Published in final edited form as:

Gait Posture. 2017 October ; 58: 103–107. doi:10.1016/j.gaitpost.2017.07.114.

Crossover Study of Amputee Stair Ascent and Descent Biomechanics Using Genium and C-Leg Prostheses with Comparison to Non-Amputee Control

Derek J. Lura^a, Matthew W. Wernke^b, Stephanie L. Carey^b, Jason T. Kahle^c, Rebecca M. Miro^b, and M. Jason Highsmith^{b,e,f}

^aFlorida Gulf Coast University, 10501 FGCU Blvd. S., Fort Myers, FL 33965

^bUniversity of South Florida, 4202 E. Fowler Ave., Tampa, FL 33620

^cOP Solutions. Tampa, 12206 Bruce B Downs Blvd, Tampa, FL 33612

^eExtremity Trauma & Amputation Center of Excellence. US Department of Veterans Affairs. Tampa, FL. USA

^fUS Army Reserves. 319th Minimal Care Detachment. Pinellas Park, FL. USA

Abstract

This study was a randomized crossover of stair ambulation of Transfemoral Amputees (TFAs) using the Genium and C-Leg prosthetic knees. TFAs typically have difficulty ascending and descending stairs, limiting community mobility. The objective of this study was to determine the relative efficacy of the Genium and C-Leg prostheses for stair ascent and descent, and their absolute efficacy relative to non-amputees. Twenty TFAs, and five non-amputees participated in the study. TFAs were randomized to begin the study with the Genium or C-Leg prosthesis. Informed consent was obtained from all participants prior to data collection and the study was listed on clinicaltrials.gov (#NCT01473662). After fitting, accommodation, and training, participants were asked to demonstrate their preferred gait pattern for stair ascent and descent and a step-over-step pattern if able. TFAs then switched prosthetic legs and repeated fitting, accommodation, training, and testing. An eight camera Vicon optical motion analysis system, and two AMTI force plates were used to track and analyze the participants' gait patterns, knee flexion angles, knee moment normalized by body weight, and swing time. For stair descent, no significant differences were found between prostheses. For stair ascent, Genium use resulted in: increased ability to use a step-over-step gait pattern ($p=0.03$), increased prosthetic side peak knee flexion ($p<0.01$), and increased swing duration ($p<0.01$). Changes in contralateral side outcomes and in knee moment were not significant. Overall the Genium knee decreased deficiency in gait patterns

Corresponding Author: Derek J. Lura, PhD, Assistant Professor, Department of Bioengineering, U.A. Whitaker College of Engineering, Florida Gulf Coast University, 10501 FGCU Boulevard South, Fort Myers, Florida, 33965-6565, dlura@fgcu.edu, Phone: 1-239-590-7832, Fax: 1-239-590-7304.

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for stair ascent relative to the C-Leg, by enabling gait patterns that more closely resembled non-amputees.

Keywords

Stair Climbing; Gait; Rehabilitation; Step over step (SOS); Step to gait (ST); Transfemoral Amputees (TFAs)

Introduction

While non-amputees typically ascend and descend stairs with a reciprocal step-over-step (SOS) gait pattern, transfemoral amputees (TFAs) have classically utilized a non-reciprocal step-to (ST) gait pattern [1]. In SOS stair ascent each foot step advances one stair and gait parameters are typically symmetric. During ST gait the one limb is advanced one stair, or two in high activity users, and then the other limb is advanced to the same stair, resulting in an asymmetric gait. While stair ascent and descent has been documented as a functional challenge for TFAs [2], advances in training of users and the design of prostheses have enabled TFAs to use a SOS gait pattern for stair descent [3] and ascent [4,5].

Utilizing the techniques similar to those described by Highsmith et al., users with stance yielding knees have been able to descend stairs with a SOS gait by allowing the knee to yield significantly during stance, effectively “riding” the knee down the stairs [3]. This technique does not require significant ankle flexion, as the prosthetic foot rotates about the edge of the stair. Evaluation of mechanical and C-Leg (Otto Bock Healthcare, Duderstadt, Germany) knees has found that the C-leg improved users' ability to descend stairs, as measured observationally using the Stair Assessment Index. However, it did not affect users' ability to ascend stairs [6]. On the Montreal Rehabilitation Performance Profile for stair descent, the C-Leg was also found to improve stair descent (observationally) for the majority (63%) of participants relative to non-microprocessor knee systems [7].

Temporal analyses of stair ascent and descent have had mixed results. Hafner et al. [8] studied timed stair ascent and descent on a 6-step staircase with bilateral handrails, but did not find significant difference between passive (varied), adaptive (Rheo Knee II, Ossur, Reykjavik, Iceland), and active (Power Knee II, Ossur) knees. Similarly Wolf et al. studied stair ascent and descent in five Operation Iraqi Freedom / Operation Enduring Freedom service members [9]. Participants were asked to utilize a SOS gait pattern and to use the handrail as little as possible. They found no significant difference in ascent or descent speeds between the C-Leg and Power Knee, but did find significant differences in knee and ankle power. Lawson et al. [10] and Hoover et al. [11] have also developed a novel powered prosthesis which enabled reciprocal SOS gait for stair ascent and descent, but each was only demonstrated for one TFA participant.

The Genium knee (Otto Bock Healthcare) offers a more advanced sensor array than the C-Leg. Otto Bock reports that this enables the user perform a variety of tasks that are typically very difficult for TFAs, including ascending and descending stairs using a SOS gait pattern [12]. The goal of our study was to determine if the Genium allowed for improved stair

ascent compared to the C-leg, by performing a controlled, randomized crossover study in a heterogeneous population while providing appropriate accommodation and training for each knee.

Methods

This study was a randomized cross-over study of a heterogeneous sample of 20 TFA participants using Genium and C-Leg prosthetic knees. Outcomes were the participants' ability to successfully demonstrate the use of the SOS gait pattern, their preferred gait pattern, peak knee flexion, peak knee moment (normalized by body weight), and swing time while ascending and descending stairs. Stair SOS or ST gait pattern was selected as an outcome because it is the most obvious functional difference between typical amputee and non-amputee stair ascent and descent patterns. Swing phase flexion was assessed because it was believed to be a pre-requisite to achieve the toe clearance needed to facilitate SOS gait. Knee moment was evaluated to determine kinetic differences between the knees that might be independent of kinematic measures. Swing duration was assessed to evaluate relative cadence and temporal asymmetry.

The study protocol was approved by the University of South Florida's Institutional Review Board. Informed consent was obtained prior to data collection and the study was listed on clinicaltrials.gov (#NCT01473662). Adult, unilateral TFAs of any etiology who used a C-Leg prosthesis for at least one year were recruited. Upon enrollment and using concealed allocation, TFA participants were randomized off-site to initially accommodate and test with the Genium knee or their C-Leg prosthesis. Regardless of knee system, subjects were trained by the study physical therapist in the functions of their respective knee and then provided an accommodation period. The training protocols used in the study were previously published [3,5]. An accommodation period of at least 2 weeks, but not more than 3 months was allowed for each participant. Participants were considered accommodated after verbally reporting and physically demonstrating their ability to walk independently on level ground, inclines, declines, up and down stairs, and on uneven ground. After accommodation, participants were scheduled for their initial test. After the initial test, TFA participants were switched to and trained with the opposite prosthesis, and then (re)accommodated prior to scheduling the second test. A licensed prosthetist ensured fit and alignment of all prosthetic components prior to accommodation with each limb. Stair ambulation was comparably studied using a cross-section of five, healthy, non-amputee control subjects.

Given its established reliability, validity, and sensitivity, 3-D motion analysis was used as outlined below to assess study outcomes [13]. An 8 camera Vicon (Oxford, UK) motion analysis system, and AMTI (Watertown, MA) force plates with attached stair platforms were used to collect participant kinematics and ground reaction forces. Passive reflective markers were positioned superior to the 2nd metatarsal head, posterior to the calcaneus, lateral to the greater trochanter, lateral epicondyle of the femur, and lateral malleoli of the ankle (or approximate location on prosthetic side). Rigid marker clusters were also placed on the lateral thighs and shanks. Marker data were recorded at 120 Hz.

For each test, participants were first asked to demonstrate a SOS ascent and descent gait pattern if able. Participants were then asked to demonstrate their preferred, or self-selected gait pattern if different from the SOS pattern. The staircase used was custom built for the study and consisted of an 8 foot long gait lane, follow by 2 instrumented steps (split left/right), and a 3rd step onto a raised 4' by 4' wide platform. All steps had a rise of 7" and a width of 11". For all trials, participants were asked to refrain from using the hand-rail, unless they became unstable. If participants used the handrail, they were asked to repeat the trial without using the handrail if able.

All outcomes were calculated in Visual 3D v5 (C-Motion. Germantown MD, USA). A lower-body segment link-based model was defined using the collected marker data. Visual assessment of each trial including marker and ground reaction force data were used to determine if the participant used a ST or SOS gait. The link-based model was used to calculate knee flexion angles and extension moments. Moment data was filtered using a low-pass Butterworth filter with a cutoff frequency of 6Hz, and normalized by body mass. Toe off and heel strike were determined using foot markers (to determine appropriate foot) and vertical ground reaction force.

For the control participants a paired samples, two-tailed, T-test was used to determine if differences between right and left side outcomes were significantly different. For comparison to prosthetics and contralateral conditions left and right outcomes for control participants were considered to be in the same category. McNemar's test was used to determine if wearing the C-Leg or Genium resulted in a significant change in the number of TFA participants who were able to perform SOS gait, or if there was a change in the number who preferred SOS gait. A multivariate analysis of variance, with post-hoc Tukey HSD comparison of means, was then used to compare differences in peak knee flexion, normalized peak knee extension moment, and swing duration between the different knee groups; Non-Amputee Control (NA), Genium-Prosthetic (GP), C-Leg-Prosthetic (CP), Genium-Contralateral (GC), or C-Leg-Contralateral (CC). The same statistical tests were performed for the ascent and descent trials across knee groups, as well as comparing gait type; SOS or ST. All statistics were calculated in SPSS 24 (IBM, NY, USA).

Results

Twenty TFAs (16 Male, 4 Female), and five non-amputee controls (3 Male, 2 Female) were recruited to participate in the study. Participant demographics are given in Table 1.

A Shapiro-Wilk test was performed as part of a post-hoc analysis and found that, for SOS ascent non-amputee (NA) peak knee flexion ($p=0.05$), C-Leg contralateral (CC) knee extension moment ($p<0.01$), and Genium contralateral (GC) swing period ($p=0.02$) deviated significantly from a normal distribution. For ST ascent only C-Leg Contralateral (CC) knee flexion deviated significantly ($p=0.04$) from the normal distribution. For SOS descent, C-Leg contralateral (CC) knee flexion ($p=0.01$) as well as C-Leg Prosthetic and Contralateral (CP and CC), and Genium Contralateral (GC) swing periods ($p<0.01$) were all found to significantly deviate from the normal distribution.

All participants who were recruited for the study completed all training, accommodation, (for TFAs) and testing. However, since participants were not asked to perform the ST gait if they preferred the SOS gait, and not all participants were able to perform the SOS gait, each grouping did not have the same number of trials. For the descent trials, since only one participant preferred the ST gait for descent with the Genium there was not a sufficient sample to perform statistical analysis with for study outcomes for ST descent.

Non-amputee participants always preferred the SOS gait pattern. Only peak knee extension moment during ascent showed a significant difference between left and right side ($p=0.04$), with the self-reported dominant limb expressing a higher moment. Knee flexion and swing duration demonstrated symmetric, reciprocal gait with no significant difference between left and right. Mean peak flexion angles, normalized peak knee extension moment, and swing duration for Non-Amputee participants are given in Table 2.

Descent

All participants were able to demonstrate SOS gait for stair descent using both the Genium and the C-Leg. Three participants preferred the ST gait while using the C-Leg and only one participant preferred the ST while using the Genium. There were no significant differences in the number of participants who preferred or were able to perform the SOS for stair descent. Since so few participants preferred the ST gait multiple comparisons were only performed for the SOS condition.

Figure 1 presents the mean peak flexion angles, extension moments, and swing times for SOS stair descent, sorted from least (left) to greatest (right). Peak flexion angles for both prosthetic knees were significantly ($p<0.01$) less than the contralateral limbs, and contralateral limb angles were significantly ($p<0.01$) less than non-amputees. Peak knee extension moment was significantly higher on the contralateral limbs relative to the non-amputees ($p=0.01$), and the prosthetic knees ($p<0.01$). The prosthetic limbs both had a lower peak moment than the control, however this difference was not significant for either limb.

Although not significantly different, swing durations were longer for the C-Leg relative to the Genium for stair descent. Swing periods were longest for the prosthetic limbs, followed by the contralateral limb, and the controls had the shortest swing duration. The greatest difference in mean swing time was between the C-Leg (prosthetic side) and control with a mean period of 0.77 seconds and 0.54 seconds ($p=0.06$) respectively.

Ascent

Figure 2 presents the mean peak flexion angles, extension moments, and swing times for SOS stair ascent. For stair ascent, TFAs using the C-Leg predominantly chose a ST gait, with only four able to demonstrate a SOS gait, and only one preferring the SOS for stair ascent. Conversely, while using the Genium, 17 participants were able perform the SOS stair ascent pattern, and 7 participants preferred the SOS gait. This represented a significant increase for the number of TFAs able to perform ($p<0.01$), and the number who preferred ($p=0.03$), the SOS pattern while using the Genium relative to the C-Leg.

As can be seen in Figure 2, when C-Leg users demonstrated a SOS gait pattern, they had a significantly decreased prosthetic side (CP) knee flexion. Participants using the Genium prosthetic side (GP) demonstrated the highest peak knee flexion while using the SOS gait pattern (higher than controls), but was only significantly different from C-Leg prosthetic (CP, $p<0.01$) and Genium contralateral side (GC, $p=0.03$). For knee extension moment both C-Leg and Genium prosthetic (CP & GP) knees produced significantly less moment relative to non-amputees and the contralateral sides (NA, CC, & GC). Genium use did result in higher extension moments on the prosthetic and contralateral sides relative to the C-Leg, however these differences were not (statistically) significant. Contralateral SOS swing durations were very near the control swing durations ($p=1.00$). Prosthetic side swing durations were significantly longer than control and the contralateral side ($p<0.01$), and Genium prosthetic side (GP) was also significantly longer than those for the C-Leg (CP, $p<0.01$).

For ST ascent there were only minor differences between the Genium and C-Leg. Both knees produced very little knee flexion and knee extension moment, and had longer swing durations on the prosthetics side, as shown in Figure 3.

Discussion

The Genium knee increased the number of users who were able to achieve and that preferred the SOS gait pattern for stair ascent relative to the C-Leg. This is important, as SOS presents a more natural stair ascent pattern, as evidenced by the fact that all control participants used an SOS pattern and that many (7 of 17 who were able with the Genium) of the TFAs preferred the SOS pattern. However, the ST pattern is generally considered more stable and was preferred by 19 of 20 participants with their conventional (C-Leg) prosthesis. It should be noted that the majority of TFAs (10 of 17) who were able to perform the SOS for stair ascent still chose to use a ST gait as their preferred pattern, this is likely due to the comfort and stability of their previously established gait pattern while using a prosthesis.

Results agree with a previous study which found improvement in gait parameters with use of the Genium (aka X2) knee for stair ascent. Aldridge Whitehead et al. studied stair ascent in young active male TFAs [14], reporting that the majority of participants (13 of 14) preferred a ST or skip-step (an ST gait that advances two stairs per stride) gait on their conventional prostheses, which were a C-Leg or Total Knee (Ossur), and that the majority (10 of 14) preferred a SOS gait while using the Genium knee. While the adoption rate of the SOS as the preferred gait style was not as high in our study, we did observe a more heterogeneous representation of the amputee population, and our participants were asked to not use handrails during testing.

Functional differences between in prosthetic knees observed in this study seem to stem from the ability of the knee to flex during the swing phase of stair ascent. In the few cases where C-Leg users were able to ascend using the SOS pattern, participants still did not utilize knee flexion to achieve toe clearance. Instead, a combination of hip-hike, circumduction, and jumping off of the contralateral limb was observed. In the instances where the ST gait was demonstrated with Genium, it appears the Genium prosthesis was used similarly to the C-

Leg. Perhaps confidence, balance, strength or other factors contributed to some user's inability to perform a SOS pattern, or their preference of the ST pattern. Peak knee extension moments were not significantly different between the Genium and C-Leg knees. There was also no a significant difference in contralateral knee moment for use of either prosthetic knee, or use of the SOS or ST gait pattern.

Although Genium use resulted in increased swing time relative to the C-Leg, the authors feel this difference is less important than the change from ST to SOS gait. The increased swing time may emanate from the additional time needed for the amputee to activate the swing flexion mode, the time needed to place and load the foot confidently or some combination thereof. The increased swing time may also partially explain why prosthetic knees that enable a SOS pattern have not reported significant changes in ascent or descent speed [9,15], or on timed measures like the timed stair test [8]. Further, it has been pointed out that relative to other outcomes such as safety, stair ambulation speed may not be as critical of an outcome [7].

Although not an a priori hypotheses in this study, age and residual limb length seemed to have an effect on success in ability and preference of the SOS gait during stair ascent. The three participants who were unable to ascend the stairs using the SOS gait were all over the age of 50, and only 2 of 10 participants over the age of 50 preferred the SOS gait. Where 5 of 10 participants under the age of 50 preferred the SOS gait. None of the participants with residual limb lengths less than 50% preferred the SOS gait, although this was limited to 4 of the 20 participants. Future studies with larger sample sizes would be helpful to further determine the extent to which limb length, age, etiology, and other factors may be roles in stair ambulation capabilities in TFAs.

Primary limitations of this study include the length of the stair case used. With only three steps it is difficult to confirm if gait patterns would remain stable, or if participants would have chosen different gait patterns for longer ascents and descents. Additionally, only the first two steps were instrumented, requiring the kinematic identification of first toe off and last heel strike for SOS gait. Limited sample size, and the inability to control for number of participants using each gait pattern resulted in uneven group sizes for statistical calculations.

Conclusions

Use of the Genium knee enabled the majority of the participants to use a reciprocal SOS gait pattern for stair ascent, increased knee flexion during swing phase of stair ascent, and generally contributed to a more symmetric gait. However, there was not a significant change in gait parameters for participants while descending stairs, and the swing duration while using the Genium for stair ascent was marginally longer than while using the C-Leg.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgments

Conflict of Interest Statement: This project was funded in part by the Florida High Tech Corridor/U.S.F. Connect (U.S.F. Grant #FHT 10-26), the National Institutes of Health, and Otto Bock Healthcare (U.S.F. Grant #6140101200). Funding agencies had no direct contribution to this article or the decision to publish their work. The authors are solely responsible for the content of this manuscript.

Each of the authors has read and concurs with the content in the final manuscript. The material within has not been and will not be submitted for publication elsewhere except as an abstract.

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Highlights

- Genium knee improves stair ascent gait for amputees relative to C-Leg.
- Genium did not significantly change gait for stair descent relative to C-Leg.
- Genium and C-Leg knees show significant differences relative to non-amputees.

Figure 1. Stair Descent Step-Over-Step (SOS) gait, Genium Prosthetic (GP) and Contralateral (GC, n=20), C-Leg Prosthetic (CP) and Contralateral (CC, n=20), and Non-Amputees (NA, n=10). Mean values with ± 1 standard deviation bars.

Figure 2. Stair Ascent Step-Over-Step (SOS) gait, Genium Prosthetic (GP) and Contralateral (GC, n=17), C-Leg Prosthetic (CP) and Contralateral (CC, n=4), and Non-Amputees (NA, n=10). Mean values with ± 1 standard deviation bars.

Figure 3. Stair Ascent Step-To (ST) gait, Genium Prosthetic (GP) and Contralateral (GC, n=13), C-Leg Prosthetic (CP) and Contralateral (CC, n=19). Mean values with ± 1 standard deviation bars.

Table 1
Participant demographic information. All parameters were recorded at the time of enrollment in the study.

ID	Gender	Age (years)	Height (cm)	Weight (kg)	Amp. Etiology	Amp. Side	Amp. Year	RL Length (cm)
A01	M	15	88	98	Malignancy	R	1969	5
A02	M	68	75	87	Trauma	R	1965	27
A03	M	55	196	111	Trauma	L	2003	16
A04	M	41	176	74	Trauma	R	2010	24
A05	M	17	92	291	Trauma	R	2007	30
A06	M	50	175	78	Trauma	R	1992	27
A07	M	55	180	78	PVD	R	2008	38
A08	M	24	178	66	Malignancy	L	2005	35
A09	M	55	170	81	Trauma	R	2007	28
A10	F	40	172	60	Trauma	L	1973	29
A11	F	27	178	71	Malignancy	R	2000	42
A12	M	56	176	86	Trauma	L	1974	19
A13	M	62	177	77	Trauma	L	1968	34
A14	M	38	171	66	Trauma	L	2002	24
A15	M	57	180	101	Trauma	R	1996	28
A16	M	33	188	112	Trauma	R	2004	28
A17	F	53	154	84	PVD	R	2001	26
A18	M	51	175	77	Malignancy	L	2006	19
A19	M	29	177	103	Trauma	R	2009	23
A20	F	44	161	57	Trauma	R	1988	29
C01	M	37	176	72	n/a	n/a	n/a	n/a
C02	M	59	175	61	n/a	n/a	n/a	n/a
C03	F	66	166	54	n/a	n/a	n/a	n/a
C04	F	77	157	68	n/a	n/a	n/a	n/a
C05	M	57	177	78	n/a	n/a	n/a	n/a

Table 2

Non-amputee gait outcomes for stair decent and ascent.

		Peak Flexion (Deg)	Peak Moment (Nm/kg)	Swing Time (Sec)
Descent	Right	97 (5)	1.19 (0.12)	0.53 (0.09)
	Left	93 (6)	1.01 (0.25)	0.55 (0.13)
	Combined	95 (6)	1.10 (0.21)	0.54 (0.11)
Ascent	Right	93 (7)	1.32 (0.25)	0.53 (0.04)
	Left	92 (10)	1.04 (0.29)	0.54 (0.05)
	Combined	92 (8)	1.18 (0.30)	0.54 (0.04)