Lower Limb Prostheses

Policy

*Please see amendment for Pennsylvania Medicaid at the end of this CPB.*

Aetna considers lower limb prostheses medically necessary for performing normal daily activities when the following criteria are met:

1. Member is motivated to ambulate; and
2. Member meets the specific criteria for lower limb prostheses set forth below; and
3. Member will reach or maintain a defined functional state within a reasonable period of time.

Aetna considers lower limb prostheses experimental and investigational for all other indications because of insufficient evidence in the peer-reviewed literature when these criteria are not met.

Aetna does not cover a replacement prosthesis unless the member's medical needs are not being met by the current prosthetic or it is broken and cannot be repaired.
Aetna considers "water leg" (an attachment for persons with lower limb prostheses to shower or swim) a convenience item, and not medically necessary. Aetna considers the Genium X-3 and similar devices water prostheses.

**Foot Prosthesis**

- A solid ankle-cushion heel (SACH) foot is considered medically necessary for persons whose functional level is 1⁺ or above.
- An external keel SACH foot or single axis ankle/foot is considered medically necessary for persons whose functional level is 1⁺ or above.
- A flexible-keel foot or multi-axial ankle/foot is considered medically necessary for persons whose functional level is 2⁺ or above.
- A flex foot system, energy storing foot, multi-axial ankle/foot, dynamic response foot with multi-axial ankle, shank foot system with vertical-loaded pylon or flex-walk system or equal is considered medically necessary for persons whose functional level is 3⁺ or above.
- An user-adjustable heel height feature is considered not medically necessary.

*Note:* Foot covers are included in the reimbursement for a prosthetic foot component and are not separately payable.

**Knee Prosthesis**

- A fluid or pneumatic knee is considered medically necessary for persons whose functional level is 3⁺ or above.
- A single axis constant friction knee and other basic knee systems are considered medically necessary for persons whose functional level is 1⁺ or above.
- A high-activity knee control frame is considered medically necessary for members whose function level is 4⁺.
Ankle Prosthesis

- An axial rotation unit is considered medically necessary for persons whose functional level is 2 or above.

Hip Prosthesis

- A pneumatic or hydraulic polycentric hip joint is considered medically necessary for members whose functional level is 3 or above.

Sockets

- Test (diagnostic) sockets for immediate post-surgical or early-fitted prostheses are considered not medically necessary.
- Two test (diagnostic) sockets for an individual prosthesis are considered medically necessary. Additional documentation of medical necessity is required for more than 2 test sockets.
- No more than 2 of the same socket inserts per individual prosthesis at the same time are considered medically necessary.
- Socket replacements are considered medically necessary if there is adequate documentation of functional and/or physiological need, including but is not limited to: changes in the residual limb; functional need changes; or irreparable damage or wear/tear due to excessive weight or prosthetic demands of very active amputees.

Prostheses have no proven value for persons whose potential functional level is 0.

Note: When replacing the socket on an existing prosthesis, socket replacement codes (L5700, L5701, L5702, L5703) should be used as base code. These socket replacement codes should not be used when replacing an entire prosthesis (e.g., a socket with a foot, knee and/or other components that
would substantially make an entire prosthesis. Use of socket replacement codes are considered duplicative and not medically necessary when an entire prosthesis, such as feet and knees, are billed with a socket replacement code.

**Accessories**

Stump stockings and harnesses (including replacements) are considered medically necessary when they are essential to the effective use of the artificial limb.

Prosthetic sheaths/socks, including a gel cushion layer (prosthetic gel stockings; 12 in 12 months) are considered medically necessary.

No more than 2 socket inserts per individual prosthesis are considered medically necessary.

No more than two replacement liners per prosthesis in 12 months are considered medically necessary.

A prosthetic donning sleeve is considered not medically necessary.

**Microprocessor-Controlled Lower Limb Prostheses**

Aetna considers microprocessor-controlled leg prostheses (“Addition to lower extremity prosthesis, endoskeletal knee-shin system, microprocessor control feature, swing and stance phase, includes electronic sensor (s), any type”) (e.g., Otto Bock C-Leg; Otto-Bock Genium Bionic Prosthetic System (also known as Otto-Bock Genium X3; Otto Bock HealthCare, Minneapolis, MN), Intelligent Prosthesis (Endolite North America, Centerville, OH), and Ossur Rheo Knee/Ossur RKXC Knee (Ossur-Flexfoot, Aliso Viejo, CA)) medically necessary in otherwise healthy, active community ambulating adults (18 years of age or older) (functional level 3 or above) with a knee disarticulation
amputation or a trans-femoral amputation from a non-vascular cause (usually trauma or tumor) for whom this prosthesis can be fitted and programmed by a qualified prosthetist trained to do so.

A powered flexion-extension assist ("Addition to lower extremity prosthesis, endoskeletal knee-shin system, powered and programmable flexion(extension assist control, includes any type of motor(s)") ) is only considered medically necessary when the member meets all of the criteria below:

1. Has a microprocessor (swing and stance phase type) controlled (electronic) knee; and
2. K3 functional level only; and
3. Weight greater than 110 lbs and less than 275 lbs; and
4. Has a documented comorbidity of the spine and/or sound limb affecting hip extension and/or quadriceps function that impairs K-3 level function with the use of a microprocessor-controlled knee alone; and
5. Is able to make use of a product that requires daily charging; and
6. Is able to understand and respond to error alerts and alarms indicating problems with the function of the unit.

Aetna considers microprocessor-controlled leg prostheses (e.g., Otto Bock C-Leg, Otto-Bock Genium Bionic Prosthetic System, Intelligent Prosthesis, and Ossur Rheo Knee) experimental and investigational for gait management in spinal cord injury because of insufficient evidence in the peer-reviewed literature.

Aetna considers the C-Leg Protector experimental and investigational because its clinical value has not been established.
**Note:** With the exception of items described by specific HCPCS codes, there should be no separate billing and there is no separate payment for a component or feature of a microprocessor controlled knee, including but not limited to real time gait analysis, continuous gait assessment, or electronically controlled static stance regulator.

Aetna considers a microprocessor-controlled ankle-foot prostheses (e.g., PowerFoot BiOM, iWalk, Bedford, MA; Proprio Foot, Ossur, Aliso Viejo, CA) medically necessary for members whose functional level is 3* or above.

Aetna considers a microprocessor foot or ankle system addition with power assist which includes any type motor not medically necessary.

Aetna considers the Ossur Symbiotic Leg experimental and investigational because its clinical value has not been established.

**Prosthetic Shoe**

Aetna considers a prosthetic shoe medically necessary for a partial foot amputation when the prosthetic shoe is an integral part of a covered basic lower limb prosthetic device.

**Powered Lower Limb Prosthesis**

Aetna considers powered lower limb prosthesis (e.g., Power Knee, Ossur, Foothill Ranch, CA) experimental and investigational because there is inadequate evidence of their effectiveness.

**Robotic Lower Body Exoskeleton Suits**
Aetna considers robotic lower body exoskeleton suits (e.g., the ReWalk, Argo Medical Technologies Ltd, Marlborough, MA) experimental and investigational because there is inadequate evidence of their effectiveness.

*Note: Clinical assessments of a member's rehabilitation potential should be based on the functional classification levels listed in the appendix.

Adjustable Click Prosthesis

Aetna considers adjustable click prostheses (e.g., Revo and Boa click systems) experimental and investigational because of insufficient published evidence of their safety and effectiveness.

Non-Medically Necessary Prostheses

Aetna considers the following not medically necessary:

- Duplication or upgrade of a functional prosthesis; or
- Lower limb prosthesis for a functional level of 0; or
- Prosthetic devices or prosthetic components that are primarily for cosmesis; or
- Prosthetics used for activities other than normal daily living, including, but may not be limited to, those utilized for leisure or sporting activities such as skiing or swimming; or
- Repair or replacement of a prosthesis for appearance, comfort, convenience or individual abuse, misuse or neglect; or
- Repair or replacement of parts of a duplicate prosthesis; or
- Test sockets for an immediate prosthesis; or
- Water prosthesis (designed to be used for showering, swimming, etc.).
Notes: Protective outer surface covering systems (L5962, L5964, and L5966) are specialized covers intended to be worn over an existing prosthesis. They are considered medically necessary for members who have special needs for protection against unusually harsh environmental situations where it is necessary to protect the lower limb prosthesis beyond the level of protection that is afforded by covers described by HCPCS codes L5704 - L5707. They are not for cosmetic or convenience reasons, or for everyday usage in a typical environment. Protective outer surface coverings are different from the covering that is already reimbursed as part of the covers described by HCPCS codes L5704 - L5707. When billing for the protective outer surface covering systems (L5962, L5964 and L5966), information regarding the type of protective cover provided (i.e., manufacturer name, make, model or type) must be included in practitioner’s notes in order to ensure correct coding.

Evaluation of the member, measurement and/or casting, and fitting/adjustments of the prosthesis are included in the allowance for the prosthesis. There is no separate payment for these services.

There is no separate payment if CAD-CAM technology is used to fabricate a prosthesis. Reimbursement is included in the allowance of the codes for a prosthesis.

Powered base items are those that contain the power source (battery). At the time that a base item is billed, all necessary batteries and/or battery chargers are considered as included in the payment for the powered base item. There is no separate payment for batteries (L7360, L7364, and L7367) and/or battery chargers (L7362, L7366, and L7368) billed concurrently with a powered base item.

Aetna does not consider warranties or guarantees beyond the base warranty included in a device a medical benefit. Additional warranties and guarantees beyond the included
base warranty or manufacturer warranty, are considered non-medically necessary convenience items. Items billed for replacement that are still under manufacturer warranty are considered not medically necessary.

Correct Coding of Endoskeletal Prosthetic Knee-Shin Systems

The endoskeletal prosthetic lower extremity codes (L5312, L5321, L5331, L5341) (Group 1 codes) include reimbursement for a molded prosthetic socket, an endoskeletal single axis knee-shin system and a SACH foot.

The knee-shin systems (L5610, L5611, L5613, L5616, L5810, L5811, L5812, L5814, L5816, L5818, L5822, L5824, L5826, L5828, L5830, L5840) (Group 2 codes) are considered an upgrade to the endoskeletal prosthetic lower extremity (Group 1) codes listed above. The member may qualify for these upgraded knee-shin systems. Qualification is dependent on medical documentation and assigned K-Level modifier (K0-K4). These Group 2 L-codes can fully describe a complete prosthetic knee-shin system commonly referred to as a "base knee code". The use of two L-codes from this group to fully describe the knee-shin system would be considered incorrect coding (unbundling).

The Group 3 codes (L5925, L5930, L5845, L5848, L5850, L5856, L5857, L5858, L5859) includes a secondary list of L-codes which describe other features and functions not found in the Group 2 "base knee codes". These addition codes describe additional features and/or functions that do not describe a complete knee-shin system and must be used in combination with an L-code with a base knee-shin system. The use of Group 3 L-codes may also depend on the medical documentation and the assigned K-Level modifier (K0-K4).

HCPCS code L5999 must not be used to bill for features or functions of the knee-shin system included in Group 1, Group
2 or Group 3 code lists. Use of HCPCS code L5999 in this manner will be considered incorrect coding (unbundling).

See also

CPB 0399 - Myoelectric Upper Limb Prosthesis
(../300_399/0399.html)
, and

CPB 0630 - Prosthetic Limb Vacuum Systems
(../600_699/0630.html)
.

Background

A prosthesis or prosthetic is an artificial device that replaces a missing body part. Examples of prostheses include eyes, maxillofacial (jaw and face), arms, breasts, ears, legs, hands and feet.

A lower limb prosthesis is designed to replace portions of the lower extremity to improve function. A prosthetic knee performs several functions: it provides support during the stance phase of ambulation, produces smooth control during the swing phase and maintains unrestricted motion for sitting and kneeling. The prosthetic knee may have a single axis with a simple hinge and a single pivot point or it may have a polycentric axis with multiple centers of rotation, which is more similar to the anatomic human knee. Pylons are the connection between the residual limb and the prosthetic joint.

The prosthetic foot also has several basic functions: provides a stable weight-bearing surface, absorbs shock, replaces lost muscle function and biomechanics of the foot, replicates the anatomic joints of the ankle and foot and restores appearance.
Multiaxial prosthetic feet permit movements in any direction: plantar flexion, dorsiflexion, inversion, eversion and a slight amount of rotation around a vertical axis. Multiaxial feet are appropriate for those who ambulate on uneven terrain, such as community ambulators and active adults or athletes.

The solid ankle cushion heel (SACH) consists of a rigid keel covered by semi-noncompressible foam and a synthetic rubber heel wedge. The cushion heel compresses when weight is applied, allowing the forefoot to approach the floor. The amount of simulated plantar flexion depends on the relative softness of the heel material and weight of the amputee. Because the keel is rigid, the SACH foot does not provide dorsiflexion; this makes its usefulness on uneven surfaces limited.

Conventional lower limb prostheses employ exclusively mechanical control; these may include a pneumatic or hydraulic damping cylinder, which is adjusted by a prosthetist, to provide optimum gait parameters at the patient's conventional walking speed. If a patient walks at a different speed, the patient must compensate for the pendulum action of the prosthesis to alter stride length or step rate by tilting the pelvis, or by other maneuvers, to delay extension to ensure that the foot is in the right place for the next step. These maneuvers lead to an abnormal gait and require extra effort and concentration. Aetna’s policy on standard lower limb prostheses is based on Medicare DME MAC criteria.

The microprocessor-controlled lower limb prosthesis (also known as computerized lower limb prostheses) is relatively new to the United States, although a different brand of microprocessor-controlled lower limb prosthesis has been in use in Europe for many more of years. These prostheses employ a microprocessor-controlled knee extension damper, which is designed to detect step time and alter knee extension level to suit walking speed. More advanced microprocessor controlled lower limb prostheses, such as the C-leg, also have
multiple sensors that gather and calculate data on, for example, amount of vertical load, sagittal plane ankle movement, and specifics of knee joint movement. These prostheses are claimed to be a significant improvement over the conventional mechanically controlled prostheses.

Claimed advantages of the microprocessor-controlled lower limb prostheses include: decreased effort involved in walking; improved gait symmetry; increased confidence by the patient in the prosthesis; more natural movement, including on stairs, inclines, and uneven terrain; the perception that participation in activities such as sports is possible; and the avoidance of falls.

The Otto Bock C-leg was cleared by the Food and Drug Administration (FDA) based on a 510(k) application; FDA clearance was based on the Otto Bock C-leg’s substantial equivalence to a predicate device that was on the market prior to the date of enactment of the 1976 Medical Device Amendments to the Food, Drug and Cosmetic Act.

A number of systematic evidence reviews have identified limitations in current literature on microprocessor controlled knees. The majority of this literature evaluates intermediate outcomes, although some studies have focused on actual functional outcomes. However, the bulk of all of these studies show improvement in outcomes when the microprocessor-controlled knee is used as compared to a more traditional non-microprocessor-controlled knee.

The first systematic evidence review of microprocessor controlled knees was prepared by the Department of Veterans Affairs Technology Assessment Program (VA TAP) (MDRC, 2000). The VA TAP assessment reviewed the evidence supporting the use of computerized lower limb prostheses such as the Otto Bock C-leg and the Intelligent Prosthesis, a microprocessor-controlled lower limb prosthesis that is slightly different than the Otto Bock C-Leg (MDRC, 2000). The VA TAP found, upon review of published studies, that users'
perceptions of the microprocessor-controlled prosthesis are favorable. They also found that, although the energy requirements for ambulation (compared to requirements for conventional prostheses) are decreased at walking speeds slower or faster than the amputee's customary speed, energy requirements are not significantly different at customary speeds. The VA TAP found that the reported results on ability to negotiate uneven terrain, stairs, or inclines are "mixed."

At that time, the VA TAP found the evidence of effectiveness of the microprocessor-controlled lower limb prostheses (Intelligent Prosthesis, Otto Bock C-leg) to be limited (MDRC, 2000). Regarding the evidence of effectiveness, the report drew the following conclusions: "The published research is a small body of work. Less than 3% of the published and indexed articles represent structured research, with the larger fraction of published articles being purely descriptive or frankly promotional. Most of the available structured research is based on a slightly different microprocessor-controlled prosthesis (the [Endolite] Intelligent Prosthesis (IP), Blatchford, United Kingdom). The IP is associated with many of the same potential benefits as the C-LEG."

The VA TAP reported (MDRC, 2000): "Published studies have enrolled highly selected samples of amputees who do not have additional medical problems, whose amputations were secondary to trauma or congenital defects, and who are fit and active. These and similar characteristics have been shown to be independently predictive of successful rehabilitation or return to normal living after amputation, and may confound the results of the non-randomized, uncontrolled microprocessor-controlled prosthesis studies that have been published to date.

- Results in the highly selected patients who have participated in the available published studies may not be directly transferable to VA amputees, who are likely
to have multiple additional medical problems and amputations secondary to vascular disease.

- The selective inclusion for research patients noted above undoubtedly introduce bias into study results, precluding definitive attribution of improvements in gait, energy expenditure, etc., to the computerized prosthesis.

An assessment conducted by the Washington State Department of Labor and Industries (2002) concluded "due to the small number of studies and study participants, evidence of the broad effectiveness of microprocessor-controlled prosthetic knees remains inconclusive."

An evidence review prepared by the Evidence Based Group of the Workers Compensation Board of British Columbia (Martin, 2003) concluded that, "to date, the published research on computerized knee prosthesis is very limited. Less than 3% of published and indexed research represents structured research. Most published articles are purely descriptive or promotional in nature." The evidence review noted: "Published studies enrolled highly selected sample of amputees who did not have additional medical problems and who were fit and active. These characteristics have been shown to be independently predictive of successful rehabilitation or return to 'normal' living after amputation. Thus, these variables are most likely to confound the results of the non-randomized, uncontrolled studies on microprocessor controlled knee prosthesis that have been published to date." The evidence review concluded that, "at present, the small number of studies on computerized knee prostheses does not conclusively show the effectiveness of the prostheses" in reducing energy expenditure particularly in normal speed walking, improving ability to walk on uneven terrain, improving ability to climb and descend stairs, and increasing walking distance.
Additional studies have been published since these technology assessments were published. Although each of these studies have flaws, the bulk of the studies show improvement in outcomes when the microprocessor-controlled knee is used as compared to a standard hydraulic knee. Similar to previously published studies, Stinus (2000) authored an uncontrolled descriptive study involving a selected group of 15 patients, reporting on their subjective assessments of the microprocessor-controlled lower limb prosthesis compared with previously fitted mechanically controlled prosthetic knee joints. This study did not include objective assessments of improvements in function and reductions in disability compared with conventional prostheses. Schmalz, et al (2002) reported on the results of a randomized controlled clinical study comparing conventional hydraulic knees with electronically controlled knee joints during walking on a treadmill. The investigators reported reductions in oxygen consumption in persons with electronically controlled knees compared to patients with conventional hydraulic knees when walking at speeds other than the amputee’s customary walking speeds. This study, however, did not assess differences in function between these groups. Similarly, a study by Chin et al (2003) of 8 traumatic amputees fitted with an Intelligent Prosthesis compared to 14 normal non-amputee controls reported a 24% greater energy expenditure compared to controls walking at equal speeds. However, this study did not assess reductions in disability and improvements in function with the Intelligent Prosthesis.

In a subsequent study, Chin et al (2005) reported on changes in oxygen consumption of 3 amputees after prescription of a microprocessor-controlled prosthesis. The change in energy expenditures reported was highly variable among subjects, with 1 subject reporting a minor (4.9%, 11.6% and 105%) reductions in oxygen consumption, another reporting changes in energy expenditures of 10.3%, 14.9% and 23.3% depending upon speed, and the third subject reporting larger changes in energy expenditures (39.6%, 24.6% and 23.3%).
The study provided no details about how these cases are selected. Thus, one is not able to determine whether one can generalize from this selected set of individual cases to other amputees. The study suffers from the same flaws as the previous study by the same investigator group; it does not represent a stronger study, in terms of design, than previous published studies. The study by Chin et al (2005) is a pre-/post-study, without concurrent controls; other factors may have accounted for changes in energy expenditures after prescription of the microprocessor controlled prosthesis, including the training program and practice subjects received to improve their ability to walk with a microprocessor-controlled prosthesis before their energy expenditures were re-assessed. The study by Chin et al also suffered from the limitations of his previous study in that it assessed differences in oxygen consumption, an intermediate endpoint, and did not assess clinically relevant endpoints of reductions in disability and improvement in function.

A study by Johansson et al (2005) compared the magnetorheological-based Ossur Rheo prosthesis to the hydraulic-based Otto-Bock C-Leg microprocessor-controlled prosthesis to a standard hydraulic-based (Mauch) prosthesis. The study found no statistically significant difference between the C-Leg microprocessor controlled prosthesis and a standard hydraulic (Mauch) prosthesis in metabolic expenditure (as measured by oxygen consumption) with walking, the primary study endpoint. The investigators (from a group headed by an inventor and patent-holder of the Ossur Rheo microprocessor-controlled leg prosthesis) reported a 5 % lower average metabolic consumption with walking using the Ossur Rheo prosthesis, and a 2 % lower average metabolic consumption with walking using the C-leg microprocessor-controlled prosthesis compared to a standard hydraulic (Mauch) prosthesis; the latter difference did not achieve statistical significance. There is also a question about the clinical significance of such small differences in metabolic expenditure.
consumption, especially among the younger active amputees for whom microprocessor-controlled prostheses are most commonly prescribed.

The study by Johansson et al (2005) also evaluated differences in kinetics, kinematics, and electromyographic data between the C-Leg, the Ossur Rheo prosthesis, and standard hydraulic prostheses in walking sessions performed in the laboratory. However, the study fails to show how any identified differences in these intermediate outcomes, while statistically significant, translated into tangible, clinically significant reductions in disability and improvements in function. The small size of the study (n = 8) may limit one's ability to generalize its findings to other amputees. Observed differences between microprocessor-controlled prostheses and the standard hydraulic-based Mauch prosthesis may be due, in part, to the fact that half of the study subjects had been using a microprocessor-controlled prostheses as their usual prosthesis prior to study initiation, and only 1 study subject used the Mauch hydraulic prosthesis as her usual prosthesis prior to study initiation. In addition, laboratory-based evaluation of prostheses and their components may not necessarily reflect the characteristics of the prostheses when used outside of the clinical setting (in real life situations), and in subjects with more experience with use of these particular prosthetics.

A study by Datta et al (2005) comparing the Intelligent Prosthesis microprocessor-controlled prosthesis to conventional pneumatic leg prostheses in 10 amputees found no significant difference in metabolic expenditures (oxygen consumption) at average walking speeds. The study also found no significant differences in temporal and spatial parameters of gait between the 2 types of knee joint, nor any significant differences in gait by observational video analysis. The study found statistically significantly lower energy expenditures using the Intelligent prosthesis (0.30 ml/kg.m) compared to the standard pneumatic prosthesis (0.33 ml/kg.m)
only when subjects walked at about half normal speed. However, the clinical significance of this degree of difference in metabolic expenditure, which is only manifest at slow walking speeds, is in question, especially for younger, healthy subjects.

A study by Swanson et al (2005) evaluated body image and function in 8 amputees using the Otto-Bock C-Leg. However, the study did not include a comparison group of individuals using a standard hydraulic-based prosthesis. Thus, no conclusions can be drawn regarding differences in body image and function levels of individuals using the C-Leg and individuals using a standard hydraulic-based prosthesis.

In a randomized, controlled cross-over study comparing the C-leg to a standard mechanical knee (Mauch SNS knee), Orendurff et al (2006) found that, at measured walking speeds, the C-Leg did not significantly improve gait efficiency in transfemoral (TF) amputees. Eight TF amputees were randomized to the Mauch SNS knee and the C-Leg microprocessor-controlled knee. The subjects were given a 3-month acclimation period in each knee. Then, their net oxygen cost (mL/kg/m) was measured while they walked overground at 4 speeds in random order: 0.8 m/s, 1.0 m/s, 1.3 m/s, and self-selected walking speed (SSWS). The C-Leg caused small reductions in net oxygen cost that were not statistically significant compared with the Mauch SNS at any of the walking speeds (p > 0.190). Subjects chose higher SSWSs with the C-Leg compared with the Mauch SNS (mean +/- standard deviation = 1.31 +/- 0.12 m/s versus 1.21 +/- 0.10 m/s, respectively, p = 0.046) but did not incur higher oxygen costs (p = 0.270), which suggests greater efficiency only at their SSWS.

A randomized cross-over study by Segal et al (2006) comparing the C-Leg to a standard mechanical knee (Mauch SNS knee) found no significant differences in gait biomechanics. After subjects had a 3-month acclimation
period with each prosthetic knee, typical gait biomechanical data were collected in a gait laboratory. The investigators reported that, at a controlled walking speed (CWS), peak swing phase knee-flexion angle decreased for the C-Leg group compared with the Mauch SNS group (55.2° +/- 6.5° versus 64.41° +/- 5.8°, respectively; p = 0.005); the C-Leg group was similar to control subjects' peak swing knee-flexion angle (56.0° +/- 3.4°). Stance knee-flexion moment increased for the C-Leg group compared with the Mauch SNS group (0.142 +/- 0.05 versus 0.067 +/- 0.07 N²m, respectively; p = 0.01), but remained significantly reduced compared with control subjects (0.477 +/- 0.1 N²m). Prosthetic limb step length at CWS was less for the C-Leg group compared with the Mauch SNS group (0.66 +/- 0.04 versus 0.70 +/- 0.06 m, respectively; p = 0.005), which resulted in increased symmetry between limbs for the C-Leg group. Subjects also walked faster with the C-Leg versus the Mauch SNS (1.30 +/- 0.1 versus 1.21 +/- 0.1 m/s, respectively; p = 0.004). The C-Leg prosthetic limb vertical ground reaction force decreased compared with the Mauch SNS (96.3 +/- 4.7 versus 100.3 +/- 7.5 % body weight, respectively; p = 0.0092). The investigators concluded: "Our study demonstrated minimal differences between the gait biomechanics of subjects walking with the C-Leg compared with the Mauch SNS, a non-computerized prosthetic knee, during constant speed ambulation at approximately TF amputee SSWS."

Klute et al (2006) found that a microprocessor controlled knee no effect on amputees functional level compared to mechanical knees. To investigate the effect of prosthetic interventions on the functional mobility of lower-extremity amputees, the investigators conducted a cross-over study involving 5 TF amputees comparing a microprocessor controlled knee (C-Leg) to a non-microprocessor controlled knee (Mauch SNS). The investigators reported that knee type had no effect on the daily activity level or duration for TF amputees.
A study by Seymour et al (2007) (n = 13) comparing the C-leg to various non-microprocessor controlled knees reported decreased oxygen consumption with the C-leg. However, this study is of weaker design than the studies by Orendurff et al (2006) and Segal et al (2006) described above, in that it was a simple pre-post study, which is of weaker design than a randomized controlled clinical trial. Another recently reported study comparing functional performance of microprocessor controlled and mechanical knees is also of weaker design (Hafner et al, 2007) (n = 21).

There is limited evidence for the use of microprocessor-controlled knees in patients with unilateral hip disarticulation. Chin et al (2005) compared the energy expenditure during walking in 3 patients, aged between 51 and 55 years, with unilateral disarticulation of the hip when using the mechanical-controlled stance-phase control knee (Otto Bock 3R15) and the microprocessor-controlled pneumatic swing-phase control knee (Intelligent Prosthesis, IP). All had an endoskeletal hip disarticulation prosthesis with an Otto Bock 7E7 hip and a single-axis foot. The energy expenditure was measured when walking at speeds of 30, 50, and 70 m/min. Two patients showed a decreased uptake of oxygen (energy expenditure per unit time, ml/kg/min) of between 10.3 % and 39.6 % when using the IP compared with the Otto Bock 3R15 at the same speeds. One did not show any significant difference in the uptake of oxygen at 30 m/min, but at 50 and 70 m/min, a decrease in uptake of between 10.5 % and 11.6 % was found when using the IP. The use of the IP decreased the energy expenditure of walking in these patients.

The California Technology Assessment Forum (CTAF, 2007) recommended the use of a C-Leg microprocessor-controlled prosthetic knee in otherwise healthy, active K3-K4 community ambulating adults with a trans-femoral amputation from a non-vascular cause (usually trauma or tumor) for whom this prosthesis can be fit and programmed by a qualified prosthetist trained to do so. (Note: Medicare level K3 refers to
unlimited community ambulator, while level K4 refers to active adult, athlete, who has the need to function at a K3 level in daily activities).

A technology assessment of microprocessor-controlled prosthetic knees prepared by the CTAF (2007) noted that the majority of available literature evaluated intermediate outcomes; however, 3 studies were identified that focused on actual functional outcomes. The CTAF assessment found that the bulk of all of these studies show improvement in outcomes when the microprocessor-controlled knee is used as compared to a more traditional non-microprocessor-controlled (NMC) knee. The CTAF assessment reported: "While it is unclear how some of the intermediate outcomes impact on clinical or functional outcomes, the functional outcomes of improved gait biomechanics, improved balance, few falls, improved performance on an obstacle course and going down stairs and hills, as well as fewer self-reported falls have obvious benefit for the prosthetic users. While none of the studies is without flaws; however, the bulk of the evidence is in favor of the studied microprocessor-controlled prosthetic knees for the populations enrolled." The CTAF assessment concluded that it appears that healthy, active adults with a trans-femoral amputation for a non-vascular cause (usually trauma or tumor) derive functional benefit from wearing a microprocessor-controlled knee.

According to the CTAF assessment, there are questions remaining about microprocessor-controlled prosthetic knees (CTAF, 2007). The CTAF assessment notes that many of the studies attempted to enroll more individuals, but some of their enrollees either could not be fit with the prosthesis or could not adapt to it. It is unclear whether there are particular predictors of who these people might be -- is it something to do with the interface between stump and socket, or are there other important predictors? The CTAF assessment also observed that all of the studies were of individuals who were long-term users of an NMC previously; is there a population who should
be offered a microprocessor-controlled prosthetic knee as their initial prosthesis? The CTAF assessment commented that most of the studies enrolled active adults, and only a few enrolled moderately active or older dysvascular adults -- is there a group of moderately active adults whose activity level would improve even more with this technology? "Perhaps these researchers would have observed even greater differences if they had studied somewhat less active individuals with the potential for enhanced mobility with a more responsive prosthesis."

The Proprio Foot (Ossur, Alsio Viejo, CA) is a microprocessor-controlled prosthetic ankle-foot system for lower-extremity amputees. It is designed to adjust to uneven ground, ramps, stairs, and other environmental obstacles. It consists of 4 parts: (i) an energy storing prosthetic foot, (ii) a battery-powered prosthetic ankle that dorsiflexes and plantarflexes during swing phase, (iii) a microprocessor that controls dorsiflexion and plantarflexion in real time and in response to changes in the underlying terrain by sampling ankle position more than 1,000 times per second, and (iv) a lithium-ion battery and charger. Its Terrain Logic software permits the adjustment to surface gradients of up to 20 degrees.

Published evidence on microprocessor-controlled ankle-foot orthoses is limited to small studies examining the short-term effects on kinematic parameters, which are considered short-term surrogate outcomes (Fradet et al, 2010; Alimusaj et al, 2009; and Wolf et al, 2009). However, there is a lack of data on other relevant aspects of ambulation (e.g., daily step frequency, estimated step distance, stopping and standing safely, adaptation to different walking speeds, and fall frequency). In addition, there is a lack of reliable published evidence of the impact of microprocessor-controlled ankle-foot prostheses compared to standard ankle-foot prostheses on other relevant outcomes, including energy expenditure,
cognitive requirements of ambulation, and patient-centered outcomes (quality of life, impact on activities of daily living, work, and work performance).

A systematic evidence review prepared for the Washington State Health Technology Advisory Committee (Henrickso, et al., 2011) found no studies of the Proprio Foot or other microprocessor controlled foot devices that met inclusion criteria for the systematic evidence review. The review stated that "[t]here is insufficient evidence to evaluate the comparative effectiveness, safety, or cost effectiveness of microprocessor-controlled foot devices."

Bellmann et al (2012) examined the immediate biomechanical effects after transition to a new microprocessor-controlled prosthetic knee joint. Subjects were men (n = 11; mean age ± SD, 36.7 ± 10.2 years; Medicare functional classification level, 3 to 4) with unilateral TF amputation. Two microprocessor-controlled prosthetic knee joints: C-Leg and a new prosthetic knee joint, Genium were used in this study. Main outcome measures included static prosthetic alignment, time-distance parameters, kinematic and kinetic parameters, and center of pressure. After a half-day training and an additional half-day accommodation, improved biomechanical outcomes were demonstrated by the Genium: lower ground reaction forces at weight acceptance during level walking at various velocities, increased swing phase flexion angles during walking on a ramp, and level walking with small steps. Maximum knee flexion angle during swing phase at various velocities was nearly equal for Genium. Step-over-step stair ascent with the Genium knee was more physiologic as demonstrated by a more equal load distribution between the prosthetic and contralateral sides and a more natural gait pattern. When descending stairs and ramps, knee flexion moments with the Genium tended to increase. During quiet stance on a decline, subjects using Genium accepted higher loading of the prosthetic side knee joint, thus reducing same side hip joint loading as well as postural sway. The authors concluded that
in comparison to the C-Leg, the Genium demonstrated immediate biomechanical advantages during various daily ambulatory activities, which may lead to an increase in range and diversity of activity of people with above-knee amputations. Results showed that use of the Genium facilitated more natural gait biomechanics and load distribution throughout the affected and sound musculoskeletal structure. This was observed during quiet stance on a decline, walking on level ground, and walking up and down ramps and stairs.

Bellmann et al (2012) reported a biomechanical study to assess objective gait measurements and calculate joint kinematics and kinetics as subjects ascended stairs. The investigators stated that results demonstrated that climbing stairs step over step is more biomechanically efficient for an amputee using the Genium prosthetic knee than the previously possible conventional method where the extended prosthesis is trailed as the amputee executes one or two steps at a time. The investigators explained that there is a natural amount of stress on the residual musculoskeletal system, and it has been shown that the healthy contralateral side supports the movements of the amputated side. The mechanical power that the healthy contralateral knee joint needs to generate during the extension phase is also reduced. Similarly, there is near normal loading of the hip joint on the amputated side.

Highsmith et al (2016) conducted a study to determine if laboratory determined benefits of Genium are detectable using common clinical assessments and if there are economic benefits associated with its use. This study utilized a randomized AB crossover study with 60 day follow-up including cost-effectiveness analysis. Twenty transfemoral amputee (TFA) patients tested with both knees in mobility and preference measures. Incremental cost-effectiveness ratios (ICER) were calculated based on performance measures. Stair Assessment Index scores improved with Genium. Mean stair completion times and descent stepping rate were not different between knees. Stair ascent stepping
rate for C-Leg was greater compared with Genium (p = 0.04). Genium use decreased Four square step test completion time and increased functional level and step activity (p ≤ 0.05). Further, Genium use improved (p ≤ 0.05) function and safety in 3 out of 5 Activities of Daily Living (ADL) survey domains. Finally, more subjects preferred Genium following testing. Functional measures were used to calculate ICERs. ICER values for Genium fall within established likely-to-accept value ranges. The authors concluded that, compared with C-Leg, Genium use improved stair walking performance, multi-directional stepping, functional level, and perceived function. In this group of community ambulators with TFA, Genium was preferred, and, while more costly, it may be worth funding due to significant improvements in functional performance with ADLs.

Kannenberg et al (2013) conducted a study with 10 unilateral transfemoral amputees (Medicare Functional Classification level 3 and 4) to investigate whether the Genium Knee is able to further improve the perceived safety and difficulty of 45 activities of daily living as compared with the C-Leg. Results show that after 3 months of Genium use, it could be shown that perceived safety improved in 27 activities (60 %) and perceived difficulty improved in 24 activities (53 %). Improvements were seen in the categories of Family and Social Life as well as Mobility and Transportation. The authors concluded that these findings create the basis for further improvement of independence and participation of amputees in family, business, and social life by using the Genium Bionic Prosthetic Knee.

The Prosthesis Evaluation Questionnaire (PEQ) evaluates prosthetic-related function and quality of life. The PEQ has been used in microprocessor knee literature to compare perceptive response between C-Leg and non-microprocessor-controlled knee mechanisms. Highsmith et al (2014) studied perceived differences in prosthetic function and quality of life following accommodation with a Genium compared with
a C-Leg. Twenty people with TFA participated in this randomized crossover study. C-Leg users randomized to test first with their own C-Leg or a Genium then crossed over into the other condition for repeated testing. Non-knee prosthetic attributes were held constant. Participants completed the PEQ for each knee condition to compare perceived differences in prosthetic function and quality of life. Genium use resulted in significant improvements (p ≤ 0.05) in the following scales — Perceived Response, Social Burden, Utility, and Well-Being — as well as in individual items related to improved standing comfort, satisfaction with walking ability, and improved gait in tight spaces, hills, and slippery surfaces (p < 0.025). As a result of using the Genium, patients perceive improvements in prosthetic-related quality of life and function. Further, patients perceive improvements in very specific mobility functions related to ambulation on complex settings.

Highsmith et al (2016) conducted a study using a randomized experimental crossover of TFA patients using Genium and C-Leg microprocessor knee (MPKs) (n = 20). Biomechanical gait analysis by 3D motion tracking with floor mounted force plates of TFA patients ambulating at different speeds on 5° ramps was completed. Knee moment DoA was significantly different between MPK conditions in the slow and fast uphill as well as the slow and self-selected downhill conditions. In a sample of high-functioning TFA patients, Genium knee system accommodation and use improved knee moment symmetry in slow speed walking up and down a five degree ramp compared with C-Leg. Additionally, the Genium improved knee moment symmetry when walking downhill at comfortable speed. These results likely have application in other patients who could benefit from more consistent knee function, such as older patients and others who have slower walking speeds.

Lura et al (2015) used a randomized experimental crossover of persons with transfemoral amputation using the Genium and C-Leg microprocessor knees (n = 25), with an observational sample of non-amputee controls (n = 5). Gait
analysis by 3D motion tracking of subjects ambulating at different speeds on level ground and on 5° and 10° ramps was completed. The investigators found that use of the Genium resulted in a significant increase in peak knee flexion for swing (5°, p < 0.01, d = 0.34) and stance (2°, p < 0.01, d = 0.19) phases relative to C-Leg use. There was a high degree of variability between subjects, and significant differences still remain between the Genium group and the control group's knee flexion angles for most speeds and slopes. The investigators concluded that the Genium knee generally increases flexion in swing and stance, potentially decreasing the level of impairment for persons with transfemoral amputation. The investigators stated that this study demonstrates functional differences between the C-Leg and Genium knees to help prosthetists determine if the Genium will provide functional benefits to individual patients.

Highsmith et al (2014) conducted a project to determine if walking speed increases and if ambulatory-related exertion decreases in transfemoral amputees (TFAs) using the novel Genium microprocessor knee. A second purpose was to determine if directional and postural control improves with the Genium knee. Twenty-five (n = 25) subjects consented to participate in the study; 20 subjects had unilateral TFA, and 5 non-amputees served as controls. A randomized A–B cross-over design was used. Gait speed increases in TFAs were not observed in preliminary analyses. However, gait biomechanical improvements such as swing phase knee flexion angle consistency were reported. Such improvements may be perceptible to the user in short and mid-distance walking tests. Significant differences were observed between TFAs and controls for walking test times, but no differences were found between knee systems. A trend of decreased perceived exertion was observed with Genium compared with C-Leg, but differences did not reach significance. Controls consistently rated greater exertion during walking, possibly as a result of walking faster. TFAs show considerable impairment compared to controls in directional control, and the Genium
tends to improve rearward-directed control. The C-Leg significantly improves control over the prosthetic forefoot. Postural control was not different between the two knee systems. During short to medium distances, the Genium sustains walking speed improvements realized by the C-Leg but at potentially decreased levels of perceived exertion. However, C-Leg use results in improved anterolateral directional control compared with Genium, likely due to its toe load requirement. Conversely, Genium use tended to improve control in rearward directions.

Powered prosthetic devices, which utilize signals from muscle activity in the remaining limb to bend and straighten the device, are being researched. These devices use sensors and electronics to process data and control movement and power of the knee. Examples of these devices are the Power Knee (Ossur, Foothill Ranch, CA). According to the manufacturer, the Power Knee is the first motorized prosthetic knee available for TF amputees weighing up to 275 pounds. It is designed for use by functional level K3 individuals with a documented co-morbidity in their sound limb or spine and by bilateral amputees. The knee houses an electro-mechanical actuator that actively initiates and controls all aspects of the user's gait. It also provides powered knee flexion and extension under full user load. The motor initiates appropriate movement and function based on data collected through accelerometers, gyroscopes, a torque sensor, and a load sensor. When users walk with the Power Knee, the device samples knee position and loads at the rate of 1,000 times/second to provide appropriate power for the user in all 3 phases of the extension portion of the gait cycle. At heel strike, the motor permits and encourages active stance flexion, functioning to replace foot/ankle, knee, and hip muscles. This allows a flexion moment that more accurately replicates able-bodied gait while simultaneously providing full support and stability for users. The motor-controlled knee flexion at heel strike also reduces the impact on users, permitting a smoother transition from the sound side to the prosthetic side, facilitating a more
symmetrical gait. When users walk down declines and stairs, the Power Knee allows leg-over-leg descent. When users stand still, it permits them to stand with the prosthetic knee flexed, as the electro-mechanical motor actively support the user's weight. The Power Knee’s motor actively extends the knee from a flexed (seated) position into an extended (standing) one. The motor provides an affirmative, dynamic response that resists gravity, lifting the user up. Upon initial use, a practitioner must program and align the knee. Once programming and alignment are complete, the user needs only to press the power button to use the device. The user must also charge the lithium-polymer batteries that power the device. A 3.5-hour charge is recommended to ensure maximum battery life. On a full charge, battery life is up to 12 hours depending on the user's activities. Each Power Knee comes with 2 batteries.

The BiOM is a below knee robotic prosthesis that designed for use by individuals with lower extremity amputation. This prosthesis, which includes the foot, ankle, and lower calf, uses robotics to replicate the calf muscles and Achilles tendon. With each step, the BiOM provides a powered push-off which propels the wearer forward. Powered plantar flexion enables the prosthesis to normalize the gait and metabolic demands to those of non-amputees. With its bionic functionality, this prosthesis can resolve clinical issues faced by amputees, including tiredness, slowness, and a feeling of being unstable on their feet. The robotic muscle power provided by the BiOM during toe-off requires less energy from the user. It also provides more power when the user walks faster and less when the user walks slower, which produces a natural gait at variable speeds. Users are able to negotiate stairs and inclines with increased confidence and stability due to improved articulation and the design’s ability to mechanically yield and conform.
Mancinelli et al (2011) stated that passive-elastic foot prostheses cannot produce network. Consequently, passive-elastic foot prostheses are limited in their ability to enable a biologically-realistic gait pattern in transtibial amputees. This shortcoming results in difficulties in balance and walking and leads to high levels of oxygen consumption during locomotion. A powered prosthesis has the potential for overcoming these problems and allowing transtibial amputees to achieve a biologically-realistic gait pattern. In this study, these researchers compared the effects of the Ceterus by Ossur, a traditional passive-elastic prosthesis, with those of the PowerFoot Biom (iWalk, Cambridge, MA), a recently-developed powered prosthesis. Gait biomechanics and metabolic cost were compared in a group of 5 transtibial amputees during level-ground walking. The results provided preliminary evidence that the use of a powered prosthesis leads to a decrease in the level of oxygen consumption during ambulation due to improvements in ankle kinematics and kinetics primarily during late stance. An average decrease in oxygen consumption of 8.4% was observed during the study when subjects used the PowerFoot compared to the Ceterus. An average increase of 54% was observed in the peak ankle power generation during late stance. The authors concluded that these findings suggested that powered prostheses have the potential for significantly improving ambulation in transtibial amputees.

Aldridge and colleagues (2012) noted that during stair ascent (STA) persons with transtibial amputation (TTA) typically adopt a hip strategy to compensate for the limited ankle motion and joint power that is characteristic of conventional energy storing and returning (ESR) prosthetic feet. The purpose of this investigation was to determine if providing ankle power via a powered prosthetic device (BiOM) normalized STA kinematics and kinetics. A total of 11 individuals with TTA participated in 2 STA gait analysis sessions: (i) using an ESR foot, and (ii) using the BiOM. Eleven height- and weight-matched able-
bodied controls (CONT) were also assessed. Lower extremity peak kinematic and kinetic values were calculated at a self-selected and controlled cadence (80 steps/min). Increased prosthetic limb peak ankle plantar-flexion and push-up power were observed while using the BiOM as compared to ESR. Peak ankle power was not significantly different between BiOM and CONT indicating normalization of ankle power generation. However, peak ankle plantar-flexion was significantly lower than CONT. Limb asymmetries including greater prosthetic limb hip flexion and power during stance, and decreased prosthetic limb knee power during stance were observed in the BiOM and ESR conditions. The authors concluded that these findings suggested that the BiOM successfully increased ankle motion and restored ankle power during STA. These differences did not, however, reduce the use of a hip strategy while ascending stairs. They stated that additional device specific training may be necessary to utilize the full benefits of the device.

However, due to the small sample sizes in these studies, it is unclear if these preliminary findings would be observed in the general TTA population. Further investigation is needed to establish a meaningful clinical outcome benefit of the iWalk BiOM prosthetic foot over the conventional ankle-foot prosthesis. Furthermore, the Washington State Health Care Authority (2011) does not cover microprocessor-controlled lower limb prostheses for the feet and ankle (e.g., the iWalk PowerFoot BiOM).

Wearable robotic exoskeletons have been developed to reportedly help individuals ambulate despite partial or complete paraplegia. The devices include fitted braces for the legs and upper body with motorized hip and knee joints, a backpack containing a computer and rechargeable batteries, an array of upper body motion sensors and a computer based wireless control system worn on the individual’s wrist. Crutches are also used to provide the user with additional stability when walking, standing or rising from a chair.
Typically, these devices are indicated for use by people with paraplegia due to spinal cord injuries at levels T7 to L5 when accompanied by a specially trained caregiver and for individuals with spinal cord injuries at levels T4 to T6 where the device is limited to use in rehabilitation institutions. Examples of devices include, but may not be limited to, the following: ESKO GT system (for use only in rehabilitation institutions); Indego powered exoskeleton; and ReWalk personal system. Generally, the use of these devices requires that individuals are able to stand using an assistive device (e.g., standing frame) and their hands and shoulders are able to support crutches or a walker.

Federici et al (2015) reviewed the clinical effectiveness of various types of active, powered, wearable lower limb exoskeletons for the rehabilitation of gait disorders in paraplegic patients resulting from central nervous system lesions caused by, for example, SCIs or CVAs. The most commonly studied exoskeletons were the HAL, ReWalk, and the Vanderbilt lower limb exoskeleton. Studies of exoskeleton use in neurorehabilitation contexts have mostly evaluated the safety of the devices, the physical and cognitive effort required to use them, how easy it is to learn to use them and how effectively they enhance patients’ gait. The studies confirmed that the HAL, Tibion Bionic Technologies, and Ekso devices were safe to use in controlled environments, and with the assistance of expert professionals (i.e., physiotherapists). The authors found no studies evaluating the effectiveness of exoskeletons outside laboratory or clinical settings, and hence no evidence of their effectiveness in everyday living environments, for example for walking on rough surfaces such as a sidewalk or a staircase with uneven steps. The authors noted that there is a dearth of experimental evidence demonstrating that exoskeletons are more effective than other rehabilitative techniques and technologies. They also noted that none of the publications reviewed analyzed users’ experiences with an exoskeleton in activities of daily living.
Louie et al (2015) systematically reviewed the literature to determine the gait speed attained by individuals with SCI when using a powered exoskeleton to walk, factors influencing this speed, and characteristics of studies involving a powered exoskeleton (e.g., inclusion criteria, screening, and training processes). A systematic search in computerized databases was conducted to identify articles that reported on walking outcomes when using a powered exoskeleton. Individual gait speed data from each study was extracted. Pearson correlations were performed between gait speed and (i) age, (ii) years post-injury, (iii) injury level, and (iv) number of training sessions. Fifteen articles met inclusion criteria, 14 of which investigated the powered exoskeleton as an assistive device for non-ambulatory individuals and one which used it as a training intervention for ambulatory individuals with SCI. The mean gait speed attained by non-ambulatory participants (n = 84) while wearing a powered exoskeleton was 0.26 m/s, with the majority having a thoracic-level motor-complete injury. Twelve articles reported individual data for the non-ambulatory participants, from which a positive correlation was found between gait speed and (i) age ($r = 0.27, 95\%\ CI: 0.02$ to $0.48,$ $p = 0.03, 63$ participants), (ii) injury level ($r = 0.27, 95\%\ CI: 0.02$ to $0.48,$ $p = 0.03, 63$ participants), and (iii) training sessions ($r = 0.41, 95\%\ CI: 0.16$ to $0.61,$ $p = 0.002, 55$ participants). The authors stated that this systematic review has some limitations. The level of evidence in the current literature is limited to studies with a small number of participants. In addition, a true control group (without a device to walk) is not relevant as most participants would not have been able to walk without the exoskeleton; however, future studies could compare different orthotic, FES, or exoskeleton systems. There was heterogeneity in the study characteristics (device, control of stepping, training duration, outcome measurement), which made it challenging to compare results and reduces the ability to generalize results. However, the authors attempted to overcome this by aggregating participant data to allow statistical analysis to explore correlations.
between participant characteristics and outcomes. The authors stated that, in the future, it would be useful for studies to report on the exact intensity of training, using such measures as number of steps or walking time. Lajeunesse et al (2016) stated that rehabilitation professionals have little information concerning lower limb exoskeletons for people with paraplegia. This study has 4 objectives: (i) outline the characteristics of the exoskeletons' design and their usefulness evidence as assistive mobility devices in the community for the ReWalk, Mina, Indego, Ekso (previously known as the eLEGS) and Rex; (ii) document functional mobility outcomes of using these exoskeletons; (iii) document secondary skills and benefits achieved with these exoskeletons, safety, user satisfaction and applicability in the community; and (iv) establish level of scientific evidence of the selected studies. These researchers performed a systematic review of the literature (January 2004 to April 2014) using the databases PubMed, CINAHL and Embase and groups of keywords associated with "exoskeleton", "lower limb" and "paraplegia". A total of 7 articles were selected. Exoskeleton use is effective for walking in a laboratory but there are no training protocols to modify identified outcomes over the term usage (ReWalk: 3 months, Mina: 2 months and Indego: 1 session). Levels of evidence of selected papers are low. The authors concluded that the applicability and effectiveness of lower limb exoskeletons as assistive devices in the community have not been demonstrated. They stated that more research is needed on walking performance with these exoskeletons compared to other mobility devices and other training contexts in the community. Characteristics of the exoskeletons' design and their usefulness evidence as assistive mobility devices in the community were addressed for the ReWalk, Mina, Indego, Ekso and Rex; ReWalk, Indego and Mina lower limb exoskeletons were effective for walking in a laboratory for individuals with complete lower-level SCI. The ReWalk has the best results for walking, with a maximum speed of 0.51 m/s.
after 45 sessions lasting 60 to 120 mins; it is comparable to the average speed per day or per week in a manual wheelchair. The level of scientific evidence is low. These investigators stated that further studies are needed to provide more information about performance over the longer term when walking with an exoskeleton, compared to wheelchair mobility, the user's usual locomotion, the use of different exoskeletons or the training context in which the exoskeleton is used.

An industry funded consulting firm published a systematic evidence review (Miller et al, 2016) that included a total of 14 studies (8 ReWalk, 3 Ekso, 2 Indego, and 1 unspecified exoskeleton) representing 111 patients were included in the analysis. Training programs were typically conducted three times per week, 60 to 120 minutes per session, for 1 to 24 weeks; 10 studies utilized flat indoor surfaces for training and 4 studies incorporated complex training, including walking outdoors, navigating obstacles, climbing and descending stairs, and performing activities of daily living. Following the exoskeleton training program, 76% of patients were able to ambulate with no physical assistance. The weighted mean distance for the 6-minute walk test was 98 m. The physiologic demand of powered exoskeleton-assisted walking was 3.3 metabolic equivalents and rating of perceived exertion was 10 on the Borg 6 to 20 scale, comparable to self-reported exertion of an able-bodied person walking at 3 miles per hour. Improvements in spasticity and bowel movement regularity were reported in 38% and 61% of patients, respectively. No serious adverse events occurred. The incidence of fall at any time during training was 4.4%, all occurring while tethered using a first-generation exoskeleton and none resulting in injury. The incidence of bone fracture during training was 3.4%. The authors asserted that these risks have since been mitigated with newer generation exoskeletons and refinements to patient eligibility criteria. The authors noted that as with any meta-analysis, interpretation of outcomes may be confounded by issues related to individual study designs and by issues
inherent in the analysis of summary data. There was considerable variation in the consistency of outcome reporting among studies. Development of minimum reporting standards for powered exoskeleton clinical trials is recommended to facilitate comparisons among studies. Additionally, the number of studies limited the ability to explore sources of heterogeneity such as age, level of injury, and duration of injury.

This analysis was funded by ReWalk and the authors are from "Miller Scientific Consulting". The meta-analysis combined results using a variety of exoskeleton devices, subject characteristics, and settings and reported "considerable variation in outcome reporting among studies" and substantial heterogeneity among most study outcomes. A major drawback of this meta-analysis was a lack of critical assessment of the quality of the studies included in the meta-analysis.

The ReWalk exoskeleton (Argo Medical Technologies Ltd, Marlborough, MA) is designed for persons with a spinal cord injury (SCI) who retain upper-limb strength and mobility to manage stabilizing crutches. It is worn outside clothing and weighs 44 pounds. It consists of an upper-body harness, lower-limb braces, motorized joints, ground-force sensors, a tilt sensor, a locomotion-mode selector, and a backpack carrying a computerized controller and rechargeable battery. The device is strapped to the user at the waist, alongside each lower limb, and at the feet. Ordinary crutches help maintain stability. The ReWalk exoskeleton comes in 2 sizes: (i) one that fits persons 5 feet 3 inches to 5 feet 9 inches in height, and (ii) one that accommodates persons up to 6 feet 3 inches. The ReWalk can be worn by individuals weighing up to 220 pounds. Two types of the ReWalk exoskeletons are available: (i) the institutional version, the ReWalk-I, which is designed for rehabilitation centers and physician private practices, and (ii) a personal version, the ReWalk-P, which is
designed for an individual's sole use. According to the product labeling, the ReWalk is currently indicated for use only with supervision of a specialty-trained companion.

The ReWalk system comprises a set of computer-controlled, motorized leg braces that restore the ability to walk with crutches to patients with paraplegia who retain the ability to use their hands and shoulders for walking with crutches and who have good bone density and cardiovascular health (ECRI, 2013). The wearable support system uses an array of sensors and proprietary computer algorithms to analyze body movements and manipulate the motorized leg braces to help users maintain proper gait using crutches for walking, climbing stairs, and other movements. The onboard computer, sensor array, and rechargeable batteries that power the wearable exoskeleton are contained in a backpack that users wear in addition to the leg braces.

In a pilot study, Zeilig et al (2012) evaluated the safety and tolerance of use of the ReWalk exoskeleton ambulation system in people with SCI. Measures of functional ambulation were also assessed and correlated to neurological spinal cord level, age, and duration since injury. A total of 6 volunteer participants were recruited from the follow-up outpatient clinic. Safety was assessed with regard to falls, status of the skin, status of the spine and joints, blood pressure, pulse, and electrocardiography (ECG). Pain and fatigue were graded by the participants using a visual analog scale pre- and post-training. Participants completed a 10-statement questionnaire regarding safety, comfort, and secondary medical effects. After being able to walk 100 m, timed up and go, distance walked in 6 minutes and 10-m timed walk were measured. There were no adverse safety events. Use of the system was generally well-tolerated, with no increase in pain and a moderate level of fatigue after use. Individuals with lower level of SCI performed walking more efficiently. The authors concluded that volunteer participants were able to ambulate
with the ReWalk for a distance of 100 m, with no adverse effects during the course of an average of 13 to 14 training sessions. The participants were generally positive regarding the use of the system. Moreover, the authors stated that the potential benefits of the ReWalk are many, including improved functional mobility, cardio-vascular and respiratory status, bone metabolism, and bowel and bladder function, as well as reduction of spasticity and neuropathic pain, but efficacy still needs to be demonstrated in a larger study. Also, these researchers noted that this study did not include any female subjects, individuals with tetraplegia, children, or older adults; future large-scale inclusive studies are needed.

In an open, non-comparative, non-randomized study, Esquenazi et al (2012) evaluated the safety and performance of ReWalk in enabling people with paraplegia due to SCI to carry out routine ambulatory functions. All 12 subjects have completed the active intervention; 3 remained in long-term follow-up. After training, all subjects were able to independently transfer and walk, without human assistance while using the ReWalk, for at least 50 to 100 m continuously, for a period of at least 5 to 10 mins continuously and with velocities ranging from 0.03 to 0.45 m/sec (mean of 0.25 m/sec). Excluding 2 subjects with considerably reduced walking abilities, average distances and velocities improved significantly. Some subjects reported improvements in pain, bowel and bladder function, and spasticity during the trial. All subjects had strong positive comments regarding the emotional/psychosocial benefits of the use of ReWalk. The authors concluded that the ReWalk holds considerable potential as a safe ambulatory powered orthosis for motor-complete thoracic-level SCI patients. Most subjects achieved a level of walking proficiency close to that needed for limited community ambulation. A high degree of performance variability was observed across individuals. Some of this variability was explained by level of injury, but other factors have not been completely identified. The authors stated that further development and application of this rehabilitation tool to
other diagnoses are expected in the future.

Spungen et al (2013) reported on a single-group, pre/post intervention pilot study to determine the number of sessions and level of assistance needed to execute standing, walking, and stair climbing skills with a ReWalk a powered exoskeleton. Seven persons with motor-complete paraplegia were studied over an average of 45 ± 20 sessions. Sessions consisted of 1 to 2 hours of standing and overground ambulation for 3 sessions per week. All 7 participants learned to perform sit-to-stand, stand-to-sit, and to walk 50 to 166 meters in 6 minutes with none (n=4) to varying levels (n=3) of assistance. Four of 7 participants learned to ascend and descend five or more stairs with assistance, and these 4 also achieved some outdoor-specific walking skills. No relationship with achievement of exoskeletal-assisted mobility skills was found with duration or level of SCI; however, the participant with the highest cord lesion (thoracic level 1) did require the most assistance. The authors concluded that these preliminary results suggest that exoskeletal-assisted walking and other mobility skills can be performed independently by persons with motor-complete SCI.

Fineberg et al (2013) conducted a study using vertical ground reaction force (vGRF) to show the magnitude and pattern of mechanical loading in persons with spinal cord injury (SCI) during powered exoskeleton-assisted walking with ReWalk. The authors conducted a cross-sectional study to analyze vGRF during powered exoskeleton-assisted walking compared with vGRF of able-bodied gait. Six persons with thoracic motor-complete SCI (T1-T11 AIS A/B) and three age-, height-, weight- and gender-matched able-bodied volunteers participated. SCI participants were trained to ambulate over ground using a ReWalk. vGRF was recorded using the F-Scan system (TekScan, Boston, MA, USA). Peak stance average (PSA) was computed from vGRF and normalized across all participants by percent body weight. Peak vGRF was determined for heel strike, mid-stance, and toe-off. Relative
linear impulse and harmonic analysis provided quantitative support for analysis of powered exoskeletal gait. The investigators reported that participants with motor-complete SCI, ambulating independently with a ReWalk, demonstrated mechanical loading magnitudes and patterns similar to able-bodied gait. Harmonic analysis of PSA profile by Fourier transform contrasted frequency of stance phase gait components between able-bodied and powered exoskeleton-assisted walking.

Asselin et al (2015) reported on heart rate and oxygen demand of powered exoskeleton-assisted walking in persons with paraplegia. As part of an ongoing clinical study, eight non-ambulatory persons with paraplegia were trained to ambulate with a ReWalk powered exoskeleton. Measurements of oxygen uptake (VO2) and heart rate (HR) were recorded for 6 mins each during each maneuver while sitting, standing, and walking. The average value of VO2 during walking (11.2 +/- 1.7 ml/kg/min) was significantly higher than those for sitting and standing (3.5 +/- 0.4 and 4.3 +/- 0.9 ml/kg/min, respectively; p < 0.001). The HR response during walking was significantly greater than that of either sitting or standing (118 +/- 21 versus 70 +/- 10 and 81 +/- 12 beats per minute, respectively; p < 0.001). The authors stated that these findings suggest that routine use of this device to increase activity expenditure may be expected to have positive cardiopulmonary and metabolic benefits, although the results of this study did not address long-term changes in oxygen demand with habitual use.

White et al (2015) examined short-term changes in patients’ joint range of motion as a consequence of one week of intensive powered exoskeleton training as part of a physiotherapy program. Sixteen participants aged 21-69 years with spinal cord injury between C3 and T12 (ASIA Impairment Scale A-D) visited the therapy center. Passive range of motion of ankle dorsi-flexion, hip extension and shoulder internal rotation and extension was measured using goniometry.
Participants then undertook the training program which included use of parallel bars, crutches, different surfaces, and stairs/sitting/standing/walking. The program is supplemented by the use of functional electrical stimulation, far-infrared heat therapy and physiotherapy for exercise preparation. After five days range of motion was re-measured. Paired t-tests were run on bilaterally averaged pre and post ranges of motion, accepted significance value was p≤0.05. Mean dorsi-flexion increased from 1.7° (plantigrade = 0) to 6.9° (t(11)-6.3;p < 0.001). Mean hip extension increased from 8.2° to 14.1° (t(13)-3.5;p=0.017). There were no significant changes to shoulder extension (pre-64.7, post-66.7°, n = 9) or shoulder internal rotation (pre-74.3, post-78.9°, n = 11). The authors concluded that, although this was a pilot study and lacked a control condition, the addition of ReWalk technology was novel as part of a physiotherapy program. The authors stated that participation in the training program appeared to result in significant increases in ankle dorsi-flexion and hip extension which may be beneficial for all types of ongoing upright weight-bearing therapy in this population.

Yang et al (2015) sought to evaluate exoskeletal-assisted walking (EAW) velocity, number of sessions, and level of assistance (LOA) and the relationships among them. The secondary aims were to report on safety and the qualitative analysis of gait and posture during EAW in a hospital setting. Twelve individuals with SCI ≥ 1.5 years who were wheelchair users participated. They wore a powered exoskeleton (ReWalk; ReWalk Robotics, Inc., Marlborough, MA) with Lofstrand crutches to complete 10-meter (10 MWT) and 6-minute (6MWT) walk tests. LOA was defined as modified independence (MI), supervision (S), minimal assistance (Min), and moderate assistance (Mod). Best effort EAW velocity, LOA, and observational gait analysis were recorded. Seven of 12 participants ambulated ≥ 0.40 m/s. Five participants walked with MI, 3 with S, 3 with Min, and 1 with Mod. Significant inverse relationships were noted between LOA and EAW velocity for both 6 MWT (Z value = 2.63, Rho = 0.79, p
= .0086) and 10 MWT (Z value = 2.62, Rho = 0.79, p = .0088).
There were 13 episodes of mild skin abrasions. MI and S
groups ambulated with 2-point alternating crutch pattern,
whereas the Min and Mod groups favored 3-point crutch gait.
The authors concluded that the ReWalk is a safe device for in-
hospital ambulation.

Talaty et al (2013) reported preliminary analysis of how
walking kinematics differed across 12 subjects using the
ReWalk. All subjects met basic criteria to be able to use the
ReWalk – including items such as sufficient bone mineral
density, leg passive range of motion, strength, body size and
weight limits. All subjects received approximately the same
number of training sessions. However there was a wide
distribution in walking ability. Walking velocities ranged from
under 0.1 m/s to approximately 0.5 m/s. The authors stated
that this variability was not completely explained by injury
level. The remaining sources of that variability are not clear at
present.

Raab et al (2016) reported on a single case study investigating
to what extent the quality of life (QoL) of patients with spinal
cord injury can be influenced by the training with an
exoskeleton. The study was carried out at a hospital for
neurological rehabilitation in Germany. One patient (male, 22
years), initially unable to walk independently after traumatic
spinal cord injury with neurological level Th11 (ASIA
Impairment Scale C) was recruited for this study 1 year after
injury. The progress of the first 6 months of ReWalk training
was documented and as primary outcome measure the QoL
was measured with SF-36 questionnaire. Secondary outcome
measures were ASIA scale, Berg-Balance-Scale and Dynamic
Gait Index. The authors reported that, at the end of the study
period the patient was able to walk independently supervised
by one person. QoL, mobility, risk of falling, motor skills and
control of bladder and bowel functions were improved. A
positive effect of robot-assisted gait training on various areas
of the QoL was shown. The authors stated that subsequent studies should aim to verify this effect through a higher number of patients and to different injury levels.

Benson et al. (2016) conducted a longitudinal, prospective, self-controlled study to assess the feasibility of conducting a well-powered trial evaluating the neurological and functional effects of using an exoskeleton in individuals with chronic motor complete or incomplete spinal cord injury at a UK specialist spinal cord injuries center. Enrolled subjects were assigned to 20 ReWalk exoskeleton training sessions over a 10-week training period. Feasibility measures, clinical and mobility outcome measures and measures appraising subjects’ disability and attitude towards assistive technology were assessed before, during and after the study. Descriptive statistics were applied. Out of 60 candidates, 10 (17%) were enrolled and 5 (8%) completed the training program. Primary reasons for not enrolling were ineligibility (n = 24, 40%) and limited interest to engage in a 10-week training program (n = 16, 27%); 5 out of 10 enrolled subjects experienced grade I/II skin aberrations. While walking speeds were higher and walking distances were longer in all exoskeleton users when compared with non-use, the exoskeleton did generally not meet subjects’ high expectations in terms of perceived benefits. The authors concluded that the conduct of a controlled trial evaluating the benefits of using exoskeletons that require a lengthy user-commitment to training of individuals with chronic motor complete or incomplete spinal cord injury comes with considerable feasibility challenges. Vigilance is required for preventing and detecting medical complications in spinal cord injury exoskeleton users.

Lonini et al. (2016) noted that clinical scores for evaluating walking skills with lower limb exoskeletons are often based on a single variable, such as distance walked or speed, even in cases where a host of features are measured. In a pilot study, these researchers ascertained how to combine multiple features such that the resulting score has high discriminatory
power, in particular with few patients. A new score is introduced that allows quantifying the walking ability of patients with SCI when using a powered exoskeleton. A total of 4 SCI patients were trained to walk over ground with the ReWalk exoskeleton. Body accelerations during use of the device were recorded by a wearable accelerometer and 4 features to evaluate walking skills were computed. The new score is the Gaussian naive Bayes surprise, which evaluates patients relative to the features' distribution measured in 7 expert users of the ReWalk. These investigators compared their score based on all the features with a standard outcome measure, which is based on number of steps only. All 4 patients improved over the course of training, as their scores trended towards the expert users' scores. The combined score (Gaussian naive surprise) was considerably more discriminative than the one using only walked distance (steps). At the end of training, 3 out of 4 patients were significantly different from the experts, according to the combined score (p < 0.001, Wilcoxon Signed-Rank Test). In contrast, all but 1 patient were scored as experts when number of steps was the only feature. The authors concluded that integrating multiple features could provide a more robust metric to measure patients' skills while they learn to walk with a robotic exoskeleton; testing this approach with other features and more subjects remains as future work.

Platz et al (2016) reported on an observational single center study with a 4-week to 5-week intensive inpatient device-training using the ReWalk powered exoskeleton. All 7 individuals with spinal cord injury who commenced the device-training completed the course of training and achieved basic competences to use the system, that is, the ability to stand up, sit down, keep balance while standing, and walk indoors, at least with a close contact guard. User satisfaction with the system and device-training was documented for several aspects. The quality of life evaluation (SF-12) indicated that the use of the powered exoskeleton can have positive effects on the perception of individuals with SCI regarding what they
can achieve physically. Few adverse events were observed: minor skin lesions and irritations were observed; no falls occurred. The authors stated that this observational study was based on a small number of participants. Accordingly, the data is not necessarily representative for other individuals with SCI.

Khan, et al. (2019) reported on a study where participants with chronic (> 1 yr) motor complete or incomplete spinal cord injury, who were primarily wheelchair users, were trained to walk in the ReWalk powered exoskeleton for 12 weeks. Measures were taken before, during, immediately after, and 2-3 months after training. Measures included walking progression, sitting balance, skin sensation, spasticity, and strength of the corticospinal tracts. Twelve participants were enrolled with 10 completing training. The investigators reported that the progression in training required about 45 sessions to reach 80% of final performance in training. By the end of training, participants walked at speeds of 0.28-0.60 meters per second, and distances of 0.74-1.97 km in 1 hour. The effort of walking was about 3.3 times that for manual wheelchair propulsion. One non-walker with an incomplete injury became a walker without the ReWalk after training. The investigators reported that sitting balance was improved in some, as seen from the limits of stability and sway speed. Neuropathic pain showed no long term changes. Change in spasticity was mixed with suggestion of differences between those with high versus low spasticity prior to training. The strength of motor pathways from the brain to back extensor muscles remained unchanged. Minor adverse events were encountered by the participants and trainer (skin abrasions, non-injurious falls). The majority of participants could walk on uneven surfaces outdoors. Some limitations were encountered in home-like environments.

Manns, et al. (2019) evaluated the expectations and experiences of persons with spinal cord injury, training with the ReWalk exoskeleton. A qualitative research design with individual interviews was used. Eleven participants with spinal
cord injury, taking part in 12 weeks of 4 times weekly training using the ReWalk, were interviewed before, immediately after, and 2 months after training. Interviews were audio recorded and transcribed verbatim. A six stage approach to thematic analysis was used. The investigators found that the theme consistently expressed was the exoskeleton allowed participants to do everyday activities, like everyone else, such as looking people in the eye or walking outside. Their experiences were captured in three categories: 1) learning, a description of both expectations for learning and perspectives on how learning occurred; 2) changing, perspectives on perceived changes with training; and 3) contributing, which captured participant perspectives on contributing to research, including the giving of direct feedback regarding the exoskeleton (i.e., what worked and what could be changed).

Guanziroli, et al. (2019) assessed if walking ability of motor complete spinal cord injury (SCI) patients at thoracic or lower level, using a wearable powered exoskeleton (ReWalk), can be influenced by different exoskeleton software control. Fifteen SCI chronic patients (4 females and 11 males) were recruited and divided in two groups: group 1, trained with the first software generation of ReWalk, and group 2, trained with the second software generation, a software upgrade of the previous version. Subjects were trained during three 60-minute sessions a week, during at least eight weeks using ReWalk, a wearable lower limb powered exoskeleton that allows thoracic or lower level motor-complete individuals with SCI to walk, stand, sit and climb/descend stairs. Outcome measures, collected at the end of the training period wearing the exoskeleton, were: 6-min Walking Test, 10-m Walking Test, and the time necessary to pass from sitting to standing and start to walk (STS-time). For each group Pearson Coefficient was calculated to explore correlations between the subjects' characteristics and gait performance reached at the end of the training period. Group 1 showed correlation between performances and weight, height, neurological lesion level, while group 2 showed no correlation between performances.
weight and height, but correlation only with neurological lesion level. Group 2 covered more distance in 6 min (+124.52%) and required less time (-70.34%) to perform 10 mtWT and to STS-time (-38.25%) if compared to group 1.

Muijzer-Witteveen, et al. (2018) examined which information would be most important to receive while using an exoskeleton and how this feedback should be provided. To investigate the preferences of users of an exoskeleton, a questionnaire was filled out by 10 SCI subjects who underwent a training program with a commercial exoskeleton (ReWalk). The questionnaire consisted of questions about the use of the exoskeleton to identify which information is missing and which instructions from the therapists were needed to be able to control the exoskeleton. The second part of the questionnaire focused on the possibilities of sensory feedback and preferences for stimulation methods (auditory, vibrotactile or visual) and feedback timing (discrete or continuous) were investigated. Furthermore, six options for feedback parameters (step initiation, continuous and discrete gait phases, foot position and mediolateral and anteroposterior weight shift) were proposed and the respondents were asked to indicate their preferences. Three feedback parameters (feedback about mediolateral and anteroposterior weight shift and feedback about step initiation) were considered as possibly helpful by the respondents. Furthermore, there were slight preferences for the use of vibrotactile (over auditory and visual) and discrete (over continuous) feedback.

van Dijsseldonk, et al. (2017) sought to develop and test the hierarchy and reliability of a framework for measuring the progress in the ability to perform basic and advanced skills. Twelve participants with paraplegia were given twenty-four training sessions in 8 weeks with the Rewalk-exoskeleton. During the 2nd, 4th, and 6th training week the Intermediate-skills-test was performed consisting of 27 skills, measured in an hierarchical order of difficulty, until two skills were not achieved. When participants could walk independently, the
Final-skills-test, consisting of 20 skills, was performed in the last training session. Each skill was performed at least two times with a maximum of three attempts. As a reliability measure the consistency was used, which was the number of skills performed the same in the first two attempts relative to the total number. Ten participants completed the training program. Their number of achieved intermediate skills was significantly different between the measurements $XF_2(2) = 12.36, p = 0.001$. Post-hoc analysis revealed a significant increase in the median achieved intermediate skills from $4 [1-7]$ at the first to $10.5 [5-26]$ at the third Intermediate-skills-test. The rate of participants who achieved the intermediate skills decreased and the coefficient of reproducibility was 0.98.

Eight participants met the criteria to perform the Final-skills-test. Their median number of successfully performed final skills was $16.5 [13-20]$ and $17 [14-19]$ skills in the first and second time. The overall consistency of $>70\%$ was achieved in the Intermediate-skills-test (73%) and the Final-skills-test (81%).

Eight out of twelve participants experienced skin damage during the training, in four participants this resulted in missed training sessions. The framework proposed in this study measured the progress in performing basic and advanced exoskeleton skills during a training program. The investigators concluded that the hierarchical ordered skills-test could discriminate across participants' skill-level and the overall consistency was considered acceptable.

Fritz, et al. (2019) provided an overview of the features and limitations of the four robotic exoskeleton products (EKSO Bionics, ReWalk, Rex Bionics, and Indego) that are currently being used in in the United States in rehabilitation settings. The authors stated that available devices appear to be better suited for rehabilitation settings than for home use. Device weight, the need for upper extremity supports, supervision requirements, and a limited range of movements are all issues that limit functionality and restrict opportunities for using such devices in real-world contexts. Designing the next generation of exoskeletons to be more useful in everyday life will require
further collaboration among engineers, clinicians, and patients. The authors stated that further development of exoskeleton technologies is warranted to improve the devices for real-world use.

He, et al. (2017) noted that, in 2014, the US Food and Drug Administration approved marketing of the ReWalk Personal Exoskeleton as a class II medical device with special controls. Since then, Indego and Ekso have also received regulatory approval. With similar trends worldwide, this industry is likely to grow rapidly. On the other hand, the regulatory science of powered exoskeletons is still developing. The type and extent of probable risks of these devices are yet to be understood, and industry standards are yet to be developed. To address this gap, Manufacturer and User Facility Device Experience, Clinicaltrials.gov, and PubMed databases were searched for reports of adverse events and inclusion and exclusion criteria involving the use of lower limb powered exoskeletons. Current inclusion and exclusion criteria, which can determine probable risks, were found to be diverse. Reported adverse events and identified risks of current devices are also wide-ranging. In light of these findings, the authors compared current regulations, standards, and regulatory procedures for medical device applications in the USA, Europe, and Japan. The authors stated that there is a need to raise awareness of probable risks associated with the use of powered exoskeletons and to develop adequate countermeasures, standards, and regulations for these human-machine systems. With appropriate risk mitigation strategies, adequate standards, comprehensive reporting of adverse events, and regulatory oversight, powered exoskeletons may one day allow individuals with gait disabilities to safely and independently ambulate.

The Ekso (formerly eLegs) system is another powered exoskeleton device for patients with paraplegia or lower-extremity paresis due to neurologic conditions, including spinal cord injuries, multiple sclerosis, amyotrophic lateral sclerosis,
or Guillain-Barré syndrome (ECRI, 2013). It incorporates technology similar to that of the ReWalk system. The 45 lb Ekso system is based on the Human Universal Load Carrier that the U.S. military uses; it is a motorized exoskeleton designed to allow users to carry up to 200 lb continuously for several hours over any terrain. The manufacturer states that transfer to and from a patient’s wheelchair and the powered exoskeleton device takes less than 5 minutes and that the user requires little to no assistance. The company estimates the battery life for this device to be 3 hours.

The Ekso robotic exoskeleton is a motorized orthosis device for use in rehabilitation activities for people who have weak or paralyzed legs and sufficient arm strength to use crutches (NICE, 2017). It is intended to help people to relearn to stand and walk. The innovative aspect of the Ekso GT robotic exoskeleton is the SmartAssist software that is incorporated in the device (NICE, 2017). This allows physiotherapists to set the power for each leg independently to best suit the user. Multiple patients can use each Ekso robotic exoskeleton, with it being adapted to their specific needs. The intended place in therapy would be instead of, or in addition to, existing rehabilitation activities including physiotherapy, exercise, strength training, walking therapies with or without support, and functional electrical stimulation.

A MedTech Innovation Briefing (NICE, 2017) stated that the key points from the evidence summarized in this briefing are from 1 systematic review and 5 case series, involving a total of 41 patients in a rehabilitation setting. After using Ekso, these patients were able to walk without assistance from physiotherapists and their walking speed and distance increased. No serious adverse events were reported. The briefing stated that key uncertainties around the evidence are that the included studies were small and non-comparative. The briefing stated that the resource impact is currently unclear because of a lack of evidence.
Kolakowsky-Hayner et al conducted a prospective pilot study in a spinal cord injury rehabilitation center outpatient gym to evaluate feasibility and safety of Ekso to aid ambulation in individuals with SCI. Eight individuals, at least 18 years of age, with complete T1 SCI or below, within 2 years of injury, completed initial inpatient rehabilitation. All participants signed informed consent, had been cleared from requiring spinal orthoses, met inclusion criteria, and were pre-screened based on device requirements and medical stability. The subjects received 6 weekly sessions with graduated time and less assistance in the Ekso device. Outcome measures included skin evaluation, blood pressure, pain level, spasticity, time and level of assistance needed to transfer into and don device; time ambulating; time up in device; assistive devices used during ambulation; step length; distance walked; level of assistance during use; losses of balance; number of falls and level of assistance needed to doff and transfer out of device. The investigators reported no major skin effects, minimal pain reports, no known fractures, swelling, or other adverse events. Level of assistance ranged from dependent to moderate independent, average set up time was 18.13 minutes, and loss of balance and falls were infrequent. The investigators concluded that bionic exoskeletons such as Ekso are safe for those with complete thoracic SCI in a controlled environment, in the presence of experts, and may eventually enhance mobility in those without volitional lower extremity function. There appears to be a training effect in the device but further trials are needed. The investigators stated that future studies of bionic exoskeletons as gait training devices are warranted, and that future studies of bionic exoskeletons as a clinical tool to alleviate secondary complications should be considered.

Kozlowski et al (2015) sought to quantify the time and effort required by persons with SCI to learn to use the Ekso exoskeleton for assisted walking. A convenience sample was enrolled to learn to use the first-generation Ekso powered exoskeleton to walk. Participants were given up to 24 weekly sessions of instruction. Data were collected on assistance
level, walking distance and speed, heart rate, perceived exertion, and adverse events. Time and effort was quantified by the number of sessions required for participants to stand up, walk for 30 minutes, and sit down, initially with minimal and subsequently with contact guard assistance. Of 22 enrolled participants, 9 screen-failed, and 7 had complete data. All of these 7 were men; 2 had tetraplegia and 5 had motor-complete injuries. Of these, 5 participants could stand, walk, and sit with contact guard or close supervision assistance, and 2 required minimal to moderate assistance. Walk times ranged from 28 to 94 minutes with average speeds ranging from 0.11 to 0.21 m/s. For all participants, heart rate changes and reported perceived exertion were consistent with light to moderate exercise.

In a case series from an academic research center, Kressler et al. (2014) explored responses to overground bionic ambulation (OBA) training with the Ekso exoskeleton three days per week for 6 weeks from an interdisciplinary perspective including key components of neuromuscular activation, exercise conditioning, mobility capacity, and neuropathic pain. Persons (n = 3; 2 men, 1 woman) aged 26 to 38 years with complete spinal cord injury (SCI) (American Spinal Injury Association Impairment Scale grade A) between the levels of T1 and T10 for 1 year or longer. To obtain a comprehensive understanding of responses to OBA, an array of measures were obtained while walking in the device, including walking speeds and distances, energy expenditure, exercise conditioning effects, and neuromuscular and cortical activity patterns. Changes in spasticity and pain severity related to OBA use were also assessed. With training, participants were able to achieve walking speeds and distances in the OBA device similar to those observed in persons with motor-incomplete SCI (10-m walk speed, 0.11 to 0.33 m/s; 2-min walk distance, 11 to 33 m). The energy expenditure required for OBA was similar to walking in persons without disability (i.e., 25% to 41% of peak oxygen consumption). Subjects with lower soleus reflex excitability walked longer during training, but there was no
change in the level or amount of muscle activity with training. There was no change in cortical activity patterns. Exercise conditioning effects were small or nonexistent. However, all participants reported an average reduction in pain severity over the study period ranging between 1.3 and 1.7 on a 0-to-6 numeric rating scale. The authors concluded that OBA training improved mobility in the OBA device without significant changes in exercise conditioning or in neuromuscular or cortical activity. However, pain severity was reduced and no severe adverse events were encountered during training. OBA therefore opens the possibility to reduce the common consequences of chronic, complete SCI such as reduced functional mobility and neuropathic pain.

Giulia et al (2016) investigated the acceptability of overground robot-assisted walking and its effect on pain and spasticity. Twenty-one SCI persons participated in a single walking session assisted by a powered robotic exoskeleton. Pain assessed using a Numeric Rating Scale (NRS) and muscle spasticity, assessed as subjective perception using an NRS scale and as objective assessment using the Modified Ashworth scale and the Penn scale, were evaluated before and after the walking experience. Positive and negative sensations were investigated using a questionnaire. The patient’s global impression of change (PGIC) scale was administrated as well. After the walking session, a significant decrease in the muscle spasticity and pain intensity was observed. The SCI persons recruited in this study reported (i) a global change after the walking session, (ii) high scores on the positive and (iii) low scores on the negative sensations, thus indicating a good acceptability of the robot-assisted walking.

In contrast to other exoskeletons, HAL (hybrid assistive limb) exoskeleton (Cyberdyne Inc., Japan) offers the possibility of monitoring muscle contractions via surface EMG-electrodes at the extensor-flexor muscle region of the lower extremities.
(Sczesny-Kaiser et al., 2015). This allows for voluntary machine-supported motion using minimal signals recorded from hip and knee flexors and extensors.

Nilsson et al (2014) investigated the safety and feasibility of the exoskeleton Hybrid Assistive Limb (HAL) for intensive gait training as part of a regular inpatient rehabilitation program for hemiparetic patients with severely impaired gait early after stroke. Eligible were patients until 7 weeks after hemiparetic stroke. Training with HAL was performed 5 days per week by the autonomous and/or the voluntary control mode offered by the system. The study protocol covered safety and feasibility issues and aspects on motor function, gait performance according to the 10 Meter Walking Test (10MWT) and Functional Ambulation Categories (FAC), and activity performance. Eight patients completed the study. Median time from stroke to inclusion was 35 days (range of 6 to 46). Training started by use of the autonomous HAL mode in all and later switched to the voluntary mode in all but one and required one or two physiotherapists. Number of training sessions ranged from 6 to 31 (median 17) and walking time per session was around 25 minutes. The training was well tolerated and no serious adverse events occurred. All patients improved their walking ability during the training period, as reflected by the 10MWT (from 111.5 to 40 seconds in median) and the FAC (from 0 to 1.5 score in median).

Sczesny-Kaiser et al (2015) sought to assess whether robotic-assisted bodyweight supported treadmill training (BWSTT) with hybrid assistive limb (HAL) exoskeleton affects cortical excitability in the primary somatosensory cortex (S1) in SCI patients, as measured by paired-pulse somatosensory evoked potentials (ppSEP) stimulated above the level of injury. Eleven SCI patients took part in HAL assisted BWSTT for 3 months. Pulse paired stimulation techniques of somatosensory evoked potentials (PpSEP) were conducted before and after this training period, where the amplitude ratios (SEP amplitude following double pulses - SEP amplitude
following single pulses) were assessed and compared to eleven healthy control subjects. To assess improvement in walking function, the investigators used the 10-m walk test, timed-up-and-go test, the 6-min walk test, and the lower extremity motor score. PpSEPs were significantly increased in SCI patients as compared to controls at baseline. Following training, ppSEPs were increased from baseline and no longer significantly differed from controls. Walking parameters also showed significant improvements, yet there was no significant correlation between ppSEP measures and walking parameters. The investigators concluded that the findings suggest that robotic-assisted BWSTT with HAL in SCI patients is capable of inducing cortical plasticity following highly repetitive, active locomotive use of paretic legs. While there was no significant correlation of excitability with walking parameters, brain areas other than S1 might reflect improvement of walking functions. The investigators posited that EEG and neuroimaging studies may provide further information about supraspinal plastic processes and foci in SCI rehabilitation.

In a pilot study, Aach et al (2014) examined if locomotor training with the exoskeleton hybrid assistive limb (HAL) exoskeleton is safe and can increase functional mobility in chronic paraplegic patients after SCI. This trial was a single-case experimental A-B (pre-post) design study by repeated assessments of the same patients. The subjects performed 90 days (5 times per week) of HAL exoskeleton body weight supported treadmill training with variable gait speed and body weight support. A total of 8 patients with chronic SCI classified by the American Spinal Injury Association (ASIA) Impairment Scale (AIS) consisting of ASIA A (zones of partial preservation [ZPP] L3 to S1), n = 4; ASIA B (with motor ZPP L3 to S1), n = 1; and ASIA C/D, n = 3, who received full rehabilitation in the acute and sub-acute phases of SCI. Functional measures included treadmill-associated walking distance, speed, and time, with additional analysis of functional improvements using the 10-m walk test (10MWT), timed-up and go test (TUG test),
6-minute walk test (6MWT), and the walking index for SCI II (WISCI II) score. Secondary physiologic measures including the AIS with the lower extremity motor score (LEMS), the spinal spasticity (Ashworth scale), and the lower extremity circumferences. Subjects performed standardized functional testing before and after the 90 days of intervention. Highly significant improvements of HAL-associated walking time, distance, and speed were noticed. Furthermore, significant improvements have been especially shown in the functional abilities without the exoskeleton for over-ground walking obtained in the 6MWT, TUG test, and the 10MWT, including an increase in the WISCI II score of 3 patients. Muscle strength (LEMS) increased in all patients accompanied by a gain of the lower limb circumferences. A conversion in the AIS was ascertained in 1 patient (ASIA B to ASIA C); 1 patient reported a decrease of spinal spasticity. The authors concluded that hybrid assistive limb exoskeleton training resulted in improved over-ground walking and led to the assumption of a beneficial effect on ambulatory mobility. However, they stated that evaluation in larger clinical trials is needed.

Chihara et al (2016) investigated factors predicting the effects of HAL in 15 patients at our institution with central nervous system injury, primarily due to stroke, who underwent training using HAL during the acute phase. Patients were classified as either “with HAL suitability” or “without HAL suitability” based on scores from 10-m walking speed, gait, satisfaction, and pain. In both groups, Brunnstrom stage before HAL intervention, Fugl-Meyer assessment (FMA), stroke impairment assessment set (SIAS), and functional independence measure (FIM) were evaluated. Although motor function items did not differ significantly, FIM cognitive function items (p = 0.036), visuospatial perception items on SIAS (p = 0.0277), and pain items on SIAS (p = 0.0122) differed significantly between groups. The authors stated that these results indicated that training using HAL does not involve pain in patients with central nervous system injury during the acute
phase, and exhibits positive effects in patients without pain and with high communication ability and visuospatial perception function.

Wall et al (2015) reviewed the literature on clinical applications of the Hybrid Assistive Limb (HAL) system for gait training. A systematic literature search was conducted using Web of Science, PubMed, CINAHL and clinicaltrials.gov and additional search was made using reference lists in identified reports. Abstracts were screened, relevant articles were reviewed and subject to quality assessment. Out of 37 studies, 7 studies fulfilled inclusion criteria. Six studies were single group studies and 1 was an explorative randomized controlled trial. In total, these studies involved 140 participants of whom 118 completed the interventions and 107 used HAL for gait training. Five studies concerned gait training after stroke, 1 after spinal cord injury (SCI) and 1 study after stroke, SCI or other diseases affecting walking ability. Minor and transient side effects occurred but no serious adverse events were reported in the studies. Beneficial effects on gait function variables and independence in walking were observed. The accumulated findings demonstrate that the HAL system is feasible when used for gait training of patients with lower extremity paresis in a professional setting. Beneficial effects on gait function and independence in walking were observed but data do not allow conclusions. The investigators stated that further controlled studies are recommended.

Swank, et al. (2020) sought to compare temporospatial, kinematic, and muscle activity gait characteristics before and after a single EKSO session and examine kinematic symmetry between involved and uninvolved limbs. Participants post-stroke walked under two conditions: pre-EKSO, and immediately post-EKSO. A 10-camera motion capture system synchronized with 6 force plates was used to obtain temporospatial and kinematic gait characteristics from 5 walking trials of 9 meters at a self-selected speed. Surface EMG activity was obtained from bilateral gluteus medius,
rectus femoris, medial hamstrings, tibialis anterior, and soleus muscles. Wilcoxon Signed Rank tests were used to analyze differences pre-and post-EKSO. Single EKSO session consisted of 22.3±6.8 minutes total time (walk time=7.2±1.5 minutes) with 250±40 steps. Six ambulatory (Functional Ambulation Category, range=4-5) adults (3 female; 44.7±14.6 years) with chronic stroke (4.5±1.9 years post-stroke) participated. No significant differences were observed for temporospatial gait characteristics. Muscle activity was significantly less post-EKSO in the involved leg rectus femoris during swing phase (p=0.028). Ankle dorsiflexion range of motion on the involved leg post-EKSO was significantly less during stance phase (p=0.046). Differences between involved and uninvolved joint range of motion symmetry were found pre-EKSO but not post-EKSO in swing phase hip flexion and stance phase knee flexion and knee extension. The investigators concluded that EKSO training appears capable of altering gait in people with chronic stroke and a viable intervention to reduce gait dysfunction post-stroke.

Rojek, et al. (2020) sought to evaluate the effects of EKSO GT exoskeleton-assisted gait training on balance, load distribution, and functional status of patients after ischemic stroke. Study outcomes were based on 44 patients aged 55-85 years after ischemic stroke who were previously randomly assigned into two groups: experimental (with EKSO GT rehabilitation) and control (with classical rehabilitation). At baseline and after 4 weeks of treatment, the patients were evaluated on balance, load distribution, and functional status using, respectively a stabilometric platform, the Barthel Index, and the Rivermead Mobility Index. In the experimental group, balance improved regarding the variables describing sway area as ellipse major and minor axes. In the control group, improvement was noted in sway velocity. After the therapy, total load distribution on feet in both groups showed a small and insignificant tendency toward reduction in the amount of uninvolved limb loading. In the control group, significant load transfer from the backfoot to the forefoot was noted. Both forms of rehabilitation caused
significant changes in functional status. The investigators concluded that both training with the use of the EKSO GT exoskeleton and classical physiotherapy lead to functional improvement of patients after ischemic stroke. However, in the experimental group, improvement was observed in a larger number of categories, which may suggest potentially greater impact of treatment with the exoskeleton on functional status. Also, both forms of rehabilitation caused significant changes in balance, but the investigators had noted some trends indicating that treatment with exoskeleton may be more beneficial for some patients. The load transfer from the backfoot to the forefoot observed in the control group was an unfavorable phenomenon. The investigators suggested that the Ekso GT exoskeleton may be a promising tool in the rehabilitation of patients after stroke.

Swank, et al. (2019) examined whether wearing a robotic exoskeleton affects temporospatial parameters, kinematics, and muscle activity during gait. The study was completed by 15 healthy adults (mean age 26.2 [SD 8.3] years; 6 males, 9 females). Each participant performed walking under 2 conditions: with and without wearing a robotic exoskeleton (EKSO). A 10-camera motion analysis system synchronized with 6 force plates and a surface electromyography (EMG) system captured temporospatial and kinematic gait parameters and lower extremity muscle activity. For each condition, data for 5 walking trials were collected and included for analysis. Differences were observed between the 2 conditions in temporospatial gait parameters of speed, stride length, and double-limb support time. When wearing EKSO, hip and ankle range of motion (ROM) were reduced and knee ROM increased during the stance phase. However, during the swing phase, knee and ankle ROM were reduced when wearing the exoskeleton bionic suit. When wearing EKSO, EMG activity decreased bilaterally in the stance phase for all muscle groups of the lower extremities and in the swing phase for the distal muscle groups (tibialis anterior and soleus) as well as the left medial hamstrings. The investigators concluded that wearing
EKSO altered temporospatial gait parameters, lower extremity kinematics, and muscle activity during gait in healthy adults. EKSO appears to promote a type of gait that is disparate from normal gait in first-time users. The investigators stated that more research is needed to determine the impact on gait training with EKSO in people with gait impairments.

Swank et al. (2010) sought to determine the feasibility of integrating the Ekso Gait Training device into inpatient rehabilitation in a neurologic population. The study included a longitudinal cohort design and convenience sample including physical therapists trained to use the Ekso Bionics Ekso GT robotic exoskeleton or inpatients with stroke or SCI. Therapists completed a focus group and survey at baseline and 6 months after initial Ekso training. Patients completed a survey indicating their satisfaction with using the Ekso. Twenty-five patients used the Ekso an average of 4.5 sessions during their 38.5-day rehabilitation stay. Survey and focus group feedback revealed that therapists encountered measurement difficulties with the Ekso and limited treatment time influencing effectiveness of usage. After 6 months, therapists reported an improvement in feasibility. Patients tolerated Ekso sessions well, without any complications or adverse incidents, and reported improved mobility post session. The investigators concluded that integrating Ekso gait training into clinical practice was not seamless but appears feasible. Barriers were addressed within the rehabilitation team and received administrative support in a process lasting several months. Patients enjoyed walking in Ekso and felt secure within the device.

Poritz, et al. (2020) reported on the results of a robotic exoskeleton user satisfaction questionnaire completed by participants utilizing two robotic exoskeletons. Seven individuals with physical disabilities engaged in two exoskeleton-assisted training phases with the REX and the Ekso 1.1 (Ekso), after which they completed a user satisfaction questionnaire. The questionnaire consisted of structured items
with a Likert scale, which were averaged and compared, as well as free response questions, which were interpreted thematically. Participants reported some differences in user satisfaction between the two exoskeletons. They indicated higher satisfaction with transferring in and out of the REX and with its appearance and higher satisfaction with the transportability of the Ekso. Expectations for exoskeleton use were relatively similar for the two devices, with some exceptions. Whereas participants indicated that many changes should be made to both exoskeletons, they reported that some were more necessary for the REX and others were more necessary for the Ekso. Participants reported that they would be somewhat likely to use both exoskeletons at home and in the community if they were available.

Gorman, et al. (2019) reported on a randomized dual center controlled clinical trial to determine and compare the cardiorespiratory impact of 3 months of aquatic and robotic therapy for individuals with chronic motor incomplete spinal cord injury (CMISCI). Thirty-one individuals at two rehabilitation specialty hospitals with CMISCI with neurological level between C2-T12 at least 1 year post injury were randomized to either aquatic or robotic treadmill therapy for 36 sessions. Customized sessions lasted 40-45 min at 65-75% heart rate reserve intensity with peak oxygen consumption (peak VO2) measured during arm ergometry at baseline and post intervention. Additional peak robotic treadmill VO2 assessments were obtained before and after training for participants randomized to robotic intervention. Peak VO2 measured with arm ergometry was not significantly different with either aquatic intervention (8.1%, p = 0.14, n = 15) or robotic intervention (-0.7%, p = 0.31, n = 17). Peak VO2 measured with robotic treadmill ergometry demonstrated a statistical improvement (14.7%, p = 0.03, n=7, two-tailed t-test) across the robotic intervention.

Comparison between the two interventions demonstrated a trend favoring aquatic therapy for improving arm ergometry peak VO2 (ANOVA, p = 0.063). The authors concluded that
neither 3-month exercise interventions statistically improved arm cycle ergometry peak VO2, the study's cardiorespiratory surrogate marker, although percent improvement was greater in the aquatic exercise condition. Robotic ergometry peak VO2 did improve for the robotic intervention, confirming previous work. These results suggest that either intervention may hold utility in improving cardiorespiratory fitness in CMISCI, but peak VO2 measurement technique appears critical in detecting effects.

Alamro, et al. (2018) conducted a study to characterize and compare the activation of the trunk muscles during walking with two robotic gait training devices (Ekso and Lokomat) in people with high thoracic motor-complete SCI. Participants with chronic motor-complete paraplegia performed 3 speed-matched walking conditions: Lokomat-assisted walking, Ekso-assisted walking overground, and Ekso-assisted walking on a treadmill. Surface electromyography (EMG) signals were recorded bilaterally from the rectus abdominis (RA), external oblique (EO), and erector spinae (ES) muscles. Greater recruitment of trunk muscle EMG was elicited with Ekso-assisted walking compared to the Lokomat. Similar levels of trunk EMG activation were observed between Ekso overground and Ekso on the treadmill, indicating that differences between Ekso and Lokomat could not be attributed to the use of a hand-held gait aid. The level of trunk EMG activation during Lokomat walking was not different than that recorded during quiescent supine lying.

Baunsgaard, et al. (2018) conducted a prospective, observational multicenter study to explore changes in pain, spasticity, range of motion, activities of daily living, bowel and lower urinary tract function and quality of life of individuals with spinal cord injury following robotic exoskeleton gait training. Subjects underwent three training sessions per week for 8 weeks using an Ekso GT robotic exoskeleton. Included were individuals with recent (<1 year) or chronic (>1 year) injury, paraplegia and tetraplegia, complete and incomplete injury,
men and women. Fifty-two participants completed the training protocol. Pain was reported by 52% of participants during the week prior to training and 17% during training, but no change occurred longitudinally. Spasticity decreased after a training session compared with before the training session (p <0.001), but not longitudinally. Chronically injured participants increased Spinal Cord Independence Measure (SCIM III) from 73 to 74 (p=0.008) and improved life satisfaction (p = 0.036) over 8 weeks of training. Recently injured participants increased SCIM III from 62 to 70 (p < 0.001), but no significant change occurred in life satisfaction. Range of motion, bowel and lower urinary function did not change over time.

Gorgey, et al. (2017) studied whether the use of a powered exoskeleton can improve parameters of physical activity as determined by walking time, stand up time, and number of steps in persons with spinal cord injury (SCI). Three men with complete (1 C5 AIS A and 2 T4 AIS A) and one man with incomplete (C5 AIS D) SCI participated in a clinical rehabilitation program. In the training program, the participants walked once weekly using a powered exoskeleton (Ekso) for approximately 1 hour over the course of 10 to 15 weeks. Walking time, stand up time, ratio of walking to stand up time, and number of steps were determined. Oxygen uptake (L/min), energy expenditure, and body composition were measured in one participant after training. Over the course of 10 to 15 weeks, the maximum walking time increased from 12 to 57 minutes and the number of steps increased from 59 to 2,284 steps. At the end of the training, the 4 participants were able to exercise for 26 to 59 minutes. For one participant, oxygen uptake increased from 0.27 L/min during rest to 0.55 L/min during walking. Maximum walking speed was 0.24 m/s, and delta energy expenditure increased by 1.4 kcal/min during walking. Body composition showed a modest decrease in absolute fat mass in one participant.
Bach Baunsgaard (2018) et al. conducted a prospective pre-post study at nine European rehabilitation centers to assess the safety, feasibility, training characteristics and changes in gait function for persons with spinal cord injury (SCI) using the robotic exoskeletons from Ekso Bionics. Subjects underwent robotic exoskeleton gait training, three times weekly over 8 weeks. Time upright, time walking and steps in the device (training characteristics) were recorded longitudinally. Gait and neurological function were measured by 10 Meter Walk Test (10 MWT), Timed Up and Go (TUG), Berg Balance Scale (BBS), Walking Index for Spinal Cord Injury (WISCI) II and Lower Extremity Motor Score (LEMS). Fifty-two participants completed the training protocol. Subjects median age was 35.8 years (IQR 27.5-52.5), and included 36 men and 16 women, with neurological level of injury at C1-L2 and severity AIS A-D (American Spinal Injury Association Impairment Scale). The time since injury (TSI) was less than 1 year in 25 subjects, and greater than 1 year in 27 subjects. No serious adverse events occurred. Three participants dropped out following ankle swelling (overuse injury). Four participants sustained a Category II pressure ulcer at contact points with the device but completed the study and skin normalized. Training characteristics increased significantly for all subgroups. The number of participants with TSI < 1 year and gait function increased from 20 to 56% (P = 0.004) and 10MWT, TUG, BBS and LEMS results improved (P < 0.05). The number of participants with TSI > 1 year and gait function, increased from 41 to 44% and TUG and BBS results improved (P < 0.05).

The Indego exoskeleton (Parker Hannifin Corporation, Macedonia, OH) incorporates 4 motors for powered movement of bilateral hip and knee joints in the sagittal plane, in addition to built-in ankle-foot-orthoses (AFOs) at both ankle joints to provide ankle stability and transfer the weight of the exoskeleton to the ground.
Hartigan et al (2015) conducted a study to evaluate mobility outcomes for individuals with SCI after 5 gait-training sessions with the Indego powered exoskeleton, with a primary goal of characterizing the ease of learning and usability of the system. Sixteen subjects with SCI were enrolled in a pilot clinical trial at Shepherd Center, Atlanta, Georgia, with injury levels ranging from C5 complete to L1 incomplete. An investigational Indego exoskeleton research kit was evaluated for ease of use and efficacy in providing legged mobility. Outcome measures of the study included the 10-meter walk test (10MWT) and the 6-minute walk test (6MWT) as well as measures of independence including donning and doffing times and the ability to walk on various surfaces. At the end of 5 sessions (1.5 hours per session), average walking speed was 0.22 m/s for persons with C5-6 motor complete tetraplegia, 0.26 m/s for T1-8 motor complete paraplegia, and 0.45 m/s for T9-L1 paraplegia. Distances covered in 6 minutes averaged 64 meters for those with C5-6, 74 meters for T1-8, and 121 meters for T9-L1. Additionally, all participants were able to walk on both indoor and outdoor surfaces.

Evans et al (2015) conducted a pilot study to evaluate the acute cardiorespiratory and metabolic responses associated with Indego exoskeleton-assisted walking overground and to determine the degree to which these responses change at differing walking speeds. Five subjects (4 male, 1 female) with chronic SCI (AIS A) volunteered for the study. Expired gases were collected during maximal graded exercise testing and two, 6-minute bouts of exoskeleton-assisted walking overground. Outcome measures included peak oxygen consumption (VO2peak), average oxygen consumption (VO2avg), peak heart rate (HRpeak), walking economy, metabolic equivalent of tasks for SCI (METssci), walk speed, and walk distance. Significant differences were observed between walk-1 and walk-2 for walk speed, total walk distance, VO2avg, and METssci. Exoskeleton-assisted walking resulted in % VO2peak range of 51.5 % to 63.2 %. The metabolic cost of exoskeleton-assisted walking ranged from 3.5 to 4.3
Tefertiller, et al. (2018) assessed the safety and mobility outcomes utilizing the Indego powered exoskeleton in indoor and outdoor walking conditions with individuals previously diagnosed with a spinal cord injury (SCI). The investigators conducted a multicenter prospective observational cohort study in outpatient clinics associated with 5 rehabilitation hospitals. A convenience sample of nonambulatory individuals with SCI (N = 32) completed an 8-week training protocol consisting of walking training 3 times per week utilizing the Indego powered exoskeleton in indoor and outdoor conditions. Participants were also trained in donning/doffing the exoskeleton during each session. Safety measures such as adverse events (AEs) were monitored and reported. Time and independence with donning/doffing the exoskeleton as well as walking outcomes to include the 10-meter walk test (10MWT), 6-minute walk test (6MWT), Timed Up & Go test (TUG), and 600-meter walk test were evaluated from midpoint to final evaluations. All 32 participants completed the training protocol with limited device-related AEs, which resulted in no interruption in training. The investigators reported that the majority of participants in this trial were able to don and doff the Indego independently. Final walking speed ranged from 0.19 to 0.55 m/s. Final average indoor and outdoor walking speeds among all participants were 0.37 m/s (SD = 0.08, 0.09, respectively), after 8 weeks of training. Significant (p < .05) improvements were noted between midpoint and final gait speeds in both indoor and outdoor conditions. Average walking endurance also improved among participants after training.

Takahashi and colleagues (2015) stated that in persons post-stroke, diminished ankle joint function can contribute to inadequate gait propulsion. To target paretic ankle impairments, these researchers developed a neuromechanics-based powered ankle exoskeleton. Specifically, this exoskeleton supplies plantar-flexion assistance that is
proportional to the user's paretic soleus electromyography (EMG) amplitude only during a phase of gait when the stance limb is subjected to an anteriorly directed ground reaction force (GRF). In a feasibility study, these investigators examined the short-term effects of the powered ankle exoskeleton on the mechanics and energetics of gait. Investigators fabricated a lightweight ankle exoskeleton for each individual's paretic limb. A total of 5 subjects with stroke walked with a powered ankle exoskeleton on the paretic limb for 3 sessions (5 mins each session). They analyzed the peak paretic ankle plantar-flexion moment, paretic ankle positive work, symmetry of GRF propulsion impulse, and net metabolic power. The exoskeleton increased the paretic plantar-flexion moment by 16 % during the powered walking trials relative to unassisted walking condition (p < 0.05). Despite this enhanced paretic ankle moment, there was no significant increase in paretic ankle positive work, or changes in any other mechanical variables with the powered assistance. The exoskeleton assistance appeared to reduce the net metabolic power gradually with each 5-min repetition, though no statistical significance was found. In 3 of the subjects, the paretic soleus activation during the propulsion phase of stance was reduced during the powered assistance compared to unassisted walking (35 % reduction in the integrated EMG amplitude during the 3rd powered session). The authors concluded that the findings of this feasibility study demonstrated that the exoskeleton can enhance paretic ankle moment. Moreover, they stated that future studies with greater sample size and prolonged sessions are needed to evaluate the effects of the powered ankle exoskeleton on overall gait outcomes in persons post-stroke.

Wilcox et al (2016) examined peak interaction forces and electromyography (EMG) analysis to examine whether such interaction forces are due to the muscular activity of the participant or the movement of the REX Personal (Rex Bionics, New Zealand) exoskeleton itself. Interestingly, the authors found that peak forces preceded peak EMG activity.
This study did not find a significant correlation between EMG activity and force data, which would indicate that the interaction forces can largely be attributed to the movement of the exoskeleton itself. However, we also report significantly higher correlation coefficients in muscle/force pairs located at the anterior aspect of the right leg. In their previous research, the authors have shown peak interaction forces at the same locations, which suggests that muscular activity of the participant makes a more significant contribution to the interaction forces at these locations.

Birch, et al. (2017) reported interim results of the RAPPER II study investigating the feasibility, safety and acceptability of using the REX self-stabilizing robotic exoskeleton in people with spinal cord injury (SCI) who are obligatory wheelchair users. Feasibility was assessed by the completion of transfer into the REX device, competency in achieving autonomous control and completion of upper body exercise in an upright position in the REX device. Safety was measured by the occurrence of serious adverse events. Device acceptability is assessed with a user questionnaire. RAPPER II is a prospective, multi-center, open label, non-randomized, non-comparative cohort study in people with SCI recruited from neurological rehabilitation centres in the United Kingdom, Australia and New Zealand. This report was the planned interim report of the first 20 participants. Each completed a transfer into the REX, were trained to achieve machine control and completed Timed Up and Go (TUG) tests as well as upper body exercises in standing in a single first time session. The time to achieve each task as well as the amount of assistance required was recorded. After finishing the trial tasks a User Experience questionnaire, exploring device acceptability, was completed. All participants could transfer into the REX. The mean transfer time was 439 s. Nineteen completed the exercise regime. Eighteen could achieve autonomous control of the REX, 17 of whom needed either no assistance or the help of just one therapist. Eighteen participants completed at least one TUG test in a mean time of 313 s, 15 with the
assistance of just one therapist. The questionnaire demonstrated high levels of acceptability amongst users. There were no serious adverse events.

Arazpour et al (2013) analyzed the energy expenditure during walking with mechanical orthoses (hip knee ankle foot orthosis (HKAFO) and the isocentric reciprocating gait orthosis (IRGO)) compared with a new powered gait orthosis (PGO) in patients with SCI. Five patients with SCI who were experienced users of HKAFOs participated in this study. Subjects were also fitted with an IRGO and PGO and underwent a specific gait training program. Patients walked along a flat walkway using the three types of orthosis at their self-selected walking speed. A stop watch and a polar heart rate monitor were used to measure the speed of walking and heart rate. The authors reported that walking speed, the distance walked and the physiological cost index (PCI) all improved with both the new PGO and the IRGO as compared with the HKAFO.

Gholizadeh et al (2014a) noted that a number of prosthetic suspension systems are available for trans-tibial amputees. Consideration of an appropriate suspension system can ensure that amputee’s functional needs are satisfied. The higher the insight to suspension systems, the easier would be the selection for prosthetists. These investigators attempted to find scientific evidence pertaining to various trans-tibial suspension systems to provide selection criteria for clinicians. Databases of PubMed, Web of Science, and ScienceDirect were explored to find related articles. Search terms were as follows: “Transtibial prosthesis (32), prosthetic suspension (48), lower limb prosthesis (54), below-knee prosthesis (58), prosthetic liner (20), transtibial (193), and prosthetic socket (111)”. Two reviewers separately examined the papers. Study design (case series of 5 or more subjects, retrospective or prospective), research instrument, sampling method, outcome measures and protocols were reviewed. Based on the selection criteria, 22 articles (15 prospective studies, and 7 surveys) remained. Sweat control was found to be a major
Concern with the available suspension liners. Donning and doffing procedures for soft liners were also problematic for some users, particularly those with upper limb weakness. Moreover, the total surface bearing (TSB) socket with pin/lock system is favored by the majority of amputees. The authors concluded that no clinical evidence was available to suggest what kind of suspension system could have an influential effect as a "standard" system for all trans-tibial amputees. However, among various suspension systems for trans-tibial amputees, the Iceross system was favored by the majority of users in terms of function and comfort.

Gholizadeh et al (2014b) examined the scientific evidence pertaining to various trans-femoral suspension systems to provide selection criteria for clinicians. Databases of PubMed, Web of Science, and ScienceDirect were explored. The following key words, as well as their combinations and synonyms, were used for the search: transfemoral prosthesis, prosthetic suspension, lower limb prosthesis, above-knee prosthesis, prosthetic liner, transfemoral, and prosthetic socket. The study design, research instrument, sampling method, outcome measures, and protocols of articles were reviewed. On the basis of the selection criteria, a total of 16 articles (11 prospective studies and 5 surveys) were reviewed. The main causes of reluctance to prosthesis, aside from energy expenditure, were socket-related problems such as discomfort, perspiration, and skin problems. Osseo-integration was a suspension option, yet it is rarely applied because of several drawbacks, such as extended rehabilitation process, risk for fracture, and infection along with excessive cost. The authors concluded that no clinical evidence was found as a "standard" system of suspension and socket design for all trans-femoral amputees. However, among various suspension systems for trans-femoral amputees, the soft insert or double socket was favored by most users in terms of function and comfort.
According to the Ottobock website, the C-Leg Protector 4X160 represents the modern solution for C-Leg and C-Leg compact wearers. The C-Leg Protector covers and protects the joints of the C-Leg Product Line, including the tube adapter, and provides a cosmetic contour in the calf area. The manufacturer states that the result is an attractive appearance without any functional restrictions. The website states that the C-Leg Protector can be used on right or left sides and is quick and easy to adjust. According to the manufacturer, during everyday use, the patient can put it on, take it off, and clean it easily if needed.

The Ossur Symbiotic Leg (Ossur Americas, Foothill ranch, CA), a microprocessor knee/foot unit, combines the capabilities of the bionic products, RHEO KNEE and PROPRIO FOOT, into a single integrated unit offering functionality for TF (above knee) amputees. The prosthesis was designed to enable users to experience confident mobility on all terrains without gait deviations or compensations. This new product, which is the first of its kind in the market, has been in user testing for over a year and will be available on a limited basis in late 2011.

Alimusaj et al (2009) stated that conventional prosthetic feet cannot adapt to specific conditions such as walking on stairs or ramps. Amputees are therefore forced to compensate their prosthetic deficits by modifying the kinematics and kinetics of their lower limbs. The Proprio-Foot (Ossur) intends to reduce these compensation mechanisms by automatically increasing dorsiflexion during stair ambulation thanks to an adaptive microprocessor-controlled ankle. These investigators analyzed the biomechanical effects of the dorsiflexion adaptation in trans-tibial (TT) amputees during stair ambulation. A total of 16 TT amputees and 16 healthy controls underwent conventional 3D gait analysis. Kinematics and kinetics of the lower limbs were compared during stair ascent and descent performed by patients with the prosthetic foot set to a neutral ankle angle and with an adapted
dorsiflexion ankle angle of 4 degrees. Norm distance as well as minimum and maximal values of sagittal kinematics and kinetics were calculated for comparisons between patients and control subjects. For both stair ascent and descent, an improvement of the knee kinematics and kinetics could particularly be noticed on the involved side with an increase of the knee flexion and an increase of the knee moment during stance. The authors concluded that despite its additional weight compared to a conventional prosthetic ankle, the Proprio-Foot should be beneficial to active TT amputees whose knee musculature strength does not constitute a handicap.

Wolf et al (2009) stated that the technological advances have been made in developing highly functional prostheses are promising for very active patients but it is unknown whether they cause an increase in biomechanical load along with possibly negative consequences for pressure conditions in the socket. Therefore, this study monitored the socket pressure at specific locations of the stump when using a microprocessor-controlled adaptive prosthetic ankle under different walking conditions. A total of 12 unilateral TT amputees (TTAs) between 43 and 59 years of age were provided with the Proprio-Foot (Ossur) and underwent an instrumented 3D gait analysis in level, stair, and incline walking, including synchronous data capturing of socket pressure. Peak pressures and pressure time integrals (PTI) at 3 different locations were compared for 5 walking conditions with and without using the device's ankle adaptation mode. Highest peak pressures of 2.4 k Pa/kg were found for incline ascent at the calf muscle as compared to 2.1 k Pa/kg in level walking with large inter-individual variance. In stair ascent a strong correlation was found between maximum knee moment and socket pressure. The most significant pressure changes relative to level walking were seen in ramp descent anteriorly towards the stump end, with PTI values being almost twice as high as those in level walking. Adapting the angle of the prosthesis on stairs and ramps modified the pressure data.
such that they were closer to those in level walking. The authors concluded that pressure at the stump depended on the knee moments involved in each walking condition. Adapting the prosthetic ankle angle is a valuable means of modifying joint kinetics and thereby the pressure distribution at the stump. However, large inter-individual differences in local pressures underline the importance of individual socket fitting.

Fradet et al (2010) noted that the fixed neutral position of conventional prosthetic feet causes difficulties for TTAs when walking on ramps. New microprocessor-controlled prosthetic ankles such as the Proprio-Foot (Ossur) aim to reduce these difficulties by modifying the prosthetic ankle angle according to the gait condition. These researchers evaluated the biomechanical effects of adaptation of the prosthetic ankle on ramp ambulation in TTAs. A total of 16 TTAs and 16 controls underwent a conventional 3D gait analysis while walking up and down a ramp. Trans-tibial amputees walked with the prosthetic foot set to a neutral mode angle and set to the adapted mode. Norm distance, sagittal kinematics and kinetics were calculated for comparisons between TTAs and controls. During ramp ascent, the dorsiflexion brought about by the adapted prosthetic ankle reduced the increased knee extension noted on the TTAs’ involved side and the increased plantar-flexion on their sound side. During ramp descent, the plantar-flexion of the adapted mode increased the adaptation mechanisms observed in TTAs. The authors concluded that these findings suggested that the adapted mode leads to more physiologic kinematics and kinetics in the lower limbs in TTAs during ramp ascent but not during ramp descent. However, in the adapted mode, patients reported feeling safer during ramp descent, thus indicating that there might be other safety related measures such as toe-clearance or co-efficient of friction influencing this perception. (This study appeared to have the same subjects (n = 16) and controls (n = 16) as the 2009 study by Alimusaj et al; and Fradet was the 2nd author in that study).
In an unpublished study, Ludviksdottir (2012) evaluated the effect on mobility and safety for lower limb amputees (LLA; n = 8) when changing from a carbon fiber prosthetic foot to a bionic foot. Results suggested that user mobility improves when using the bionic foot and subjects experienced fewer falls and stumbles. The authors concluded that despite the limitation of the study, which is small sample size (n = 8) and mixing above knee and below knee amputees, the results indicated that improvements in perceived mobility and reduced risk of falling while using the bionic foot—may relate to the intelligent functions offered by the bionic foot; in particular, the toe-lift in swing and terrain adaptation, functions which are not offered by mechanical prosthetic feet. They stated that to confirm these preliminary findings, a larger study is needed.

Rosenblatt et al (2014) stated that people with amputation are at increased risk of falling compared with age-matched, non-disabled individuals. This may partly reflect amputation-related changes to minimum toe clearance (MTC) that could increase the incidence of trips and fall risk. This study determined the contribution of a dorsiflexing prosthesis to MTC. These researchers hypothesized that regardless of speed or incline the active dorsiflexion qualities of the ProprioFoot would significantly increase MTC and decrease the likelihood of tripping. A total of 8 TTAs walked on a treadmill with their current foot at 2 grades and 3 velocities, then repeated the protocol after 4 weeks of accommodation with the ProprioFoot. A mixed-model, repeated-measures analysis of variance was used to compare MTC. Curves representing the likelihood of tripping were derived from the MTC distributions and a multiple regression was used to determine the relative contributions of hip, knee, and ankle angles to MTC. Regardless of condition, MTC was approximately 70% larger with the ProprioFoot (p < 0.001) and the likelihood of tripping was reduced. Regression analysis revealed that MTC with the ProprioFoot was sensitive to all 3 angles, with sensitivity of hip and ankle being greater.
The authors concluded that the ProprioFoot may increase user safety by decreasing the likelihood of tripping and thus the pursuant likelihood of a fall.

Rosenblatt et al (2017) noted that individuals with TTA are at increased risk of falling. The absence of an ankle joint and the associated musculature in these individuals can reduce clearance between the prosthetic foot and ground during the swing phase of gait, which may increase the risk of stumbling and in turn falling. In a prospective, cohort study, these researchers attempted to associate minimum toe clearance (MTC; defined as a local minimum of the vertical displacement of the toe from toe-off to heel-strike relative to its position during mid-stance) during gait in the laboratory with community-based, trip-related stumbles by individuals with TTA using conventional feet. Participants completed electronic surveys to prospectively report stumbles and falls for 1 year thereafter. A volunteer sample of 8 unilateral, trans-tibial amputees who were K3- or K4-level ambulators and current patients at a local prosthetic clinic participated in this study. All participants completed the entire 1-year follow-up study. Prosthetic-side MTC while walking on a level treadmill at self-selected velocity (SSV) and self-reported trip-related stumbles in the community were recorded. Prosthetic-side MTC was more than 50 % lower for participants who reported 1 or more trip-related stumbles on that side compared with participants who reported zero trip-related stumbles on the prosthetic side (MTC = 12.3 ± 0.8 mm versus 25.6 ± 5.4 mm, respectively; p = 0.036). The authors concluded that this was the 1st study relating laboratory-based measures to prospective stumbles by prosthesis users. The results suggested that prosthesis users with low MTC may be at increased risk of experiencing a trip-related stumble in the community. They stated that these preliminary findings justified the need for a larger study to relate MTC and the causes of community-based stumbles and falls by individuals with TTA.
This study had several drawbacks: (i) given the small sample size (n = 8), the study may be under-powered to detect a relationship between prosthetic-side MTC and any-cause stumbles, although, as discussed, these results were expected and logical. To minimize the influence of small sample size, these researchers included data from 2 participants (P7 and P14) who did not walk on a treadmill at 0 % grade and at SSV. However, inclusion was justified, and given the large effect size, even excluding these subjects would not result in p > 0.05, (ii) based on the definition, self-report of stumbles may be more subjective than that of falls, which may explain the high inter-subject variability in this measure (e.g., the high number of stumbles reported by participant P7 may reflect individual hyper-vigilance with regard to balance loss. This subject may have reported events that other participants ignored or deemed unimportant to report. Increasing sample size would reduce this variability, and (iii) the results of this study were limited to subjects who were 30 years of age and older and may not generalize to younger prosthesis users.

Powered Lower Limb Prosthesis

Carey et al (2015) stated that the choice of a myoelectric or body-powered upper-limb prosthesis can be determined using factors including control, function, feedback, cosmesis, and rejection. Although body-powered and myoelectric control strategies offer unique functions, many prosthesis users must choose one. These investigators performed a systematic review to determine differences between myoelectric and body-powered prostheses to inform evidence-based clinical practice regarding prescription of these devices and training of users. A search of 9 databases identified 462 unique publications. A total of 31 of them were included and 11 empirical evidence statements were developed. Conflicting evidence has been found in terms of the relative functional performance of body-powered and myoelectric prostheses.
Body-powered prostheses have been shown to have advantages in durability, training time, frequency of adjustment, maintenance, and feedback; however, they could still benefit from improvements of control. Myoelectric prostheses have been shown to improve cosmesis and phantom-limb pain and are more accepted for light-intensity work. The authors concluded that current evidence is insufficient to conclude that either system provides a significant general advantage. Prosthetic selection should be based on a patient's individual needs and include personal preferences, prosthetic experience, and functional needs. This work demonstrated that there is a lack of empirical evidence regarding functional differences in upper-limb prostheses.

Proprio Foot

Gailey et al (2012) examined the application of outcome measures to determine changes in function caused by standardized functional prosthetic gait training and the use of 4 different prosthetic feet in people with unilateral trans-tibial limb loss; 2 self-report measures (Prosthetic Evaluation Questionnaire-Mobility Scale [PEQ-13] and Locomotor Capabilities Index [LCI]), and 3 performance-based measures (Amputee Mobility Predictor with a prosthesis [AMPPRO], 6-minute walk test [6MWT] and step activity monitor [SAM]) were used. A total of 10 people with unilateral trans-tibial limb loss, 5 with peripheral vascular disease (PVD) and 5 without PVD, completed testing. Subjects were tested at baseline and after receiving training with their existing prosthesis and with the study socket and 4 prosthetic feet, i.e., SACH (solid ankle cushion heel), SAFE (stationary attachment flexible endoskeletal), Talux, and Proprio Feet, over 8 to 10 weeks. Training was administered between testing sessions. No differences were detected by the PEQ-13, LCI, 6MWT, or SAM following training and after fitting with test feet. The AMPPRO demonstrated differences following training with the existing prosthesis in the PVD group and between selected feet from
baseline testing (p <= 0.05). Significant differences were found between the PVD and the non-PVD groups (p <= 0.05) in the AMPPRO and 6MWT when using the Proprio Foot. Self-report measures were unable to detect differences between prosthetic feet.

The authors stated that drawbacks related to this study were similar to many studies that examined prosthetic components. For example, the small sample size (n = 10) was not related to recruiting but rather to the cost and time constraints needed to train each subject, fabricate the sockets, maintain the prostheses, and buy the prosthetic feet and other prosthesis-related components. A larger study population would certainly increase the power of this study and increase the confidence in the results. Additionally, alternative prosthetic foot designs might demonstrate different results from those feet selected in this trial; because of the constraints previously described, this study was limited to 4 feet. These investigators hoped that this article motivated further research to examine the use of these and other self-report and performance-based outcome measures in a larger sample of individuals who are functioning at all levels and, in particular, at the lower levels. In addition, these researchers did not evaluate the value of the prosthetic socket and suspension system and this should be incorporated into future studies. Lastly, using instrumented functional gait analysis, such as force distribution, stride length, and step width, could provide objective findings in determining potential differences among different prosthetic feet.

Delussu and colleagues (2013) determined the energy cost of walking (ECW) of a bionic foot (Proprio-Foot) during ambulation on floor and on treadmill (at different slopes) compared to walking with a dynamic carbon fiber foot (DCF). These researchers evaluated trans-tibial amputees (TTAs) perceived mobility with the prosthesis and their walking ability on stairs and ramps. The ECW tests were conducted on a regular floor surface and on treadmill with -5 %, 0 % and 12 %
slopes. In all conditions, TTAs were asked to walk at their own self-selected speed. Metabolic and cardiac data were collected using a portable gas analyzer. Tests were carried out at 6 data collection points: (i) with a standard suction system (SSS) and the DCF; (ii) with the DCF after 7 weeks of using a hypobaric suspension system (HSS) with the DCF; (iii) after 1 hour of Proprio-Foot use together with the HSS; and 3 more testing sessions were carried out at 30-day intervals, i.e., after 30, 60 and 90 days of Proprio-Foot use together with the HSS; TTAs perceived mobility using the prosthesis and walking ability on stairs and ramps were assessed. A total of 10 TTAs completed the measurements; ECW with the Proprio-Foot obtained in the final floor-walking test was significantly lower than ECW with the DCF ($p = 0.002$). No significant improvements were observed for perceived mobility or walking ability. The authors concluded that these findings suggested that use of the Proprio-Foot can lower the ECW for TTAs in spite of its added weight compared to DCF. Moreover, they stated that further studies are needed to investigate ECW, quality of life (QOL), perceived mobility and motor capability in older and/or less active TTAs.

This study had several drawbacks. First, small sample size ($n = 10$). Second, the authors were aware that to achieve the secondary aim, i.e., to compare the effects of the Proprio Foot on ECW with those of the DCF, the same data collection should had been carried out in TTAs using the Proprio-Foot in association with their usual standard suction socket. Finally, the subjects included TTAs with high functional status who had a young mean age. Thus, the results could not be generalized across a wider population.

Agrawal et al (2013) stated that contrary to stance-phase dorsiflexion of conventional prosthetic feet, the microprocessor-controlled Proprio Foot allows swing-phase dorsiflexion on stairs. These researchers compared Symmetry in External Work (SEW) between a microprocessor-controlled
foot and conventional prosthetic feet in 2 groups with unilateral trans-tibial amputation (TTA) (Medicare Functional Classification Levels K-Level-2 and K-Level-3) during stair ascent and descent. A total of 10 subjects were evaluated while wearing 3 conventional prosthetic feet -- solid ankle cushion heel (SACH), stationary attachment flexible endoskeleton (SAFE), and Talux-and the Proprio Foot using a study socket and were given a 10- to 14-day accommodation period with each foot. Ground reaction forces (GRFs) were collected using F-scan sensors during stair ascent and descent. The SEW between the intact and amputated limbs was calculated for each foot. During stair ascent, the Proprio Foot resulted in a higher inter-limb symmetry than conventional prosthetic feet, with significant differences between the Proprio and SACH/SAFE feet. The swing-phase dorsiflexion appeared to promote greater inter-limb symmetry because it facilitated forward motion of the body, resulting in a heel-to-toe center of pressure trajectory. During stair descent, all feet had low symmetry without significant differences between feet. The movement strategy used when descending stairs, which was to roll over the edge of a step, had a greater influence on symmetry than the dorsiflexion features of prosthetic feet. The authors concluded that individuals with unilateral TTA who function at either K-Level-2 or K-Level-3 and have to negotiate stairs on a regular basis, within their home, community, or work environment, may benefit from the use of the Proprio Foot or other microprocessor-controlled feet that allow active dorsiflexion during swing.

The authors stated that this study had several drawbacks. The altered strategies employed by the subjects while descending stairs suggested the possibility of work calculation limitations only for this task because of the shortcomings of current insole sensor technology. Since the F-scan sensors were capable of measuring only the normal forces applied to the sensor, movement of the prosthetic foot over the edge of the step may have resulted in GRFs having a substantial shear component. The SEW results during stair descent should
therefore be interpreted and weighed appropriately. This strategy of rolling over the edge of the step during stair descent presented a significant challenge in the measurement of GRFs with commercially available instrumentation. However, with some error, the SEW measure was able to quantifying the asymmetry that was apparent during stair descent. An advantage of determining inter-limb symmetry with measures like the SEW -- as opposed to comparing movement kinetics in subjects without amputation -- was the ability to quantify similarity in strategies used by the intact and prosthetic limbs to move the body during the stair negotiation. The absence of motion-capture data restricted the ability to determine the joint kinematics, which limited the discussion to clinical observation and findings published in the literature. All prosthetic fitting and alignment procedures were performed by the same board-certified prosthetist using standard protocols as stated in the manufacturer's technical manual. At the time of data collection, there were no commercially available, reliable, and valid devices that could quantify dynamic alignment of a prosthetic foot.

Struchkov and Buckley (2016) noted that walking down slopes and/or over uneven terrain is problematic for unilateral TTAs. Accordingly, "ankle" devices have been added to some dynamic-response feet. This study examined if the use of a microprocessor controlled (MPC) passive-articulating hydraulic ankle-foot device improved the gait biomechanics of ramp descent in comparison to conventional ankle-foot mechanisms. A total of 9 active unilateral TTA repeatedly walked down a 5° ramp, using a hydraulic ankle-foot with microprocessor active or inactive or using a comparable foot with rubber ball-joint (elastic) "ankle" device. When inactive the hydraulic unit's resistances were those deemed to be optimum for level-ground walking, and when active, the plantar- and dorsi-flexion resistances switched to a ramp-descent mode. Residual limb kinematics, joints moments/powers and prosthetic foot power absorption/return were compared across ankle types using ANOVA. Foot-flat
was attained fastest with the elastic foot and second fastest with the active hydraulic foot ($p < 0.001$). Prosthetic shank single-support mean rotation velocity ($p = 0.006$), and the flexion ($p < 0.001$) and negative work done at the residual knee ($p = 0.08$) were reduced, and negative work done by the ankle-foot increased ($p < 0.001$) when using the active hydraulic compared to the other 2 ankle types. The authors concluded that the greater negative “ankle” work done when using the active hydraulic compared to other 2 ankle types, explained why there was a corresponding reduction in flexion and negative work at the residual knee. They stated that these findings suggested that use of a microprocessor controlled hydraulic foot would reduce the biomechanical compensations used to walk down slopes.

The authors stated that this study had several drawbacks. First, with only 1 force platform within the ramp system, only trials where the prosthetic limb landed on the force platform were undertaken. Expanding the protocol to include trials in which the intact limb landed on the platform would have increased the likelihood of participants becoming fatigued. These researchers chose to remotely “trigger” the MPC foot into its “ramp descent” mode using Bluetooth connection to the device. Although this is not what would happen when such a device is used in the “real world”, these investigators felt that it was more important to assess the effects of the hydraulic resistance alterations associated with the device’s “ramp descent” mode, rather than to test if and when switching to this mode occurred. Second, all participants were familiarized to using either an Elan or Echelon VT foot, both of which were hydraulic ankle-foot devices. Although these investigators found that the type of habitual foot participants used had minimal effect on results, having only 20 mins to become familiar with the non-hydraulic Epirus foot may mean the issue of familiarity is a confounding factor. The relatively short familiarization period may explain why certain parameters investigated returned relatively high group standard deviation values. Finally, there was no comparison of ramp-descent...
with a non-articulating (rigid ankle) prosthetic ankle-foot. This was because it was felt that a 4th foot condition would be problematic due to potential fatigue issues for participants, and/or that the biomechanical compensation required when using such feet might have “carry-over” effects to the other foot conditions, especially as all participants habitually used an articulating ankle-foot device.

Pro-Flex Foot

Childers and Takahashi (2018) stated that prosthetic feet are designed to store energy during early stance and then release a portion of that energy during late stance. The usefulness of providing more energy return depends on whether or not that energy transfers up the lower limb to aid in whole body propulsion. These researchers examined how increasing prosthetic foot energy return affected walking mechanics across various slopes. A total of 5 individuals with a unilateral TTA walked on an instrumented treadmill at 1.1 m/s for 3 conditions (level ground, +7.5°, −7.5°) while wearing a prosthetic foot with a novel linkage system and a traditional energy storage and return foot. The novel foot (NF) demonstrated greater range of motion (ROM; \( p = 0.0012 \)), and returned more energy (\( p = 0.023 \)) compared to the traditional foot. The increased energy correlated with an increase in center of mass (CoM) energy change during propulsion from the prosthetic limb (\( p = 0.012 \)), and the increased prosthetic limb propulsion correlated to a decrease in CoM energy change (i.e., collision) on the sound limb (\( p < 0.001 \)). The authors concluded that these findings showed that this NF was able to return more energy than a traditional prosthetic foot and that this additional energy was used to increase whole body propulsion. They stated that the novel linkage system in the Pro-Flex foot allowed it to have more ROM and better conform to different slopes. The Pro-Flex foot was able to leverage its additional ROM to absorb and return more energy than the more traditional Vari-Flex foot. The additional energy return from the Pro-Flex foot translated up the kinematic chain.
to effect the whole body CoM in such a way that it enabled
more energy for propulsion than the Vari-Flex foot. There was
a significant inverse relationship between increasing CoM
energy change during propulsion from the amputated limb and
negative work absorbed by the sound limb during collision with
the Pro-Flex foot and this rendered some support that the Pro-
Flex foot has promise to reduce sound limb loading. However,
there were no other differences in other variables that
correlated with reducing the risk of developing knee
osteoarthritis, most likely due to the low sample size and low
statistical power.

Heitzmann and colleagues (2018) noted that persons with TTA
showed a greater peak prosthetic ankle power (push-off)
when using energy storing and returning (ESAR) prosthetic
feet as compared to solid-ankle cushion-heel feet. ESAR feet
further contribute to the users' body support and thus limit
prosthetic ankle motion. To improve ankle motion, articulating
prosthetic feet have been introduced. However, articulating
feet may diminish push-off. These investigators examined if a
novel prosthetic foot, with a serial layout of carbon fiber leaf
springs, connected by a multi-center joint construction, has
advantages in kinematics and kinetics over a conventional
ESAR prosthetic foot. A total of 11 individuals with unilateral
TTA were fitted with the NF and a conventional ESAR Foot
(CF) and underwent 3-D gait analysis. As an additional power
estimate of the prosthetic ankle, a unified, deformable,
segment (UD) model approach was applied; 11 matched
individuals without impairments served as a reference. The
NF showed an effective prosthetic ankle ROM that was closer
to a physiologic ankle ROM, at 31.6° as compared to 15.2°
with CF (CF versus NF, p = 0.003/NF versus reference, p =
0.171) without reducing the maximum prosthetic ankle joint
moment. Furthermore, the NF showed a great increase in
prosthetic ankle power (NF 2.89 W/kg versus CF 1.48 W/kg
CF versus NF p < 0.001) and a reduction of 19% in the peak
knee varus moment and 13% in vertical ground reaction
forces on the sound side for NF in comparison to CF. The
authors concluded that the NF showed that serial carbon fiber leaf springs, connected by a multi-center joint construction provided a larger ankle joint ROM and higher ankle power than a conventional carbon fiber structure alone. Consequently, load was taken off the contralateral limb, as measured by the decrease in vertical ground reaction forces and peak knee varus moment.

The authors stated that this study had several drawbacks. The different accommodation times of 2 weeks for the CF and only 30 to 45 mins for the re-fitted NF may have affected the results. As NF was a pilot production product, these researchers had no experience with the product, but decided to have initial trials with the NF in a controlled environment, and therefore abandoned a 2-week accommodation. However, these investigators thought that a satisfactory accommodation period for NF was given as the subjects could get accustomed to it in various terrains. Another potential drawback of the study was the fixed order of measurements (NF first; CF second). This conceivably may have introduced a bias, but these measurement conditions were chosen due to a number of practical reasons increasing the feasibility of this study, as well as ensuring that removing and replacing markers between experimental conditions was not necessary.

Individuals who has had a TTA walked slightly, but significantly slower with the NF (0.06 m/s) compared to CF and differences in kinetics may thus be attributed to speed as a confounding factor. Since a violation of normal distribution could occasionally be accepted in parametric tests, the authors retrospectively compared kinetics using a multi-variate analysis of co-variance (MANCOVA), with speed as a co-variate. This retrospective analysis confirmed the results of the original, non-parametric statistical analysis (peak dorsi plantar flexion power conventional model NF 2.89 ± 0.90, CF 1.48 ± 0.35 W/kg, p < 0.001; UD model NF 2.77 ± 0.70, CF 2.12 ± 0.49 W/kg, p = 0.002). Thus, these researchers were confident that the differences in kinetics reflected the effects of the feet not the difference in walking speed.
Appendix

Clinical assessments of a member's rehabilitation potential should be based on the following classification levels:

<table>
<thead>
<tr>
<th>Level</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0:</td>
<td>Does not have the ability or potential to ambulate or transfer safely with or without assistance and a prosthesis does not enhance their quality of life or mobility.</td>
</tr>
<tr>
<td>1:</td>
<td>Has the ability or potential to use a prosthesis for transfers or ambulation on level surfaces at fixed cadence. Typical of the limited and unlimited household ambulator.</td>
</tr>
<tr>
<td>2:</td>
<td>Has the ability or potential for ambulation with the ability to traverse low level environmental barriers such as curbs, stairs or uneven surfaces. Typical of the limited community ambulator.</td>
</tr>
<tr>
<td>3:</td>
<td>Has the ability or potential for ambulation with variable cadence. Typical of the community ambulator who has the ability to traverse most environmental barriers and may have vocational, therapeutic, or exercise activity that demands prosthetic utilization beyond simple locomotion.</td>
</tr>
<tr>
<td>4:</td>
<td>Has the ability or potential for prosthetic ambulation that exceeds basic ambulation skills, exhibiting high impact, stress, or energy levels. Typical of the prosthetic demands of the child, active adult, or athlete.</td>
</tr>
</tbody>
</table>

This expectation of functional ability information must be clearly documented and retained in the prosthetist's records. The simple entry of a K modifier in those records is not
sufficient. There must be information about the member's history and current condition that supports the designation of the functional level by the prosthelist.


Note: Consistent with DME MAC policy, when an initial below knee prosthesis (L5500) or a preparatory below knee prosthesis (L5510-L5530, L5540) is provided, prosthetic substitutions and/or additions of procedures and components are considered medically necessary in accordance with the functional level assessment except for codes L5629, L5638, L5639, L5646, L5647, L5704, L5785, L5962, L5980 which will be considered not medically necessary.

- Addition to lower extremity, below knee, acrylic socket (L5629)
- Addition to lower extremity, below knee, leather socket (L5638)
- Addition to lower extremity, below knee, wood socket (L5639)
- Addition to lower extremity, below knee, air-fluid, gel or equal, cushion socket (L5646)
- Addition to lower extremity, below knee suction socket (L5647)
- Custom shaped protective cover, below knee (L5704)
- Addition, exoskeletal system, below knee, ultra-light material (titanium, carbon fiber or equal) (L5785)
- Addition, endoskeletal system, below knee, flexible protective outer surface covering system (L5962)
• All lower extremity prostheses, flex foot system (L5980)

Consistent with DME MAC policy, when a below knee preparatory prefabricated prosthesis (L5535) is provided, prosthetic substitutions and/or additions of procedures are considered medically necessary in accordance with the functional level assessment except for codes L5620, L5629, L5645, L5646, L5670, L5676, L5704, and L5962 which will be considered not medically necessary.

• Addition to lower extremity, test socket, below knee (L5620)
• Addition to lower extremity, below knee, acrylic socket (L5629)
• Addition to lower extremity, below knee, flexible inner socket, external frame (L5645)
• Addition to lower extremity, below knee, air, fluid, gel or equal, cushion socket (L5646)
• Addition to lower extremity, below knee, molded supracondylar suspension ('PTS' or similar) (L5670)
• Addition to lower extremity, below knee, knee joints, single axis, pair (L5676)
• Custom shaped protective cover, below knee (L5704)
• Addition, endoskeletal system, below knee, flexible protective outer surface covering system (L5962)

Consistent with DME MAC policy, when an above knee initial prosthesis (L5505) or an above knee preparatory (L5560-L5580, L5590-L5600) prosthesis is provided, prosthetic substitution and/or additions of procedures and components are considered medically necessary in accordance with the functional level assessment except for codes L5610, L5631, L5640, L5642, L5644, L5648, L5705, L5706, L5964, L5980, and L5710-L5780, L5790-L5795 which will be considered not medically necessary.
- Addition to lower extremity, endoskeletal system, above knee, hyrdracadence system (L5610)
- Addition to lower extremity, above knee or knee disarticulation, acrylic socket (L5631)
- Addition to lower extremity, knee disarticulation, leather socket (L5640)
- Addition to lower extremity, above knee, leather socket (L5642)
- Addition to lower extremity, above knee, wood socket (L5644)
- Addition to lower extremity, above knee, air, fluid, gel or equal, cushion socket (L5648)
- Custom shaped protective cover, above knee (L5705)
- Custom shaped protective cover, knee disarticulation (L5706)
- Addition, endoskeletal system, above knee, flexible protective outer surface covering system (L5964)
- All lower extremity prostheses, flex foot system (L5980)
- Addition, exoskeletal knee-shin system, single axis, manual lock (L5710)
- Additions, exoskeletal knee-shin system, single axis, manual lock, ultra-light material (L5711)
- Addition, exoskeletal knee-shin system, single axis, friction swing and stance phase control (safety knee) (L5712)
- Addition, exoskeletal knee-shin system, single axis, variable friction swing phase control (L5714)
- Addition, exoskeletal knee-shin system, polycentric, mechanical stance phase lock (L5716)
- Addition, exoskeletal knee-shin system, polycentric, friction swing and stance phase control (L5718)
- Addition, exoskeletal knee-shin system, single axis, pneumatic swing, friction stance phase control (L5722)
- Addition, exoskeletal knee-shin system, single axis, fluid swing phase control (L5724)
- Addition, exoskeletal knee-shin system, single axis, external joints fluid swing phase control (L5726)
- Addition, exoskeletal knee-shin system, single axis, fluid swing and stance phase control (L5728)
- Addition, exoskeletal knee-shin system, single axis, pneumatic/hydra pneumatic swing phase control (L5780)
- Addition, exoskeletal system, above knee, ultra-light material (titanium, carbon fiber or equal) (L5790)
- Addition, exoskeletal system, hip disarticulation, ultra-light material (titanium, carbon fiber or equal) (L5795)

Consistent with DME MAC policy, when an above knee preparatory prefabricated prosthesis (L5585) is provided, prosthetic substitution and/or additions of procedures and components are considered medically necessary in accordance with the functional level assessment except for codes L5624, L5631, L5648, L5651, L5652, L5705, L5706, L5964, and L5966 which will be considered not medically necessary.

- Addition to lower extremity, test socket, above knee (L5624)
- Addition to lower extremity, above knee or knee disarticulation, acrylic socket (L5631)
- Addition to lower extremity, above knee, air, fluid, gel or equal, cushion socket (L5648)
- Addition to lower extremity, above knee, flexible inner socket, external frame (L5651)
- Addition to lower extremity, suction suspension, above knee or knee disarticulation socket (L5652)
- Custom shaped protective cover, above knee (L5705)
- Custom shaped protective cover, knee disarticulation (L5706)
- Addition, endoskeletal system, above knee, flexible protective outer surface covering system (L5964)
- Addition, endoskeletal system, hip disarticulation, flexible protective outer surface covering system (L5966)
Codes for ultra-light materials may only be used when materials such as carbon fiber, fiberglass, Kevlar, or other advanced composite lamination materials are used in the fabrication of a socket for an endoskeletal prosthesis. They are not used for ultralight materials used in other components of a prosthesis—e.g., knee/shin system, pylon, ankle, foot, etc.

**CPT Codes / HCPCS Codes / ICD-10 Codes**

Information in the [brackets] below has been added for clarification purposes. Codes requiring a 7th character are represented by "+":

<table>
<thead>
<tr>
<th>Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Other CPT codes related to the CPB:</td>
<td></td>
</tr>
<tr>
<td>27590-27596</td>
<td>Amputation, thigh, through femur</td>
</tr>
<tr>
<td>HCPSC codes covered if selection criteria are met:</td>
<td></td>
</tr>
<tr>
<td>L5000-L5782, L5785-L5972, L5974-L5988, L5999</td>
<td>Lower limb prostheses</td>
</tr>
<tr>
<td>L5930</td>
<td>Addition, endoskeletal system, high activity knee control frame [covered for members whose functional level is 4]</td>
</tr>
<tr>
<td>L5940</td>
<td>Addition, endoskeletal system, below knee, ultra-light material (titanium, carbon fiber or equal) [only covered when ultra-light materials are used in the fabrication of a socket for an endoskeletal prosthesis]</td>
</tr>
<tr>
<td>Code</td>
<td>Code Description</td>
</tr>
<tr>
<td>--------</td>
<td>----------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>L 5950</td>
<td>Addition, endoskeletal system, above knee, ultra-light material (titanium, carbon fiber or equal) [only covered when ultra-light materials are used in the fabrication of a socket for an endoskeletal prosthesis]</td>
</tr>
<tr>
<td>L 5960</td>
<td>Addition, endoskeletal system, hip disarticulation, ultra-light material (titanium, carbon fiber or equal) [only covered when ultra-light materials are used in the fabrication of a socket for an endoskeletal prosthesis]</td>
</tr>
<tr>
<td>L7510, L7520</td>
<td>Repair prosthetic device, labor component, per 15 minutes</td>
</tr>
<tr>
<td>L8400, L8410</td>
<td>Prosthetic sheath, below and above knee, each</td>
</tr>
<tr>
<td>L 8417</td>
<td>Prosthetic sheath/sock, including a gel cushion layer; below knee or above knee, each [12 in 12 months]</td>
</tr>
<tr>
<td>L8420, L8430</td>
<td>Prosthetic sheath, below and above knee, each</td>
</tr>
<tr>
<td>L8440, L8460</td>
<td>Prosthetic shrinker, below and above knee, each</td>
</tr>
<tr>
<td>L 8470 - L 8485</td>
<td>Prosthetic socks</td>
</tr>
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</table>

**HCPCS codes not covered for indications listed in the CPB:**

<table>
<thead>
<tr>
<th>Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>L 5969</td>
<td>Addition, endoskeletal ankle-foot or ankle system, power assist, includes any type motor(s)</td>
</tr>
<tr>
<td>L 5973</td>
<td>Endoskeletal ankle foot system, microprocessor controlled feature, dorsiflexion and/or plantar flexion control, includes power source</td>
</tr>
<tr>
<td>Code</td>
<td>Code Description</td>
</tr>
<tr>
<td>------------</td>
<td>-------------------------------------------------------------------</td>
</tr>
<tr>
<td>L 5990</td>
<td>Addition to lower extremity prosthesis, user adjustable heel height</td>
</tr>
<tr>
<td>L 7360</td>
<td>Six volts battery, each</td>
</tr>
<tr>
<td>L 7362</td>
<td>Battery charger, six volts, each</td>
</tr>
<tr>
<td>L 7364</td>
<td>Twelve volts battery, each</td>
</tr>
<tr>
<td>L 7366</td>
<td>Battery charger, twelve volts, each</td>
</tr>
<tr>
<td>L 7367</td>
<td>Lithium ion battery, rechargeable, replacement</td>
</tr>
<tr>
<td>L 7368</td>
<td>Lithium ion battery charger, replacement only</td>
</tr>
<tr>
<td>L 7600</td>
<td>Prosthetic donning sleeve, any material, each</td>
</tr>
</tbody>
</table>

ICD-10 codes covered if selection criteria are met:

<table>
<thead>
<tr>
<th>Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q72.811 -</td>
<td>Other reduction defects of lower limb</td>
</tr>
<tr>
<td>Q72.899</td>
<td></td>
</tr>
<tr>
<td>S88.011+</td>
<td>Traumatic amputation of lower leg</td>
</tr>
<tr>
<td>-</td>
<td></td>
</tr>
<tr>
<td>S88.929+</td>
<td></td>
</tr>
<tr>
<td>S98.011+</td>
<td>Traumatic amputation of foot</td>
</tr>
<tr>
<td>-</td>
<td></td>
</tr>
<tr>
<td>S98.929+</td>
<td></td>
</tr>
<tr>
<td>Z89.411 -</td>
<td>Acquired absence of leg, toe(s), foot, and ankle</td>
</tr>
<tr>
<td>Z89.619</td>
<td></td>
</tr>
<tr>
<td>Z89.511 -</td>
<td>Acquired absence of leg below knee</td>
</tr>
<tr>
<td>Z89.529</td>
<td></td>
</tr>
<tr>
<td>Z89.611 -</td>
<td>Acquired absence of leg above knee</td>
</tr>
<tr>
<td>Z89.629</td>
<td></td>
</tr>
</tbody>
</table>

Protective outer covering systems:

HCP CS codes covered if selection criteria are met:

<table>
<thead>
<tr>
<th>Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>L 5704</td>
<td>Custom shaped protective cover, below knee</td>
</tr>
<tr>
<td>Code</td>
<td>Code Description</td>
</tr>
<tr>
<td>--------</td>
<td>----------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>L5705</td>
<td>Custom shaped protective cover, above knee</td>
</tr>
<tr>
<td>L5706</td>
<td>Custom shaped protective cover, knee disarticulation</td>
</tr>
<tr>
<td>L5707</td>
<td>Custom shaped protective cover, hip disarticulation</td>
</tr>
<tr>
<td>L5962</td>
<td>Addition, endoskeletal system, below knee, flexible protective outer surface covering system</td>
</tr>
<tr>
<td>L5964</td>
<td>Addition, endoskeletal system, above knee, flexible protective outer surface covering system</td>
</tr>
<tr>
<td>L5966</td>
<td>Addition, endoskeletal system, hip disarticulation, flexible protective outer surface covering system</td>
</tr>
</tbody>
</table>

**Microprocessor-controlled leg prostheses:**

**HCP CS codes covered if selection criteria are met:**

<table>
<thead>
<tr>
<th>Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>L5856</td>
<td>Addition to lower extremity prosthesis, endoskeletal knee-shin system, microprocessor control feature, swing and stance phase; includes electronic sensor(s) any type [not covered for gait management in spinal cord injury]</td>
</tr>
<tr>
<td>L5857</td>
<td>Addition to lower extremity prosthesis, endoskeletal knee-shin system, microprocessor control feature, swing phase only; includes electronic sensor(s), any type [not covered for gait management in spinal cord injury]</td>
</tr>
<tr>
<td>Code</td>
<td>Code Description</td>
</tr>
<tr>
<td>----------</td>
<td>------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>L 5858</td>
<td>Addition to lower extremity prosthesis, endoskeletal knee-shin system, microprocessor control feature, stance phase only, includes electronic sensor(s) any type [not covered for gait management in spinal cord injury]</td>
</tr>
<tr>
<td>L 5973</td>
<td>Endoskeletal ankle foot system, microprocessor controlled feature, dorsiflexion and/or plantar flexion control, includes power source</td>
</tr>
<tr>
<td>L 7367 - L 7368</td>
<td>Lithium ion battery, rechargeable, replacement and ion battery charger</td>
</tr>
</tbody>
</table>

**ICD-10 codes covered if selection criteria are met:**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>S88.011+</td>
<td>Traumatic amputation of lower leg</td>
</tr>
<tr>
<td>S88.929+</td>
<td></td>
</tr>
<tr>
<td>S98.011+</td>
<td>Traumatic amputation of foot at ankle level</td>
</tr>
<tr>
<td>S98.929+</td>
<td></td>
</tr>
<tr>
<td>Z89.411 - Z89.619</td>
<td>Acquired absence of leg, ankle and foot</td>
</tr>
</tbody>
</table>

**ICD-10 codes not covered for indications listed in the CPB:**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>S12.000+</td>
<td>Fracture of vertebral column</td>
</tr>
<tr>
<td>S12.9xx+</td>
<td></td>
</tr>
<tr>
<td>S22.000+</td>
<td></td>
</tr>
<tr>
<td>S22.089+</td>
<td></td>
</tr>
<tr>
<td>S32.000+</td>
<td></td>
</tr>
<tr>
<td>S32.2xx+</td>
<td></td>
</tr>
<tr>
<td>Code</td>
<td>Code Description</td>
</tr>
<tr>
<td>----------</td>
<td>--------------------------------------</td>
</tr>
<tr>
<td>S14.0xx+</td>
<td>Injury of nerves and spinal cord</td>
</tr>
<tr>
<td>-</td>
<td></td>
</tr>
<tr>
<td>S14.9xx+</td>
<td></td>
</tr>
<tr>
<td>S24.0xx+</td>
<td></td>
</tr>
<tr>
<td>-</td>
<td></td>
</tr>
<tr>
<td>S24.9xx+</td>
<td></td>
</tr>
<tr>
<td>S34.01x+</td>
<td></td>
</tr>
<tr>
<td>-</td>
<td></td>
</tr>
<tr>
<td>S34.9xx+</td>
<td></td>
</tr>
</tbody>
</table>

Adjustable click systems (e.g., Revo and Boa click systems):

HCPSC codes not covered for indications listed in the CPB:

Adjustable click systems (e.g., Revo and Boa click systems) - no specific code:

The above policy is based on the following references:


4. Aldridge JM, Sturdy JT, Wilken JM. Stair ascent kinematics and kinetics with a powered lower leg
system following transtibial amputation. Gait Posture.  

5. Alimusaj M, Fradet L, Braatz F, et al. Kinematics and  
kinetics with an adaptive ankle foot system during  
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6. Arazpour M, Bani MA, Hutchins SW, Jones RK. The  
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2015;52(2):147-158.

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9. Au S, Berniker M, Herr H. Powered ankle-foot  
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after spinal cord injury: Safety, feasibility and gait  
function following 8 weeks of training with the  
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vs dynamically balanced gait: Analysis of a robotic  
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87. Memorandum from Janet Murphy, Acting Deputy Secretary for Health for Operations and Management (10N), Department of Veterans Affairs, to medical center directors regarding clinical protocol for veteran use of the ReWalk Powered Exoskeleton, Washington, DC, December 10, 2015.


130. Takahashi KZ, Lewek MD, Sawicki GS. A neuromechanics-based powered ankle exoskeleton to


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Amendment to
Aetna Clinical Policy Bulletin Number: 0578 Lower Limb Prosthesis

There are no amendments for Medicaid.