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

Ava D. Segal, MS;[1–2*] Michael S. Orendurff, MS;[1,3] Glenn K. Klute, PhD;[1–2,4] Martin L. McDowell, CPO;[1] Janice A. Pecoraro, RN;[1] Jane Shofer, MS;[1] Joseph M. Czerniecki, MD[1,3]

[1]Department of Veterans Affairs (VA), Rehabilitation Research and Development Center of Excellence for Limb Loss Prevention and Prosthetic Engineering, VA Puget Sound Health Care System, Seattle, WA; Departments of [2]Mechanical Engineering, [3]Rehabilitation Medicine, and [4]Electrical Engineering, University of Washington, Seattle, WA

Abstract—The C-Leg® (Otto Bock, Duderstadt, Germany) is a microprocessor-controlled prosthetic knee that may enhance amputee gait. This intrasubject randomized study compared the gait biomechanics of transfemoral amputees wearing the C-Leg® with those wearing a common noncomputerized prosthesis, the Mauch SNS® (Ossur, Reykjavik, Iceland). After subjects had a 3-month acclimation period with each prosthetic knee, typical gait biomechanical data were collected in a gait laboratory. At a controlled walking speed (CWS), peak swing phase knee-flexion angle decreased for the C-Leg® group compared with the Mauch SNS® group (55.2° ± 6.5° vs 64.41° ± 5.8°, respectively; p = 0.005); the C-Leg® group was similar to control subjects' peak swing knee-flexion angle (56.0° ± 3.4°). Stance knee-flexion moment increased for the C-Leg® group compared with the Mauch SNS® group (0.142 ± 0.05 vs 0.067 ± 0.07 N•m, respectively; p = 0.01), but remained significantly reduced compared with control subjects (0.477 ± 0.1 N•m). Prosthetic limb step length at CWS was less for the C-Leg® group compared with the Mauch SNS® group (0.66 ± 0.04 vs 0.70 ± 0.06 m, respectively; p = 0.005), which resulted in increased symmetry between limbs for the C-Leg® group. Subjects also walked faster with the C-Leg® versus the Mauch SNS® (1.30 ± 0.1 vs 1.21 ± 0.1 m/s, respectively; p = 0.004). The C-Leg® prosthetic limb vertical ground reaction force decreased compared with the Mauch SNS® (96.3 ± 4.7 vs 100.3 ± 7.5 % body weight, respectively; p = 0.0092).

Key words: amputee, biomechanics, C-Leg®, gait, kinematics, kinetics, knee, microprocessor, rehabilitation, transfemoral.

INTRODUCTION

Lower-limb amputees must relearn basic ambulatory skills to successfully function within the community. The two primary concerns for lower-limb amputees are comfort and mobility [1]. Despite continuous advances in prosthetic technology, 55 percent of amputees report they are unable to use their prosthesis to the extent they desire [2].

Most transfemoral (TF) amputees wear a noncomputerized prosthetic knee that incorporates friction, pneumatic, or hydraulic swing phase control. These devices are thought to be limited because the resistance setting that controls the rate of knee extension during swing remains constant and is therefore only optimal at specific walking speeds, which results in nonoptimal kinematics at a complete range of speeds. In addition, these nonadaptive, mechanically passive devices do not incorporate adaptive stance phase control, which requires the amputee

Abbreviations: %BW = percent body weight, CWS = controlled walking speed, OHS = opposite heel strike, SD = standard deviation, SSWS = self-selected walking speed, TF = transfemoral, VGRF = vertical ground reaction force.

***Address all correspondence to Ava D. Segal; Center of Excellence for Limb Loss Prevention and Prosthetic Engineering, VA Puget Sound Health Care System, 1660 South Columbian Way, Mail Stop 151, Seattle, WA 98108; 206-277-3090; fax: 206-764-2808. Email: avasegal@gmail.com**

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to lock the knee mechanism in full extension during stance to avoid buckling. These limitations result in gait asymmetries [3–4], such as increased prosthetic swing phase knee flexion and decreased prosthetic stance phase knee flexion, which may contribute to such problems as increased metabolic cost [5] and secondary disability [6–8]. Therefore, further developments in prosthetic technology are needed to normalize amputee ambulation and minimize gait asymmetries.

Past research has suggested that many challenges associated with TF-amputee ambulation are caused by gait asymmetries associated with stance phase kinetics [3–4,6]. For example, previous research demonstrated that amputee subjects had decreased loading on the prosthetic limb with increased loading on the intact limb compared with control subjects [9]. The higher forces on the intact limb may result from the lack of damping of the prosthetic knee during stance because of a decrease in prosthetic knee flexion, which causes excessive rise of the center of mass over the prosthetic limb [4–5]. The high forces shown to occur at the intact limb are thought to lead to pain and joint degeneration, which explains why TF amputees have a higher incidence of degenerative arthritis in their intact limbs compared with nondisabled subjects [6–8]. Specifically, coronal knee moments have been shown to be a major determinant of the load distribution during walking, with a significant correlation between external knee-adduction moment and bone distribution between the proximal-medial and proximal-lateral plateaus [10]. Sagittal-plane moments have also been shown to play a role in determining the overall compressive load on the knee joint. Therefore, both coronal and sagittal-plane knee moments are relevant measures when the relationship between loading and knee osteoarthritis is studied [10]. In a recent study of transtibial amputees, researchers measured coronal knee moments and found an increase in abduction moment of 56 percent compared with the prosthetic limb and 10 percent compared with the control group [11]. Despite the high occurrence of osteoarthritis in the intact limb of TF amputees, few studies have examined coronal knee moments [12].

In addition to the inability to use normal stance phase knee flexion to maintain stability and avoid inadvertent knee buckling [3], TF amputees have another common asymmetry: increased hip extensor activity for assisting stabilization of the knee. The increased hip power output may help compensate for the lack of ankle power generated by the prosthetic foot [13]. Mechanical power measurements, defined as the product of the joint moment of force and the angular velocity, are important measures of muscle function during concentric and eccentric phases of gait [14]. Therefore, increased power measurements may result in increased fatigue and secondary disability. Advances in prosthetic technology attempt to normalize amputee biomechanics, thereby minimizing gait asymmetries that may contribute to secondary joint pain and disability.

A novel prosthetic knee was recently developed, incorporating a microprocessor-controlled variable-damping mechanism that uses onboard sensors to collect real-time data and subsequently control stance and swing phase movements. This technology is intended to normalize the swing and stance phases of gait over a wide range of walking speeds [15], offering "the closest possible approximation to natural gait," as stated by the manufacturer. This type of prosthesis is alleged to adjust automatically, which results in a reduced need for muscular compensation on the contralateral limb. Potential benefits of this technology include decreased effort in walking; improved gait symmetry; increased confidence; more natural movement on stairs, inclines, and uneven terrain; and fewer falls [16]. Reports from subjects wearing these prostheses have been positive [17]. However, little scientific evidence supports these claims or justifies the increased cost compared with noncomputerized prostheses.

Few peer-reviewed studies have examined the novel microprocessor-controlled prosthetic knees. Aeyels et al. developed a self-contained, passive prosthetic system controlled by a microcomputer [18]. They used a simple control algorithm to control stance-phase knee flexion and reported that one subject achieved controlled knee flexion during the first 30 percent of stance after receiving extensive gait training and reassurance that the knee would maintain a few degrees of flexion without buckling. This case study demonstrated the feasibility of obtaining prosthetic knee flexion during stance; however, patient acceptance has been limited because subjects associate knee flexion during stance with buckling. A more recent study compared two microprocessor-controlled variable-damping prosthetic knees (C-Leg®, Otto Bock, Duderstadt, Germany and Rheo, Ossur, Reykjavik, Iceland) with a noncomputerized knee (Mauch SNS®, Ossur) after a 10-hour acclimation period with each knee [19]. Johansson et al. reported that the variable-damping knees exhibited (1) an enhanced smoothness of gait by a lower root-mean-square jerk derived from accelerometer data and

(2) a decrease in the following prosthetic limb biomechanical variables: hip work produced, peak hip-flexion moment at terminal stance, and peak hip power generation at toe-off. In addition, they reported an ~4° increase in knee-flexion angle at terminal swing for the C-Leg® group. No significant differences, however, were noted in the intact limb gait biomechanics with the C-Leg®.

Another study by Kastner et al. compared the C-Leg® with two other conventional knees (models 3R45 and 3R80, Otto Bock) in 10 subjects and found no statistically significant differences between the knees for loading or temporal parameters [20]. They reported that the angular velocity at the knee was significantly slower for the C-Leg® at the beginning of swing phase, suggesting that the knee swung more "harmoniously and calmly" compared with the other knees. Also, subjects achieved the fastest time for a 1,000 m walk test with the C-Leg®. A limited acclimation period of only 10 minutes per knee may have minimized the differences reported between the three prosthetic knees. Schmalz et al. compared the metabolic cost of the C-Leg® with a conventionally controlled hydraulic single-axis knee joint (3Cl, Otto Bock) in six TF amputees and reported a decrease in metabolic cost associated with walking at slower and medium walking speeds (0.5–1.2 m/s) with the C-Leg® [21]. However, the biomechanical variables associated with this decrease in metabolic cost at average and slower walking speeds remain unclear. Few rigorous studies have been conducted that objectively demonstrate the benefits of computerized prostheses and many current publications are either descriptive or promotional or use short acclimation periods [16]. Therefore, further biomechanical research is necessary to determine the efficacy of these devices.

Our study compared the differences in gait biomechanics of subjects wearing the C-Leg® versus a noncomputerized prosthesis (Mauch SNS®) using a within-subject design. The principal hypotheses addressed were (1) prosthetic limb stance-phase knee-flexion angle and moment would increase for C-Leg® compared with Mauch SNS®, (2) intact limb coronal knee moment for C-Leg® would decrease compared with Mauch SNS®, (3) intact limb hip, knee, and ankle sagittal-plane power and prosthetic limb sagittal-plane hip power would decrease for C-Leg® compared with Mauch SNS®, and (4) vertical ground reaction force (VGRF) would decrease for C-Leg® compared with Mauch SNS® because of knee function that more closely mimics normal knee gait biomechanics.

METHODS

Subjects

Of the 12 unilateral TF amputees who gave informed consent to participate in this study and were appropriate candidates for the C-Leg®, 1 could not acclimate to the C-Leg® and chose to withdraw and 3 withdrew because of health problems.

The 8 subjects (7 male) who completed the study ranged in age from 28 to 60 (47 ± standard deviation [SD] of 13 years), with an average height of 1.73 ± 0.04 m and weight of 79.6 ± 10.4 kg. Data presented as mean ± SD unless otherwise noted. All subjects wore a prosthesis with a Mauch SNS® knee unit for at least 8 hours a day for more than 1 year and could ambulate without upper-limb aids on flat surfaces, stairs, and inclines. All subjects were free from neurological deficits and underlying musculoskeletal disorders that might have affected gait characteristics. **Table 1** gives the specific components each subject used for each condition (C-Leg® and Mauch SNS®). The socket and suspension systems did not vary across conditions. However, foot type did vary because the C-Leg® requires the use of a limited selection of Otto Bock-manufactured prosthetic feet. To maintain the study's clinical relevance, we used the expert opinions of a prosthetist and physiatrist to determine the optimal prescription for the Mauch SNS® and the optimal C-Leg® system, as is done in a typical clinical setting. Therefore, we decided that when the subjects were converted to the C-Leg®, we would provide an Otto Bock prosthetic foot that not only best replicated the mechanical characteristics of their original foot but also would be best suited to their functional needs.

An additional 9 nondisabled control subjects (6 male), free from any known gait pathology, gave informed consent to participate in biomechanical data collection. Their ages ranged from 20 to 44 (29 ± 8 years), with an average height of 1.74 ± 0.05 m and weight of 73.6 ± 10 kg. We used this control data as a baseline comparison only when differences were found between the C-Leg® and Mauch SNS® groups.

Design

Two amputee subjects were enrolled together and then randomized to begin wearing either the computer-controlled prosthetic knee, C-Leg®, or the noncomputerized hydraulic prosthetic knee, Mauch SNS®. Subjects were enrolled in this manner so that two subjects could

Table 1.
Specific components used by each transfemoral amputee who completed study.

Subject	Socket	Suspension	Foot (C-Leg®*)	Foot (Mauch SNS®†)
1	Thermoplastic	Pin	OB 1D25 (Dynamic Plus)	Seattle Lite Foot‡
2	Thermoplastic	Pin	OB 1D25 (Dynamic Plus)	Seattle Lite Foot
3	Thermoplastic	Pin	OB 1D25 (Dynamic Plus)	Seattle Lite Foot
4	Thermoplastic	Pin	OB 1D25 (Dynamic Plus)	Seattle Lite Foot
5	Carbon Fiber	Pin	OB 1C40 (C-Walk)	Flex Walk Foot†
6	Carbon Fiber	Pin	OB 1E40 (LuXon Max)	Flex Walk Foot
7	Carbon Fiber	Suction	OB 1E40 (LuXon Max)	Flex Walk Foot
8	Carbon Fiber	Suction	OB 1D25 (Dynamic Plus)	Seattle Lite Foot

Note: Socket and suspension systems did not vary throughout study. However, foot often varied to accommodate specific Otto Bock (OB) foot required for C-Leg®.
*Otto Bock, Duderstadt, Germany.
†Ossur, Reykjavik, Iceland.
‡Seattle Systems, Poulsbo, Washington.

complete the protocol simultaneously, which maximized the available C-Leg® units for the study. Before randomization, the same experienced prosthetist, certified by Otto Bock to properly fit the C-Leg®, examined each amputee to verify that (1) the socket fit was comfortable and the overall mechanical function of the prosthesis was sound and properly aligned for stability and comfort and (2) the attachment mechanism of the prosthetic knee to the prosthetic socket would accommodate the C-Leg®. If the hardware would allow an easy exchange between the Mauch SNS® and C-Leg®, it was used for the experimental prosthesis. If the socket could not accommodate the C-Leg® attachment, a duplicate of the subject's current prosthetic socket was made with an altered attachment design to accommodate both the Mauch SNS® and C-Leg® knee units. This duplicate prosthesis became the experimental prosthesis. After any changes were made to the original prosthesis, subjects acclimated to the altered prosthesis for approximately 1 month before initial baseline measurements and were taken. After baseline, subjects either switched to wear the C-Leg® or remained wearing the Mauch SNS®. Each subject spent at least 3 months acclimating to the given prosthesis and then returned to the laboratory for data collection. After this data collection, the subject switched to the other prosthesis, again acclimated for 3 months, then returned to the laboratory for data collection. **Figure 1** is a schematic of the crossover design.

Protocol

The same researcher placed 38 reflective markers on each subject's hands, arms, head, trunk, legs, and feet according to Vicon's Plug-In Gait model (Oxford Metrics, Oxford, England). Measurements were taken from each individual according to the requirements for static and dynamic modeling. Each subject walked 10 trials at a self-selected walking speed (SSWS) and 10 trials at a controlled walking speed (CWS) of 1.11 ± 0.11 m/s, which approximates the previously determined average walking speed for TF amputees [13,22].

Data were collected with a 10-camera Vicon 612 motion system at 120 Hz and synchronized with an

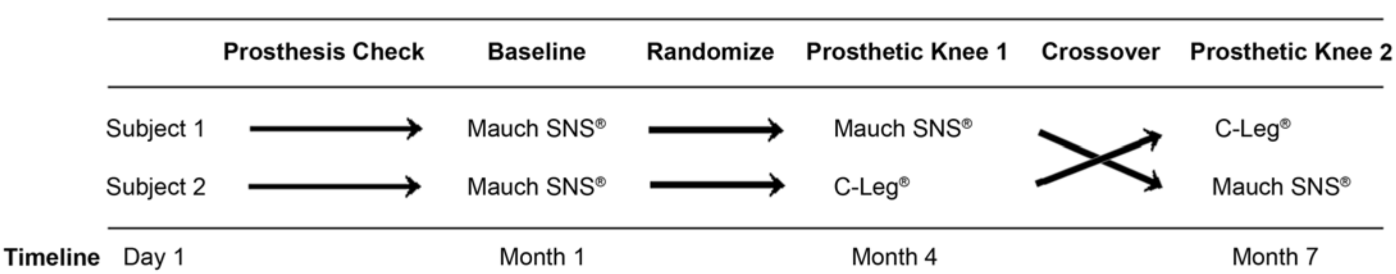

Figure 1.
Schematic flow diagram of study design.

embedded force plate (Kistler, Winterthur, Switzerland) at 600 Hz. Raw marker trajectories were filtered with Vicon's Woltring quintic spline algorithm with a mean-square-error value of 20. We labeled the markers, determined foot contact events, and calculated three-dimensional kinematics and kinetics for each trial using the Plug-In Gait model. We calculated the knee moments and sagittal hip, knee, and ankle powers based on the trajectory and force plate data. This protocol was repeated three times for each subject: at baseline, after the first 3-month acclimation with one prosthetic knee, and after the second 3-month acclimation with the other prosthetic knee. We extracted specific peaks and values at gait cycle events for each trial using the Event Analyzer (Vaquita Software, Zaragoza, Spain) and then averaged across trials for each condition. Our statistical analysis evaluated all the trials with a model to account for repeated measures to test the different hypotheses (the next section gives more details of the statistical analysis). The control subjects' kinematics and kinetics were similarly collected with the Vicon system, but in a single data collection session.

Statistical Analysis

We used linear mixed-effects models to identify statistically significant differences in gait biomechanical variables at a CWS (1.11 ± 0.11 m/s). Linear mixed-effects models are a class of models that include repeated measures analysis of variance [23] and account for both fixed and random effects. The fixed effects for our study were the average differences in gait biomechanical variables by prosthetic knee type (C-Leg® vs Mauch SNS®). These models also estimated random effects due to differences in mean biomechanical variables across subjects, as well as the random effects associated with minimized variability since subjects were tested with both prostheses. Failure to account for both types of random effects could result in the underestimation of type I error. We performed all statistical analyses using S-PLUS 6.2 for Windows (Insightful Corporation, Seattle, Washington) and R 2.2.0 (Free Software Foundation, Boston, Massachusetts).

Initially, we compared baseline measurements with Mauch SNS® measurements to determine whether mere participation in a study led to statistically significant biomechanical differences. Then we compared Mauch SNS® measurements with C-Leg® measurements for both the prosthetic and intact limbs. We then compared the gait biomechanical variables that demonstrated statistically significant differences between the C-Leg® and Mauch SNS® measurements with the control subjects' data to determine how close the prostheses approximated normal walking.

We examined the following biomechanical variables based on the previously defined hypotheses, with statistical significance set at $p < 0.05$: peak knee-flexion angle during stance, knee-flexion angle at opposite heel strike (OHS), peak knee-flexion angle during swing, peak knee-flexion moment, peak coronal knee moment for the intact limb, peak sagittal-plane hip power in early and late stance, peak sagittal-plane knee power for the intact limb in early and late stance, peak sagittal ankle power for the intact limb in late stance, maximum VGRF from early to midstance (10%–50% of stance phase), and timing of the maximum VGRF from early to midstance. We also examined temporal parameters for the two walking speeds.

RESULTS

No statistically significant differences were found between the baseline and Mauch SNS® measurements. Therefore, we made further comparisons with the C-Leg® measurements using only the Mauch SNS® data. **Table 2** presents the average temporal parameters (walking speed and step length) for each knee at SSWS and CWS. SSWS increased for the C-Leg® compared with the Mauch SNS® (1.31 ± 0.1 vs 1.21 ± 0.1 m/s, respectively; $p = 0.004$). At the CWS, the prosthetic limb step length decreased for C-Leg® compared with the Mauch SNS® (0.66 ± 0.04 vs 0.70 ± 0.06 m, respectively; $p = 0.005$). The C-Leg® prosthetic limb step length was closer to the intact limb step length (0.64 ± 0.06 m) and was therefore more symmetrical compared with the Mauch SNS®.

Because the amputee subjects chose to walk at a different speed when wearing the C-Leg® compared with the Mauch SNS®, we only compared the gait biomechanical variables for CWS. This decision was based on previous work that reported that alterations in walking speed resulted in systematic changes in peak kinematic and kinetic variables [24]. **Table 3** gives the mean and SD for the CWS gait biomechanical parameters of interest at specified points in the gait cycle. **Table 3** also presents the associated *p*-values for the comparisons between the C-Leg® and the Mauch SNS® (significance set at $p < 0.05$). Average angle, moment, and power curves across all subjects and trials for the hip, knee, and ankle at CWS across the gait cycle are presented in **Figure 2** for the intact limb and in **Figure 3** for the prosthetic limb. C-Leg®, Mauch SNS®, and control subject data are included in each plot.

We compared both prosthetic and intact limb knee-flexion angles at three different times during the gait cycle: peak during early stance, at OHS, and peak during swing (**Figures 2(b)** and **3(b)** are intact and prosthetic limbs, respectively). Peak knee-flexion angle during stance and knee flexion at OHS were not significantly different for the C-Leg® compared with the Mauch SNS® for either the intact or prosthetic limbs. The C-Leg®

Table 2.
Mean ± standard deviation for temporal parameters for each condition at self-selected and controlled walking speed of 1.11 ± 0.11 m/s. Statistically significant difference between C-Leg®* and Mauch SNS®† set at $p < 0.05$.

Temporal Parameters	Intact Limb			Prosthetic Limb		
	C-Leg®	Mauch SNS®	*p*-Value	C-Leg®	Mauch SNS®	*p*-Value
Step Length (m)						
Controlled Walking Speed	0.64 ± 0.06	0.64 ± 0.06	0.7	0.66 ± 0.04	0.70 ± 0.06	0.005
Self-Selected Walking Speed	0.69 ± 0.06	0.67 ± 0.05	0.05	0.72 ± 0.07	0.71 ± 0.6	0.8
Walking Speed (m/s)						
Controlled Walking Speed	1.12 ± 0.05	1.12 ± 0.05	0.8	1.12 ± 0.05	1.12 ± 0.05	0.8
Self-Selected Walking Speed	1.30 ± 0.1	1.21 ± 0.1	0.004	1.29 ± 0.1	1.20 ± 0.1	0.003

*Otto Bock, Duderstadt, Germany.
†Ossur, Reykjavik, Iceland.

Table 3.
Mean ± standard deviation for selected sagittal plane biomechanical variables for subjects walking at controlled walking speed of 1.11 ± 0.11 m/s. Statistically significant difference between C-Leg®* and Mauch SNS®† set at $p < 0.05$.

Biomechanical Variable	Intact Limb			Prosthetic Limb		
	C-Leg®	Mauch SNS®	*p*-Value	C-Leg®	Mauch SNS®	*p*-Value
Knee Kinematics (°)						
Peak Knee Flexion (early stance)	13.5 ± 5	11.4 ± 6	0.4	–2.0 ± 3	–4.3 ± 5	0.2
Knee Flexion (at opposite heel strike)	–1.1 ± 4	0.61 ± 5	0.4	–0.6 ± 4	–2.5 ± 6	0.2
Peak Knee Flexion (swing)	52.9 ± 4	52.9 ± 4	0.9	55.2 ± 7	64.4 ± 6	0.005
Knee Kinematics (N•m/kg)						
Peak Knee-Flexion Moment (early stance)	0.64 ± 0.1	0.50 ± 0.2	0.2	0.14 ± 0.05	0.067 ± 0.07	0.01
Peak Coronal Knee Moment	0.56 ± 0.1	0.52 ± 0.1	0.3	—	—	—
Hip Power (W/kg)						
H1 Power Maximum	0.57 ± 0.4	0.72 ± 0.6	0.3	0.46 ± 0.1	0.49 ± 0.2	0.7
H3 Power Maximum	0.85 ± 0.3	0.67 ± 0.1	0.09	0.75 ± 0.3	0.83 ± 0.3	0.3
Knee Power (W/kg)						
K1 Power Minimum	–1.03 ± 0.5	–0.74 ± 0.4	0.2	—	—	—
K3 Power Minimum	–0.38 ± 0.2	–0.38 ± 0.2	0.9	—	—	—
Ankle Power (W/kg)						
A2 Power Max	3.17 ± 0.5	3.65 ± 0.8	0.05	—	—	—
Vertical GRF						
Peak GRF from 10%–30% of gait cycle (%BW)	119 ± 11	114 ± 8	0.06	96.3 ± 4.7	100.3 ± 7.5	0.009
Time of Peak GRF (s)	0.148 ± 0.06	0.156 ± 0.04	0.4	0.214 ± 0.06	0.182 ± 0.05	0.07

Note: Positive (+) indicates power produced and negative (–) indicates power absorbed, as defined in Winter DA. Energy generation and absorption at the ankle and knee during fast, natural, and slow cadences. Clin Orthop Relat Res. 1983;(175):147–54. [PMID: 6839580], and Winter DA, Sienko SE. Biomechanics of below-knee amputee gate. J Biomech. 1988;21(5):261–67. [PMID: 3417688].
*Otto Bock, Duderstadt, Germany.
†Ossur, Reykjavik, Iceland.
H1 = peak sagittal-plane hip power in early stance (+), H3 = peak sagittal-plane hip power in late stance (+), K1 = peak sagittal plane knee power in early stance (–), K3 = peak sagittal-plane knee power in late stance (–), A2 = peak sagittal-plane ankle power in mid-stance (–), GRF = ground reaction force, BW = body weight.

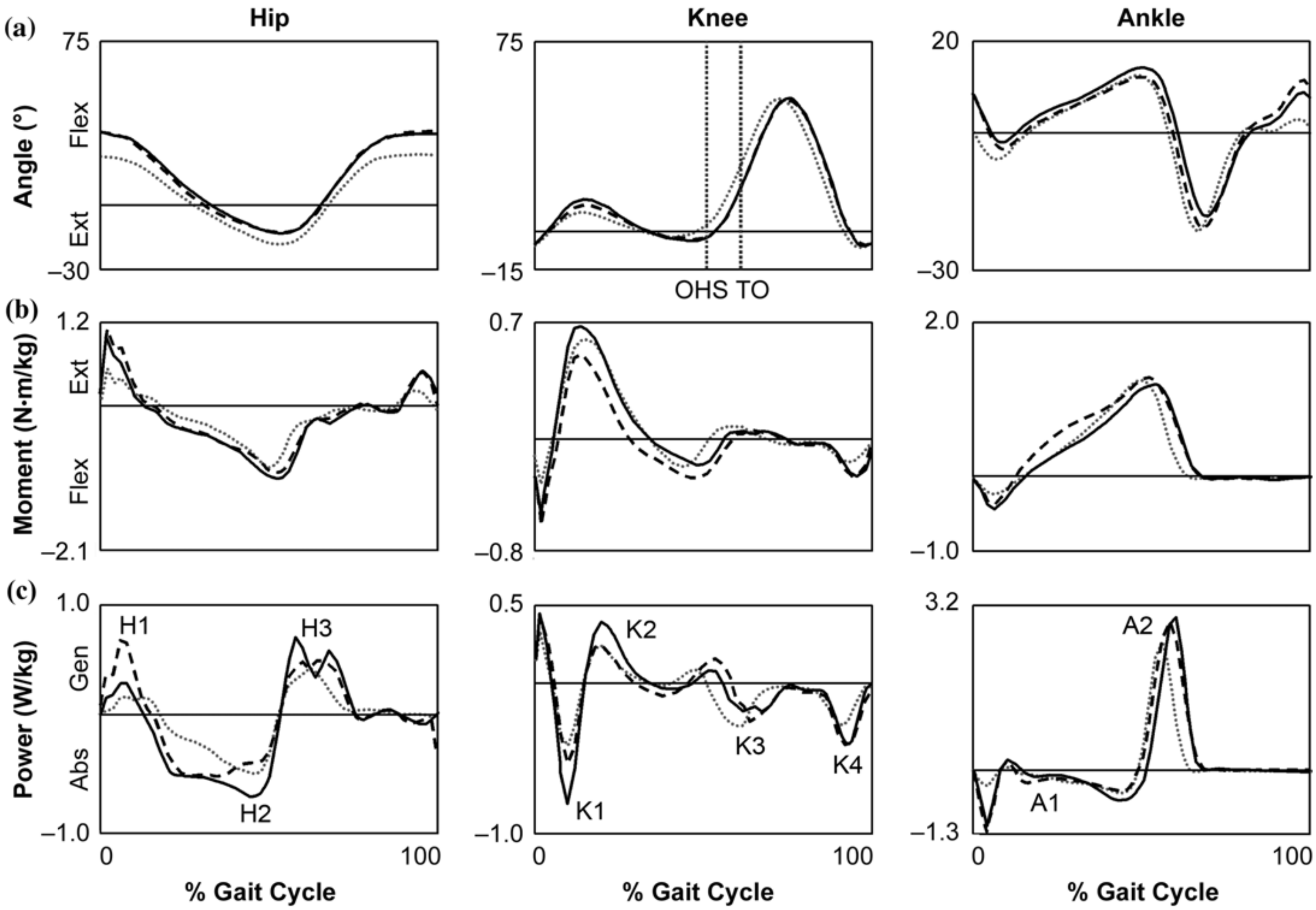

Figure 2.
Kinematics and kinetics of intact limb for subjects wearing C-Leg® (solid line) versus Mauch SNS® (dashed line) versus control group (dotted line). For all subjects and trials, average **(a)** angle curves, **(b)** moment curves, and **(c)** power curves are shown for hip, knee, and ankle for controlled walking speed (1.11 ± 0.1 m/s). Graphs plotted as percentage of gait cycle (% Gait Cycle), where 0% is heel strike and 100% is subsequent heel strike. Specific moments in gait cycle were examined for knee angle data (**(a)**, center panel). Therefore, average time of amputee opposite heel strike (OHS) and toe-off (TO) are identified. Ext = extension, Flex = flexion, Gen = generated, Abs = absorbed, H1 = peak sagittal-plane hip power in early stance (+)*, H2 = peak sagittal-plane hip power in mid-stance (–), H3 = peak sagittal-plane hip power in late stance (+), K1 = peak sagittal-plane knee power in early stance (–)*, K2 = peak sagittal-plane knee power in mid-stance (+), K3 = peak sagittal-plane knee power in late stance (–), K4 = peak sagittal-plane knee power in late swing (–), A1 = peak sagittal-plane ankle power in early stance (–), A2 = peak sagittal-plane ankle power in late stance (+). *Positive (+) indicates power produced; negative (–) indicates power absorbed. Power curves include specific peaks defined in Winter DA. Energy generation and absorption at the ankle and knee during fast, natural, and slow cadences. Clin Orthop Relat Res. 1983;(175):147–54. [PMID: 6839580], and Winter DA, Sienko SE. Biomechanics of below-knee amputee gait. J Biomech. 1988;21(5):361–67. [PMID: 3417688].

prosthetic limb peak knee-flexion angle during swing was significantly decreased compared with the Mauch SNS® (55.2° ± 6.5° vs 64.4° ± 5.8°, respectively; p = 0.005), with C-Leg® prosthetic limb swing-phase peak knee-flexion angle not significantly different from the intact limb (52.9° ± 3.8°) or control subjects (56.0° ± 3.4°) (**Figure 4**); however, the Mauch SNS® swing phase peak knee-flexion angle was significantly different from control subjects (p = 0.002).

Prosthetic limb peak knee-flexion moment during early stance was significantly increased for the C-Leg® compared with the Mauch SNS® (0.142 ± 0.052 vs 0.067 ± 0.074 N•m, respectively; p = 0.01). However, both prosthetic knee moments remained significantly decreased

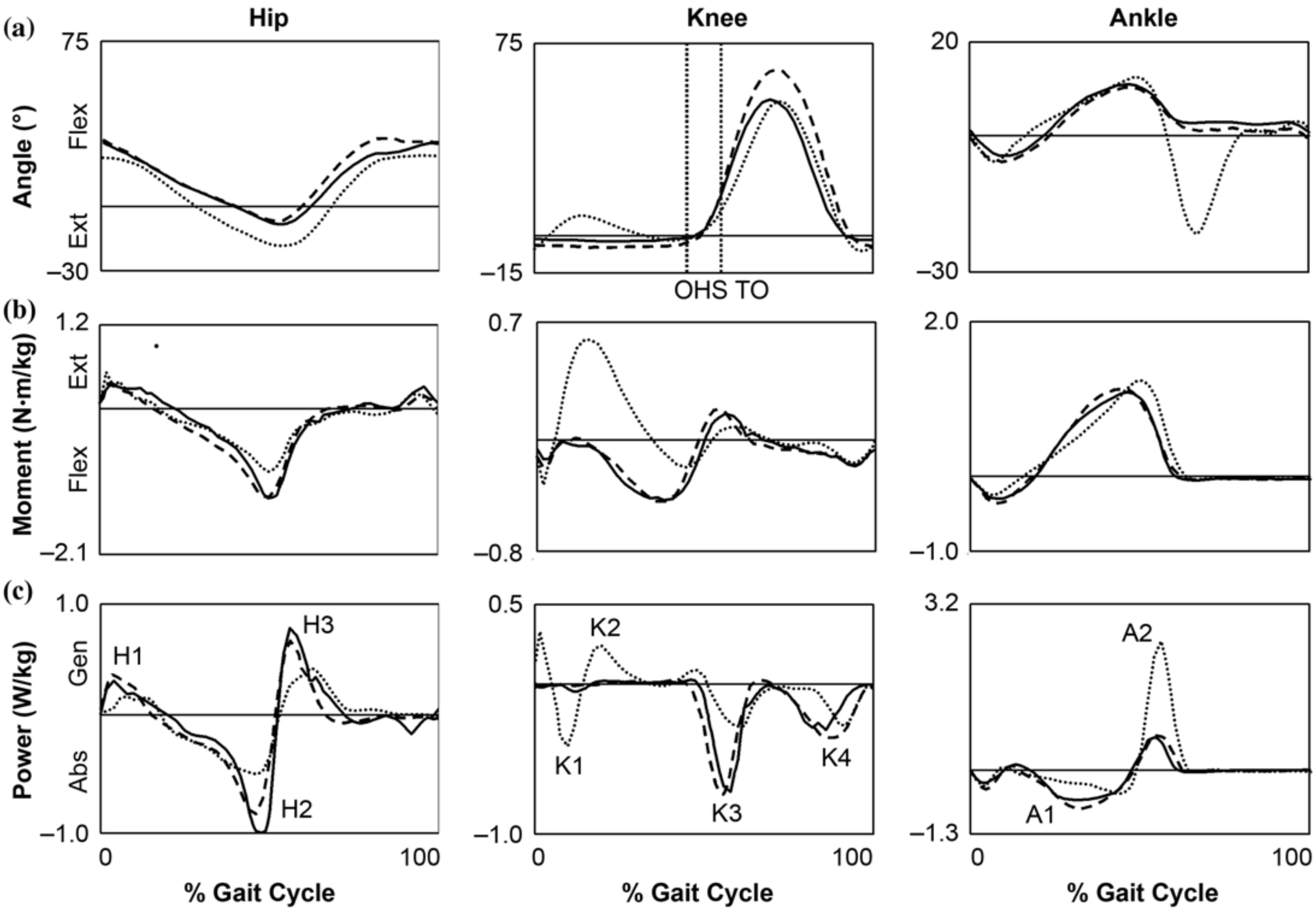

Figure 3.

Kinematics and kinetics of prosthetic limb for subjects wearing C-Leg® (solid line) versus Mauch SNS® (dashed line) versus control group (dotted line). For all subjects and trials, average **(a)** angle curves, **(b)** moment curves, and **(c)** power curves are shown for hip, knee, and ankle for controlled walking speed (1.11 ± 0.1 m/s). Graphs plotted as percentage of gait cycle (% Gait Cycle), where 0% is heel strike and 100% is subsequent heel strike. Specific moments in gait cycle were examined for knee angle data (**(a)**, center panel). Therefore, average time of amputee opposite heel strike (OHS) and toe-off (TO) are identified. Ext = extension, Flex = flexion, Gen = generated, Abs = absorbed, H1 = peak sagittal-plane hip power in early stance (+)*, H2 = peak sagittal-plane hip power in mid-stance (–), H3 = peak sagittal-plane hip power in late stance (+), K1 = peak sagittal-plane knee power in early stance (–)*, K2 = peak sagittal-plane knee power in mid-stance (+), K3 = peak sagittal-plane knee power in late stance (–), K4 = peak sagittal-plane knee power in late swing (–), A1 = peak sagittal-plane ankle power in early stance (–), A2 = peak sagittal-plane ankle power in late stance (+). *Positive (+) indicates power produced; negative (–) indicates power absorbed. Power curves include specific peaks defined in Winter DA. Energy generation and absorption at the ankle and knee during fast, natural, and slow cadences. Clin Orthop Relat Res. 1983;(175):147–54. [PMID: 6839580], and Winter DA, Sienko SE. Biomechanics of below-knee amputee gait. J Biomech. 1988;21(5):361–67. [PMID: 3417688].

compared with the control subjects (0.477 ± 0.1 N•m, $p < 0.001$), as well as compared with the intact limb for the C-Leg® and Mauch SNS® (0.637 ± 0.14 N•m and 0.498 ± 0.24 N•m, respectively; $p < 0.001$) (**Figure 5**).

The C-Leg® and Mauch SNS® peak coronal knee moments for the intact limb were not significantly different. Also, no significant differences were detected for the intact limb hip, knee, and ankle muscle power outputs or the prosthetic limb hip power outputs, as can be seen in **Table 3**. The peaks of the power curves are presented graphically in **Figures 2(c)** and **3(c)** and correspond to specific power phases clearly defined by previous literature [25–26].

Finally, the maximum VGRF from 10 to 50 percent of stance phase decreased for the C-Leg® compared with the

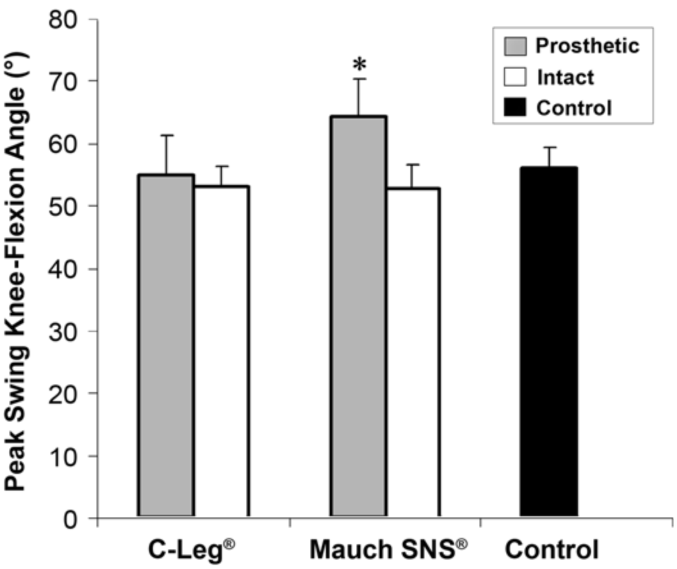

Figure 4.
Average peak knee-flexion angle during swing phase. Control subject data included for comparison. *Statistically significant difference from control ($p < 0.05$).

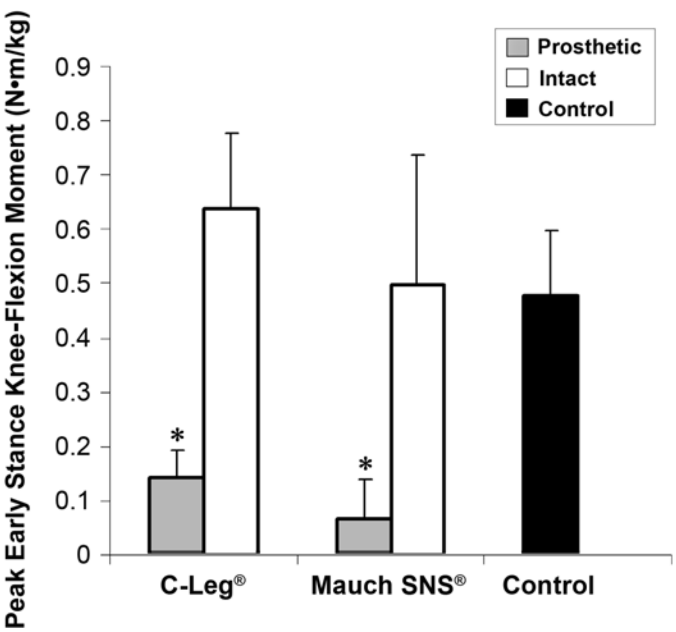

Figure 5.
Average peak knee-flexion moment during early stance phase. Control subject data are included as basis for comparison. *Statistically significant difference from control ($p < 0.05$).

Mauch SNS® (96.3 ± 4.7 vs 100.3 ± 7.5 percent body weight [%BW], respectively; $p = 0.009$). The C-Leg® VGRF for the intact limb demonstrated an increasing trend (119 ± 11 vs 114 ± 8 %BW, respectively); however, this difference was not statistically significant ($p = 0.06$). The timing of the initial peak was not significantly different between knees for either limb.

DISCUSSION

Using a within-subject design and CWS, we developed explicit hypotheses based on manufacturer claims and empirical observation for this comparison of gait biomechanics of TF amputees wearing a microprocessor-controlled prosthetic knee compared with a noncomputerized prosthesis. We chose a series of specific lower-limb kinematic and kinetic variables for comparison to test the hypotheses.

One primary difference between the two knees was prosthetic limb peak knee-flexion angle during swing. The C-Leg® demonstrated decreased peak swing-phase knee-flexion angle compared with the Mauch SNS®, with the C-Leg® knee-flexion angle not significantly different from the control subjects. Kastner et al. reported similar findings, attributing the lower maximum swing-phase knee flexion angle to higher damping [20]. To be sure both limbs were properly adjusted in the present study, the same experienced prosthetist set the swing phase control using veteran amputee feedback. Programming the C-Leg® is a subjective and complex process that incorporates Otto Bock Slider® software to tune the load-sensing and flexion-damping characteristics of the knee. The specific settings may differ substantially based on each patient's gait characteristics and preferences. Presently, few guidelines exist on how to program the C-Leg® to maximize its capabilities. Future research should explore the different settings and determine how they affect amputee gait biomechanics.

Significant differences were also found for some of the temporal parameters. First, subjects chose to walk at a faster speed when wearing the C-Leg® versus the Mauch SNS®. At the CWS, subjects' step length was more symmetrical for the C-Leg® than for the Mauch SNS®. Both results suggest functional improvements related to the C-Leg®. Other studies have demonstrated improvements in gait symmetry related to changing components, where a hydraulic swing-control knee produced more symmetrical gait compared with a constant-friction knee component [22]. However, these improvements were not demonstrated in previous research on the C-Leg® [19–20], perhaps because of shorter acclimation periods.

One comparison for the VGRF demonstrated statistical significance; the C-Leg® prosthetic limb maximum VGRF from 10 to 50 percent of stance phase decreased compared with the Mauch SNS®. The timing of this peak was not significantly different. Prosthetic limb loading remained decreased compared with the intact limb for both types of prosthetic knees, similar to previous research [9]. Therefore, the C-Leg® maximum VGRF from early to midstance was more asymmetrical than that of the Mauch SNS®. The decreased prosthetic limb VGRF for the C-Leg® may have been related to the smaller step length found for the prosthetic limb at CWS. The smaller step length may have led to less center of mass excursion and, therefore, less opportunity to develop momentum. Previous research on the C-Leg® reported no differences in stance phase loading [20], again perhaps because of a shorter acclimation period. Further research should explore VGRF to determine the exact mechanisms that caused the further decrease in prosthetic limb peak VGRF for the C-Leg®.

One of the manufacturer's proposed advantages of the C-Leg® is that it minimizes intact limb joint muscle demand through improved prosthetic knee function. By reducing compensation on the contralateral limb, this technology may decrease both pain and the incidence of degenerative arthritis, which are debilitating secondary disabilities for TF amputees [7–9]. Previous research has suggested that the major determinants of load distribution during walking are coronal and sagittal plane knee moments, which have been correlated with knee osteoarthritis [10]. Our study demonstrated no statistically significant differences between the two prostheses for the intact limb coronal and sagittal-plane knee moments. This finding is consistent with previous research of constant speed straight-line walking [19–20]. Perhaps more vigorous activities than constant speed straight-line walking need to be examined for differences between these prosthetic components to be detectable.

Since the manufacturer proposes in its instructions that the C-Leg® improves amputee gait through more natural and smooth movement, we also hypothesized that a decrease in the prosthetic limb sagittal-plane hip power requirements would be associated with the C-Leg®. However, we found no statistically significant differences between the two knees for this variable. Johansson et al.'s recent study of TF amputees walking at SSWS demonstrated a decrease in hip power generation at toe-off for the C-Leg® compared with the Mauch SNS® [19]. This different finding may be the result of the significantly shorter acclimation period of only 10 hours per knee.

Another potential advantage of the C-Leg® is that it allows controlled stance-phase knee flexion, duplicating what occurs in nondisabled gait. However, our study demonstrated that the C-Leg® did not normalize stance-phase knee-flexion angle at a constant walking speed. Both the C-Leg® and Mauch SNS® demonstrated similar peak stance-phase knee-flexion angles, which were less than zero. Although this slight shift below zero for knee flexion during stance was most likely attributed to marker placement or prosthetic alignment (as opposed to actual hyperextension), both knees demonstrated a constant sagittal-plane knee angle until just before toe off at the end of stance. Therefore, the absence of any dynamic range in prosthetic knee flexion, as depicted in **Figure 2(b)**, confirms a lack of increase in prosthetic stance-phase knee flexion for both prostheses. These results are consistent with previous studies of noncomputerized knees [5,12,15], as well as the C-Leg® [20]. Johansson et al. reported that the C-Leg® maintained approximately 3° of knee-flexion angle during stance, which was a significant increase compared with the two other tested prostheses [19]. However, in our study, stance-phase knee-flexion angle remained constant until just before toe-off and was still less than one-quarter of the magnitude of control subjects' stance phase knee-flexion (11.8° ± 3.0°). Since a significant dynamic change in knee flexion did not occur, this slight increase was more likely due to marker placement than an actual increase in knee-flexion angle. A few studies have demonstrated the feasibility of obtaining knee flexion during stance in TF amputee gait with a patient interactive gait simulator [27], a microcomputer-controlled knee joint [18], and a modified echo control system [28]. Aeyels et al. explained that despite its feasibility, stance-phase knee flexion is difficult for TF amputees because they associate knee flexion with buckling and falling [18]. The significant increase in prosthetic limb sagittal knee moment found in our study may suggest a potential for controlled stance-phase knee flexion with the C-Leg®. Therefore, extensive gait training may be necessary for subjects to achieve more normal stance-phase knee motion. Further research should explore the effects of rehabilitation programs on TF amputees wearing such novel components as the C-Leg®.

Besides the lack of a specific rehabilitation program to retrain the amputees in the use of the C-Leg®, our study had a few other limitations that should be noted. First, the number of subjects included in the protocol was relatively small. This reflects some of the difficulties of a study design with prolonged acclimation periods, which limits recruitment and also increases drop out because of changes in social or medical factors. Specifically, the population studied included only traumatic amputees of a given functional status who had used a common prosthetic knee for many years before entering the study. Therefore, generalizing the results across a broader population is difficult. The small study population also may not have provided adequate power to detect smaller differences between the two components. The differences not found to be statistically significant were relatively small (<1 SD in magnitude) and may not have had a strong clinical impact. However, speculating on the impact of smaller biomechanical changes is difficult because the magnitude of biomechanical differences that have clinical relevance has not been clearly defined in previous literature. Using the statistical software PASS*, we estimated that at least 80 percent power existed to detect a difference of 1 SD in this crossover study of eight subjects, two within-subject protocols (excluding the baseline visit) with 5 trials per protocol at the 0.05 significance level. Therefore, larger differences that would most likely have the greatest clinical impact were detectable in the present study. Only the smaller differences that may have less clinical relevance were potentially overlooked.

Another limitation of our study was that the protocol only examined SSWS and one similar CWS, which approximated previously determined average TF-amputee walking speed [13,22]. Only the CWS gait biomechanical variables were compared since the SSW for the C-Leg® was found to be significantly different than the Mauch SNS® SSWS. This decision was based on previous research that reported a systematic change in gait biomechanics associated with changes in walking speed, especially related to knee flexion during stance [24]. Specifically, 60 to 72 percent of the variance for knee-flexion angle and moment was associated with walking speed. Because we controlled walking speed, changes found in gait biomechanics were most likely attributed to the change in prosthetic component and not a change in walking speed. However, future research that examines a complete range of walking speeds as well as changes in speed would be valuable, because the subjects in this study reported that the C-Leg® seemed to automatically adjust to a variety of walking speeds and surface terrains. Therefore, more significant biomechanical differences might have been evident during walking speed adjustments and changes in terrain. Further research should explore the biomechanics of TF amputees walking under these varied conditions.

Controlling foot type is another aspect of the study design that should be discussed. In our study, foot type was not controlled because the C-Leg® required an Otto Bock-manufactured foot, which was different than the previously prescribed foot for the Mauch SNS®. Without controlling for foot type, variability in the gait measurements may have increased and affected the statistical analysis. However, exactly how foot type affects amputee gait biomechanics remains unclear [29]. Therefore, changing the initial Mauch SNS® system prescription may have caused significant differences related to a system that is not used clinically. To maintain the clinical relevance of the study, we examined two complete prosthetic systems that are actually prescribed in the clinic and considered the optimal prescriptions based on expert prosthetist and physiatrist experience. Controlling foot type may have minimized variability in the study, but at the expense of examining prosthetic systems never actually prescribed in the clinic.

Little research has examined the effect of acclimation period on kinematic and kinetic variables. Therefore, we chose the 3-month acclimation period based mainly on physician expertise. The only known literature to date that has examined amputee acclimation period was a study by English et al., who examined several biomechanical parameters of a single subject wearing two different knee mechanisms and recommended an acclimation time of at least 3 weeks [30]. Since our study examined a novel component, we implemented a longer acclimation period. Because of the lack of scientific evidence, however, whether a 3-month acclimation period was sufficient for stabilization of gait parameters is unknown. A future study on the effects of acclimation time for different prosthetic components on amputee gait biomechanics would be valuable for future comparative research.

*Power Analysis and Sample Size (PASS) Software. Hintze J, NCSS and PASS. Number Cruncher Statistical Systems. Kaysville (UT); 2001.

Even though our study did not present overwhelming evidence for biomechanical improvements in steady gait with the C-Leg®, seven of the eight participants who completed the study were pleased with the prosthetic knee and chose to switch to it permanently after completing the study. Subjects commented informally on why they wanted to keep the C-Leg®: they did not fall as much and they had increased confidence. Also important to note is that one subject dropped out of the study because he felt that the C-Leg® performed poorly compared with the Mauch SNS®. Therefore, the C-Leg® may not be ideal for all amputees. This underscores the need for additional studies to determine which patient populations will benefit from this technology.

CONCLUSIONS

Our study demonstrated minimal differences between the gait biomechanics of subjects walking with the C-Leg® compared with the Mauch SNS®, a noncomputerized prosthetic knee, during constant speed ambulation at approximately TF amputee SSWS. Future gait biomechanical research should examine a battery of more challenging ambulatory tasks, including changes in walking speed, uneven terrain, and obstacle avoidance.

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