QUALITY FOR LIFE

Otto Bock Microprocessor-Controlled Knees

Clinical Evidence and Background Information

Why Microprocessor-Controlled Knees

Microprocessor-controlled Prosthetic Knees (MPK) have set the standard for stability and ease of use for transfemoral amputees. All microprocessor knees work by employing multiple sensors within the body of the prosthesis. These provide data to an on-board microprocessor so that it knows where the joint is in the gait cycle. The microprocessor then controls the function of the joint, causing it to increase or decrease flexion and extension resistance.

Why Hydraulic MPKs over Non-hydraulic MPKs

There are presently two main systems on the market for creating this extension and flexion resistance: magnetorheological (MR) and hydraulic.

A magnetorheological (MR) fluid system contains fluid with minute iron particles, which, in conjunction with rotary blades, create resistance when a magnetic field is applied. If there is no battery power, or the joint is otherwise damaged, a magnetic field can not be applied, and the default for the system is to have no resistance, so that the joint goes into free swing.

The advantages of the MR system include minimal fluid drag in the knee, allowing it to go into knee flexion more easily, which reduces energy expenditure.

The disadvantage of a free-swing default is that it does not offer maximum security against falls partially because it cannot engage resistance until it receives sensory feedback from the ground reaction force.

With hydraulic fluid systems, on the other hand, the default for the system (such as when the battery is empty) is to provide stance resistance. In the hydraulic system, the microprocessor controls tiny valves, which open and close to affect the flow of hydraulic fluid in the joint, thereby increasing or decreasing resistance. When the system has a discharged battery or is somehow damaged it returns to the pre-set maximum flexion resistance. The result is a knee that provides resistance against flexion and thus provides stability.

The advantages of hydraulic systems are that they help to reduce stumbles and falls, because of the default stance flexion resistance. They also shift between phases of gait smoothly and provide controlled stair and slope descent.

One of the disadvantages is that the leg, because of the flexion resistance, cannot always flex in a passive state, such as when sitting.

How C-Leg® Technology Works

The C-Leg and Compact are microprocessor-controlled knee joints, and are controlled by means of feedback from sensors, unique software in the microprocessor, and a hydraulic system that creates resistance.

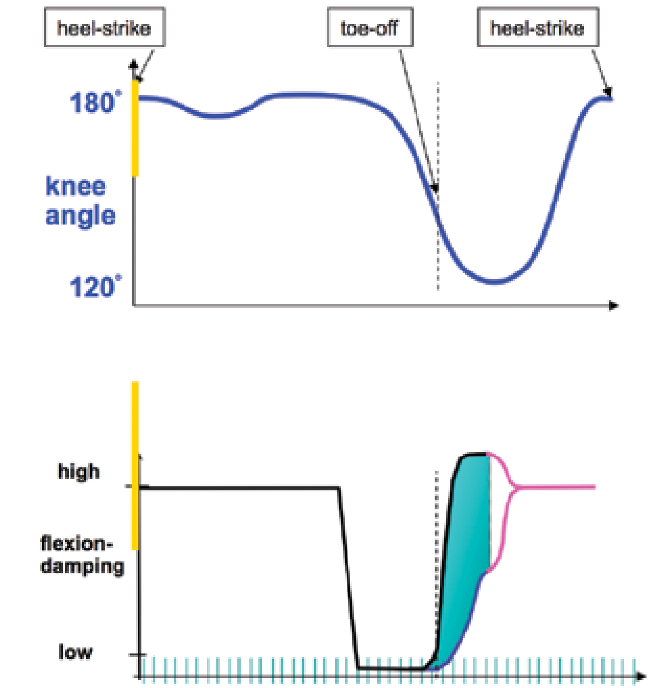
Sensor data is provided by two sensors. A knee angle sensor constantly measures the flexion angle and the angular speed of the joint. It supplies the microprocessor with necessary information for dynamic control of heel rise during swing phase, as well as stability during stance phase.

A moment sensor located in the tube adapter measures the ankle moment from heel-strike to toe-off and lets the microprocessor know just where the user is in the gait cycle. Because the moment sensor is located as far as possible away from the knee joint, it provides a longer lever arm and allows for more precise measurements.

This sensor data is processed 50 times a second by software that contains algorithms based on the walking habits of thousands of people. The software considers the real-time sensor data, and then establishes which phase of gait the user is in to determine the most appropriate resistance and setting. It then sends signals to open and close the valves in the hydraulic cylinder, thereby increasing and decreasing resistance for flexion and extension.

"We've done a ton of C-Leg fittings here, even before they were authorized from insurance, and we've had pretty good luck getting reimbursed even before the L-Codes came out.

"I started putting people on C-Legs to help prevent falls. I'd seen a lot of wrist fractures from transfemoral amputees falling down – and head injuries, too, when



Knee Angle (upper graphic) and Flexion Resistance (lower graphic) of a C-Leg going through a normal gait cycle.

Early in Mid-stance, when the knee comes into full extension, the flexion valve drops from high to low resistance to allow for easy initiation of swing phase (indicated by the dotted vertical lines, where the toe comes off the ground). How rapidly the knee was flexing prior to toe-off determines how rapidly the flexion valve will close to control heel rise. Once the knee stops moving (indicated by maximum knee flexion angle) the flexion valve goes back to the security of the preset stance resistance.

Ultimately, this allows the C-Leg® to be proactive instead of reactive. A reactive system can only respond to a trip or stumble by receiving sensor information after the prosthesis has encountered the ground—and by then it could be too late to avoid a fall.

The C-Leg is proactive because it anticipates what demands are about to be placed on the system and prepares itself accordingly. If anything causes the user to stumble the system is already offering flexion resistance, and thus can help prevent a fall.

they fell backwards. But the C-Leg is so stable that people fit with it went from falling once a week to only falling once a year. In over 85 fittings I've only had one patient with a massive fall with a C-Leg in that time, and that's when she was putting gas in her car and got tangled up in the gas line."

~ CP from Fargo, ND

Who is Best Suited for MPK Technology?

The C-Leg is designed for more active users who can take advantage of its dynamic swing control and multiple user modes, while the Compact is right for less active users who need stability for day-to-day activities.

C-Leg Technology is Appropriate for a Wide Range of People Who:

- Are transfemoral amputees, including those with bilateral limb deficiencies or hip disarticulation amputations;
- Are involved in activities that require a high level of stance stability;
- Walk or have the potential to walk on uneven terrain;
- Frequently descend stairs or negotiate slopes.

The C-Leg is Ideal for People Who:

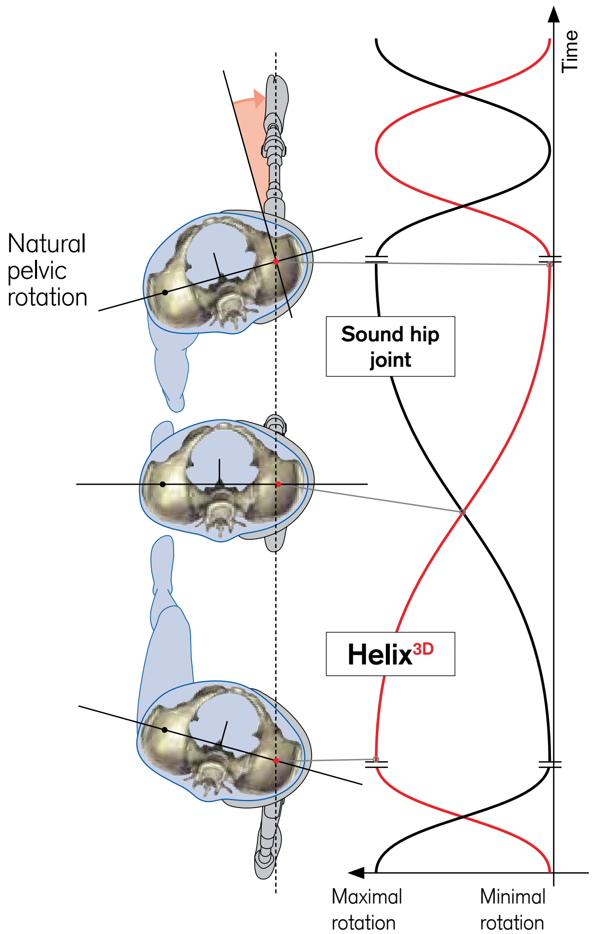
- Currently are or have the potential to be unlimited community ambulators;
- Can utilize Second Mode for varied activities such as bicycling, roller-blading,or extended periods of standing;
- Have the ability or potential to walk faster than 3 mph/5 kph or walk up to 3 miles/5 km a day;
- Are involved in activities requiring a high level of stance phase security as well as efficient swing phase control;
- Change direction and speed suddenly for work, sport, or home activities;
- Would benefit from automatic swing phase adjustments because of their activity level;
- Would improve their gait when using stance extension damping following stance flexion.

The Compact is Ideal for People Who:

- Currently are or have the potential to be community ambulators;
- Need a high degree of stance phase stability;
- Tend to walk at their self-selected speed and would not benefit from highly variable swing phase adjustments;
- Do not frequently engage in activities that would require the benefits of the Second Mode option.

The C-Leg® and Helix3D for Hip Disarticulation Patients

The Helix3D Hip Joint System is suitable for hip disarticulation and hemipelvectomy patients. It has been designed to work with a prosthetic knee that offers stance flexion and extension resistance, swing flexion and extension resistance, and stance stability, and thus is approved for use only with the C-Leg® prosthesis. These features allow it to offer the user maximum security and function for a wide range of everyday activities.



The Helix3D Hip Joint Prosthesis:

- Produces a three-dimensional hip movement to compensate for pelvic rotation and promotes a symmetrical and natural gait pattern;
- Allows for leg length reduction during the swing phase. This helps reduce the risk of falling and increases security;
- Allows for a dampened, controlled heel strike in the stance phase with significantly reduced hyperlordosis as well as a natural hip joint extension;
- Improves sitting posture and reduces pelvic obliquity to a minimum;
- Has a large flexion angle that makes it easier to accomplish activities of daily living, such as putting on shoes or getting into a car;
- MOBIS* Mobility grades 2 and 3. Weight limit of up to 220 lbs/100 kg;
- Includes integrated springs that make it noticeably easier to initiate swing phase. Energy stored during the stance phase is used during the swing phase initiation to compensate for the missing hip muscles and to reduce the amount of energy needed for walking;
- Provides three-dimensional movement of the hip joint during walking that closely resembles the normal hip movement in the sound leg.

*The MOBIS® system does not accord with K Levels. Please visit www.ottobockus.com for more information about MOBIS.

"Over the past eleven years we have fit multiple transfemoral patients with C-Leg technology with remarkable success. The stance stability function has been important for reducing traumatic falls and injuries, and most of our patients have been positive; they comment that it is easier for them to ambulate over various terrains, and descend stairs and ramps step-over-step. They have also reduced their falls and experienced increased stability and gained confidence when walking in a crowd."

~ CP from Schenectady, NY

C-Leg® Technology is the Most Researched Technology in Prosthetics

Stair Descent, Reduction in Falls:

Falling is a major health problem that affects many Americans, with over 15,000 deaths annually [1] Injuries sustained during a fall often require treatment and may lead to temporary or permanent disability.

"Falls and the interrelated category of being struck by or against objects accounted for more than 30% of injury costs, making them a strong prevention target." [2]

With most prosthetic knees users worry about stumbling and falling. This fear causes prosthetic users to compensate with changes in gait and may keep their prosthetic knee straight with each step.

C-Leg technology constantly adjusts to the user's movements, anticipating what the user is doing and accommodating every change in real-time, and has been proven to reduce the incidence of falls by 64% when compared to mechanical knees.[3]

In a 2007 study [4], transfemoral amputees who shifted from mechanical to MPKs reported a significant ($P < .01$) decrease in reported number of stumbles and falls, and a decrease in frustration with falling. Users have less difficulty multitasking when using the MPK, and subject satisfaction was also significantly ($p > .001$) greater than with the mechanical knee. Finally, users found improved stair descent with the C-Leg ($p < .001$).

Gait Improvements

Recent research comparing a non-MPK with a MPK performed objective measurements for gait and balance. The subjects participating in the study showed significantly improved gait characteristics with the C-Leg MPK over a non-MPK, including:

- Improved equilibrium ($p < 0.001$) [5];
- A flexed knee during loading response instead of a hyper-extended knee ($p < 0.01$), which resulted in a change from an internal knee flexor moment to a knee extensor moment [5];
- A decrease in the peak swing phase knee flexion angle, resulting in more controlled heel rise ($p = 0.005$) [6];
- Prosthetic limb step length at a controlled walking speed was less for the C-Leg than an non-MPK ($p = 0.005$), which resulted in increased symmetry between limbs for the C-Leg users and faster walking speed [6];
- The C-Leg vertical ground reaction force decreased compared with non-MPK ($p=0.0092$).[6]

Energy Efficiency

Studies performed in the last few years show that lower limb amputees expend more energy for walking and avoiding obstacles than able bodied users. They also found, however, that MPKs are more efficient than non-MPKs and that the C-Leg seems to be more efficient in most areas than other MPKs.[7]

In a comparison between the Intelligent Prosthesis (IP) and C-Leg MPKs [7], it was found that at walking speeds of 30 m/min the oxygen rate (ml/kg/min) of the IP and C-Leg, respectively, were 42.5% and 33.3% higher than the able bodied group. At the higher walking speed of 90 m/min were 61.9% and 55.2% ($p < 0.05\%$) respectively.

In another study conducted by Seymour, et al., comparing the C-Leg MPK with non-MPKs in the areas of energy expenditure, obstacle course negotiation, and quality of life, study participants were asked to walk at self-selected and fast walking speeds on a treadmill, as well as to walk through a standardized obstacle course while carrying a 10 lb. load and also with no load. "Statistically significant values were found in oxygen consumption between prostheses at both typical and fast paces with the C-Leg showing decreased values. Use of the C-Leg resulted in a statistically significant decrease in the number of steps and time to complete the obstacle course." [8]

Users Report Lowered Cognitive Demand While Using C-Leg® Versus Non-Mpk Knees

In two separate studies users reported that the C-Leg required less cognitive attention, although this did not translate into improved performance on neuropsychologic screening instruments.[9]

“Users reported a significant ($P < 0.05$) decrease in frequency of stumbles and falls, frustration with falling, and difficulty in multitasking while using the microprocessor knee.”[4]

Quality of Life & Body Image

Recent studies show that MPKs, and the C-Leg in particular, help improve satisfaction for amputees with their daily lives[5] and re-establish improved body image. A study by Bunce and Breakey[10] employed a survey to examine detailed aspects about how an amputee feels about his or her body experience, including body image, function, and behavioral avoidance in social situations. Body image was found to be significantly improved with C-Leg ($p < 0.001$). Body function, affect distress, and behavior avoidance subsets were most strongly affected.

Furthermore, 90% reported improvement in function and transformation in meaning and character of their everyday surroundings. 90% also reported that C-Leg reduced the sense of deficiency and displacement in relation to others. By significantly enhancing the ability to walk, the C-Leg has enabled users to approach the behavioral pace and performance of able-bodied persons.

MPK Resources at Otto Bock HealthCare

Otto Bock has developed multiple ways to support practitioners as they prepare to work with patients who can take advantage of C-Leg® technology.

- **Check Out the C-Leg—No Strings Attached:** Otto Bock sales reps now have a sample C-Leg to use at their discretion, so you can confer with a patient with no obligation to purchase. Simply speak with your Otto Bock sales rep.
- **Great Educational Opportunites:** Otto Bock offers a variety of educational options. You can participate in hands-on courses in a classroom, or get qualified with a completely online class. You can even take a hybrid of the two with our 'Fast Track' option by doing preparatory work online and then participating in a hands-on class as part of a 'Test Drive' event.
- **Clinical Support:** take advantage of our outstanding clinical support—by phone, online, with a webcam, or in person.
- **Host a No-Obligation Test Drive event:** You invite prospective C-Leg candidates to take the C-Leg for a no-obligation Test Drive, and we provide an Otto Bock prosthetist for support. We even provide email and print invitations.
- **Information at Your Fingertips:** Visit our 'For Professionals' Link at www.clegstories.com and find everything you need for clinical, technical, marketing and reimbursement information.
- **Hard to Fit Patient? Partner with Us!** With our new Cooperative Care program at the Otto Bock Innovation Center, Otto Bock clinicians partner with you to create the best possible outcome for your difficult cases. To find out more, speak with your Otto Bock sales representative.

The Future of MPKs: Genium Intuitive Microprocessor-Controlled Knee

Otto Bock HealthCare is currently finalizing development of the Genium Microprocessor-controlled Knee. Genium is the result of many years of intensive research and development and 14 years of practical experience with the C-Leg® MPK. The Genium system uses advanced-process measuring and control technologies to attain functionalities that far exceed those of today's prosthetic solutions.

Genium allows patients to walk with greater efficiency, as well as up stairs, backwards, and over obstacles. It does this by combining multiple sensors and sophisticated rule sets to offer unique features that optimize gait and increase security.

Genium will not be available until late 2011. It will not replace the C-Leg, but instead represents the beginning of a second line of microprocessor-controlled knees with different characteristics and benefits that address the challenges of a much broader set of activities of daily living.

(1) Finkelstein Eric A., Corso Phaedra S., Miller Ted R. Incidence and Economic Burden of Injuries in the United States. Oxford University Press, 2006.

(2) Corso P, Finkelstein E, Miller T, Fiebelkorn I, Zaloshnja E. Incidence and lifetime costs of injuries in the United States. Injury Prevention, 2006, 12: 212-218.

(3) Kahle JT, Highsmith MJ, Hubbard SL. Comparison of Non-microprocessor Knee Mechanism versus C-Leg on Prosthesis Evaluation Questionnaire, Stumbles, Falls, Walking Tests, Stair Descent, and Knee Preference. Journal of Rehabilitation research and Development, 2008, 45 (1) 1-14.

(4) Hafner BJ, et al. Evaluation of Function, Performance, and Preference as Transfemoral Amputees Transition from Mechanical to Microprocessor Control of the Prosthetic Knee. Archives Physical Medicine Rehabilitation, 2007, 88(2) 207-17.

(5) Kaufman KR, et al. Energy Expenditure and Activity of Transfemoral Amputees Using Mechanical and Microprocessor-Controlled Prosthetic Knees. Archives Physical Medicine Rehabilitation, 2008, 89 1380-1385.

(6) Segal AD, et al. Kinematic and Kinetic Comparisons of Transfemoral Amputee Gait Using C-Leg and Mauch SNS Prosthetic Knees. Journal of Rehabilitation Research & Development, 2006, 43(7) 857-870.

(7) Chin T, et al. Comparison of Different Microprocessor Controlled Knee Joints on the Energy Consumption During Walking in Trans-Femoral Amputees: Intelligent Knee Prosthesis (IP) Versus C-Leg. Prosthetics and Orthotics International, 2006 30(1): 73-80.

(8) Seymour R, et al. Comparison Between the C-leg Microprocessor-Controlled Prosthetic Knee and Non-Microprocessor Control Prosthetic Knees: A Preliminary Study of Energy Expenditure, Obstacle Course Performance, and Quality of Life Survey. Prosthetics and Orthotics International, 2007, 31(1), 51-61.

(9) Williams RM, et al. Does Having a Computerized Prosthetic Knee Influence Cognitive Performance During Amputee Walking? Archives of Physical Medicine and Rehabilitation, 2006, 87: 989-994.

(10) Bunce DJ, Breakey JW. The Impact of C-Leg on the Physical and Psychological Adjustment to Transfemoral Amputation. Journal of Prosthetics and Orthotics, 2007, 19 (1) 7-14.

QUALITY FOR LIFE

USA 800.328.4058 • Fax 800.962.2549 • www.ottobockus.com
Canada 800.665.3327 • Fax 800.463.3659 • www.ottobock.ca