“The C-Leg® and proprioception: how a microprocessor-controlled knee prosthesis mimics the human body’s system of awareness of position and production of movement”

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With special thanks to Dr. Joe Yanke, Sr. and Dr. Joe Yanke, Jr.
at Hanger Prosthetics & Orthotics in New Philadelphia, OH
and to Cale Konetchy, CP, and Jerry Gohman, RTP, at Otto Bock Healthcare® U.S.

Submitted in partial fulfillment of the requirements for graduation from the

Malone University Honors Program

April 5, 2011

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ABSTRACT

In the human body, the process of producing voluntary movement takes place in three general steps: sensory input via sensory nerves, integration in the brain, and motor output via motor neurons to the muscles. An integral component of this sensory information is proprioception, the sensation of the position and motion of the body and its parts. Each movement is then monitored and modified by the cerebellum to ensure accuracy and fluidity of the movement. Advances in biotechnology have allowed prosthetic devices to more closely mimic this natural system. One such device is the C-Leg®, a microprocessor-controlled knee prosthesis for above-knee amputees that is manufactured by the German company Otto Bock®. Its function mimics the body's processes of producing voluntary movement. Two sensors in the device receive and transmit "sensory input," including information about the device's position and motion (proprioception). Wires inside the prosthesis send this information to a central microprocessor, where the data is integrated. Programmed algorithms allow the received sensory data to be compared with data about thousands of different gait patterns. Based on the results of this comparison, the microprocessor "chooses" an appropriate gait phase and recommends a course of action. The microprocessor then sends this "motor output" through dedicated wires to the device's servo motors, which adjust the hydraulic cylinder valves to provide the amount of resistance needed for that particular phase. This thesis describes the similarity of function in the body and the C-Leg®, as well as provides introductory information about amputation and prosthetics in general.

Statement of Purpose

Since the age of five I aspired to be a physician. Therefore, I began my college career assuming I would continue to medical school and eventually earn an MD. One day while planning for the future, my mother and I were discussing the specialty of medicine I would pursue in graduate school. Unsure of what my interests were, she and I began to brainstorm and search online. Eventually, and serendipitously, we stumbled upon an outstanding branch of the Allied Health professions: orthotics and prosthetics (O&P). It is a rapidly growing, cross-discipline field, employing the latest in technological advances and offering virtually unlimited opportunities to improve the lives of those with limited mobility. The field calls for skills and proficiency in the biological sciences, mathematics, computer technology, and even art, each of which I genuinely enjoy. Just as importantly, one must also have a compassionate heart, an enthusiastic spirit, and a great propensity for patience. I was instantly captivated.

Consequently, I amended my major by adding several courses to my schedule in preparation for graduate school. I also began subscribing to a monthly magazine called *The Edge*, which is published for O&P professionals and reports the latest research in the field. It was in this publication that I first learned of the C-Leg® microprocessor knee. The C-Leg® is a technologically-advanced leg prosthesis which utilizes nanocomputing and advanced mechanics to duplicate the function of the human knee more accurately than traditional prostheses. Monumental progress in prosthetic devices, such as the C-Leg®, has reduced the physical and mental energy needed for amputees to walk on a regular basis(1) and thus has greatly improved the quality of life for those with limited mobility.

In addition to supplementary coursework to prepare for graduate school, I have also spent a number of hours shadowing at O&P clinics. These have included the University of Illinois Medical Center (affiliated with Scheck & Siress), in downtown Chicago; Yanke Bionics, in Akron, OH; and Hanger Prosthetics & Orthotics, in New Philadelphia, OH. At these facilities I was able to observe the O&P profession in action, interacting with remarkable patients and experiencing the personal care and devotion given to each one. My utmost gratitude is extended to Dr. Joe Yanke, Sr., and his son Dr. Joe Yanke, Jr., practitioners at Hanger Prosthetics and Orthotics. One of their patients has stood prominently in my memory since my first visit at this office. He was wearing the C-Leg® prosthesis that was mentioned in *The Edge*. His positive experience with the C-Leg® introduced me to the excellent progress of current bionic research, and convinced me that helping people regain their mobility was the most fitting career for me.

In the past, O&P professionals were required only to take an examination administered by the American Board of Certification (ABC) prior to practicing. In more recent years, the completion of O&P baccalaureate studies was included in the requirements, to be followed by ABC examination and certification. This type of program, however, was phased-out in 2010.(2) The field now requires completion of baccalaureate coursework which includes specific prerequisite courses, followed by completion of a Master's degree program in Orthotics and Prosthetics at an accredited institution and subsequent ABC certification. Only four universities are currently offering the Master's program needed for certification. I have chosen Eastern Michigan University (EMU) in Ypsilanti, MI. Part of the Master's program at EMU includes three consecutive thesis courses.(3) It is my hope that this undergraduate thesis work may adequately serve as a pilot for a future graduate thesis project, so that I may have a springboard from which to begin a more comprehensive body of work. Future research interests are outlined in Section V.

In preparation for graduate studies in O&P, I have been attempting to supplement my regular studies in order to develop a familiarity with this field. This Honors thesis is the product of these studies outside the standard General Biology curriculum. In summary, the purpose of my thesis has been threefold: first, to expand my general knowledge of prosthetics, with a focus on leg amputations and prostheses; second, to more fully and specifically understand the remarkable technology of the C-Leg®; and third, to establish a practically-applied body of knowledge to launch my graduate thesis work.

I. Introduction

Prosthetics is a division of the Allied Health Professions that involves functional, and sometimes cosmetic, replacement of an absent or amputated part of the body.(2) *Orthotics* is a related profession, often coupled with prosthetics, which involves supplementation or stabilization of an injured or otherwise compromised part of the body.(2) The *prosthesis* is a device which replaces a missing body part. The *orthosis*, on the other hand, is a device which supplements an existing body part. For example, an ankle-foot orthotic (AFO) is a stiff, usually plastic device which stabilizes the ankle joint.(4) This thesis focuses on above-knee leg amputations and prostheses. The *prosthetist* is a certified professional in prosthetics. Certification allows prosthetists to see patients, fabricate prostheses, and fit and adjust prosthetic devices as needed.

Categories of Amputees

Limb absence can result from two general causes: congenital absence or acquired absence. Congenital limb absence, technically termed *dysmelia*(5), is a condition in which a body part has been missing since birth, usually due to abnormal prenatal development. Literature in the field often refers to this group as "congenital amputees."(6,7) It should be noted, however, that dysmelic patients have always been missing the limb, and technically have not had the limb amputated despite the convention to label them as such. This thesis will refer to those with congenitally absent limbs as dysmelic. Causes of dysmelia may include exposure to certain chemicals and drugs which disrupt fetal development and result in physical deformities. One such substance is the drug thalidomide. In the late 1950s, thousands of German children were born with dysmelic arms and legs because of the devastating effects of thalidomide.(8) The drug inhibits the process of angiogenesis (formation of new blood vessels) in the developing fetus, stunting the growth of the forming limbs.(9) It had been formulated to ameliorate morning sickness in pregnant women, and was very effective for this purpose. When these women's infants were born, however, the hidden effects of the drug were discovered. Use of the drug was widespread in Germany. It would have been released in the United States at that time under the market name Kevadon™ without the careful attention of FDA Pharmacologist Dr. Frances Kelsey.(8)

Acquired absence, on the other hand, involves the loss of a previously intact limb or body part. The intention of surgical removal, called *amputation*, is to eliminate the affected portion of the body while retaining as much of the healthy structures as possible. Common causes leading to amputation include cancer, infection, injury sustained during military service, and degeneration of the vessels which supply the limb (dysvascular disease).

According to a study of American amputees from 1988 to 1996, 82% of lower-limb amputations were due to dysvascular diseases like diabetes.(10) Other causes of acquired limb absence may include trauma resulting in severance of the limb or body structure. In general, the cause of limb absence has no bearing on a patient's options for the prosthesis.

Types of Leg Amputations

Leg amputations can be divided into two major categories: below the knee (*BK*) or above the knee (*AK*). A below-knee amputation (BKA) transects the lower leg across the tibia and fibula, between the knee and the ankle joints. It is also called *transtibial amputation*.(11) Disarticulation of the ankle joint is called a *Symes amputation*(12), and is not considered to be a BKA. An above-knee amputation (AKA) involves removal at or above the knee while still leaving a portion of the pelvis intact. Amputation involving removal of the entire pelvis is called a *hemicorporectomy*(13) or translumbar amputation. It is, quite literally, a removal of half the body. This procedure is very rare and is not considered an AKA.(13)

The sub-categories of AKA are named according to the part of the leg that is transected. AKA at the lowest level is a *knee disarticulation*, in which the knee joint itself has been separated between the distal head of the femur and the proximal head of the tibia.(11) The patella (kneecap) is usually not retained, as it would be nonfunctional and would simply interfere with the fit of the prosthesis. *Transfemoral amputation* involves transection across the femur, above the knee yet retaining the hip joint.(11) *Hip disarticulation* removes the entire femur up to the greater trochanter and femoral head, retaining the acetabulum of the pelvic ilium.(11) A *hemipelvectomy* (or transpelvic amputation) transects the ilium and/or ischium of the pelvis, and may or may not separate the pubic symphysis.(11) This procedure still retains a portion of the pelvis. This type of amputation requires specialized harnessing equipment to secure the prosthesis to the body, such as laced leather shorts or a soft plastic seat. *Bilateral amputation* involves removal of the same limb on both sides of the body(11); for example, a bilateral BKA. Bilateral amputees may use prostheses under the close supervision of a prosthetist.

Care of the Residual Limb

The portion of the limb that remains after amputation or that has been affected by congenital defect is informally called the *stump*.(11) The more proper, medical term is *residual limb*.(11,14) Both terms are regularly used in practice, depending on the personal preference of the prosthetist. The remaining, healthy limb on the opposite side of the body is called the *sound limb*. Following surgical amputation, localized edema (swelling of the tissue) is very common. The residual limb may change considerably in size and shape during the healing process due to edema, daily weight loss or gain, and retention of fluids.(14) Therefore, it is advised that surgical amputees follow a good diet and exercise plan to control fluctuations in the size of their residual limb.(14) Wearing either elastic bandaging or "shrinker" socks is also recommended, both to reduce edema and to keep the limb in shape for a prosthesis.

Whether dysmelic or acquired, an amputee who uses a prosthesis must be sure to cleanse and dry the limb and the prosthetic socket (the "cup" which holds the limb) daily to avoid skin irritation.(14) Though dysmelic patients are less likely to develop skin infections, as the skin is not in the process of healing, cleanliness is still a necessity for overall health of the residual limb. For surgical amputations, massaging the limb several times a day is also advised. Massaging reduces the skin's sensitivity so that wearing a device for long periods of time becomes more bearable. (14) It also promotes blood flow to the traumatized region, which can speed the healing process, and helps keep the remaining muscles loosened. The patient should also avoid placing pillows underneath the limb or between the legs while sitting or sleeping. Resting the limb in a crutch handle is also not advised, as these practices may tighten the muscles in the residual limb and cause considerable pain.(14)

Each patient wears his or her prosthesis differently. Most, however, will wear special prosthetic socks around the limb to provide extra softness and cushion. Wool is a common material, as it keeps its shape well, wicks away perspiration, and resists wrinkling.(15) Cotton, another natural fiber, is also used for its breathability and hypoallergenic nature though is limited in its absorbency.(15)Synthetic blends are most commonly used.(15) The patient can adjust the number of socks worn to improve the fit of the prosthesis, as the limb may swell or shrink during the day even after the healing period.(14) It is recommended that these socks be changed and washed at least daily to minimize irritation of the skin of the residual limb. Amputees are advised to avoid wearing damp socks or bandaging, as this is likely to irritate the skin. Applying lotion to the limb is also discouraged, unless it is specifically doctor-recommended.(14)

The Biomimetic Goals of Prosthetic Devices

The human body is an unparalleled marvel. When one of its parts is lost, the ideal replacement would be a flesh-and-blood duplicate of that body part. Accordingly, prostheses are designed and fabricated to mimic the appearance and function of the lost body part. The science of using the designs of nature to inspire the designs of technological systems, methods of processing, materials, and apparatuses is called *biomimetics*(16)—literally, "mimicking life." A related branch of engineering called *bionics* deals with specifically mechanical or robotic devices,(17) which likewise uses nature's blueprints as a guide for their design and function. For example, the microprocessor-controlled C-Leg® knee (to be discussed later in Section IV) is a bionic knee device.

A next-generation branch of bionics called *cybernetics* deals with technologically-advanced mechanisms which are physically integrated into the patient's nervous system. This integration allows impulses from the brain to be transmitted through the body's nerves, which conduct the impulse through electrodes to power coils in the device. The power coils are linked to wires that control motors within the device, according to the commands originating in the patient's brain. Such devices are called *cybernetic* or *neural prostheses*.(18),(17)

Curiously, although the prosthesis is fabricated to mimic a sound limb's shape and size, it is not made to approximate the weight of the amputated limb. The weight of an amputated leg segment averages between five and ten pounds.(19) Most leg prostheses, in contrast, weigh only two to three pounds. After their first fitting, however, patients frequently comment that the device is very heavy. Minimizing the weight of the prosthesis aids an amputee in the transition to walking with a prosthetic device.

Prosthetic Components: the Socket

The cup-like container which serves as the point of attachment to the body is called the *socket*.(11) The socket is designed to fit the residual limb, so that it can be worn securely and confidently while minimizing friction with the skin. There are many different methods for fabricating the prosthetic socket; thus, each fabricator has a somewhat unique or preferred method for constructing it, which is partly where the profession requires a measure of creativity.

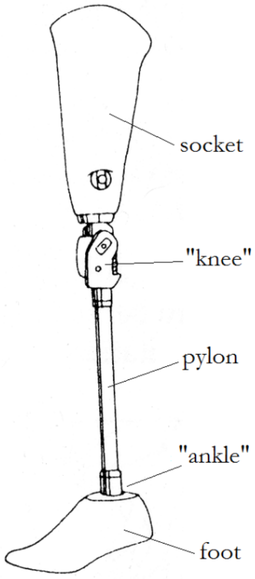

Fig. 1 The components of an above-knee prosthesis (see *Figure References*, p.60)

In one method, the practitioner takes an impression of the residual limb and fills it with plaster to create a casting of the limb. A molten sheet of plastic is then laid over the plaster casting and vacuum-molded to create an exact replica of the residual limb's negative space. Softer, more pliable polymers are used for the preparatory prosthetic socket so that it can be easily adjusted during the period of residual limb stabilization. Harder polymers are used to create the definitive socket.(14) This affords the stability required of a long-term, heavy-use device. Many definitive sockets are fabricated to be flesh-colored and thus more cosmetically realistic. If desired, however, specialized transfer paper can be applied to the molten plastic, so that the definitive socket will be covered in a colorful pattern. A few examples are camouflage, flowers, and the American stars and stripes.

In another method for designing the socket, which is one of the field's junctures with computer technology, the residual limb is placed in a machine programmed with computer-assisted design (CAD) software such as Insignia™ from Hanger Orthopedics, Inc.(4) The machine analyzes the shape of the residual limb with a laser beam, which transmits this data to a computer to create a digital composite image of the limb. From this positive image, the limb's negative space—in effect, the shape of the socket—can be determined. The CAD program then directs a lathe to carve the socket out of the appropriate material in the shape of the limb's negative space, so that the residual limb has an excellent fit in the socket.

Plastic sockets commonly have a hole and stem valve on the inner thigh to allow for suctioning of air(14), which insures a tight and secure fit. Other styles of prostheses may require the patient to insert the residual limb into the socket and "pump" the air out with the limb by moving it

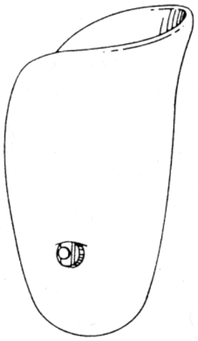

Fig. 3 Suction valve

up and down. A residual limb which varies in size or has bony protrusions may require a prosthesis made with a small "door." This door can be opened and closed to allow comfortable insertion of the limb into the socket. Prostheses for extensive transfemoral and hemipelvectomy patients may utilize a leather corset-type outfit or a belt to secure the rest of the prosthesis to the body.

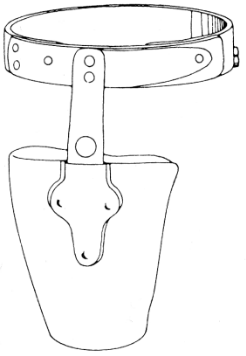

Fig. 4 Pelvic belt

The Prosthetic Pylon

In most leg prostheses, a rod-like shaft or tube called the *pylon*(14) is mounted below the socket. The pylon is the load-bearing column of the prosthesis; thus, it must be strong enough to support body weight. The pylon roughly correlates to the long bones of the leg. For BKA prostheses, a pylon corresponding to the tibia and fibula connects the knee or lower-leg socket to the ankle/foot complex. For extensive transfemoral and hemipelvectomy prostheses, an additional pylon corresponding to the femur connects the socket to the knee joint. Each pylon can be adjusted in length to allow proper distance between the foot, knee, and hip (and the corresponding prosthetic components) so the prosthetic leg portions are the same height as the corresponding portions of the sound leg.

The composition of the pylon will vary depending on the patient's needs, expectation of mobility, and insurance coverage. A pylon made of dense wood, for example, would be inexpensive and suitable for an amputee who expects or is capable of only limited walking around his or her one-story house. Titanium, on the other hand, is a more expensive material, but it offers much more strength and durability while remaining lightweight. A relatively new material called carbon fiber also offers tremendous strength and durability without compromising its minimal weight.

The Prosthetic Foot

The foot chosen to complete the prosthesis will vary greatly depending on the needs of the amputee. The considerations in choosing a foot are more for functional biomimesis than cosmetic biomimesis, as the foot will often be covered by a shoe. However, the simplified shapes most common for foot prostheses in the current market may undervalue the importance of foot physiology in human balance and movement.(20)

For those who simply require a walking foot, a suitable form can be fashioned from wood to approximate the mirror image of their other foot inside a shoe. For those who wish to run, a flexible C-shaped "foot" can be attached, which looks much less like a human foot but affords the bounce needed for running. For those who wish to hike or climb mountains (yes, there are mountain-climbing amputees), a heavy-duty rubber stump-like attachment can be secured to the pylon, which also looks very little like a human foot but gives the amputee the grip and stability needed for rock-climbing. Prosthetic feet are relatively easily interchanged; thus an amputee participating in a variety of activities has the option of ordering several different feet appropriate for these diverse activities. A surprising variety of shoes can be appropriate for a prosthetic foot as well—provided that the shoe is constructed well, will provide stability, and will not affect the patient's gait.(12) Once a particular type of shoe is chosen, the heel of the prosthetic foot is adjusted to this shoe type. Thus, the patient's shoe options become more limited, as wearing shoes of a different heel height will affect the patient's gait and alignment of the prosthetic leg.(14)

Prosthetic Cosmesis

Some patients prefer that the public see the prosthesis apparently, to avoid the embarrassment of speculative staring. Others desire to have a cosmetic cover, or *cosmesis*, applied to the outside of the prosthetic device. The cosmesis may be a soft foam cover or a hard laminate shell, depending on whether it was made with the endoskeletal or exoskeletal method (as described above). The laminate cosmesis can be coated in any color plastic available at the prosthesis fabrication facility, and contributes to the structural integrity of the prosthesis. The foam cosmesis has no mechanical function in the prosthesis; it is purely aesthetic. Manufacturers offer several different flesh-colored foam cosmesis options.

The "Preparatory" and the "Definitive" Prostheses

The process of learning to use a prosthesis every day involves two phases: temporary and permanent (or long-term). The temporary phase spans the healing process. The first round of fabrication will create the temporary or *preparatory prosthesis*.(14) The socket of the preparatory prosthesis is made with a pliable, easily-adjusted plastic polymer. The patient is fitted for the preparatory prosthesis as soon as possible after surgery. This practice not only allows the limb to adjust to the physical restrictions of the socket, it also enables the patient to begin resuming life as usual. Individualized therapy and gait training aid the patient in restoring the ability to walk. The amount of time this device can be worn is gradually increased as the amputee becomes more skilled and comfortable with using it. Typically, the prosthetist will make numerous mechanical adjustments to the device to ensure maximum comfort, complete functionality, proper walking gait, and symmetry between the sound leg and prosthesis. Indeed, the more closely an amputee's gait resembles natural gait, the more likely he will be to use the device and the more successful he will be in resuming pre-injury activities. Layers of foam may also be glued inside the edge of the limb socket using strong adhesives, providing a more comfortable interface between the skin and the prosthesis. This series of gait-focused adjustments is called *dynamic alignment*.(4,14)

The long-term phase is reached when the residual limb stabilizes in size and shape. At this time, the permanent or *definitive prosthesis*(14) can be constructed out of a more solid plastic polymer. This device is much more durable, but is accordingly more difficult to modify. The definitive prosthesis has an average lifetime of five years.(21)

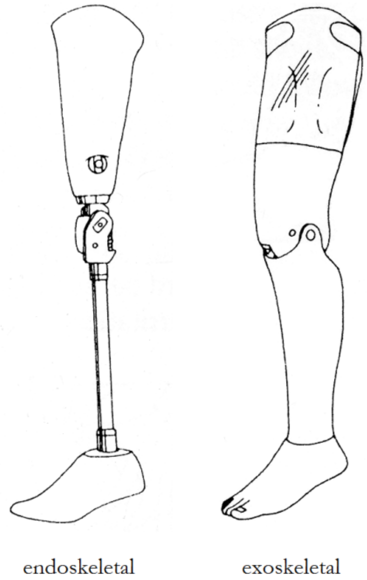

Fig. 2 Two methods of fabrication

The prosthesis can be fabricated in one of two ways: the endoskeletal method and the exoskeletal method.(14) The way in which it is made will depend on the patient's activity level. In the endoskeletal method, the pylon tube is simply covered with soft, flesh-colored foam that is shaped to match the sound limb. In the exoskeletal method, a hollow calf-shaped case is fitted between the socket and the foot and then filled with dense, solid foam. This method does not incorporate a true pylon. Plastic laminate is then coated on the entire leg for additional strength and durability. The C-Leg®, a microprocessor-controlled knee prosthesis, exhibits aspects of both. The outer case for the computerized components is shaped like a human calf and composed of durable carbon fiber. Below the casing is an adjustable pylon, connecting it to the prosthetic foot.

Mobility Classifications

Each patient is capable of and desires a different level of activity than another patient. Some may simply want or only be able to navigate indoors on level ground. Others will want to continue their active lifestyle of rock-climbing and triathlons. Each patient is individually assessed based on his or her needs, expectations, and abilities and placed into the corresponding category of mobility. These categories are used to determine the type of prosthesis most beneficial to the patient and the extent of therapy needed to regain the expected locomotive abilities. Clinicians must have a method of quantifying these abilities, so that the patient can be fitted with the type of prosthesis most appropriate for his or her needs. There are several schemata for these classifications.

The classification scheme most commonly accepted in America is the K-level classifications, also called *functional levels*. These are based on the patient's desires and expectations, prior prosthesis use, current and potential abilities to ambulate, and any other special or extenuating circumstances. This system consists of five levels (4):

0. *Non-ambulatory* – the patient does not have the ability/potential to walk, and the use of a prosthesis would not be beneficial

1. *Limited and unlimited household ambulatory* – the patient has the ability/potential to walk, though at a fixed speed (*cadence*) and on a level surface (such as indoors), and the use of a prosthesis would be beneficial to some extent

2. *Limited community ambulatory* – the patient has the ability/potential to walk at fixed cadence, on slightly uneven surfaces, and over small steps or obstacles

3. *Community ambulatory* – the patient has the ability/potential to vary his or her cadence, overcome most environmental obstacles, and engage in activity requiring locomotion beyond walking

4. *Active adult or child, athlete* – the patient has the ability/potential to engage in activity beyond simple locomotion involving high levels of impact or stress.

Hanger, Inc. uses the PAVET™ protocol, or the "Patient Assessment Validation Evaluation Test," to place patients into a functional category. This process evaluates the patient's everyday activities prior to amputation (and whether the patient desires to continue them), the patient's physical capabilities, and any special considerations that might affect the patient’s ability to use a prosthesis, such as those requiring safety restrictions or added stability. These might include heart disease, impaired vision, or exceptional height or weight.(22) For patients in K-levels 3 and 4 who may be eligible for microprocessor knee (MPK) technology such as the C-Leg®, prosthetists at a Hanger facility may use the MPK Program™ questionnaire to determine whether the patient would benefit from, and thus qualify for, MPK technology. These assessments are important in determining the details of a clinic’s reimbursement for an MPK from the manufacturer.

Otto Bock®, the manufacturer of the C-Leg®, has created its own classification scheme called MOBIS®. This scheme is not accepted by most U.S. insurance policy providers. Though not identical to the functional levels, this system is similar in its five levels (23,24):

Fig. 5 MOBIS® mobility system by Otto Bock®

0. *Unable to Walk:* Physical and/or psychological limitations prevent the patient from walking with a prosthesis, even when aided

1. *Indoor Walker:* The patient has the ability or potential to use a prosthesis to walk on level floors at minimal speeds, distances, and time intervals

2. *Restricted Outdoor Walker:* The patient has the ability or potential to use a prosthesis to walk on level or slightly unlevel ground and navigate small obstacles, though at slower speeds and shorter time periods

3. *Unrestricted Outdoor Walker:* The patient has the ability or potential to use a prosthesis to walk on unlevel ground and navigate most obstacles, with varying speeds and longer time periods; use may be limited by excessive mechanical demands

4. *Unrestricted Outdoor Walker with Especially Rigorous Demands:* The patient has the ability to use an appropriately-designed prosthesis to engage in a high activity level with high functional demands, in addition to the abilities of the Unrestricted Outdoor Walker; duration and distance of use essentially unlimited.

These categories are helpful to prosthetists for developing therapy goals and activity-specific prostheses for their patients. A prosthesis fabricated for everyday walking, for example, is constructed differently from a prosthesis used for running. Some lower-limb amputees order several different prosthetic legs to accommodate the various activities in which they regularly participate. As these patients exemplify, enduring an amputation does not necessarily mean a patient's lifestyle is limited. In many cases, those who were avid cyclists, swimmers, hikers, or runners before being injured can continue this active lifestyle.

II. The Anatomy of the Knee Joint and the Kinesiology of Gait

It will prove useful to introduce the physical components of the knee before moving into a discussion of the physics of walking, so that the components and forces which must be reproduced by a knee simulation prosthesis may be more fully appreciated. The elements of anatomy mentioned here will be limited to what is most relevant in comparison with the C-Leg® microprocessor knee prosthesis.

Skeletal Components of the Leg and Knee

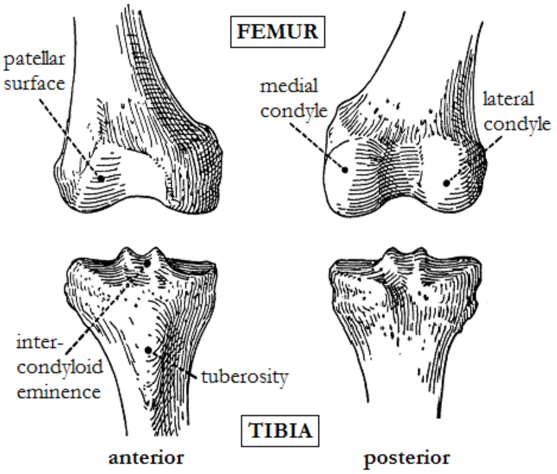

Fig. 6 Anterior and posterior views of bones of knee joint
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The knee, or tibiofemoral joint, is a modified hinge synovial joint and is the most complex articulation of the human body.(25) Because it is a synovial joint, by definition it is enveloped by several layers of fibrous connective tissue which contain lubricating synovial fluid, called the *joint capsule*. The tibiofemoral joint capsule is formed mostly by the tendons of the surrounding muscles and the ligaments which tie the tibia, femur, and patella together.

Because it is a modified hinge joint, the knee is capable of mainly "open and close" movement like a door; that is, the angle between the lower leg and the upper leg can vary from 180° while standing to approximately 20° (bending posteriorly), depending on the extensibility of the muscles and ligaments when bending the knee. A decrease in this angle is called flexion, and an increase in this angle back to the "straight" condition is called extension. The C-Leg® is capable of replicating both of these natural movements. Hyperextension, in which the tibia extends anteriorly in relation to the femur, typically results in injury to the joint.(25) While in flexion, the knee is also capable of slight internal (medial) and external (lateral) rotation,(26),(25) giving it a modification from simple hinge joints. The C-Leg®'s knee portion is constrained within a carbon fiber

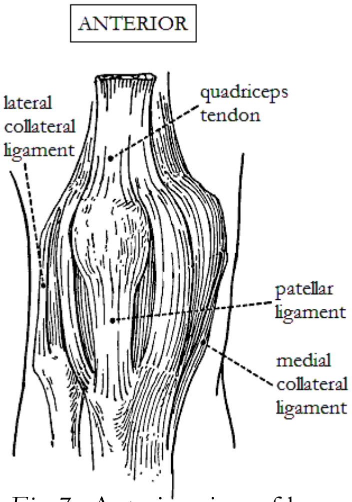

Fig. 7 Anterior view of knee joint showing ligaments

casing, and thus is not capable of internal rotation, external rotation, and hyperextension. While not negatively impacting the user's walking ability, this inability may limit certain activities requiring a rotationally flexible knee joint. Playing tennis, for example, causes rotational stress that a prosthetic knee may be unable to accommodate. Gait therapy aids these users in learning how to perform modified versions of actions, so they can play tennis while still exercising caution.

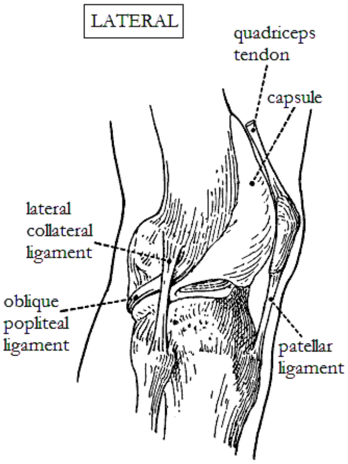

Fig. 8 Lateral view of knee joint showing ligaments

The distal head of the femur articulates with the proximal plateaus of the tibia. The patella (kneecap) fits in a small depression of the femur called the patellar surface, held in place by the quadriceps femoris tendon superiorly and the patellar ligament inferiorly. Behind the patella, the anterior cruciate ligament (ACL) crosses from the tibia, between the medial (inner) and lateral (outer) condyles of the femur, and upwards to the posterior surface of the femur. It acts like a high-tension rubber band to minimize the ability of the knee joint to rotate about itself, to prevent hyperextension of the joint, and to keep the tibia from moving too far forward from the femur. The posterior cruciate ligament (PCL) functions as a counteracting rubber band, attached at the posterior intercondylar surface and crossing the ACL (hence the name "cruciate") through the intercondylar space to then fasten on the medial condyle of the femur. It is the main stabilizer of the knee and provides its central axis of rotation. It also keeps the tibia from moving too far posteriorly from the femur, which is what enables us to

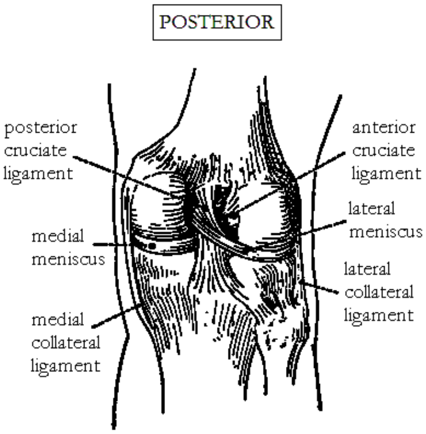

Fig. 9 Posterior view of knee joint showing cruciate ligaments

walk step-over-step on staircases or inclines. The C-Leg® affords enough similarity to these anatomical elements to enable its users to walk step-over-step, unlike users of traditional knee prostheses.

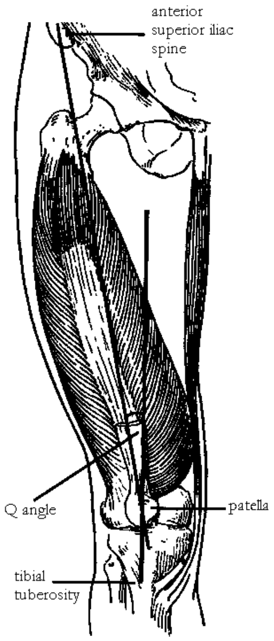

Fig. 10 Q angle

Anatomically, the leg is not perpendicular to the ground. The femur slants medially from the pelvis to the knee, creating an angled pull by the quadriceps muscle called the *Q angle*. Females generally have a larger Q angle than males(26) because of their wider pelvic girdles. Prosthetists attempt to match an amputee's Q angle for the residual limb inside the socket to improve stability during gait.(27) The tibia, on the other hand, is approximately perpendicular from the knee downward. Slanting of the tibia constitutes a pathological deformity, commonly called "knock-knee" (genu valgum) or "bow-leg" (genu varum). Valgus and varus tendencies are designated by the position of the most distal bone in relation to the body's midline(28); in this case, the tibia.

Muscular Components of the Leg and Knee

Overlaying these bones and ligaments are the muscles that act on the knee joint. They work in opposing pairs on either side of an articulation by pulling on the joint in opposite directions. The initiator of the movement is called the agonist and its opponent, which terminates the movement, is called the antagonist.(29) This allows them to dynamically and precisely control the beginning and ending of motions. The points at which muscles attach to bones are labeled the origin and the insertion. The origin is the more stationary attachment. The insertion is the attachment to the more mobile bone.(29)

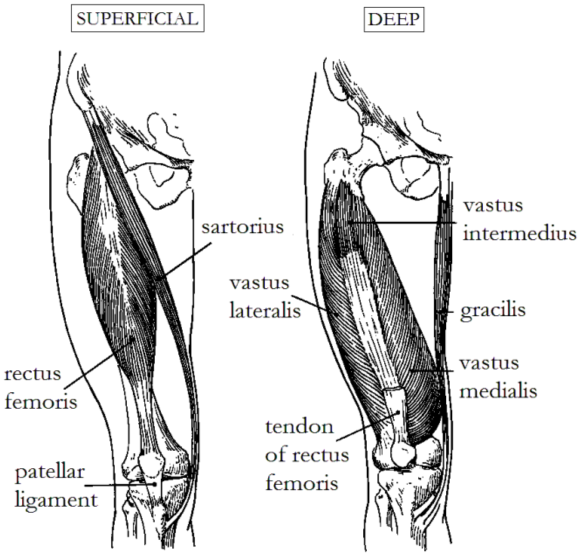

Fig. 11 Anterior muscles of thigh, superficial and deep layers

In the upper leg, the anterior and posterior muscles engage in extension and flexion of the knee, respectively. The anterior quadriceps are a group of four muscles: the rectus femoris, the vastus medialis, the vastus intermedius, and the vastus lateralis (the three vasti). These muscles bring the knee into extension. When these muscles contract, the distance between the pelvis (the muscular origin) and the inferior segment of the femur (the muscular insertion) shortens, pulling the condyles of the femur in the anterior direction and thus extending the knee.

Those that engage in flexion (the opposing movement), located in the posterior thigh, are the hamstrings: the biceps femoris, the semimembranosus, and the semitendinosus. The shortening of these muscles pulls the lower leg closer to the femur, thus flexing the knee. In addition to the hamstrings, the anterior sartorius and the medial gracilis aid in knee flexion. Posterior to the knee itself, the popliteus maintains stability and limits rotation of the knee, ensuring that it remains properly aligned with the upper and lower leg.

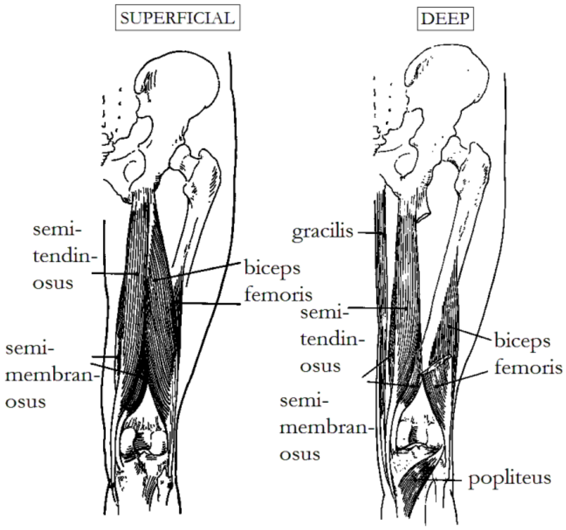

Fig. 12 Posterior muscles of thigh, superficial and deep layers

In the posterior lower leg, the most superficial muscle is the gastrocnemius, named for its large muscle belly. This muscle brings the lower leg up during knee flexion. During its opposing action, it helps to maintain knee extension while the leg is bearing weight. Its bifurcated, superior origin is from the medial and lateral condyles of the femur, attached on their posterior surface. Its large, inferior insertion to the calcaneus, or the heel bone, is commonly called the Achilles tendon. Deep to the gastrocnemius is the soleus, another strong muscle which accomplishes roughly the same action on the knee. Other deep flexor muscles enhance the activity of the aforementioned muscles of the posterior lower leg.

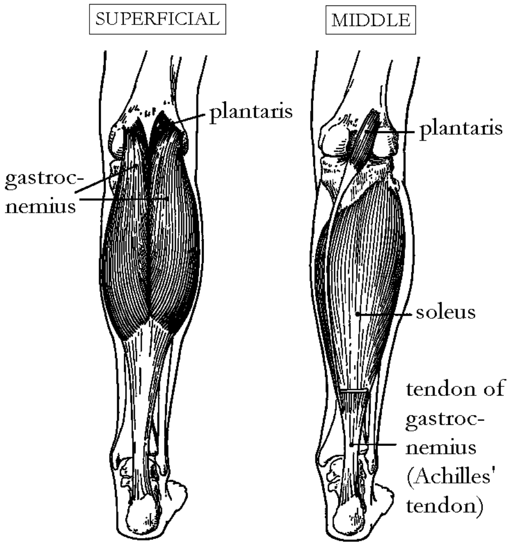

Fig. 13 Posterior muscles of lower leg, superficial and middle layers

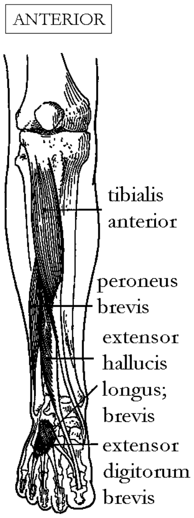

Fig. 14 Anterior muscles of the lower leg, superficial layer

The anterior muscles of the lower leg are involved mainly in ensuring stability during the gait cycle.(26) The most noteworthy of these is the tibialis anterior.

Nervous Components of the Leg and Knee

Innervation is another vital component of producing movement. It enables communication between the components of the body through conduction of electrical impulses. Indeed, as many neurologists say, “the nerves run the show.” Without innervation, muscles are powerless to contract in a coordinated manner, and no intentional or organized movement is produced.

The parts of the nervous system which coordinate voluntary movement are organized into a loop of sensory (afferent) neurons, interneurons (association neurons), and motor (efferent) neurons.(30) Stimulation of sensory neurons in a muscle from heat, touch, pressure, or vibration will trigger a nerve impulse, which travels towards the central nervous system (CNS) along the sensory nerve pathways. This impulse will then be transferred to interneurons within the CNS (the brain and spinal cord), where the sensory information will be processed and will acquire meaning. An appropriate action command will then be conducted from the interneurons to motor neurons, which then travel to a particular muscle or muscle group to elicit the desired response.(31) These three segments of the loop provide a framework for understanding the sequence of events involved in the production of movement: sensory input, data integration, and motor output.

Nerves exit the spinal cord in large bundles called plexuses. From the plexuses arise major nerve branches, which then travel to specific areas of the extremities. The major plexuses from which the major innervations of the leg arises are the lumbar plexus and the sacral plexus.(32) The nerves mentioned here are limited to those controlling mainly the leg and the knee.

From the lumbar plexus, five major nerves arise which innervate the muscles of the leg and the knee. One of these, the medial femoral cutaneous nerve, runs near the sartorius muscle. Its branches form the prepatellar plexus, a cluster of nerves which receive and send data about the entire knee region, making it very important in proprioception. This nerve may branch further, paired with a branch of the saphenous

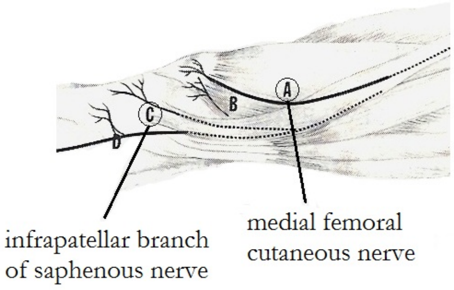

Fig. 15 Medial nerves of the knee

nerve, to enter the knee joint at the medial retinaculum (connective tissue in the knee).(33) The saphenous nerve itself innervates the anterior inferior area of the knee joint capsule, which transmits information from the mechanoreceptors (proprioceptive informants) within it.(32,33) The largest nerve exiting in the lumbar plexus is the femoral nerve. This nerve supplies the extensors of the knee; that is, the quadriceps group.(32,33) The aptly-named obturator nerve passes through the large obturator foramen of the pelvis. It divides into an anterior and a posterior branch. The anterior branch supplies the membranous structures surrounding the knee. The posterior branch of the obturator nerve is bound to the popliteal artery and travels through the musculature of the knee to form the popliteal plexus(33), a major junction of nerves innervating the knee.

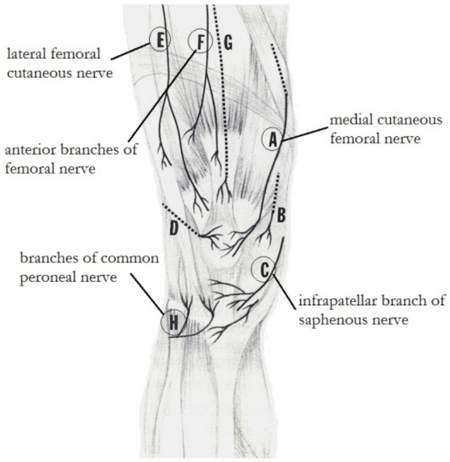

Fig. 16 Anterior nerves of the knee

From the sacral plexus, five major nerves arise which innervate mainly the muscles of the leg. The large sciatic nerve is the longest in the body. When damaged or irritated, it is the cause of aggravating leg pain called sciatica.(32) The sciatic nerve is a coupling of two distinct nerves which are tissue-bound together: the tibial nerve and the common fibular nerve (also called the common peroneal nerve).(32,33) They separate at the lower part of the thigh to innervate their respective areas of the leg. The tibial nerve supplies the muscles of the lower leg, including the

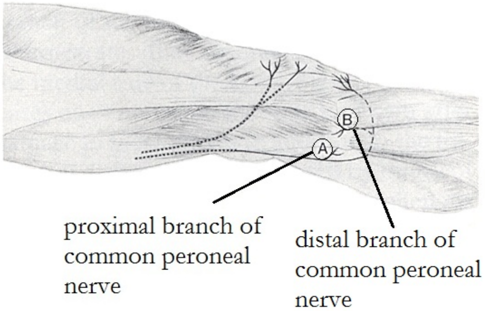

Fig. 17 Branches of common peroneal nerve

gastrocnemius, the soleus, the popliteus, and several of the lower leg flexors.(32,33) The common fibular nerve branches into the superficial fibular and deep fibular nerves, which innervate other muscles and skin areas of the lower leg, most notably the tibialis anterior.(32,33)

The Gait Cycle

For most of us, an action as routine as walking (also called *ambulation*) is performed subconsciously, requiring little mental or physical input. Indeed, walking relies heavily on our reflexes.(34) It appears to be a relatively easy activity and is not often analyzed by those who have no difficulty with it. To the contrary, however, walking is actually a complex series of motions. Each person has a somewhat unique method or pattern of walking, called *gait*. In order for therapists and practitioners to analyze gait more easily, each motion carried out can be categorized into one of two distinct phases of walking, each of which is further broken down into associated subphases. This repeated pattern of walking stages is called the *gait cycle*, and each stage is referred to as a *gait phase*.

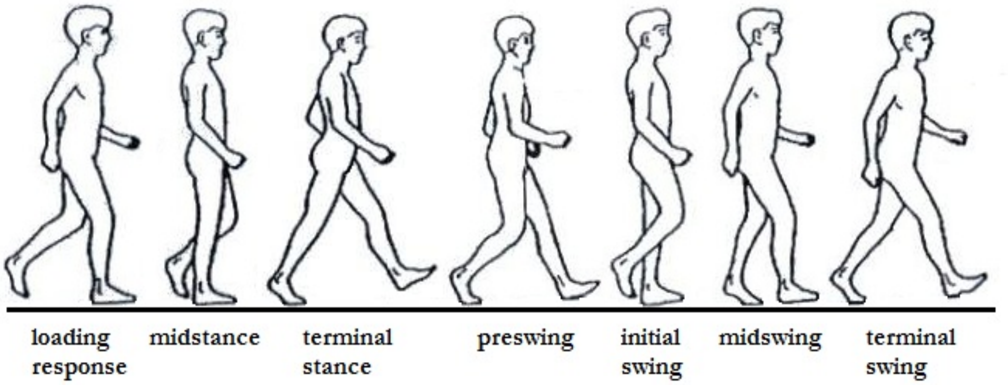

Fig. 18 The gait cycle

There are two main gait phases: the *stance* (or support) *phase* and the *swing phase*.(34) If the right foot begins the gait cycle, the stance phase will last from the time the right heel contacts the ground (heel strike) until the right toes leave the ground (toe-off). This constitutes about 60% of the gait cycle. During this time, the right leg is more or less supporting the body's weight, and the rest of the body must move to appropriately maintain equilibrium. The first part of stance phase is the *loading response*, lasting from initial ground contact of the right foot until toe-off of the left foot. The pelvis tilts toward the right, while the spine curves to the left and is stiffened by contraction of the erector spinae in the back. The gluteals and hamstrings then contract, which stabilize the hip in preparation for weight-bearing. The quadriceps femoris and deeper vasti muscles (vastus medialis, vastus intermedius, and vastus lateralis) then contract, allowing slight flexion of the knee until midstance. Contraction of the tibialis anterior, extensor digitorum longus, hallucis longus, and the muscles within the foot stabilize the ankle and foot to provide a sure step. The next subphase is *midstance*, in which the foot is flat, the right leg is perpendicular to the ground, and the spinal column has straightened. At this point, the right leg is bearing the body's full weight while the left leg swings. The slight inward shifting of the knee, together with the accompanying change of forces at the knee, is the *valgus moment*. As the body begins to move and tilt forward, the quadriceps contract so that the knee is in full extension. At the same time, the right foot dorsiflexes and the spine curves to the right. Contraction of the gastrocnemius, soleus, and tibialis posterior strengthen and stabilize the lower leg, ankle, and foot so that the right side of the body may be balanced with the left. During *terminal stance*, the body is moving forward as the hamstrings contract. Further dorsiflexion of the foot prepares the leg for toe-off. The slight outward shifting of the knee, together with the accompanying change in forces at the knee, is the *varus moment*. Finally, the *preswing* phase involves toe-off of the right foot and flexion of the knee in preparation for swing phase. For some individuals, there may be slight dorsiflexion of the right foot to avoid dragging it on the ground if knee flexion does not lift the foot high enough. The left leg is in midstance at this point.

The swing phase accounts for 40% of the gait cycle, in which the leg is not in contact with the ground (is not supporting the body's weight) and swings forward. During the *initial swing*, the hip is moved forward primarily by the iliopsoas as the pelvis shifts to the left, the spine curves to the right, and the knee is further flexed. The psoas and quadratus lumborum muscles support the pelvis to preclude excessive shifting to the left. The next subphase, *midswing*, involves extension of the knee by the quadriceps as the leg swings fully forward. Lastly, during *terminal swing*, the right knee is fully extended as the ankle prepares for heel strike, which is stabilized by the tibialis anterior, extensor digitorum longus, extensor hallucis longus, and peroneus tertius. The cycle then begins again as the right leg heel-strikes in the loading response.(34)

Separation of gait into subphases is helpful for prosthetists and physical therapists who must ensure patients' gait is non-pathological and aesthetically convincing. Analysis of each subphase will determine the adjustments to be made during dynamic alignment. It is also important to make sure each component of the prosthesis is in a proper position to bear the patient's weight. For example, if the foot is angled just slightly laterally or medially, the patient will have great difficulty in maintaining a normal gait cycle. The prosthetist must also take note of the patient's weight distribution, ensuring that the patient will not need to rely more heavily on one leg or the other. The normal weight distribution on the foot is 40% on the ball and 60% on the heel.(35) A patient's prosthesis must be adjusted so that the body's weight is correctly distributed; if it is not, the hip joint may be stressed by improper alignment and the effort required to walk normally will be much greater.

Physical Forces Involved in Ambulation

A number of different forces act upon and are created by the body during ambulation. It is important to remember that each active force is coupled with a reactive force of equal magnitude and opposite direction. *Gravity*, for instance, pulls downward on the body, giving it weight. This is the vertical component of motion. The *normal* (perpendicular) *force*, in turn, exerts force upward from the ground to the foot; it effectively pushes back on the body. *Friction* between the feet and the ground also contributes to locomotion. The foot pushes backward against the ground, overcoming the forward push of the ground against the foot. Without friction, locomotion would not be possible, as the foot could exert no push against the ground. Surmounting the body's *inertia*—its tendency to remain in a preexisting state of motion or station—constitutes the horizontal component of motion. The distance traveled by a body divided by the time in which this distance was crossed yields the object's *speed*. Speed is a scalar quantity, having only magnitude. *Velocity*, on the other hand, consists of an object's speed and the particular direction in which it is traveling. It is thus a vector quantity. The rate at which velocity changes is called *acceleration*, which is also a vector quantity.(36) If an object's acceleration and its velocity are in the same direction, the object is said be positively accelerating, or simply accelerating. If they are in opposite direction, the object is said to be negatively accelerating, or decelerating.(36)

It must be noted that the human body's weight is distributed unevenly in space; in other words, it is an irregular object. When visualizing translatory (linear) motion of an irregular object—for example, the body during ambulation—it is helpful to treat all forces as if they act equally about a single point containing the body's whole mass. This point is called the *center of mass*.(36) The attraction of the body to Earth's center due to gravity gives the body weight. The center of mass can also be regarded as the object's *center of gravity*, the point where an object can be balanced without a tendency to rotate.(37) Therefore, all the forces acting on the body's center of mass can also be treated as a single force, consisting of the vector sum of each constituent force. This simplification gives an accurate picture when dealing with forces acting on the whole body. When discussing forces acting on only a part of the body—such as the knee—however, this simplification likely will not hold and the individual forces must be considered.

During locomotion, the body's center of mass is constantly moving—the torso oscillates up and down as the legs swing forward and backward; the arms may be moved in any direction desired; a slight limp may cause the favoring of one leg over the other. The body must adjust accordingly in order to maintain equilibrium, in spite of this constant shifting of its center of mass. In fact, balance is continuously lost and regained during each subphase of the gait cycle.(34) These equilibrium-preserving adjustments are made through the coordinated action of the muscles in the leg and the rest of the body. Each of the forces mentioned above and the required actions of these muscle groups must be considered when designing and adjusting prosthetic legs which utilize a knee simulator, such as the C-Leg®.

Since the knee is a loosely-constrained synovial joint, it has a degree of freedom in this angled state during ambulation. This freedom allows external forces to produce rotary or angular motion at the knee, during activities such as walking, running, or playing tennis. For example, during the varus and valgus moments the knee rotates slightly out of alignment with the rest of the leg. The force with which an object is rotated is termed *torque*,(38) and can be measured in Newton-meters (Nm) or foot-pounds (ft-lb). For 20-40 year-old males, knee flexion at an angular speed of 60°/second causes the knee to experience an average torque of

113 ft-lbs(39) (133 Nm). Extension of the knee at this speed results in a torque of 177 ft-lbs(39) (240 Nm), which is about how much torque a 2011 Ford Escape XLS engine produces at 4500 rpm.(40) Since the C-Leg®'s knee portion is not made to rotate about its axis (internal or external rotation), no torque would be produced or sensed while using it; thus, the C-Leg® has no torque sensor. There is also no varus or valgus moment for the C-Leg®.

The coordination of these anatomical components and forces is essential for successful production of voluntary movement, and must be accurately reproduced if the C-Leg® is to provide its users with a satisfactory ambulation experience. The methods by which the C-Leg® accomplishes this simulation are explained in Section IV.

III. Human Proprioception and the Production of Voluntary Movement

The processes of human proprioception and voluntary movement are very complex. Thus, any mechanic system which attempts to reproduce such processes must be accordingly complex. Indeed, the processes within the C-Leg® are advanced, but are nevertheless infinitely less so than the body itself. Before discussing the operations of the C-Leg®, a simplified explanation of each human process will be provided, which will then be compared to the processes within the C-Leg®.

The Submodalities of Proprioception and their Receptors

Proprioception is the body's ability to sense where its members are and what they are doing; literally, it comes from the Latin *proprius* for "one's own"(41) and *perceptio* for "comprehension" or "gathering".(42) The body uses this information to determine where to place certain body parts while moving, to keep a limb in a steady position, to maintain equilibrium(43), and even to remember movements for specific procedural actions.(31) For instance, patients suffering from sensory-inhibiting neuropathy which interferes with proprioceptive feedback cannot hold their limbs in a stable position unless they can see those limbs.(43) Proprioception can be divided into two submodalities, or different types of sensation (a nerve's sensory modality is its specialized capability to carry a certain type of sensory information). The first submodality is limb position sense, which involves the transmission of sensory data concerning the static orientation of the body in space.(43) The second is kinesthesia, which involves the sensation of bodily motion, including the speed and direction of the movement.(43) Both of these submodalities are imperative for proper control of movement, and are integral to the function of the C-Leg®.

Proprioception is considered one of the general, somatic senses, along with tactile and thermal sensations.(31) Thus, proprioceptive information is relayed to the brain as sensory data. The receptors of this sensory data are called proprioceptors; specifically, they may be one of three general kinds: muscle spindle fibers, cutaneous mechanoreceptors, and joint capsule mechanoreceptors.(43)

Muscle spindle fibers provide a means of "measuring" the length of a muscle, and thus the tension (degree of contraction) within it. Muscle spindles are more plentiful in muscle groups concerned with more finely-controlled movements, and also predominate in the muscle belly.(44) The muscle spindle is comprised of groups of specialized, intrafusal ("within the spindle") muscle fibers, which are wrapped in the endings of sensory (afferent) neurons. When a muscle contracts, protein filaments within the individual muscle fibers are pulled inward toward the center of the cell, subsequently shortening it. Stronger contraction results in more extensive overlapping of the protein filaments, and more extensive shortening of the muscle fiber. The intrafusal fibers are thus pulled inward and stretched according to the degree of muscle contraction, which will then relay the "length" of the muscle to the brain.

In the knee, "measurement" of the angle of flexion or extension seems to be mostly reliant on the muscle spindle receptors.(43) This is supported by the fact that patients with total joint replacements were studied and found to retain considerable proprioceptive ability(43), even though the artificial joint itself has no nervous components. Afferent joint nerves, in general, do not seem to play a prominent part in relaying information about static position. Moreover, it has been found that the knee joint sensory nerves are only sensitive to extreme joint angles(43) and rapid changes in joint angles for short periods of time.(44)

Mechanoreceptors are specialized sensors which detect mechanical stimuli such as cell stretching, pressure, and vibration in the skin and underlying connective tissues.(31) Cutaneous mechanoreceptors, also called touch receptors, are incorporated into the skin (the cutaneous membrane) covering the body's exterior. Type I cutaneous mechanoreceptors, or Merkel discs, are free nerve endings in the stratum basale of the skin's epidermis. Type II cutaneous mechanoreceptors, or Ruffini corpuscles, are located in the dermis and in the ligaments and tendons of joints. Pacinian (lamellated) corpuscles are nerve dendrites encapsulated in connective tissue which are sensitive to sensations of pressure.(31) They are widespread in the body. Pacinian corpuscles are located in the dermis, the subcutaneous layer, muscles, tendons, and joint capsules. These corpuscles are sensitive to the pressures produced by movement of the limbs. Thus, they can measure the acceleration and deceleration or velocity of the moving body parts based on these pressure measurements.

Joint capsule mechanoreceptors are located inside joint (articular) capsules, the layers of connective tissue surrounding the articulating bones of a joint which are filled with synovial fluid. Only synovial joints, such as the knee, are surrounded by a joint capsule. The outer (superficial) layer consists of long, bundled collagen fibers within dense irregular connective tissue (ligaments) which provides the joint with mechanical durability and strength. The inner (deep) layer consists of elastic fibers within areolar connective tissue, equipping the joint with varying degrees of flexibility from person to person. Embedded within these tissues are mechanoreceptors which transmit information about the movement and position of the joint to the brain. Pacinian corpuscles located within the joints, as mentioned in the preceding paragraph, are another form of joint mechanoreceptors. Free nerve endings and Ruffini corpuscles in the articular capsules also respond to pressure, providing information about the forces being exerted upon and within the joint. In the knee, for example, this information would tell the brain that weight is being placed on the knee.

The Production and Mediation of Voluntary Movement

In order for the body to coordinate its muscle groups into meaningful movements, the central nervous system must be continuously supplied with sensory data, so that this data can be processed in the brain and coordinate the contractions of the appropriate muscle groups. Indeed, production of voluntary movement can be simply explained as a cycle of these three steps: sensory input, data integration, and motor output. This cycle is carried out via communication between the body, the nerves and the brain, so that each movement is accurate and precise.

In his book *Principles of Neural Science*, Eric Kandel links these three steps into an explanation of voluntary movement.(45) The first step is identification of the target—that is, the conception of the desired movement. In order for the body to know what it must do next, it must first understand what it is already doing. This function is fulfilled by input from millions of sensory (afferent) neurons distributed throughout the body. These neurons are called peripheral receptors, as they are part of the peripheral nervous system (PNS). One of the types of sensory input is proprioception, as explained previously.

As they transmit impulses toward the brain, these sensory neurons gather into nerves, which then bundle into nuclei before merging with the spinal cord (thus joining the central nervous system, or CNS) and are routed through the thalamus before reaching the somatosensory cortex of the brain. Nerve nuclei are termed tracts after entering the CNS. This change of name simply reflects the location of these nerve bundles; their function is identical in the PNS and CNS. Just as there are specific receptors dedicated to certain parts of the body, there are dedicated regions of higher nervous areas for each area of the body, such as the somatosensory cortex of the brain. Areas requiring finer control cover a larger representative area of the somatosensory cortex. This is called somatotopic organization, which is retained throughout the sensory pathway—from the peripheral nerves, through the spinal cord, and eventually to the appropriate region of the brain. (There is evidence that this organization may shift, however, following amputation.(6,46)) The transmission of a sensation of pressure on the medial side of the ankle, for instance, might follow a pathway such as follows: tibial nerve, sciatic nerve, sacral plexus, dorsal (posterior) root ganglia of the spinal cord, afferent (ascending) tracts of the spinal cord, thalamus, "ankle area" of somatosensory cortex.(31) After being routed to the appropriate sensory region by the thalamus, the data is sent to the posterior parietal cortex, where it is incorporated into a coherent picture of the desired movement.

As outlined by Kandel, the second step is planning the actions that are required to accomplish the desired movement. In order to plan this movement, the brain must first determine which sensory information is meaningful for the movement. It must then utilize this data properly, sending it to the appropriate regions of the brain that will control the needed muscle groups. This process is called integration. It is governed by the premotor areas of the frontal cortex, while the thalamus continues its job as "traffic conductor" by routing information to the appropriate region of the motor cortex. Also involved in integration are the connecting or interneurons, which make interaction between sensory neurons and motor neurons possible. These interactions may exist in simple or complex networks, with the interneurons linking sensory neurons to either a few or many motor pathways.(44)

The third step, as explained by Kandel, is execution of these actions. The brain must collect the appropriate information after integration and use it to coordinate and command the muscle groups needed for the movement, which can be collectively called motor output. Impulses from the premotor areas of the frontal cortex are sent to the primary motor cortex, which is somatotopically organized much like the somatosensory cortex. This means that specific regions of the motor cortex control the activity of specific muscle groups in the body. The motor cortex communicates with these various muscle groups via the descending corticospinal tract of the spinal cord. Therefore, an impulse to move the ankle might follow the above-described sensory pathway in reverse: primary motor cortex, descending (efferent) tracts of the spinal cord, ventral (anterior) root ganglia of the spinal cord, sacral plexus, sciatic nerve, tibial nerve. The juncture between a motor neuron and the muscle fibers it controls is called the motor unit. Muscle groups with more finely-controlled movement will have a smaller ratio of muscle fibers per motor neuron. Muscle fibers belonging to one motor unit may also overlap with other motor units, and thus may be involved in several different types of actions. The degree of contraction of these muscles varies depending on the action to be performed, based on the number of participating motor units and the frequency of motor unit stimulation from the motor cortex.(44)

It is important to note that the brain continues to receive sensory input through all phases of the movement, ensuring that the movement is being executed in the manner it was meant to be. These phases do not occur statically but dynamically, with motions being constantly evaluated and corrected based on the received sensory input. The fine-tuning (initiation, timing, and smoothness) of movement is mediated by the cerebellum and the basal ganglia.(45) The basal ganglia, as part of its role in homeostasis, specifically controls coordination of learned procedures.(44) The cerebellum (or "little brain") constitutes a feedback center comparing the attempted or ideal movement with the actual movement. It coordinates and adjusts the activity of muscle groups so that movement is accurate, precise, and seamless.(44)

Also interesting to note is the body's ability to remember sequences of performed actions, called *procedural memory*.(47) It allows the human body to execute motions without consciously thinking about them. As one practices a movement over and over, this routine becomes encoded and embedded in the brain and is later accessed when this action is to be performed again. As an example, it is unlikely that most of us consciously plan each step we take; that is, walking draws on procedural memory to a significant extent. Our steps and movements simply “feel correct.” This element of movement production is also, in a sense, reproduced by the C-Leg® (to be explained in Section IV).

An Overview of Movement

The circuit of sensory input, data integration, motor output, and movement evaluation involved in the production of voluntary motion requires the coordination of the body’s bones, muscles, nerves, and brain. Flexion of the right knee, for example, involves the transmission of a nerve impulse the knee to the brain and back to the knee flexor muscles, while being simultaneously monitored and modified as well. First, sensory receptors in the knee joint receive input about the joint’s movement and position which indicate the need to flex the knee. A certain knee velocity during the gate cycle, measured by joint capsule mechanoreceptors, may signify “swing phase” and that the knee must be flexed. This signal travels through the nerves in the right knee though the lumbar plexus, to the spinal cord, and then to the brain. In the brain, the ascending sensory neurons synapse with interneurons to gather sensory data about the knee in the thalamus. The thalamus then routes the relevant velocity data to the “knee” area of the somatosensory cortex, where the information can be identified as belonging to the knee region. The impulse is then sent to the posterior parietal cortex, where other proprioceptive sensations from the right knee (such as joint angle) gather to aid in the planning of flexion. Integrative input from the basal ganglia confirms that the body is following a learned pattern of walking, and that the right knee must be flexed to correctly perform this motion. Flexion is then “planned” in the premotor areas of the frontal cortex, so that the knee flexors (hamstrings) will be specifically stimulated to contract. These impulses travel via the thalamus to the “hamstrings” region of the primary motor cortex, where the motion plan can be implemented. Impulses signifying muscle contraction then cross the synapse between interneurons and motor neurons, thereby becoming a motor command. This contraction impulse travels through the descending pathway of the corticospinal tract of the spinal cord, through the sacral plexus, through the sciatic nerve to its tibial component, and finally to the hamstrings, which then contract. Muscle spindle receptors within the hamstrings will monitor their degree of contraction. When sufficiently stretched, the spindle receptors are stimulated to transmit a sensory signal to the brain (following a similar pathway as outlined above) to cease sending signals for muscle contraction, and therefore to terminate flexion.

Simultaneously, and continuously, a flood of sensory feedback is relayed through the basal ganglia and cerebellum during the entire movement to ensure it was performed properly. This feedback allows the cerebellum to modify the flexion command in response to changes such as shift in center of mass. Thus, the cycle of sensory input, integration, motor output, and evaluation is completed.

IV. The C-Leg®

The C-Leg® is a microprocessor-controlled knee prosthesis. It offers a superior mobility experience for amputees because of its advanced, computerized technology. Because of their functional limitations, most above-knee prostheses require the patient to walk one step at a time when ascending or descending staircases and to exercise caution when navigating inclined surfaces. With the C-

Fig. 19 The C-Leg® from Otto Bock®

Leg®, a patient can walk step-over-step and cross uneven ground with ease. It simulates the actions of the knee, and the processes which govern them, by gathering and processing data in a similar manner as the human body. Internal sensors located in the upper portion of the case and in the pylon provide a microprocessor with information about the patient's movements. This data is then interpreted in the processor, utilized to control the action of the device's motors, and evaluated in preparation for the next movement. This continuous cycle (input, integration, output, evaluation) mimics and attempts to accurately reproduce the human body's processes of producing voluntary movement. Because of this similarity, the device is able to reproduce the motions of the human knee more accurately than non-microprocessor knee prostheses, and thus might be called a knee simulator. C-Leg® users are able to engage in active lifestyles and enjoy a higher quality of life because of the lowered physiological demands offered by microprocessor knees.(1)

The C-Leg® is manufactured by Otto Bock HealthCare®. Though it is based in Germany, the company has established offices and facilities worldwide. Following its success in Europe in 1997(48), the C-Leg® was released in the United States in 1999.(49) For the past ten years, most prosthetists have agreed that it is the gold standard of microprocessor knee (MPK) technology.(50) Today, over 40,000 units have been sold worldwide.(49)

Indications and Contraindications

The C-Leg® is indicated for above-knee (AK) amputees in MOBIS® or K-level categories 3 and 4, and is most appropriate for those weighing less than 125 kilograms (275 pounds).(51) In order for the C-Leg®'s technology to be most beneficial, users should be able to do at least one of the following, as outlined by Otto Bock®'s guidelines: walk at least 3 miles per hour and at varying speeds; walk 3 miles or more in a day; navigate terrain with uneven slopes or with some obstacles, such as staircases and playgrounds; and engage in activities requiring sudden changes in speed or direction, such as sports. Users should also foresee a benefit from the two pre-set modes that can be programmed into the microprocessor, which will be further explained below in *C-Leg® Function*. Bilateral AK amputees may be fit for two C-Leg®s under the close supervision of a prosthetist.(51)

Though the C-Leg® offers the opportunity of an active lifestyle to many amputees, there are cases in which it is contraindicated. As discussed before, below-knee (BK) amputees retain the knee joint after amputation, and thus have no need for a prosthesis utilizing a knee simulator. For AKA patients who do not engage in the activities specified above, the C-Leg® may represent an unnecessary or extravagant option. Those who cannot properly care for an MPK due to living situations or mental disabilities would also likely not receive the full benefits of using a C-Leg®. Less sophisticated prostheses can offer these patients the mobility they desire without the expense of MPK technology. An additional consideration for C-Leg® users is the 45-hour battery life. Any activity that keeps a patient away from electrical sources for longer than this amount of time would be unadvised.

Materials, Components, and Accessories

As mentioned before, prostheses are not fabricated to match the weight of the leg portion that was removed by amputation, but rather to be as light as possible. In order to minimize weight and maximize strength, the outer casing of the C-Leg® is made with carbon fiber.(48) Its chemical structure is similar to graphite; that is, it consists of many carbon atoms covalently bonded together in long, parallel fibers. The carbon atoms may be bound in a matrix of carbon or a variety of other elements, depending on the usage specifications. The C-Leg® material utilizes a solely carbon matrix.(49) The strength of the bonds among the fibers themselves and between the carbon and matrix element gives carbon fiber strength along the axis of the fibers.(52) As a result, the C-Leg® is resistant to splintering upon blunt, sideways impact. However, it is susceptible to sharper impacts along this parallel axis, in which the pressure of the blow is concentrated on one point. Carbon fiber is also an electrical and thermal insulator(52), which reduces electrical interference between the internal components. Its non-metal composition also makes it water-resistant; in other words, exposure to a small amount of water will not short-circuit the electrical current within the device. A user may perform an action like washing his car, for instance. The user must be careful, however, to exercise caution while in the proximity of water. The C-Leg® is not waterproof, and will be damaged if submerged. The outer case is also coated with plastic laminate for added strength.(48) The pylon is made of aluminum.(53)

The C-Leg® consists of two separate parts. Appropriate to its function as a knee simulator, the upper frame (see Fig. 19) is shaped somewhat like the human calf. This segment houses the microprocessor, hydraulic components, and the sensor for knee angle and velocity. The lower segment is the tube adapter, or pylon. It is adjustable to match the height of the sound leg and houses the sensor for weight and pressure. The pylon functions much like the tibia of the leg. These two pieces are fitted together to form a functional unit. At the apex of the upper frame, an extension called the adapter provides the method attachment to the prosthetic socket. The adapter on the C-Leg® is available in two types: the pyramid adapter, which is appropriate for most cases; and the threaded connector, which is suitable for patients with very long residual limbs (such as knee disarticulation amputees).(48) Anterior to the socket adapter are two electronic ports where the battery-charging and programming cords connect.

The posterior face of the upper segment encloses a hydraulic cylinder, which simulates the action of the muscles in the lower leg. The cylinder is filled with air-free oil(54), which ensures that the fluid pressure within the cylinder is consistent. Muscles in the body are paired as agonists and antagonists; that is, they pull on bones in opposite directions to control the beginning and ending of movements. This pulling opposition creates tension between their coupled forces.(29) Resistance inside the hydraulic cylinder replicates the forces of these opposing muscle groups. When the knee of the C-Leg® is flexed, the flexion valve in the hydraulic cylinder cause the cylinder to shorten, forcing the knee to bend at its pivot point and enter an angle of flexion. This mimics the action of the gastrocnemius and the soleus, for example, which pull the knee into flexion by contracting. The contraction of these muscles causes them to shorten, which pulls the thigh and the foot closer together as the knee bends into an angle of flexion.

The resistance provided by the hydraulic cylinder is controlled by servo motors, which adjust the cylinder's valves. There are two valves which control the cylinder: a flexion valve and an extension valve. There are two servo motors as well, one for each valve. Servo motors are feedback-regulated motors which respond to the commands of a distal controller(55); in this case, the microprocessor. Its actions are dependent upon information about time, position, and velocity, which are provided by the two C-Leg® sensors. This information is used to inform the servo motor's motion profile(55), a programmed series of simple instructions allowing the motor to finely adjust its movements in response to the values its receives about the device's motion. Thus, the microprocessor's interpretation of sensory data will determine whether the knee is in flexion or extension, and therefore which servo motor will move and which valve will open. Details about the microprocessor itself are proprietary.(49,56)

Inside the C-Leg® is a series of wire networks which are similar in function to the body's nervous system. That is, it enables the sensors, microprocessor, servo motors, and hydraulic cylinder to communicate with each other. These networks connect the two sensors to the microprocessor, which transmits sensory data much like the ascending sensory pathways send information to the brain. The wires exiting the microprocessor leading to the servo motors carry "motion commands," mimicking the descending motor pathways which instruct muscles to contract and produce a desired movement. As in the human nervous system, these wires are dedicated to specific communication circuits between the sensors, microprocessor, servo motors, and hydraulics.

C-Leg® Function

The C-Leg® is designed to give its wearers a more natural and secure locomotive experience than traditional, non-computerized knee prostheses. For example, amputees with traditional knee prostheses must ascend and descend staircases one step at a time. In contrast, most C-Leg® wearers are able to walk step-over-step after practicing. In order to mimic natural human gait, the C-Leg® must accurately reproduce not only the bones, muscles, and nerves affecting the knee, but also the communication that takes place between them. As described previously, the production of human movement can be described simplistically as a cycle of sensory input, data integration, motor output, and movement evaluation. Part of this sensory input consists of an awareness of the body's position and movement. The C-Leg® was designed to perform a similar cycle of dynamic data acquisition, transmission, and evaluation. This data provides information to the microprocessor about the device's position and the extent of its motion, which are essentially proprioceptive sensations.

The C-Leg®'s "sensory input" comes from two sensors, both of which collect data every 0.2 seconds. While not operating nearly as rapidly as the neurons in the body, this interval is short enough to provide a large amount of "sensory data" for the microprocessor. The first sensor is in the upper portion of the device. It provides information about the knee's angle of flexion and extension and velocity of lateral and angular movement. This provides the microprocessor with data about how fast the user is walking and how fast the knee is rotating vertically. It should be noted that although this sensor perceives angular velocity, the knee cannot rotate about the horizontal axis, as the casing is too rigid to permit rotational movement. Unlike the human body, the sensor determines the direction of movement because of a magnetic implant. Movement across a specific distance will cause a shift in the magnet's alignment, which allows the sensor to measure that specific distance. Dividing that distance by the amount of time in which the reading was taken, a simple calculation performed in the processor, gives the knee's linear velocity.

The second sensor is in the pylon or tube adapter, several inches above the prosthetic foot. This sensor gathers information about weight placement and the angle and forces at the ankle. When the user places weight on the device, it is compressed slightly, which translates to the strain gauge in the sensor that the device is bearing weight. When the weight is removed, the gauge senses the resulting elongation and interprets it as a reduction of weight. This process is similar to the function of muscle spindle fibers in the human body. The sensor can distinguish between anterior and posterior emphasis of body weight, enabling it to measure the distribution of weight between the heel and toe (heel and toe loads) despite the fact that there is no sensor in the foot. Information about the "ankle" is also taken indirectly. There is no true ankle—as it is simply the juncture between pylon and foot—and no sensor in this segment. However, the relative angle between the pylon and the rest of the prosthesis enables the sensor to obtain information about the ankle and foot. For example, when the user places weight on the toe at the end of the normal gait cycle, the pylon tilts posteriorly from the knee. This tilt produces an angle between the foot and pylon, which can be detected and measured by the sensor. Just as this movement would cause the foot to bend in the human body, the data translates to the microprocessor as dorsiflexion of the foot at the end of the gait cycle.

Data gathered by the sensors is then sent to the microprocessor through internal wires, analogous to the body's sensory neurons which lead to the brain. In the microprocessor, comparable to the brain, this data is "integrated" or processed to find meaning in the waves of sensor signals, much like in the brain. This is accomplished by putting the received sensory information through a series of mathematical procedures and equations, called algorithms. These algorithms in the microprocessor are analogous to the many patterns of movements stored in the brain as procedural memory. The sensory data is compared step-by-step with pre-programmed data corresponding to thousands of different gait cycles, such as walking, running, or stair-climbing. Each phase of each gait variation has a distinct set of data about the appropriate pressures, velocities, and flexion angles for that phase. The sensory data are run through rule sets, which consist of true-false conditional statements that enable the processor to determine which processes must occur. For example, for the C-Leg® to switch into swing phase, it must sense that the knee is fully extended and that approximately 70% of the body's weight is being supported on the forefoot.(57) If these conditions are not met, the microprocessor will not send the motor commands to begin swing phase. In other words, if the received data are run through the rule set and the proper statements are found to be true, then the processor will send these movement commands to the servo motors to elicit the desired movement. If any of them are found to be false—that is, if the data do not match the phase description data well enough—then the process will not occur. After the algorithms compare these data sets, it chooses the most appropriate and closest-matching phase to determine the amount of resistance needed by the hydraulics before the user makes his or her next move. This process of data sorting is similar to the flow of data in the thalamus, or "traffic conductor" of sensory information in the brain.

After determining the proper resistance level, the microprocessor sends commands to servo motors in the C-Leg®. Since these commands cause and control the movement of these servo motors, they could be called "motor output" as it is in the human body. The servo motors then move the appropriate valve in the hydraulic cylinder, adjusting the resistance provided by it to bring the knee into flexion or extension. The muscle groups in the lower leg function in much the same way, obeying commands from the motor cortex to contract to the degree needed for that particular gait phase.

The gait phases outlined earlier are simply a starting point for analyzing locomotion. A user may need to stop mid-step to pick up or avoid an object, for instance, thus deviating from the idealized gait cycle. The actions and behavior of the C-Leg® may also be imperfect. Therefore, the constant input of new sensory data is not only used for proprioceptive purposes, but also for evaluative purposes. Just as the cerebellum evaluates the body's movements for accuracy and fluidity, the updated sensory data gives feedback to the microprocessor to ensure each command is being executed properly. It is also used to collect information about the conditions which will influence the next action. The accuracy of this feedback is advanced enough to provide "stumble recovery" for the patient, which is unique to the C-Leg®. If the sensors detect that balance is being lost, the knee will automatically stiffen, giving the patient the stability needed to regain balance and avoid an embarrassing fall. Altogether, these processes mirror those which occur in the human body. Though simplified, the gold-standard technology of the C-Leg® mimics the function of the human knee to provide users with a more natural gait than non-microprocessor knees.

Programming software and hardware

Electronic adjustments of the C-Leg® are completed with the prosthetist's computer or laptop, using a specific software program developed by Otto Bock® called C-Soft.(58) A patient who feels that the knee feels stiff—that is, the knee requires too much effort to bend—could have several settings adjusted through C-Soft to correct this problem. The C-Soft program provides the interface over which a C-Leg®-certified prosthetist can modify every programmable aspect of the device, ensuring optimum function and ease of use for the patient. This programming can be compared to activities meant to improve hand-eye coordination in humans, in which perception training is utilized to alter and improve the performance and communication of the sensory, integrative, and motor systems.

During adjustments, practitioners may connect the C-Leg® to a computer with a connection cable. However, it is possible and likely simpler to program the C-Leg® wirelessly. To do this, a device called BionicLink is attached to the programming port at the top of the knee. BionicLink utilizes wireless Bluetooth® networks to transmit data between the microprocessor and the prosthetist's computer, so that the microprocessor's settings may be modified without the potential complication of cords tangling. This also enables the patient to walk freely in the prosthetist's office during adjustment visits without the constraint of staying within the cable's length of the computer. An additional benefit is the ability to leave cosmetic covers on the prosthesis, whereas using a cord requires its removal. This allows adjustments to be made while taking the cover's influence on function into account.(58) Overall, this wireless method of programming with C-Soft and BionicLink helps make adjustments more accurate and less complicated for both the patient and the prosthetist.

As mentioned previously, the microprocessor's programming consists of data sets and algorithms. These patterns serve as the guidelines for the C-Leg®'s control of motion. Noteworthy features of this programming are the second mode, the Standing Mode, and Stumble Recovery. The microprocessor is programmed with the capability to switch between two preset modes when the appropriate button is pressed on the C-Leg® remote (included with the device) and when the user executes a certain series of toe taps. The first mode, for example, would most likely be everyday walking, including the adjusted settings which constitutes that user's unique gait. The second mode might be a modified resistance level for playing a favorite sport, for instance, so that the knee offers a consistently higher degree of resistance than would normally be used for walking. Another specialized feature programmed by Otto Bock® is the Standing Mode, in which the knee stiffens or locks at a certain degree of extension to reduce the amount of effort needed to maintain a standing position. As mentioned before, the C-Leg® is also programmed to offer Stumble Recovery, in which the knee will stiffen to provide enough stability for the user to regain balance, thus avoiding a fall.

Using the C-Leg®

Despite its advancements, the C-Leg® has limitations as a mechanical device. The batteries are expended after approximately 45 hours of functioning, and require five hours to recharge. Patients may order an extra battery to extend its usage time. A cosmetic-protective cover can be ordered from Otto Bock® in several different colors. While not necessary, this cover provides added protection for the device and its connection ports, as well as slip-resistance if the patient kneels on the knee. The C-Leg® is also compatible with a regular foam or plastic cosmesis, if desired.

Many people would agree that walking is much easier with two sound legs. However, the use of a microprocessor knee appears to significantly reduce the physiological costs of ambulation, compared with the use of traditional or non-bionic knees.(1) Nevertheless, re-learning how to walk with a prosthesis is very difficult. Amputees are trained by their prosthetist and physical therapist to use the prosthesis and to re-learn correct gait.(53) In a sense, they must re-program their procedural memory of ambulation. An amputee may also find it difficult to perform other non-ambulatory motions, such as those involved in playing sports. The prosthetist and physical therapist will work with the patient to learn how to modify their execution of these actions to accommodate the limitations of using a prosthesis. With many hours of practice, walking and other tasks become routine as the body's procedural memory re-learns the proper movements. The more closely the prosthesis mimics the lost limb, the more quickly procedural memory will adapt to these new methods of movement.

V. Future Research and Educational Objectives

The Master of Orthotics and Prosthetics program at Eastern Michigan University includes three thesis courses, as well as an independent study to be completed in the final semester.(3) Research in bionic devices is typically the subject of those studying robotics in a bioengineering field, not that of an Orthotics and Prosthetics student. However, such devices are excellent options for many amputees. The clinical success of bionic prostheses such as the C-Leg®(1) warrants further investigation into these subjects and their clinical applications. An introduction to these topics and devices, at the least, is important for practitioners in the field so that informed decisions can be made regarding the patients' use of bionic devices. Therefore, this thesis will serve as a springboard for future studies in other types of bionic technology. Research topics in bioengineering are also promising ideas for independent study.

Another promising idea lies in the "future" of prostheses: cybernetics. Such devices are physically integrated into the patient's nervous system, offering a level of movement control that is not possible with traditional or even bionic devices.(17) Though developments in this field directly impact and are used in prosthetics, they also fall into the realm of bioengineering rather than prosthetics. Cybernetic devices are still in the experimental stages, but there has been considerable success in several cases. Research in this field has also developed prototypes of simulation skin which not only looks like real human skin, but can also "feel" sensations like pressure and heat.(17) It is hoped that technology such as this can become an option for the cosmesis in the future.

Beyond the physical aspects of amputation and a working knowledge of devices available for amputees, an awareness of the emotional and psychological complications is also a significant component of clinical practice. For example, exceedingly common corollaries of amputation are phantom limb sensations (PLS) and phantom limb pain (PLP). These are phenomena in which traumatic amputees still sense the presence of the amputated limb, and may experience feelings of heat, pain, clenching, movement, or itching in the phantom.(59) They are experienced by most traumatic amputees(59,60) and may persist for ten years or more before noticeably deteriorating.(61) Current research suggests they are caused by the active remnants of neural networks that previously led to the sound limb. These severed nerves continue to transmit sensory information to the brain in the absence of real, organic stimuli. Research also suggests that PLS can cause areas of the cortex which previously controlled the amputated limb to become part of other areas, which is known as cortical reorganization or remapping.(7,46) Despite many years of extensive study(62), PLS is still not fully understood.(59,61,63) Independent study of PLS would provide a practitioner with an increased understanding of the psychological impacts of amputation, as well as contribution to the growing body of knowledge concerning PLS.

In light of the physical connection between the patient's nervous system and a cybernetic device, as well as the role of the nervous system in PLS and PLP, the implications of this connection may be noteworthy and deserving of extensive study as well.

Acknowledgements

I would like to extend my deepest gratitude to the following persons and organizations:

Malone University
My advisor: Dr. Nicholette Rogers, assistant professor of Biology
My committee: Steve Wirick, instructor of Human Performance
Earl Rodd, assistant professor of Computer Science
Elizabeth Rettew, MSN, RN, CNP, associate professor of Nursing
Dr. Diane Chambers, director of the Honors Program and professor of English
Dr. Donghai Chen, professor of Chemistry and Physics

Hanger Prosthetics & Orthotics, New Philadelphia, OH

Dr. Joe Yanke, Sr.

Dr. Joe Yanke, Jr.

Otto Bock HealthCare® U.S.

Cale Konetchy, CP, clinical specialist in prosthetics

Jerry Gohman, RTP, technical support manager

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