ATLAS OF Prosthetics

Lower Limb Prosthetic Research In The 21st Century

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Overview:

The last decade of the 20th century and the first years of the new millennium have been a period of rapid technological advances in lower limb prostheses. Paradoxically, this has occurred concurrently with an estimated reduction in funding for amputee care of 20 percent compared to prior decades. Despite these technological improvements in components and materials, aggregating studies from Europe and the United States suggests that overall amputee satisfaction with the prosthesis has remained relatively constant, varying between 70-75% of those polled. Figure 1 illustrates the relationship between these selected parameters, graphically demonstrating the challenge: to increase amputee satisfaction despite declining health care funding.

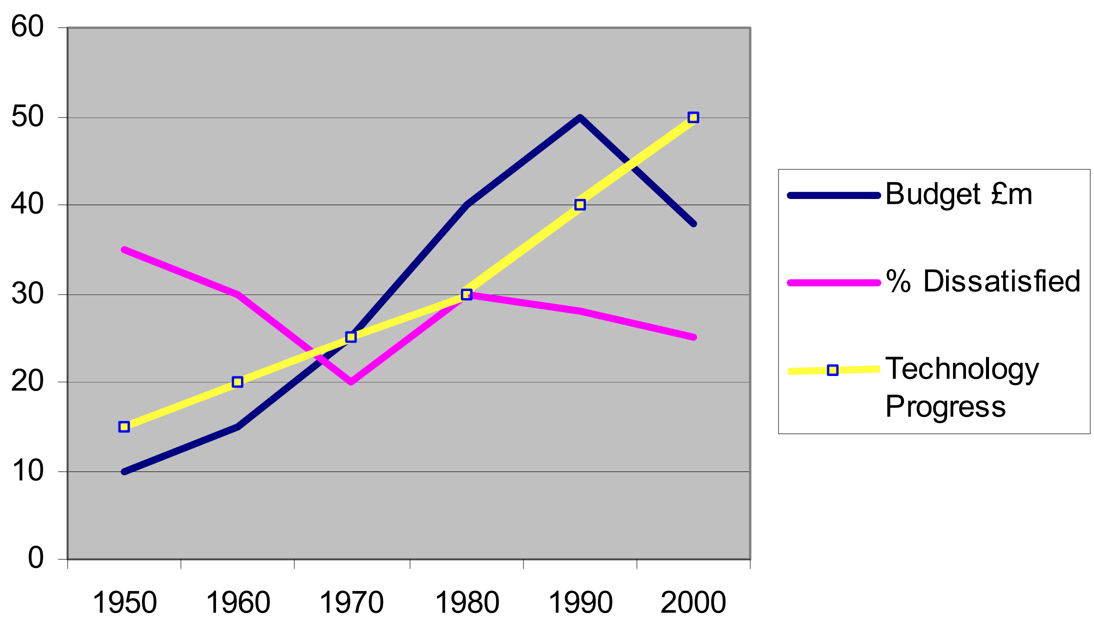


Fig 1- Technology progress, prosthetic budget and amputee disatisfaction

In the prior edition of this Atlas, Charles Pritham postulated that pending decreases in academic research in prosthetics might force commercial component manufacturer to divert profits into increased product research to fill the void. The accuracy of that prediction was borne out during the 1990s when published research from universities and government research organisation dropped dramatically. In the past fifteen years, virtually all applied research has come from the commercial sector: new suspension options, innovative socket configurations, advances in knee mechanisms, and guidelines for prescription and reimbursement of prostheses.

Increased understanding of the biomechanics of locomotion combined with clinical experimentation has led to a steady evolution in lower limb socket design. In general, today's sockets emphasize diffuse rather than localized weight bearing, to reduce peak pressures and hopefully increase amputee comfort. Advances in material technology have led to the use of novel polymers for the manufacture of socket liners, and to the creation of ever thinner, lighter, and stiffer sockets for transmission of weight bearing loads. Alternatives such as direct skeletal attachment via osseointegration and limb transplantation are being explored as alternatives to the use of external prostheses.

In the final decade of the 20th century, the combination of amputees' expectations and industrial competition resulted in many new lower limb component developments. American companies combined advance prosthetic feet with various shock absorbing systems while European firms took the lead in developing novel components such as a rotary hydraulic knee and microprocessor-controlled knee mechanisms. This was also a period of rapid growth and consolidation of prosthetic component manufacturers worldwide, often through the purchase of young and innovative companies by established and better funded multinational firms. This has resulted in the creation of several major multinational competitors with sufficient sales to privately fund ongoing research activities.

Current Developments:

Prior to the 1990s, virtually all information about socket-limb interface pressures was based on static measurements. The availability of low cost dynamic transducers combined with an increased understanding of soft tissue mechanics has resulted in new concepts in amputation surgery, prosthetic socket design, and the use of new materials to enhance control of the prosthesis by the amputee. Increased control of the prosthesis requires and facilitates improvements in prosthetic components, and a renewed focus on enabling the amputee to engage in a full range of normal activities of daily living.
The recent growth of regulatory requirements and the development of International Standards Organization testing protocols for endoskeletal lower limb prosthetic components has raised the bar for the manufacture of high quality products, which are safe and reliable and yet economically competitive.

Centralized Fabrication

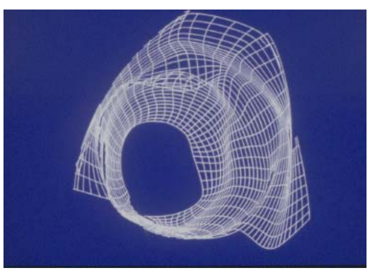
Centralized fabrication, the use of technology to provide an economic and professional advantage, has been suggested as one strategy to cope with diminishing health care funding for rehabilitation. More extensive use of computer aided design and manufacturing has also been postulated as a method to deliver care with less financial resources. While both trends have increased in clinical practice, further development integrating these two concepts into one cohesive alternative to current on-site manual fabrication can be anticipated.

The concept of the Computer Aided Prosthetic Laboratory was first described in 1990s but has not yet been fully realized. Potential uses for such knowledge-based concepts in routine clinical service are summarized below:

Computer Aided Prosthetic Laboratory Concepts

•Both limbs are scanned automatically as amputee enters clinic
•Amputee's gait is assessed; CAPL suggests type of ankle, foot, knee control and alignment
•Residual limb geometry is scanned; ability to voluntary control prosthesis is assessed
•CAPL makes a diagnostic socket using rapid prototyping methods, with integrated sensors, ready for fine adjustments by the prosthetist
•Custom protective-cosmetic system is manufactured while amputee socket is being fitted
•CAPL records all data and delivers the limb in one session, and is capable of making exact replica anytime in the future
•CAPL controls central inventory, arranging Just In Time delivery of required components and materials
•CAPL eliminates need for casting, enhances amputee perception of the prosthesis, and reduces labor costs

Limb/Socket interaction



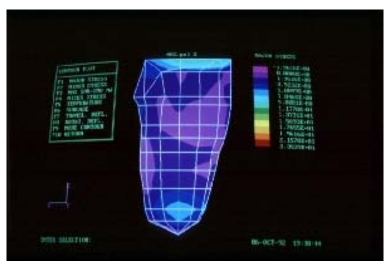


Illustration from Finite element analysis results from residual limb scanned during gait analysis

The primary requisite for successful use of an artificial limb is a comfortable, secure, and well-fitted socket. The amputee's willingness for rehabilitation and optimum biomechanical alignment of the selected components are secondary requirements to gain full benefit from functional components. Proprioceptive feedback and sensations of comfort/discomfort largely determine whether the prosthesis feels as if it is an integral part of the body or not. These factors are all functions of the limb/socket interface, illustrating the importance of this subjective aspect of prosthetic care.

The desire for the best possible fitting has led to widespread acceptance of the use of a clear test socket, to:

(1) Evaluate the accuracy of casting and rectification performed by the prosthetist before the final socket is manufactured;
(2) Obtain sufficient information on present methods of casting and rectification and to use this information to develop improved methods for casting and rectification;

(3) Produce accurately and correctly fitting sockets, with very close tolerances, so that the fitting of hard sockets could be facilitated.

Limitations to this method include the primarily static nature of most test sockets, as well as the qualitative nature of the data used to evaluate the fit of the socket. This has led to investigations of pressure magnitudes and variations at the limb/socket interface, particularly under dynamic walking conditions.

Early studies were of limited value due to shortcomings in available measurement technology. Mueller and Hettinger (1954, 1955) measure dynamic pressure at the interface using a pneumatic transducer. This transducer measured pressure over a relatively large area of 25 sq cm. Boni (1962) developed a transducer comprising silver electrodes bonded to a conductive rubber and measured 9/16 inch diameter and approximately 1 inch thick.

In their extensive studies on interface pressures, Appoldt et al (1967, 1968, 1969, 1970) used strain gauges of various configurations and manufacture before finally opting for diaphragm mounted semiconductor strain gauges (wired in a full bridge configuration). This transducer measured only 0.02 inches thick and was encapsulated in a droplet of silicone rubber for improved dynamic response. As with earlier studies, modifications to the socket was required to accommodate the transducer. Maximum dynamic values of c.175 KN/m2 were obtained at the brim of transfemoral sockets. Corell (1969) selected a similar but less expensive sensor but reported problems with repeatability. Rae and Cockrell (1971), Person et al (1974) and Jousse (1975) and Burgess and Moore (1977) have all published studies using strain gauge transducers. Redhead (1979) used silicon etched diaphragm transducers that required extensive modifications to the socket. Meier et al (1973) used capacitance transducers of relatively large dimensions (20mm diam, 2mm thick) to investigate the interface pressure in transtibial prostheses. Other investigators have used hydraulic pressure transducers (Naeff and Val Pijkeren (1980)) and hybrid electronic transducer systems (Isherwood (1978)).

The current generation of pressure transducers and miniature force strain gauges offers new opportunity for dynamic measurements of the skin-socket interface. Only recently have transducers using electro-textile materials been developed enabling incorporation of pressure/force measurements at the interface without modifying the existing socket. There are now various studies focusing on the dynamics of interface measurements. The North American project is being lead by Saunders while the European Consortium is headed by Ossur.

The acquisition of stump/socket interface pressure data has important implications in improving socket design, especially using CAD/CAM applications. In vivo data could be fed back into the computer to control socket design and manufacturing in the future.

Testing of interface pressures during locomotion

In an effort to evaluate interface pressure transducers under dynamic conditions and to concurrently determine the quality of fit between stump and socket, tests were carried out on nine healthy male amputee subjects, ranging in age from 30 years to 60 years. The Amputee Activity Assessment Form (Day (1976) showed a range of reported activity between 12 and 42. The socket designs of this group of transtibial and transfemoral amputees varied.

Selection of socket transducer sites

Transducers were placed in the socket around those areas ascribed as 'pressure sensitive' and 'pressure tolerant', based on the rationale being that unusual pressures in these areas would indicate a potentially poor fit of the socket in that region. With the transducer fitted prosthesis donned and with the associated pointer and telemetry equipment worn on a waist belt, the patient was instructed to walk normally along a defined walkway incorporating two Kistler (type 92651A) force plates.

Results from transtibial testing

Interface pressures and ground reaction forces were measured and recorded. Peak pressures at each transducer site for the seven transtibial subjects are shown in Table 1. Although the range in peak pressure values was wide, the temporal pattern of pressure build up was similar for all patients.

	PATIENT								
	1*	1	1*	2	3*	4	5	6	7
Transducer Position	Test A	Test B	Test A	Test B					
Patella Bar	375	223	189	180	204	214	124	266	104
Fibula Head	40	110	51	20	20	215	38	26	83
Medial Hamstring	93	43	31	Fail	52	151	95	23	25
Lateral Hamstring	49	15	40	18	Fail	108	55	N/R**	58
Distal end of Tibia	0	24	0	0	0	0	0	50	0
Mid Posterior Calf	201	108	121	130	94	45	119	253	138
Sub Popliteal Fossa								88	
Lateral Tibia Crest	123	160	156						
Supra Patellar Bar					74				

** These results were recorded using a hardwire method. All other measurements were made via the 8 channel amplifier and MT8 telemetry system*
*** Sub popliteal site selected instead of lateral hamstring*

Table 1 Average peak interface pressures (KN/m^2) for transtibial subjects tested

The run to run variation in pressure at the various transducer sites showed a maximum of ± 11%, but was less than ± 6 % at five of the six sites, and thus within the standard deviation of the mean of the FSR transducer.

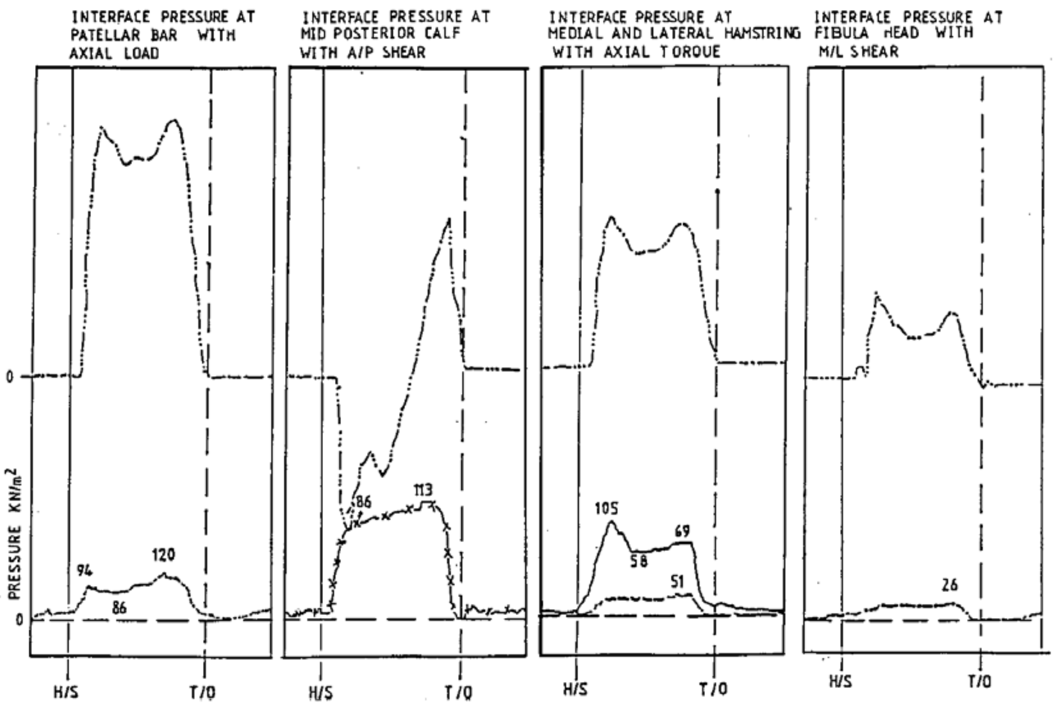


Fig.3. Interface pressures at various transducer sites with force plate data superimposed, for patient 5.

Fig 3 (Interface pressures at various transducer sites with force plate data superimposed for one transtibial patient)

Results from transfemoral testing

Interface pressures and ground reaction forces were measured and recorded for two transfemoral subjects. The average peak pressures at the various transducer sites are shown in Table 2.

Transducer Site	Average Peak Interface Pressure KN/m2	
	Patient 8	Patient 9
Ischial tuberosity	325	345
Lateral ischial seat	238	
Scarpa's triangle	72	70
Mid vastus lateralis	108	80
Distal ant. Femur	0	68
Anterior medial brim	255	120
Greater trochanter	N/A	350

Table 2 Average peak interface pressures for transfemoral patients tested

The run to run variation in pressure at the various transducer sites showed a maximum of ± 11.37% with five of the six sites less than ± 10%, thus within the standard deviations of the mean of the FSR transducer.

As expected, the highest interface pressures were recorded at the ischial tuberosity transducer site with only 20 KN/m2 difference between the two patients. For both patients, the ischial tuberosity transducer indicated loading throughout the gait cycle, with a constant load of approximately 140 KN/m2 registered throughout the swing phase.

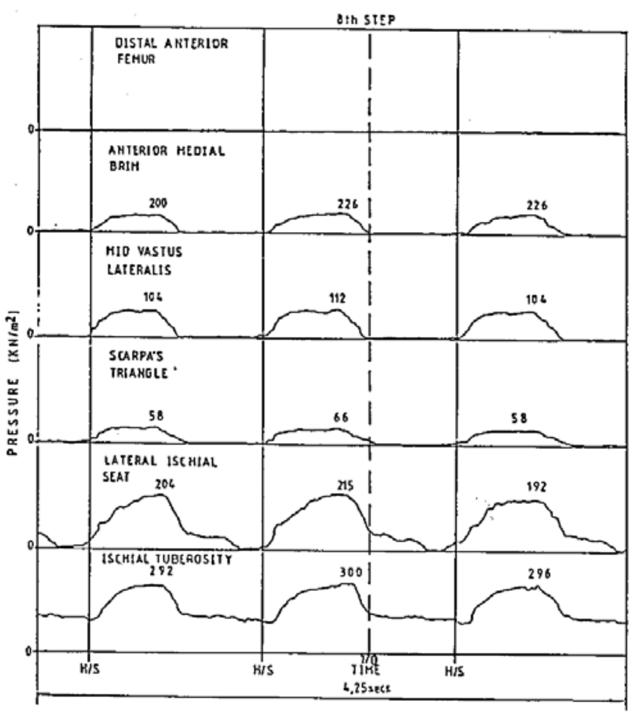


Fig.4. Interface pressure measurements (KN/m^2) at various transducer sites, for patient 8.

Fig 4 -Interface pressure measurements (KN/m2) at various transducers sites for patient 8

Discussion of interface measurements

Two patients showed peak pressures at the fibular head transducer site in excess of 150 KN/m2, one of these being as high as 215 KN/m2, higher than the pressure recorded at the patellar bar site. The implication is that the fibular head is providing a horizontal reaction force as the body weight is transferred from the sound to the prosthetic side, consistent with the maximum peak mediolateral shear force measurements of the force plates.

An alternative reason for this anomalous result might be found to be a result of medio-lateral instability. As a consequence of this subjects short residual limb length, lateral stabilizing forces applied by the socket may be less effective in controlling mediolateral instability. This patient showed consistently high interface pressure readings (> 100 KN/m2) at the proximal sites within the socket but low interface pressure readings (< 50 KN/m2) at the more distal sites.

Significantly, interface pressures measured at the medial hamstring transducer site, another proximal pressure sensitive area, showed values greater than 90 KN/m2 for the two patients mentioned above. It could be argued that the reason for the high pressure values lies in the lack of knee stability inherent with short residual limbs.

The interface pressure developed at the patellar bar transducer site shows a characteristic double peak. The initial peak, occurring shortly after heel strike, is a result of the deceleration of the centre of gravity relative to its position during the latter part of the swing phase. During mid stance phase, there is zero acceleration of the centre of gravity and this results in the axial load, and hence the patellar bar interface pressure, falling to a value corresponding to that produced by body weight alone. Upon rollover and push off, the absence of active plantar flexor muscle action results in the amputee applying active knee extension.

The reaction force due to acceleration of the center of gravity in an upward direction results in an increase in pressure at the patellar bar interface. This is likely to be further increased by the anatomical change to the patellar tendon when, due to the extensor action of the rectus femoris muscle, it is put into tension relative to the underlying skeletal structures. This combination of effects results in the push off phase developing a higher peak pressure than that occurring during the initial shock-absorbing phase. This characteristic pattern of interface pressure at the patellar bar is in keeping with those recorded by Isherwood (1978), Peakson et al (1973) and Rae and Cockrell (1962). Active knee extension (at push off) increases force on the anterior distal area and decreases pressure on the patellar tendon.

This study demonstrated the need to look at socket interface pressures as a dynamic entity. In fact, assumptions made based on static models of tissue mechanics now seem to be incorrect. Most areas of the residual can tolerate much higher loads than expected if they are for a short duration only. The main cause of tissue injury and discomfort arises from prolonged application of pressure, presumably due to incorrect distribution of pressures within socket.

Role of osseointegration in future lower limb prosthetic research

Branemark (1996) has described the use of implants for direct connection of external prostheses to the skeleton via an internal prosthesis. Branemark and his co-workers at Gothenburg in Sweden have been developing this idea for many years. Recently they published fairly successful results both in lower and upper limb fitting. This osseointegration concept is based on the use of pure titanium implants which, after a systematic healing and weigh bearing protocol, provide very good load bearing properties. These implants have been tried in different sizes varying from partial finger to femoral sizes.

This interface requires routine daily cleaning to reduce the risk of infection. Many transfemoral amputees who have been using osseointegrated prostheses have developed a wider range of walking speeds (2- Bergkvist et al 1996). Despite over 30 years of success in dental and maxillofacial implants and fitting over 450,000 patients with 95% success rate, Branemark is being cautious in the use of osseointegration to attach lower and upper limb prostheses.

The potential for osseointegration to provide more control over the prosthesis and the increased power transfer between amputee and limb are of significant magnitude to provide new challenges for prosthetic component design. More sophisticated designs might include special mechanisms for absorption of shock load and axial rotational torque to avoid direct transmission of these stresses to the bone interface. The use of a microprocessor to provide closed loop control of knee and ankle movement, new possibilities for EMG control and biofeedback, and the potential to suspend far heavier prostheses opens up new potential for future research advances in artificial limb technology.

There are potential limitations, however. A mechanical fail-safe mechanism, adjustable to different level of activities, is essential to avoid loosening or breakage of the implant. The cosmetic appearance and psychological issues associated with osseointegration require specialized training. The reliability and limited scope for repair, significant cost of the initial surgery and possible subsequent surgeries, and feasibility of reverting to wearing conventional prosthetic devices remain barriers to more widespread utilization of this method.

Increased use of soft tissues for force transmission

In recent years, there has been renewed interest in clinical exploration of the ability of the soft tissues to serve as a medium for force transmission. This is based on the similarity of the soft tissues to fluids, which are incompressible and can therefore transmit forces when properly constrained within a container.

Prior studies have shown that there is a longitudinal internal piston action of the skeletal elements in the socket. In theory, longitudinal movement of the skeleton into the socket could be prevented by the incompressible nature of the residual limb tissues contained within a rigid socket.

One requirement for force transmission in this manner is that the soft tissues of the residual limb be contained in a vessel that accurately matches the volume of the residual limb. Various pressurised casting systems have been developed in an effort to accomplish this theoretical goal. Combining pressure casting with a silicone liner having distal fixation to the socket has been proposed as one method to achieve an efficient connection between the skeleton and the socket.

Vacuum casting has also been advocated but this does not have the same effect as pressurized casting. When a vacuum is created only between the surfaces of the residual limb and the casting apparatus, no load is applied to the soft tissues although an accurate replication of the unloaded surface shape and volume are achieved. With pressure casting, in contrast, the shape and volume of the residual limb is influenced in response to the load applied to the soft tissues. The soft tissues displace and stabilize, the degree of displacement being dependent on the load applied, which is determined by the casting pressure.

Illustration of pressure casting apparatus and finished socket with suspension sleeve

Pressurized casting is thought to produce a ‘volume matched’ and ‘surface matched’ impression. This means that, in the casting situation at least, the shape of the soft tissues change in response to the equal pressure being applied. However, the shape of the socket needs to be adjusted in order to minimize pressure peaks that may occur in the dynamic situation either by making a conventional relief or by building a silicone pressure pad into the surface of the socket where a pressure peak is likely to occur.

Review of Prosthetic Component Developments

Application of Microprocessor Control to Lower Limb Prostheses

Research the Massachusetts Institute of Technology in early 1970’s demonstrating the feasibility of using a computer to control the prosthetic knee the was dismissed as impractical at the time. In 1986, when Nakagawa of Hoyogo Rehabilitation Hospital described a simpler application of microprocessor technology based on concepts developed by Belgrade University, there was still significant doubt about the clinical acceptability of such technology. It was not until the early 1990’s that Zahedi described the first commercial application of microprocessor control to prosthetic knee mechanisms.

The traditional viewpoint has been that the knee joint should be designed to provide stance control during the weight bearing phase of locomotion and swing control during the non-weight bearing phase, enable the amputee to sit down and, in certain cultures, to kneel. More recent research has demonstrated that this simplistic view of prosthetic knee function is not accurate.

Preliminary investigation has shown the following activities undertaken during a typical day by a lower limb amputee:

–<u>Typical amputee’s activities ----- Per day</u>

•Changes Walking speed	437 times
•Stumbles	108 times
•Stop and stands	1450 times
•Sits	48 times
•Descends stairs	23 times
•Descends ramps	38 times

Interestingly, stopping and standing with a stable knee is one of the most frequently required functional requirements. The need to change walking speed occurs more often than descending stairs and ramps. These data were based on 15 amputees wearing an electronic knee that recorded these activities over a period of 3 months.

Data such as these suggest that future prosthetic knee joints must provide stumble control, in most cases before the amputee is aware of the need, as well as support during stance to permit slowing down. In addition, the knee joint must alter the swing characteristics for slow, preferred and fast walking speeds, as well as provide stable support when standing. Additional stability during stair and ramp descent is also required. The specific type of mechanism for achieving the above requirements is neither clear nor critical. If microprocessor controls or mechatronic solutions provide the most reliable and cost effective solution, then prosthetic component design will continue to evolve in those directions.

Microprocessor control of hydraulic and pneumatic knee resistances

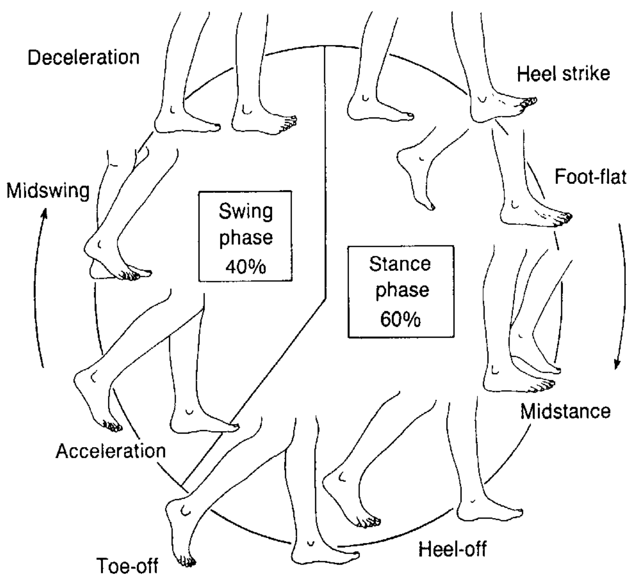
All currently available prosthetic components are passive systems: energy-dissipating replacements for human limbs. Current power sources and actuators have far too low a mass to energy capacity ratio to actively power lower limb components under weight bearing loads. Microprocessor-controlled passive prosthetic knees are now clinically available worldwide, and have been shown to offer a wider range of walking speeds than earlier fluid-controlled systems that could only be set by the prosthetist for a fixed range of resistances.

Consider the following requirements for prosthetic knee function during level walking:

- At **heel strike** the prosthetic knee must be stabilized as the foot begins plantar flexion.
- During this **Load Bearing** period, the prosthesis has two major functions:
    - support of the body weight and
    - reduction in the impact of heel strike

  This is achieved by a yielding flexion of the knee joint, which requires high flexion resistance

- During the **single support phase**, the body moves over the stabilized leg like an inverse pendulum. During this phase, the ground reaction force vector changes its position from heel to forefoot. This means that the flexed knee tends to extend rapidly so an appropriate extension resistance is necessary to prevent abrupt extension of the knee. This resistance should adapt to different gait speeds.



At the **end of single leg support**, the maximum vertical load is generated and knee flexion begins shortly thereafter to prepare the limb for swing phase. Therefore the knee resistance to flexion should be minimal.

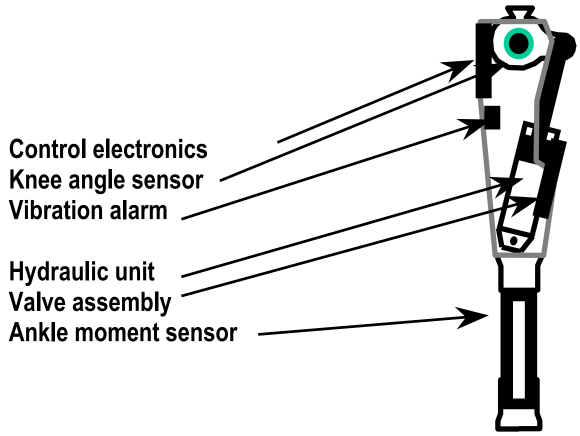
- **Swing phase** starts with the knee already flexed 30 degrees; the maximum knee angle is 55 to 65 degrees and time for achieving this range of knee motion is very short. The prosthetic knee should start with minimal flexion resistance and adapt automatically to a wide range of gait speeds.

At **midswing** the shank changes the direction of rotation due to mass reaction forces and the knee starts to extend.

- **Terminal swing phase** starts when the shank is in vertical position and ends when the extended leg hits the ground again. It is important that the knee joint extends quickly so that the leg is fully extended, yet the terminal impact should be minimal.

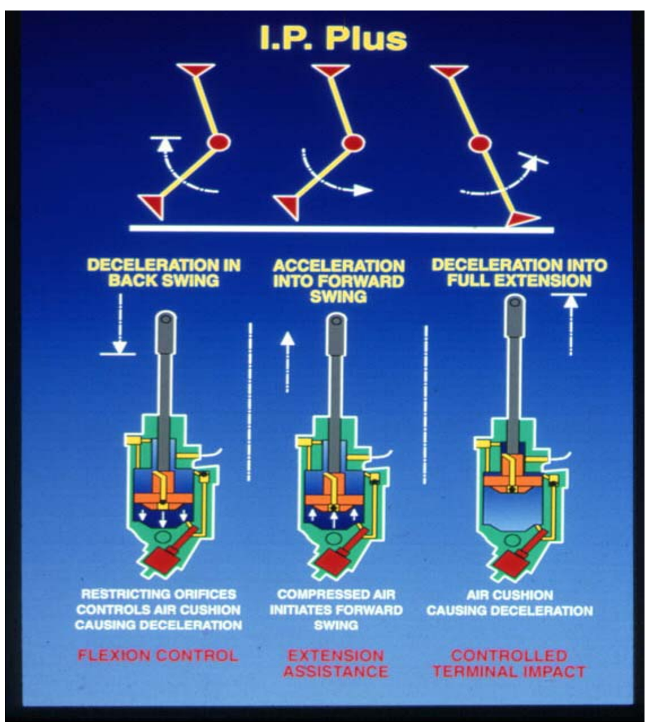
This complex dynamic procedure can be best handled with an electronically controlled knee joint with hydraulic resistance during swing phase and stance phase. The basic principle of this system is the detection of the current state of gait of the amputee by integrated sensors and the immediate adaptation of the flexion resistance and extension resistances of the prosthetic knee. The most important input signals are the knee flexion angle, the angular speed of the knee joint and the Anterior/Posterior bending moment of the shank. A hydraulic cylinder generates the required resistances for flexion and extension.

The illustration below depicts the sensors and electronic elements of the C-Leg components, which function as described above.



Recent developments providing microprocessor-controlled pneumatic swing phase control have been well documented by Zahedi (8,9). Clinical experience with nearly 10,000 such devices has demonstrated that microprocessor control can optimize knee resistance over the entire range of the amputee's walking speed and result in a more energy efficient gait.

The figure below illustrates how the Intelligent Prosthesis Plus uses microprocessor control to optimize pneumatic resistance to knee flexion and extension during swing phase.



In 1996, Zahedi et al (2000) began work on the next generation of microprocessor control by analyzing the activities that amputees undertake. Prior researchers and developers focused only on the primary function of walking. Real-time monitoring showed that amputees undertake many activities including standing, slowing down, walking at various speeds, and descending ramp and stairs. The aim of the project was to create a prosthetic knee capable of adapting to different modes of locomotion while optimizing voluntary use of the amputee's hip joint strength.

This development provides stance control ranging from minimal resistance to a yielding lock, and is capable of detecting level walking, ramp descent, stair descent, sitting, standing and stumble conditions. The stance resistance is set to a pre-programmed level for these different modes, which the prosthetist matches the amputee's level of voluntary muscle control.

Rapid detection of different modes of locomotion is accomplished by the use of microprocessor technology and a range of sensors detecting kinetic and kinematic parameters around the knee. The prosthetist uses a remote control programmer to adjust and fine tune motor valve controls and to adjust the resistance to flexion in stance and swing to individualize the function for specific amputees.

The key concept in this knee design is to create a prosthesis that is accurately matched to an amputee's hip strength and ability to control the limb in all modes of ambulation. Clinical results suggest that most active amputees are able to control the prosthesis during level walking but may need additional support from the device when stopping or during ramp and stair descent. Amputees with limited hip power may need stumble control assurance during initiation of level walking. Most amputees seem to benefit from the ability to have a standing mode, allowing them to relax without concern that the prosthetic knee may collapse.

The Adaptive Knee, illustrated below, combines the proven swing phase control from the earlier Intelligent Prosthesis with a novel microprocessor-controlled hydraulic cylinder that provides variable stance stability for standing, stopping, stumble recovery, sitting, and stair or ramp descent.

Future of microprocessor technology

The widespread clinical acceptance of the integration of microchips into prosthetic knee mechanisms sets the stage for a range of exciting future advances. The immediate challenge is to increase processing power, to create an artificial leg that can manage balance, stability, and comfort on its own. MIT's Leg Laboratory, a research facility dedicated to studying locomotion and reproducing it robotically, is working on a knee that will automatically adapt as the amputee's gait changes so the prosthetist won't have to make continual minor adjustments. Sensors generate a digital snapshot of the wearer's gait, which is analysed by onboard software. Damping of knee motion is performed by metal plates separated by an iron-rich substance called magnetorheological fluid. The microprocessor switches the magnetic field around the fluid on and off, altering the way plates move past each other, and thus adjusting the resistance in the knee. This magnetic system operates under lower pressure than the more familiar oil-filled hydraulic cylinders.

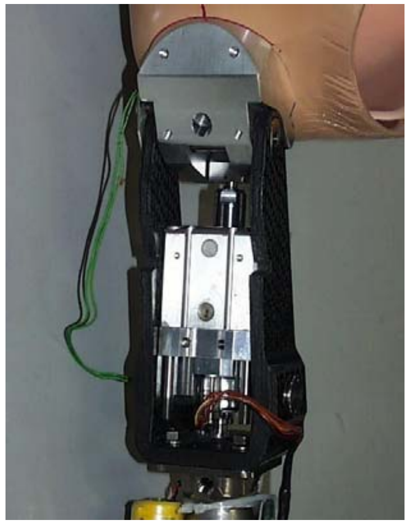
Sandia National Laboratories, teamed with a group of Russian nuclear scientists funded by the Department of Energy, is also developing a microchip-embedded knee. German and British companies are working on versions of their own. In another project, the Seattle Orthopedic Group Inc., a private prosthetic component manufacturer, and Sandia, again working with Russian researchers, are collaborating to create a Smart Integrated Lower Limb that will be entirely digitally controlled. Not only the knee, but also the ankle, foot, and leg socket will gather information from sensors and receive instructions from a software-guided chip.

The concepts of an Intelligent Hip Joint as described by Nakagawa and a Microprocessor-controlled prosthetic foot described by Zahedi are the short-term future of microprocessor control to compliment available knee controls. Use of bluetooth technology for communication between ankle, knee and hip will make interactive control on a commercial scale feasible. Formulation of a standard protocol would enable prescription of different feet, knee, and hip joints, regardless of the manufacturer.

Intelligent prosthetic hip joint

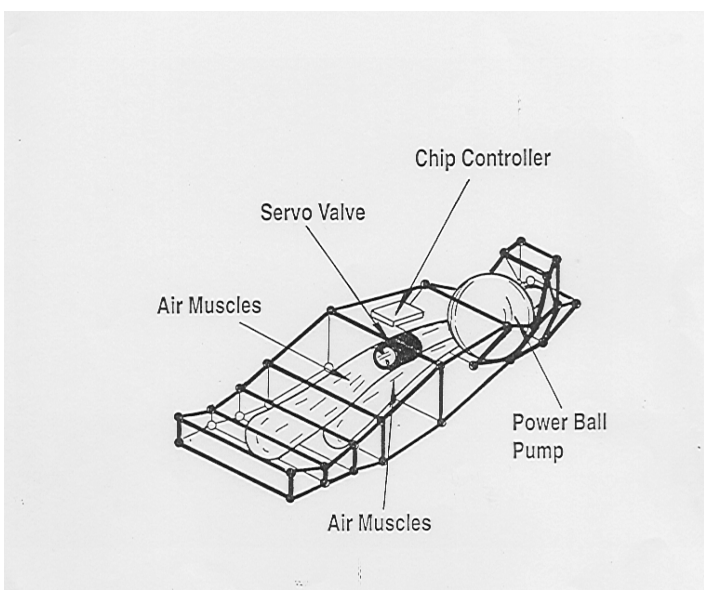
Hip disarticulation prostheses could be improved by controlling the swing of the hip joint. Careful observation and gait analysis have demonstrated that hip flexion angular velocity of current prostheses is slower than in normal gait, and mechanical means to accelerate hip flexion have been used clinically with some success. In this prototype, a pneumatic cylinder is compressed by the body weight of the user during stance phase. This air spring then accelerates thigh flexion in early swing phase. The compression varies depending upon walking speed and is controlled by microprocessor positioning of the valve. This component permits hip disarticulation amputees to vary their cadence with less effort than with simpler mechanical hip joints.

This prototype of a microprocessor-controlled pneumatic hip joint enables hip disarticulation amputees to walk at varying speeds with less effort than with a mechanical joint.



The Microprocessor controlled Ankle Foot Complex

The sketch below shows one concept for a prosthetic foot that uses space frame technology for load structures and air muscles as principle stiffeners. The power ball pump provides controlled ankle movement and generates the air pressure required to provide correct stiffness to the structure. This assembly can be loaded to absorb and restore energy at correct points in the gait cycle and to respond to changes in cadence. The ability of the frame to absorb shock loads and provide axial rotation in a very low



The Intelligent Foot - A micro processor control foot.

The foot is constructed based on space frame, made of three section simulating the calcaneus, the transmetatarsal and a joining frame which houses a rubber ball. Inside the links of the space frame which are made of composites runs rubber bellows like air muscles which once filled with air it will alter the stiffness of the space frame. Two main muscles run at the calcaneus section controlling the planter flexion at heel contact and provide M_L stability. As the arch of the frame comes into contact with the ground the ball pressurises and pumps air to 3 raws of the air muscles which control the dorsiflexion of the foot and inversion and eversion by controlling the relative movements of the frames section to each other. A micro processor controls a valve which in turn allows the flow of the air from back of the foot to the front through the air pump which is the ball inside. The system is programmed for the amputee activity, speed of walking and weight, so that as amputee walks slowly the foot is quite flexible and deforms easily while maintain performance. As the amputee walks fast or applies larger load, or deflects the front frame relative to rear frame in a much larger value than normal, the system automatically stiffens the frame to provide support and take out shocks.

profile design makes this concept potentially suitable for many lower limb prostheses.

Cosmesis – The overlooked need

For many modern amputees, having a prosthesis with a lifelike appearance is as important as receiving one that is highly functional. Today's patient often demands an external covering that, in addition to protecting the components, is lifelike, durable, light weight, feels like normal skin, and is shaped and colored to closely match the surviving leg.

Several manufacturers have developed elastomeric coverings, often made from silicone resins, that increase both the durability and cosmesis of artifical limbs. Patient acceptance has been excellent, particularly for transtibial prostheses. Unfortunately, when such coverings cross the knee joint, they tend to restrict flexion, so additional research is required to overcome this limitation.

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