International C-Leg Studies

3rd Edition

Quality for life

Literature Overview

International C-Leg Studies

As a manufacturer of innovative, high-quality products in the Orthobionic® field, Otto Bock continuously strives for better solutions to help people with limited mobility regain maximum safety, freedom of movement and quality of life. The C-Leg underscores this claim particularly well.

Since its introduction, the influence of the C-Leg leg prosthesis system on the fitting quality for leg amputees has been examined in numerous scientific studies with a wide variety of objectives. The C-Leg is considered the most frequently evaluated and most comprehensively documented leg prosthesis system in technical literature worldwide.

As the number of different leg prosthesis systems and corresponding advertising claims by the manufacturers continues to increase, medical and biomechanical studies as well as technical literature are gaining more and more significance. They are the only way to assure the independent, objective assessment of practical benefits, and are therefore of key importance to various interest groups in the orthopaedic sector. For the prescribing doctor and health insurer as well as the service provider and well-informed prosthesis wearer, they are essential for a thorough evaluation of the individual benefits offered by a component in the respective fitting situation.

More than 35,000 fittings with the fully microprocessor-controlled C-Leg prosthesis system around the world confirm the key advantages of this unique technology. The studies summarised in this brochure prove that C-Leg users benefit from:

- A significant reduction in the frequency of falls
- An improvement in divided attention
- Increased activity and a larger radius of movement
- Enhanced confidence in the prosthesis.

The objective of compiling the C-Leg studies and publications presented in this brochure was to make them accessible to interested readers in a compact, concise and comprehensive form. This applies to the international audience in particular, since most of the publications are available only in German or English. Thanks to a comprehensive bibliography, using the original texts for more detailed study is readily possible.

Additional information on the C-Leg product line is available from the Otto Bock subsidiaries around the world listed in the appendix.

Content

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What does the C-Leg achieve?

As a manufacturer of innovative, high-quality products in the Orthobionic® field, Otto Bock continuously strives for better solutions to help people with limited mobility regain maximum safety, freedom of movement and quality of life. The C-Leg underscores this claim particularly well.

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A simple step is a complex sequence of motions. Processes that are almost fully automated during normal walking have to be consciously controlled by transfemoral amputees at all times in order not to stumble or fall. This requires a high degree of concentration, for example when walking at different speeds or on varying ground or floor conditions.

In developing the C-Leg, we placed highest priority on achieving an optimal degree of safety in all phases of walking. Customizable software settings enable an intelligent control of the C-Leg - the system always recognizes the specific phase of gait performed by the user. A knee angle sensor measures step length and frequency and delivers information to achieve a safe stance phase as well as data for the dynamic control of the swing phase required to ensure a natural gait pattern. For safe standing, the system is equipped with an additional load sensor that uses a strain gauge to capture heel strike and forefoot load. To coordinate all measurement and control processes, values reflecting the current gait status are transmitted to the integrated microprocessor 50 times per second. The microprocessor ensures that the damping of the hydraulic unit is always adjusted to the specific situation, from highest safety during heel strike to the easy changeover to swing. This is always done in real time – irrespective of whether the C-Leg user is walking fast or slowly, or with long or short steps. As a result, the user may move freely and easily whatever the surface – be it on level or uneven ground or when descending stairs or walking on inclines. In addition, efficient control of the C-Leg reduces the strain on the contralateral side of the leg amputee's body.
In addition to the normal mode, the C-Leg allows the user to switch to a special mode including individually configurable hydraulic resistance values, e.g. for cycling, inline skating or cross-country skiing. The latest generation of the C-Leg presented in 2006 includes additional modern features such as a wireless remote control used for switching modes easily and for the independent, individual fine-tuning of swing-through phase control by the C-Leg user. An additional standing mode permits stabilisation of the knee joint at any flexion angle up to 70° – without having to expend muscular strength.
A lithium-ion battery ensures energy supply to the C-Leg, with sufficient capacity to operate for approx. 40 to 45 hours. We offer a three-year warranty for the leg prosthesis system under the condition that the annual service checks are carried out. Subject to additional payment, this warranty may be extended to a total period of five years.

The C-Leg is approved for transfemoral amputees with a body weight of up to 125 kg. It was developed especially for the needs of active prosthesis wearers. The C-Leg is part of the C-Leg product line, which also includes the C-Leg compact, tailored to older and/or less mobile prosthesis wearers' need for greater security. No scientific literature is available for the C-Leg compact to date. Publications will be added to future editions of this brochure as they become available.

The following indications and contraindications for the C-Leg and C-Leg compact systems are recommended by the manufacturer. These and other potential indications must be assessed by the prescribing physician on a case-by-case basis. The following page includes a precise description of the individual mobility grades according to the Otto Bock MOBIS system.

Indications

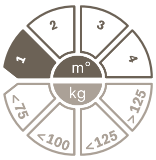
The following indications and contraindications for the C-Leg and C-Leg compact systems are recommended by the manufacturer. These and other potential indications must be assessed by the prescribing physician on a case-by-case basis. The following page includes a precise description of the individual mobility grades according to the Ottobock MOBIS system.

Mobility Grades 2 and 3	**Mobility Grades 3 and 4**
Amputees (amputee level knee disarticulation and higher)	
Additional medical issues and/or complications due to an injury can exacerbate the original limitations caused by amputation, i.e.:	
• Contralateral joint instabilities • Arthritis of the joints of the lower extremity • Contralateral amputation below the knee • Amputation of the upper extremity • Complicated post-traumatic conditions • Multiple handicaps	
Obvious neuromuscular deficit in the extremities (such as plexus paralysis) including deficits in the residual limb musculature.	
• Amputees who have the ability to walk 3-5 kmph (2-3 mph) per hour • Amputees able to perform movements which are advantageous for their everyday life and which require flexion of the knee joint under weight bearing, e.g. sitting down, walking on uneven ground, negotiating on slopes and stairs • Amputees with professional activities requiring a high level of stance safety • Amputees with unilateral hip disarticulation amputation, and amputees with hemipelvectomy amputation with good walking ability	• Amputees who have the ability to vary their cadence and to walk fast (> 5 kmph or 3 mph) and/or walk long distances (> 5 km or 3 miles per day) • Amputees walking on uneven ground or slopes or climbing/descending stairs often (> 100 steps per day) • Persons with professional activities requiring a high level of stance safety, particularly efficient swing phase control and who walk for extended periods • Amputees who have to change their movements and speed quickly in sudden, unexpected situations (e.g. people responsible for young children) • Amputees who require the additional modes (e.g. for standing with the knee slightly flexed while weight bearing)
C-Leg compact	**C-Leg**

Bilateral fittings
Active people with bilateral transfemoral amputations can be fit with the C-Leg under closely monitored fitting situations

Contra-indications
- Amputees with Mobility Grade 1 (“indoor walker”)
- Cognitive ability or living situations that do not allow correct handling of the C-Leg

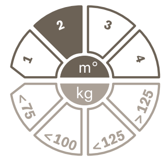
Mobility Grades and Therapy Objectives



Mobility Grade 1

Indoor walkers
Indoor walkers have the ability or potential to use a prosthesis for transfer purposes at minimal speed on level floors. The distance and length of time they can walk are seriously limited due to their restriction.

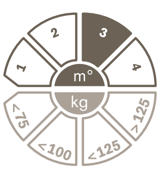
Therapy goal
Restoration of the amputee's ability to stand and to walk indoors with limited ability.



Mobility Grade 2

Restricted outdoor walkers
Amputees have the ability or potential to move slowly with a prosthesis and to master low obstacles such as curbs, steps or uneven ground. The distance and length of time they can walk are seriously limited due to their restriction.

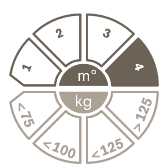
Therapy goal
Restoration of the amputee's ability to stand and to walk indoors and outdoors with limited ability.



Mobility Grade 3

Unrestricted outdoor walkers
Unrestricted outdoor walkers have the ability or potential to move with prosthesis with variable cadence while simultaneously mastering most obstacles. They also have the ability to move in wild terrain and can carry out career-related, therapeutic and other activities that do not place above-average demands on the prosthesis. Unrestricted outdoor walkers may also have an increased need for security due to secondary conditions (additional handicaps, special living circumstances) in connection with medium to high mobility activities. The distance and length of time they can walk do not differ significantly from non-impaired, healthy individuals.

Therapy goal
Restoration of the amputee's ability to walk and move without any limitations indoors and with only nonessential limitations outdoors.



Mobility Grade 4

Unrestricted outdoor walkers with especially rigorous demands
Unrestricted outdoor walkers with especially rigorous demands have the same ability or potential as unrestricted outdoor walkers. Their walking distance and duration are not limited. However, due to their rigorous functional demands, their prostheses need to sustain a high degree of shock, tension, and torsion.

Therapy goal
Restoration of the amputee's ability to stand, walk, and move both indoors and outdoors without any limitations.

Indication for the C-Leg Knee Joint System in Prosthetic Fittings for Amputees with Short Transfemoral Residual Limbs

Authors: S. Blumentritt[1,2], J. Braun[1], M. Bellmann[1], T. Schmalz[1]
Published in: Medizinisch Orthopädische Technik 129 (2009(5)) 61-74

Study Objective

The objective was to determine in a biomechanical study the effects of residual limb length on the gait pattern of the transfemoral amputee, and whether the length of the residual limb affects the function of the C-Leg – potentially having a key impact on the indications.

Study Design

Test subjects:	1st group with short residual limbs: 10 unilateral transfemoral amputees, residual limb length (tuber ossis ischii to medial tibial plateau on contralateral side) 20% (min. 5%, max. 36%). 2nd group with moderate to long residual limbs: 8 unilateral transfemoral amputees, residual limb length 53% (min. 37%, max. 70%)
Prosthetic joint:	C-Leg (Otto Bock HealthCare GmbH, Germany)
Prosthesis alignment:	The prosthesis alignment followed the recommendations of the manufacturer for a transfemoral prosthesis and was adjusted with the LASAR Posture alignment device.
Measurement technology:	Optoelectronic camera system (VICON, Oxford Metrics, GB) in combination with a force plate (Kistler, CH)
Parameters:	Time-distance parameter, kinematics, kinetics, residual switching time (special parameter to evaluate the switching function of the C-Leg)
Approach:	The test subjects initially completed 7 to 10 trials, walking on an even surface at the speed of their choice. The measurements continued at a slow followed by a fast walking speed. The statistical evaluation was conducted using the Mann-Whitney U test.

Results

Alignment:	The static alignment of the knee joint and foot component did not vary between the groups. The distance between the load line and trochanter major was smaller compared with the group with moderate to long residual limbs. This means the prosthesis of the short residual limb group was marginally more secure in terms of alignment.
Time-distance parameter:	The amputees with short residual limbs walked more slowly at all three walking speeds, the prosthesis side stride was shorter and the stride length on the contralateral side was equal in both groups. The prosthesis side stance phase duration is independent of the residual limb length, but on the sound side it is longer among amputees in the short residual limb group.
Kinematics:	The knee angle gradient does not differ significantly while walking on a level surface. The thigh segment angle is significantly larger by approximately 5 degrees over the entire gait cycle in the short residual limb group, which means they walk with the thigh segment more extended.
Kinetics:	The short residual limb group tends towards lower external sagittal knee moments in the first part of the stance phase on the prosthesis side, while higher extension moments are measured in the second half of the stance phase. In this group, the prosthesis side hip moments at the beginning of the stance phase are highly significantly reduced by approximately 50% for all walking speeds and hip moments are also lower during the initiation of the swing-through phase. The switching function of the C-Leg during the initiation of the swing-through phase was reliable among all test subjects. No errors were observed, although it was determined that what is known as the residual switching time was lower in the short residual limb group. Nevertheless, the residual switching time is long enough to assure the functionality of the C-Leg for the amputee.

Conclusion

The motor function of the amputee with a short transfemoral residual limb differs significantly in comparison with the amputee with a medium or long residual limb. This is due to the poorer residual limb performance of the short residual limb. As another consequence of the poorer residual limb performance, these amputees move with less stance phase security at the beginning of the one-legged stance phase and are therefore exposed to an increased potential risk of falling. The required security while walking can be assured only by selecting an appropriate knee joint.

The functionality of the C-Leg is not affected by the residual limb length of the transfemoral amputee.

This means the C-Leg is indicated for amputees with short transfemoral residual limbs in particular, since it offers the technical prerequisites to compensate for security deficits caused by the residual limb and its functionality is not affected by the residual limb length.

1 R&D Biomechanics, Otto Bock Healthcare GmbH, Duderstadt/Göttingen, Germany
2 Medical Department, Georg-August University, Göttingen, Germany

Differences in function and safety between Medicare Functional Classification Level 2 and 3 transfemoral amputees and influence of prosthetic knee joint control

Authors: B.J. Hafner[1], D.G. Smith[1]
Published in: Journal of Rehabilitation Research and Development 46 (2009) 417-434

Objective of publication

This study investigated the effect of the C-Leg compared to a conventional, mechanical knee component on walking at various speeds and on crossing obstacles outside the home among transfemoral amputees with mobility grade 2 and 3.

Study Design

Patients and method: See study "Evaluation of function, performance and preference…" on page 22. Phase B2 was extended to 12 months. In addition, examinations took place after 4, 8 and finally after 12 months during this period.

Recording and assessment methods

- Walking on inclines – Hill Assessment Index
- Walking on stairs – Stair Assessment Index
- A task for cognitive stress (divided attention)
- Obstacle course (lawn, small pieces of wood, sand, and one cement ramp and set of stairs respectively)
- Prosthesis evaluation questionnaire (Prosthesis Evaluation Questionnaire PEQ, nine sub-scales)
- PEQ addendum for the subjective reporting of the number of tripping events, near-falls and uncontrolled falls in the preceding 4 weeks and the subjective assessment of satisfaction, concentration and fear

For a detailed description, please see the study "Evaluation of function, performance and preference…" on page 22.

Results

The microprocessor-controlled stance-phase damping function of the C-Leg contributed to a significant improvement in gait quality. This applies to walking on stairs and inclines, walking speed (on inclines, while walking down stairs, on the obstacle course, while performing a task with divided attention) and the ability to multi-task. A significant reduction (p>0.01) of falls was reported by patients with mobility grade 2; an increase in patient satisfaction was noted with the C-Leg (20.6% increase for MG 2, 37.8% increase for MG 3; p=0.002). For 8 of the 9 sub-scales, improvements were noted with the C-Leg for both the mobility grades studied. The improvements were in the areas of locomotion (MG 3, p=0.01), appearance, frustration, reaction of others, social stress, well-being, benefits (MG 3, p=0.01) and noise (MG 3, p=0.046).

Over the study period, 50% of patients with mobility grade 2 were able to improve their mobility grade by one level; 33% of patients with mobility grade 3 were able to do the same.

The authors attribute this increase to the fact that patients with limited mobility also benefit from the security of advanced technology that is normally reserved for more active patients. Functional and physical impairments are compensated so that a higher mobility grade can be achieved. Furthermore, uncontrolled falls can be reduced through the use of the C-Leg, which in turn can lead to fewer injuries and therefore to a reduction in long-term healthcare costs, especially in a group of amputees with a high risk of falls and therefore injuries.

1 Prosthetics Research Study, Seattle, WA

Costs and consequences of a prosthesis with an electronically stance and swing phase controlled knee joint

Authors:	H.A.M. Seelen[1,3], B. Hemmen[1], A.J. Schmeets[1,2], A.J.H.A. Ament[2], S.M.A.A. Evers[2]
Published in:	Technology and Disability 21 (2009), 25-34

Study Objective

The study investigated whether a microprocessor-controlled prosthetic knee joint or a non-electronically controlled knee joint is preferable in terms of cost and functional health.

Method

Subjects:	A total of 26 subjects (unilateral transfemoral amputees and patients with a knee or hip disarticulation) were divided into two groups. Thirteen of these subjects were fitted with a microprocessor-controlled knee joint (C Group) whereas the other 13 were fitted with a non-electronic knee joint (N Group).
Knee joints used:	Microprocessor-controlled: C-Leg; non-electronic knee joints: 3R80, Ultimate, Total Knee, Proteval, 3R92
Data collection:	Over a one-year period, direct and indirect costs were recorded from the beginning of the rehabilitation period using a questionnaire (PRODISQ) as well as database entries at the Hoensbroek Rehabilitation Hospital. The items recorded included treatment cost, cost of nursing and care, costs incurred for the patients and their families, productivity cost, and total cost. Functional health was measured using the SF-36 (SF-06).

Results

Total costs ranged from EUR 39,350 (C Group) to EUR 46,038 (N Group). According to this data, treatment costs, such as the cost of fitting the prosthesis, are 28.2% higher in the C Group (p=0.042). The costs to be covered by the patients and their families totaled EUR 7,094 (C Group) and EUR 12,992 (N Group) (p=0.053). In the N Group, the costs of domestic help and assistance were higher by EUR 4,058 (p=0.007), whereas the loss of productivity was also more significant in this group (p=0.051). The analysis of the SF-06 items and the SF-36 sub-items revealed higher outcomes in the C Group whilst p values ranged from 0.001 to 0.071.

The authors conclude from the findings that despite the higher initial cost of fitting a microprocessor-controlled knee joint, these expenses must be set off against expenditures in other areas, and are thus compensated. In addition, functional health is considered better if a C-Leg is fitted, as compared to a conventional prosthetic knee joint.

1 Rehabilitation Foundation Limburg, Hoensbroek, The Netherlands
2 Research School CAPHRI, Department of Health Organization, Policy and economics, Maastricht University, Maastricht, The Netherlands;
3 Research School CAPHRI, Department of Rehabilitation Medicine, Maastricht University, Maastricht, The Netherlands

Functional Principles of Current Microprocessor-Controlled Prosthetic Knee Joints[1]

Authors: M. Bellmann[2], T. Schmalz[2], S. Blumentritt[2,3]
Published in: Orthopädie-Technik, 60 (2009), 297-303

Objective of publication

This publication should contribute to describing currently available microprocessor-controlled prosthetic knee joints with regard to their design, the sensor and switching technologies used, and the resulting functional characteristics when used by the patient.

Components

Adaptive2 (Blatchford, United Kingdom), C-Leg (Otto Bock, Germany), Rheo Knee (Össur, Iceland) and Synergy Knee (also termed Hybrid Knee or Energy Knee; Nabtesco, Japan).

Content

Due to the technologies used, the joints are already distinguishable by their design. Various principles are applied to generate different internal joint resistance levels that need to be adjusted to diverse gait situations. For instance, high resistance levels are generated through hydraulic or magneto-rheological mechanisms for knee flexion during the stance phase. Hydraulic, magneto-rheological, and pneumatic concepts are used to provide lower resistance levels to control the swing phase. Beyond these design varieties, the sensor-based capturing of gait parameters and the principles of switching between the resistance levels also differ. These variances result in tangible functional differences for the patient in everyday gait situations. Nine unilateral transfemoral amputees were fitted with prostheses for everyday use and included in a comparative biomechanical study to document the experience gained with these joints.

Functional differences were already apparent during walking on level ground. The differences in the functioning of the knee joints increase during demanding types of movement that require a high amount of motor activity, such as walking down stairs and ramps, and safety-critical features can be identified. The patient support provided by the technical options to prevent falling after gait cycle disruptions or stepping on an obstacle also varies. These features were investigated in separate safety tests. In this regard, the C-Leg technology offers many benefits in everyday gait situations due to its reliable, easy-to-use switching and sensor system.

1 The complete study is available as a special print with article number 646D406=GB
2 R&D Biomechanics, Otto Bock Healthcare GmbH, Duderstadt/Göttingen, Germany
3 Medical Department, Georg-August University, Göttingen, Germany

The Safety of C-Leg: Biomechanical Tests

Authors: S. Blumentritt[1,2], T. Schmalz[1], R. Jarasch[3]
Published in: Journal of Prosthetics and Orthotics 21 (2009), 1-14

Study Objective

To develop a methodology to determine safety characteristics of prosthetic knee joints that are of particular relevance for fall prevention in critical everyday situations. For these critical situations, a comparison is made of three prosthetic knee joints: the 3C1 (Mauch hydraulics), 3R80 (rotary hydraulics), and C-Leg (electronically controlled linear hydraulics).

Study Design

Method:	As part of a pilot study on three subjects, critical everyday situations that pose the risk of falling are replicated in the gait laboratory: abrupt stopping and negotiating on the prosthesis side, stepping on an obstacle, or disrupting the swing phase extension to simulate stumbling.
Measuring equipment:	Biomechanical parameters (knee angle, external knee and hip moment) were measured using an optoelectronic camera system (VICON, Oxford Metrics, UK) in combination with force plates (Kistler, Switzerland).
Procedure:	During all tests, subjects were secured against falling by wearing a safety vest. The subjects were requested to walk at a medium speed that they were to determine themselves.
Stopping and negotiating:	The test supervisor gave a hand signal to the subject to stop immediately upon the next step on the prosthesis side, or to negotiate an obstacle perpendicular to the direction of walking. These signals were given randomly during mid-stance on the contralateral side.
Stepping on an obstacle:	Three 20 cm long, 2 cm wide obstacles were placed on the walkway. These obstacles consisted of different materials and had varying heights: 1) a 1 cm thick rubber strip, 2) a 1 cm thick rubber strip with a 0.5 cm cork layer, and 3) a 1.5 cm thick PVC strip. The subjects started walking from a variable marking so that the obstacle could be hit by the heel, mid-foot or forefoot during normal walking.
Simulation of stumbling and tripping:	A person who walked behind the subject very briefly pulled a string that was attached directly above the prosthetic foot in order to disturb the extension movement at varying knee angles during the swing phase.
Subjects:	Three unilateral transfemoral amputees (mobility level 3 to 4) took part in the tests. All of them were very experienced, routine users of the prosthetic knee joint systems tested. Their ages ranged from 25 to 43 years, the amputation had been performed nine to 25 years before the test.

Results

The patients were walking at a speed of approx. 1.3 m/s when they were faced with the critical situation.

Stopping with the C-Leg proved to be safer and easier compared with the other knee joint systems. For the 3R80, knee flexion showed a significant increase at the time of loading whereas the knee joint remained extended in the case of the 3C1. This situation is considered safety-critical because the situation-dependent switching of the Mauch hydraulics unit results in the joint switching to the low swing phase resistance as soon as loading occurs. A stopping movement under load may thus lead to a collapse of the prosthesis. For the 3C1 and the 3R80, it was found that the compensatory movements of the trunk were significantly stronger than for the C-Leg.

Vertical negotiating is best supported by the C-Leg and the 3C1 provides the least support.

All three joints enable stepping on an obstacle with the forefoot without posing major problems. If, however, the mid-foot area hits the obstacle, both the C-Leg and the 3R80 provide a sufficient degree of safety. In some cases, the use of the 3C1 resulted in falls because the high stance-phase resistance is switched off as soon as heel contact is made, irrespective of the foot position on the obstacle. When stepping on the obstacle with the heel, the use of the 3C1 and the 3R80 may result in falling since the knee joint extension moment upon loading is sufficient to switch the 3C1 to swing-phase resistance. In contrast, when using the 3R80, the knee flexion beginning shortly after heel contact may prevent switching to the high stance-phase resistance.

Stumbling and tripping: Both the 3C1 and the C-Leg switch to the high stance-phase resistance during the swing-phase extension movement and can thus be loaded in flexion after the disruption of the swing-phase extension. Following the disruption, the 3R80 remains in the low swing-phase resistance mode. If the flexed prosthesis is loaded after the disruption, the use of this joint will result in falling.

In none of these situations was the use of the C-Leg critical to safety. Rather, the prosthesis offered the highest potential for the prevention of uncontrolled falling.

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2 University Göttingen, Germany

Comparison of non-microprocessor knee mechanism versus C-Leg on Prosthesis Evaluation Questionnaire, stumbles, falls, walking tests, stair descent, and knee preference

Authors: J.T. Kahle[1], M.J. Highsmith[1,2], S.L. Hubard[3,4]

Published in: Journal of Rehabilitation Research and Development 45 (2008), 1-14

Study Objective

In a series of nine clinical measurements, individual performance during the use of non-microprocessor prosthetic knee joints versus the C-Leg was investigated in 19 transfemoral amputees.

Study Design

Method:	The study comprised nine specific parts: a prosthesis evaluation questionnaire to assess quality of life (evaluation using defined scores), the documentation of stumbles and falls (recorded individually during everyday activity), walking on a 75 m long, level walkway at the fastest possible and at a comfortable speed (time measurement), walking on a 38 m long walkway with various surfaces (grass, stones and sand) at the fastest possible speed (time measurement), walking on a short walkway, 6 m long, level ground (time measurement), stair descent over six steps under laboratory conditions (evaluation using a composite score), and individual knee preferences.
Procedure:	Following their recruitment, the subjects continued to use their prostheses with non-microprocessor joint mechanisms for another 90 days. After this stage, all situations except knee preference were investigated, and the prostheses were fitted with the C-Leg immediately thereafter. A technician then gave special instructions regarding the C-Leg functionality (consulting a physiotherapist if required), and the joint settings were optimized in two follow-up sessions. This step was followed by a 90-day familiarization phase, which was concluded by the repeat measurement that also included the indication of knee preference.
Group of subjects:	19 (initially 21) subjects at an average age of 51 ± 19 participated in the study. Reasons for amputation were trauma, peripheral arterial disease, congenital defects, and osteosarcoma. Inclusion criteria were transfemoral amputation or knee disarticulation, extensive experience in the use of the current non-microprocessor prosthesis, at least one completed physiotherapy treatment phase, and the ability to walk in public with or without aids, but without human support. In addition, mobility level 2 should have been achieved.

Results

The assessment of prosthesis-related quality of life in the evaluation questionnaire revealed that quality of life could be increased by 20% when using the C-Leg. When wearing the non-microprocessor joint, subjects mentioned an average of seven stumbles and three falls, whereas only three stumbles and one fall were reported on average for the C-Leg. Subjects walked fastest with the C-Leg on all surfaces. Compared with the non-microprocessor joints, the time required could be reduced by 12% when walking at the fastest possible speed on the 75 m level walkway and by 21% when walking at the fastest possible speed over 38 m on uneven ground. During stair descent, 12 subjects reported an improvement when using the C-Leg. Two subjects completed this test with better results when using the non-microprocessor joint. No difference was documented in five cases. After the tests, 14 subjects indicated a preference for the C-Leg and their wish to use it in their prostheses worn for everyday activity. Two other subjects intended to continue the use of their non-microprocessor joint for cosmetic reasons (e.g. because there was no option to adjust the heel when using the C-Leg prosthesis). In another case, the patient indicated that the non-microprocessor joint provided a higher degree of patient control over the prosthesis. Two other subjects stated that the price of the C-Leg was too high. Of the five subjects who preferred the non-microprocessor joint for everyday use, four had been using such a joint for more than ten years (in some cases, this period of use was significantly longer than ten years). A total of nine subjects were allocated to mobility level 2 at the beginning of the study. Four of them were able to improve their functional performance as a result of C-Leg use, and were upgraded to mobility level 3 at the end of the study.

In conclusion, particularly amputees with restricted performance should be provided with highly functional components in order to enhance their activity and mobility. According to the authors, the design applied to this study can be used by orthopedic technicians in their day-to-day clinical fitting practice to collect data and to evaluate their patients.

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4 Department of Occupational Therapy, University of Florida, Gainesville, FL, USA

Cost utility analysis of knee prosthesis with complete microprocessor control (C-Leg) compared with mechanical technology in trans-femoral amputees

Authors:	S. Gerzeli[1], A. Torbica[1], G. Fattore[1]
Published in:	European Journal of Health Economy (2008)

Study Objective

In this study, a cost-utility analysis was carried out for a microprocessor-controlled prosthetic knee joint system and alternative mechanical joints.

Study Design

Knee joints: C-Leg (Otto Bock HealthCare, Germany), mechanical components with polycentric design (no manufacturer information provided)

Method: For the purpose of a cost-utility analysis, the situation of unilateral transfemoral amputees fitted with prostheses at the INAIL Center in Italy was documented over a five-year period. All costs associated with prosthetic fitting were recorded and the health-related quality of life determined.

Procedure: Each year, ten patients fitted with a C-Leg were selected randomly. These patients were matched with other patients with an almost identical profile (sex, age, reason for amputation) who used a prosthesis with a mechanical knee joint. In both groups, all costs incurred during the study period were recorded retroactively. This economic data can be divided into two categories. On the one hand, all costs were identified that were directly attributable to the healthcare system, such as the technical part of prosthetic fitting (components, materials, trial fittings etc.), hospital stays, medication, monitoring and follow-up by specialist medical practitioners, rehabilitation, diagnostics, and laboratory tests. On the other hand, costs associated with the social disadvantages caused by the amputation were documented, such as transport costs, overnight stays, informal care, or the loss of the patient's ability to work. In addition, health-related quality of life was determined for the individual prostheses. For this purpose, a standardized EuroQol (EQ-5D) questionnaire was used, which includes five categories on the basis of which the health-related fitting outcome can be evaluated. These categories are mobility, self-care, general activities, pain/discomfort, and anxiety/depression. As a result, points are assigned to the so-called "Quality-Adjusted Life Years" (QALY). A qualified research associate conducted telephone interviews with the subjects.

Group of subjects: 100 unilateral transfemoral amputees, average age 45.8 ± 11.8 years (C-Leg) and 45.0 ± 12.0 years (mechanical knee joints), period since amputation 13.7 ± 1.7 years vs. 13.3 ± 2.0 years, period since first prosthetic fitting 9.0 ± 0.7 years vs. 8.0 ± 0.8 years

Results

The analysis of patient data revealed that the number of amputees who used the C-Leg who were married was significantly higher (86% vs. 56%), and that they used their prosthesis for a longer period during the day (13.5 vs. 11.7 hours). In the quality of life evaluation using the EQ-5D, it was found that the amputees achieved an improvement with the C-Leg in all five categories. A statistically significant increase was documented for physical mobility and degree of use. The difference between the findings recorded for each of the groups resulted in an absolute improvement in quality of life by 9% when using the C-Leg. The analysis of the individual cost items showed that the patients who used the C-Leg underwent prosthesis-related inpatient treatment more often (12% vs. 8%) and that these hospital stays lasted longer (24.3 vs. 11.5 days). The average annual hospital costs were almost identical in the two groups (EUR 324.00 vs. EUR 344.00). When performing work activities, the patients who used a mechanical knee joint suffered significantly more severe problems. Some 38% of them had to abandon their jobs, as opposed to 26% of the C-Leg patients, while the number of lost workdays was also higher (10.1 vs. 3.2 days). For the C-Leg users, the total annual cost per patient (excluding technical costs related to the prosthesis) amounted to EUR 9,635.00, compared to EUR 12,953.00 for other joints, if the social cost aspects are covered. Over the five-year lifecycle, the costs directly associated with prosthesis fitting, such as purchasing joints or repairs, were estimated at EUR 7,449.00 for the mechanical components and EUR 22,744.00 for the C-Leg. When considering the number of QALY points achieved for both prosthetic knee joints and adding up all costs incurred, the C-Leg fitting resulted in a total amount of EUR 66,669.00 compared to EUR 66,927.00 documented for a fitting with an alternative, polycentric joint.

On the basis of these findings, the authors argue that a C-Leg fitting increases quality of life. This prosthesis system is a cost-effective technology when considering all social aspects and taking into account all costs incurred after amputation.

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Cost-Effectiveness of C-Leg Compared With Non-Microprocessor-Controlled Knees: A Modelling Approach

Authors: T.H. Brodtkorb[1,2], M. Henriksson[1], K. Johannesen-Munk[2], F.Thidel[l2]

Published in: Archive of Physical Medicine and Rehabilitation 89 (2008), 24-30

Study Objective

Using a modified Markov decision analysis model, costs and fitting outcomes are to be estimated for the C-Leg and non-microprocessor prosthetic knee joints.

Study Design

Procedure: At three Swedish and five Danish hospitals, outpatient interviews were conducted with 20 unilateral transfemoral amputees and orthopedic technicians covering the aspects of costs, classification and duration of problems, durability of knee joint systems, and health-related quality of life.

Method: The interview consisted of questions regarding the prosthetic knee components in relation to costs, periods of service and trial fittings, problems, incidence of problems and periods until problems were resolved, as well as questions regarding health-related quality of life. The main parameter for analysis was the increase in cost per QALY (quality-adjusted life year).

Group of subjects: The 20 unilateral transfemoral amputees were older than 18 years (41.0 ± 2.5 years), the amputation had been performed 16.0 ± 2.6 years ago, and the C-Leg was fitted 45.0 ± 5.2 months before the interview. All patients had been previously fitted with non-microprocessor controlled prosthetic knee joints. All five participating orthopedic technicians were experienced in the fitting of both the C-Leg and non-microprocessor prosthetic knee joints.

Results

For a defined C-Leg lifecycle of eight years, the additional cost of fitting such a system amounted to EUR 7,657.00 (according to the euro cost base in 2006) while QALY efficiency increased by a factor of 2.38 in the same period. This results in an additional cost of EUR 3,218.00 per QALY for the C-Leg. In comparison with non-microprocessor controlled prosthetic knee joints, the C-Leg, with a simultaneous increase in health-related quality of life, can be considered economical.

The authors state that a cost-utility analysis is an additional key piece of information for health insurers and reimbursers, and should thus be used as a decision-making aid, particularly for high-priced medical products. They also mention that the approach described in the article would become even more significant if detailed interviews and parameters that can be measured biomechanically were included.

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The Impact of C-Leg on the Physical and Psychological Adjustment to Transfemoral Amputation

Authors: D.J. Bunce[1], J.W. Breakey[2]
Published in: Journal of Prosthetics and Orthotics 19 (2007), 7-14

Study Objective

The study is to determine the influence, and the nature of this influence (if any), that the shift from a mechanical to a microprocessor-controlled prosthetic knee joint may have on the body image of amputees.

Study Design

Method: A survey was used to interview 42 transfemoral amputees immediately before their conversion to the C-Leg system and six months after this conversion.

Procedure: In total, 20 items were documented in a Likert-scale questionnaire and on the Amputee Body Image Scale (ABIS), and demographic data were collected. The ABIS describes the body perception of the amputee. This scale is applied to the following areas: body appearance, bodily functions, psychological stress, and restrained behavior in social settings.

In addition, comprehensive interviews were conducted with 10 patients who had used the C-Leg for at least one year, and who had previously been fitted with a mechanical knee joint.

Group of subjects: 42 patients: transfemoral amputees (approx. 90%), knee disarticulation (approx. 5%), hip disarticulation (approx. 2%), deformities (approx. 2%); 81% male, average age 45.5 ± 12.5 years; 71% of the amputations were performed due to trauma; the average period since amputation was 19.9 ± 15.4 years.

Results

Amputee Body Image Scale (ABIS): The ABIS and body image scores were significantly elevated when using the C-Leg. The magnitude of the effect was high and statistically significant. It was found that the questions regarding bodily functions, emotional stress, and restrained behavior in social settings strongly correlated with each other. In the interview, 90% of the amputees reported that the C-Leg had a more natural and fluid gait pattern and that amputees were better able to perceive their surroundings. Also, 90% of the amputees stated that the functional improvement provided by the C-Leg affected the character and significance of their everyday surroundings. Objects, steps and surfaces that were previously perceived as obstacles and were thus avoided, resumed their once familiar, pre-amputation character to a significant extent. In this respect, 90% of the amputees reported that the use of the C-Leg system reduced their perception of a deficit or disadvantage in relation to others. According to their statements, the C-Leg enables its users to walk at normal speed and to achieve the performance of non-amputees. Amputees found that the more natural and fluid gait pattern of the C-Leg made them appear more natural in the presence of others, which meant that they were less affected by being identified and treated as persons with a disability.

The authors conclude that the use of the C-Leg has a statistically significant positive effect on body image, which is of high clinical significance. The patients feel that their self-consciousness in relation to their surroundings and to others is improved. They feel safe and secure, able, satisfied, and normal. For the patients, this outcome results in the welcome perception of autonomy and increased determination, which allows them to fully utilize their opportunities and to find their way back into the life they were used to before the amputation.

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Biomechanical analysis of stair ambulation in lower limb amputees

Authors	T. Schmalz[1], S. Blumentritt[1], B. Marx[2]
Published in:	Gait and Posture 25 (2007), 267-278

Study Objective

This study includes a complex biomechanical analysis of patterns of stair ascent and descent in transtibial amputees and of stair descent in transfemoral amputees.

The following section refers to transfemoral amputees only.

Study Design

Knee joint:	C-Leg (Otto Bock HealthCare, Germany)
Method:	The measurement stair used consisted of several steps whose dimensions were modeled on standard steps. One of these steps was firmly connected to a force plate.
Procedure:	To assess both the prosthesis side and the unaffected side, patients had to tread on the activated step with the prosthesis in the first test run and with the unaffected limb in the second test. Patients were granted several minutes to become familiar with this test setup and a break of at least ten minutes prior to the measurement.
Measuring equipment:	A force plate (Kistler, Switzerland) was used to measure ground reaction forces, an optoelectronic motion analysis system (Vicon, UK) recorded the patients' movements.
Group of subjects:	The following inclusion criteria were applied: the ability of the patients to walk down stairs step-over-step, their ability to walk a distance of at least 5 km per day without problems, and no other orthopedic or neurological conditions. Twelve unilateral transfemoral amputees participated in the study (age 37.8 ± 8 years, period since amputation 14.7 ± 7 years). All of them used a C-Leg knee joint system and a 1D25 prosthetic foot (Otto Bock HealthCare). A healthy control group included 20 subjects (age 30 ± 10 years).

Results

During stair descent, orthopedically unaffected subjects tread on the steps in the forefoot area with strong plantar flexion whereas amputees tread on the steps with their prosthetic foot, which is not capable of active plantar flexion, in plantigrade position. During this movement, the mid-foot is positioned on the edge of the step, and rolls over the edge upon commencement of weight bearing. In the terminal support phase, this leads to a significantly reduced vertical and horizontal ground reaction force. Despite this fact, the sagittal knee moment progressions measured on the prosthesis side come very close to those of healthy subjects. The more anterior foot position reduces the lever between the ground reaction force and the center of rotation of the ankle, which is demonstrated by reduced dorsal extension moments of the ankle. The higher maximum values measured for the ground reaction force components on the contralateral side are indicative of a higher loading of the unaffected side. This in turn is represented by elevated maximum values that were recorded for sagittal ankle and knee moments. To compensate this resulting asymmetric pattern, transfemoral amputees set the contralateral foot onto the step with even greater plantar flexion than the healthy controls.

The author outlines that the limited dorsal extension capability of the prosthetic foot requires the amputee to employ a particular strategy when walking down stairs. This phenomenon should be borne in mind when developing future prosthetic feet. Transfemoral amputees in particular should position the prosthetic foot centrally on the edge of the step in order to fully utilize the performance of the hydraulic unit of the C-Leg. The amputee is able to fully load the prosthesis side immediately at the beginning of the stance phase as a result of the high stance-phase flexion resistance already set prior to treading on the step, and is thus able to immediately initiate the knee flexion required for stair descent. As a result, the additional loading of the contralateral side can be minimized in comparison with other prosthetic knee joints [see study by Schmalz et al., 2002].

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Comparison between the C-Leg microprocessor-controlled prosthetic knee and non-microprocessor controlled prosthetic knees: A preliminary study of energy expenditure, obstacle course performance and quality of life survey

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Published in: Prosthetics and Orthotics International 31 (2007), 51-61

Study Objective

Non-microprocessor controlled knee joints were compared with the C-Leg with regard to metabolic energy expenditure, obstacle course performance, and quality of life achieved.

Study Design

Knee joints: C-Leg, 1 3R80, 1 3R90 (all Otto Bock HealthCare, Germany); 6 SNS Mauch, 1 Total Knee (all Össur, Iceland), 1 Catech (no information provided), 1 Seattle Fusion (no information provided)

Procedure: Both for the C-Leg and the non-microprocessor controlled (NMC) joints, the tests were carried out on a single day in a randomized setting and without any extended familiarization phase.

Prior to the measurement, a comfortable and a fast, self-selected walking speed were determined during treadmill familiarization. The protocol included an eight-minute test (1 minute of warm-up, 3 minutes at self-selected comfortable walking speed, 3 minutes at self-selected fast walking speed, and 1 minute of relaxation). Following a ten-minute relaxation phase, the exercise was repeated for the other test prosthesis.

Subjects passed the standardized obstacle course (Standardized Walking Obstacle Course) under two conditions: with and without carrying a 4.5 kg shopping basket. Each condition was tested four times for the same prosthesis. The measurement parameters recorded included total time, number of steps, steps outside the course markings, and stumbling (loss of balance or of contact with the obstacles).

For the purpose of assessing quality of life, the patients filled in a questionnaire on their own on the basis of using the C-Leg. This questionnaire (SF-36v2) is a nationally recognized instrument in the United States. Its questions are structured according to physical (general health, physical pain, physical function, and physical functionalities) and mental attributes (vitality, social functions, emotional function, and mental health). Each of the sub-categories consists of two to ten individual questions.

Measuring equipment: Treadmill (no manufacturer information provided), Medical Graphics CardioO2/ECG Exercise System (Medical Graphics Corporation, Mn), heart rate monitor (Polar, Finland).

Group of subjects: Twelve unilateral transfemoral amputees and one patient with knee disarticulation participated in the study. All subjects were using the C-Leg at the time of the study (16 ± 15 months) but had previously used an NMC joint for a long time (average age 46 ± 13 years, height 175 ± 13 cm, weight 79 ± 13 kg, 11 male and 2 female patients). The inclusion criteria were mobility level 4, no concomitant conditions and a reason for amputation other than vascular disease.

Results

One of the subjects did not take part in the energy expenditure measurement due to lack of time. Two other patients did not participate due to pain and their fear of falling on the treadmill when using the NMC joint. The mean walking speed amounted to 49 ± 15 m/min whereas the fast speed equaled 70 ± 20 m/min. Relative oxygen consumption when walking with the C-Leg at a comfortable speed reached 12.6 ± 1 ml/kg/min, compared with 13.5 ± 2 ml/kg/min with the NMC joint (oxygen cost 0.29 ± 0.09 ml/kg/m vs. 0.30 ± 0.09 ml/kg/m). At the fast speed, relative oxygen consumption of 16.0 ± 2 ml/kg/min was measured for the C-Leg, compared to 17.2 ml/kg/min for the NMC joint (oxygen cost 0.23 ± 0.06 ml/kg/m vs. 0.25 ± 0.05 ml/kg/m). All differences were statistically significant. There were no significant heart rate differences.

Evaluation of obstacle course performance: When using the C-Leg, significantly fewer steps and a shorter time were needed both with and without the additional weight, and fewer slips were detected. No stumbling was seen in either case.

In the quality of life assessment, the scores for the C-Leg (all 13 subjects were included) were higher than the standard data recorded among the US population for limitations in using one arm or one leg. This applies to both physical and mental attributes.

The authors conclude that the benefits brought about by the C-Leg relate to an increased functional mobility and performance in the domestic environment and in social settings. The quality of life index is considered high.

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Gait and balance of transfemoral amputees using passive and mechanical and microprocessor-controlled prosthetic knees

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Published in: Gait and Posture 26 (2007), 489-493

Study Objective

This study compared a mechanical prosthetic knee joint with a linear hydraulic unit (Mauch SNS or equivalent) with the C-Leg prosthetic knee joint system with respect to their performance when walking on level ground and keeping one's balance.

Study Design

Knee joints:	C-Leg (Otto Bock HealthCare, Germany) and Mauch SNS (Össur, Iceland)
Method:	A crossover design was chosen for this study. An identical socket was used and only the knee components exchanged. Following the completion of the tests with the mechanical knee joint, the patients were fitted with the C-Leg and granted an average familiarization period of 18 ± 8 weeks. After this period, the tests were repeated with this joint.
Procedure:	Walking on level ground was tested at the initial stage. The patients performed a so-called sensory organization test on a posture plate to ensure an objective balance assessment. This test comprises three balance-related components (visual, somatosensory, and vestibular stimuli) and is carried out under conditions that vary in terms of visual stimuli and walking surface quality. Patients had to adopt an upright posture. Their feet were positioned on the plate in a reproducible fashion, and they were secured against falling by a safety vest. Three repetitive, 20-second tests were to be completed one after another in the six specific situations. The parameter measured by means of the plate was the angle of variation of the body's center of gravity. Depending on the angles measured in the specific situations, scores were assigned to the patients for keeping their balance. The mean scores were transferred to composite categories for the purpose of further analyses.
Measuring equipment:	Kinematics analysis system EvaRT 4.0 Systems (Motion Analysis Corporation, CA), two AMTI force plates, BP2416 (Advanced Mechanical Technology, MA), two Kistler force plates, 9281B (Kistler Instruments Corp., NY), OrthoTrak 5.0 analysis software (Motion Analysis Corp., CA), computer-aided dynamic posture plate (Equitest, NeuroCom International Inc., Oregon)
Group of subjects:	Fifteen unilateral transfemoral amputees (12 men, 3 women) took part in the study. Their average age was 42 ± 9 years, and they had been using a prosthesis for 20 ± 10 years. Inclusion criteria were an age of at least 18 years, a period of at least two years since the amputation and an activity level of 3 or 4. Exclusion criteria were chronic skin problems and other concomitant diseases. In addition, patients must have had extensive experience in the use of their conventional prosthesis with mechanical knee joint (Mauch SNS or equivalent).

Results

When using the knee joints equipped with a Mauch SNS hydraulic unit, knee extension moments were measured internally in the early stance phase that forced the knee into a hyperextension of approx. 4°. By contrast, internal flexion moments were measured in this phase of the gait cycle using the C-Leg that enabled stance phase flexion and thus made the gait pattern appear more natural. These changes were statistically significant.

In all six situations included in the sensory organization test, higher balance scores were achieved with the C-Leg. The analysis of the composite scores in the individual categories also showed a significant improvement in keeping one's balance with the C-Leg.

The authors attribute the documented variations between the joint mechanisms to the fact that the patient must keep the joint in extension when using the joint with the Mauch SNS hydraulic unit by actively contracting the hip extensors in order to prevent collapse. This movement is not required when using the C-Leg. This means that the better balance and higher stability are indicative of a lower risk of falling. The authors point out that the investigations referred to above could not demonstrate that amputees with limited walking ability would also benefit from the advantages of a microprocessor-controlled knee joint. For this reason, further studies are required to evaluate this question.

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Evaluation of function, performance and preference as transfemoral amputees transition from mechanical to microprocessor control of the prosthetic knee[1]

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Published in:	Archives of Physical Medicine and Rehabilitation 88 (2007), 207-217

Study goal

Within the context of a methodologically extensive examination of unilateral transfemoral amputees, the change from mechanical control to a microprocessor guided control of the prosthetic knee joint is observed, and the functional ability, performance characteristics and individual preference for the two control mechanisms are recorded.

Study design

Test subjects:	21 unilateral transfemoral amputees, mobility grades 2 to 3, over the age of 18 years, amputee for least two years, utilization of a mechanical knee joint in the preceding care. 17 of the 21 test subjects completed the study.
Examined joints:	Mechanical joints of the everyday prosthesis (monocentric and polycentric) as compared to the C-Leg
Implemented in:	everyday life and under laboratory conditions
Method:	controlled reversing A-B-A-B study: A1 is the initial situation with a mechanical joint (NMP1): For a period of 2 months while recording patient activity, finishing with a record of the function, performance and perceived assessment of the mechanical knee joint; B1: Intervention measurement with a microprocessor controlled joint (MP1): after the determination of optimal prosthetic adjustment (without further adjustments), for 2 months analogously to A1; A2 initially provides an adaptation period of 2 weeks for NMP with subsequent recording of the functionality of these joints; B2: for a time period of four months, the test subjects were permanently able to select between two prostheses (NMP or MP); use was respectively recorded via patient activity following functional evaluation of the MP.

Methods for recording and evaluation

Patient activity:	Number and frequency of steps with StepWatch2 step activity monitor (Cyma Corporation, Mountlake Terrace, WA), complemented by extrapolation of the daily walking distance by means of multiplying the step frequency with an average step length; utilized during all periods.
Base mobility:	performed by therapists using the Amputee Mobility Predictor (AMP) in each session. Health status: performed by the test subject using Short-Form 36 (QualityMetric, Inc. Lincoln, RI) in each session.
Walking on a level surface:	Data concerning step symmetry on a 30 foot (9.14 m) walking distance
Walking up/down stairs:	Evaluation using a stair evaluation index: Stair Assessment Index (SAI), 12 step stairway.
Walking up/down inclines:	Evaluation using an incline evaluation index: Hill Assessment Index (HAI), inclination of 19° with a length of 94 feet (28.65 meters).
Walking on uneven terrain:	Obstacle course with a grass surface, wood chips, sand, a ramp and stairs; the time required with a self-selected speed was measured.
Perceptive abilities:	Walking while telephoning using a mobile telephone with an examiner who stated number blocks of 2 to 5 digits in a random order and which the test subject had to repeat; the parameter consisted of the test speed and the precision of the repetition.
Evaluation of performance capabilities and satisfaction:	performed by the test subject him/herself with a prosthesis evaluation sheet: Prosthesis Evaluation Questionnaire (PEQ) after the respective function tests.

Results

In the tests which were performed under laboratory conditions, the step length showed a trend of a slight increase on the prosthesis side with the C-Leg by comparison to the unaffected side. Walking down stairs with the C-Leg was evaluated as significantly improved, while walking up stairs was equal with both systems in the comparison. The joint systems also showed significant differences in walking down inclines. Both the evaluation index and the required time were evaluated as better with the C-Leg. The required time for passing through the obstacle course as well as the evaluation of split attention was evaluated as better with the microprocessor controlled joint in the trend. In the individual evaluation of the joints, 14 out of 17 test subjects preferred the C-Leg, 2 stated no preference, and 1 preferred his mechanically guided system. The evaluation of the performance capabilities of the joint systems by the test subjects themselves showed that the frustration due to falls, the frequency of stumbling and staggering as well as partially controllable and uncontrollable falling was reduced with the C-Leg. The evaluation of the activity measurements, general functionality and health status showed no changes within the examination time period.

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1 The complete study is available as a special print with article number 646D274=GB
2 Prosthetic Research Study, Seattle, WA./USA
3 NMP: none microprocessor controlled knee joint; MP: microprocessor controlled knee joint

Prosthetic Intervention on activity of lower-extremity amputees

Authors: G.K. Klute[1,2], J.S. Berge[1], M.S. Orendurff[1,3], R.M. Williams[1,3], J.M. Czerniecki[1,3]

Published in: Archive of Physical Medicine and Rehabilitation 87 (2006), 717-722

Study Objective

The effect of component modifications on the fitting of prostheses to transtibial and transfemoral amputees was investigated. Also, the extent to which certain modifications affect mobility over a period of one week was evaluated.

The following discussion refers exclusively to transfemoral amputees.

Study design

Knee joints:	C-Leg (Otto Bock HealthCare, Germany) and Mauch SNS (Össur, Iceland)
Measuring equipment:	StepWatch activity monitor (no manufacturer information provided)
Method:	In a crossover design, subjects were randomized to either C-Leg fitting or fitting of a Mauch SNS prosthetic knee joint.
Procedure:	Following a three-month familiarization period, the StepWatch monitor was incorporated in the respective prosthesis, and patient activity was measured for one week. After this measurement, the knee joint was replaced by the other prosthesis, and the procedure referred to above was repeated. During the test period, the socket remained the same but different foot components were used. The activity measured was divided into “activity per day” (i.e. steps per day), “duration of activity” (minutes per day) and “type of activity” (duration of an activity unit, steps per period, and frequency of occurrence of a unit based on a minute interval).
Group of subjects:	Five out of fifteen participating subjects were analyzed. Reasons for amputation were trauma (four subjects) and tumor (one subject). The average age was 48 ± 12 years, the amputation had been performed 21 ± 11 years ago, and the average patient weight was 73 ± 9 kg.

Results

Nineteen subjects gave their consent to participate in the study. Four of them discontinued the study prematurely due to the long study period, three had to terminate their participation due to health problems, and three other patients were excluded from the study because they did not use the test prosthesis during the entire period. Another three subjects terminated the study prematurely because of problems in the familiarization phase during C-Leg fitting. As a result, the data of the six remaining patients were included in the analysis.

The knee type had no influence on activity (2,657 ± 737 steps per day with the C-Leg, 2,675 ± 976 steps per day with the Mauch SNS prosthesis) and on duration of activity (273 ± 65 minutes per day with the C-Leg, 260 ± 100 minutes per day with the Mauch SNS). Also, no difference was found for the use of the prosthesis on weekdays and weekends. The amputees performed a large number of short-interval movements (1 to 2 minutes), which consisted of fewer than 17 steps per minute. Activities with a duration of over ten minutes were performed only once a day. For these activities, the highest step frequency was reported (70 steps per minute). Long-term activities (longer than 15 minutes) were documented very rarely (less than once a day).

From these findings, the author concludes that the adaptation, prosthetic alignment and components should be optimized particularly for activities with a duration of one to two minutes that involve only a few steps.

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Does having a computerized prosthetic knee influence cognitive performance during amputee walking?

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Published in: Archive of Physical Medicine and Rehabilitation 87 (2006), 989-994

Study Objective

A comparative evaluation was made of cognitive performance and of the perception of cognitive load during ambulation with the C-Leg and the Mauch SNS hydraulic system.

Study design

Knee joints:	C-Leg (Otto Bock HealthCare, Germany) and Mauch SNS (Össur, Iceland)
Method:	In a crossover design, subjects wearing the respective knee component were tested after an adaptation period of three months.
Procedure:	The toss of a coin determined which joint was to be used in the first part of the test. The evaluation was split in two phases: pre- and post-crossover. In the respective phase, both objective cognitive performance and subjective cognitive load were recorded. One-minute tasks were resolved both at a self-selected and a controlled walking speed, such as (1.) serial subtraction, (2.-4.) the so-called "Controlled Oral Word Association Test" (consisting of three sub-tests) and (5.) a categorization test. The controlled walking speed was determined prior to the tests when walking over a distance of 60 meters without cognitive load. The self-selected speed was the speed chosen when completing the test without any controls or requirements. The controlled walking speed had to be adhered to during the repeat tests.
Subjects:	Of the original 18 subjects participating, eight (1 female, 7 male) were analyzed at the end of the study. The average age was 48.5 ± 10.1 years. Seven of them were employed. Inclusion criteria were the use of a non-microprocessor controlled knee joint (Mauch SNS) over a period of at least three years and a daily wearing period of at least eight hours. Subjects had to be able to walk without aids, to ascend or descend three steps on a stair, and to walk on a 30 m ramp.

Results

In none of the cognitive performance tests were any significant differences revealed between the two knee joint systems. Nor were there any statistically significant differences in the self-selected walking speed (1.06 ± 0.06 m/s with the C-Leg vs. 1.03 ± 0.06 m/s with the Mauch SNS). However, differences between the knee joint systems were identified in terms of subjective cognitive load. The C-Leg requires less attention during walking, which is why the subjective cognitive load is lower when using this knee joint.

The author outlines that the use of a microprocessor-controlled prosthetic knee joint requires less attention even in the easy-to-manage situations investigated in this study, according to the subjective assessment made by the amputees. According to the author, this subjective experience was not consistent with the neuropsychological test results and the measured walking speed. Although a microprocessor-controlled prosthetic knee joint is an adequate fitting for the majority of amputees, further studies are required to identify which groups of users (e.g. new amputees or amputees with complex physical and cognitive limitations) would benefit from such a component.

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Gait efficiency using the C-Leg

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Study Objective

This study compared gait efficiency after long-term familiarization with the C-Leg knee joint system and a Mauch SNS knee joint.

Study design

The familiarization phase, the time sequence, the organization of the study, and the group of subjects included were identical to the study entitled "Does having a computerized prosthetic knee influence cognitive performance during amputee walking?" by Williams et al. In addition, metabolic energy expenditure was measured at different walking speeds to determine oxygen cost.

Knee joints: C-Leg (Otto Bock HealthCare, Germany) and Mauch SNS (Össur, Iceland)

Procedure: On a rectangular course, the patients walked at four different speeds (0.8 m/s, 1.0 m/s, 1.3 m/s and a self-selected speed). Except in the case of the self-selected speed, patients were guided by a monitoring cart advancing in parallel (Velocart), which defined the required constant speed throughout the test. Patients walked at the various speeds until at least a two-minute steady state was reached for oxygen consumption. This exercise was followed by a relaxation phase in seated position until the baseline state prior to the exercise was reached again. This procedure was repeated for all walking speeds.

Measuring equipment: portable telemetric system VmaxSt (Sensormedics, Yorba Linda, California).

Results

When using the C-Leg, minor reductions in oxygen cost were measured for all documented walking speeds. However, these reductions were not statistically significant (0.8m/s: 0.254 ±0.019 mL/kg/m C-Leg vs. 0.235 ± 0.022 mL/kg/m Mauch SNS; 1.0 m/s: 0.214 ± 0.020 mL/kg/m C-Leg vs. 0.224 ± 0.025 mL/kg/m Mauch SNS; 1.3 m/s: 0.209 ± 0.016 mL/kg/m C-Leg vs. 0.220 ± 0.019 mL/kg/m Mauch SNS). In four subjects, an improvement was measured for the C-Leg. No difference was found in three subjects, and a minor deterioration was measured for one patient. The self-selected speed was higher for the C-Leg compared with the Mauch SNS joint (1.31 ± 0.12 m/s with the C-Leg; 1.22 ± 0.10 m/s with the Mauch SNS), but oxygen cost did not increase.

In some patients, the use of the C-Leg resulted in a significant reduction in oxygen cost across a wide range of walking speeds, yet not all of the patients were able to adapt equally well to the C-Leg.

When asked about their preference, seven subjects identified the C-Leg and justified this choice primarily with the high degree of safety against falling, and also with the better ability to adapt to various selected walking speeds.

In order to achieve a perfect prosthetic fitting, the author calls for an objective, plausible, and more comprehensive assessment of each individual gait pattern in order to optimize gait efficiency.

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Comparison of different microprocessor controlled knee joint on the energy consumption during walking in trans-femoral amputees: Intelligent Knee (IP) versus C-Leg

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Published in: Prosthetics and Orthotics International 30 (2006), 73-80

Study Objective

This study investigated the characteristic differences between the Intelligent Knee (IP) and the C-Leg with respect to energy consumption and walking speeds in transfemoral amputees.

Study design

Knee joints:	C-Leg (Otto Bock HealthCare, Germany) and Intelligent Knee (Nabtesco, Japan)
Prosthetic foot:	Sure Flex 3 (Össur, Iceland) in three cases, C-Walk (Otto Bock HealthCare, Germany) in one case.
Procedure:	Socially active transfemoral amputees who had already adapted to the IP underwent training to increase their walking speed. Their energy consumption when using the IP was measured after completion of training. Thereafter, the patients were fitted with the C-Leg and energy consumption was measured again after their adaptation to this joint. The test performed to measure energy consumption included a five-minute interval at four different walking speeds (30, 50, 70, and 90 m/min). Between these test runs, the patients were able to relax for 15 minutes. A 100 m rectangular course was used for the walking tests. The members of a control group who were recruited for the study did not undergo any training to increase their walking speed.
Measuring equipment:	portable telemetric system (K4 system, COSMED, Italy)
Group of subjects:	Four unilateral transfemoral amputees, all male, age 24 ± 7.6 years, weight 56.5 ± 8.6 kg, reasons for amputation: trauma (3), tumor (1); in all cases, subjects were fitted with an ischium-supported socket; the control group comprised 14 subjects (10 male, 4 female) with characteristics similar to those of the amputees (age 25.2 ± 4.0 years, weight 62.5 ± 15.3 kg)

Results

Both for C-Leg and IP amputees and for healthy controls, the efficient walking speed determined on the basis of oxygen cost was 70 m/min.

At a walking speed of 30 m/min, oxygen uptake was significantly higher than in the control group, amounting to an increase of 42.5% in the case of the IP and of 33.3% in the case of the C-Leg. At 50 m/min, these values amounted to 56.6% for the IP and 49.5% for the C-Leg; at 70 m/min, 57.8% and 51.2% were measured; at 90 m/min, the values amounted to 61.9% and 55.2%, respectively. No statistically significant differences between the prosthetic knee joints were found.

The author comments that the energy consumed by the amputees that was determined in this study was lower than in previous studies, and that the very minor differences in efficient speeds between the healthy controls and the amputees were due to the special gait training undergone by the amputees. At low and medium speeds, the amputees walk slightly more efficiently with the C-Leg compared with the IP. It is assumed that an even more significant advantage of the C-Leg is its integrated stance phase control, but this feature was not tested as part of the protocol. This assumption refers to everyday situations, such as walking on stairs or ramps or on uneven surfaces.

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Do microprocessor-controlled knees work better?

Authors:	K.R. Kaufmann[1], B. Iverson1, D. Padgett[1], R.H. Brey[2], J.A. Levine[3], M.J. Joyner[4]
Published in:	Journal of Biomechanics 39 (2006), 70

Study Objective

This study compared a mechanical prosthetic knee joint with a linear hydraulic unit (Mauch SNS or CaTech) to the C-Leg prosthetic knee joint system with respect to performance when walking on level ground, in terms of metabolic energy expenditure, activity level, and the ability to keep one's balance. Patient feedback was also documented.

Study design

Knee joints:	C-Leg (Otto Bock HealthCare, Germany), Mauch SNS (Össur, Iceland), CaTech (no manufacturer information provided)
Method:	The study was split in two phases: Patients were first tested during use of the mechanical knee joint. They were then converted to the C-Leg, and the measurements were repeated in an identical fashion after an eight-week adaptation phase.
Procedure:	The balance of the patients was captured on a measuring plate (see the study by Kaufmann et al.: "Gait and balance of transfemoral amputees"). Metabolic energy expenditure was measured at three different walking speeds (0.45 m/s, 0.9 m/s, 1.3 m/s). To complement the findings, total daily energy consumption was measured for a period of ten days by means of the "Doubly-Labeled Water" test. In addition, the patients' activity level was measured, and their feedback was documented in a prosthesis evaluation questionnaire (PEQ).
Measuring equipment:	computer-aided dynamic posture plate (Equitest, NeuroCom International Inc., Oregon), respiratory mass spectrometer to measure metabolic energy expenditure (no manufacturer information provided), StepWatch Monitor (no manufacturer information provided)
Group of subjects:	13 transfemoral amputees who had worn their prosthesis for an average period of 19 ± 11 years participated in the study. Their average age was 43 ± 9 years.

Results

Both gait and balance characteristics were significantly improved by the C-Leg, which was also reflected by an increase in the level of patient activity. The number of steps rose by 18%, and the total daily metabolic energy expenditure increased. No differences were found in the energy consumption measurements carried out for walking on level ground at three different speeds. A strong trend toward greater amputee satisfaction was documented for the use of the microprocessor-controlled prosthetic knee joint.

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Exoprothetische Kniemechanismen mit Umschreibung des Indikationsbereiches[1]

Authors: S. Blumentritt
Published in: APO-Revue 25 (2006), 8-18

Publication goal

Using the description of biomechanical characteristics of various prosthetic knee joint systems in everyday situations, particularly with reference to the risk of falling, a subdivision of knee joints is made in accordance with the indication.

Contents

Starting with the publication “Biomechanische Aspekte zur Indikation von Prothesenkniegelenken“ (“Biomechanical aspects concerning the indication of prosthetic knee joints”) by S. Blumentritt (Orthopädie-Technik 55 (2004), 508-521; also see page 22 of this brochure), this edition also discusses the functional mechanisms of knee joint systems which are of great significance when considering safety regarding uncontrolled falls. Aside from the other aspects that are discussed in the named article, this aspect of safety should be carefully considered when determining indications and in the prescription of prosthesis components in order to provide a realistically designed rehabilitation goal for the amputee.

Two locomotion situations which are demanding for patients are found in alternately walking down stairways and inclines. In conventional mechanical joints which enable bending under load (such as the described Mauch hydraulic knee joint and the 3R80 rotational hydraulic knee), the patient must actively carry out a specific residual limb movement to switch between the standing and swinging phases (Mauch – no initial extension, 3R80 – initial extension). This may cause an increased risk of falling, particularly if there is a control error on stairs. The C-Leg, which is switched by means of sensor data, frees the patient from this conscious control process, so that the residual limb action can concentrate solely on motor tasks. The safety potential of a joint - which is relevant for an amputee in everyday life – can, among other things, be objectivized under laboratory conditions through the use of measurement technology. Critical situations such as sudden stopping, avoidance, stepping on obstacles, or catching on something can be simulated, providing conclusions about the reliability of the joint system when changing between stance and swing phase resistance levels. Herein it is possible to prove that the sensor-based electronic controls of the C-Leg reduce the risk of falling. When stepping on a stone, for instance, the Mauch hydraulics switch into the swing phase resistance early, which increases the risk of falling.

Due to the differing demands which are placed on the patient for safely controlling the prosthetic knee joints in numerous everyday situations, the indication of Mauch hydraulics is regarded as suitable solely for mobility grade 4. Load dependent switching systems (such as the 3R80 rotational hydraulic knee) are assigned to mobility grades 3 and 4. The C-Leg technology expands the care spectrum due to its additional higher safety reserves, and for this reason fufills criteria for mobility grades 2, 3 and 4.

1 Otto Bock HealthCare GmbH, Duderstadt/Germany

Kinematic and kinetic comparisons of transfemoral amputee gait using C-Leg and Mauch SNS prosthetic knees

Authors: A.D. Segal[1,2], M.S. Orendurff[1,3], G.K. Klute[1,2,4], M.L. McDowell[1], J.A. Pecoraro[1], J. Shofer[1], J.M. Czerniecki[1,3]

Published in: Journal of Rehabilitation Research and Development, 43 (2006), 857-870

Study goal

Using biomechanical parameters, functional differences between the prosthetic knee joint systems C-Leg (Otto Bock, Duderstadt, Germany) and Mauch SNS (Össur, Reykjavik, Iceland) are to be determined and described for walking on level ground.

Study design

Test subjects:	8 unilateral transfemoral amputees, amputation due to trauma, age 47±13 years, height 173±5 cm, weight 79.6±10.4 kg, no known additional pathological conditions, everyday care with Mauch SNS for more than 1 year, prosthesis worn for 8 hours every day, all test subjects able to walk on level ground, stairs and inclines.
Control group:	9 healthy persons, age 29±8 years, height 174±5 cm, weight 73.6±10 kg
Prosthetic Components:	C-Leg with recommended prosthetic feet 1D25, 1C40, 1E40 (all Otto Bock, Duderstadt, Germany), Mauch SNS with two prosthetic foot types: Seattle Lite (Seattle Systems, Poulsbo, WA), Flex Walk (Össur, Reykjavik, Iceland)
Method:	Two test subjects respectively underwent the study, which was subdivided into three phases with equal time. After an initial assessment of the prosthetic care and possible readjustment by a certified prosthetic specialist, a one month phase with a subsequent measuring session (baseline) was completed with the Mauch SNS. After this phase, one of the test subjects was randomly selected and provided with the C-Leg, whereupon a three month acclimation period with a subsequent measuring session followed. For the last phase, the joints were exchanged in both test subjects and they underwent another three month acclimation phase, which was followed by the last measuring session.
Measuring protocol:	Level walking, both with a self-selected and with a controlled walking distance (1.11 m/s).
Measuring technology:	10 camera system Vicon 612 with 120Hz recording frequency (Oxford Metrics, Oxford, England), 1 force measuring plate with a sensing rate of 600Hz (Kistler, Winterthur, Switzerland), marker model Plug-in-Gait by Vicon

Results

No differences were found between the baseline measuring situation (with Mauch SNS) and the measurement with the Mauch SNS after the three month phase. The joint comparison was performed using the data which were obtained after the respective three month acclimation phase.

The self selected walking speed is faster with the C-Leg. For the joint comparison, however, the authors selected the parameters which were measured at the controlled walking speed. Therefore the measured step length with the C-Leg is shorter on the prosthetic side, and the difference between the prosthetic side and the unaffected side is lesser, which is reflected in increased gait symmetry.

The maximum swing phase flexion angle is significantly lesser when compared to the Mauch SNS and does not significantly differ by comparison to the unaffected side or to the control group. Therefore the progression of the swing phase angle can be evaluated as nearly physiological. On the prosthetic side, the knee flexion momentum is less at the beginning of stance phase when compared to the control group, but significantly higher than with the Mauch SNS. The authors evaluate this with a higher potential for stance phase flexion while walking on an even surface with the C-Leg. Both the muscular performance of the unaffected side and that of the hip on the prosthetic side, as well as the mechanical performance of the joints on the prosthetic side do not differ significantly in the joint comparison. The maximum of the vertical ground reaction force is minimally but significantly lesser on the prosthetic side with the C-Leg.

Even though the authors regard the advantages of the C-Leg for isolated, controlled, level walking as not outstanding, seven out of eight of the test subjects wanted to use this joint as their everyday prosthesis in the long term after the end of the study. As their reason for this desire they stated that it was because they fell less often when compared to the Mauch SNS and therefore placed greater trust in this system. Only one test subject, who did not complete the study, was dissatisfied with the C-Leg.

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Long-term results with the C-Leg knee joint system – results of a patient survey

Authors: B. Drerup[1], K. Bitterle[1], H. H. Wetz[1], N. Osada[2], R. Schmidt[1]
Published in: Medizinisch Orthopädische Technik 126 (2006) 89-98

Study goal

Based on a patient survey in a total of 56 amputees who had received care with the C-Leg knee joint system, it will be shown which problems the patients experienced with their previous conventional care, which expectations they had concerning treatment with the C-Leg, and to which degree the C-Leg produced functional improvements or deteriorations.

Study design

Test subjects: 56 test subjects, of which 30 were unilateral transfemoral amputees (proximal third: 4, central third: 20, distal third: 6), 2 bilateral transfemoral amputees, 3 knee disarticulations, 1 hip disarticulation, 1 hemipelvectomy; average age 48 years; cause of the amputation: 39 trauma; 6 tumor, 6 deformity, 1 circulation disturbance, 1 war injury, 3 other.

Method: Questionnaire, divided into 3 segments: 1. Medical history and prior care (historical questions about the person, the amputation and preceding care), 2. residual limb conditions (questions conceived for optional questioning by telephone), 3. comparison between conventional prosthetic knee joints and C-Leg (30 before / after questions, content adapted from the profile survey sheet of the German Medical Service of Leading Associations of Health-care Insurance Providers (= Medizinischer Dienst der Spitzenverbände der Krankenkassen [MDS]), performed directly after the treatment and in the further course of the examination); additional verification of the criteria of functional gain as per Wetz et al. as defined by the testing location (2005; also see p. 15 in this brochure) (except about gait harmonization)

Results

27 patients stated no problems as compared to the prior examination, 12 answers reported falls and another 12 calls reported a lack of feeling secure. 5 patients described difficult and slow walking as compared to the preceding examination as well as premature fatigue and high demands on concentration. In 4 cases, walking on stairs and inclines was assessed as difficult. Aside from back pain, hip problems and a vertebral disk prolapse, poor gait and excessive strain on the contralateral side were cited. One questioned person was not able to receive care until the C-Leg was used, due to spastic paralysis. According to the survey, 19 patients were assigned to activity level 2 prior to the C-Leg treatment, while 30 patients were assigned to level 3,and 6 patients were assigned to level 4. The patient with spastic paralysis was initially assigned to level 0. Of the treatments, which were usually assessed as high quality, 4 were evaluated as insufficient care (long knee or braking knee joint).

22 patients stated that their highest expectation with the C-Leg concerned increased walking security, followed by reduced energy consumption and/or use of force and an improved ability to handle inclines (each named 7 times).

A more harmonious gait, increased activity levels and a better ability to handle inclines were expected by 6 patients respectively. The expectations were completely fulfilled in more than half of the surveyed persons (30), while they were partially fulfilled in 21 persons. Only 5 persons did not have either expectations fulfilled. Among these patients, it was notable that two of them had been amputees for many years (20 and 38 years respectively). They stated major problems concerning the mental adjustment. One patient who also complained about a poor socket fit felt that the increased weight of the new joint was an uncertainty factor. Another patient, who had clearly reduced muscle strength, stated a feeling of being externally controlled as well as feeling dependent on a power source. By comparison to the conventional preceding care, improvements were shown with regard to walking on stairs and inclines as well as the ability to handle uneven and uncertain terrain. The reduction in falls was even statistically significant. 26 patients stated frequent falling with the previous care, wherein only occasional falling was mentioned among all surveyed persons after treatment with the C-Leg. The reduction in the use of aids was also statistically significant. Out of 18 patients, 15 had previously been dependent on the use of one walking support, while 3 required two walking supports. With the C-Leg, only 8 still needed to use a support. The number of freely mobile patients increased from 64 % to 84 % with the C-Leg. One patient still required the use of a rolling walker after the change. With a nearly unchanged daily duration of use, more than half of the patients (30) covered a longer walking distance with the C-Leg. The comparison of treatments according to the criteria of the clinical testing location showed that the C-Leg brought the greatest improvements in changing walking speeds and divided attention. A few patients evaluated the previous care as being better in this regard. In the statements about evaluations of the progress which were provided by 39 patients, there was a recognizable tendency to note steady improvements with the increased duration of use among the patients who noticed improvements immediately after the new treatment. It was only in sub-listed items that no improvements were named in individual cases. The patients who noticed a worsened situation immediately after the joint change were not able to improve at a later time.

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How frequently do patients with lower extremity amputations fall?

Authors:	B. Greitemann[1], H. Bui-Khac[1]
Published in:	Medizinisch Orthopädische Technik 126 (2006) 81-86.

Study goal

In this partial aspect of a greater overview study concerning participation disturbances of amputees, the frequency of falls is to be examined by means of a survey which was performed more than one year after the end of the rehabilitation period.

Study design

Test subjects:	71 patients of which 5 were double amputees, a total of 76 amputation levels: 36 transfemoral, 30 transtibial, 6 knee dislocations, 3 hip dislocations, 1 forefoot amputation, average age between 50 and 60 years (9th – 85th year of life); amputation causes: approx. 62% arterial occlusion disorders, 8.5 % malignant tumors, 14.1% trauma, 5.6% osteomyelitis, 9.9% other
Knee joints:	6 joints with fixation, 20 monocentric (7 with hydraulic and 5 with pneumatic swing phase control), 10 polycentric (four and seven axis systems)
Method:	Examination and questioning of the patients at least one year after discharge from rehabilitation with the following points of emphasis: remaining participation disturbances, problems in everyday life and frequency of falling. The questions are adapted to the rehabilitative perspective which orients itself to the ICF (International Classification of Rehabilitation) of the World Health Organization (WHO).

Results

In nearly all cases of the patients who were treated outside the rehabilitation clinic, major changes in the residual limb within the first weeks after the amputation led to refitting of the socket, structural corrections or completely new treatments (in 26 % of the patients). Therefore the fitting of the socket, the selection of components and the prosthetic structure for the rehabilitation process are already of great significance at the beginning of the rehabilitative measures. The author therefore makes his case for an initial fitting during the rehabilitation process.

The daily and weekly duration of use of the prostheses extends from 6 to more than 12 hours on 7 days of the week (54 patients) to less than 2 hours per day (9 patients) as well as only short durations of use for specific events on 2 to 6 days per week (8 patients), which shows major differences in the activity levels of the examined patients.

Particularly in transfemoral amputees, balance disturbances and uncontrolled moments frequently lead to falls. Most of the utilized prosthetic knee joints only have stability when they are extended. As soon as the prostheses are bent for an ergonomic gait they permit mobility which means a loss of security for the patient. In particular while walking on stairs or inclines where the knee joint released too early, the risk of falling was clearly increased. Despite training in prophylaxis against falling, which was completed by every patient in the course of the rehabilitation measures, 33 patients suffered at least one fall within one year, wherein the named causes included acutely occurring stump pain and muscle weakness, poor socket fit and handling problems as well as moments where it was not possible to exercise an influence, such as when they were surprised. Nearly half of the patients stated 2 to 10 falls per year; one patient even stated 15 falls. Therefore the risk of falling is a significant injury hazard for amputees.

The resulting conclusions are that the risk of falling should be taken into account not only within the context of rehabilitation and in further follow-up care measures with prophylactic training against falling, but also when the entire prosthetic device is created in the first place. Herein the selection of the components – particularly with the knee joints – is of major significance. In some patients a fixed joint would be the solution, however some can receive optimal care with an electronically controlled knee joint. With these electronically-controlled knee joints, the frequency of falls can be considerably reduced.

Herein the authors already refer to the C-Leg knee joint system in the introduction. Meanwhile, several judgments were passed by the highest federal court within Germany in which the risk of falling and thereby injury of a patient is shown as a significant reduction of amputee participation and must be balanced. The use of a C-Leg can make a significant contribution to this, which explains the increasing frequency with which amputees try to receive care with this knee joint system.

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The Impact of the C-Leg Knee Joint Component manufactured by Otto Bock on the Fitting Quality provided to Transfemoral Amputees

A Clinical Biomechanical Study on Narrowing of Indication Criteria

Authors:	H. H. Wetz[1], U. Hafkemeyer[1], J. Wühr[1] and B. Drerup[1]
Published in:	Der Orthopäde 34 (2005), 298-319

Objective

A critical evaluation shall serve to examine the manufacturer's indication criteria, and if necessary adjust or expand them using internal differentiation. The patient C-Leg system is compared with previously acceptable fitting for everyday use. It is anticipated that the patient will become more confident and perform better with a pattern closely approaching a natural gait.

Design

Subjects:	25 patients, activity levels (AL) 2 (5), AL 3 (13), and AL 4 (7).
Method:	Evaluation of seven functional benefit criteria: 1) increased safety, 2) relief for the contralateral side, 3) integration into the body's motor behavior, enabling sharing of attention, 4) walking at varying speed, 5) reduction of effort, 6) harmonization of the gait pattern, and 7) reduction in appliances used.
Familiarization period:	individually determined period of familiarization with the C-Leg trial fitting.
Measurement methods:	L.A.S.A.R. posture device for static alignment, GAITRite portable carpet for time-distance parameters, VICON system for kinematics, Kistler forceplates for kinetics, portable pulse oximetry system to record circulation parameters to determine the degree of effort expended, digital photographs, and video recordings.
Procedure:	In a first step, the final fitting with the existing prosthesis for normal, everyday use will be evaluated clinically and biomechanically. Components of the initially evaluated normal prosthesis:
Knee joints:	3R80, 3R60, 3R49, 3R40, Mauch XG, Endolite ESK, Total Knee, Teh Lin, KP3 Prosthetic feet: 1C40, Dynamik Plus 1D25, Dynamik 1D35, Seattle Light, Flexwalk, Variflex, Sach, Greisinger Plus. In the second step, the same methods are applied to evaluate the prosthesis in combination with the C-Leg.

Results

The Klinische Prüfstelle Münster (Clinical Testing Facility in Münster) has defined seven criteria for functional benefits that patients can achieve when using the C-Leg.

Almost all patients (23) – with the exception of one AL 2 and one AL 3 patient – showed a functional improvement according to least one of the criteria. Three patients met six or seven functional improvement criteria. At all activity levels, patients with multiple disabilities enjoy a functional benefit for at least one of the criteria when using the C-Leg. AL 2 patients can also achieve a considerable functional benefit arising from the use of the C-Leg, provided the mobility of the residual limb and the patient's muscular status and cognitive abilities are not significantly restricted. Active patients (AL 3 and 4) benefited most in this study. However, several highly active AL 4 patients indicated that they felt dominated by the electronically controlled knee component.

Conclusion for clinical practice: The indication should always be determined by trial fitting based on an assessment of the functional benefit. A one-day trial fitting is sufficient for patients with activity levels 2 and 3, while highly active patients should be given a one-week period to test the prosthetic joint.

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Function and Body Image Levels in Individuals with Transfemoral Amputations using the C-Leg

Authors: E. Swanson[1], J. Stube[2] and P. Edman[3]
Published in: Journal of Prosthetics and Orthotics 17 (2005), 80-84

Objective

On the basis of psychosocial and physical parameters, it was evaluated to which extent C-Leg users with transfemoral amputation residing in a defined region of the United States enjoyed greater independence, more personal satisfaction, and a positive body image in their functional role performance.

Design

Subjects: Eight transfemoral amputees, currently using the C-Leg, with no cognitive limitations.

Measurement methods/ assessment procedures: RNL (Reintegration to Normal Living Index) [11-item questionnaire covering a comprehensive set of day-to-day activities and relationships], Situational Inventory of Body-image Dysphoria (SIBID) [a multidimensional body image survey including a 5-point scale format covering 50 specific situations], Function and Body-Image Survey [six open-ended questions regarding personal thoughts, opinions, and experiences about the C-Leg, and the individual's current functional abilities].

Data analysis: SPSS statistical software package (version 11.0.1), Spearman's rho.

Results

The first hypothesis, that independence in functional role performance would be enhanced by the use of the C-Leg, was supported, to a statistically significant extent, by four RNL and SIBID categories. The higher an amputee's functional role performance, the higher his self-efficacy ($rs = 0.86$; $p < 0.01$), the higher his social integration ($rs = 0.74$; $p < 0.05$), the higher his comfort level with personal relationships ($rs = 0.71$; $p < 0.05$), and the lower his feelings of psychological distress ($rs = -0.77$; $p < 0.05$). The responses given in the category of social scrutiny were not found to correlate with functional role performance ($rs = 0.03$; $p > 0.05$).

The second hypothesis, that increased functional independence correlates with an enhanced body image, was not confirmed statistically. However, an inverse relationship was found whereby a person who experienced more independence in functional role performance experienced fewer dysfunctional feelings about body image ($rs = -0.43$; $p > 0.05$). The C-Leg users showed a high degree of role participation (including feelings of safety and security), functional activity (walking on an even surface, climbing stairs, effort/relaxation, work performance, and fewer exhaustion symptoms) and self-confidence (social integration). One significant correlation is that patients reported an improved body image as they were able to move with a more natural gait and felt safer and more secure in public due to the stance phase stability provided by the C-Leg.

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Embedment of Hip Disarticulation Prostheses with Ischial Containment

Author: D. Hauser[1]
Published in: Orthopädie-Technik 56 (2005), 408-411

Content

The article describes a new socket technique to be used in hip disarticulation patients. Proceeding from the idea of using an ischial containment socket technique in transfemoral amputees that had emerged in the 1980s, functional and comfort improvements provided by the new fitting option are outlined.

In his description, the author refers to the beneficial use of the C-Leg as a knee prosthesis component of a hip disarticulation prosthesis (as experienced in seven patients). The use of the C-Leg, which offers active stabilization of the stance phase, allows for a prosthetic alignment in which the knee center can be located in a more anterior position in comparison to conventional prosthetic knee joints. This makes the initiation of the swing phase much easier. As a result, patients report less backache and muscular tension. In addition, patients appreciate the higher level of safety provided by the C-Leg, which significantly reduces the risk of falling. The C-Leg also offers the possibility of walking downhill step-over-step in a more dynamic manner, without needing a sidestep maneuver to maintain a safe position.

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A Clinical Comparison of Variable-Damping and Mechanically Passive Prosthetic Knee Devices

Authors: J.L. Johansson[1], D.M. Sherill[1], P.O. Riley[1], P. Bonato[1], H. Herr[1]

Published in: American Journal of Physical Medicine and Rehabilitation 84 (2005), 563-575

Objective

Using kinetic, kinematic, metabolic, and electromyographic parameters, this investigation sets out to compare the differences between two prosthetic knee joints with electronic damping adjustment (Rheo Knee, Össur; C-Leg, Otto Bock) and a conventional, mechanically passive joint (Mauch SNS-Hydraulik) at self-selected walking speeds.

Design

Subjects:	Eight unilateral transfemoral amputees with an activity level (AL) of at least 3.
Methods/test setup:	The metabolic cost was measured on a 400-m indoor track at self-selected walking speeds, using a portable breath-by-breath telemetric system. For one and the same subject, the same speed was used for all tested prosthetic knees; this was ensured by a vehicle programmed to move in parallel at the speed chosen by the amputee. Kinematic and kinetic data were collected at self-selected walking speeds in a gait analysis laboratory using forceplates and an optoelectronic system. In addition, EMG electrodes were used to bilaterally record the activity of the gluteus maximus and gluteus medius muscles. Also, accelerometers were positioned at the thighs and shanks in order to collect related data.
Procedure:	Before the study began, each subject had approx. 10 hours to familiarize themselves with each tested knee prosthesis that was not his or her usual system. The order in which the knee prostheses were evaluated was randomized. Two systems were tested during the first session; the third knee prosthesis was evaluated on a second testing day. Manufacturer recommendations were followed when aligning each prosthesis.
Measurement methods:	Portable breath-by-breath telemetric system (Cosmed, K4b2, IT), accompanying vehicle with programmable velocity, forceplates and optoelectronic 3D motion analysis system (Vicon, Oxford Metrics, UK), EMG system (Motion Labs, LA), acceleration sensors (Temec B.V., NL).
Prosthetic foot:	the Allurion foot (Össur) was used for all prostheses.
Prosthetic socket:	was the same for each of the three tested knee systems.

Results

The metabolic cost measurement showed that the subjects walked with the three knee systems at significantly differing speeds. The rate of oxygen consumption for users wearing the Rheo knee was 5% lower than with the hydraulic-based Mauch system (statistically significant) and 3% lower than with the C-Leg (not significant). There was a 2% difference between the C-Leg and Mauch systems (not significant).

The only difference in the time-distance parameters occurred for the step time, which was longer for use of the Rheo knee compared with the C-Leg and Mauch prostheses. No significant differences or trends were recorded for the unaffected side. In comparison to the variable-damping systems, the hydraulic-based Mauch prosthesis was found to show greater negative hip work production in the stance phase, greater positive hip work production in the swing phase and a larger peak hip flexion torque at terminal stance. For the Mauch, a larger peak hip power generation was measured at toe-off. For the Rheo knee, the lowest peak hip extension torque values were recorded during late swing. With the C-Leg, the peak knee extension angle was found to be largest during terminal swing. The same applies to angular velocities (both findings significant). The hydraulic-based Mauch system showed higher values for peak knee extension torque at toe-off. Peak knee flexion torque during terminal swing was lowest for the Rheo knee (both significant). Both plantarflexion and foot compression were found to be largest during early stance when using the Rheo knee and the hydraulic Mauch system. During mid to terminal stance, the Rheo and Mauch prostheses had lower peak dorsiflexion torques than the C-Leg. Also, plantarflexion torques were higher with the C-Leg for about 30% of the gait cycle. The EMG data analysis showed that the Rheo knee was associated with a lower level of muscular activity compared with the other systems. Movements of the variable-damping systems were performed more harmoniously than those of the mechanically passive, hydraulic-based Mauch system. This was documented by the recorded accelerometer data.

The findings arrived at for the various aspects suggest that magnetorheological-based systems have advantages over hydraulic-based systems. Likewise, the results make clear that electronically controlled, variable prosthetic knee joints present some significant advantages over mechanically passive damping systems.

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Analysis of the Socio-Medical Evaluation Following Prosthetic Fitting of the Electronic C-Leg Knee Joint

Authors: R. Lindig[1], K. Stahl[1], U. Heine[1]
Published in: Medizinisch Orthopädische Technik 124 (2004), 65-73

Objective of publication

Indication criteria are reviewed and assessed on the basis of a socio-medical evaluation of prosthetic C-Leg fittings, leading to the request for an individual assessment of the insured, of his or her previous fittings, and of the benefit that may be expected from a C-Leg fitting.

Content

In the introductory section, the indication criteria of the C-Leg and the characteristics specified by the manufacturer are outlined. In addition to the prescription and justification by the prescribing physician, which previous experience shows are likely to be inadequate, a request is made to implement a multidisciplinary evaluation of the insured. At the Medical Service of the Public Health Insurance Companies, Westfalen-Lippe Region (MDK-WL), an evaluation of the criteria required for assessment such as necessity, suitability and cost efficiency is carried out by a team consisting of physicians specializing in social medicine and a certified prosthetist/orthotist. Apart from a mobility grade classification, this procedure also comprises individual assessments of the following aspects: review of the patient's general clinical status, day-to-day activities, family duties such as childcare or looking after family members in need of care, occupations with special mobility requirements, pain problems, personal wishes or preferences and expectations as to mobility, special consideration of the residual limb, evaluation of previous fitting, and inspection of static alignment, as well as a visual analysis of stance and gait, daily walking and wearing time, and an assessment of the achievable activity level.

This procedure is outlined using 17 insured individuals who were evaluated in 2002 and 2003 and had applied for a C-Leg fitting. The authors highlight the importance of an individual assessment. There appears to be a special need for an evaluation of the previous prosthetic fitting. Following a check of socket fit, prosthetic alignment, and functionality of components, as well as of a potentially necessary correction and improvement, the added functional benefit that the C-Leg provides to the amputee should be evaluated first. The amputee must meet certain physical requirements to fully benefit from all advantages. The safety aspect alone does not constitute an indication. Depending on each individual case, childcare or the necessity of looking after family members in need of care can be an indication criterion. Following a trial fitting, insured individuals with multiple disabilities should be thoroughly evaluated. A C-Leg fitting is not necessarily suitable for these patients. The authors state that the C-Leg is optimally suited to active outdoor walkers who are able, despite having received optimal previous fittings, to compensate for further limitations of their abilities caused by the amputation. To this end, they require certain mental and physical prerequisites in order to be able to make use of the functional advantages of the C-Leg, such as efficient walking at high speeds, safety on uneven terrain, safe step-over-step walking on stairs and slopes. As a prerequisite to an optimal prosthetic fitting, the authors stress the importance of the generally requested good socket fit, the best possible prosthetic alignment and an exact joint parameter adjustment.

1 Medizinischer Dienst der Krankenkassen, Westfalen-Lippe, Bielefeld (Medical Service of the Public Health Insurance Companies, Westfalen-Lippe region, Bielefeld/Germany)

Measurement of Knee Center Alignment Trends in a National Sample of Established Users of the Otto Bock C-Leg Microprocessor-Controlled Knee Unit

Authors: L. L. Willingham[1], N. C. Buell[1], K. J. Allyn[1], LCPO, B. J. Hafner[1] and D. G. Smith[1]
Published in: Journal of Prosthetics and Orthotics 16 (2004), 72-75

Objective

C-Leg prosthetic fittings were evaluated in terms of the knee center being aligned "too stable" or "too posterior", using the distances between the reference line and the knee center that were measured with the L.A.S.A.R. posture device (Otto Bock) in the course of a static alignment analysis, as well as findings of a subjective visual analysis of gait patterns. As a result, it can be evaluated if the alignment or positioning of the C-Leg, especially in the sagittal plane, corresponds to the recommendations issued by the manufacturer, and if the amputee is able to benefit from all advantages the C-Leg offers, or whether incorrect alignment leads to functional deficits.

Design

Subjects: 21 transfemoral amputees, currently using the C-Leg.

Measurement methods: Capture of the static prosthetic alignment using the L.A.S.A.R. posture device, visual gait analysis carried out by a certified prosthetist/orthotist with extensive clinical experience.

Results

In 20 of the 21 participants, the prosthetic limb was aligned with the knee center posterior to the L.A.S.A.R. posture reference line (0-79 mm; mean 39 mm). In one case, the knee center was in the reference line. Only one prosthesis met the alignment recommendation contained in the training course material for C-Leg fitting, which states that the knee center should be aligned 0 to 5 mm anterior to the reference line. The visual gait analysis revealed deviations from normal gait patterns, such as decrease in weight shift, lateral trunk lean, pelvic obliquities, decrease in hip extension, uneven arm swing, hip hiking, uneven step length, abnormal swing phase, and uneven heel rise/vaulting. These deviations are due to suboptimal prosthetic alignment.

Published Comment on the Above Study

Author: J. E. Uellendahl[2]
Published in: Journal of Prosthetics and Orthotics 17 (2005), 97-99

Content

Uellendahl initially states that the classic prosthetic alignment procedure consists of three steps: 1) bench alignment, 2) static alignment optimization (for example using the L.A.S.A.R. posture device), and 3) dynamic alignment optimization. According to the author, the manufacturer's recommendation for the positioning of the C-Leg knee center relates to bench alignment (first step), not to static alignment optimization with the L.A.S.A.R. posture device (second step), as assumed in the study. In addition to the manufacturer instructions on the knee center, the position of the prosthetic foot must be considered. As regards the positioning of the prosthetic limb during the static alignment optimization procedure with the L.A.S.A.R. posture device, Uellendahl refers to an alignment recommendation presented by Blumentritt at the 2004 ISPO Meeting in Kong Kong. This recommendation states that the knee center be aligned 30 mm posterior to the L.A.S.A.R. load line. In conclusion, Uellendahl considers the authors' interpretation of results as inaccurate. Citing a patient example, he comments on the statement of the original article that stance phase flexion should be performed only if the knee center is located on or anterior to the L.A.S.A.R. load line. According to him, his patient performed a clear initial knee flexion during loading response, despite the fact that the knee center had been aligned 42 mm posterior to the L.A.S.A.R. load line. However, Uellendahl also supports the opinion that an unfavorable static alignment considerably limits the overall functionality of the prosthetic fitting.

1 Prosthetics Research Study (PRS), Seattle/USA
2 Hanger Prosthetics & Orthotics, Phoenix/USA

Response of the Authors to Uellendahl's Comment

Author: L. L. Willingham[1], N. C. Buell[1], K. J. Allyn[1], LCPO, B. J. Hafner[1] and D. G. Smith[1]
Published in: Journal of Prosthetics and Orthotics 17 (2005), 100-102

Content

In response to Uellendahl's statement that the recommendation (0 to 5 mm anterior to the reference line) refers to bench alignment, the authors refer to the C-Leg fitting training course manual published by the manufacturer in 2001. There it says, "Alignment of the knee center 0 to 5 mm anterior to the load line." The interpretation of the term "load line"led to the assumption that the recommendation related to the static alignment optimization with the L.A.S.A.R. posture unit (second step). In addition, the authors point out that Blumentritt presented his recommendations to the 2004 ISPO Meeting in Hong Kong one month after publication of the study, and that a revised version of the C-Leg fitting training course materials has not been published yet. Regarding the data gathered in the study, the authors state that, nonetheless, approx. 50% (11 of 21) of prosthetic fittings were aligned "too stable" compared to manufacturer specifications, and that this situation resulted in deviations from the normal gait pattern. For this reason, further investigations are considered necessary in order to provide recommendations for optimal prosthetic alignment.

1 Prosthetics Research Study (PRS), Seattle/USA

Biomechanical Aspects for the Indication of Prosthetic Knee Joints

Author: S. Blumentritt[1]
Published in: Orthopädie-Technik 55 (2004), 508-521

Objective of publication

Presentation of a biomechanics-based classification of prosthetic knee joints as a basis for fitting in line with the indication.

Content

This article presents a possible classification of prosthetic knee joint indications that considers biomechanical aspects. A comprehensive introductory section describes the biomechanical characteristics of the sound knee joint and of the walking process using a transfemoral prosthesis. In the following parts of the article, the expected and envisaged degree of rehabilitation of an amputee is compared with the technical and functional options provided by various prosthetic knee joint designs. This establishes a basis for judging which design is best suited to the specific type of rehabilitation.

Based on the remaining motor ability to control the prosthesis via the residual limb, various everyday movements can be performed that are enabled or supported to a varying extent by certain prosthetic knee joint designs. The ability of the amputee to walk down stairs or slopes safely step-over-step and to sit down while loading the prosthetic limb side constitute a high degree of rehabilitation. Such movements can be performed only with prosthetic knee joint designs that allow flexion under load to overcome a certain resistance (yielding). In addition, a natural gait pattern ranks among the essential requirements of the amputee. This can be met, on the one hand, by a swing phase control that is operated according to walking speed and, on the other hand, by a possible initial stance flexion.

Within the presented classification, the C-Leg has a special status. Due to the integrated sensor technology capturing individual gait situations and the derived joint resistances, the patient no longer has to actively control the prosthesis, allowing residual limb action to be fully used for the motor sequence of walking, without having to stabilize the stance phase. According to the mobility grade classification, the prosthetic joint is suitable for grades 2 to 4. Amputees with lower mobility grades undoubtedly benefit from the high safety potential offered by the joint. Active patients also benefit from this high degree of safety, as the possibility of walking safely on uneven terrain extends the environment that they can actively explore. In addition, the microprocessor-controlled swing phase adaptation allows for dynamic walking at varying speeds. However, very active amputees may feel that they lose a certain degree of control over their movements due to the activity of the electronic control unit.

1 Otto Bock HealthCare GmbH, Duderstadt/Germany

Energy Expenditure and Gait Characteristics of a Bilateral Amputee Walking With C-Leg Prostheses Compared With Stubby and Conventional Articulating Prostheses

Authors: J. Perry[1], J. M. Burnfield[1], C.J. Newsam[1], P. Conley[1]

Published in: Archive of Physical Medicine and Rehabilitation 85 (2004), 1711-1717

Objective

This single-case study was to quantify differences in metabolic energy expenditure between short (stubby) prostheses without a knee joint, normal-length prostheses with a conventional Mauch SNS hydraulic system and prostheses with the C-Leg. In order to evaluate loads and motor behavior, an additional gait analysis was carried out as a complement to C-Leg fitting.

Design

Subject: A male patient who underwent bilateral knee disarticulations and bilateral transradial amputations after the onset of meningococcemia.

Method: After each of the three prosthetic fittings, the patient received separate gait training. Wearing the short prostheses and the prostheses with conventional knee joints, the patient was subjected to a measurement of metabolic energy expenditure and an analysis of gait characteristics on two different days in 1997. Following C-Leg fitting in 2003, additional measurements were performed to collect kinematic and kinetic data.

Metabolic energy expenditure was measured on a 60.5 m outdoor track. The subject was to walk for 20 minutes at a self-selected pace. At the beginning of the exercise and after 3, 9, 14, and 19 minutes, samples of expired air were taken and analyzed for oxygen and carbon dioxide concentration, and the oxygen cost was calculated (mL O2/kg/m). These results were expressed as a percentage of values found in healthy individuals (N = normal). The distance traveled during the indicated period was measured. Soles fixed under the shoes were used to measure stride characteristics. For the C-Leg, kinematic and kinetic data were recorded as the subject walked across a 10 m indoor walkway using integrated forceplates and an optoelectronic 3D motion analysis system. Only the right-hand side was evaluated.

Measurement methods: Modified Douglas bag system fitted with a one-way valve, Stride Analyzer with insoles for measurement (B&L Engineering, CA), Kistler forceplates (Kistler Corp., NY) to record ground reaction forces, Vicon 3D motion analysis system (Oxford, UK).

Foot components used: Stubbies: Seattle Lite Foot; prostheses with conventional knee joints: Seattle Lite Foot and Standard Multiflex Ankle (Endolite), C-Leg: Luxon Max (Otto Bock).

Prosthetic socket: Ischial containment and supracondylar suspension/undercut in all cases.

Results

During energy expenditure measurement, the subject walked faster (71.5 m/min) and farther (1,430 m) when wearing the C-Legs than with prostheses with a conventional knee joint (805 m, 41.3 m/min) or stubbies (772 m, 38.6 m/min). The rate of oxygen consumption (mL O2/kg/min) was highest with the hydraulic-based Mauch prostheses (118%-148% N), followed by the stubbies (95%-124% N) and the C-Legs (94%-102% N). By contrast, oxygen cost (ml O2/kg/m) was significantly lower with the C-Leg (120%-167% N) than with the stubbies (212%-225% N) and the Mauch prostheses (265%-304% N). Both at rest and while walking, the subject's heart and respiratory rates were highest for the C-Leg (2003). Following fitting of the Mauch hydraulic prostheses in 1997, the patient considerably reduced his physical activity as he started using a motorized wheelchair to overcome longer distances. Later, this also applied to his C-Leg use. Therefore the elevated resting heart and respiratory rates while wearing the C-Legs are to be attributed to a state of deconditioning. The C-Leg advantages arising from the physiological parameters (oxygen consumption and cost) are to be considered more significant.

The analysis of kinematic and kinetic data showed that the gait pattern of a patient with bilateral knee disarticulations is almost identical to that of a unilateral amputee. The C-Leg prosthesis does not directly contribute to a noticeable gait improvement but seems to significantly reduce the muscular effort while also enhancing safety. Additionally, the subject needed a forearm crutch when walking with the hydraulic-based Mauch prostheses while he did not require any aids with the C-Legs.

1 Pathokinesiology Laboratory, Rancho Los Amigos National Rehabilitation Center, Downey/USA
Hanger Prosthetics & Orthotics, Downey/USA

Indications for the C-Leg – Fundamentals and Decision-Making Aids

Authors: H. Kristen, R. Nimmervoll
Published in: Medizinisch Orthopädische Technik 124 (2004), 67-77

Objective of publication

This article sets out to provide health insurance companies with fundamentals to aid their decision-making process on covering the cost of a C-Leg fitting. The publication refers to a procedure being practiced in Austria that serves as a basis for the ultimate decision.

Content

In the introductory section, the authors state that the technical and functional potential of the C-Leg, and thus the advantages for the patient, can be fully used if certain requirements are met. They deal thoroughly with the fundamentals of any prosthetic fitting. One of the authors' core statements is that it is not only the selection of components that is instrumental to the patient's successful rehabilitation but also, to a considerable extent, the physical constitution of the amputee. A prosthetic fitting needs to be seen as an overall concept that requires optimal fit of the socket as the interface between body (residual limb) and appliance (prosthesis) and an optimal prosthetic alignment.

As one distinct C-Leg feature, the unique combination of a harmonious swing phase control over a wide speed range with a high degree of safety due to the stance phase damping in case of sudden disruptions of the gait cycle is mentioned. From the authors' point of view, the use of walking aids, walking at low speeds, and restricted motor capability of the residual limb when controlling the prosthesis on stairs or inclines constitute contraindications for the use of a C-Leg. By contrast, patients with weaknesses on the unaffected side or additional amputations (also upper extremity) enjoy benefits resulting from the safety of the C-Leg. When looking exclusively at the safety aspect of a prosthesis, however, the authors state that the required orthopedic technology expertise and other components available on the market could also be used to provide a high degree of safety to the patient.

The characteristics and requirements that a prosthetic knee joint should fulfill in the individual phases of walking are described extensively. In addition, factors relating to prosthetic alignment that would lead to unfavorable functional characteristics of the prosthesis are mentioned. Owing to its most diverse adjustment parameters, the C-Leg offers the possibility of adjusting the prosthesis optimally to the individual phases of the gait cycle. This requires extensive knowledge of the biomechanical situation of the amputee and the properties of the prosthetic joint. In this respect, the authors point out that the prosthetic alignment should be optimal also when a C-Leg is fitted. The electronic control unit of the joint might compensate for unfavorable alignment. Therefore the utmost degree of care should be applied. As a critical factor, the adjustment of the so-called forefoot load is mentioned, which is important when it comes to switching from the stance phase resistance to the low swing phase resistance. Incorrect adjustment may lead to malfunctions.

The authors recommend implementing a quality control scheme when using higher-price components such as the C-Leg. This scheme would involve a gait analysis and a clinical examination (including documentation of socket fit and prosthetic alignment) of both the previous fitting and the C-Leg trial fitting. In order to objectively aid the decision-making process, this examination should be carried out even before the health insurance provider agrees to cover the cost of fitting. In addition, quality checks should be performed after C-Leg fitting. Besides functional checks, an incorrect alignment or inadequate socket fit can also be detected and modified, providing an added benefit to the overall prosthesis concept. The authors cite three examples to demonstrate the criteria used in Austria to consent to, or refuse, a C-Leg fitting based on these quality control procedures. According to this approach, there are the following indication criteria: good physical performance, an achievable walking speed of 5 km/h, a good gait pattern without walking aids (low step and load asymmetries), and the full utilization of all features. On the other hand, contraindications are a lasting poor physical performance, a low walking speed of 3 km/h, a gait pattern that has not improved, weak residual limb muscles, and the lack of the ability to make full use of the potential of the prosthetic joint. An interdisciplinary cooperation of all parties involved in the fitting process should be envisaged in order to ensure optimal C-Leg fitting.

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Rehabilitationszentrum Weißer Hof, Klosterneuburg (Weisser Hof Rehabilitation Center, Klosterneuburg/Austria)

The C-Leg Experience – A Gait Analysis Comparison with Conventional Prosthetic Knee Joints

Authors:	R. Nimmervoll[1], J. Kastner[1], H. Kristen[2]

Published in:	Orthopädie-Technik 54 (2003), 562-565

Objective

Gait analysis procedures were to be applied to objectively show if and to what extent the C-Leg offers advantages to the amputee compared with conventional, swing phase-controlled prosthetic knee joints. These evaluations should be used for the definition of indication criteria and serve to document fitting results that the Austrian social insurance institutions require to consent to a C-Leg fitting.

Design

Subjects:	50 transfemoral amputees, fitted with conventional prosthetic joints.
Method/test setups:	Static alignment analysis positioning the prosthetic side on a forceplate (loading situation), walking on a level floor at self-selected speed (ground reaction forces), walking on the treadmill at 3, 4 and 5 km/h (kinematic parameters of knee and hip joints).
Measurement methods:	Kistler forceplates with linked video recording to define the vector on the image and integrated measurement software to determine the point of applied force; 2D kinematic analysis (50 Hz online kinematics), treadmill, variance analysis with ANOVA 2.
Procedure:	Static alignment check and correction of prosthesis for everyday use according to alignment guidelines if required, subsequent gait analysis measuring ground reaction forces and treadmill test to gather kinematic data, followed by a prosthesis conversion to the C-Leg and repetition of the tests after a one-day familiarization phase with gait training. Prosthetic joints for everyday use: 31 single-axis and 19 multi-axis joints, of which 15 use pneumatic and 35 with hydraulic swing phase control.

Results

The C-Leg achieved a better symmetry in terms of load duration and magnitude while attaining a slightly higher walking speed. At the speeds measured on the treadmill, the knee angle courses were significantly closer to those on the unaffected side when using the C-Leg. With the C-Leg, the mean knee angle difference between slow and fast walking was less than 10° while this value amounted to 16° when using the other joints. In addition, the hip flexion velocity during initial swing and the knee angle velocity during terminal swing phase extension were lower than for the conventional joints. Both values were closer to those recorded for the unaffected side. In general, significantly better symmetry was found between the C-Leg and the sound side. Amputees mentioned that the C-Leg enabled a smoother course of movement that required less effort. Subjects with the ability to move on uneven terrain and on inclines emphasized the particularly safe heel strike. The gait deviations found in isolated cases were due to the amputees' motor deficits and were not compensated by using the C-Leg alone. Amputees with restricted motor abilities require thorough gait training to become familiar with all existing C-Leg features and advantages.

1 Rehabilitationszentrum Weißer Hof, Klosterneuburg (Weisser Hof Rehabilitation Center, Klosterneuburg/Austria)
2 Forschungsinstitut für Orthopädietechnik Wien (Institute for Orthopedic Technology Research, Vienna/Austria)

Energy expenditure and biomechanical characteristics of lower limb amputee gait: The influence of prosthetic alignment and different components

Authors:	T. Schmalz[1], S. Blumentritt[1], R. Jarasch[2]
Published in:	Gait and Posture 16 (2002), 255-263

Study Objectiv

The influence of prosthetic alignment and various prosthetic components on the energy expenditure and biomechanical characteristics in lower limb amputees was investigated.

The following discussion refers exclusively to transfemoral amputees.

Study Design

Method:	The evaluation of transfemoral amputees is split in two approaches: 1. (T3) Energy expenditure and biomechanical gait parameters with the same prosthetic knee joint (3R80, rotary hydraulics, Otto Bock HealthCare) and an identical prosthetic foot (1D25, Otto Bock HealthCare) with different prosthetic alignments (isolated sagittal displacement of the knee joint by 1 or 2 cm from its optimal alignment position in anterior and posterior direction); 2. (T4) Energy expenditure during walking with a conventional uniaxial knee joint with Mauch SNS hydraulics (3C1, Otto Bock HealthCare) and a microprocessor-controlled knee joint (C-Leg, Otto Bock HealthCare) and an identical prosthetic foot (1D25, Otto Bock HealthCare) with optimized prosthetic alignments in each case.
Measuring equipment:	Treadmill (Enraf Nonius, Netherlands) to control walking speed, CPX system (Med Graphics, USA) to measure oxygen consumption, heart rate monitor (Polar Electro Oy, Finland), capture of biomechanical parameters when walking on level ground using an optoelectronic camera system (Delft Motion Analysis, Netherlands) in combination with force plates (Kistler, Switzerland).
Procedure:	Prior to the tests, an extensive treadmill adaptation phase was used to determine a comfortable walking speed for each patient. Thereafter, prosthetic alignment was documented using the L.A.S.A.R. Posture device, and a gait analysis performed. The protocol to measure energy expenditure included 15 minutes of walking on the treadmill at three different speeds (five minutes each): 1. a medium, self-selected speed (3.0 to 3.8 km/h with the 3R80, 2.9 to 4.2 km/h with the 3C1 and C-Leg), 2. a slow speed (-20%), and 3. a fast speed (+20%). For the purpose of the analysis, oxygen consumption and heart rate were each averaged over the last minute in steady state. The alignment tests for the 3R80 knee joint were carried out in the following sequence: optimal alignment, knee 1 cm posterior, knee 2 cm posterior, knee 1 cm anterior, knee 2 cm anterior. Patients were granted 30 minutes of relaxation between these tests.
Group of subjects:	For all subjects, inclusion criteria were unilateral transfemoral amputation, trauma as the reason for amputation, and a daily walking distance of at least 5 kilometers without aids. T3: 6 patients (33 ± 6 years, period since amputation 13 ± 6 years), T4: 6 patients (37 ± 7 years, period since amputation 13 ± 9 years).

Results

T3 (alignment variations using 3R80): Average walking speeds and step lengths showed no significant difference across all alignment variations. By contrast, important biomechanical parameters were influenced significantly. For instance, in the mid-stance phase, a systematic increase in the external sagittal hip moment was observed in line with the degree of knee displacement in anterior direction. This increase must be compensated by higher activity of the hip extensors in order to prevent knee joint collapse. The displacement of the knee joint in posterior direction had no significant influence on metabolic energy expenditure whereas the anterior displacement led to a significant increase in energy expenditure for all walking speeds tested. A significant heart rate increase was measured only in the case of a 2 cm displacement in anterior direction and at the fast walking speed.

T4 (comparison of 3C1 Mauch SNS and C-Leg): When using the C-Leg, a significant reduction in oxygen consumption by 6 to 7% was measured during walking at medium (and to a certain extent slow) speeds. At the high speeds, the 4% reduction in consumption is not statistically significant. The heart rate revealed similar patterns but showed no significant difference across all walking speeds.

According to these tests, prosthetic alignment has a crucial influence on metabolic energy expenditure. This means that the 2 cm displacement in anterior direction from the optimal alignment results in a distinct increase in oxygen consumption by 13%. Compared with a knee joint with a Mauch SNS hydraulics system, the C-Leg provides a reduction in metabolic energy expenditure across a wide range of speeds.

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2 Orthopaedic Workshop, Otto Bock HealthCare GmbH, Göttingen, Germany

Performance of Various Prosthetic Knee Joints Fitted to Transfemoral Amputees when Walking Down Stairs[1]

Authors:	T. Schmalz[2], S. Blumentritt[2] and R. Jarasch[2]
Published in:	Orthopädie-Technik 53 (2002), 586-592

Objective

The performance of various prosthetic knee joints offering the possibility of walking down stairs step-over-step through yielding is to be evaluated against performance of a group of healthy controls.

Design

Subjects:	12 transfemoral amputees and 21 healthy participants.
Method/test setup:	2-step stair with a DIN standard step height (17.5 cm), lower step in contact with forceplate.
Measurement methods:	Kistler forceplate (scan rate 400 Hz), optoelectronic kinematics measurement system (Primas, scan rate 100 Hz).
Components used:	3C1 (Mauch, hydraulic), 3R80 (rotary hydraulic), C-Leg (electronically controlled hydraulic unit), standard prosthetic foot 1D25 (all components manufactured by Otto Bock HealthCare GmbH).
Measurement procedure:	Following an intensive trial phase, subjects performed six valid attempts on the step arrangement, and repeated these attempts once. In one session, their unaffected side came into contact with the measuring step; in the other the behavior of the prosthesis side was measured.

Results

In all cases, the C-Leg was placed at the top of the ranking established by the subjects wih respect to subjective overall comfort. Nine participants ranked the 3R80 second, three ranked the 3R80 third. Correspondingly, the 3C1 ranking was inverse. The recorded horizontal ground reaction forces show that walking with the C-Leg contributed to a reduction in the load acting on the contralateral side. When making contact with the step, subjects exerted more force on their prosthesis side compared to the 3R80 and the 3C1, which leads to a lower force impact during the following step made with the unaffected side. Quickly relieving the prosthesis side at the end of the stance phase, as observed with conventional joints, was not seen with the C-Leg. This also contributed to relieving the healthy side. The course of both knee angle and knee and hip moments was more natural with the C-Leg than with the other two prosthetic joints. The C-Leg does not require any special control mode or activity in order to use stairs. In order to activate the stance phase resistance, the load-dependent stance phase stabilization provided by the 3R80 requires a hip joint extension to be performed by the amputee shortly after making contact with the step.

1 Die vollständige Studie kann als Sonderdruck unter dem Kennzeichen 646D163 bzw. 646D163=GB bestellt werden.
2 Otto Bock HealthCare GmbH, Duderstadt

Gait Analysis Assessment of Knee Joint Settings and Prosthetic Alignment using the Sensor Technology Integrated in the C-Leg Knee Joint

Author: R. Pawlik
Published in: Orthopädie-Technik 52 (2001), 505-509

Objective of publication

This article initially describes the C-Leg sensor technology and goes on to evaluate to what extent sensor data can be used as an aid to assess knee joint settings and prosthetic alignment.

Content

To capture current step data, a knee angle sensor, ankle moment sensor and axial force sensor are used. During walking, recorded data can be transmitted, via a cable connection, to a desktop or laptop computer, and can be visualized using a software package. Additional captured parameters include the settings of the extension and flexion valves. The authors mention that this method has advantages over a gait analysis performed in the laboratory as it can be practiced quickly and both outdoors and on stairs. However, relatively few parameters are available, and these are restricted to the prosthesis side.

On the one hand, the knee joint setting can be assessed using the course of the knee angle. During swing, this angle usually equals approx. 60 to 65° and should show only a minor increase during fast walking. On the other hand, stance phase flexion and extension can be captured. This serves as a means of checking whether the amputee makes use of this joint feature and if the settings are optimal.

Alignment modifications were performed on one subject in order to assess the possibility of optimizing the alignment by using the software referred to above. These included changes in the plantarflexion of the prosthetic foot (1D25, Otto Bock) and in the socket preflexion, which were carried out using a sliding adapter in the sagittal plane, and documented. At a plantarflexion angle of 97° (i.e. the angle between the line connecting the greater trochanter with the foot center and the floor the amputee stood on), the amputee experienced a comfortable roll-over behavior with a transition from heel load to forefoot load at approx. 30% of the stance phase duration, according to the software. In the case of insufficient plantarflexion (94°), this transition occurred later (at approx. 37% of the stance phase duration). There was also an increase in stance flexion. When investigating the impact of various socket preflexion angles (i.e. the angle between the line connecting the greater trochanter with the foot center and the longitudinal axis of the socket), it was found that a 6° flexion (i.e. 2° above the optimum of 4°) led to a minor, visible asymmetry with shorter steps made with the prosthesis. A zero-degree socket preflexion resulted in a step length increase. In addition, the amputee had to perform a more significant extension after heel strike in order to avoid excessive stance flexion. This compensatory movement increased the pressure on the ischium. Many of these changes, such as the step length asymmetry, cannot be recognized on the graphs generated by the software. The only noticeable change is the higher heel strike dynamics at zero-degree socket preflexion.

The use of the software can support the correct adjustment of the knee joint. The prosthetic alignment in the sagittal plane can be supported only on the basis of extensive experience as the graph variances may be caused by various factors. For this reason, additional methods are required to optimize alignment, such as the visual gait analysis. It is possible, however, to capture both positive and negative impacts of alignment modifications.

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The C-Leg Knee Joint System – Clinical Fitting Statistics

Author: L. Köcher[1]
Published in: Medizinisch Orthopädische Technik 121 (2001), 129-134

Objective

This study sets out to statistically process and analyze fitting data gathered during the controlled market launch of the C-Leg after its presentation at the 1997 World Congress in Nuremberg/Germany.

Design

Subjects: 108 randomly selected transfemoral amputees (90 from Germany, 18 from Austria); the mean period between amputation and C-Leg fitting was 16.9 years; the mean duration of C-Leg use amounted to 9.6 months.

Method: Telephone interview using a specially designed questionnaire containing four sections (data collected: 1) personal details, 2) information about the social environment of the respondent, 3) data regarding the prosthetic technology used for current and previous fittings, and 4) assessment of prosthetic fitting). Sections 1 to 3 were answered on the basis of closed questions; Section 4 consisted of open-ended questions. Sections 1 and 2 were to be answered primarily by amputees, Section 3 by the technician and Section 4 by both. The interviews were conducted by just one person between July and September 1999.

Results

In 78% of cases, the amputation was the result of trauma. The “average residual limb” was medium to long with a conical shape and fully developed residual limb force. Further limitations or disabilities were presented by 30% of the amputees. They had sufficient stance stability (i.e. standing with the prosthesis without any other aids), showed no signs of paralysis or vestibular disorders and were not affected by impaired vision or cardiovascular diseases.

The survey demonstrated that the private and social environments were very diverse. The environments were characterized by high demands imposed on amputees as a result of their work and lifestyles since many of them traveled long distances (judging by their ability to walk in terms of distance and duration) (1-5 km: 52 mentions, > 5 km: 31 mentions; 60-120 minutes: 28 mentions, >120 minutes: 56 mentions). In some cases, hobby activities also contribute to higher strain and stress. Of the respondents, 93% were classified as Mobility Grades 3 (unrestricted outdoor walker) and 4 (unrestricted outdoor walker with especially rigorous demands). Components used in previous fittings - both knee joints and feet - indicated the above-mentioned medium-to-high functional demands of amputees. Respondents indicated a high degree of satisfaction with, and acceptance of, their fittings (101 of 108 patients reported a fitting improvement). In particular, they mentioned a significant improvement in motor behavior and a considerably higher degree of protection against buckling of the prosthesis.

As a result of the high degree of safety offered by the C-Leg in many situations (such as climbing stairs, mastering inclines or walking on uneven terrain), many amputees enjoyed an expansion of the living environment that they can actively explore, which contributed to an increase in their quality of life. Likewise, subjects reported better integration into work and family due to significantly enhanced self-esteem. Another important factor was the relief experienced on both the prosthesis and the unaffected side, and on the entire trunk, as a result of reduced effort.

Aspects mentioned by amputees that compared negatively with previous fittings related to a more complicated connection of the charging cable (due to prior removal of cosmetic cover) and to the necessity of recharging the battery daily. However, these disadvantages were accepted after weighing them against all existing advantages. The wide range of activity levels and mobility grades of amputees enrolled in this study suggests that the C-Leg might also be fitted to patients not classified in the medium to high levels or grades. Thus amputees with lower activity levels and mobility grades also benefit from the high degree of safety, in particular in the case of initial fitting, and later on from the C-Leg’s adaptability to various gait situations.

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Biomechanics and Evaluation of the Microprocessor-Controlled Exoprosthetic C-Leg Knee Joint

Author: H. Stinus[1]

Published in: Zeitschrift für Orthopädie 138 (2000), 278-282

Objective

A clinical survey of amputees fitted with the C-Leg and their orthopedic technicians sets out to evaluate the function of this prosthetic knee joint, which includes a microprocessor-controlled stance phase stabilization and swing phase control, in comparison to previously fitted conventional prostheses.

Design

Subjects:	15 transfemoral amputees, both with and without limitations or disabilities of other limbs (upper and lower extremities).
Method:	Post-marketing surveillance study over a period of 6 to 14 months, including a survey of amputees and their technicians who fitted their prostheses.
Questions to the orthopedic technician:	Assessment of adjustment range, functionality, gait pattern, and patient acceptance compared to the previous fitting; scale of 1 to 4 to be applied (reaching from “significant improvement” to “significant deterioration”).
Questions to amputee:	Assessment of stance phase stability, swing phase control, and dynamics of the knee joint compared to previous fitting; scale of 1 to 4 to be applied (reaching from “significant improvement” to “significant deterioration”); additional question to amputee whether he/she would recommend the C-Leg to other patients (Yes/No); determination of activity level (walking duration and distance), socket, and components of previously fitted prosthesis (prosthetic knee joints and feet).

Results

On average, patient activity can be considered high, which is supported by the reported leisure activities (such as cycling or hiking) and the mean daily walking distance (1-5 km) and duration (60-120 min). Likewise, the components used in previous fittings suggest a physically active patient population. Of interest is the fact that participants with multiple disabilities indicated a generally higher activity level after C-Leg fitting than unilateral amputees. This suggests that patients with multiple disabilities in particular benefit from the C-Leg. All amputees reported an expansion of their range of action as a result of C-Leg use and assigned a “1” (“significant improvement”) to stance phase stability, swing phase control, and dynamics of the C-Leg. They would also recommend the component, without exception. Two subjects reported that they stumbled during the study period but could avoid falling. According to their statements, such a situation would inevitably have resulted in a fall with the previously fitted prosthesis. Orthopedic technicians graded both adjustment range and functionality with a “1” (“significant improvement”) while the gait pattern received an average grade of 1.2. During the entire testing phase, three defects occurred in the electronic unit but the integrated safety mode worked properly. The causes of these defects were remedied and optimized in series production. The only negative point mentioned was the higher price of the C-Leg.

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„What does the C-Leg achieve?“ – A Gait Analysis Comparison of C-Leg, 3R45, 3R80

Authors: J. Kastner[1], R. Nimmervoll[2], P. Wagner[2]

Published in: Medizinisch Orthopädische Technik 119 (1999), 131-137.

Objective

Using an instrumental gait analysis, the value of a computer-based mechanical control unit shall be evaluated and its possible advantages discussed.

Design

Subjects:	Ten unilateral transfemoral amputees.
Methods/test setups:	Evaluation of the loading by ground reaction forces, investigation of swing phase behavior aided by kinematic data gathered on the treadmill (3, 4 and 5 km/h), treadmill test (up- and downhill, each exercise to be carried out for 3 minutes at 3 km/h at a 10% gradient) including heart rate monitoring, and a 1,000 m field test with heart rate and time monitoring in order to compare load intensities.
Measurement methods:	Kistler forceplates with linked video recording to define the vector on the image and integrated measurement software to determine the point of applied force; 2D kinematic analysis (50 Hz online kinematics), treadmill.
Procedure:	To prevent familiarization effects, the order in which the knee joints were evaluated was randomized. Only the joints were replaced. The prosthetic alignment remained unchanged and was monitored by means of the image vector according to manufacturer instructions. Prior to the treadmill test, subjects were given a 10-minute familiarization period. Then the swing phase control was corrected. Measurements were made in the following sequence: loading, swing phase control, treadmill (uphill/downhill), 1,000 m field test.

Results

The evaluation of loads did not reveal any significant differences. Load time, total load, and medium support minimum were almost identical. For the C-Leg, the asymmetry between unaffected and prosthesis side was minimally higher than for the other joints (not significant). At the same time, a trend toward a higher relief maximum was recorded for the C-Leg. For cycle time, cycle length, and swing and stance leg time, the swing phase investigation of the joints on both the healthy and the prosthesis side did not show any significant difference across the joints. At all speeds, the maximum flexion angle is lower with the C-Leg ($p < 0.05$) and comes very close to the angle recorded on the unaffected side. The same applies to flexion and extension angle speeds, which are lower for the C-Leg at all tested walking speeds and come close to the values documented for the healthy side. On the prosthesis side, the differences between the individual joints are statistically significant. For the thigh angle, lower values were recorded on the prosthesis side when using the C-Leg starting from a walking speed of 4 km/h compared to the other joints, which suggests a lower level of activity during prosthesis control. Heart rates recorded during up- and downhill walking on the treadmill showed no differences across joints. In this test setup, the use of the C-Leg led to some insecurity during initial swing, which was due to an incomplete forefoot roll-over. In the 1,000 m field test, all of the participants walked fastest with the C-Leg.

When a new C-Leg fitting is intended, this should be supported by gait training in order to make full use of the potential of the prosthetic joint. Also, the technician should work with the utmost degree of care when aligning and adjusting the prosthesis.

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Metabolic Energy Expenditure in Amputees walking with the C-Leg Prosthetic Knee Joint

Authors: T. Schmalz[1], S. Blumentritt[1], K. Tsukishiro, L. Köcher, H. Dietl

Published in: Abstracts IXth World Congress of the ISPO, 459-460, June 28 – July 3 1998, Amsterdam, NL.
[This abstract publication is an excerpt from: T. Schmalz, S. Blumentritt and R. Jarasch: Energy expenditure and biomechanical characteristics of lower limb amputee gait: The influence of prosthetic alignment and different prosthetic components. Gait & Posture (2002) 16: 255-263]

Objective

This investigation compares the metabolic energy expenditure in transfemoral amputees during walking with the 3C1 (CaTech/Mauch, hydraulic, monocentric) and the C-Leg (electronically controlled hydraulic unit, monocentric).

Design

Subjects: Six transfemoral amputees, long-term 3C1 users who underwent a C-Leg testing phase lasting several weeks, amputation exclusively due to trauma.

Methods/test setup: Treadmill test at a self-selected, medium walking speed, a walking speed reduced by 20% and a walking speed increased by 20%. The measurement consisted of a 15-minute testing protocol (5 min medium, 5 min low, 5 min high speed). The prosthetic alignment was identical for both joints, which was documented and validated by using the L.A.S.A.R. posture device. In all cases, the Dynamik Plus prosthetic foot (Otto Bock) was used. The 3C1 was generally tested first.

Measurement methods: Treadmill (Enraf Nonius, NL) with speed adjustment, respiratory analysis with CPX cardiopulmonary exercise system (Medical Graphics, USA) parameters, heart rate measurement with Polar Sport Tester (Polar Electro Oy, FIN).

Procedure: A 10-minute trial phase was used to prepare and determine the speeds to be chosen. Then the test protocol was carried out with the 3C1. Following a 30-minute relaxation phase, the same protocol was repeated for the C-Leg.

Results

Compared with the 3C1, reduced mean values for VO2 and VCO2 were recorded during walking with the C-Leg. Oxygen consumption was 4 to 7% lower with the C-Leg. The difference to the 3C1 was most significant during walking at low speed. Also, compared with the 3C1, the mean heart rate was lower when using the C-Leg in the individual speed ranges. This suggests that walking with the C-Leg - especially in the medium and low speed ranges mainly occurring in everyday life situations - is possible at a lower energy expenditure. Compared with the individually set hydraulic resistance of the 3C1 matching a certain speed range, the advantage of the C-Leg lies in the possibility of its electronic adjustment of hydraulic resistances to the walking speeds chosen.

1 Otto Bock HealthCare GmbH, Duderstadt/Germany

The C-Leg – A New System for Fitting of Transfemoral Amputees

Authors: H. Dietl[1], R. Kaitan[1], R. Pawlik[1], P. Ferrara[1]
Published in: Orthopädie-Technik 49 (1998), 197-211

Objective of publication

A new prosthesis system to be fitted to transfemoral amputees is presented that uses new technologies to enable stance and swing phase resistance adjustment to the specific gait situation.

Content

The authors initially provide a thorough and extensive description of the biomechanics of walking with a transfemoral prosthesis, and of the requirements derived for a prosthetic knee joint, followed by an account of the technical implementation of the concept.

The joint concept includes the electronic control of the stance and swing phases on the basis of the analyzed biomechanical parameters described before. Such a control unit presents the following advantages: safe stance phase with less effort required to initiate swing and safe walking on uneven terrain without additional residual limb activity, a stance phase flexion to reduce heel strike forces, safe and comfortable walking, e.g. on stairs and inclines, through provision of the required flexion resistances, implementation of special features to cater to dancing and cycling activities, real-time control of swing phase movements in order to achieve a harmonious gait pattern at varying speeds without excessive back-/upward heel swing and an excessively rigid extension stop, individual, software-based adjustment of swing and stance phase to height, weight and activity of the patient.

A complex sensor arrangement is required to implement this system. These sensors should detect the current walking phase of the amputee in order to provide the necessary resistance. The motion resistance is provided by a hydraulic unit separately generating resistances for swing and stance phases via servomotor-controlled valves. Key sensor parameters used for this purpose are the knee angle and the sagittal shank flexion moment in the stance phase. Two microcontrollers process the sensor signals and control the servomotors that adjust the valves as required for the specific gait phase. The power needed for this control system is provided by a lithium-ion battery. The electronic control unit is operated by a software program. This program is built as a network of rules whereby each rule corresponds to a unique combination of input signals and adjusts the valves until they reach their respective positions. For walking on level ground, there is a typical sequence of five rules that are applied one after another: stance phase, forefoot load, swing initiation, swing flexion and extension. These rules are complemented by sub-programs. During swing, the valves are continuously adjusted. Initially, a low resistance is set in order to initiate the swing phase. Towards the end of extension, this resistance increases to ensure appropriate damping. The rate of this increase depends on the dynamics of the shank (fast or slow movement). The electronic unit offers the opportunity of combining the advantages of the hydraulic and pneumatic systems with those of the knee joint with friction brake, without their respective disadvantages. A multi-stage safety system (vibration and sound alarm) warns the amputee if the battery is low. If the battery is empty or the electronic unit defective, the prosthetic joint switches to a high stance phase resistance and enables safe walking without buckling. For optimum fitting, a good socket fit and correct prosthetic alignment continue to be essential requirements that must be met.

In the course of a controlled market launch, 40 amputees were fitted with the C-Leg. Almost all of them were interested in definitive fitting. After just a short period of use, all amputees recognized substantial advantages arising from the optimized swing phase control. They reported more comfortable walking with less effort. Amputees considered the reliability of the prosthesis in the stance phase the greatest advantage. Two of the amputees reported an influence by the electronic unit.

With the C-Leg, a prosthetic concept was implemented that provides amputees with added comfort and, at the same time, a high degree of safety as a result of the use of new technologies. It includes stabilization with less muscular effort, stance phase flexion, easier swing phase initiation, and swing phase control adjusted to the movement of the sound leg. Also, it enables a more harmonious and symmetrical gait while the sound limb is relieved when walking on stairs and inclines. This considerable technical effort justifies the higher price that was set on the basis of development and production costs. However, the added features put this price in perspective.

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