Material Fatigue in the Prosthetic SACH foot: Effects on Mechanical Characteristics and Gait

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ABSTRACT

The effects of material fatigue on the prosthetic foot appear to have received little attention. The purpose of this study was to examine fatigue effects in terms of their influence on amputee gait. It was hypothesised that the mechanical characteristics of the prosthetic SACH feet would be compromised after fatigue loading and that the artificial 'aging' of these feet would influence biomechanical characteristics of gait. Kingsley SACH type KO51 and Otto Bock SACH type 1S49, right side, size 26, were tested. Three specimens of each were fatigued by a cyclic tester which approximated forces on the foot during the gait cycle. Static compliance of the heel and forefoot was measured and impact tests were performed to evaluate the shock absorption capacity of the prosthetic feet. Four trans-tibial amputees were recruited and each fitted with new and fatigued prosthetic feet of both types. Temporal data was collected via the Stride Analyser System and ground reaction force data was obtained using a Kistler force platform. A two-way (foot type x foot age) repeated measures ANOVA was performed. The Kingsley prosthetic feet were found to undergo premature delamination and failure without the recommended interface plate between the foot and the pyramid adapter. Further tests incorporating an interface plate solved this problem. Drop test results indicated that Kingsley feet provided significantly better shock absorption and that shock absorption increased with a minimal amount of fatigue. The Otto Bock feet were significantly stiffer in the heel region at each level of fatigue, while the Kingsley feet were significantly stiffer in the forefoot region. Both brands of feet followed a similar trend of an initial increase in stiffness after 5,000 cycles, then a decrease after 10,000 cycles. The mean duration of the heel loading phase of the 'new' Kingsley test sample was significantly longer than the fatigued test sample. It was also demonstrated that as the stiffness of the rearfoot increases, so does the duration of the loading phase ($r = 0.952$).
STATEMENT OF AUTHORSHIP

This thesis contains no material published elsewhere or extracted in whole or part from a thesis by which I have qualified for or been awarded another degree or diploma.

No other person's research has been used without due acknowledgment in the main text of the thesis.

This thesis has not been submitted for award of any degree or diploma in any other tertiary institution.

All the subject testing procedures reported in this thesis were approved by the Faculty Human Ethics Committee, Faculty of Health Sciences, La Trobe University.

Signature .................................

Date .................................
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CHAPTER 1
INTRODUCTION

The effects of material fatigue on the prosthetic SACH foot appear to be relatively unknown. Limited previous investigations conducted by Daher (1975), Wevers and Durance (1987), and Toh et al (1993) focused upon mechanical characteristics of the prosthetic feet and did not analyse fatigue in terms of its influence upon the amputee's gait. Each of these studies continued the fatigue process until failure of the prosthetic feet occurred.

Currently it appears that prosthetists within Melbourne facilities determine when a prosthetic SACH foot should be replaced based substantially upon cosmetic reasons. It seems that little emphasis is placed upon the biomechanical effects of the 'aged' prosthetic SACH foot.
CHAPTER 2
LITERATURE REVIEW

RECOGNISED STANDARDS FOR PROSTHETIC COMPONENTS

Various test standards exist for lower limb prostheses and their components to ensure they are structurally adequate for use by the amputee. The main standards which are currently referred to in research reports are the:

- ISPO Philadelphia 1977 recommendations,
- Draft ISO 10328 Standard,
- Final form of the ISO 10328 Standard,
- ISO 9000 Standard and derivatives, 9001, 9002.

The ISPO Philadelphia 1977 recommendations were a result of a conference of the International Society for Prosthetics & Orthotics held in Philadelphia in 1977 (Rehab Tech, 1995). The primary objective of the conference was to develop standard values and testing procedures for lower limb prostheses and their components. It gathered and assessed information from previous conferences to decide upon these standards.

The ISO DIS 10328 is a draft standard which developed from the work completed at the 1977 Philadelphia Conference (Rehab Tech, 1995). It was prepared by the International Organization for Standardization (ISO). This Standard is now superseded by the release of its final form - the ISO 10328 Standard, which was published in 1996.
The ISO 9000 and derivatives are a manufacturing quality standard, which is quite different to the aforementioned standards. It ensures that the manufacturing, supply and consistency of a component will be maintained (Rehab Tech, 1995). Only a few of the prosthetic componentry companies are ISO 9000 accredited.

The ISPO Philadelphia 1977 recommendations and the ISO 10328 standards involve numerous different structural tests to assess the physical and mechanical characteristics of the component/prosthesis.

The principle tests required for ankle-foot devices are the:

- Static proof test,
- Static failure test &
- Cyclic test.

The static proof test and the static failure test assess the structural strength of the ankle-foot device by applying specified loads, according to the particular standard, to the heel and forefoot area of the foot. Two test samples must withstand the static proof test without fracture or failure to function and then continue to the static failure test which records the maximum test force reached before failure and notes what type of failure occurs (International Organization for Standardization, 1994). However, it is the cyclic test which is most relevant to the fatigue process of a prosthetic foot.

For the cyclic test to be conducted the test sample (prosthetic foot) must be correctly aligned within the testing equipment. Alternating forces are then applied to the heel and forefoot at a specified frequency of between 0.5 Hz and 3 Hz (International Organization for Standardization, 1994). The wave form must be inspected and the test continued until failure occurs or $2 \times 10^6$ cycles (according to the ISO 10328 standard) for both the heel and
forefoot. If requested, the test sample is examined at X4 magnification for the inspection of any cracks present (International Organization for Standardization, 1994).

Once the cyclic test is completed, a final static force is applied to the heel and forefoot area and maintained for 30 seconds (International Organization for Standardization, 1994). The whole procedure is then completed on a second test sample. The cyclic test analyses the durability and fatigue characteristics of the prosthetic foot.

Although these different structural tests and standards have been developed for the prosthetic industry, there is currently no legal requirement of compliance before components are able to be sold. Therefore, currently any prosthetic component can be applied to a patient's prostheses without complying to any one of the above mentioned standards.

THE PROSTHETIC SACH FOOT

The Solid-Ankle-Cushion-Heel (S.A.C.H.) Prosthetic Foot is still one of the most commonly prescribed prosthetic feet in Australia today (Private Communication 1.). Since it was developed in the early 1950's by the University of California, Berkeley, (Radcliffe & Foort, 1961) various other types of prosthetic feet have been designed and are available in Australia, including uniaxial, multiaxial and energy storing feet.

The SACH foot is light in weight, relatively durable and inexpensive in comparison to other prosthetic designs. It is commercially available in various different shapes, heel heights, and cosmetic colors. There are no moving components within the SACH foot, and therefore little maintenance is required. It consists of a wooden keel embedded in a foam/rubber material. (Refer to Figure 2.1)
The density of the heel wedge can vary between soft, medium and hard according to the gait characteristics, activity level, age, weight and preference of the amputee. It is this heel wedge which absorbs a proportion of the transient shock of impact at heel-strike by compressing and allowing limited plantarflexion (Goh et al. 1984). The internal keel extends to the toe break and determines the resistance to dorsiflexion by the length of the keel, and the stability of the base of support by the width. (American Academy of Orthopaedic Surgeons, 1992.)

The SACH design was originally conceived for use with an exoskeletal prosthesis. Since then, only minimal changes in the design have occurred. Currently the majority of prosthesis' made in Australia are endoskeletal in design, however SACH feet are still quite
a popular type of prosthetic foot prescribed (Private Communication 1.). It is therefore recommended by the manufacturers and the local distributors that an interface plate, constructed from copolymer polypropylene or similar material approximately 6mm thick, be applied to the SACH feet in an endoskeletal prosthesis (Kingsley Mfg co.)

An interface plate is designed to be placed between the flat superior surface of the prosthetic SACH foot and the pyramid adapter (Figure 4.4). The plate must cover the entire ovoid shape of the superior mounting surface. A central hole within the plastic surface allows the ankle bolt to reach the pyramid adapter.

The purpose of the interface plate with endoskeletal prostheses is to distribute the forces encountered during the gait cycle more evenly within the prosthetic foot. The exoskeletal design which supports the entire superior surface of the prosthetic SACH foot by the ankle interface prevents the foam/rubber of the heel section from distorting proximally at heel-strike (Kingsley Mfg co.). When additionally contained within a shoe, the heel region has no option but to compress and absorb shock through the material. Without an interface plate applied to an endoskeletal system, it is found that shearing forces increase in intensity and cause early delamination of the foam/rubber from the keel and premature failure of the heel bumper. Despite the information advocating the use of an interface plate, prosthetists within Melbourne and Australia appear not to use them with the SACH foot in an endoskeletal prosthesis (Private Communication 1.).

From this author's experience, and that of colleagues, it is evident that the SACH foot is worn by Australian amputees for approximately 2 -3 years before being replaced, if not prematurely failing. The decision to prescribe a new foot is determined by any form of structural failure of the foot, breakdown of the material, cosmetic reasons, change in
medical condition or patient request. Currently, under the Victorian Artificial Limb Program (V.A.L.P.), an amputee is eligible to receive a new SACH foot after 3 years wear.

MECHANICAL TESTS APPLIED TO THE PROSTHETIC FOOT

Numerous investigations have analysed and compared different types of prosthetic feet by means of mechanical testing (e.g. Barr et. al., 1992, Ehara et. al., 1993, Menard et. al., 1992, Mizuno et. al., 1992, Torburn, et. al., 1990, Wirta et. al., 1991 etc.). Gait analysis, angular kinematics, kinetics, ground reaction force data, e.m.g's and metabolic function have all been utilised when comparing the performance of a prosthetic foot. All these different tests require the amputee to ambulate while wearing the prosthetic foot.

One important characteristic of a prosthetic foot is its ability to absorb the transient shock at heel-strike. When a limb is amputated, many important natural shock absorbers are lost, such as bone, the compressible heel pad and the subtalar joint which plays a significant role in damping shock (Arya, et al., 1995.).

For an amputee, the prosthetic foot must now take over the role of dissipating incoming forces at heel-strike. If the prosthetic foot insufficiently attenuates shock waves, negative consequences may develop throughout the rest of the body (Lafortune & Hennig, 1992, Light et. al., 1980, Voloshin & Wosk, 1982, Wosk & Voloshin, 1981). This could include an overload to the soft tissue of the stump and skeletal joints, low back pain and other similar symptoms due to the shock waves only beginning their process of dissipation at stump level, not foot level.

Various studies concerning the shock absorption capacity of various items, including prosthetic feet, calcaneal heel pads, shock absorbing materials, the influence of foot orthoses and footwear etc. have been performed in the last decade. Numerous approaches in the measurement of shock absorption were performed, however no one distinct method
within the published literature appears to be preferred. Each popular method will be briefly discussed within this chapter to provide an overview of the different methods used.

Several reports have analysed the shock absorbing potential of prosthetic feet when comparing and evaluating different types of commercially available prosthetic feet (van Jaarsveld et. al., 1990a, van Leeuwen et. al., 1990, Wirta et. al., 1991, Lehmann et. al., 1993a, Lehmann et. al., 1993b, Arya et. al., 1995). Most of the studies utilised an accelerometer mounted to the prosthesis to measure the shock waves transmitted through the prosthetic foot due to heel-strike while the amputee was walking. Both van Jaarsveld and colleagues and van Leeuwen and colleagues in 1990 measured the axial accelerations and dorso-ventral, otherwise known as tangential accelerations, at heel-strike via accelerometers when comparing prosthetic feet. Both reports did not confidently state which prosthetic foot had the best shock absorption capacity due to differing results within their experiment, although van Jaarsveld did point out that the choice of foot type influenced the magnitude of the accelerations in the axial direction.

Lehmann and colleagues in 1993 placed importance on the ability of the prosthetic feet to attenuate only high frequency vibration referred to as the shock factor. Johnson suggests this shock factor, which is the spectral content of the acceleration transient above 50 Hz corresponds to shock phenomena. Lehmann found in two different investigations that the SACH foot had the smaller shock factor, and is therefore less likely to transmit high frequency vibrations. In the second study, the Seattle Foot had the lowest shock transmission at running speeds.

Arya (1995) also found the SACH foot had a better shock absorption capacity when compared to different types of prosthetic feet. They found the difference in shock applied to the prosthetic feet by measuring the magnitude and rate of change of vertical ground reaction forces. The previous studies measured the shock transmitted through the prosthetic foot.
Subjective responses from Wirta and colleagues' investigation in 1991 illustrate that the preferred devices (prosthetic components below the socket) were the ones that developed the least shock and the greatest damping during walking. Results such as Wirta's, stress the importance of the shock absorption capacity of the prosthetic foot not only to prevent degenerative changes occurring in the remaining anatomical structures, but for the amputee's comfort and preference of prosthetic foot type.

All of these reports investigating either the shock transmitted, or the shock applied to the residual limb utilised amputees walking in a test environment. However, the reliability of drawing conclusions from gait cycle data alone has been questioned. Lees and Bouracier in 1994 report a 'movement pattern fixation' phenomena to occur while running. They found that in their investigation, 13 out of the 14 subjects tested displayed significant differences in one or more of the ground reaction force variables tested across three different test sessions while testing conditions remained the same. These interesting test results utilising the subject's running could possibly also be applied to walking. They report extreme caution should be exercised when interpreting gait test results and Seliktar and colleagues in 1979 also acknowledge that biases may exist when a subject is asked to target himself or herself upon a force plate.

It therefore seems that mechanical tests which can be performed in a more controlled environment, such as in a laboratory, would exclude subject variability. Jorgensen and Bojsen-Moller (1989) measured the shock absorbency of cadaver heel pads, EVA foam and Sorbothane via drop tests performed on a force plate. This controlled mechanical test provided relatively accurate results with 96% reproducibility of the measurements from the setup.

Noe et. al. (1993), and Retschko et. al. (1995), utilised a different type of controlled mechanical test to imitate heel impact when investigating the shock absorbing potential at the heel. It involved a pendulum with a fixed mass striking the distal aspect of the
calcaneus, while accelerometers recorded the transmitted shock at the heel and applied shock at the hammer.

A different controlled mechanical test performed by van Jaarsveld (1990b), measured the stiffness and hysteresis properties of prosthetic feet. These measurements were taken from a 3-D stiffness measuring device which varied the position of the foot to simulate normal walking, from -30°, representing heel-strike, to 35° representing toe off. Measurements were taken each degree providing a thorough analysis on the influence of footwear and comparison of the mechanical characteristics of different types of prosthetic feet. It was noted by van Jaarsveld in the introduction of his research report that, 'The influence of the mechanical properties of the prosthetic foot on different aspects of gait is not yet fully understood,' and only briefly attempted to explain how a difference in stiffness and hysteresis of the prosthetic foot would alter the gait cycle. However only controlled mechanical tests were performed, there were no amputee subject tests to confirm these comments.

Lehmann and colleagues in 1993, within two separate reports, conducted a similar analysis determining the load vs. deflection (compliance) of prosthetic feet via a static loading machine. Measurements were only obtained at the heel and forefoot area of the prosthetic foot, however actual subject testing was conducted to relate the results found by the mechanical tests directly to the amputee's gait cycle.

Both investigations found the heel of the SACH foot to be more compliant in comparison to other different types of prosthetic feet. Lehmann endeavored to explain how a difference in compliance would affect the amputee's gait cycle. He concludes that because the heel of the SACH foot is 'softer', it compresses more allowing the centre of pressure to move further forward and in turn causing the ground reaction force line to come closer to the knee, thus reducing the knee moment. He states that the heel-strike phase (the percentage of the gait cycle between heel-strike and toe strike) should also be shorter with the more compliant heel.
Compliance of the heel of prosthetic SACH feet was determined by Goh and colleagues in 1984, and Skinner and colleagues in 1985. However, the measurements recorded were not related back to the amputee’s gait. Goh observed that for a particular amputee, the heel stiffness preferred for the uniaxial feet was always more stiff than that of the preferred SACH foot according to the load vs. deflection graph. While Skinner noted a constant static response of the "medium" and "regular" grades of the foot, suggesting consistency in the static response performance of the grades, and among manufacturers.

THE EFFECTS OF FATIGUE ON THE PROSTHETIC FOOT

The durability and fatigue characteristics of the prosthetic foot are very important when deciding which type of prosthetic foot to prescribe for a particular patient. Therefore a number of studies have cycled prosthetic feet to assess their durability and wear via a cyclic tester which mimics natural gait (Burgess et. al., 1985, Daher, 1975, Rehab. R & D Eval. Unit, 1991, Wevers & Durance, 1987).

In 1975 Daher conducted an extensive investigation in which nine types of SACH feet were subjected to cyclic testing to assess the durability of the materials and design of the foot. Unless breakdown occurred, the foot was cycled for 500,000 cycles at a load which simulated an active amputee weighing approximately 100 kg. Daher found that major permanent deformation and changes in resistance at the heel occurred within only 5,000 cycles.

Wevers and Durance in 1987 also conducted dynamic testing on prosthetic SACH feet, but they loaded the whole trans-tibial prostheses not the foot alone. Their results were similar
to Daher's with rapid wear and structural component failures of the feet at less than 100,000 cycles.

However their testing protocol differed to Daher's and this would influence the results obtained. Wevers and Durance chose not to put footwear on the prosthetic feet like Daher did, because they reported shoes altered the characteristic of the feet, but did not explain how they actually did so. Also due to the variety of shoes available it was thought meaningless. Nevertheless, the SACH foot is designed to be worn with a shoe. The profile of the foot takes into account the heel height of the shoe worn. It is questionable if the applied forces during fatiguing adequately mimic those of gait with no footwear.

A more recent study evaluating the fatigue testing of energy storing prosthetic feet by Toh and colleagues in 1993 utilised a simple machine which did not mimic gait but applied cyclic vertical loads to the heel and forefoot only. The feet were dynamically tested for 500,000 cycles and the load chosen was 1.5 X the body weight of the amputee. They found this simple, inexpensive approach to cyclic testing produced similar results to those from the more complex machines. Toh found that the Lambada feet displayed excellent fatigue properties with only minimal permanent deformation.

The ISPO 1977 Standards recommend that the maximum frequency for cyclic tests should be 1 Hz for assemblies containing non-metallic components. Wevers and Durance and, I believe, Daher both set their cyclic testing frequency at 1 Hz, however Toh and colleagues set their loading frequency at 2 Hz to shorten the duration of the test. Wevers and Durance report that if the frequency is set higher it could influence the samples breakdown in fatigue, due to affects such as heat generation, and therefore alter Toh’s results.

Static compliance tests, previously mentioned as being mechanical tests which are utilised to compare and analyse prosthetic feet, were performed within Daher's and Toh's studies.
They were conducted at the same time intervals throughout the cyclic testing, - after 5,000, 10,000, 20,000, 50,000 cycles and at each additional 100,000 cycles. Both Daher and Toh found changes in resistance in the prosthetic foot very early on in the cyclic testing.

Unlike Daher's and Toh's study, Wever's and Durance tested multiple feet of the same design. Four different types of SACH feet were tested with four specimens each. Interestingly, the number of cycles to breakdown varied quite significantly between each of the four specimens of the same style. For example, the average life of the Otto Bock feet was 43,800 cycles with a standard deviation of 12,900 cycles for the four specimens. Perhaps if Daher and Toh had tested multiple feet of the same design, obtaining an average result between each style, it would have an effect on their conclusion.

X-rays of the SACH feet taken prior to and upon completion of fatigue testing are an effective way of observing internal physical breakdown. Both Daher and Toh utilised x-ray equipment to gain further insight into the changes which had occurred after fatigue testing. Daher found four out of the nine different types of SACH feet had undergone delamination of the foam from the keel after the cyclic testing, while Toh also reported delamination occurring in the Proteor SACH foot.

Other than static compliance tests, no other type of mechanical test was applied to the prosthetic feet once they were fatigued or during the process of cyclic testing.

Fatigue testing of prosthetic components is also mentioned within two different published reports describing the development and evaluation of the VA Seattle Foot and the VA Seattle Ankle. (Burgess et. al., 1985, Rehab. R&D Eval. Unit., 1991). Both groups of researchers stressed the importance of testing the durability of the prosthetic components. The report on the VA Seattle Foot explained how it also obtained load-deflection
characteristics as a part of the structural analysis to develop the right combination of thermoset and thermoplastic matrices and reinforcements.

A report by Kabra et. al. 1991 utilised a simple, low cost machine to fatigue the Jaipur Foot, similar to Toh's device, however it appears to only simulate forefoot loading. A load-deflection analysis was also performed using a sling which passes around the foot, connects to a spring balance and reads the net acting force while the degree of movement was read from a goniometer. The authors report these simple testing machines deliver reproducible results and is yet another method of laboratory testing which should be considered. Like all of the other reports conducting fatigue tests on prosthetic feet, there was no analysis of gait variables or other mechanical tests once the cyclic testing was completed.

Shock absorption has been acknowledged as an important feature when comparing different types of prosthetic feet. There is much doubt of the reliability of measurements taken from gait tests alone due to the subject altering their gait style when being analysed in the laboratory setting and accommodating to different prosthetic componentry. For this reason some investigators have performed static mechanical tests to avoid variability introduced by a subject (Jorgensen and Bojsen-Moller, 1989, Noe et. al. 1993, Retschko et. al. 1995). However, there currently appears to be no measurement of shock absorption with controlled mechanical tests for comparison between differing prosthetic feet.
Limited previous investigations have been conducted that focused upon mechanical characteristics of the prosthetic foot. Each of these studies continued the fatigue process until failure of the prosthetic foot occurred. They did not analyse fatigue effects in terms of their influence upon the amputee gait. The purpose of this study was to examine these effects.

It was hypothesised that:

1) The mechanical characteristics of the prosthetic SACH feet would be compromised upon completion of the fatigue test, reflected in the load Vs deflection analysis.

2) The heel bumper material of the prosthetic SACH feet would deteriorate after the fatigue loading, effecting its ability to attenuate shock waves at heel-strike.

3) The artificial 'aging' of the prosthetic SACH feet would influence several biomechanical gait parameters such as temporal gait characteristics, and forces generated during the stance phase.

In order to test these hypotheses, prosthetic SACH feet were aged by means of a cyclic tester and mechanical behaviors of the prosthetic feet were analysed during the fatigue loading process. Subsequent biomechanical gait tests were performed with the new and fatigued prosthetic feet samples. Relationships were established between the controlled mechanical tests and biomechanical aspects of gait.
CHAPTER 3
METHOD

INTRODUCTION

In order to fatigue the prosthetic SACH feet, a reliable machine which mimicked the loads applied to the foot during the walking cycle was used. The fatigue tester was suitable for this investigation as it applied forces approximating ground reaction forces for the normal walking cycle. It allowed differing magnitudes of downward forces to be applied, control of the stride frequency and the opportunity to interrupt or stop the cycling procedure at any time.

At periodic intervals the foot was removed from the apparatus and subjected to two different types of controlled tests. One test measured the compliance of the prosthetic foot at the heel and forefoot on an electromechanical universal testing machine, while the other measured an impact force via a controlled laboratory test. These objective, mechanical tests were performed upon the prosthetic feet to provide reliable, reproducible results which provide a control for the influence of external factors.

Similar cyclic testing and measuring of compliance of prosthetic feet has been performed in previous investigations (Daher, 1975, Wevers and Durance, 1987, Toh et al, 1993) however, there was no discussion of how this fatigue process could affect the amputee's walking cycle. It was therefore decided to recruit subjects in this investigation to link the results from the controlled mechanical tests to the results from biomechanical gait tests upon the subjects.
THE FATIGUE TESTER

The fatigue tester, or cyclic machine as it is sometimes known, was designed to test differing prosthetic componentry, assemblies and materials, for various purposes. It differs from the machine described within the ISO (International Standards Organisation) prosthetics standards, in that it mimics the gait cycle more accurately. These standards were introduced to maintain the quality and safety of componentry within the prosthetic industry. Subjecting a particular component to a fatigue test is a reliable way to determine the life of the component and the specification of loads that can be applied safely during the simulated gait cycle.

The fatigue tester applies a fluctuating load to approximate the gait cycle as closely as possible. The direction of application of the force, with respect to the test specimen, is also constantly changing as the prosthesis is moving, to simulate the moments placed upon the componentry during the normal walking cycle.

Figure 3.1 displays the fatigue tester from the frontal view. The machine consists of a metal frame which supports the weights that apply the load to the test specimen. The cross head, positioned over the treadmill, moves up and down at a rate which is determined by the rotational frequency of the cam wheels. The up and down motion causes an oscillating load to be applied to the foot while the treadmill is running.

A conventional prosthetic component, a pyramid adapter, is attached to the cross head. Below this is a hinge joint which allows free movement of the test specimen in the sagittal plane. An Otto Bock modular pylon, which represents the 'leg', is connected to both the hinge joint and the prosthetic SACH foot via pyramid adapters.
Figure 3.1. The fatigue tester
(At all times during the investigation, all screws within the pyramid adapters were tightened to the recommended torque, 15 Nm, and the ankle bolt connecting the SACH foot to the pyramid adapter was continually tightened to the recommended torque of 20 Nm.) A magnet is used to hold the prosthetic foot clear of the treadmill belt during mid-swing phase to ensure a regular gait (a quicker swing phase) before heel-strike occurs again.

The number of cycles completed by the test specimen is recorded by a counter which records the number of revolutions of the cam wheels. The frame and associated componentry weighs 37 kg. Extra weight can be applied to the test specimen above the frame. In this investigation an extra 60 kg was added to the machine, simulating the fatigue process upon the SACH foot by a person weighing approximately 97 kg.

Previous tests conducted at Rehab-Tech, have shown that the downward force applied by the fatigue tester is approximately 1.3 X the weight over the cross head during loading phase. This force decreases during midstance, then increases once again during push-off. The downward applied force, varies slightly with the frequency of the test.

The frequency of the cyclic loading can also be easily manipulated by changing the speed of the treadmill. The recommended frequency within the ISO standards is 1 Hz (60 strides per min.) Any frequency higher than this (Wevers and Durance, 1987) can accelerate the fatigue process and the results will not be representative of true fatigue at normal walking velocities. Higher frequencies can cause the generation of excessive heat within the test prosthetic foot and hence hasten fatigue. The frequency was to be 1 Hz for these tests, however the test prosthesis did not swing through quick enough during swing phase, therefore the frequency was lowered to 0.83 Hz (50 strides per min.) to allow adequate time for the prosthetic foot to clear the treadmill before heel-strike.

THE COMPLIANCE TESTING MACHINE
The electromechanical universal testing machine, (Instron TTBL), was used within this investigation to record the load-deformation response of the SACH feet. This testing device can measure tension, and in this particular case, compression. Figure 3.2 illustrates the apparatus.

Figure 3.2. The electromechanical universal testing machine
The crosshead is set at a constant speed, for this particular type of test 5cm/min was chosen, and the chart is set at a constant speed, for this test 10 cm/min was chosen. As a downward load is applied, the strain-gauge bridge in the load cell undergoes a change in resistance, an amplifier magnifies the response, which drives the pen across the chart, producing a load vs. displacement graph.

The test prosthetic feet were attached to an Otto Bock modular pylon, (via the ankle bolt and pyramid adapter) which was attached to the test jig (via a pyramid adapter), which was in turn securely attached to the crosshead. Measurements were recorded at both the heel and the forefoot of the prosthetic feet. Measurements at the heel were taken at a 20 degree angle to the load cell, representing the loading phase of the gait cycle (Figure 3.3), and the forefoot measurements were initially also taken at a 20 degree angle to the load cell, representing the push off phase, but as the load was applied the prosthetic forefoot did dorsiflex at the toe-break region (Figure 3.4).

Prior to each testing session the machine was calibrated using weights of a known mass.
Figure 3.3. Measurement of compliance at the heel region

Figure 3.4. Measurement of compliance at the forefoot region
THE TEST PROSTHETIC FEET

The prosthetic SACH foot brand and style chosen for analysis were the Otto Bock -Style 1S49, and the Kingsley -Style KO51. After an informal survey of various prosthetic facilities in Melbourne, these two styles appeared to be the most commonly prescribed SACH feet. Sales figures from the Australian distributor of the Otto Bock prosthetic feet confirmed that style 1S49, size 26, right was the best-selling size and side. Therefore this was the side and size purchased for ease of subject selection. Otto Bock style 1S49 is commercially available with medium heel density, and therefore the Kingsley style KO51 was also ordered with medium heel density. The Kingsley prosthetic foot is commercially available in soft, medium and hard heel density.

The main difference between the two different brands and styles of SACH feet chosen for analysis is that the Kingsley SACH style KO51 consists of an open-cell Medathane™ material of varying density. While the Otto Bock style 1S49, consists of a polyurethane body with a closed cell material covering the entire outer surface of the prosthetic SACH foot. Due to the external covering on the Otto Bock prosthetic feet, which could possibly disguise internal failures, the prosthetic feet were cut longitudinally from the mid-heel to the mid-second metatarsal after fatigue loading to identify any internal changes in the prosthetic feet.

Both the Otto Bock -Style 1S49 and the Kingsley -Style KO51 have a 10mm heel height which allowed interchanging of the prosthetic feet without altering the alignment of the subject's prosthesis.

The mass of each prosthetic foot was recorded (Table 3.1). The variance in weight illustrates slight manufacturing differences between the individual samples.
<table>
<thead>
<tr>
<th>TEST SAMPLE</th>
<th>MASS (GMS)</th>
<th>TEST SAMPLE</th>
<th>MASS (gms)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Otto Bock 1.</td>
<td>465</td>
<td>Kingsley 1.</td>
<td>512</td>
</tr>
<tr>
<td>Otto Bock 2.</td>
<td>463</td>
<td>Kingsley 2.</td>
<td>528</td>
</tr>
<tr>
<td>Otto Bock 3.</td>
<td>467</td>
<td>Kingsley 3.</td>
<td>524</td>
</tr>
<tr>
<td>Otto Bock 4.</td>
<td>480</td>
<td>Kingsley 4.</td>
<td>523</td>
</tr>
<tr>
<td>Otto Bock 5.</td>
<td>455</td>
<td>Kingsley 5.</td>
<td>519</td>
</tr>
</tbody>
</table>

Table 3.1 The mass of the individual test prosthetic feet

Despite the information supporting the use of an interface plate with the endoskeletal system (refer to literature review - the prosthetic SACH foot), many prosthetists within Melbourne and Australia do not use one. As the aims of this investigation are directed towards the clinical aspects of the prosthetic industry, it was decided to test the prosthetic feet without the interface plate as this appears to be standard practice (Private Communication 1.).

SUBJECTS

Four subjects were recruited from the definitive program of Caulfield General Medical Centre with permission from the treating prosthetists and Rehabilitation Specialist. Selection criteria required:

- Trans-tibial amputation of the right lower-limb
- A size 26 prosthetic foot
- A relatively constant and established gait pattern
- No gait aids required for walking
- No significant medical problems other than the amputation
Originally it was hoped to recruit subjects with a prosthetic SACH foot on their existing prostheses so they would be familiar with this type of prosthetic foot and time for familiarisation would be reduced. However, this proved to be difficult as patients who attended Caulfield General Medical Centre with a prosthetic SACH foot were either elderly patients who required gait aids to assist their gait cycle, or new amputees within the interim program still learning how to walk correctly with a prosthetic leg. It was found that many of the patients that originally had worn a prosthetic SACH foot had progressed to wearing uniaxial, multiaxial or energy storing feet. Therefore only one subject was found with an existing prosthetic SACH foot on their prostheses, while the others had Seattle ankles. Table 3.2 lists the subjects’ characteristics, while Table 3.3 lists the differing componentry within the subjects existing prostheses.
<table>
<thead>
<tr>
<th>Subject</th>
<th>Sex</th>
<th>Age (yrs)</th>
<th>Weight (kgs)</th>
<th>Cause of amputation</th>
<th>Time since amputation (yrs)</th>
<th>Medical condition</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>M</td>
<td>50</td>
<td>90</td>
<td>Trauma</td>
<td>16</td>
<td>Good</td>
</tr>
<tr>
<td>2</td>
<td>M</td>
<td>40</td>
<td>80</td>
<td>Infection</td>
<td>1.6</td>
<td>Good</td>
</tr>
<tr>
<td>3</td>
<td>M</td>
<td>62</td>
<td>96</td>
<td>Cancer</td>
<td>4.1</td>
<td>Good</td>
</tr>
<tr>
<td>4</td>
<td>M</td>
<td>84</td>
<td>57</td>
<td>Circulatory Disease</td>
<td>2.5</td>
<td>Monitoring of blood pressure</td>
</tr>
</tbody>
</table>

Table 3.2. Subject characteristics.

<table>
<thead>
<tr>
<th>Subject</th>
<th>Type</th>
<th>Age of prosthesis (months)</th>
<th>Prosthetic foot type</th>
<th>Socket</th>
<th>Suspension</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Endoskeletal</td>
<td>18</td>
<td>Otto Bock SACH - 1S70</td>
<td>Laminated resin, kemblo liner</td>
<td>PTB cuff</td>
</tr>
<tr>
<td>2</td>
<td>Endoskeletal</td>
<td>18</td>
<td>Seattle foot - Blatchford ankle</td>
<td>Thermoplastic, pelite liner</td>
<td>PTB cuff</td>
</tr>
<tr>
<td>3</td>
<td>Endoskeletal</td>
<td>24</td>
<td>Seattle foot - Blatchford ankle</td>
<td>Thermoplastic, pelite liner</td>
<td>Supracondylar</td>
</tr>
<tr>
<td>4</td>
<td>Endoskeletal</td>
<td>18</td>
<td>Seattle foot - Blatchford ankle</td>
<td>Laminated resin, pelite liner</td>
<td>PTB cuff</td>
</tr>
</tbody>
</table>

PTB = Patella Tendon Bearing

Table 3.3. Prosthetic componentry of subjects existing prostheses.
PROCEDURE

Introduction

Five Otto Bock prosthetic SACH feet type 1S49 and five Kingsley prosthetic SACH feet type KO51 (side-right, size-26) were purchased. It was decided to fatigue the prosthetic SACH feet in standard leather shoes, as Daher (1975) did in a similar investigation, as this better represents the true wear of prosthetic feet. Also prosthetic SACH feet are intended to be worn with a shoe and their design takes into account the pitch of the shoe. Therefore socks and standard leather lace-up shoes, kindly donated by the Florsheim shoe company, were applied to the prosthetic feet for the fatigue process.

Before the fatigue process began, different measurements and readings were taken of the prosthetic feet. Each prosthetic foot was weighed, and shore "A" readings were taken at various points around the prosthetic feet, measuring the 'hardness' of the material. This was done with a simple shore durometer (Zwick & Co.). Six sites around the prosthetic feet were measured, however these measurements will not be further reported due to their unreliability as no allowance was made for creep within the material.

An impact or 'drop' test was performed on all the prosthetic feet before fatiguing commenced. This controlled mechanical test consists of a pre-loaded prosthetic foot attached to an L shaped pendulum (Figure 3.6). This is dropped from the vertical position onto the force plate, simulating heel-strike, which measures the externally applied load. The impact force provides a measure of the shock absorption properties of the prosthetic foot at heel-strike.

The apparatus consists of a steel arm which is tightly secured into the walkway adjacent to the forceplate. The prosthetic foot is attached to this steel arm via a pyramid adapter,
7° of 'toe-out' (external rotation of the prosthetic foot). The testing jig is 2083 gms and an additional weight of 497gms is also attached to simulate the effect of body weight at heel-strike.

The steel arm is brought up to the vertical position in line with a ruler for placement (Figure 3.5), then released by the investigator to impact the forceplate. The prosthetic foot hits the forceplate at an angle of 25°, (Figure 3.6), measured with a protractor, along the longitudinal line of the prosthetic foot which is reported as the angle with which the prosthetic foot generally contacts the ground (American Academy of Orthopaedic Surgeons, 1981). The computer program BioWare was used to display and analyse the forceplate output. Five drop test trials were conducted for each prosthetic foot to ensure the repeatability of the tests and to provide a confident average result.
Figure 3.5.  Impact (drop) test - Steel arm in the initial vertical position

Figure 3.6.  Impact (drop) test - Prosthetic foot in contact with the forceplate
Testing of the compliance of the prosthetic feet was also performed before the prosthetic feet were placed in the fatigue tester. This analysis took place on the electromechanical universal testing machine, (refer to Figure 3.2, page20) at Monash University, Mechanical Engineering Department. Each prosthetic foot was initially set up in the test jig to just contact the load cell prior to compression. They were then loaded to a maximum of 1100 Newtons, with the crosshead traveling at a constant speed of 5 cm/min. The prosthetic feet were then unloaded at the same rate to the initial position. During this process of loading, the measurements were graphed in a load Vs displacement graph with the chart moving at 10 cm/min. to magnify the curve of the graph. Measurements of the compliance of the prosthetic foot were taken at the heel and at the forefoot.

**Fatigue Testing**

The test prosthetic feet were attached to the fatigue tester in a relatively neutral alignment (as determined by the pyramid adapter) with 7° of ‘toe-out’. Within a brief, preliminary operation, minor alignment adjustments were made after closely observing the prosthetic feet while the treadmill was running. The adjustments were to ensure that the motion of the prosthetic feet approximated motion during the gait cycle. A 97 kg load was applied to the prosthetic feet and the frequency remained at 0.83 Hz.

Various difficulties were encountered when running the fatigue tester. Due to the substantial testing of the numerous prosthetic feet, the fatigue tester was subjected to vigorous testing itself and several parts needed to be replaced as failures occurred. Therefore the machine had to be closely monitored while running.

Three Otto Bock and three Kingsley prosthetic feet were subjected to fatigue testing. The two remaining prosthetic feet of each brand were left unfatigued to be used later within the subject biomechanical analysis.
The fatigue tester was stopped at periodic intervals, after 5,000, 10,000, 20,000, 50,000, 100,000 & 200,000 cycles. At these points, compliance testing of both the heel and forefoot and the impact 'drop' test were performed. If the prosthetic foot failed during this period, the fatiguing was discontinued.

Observations of visual changes as the prosthetic feet were fatigued were also recorded. This included the presence of superficial creases, delamination of the wooden keel from the rubber mould, cracks and so forth.

**Subject Biomechanical Testing**

The prospective subjects were initially contacted by phone, then prior to testing, letters regarding the nature of the investigation were sent to participants. Each subject signed an Informed Consent Form before beginning the biomechanical gait testing (Appendix A). They were asked some personal information regarding their amputation and prosthesis, and were then weighed. (Results documented in Tables 3.2 & 3.3, pp 26)

The subjects were biomechanically assessed with a fatigued and new Otto Bock SACH foot and a fatigued and new Kingsley SACH foot. (Mechanical tests showed that the Otto Bock feet were mechanically similar to each other during the fatigue process as were the Kingsley feet). Therefore data was collected from four different conditions.

The order of testing the prosthetic feet was determined using a Latin Square design, to eliminate any series effect. Both the Otto Bock SACH foot style 1S49 and Kingsley SACH foot style KO51 had a 10 mm heel height, therefore the same alignment could be maintained while the prosthetic feet were interchanged.
Only subject 1. had a prosthetic SACH foot on his existing prosthesis, which allowed quick interchange between his prosthetic foot and the test prosthetic feet, via the ankle bolt connection. While the other three subjects had prosthetic ankles which required dismantling of their prostheses due to the differing height of attachment of the ankle bolt. It was therefore necessary to replace their componentry below the socket and realign the prosthesis with a test prosthetic foot attached. An optimal alignment was achieved by the investigator and checked by another qualified prosthetist.

The subjects were asked to walk at their normal, comfortable cadence while data was collected within two different types of biomechanical tests. The first test involved collecting temporal data via the Stride Analyser System which utilises insoles within the subject's shoes. Separate footswitches are placed under the heel, first metatarsal head, fifth metatarsal head and hallux for both the prosthetic foot and the anatomical foot. Closure of a footswitch generates an electrical signal that indicates when these areas of the foot are bearing weight. The footswitches are connected to a backpack that electronically records the temporal information collected from these insoles. The small backpack is securely attached around the subject's waist while walking.

A 6 meter walkway was established where the walking trials could be performed. The subjects were given a short period of acclimatization before data was gathered. A light gate system was used to trigger the electronic backpack for data collection. This utilised a light detector attached to the subject's shoulder, (which in turn was connected to the backpack) and a light at either end of the walkway. The subject began walking 2 meters before the start of the walkway, thus eliminating acceleration data, and as they walked past the first light erected on a stand, the detector triggered the back-pack on. As they passed the second light, 6 metres away, the detector triggered the back-pack to stop collecting data. The subject then continued for another 2 meters thus eliminating any deceleration data.
The subjects completed five trials with each type of foot to provide a good amount of data to produce average results from. After each trial the backpack was connected to the computer with the application software, Stride Analyser Program - Version 1.00, (copyright Professional Staff Association of Rancho Los Amigos Medical Center, Inc., 1985) which analysed the data.

The second biomechanical gait test involved collecting ground reaction force data via a Kistler force platform. The subject began walking 3 meters before the force plate, told not to 'aim' for the surface, and continued to walk 3 meters after the force plate. Five successful hits were recorded when the prosthetic foot made appropriate contact with the force plate which was mounted flush with the floor surface. The Kistler force plate, was controlled using the computer program 'Kistler BioWare Version 2.01. Kistler Instrument Corporation, Kistler Instrument AG'. The ground reaction force data was stored and then analysed using this software package.

A questionnaire (Appendix B) was used to ascertain each subjects subjective assessment of each prosthetic foot. The subjects were asked to rate the feet using a graduated scale, between hard to very soft at heel-strike and again at push-off. Each subject's preferred test prosthetic foot was also noted.

DATA ANALYSIS

The Compliance Test

Force versus extension graphs were plotted. The graphs exhibited hysteresis as the prosthetic foot was loaded and then unloaded. Figure 3.7 displays a typical graph for the loading/unloading cycle of the heel of an Otto Bock SACH foot, while Figure 3.8 displays a typical graph for the loading/unloading cycle of the forefoot of an Otto Bock SACH foot.
It is clearly shown that at the beginning of the test, with little force applied, there is substantial compression of the rubber material and as the force increases the compression tends to plateau. Measurements from the loading curve were taken at 300, 600 and 900 Newtons (similar to the range of the ground reaction force generated during walking for an
adult). The gradient of the graph represents the stiffness or compliance of the material at a particular load. This was calculated at 600 Newtons on the loading curve. It was mathematically approximated by calculating the gradient of the straight line between the coordinates at 300 and 900 Newtons.

**The Drop Test**

This type of controlled test was performed to assess the shock absorption properties of the prosthetic SACH feet at heel-strike. The more shock that is absorbed at the prosthetic foot level, the less shock that is transmitted to the residual limb. Figure 3.9 illustrates a typical vertical ground reaction force reading as the foot hits the force plate, rebounds into the air, and hits the force plate again.

Many important variables were extracted from these graphs:

1. The maximum value of the first peak,
2. The time the maximum value of the first peak occurred,
3. The maximum value of the second peak,
4. The time the maximum value of the second peak occurred &
5. The time difference between the two peaks.

The impact shock is represented by the magnitude of the first peak, measure no.1. However the time over which the force is applied to reach this value, measure no. 2., is also important, as a higher rate of application of force can result in greater shock.
Figure 3.9. Impact (drop) test - A typical vertical ground reaction force reading

Measures no. 3. & 4. give an indication as to how much energy has been absorbed after the initial impact, which is the most severe and damaging to the residual limb, while measure no. 5. is concerned with the energy return of the prosthetic SACH foot which was beyond the scope of this thesis hence not analysed.

Due to the nature of this controlled, impact test, the time to which the maximum value of the first peak occurred, measure no. 2., did not differ significantly. It was therefore decided to use measure no.1., the maximum value of the first peak, which gives an index of the impact shock within the statistical analysis although the other variables were still collected.
**The Stride Analyser Test**

Various temporal gait parameters can be collected from utilising this system. However the information which is most relevant to this investigation is within the duration of specific phases of the gait cycle. Two variables, a heel loading phase and a push-off phase were collected from the footswitch data. The heel loading phase was determined by calculating the duration between heel switch contact and first metatarsal head switch contact (heel-strike to ball contact). While the push-off phase was calculated by recording the duration between heel-off (the heel footswitch was open) and foot-off (all footswitches deactivated for that foot).

The push-off phase, as defined by Winter (pp. 4., 1988) is the period in time in late stance when plantar flexion is taking place, and begins shortly after heel off and ends with toe off.’ However within many of the subject trials the prosthetic foot's hallux switch was not activated at all, which is common with prosthetic feet. Therefore the time when the prosthetic foot's first metatarsal head left the floor had to be recorded instead (slightly decreasing the duration of the 'push-off' phase).

The subjects walked five times with each prosthetic foot, with approximately five strides within the designated walkway. Measurements were taken for each step of the prosthetic foot where differences could possibly be found as the foot was fatigued.

Foot switch information for three of the subjects was tabulated and analysed. Subject no. 4.’s data was extremely difficult to analyse as he had a very slow gait, with small stride lengths and unreliable operation of the footswitches.

**Ground Reaction Force Information**
Numerous variables can also be extracted from the force plate information. Within this investigation however, the following variables were collected:

- The maximum value of the heel-strike transient, and the time at which it occurred. (The heel-strike transient is commonly referred to as the peak, series of peaks, or noticeable change in gradient during weight acceptance of the vertical component ground reaction force. Refer to Figure 3.10)

Figure 3.10 A typical vertical ground reaction force graph. (Note the points at which data was collected from the heel-strike transient).
STATISTICAL ANALYSIS

Initially a two-way repeated measures ANOVA was performed, with fatigue and foot type the independent variables. Within the mechanical tests, the variable fatigue had three levels, 0, 5,000 & 10,000 cycles. While foot type had two levels, Otto Bock and Kingsley. This type of statistical analysis was conducted for the:

- Rearfoot stiffness at 600 N from the compliance test
- Forefoot stiffness at 600 N from the compliance test
- Impact force peak from the 'drop' test

Within the subject biomechanical data, the variable fatigue had two levels, pre-fatigue and post-fatigue, and the variable foot type remained with two levels, Otto Bock and Kingsley. A repeated measures ANOVA was performed so the subjects were their own control. This type of statistical analysis was conducted for the:

- Loading phase from the stride analyser system
- Push-off phase from the stride analyser system
- Heel-strike transient from the ground reaction force data.

The level of significance was set at 0.05. Simple main effects was performed post hoc to examine the effects, followed by Tukey's HSD test, which made pairwise comparisons to identify the differences.

A correlation was also performed between the heel stiffness data and the loading phase duration information.
CHAPTER 4
RESULTS

THE FATIGUE TESTING

The fatigue process was interrupted after 5,000, 10,000, 20,000, 50,000, 100,000 and 200,000 cycles if premature failure did not occur earlier. At these times not only mechanical tests were performed, but close visual examination of the prosthetic feet.

_The Otto Bock Prosthetic Feet Type 1S49_

All three fatigued test samples displayed a superficial crease posterio/lateral after 5,000 cycles, and after 10,000 cycles a similar crease was observed posterio/medial. These superficial creases became minimally deeper and longer as the fatigue process continued. After 100,000 cycles all the test samples displayed a crease superiorly along the toe-break. This crease increased in length from on average 4 cm to 6 cm after one test sample continued to 200,000 cycles (Figure 4.1). Numerous qualified prosthetists regarded the prosthetic foot unworthy for patient wear due to this cosmetic factor, therefore cycling was ceased after 200,000 cycles. When the prosthetic foot was cut in half, there was no internal failure identified (Figure 4.2).

The remaining two Otto Bock prosthetic feet were left unfatigued for the subject biomechanical analysis.
Figure 4.1 Otto Bock SACH – 200,000 cycles.
(Note crease along toe-break region)

Figure 4.2 Otto Bock SACH – 200,000 cycles. (Sagittal cross-section)
The Kingsley Prosthetic Feet Type KO51

Delamination of the foam rubber from the wooden keel was observed in the three test samples at the first inspection, after 5,000 cycles. Premature failure occurred after 20,000 cycles for two of the test samples. The mode of failure appeared to be shearing forces at the heel bumper which caused the material at the heel region to be forced proximally at heelstrike, as the wooden keel experienced an opposing downward force, eventually causing deep cracks medially and inferiorly (Figure 4.3).

The three Kingsley test samples had a piece of pelite attached to fill the back of the shoe. Tape had been wound round the prosthetic feet, near the inferior surface (similar to the placement where cracks had occurred), to attach this pelite. It was initially thought that this tape could have had an effect on the breakdown observed. Therefore a control test sample, Kingsley number 5, was fatigued without the pelite insert attached directly to the prosthetic foot, however the same mode of failure occurred after 20,000 cycles.

The untimely failure of the Kingsley SACH feet prompted the investigators to fatigue a test sample, Kingsley number 4, once the subject gait tests were completed, with an interface plate attached. The interface plate, a piece of polyethylene, 4.1 mm in height, was attached between the superior surface of the foot and the pyramid adapter (Figure 4.4). (Due to the compressibility of the plastic material, the ankle bolt was torqued to 30 Nm.) This test sample withstood 20,000 cycles, with no noticeable delamination around the wooden keel. Only a small crack was noticed on the inferior surface of the prosthetic foot, medial to the ankle bolt. Table 4.1 summarises the number of cycles completed by each individual test sample.
Figure 4.3. Kingsley SACH - 20,000 cycles.  
(Note deep cracks medially)

Figure 4.4. Interface plate attached to Kingsley SACH
<table>
<thead>
<tr>
<th>FOOT TYPE</th>
<th>NO. OF CYCLES COMPLETED</th>
</tr>
</thead>
<tbody>
<tr>
<td>Otto Bock 1.</td>
<td>200,000</td>
</tr>
<tr>
<td>Otto Bock 2.</td>
<td>100,000</td>
</tr>
<tr>
<td>Otto Bock 3.</td>
<td>100,000</td>
</tr>
<tr>
<td>Kingsley 1.</td>
<td>20,000 *</td>
</tr>
<tr>
<td>Kingsley 2.</td>
<td>20,000 *</td>
</tr>
<tr>
<td>Kingsley 3.</td>
<td>10,000</td>
</tr>
<tr>
<td>Kingsley 4. (Interface plate)</td>
<td>20,000</td>
</tr>
<tr>
<td>Kingsley 5. (Control)</td>
<td>20,000 *</td>
</tr>
</tbody>
</table>

* Failure

Table 4.1. The number of cycles completed by each test sample.

So that there was a Kingsley foot for biomechanical analysis, Kingsley test sample no. 3 was fatigued to only 10,000 cycles to avoid mechanical failure. Delamination had occurred early on in the fatigue process, and the test sample was cut longitudinally once the subject tests were completed to examine any internal failure (Figure 4.5). It is seen that the delamination in the posterior aspect of the wooden keel had actually progressed, causing internal cracks migrating inferiorly.
Figure 4.5. Kingsley SACH - 10,000 cycles.
(Sagittal cross-section)
THE DROP TEST

The mean impact forces (N) and their standard deviations (S. Dev.) measured for both the Otto Bock and Kingsley prosthetic feet at 0, 5,000 and 10,000 cycles are listed within Table 4.2 and illustrated in Figure 4.6.

<table>
<thead>
<tr>
<th>TYPE</th>
<th>0 CYCLES</th>
<th>5,000 CYCLES</th>
<th>10,000 CYCLES</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean</td>
<td>S. Dev.</td>
<td>Mean</td>
</tr>
<tr>
<td>Otto Bock</td>
<td>983.97</td>
<td>33.30</td>
<td>1006.90</td>
</tr>
<tr>
<td>Kingsley</td>
<td>821.03</td>
<td>18.02</td>
<td>741.70</td>
</tr>
</tbody>
</table>

Table 4.2. Mean impact forces and standard deviations recorded for the Otto Bock and Kingsley prosthetic feet at periodic intervals during the fatigue testing.

![THE PEAK FORCES GENERATED FROM THE IMPACT TEST](image_url)

Figure 4.6. The relationship between the mean impact force recorded and the degree of fatigue within the drop test.
A two-way repeated measures ANOVA was performed. This is recorded in Table 4.3. Each variable, the type of prosthetic foot, the degree of fatigue, age, and the interaction effect was significant. Simple main effects was used post hoc to examine the effects of level of fatigue on the peak force within the two types of prosthetic feet (Table 4.4). It demonstrates that the type of prosthetic foot is significantly different at each level of fatigue and the degree of fatigue, age, is significant within the Kingsley prosthetic feet.

<table>
<thead>
<tr>
<th>Source of Variation</th>
<th>SS</th>
<th>DF</th>
<th>MS</th>
<th>F</th>
<th>Sig of F</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type</td>
<td>233403.89</td>
<td>1</td>
<td>233403.89</td>
<td>146.31</td>
<td>0.000</td>
</tr>
<tr>
<td>Age</td>
<td>4809.64</td>
<td>2</td>
<td>2404.82</td>
<td>11.19</td>
<td>0.005</td>
</tr>
<tr>
<td>Type by Age</td>
<td>9527.59</td>
<td>2</td>
<td>4763.79</td>
<td>22.18</td>
<td>0.001</td>
</tr>
</tbody>
</table>

Table 4.3. Repeated measures ANOVA performed on the type of prosthetic foot and the degree of fatigue, age, within the drop test.

<table>
<thead>
<tr>
<th>Source</th>
<th>SS</th>
<th>DF</th>
<th>MS</th>
<th>F</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type at 0 cycles</td>
<td>39821.23</td>
<td>1</td>
<td>39821.23</td>
<td>24.96 *</td>
</tr>
<tr>
<td>Type at 5,000 cycles</td>
<td>105496.56</td>
<td>1</td>
<td>105496.56</td>
<td>66.13 *</td>
</tr>
<tr>
<td>Type at 10,000 cycles</td>
<td>97614.01</td>
<td>1</td>
<td>97614.01</td>
<td>61.19 *</td>
</tr>
<tr>
<td>Age at Otto Bock</td>
<td>822.51</td>
<td>2</td>
<td>411.26</td>
<td>1.91</td>
</tr>
<tr>
<td>Age at Kingsley</td>
<td>13514.65</td>
<td>2</td>
<td>6757.33</td>
<td>31.46 *</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Type</th>
<th>F crit, df = 1/4, 7.71</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>F crit, df = 2/8, 4.46</td>
</tr>
</tbody>
</table>

* Significant effect

Table 4.4. Simple Main Effects performed on the degree of fatigue, age, and the type of prosthetic foot within the drop test.
The Tukey’s HSD analysis was performed to make pairwise comparisons (Table 4.5). Significant differences were found to lie within the Kingsley prosthetic feet between 0 - 5,000 cycles and 0 - 10,000 cycles. Measurement of the peak force from the impact test was continued at periodic intervals beyond 10,000 cycles to 200,000 cycles for Otto Bock (O.B.) test sample 1, and to 100,000 for Otto Bock test sample 2 and 3 (Table 4.6, Figure 4.7).

\[
\begin{array}{cccc}
0 \text{ cycles} & 5,000 \text{ cycles} & 10,000 \text{ cycles} \\
0 \text{ cycles} & 0 & 79.33^* & 84.8^* \\
5,000 \text{ cycles} & 0 & 5.47 & \\
10,000 \text{ cycles} & 0 & \\
\end{array}
\]

* Significant effect.

Table 4.5. Tukey’s HSD analysis performed on the Kingsley prosthetic feet at each level of fatigue.

Table 4.6. The impact forces recorded for the Otto Bock prosthetic feet during the fatigue process within the drop test.

\[
\begin{array}{cccccccc}
& 0 & 5,000 & 10,000 & 20,000 & 50,000 & 100,000 & 200,000 \\
O.B.1 & 960.62 & 1020.33 & 1009.45 & 1036.78 & 1048.16 & 1049.43 & 995.28 \\
O.B.2 & 969.23 & 973.53 & 964.42 & 969.73 & 961.89 & 952.28 & \\
O.B.3 & 1022.10 & 1026.91 & 1000.09 & 1026.91 & 1090.67 & 1027.92 & \\
Average & 983.98 & 1006.92 & 991.32 & 1008.53 & 1033.57 & 1009.88 & \\
\end{array}
\]
Figure 4.7. The relationship between the mean impact force recorded for the Otto Bock prosthetic feet and the degree of fatigue within the drop test.
REARFOOT STIFFNESS

The mean values of the stiffness (N/mm) and their standard deviations (S. dev.) at the rearfoot for both the Otto Bock and Kingsley prosthetic feet at 0, 5,000 and 10,000 cycles are listed within Table 4.7 and illustrated in Figure 4.8.

<table>
<thead>
<tr>
<th>TYPE</th>
<th>0 CYCLES</th>
<th>5,000 CYCLES</th>
<th>10,000 CYCLES</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean</td>
<td>S. Dev.</td>
<td>Mean</td>
</tr>
<tr>
<td>Otto Bock</td>
<td>65.533</td>
<td>2.021</td>
<td>69.467</td>
</tr>
<tr>
<td>Kingsley</td>
<td>52.600</td>
<td>1.735</td>
<td>53.633</td>
</tr>
</tbody>
</table>

Table 4.7. Mean values of stiffness at the rearfoot and standard deviations recorded for the Otto Bock and Kingsley prosthetic feet at periodic intervals during the fatigue testing.

Figure 4.8. The relationship between the stiffness at the rearfoot and the degree of fatigue.
A two-way repeated measures ANOVA was performed recorded in Table 4.8. Each variable, the type of prosthetic foot and the degree of fatigue, age, was significant. Simple main effects was used post hoc to examine the effects of level of fatigue on the rearfoot stiffness within the two types of prosthetic feet (Table 4.9). It demonstrates that the type of prosthetic foot is significantly different at each level of fatigue and the degree of fatigue, age, is significant within both the Kingsley and Otto Bock prosthetic feet.

<table>
<thead>
<tr>
<th>Source of Variation</th>
<th>SS</th>
<th>DF</th>
<th>MS</th>
<th>F</th>
<th>Sig of F</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type</td>
<td>951.93</td>
<td>1</td>
<td>951.93</td>
<td>49.25</td>
<td>0.002</td>
</tr>
<tr>
<td>Age</td>
<td>248.02</td>
<td>2</td>
<td>124.01</td>
<td>15.77</td>
<td>0.002</td>
</tr>
<tr>
<td>Type by Age</td>
<td>6.54</td>
<td>2</td>
<td>3.27</td>
<td>0.42</td>
<td>0.673</td>
</tr>
</tbody>
</table>

Table 4.8. Repeated measures ANOVA performed on the type of prosthetic foot and the degree of fatigue, age, for rearfoot stiffness.

<table>
<thead>
<tr>
<th>Source</th>
<th>SS</th>
<th>DF</th>
<th>MS</th>
<th>F</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type at 0 cycles</td>
<td>250.8937335</td>
<td>1</td>
<td>250.8937335</td>
<td>12.98 *</td>
</tr>
<tr>
<td>Type at 5,000 cycles</td>
<td>376.073334</td>
<td>1</td>
<td>376.073334</td>
<td>19.46 *</td>
</tr>
<tr>
<td>Type at 10,000 cycles</td>
<td>331.5415335</td>
<td>1</td>
<td>331.5415335</td>
<td>17.15 *</td>
</tr>
<tr>
<td>Age at Otto Bock</td>
<td>130.760312</td>
<td>2</td>
<td>65.380156</td>
<td>8.31 *</td>
</tr>
<tr>
<td>Age at Kingsley</td>
<td>123.795978</td>
<td>2</td>
<td>61.897989</td>
<td>7.87 *</td>
</tr>
</tbody>
</table>

Type F crit, df = 1/4, 7.71
Age F crit, df = 2/8, 4.46 * Significant effect

Table 4.9. Simple Main Effects performed on the degree of fatigue, age, and the type of prosthetic foot for rearfoot stiffness.
The Tukey's HSD analysis was performed to make pairwise comparisons for the Kingsley prosthetic feet (Table 4.10) and Otto Bock prosthetic feet (Table 4.11). Significant differences were found to lie within the Kingsley prosthetic feet between 0 - 10,000 cycles and 5,000 - 10,000 cycles. While a significant difference in the Otto Bock prosthetic feet was found between 5,000 - 10,000 cycles.

\[ \alpha = 0.05, \text{HSD} = 6.5393 \]

<table>
<thead>
<tr>
<th></th>
<th>0 cycles</th>
<th>5,000 cycles</th>
<th>10,000 cycles</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 cycles</td>
<td>0</td>
<td>-1.033</td>
<td>7.3 *</td>
</tr>
<tr>
<td>5,000 cycles</td>
<td>0</td>
<td>8.333 *</td>
<td></td>
</tr>
<tr>
<td>10,000 cycles</td>
<td></td>
<td>0</td>
<td></td>
</tr>
</tbody>
</table>

* Significant effect.

Table 4.10. Tukey's HSD analysis performed on the Kingsley prosthetic feet at each level of fatigue.

\[ \alpha = 0.05, \text{HSD} = 6.5393 \]

<table>
<thead>
<tr>
<th></th>
<th>0 cycles</th>
<th>5,000 cycles</th>
<th>10,000 cycles</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 cycles</td>
<td>0</td>
<td>-3.934</td>
<td>5.366</td>
</tr>
<tr>
<td>5,000 cycles</td>
<td>0</td>
<td>9.3 *</td>
<td></td>
</tr>
<tr>
<td>10,000 cycles</td>
<td></td>
<td>0</td>
<td></td>
</tr>
</tbody>
</table>

* Significant effect.

Table 4.11. Tukey's HSD analysis performed on the Otto Bock prosthetic feet at each level of fatigue.
Measurement of the stiffness at the rearfoot (N/mm) was continued for the three Otto Bock test samples as they continued the fatigue loading (Table 4.12, Figure 4.9).

<table>
<thead>
<tr>
<th>No. of cycles</th>
<th>O.B.1</th>
<th>O.B.2</th>
<th>O.B.3</th>
<th>Average</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>66.667</td>
<td>63.158</td>
<td>66.667</td>
<td>65.497</td>
</tr>
<tr>
<td>5,000</td>
<td>75</td>
<td>66.667</td>
<td>66.667</td>
<td>69.445</td>
</tr>
<tr>
<td>10,000</td>
<td>61.538</td>
<td>55.814</td>
<td>63.158</td>
<td>60.17</td>
</tr>
<tr>
<td>20,000</td>
<td>58.537</td>
<td>54.545</td>
<td>60</td>
<td>57.694</td>
</tr>
<tr>
<td>50,000</td>
<td>57.143</td>
<td>53.333</td>
<td>64.865</td>
<td>58.447</td>
</tr>
<tr>
<td>100,000</td>
<td>68.571</td>
<td>61.539</td>
<td>66.667</td>
<td>65.592</td>
</tr>
<tr>
<td>200,000</td>
<td>61.539</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table 4.12. The rearfoot stiffness values recorded for the Otto Bock prosthetic feet during the fatigue process.

Figure 4.9. The relationship between the stiffness at the rearfoot and the degree of fatigue for the Otto Bock prosthetic feet.
FOREFOOT STIFFNESS

The mean values of the stiffness (N/mm) and their standard deviations (S. dev.) at the forefoot for both the Otto Bock and Kingsley prosthetic feet at 0, 5,000 and 10,000 cycles are listed within Table 4.13 and illustrated in Figure 4.10.

<table>
<thead>
<tr>
<th>TYPE</th>
<th>0 CYCLES</th>
<th>5,000 CYCLES</th>
<th>10,000 CYCLES</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean</td>
<td>S. Dev.</td>
<td>Mean</td>
</tr>
<tr>
<td>Otto Bock</td>
<td>124.43</td>
<td>7.68</td>
<td>135.93</td>
</tr>
<tr>
<td>Kingsley</td>
<td>144.13</td>
<td>5.08</td>
<td>167.60</td>
</tr>
</tbody>
</table>

Table 4.13. Mean values of stiffness at the forefoot and standard deviations recorded for the Otto Bock and Kingsley prosthetic feet at periodic intervals during the fatigue testing.

Figure 4.10. The relationship between the stiffness at the forefoot and the degree of fatigue.
A two-way repeated measures ANOVA was performed recorded in Table 4.14. Each variable, the type of prosthetic foot, the degree of fatigue, age, and the interaction effect was significant. Simple main effects was used post hoc to examine the effects of level of fatigue on the forefoot stiffness within the two types of prosthetic feet (Table 4.15). It demonstrates that the type of prosthetic foot is significantly different at 5,000 and 10,000 cycles, and the degree of fatigue, age, is significant within both the Kingsley and Otto Bock prosthetic feet.

<table>
<thead>
<tr>
<th>Source of Variation</th>
<th>SS</th>
<th>DF</th>
<th>MS</th>
<th>F</th>
<th>Sig of F</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type</td>
<td>4691.58</td>
<td>1</td>
<td>4691.58</td>
<td>45.15</td>
<td>0.003</td>
</tr>
<tr>
<td>Age</td>
<td>932.60</td>
<td>2</td>
<td>466.30</td>
<td>57.60</td>
<td>0.000</td>
</tr>
<tr>
<td>Type by Age</td>
<td>500.10</td>
<td>2</td>
<td>250.05</td>
<td>30.89</td>
<td>0.000</td>
</tr>
</tbody>
</table>

Table 4.14. Repeated measures ANOVA performed on the type of prosthetic foot and the degree of fatigue, age, for forefoot stiffness.

<table>
<thead>
<tr>
<th>Source</th>
<th>SS</th>
<th>DF</th>
<th>MS</th>
<th>F</th>
<th>Sig of F</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type at 0 cycles</td>
<td>582.14</td>
<td>1</td>
<td>582.14</td>
<td>5.60</td>
<td></td>
</tr>
<tr>
<td>Type at 5,000 cycles</td>
<td>1504.19</td>
<td>1</td>
<td>1504.19</td>
<td>14.47*</td>
<td></td>
</tr>
<tr>
<td>Type at 10,000 cycles</td>
<td>3105.38</td>
<td>1</td>
<td>3105.38</td>
<td>29.88*</td>
<td></td>
</tr>
<tr>
<td>Age at Otto Bock</td>
<td>480.79</td>
<td>2</td>
<td>240.39</td>
<td>29.69*</td>
<td></td>
</tr>
<tr>
<td>Age at Kingsley</td>
<td>951.93</td>
<td>2</td>
<td>475.97</td>
<td>58.79*</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Type</th>
<th>F crit, df = 1/4, 7.71</th>
<th>*</th>
<th>Significant effect</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>F crit, df = 2/8, 4.46</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table 4.15. Simple Main Effects performed on the degree of fatigue, age, and the type of prosthetic foot for forefoot stiffness.
The Tukey's HSD analysis was performed to make pairwise comparisons for the Kingsley prosthetic feet (Table 4.16) and the Otto Bock prosthetic feet (Table 4.17). Differences were found to lie within the Kingsley prosthetic feet between 0 - 5,000 cycles and 0 - 10,000 cycles. While a significant difference in the Otto Bock prosthetic feet was found between 0 - 5,000 cycles and 5,000 - 10,000 cycles.

alpha = 0.05, HSD = 6.6384

<table>
<thead>
<tr>
<th></th>
<th>0 cycles</th>
<th>5,000 cycles</th>
<th>10,000 cycles</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 cycles</td>
<td>0</td>
<td>-23.47 *</td>
<td>-19.67 *</td>
</tr>
<tr>
<td>5,000 cycles</td>
<td>0</td>
<td>3.8</td>
<td>0</td>
</tr>
<tr>
<td>10,000 cycles</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Significant effect.

Table 4.16. Tukey's HSD analysis performed on the Kingsley prosthetic feet at each level of fatigue.

alpha = 0.05, HSD = 6.6384

<table>
<thead>
<tr>
<th></th>
<th>0 cycles</th>
<th>5,000 cycles</th>
<th>10,000 cycles</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 cycles</td>
<td>0</td>
<td>-11.5 *</td>
<td>6.13</td>
</tr>
<tr>
<td>5,000 cycles</td>
<td>0</td>
<td>17.63 *</td>
<td>0</td>
</tr>
<tr>
<td>10,000 cycles</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Significant effect.

Table 4.17. Tukey's HSD analysis performed on the Otto Bock prosthetic feet at each level of fatigue.
Measurement of the stiffness at the forefoot (N/mm) was continued for the three Otto Bock test samples as they continued the fatigue loading (Table 4.18, Figure 4.11).

<table>
<thead>
<tr>
<th>No. of cycles</th>
<th>0</th>
<th>5,000</th>
<th>10,000</th>
<th>20,000</th>
<th>50,000</th>
<th>100,000</th>
<th>200,000</th>
</tr>
</thead>
<tbody>
<tr>
<td>O.B.1</td>
<td>120</td>
<td>133.33</td>
<td>114.29</td>
<td>120</td>
<td>126.32</td>
<td>133.33</td>
<td>141.18</td>
</tr>
<tr>
<td>O.B.2</td>
<td>120</td>
<td>133.33</td>
<td>114.29</td>
<td>109.09</td>
<td>141.18</td>
<td>150</td>
<td></td>
</tr>
<tr>
<td>O.B.3</td>
<td>133.33</td>
<td>141.18</td>
<td>126.32</td>
<td>120</td>
<td>160</td>
<td>150</td>
<td></td>
</tr>
<tr>
<td>Average</td>
<td>124.44</td>
<td>135.95</td>
<td>118.29</td>
<td>116.36</td>
<td>142.49</td>
<td>144.44</td>
<td></td>
</tr>
</tbody>
</table>

Table 4.18. The forefoot stiffness values recorded for the Otto Bock prosthetic feet during the fatigue process.

Figure 4.11. The relationship between the stiffness at the forefoot and the degree of fatigue for the Otto Bock prosthetic feet.
HEEL LOADING PHASE DURATION

The mean values of the duration of the loading phase (msecs) and their standard deviations (S. dev.) for both the pre-fatigued and post-fatigued Otto Bock and Kingsley prosthetic feet are listed within Table 4.19 and illustrated in Figure 4.12.

<table>
<thead>
<tr>
<th>TYPE</th>
<th>PRE-FATIGUE</th>
<th>POST-FATIGUE</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean</td>
<td>S. Dev.</td>
</tr>
<tr>
<td>Otto Bock</td>
<td>262.17</td>
<td>23.58</td>
</tr>
<tr>
<td>Kingsley</td>
<td>211.83</td>
<td>12.28</td>
</tr>
</tbody>
</table>

Table 4.19. Mean heel loading durations and standard deviations recorded for both the pre-fatigued and post-fatigued Otto Bock and Kingsley prosthetic feet.

Figure 4.12. The duration of the heel loading phase with pre and post-fatigue test samples.
A two-way repeated measures ANOVA was performed recorded in Table 4.20. Only the variable age was significant. Simple main effects was used post hoc to examine the effects of fatigue on the duration of the heel loading phase within the two types of prosthetic feet (Table 4.21). It demonstrates that age, has a significant effect within the Kingsley prosthetic feet.

<table>
<thead>
<tr>
<th>Source of Variation</th>
<th>SS</th>
<th>DF</th>
<th>MS</th>
<th>F</th>
<th>Sig of F</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type</td>
<td>9767.53</td>
<td>1</td>
<td>9767.53</td>
<td>6.65</td>
<td>0.123</td>
</tr>
<tr>
<td>Age</td>
<td>460.78</td>
<td>1</td>
<td>460.78</td>
<td>65.37</td>
<td>0.015</td>
</tr>
<tr>
<td>Type by Age</td>
<td>135.74</td>
<td>1</td>
<td>135.74</td>
<td>0.48</td>
<td>0.559</td>
</tr>
</tbody>
</table>

Table 4.20. Repeated measures ANOVA performed on the type of prosthetic foot and the degree of fatigue, age, for the duration of the heel loading phase.

<table>
<thead>
<tr>
<th>Source</th>
<th>SS</th>
<th>DF</th>
<th>MS</th>
<th>F</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type at pre-fatigue</td>
<td>3800.27</td>
<td>1</td>
<td>3800.27</td>
<td>2.59</td>
</tr>
<tr>
<td>Type at post-fatigue</td>
<td>6103.17</td>
<td>1</td>
<td>6103.17</td>
<td>4.15</td>
</tr>
<tr>
<td>Fatigue at Otto Bock</td>
<td>48.17</td>
<td>2</td>
<td>24.09</td>
<td>3.42</td>
</tr>
<tr>
<td>Fatigue at Kingsley</td>
<td>548.36</td>
<td>2</td>
<td>274.18</td>
<td>38.89 *</td>
</tr>
</tbody>
</table>

Type  F crit, df = 1/2, 18.51
Fatigue  F crit, df = 2/2, 19

Table 4.21. Simple Main Effects performed on the degree of fatigue, age, and the type of prosthetic foot for the duration of the heel loading phase.
PUSH-OFF PHASE DURATION

The mean values of the duration of the push-off phase (msecs) and their standard deviations (S. dev.) for both the pre-fatigued and post-fatigued Otto Bock and Kingsley prosthetic feet are listed within Table 4.22 and illustrated in Figure 4.13.

<table>
<thead>
<tr>
<th>TYPE</th>
<th>PRE-FATIGUE</th>
<th>POST-FATIGUE</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean</td>
<td>S. Dev.</td>
</tr>
<tr>
<td>Otto Bock</td>
<td>355.30</td>
<td>76.08</td>
</tr>
<tr>
<td>Kingsley</td>
<td>364.00</td>
<td>82.94</td>
</tr>
</tbody>
</table>

Table 4.22. Mean push-off phase durations and standard deviations recorded for both the pre-fatigued and post-fatigued Otto Bock and Kingsley prosthetic feet.

Figure 4.13. The duration of the push-off phase with pre and post-fatigue test samples.
A two-way repeated measures ANOVA was performed recorded in Table 4.23. No variables were reported as being significant.

<table>
<thead>
<tr>
<th>Source of Variation</th>
<th>SS</th>
<th>DF</th>
<th>MS</th>
<th>F</th>
<th>Sig of F</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type</td>
<td>1.01</td>
<td>1</td>
<td>1.01</td>
<td>0.00</td>
<td>0.987</td>
</tr>
<tr>
<td>Age</td>
<td>412.54</td>
<td>1</td>
<td>412.54</td>
<td>1.38</td>
<td>0.361</td>
</tr>
<tr>
<td>Type by Age</td>
<td>197.80</td>
<td>1</td>
<td>197.80</td>
<td>2.41</td>
<td>0.261</td>
</tr>
</tbody>
</table>

Table 4.23. Repeated measures ANOVA performed on the type of prosthetic foot and the degree of fatigue, age, for the duration of the push-off phase.

HEEL STRIKE TRANSIENT
The mean values of the heel strike transient (Newtons) and their standard deviations (S. dev.) for both the pre-fatigued and post-fatigued Otto Bock and Kingsley prosthetic feet are listed within Table 4.24, and illustrated in Figure 4.14.

<table>
<thead>
<tr>
<th>TYPE</th>
<th>PRE-FATIGUE</th>
<th></th>
<th>POST-FATIGUE</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean</td>
<td>S. Dev.</td>
<td>Mean</td>
<td>S. Dev.</td>
</tr>
<tr>
<td>Otto Bock</td>
<td>147.13</td>
<td>46.10</td>
<td>164.15</td>
<td>43.32</td>
</tr>
<tr>
<td>Kingsley</td>
<td>148.68</td>
<td>55.42</td>
<td>130.50</td>
<td>50.04</td>
</tr>
</tbody>
</table>

Table 4.24. The mean values of the heel strike transient and standard deviations, recorded for both the pre-fatigued and post-fatigued Otto Bock and Kingsley prosthetic feet.

Figure 4.14. The peak force of the heel strike transient with pre and post-fatigue test samples.
A two-way repeated measures ANOVA was performed (Table 4.25) however, no significant values were identified.

<table>
<thead>
<tr>
<th>Source of Variation</th>
<th>SS</th>
<th>DF</th>
<th>MS</th>
<th>F</th>
<th>Sig of F</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type</td>
<td>1030.41</td>
<td>1</td>
<td>1030.41</td>
<td>2.07</td>
<td>0.246</td>
</tr>
<tr>
<td>Age</td>
<td>1.32</td>
<td>1</td>
<td>1.32</td>
<td>0.01</td>
<td>0.915</td>
</tr>
<tr>
<td>Type by Age</td>
<td>1239.04</td>
<td>1</td>
<td>1239.04</td>
<td>3.61</td>
<td>0.154</td>
</tr>
</tbody>
</table>

**Table 4.25.** Repeated measures ANOVA performed on the *type* of prosthetic foot and the degree of fatigue, *age*, for the peak force of the heel strike transient.
REARFOOT STIFFNESS VS LOADING PHASE DURATION

The rearfoot stiffness (N/mm) of the test biomechanical samples, and the mean heel loading phase duration (msecs) with standard deviations (S. dev.) of the prosthetic feet are listed within Table 4.26. A correlation was performed between the rearfoot stiffness, and the duration of the heel loading phase producing a coefficient of 0.952 (Figure 4.15).

<table>
<thead>
<tr>
<th>TYPE</th>
<th>REARFOOT STIFFNESS</th>
<th>LOADING DURATION</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean</td>
<td>S. Dev.</td>
</tr>
<tr>
<td>Otto Bock pre-fatigue</td>
<td>66.66</td>
<td>262.17</td>
</tr>
<tr>
<td>Otto Bock post-fatigue</td>
<td>61.53</td>
<td>256.50</td>
</tr>
<tr>
<td>Kingsley pre-fatigue</td>
<td>55.81</td>
<td>211.83</td>
</tr>
<tr>
<td>Kingsley post-fatigue</td>
<td>45.28</td>
<td>192.71</td>
</tr>
</tbody>
</table>

Table 4.26. The mean values and standard deviations of the rearfoot stiffness and heel loading phase duration recorded for both the pre-fatigued and post-fatigued Otto Bock and Kingsley prosthetic feet.
Figure 4.15. The relationship between rearfoot stiffness and duration of heel loading phase.
QUESTIONNAIRE

Q1. When your heel strikes the ground, how does the test prosthetic foot feel?

   *In reference to neutral, negative towards hard, positive towards very soft.*

<table>
<thead>
<tr>
<th>TYPE</th>
<th>SUBJECT</th>
<th>1.</th>
<th>2.</th>
<th>3.</th>
<th>4.</th>
<th>VALUE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Own pros. foot</td>
<td></td>
<td>-0.8</td>
<td>0.9</td>
<td>0</td>
<td>0</td>
<td>0.025</td>
</tr>
<tr>
<td>New Otto Bock</td>
<td></td>
<td>-2.7</td>
<td>-2.7</td>
<td>-0.4</td>
<td>-1.6</td>
<td>-1.85</td>
</tr>
<tr>
<td>Fatigued Otto Bock</td>
<td></td>
<td>-3.2</td>
<td>-1.4</td>
<td>0</td>
<td>-0.9</td>
<td>-1.375</td>
</tr>
<tr>
<td>New Kingsley</td>
<td></td>
<td>-2.4</td>
<td>-1.3</td>
<td>-0.6</td>
<td>0</td>
<td>-1.075</td>
</tr>
<tr>
<td>Fatigued Kingsley</td>
<td></td>
<td>-2.6</td>
<td>3</td>
<td>4.2</td>
<td>0</td>
<td>1.15</td>
</tr>
<tr>
<td>Preferred pros. foot</td>
<td>New Otto</td>
<td>Fatigued</td>
<td>Fatigued</td>
<td>Fatigued</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bock</td>
<td></td>
<td>Bock</td>
<td>Kingsley</td>
<td>Otto Bock</td>
<td>Kingsley</td>
<td></td>
</tr>
</tbody>
</table>

Table 4.27. Subjective assessment of heel compliance.

Q 2. Prior to your foot leaving the ground, how does the test prosthetic foot feel?

   *In reference to neutral, negative towards hard, positive towards very soft.*

<table>
<thead>
<tr>
<th>TYPE</th>
<th>SUBJECT</th>
<th>1.</th>
<th>2.</th>
<th>3.</th>
<th>4.</th>
<th>VALUE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Own pros. foot</td>
<td></td>
<td>1.3</td>
<td>3.7</td>
<td>0</td>
<td>0</td>
<td>1.25</td>
</tr>
<tr>
<td>New Otto Bock</td>
<td></td>
<td>-2.3</td>
<td>2.2</td>
<td>-0.5</td>
<td>0</td>
<td>-0.15</td>
</tr>
<tr>
<td>Fatigued Otto Bock</td>
<td></td>
<td>-3.3</td>
<td>1.8</td>
<td>0</td>
<td>0</td>
<td>-0.375</td>
</tr>
<tr>
<td>New Kingsley</td>
<td></td>
<td>-2.2</td>
<td>3.3</td>
<td>-0.4</td>
<td>-0.9</td>
<td>-0.05</td>
</tr>
<tr>
<td>Fatigued Kingsley</td>
<td></td>
<td>-2.4</td>
<td>2.6</td>
<td>0</td>
<td>0.6</td>
<td>0.2</td>
</tr>
<tr>
<td>Preferred pros. foot</td>
<td>New Otto</td>
<td>Fatigued</td>
<td>Fatigued</td>
<td>Fatigued</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bock</td>
<td></td>
<td>Bock</td>
<td>Kingsley</td>
<td>Otto Bock</td>
<td>Kingsley</td>
<td></td>
</tr>
</tbody>
</table>

Table 4.28. Subjective assessment of forefoot compliance.
Q 3. Overall, which test prosthetic foot did you prefer?

Subject 1. - New Otto Bock
Subject 2. - Fatigued Kingsley
Subject 3. - Fatigued Otto Bock
Subject 4. - Fatigued Kingsley

Q 4. Do you have any additional comments about the different prosthetic feet?

Subject 1. - Found the fatigued Kingsley slightly wider.
Subject 2. - Found the fatigued Kingsley had the better impact at heelstrike, and prefer this foot over my own prosthetic foot.
Subject 3. - Preferred the fatigued Otto Bock foot. It was closest to my own prosthetic foot.
Subject 4. - The fatigued Kingsley was overall softer, and I preferred this feeling.
CHAPTER 5
DISCUSSION

THE FATIGUE TESTER

The fatigue tester does not exactly replicate the normal prosthetic gait cycle, however it does give a good indication of the load that can be applied to the prosthetic feet, and the type of breakdown that can occur. The following variables make it difficult to directly relate the results found from this type of 'artificial' fatigue process to the fatigue displayed in everyday amputee wear:

- Firstly, the prosthetic feet attached to the fatigue tester are continually loaded for hours on end. This constant loading and unloading, which is rarely seen within the amputee population, generates heat within the material which is not easily dissipated with socks and shoes applied. This development of heat can accelerate the fatigue process, with breakdown occurring quicker.

- It was not possible to measure the exact force being applied to the prosthetic feet while on the fatigue tester within this investigation due to an unfortunate equipment failure. However, previous research conducted on the fatigue tester estimated a peak force of approximately 1.3 X the weight over the cross head, in this case 97 kg, during loading phase. The force decreased during midstance, and increased once again during push-off, similar to the forces generated from a normal prosthesis. Therefore the results found from this fatigue tester can be related to that of a 97 kg amputee.

- The correct alignment of the prosthetic foot was determined by two qualified prosthetists, aiming to achieve the most 'optimal' position. The alignment was not altered throughout the testing period allowing direct comparison between the individual prosthetic
feet. The alignment of the prosthetic foot on an amputee's prosthesis however is quite unique due to factors such as gait style and preference. An 'optimal' alignment, strived for on the fatigue tester, may not be representative of an individual's gait.

**ANALYSIS OF RESULTS**

**Introduction**

Throughout all of the different mechanical tests during the fatigue process, the individual prosthetic feet from each different brand behaved similar to the other test samples of the same brand. Small variations were noted, however they were not substantial. Based on the results from this sample selection it is possible to generalise the results within each test, and refer to the Otto Bock prosthetic feet as a whole with specific characteristics and the Kingsley prosthetic feet as a whole with particular behaviors.

The results obtained from the fatigue testing demonstrated that the Kingsley prosthetic feet have a high susceptibility to premature failure without the application of the interface plate. The Otto Bock prosthetic feet, which have a significantly stiffer heel bumper with an application force of 600 N, has the ability to withstand the shearing forces placed upon the prosthetic feet at heelstrike without delamination occurring or cracks developing.

The Kingsley test sample that had an interface plate applied, underwent the fatigue process without delamination occurring and failure was postponed. It appeared that the interface plate prevented the foam/rubber of the heel bumper from distorting proximally at heelstrike, therefore decreasing the shear forces in this region. The heel section remained contained
between the heel counter of the shoe and the surface of the interface plate, reducing distortion under load.

The type of leather shoe applied during the fatigue process may also have had an influence on the type of failure noted for the Kingsley prosthetic feet. The sole appeared to be quite stiff in the midfoot region which may have restricted free movement of the prosthetic foot concentrating undue forces in this area.

**The Impact 'Drop' Test**

The peak impact force from the controlled 'drop' test gave significantly different results between the two different brands of prosthetic feet at each level of fatigue. The Otto Bock prosthetic feet produced a much higher force when impacting the force plate indicating that less shock was attenuated through the material of the heel bumper.

The level of fatigue also significantly affected the peak of the impact force measured from the Kingsley prosthetic feet between 0 - 5,000 cycles and 0 - 10,000 cycles. The impact force measured decreased significantly after fatigue loading. These results demonstrate that once the Kingsley feet undergo a minimal amount of fatigue, a change occurs in the material of the heel bumper (possibly microscopic breakdown) and more shock at the heel bumper region is able to be attenuated.

The significant interaction effect between the two variables, level of fatigue and foot type, explains that the Otto Bock prosthetic feet fatigue in a different manner in respect to the impact force of the drop test when compared to the Kingsley. The Otto Bock prosthetic feet maintained a relatively constant impact force value during the cyclic period of 0 - 10,000 cycles, however the Kingsley prosthetic feet displayed a significant drop in the value of the mean impact force illustrating that a change had occurred in its mechanical behavior.
**Rearfoot Stiffness**

The results from the testing of the stiffness at the rearfoot, demonstrate that the two different brands of prosthetic feet have a significantly different value of stiffness at the heel section throughout the fatigue process from 0 - 10,000 cycles. The Kingsley prosthetic feet are significantly more compliant at each level of fatigue.

The effect that the fatigue process had on the stiffness of the rearfoot was significant for both the Otto Bock and Kingsley prosthetic feet. The Otto Bock prosthetic feet displayed a slight increase in the stiffness after 5,000 cycles, followed by a significant decrease in rearfoot stiffness after 10,000 cycles. The Kingsley prosthetic feet followed a similar trend of an initial increase in stiffness, then a decrease. This effect may be due to compacting of the material after 5,000 cycles, increasing the stiffness. While further fatigue loading after 5,000 cycles begins to degrade the heel material, decreasing the stiffness.

**Forefoot Stiffness**

The stiffness at the forefoot yielded quite different results with the Otto Bock prosthetic feet being significantly more compliant with an application force of 600N. This difference increased as the fatigue process continued. Initially, a slight difference was noted between the two different brands, then after 5,000 cycles a significant difference was illustrated, followed by a greater difference at 10,000 cycles with the Kingsley prosthetic feet being significantly stiffer.

The effect that the amount of fatigue had upon the stiffness of the forefoot was significant for both the Otto Bock and Kingsley prosthetic feet. The Otto Bock test samples increased in forefoot stiffness after 5,000 cycles, then decreased in stiffness at 10,000 cycles, becoming more compliant than the original measurement before the fatigue process. The Kingsley test samples displayed a similar trend, increasing in stiffness after 5,000 cycles, and decreasing stiffness after 10,000 cycles. This effect, which is similar to the phenomena
experienced in the rearfoot, may possibly be explained by compacting of the material in the forefoot region after 5,000 cycles, then with further loading leading to increased flexibility due to deterioration of the material.

Although the trend in influence of fatigue appeared similar between the Otto Bock and Kingsley prosthetic feet, the interaction effect did yield a significant difference. The difference lay within the significant increase in stiffness at 5,000 cycles for the Kingsley prosthetic feet with only a minimal decrease in stiffness at 10,000 cycles which remained stiffer at the forefoot than the original measurement before the fatigue process. The Otto Bock prosthetic feet decreased dramatically in forefoot stiffness between 5,000 - 10,000 cycles.

*Further Mechanical data for the Otto Bock Prosthetic Feet*

Measurements of the peak force from the impact test and compliance at the rearfoot and forefoot was continued at periodic intervals beyond 10,000 cycles to 200,000 cycles for Otto Bock test sample 1, and to 100,000 for Otto Bock test sample 2 and 3. Tables 4.6, 4.12 and 4.18 respectively illustrate the mean values obtained from these mechanical tests. In all three graphs there is a similar initial increase in the value measured at 5,000 cycles, followed by a decrease at 10,000 cycles, as previously reported. The continuation of the fatigue loading appears to demonstrate a second increase in the value measured at approx. 50,000 - 100,000 cycles, followed by a decrease at 200,000 cycles. This trend is apparent in all three of the different mechanical tests.

These results demonstrate an interesting phenomena which is difficult to objectively explain. The prosthetic foot is a complex structure made from various materials. To predict changes in the mechanical data as the prosthetic foot is fatigued is difficult, as a
complex interaction between stiffening, degradation, breakdown and so forth appears to occur between the various internal components. More detailed mechanical testing would be necessary to confidently form any solid conclusions from the mechanical tests performed within the continuation of fatigue loading.

**Heel Loading Phase Duration**

The subject biomechanical gait tests produced a significant effect of influence of fatigue within the duration of the heel loading phase for the Kingsley prosthetic feet. The mean duration of the 'new' Kingsley test sample was significantly longer than the fatigued test sample. The mean duration of the 'new' Otto Bock prosthetic foot was also minimally longer than the fatigued sample.

**Push-off Phase Duration**

The mean duration of the push-off phase with degree of fatigue did not demonstrate any significant effects as the variation between scores was great.

**Measurement of the heel strike transient**

The subject biomechanical tests performed upon the force plate measured the force at which the heel strike transient peaked. This value is very sensitive to the amputees' gait style, and easily manipulated by the way the amputee chooses to strike the ground. Possibly due to this reason and the subconscious positioning upon the force plate by the amputees, no significant effects of the influence of fatigue or foot type were noticed. Subjects tended to walk slowly producing a small heel strike transient.
**Rearfoot Stiffness vs. Duration of Loading Phase**

The stiffness at the rearfoot was found to be highly correlated with the duration of the loading phase. This result demonstrates that there is a strong relationship indicating that as the stiffness of the rearfoot increases, so does the duration of the loading phase.

Previous statistical analyses performed within this investigation support this claim. The Otto Bock prosthetic feet were found to be less compliant at the rearfoot within the stiffness testing, and within the temporal gait analysis, both the 'new' and fatigued Otto Bock test samples had the longer loading phase.

**Questionnaire**

The subjective feedback provided by the subjects produced some interesting results. Within question 1, 'When your heel strikes the ground, how does the test prosthetic foot feel?' each subject appeared to compare the test prosthetic feet to their existing prosthetic foot, considering that to be of neutral stiffness. Each subject found all the test prosthetic feet to be *harder* at the heel region, except the fatigued Kingsley, which was found to have a significantly more compliant rearfoot stiffness. Subjects 2 and 4 preferred this *soft* feeling at heel impact, favoring the fatigued Kingsley among all the test samples.

Within question 2, 'Prior to your foot leaving the ground, how does the test prosthetic foot feel?', once again each subject found all the test prosthetic feet to be *harder* at the forefoot region, except the fatigued Kingsley. However, the fatigued Kingsley actually significantly increased in stiffness after fatigue loading at the forefoot. Perhaps the subjects perceived there was more flexibility at the forefoot as the heel bumper was so *soft*. Subjects 2 and 4 still preferred the fatigued Kingsley believing it to be more compliant.
Within the comments section, Subject 2 found the fatigued Kingsley provided better impact at heelstrike. This is supported by the findings within the controlled impact test. The fatigued Kingsley measured the lowest peak force at impact within the ground reaction force data indicating that it attenuated the most shock at the heel bumper. Subject 2 and 4 overall preferred the fatigued Kingsley. Subject 3 preferred the fatigued Otto Bock as it performed the closest to his own prosthetic foot, while Subject 1 preferred the new Otto Bock with the harder feeling at heel impact and push-off.

**COMPARISON WITH PREVIOUS INVESTIGATIONS**

The durability and fatigue characteristics of the prosthetic foot have been analysed via a cyclic tester within previous investigations (Burgess et. al., 1985, Daher, 1975, Rehab. R & D Eval. Unit, 1991, Wevers & Durance, 1987).

Daher (1975) conducted an extensive investigation in which nine various types of SACH feet were subjected to cyclic testing to assess the durability of the materials. He found that changes in resistance at the heel occurred after only 5,000 cycles. Many of the commercially available feet after fatigue testing had a reduced resistance to loading due to compacting of the foam. These findings, indicating increased compliance, are in disagreement with the results found within this study, however significant changes were noted after 5,000 cycles. Both the Otto Bock and Kingsley prosthetic feet significantly increased their value of stiffness at the rearfoot after 5,000 cycles, and then subsequently decreased resistance to loading after 10,000 cycles. However, a value of 'stiffness' was calculated with an application force of 600 N within this investigation, whereas Daher examined both the loading and unloading curves and the area within the hysteresis curve when determining the change in resistance.
Daher also found four out of the nine different types of SACH feet had undergone delamination of the foam from the keel after the cyclic testing (This did not include the two different types of Kingsley prosthetic SACH feet that he tested). Toh et al (1993), also reported of delamination occurring in the Proteor SACH foot within a similar cyclic vertical loading test. This type of delamination of the foam material from the wooden keel is similar to the effect that the fatigue process had on the Kingsley SACH feet without an interface plate applied within this investigation. Neither of these two studies mentioned the application of an interface plate to their prosthetic SACH feet.

Wevers and Durance in 1987 also conducted dynamic testing on prosthetic SACH feet. Their results indicate rapid wear of the prosthetic feet at less than 100,000 cycles. The type of failure demonstrated was deterioration of the sole, resulting in cracks appearing. Protective footwear was not applied during the fatigue process, which may explain this phenomena at the sole. It was decided to test the prosthetic feet within standard leather shoes for this investigation as the SACH foot was originally designed to be worn with a shoe.

Wevers and Durance also fatigued Otto Bock and Kingsley prosthetic SACH feet, however the particular style numbers were not mentioned but, the development of a crease was also noted on top of the instep where the keel ended for the Otto Bock prosthetic feet which is similar to the findings within this study.

CLINICAL IMPLICATIONS
The importance of applying an interface plate to the Kingsley prosthetic SACH foot has been clearly demonstrated. The results from this investigation demonstrate that by applying a plastic interface plate to the superior surface of the Kingsley test sample, heel bumper material breakdown was postponed and delamination between the wooden keel and the foam/rubber material was prevented.

The interface plate appears to be an essential part of the Kingsley SACH foot endoskeletal prosthesis, however contained within the packaging of the Kingsley SACH type KO51, there is no recommendation of this whatsoever. The local distributors of Kingsley prosthetic feet, based in Melbourne, are aware of the significant contribution the interface plate can make to the longevity of the prosthetic foot, nevertheless communication to the prosthetic industry seems to be lacking. After personally discussing with prosthetists from various prosthetic facilities, public and private, within Melbourne and Australia, only a few people knew about an interface plate recommended for prosthetic SACH feet, and none of them actually applied an interface plate as common practice within their profession.

The correlation between rearfoot stiffness and the duration of the heel loading phase within the gait cycle is clinically important. Objective data demonstrates that as the stiffness of the heel region increases, so does the duration of the loading phase. This type of information could possibly be relevant for an amputee that is cautious when loading their prosthetic limb, or a trans-femoral amputee with the same concerns requiring stability and sufficient time to load the prosthetic limb once initial contact with the ground has been made. Information such as this could be worthy to remember when deciding which heel stiffness would be best for the amputee. Regular checking for deterioration at the heel bumper, and decreased stiffness would also be beneficial for the amputee's safety and stability during the loading phase.
The comparison between two popular manufacturers of prosthetic SACH feet has provided some thought provoking results. However, it must be remembered that all the data gathered for the statistical analysis from the test samples was without the interface plate applied, and Kingsley prosthetic SACH feet are vulnerable to premature breakdown without one applied to the endoskeletal prosthesis. Nevertheless this currently appears to be common practice in Melbourne.

**DIRECTIONS FOR FUTURE RESEARCH**

Previous reports examining the fatigue process and compliance at the rearfoot and forefoot of the prosthetic SACH foot have been published, however information concerning the influence of fatigue upon other types of prosthetic feet is limited. Fatigue testing is mentioned within two different reports describing the development and evaluation of the VA Seattle Foot and the VA Seattle Ankle. (Burgess et. al., 1985, Rehab. R&D Eval. Unit., 1991.) Both groups of researchers stressed the importance of testing the durability of the prosthetic components. The report on the VA Seattle Foot explained how it also obtained load-deflection characteristics as a part of the structural analysis to develop the right combination of thermoset and thermoplastic matrices and reinforcements with relation to the fatigue tests. Except for these two reports, mechanical characteristics of different designs of prosthetic feet is lacking in the literature.

Another area which could be further analysed is the biomechanical data obtained from the ground reaction force information within the subject tests. The magnitude and the timing for the loading peak and propulsion peak which was collected within this study, could be related to the stiffness at the heel and the forefoot respectively. This type of analysis attempting to link the mechanical information of prosthetic feet to its influence upon amputee gait could be valuable.
The mechanical characteristics of the prosthetic SACH foot were significantly compromised very early on in the fatigue process. Changes in the stiffness at the rearfoot and forefoot were significantly influenced by fatigue after 5,000 and 10,000 cycles for both the Otto Bock and Kingsley prosthetic SACH feet within this test sample. The impact force within the drop test also significantly decreased for the Kingsley prosthetic feet after minimal fatiguing.

The fatigue process also significantly influenced a temporal biomechanical gait parameter, the duration of the heel loading phase. This decreased within the Kingsley prosthetic feet after only 10,000 cycles. A strong correlation was found that demonstrated that as the stiffness of the rearfoot decreases, so does the duration of the heel loading phase.

These results may hopefully provide prosthetists with a greater understanding of the influence of fatigue upon the prosthetic SACH foot.
APPENDIX B
REFERENCES


Kingsley Mfg co. *Foot Interface Plate Information.* California, USA. (undated)


Private Communication 1.  Informal telephone poll of public and private prosthetic clinics within Victoria and Australia.


