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EFFECTS OF THE GENIUM MICROPROCESSOR KNEE SYSTEM ON KNEE MOMENT SYMMETRY DURING HILL WALKING

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Abstract

Use of the Genium microprocessor knee (MPK) system reportedly improves knee kinematics during walking and other functional tasks compared to other MPK systems. This improved kinematic pattern was observed when walking on different hill conditions and at different speeds. Given the improved kinematics associated with hill walking while using the Genium, a similar improvement in the symmetry of knee kinetics is also feasible. The purpose of this study was to determine if Genium MPK use would reduce the degree of asymmetry (DoA) of peak stance knee flexion moment compared to the C-Leg MPK in transfemoral amputation (TFA) patients. This study used a randomized experimental crossover of TFA patients using Genium and C-Leg MPKs ($n = 20$). Biomechanical gait analysis by 3D motion tracking with floor mounted force plates of TFA patients ambulating at different speeds on 5° ramps was completed. Knee moment DoA was significantly different between MPK conditions in the slow and fast uphill as well as the slow and self-selected downhill conditions. In a sample of high-functioning TFA patients, Genium knee system accommodation and use improved knee moment symmetry in slow speed walking up and down a five degree ramp compared with C-Leg. Additionally, the Genium improved knee moment symmetry when walking downhill at comfortable speed. These results likely have application in

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other patients who could benefit from more consistent knee function, such as older patients and others who have slower walking speeds.

Keywords

Amputee; Biomechanics; Gait; Knee kinetics; Physical therapy; Ramps; Rehabilitation; Slope; Transfemoral

INTRODUCTION

The Genium microprocessor knee (MPK) system (Ottobock Healthcare, Duderstadt, Germany) reportedly implements several engineering advancements over previously manufactured MPK systems (1–5). Study of these advancements has resulted in a recent body of literature showing improved performance of the Genium even when compared to the C-Leg (Ottobock Healthcare, Duderstadt, Germany), the most studied commercially available MPK system (1–5). Compared to C-Leg, Genium use resulted in improved symmetry in peak knee flexion angles during stance and swing when ascending and descending ramps in a sample of transfemoral amputation (TFA) patients (6). This improved kinematic pattern was more similar to non-amputee controls when walking on different hill conditions and at different speeds. Given the improved kinematics associated with hill walking while using the Genium, a similar improvement in the symmetry of knee kinetics is also feasible.

Due to the increased kinematic symmetry of the knee previously reported following Genium accommodation and use, the hypothesis of this study was that the Genium MPK system would increase symmetry in peak knee flexion moment during ramp gait. Thus, the study's purpose was to determine if use of the Genium MPK would reduce the degree of asymmetry (DoA) of peak stance knee flexion moment compared to the C-Leg MPK in persons with transfemoral amputation.

METHODS

The study was approved by the University of South Florida's Institutional Review Board and listed on [clinicaltrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT01473992) (#NCT01473992). Subjects gave informed consent prior to participation in the study.

Study Design Overview

This study was a randomized experimental crossover of TFA patients using Genium and C-Leg MPKs. Each subject tested on both knee conditions in a random order separated by an accommodation period of >2 weeks to <3 months, depending upon when subjects determined their readiness to test. Subjects' gait patterns were recorded using passive reflective markers and an 8-camera Vicon (Oxford, United Kingdom) motion analysis system. Subjects walked up and down 5° ramps at slow, normal, and fast walking speeds. The task variations (walking speeds, ascent/descent) were intended to evaluate knee component performance under diverse gait conditions seen during community ambulation.

Randomization and Interventions

All subjects entering the study were C-Leg users for 1 year prior to enrollment. An electronic random number generator was used to assign subjects (off site) to either continue with their C-Leg or to be fit with a Genium knee system at recruitment. The study prosthetist was notified of the subject's assigned condition via telephone on the day of the subject's knee fitting. All fittings and adjustments were performed by the study prosthetist, who was state-licensed and certified by the American Board for Certification in Orthotics, Prosthetics, and Pedorthics as well as by Ottobock Healthcare for fitting both C-Leg and Genium MPK systems. The subjects' prosthetic sockets and suspension systems were not changed for the duration of the experiment to reduce the confounding effects from fit and acclimation issues. All subjects were fit with an Ottobock Trias (standard height) or Axtion (low profile) prosthetic foot, based on limb length, for use over the study duration. Manufacturer specifications were used to set componentry alignment and were verified using the LASAR (Ottobock, Duderstadt, Germany) alignment system.

Fitting and Accommodation Periods

After enrollment, anthropometric data, randomization order, and the study foot were recorded. Knee fittings and alignment were conducted and recorded. All subjects were invited to return to the study prosthetist or physical therapist for adjustment, alignment, and training as many times as they wished to optimize their fit, comfort, and function and to mirror real clinical practice and component prescription. Visits were counted, and reasons for each visit were recorded. All subjects, regardless of which knee system they began the study with, received an initial training session from the study physical therapist for each knee system for training in transitional movements, obstacle crossing, ramps, stairs, speed variation, and variable surfaces. Portions of the training techniques used in this protocol have been previously published (1,7).

The minimum accommodation period was two weeks. After this, subjects were contacted weekly to determine their ability to walk without personal assistance on 1) level ground, 2) inclines, 3) declines, 4) up & down stairs, and 5) on uneven ground. Subjects could contact investigators at any time after the two-week minimum to declare their readiness to physically demonstrate they had accommodated to their currently assigned knee and study foot. Subjects were considered accommodated after verbally acknowledging and physically demonstrating their ability to ambulate independently on all five of the previous terrains. This study accommodation test was adapted from Hafner et al. (8,9). Following accommodation, subjects were scheduled for initial testing. Following initial testing, knee units were switched, and the process was repeated for follow-up testing.

Testing

Passive marker-based 3D motion tracking was selected to record and analyze knee movements because it is valid, reliable, and considered to be the gold standard measurement technique for gait analysis (10). Specifically, an 8-camera Vicon motion analysis system was used to collect knee kinematic data of subjects performing hill gait tasks. Passive reflective markers were attached to subjects using neoprene straps and double side adhesive collars as previously described (6). Force platforms (AMTI, Watertown, MA, USA) were embedded in

the gait platform and ramps and used to record ground reaction forces and to time events. For instance, heel strike and toe off were identified with force plate data; however, the subsequent heel strike was recorded with kinematic approximation (11). In accordance with manufacturer specifications and recommendations, the Vicon cameras were calibrated and force platforms zeroed before each session and after adjusting the ramp to the slope condition.

All subjects completed the hill walking tasks in the same order: 1) normal speed on 5° ramp uphill, 2) normal speed on 5° ramp downhill, 3) slow speed (i.e., casual) on 5° ramp uphill, 4) slow speed on 5° ramp downhill, 5) fast speed (i.e., hurried, late for appointment) on 5° ramp uphill, and 6) fast speed on 5° ramp downhill. Subjects were given the opportunity to rest between tests. A total of six different trial types were assessed, and each type was completed twice to record data over the force platform for both the prosthetic and anatomical leg.

Data Processing

Tracking segments were defined using the surface markers, and redundancy was included in the marker set to compensate for marker drop out and to increase data consistency and reliability. Frames were tracked by least squares minimization of the in-segment marker reconstruction error (12). A combination of anatomical markers and calculated joint centers were then used to define anatomical segments. Segment axes definitions were based on the recommendations of the International Society of Biomechanics (13). Joint angles were calculated from Euler angle transformations of anatomical segments.

Although the marker set used enabled tracking of the entire lower body, knee flexion moment was the measure of interest that addressed the *a priori* hypotheses, and therefore was the only measure included in this report. The gait cycle was defined from heel strike to heel strike of the involved foot. Peak knee flexion moment was defined as the maximum knee flexion moment from 0% to 30% of the gait cycle to assure peak stance flexion in the loading response. The remainder of the gait cycle (30% to 100%) was considered swing phase and was not included in this report. These definitions were used to prevent subjects who used the ‘ride-down’ strategy on the ramp descent from inflating the stance flexion angles after the loading response and further increasing deviations in subject moment data. Vertical ground reaction forces (GRF) were determined from the force plates. A 2D kinematic model was written in Vicon Bodybuilder software to determine joint angles, forces, and moments of the knee in the sagittal plane.

DoA between sound and prosthetic side knee flexion moments of the same trial type was calculated using the following equation:

$$\text{DoA} = \frac{S - P}{S + P} \times 100$$

In this equation, “S” represents the sound side knee peak stance flexion moment and “P” represents the prosthetic side knee peak stance flexion moment. As a result of this calculation, a positive value would indicate a greater moment on the sound side, a negative

value would indicate a greater moment of the prosthetic side, and a value of zero would indicate perfect symmetry between the two sides.

Statistical Analyses

Statistical analyses were performed with IBM SPSS (v21, Armonk, NY, USA). Data were compiled into a database, assessed for completeness, and descriptive analyses were performed (i.e., central tendency). The Shapiro-Wilk test was used to determine if data were normally distributed. Normally distributed data were assessed using dependent samples *t* tests for both peak stance and swing flexion moment by knee type per walking condition. For data that were not normally distributed, a Related-Sample Wilcoxon Signed Rank test was used. This test evaluates the distribution of the difference between related samples rather than the difference between means. The *a priori* level of significance was $p = 0.05$. Cohen's *d* was then calculated to represent the magnitude of effect size between knee conditions with regard to DoA of peak knee flexion moment. Cohen's *d* was interpreted as $d = 0.2$ representing a small effect, 0.5 representing a medium effect, and 0.8 representing a large effect (14). Investigators adopted the "last observation carried forward" or "next observation carried backward" methods as the study's *a priori* intention-to-treat plan (15,16).

RESULTS

Subject Demographics

Twenty TFA subjects ($n = 20$) participated and completed all study tasks with complete data from both MPK systems. The majority of subjects were male (80%) with a mean (SD) age of 46.5 years (14.2) and BMI of 26.4 kg/m² (4.2). The majority were employed (55%), 25% were governmentally classified as "disabled," and the remaining 20% were students or retired. All subjects were independent, unlimited community ambulators (Medicare functional classification level 3). The mean time since amputation was 17.7 years (15.6), and amputation etiology was predominantly traumatic (70%) followed by malignancy (20%) and peripheral vascular disease (10%). Mean relative residual limb length (SD) was 70% ($\pm 30\%$) of the sound side femur, and the mean hip flexion contracture was 12.8° (7.7) as measured with a manual goniometer in the Thomas test position. A variety of prosthetic sockets (i.e., ischial ramus containment, ischial support, subischial, quadrilateral) and suspension systems (i.e., locking liners, suction, elevated vacuum) were utilized by these subjects.

Overall

Knee moment DoA was statistically different between MPK conditions in the slow and fast uphill as well as the slow and self-selected downhill conditions (Table 1). The Genium improved knee moment DoA in all of these conditions except in the fast uphill condition, where there was no mean difference. In the latter condition, however, the increased variance, as shown with the increased SD of C-Leg compared with Genium, resulted in the statistical difference. Effect size within uphill conditions was medium for slow walking speed and small for the fast walking speed. Effect size within the downhill condition was small for the slow speed and large for the self-selected walking speed. The Genium MPK also displayed lower variance in peak knee stance flexion moment symmetry, as shown by SD, in all

walking speeds in the uphill conditions and the self-selected downhill condition. The C-Leg displayed less variance than the Genium in the slow and fast downhill conditions.

DISCUSSION

Due to engineering advancements incorporated into the Genium MPK, including a sagittal knee moment sensor, angle sensor, and gyroscope, we hypothesized Genium use would increase symmetry in peak stance knee flexion moment in TFA patients compared to the C-Leg. This hypothesis was supported, as a majority (3 of 4) of the significant differences resulted in improved knee moment symmetry with Genium use. The fourth significant finding yielded no mean difference but, rather, decreased variance in knee moment with Genium use, which was a common trend in the results when compared to C-Leg. These findings indicate accommodation and use of the Genium MPK enabled increased prosthetic gait control as reflected by more favorable DoA values and variability in knee flexion moment in stance phase during ramp ascent and descent for unilateral TFA patients capable of unlimited community ambulation.

Previous work has shown improved stability and knee flexion with C-Leg use compared to non-MPK (17,18) and MPK systems alike (19). Use of the Genium MPK has been shown to provide a more consistent stance flexion knee angle in a variety of walking speeds and terrains compared with C-Leg (6). The results of the present study corroborate the previously identified kinematic symmetry, as maximum stance flexion moments were markedly symmetrical and minimally varied with Genium MPK use compared with C-Leg use in this sample of high-functioning persons with TFA.

Although these findings were derived from generally young, healthy, and highly-active amputees, clinical application exists for elderly amputees who may display high variation in gait parameters, which leads to falls (20). Prosthetic components that reduce biomechanical gait variability may be an effective means to facilitate independence for amputees at increased fall risk (21–23).

A notable finding from this work is the improved knee moment symmetry and reduced variance in knee kinetics at slow walking conditions among MPKs. Older individuals are consistently found to have reduced gait speed relative to those in other age groups (24). This reduced gait speed may be related to a fear of falling, which could be intensified in amputees, thus contributing to notably reduced walking speed (21–23,25). Results of this work suggest that the Genium MPK system may be a desirable intervention for patients with transfemoral limb loss who range in function from high-functioning community ambulators to older amputees who walk slower and require more consistent knee performance. Current U.S. healthcare regulations mandate the ability to vary cadence in order to be considered for MPK eligibility. Elderly persons with TFA are thus at risk of denial of MPK consideration due to this requirement. However, limited community ambulators have been shown to gain as many (or more) of the benefits of MPK technology than their unlimited community ambulating peers (26).

CONCLUSION

Accommodation and use of the Genium knee system, compared with C-Leg, improved knee moment symmetry in slow speed walking up and down a five degree ramp. Additionally, the Genium improved knee moment symmetry when walking downhill at comfortable speed. At fast walking speed, variance in knee moment symmetry was lower when using Genium. These results were found in a sample of high functioning persons with unilateral transfemoral amputation; however, the results likely have application in other patients who could benefit from more consistent knee function, such as older patients and others who have slower walking speeds.

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Table 1

Degree of Asymmetry for Knee Moment during Hill Walking

Walking Speed		Slow		Self-selected		Fast	
Hill Condition	Measurement Parameter	C-Leg	Genium	C-Leg	Genium	C-Leg	Genium
Uphill	DoA (mn ± sd)	0.03 (0.15)	0.00 (0.04) ^{*M}	0.01 (0.23)	-0.01 (0.07) ^{NA}	0.00 (0.11)	0.00 (0.00) ^{*S}
Downhill	DoA (mn ± sd)	0.03 (0.06)	0.01 (0.10) ^{*S}	0.07 (0.10)	0.00 (0.01) ^{*L}	0.03 (0.04)	0.08 (0.29) ^{NA}

DoA is degree of Asymmetry.

^{*} significantly different from C-Leg (p = 0.05). When differences are significant, effect sizes are S for small, M for medium and L for large. When differences are not significant, effect size is NA (not available).