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Adaptive prosthesis – a new concept in prosthetic knee control

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SUMMARY

The aim of the project has been to provide a prosthesis which is capable of adapting to different modes of locomotion whilst optimising the hip power available to the user.

The prosthesis provides stance control ranging from minimal resistance to a yielding lock, capable of detecting level walking, ramp descent, stair descent, standing and instances of stumble. The stance resistance is set to pre-programmed levels for each mode, which matches the user's level of control.

10 amputees participated during the early development trails of the Adaptive Prosthesis for project validation. 7 used the limb for over 3 months and 3 for over 2 years. Early feedback indicated enhanced control and increased comfort and safety during ambulation and manoeuvring various terrains. Minor modification to increase reliability of cabling was also made.

KEYWORDS: Adaptive prosthesis; Knee control; Locomotion modes.

I. INTRODUCTION

For the first time technology has allowed designers to review the conventional approach to knee control. It is now possible to consider a prosthesis that is capable of being accurately matched to an amputee's power and ability to control the limb in all modes of ambulation.

Historically the 'conventional' approach to stance control in lower limb transfemoral prosthetics has been mainly the use of geometric stability which is well documented by Radcliffe[1] and Foort.[2] Reliance on voluntary control of the knee allowed design of polycentric knees where the instantaneous centre of rotation is moved to a stable region during the stance phase of the gait cycle. There are now a number of commercial variants as described by Van De Van.[3] Later, with the introduction of the brake band stabilising knee and safety knee by Blatchford[4] and Otto Bock[5] a new approach to stance control was taken, where the reliance on voluntary muscular control was minimised. In fact there are some schools of thought that suggest that over-prescription of these types of knee control to active amputees, has resulted in the creation of a generation of users who have indirectly developed atrophy. This was presented at ISPO World congress by several American researchers in Report ISPO-USA.[6]

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The other type of widely used stance control device has been the yielding type which was first described by Hinchley Mauch[7] over 20 years ago. More recently an electronic version of such a device was commercially made possible as described by James.[8] The advantages and disadvantages of these devices can be summarised as follows:

Geometric stability/polycentric – usually unsuitable for ramps and stairs, it can cause an abnormal gait deviation and effort, as it keeps the knee locked until weight is transferred.

Stabilising/safety knee – if set for walking it is unsuitable for ramp descent. It is unsuitable for stairs and the knee is locked at roll-over until the brake is released by the transfer of weight, hence a subtle interference with natural locomotion.

Single setting yielding knee – if set for walking it may not be suitable for ramp or stairs descent. It needs external or mechanical release to remove the high yield setting used for stabilisation in order to allow roll-over to take place.

I.1. Bio-mechanics of prosthetic gait

The prosthetic gait cycle, like the natural gait cycle, is divided into different regions: For stance phase, Heel strike (HS), Mid stance (MS), Heel Off (HO) and Toe Off (TO). For swing phase, Heel Off, Mid Swing and then again Heel Strike. The requirements for successful motion depend on the study of the forces between the user, the prosthesis and the environment (mostly the Ground Reaction Force, GRF). Improvement and refinement of limb control can result from the study of each section separately.

I.1.1. Stance phase. Based on observation, measurements, experimentation, and user feedback it has been found that stance control for trans femoral amputee locomotion is rarely needed during normal walking. Once the user is into their stride the inertia of the body dominates the gait with the hip musculature providing a sufficient extending moment at the knee to counter-balance the external moments that try to flex the knee at heel contact and mid-stance. Hence the need for additional support to provide resistance to flexion in the stance phase during normal walking is minimal, except in cases where amputee musculature weakness is unable to create enough power to maintain stability. However as the amputee begins to slow down the level of additional external stance support required will increase, primarily due to the fact that the body automatically leans back causing the ground reaction force falls further behind the prosthetic knee joint centre. Figure 1 below illustrates this.

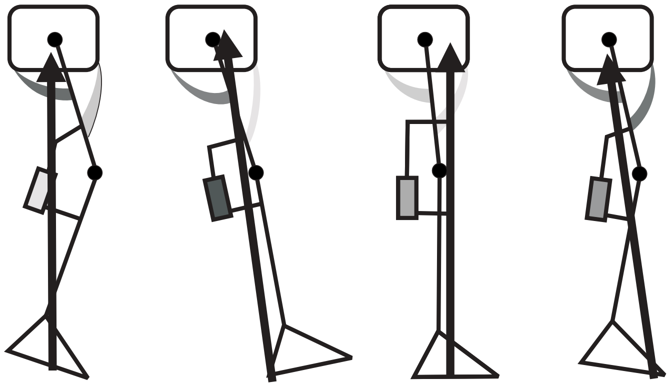

Fig. 1. Voluntary Stance Control – At mid-stance (MS) the ground reaction force is ahead of the knee so it needs to lock/resist to support the user. Heel Strike (HS), Heel Off (HO). When the wearer slows down they automatically lean backwards bringing the Ground Reaction Force *behind* the knee centre.

When considering the requirements of a stance control, it can be argued that the need for additional mechanical stance support during slowing down phase of walking cycle is more significant than normal walking speed ambulation. Equally descending ramps or stairs, during instances of stumble or whilst standing appears from many amputee's comments ideally to require additional stance support when compared to normal walking speed during everyday ambulation.

Reflecting on most amputees' daily activities, these are by far dominated by walking at an habitual, preferred speed. Naturally, stopping and then standing is associated with each walk. Less frequent activities include navigating obstacles, walking at different speeds and occasionally descending ramps or stairs.

I.1.2. Ideal swing phase control. The development of swing phase control in the last few years,[8,9] progressed significantly with the first clinically supplied microprocessor controlled leg prosthesis, the Blatchfords Intelligent Prosthesis and NABCO Intelligent Prosthesis (IP) and Blatchford Endolite Intelligent Prosthesis Plus (IP+). The IP+ benefited from a wireless remote control with a more powerful swing phase cylinder where most of the processing was carried out on the computer controller in the prosthesis. The Older IP had an ambulatory cord programmer where the data was poked into addresses in the micro controller in the prosthesis requiring the Prosthetist to carry out relatively complex calculations.

One of the limitations of these devices in earlier years was the method of sensing the speed of walking. The earlier programmes took one step to calculate the speed and one step to respond and adjust the pneumatic valve setting to create the correct resistance and extension assist. The later models benefited from better software control and provided more improved speed of walking measurement during stance and adjustment for swing prior reaching to maximum flexion. Hence on the second step an optimum swing characteristic is achieved.

For the Adaptive prosthesis an ideal swing phase control was based on field experience from nearly 10,000 IP/IP+ units which demonstrated that microprocessor control enabled the swing characteristics to be matched to the amputee's entire walking speed range and provided the basis for effective, energy efficient gait.

The microprocessor adapts the damping to match the detected walking speed. The value is derived from an interpolation of measurements taken at the slowest, preferred and fastest walking speeds, set at initial fitting. Additionally, the pneumatic cylinder provides energy storage and progressive damping at the extremes of the gait cycle. Figure 2 shows a schematic of the IP/IP+ system.

I.1.3. Optimisation of user control. The solution for enhancing user rehabilitation is to provide a dynamic prosthetic system to match the dynamics of a sound limb. This requires utilisation of a hybrid system composed of:

- the amputee's power to control the knee – the strength and mobility of existing muscles to drive the remaining leg and prosthesis;
- use of optimum alignment and geometry so that the prosthesis swings in an effective and comfortable manner;
- supplementation of any shortcomings in the amputee's voluntary control with a microprocessor controlled prosthetic knee to optimise the swing and stance phases.

The principles behind the operation of the prosthesis is that adequate voluntary hip power control uses remnant extensors and flexors, abductors and adductors muscle groups. This power is dependant on adequate length and power of the stump to provide sufficient extension moment around the knee which opposes the external moment that causes the knee to flex at heel strike and mid-stance during locomotion. If the internal and external moments are balanced then the prosthetic knee is stable.

Inadequate voluntary hip power control provides insufficient internal extension moment about the knee at heel strike to mid-stance. This could be caused by short length of flexors and extensors muscle groups and/or lack of muscular power. This leads to a higher external flexion moment during locomotion, in turn causing instability of the prosthetic knee.

Figure 3 shows the ground reaction force at three critical phases of stance phase:

At heel contact there is sufficient voluntary control to provide resistance to collapse of the knee. The adaptive prosthesis is set to provide enough resistance for the hip musculature to work against and reach its optimum power.

At mid-stance the geometric position and resistance of the device creates a stable condition.

At heel-off the yield resistance is not excessive so as not to hinder roll over hence a smooth transition into swing phase is achieved.

Study of amputee locomotion has shown that the hip and muscular stump power are dynamic. Therefore power can increase or decrease with use. Not all of the terrain that the user will walk over is smooth and level, therefore internal extension moments adequate in level walking may be inadequate when descending ramps or stairs. Hence in summary,

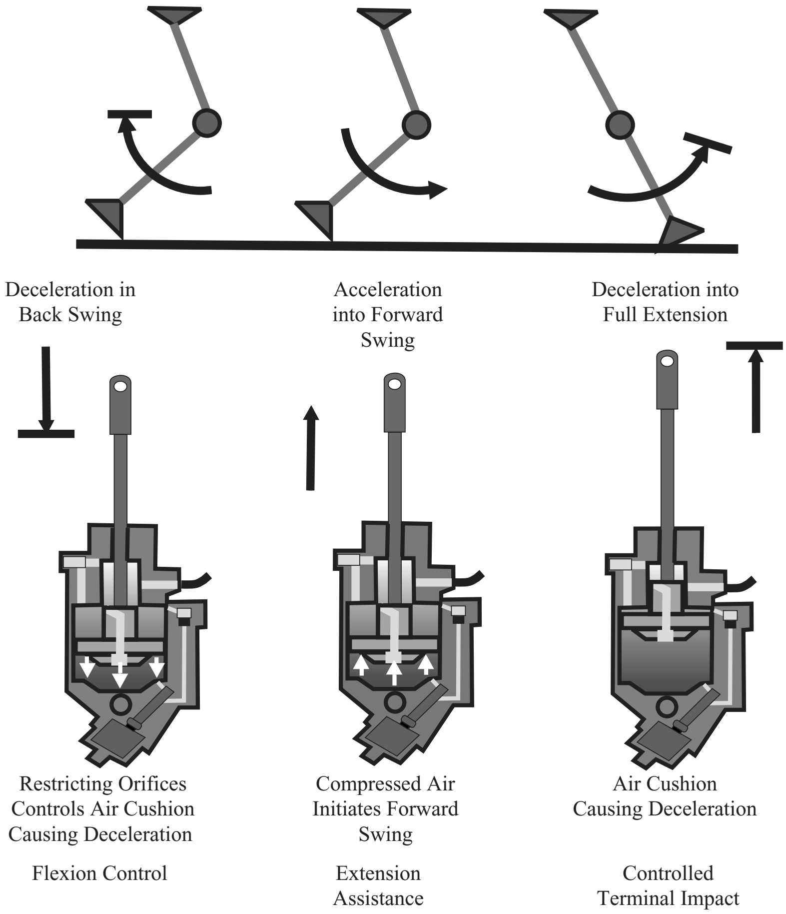

Fig. 2. Schematic of the second generation Blatchford's Intelligent Prosthesis (IP+). A microprocessor adjusts the swing rate to compensate for the change of walking pace. The stepper motor controls flow of air at pre-determined position in the swing to create sufficient air resistance to restrict excessive flexion of the knee. The compressed air then provides assistance in extending the knee quickly ready for heel strike.

Fig. 3. Ground reaction force at three phases of the stance phase. At heel strike the voluntary control of the user provides the resistance to stop the collapse of the knee, the prosthesis adapts to ensure there is sufficient resistance to enable the musculature to work against, and stop the net result of the bending moments to excessively flex the knee under the influence of external moment.

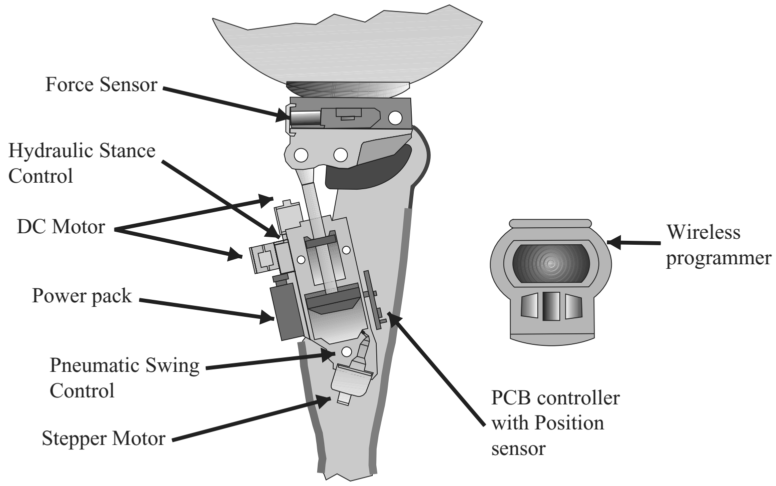

Fig. 4. Realisation of the Microprocessor controlled swing and stance controller.

an advanced adaptive prosthesis must optimise the following sources of control:

(i) efficient use of voluntary hip/stump muscular power to control knee,
(ii) use of inertia and geometric stability of the prosthesis to assist knee control,
(iii) use of a control device to optimise gait by supplementing the stance and swing control requirement.

II. THE DESIGN CRITERIA FOR MICROPROCESSOR STANCE & SWING CONTROL

To allow the device to have a wide range of applications and be an effective tool, it is possible to identify a series of criteria that it must meet.

a) It should be able to provide stance phase support with a variation of resistances from free swing to high yield to complement the needs of different amputees under all conditions.
b) It should have variable resistance during the swing phase to optimise heel rise for the entire walking speed range with an extension bias that is dependable whatever the walking speed.
c) It should be possible to adapt the knee to the specifics of the individual user and so be capable of a set of pre-programmable variables. These are stance control settings for walking, standing and ramp or stairs descent.
d) It should have programmable resistance for stumble control to suit different levels of safety and security so enabling users to recover from a stumble naturally.
e) The swing phase control should be programmable for varying walking speeds covering the entire walking speed range of an individual.
f) Independently from the other stance and swing phase control settings it should cater for different weights of foot wear, damping of inertia and terminal impact through an adjustable extension cushion.

II.1. Realisation

The study of prosthetic locomotion on level ground has shown the need for a different knee stance control at walk initiation and in the transition from walking to standing to that for normal ambulation. To achieve these objectives various means of stance control mechanisms ranging from electrorheological fluid, frictional brake, magnetic fluid, electromagnetic particle brake and hydraulic yielding devices were considered. In order to satisfy a wide range of amputees from limited activity to very active an hydraulic and pneumatic hybrid device was designed to provide a swing and stance knee control.

Figure 4 shows a schematic of a microprocessor controlled swing and stance phase control device designed to facilitate walking at various speeds, ramp and stairs descent, stumble recovery and standing support. The Adaptive Prosthesis uses a hybrid device (hydraulic and pneumatic) for stance and swing phase control in a 160 mm geometry with a stance flex uniaxial knee. The microprocessor monitors two sensors which detect various modes of locomotion and drive motors to provide the required supplementary control for the stance and swing requirements of an amputee.

The software control was optimised to simplify the programming phase and the level of input required. For example, the bending flexion knee moment measured during slow, normal and fast walking, enabled identification of an index which in turn created a threshold for determination of ramp from level walking. Similarly the knee flexion angle was used to select stairs, or the duration of stance to select standing.

Appearance is a critical part of the acceptance of a prosthesis, so it has an integral cosmesis (Figure 5) with a knee ball carrying primary cell batteries which have a lifetime of up to 3 months (depending on setting) or rechargeable batteries. A maximum flexion angle of 140° can be achieved from a robust combination of carbon fibre carrier and aluminium chassis incorporating 12 mm needle roller bearings. Figure 6 shows the carrier is demountable for ease of length adjustment, with tele-torsion and 35 mm clamp interface options.

III. FITTING SEQUENCE OF ADAPTIVE PROSTHESIS

The knee has a range of different parameters that need to be tuned to the particular size, weight and power of the patient.

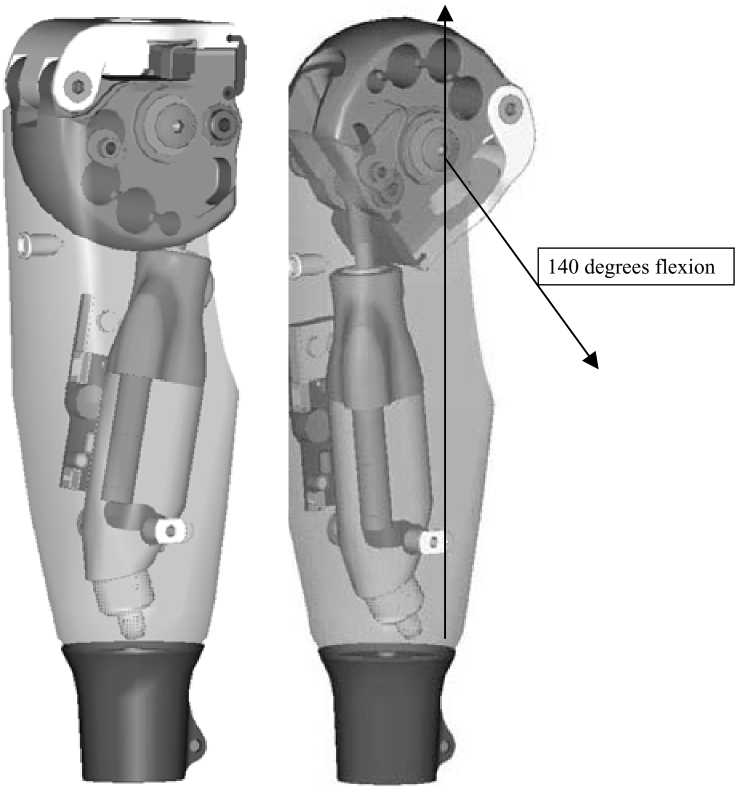

Fig. 5. Realisation of the Microprocessor controlled swing and stance controller. Left shows the knee in a neutral position, on the right the knee is fully flexed 140°. The form of the device is made to be as compact and unobtrusive as possible. The combined pneumatic and hydraulic stance and swing phase device capable of 140° of flexion. The knee joint (at the top) houses the battery pack and the force sensor used for measuring the flexion moment. The PCB location with transceiver for communication, the DC motor and stepper motors are housed inside the Carbon Fibre frame below.

The sequence of adjustment of the knee system settings is important for successful use of the limb. Figure 7 shows the communication device and the key adjustment points.

Once the basic parameters of a fitting have been achieved, ie the proper socket fit and correct limb length, the limb is donned by the user and the communication link is enabled. The limb can now be programmed by following a series of menus displayed on the Communication Device.

To commence the programming the hydraulic and pneumatic valves are set to positions for normal walking. The wearer then walks up and down on level ground and the dynamic alignment of the knee is adjusted for a stable gait. The aim is to attempt to achieve maximum voluntary hip power during the full gait cycle. Then the extension terminal impact cushion is set to arrest the knee smoothly.

Sensors are configured to establish the thresholds that the knee triggers during gait. Next the hydraulic stance support for normal walking is adjusted. Following this the hydraulic resistance settings for the ramp, stairs, standing and stumble modes can be adjusted, as well as the pneumatic damping for slow, normal and fast walking.

Most of the programming is designed to be user friendly, intuitive and automated. For example, the user is asked to walk at selected speeds for at least seven consistent steps where the speed is automatically measured, averaged and stored. These results can be reviewed by the Prosthetist and adjusted if necessary. The micro controller software calculates and provides the five pneumatic valve resistance settings and four speed boundary thresholds with their appropriate spread to be stored for the swing control. This covers the slow to fast swing speeds. The threshold settings defining the boundaries of the stance control for level walking at various speeds are also determined and stored automatically.

The amputee is then asked to walk on a slope and the stance control is adjusted by the Prosthetist for comfortable gait whilst descending ramp. The processors will automatically set the level of stance control required for the equivalent flexion moment experienced by the knee joint during this mode. The amputee is then asked to descend stairs (if amputee is capable of descending limb over limb) and the stance control is adjusted to provide sufficient resistance to enable a safe descent and loading of the prosthesis. During the first step the position sensor measures the flexion angle achieved during stairs descent and the processor will calculate the activation threshold for this mode of operation. Finally, the stance standing position setting is set.

Once program mode is exited the Prosthetist can monitor the status of the limb as the new user undertakes normal daily activities. Finally, if both parties are satisfied with the limb the Prosthetist sets the performance statistics to zero so that data recording activation frequency for each mode can be assessed at the next visit to the clinic.

III.1. The communication device

III.1.1. Key features. The Communication Device provides the means for configuring the Adaptive Prosthesis to each

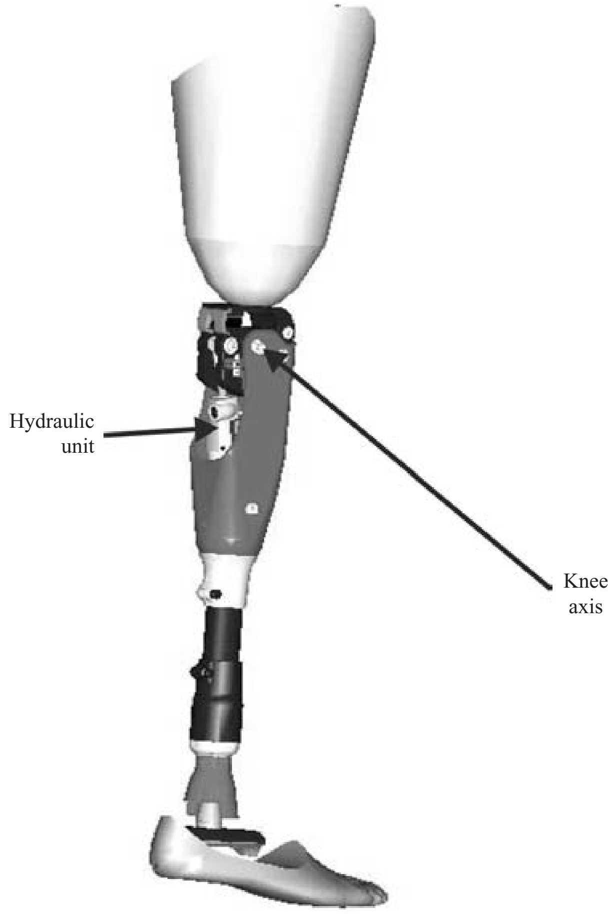

Fig. 6. Realisation of the Adaptive Prosthesis.

individual's requirements and capabilities. It was designed to incorporate the following key features.

Remote Communications Link – allows observation and diagnostics of the limb while the prosthesis is being used, without being tethered to the computer.

Interactive On-line programming – provides adjustment of the prosthesis whilst in use, automatically calculating user settings based on the training input.

Graphical User Interface – a combination of menus, icons and graphical displays guide the operator through programming and diagnostic procedures.

Smart memory card – to retain amputee specific data which can be downloaded on to an Adaptive Prosthesis at a later date.

Diagnostics – providing information on battery status, mode of operation and performance statistics.

III.1.2. System monitor screen. This screen allows the Prosthetist to monitor the status of the limb. During walking it enables them to check the walking speed and the current valve setting as an indicator of the change of speed. The stance support mode is also displayed via icons representing level walking, standing, sitting, stumble, ramp and stairs descent.

III.1.3. Ramp and stairs monitors. The ramp and stairs monitor screens provide graphical displays of the selection criteria for respective modes. It is also possible via these monitor screens to fine tune ramp or stairs selection, making initiation more or less sensitive depending on amputee preference.

III.1.4. Battery level. The battery level display screen provides a measure of how much battery life is remaining.

III.1.5. Functional test program. This test program provides a sequential list of checks that can be made on the pneumatic and hydraulic valves followed by the swing and force sensors to confirm correct operation of the Adaptive Prosthesis.

III.1.6. Statistics. The user's performance over a period of time can be monitored and data on the number of times the wearer stands, changes speed, selects ramp or stairs and stumbles can be recorded.

IV. OUTCOME OF THE PRELIMINARY STUDY

The Intelligent Prosthesis was the first commercial dynamic system, which was capable of automatically responding to cadence. Experience from nearly 10,000 IP/IP+ being used throughout the world over the last 10 years and scientific studies have proven that amputees wearing these systems walk longer and get less tired, Datta *et al.*[10] described the result of the evaluation of 7 amputees using IP. The researchers used, gait analysis data, subjective questionnaires, and cognition tests to establish level of thinking about walking when amputees participated in walking on treadmill. Other studies on IP and IP+ reported extensively by Zahedi[9]

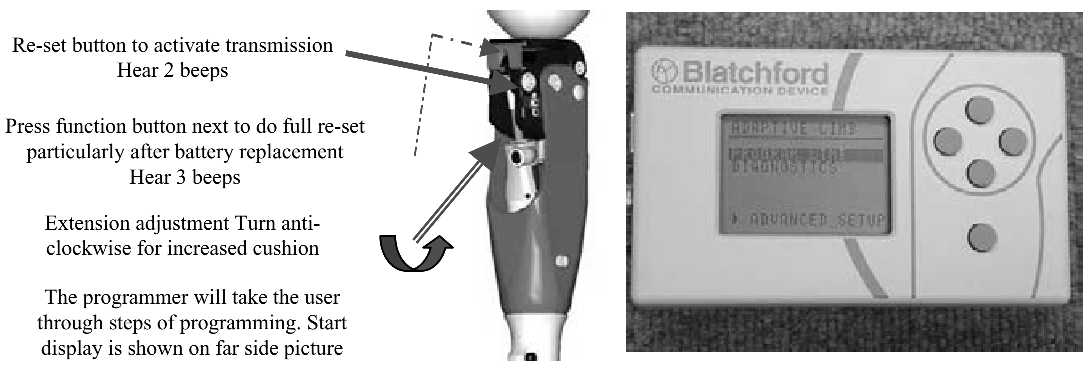

Fig. 7. Fitting sequence for the Advanced Prosthesis.

Fig. 8. Observation of the user during set up, Comparison of Ground Reaction force at Mid Stance between own limb (Uni-axial free knee with IP+ on the right) and Adaptive Prosthesis (with Stance support on the left).

described several independent studies using gait analysis, physiological measurements and sub jective questionnaires.

The Adaptive Prosthesis has undergone over 2 years of trials and already it has shown that a dynamic system capable of adapting to walking speed as well as optimising stance control for different terrain matching to the amputee's ability allows improved control and a better gait. This is associated with increased activity and voluntary control. The users can easily descend stairs, walk down slopes and find it surprisingly easy to walk up slopes. There have been 7 active amputees on long term trial who have all have shown a conversion from heavy dependence to a greater degree of voluntary control associated with increased activity.

Figure 8 shows the comparison of mid stance on the same amputee using Uniaxial Free knee with IP+ on the right, versus Adaptive prosthesis on the left. Noting the flexion of the socket, the position of the ground reaction vector may suggest optimum stance support with this limb.

Figure 9 shows ground reaction at heel contact, one of the critical phases when stance support is required, the assistance provided by the knee is clearly visible. The loading on the sound side in the form of relative position of the ground reaction force to knee and hip joint centre just before the heel strike is also shown for comparison. The external moments resulted in distance between the resultant force vector and perpendicular distance to the joint centre normalised for 100% of stance phase is shown in figure 10. Comparison with external moment pattern applied with that of conventional prosthesis indicates closer resemblance to that of normal subject. The pattern of moment curve against time during stance phase is indicative of the level of control and shows the effort required by the amputee to control the prosthesis to counter balance the external moments causing the instability.

Analysis of results have shown an enhancement of performance for free knee users, extra ability to descend ramps with ease and a more fluid and smooth gait. The results have also indicated that most active amputees are able to control the prosthesis during level walking but may need additional support from the device when wanting to stop, and during ramp and stairs descent. It has also been found that amputees may need stumble control assurance during initiation of level walking and when coming to a stop. Most amputees benefit

Fig. 9. Ground reaction at heel contact, one of the critical phases when stance support is required, the support provided by the knee is clearly visible on the right. The sound side loading prior to heel contact is also shown on the left for comparison.

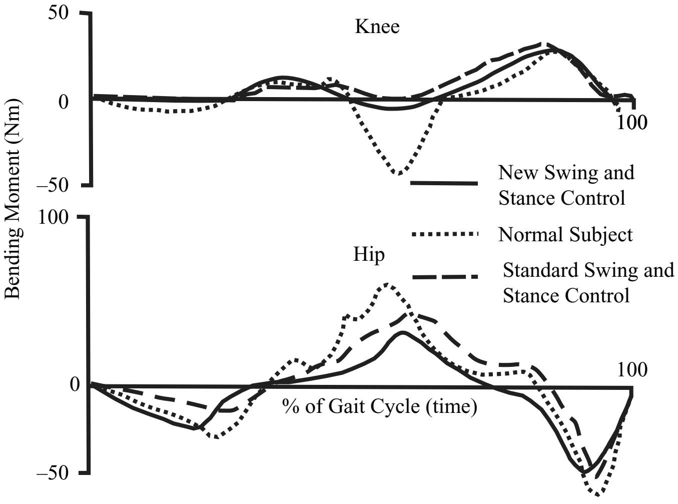

Fig. 10. Comparison of the amount of effort required to operate the Adaptive Prosthesis compared with that of a conventional prosthesis in trans femoral amputee and natural gait of normal subject. They indicate that most active amputees are able to control the prosthesis during level walking and may need additional support from the device when wanting to stop, during ramp and stair descent.

from the ability to have a standing mode, allowing them to relax.

V. CONCLUSION

Study of amputee locomotion on level ground has shown the need for different knee stance control at initiation and when slowing down to a stop. In order to satisfy the widest range of users from limited activity to very active, a hydraulic and pneumatic hybrid device was designed to provide swing and stance knee control using microprocessor technology optimised for low power consumption.

The reliability of the device and stability of the sensors were the main limitation during trails. Future work on further automation of the programming is the main area of development. Reduction in weight, size and increased in flexion angle will be other suggestions for consideration.

By 2001, over 100 Adaptive Prostheses were fitted around the world. During the 2002/3 independent amputee assessments and biomechanical analysis of a number of controlled and monitored fittings began to take place. It is anticipated that these studies will provide clinical evidence to identify the full benefits provided by the Adaptive Limb System including the use of voluntary control in maintaining the hip musculature.

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