Otto Bock®

QUALITY FOR LIFE

C-Leg® Studies

A Compact Literature Overview

C-Leg® Studies

As a manufacturer of innovative, high-quality Orthobionic® products, Otto Bock aims at implementing continuously improved solutions to return the utmost degree of safety, freedom of movement and quality of life to people with restricted mobility. The C-Leg® is instrumental to this approach. Over 13,000 patients worldwide are using this first fully microprocessor-controlled leg prosthesis system. Since its launch nine years ago, the impact of the C-Leg® system on the fitting quality provided to leg amputees has been evaluated in numerous scientific studies with diverse objectives. Today, the C-Leg® is considered the most frequently evaluated leg prosthesis system worldwide, and the most comprehensively documented in relevant literature.

Medical and biomechanical studies of the C-Leg® and related publications in specialist journals are of paramount importance to various target groups within our industry. For prescribing physicians, health insurance companies, care providers and informed prosthesis users alike, these studies and publications are instrumental to reaching an initial assessment of the individual advantages that the use of the C-Leg® can provide in the specific fitting situation.

The compilation of C-Leg®-related studies and publications contained in this brochure should provide the interested reader with a clear and compact, yet sufficiently comprehensive overview. This especially applies to our international audience, as most of the publications are available either in German or English, but not in both languages. For a targeted in-depth understanding, the original sources in the complete publication list contained in this document can be easily referred to at any time.

Further information about the C-Leg® product range can be obtained from the worldwide Otto Bock subsidiaries listed in the Appendix.

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What does the C-Leg® Achieve?

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. 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® has been approved for transfemoral amputees with a body weight of up to 125 kg.

In 2006, Otto Bock launched an advanced version of the C-Leg®. The new C-Leg® replaces the previously offered prosthesis and provides additional features, such as a Wireless Remote Control to facilitate switching between operating modes and autonomous customized fine-tuning of the swing phase to be carried out by C-Leg® users themselves (in contrast to the software-based adjustment of the C-Leg® performed by a certified orthopedic technician). An additional stance mode enables stabilization of the knee joint at any flexion angle without having to apply muscular force.
In addition, the warranty model developed for the new C-Leg® provides a service interval extension from 12 to 24 months.

The C-Leg® has been specially designed to cater to the needs of active prosthesis users. It forms part of the C-Leg® product line, to which the C-Leg®compact was added in 2004, which was targeted to the higher safety requirements of prosthesis wearers with a lower degree of mobility. No C-Leg®compact studies have been published to date. These studies will be included in future editions of this brochure when they become available.

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 Otto Bock MOBIS® system

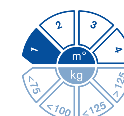
Mobility Grades 2 and 3	Mobility Grades 3 and 4
Amputees (amputee level knee disarticulation and higher)	
Additional medical issues and/or complications due to an injury can exacerbate the original limitations caused by amputation, i.e.: • Contralateral joint instabilities • Arthritis of the joints of 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®

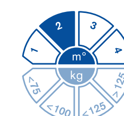
Mobility Grades and Therapy Objectives



Mobility Grade 1:

Indoor walkers

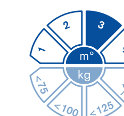
Indoor walkers have the ability or potential to use a prosthesis for transfer purposes at minimal speed on level floors. The distance and length of time they can walk are seriously limited due to their restriction.
Therapy goal: Restoration of the amputee’s ability to stand and to walk indoors with limited ability.



Mobility Grade 2:

Restricted outdoor walkers

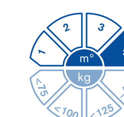
Amputees have the ability or potential to move slowly with a prosthesis and to master low obstacles such as curbs, steps or uneven ground. The distance and length of time they can walk are seriously limited due to their restriction.
Therapy goal: Restoration of the amputee’s ability to stand and to walk 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.

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, U. Hafkemeyer, J. Wühr and B. Drerup
Klinische Prüfstelle für orthopädische Hilfsmittel [Clinical Testing Facility For Orthopedic Appliances] , Klinik und Poliklinik für Technische Orthopädie und Rehabilitation [In- and Outpatient Clinic For Technical Orthopedics and Rehabilitaion], University of Münster, Münster

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: LASAR 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 enrolled subjects (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.

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

Authors: E. Swanson, J. Stube and P. Edman
Active Life Orthotics & Prosthetics, Albuquerque
Department of Occupational Therapy, University of North Dakota School Medicine & Health Science, Grand Forks
Prosthetic Department, Altru Rehabilitation Centre, Grand Forks

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 ($r_s = 0.86$; $p < 0.01$), the higher his social integration ($r_s = 0.74$; $p < 0.05$), the higher his comfort level with personal relationships ($r_s = 0.71$; $p < 0.05$), and the lower his feelings of psychological distress ($r_s = -0.77$; $p < 0.05$). The responses given in the category of social scrutiny were not found to correlate with functional role performance ($r_s = 0.03$; $p > 0.05$).

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 ($r_s = -0.43$; $p > 0.05$). 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.

Embedment of Hip Disarticulation Prostheses with Ischial Containment

Author: D. Hauser
Orthopädietechnik Botta & Söhne, Basel

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.

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

Authors: J.L. Johannson, D.M. Sherill, P.O. Riley, P. Bonato, H. Herr
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Spaulding Rehabilitation Hospital, Boston
Media Laboratory, Massachusetts Institute of Technology, Cambridge
Harvard-MIT Division of Health Science and Technology, Cambridge
Department of Physical Medicine and Rehabilitation, University of Virginia, Charlottesville

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.

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, N. C. Buell, K. J. Allyn, LCPO, B. J. Hafner and D. G. Smith
Prosthetics Research Study (PRS), Seattle

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 LASAR 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 LASAR 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 LASAR 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
Hanger Prosthetics & Orthotics, Phoenix

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 (for example using the LASAR posture device), and 3) dynamic alignment. 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 with the LASAR 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 procedure with the LASAR 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 LASAR 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 LASAR 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 LASAR load line. However, Uellendahl also supports the opinion that an unfavorable static alignment considerably limits the overall functionality of the prosthetic fitting.

Response of the Authors to Uellendahl's Comment

Author: L. L. Willingham, N. C. Buell, K. J. Allyn, LCPO, B. J. Hafner and D. G. Smith
Prosthetics Research Study (PRS), Seattle

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 static 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 with the LASAR 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.

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

Authors: R. Lindig, K. Stahl, U. Heine
Medizinischer Dienst der Krankenkassen, Westfalen-Lippe, Bielefeld [Medical Service of the Public Health Insurance Companies, Westfalen-Lippe region, Bielefeld]

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.

Biomechanical Aspects for the Indication of Prosthetic Knee Joints

Author: S. Blumentritt
Otto Bock HealthCare GmbH, Duderstadt

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.

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

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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.

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

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Rehabilitationszentrum Weißer Hof, Klosterneuburg [Weisser Hof Rehabilitation Center, Klosterneuburg]

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.

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

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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.

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

Authors: T. Schmalz, S. Blumentritt and R. Jarasch
Otto Bock HealthCare GmbH, Duderstadt

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.

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

Author: R. Pawlik
Otto Bock HealthCare GmbH, Vienna

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.

The C-Leg® Knee Joint System – Clinical Fitting Statistics

Author: L. Köcher
Otto Bock HealthCare GmbH, Duderstadt

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.

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.

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

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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.

„What Does the C-Leg® Achieve?“ – A Gait Analysis Comparison of C-Leg®, 3R45, 3R80

Authors: J. Kastner, R. Nimmervoll, P. Wagner
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Rehabilitationszentrum Weißer Hof, Klosterneuburg [Weisser Hof Rehabilitation Center, Klosterneuburg]

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.

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

Authors: T. Schmalz, S. Blumentritt, K. Tsukishiro, L. Köcher, H. Dietl
Otto Bock HealthCare GmbH, Duderstadt

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 LASAR 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.

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

Authors: H. Dietl, R. Kaitan, R. Pawlik, P. Ferrara
Otto Bock HealthCare GmbH, Vienna

Authors: 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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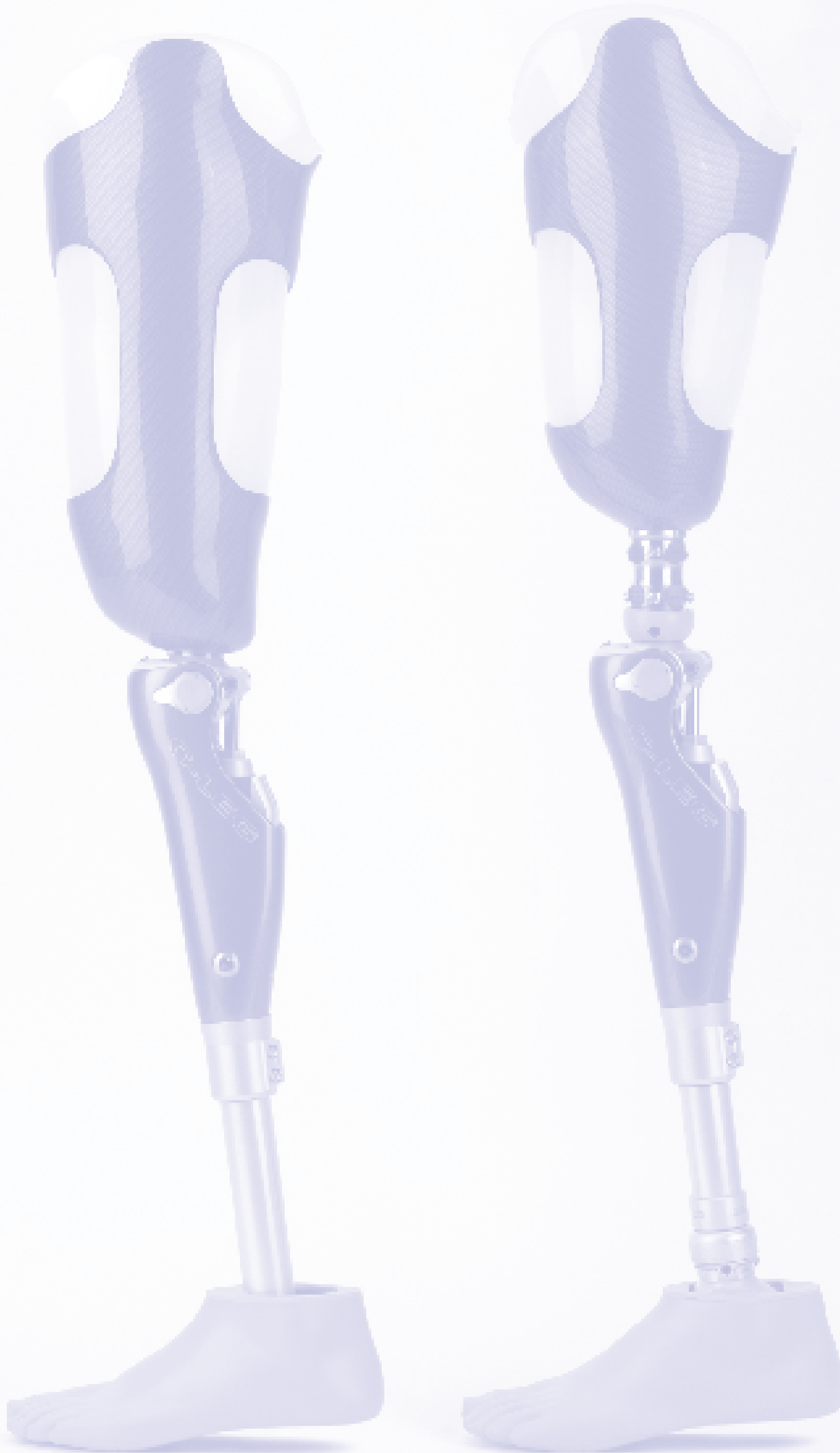

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