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Dynamic testing of below-knee prosthesis: assembly and components

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Abstract
Prosthetic assemblies for lower limb amputees are highly engineered and consist of several components each with its own failure mechanism. This paper describes the dynamic testing of HDPE rotational moulded sockets in a specially designed machine which mimics normal gait. Thus the components are subjected to all main loadings occurring during a stride such as axial loading and A–P bending about the knee and ankle. Machine details as well as the other components of the system are described. SACH feet appear to be vulnerable by rapid wear and structural component failures at less than 100,000 cycles were observed. The sockets are much less vulnerable and stand up to simulated loading of 1350 N for approximately 400,000 cycles. Metal components such as the foot bolt may also fail in fatigue if not properly tightened. References to proposed ISO standards are also included.

Introduction

As part of a test programme on prefabricated sockets for below-knee amputees, a dynamic testing machine was designed incorporating preliminary standards proposed by the International Society for Prosthetics and Orthotics (ISPO) in 1978. The machine was designed to mimic loads under normal walking conditions, with the exception of torsion along the long axis of the limb. The below-knee sockets manufactured by rotational moulding, were made from high density polyethylene (HDPE) and were mounted on an Otto Bock pylon system with SACH feet. During the testing, breakdowns of components other than the sockets occurred. The SACH feet wore out prematurely, or broke, the standard aluminium pipe pylon system failed as well as the ankle bolt. This paper describes the test machine and examines the failures of the different components.

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Method

Static ultimate load testing of prosthetic components can be simply done on a tensile and compression loading machine. While this is an important aspect of performance and safety, dynamic testing for fatigue failure of the components must also be executed. In dynamic testing, the frequency of loading usually is high so that the test duration can be shortened. However the maximum load and frequency that

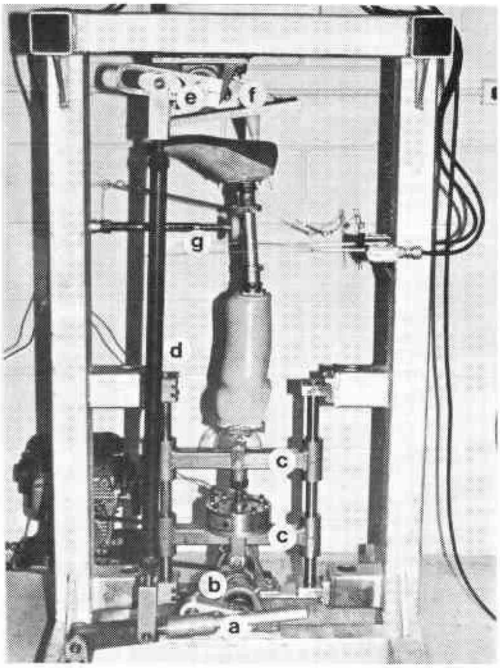


Fig. 1. Dynamic loading machine with cam drive mechanism at bottom, load cell, prosthesis and rocker plate. For explanations of components see text.

the components can sustain without any effect on its breakdown in fatigue depends on the kind of material tested. This frequency is high for metal components, but usually very low for plastic and rubber parts. For this reason, our test frequency of load cycling was chosen at 1 Hz. The loading machine shown in Figure 1 works on mechanical principles. The prosthesis is positioned upside down in the machine for ease of installation in the test frame. Cam "b" driven by "a" and rocker plate "f" combine to impose the shank-angle and loading for average gait. A commercial load cell sensor at the lower "c" cross bar was built into the slider system. This slider system "c" forces the prosthesis up against the rocker plate at the same time that the plate moves through the cam and linkage bars "d" and "e" providing for a "ground" reaction force at the foot. Stopper "g" with return spring positions the prosthesis at the beginning of the next cycle. The machine is driven by a 110 V synchronous electric motor, through a reduction gearbox, moving the sliders and the rocker plate at one cycle per second.

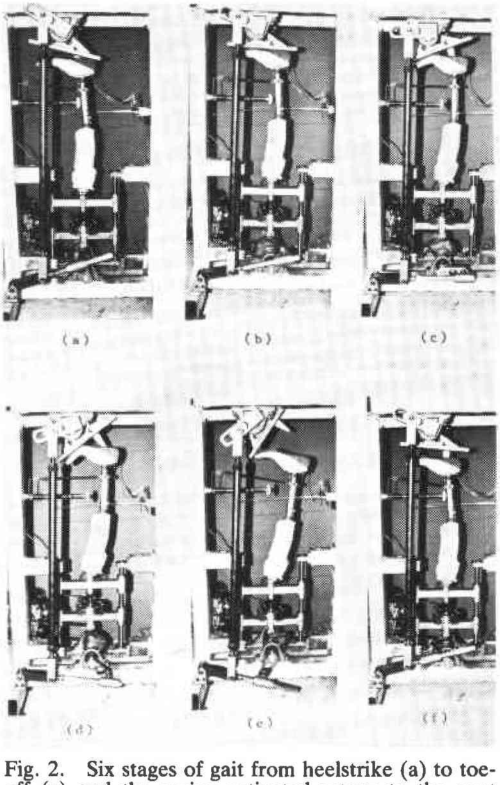
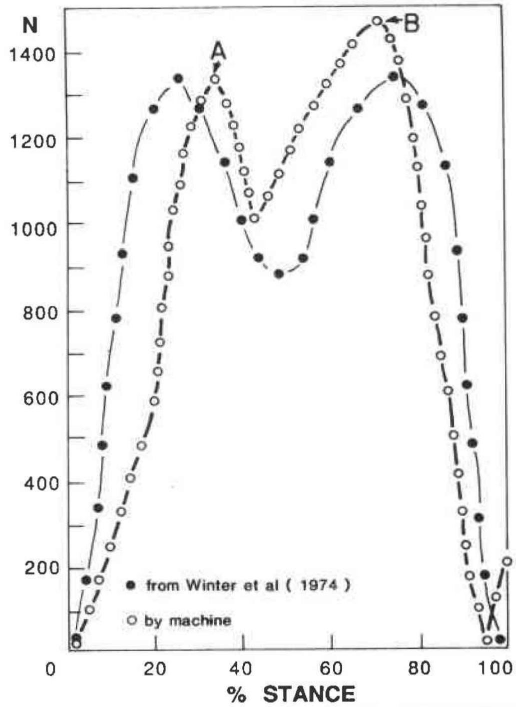


Fig. 2. Six stages of gait from heelstrike (a) to toe-off (e) and the spring activated return to the next stride.

Components of the machine are designed for infinite life. Upon failure of any part of the prosthesis, a micro switch is activated and the machine stops which enabled the researchers to run approximately 80,000 cycles daily.

Required shank angles with respect to the ground were taken from cinematrographic data by Winter et al (1974) and ranged from 17 to 20 degrees at heel strike and 57 to 61 degrees at toe-off. Figure 2 shows a series of successive stages during one gait cycle. The maximum load of 1350 N for cyclic testing was chosen according to the consensus reached at the ISPO Standard Meeting (1978). This maximum load was meant to be applied once per cycle. The resulting load curve applied by the machine as well as averaged data by Winter et al (1974) from the literature are shown in Figure 3. Also shown are the



Moment Nm	Pylon - Foot connection	Socket - Pylon connection
Plantar flexion at A	0	53.3
Dorsi flexion at B	178	99.8

Fig. 3. Desired ground reaction force (black dot) and the machine generated force (open dot) as a function of stance. Maximum moments at indicated points are added.

moments in the sagittal plane at the ankle and the socket pylon connection which inherently result from the loadbearing.

Materials

Sockets were manufactured from HDPE by a rotational moulding technique. The wall thickness was from 3.4 mm to 5.7 mm. The moulding process tended to produce thicker material in corners, thus reinforcing these areas. Figure 4 shows a socket in cross-section.

The pylon system used Otto Bock components for the pylon-socket and pylon-foot connection. The HDPE socket was connected to the pylon by a custom made aluminium-base plate with four threaded screw holes which matched the Otto bock support plate on top of the pylon.

SACH feet from four manufacturers were also tested. The Otto Bock (German) foot had a massive hardwood keel into which a groove was milled to receive a fibre reinforced stiffener (Fig 5, top). The Otto Bock (Winnipeg) foot had a smaller keel and two fibre reinforced stiffeners (Fig 5, bottom). The bottom stiffener was stapled and glued to the wooden keel. Hard rubber was moulded between the stiffeners. The rounded-off keel should also be noted as an important difference from the German design.

The Kingsley design was similar to the previous ones with only one stiffener attached to the bottom of the keel which in turn had a rounded front edge (Fig 6, top). The Kingsley foot had a stiffener moulded into the sole, 3 mm below the surface.

The U.S. Manufacturing foot looked like the Kingsley foot except that it had only one fibre reinforced stiffener which was much thicker than in the other feet (Fig 6, bottom). However, the stiffness of the total assembly was less than that of the Kingsley foot.

Foot, pylon and socket were assembled and aligned by a licensed prosthetist as follows. The sagittal mid plane of the socket was aligned 3 degrees outward from the vertical pylon axis. The socket centre line intersects the base of the foot at 0.33 times the length of the foot measured from the back of the foot. The sagittal mid plane intersects the big toe of the

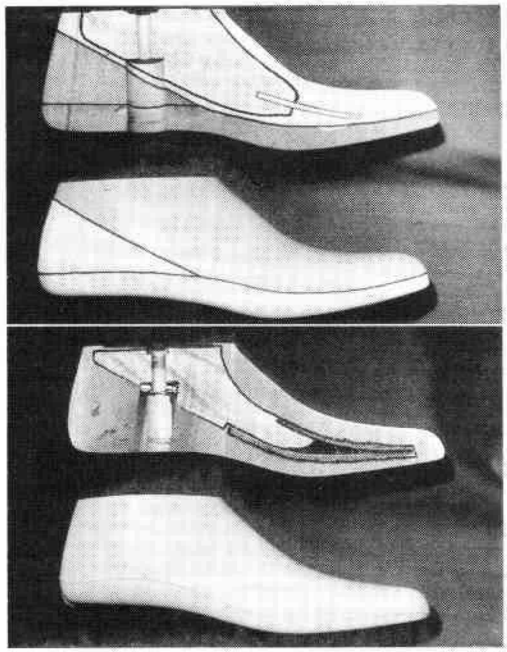


Fig. 5. Top, Otto Bock (German) design with large wooden keel and fibre reinforcement at neutral line. Bottom, Otto Bock (Winnipeg) design with two fibre reinforcements.

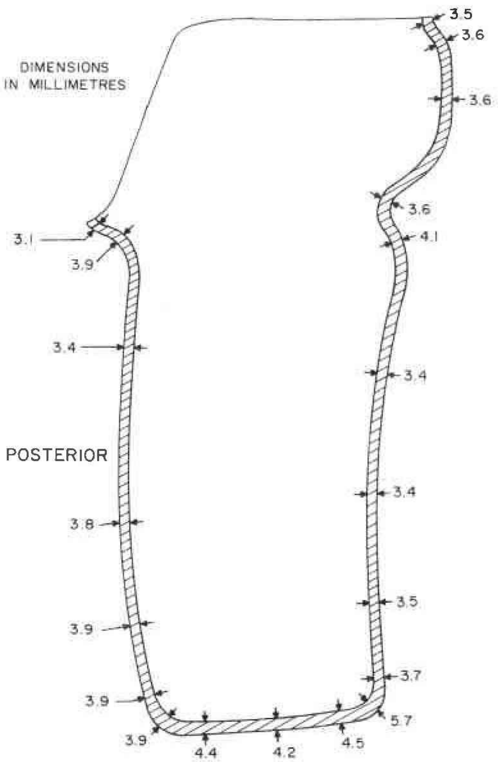


Fig. 4. HDPE rotational moulded below-knee socket in cross-section to show wall thickness at different locations.

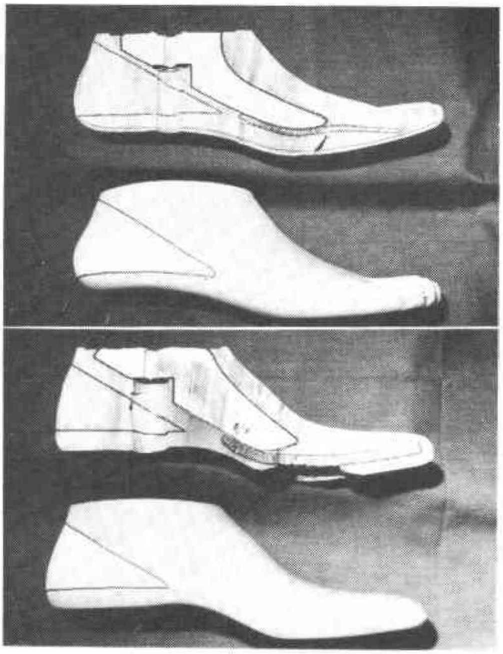


Fig. 6. Top, Kingsley design with round keel tip, well connected fibre reinforcement to keel and imbedded stiffener in sole (shown after testing). Bottom, U.S. Manufacturing Co. design with the section shown after testing. Note thick fibre stiffener.

foot. This assures that the prosthetic system is also subjected to inversion and eversion moments about the ankle. Four samples of each type of foot were tested in a complete assembly.

Results

The fatigue testing of the sockets was continued until micro cracks appeared in the HDPE socket. Micro cracks became visible through "crazing," which turned the normally opaque but glassy appearance of HDPE into a milk white texture in one localized area. If the socket was cycled a little more, the micro cracks would coalesce and form a through the wall crack, which in turn would grow quickly and render the socket useless. Table 1 lists the number of cycles at which the sockets failed. All failures occurred as a result of local bending and buckling at the anterior bottom margin of the socket where it was connected to the pylon.

During the prosthesis testing, the U.S. Manufacturing foot averaged 72,000 cycles (standard deviation 29,825). At an early stage in the testing, the soft rubber sole wore through over the entire width of the foot. This wear also

Table 1. Cycles to failure for rotational moulded below-knee sockets.

Spec. No.	Cycles to Failure
1	400,637
2	370,000
3	460,000
4	436,000*

*test discontinued – no failure

affected the stiffener until two parallel cracks developed beside the stiffener in the rubber of the sole. When the load bearing capacity of the stiffener was exhausted, the feet fractured all the way through.

A hole through the sole of the Kingsley foot wore into the sole stiffener. This in turn decreased the stiffness of the whole foot and cracks appeared in the rubber on the sole and at the instep. This was an indication of the destruction of the inside stiffener which tore after only a few more load cycles. The average life was 105,850 cycles (standard deviation 14,782 cycles).

The Otto Bock (Winnipeg) foot sole wore away after only 25% of the total cycles had been applied. A hole developed through the sole and the underlying rubber into the reinforced stiffener until the remainder of the stiffener broke off. This occurred at an average of 46,000 cycles (standard deviation 7,850 cycles).

During testing the Otto Bock (German) feet first showed a crease at the top of the instep where the keel ended. This crease grew until it spread across the width of the instep. In the later stages, the stiffness of the whole foot decreased, and in the last part of the test a crack appeared in the sole, followed by fracture through the rubber and the fibre reinforcement. The average number of cycles at which this occurred was 43,800 with a standard deviation of 12,900 for the four specimens.

All SACH feet results are listed in Figure 7.

During the testing, two pylons failed in fatigue after 897,600 and 485,900 cycles respectively. The pylons were made from 6.061 – T6 commercial aluminium tubing, Figure 8.

Frequent failure of the standard grade 10.9 ankle bolts occurred at the SACH foot-ankle interface when the bolt was tightened without using a torque wrench. After a torque of 20 Nm (15 ft.lb.) was applied to the bolt upon installation and maintained during testing, no further bolt failures occurred.

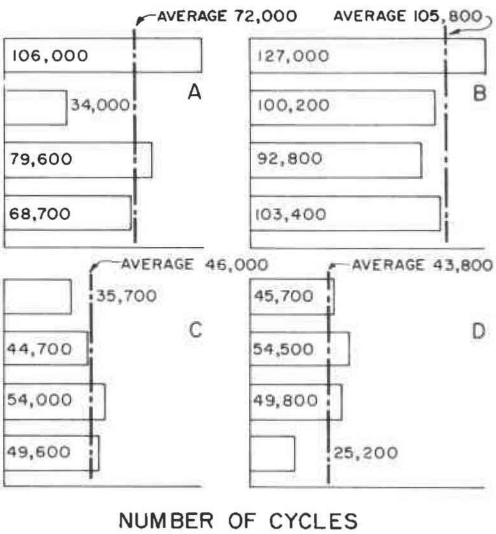


Fig. 7. Number of cycles to breakdown of all SACH feet, U.S. Manufacturing Co. (A), Kingsley (B), Otto Bock (Winnipeg) (C) and Otto Bock (German) (D).

Discussion

Static testing of prosthetic components may assure that ultimate loads of the components or assemblies are well above the loads applied in normal or occasional exceptional use of the prosthesis by the amputee. However, failure can also occur at loads equal to or below those occurring during normal use of the prosthesis. These failures are a result of fatigue or wear. Wear is usually gradual, easily observed, and leads to progressive failure of the prosthesis. Fatigue failure will occur in both metal and plastic components. However, fatigue failure may cause unexpected, sudden breakdown especially in metal components and can be catastrophic. Dynamic testing over a large number of cycles is therefore, necessary. While different testing machines may be used, the load level, frequency of application and load cycle shape are important parameters of fatigue failure. ISPO (1978) recommended standards for fatigue testing which included axial cyclic loads of 1350 N and cyclic AP bending moments about the knee of 120 Nm, as well as ankle bending moments of 140 Nm. These proposals were similar to those set by the Veteran Administration Prosthetic Centre (VAPC) (ISPO, 1978). Current attempts at standardization of performance tests for prostheses by the Japanese Association of Rehabilitation Medicine, (Kakurai, 1984) followed the same method of testing but at a lower load level.

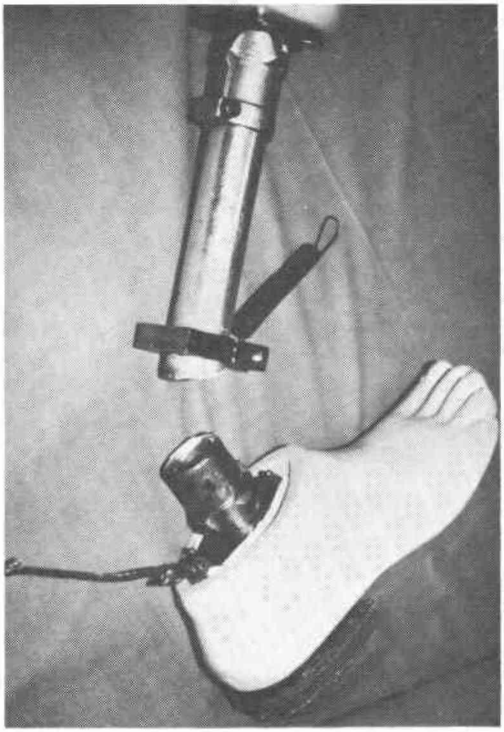


Fig. 8. Pylon fatigue failure at connector-tube interface.

Currently a draft document is being circulated on testing of lower limb prostheses by the International Standards Organization (ISO). It attempts to standardize the testing of lower limb components in their most endangered configuration simulating the forefoot-load situation from the instant of maximum dorsi-flexion ankle moment to toe-off. The loadbearing is a variable, gait dependent, resultant load FR. This force includes pre-load, to eliminate clearances in the test system, and the body weight and the dynamic loading during gait. The application of this force also produces bending moments about the ankle and knee. The authors' test machine applies the loading through the centre of the knee with the loadbearing line between this centre and the foot-ground contact point. The latter varies during gait from heel strike to toe-off as is the case in real life. The vertical machine load is measured in the test set up while the variables defined in the ISO draft are the dependent variables and can be calculated from the load output and shank angle with respect to the ground. It is clear that the sagittal bending moments about the socket-pylon connection point and ankle are most damaging, with respect to fatigue of the pylon and socket system, while the foot-ground contact force ultimately destroys the foot by wear.

Most severe loading conditions occur with mature, heavy and active amputees. However, as illustrated by the fast breakdown of the feet by wear and by fatigue failure of other components in the system, difficulties will be encountered in the design and manufacture of components to match the requirements of $3^{\star}10^{6}$ cycles as proposed by VAPC in the ISPO consensus proposal (1978).

The authors' testing machine was set to produce a peak vertical ground reaction load of 1350 N twice during each cycle which mimicked normal gait. When the maximum axial load had been set, the moments about the ankle and the socket-pylon connection point became dependent variables of the foot dimension and of shank angles at heel strike and toe-off. The slight shift in loading patterns between desired and the one achieved (Fig. 3) is of no consequence to the result of the fatigue failures. Fatigue failure is affected by the root mean square value (RMS), of the loading pattern, Rolfe and Barson (1977) and the RMS values of the achieved pattern were close to the desired value, (994 N versus 1060).

The feet were tested without protective footwear, as it was found that shoes completely altered the characteristics of the feet and the variety of footwear available rendered the observations meaningless. Wear played a role in the destruction of all feet. However, the design features of some feet predisposed them for earlier failure. This was evident with the Otto Bock (German) foot. The fibre reinforcement was positioned approximately at the neutral line of bending which decreased the efficacy of the reinforcement. The stiffness of the foot was achieved by the application of stiff rubbers for the sole and the skin. The fibre reinforcement, furthermore was poorly inserted into the wooden keel and loosened or tore as soon as progressive creasing of the dorsal section of the skin had decreased the foot's resistance to bending. The sharp edge of the keel at the fibre reinforcement insertion site was also a poor design feature. The wear resistance of the sole was very good. The Otto Bock (Winnipeg) foot utilized the fibre reinforcement much better. While the performance under test conditions was not significantly better, this foot was the lightest of the four designs. The rubber of the sole was not very wear resistant which accelerated kthe destruction in testing.

The Kingsley foot performed significantly better in fatigue testing than the others. The fibre stiffener was larger and was well attached to the heel. There was no sharp transition at the attachment site to the wooden keel. Three millimeters below the sole was an embedded fibre reinforcement. This reinforcement system made the foot stiffer than the other designs. Wear and loss of stiffness were gradual. Final fatigue failure occurred when the main fibre stiffener broke shortly after the appearance of side cracks in the rubber of the skin. This design was the heaviest among the feet tested.

The U.S. Manufacturing Co. foot was very similar in construction to the Kingsley design, although the overall stiffness was less than of the other designs. In order to achieve the required 1350 N loading, larger toe-off angles were required than normal. The sole rubber was soft and wore quickly to expose the fibre stiffener. When the stiffener broke, two large longitudinal cracks developed, at which time the test was discontinued.

The ISPO recommendations are very severe and constitute safety levels for active amputees up to 105 kg load (97.5 percentile of Caucasians, Diffrient et al (1979)). At this level of load many components of the below-knee prosthesis will not stand up to millions of cycles or one to five years if the amputee were to put the maximum load at each cycle. Solomonidis et al (1986) have shown that peak loads of 1350 N were indeed approached during outdoor activities by active amputees and that limited activity patients may at times put on high loads. The majority of prostheses however are used by persons who do not load the limb to these test levels and therefore prosthetic systems will be likely to last much longer than is indicated by this series of tests.

The bolt connection between foot and pylon must be tightened by a torque wrench to the recommended manufacturer's level or to 20 Nm (15 ft.lb.), otherwise premature failure will occur.

Metal fatigue failure may result in unexpected or accidental failure, while plastic and rubber components break down gradually. Therefore, prosthetists should pay close attention to the correct assembly of the metal components as defined by the manufacturer or designer.

Service life of the feet would be increased wearing stockings and shoes. This, however, is difficult to test as the number of parameters becomes large.

The machine loading depended on the design of the drive cam. Loading as a function of shank angles was built in. This is a drawback and for future designs of machines for full length prosthetic limb testing a hydraulic semi-controlled machine would be advisable. While the ISO Working Draft lays the groundwork for much needed standardized total prosthetic system testing, much information can also be gained by testing components only, in load simulating, simpler test machines.

Acknowledgements

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