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Meridium®

Reimbursement Guide

January 1, 2021

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Product Information

January 2021

The Meridium microprocessor-controlled prosthetic foot is designed for transtibial and transfemoral prosthetic users, both limited and full community ambulators.

The Meridium utilizes a complex sensory system (including an inertial motion unit) along with sophisticated rule sets that allow for real-time adaptive adjustments to the user's walking speed and ground conditions, whether on slopes, stairs or varying terrain including an intuitive standing lock on all surfaces. This occurs over the full ROM (14 degrees dorsiflexion and 22 degrees plantarflexion). This is a big plus for the user during everyday activities, making both greater flexibility and enhanced stability possible.

HCPCS Code [1, 2] (U.S. only)

L5973	Endoskeletal ankle foot system, microprocessor-controlled feature, dorsiflexion and/or plantar flexion control, includes power source.

Warranty

Three-year manufacturer warranty (extendable to six years); Repair costs are covered except for those associated with damages resulting from improper use.

Who Can Provide a Meridium?

The Meridium is prescribed by a physician and may only be provided by a qualified Prosthetist that has received specific product training. Ottobock employs a team of orthotists and prosthetists to educate practitioners on fabricating and fitting our products. This includes in-person training, online training, webinars, and technical bulletins. We also provide Cooperative Care Services for the more challenging fittings, which includes on-site assistance with the fitting in conjunction with product qualification training for the practitioner.

FDA Status

Under FDA's regulations, the Meridium is a Class I medical device and exempt from the premarket notification [510(k)] requirements. Given the low risk of Class I medical devices, FDA determined that General Controls are sufficient to provide reasonable assurance of the device's safety and effectiveness; therefore, safety and effectiveness research is not required for this device. The Meridium has met all the General Control requirements which include Establishment Registration (21CFR 807), Medical Device Listing (21 CFR part 807), Quality System Regulation (21CFR part820), Labeling (21CFR part 801), and Medical Device Reporting (21 CFR Part 803). The Meridium is listed under External Limb Prosthetic Component; Product Code ISH; Listing Number E253230.

Health Canada Compliance

This device meets the requirements of the Medical Device Regulations (SOR/98-282). It has been classified as a class I medical device according to the classification criteria outlined in schedule 1 of the Medical Device Regulations.

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[1] The product/device "Supplier" (defined as an O&P Practitioner or O&P patient care facility) assumes full responsibility for accurate billing of Ottobock products. It is the Supplier's responsibility to determine medical necessity; ensure coverage criteria is met; and submit appropriate HCPCS codes, modifiers, and charges for services/products delivered. It is also recommended that Supplier's contact insurance payer(s) for coding and coverage guidance prior to submitting claims. Ottobock Coding Suggestions and Reimbursement Guides are based on reasonable judgment and are not recommended to replace the Supplier's judgment. These recommendations may be subject to revision based on additional information or alpha-numeric system changes.

[2] The manufacturer's suggested retail pricing (MSRP) is a suggested retail price only. Ottobock has provided the suggested MSRP in the event that third-party and/or federal healthcare payers request it for reimbursement purposes. The practitioner and/or patient care facility is neither obligated nor required to charge the MSRP when submitting billing claims for third-party reimbursement for the product(s).

Meridium®

Features and Benefits

Real-time Adaptation over full Range of Motion

Separate control of dorsiflexion (14°) and plantarflexion (22°).

4 – Axis Kinematics

Meridium's 4-axis design allows movement of ankle, foot and separate toe section resulting in excellent adaptability, more similar to natural gait and reduced need for compensatory movements

Walking Speed changes

Real-time adaptation combined with Meridium's 4-axis design provides almost natural rollover, resulting in better control of walking speed.

Compare this to conventional prosthetic feet which have stiff ankles and only partially mimic the function of an ankle joint.

When the user changes walking speed, the dorsiflexion resistance automatically adjusts itself to the change in forces, allowing the user to easily vary gait speed without feeling any change in the foot's behavior.

Increased Foot clearance during swing

During the swing phase, the foot remains in the dorsiflexion position to provide greater ground clearance, which in turn requires less compensatory movements and allows better gait symmetry. This prevents the tip of the foot from getting caught and may help to reduce stumbles and falls

Expanded Full-Surface Contact with the Ground

Meridium allows for expanded, full-surface contact with the ground for improved stability and traction when walking on level ground, uneven terrain, and slopes.

Compare this to mechanical feet which have always represented a compromise between flexibility and stability.

Individually adjusted plantar flexion resistance allows the foot to lower itself according to the gait situation with every step.

Hydraulic resistance is adjusted during initial ground contact to achieve a comfortable heel leverage adapted to the user's stride length.

Walking on Hills and Slopes

Plantar flexion and rollover are adjusted in real time according to the incline and dorsiflexion resistance supports consistent rollover across the wide range of motion.

With each step, the foot moves to a full-surface (flat on the ground) position as the user walks up or down the slope.

Real-time adjustment and wide range of motion allow the user to place an equal load on both legs, and enables a more uniform gait symmetry.

When descending a slope, this full-surface contact prevents undesired acceleration, providing additional safety. The user also finds it easier to control knee flexion, because less flexion moment occurs.

The dorsiflexion position also provides greater ground clearance when walking up slopes. This prevents the tip of the foot from getting caught and may help to reduce stumbles and falls.

Meridium®

Features and Benefits

Walking on Uneven Ground

The advantages of real-time adjustment are particularly evident on uneven surfaces such as cobblestones, grass, forest paths, and other similarly structured surfaces. With every step, the dorsiflexion and plantar flexion angles are fully and immediately adapted to the walking surface. The improved contact with the ground increases the user's safety.

Smaller obstacles are therefore no longer perceived as a problem, but rather as if they had been smoothed over.

Stairs

The Meridium recognizes the movement pattern when walking on stairs and adjusts both dorsiflexion and rollover angle, in real time, step by step.

This allows up to full surface contact meaning that on stairs the patient doesn´t have to roll over the edge of the step anymore which provides additional stability. Benefit to the user is enhanced safety and stability.

Intuitive Stance

Meridium can differentiate between walking and standing based on the situation.

Meridium provides intuitive stance on both level ground and slopes, and the user maintains the same level of stability in either case.

Dorsiflexion is locked for stable standing and immediately returns to adaptation for walking once movement is sensed.

Backwards Walking

The Meridium adapts in real-time to the movement pattern when walking backwards. Controlled lowering of heel down to the ground for full foot flat and ease of rolling over backwards.

Relief Function

This function automatically lowers the foot to the floor when a load is placed on the heel for a prolonged period and allows the foot to be flat on the floor while sitting or standing. Helpful when in areas with minimal legroom, such as public transportation, or theaters, and cinemas.

Evidence Summary
Hydraulic and MP-Controlled Ankles for Transtibial Amputees

	Mobility need or deficit of the patient	Evidence for benefits of an hydraulic / MP controlled hydraulic ankle
Safety	Patient trips, stumbles, or falls frequently	Increase in minimal toe clearance and reduction of the risk of tripping over an unseen obstacle in below-knee amputees.
Mobility	Limited mobility and activity	Highest self-reported mobility with passive MP controlled feet than with all other types of passive prosthetic feet K2 patients can improve performance-based and self-reported mobility
Socket residual limb interface	Pain, pressure sores, bruises at the skin and soft tissues of the residual limb, especially local pain while walking on non-level surfaces	Reduction of soft tissue loading and pressure during walking, especially while walking on slopes, uneven terrain, and stairs.
Level walking	Restrictions to increase walking speed and walk longer distances	Reduction of braking forces during level walking, reduction of the perception to have to "climb over the foot" at loading response, significant increase in self-selected walking speed in both below- and above-knee amputees.
Metabolic energy expenditure	Long-distance ambulation is exhausting	Reduction in metabolic energy consumption
Slope ambulation	Difficulties to negotiate slopes and/or considerable compensatory movements when walking or standing on slopes	More symmetrical and physiological movement patterns with reduction of compensatory movements and loading of the sound and amputated side.
Uneven terrain ambulation	Difficulty to negotiate uneven terrain	More physiologic loading of residual and sound knee joint, improved uneven terrain ambulation
Stair ambulation	Difficulties to negotiate stairs and/or considerable compensatory movements when walking on stairs	More symmetrical and physiological movement patterns with reduction of compensatory movements and loading.

Evidence Summary
Hydraulic and MP-Controlled Ankles for Transtibial Amputees

Tripping – minimal toe clearance

Given the mechanical constraints imposed by a prosthesis, people with amputation tend to be at increased risk of falling compared with age-matched nondisabled individuals [1, 2]. People with amputation have been shown to have reduced minimal toe clearance (MTC) on the prosthetic limb side compared with the intact limb when walking over level ground [3, 4], with interlimb differences increasing when walking on an uneven surface [4]. The reduced MTC on the prosthetic side is likely to be at least partly due to the prosthetic foot's inability to actively dorsiflex during swing, and this may explain the greater falls risk in people with amputation. Most clinically available prosthetic feet have either a rigid, non-articulating attachment or an "ankle" device that allows elastically controlled articulation, for example, by incorporation of a rubber snubber at the point of attachment. Such elastically controlled devices have an inherent tendency to return to the neutral position once unloaded. Therefore, once the prosthetic foot leaves the ground the ankle angle returns to neutral and remains so throughout swing.

This could partly explain why MTC has been shown to be reduced on the prosthetic compared with intact side [4]. Minimal toe clearance in below-knee amputees has been demonstrated to significantly increase when using a foot with hydraulic ankle (5, 6), especially with microprocessor (MP) control (6). Compared to standard ESR feet, walking with an hydraulic ankle that provides 3° of dorsiflexion during swing significantly increased mean MTC on the prosthetic side by 18% ($p=.03$) and on the sound side by 7% (5). The lowest MTC measured in all trials with the hydraulic ankle was 4 mm, whereas with the standard ESR feet quite a few MTC values of less than only 2 mm were seen. The increase in MTC also allowed for a significantly faster self-selected walking speed ($p<.001$) (5). In a study with an MP controlled hydraulic ankle that can produce up to 10° of dorsiflexion, even bigger improvements of MTC were found in level and incline walking that increased with faster walking velocity. At 80%, 100%, and 120% of self-selected walking speed, mean MTC on the prosthetic side significantly ($p<.001$ each) increased during level walking by 28%, 74%, and 65%, respectively, and on a 5° incline by 53%, 72%, and 100%, respectively (6).

The risk of tripping over an unseen obstacle of 5 mm height decreased from 1 in 166 steps with standard ESR feet to 1 in 3,169 steps with the MP controlled hydraulic ankle (6). These results were confirmed by patient-reported feedback in a big observational study with 70 subjects with lower-limb amputations, in that 45% of individuals reported improved perception of safety and balance, 35% reported fewer stumbles and 23% fewer falls with the Meridium MP-controlled foot as compared to their customary prosthetic feet with fixed ankle attachment [6].

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Mobility

A study with a retrospective analysis of self-reported mobility in 738 patients with major diabetic and/or dysvascular lower-limb amputations found that users of microprocessor-controlled ankle-foot mechanisms (billed with L5973) reported the highest mobility assessed with the Prosthetic Limb Users´ Survey of Mobility (PLUS-M) (p=.004), which was followed by vertical loading pylon type ankle-foot mechanisms (billed with L5987), non-MP controlled hydraulic ankle-foot mechanisms (billed with L5968), flex-walk-type prosthetic feet (billed with L5981), and lastly flexfoot-type prosthetic feet (billed with L5980) [1]. Microprocessor-controlled ankle-foot mechanisms yielded the greatest level of patient-perceived mobility, even after controlling for numerous factors that may confound the results such as age, BMI, comorbid health status, time since amputation, and even amputation level [1]. Similar results were obtained in a study with 23 individuals with unilateral transtibial amputation rating their perceived mobility on the Prosthesis Evaluation Questionnaire –Mobility Section (PEQ-MS) that found significantly (p=.0.0465) better self-reported mobility when using a MP-controlled hydraulic ankle-foot mechanism as compared to a standard energy-storage-and-return (ESAR) foot [4].

A study with 5 unilateral transtibial amputees and MFCL-/K2 mobility assessed the walking spped and distance in the 2-minute walk test (2MWT) as well as limb loading in a 3D motion analysis when using a K2 foot with hydraulic ankle unit or a standard K2 foot with a rigid ankle attachment, respectively. During the 2MWT, participants walked, on average, with a 6.5% increase in self-selected walking speed (effect size d = 0.4) and thus an increased walking distance (effect size d = 0.4) when using the hydraulic ankle compared to the standard K2 foot. This increase in walking speed and distance was present across all participants. Participants also displayed more symmetrical inter-limb loading (effect size d = 0.8), increased minimum forward center-of-pressure velocity (effect size d = 0.8), and increased peak shank rotational velocity (effect size d = 1.0) when using the hydraulic ankle compared to the standard K2 foot [2]. Another study with 14 lower-limb amputees with MFCL-/K2 mobility assessed patient-reported prosthetic function and mobility assessed with the Prosthesis Evaluation Questionnaire (PEQ). When considering the subject group as a whole, the mean scores in each of the six question categories was consistently higher for the hydraulic ankle. The mean improvement across all categories was 14.7 points. This included a 17.3 point improvement in ambulation, a 17.2 point improvement in prosthesis satisfaction and a 21.9 point increase in gait satisfaction. When broken down by amputation level, trans-tibial amputees had a mean improvement across all categories of 16.6 points. For trans-femoral amputees the cross-category mean improvement was 6.2 points [3].

Evidence Summary
Hydraulic and MP-Controlled Ankles for Transtibial Amputees

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Socket residual limb interface pressure and sound limb loading to prevent deep soft tissue injuries

Deep soft tissue injury (DTI) may occur in soft tissues situated between a bony prominence and a support surface [1-5]. In below-knee amputees, the soft tissues in danger are the gastrocnemius muscle and fat tissues, compressed between the truncated tibia and fibula bones and the hard prosthetic socket. The soft tissues situated at the distal tibial end were clinically observed to be one of the most common areas of tissue damage due to high pressure generation, leading to restriction of blood flow and reduced oxygenation. The resulting tissue breakdown is the main cause of severe pain followed by high incidence of rejection of the prosthesis [6]. While healthy traumatic amputees naturally detect pain when their residual limb is under excessive or prolonged pressure, diabetic or vascular amputees who suffer from neuropathy may not respond to normal biological nerve signals due to their comorbidity, therefore subjecting their residuum to potential DTI [8].

The use of a prosthetic foot with rigid ankle, especially when walking on slopes, uneven terrain, and stairs is associated with relative movements (tilt) between the socket and the residual limb in the sagittal plane, resulting in high peak pressures in the anterior (uphill and on stairs) and posterior regions (downhill) as well as the distal end of the residual limb [7]. Thus, it can be expected that the socket tilt and the resulting peak pressures may be diminished when using a prosthetic foot with a hydraulic ankle that allows for dorsi- and plantarflexion. In a study with a hydraulic ankle that provides up to 3° of dorsi- and plantarflexion each, the residual limb loading rate and internal stresses were reduced by up two thirds in level and uneven terrain walking, slope and stair ascent and descent compared to standard ESR feet, attaining statistical significance in paved floor walking ($p<.03$) and stair ascent ($p<.01$) [8].

In a study using a microprocessor-controlled hydraulic ankle that provided up to 10° of dorsiflexion and up to 18° of plantarflexion, peak pressures and pressure time integrals inside the socket measured during slope and stair negotiation were significantly reduced [$p<.05$ to $p<.001$, depending on sensor position). The results were reduced more, and much closer to those found in level walking, when compared to the rigid ankle condition [9]. These results were also confirmed clinically with significant improvements in socket comfort while walking and standing on slopes

(SCS, p<0.001) with a MP controlled hydraulic ankle as compared to a standard energy-storage-and-return (ESAR) foot in a study with 23 individuals with unilateral transtibial amputation [11].

In conclusion, both studies suggest that using a prosthetic foot with hydraulic ankle may protect the residual limb soft tissues in below-knee amputees from high stresses, therefore preventing pressure related injury. As the Meridium foot provides up to 14° of dorsiflexion and 22° of plantarflexion with instant adaptation to changing terrain, it can be expected to diminish anterior peak pressures even more than the two feet studied.

As far as the excessive loading of the sound limb with its detrimental long-term consequences is concerned, a study with 14 subjects with unilateral lower-limb amputation (9 transtibial, 5 transfemoral) demonstrated a significant reduction in contralateral peak plantar pressures with the use of a prosthetic foot with a hydraulic ankle unit. Thus, the hydraulic ankle can have significant unloading effects on the forces acting on the sound foot. With respect to the large reductions in the transfemoral patients, the authors state that because these reductions were observed at the forefoot and metatarsal heads, it is likely that the hydraulic ankle reduced the necessity to hip-hike, due to its greater toe clearance [10].

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Evidence Summary
Hydraulic and MP-Controlled Ankles for Transtibial Amputees

Ease of walking on different surfaces

Level walking – ability to walk fast and longer distances

During normal able-bodied gait, the center of pressure (CoP) progresses throughout stance along the plantar surface of the foot from the heel forward toward the toes. Such progression reflects how the forward progression of the whole body center of mass is controlled [1]. In amputee gait, CoP forward progression will be governed by the compliance of the prosthetic foot device [2] and in particular its ability to simulate ankle function to provide 1st and 2nd rocker phases of gait. Many current so-called energy-storing and return (ESR) prosthetic feet have no articulating components, and instead deformation of the foot's flexible heel spring provides simulated plantarflexion, and deformation of the forefoot spring simulates dorsiflexion around an undefined axis. In lower-limb amputees, the CoP has been found to remain in the hindfoot area under the prosthetic foot significantly longer than in both the intact or able-bodied control limbs [1], and at times even move backwards towards the heel during early to mid-stance [1, 3]. This phenomenon is caused by an inappropriate recoil of the heel spring at about 20% of stance phase, resulting in an early heel rise or “bouncing” or unstable sensation [4], often perceived by patients as “having to climb over the foot”, “stuttering” or “dead spot”[5]. During mid- to late stance, loading of the forefoot spring results in increased energy-return from the foot into the shank, creating braking forces with a deceleration of the forward shank rotation [6]. These braking forces in early and late stance increase with faster walking speed and have to be overcome by additional work of the intact limb [1, 3, 6], resulting in restrictions to willingly increase walking speed and walk longer distances.

Studies have demonstrated that a prosthetic foot with a hydraulic ankle can significantly reduce or even eliminate the posterior displacement of the CoP in early to mid-stance and significantly increase the mean forward shank rotational velocity during weight transfer onto the prosthesis [5, 7, 8]. As a result of this significant reduction in braking forces, self-selected walking speed increased significantly in both below- and above-knee amputees [5, 7] with a concurrent reduction in speed-dependent compensatory kinetic adaptations and work of the sound limb [8]. These findings show that a hydraulic ankle allows for smoother and less faltering transfer of the bodyweight onto the prosthetic limb. Consequently, study participants reported the perception of having to ‘climb over’ their prosthesis was no longer present [5, 7], allowing them to increase walking speed and walk longer distances than with standard ESR feet.

A study with 25 lower-limb amputees showed that all unilateral subjects had a longer sound side stance phase duration than on the prosthetic side. For bilateral subjects, more time was spent on their “dominant” leg. When using the hydraulic ankle, the difference in the stance phase timing between the sound and prosthetic limbs decreased for 75% of the subjects. For the MFCL-/K3 subjects, six out of eight amputees showed improved symmetry. There was no correlation between change in symmetry and amputation level. The mean stance phase difference was significantly decreased (p=0.03), representing a 30% improvement with the hydraulic ankle. For MFCL-/K2 subjects, the results were very similar, with s6 out of 8 improving. The mean stance phase difference was also significantly reduced (p=0.02) by 34% [9].

As far as metabolic energy expenditure is concerned, several studies have demonstrated reduced metabolic energy consumption when using a non-microprocessor or microprocessor-controlled hydraulic ankle-foot mechanism [10,]. A study with a non-MP controlled hydraulic ankle compared oxygen consumption at 6 different gait speeds during level walking and at customary walking speed on 5° and 10° inclines on a treadmill to that with a standard energy-storage and return (ESAR) foot. The metabolic cost of locomotion was significantly reduced ($p<0.001$) by the hydraulic ankle-foot compared to the ESR foot. Averaged across all level walking speeds, the metabolic cost of locomotion reduced was by 11.8±2.5% with the hydraulic ankle-foot. Averaged across all gradients at the customary speed, the metabolic cost of locomotion reduced was by 20.2±3.4%. At metabolic costs of 14 ml/kg*min and 17 ml/kg*min, the mean customary walking speeds with the ESAR foot were 1.09 and 1.37 m/s, respectively. With the hydraulic ankle-foot mechanism, these speeds increased by 6-7%, to 1.18 and 1.45 m/s, respectively [10]. Similar results were found in a study comparing energy cost of walking in 10 subjects with unilateral transtibial amputation when using a MP-controlled ankle-foot mechanism and a standard energy-storage-and-return (EASR) foot during floor walking and walking on a level as well as 5° each inclined and declined treadmill. The results of this study indicate that the MP-controlled ankle-foot, despite its extra weight, is capable of reducing energy cost of walking in all the studied conditions (by 8 to 18%), but reaching statistical significance in floor walking only [11].

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Evidence Summary
Hydraulic and MP-Controlled Ankles for Transtibial Amputees

Slope negotiation

Conventional rigid prosthetic ankles lack dorsi- and plantarflexion which induces locomotion difficulties, especially when walking on slopes [1, 2]. The very limited ankle range of motion and power generation as well as reduced proprioception and tolerance of force compromise the stability of the residual limb during stance, demonstrated by shorter single support, increased early stance knee flexion, smaller joint moments and powers but increased negative (dampening) work at the residual knee measured in transtibial amputees compared to able-bodied subjects. These adaptations result in a slower walking speed on slopes with reduced knee and hip range of motion and hip moments, but greater amplitude and time of muscle activity in both limbs [1].

A study on slope ambulation demonstrated that the use of a microprocessor-controlled hydraulic ankle with up to 10° of dorsiflexion during slope ascent resulted in significant improvements in ankle kinematics (dorsiflexion) and knee and hip kinematics (range of motion) and kinetics (moments = loading) on both the prosthetic and the sound side. During slope descent, the microprocessor-controlled hydraulic ankle with up to 18° of plantarflexion improved plantarflexion and hip kinematics (range of motion) on the prosthetic side and hip kinetics (moments = loading) in the sound limb [3]. Subjectively, the patients reported that slope ambulation was easier [4] and safer [3] when walking in the adapted mode with increased dorsi- and plantarflexion, suggesting that the self-reported improvements are not fully reflected by the changes in kinematics and kinetics [3]. This may have been caused by the only partial adaptation of the studied foot to the tested inclines [3]. Descending a shallow (5°) slope with a microprocessor controlled hydraulic ankle that provides 3° of dorsiflexion and 6° of plantarflexion resulted in reduced (more normal) early stance knee flexion, slowed (better passively controlled) forward shank rotation, reduced negative (dampening) work in the residual knee and, thus, improved control over downhill walking speed as compared to a foot with fixed ankle attachment and a hydraulic ankle without microprocessor control. The authors conclude that using MP-controlled hydraulic feet will reduce the biomechanical compensations used to walk down slopes, both on the sound and amputated side. Unilateral trans-tibial amputees often report difficulty with descending slopes more slowly – the increased negative prosthetic ankle work during stance phase illustrates the increased resistance to dorsiflexion, or ‘braking effect’ provided by the MP-controlled hydraulic ankle. The reduced prosthetic shank rotation velocity in single support when using the active hydraulic ankle suggests that this technology helps to control descent speed, improving the safety of the user [5]. This was also confirmed by another study with the same microprocessor controlled hydraulic ankle. During ramp descent, the transition of prosthetic ankle moment from dorsiflexion to plantarflexion occurred earlier in stance phase with microprocessor control, slowing the angular velocity of the shank. During ramp ascent, the microprocessor controlled the dorsiflexion/plantarflexion moment transition to occur later, meaning less resistance to shank rotation in early stance and increasing walking speed by up to 6%. For both slope conditions, the kinetic (loading) asymmetry was universally decreased with microprocessor control, unloading the sound limb by 4–13% during descent and 3–11% during ascent [6]. These results were confirmed by patient-reported feedback in a big observational study with 70 subjects with lower-limb amputations, in that 97% of individuals reported improved slope ascent and 91% improved slope descent with the Meridium MP-controlled foot as compared to their customary prosthetic feet with fixed ankle attachment [7].

Conventional prosthetic feet like energy-storage-and-return (ESAR) feet provide only a limited range of ankle motion compared to the natural human ankle. In order to overcome the poor rotational adaptability, prosthetic manufacturers developed different prosthetic feet with an additional rotational joint and implemented active control in different states. One study with 4 unilateral transtibial and four unilateral transfemoral amputees compared five different microprocessor-controlled prosthetic feet (Meridium, Elan, Proprio, Triton Smart Ankle, Raize) as well as their customary ESAR feet during standing on slopes of different inclinations (level ground, upward slope of 10°, and downward slope of −10°). They most pronounced differences in biomechanical parameters were observed while standing on a downward slope. For example, on the prosthetic side, the vertical ground reaction force (limb loading) is reduced by about 20%, and there is a high knee flexion moment when using feet that are not capable of full adaptation to the downward slope. In contrast, fully adaptable feet with an auto-adaptive dorsiflexion stop (Meridium) show the least deviations in vertical ground reaction forces and knee moments compared to able-body individuals [8]. Similar results were obtained in a study that investigated standing quietly facing down a 5° slope in 6 transtibial amputees (one bilateral) wearing a fixed ankle attachment foot, a hydraulic ankle and a microprocessor-controlled hydraulic ankle. The distribution of the ground reaction force (GRF) between sound and prosthetic limbs was not significantly affected by foot type. However, the MP condition required fewer kinematic compensations, leading to a reduction in sound side support moment of 59% (p=0.001) and prosthetic side support moment of 43% (p=0.02) compared to the foot with a fixed ankle. For the bilateral participant, only the MP-controlled ankle positioned the GRF vector anterior to the knees, reducing the demand on the residual joints to maintain posture. For transtibial amputees, loading on lower limb joints is affected by prosthetic foot technology, due to the kinematic compensations required for slope adaptation. The MP-controlled ankle might be considered reasonable and necessary for bilateral amputees, or amputees with stability problems due to the reduced biomechanical compensations [9]. Another study that compared three different MP-controlled ankle-foot mechanisms (Elan, Meridium, Proprio) enrolled six persons with transtibial amputation who had customary energy-storing-and-returning (ESAR) feet. Each MP-controlled ankle data acquisition was preceded of a 2-week adaptation period at home and followed by a 3-week wash-out period with their ESAR. Lower limb angular position and moment, Center of Pressure (CoP) position, Ground Reaction Forces (GRF) and functional scores were collected during standing, level ground and 12% inclined slope walking. All MP-controlled ankle-foot mechanisms allowed for a better posture and a reduction of residual knee moment on inclined and/or declined slopes compared to the ESAR feet. Results also reflect that the Meridium foot facilitated the best control of the CoP in all tested situations [10]. These results were confirmed by patient-reported feedback in a big observational study with 70 subjects with lower-limb amputations, in that 86% of individuals reported improved standing on slopes with the Meridium MP-controlled foot as compared to their customary prosthetic feet with fixed ankle attachment [7].

However, individual responses of individuals with transtibial amputation to a MP-controlled ankle-foot mechanism during slope ambulation may not be uniform. Most studies on microprocessor-controlled ankles have focused on group-level results (inter-subject mean), but did not report individual subject results. One study built upon prior work and provided new insight by presenting subject-specific results and investigating to what extent individual responses agreed with the group-level results. It performed gait analysis on seven individuals with unilateral transtibial amputation while they walked on a 7.5 incline. The microprocessor-controlled ankle increased minimum toe clearance for all subjects. Despite behaving similarly for each user, marked differences in individual responses were observed. For instance, two users switched from a forefoot landing pattern with the microprocessor-controlled ankle locked at neutral angle to rear foot landing when the microprocessor-controlled ankle adapted to the slope, while two maintained a forefoot and three maintained a rear foot landing pattern across conditions. Changes in knee angle and moment were also subject-specific. Individual user responses were often not well represented by inter-subject mean. Although the prevailing experimental paradigm in prosthetic gait analysis studies is to focus on group-level analysis, these findings call attention to the high inter-subject variability which may necessitate alternative experimental approaches to assess prosthetic interventions [11].

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Uneven terrain ambulation

A study that investigated camber walking with a non-MP controlled hydraulic ankle and a standard foot with rigid ankle attachment found that amputees walked with significantly longer strides when using the hydraulic ankle (p=0.026). Significant differences were found between the prosthetic ankle moments of the hydraulic and fixed devices, in both symmetry and normalcy trend symmetry indices (TSI, p<0.001 for both), where the hydraulic ankle showed higher TSI values than the standard foot. This held true for all four walking conditions – normal and fast walking speed on level ground and 2.5° camber walkway. The questionnaire feedback indicated that the hydraulic ankle felt more stable, made swing phase easier, provided a more balanced feeling, was less limiting to movement and provided an overall safer feeling. This was the case for all walking conditions [1].

Another study designed a specific ramp in the gait lab to mimic uneven terrain ambulation ("Göttingen Parcours"). It consists of a 3m (10 ft) downhill walkway (10° inclination) followed by specific uphill and downhill elements with opposite inclination angles of 10° each. Four subjects with unilateral transtibial amputation were studied negotiating that uneven-terrain simulation with the MP-controlled ankle-foot Meridium or their customary energy-storage-and-return (ESAR) foot. Compared to the ESAR feet, the MP-controlled foot considerably improved the ankle adaptation to the abruptly changing slopes, which was reflected by a significantly increased stance phase dorsiflexion that was comparable to the able-bodied control group. The peak knee extension moment on the prosthetic side was significantly higher with the ESAR feet, whereas it was almost normal with the Meridium foot. Thus, the adaptable ankle joint motion of the MP-controlled ankle-foot mechanism is a crucial feature for a more natural motion pattern and results in a significant reduction in residual knee joint loading [2]. These results were confirmed by patient-reported feedback in a big observational study with 70 subjects with lower-limb amputations, in that 82% of individuals reported improved uneven terrain ambulation with the Meridium MP-controlled foot as compared to their customary prosthetic feet with fixed ankle attachment [3].

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Stair ambulation

Stair ambulation increases the kinetic demand compared with level walking [1-4] and emphasizes motor deficits. For amputees who usually suffer from restrictions of muscle strength and joint mobility, balance, or proprioception, stair ambulation becomes specifically challenging [5-8]. Thus, amputees negotiate stairs considerably slower and with greater stance asymmetry and increased muscular effort than able-bodied controls [5, 7].

During stair ascent, below-knee amputees use a particular compensation mechanism that could be a result of a strategy favoring knee stability on the prosthetic side [9]. They generate a strong hip moment to elevate the body during stance on their prosthetic side, compared to able-bodied subjects who mainly utilize a knee moment [6, 9]. The preparation of the next foot contact is also a challenge on both sides [6].When preparing step contact for the sound limb, the missing active plantarflexion of the prosthetic foot leads to an insufficient vertical position of the body´s center of mass (CoM). When preparing step contact for the prosthetic limb, the missing dorsiflexion of the foot reduces toe clearance directly prior to the support phase. Both challenges are compensated for by the sound limb through an increased knee flexion during late swing and an increased plantar flexion during late stance [6].

A study using a microprocessor- controlled hydraulic ankle with up to 10° of dorsiflexion demonstrated that the increased dorsiflexion had a tendency to diminish the ‘‘hip strategy’’ of power generation and to result in a generally more physiological gait pattern on the prosthetic side. This was reflected by the fact that the differences in able-bodied subject’s kinematics (range of motion) and kinetics (moments = loading) during stair ascent were significantly smaller than when walking with the rigid ankle. With the adapted ankle, knee flexion during loading response and mid-stance was favored and reduced the need for hip flexion at initial contact. [10]

During stair descent, amputees adopt a specific landing strategy on their prosthetic side, with the CoM positioned directly over the landing limb at initial contact. It probably ensures that the ground reaction force is positioned anterior to the knee joint center to ensure knee extension and stability [11]. At loading response, knee flexion is also restricted, possibly as a result of the reduced or missing dorsiflexion [10]. On the sound side, ground contact is initiated with increased plantar flexion, probably to compensate for the lack of dorsiflexion of the prosthetic foot, which causes the amputees to ‘‘fall’’ onto their sound limb. According these findings, stair ambulation is always challenging to below-knee amputees due to the shortcomings of standard prosthetic feet with rigid ankles in neutral position [10].

With the microprocessor-controlled hydraulic ankle (with up to 10° of dorsiflexion and up to 18° of plantarflexion), kinematics (range of motion) and kinetics (moments = loading) of the prosthetic side during stair descent were significantly closer to physiologic patterns of hip angle, moment, and power, as well as knee moment. Furthermore, knee flexion on the prosthetic limb side was more pronounced during mid-stance, which results in a greater knee extension moment and power absorption to control the bodyweight acceptance in early stance phase [10].

Both during stair ascent and descent, the most noticeable improvements provided by the increased dorsiflexion of the microprocessor-controlled hydraulic ankle were related to more physiologic knee flexion kinematics (range of motion) and kinetics (moments = loading) on the prosthetic side during stance [10]. This may diminish potential joint and muscle overuse and pain. As the Meridium foot allows for 14° of dorsiflexion and 22° of plantarflexion with instant adaptation to changing terrain, it can be expected to even better facilitate stair negotiation than the studied microprocessor-controlled foot.

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