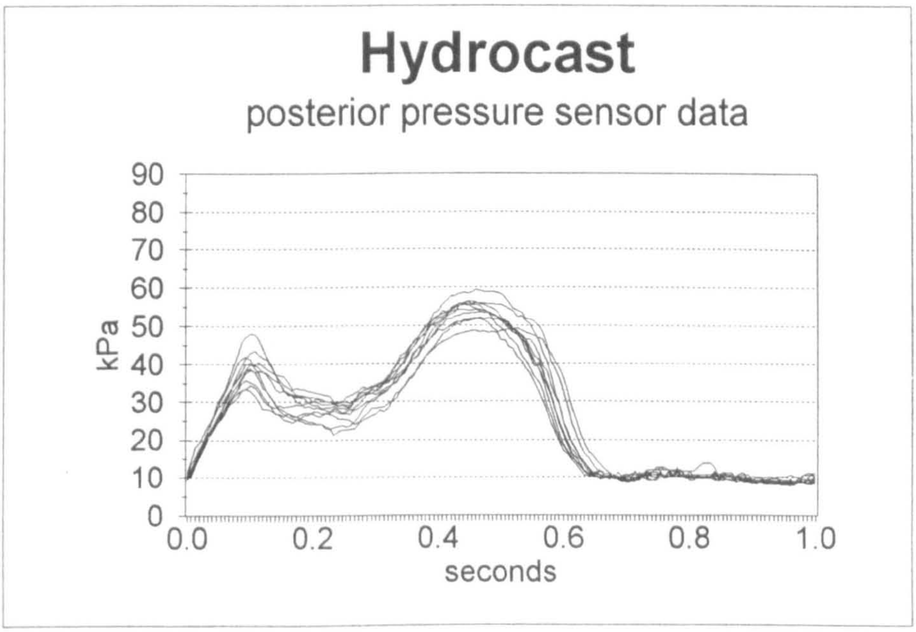

PTB
anterior pressure sensor data
kPa
90
80
70
60
50
40
30
20
10
0
0.0
0.2
0.4
0.6
0.8
1.0
seconds

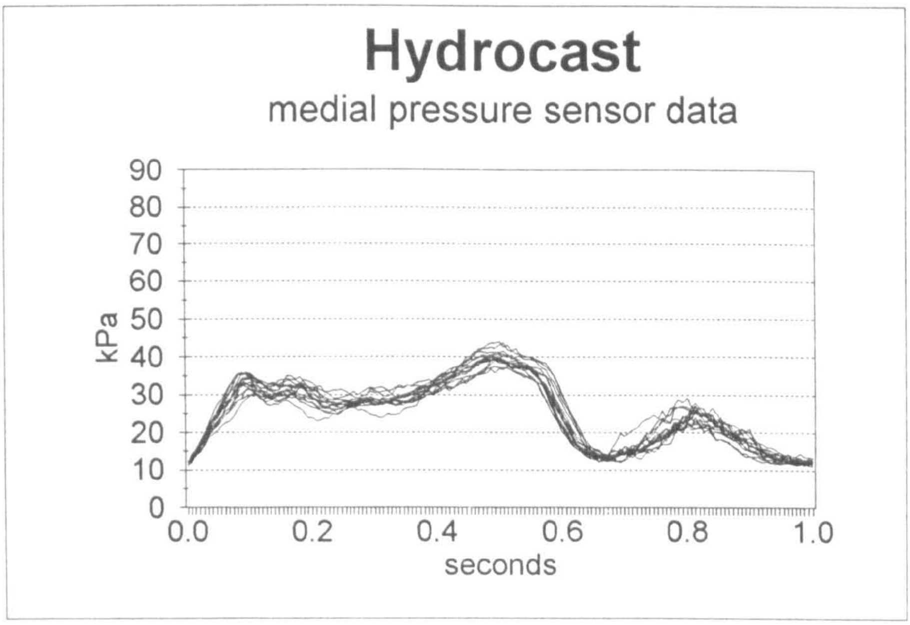

PTB
posterior pressure sensor data
kPa
90
80
70
60
50
40
30
20
10
0
0.0
0.2
0.4
0.6
0.8
1.0
seconds

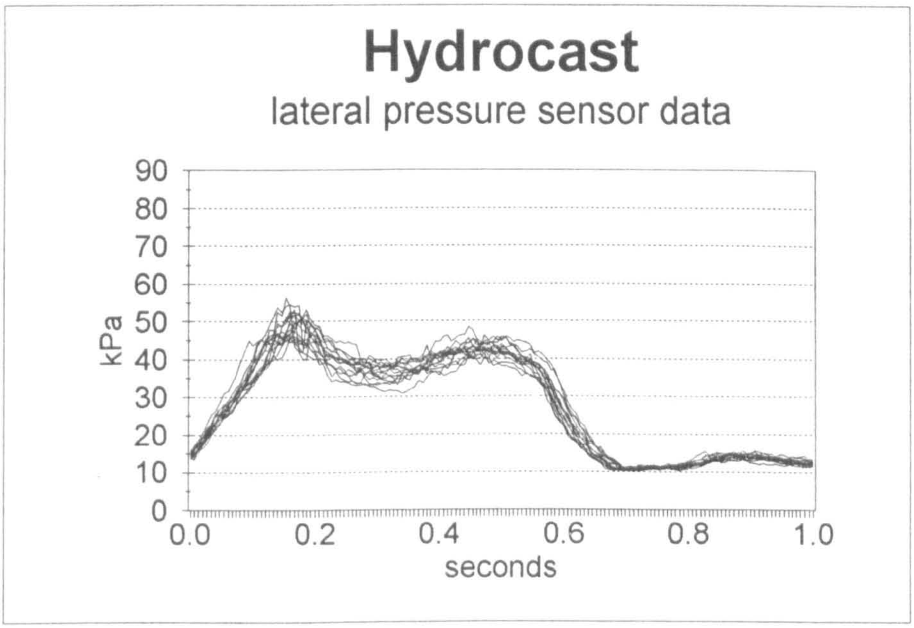

PTB
medial pressure sensor data
kPa
90
80
70
60
50
40
30
20
10
0
0.0
0.2
0.4
0.6
0.8
1.0
seconds


PTB
lateral pressure sensor data
kPa
90
80
70
60
50
40
30
20
10
0
0.0
0.2
0.4
0.6
0.8
1.0
seconds


Hydrocast
anterior pressure sensor data
kPa
90
80
70
60
50
40
30
20
10
0
0.0
0.2
0.4
0.6
0.8
1.0
seconds

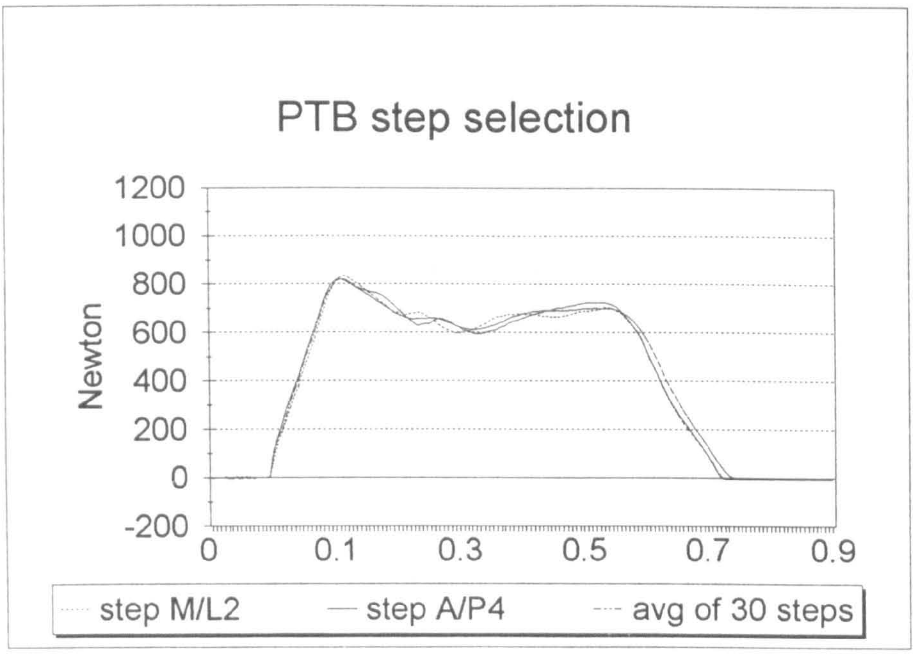

Hydrocast
posterior pressure sensor data
kPa
90
80
70
60
50
40
30
20
10
0
0.0
0.2
0.4
0.6
0.8
1.0
seconds

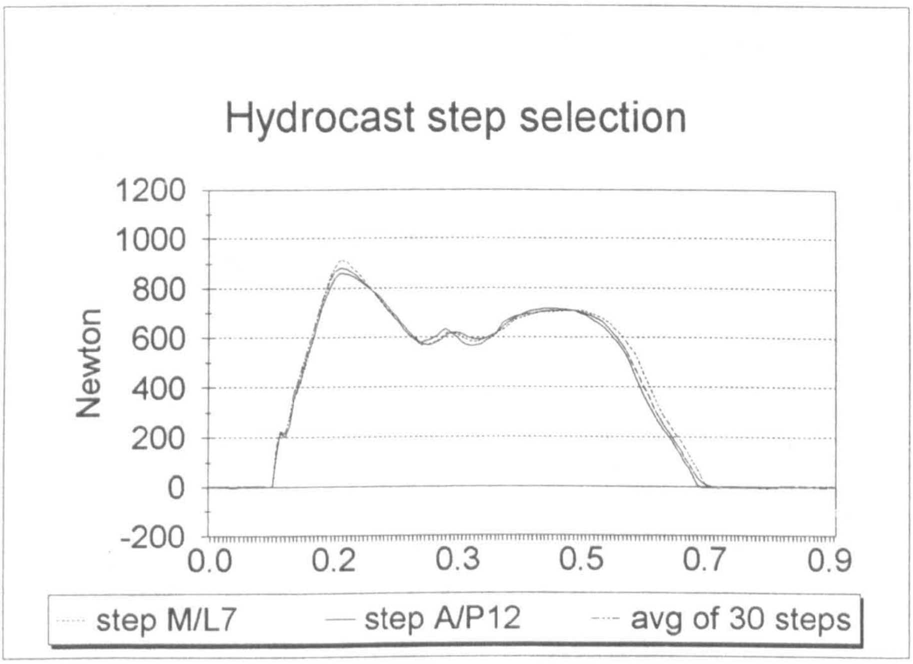

Hydrocast
medial pressure sensor data
90
80
70
60
50
40
30
20
10
0
kPa
0.0
0.2
0.4
0.6
0.8
1.0
seconds

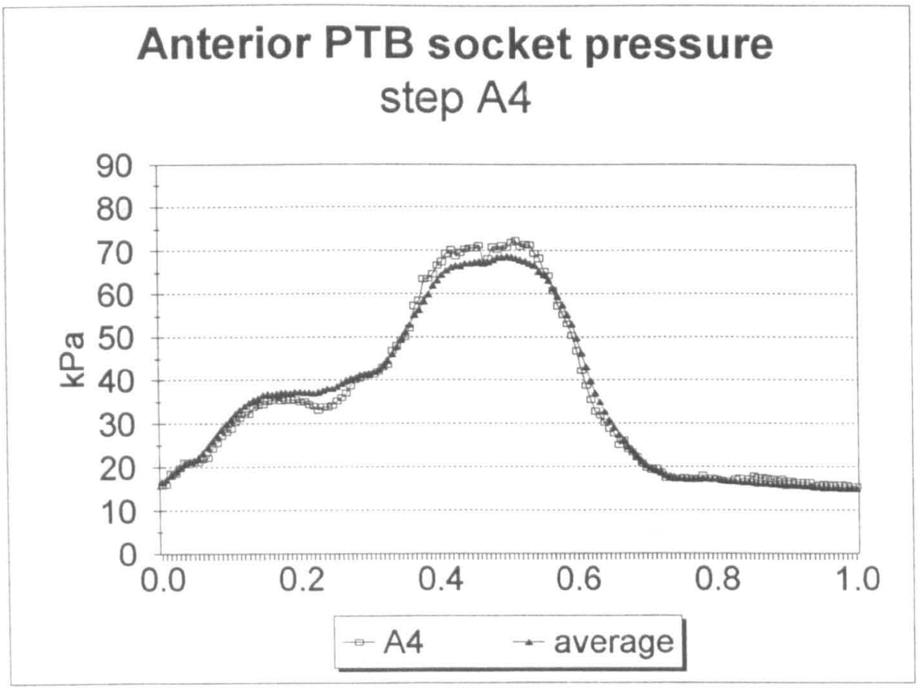

Hydrocast
lateral pressure sensor data
90
80
70
60
50
40
30
20
10
0
kPa
0.0
0.2
0.4
0.6
0.8
1.0
seconds

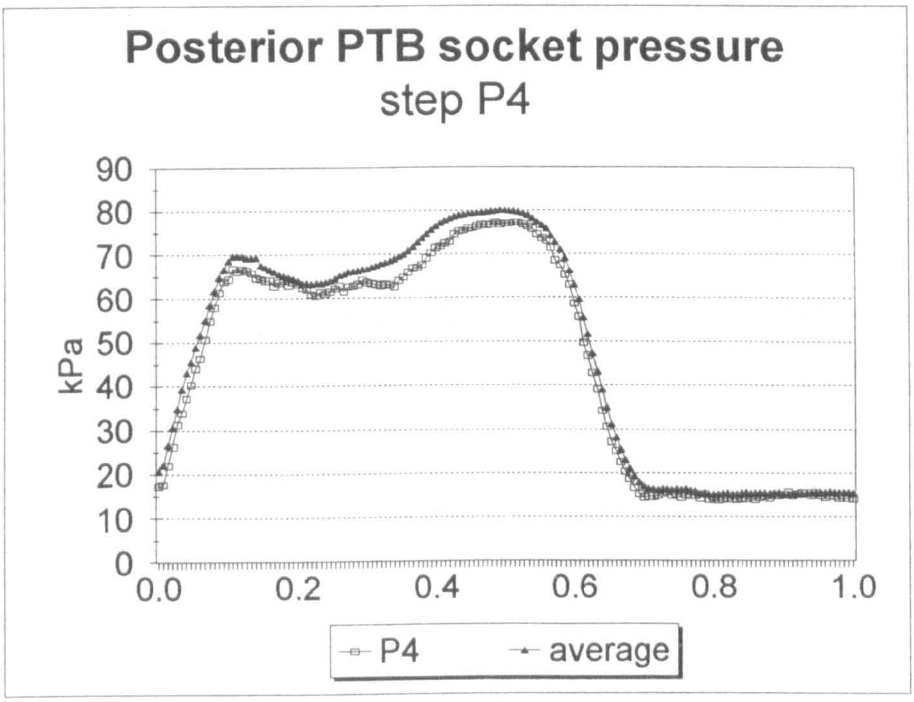
Appendix 5.5.

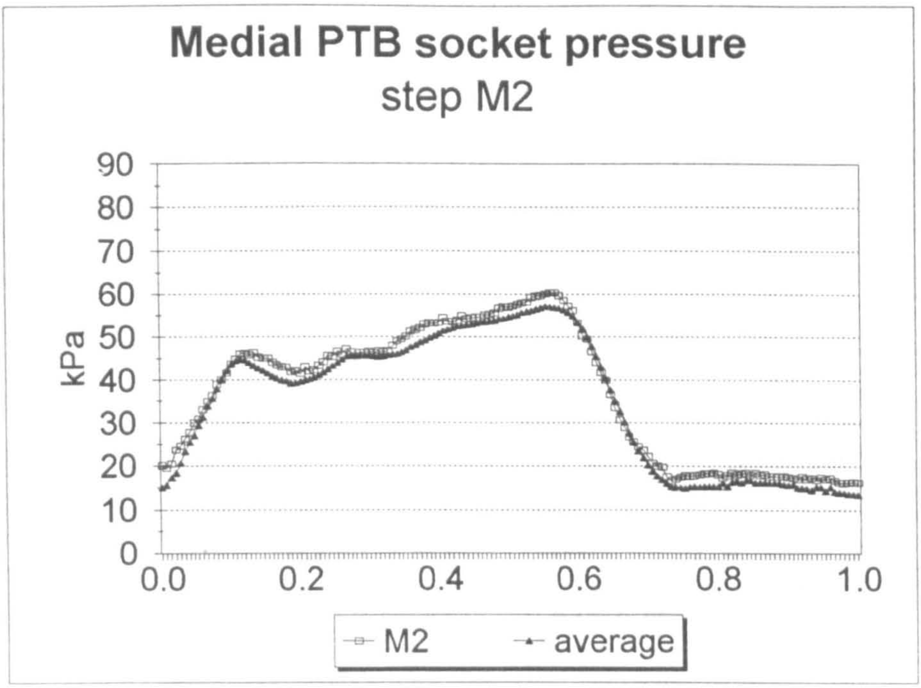
Step selection results for the 3D computer model.

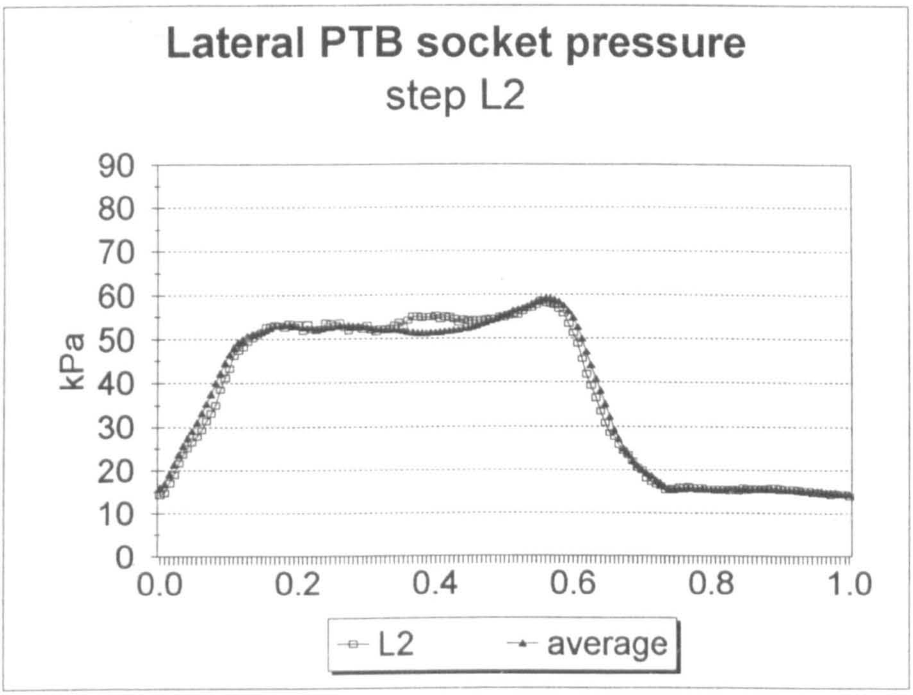

PTB step selection
1200
1000
800
600
400
200
0
-200
Newton
0
0.1
0.3
0.5
0.7
0.9
step M/L2
step A/P4
avg of 30 steps

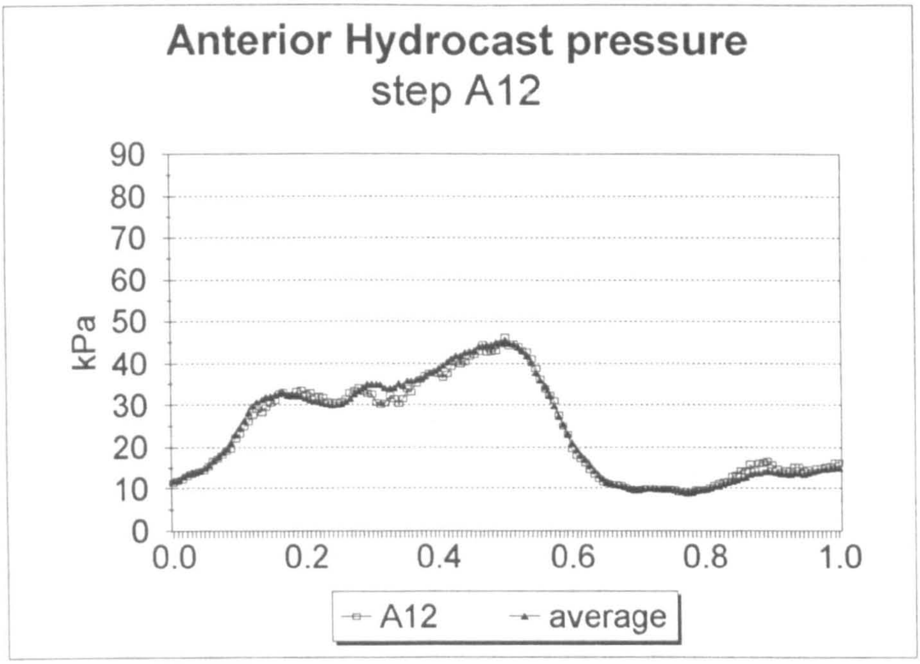

Hydrocast step selection
1200
1000
800
600
400
200
0
-200
Newton
0.0
0.2
0.3
0.5
0.7
0.9
step M/L7
step A/P12
avg of 30 steps

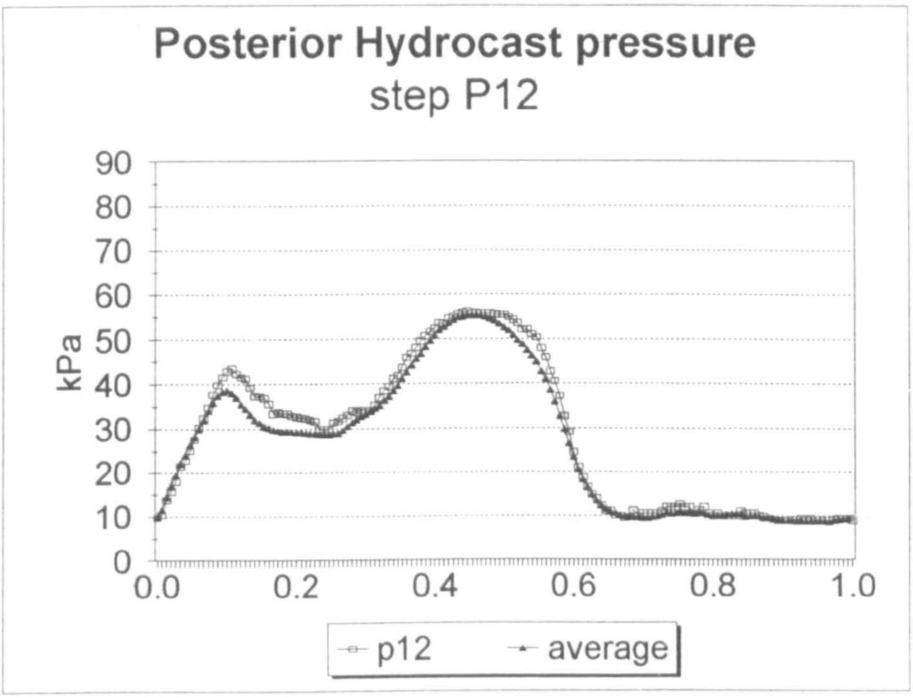

Anterior PTB socket pressure
step A4
kPa
90
80
70
60
50
40
30
20
10
0
0.0
0.2
0.4
0.6
0.8
1.0
A4
average

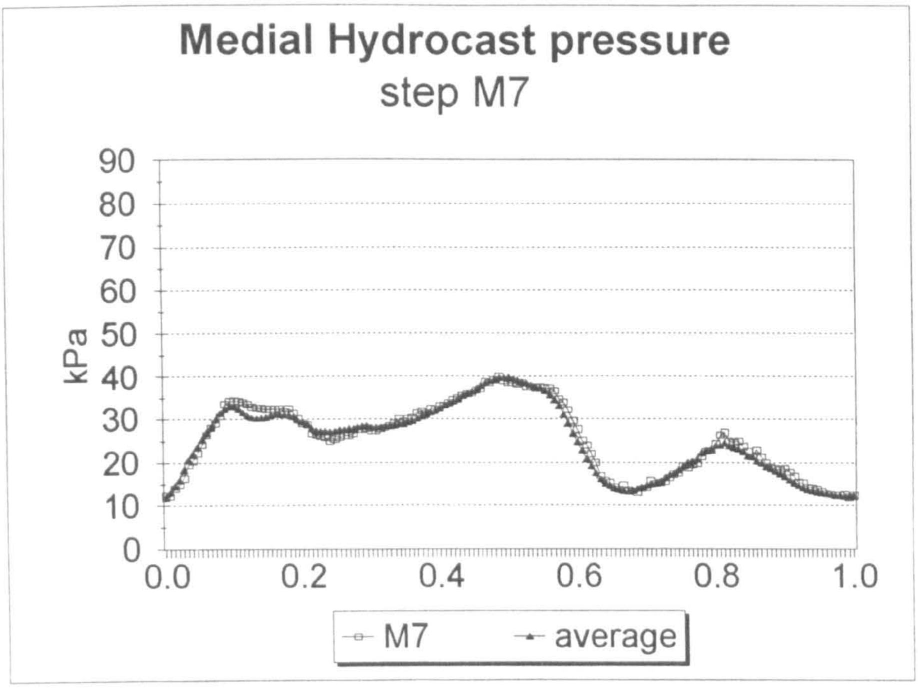

Posterior PTB socket pressure
step P4
kPa
90
80
70
60
50
40
30
20
10
0
0.0
0.2
0.4
0.6
0.8
1.0
P4
average

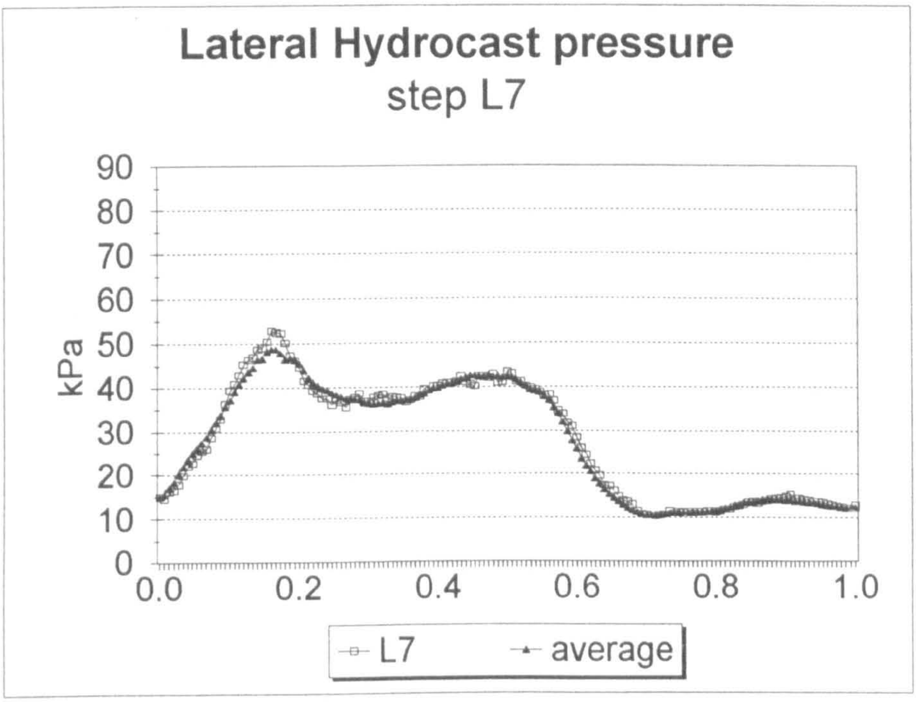

Medial PTB socket pressure
step M2
kPa
90
80
70
60
50
40
30
20
10
0
0.0
0.2
0.4
0.6
0.8
1.0
M2
average


Lateral PTB socket pressure
step L2
kPa
90
80
70
60
50
40
30
20
10
0
0.0
0.2
0.4
0.6
0.8
1.0
L2
average


Anterior Hydrocast pressure
step A12
kPa
90
80
70
60
50
40
30
20
10
0
0.0
0.2
0.4
0.6
0.8
1.0
A12
average


Posterior Hydrocast pressure
step P12
kPa
90
80
70
60
50
40
30
20
10
0
0.0
0.2
0.4
0.6
0.8
1.0
p12
average

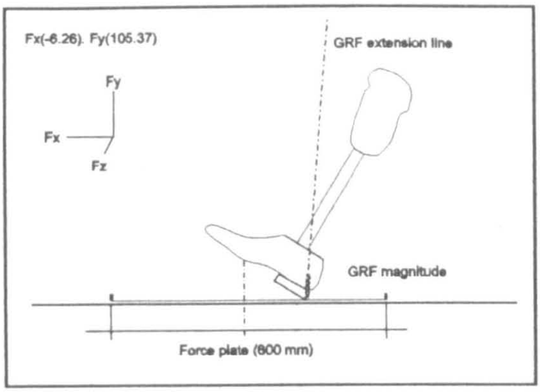

Medial Hydrocast pressure
step M7
kPa
90
80
70
60
50
40
30
20
10
0
0.0
0.2
0.4
0.6
0.8
1.0
M7
average

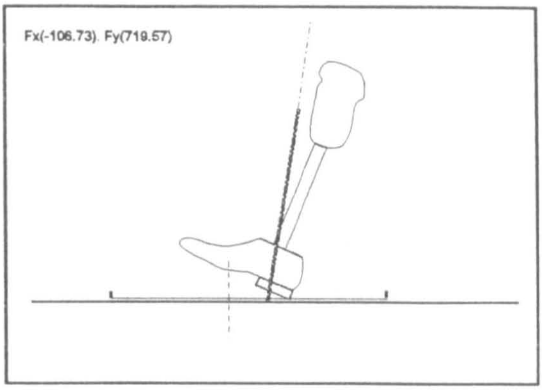

Lateral Hydrocast pressure
step L7
kPa
90
80
70
60
50
40
30
20
10
0
0.0
0.2
0.4
0.6
0.8
1.0
L7
average

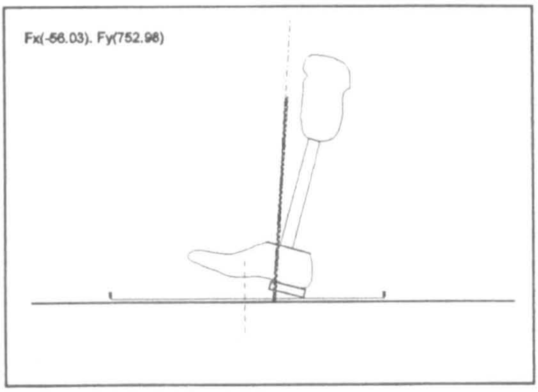
Appendix 5.7.

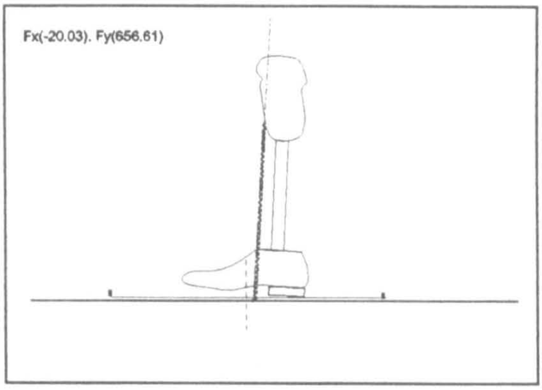
Interface pressure distribution results and force vector position.

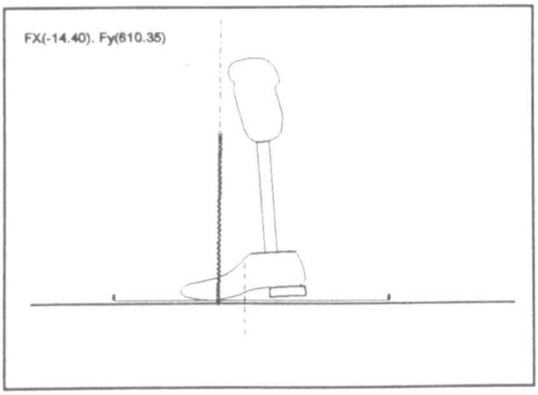
GRF position relative to the PTB prosthesis.

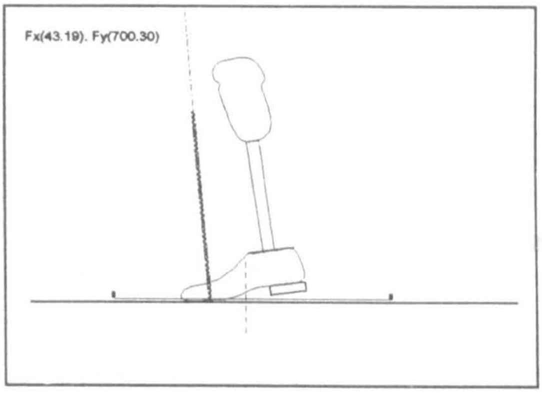


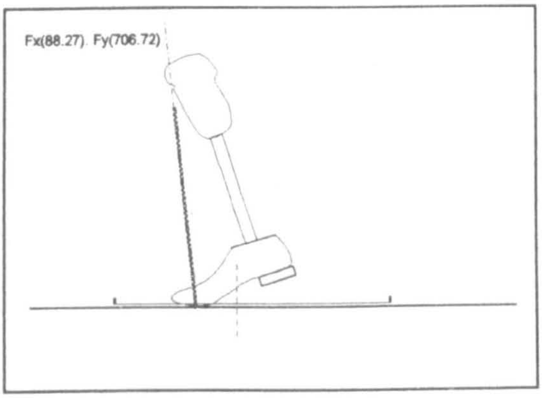


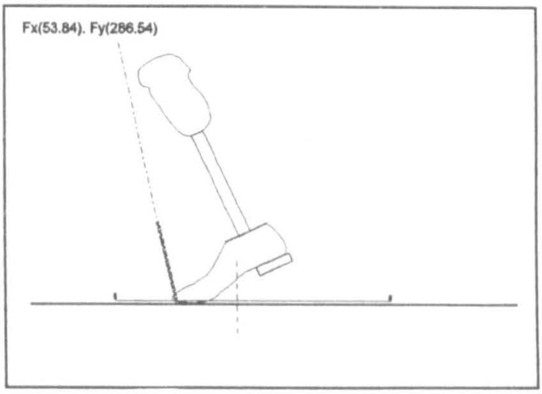




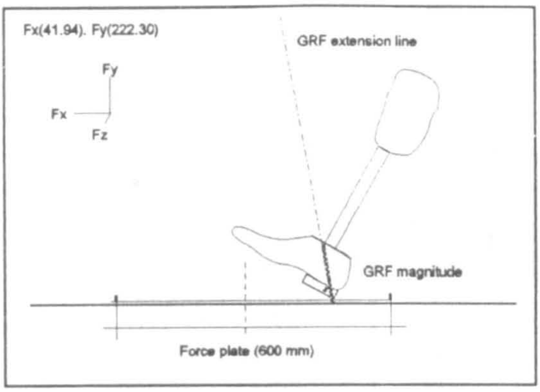


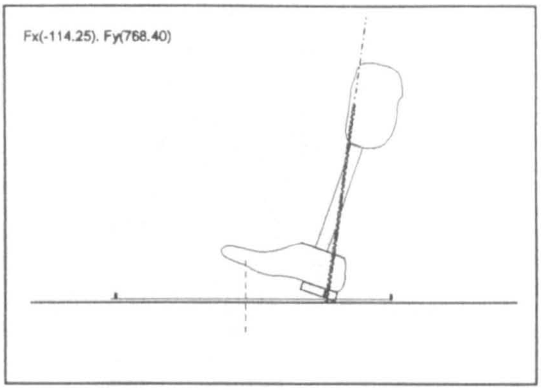


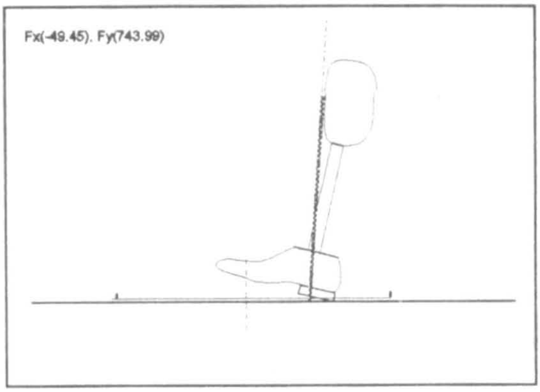


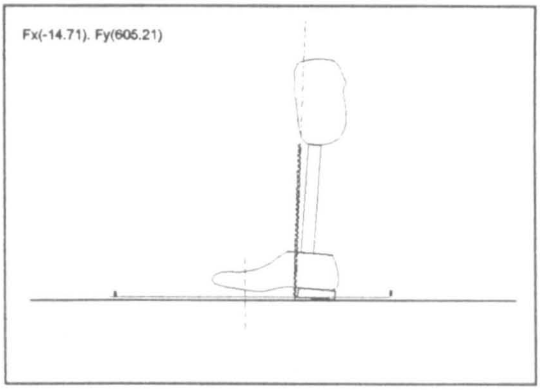


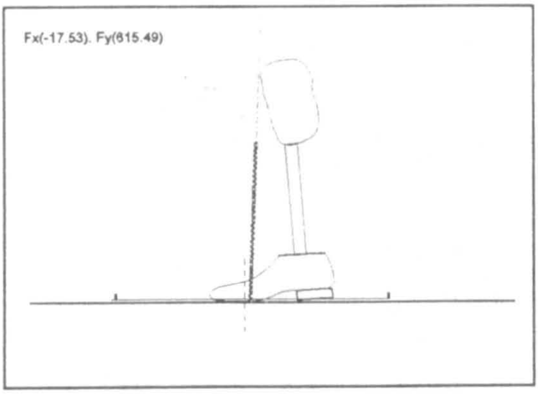
GRF position relative to the Hydrocast socket

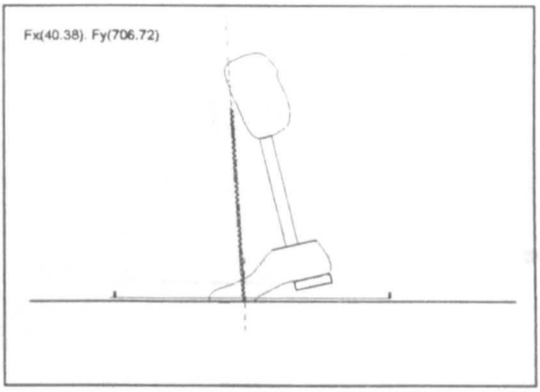


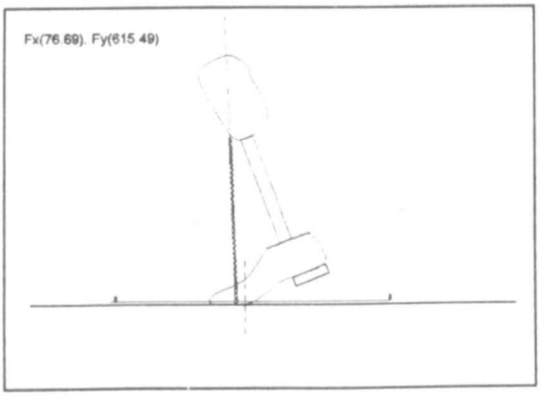


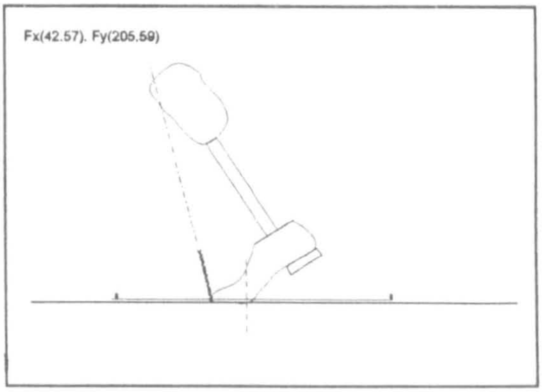




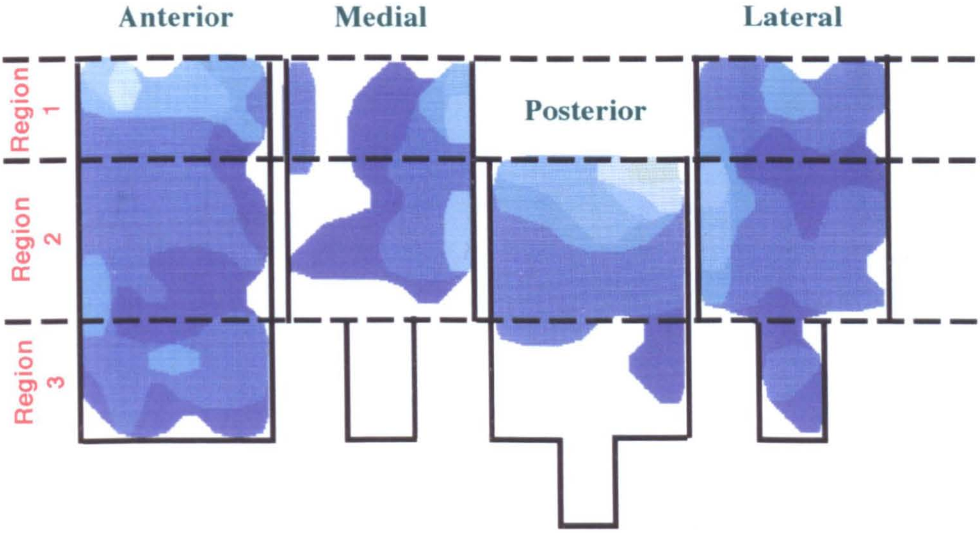




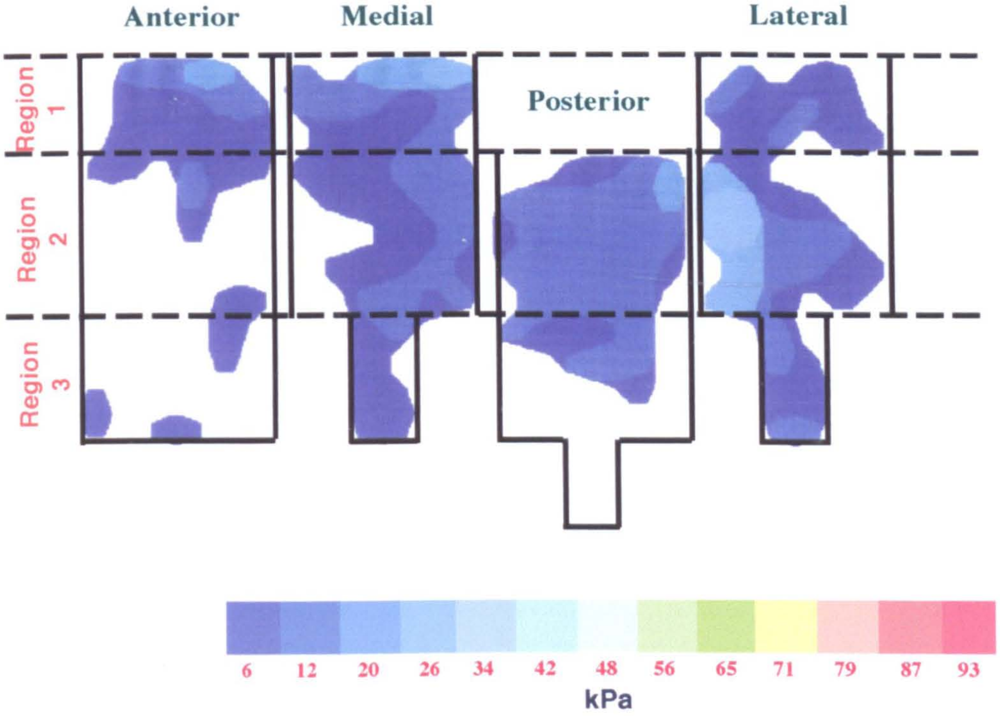




PTB Frame 1



Hydrocast Frame 1



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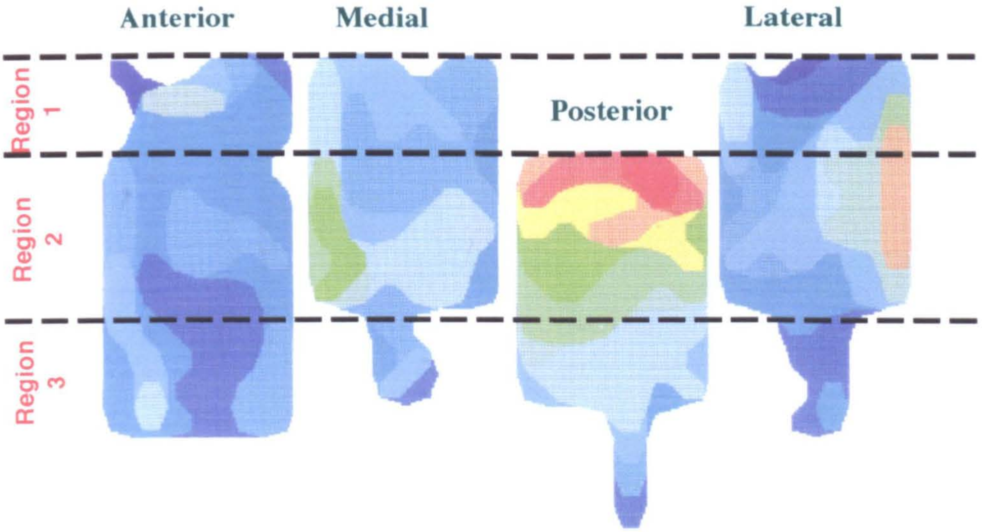
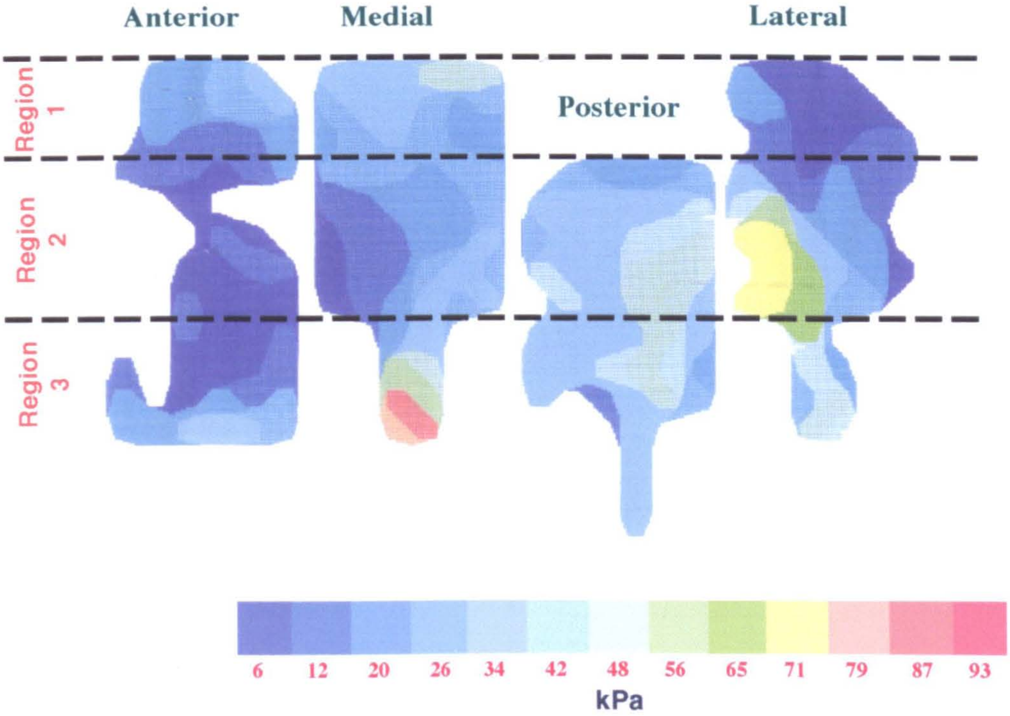
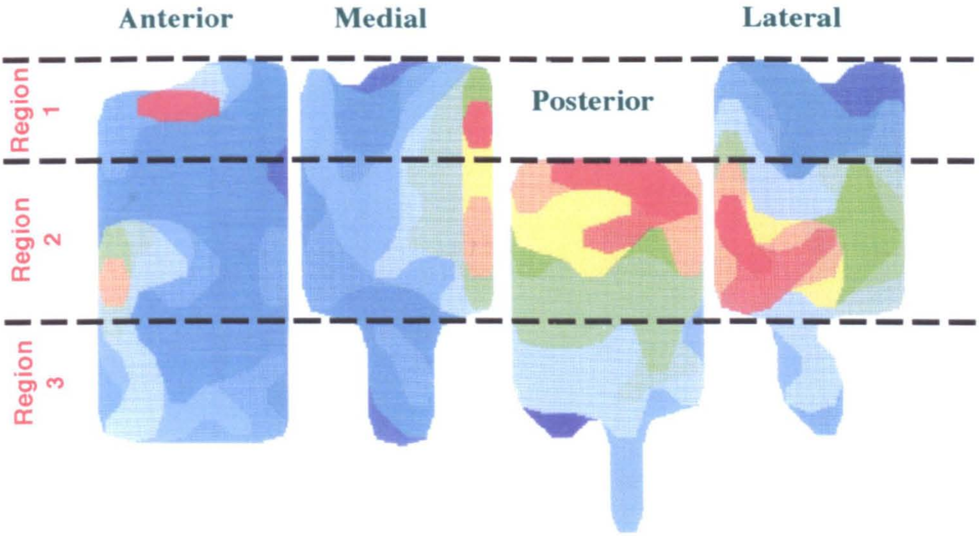
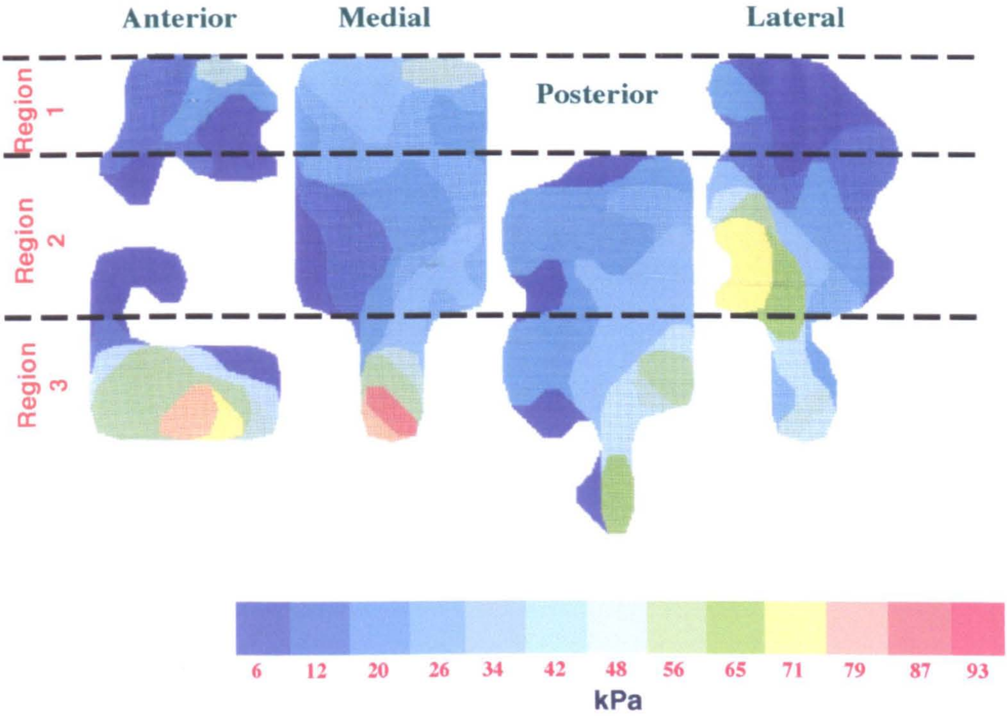


Hydrocast Frame 2



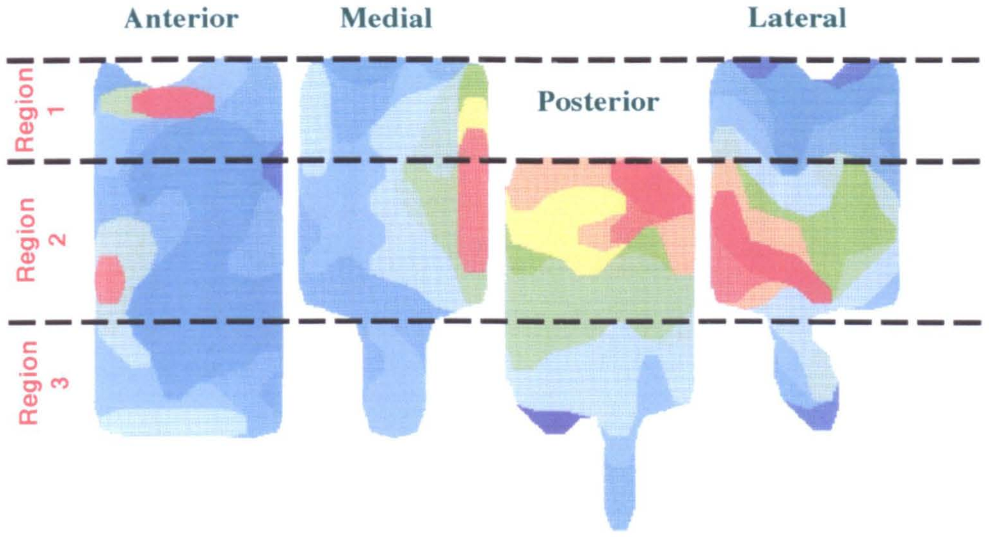


PTB Frame 3

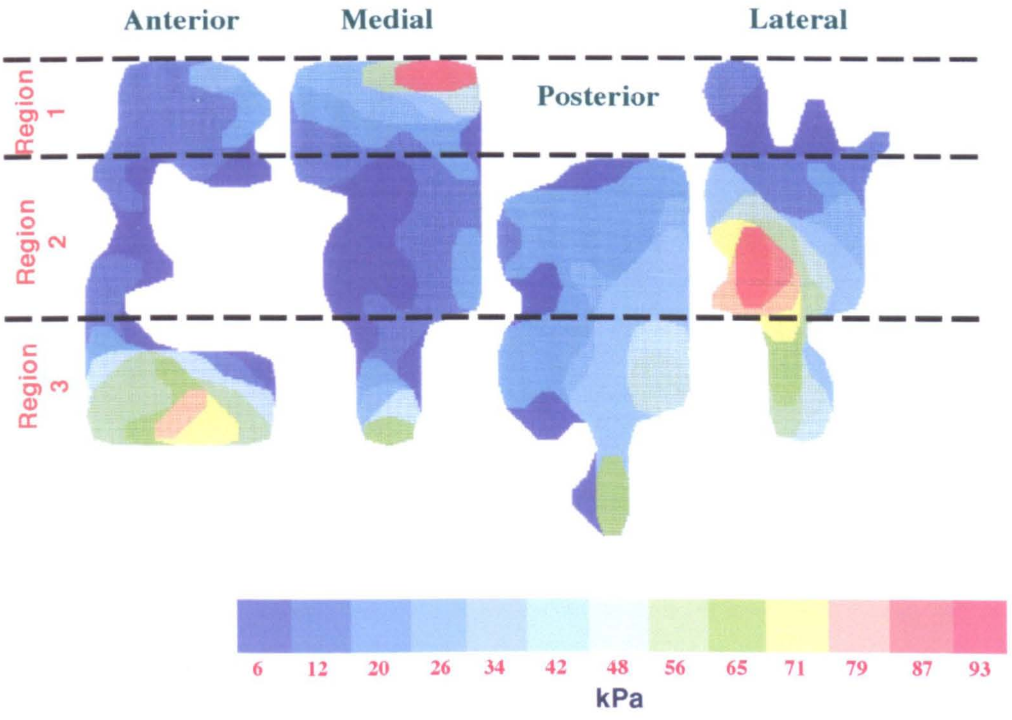


Hydrocast Frame 3

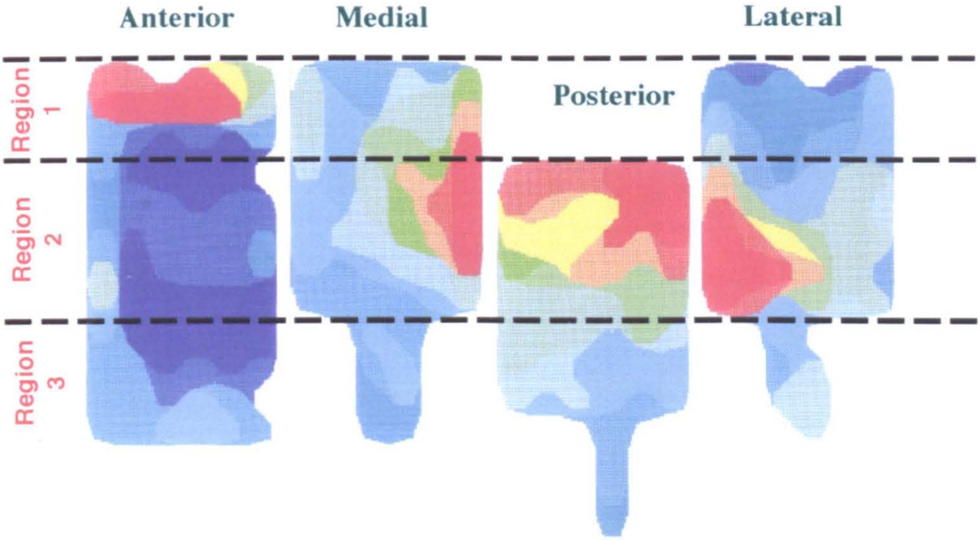
PTB Frame 4



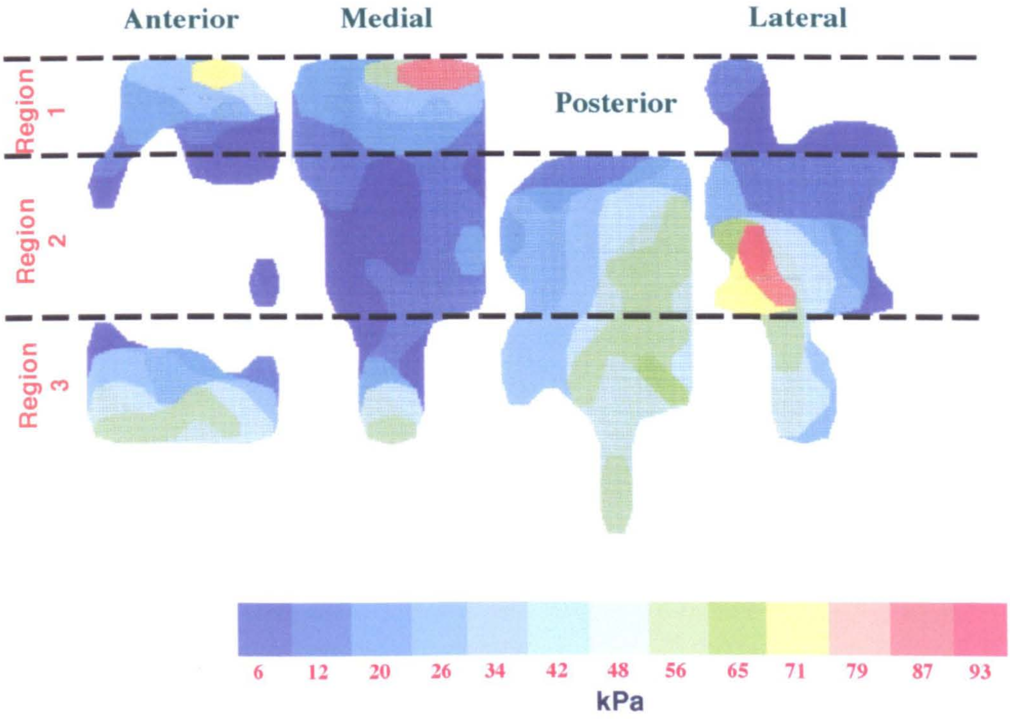
Hydrocast Frame 4



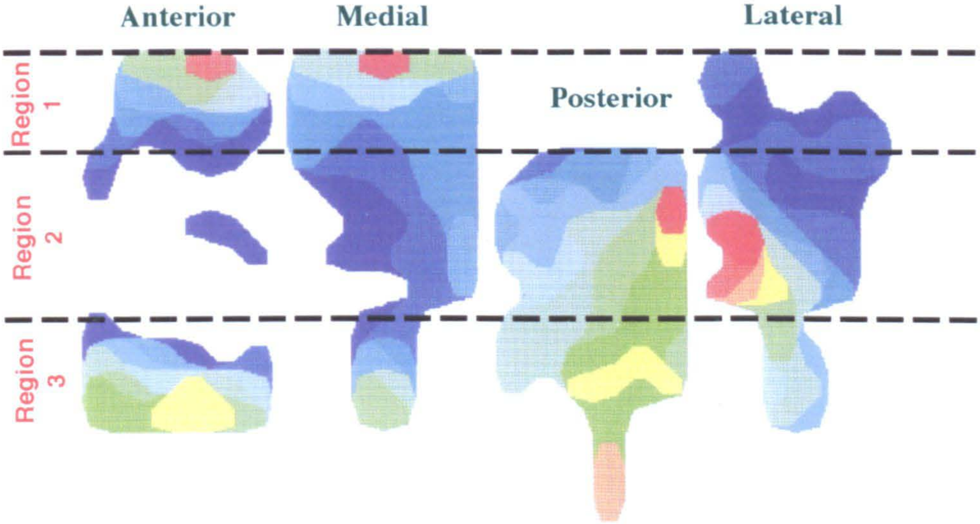
PTB Frame 5



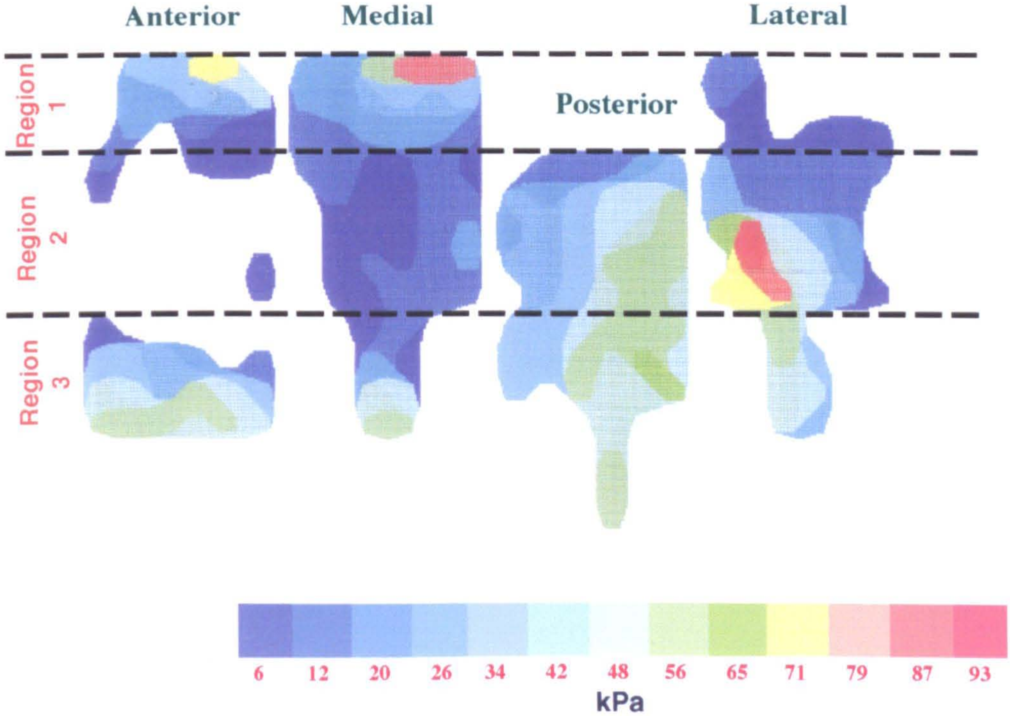
Hydrocast Frame 5



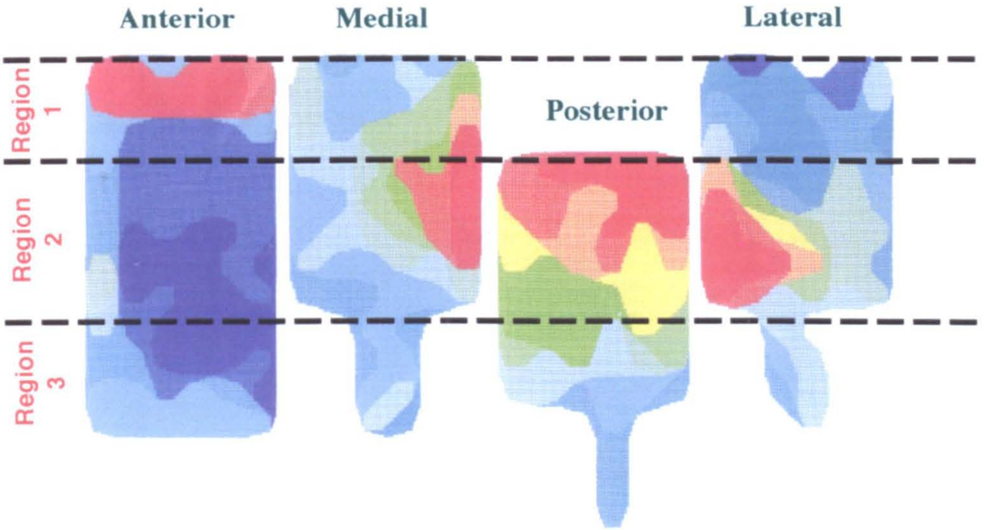
PTB Frame 6



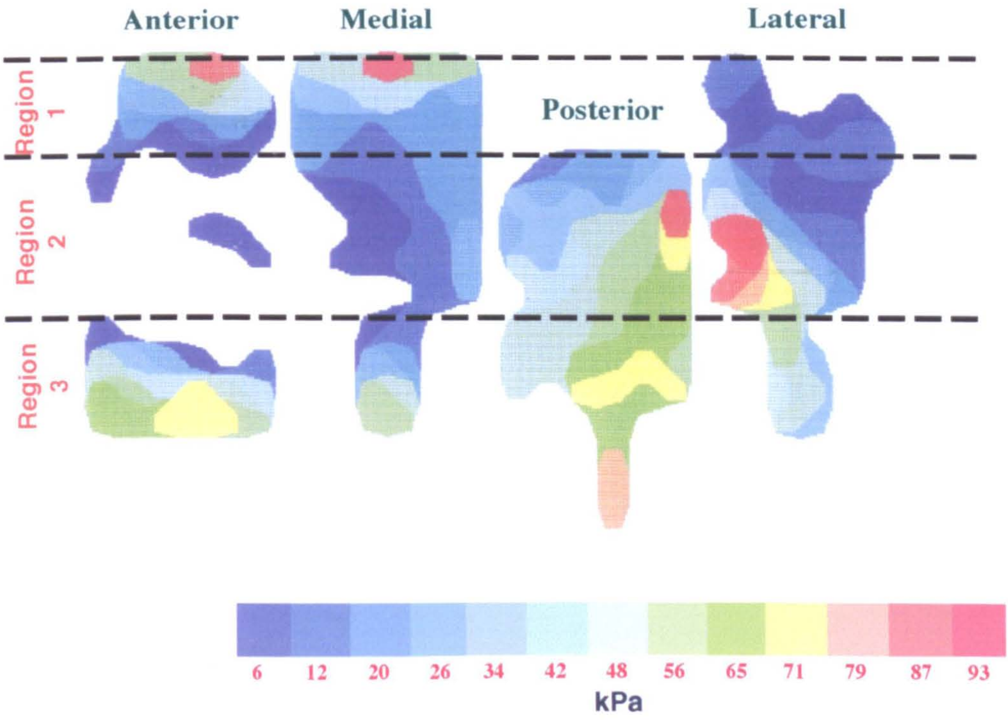
Hydrocast Frame 6



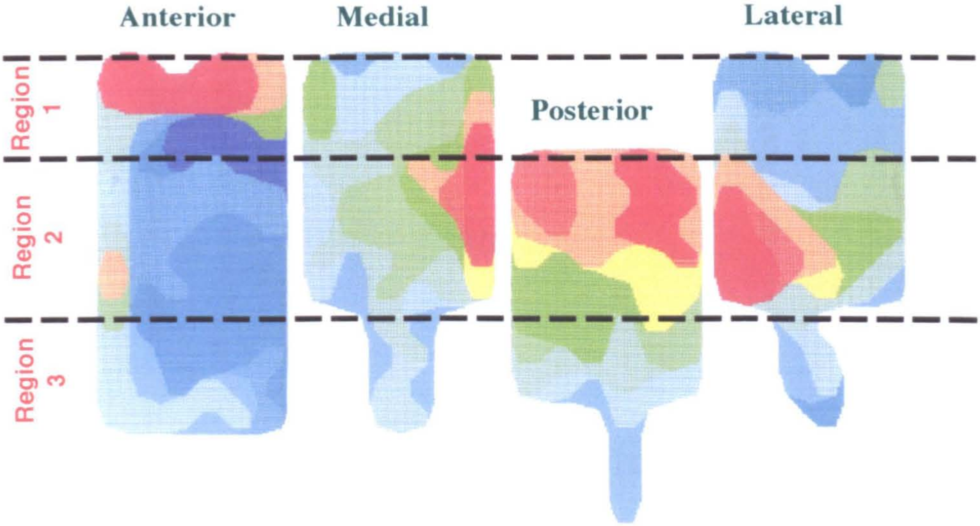
PTB Frame 7



Hydrocast Frame 7



PTB Frame 8



Hydrocast Frame 8