Department of Veterans Affairs

JRRD Volume 46, Number 3, 2009
Pages 417–434
Journal of Rehabilitation Research & Development

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

Brian J. Hafner, PhD;[*] **Douglas G. Smith, MD**
Prosthetics Research Study, Seattle, WA

Abstract—The functional differences between persons with amputation who are classified as Medicare Functional Classification Level (MFCL)-2 and -3 include the abilities to walk at various cadences and to negotiate environmental barriers outside the home. This study compared the effect of active microprocessor control and passive mechanical control of the prosthetic knee on function and safety in 17 subjects with transfemoral amputation (8 MFCL-2 and 9 MFCL-3). Assessed functional tasks included hill and stair descent, an attentional demand task, and an obstacle course. Self-reported measures included concentration, multitasking ability, and numbers of stumbles and falls. Active knee control was associated with significant improvements ($p < 0.05$) in hill and stair gait, speed (hills, obstacle course, and attentional demand task), and ability to multitask while walking for both cohorts. MFCL-2 subjects also reported a significant reduction ($p < 0.01$) in uncontrolled falls. Over the study, 50% of MFCL-2 subjects and 33% of MFCL-3 subjects transitioned to a higher MFCL. Results suggest that active knee control improves function and reduces the frequency of adverse events in a population that is at risk for falls. Use of active knee control may allow persons with amputation to expand their functional domain, transition to a higher MFCL, and access additional prosthetic options.

Key words: amputee, C-Leg®, falls, function, knee, mechanical, microprocessor, rehabilitation, safety, walking.

INTRODUCTION

Amputation of the lower limb results in a physical change in the body physiology that is often associated with functional limitations, such as an impaired ability to transfer, balance, and/or ambulate. These impairments typically compound with higher levels of amputation (i.e., amputation above the knee). To address these limitations, such individuals are often fit with a prosthetic limb that may restore some of the physical and biomechanical features of the intact foot, ankle, shin, and knee. Even with use of a prosthesis, individuals with transfemoral amputation are still often limited in their ability to ambulate and interact with their surroundings. Reduced walking speed [1–3], increased energy expenditure (i.e., oxygen cost or oxygen consumption) [1–5], asymmetrical step lengths [6–7], and decreased balance (i.e., static or dynamic) [8] are just a few of the impairments associated with transfemoral amputation.

Abbreviations: AMP = Amputee Mobility Predictor, CMS = Centers for Medicare and Medicaid Services, HAI = Hill Assessment Index, IP = Intelligent Prosthesis, MFCL = Medicare Functional Classification Level, PEQ = Prosthesis Evaluation Questionnaire, PSCP = pneumatic stance control prosthesis, QOL = quality of life, SAI = Stair Assessment Index, SC = semicontrolled, SF-36 = 36-Item Short-Form Health Survey, UC = uncontrolled, VAS = visual analog scale.

[*] **Address all correspondence to Brian J. Hafner, PhD; Prosthetics and Orthotics Program, Department of Rehabilitation Medicine, Box 356490, University of Washington, Seattle, WA 98195; 206-685-4048; fax: 206-685-3244. Email: bhafner@u.washington.edu**

DOI:10.1682/JRRD.2008.01.0007

Different prosthetic components, however, have been shown to influence these impairments to greater or lesser degrees. For example, some prosthetic knees have been shown to address many of the functional limitations previously noted. Active-control knees use microprocessors to constantly monitor and adjust the knee's resistance to flexion and extension and thereby influence a user's ability to ambulate safely and/or effectively. Two recent reports comparing the Otto Bock C-Leg® (Duderstadt, Germany) to the Össur Mauch SNS (Reykjavik, Iceland) found that persons with transfemoral amputation chose a significantly faster ($p = 0.046$ and $p = 0.004$, respectively) self-selected walking speed with the active-control (C-Leg) knee than with the passive hydraulic-control (SNS) knee [9–10]. A similar study comparing the Össur Rheo, the C-Leg, and the SNS knees found that the active-control Rheo and C-Leg knees reduced metabolic oxygen consumption by 5 and 3 percent, respectively, when compared with the SNS knee [11]. The difference between active control (i.e., Rheo) and passive control (i.e., SNS) was significant ($p = 0.009$). Segal et al. found that the subjects with transfemoral amputation wearing the active-control C-Leg walked with significantly greater ($p = 0.005$) step symmetry than when wearing the passive Mauch SNS knee [10]. Yet another study in subjects with transfemoral amputation found that the active-control Intelligent Prosthesis (IP) knee (Chas A. Blatchford & Sons Ltd; Hampshire, United Kingdom) significantly reduced ($p < 0.047$) mean sway velocity compared with a passive-control knee (i.e., Blatchford Endolite ESK, Chas A. Blatchford & Sons Ltd) [12]. Similarly, Kaufman et al. reported that subjects had significant improvements in dynamic posturography while wearing an active-control C-Leg compared with a passive-control prosthesis [13]. These reports suggest that prosthetic components can potentially mitigate many of the physical impairments brought on by amputation.

Prescription of prosthetic components is the responsibility of the managing physician, ideally with input from one or more members of the rehabilitation team, including the physiatrist, prosthetist, physical therapist, and/or occupational therapist. Choice of components is based on a number of factors, including the patient's age, weight, etiology of the amputation, physical health, history, functional goals, personal motivation, and medical coverage. However, associating an individual patient with the most suitable and appropriate components can be a challenge, particularly given the numerous prosthetic components available.

In 1995, the U.S. Department of Health and Human Services' Centers for Medicare and Medicaid Services (CMS) adopted coding modifiers used by the U.S. Health Care Financing Administration to describe individuals with lower-limb amputation (**Table 1**) [14]. This classification system is known as the Medicare Functional Classification Level (MFCL) and describes a patient's functional status, particularly as it relates to his or her potential for success with a prosthesis.

The functional differences among the MFCL levels are often used by third-party payers to assess medical necessity and designate the categories of prosthetic components for which a patient may be eligible. As a consequence, prosthetic devices that may be recommended for one MFCL may not be considered necessary for another. For example, the functional characteristics that differentiate

Table 1.
Medicare Functional Classification Level (MFCL) descriptions.

HCFA Modifier	MFCL Description
K0	MFLC-0—Does not have the ability or potential to ambulate or transfer safely with or without assistance and a prosthesis does not enhance quality of life or mobility.
K1	MFLC-1—Has the ability or potential to use a prosthesis for transfers or ambulation on level surfaces at fixed cadence. Typical of the limited and unlimited household ambulator.
K2	MFLC-2—Has the ability or potential for ambulation with the ability to traverse low-level environmental barriers such as curbs, stairs, or uneven surfaces. Typical of the limited community ambulator.
K3	MFLC-3—Has the ability or potential for ambulation with variable cadence. Typical of the community ambulator who has the ability to traverse most environmental barriers and may have vocational, therapeutic, or exercise activity that demands prosthetic utilization beyond simple locomotion.
K4	MFLC-4—Has the ability or potential for prosthetic ambulation that exceeds the basic ambulation skills, exhibiting high impact, stress, or energy levels, typical of the prosthetic demands of the child, active adult, or athlete.

HCFA = Health Care Financing Administration.

patients classified as MFCL-2 (i.e., the K2 modifier) from those classified as MFCL-3 (i.e., the K3 modifier) include the ability or potential to ambulate with variable cadence and the ability or potential to negotiate environmental barriers for purposes other than simple locomotion. Therefore, prosthetic knees that use a microprocessor to actively control the flexion and extension properties of the knee joint and allow a user to walk at varying speeds are typically only recommended for MFCL-3 or higher. However, anecdotal reports suggest that active control of the prosthetic knee offers users an improved ability to change gait speed and negotiate obstacles [15–16].

A study of 22 persons with transfemoral amputation compared their subjective experiences in both a pneumatic stance control prosthesis (PSCP) and an IP knee [17]. Users were provided an extended acclimation period for both devices (8–10 weeks and 7 months, respectively) and were subsequently asked a series of questions comparing the functional differences between the devices. Of the 22 subjects, 21 rated “walking at different speeds” as “easier” or “much easier” with the microprocessor-controlled knee. When negotiating environmental barriers, subjects reported improvements in descending stairs (5 of 22 subjects); negotiating slopes and hills (13 of 22 subjects); and walking on rough, uneven roads (14 of 22 subjects) while wearing the IP knee. Conversely, only one subject reported the IP knee to be worse in these activities than the passive-control (i.e., PSCP) knee. Therefore, these subjects appeared to report improvements in those functional characteristics that distinguish MFCL-2 and MFCL-3.

One should note that potential function alone does not drive selection of the prosthetic components for a given individual. Physical limitations also play an important role in selection of the proper prosthetic prescription. In general, MFCL-2 patients tend to be older, weaker, less coordinated, and at a higher amputation level than MFCL-3 patients. In such a population, patient safety is a primary concern for the rehabilitation team.

A survey by Gauthier-Gagnon et al. of community-dwelling persons with transtibial ($n = 228$) and transfemoral ($n = 168$) amputation found that 50 percent of all respondents had fallen in the month before the survey [18]. Furthermore, 19 percent of all respondents had fallen two or more times. A significantly higher ($p < 0.001$) percentage (63.9%) of respondents with transfemoral amputation reported falls than did respondents with transtibial amputation (42.9%). While the majority of respondents lived at home and were able to navigate environmental barriers such as stairs, 14.9 percent reported that stairs interfered with their daily activities and required that they confine themselves to a single level of the home. A similar survey by Miller et al. polled 435 persons with lower-limb amputation on the incidence of falling and found that 66.4 percent of those with transfemoral amputation reported at least one fall within the previous year [19]. Of those cases, 40.4 percent of the falls caused an injury and 19.3 percent necessitated medical attention. The dates of these surveys suggest that respondents were likely using prosthetic systems with passive control of the prosthetic knee.

When queried about perceptions of safety, 47.4 percent of the persons with transfemoral amputation in the Miller et al. survey reported a fear of falling [19]. Although not specified for the transfemoral amputation population, 76.2 percent of all respondents reported avoiding activities based on this fear. Similarly, 57.3 percent of all respondents reported problems with concentration while walking. In a follow-up study, Miller et al. examined the influence of physical, social, and psychosocial factors on balance confidence [20]. Level of amputation, need for concentration while walking, and fear of falling were all reported to significantly ($p < 0.05$) contribute to lower balance scores.

Given the typical demography of MFCL-2 and MFCL-3 patients, one could argue that MFCL-2 patients with amputation, particularly transfemoral amputation, are at equal or greater risk for falls, fear of falling, reduced confidence, and compromised balance than are MFCL-3 patients with amputation. Furthermore, these risks may actively perpetuate the functional limitations facing those individuals.

Some features offered by modern prosthetic components are intended to address many of these problems and thereby improve users’ safety. For example, active control of the prosthetic knee is purported to reduce the frequency of falling, provide more confidence, and improve balance. However, such devices are rarely recommended for MFCL-2 [21]. In general, the most technologically advanced prosthetic components are marketed and prescribed for higher functional levels (i.e., MFCL-3 and MFCL-4), while more conservative components are targeted at patients with limited mobility. Given the need for function and safety in the MFCL-2 patient population and the corresponding benefits shown and claimed by active control of the prosthetic knee, it seems appropriate to consider that such components could benefit this population.

Therefore, this study evaluated the differences in function and safety in persons with transfemoral amputation using passive mechanical-control prostheses and active microprocessor-control prostheses and the specific differences in these outcomes in MFCL-2 and MFCL-3 subjects over an extended time period. We hypothesized that active control of the prosthetic knee joint would increase function and improve safety with respect to passive control of the knee. Additionally, we hypothesized that changes to functional and safety outcomes resulting from the prosthetic intervention would be equally applicable to the MFCL-2 and MFCL-3 populations.

METHODS

The study was conducted as a nonrandomized crossover trial with repetition. Each subject was exposed multiple times to two different prosthetic interventions: a transfemoral prosthesis with a passive (i.e., mechanical) prosthetic knee and a transfemoral prosthesis with an active (i.e., microprocessor) prosthetic knee. Each subject served as his or her own control throughout the study. Human subject approval for study procedures was obtained from the University of Washington Internal Review Board. Informed consent was obtained from all subjects before enrollment.

Recruitment and Enrollment

Subjects with unilateral transfemoral amputation were recruited from the local population. Inclusion criteria for enrolled subjects included 18 years or older; at least 2 years postamputation; functional assessment at MFCL-2 or MFCL-3; and current use of a well-maintained, functional prosthetic limb with a passive-control prosthetic knee. Exclusion criteria included any health issues, such as a history of problematic skin breakdown or nonuse of an existing prosthesis, that would preclude the subject from using his or her prosthesis on a regular basis or participating in the study activities.

Candidates were evaluated for participation in study activities with a thorough physical assessment and functional evaluation by a licensed physician, a certified prosthetist, and a physical therapist experienced in amputee rehabilitation. Subjects were required to demonstrate safe and proficient use of their existing prosthesis by traversing environmental barriers (e.g., ramps, stairs, and uneven terrain) consistent with the MFCL-2 classification without assistance by the study team. Subjects were considered only upon unanimous agreement regarding prosthetic proficiency and device safety by the study evaluators. Each subject's initial MFCL was independently determined by the study prosthetist and therapist according to the CMS definitions (**Table 1**). If needed, assessment of MFCL was debated and obtained via agreement among the clinical staff.

Upon acceptance into the study, subjects were assessed for general mobility and health. Potential for ambulation was assessed by the study therapist with the Amputee Mobility Predictor (AMP), using the protocol set by Gailey et al. [22]. Subjects' self-assessed quality of life (QOL) was evaluated with the Well-Being subscale of the Prosthesis Evaluation Questionnaire (PEQ) [23]. Finally, subjects' initial self-assessed health was also evaluated with the 36-Item Short Form Health Survey (SF-36) (QualityMetric, Inc; Lincoln, Rhode Island).

Study Design

Subjects were enrolled only if they were currently using a well-fitting and properly maintained prosthesis with a passive prosthetic knee. The specific make and model of each subject's passive prosthetic knee was not controlled but was constrained to knees that incorporate mechanical friction or fluid elements in the knee joint to control the rate of knee flexion/extension. Upon enrollment, the subject was fitted with a second prosthesis that included a duplicate socket, duplicate suspension system, active prosthetic knee (Otto Bock C-Leg, Model 3C98, Otto Bock; Minneapolis, Minnesota), and an Otto Bock-approved prosthetic foot most closely matched to the subject's baseline prosthetic foot. Final enrollment and participation in the study occurred only when the subject and prosthetist agreed that the duplicate socket and associated fit were equivalent to each subject's existing prosthesis. Alignment and software settings for the test prostheses were verified by a C-Leg-certified prosthetist and therapist using the Otto Bock LASAR (Model 743L100) and observational gait analysis.

All subjects began the study in the passive-control prosthesis. Subjects were asked to wear their prosthesis normally for 2 months. Following this period of use, subjects returned for functional evaluation and assessment (see "Data Collection" section).

Subjects were then transitioned into the active-control prosthesis. Alignment and function of the prosthesis were evaluated and modified as needed to provide for safe and effective use. Subjects were allowed to accommodate to this test prosthesis on an individual basis. Subjects were allowed to return for prosthetic adjustments (including hardware and software) until they were able to demonstrate the same functional proficiency and ability to traverse environmental barriers as they did in the passive-control prosthesis. Once acclimated to the active-control prosthesis, subjects were instructed to wear it normally for another 2 months before returning for another functional evaluation and assessment.

Following assessment in the active-control prosthesis, subjects were instructed to return to their passive-control prosthesis for 2 weeks. This was intended to prevent bias toward the active-control prosthesis over the next 12 months of study because of the recent, exclusive use of that prosthesis. This period was selected based on the minimum accommodation time recommended by English et al. for persons with transfemoral amputation in clinical settings (i.e., 1 week) and research studies (i.e., 3 weeks) [24]. The 2-week period was hypothesized to be sufficient for assessment of performance because each subject had previously used his or her own passive-control prosthesis for more than 6 months and was familiar with the functional and safety characteristics of the prosthesis. All subjects were instructed to return for functional evaluation following this period of use. Before testing, subjects were again required to demonstrate basic functional proficiency in the passive-control prosthesis.

Subjects then entered an extended 12-month evaluation period. Subjects were provided with both the passive- and active-control prostheses and allowed to wear either or both prostheses as desired. Subjects were instructed to return for functional evaluation and assessment after 4, 8, and 12 months of extended use. For these three data-collection sessions, subjects were instructed to wear the prosthesis worn most often during the previous 4-month period. If the subject's usage of both prostheses was approximately even, subjects were asked to wear the prosthesis they most preferred.

Data Collection

After each period of use, subjects' function, QOL, and safety were evaluated with the examiner-assessed and self-assessed methods detailed subsequently. Evaluations were performed while the subjects wore the prosthesis corresponding to the period of use, as noted previously. This design provided at least two and as many as four evaluations for each subject in each limb.

The clinical staff assessed subjects' function in their prostheses by using a selection of outcome measures intended to measure functional ability on inclined surfaces, stairs, and uneven terrain. These tests are described in detail elsewhere but are listed here [25]. Subjects' functional level (i.e., MFCL) was assessed by the clinical staff throughout the trial in the same manner as described for the initial MFCL assessment. Function on inclines was measured with the ordinal Hill Assessment Index (HAI) rating, walking speed, and step length on a 19°, 94-foot-long paved sidewalk [25]. The HAI examines subjects' quality of gait by examining key features such as independence and foot placement. Function on stairs was similarly evaluated with the ordinal Stair Assessment Index (SAI) rating on a 12-step Americans with Disabilities Act-compliant staircase. Like the HAI, the SAI involves assessment of the quality of gait through observation of each subject's use of the handrail (or other assistive device) and foot placement on the stair steps. The SAI and HAI assessed subjects' gait as subjects walked down the inclined surface (i.e., a negative slope) and down the stairs. The ability to negotiate uneven terrain was evaluated by measurement of walking speed on a 244-foot outdoor obstacle course that included grass, wood chips, sand, a cement ramp, and cement stairs. Finally, ambulation with an attentional demand was measured by mean speed and accuracy on a verbal reverse-numbers test as subjects walked two sides of a busy city block while simultaneously responding to test questions.

Subjects' function, satisfaction, and QOL were self-assessed with the PEQ [23]. Similarly, subjects' confidence, concentration, and fear were self-reported with a customized PEQ Addendum. As part of this survey, subjects were asked to self-assess their personal stability and safety in their prosthesis by recalling the relative frequency and exact number of stumbles (i.e., an interruption in the rhythm of walking that does not lead to a fall but requires a compensatory movement to avoid a fall), semicontrolled (SC) falls (i.e., a loss of balance that leads to a partial fall wherein the subject is able to slow or stop the fall), and uncontrolled (UC) falls (i.e., a sudden loss of balance that leads to a complete fall) that had occurred in the previous 4 weeks. Complete descriptions of the PEQ Addendum questions are provided in the **Appendix** (available online only) and were scored on a visual analog scale (VAS) from 0 to 100.

Data Analysis

Each subject's data obtained from the six data-collection sessions were averaged by intervention as either a passive or an active score, corresponding to the type of knee control present in the prosthesis. We elected to average data rather than compare individual sessions for this analysis because of the variable individual accommodation to the active-knee intervention and the evaluation of the most-used intervention during the extended period of analysis (see "Study Design" section). Because of this accommodation time, the time histories of each subject's data-collection sessions were similar but not constant. Averaging the data by intervention allowed us to examine the overall effect of the interventions while also mitigating seasonal variances in the data that may occur over an extended study period.

Mean population outcome scores for the MFCL-2, MFCL-3, and combined populations were computed for each outcome measure. Inferential statistics (i.e., *p*-value and 95% confidence interval) for ratio data (i.e., speed, accuracy, and PEQ scores) were obtained with a two-tailed paired *t*-test with an a priori alpha (α) set to 0.05. Likewise, inferential statistics for ordinal data (i.e., AMP, HAI, and SAI scores) were obtained with a Wilcoxon signed rank test ($\alpha = 0.05$). Correlations between changes in MFCL rating and changes in AMP scores, PEQ scores, and SF-36 scores were performed with a Spearman rank correlation coefficient (r_s) ($\alpha = 0.05$). All statistical analyses were performed with GraphPad Prism v4.03 software (GraphPad Software, Inc; La Jolla, California).

RESULTS

Eleven MFCL-3 and ten MFCL-2 subjects were recruited for participation in the trial. Four subjects did not complete the trial. One MFCL-3 subject was unable to achieve a comfortable duplicate socket and was not deemed a suitable candidate, two MFCL-2 subjects experienced medical complications that prevented them from participating in study activities and were withdrawn by consensus of the study team, and one MFCL-3 subject chose to withdraw for personal reasons. Only subjects who were tested at least two times with either intervention were included in the per-protocol analysis. Demographic data for the 17 subjects who completed the trial are provided in **Table 2**.

Table 2.
Demographics of 17 participants with transfemoral amputation who were classified as either Medicare Functional Classification Level (MFCL)-2 or -3.

MFCL	Subject	Age	Sex	Years Since Amputation	Etiology	Passive Prosthesis: Knee Type* (Hinge, Stance, Swing)	Passive Prosthesis: Foot Type† (Hinge, Keel)
2	2.1	50	Female	2	Trauma	PC, N, HY	FA, DR
	2.2	58	Male	21	Dysfunction‡	PC, ML, ML	FA, R
	2.3	62	Female	5	Trauma	SA, HY, HY	MA, DR
	2.4	77	Male	30	Trauma	SA, HY, HY	MA, DR
	2.5	33	Male	3	Trauma	PC, N, FR	SA, R
	2.6	39	Male	2	Trauma	PC, N, HY	FA, DR
	2.7	71	Male	67	Infection	PC, N, HY	FA, DR
	2.8	67	Male	6	Vascular disease	PC, N, HY	FA, DR
3	3.1	46	Male	2	Trauma	SA, HY, HY	FA, DR
	3.2	59	Male	7	Trauma	PC, N, HY	FA, DR
	3.3	33	Male	33	Malignancy	PC, N, HY	FA, DR
	3.4	39	Female	37	Malignancy	SA, HY, HY	FA, DR
	3.5	31	Male	3	Trauma	PC, N, HY	MA, DR
	3.6	21	Male	12	Trauma	SA, HY, HY	SA, R
	3.7	36	Male	6	Infection	SA, HY, HY	SA, F
	3.8	67	Male	37	Trauma	PC, N, HY	MA, DR
	3.9	45	Female	27	Malignancy	PC, N, HY	FA, DR

*Knees are categorized by type of hinge (PC = polycentric, SA = single-axis), stance control (HY = hydraulic, ML = manual lock, N = none), and swing control (FR = friction, HY = hydraulic, ML = manual lock).

†Feet are categorized by type of hinge (FA = fixed ankle, MA = multiaxis, SA = single-axis) and keel (DR = dynamic response, F = flexible, R = rigid).

‡Amputation performed to address physical deformity and chronic musculoskeletal weakness resulting from polio.

The MFCL-2 subjects had a mean age of 57.1 years and a mean time since amputation of 17.0 years. The MFCL-3 subjects had a mean age of 41.9 years and a mean time since amputation of 18.2 years. Neither the difference in age (*p* = 0.05) nor the difference in time since amputation (*p* = 0.90) was significant between the populations. Initial evaluation of the study subjects' mobility and health showed minor differences between the MFCL-2 and MFCL-3 cohorts (**Table 3**).

The MFCL-3 subjects showed greater mean AMP, SF-36 General Health, and PEQ Well-Being scores than the MFCL-2 subjects. Only the AMP scores were significantly different (*p* = 0.004) between the populations. MFCL-2 subjects accommodated to the active-control knee in an average of 13.5 weeks, and MFCL-3 subjects required an average of 14.8 weeks (*p* = 0.78). Conversely, MFCL-2 subjects required a higher number of therapy visits (4.5 vs 3.9, *p* = 0.12) and prosthetic adjustments (4.9 vs 4.4, *p* = 0.73) than the MFCL-3 subjects.

Mean functional outcomes (including HAI score, hill self-selected walking speed, SAI score, obstacle course speed, attentional demand speed, and attentional demand accuracy) while subjects wore the active-control prosthetic knee were greater than when subjects wore the passive-control knee for both the MFCL-2 and MFCL-3 cohorts (**Table 4**).

Table 3.
Initial assessment of 17 participants with transfemoral amputation who were classified as either Medicare Functional Classification Level (MFCL) -2 or -3.

Subject	AMP Score (Maximum Score = 47)		SF-36 General Health (Maximum Score = 100)		PEQ Well-Being (Maximum Score = 100)	
	MFCL-2	**MFCL-3**	**MFCL-2**	**MFCL-3**	**MFCL-2**	**MFCL-3**
1	37	38	100	70	75	65
2	39	40	65	60	72	52
3	34	43	65	80	52	99
4	38	40	90	75	95	75
5	38	43	65	100	49	88
6	36	43	90	70	86	28
7	41	40	70	90	85	99
8	36	40	45	90	63	66
9	—	43	—	80	—	96
Mean	37.4	41.1	73.8	79.4	72.0	74.1
p-Value	0.004		0.46		0.84	

AMP = Amputee Mobility Predictor, PEQ = Prosthesis Evaluation Questionnaire, SF-36 = 36-Item Short-Form Health Survey.

Table 4.
Functional assessments of 17 participants with transfemoral amputation by Medicare Functional Classification Level (MFCL).

Outcome Measure (Instrument, Range)	MFCL	Type of Knee Control (Mean ± SD)		% Change	*p*-Value	Mean Change	95% CI
		Passive	Active				
Stair Mobility (SAI, 0–13)	2	3.3 ± 1.6	9.0 ± 3.7	NA	0.008	5.7	(3.0, 8.4)
	3	4.4 ± 2.9	10.1 ± 2.9	NA	0.004	5.6	(3.3, 8.0)
Hill Mobility (HAI, 0–11)	2	5.4 ± 3.9	7.5 ± 2.6	NA	0.008	2.2	(0.7, 3.6)
	3	7.2 ± 3.2	8.6 ± 3.3	NA	0.09	1.3	(–0.3, 2.9)
Hill Speed (m/s, 0 →)	2	1.70 ± 0.29	2.16 ± 0.41	27.1	0.002	0.46	(0.22, 0.70)
	3	2.17 ± 0.81	3.04 ± 0.95	40.1	0.017	0.87	(0.22, 1.51)
Obstacle Course Speed (m/s, 0 →)	2	0.80 ± 0.26	0.89 ± 0.26	11.3	0.02	0.09	(0.02, 0.17)
	3	1.05 ± 0.21	1.12 ± 0.22	6.7	0.007	0.07	(0.03, 0.12)
Attention Speed (m/s, 0 →)	2	0.83 ± 0.17	0.93 ± 0.18	12.0	0.02	0.10	(0.04, 0.16)
	3	1.08 ± 0.20	1.11 ± 0.22	2.7	0.22	0.03	(–0.04,0.10)
Attention Accuracy (% correct, 0–100)	2	73.3 ± 19.8	77.2 ± 20.6	5.3	0.30	3.9	(–4.3, 12.1)
	3	65.0 ± 19.4	68.7 ± 25.3	5.7	0.36	3.7	(–5.1, 12.5)

CI = confidence interval, HAI = Hill Assessment Index, NA = not applicable, SAI = Stair Assessment Index, SD = standard deviation.

As expected, the changes in functional outcomes measured between passive and active control of the prosthetic knee were similar across the entire study population. While MFCL-2 and MFCL-3 cohorts exhibited different mean scores in the passive-control knee condition, the change measured after transition to active control of the prosthetic knee was of a similar magnitude. MFCL-2 subjects also demonstrated lower mean assessed outcomes in the passive knee than MFCL-3 subjects. Therefore, the relative increase in functional outcomes measured in the MFCL-2 cohort after transition to active control of the knee was, on average, greater than in the MFCL-3 cohort.

The MFCL-2 and MFCL-3 cohorts showed similar changes in SAI score, obstacle course speed, and attention accuracy. Significant increases in SAI score and obstacle course speed were measured when subjects wore the active-control knee compared with the passive-control knee for both cohorts. The difference in attentional accuracy between interventions was not significant ($p > 0.05$) for either group.

The cohorts showed subtle differences in mean HAI score, hill speed, and attentional demand speed. In these functional outcomes, MFCL-2 subjects demonstrated larger increases with use of the active-control knee than did MFCL-3 subjects. The difference in HAI score was significant ($p = 0.008$) for the MFCL-2 cohort, and the difference in hill speed was significant for the MFCL-2 and MFCL-3 cohorts ($p = 0.002$ and $p = 0.017$, respectively). The change in attentional demand speed with use of the active-control knee was significant ($p = 0.02$) for only the MFCL-2 subjects.

When the MFCL-2 and MFCL-3 subject groups were combined as a single population, similar results were found. In all cases, the active-control knee showed improved functional outcomes when compared with the passive-control knee. Of those outcomes measured, only attention accuracy showed a nonsignificant ($p = 0.15$) difference between the interventions. Stair mobility, hill mobility, hill speed, obstacle course speed, and attention speed all showed a significant difference ($p < 0.05$) between active and passive knee control in the combined population (**Figure 1**).

Results of subjects' self-assessed function and QOL, as measured by the nine subscales of the PEQ, showed less consistency than the assessed functional outcomes. Changes measured in each cohort (i.e., MFCL-2 and MFCL-3) were not similar in all cases (**Table 5**).

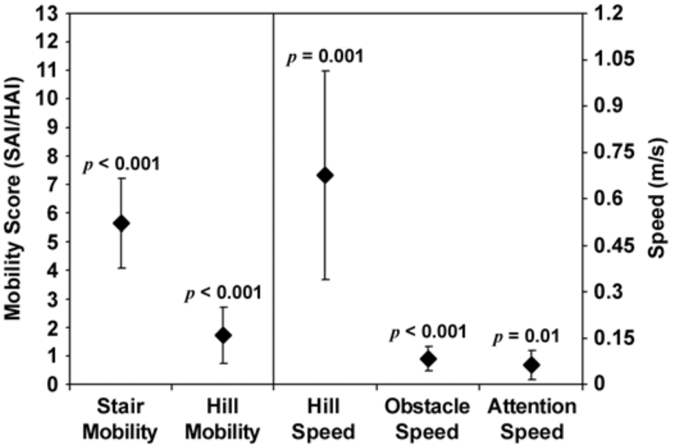

Figure 1.
Mean change and 95% confidence interval in functional outcomes scores (active vs passive knee control of prosthesis). HAI = Hill Assessment Index, SAI = Stair Assessment Index.

Subject satisfaction, as measured by question 1 of the PEQ, improved by an average of 13.0 (i.e., 20.6%) in the MFCL-2 subjects and 21.7 (i.e., 37.8%) in the MFCL-3 subjects with use of the active-control prosthesis as compared with the passive-control prosthesis. This increased satisfaction was significant ($p = 0.002$) in the MFCL-3 group.

Both the MFCL-2 and MFCL-3 subjects showed a mean increase in PEQ score in eight of the nine PEQ subscales, specifically, Ambulation, Appearance, Frustration, Perceived Response, Social Burden, Sounds, Utility, and Well-Being. However, only the MFCL-3 cohort demonstrated a significant improvement in any measure. This group showed a significant improvement in PEQ score in the Ambulation ($p = 0.01$), Sounds ($p = 0.046$), and Utility ($p = 0.01$) subscales. In each of these cases, this significant change was noted by a mean increase of greater than 15 points on the PEQ VAS.

The combined population again showed results similar to the individual subject groups in two measures. Significant improvements ($p < 0.05$) in PEQ score were found in Satisfaction (i.e., question 1 of the PEQ) and the Ambulation subscales of the PEQ (**Figure 2**). Additionally, the Well-Being subscale showed significant improvement ($p = 0.016$) for the combined population with use of the active-control knee.

In both the MFCL-2 and MFCL-3 cohorts, subjects' self-assessed confidence and concentration showed an increase in PEQ VAS scores with use of the active-control

Table 5.
Self-assessed function and quality of life of 17 participants with transfemoral amputation by Medicare Functional Classification Level (MFCL).

Outcome Measure (Instrument, Range)	MFCL	Type of Knee Control (Mean ± SD)		% Change	*p*-Value	Mean Change	95% CI
		Active	Active				
Satisfaction (VAS, 0–100)	2	63.1 ± 12.1	76.1 ± 15.5	20.6	0.14	13.0	(–5.6, 31.6)
	3	57.4 ± 21.7	79.1 ± 23.6	37.8	0.002	21.7	(10.8, 32.6)
Ambulation (PEQ Score, 0–100)	2	67.9 ± 11.2	72.7 ± 12.3	7.1	0.29	4.8	(–5.1, 14.8)
	3	61.3 ± 23.8	78.4 ± 20.7	27.9	0.01	17.1	(4.4, 29.8)
Appearance (PEQ Score, 0–100)	2	76.1 ± 17.7	77.6 ± 14.7	2.0	0.80	1.5	(–10.6, 13.7)
	3	72.1 ± 15.5	74.5 ± 18.0	3.3	0.42	2.4	(–3.8, 8.5)
Frustration (PEQ Score, 0–100)	2	71.0 ± 15.7	71.6 ± 15.8	0.1	0.92	0.6	(–13.9, 15.1)
	3	65.2 ± 26.5	85.5 ± 24.3	31.1	0.08	20.3	(–3.2, 43.8)
Perceived Response (PEQ Score, 0–100)	2	92.0 ± 9.0	95.1 ± 4.7	3.4	0.24	3.1	(–2.7, 8.8)
	3	91.7 ± 16.2	96.5 ± 6.2	5.1	0.19	4.7	(–3.2, 12.6)
Residual Limb (PEQ Score, 0–100)	2	80.9 ± 11.7	79.5 ± 13.1	–1.7	0.69	–1.4	(–10.0, 7.1)
	3	81.4 ± 18.2	79.5 ± 16.2	–2.3	0.61	–1.9	(–9.5, 5.7)
Social Burden (PEQ Score, 0–100)	2	87.2 ± 14.9	88.6 ± 13.2	1.6	0.71	1.4	(–7.2, 10.0)
	3	89.7 ± 11.6	91.1 ± 13.1	1.6	0.65	1.4	(–6.0, 8.8)
Sounds (PEQ Score, 0–100)	2	65.6 ± 26.6	68.9 ± 21.6	5.0	0.69	3.3	(–16.0, 22.5)
	3	61.2 ± 23.8	80.1 ± 16.2	30.9	0.046	18.9	(0.5, 37.3)
Utility (PEQ Score, 0–100)	2	71.9 ± 17.5	72.7 ± 14.5	1.1	0.92	0.8	(–12.9, 14.5)
	3	66.2 ± 22.7	79.2 ± 21.3	19.8	0.01	13.1	(4.0, 22.1)
Well-Being (PEQ Score, 0–100)	2	77.7 ± 12.8	82.8 ± 7.7	6.4	0.13	5.0	(–1.9, 12.0)
	3	74.4 ± 22.2	80.6 ± 18.7	8.2	0.08	6.1	(–1.1, 13.3)

CI = confidence interval, PEQ = Prosthesis Evaluation Questionnaire, SD = standard deviation, VAS = visual analog scale.

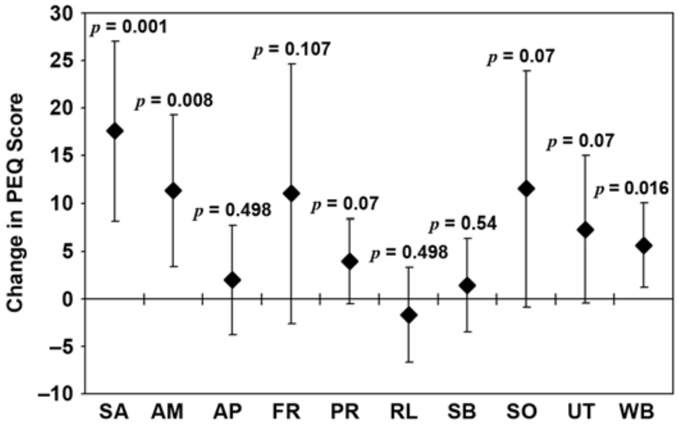

Figure 2.
Mean change in Prosthesis Evaluation Questionnaire (PEQ) scores and 95% confidence interval (active vs passive knee control of the prosthesis). AM = Ambulation, AP = Appearance, FR = Frustration, PR = Perceived Response, RL = Residual Limb, SA = Satisfaction, SB = Social Burden, SO = Sounds, UT = Utility, WB = Well-Being.

knee compared with the passive-control knee. As with the PEQ outcomes, the mean increase was larger in the MFCL-3 group than in the MFCL-2 group (**Table 6**).

Both cohorts showed mean increases of 10 percent or more in all the confidence and concentration measures while using the active-control knee compared with the passive-control knee (**Table 6**). Multitasking while walking showed a significantly improved (*p* = 0.04) score for the MFCL-2 cohort, while mental energy expenditure, confidence while walking, and multitasking while walking all showed significant improvements (*p* = 0.046, *p* = 0.004, and *p* = 0.03, respectively) for the MFCL-3 cohort in the active-control compared with the passive-control knee condition. Neither subject group showed a significant improvement with the difficulty with concentration outcome measure.

Self-assessed fear and safety outcomes, which attempted to assess subjects' fear and history of falls, were also observed to change when subjects transitioned from the passive- to the active-control prosthesis (**Table 7**). Here, beneficial (i.e., positive) changes were noted as either an increase in VAS score or a decrease in the subjects' self-reported numbers of stumbles or falls. Positive changes were noted for both cohorts in each of the measured outcomes, save for activity avoidance, for which the MFCL-2 subjects showed a negligible decrease in mean VAS score.

Table 6.
Self-assessed confidence and concentration of 17 participants with transfemoral amputation by Medicare Functional Classification Level (MFCL).

Outcome Measure (Instrument, Range)	MFCL	Type of Knee Control (Mean ± SD)		% Change	*p*-Value	Mean Change	95% CI
		Passive	Active				
Mental Energy Expenditure	2	51.1 ± 23.6	60.1 ± 9.6	17.6	0.29	9.0	(–9.6, 27.6)
(VAS, 0–100)	3	55.2 ± 24.4	74.9 ± 28.8	35.9	0.046	19.8	(0.7, 38.8)
Confidence While Walking	2	76.2 ± 12.5	86.1 ± 4.3	13.0	0.08	9.9	(–1.8, 21.6)
(VAS, 0–100)	3	67.2 ± 27.4	82.6 ± 24.1	22.9	0.004	15.4	(6.4, 24.4)
Multitasking While Walking	2	70.8 ± 18.9	85.8 ± 7.0	21.3	0.04	15.1	(0.3, 29.8)
(VAS, 0–100)	3	67.4 ± 26.9	85.0 ± 16.4	26.1	0.03	17.6	(2.1, 33.2)
Difficulty with Concentration	2	74.1 ± 25.0	82.3 ± 10.0	11.2	0.27	8.3	(–7.8, 24.3)
(VAS, 0–100)	3	79.9 ± 17.4	88.5 ± 17.7	10.7	0.17	8.6	(–4.4, 21.7)

CI = confidence interval, SD = standard deviation, VAS = visual analog scale.

Table 7.
Self-assessed fear and safety of 17 participants with transfemoral amputation by Medicare Functional Classification Level (MFCL).

Outcome Measure (Instrument, Range)	MFCL	Type of Knee Control (Mean ± SD)		% Change	*p*-Value	Mean Change	95% CI
		Passive	Active				
Activity Avoidance (VAS, 0–100)	2	87.9 ± 7.7	87.7 ± 10.4	–0.2	0.92	–0.2	(–9.0, 8.6)
	3	70.9 ± 30.9	86.9 ± 17.2	22.7	0.07	16.1	(–1.8, 33.9)
Frustration with Falls (VAS, 0–100)	2	76.6 ± 21.9	94.5 ± 6.3	23.3	0.06	17.9	(–1.2, 37.0)
	3	79.9 ± 20.7	94.8 ± 5.2	18.6	0.05	14.9	(–0.3, 30.0)
Embarrassment with Falls (VAS, 0–100)	2	78.0 ± 20.7	82.9 ± 14.3	6.3	0.63	4.9	(–17.2, 26.9)
	3	90.9 ± 12.5	93.8 ± 7.6	3.1	0.54	2.9	(–7.6, 13.4)
Stumbles (VAS, 0–100)	2	74.0 ± 14.7	85.6 ± 9.1	15.8	0.05	11.7	(–0.1, 23.4)
	3	60.4 ± 22.9	79.1 ± 12.1	31.0	0.03	18.7	(2.9, 34.6)
Stumbles (Number, 0 →)	2	4.0 ± 2.7	2.7 ± 2.2	–32.5	0.48	–1.3	(–4.4, 1.8)
	3	7.3 ± 6.0	3.7 ± 1.7	–49.3	0.09	–3.6	(–8.0, 0.8)
Semicontrolled Falls (VAS, 0–100)	2	83.8 ± 16.8	93.1 ± 6.5	11.1	0.20	9.3	(–5.9, 24.6)
	3	86.0 ± 12.2	94.3 ± 5.5	9.7	0.07	8.3	(–1.0, 17.5)
Semicontrolled Falls (Number, 0 →)	2	1.6 ± 1.5	0.6 ± 0.3	–62.5	0.11	–1.0	(–2.2, 0.2)
	3	2.9 ± 4.7	0.7 ± 0.9	–75.9	0.16	–2.2	(–5.7, 1.4)
Uncontrolled Falls (VAS, 0–100)	2	93.9 ± 3.3	98.1 ± 1.9	4.5	0.01	4.2	(1.4, 6.9)
	3	93.1 ± 6.8	97.8 ± 2.1	4.9	0.10	4.6	(–1.2, 10.4)
Uncontrolled Falls (Number, 0 →)	2	0.5 ± 0.5	0.0 ± 0.1	–80.0	0.01	–0.4	(–0.8, –0.1)
	3	0.5 ± 0.3	0.4 ± 0.5	–20.0	0.28	–0.1	(–0.6, 0.5)

CI = confidence interval, SD = standard deviation, VAS = visual analog scale.

Increased mean VAS scores and a mean reduction in numbers of adverse events were observed in each of the other outcomes for both subject groups. While no significant decreases in the mean VAS score for the fear outcomes were noted, several safety outcomes showed significant changes when the subjects wore the active-control prosthesis as compared with the passive-control prosthesis.

The MFCL-3 group reported a significant increase (i.e., improvement) in the mean VAS score relating to the relative frequency of stumbles ($p = 0.03$). However, this finding was not mirrored in a significant decrease ($p = 0.09$) in reported number of stumbles. Analysis of SC falls showed that neither cohort reported a significantly reduced frequency of falls or a significant difference in the reported number of falls. Only the MFCL-2 subjects showed a significant decrease in UC fall events, but that data revealed that frequency ($p = 0.01$) and reported number ($p = 0.01$) of UC falls were significantly improved in the active-control prosthesis compared with the passive-control prosthesis.

Analysis of the combined population data of the PEQ Addendum showed marked changes in mean outcome scores due to the influence of the active-control prosthesis. Mental energy, confidence, multitasking, frustration, stumble frequency, SC fall frequency, and UC fall frequency showed significantly higher ($p < 0.05$) mean scores in the active knee than the passive knee (**Figure 3**). However, no significant difference was noted for the activity avoidance or embarrassment measures. The mean number of reported UC falls for the combined population also significantly decreased ($p = 0.016$) when subjects wore the active-control knee as compared with passive control of the prosthesis.

Upon conclusion of the study, all subjects were again evaluated for functional level by the study team. Eight subjects (i.e., four MFCL-2 and four MFCL-3) were assessed at the same MFCL as when they began the study. Of the subjects initially rated as MFCL-2, 50.0 percent were rated as MFCL-3 upon conclusion of the study. Similarly, 33.3 percent of the initially rated MFCL-3 subjects transitioned to MFCL-4. Conversely, two MFCL-3 subjects were rated as MFCL-2 upon final evaluation. Other assessed and self-assessed outcomes varied by subject (**Table 8**).

The change in AMP score significantly correlated with the change in MFCL rating ($r_s = 0.62$, $p = 0.008$). Neither a change in PEQ Well-Being nor a change in SF-36 General Health correlated with a change in MFCL rating ($r_s = -0.30$ and $r_s = -0.04$, respectively).

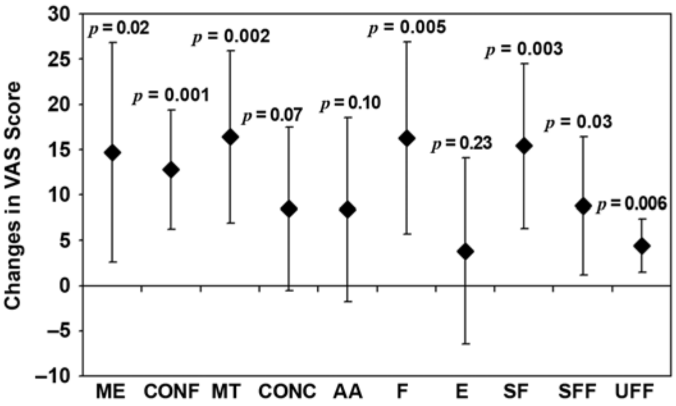

Figure 3.
Mean change and 95% confidence interval in Prosthesis Evaluation Questionnaire Addendum visual analog scale (VAS) scores (active vs passive knee control of the prosthesis). AA = Activity Avoidance, CONC = Concentration, CONF = Confidence, E = Embarrassment, F = Frustration, ME = Mental Energy, MT = Multitasking, SF = Stumble Frequency, SFF = Semicontrolled Fall Frequency, UFF = Uncontrolled Fall Frequency.

DISCUSSION

The two cohorts studied here (i.e., the MFCL-2 and MFCL-3 subject groups) represent the largest populations of prosthesis users. While these groups are similar in their functional environment (i.e., home and the community), they differ greatly in their functional ability to navigate those environments. Functional differences such as the ability to change cadence and/or participation in "vocational, therapeutic, or exercise activities" distinguish the MFCL-3 from the MFCL-2 level (**Table 1**) [14]. Individuals classified as MFCL-2 are commonly challenged by the effects of increased age, higher levels of amputation, compromised physical strength, and/or limited coordination. Therefore for these individuals, safety and stability are often prioritized in the prosthetic prescription over performance and efficiency.

The enrolled MFCL-2 cohort demonstrated the expected characteristics of this group, including a higher age and lower assessed mobility score. Although subjects' self-assessed general health and well-being scores were higher for the MFCL-3 group, the scores were not significantly different between the MFCL-2 and MFCL-3 populations. This finding suggests that persons with amputation may not associate their overall condition with their disability or functional status. This finding is consistent with Legro et al., who found that the General Health subscale of the PEQ did not differ significantly among age groups of persons with lower-limb amputation [23]. MFCL-2 subjects, on average, required slightly more therapy visits and prosthetic adjustments to accommodate to the active-control knee but, interestingly, required less overall time to accommodate. The extra visits may have sped up the time to accommodation, though a larger study would be needed to draw such a correlation.

One limitation to the presented study is the sample size of the subject groups (i.e., $n = 8$ and $n = 9$ for the MFCL-2 and MFCL-3 cohorts, respectively). This limitation is common to experimental limb-loss research, particularly when long-term accommodation to a prosthesis is required. However, similar studies of subjects with transfemoral amputation have shown differences between active and passive control of the knee joint in samples of 8 to 15 subjects [9–11,13]. Given the differences in initial age and mobility between the MFCL-2 and MFCL-3 subjects in this study, subjects were first analyzed as individual cohorts. However, given the relative similarities in other demographic characteristics, populationwide statistics

Table 8.
Comparison of participants' initial and final functional levels and health outcomes.

Subject	MFCL			AMP			PEQ Well-Being			SF-36 General Health		
	Initial	Final	Δ	Initial	Final	Δ	Initial	Final	Δ	Initial	Final	Δ
1	2	2	0	37	39	2	75	95	20.0	100	100	0
2	3	2	–1	38	32	–6	65	72	7.0	70	60	–10
3	2	3	1	39	39	0	72	58	–14.0	65	60	–5
4	3	3	0	40	39	–1	52	93	40.5	60	90	30
5	2	2	0	34	32	–2	52	73	21.5	65	60	–5
6	2	3	1	38	40	2	95	86	–9.0	90	75	–15
7	2	3	1	38	41	3	49	68	19.0	65	55	–10
8	3	4	1	43	42	–1	99	96	–2.5	80	75	–5
9	2	3	1	36	43	7	86	93	7.0	90	85	–5
10	3	3	0	40	40	0	75	45	–30.5	75	70	–5
11	3	4	1	43	42	–1	88	82	–6.0	100	100	0
12	3	3	0	43	41	–2	28	26	–2.0	70	15	–55
13	3	2	–1	40	37	–3	99	99	0.5	90	85	–5
14	3	3	0	40	39	–1	66	69	2.5	90	75	–15
15	3	4	1	43	42	–1	96	99	2.5	80	70	–10
16	2	2	0	41	39	–2	85	84	–1.0	70	65	–5
17	2	2	0	36	37	1	63	79	16.0	45	40	–5
Mean	2.5	2.8	0.3	39.4	39.1	–0.3	73.1	77.3	4.2	76.8	69.4	–7.4

AMP = Amputee Mobility Predictor, MFCL = Medicare Functional Classification Level, PEQ = Prosthesis Evaluation Questionnaire, SF-36 = 36-Item Short-Form Health Survey.

were also considered. The combined analysis of subjects with amputation who have dissimilar characteristics is also not uncommon because of the relatively small populations from which to draw subjects and the varied etiologies, ages, and activity levels present in said groups. Here, the results obtained in the functional and self-assessed outcomes suggest that combined analysis is appropriate and that the cohort-level analysis may then interpret the specific influences of knee-control methodologies on the individual activity groups.

Functional evaluations of the MFCL-2 and MFCL-3 cohorts showed significant differences for both groups between use of active and passive control of the prosthetic knee. Notably, significant differences were found in quality of stair and hill descent (as measured by the SAI and HAI, respectively), speed of hill descent, and speed of walking on uneven terrain. Although active knee control has been found to reduce energy expenditure on level ground [11,13,26] and on treadmills [27], the effect of knee control on negotiating environmental barriers such as stairs and inclines has not been thoroughly investigated. A recent study by Seymour et al. measured significantly reduced ($p < 0.004$) steps and time as subjects with transfemoral amputation walked an obstacle course with the active-control C-Leg as opposed to a passive-control prosthesis [28]. The course used in that study was limited to level ground and turns on an indoor track. The data presented here suggest that active control of the knee also allows significantly increased speed when uneven terrain, steps, and inclines are included in an outdoor course. Given the requirement for MFCL-2 patients to traverse such barriers in order to transition to MFCL-3, active control of the prosthetic knee would seem to benefit that goal.

The need for concentration during walking is recognized as a challenge in prosthetic gait. Research by Miller et al. noted that 44.7 percent of persons with amputation who reported falling in the last 12 months experienced problems with concentration while ambulating [19]. This same problem was found both to be the largest contributor to a fear of falling [19] and to negatively correlate with balance confidence [29]. Here, we have attempted to quantify the effect of knee control on this rather abstract concept. Both the MFCL-2 and MFCL-3 cohorts demonstrated increased speed while ambulating with the active knee during a demanding attentional task (i.e., a reverse numbers test), and this increase was significant with the MFCL-2 cohort. Both groups showed a minor increase in accuracy of reverse number responses, but neither was significant. This finding would suggest that persons with amputation are able to maintain the same level of concentration while improving their ability to ambulate when using active knee control. This assessment is supported by responses in the PEQ Addendum, in which both groups scored significantly higher multitasking scores while using the active-control knee than when using the passive-control knee but did not show those same significant differences in the mental energy and concentration questions. Additionally, the MFCL-3 cohort reported significantly higher confidence scores while using the active-control knee. This result agrees with subjective feedback in another recent study in which seven of eight similar subjects preferred the active-control C-Leg over the passive-control Mauch SNS knee, citing increased confidence in the knee as one reason for their choice [10].

Other studies of the impact of knee control on cognition have shown dissimilar results. A study by Williams et al. found no significant change in cognitive results or speed in subjects with transfemoral amputation using an active-control C-Leg and a passive-control Mauch SNS knee [30]. A pilot study by Heller et al. also showed no significant difference in cognitive accuracy in subjects comparing an active-control IP knee and a passive knee [12]. Those cognitive tests were conducted along an indoor test track [30] and on a treadmill [12], while those described in this study were conducted in a more natural setting (i.e., a sidewalk along a busy city street). This difference in setting may have contributed to the differences reported. Given the abstract nature of this concept and the difficulty in measuring it, more research is needed to understand the influence of knee control on attentional demand, particularly as it relates to setting and real-world activity.

Subjects' impression of function and QOL varied somewhat between the MFCL cohorts. While both cohorts reported mean increases in all PEQ subscales except Residual Limb, the MFCL-3 subjects were significantly more satisfied and felt improvements in walking ability, noise, and usefulness (as measured by the Ambulation, Sounds, and Utility PEQ subscales) with the actively controlled C-Leg as compared with their passively controlled prosthesis. These data suggest that subjects with higher activity levels may be more aware of those benefits provided by active control of the prosthesis. An evaluation of subjects' initial cognitive status may be useful in future research to assess each individual's sensitivity to perceived changes in these domains.

Persons with amputation, much like the elderly population, face apparent physical limitations that include compromised strength and balance. Despite an elevated frequency of falling events in the amputee population that is estimated at twice that of persons over 65 years of age [18,31], very little research has been conducted in this at-risk population. To date, research has focused on incidence rates [18,31] and obstacle avoidance [32–33] but has not addressed the influence of prosthetic intervention on these events. In this study, the influence of prosthetic knee control on falls and related safety was evaluated through subjects' perceived frequency of fall events, frustration with falls, and limitations in activity as a result of falls. In addition, subjects were asked to recall the number of stumbles, SC falls, and UC falls they experienced while using each prosthesis. This format for assessment of falling events was intended to address limitations with retrospective recall by asking similar questions two different ways, both as a raw number and as a relative frequency (i.e., along a spectrum from "all of the time" to "none of the time").

The MFCL-2 and MFCL-3 cohorts both reported a smaller average number of stumbles, SC falls, and UC falls while wearing the active-control knee. The only significant reduction in number of adverse events was noted in the MFCL-2 cohort for UC falls. This group reported a significantly lower number of falls in the active-control knee than the passive-control knee. Furthermore, the MFCL-2 cohort also reported a significantly lower frequency of UC falls (i.e., VAS score for relative frequency of the adverse event). This result is consistent with a recent study by Segal et al. wherein the majority of subjects preferred the C-Leg over a passive-control knee partly because of a reduced number of falling events [10]. This finding suggests that active knee control effectively controls high-impact fall events (i.e., UC falls) in an at-risk population.

Though changes to assessed performance and subjects' perceived function, QOL, and safety were hypothesized to occur with use of the active-control knee, one unexpected result was discovered on final assessment of MFCL after the extended study period. On evaluation, we found that one-half of the MFCL-2 cohort had so improved their functional ability that they were reclassified as MFCL-3. Likewise, one-third of those originally classified as MFCL-3 were subsequently able to participate in high-impact activities and were correspondingly reclassified as MFCL-4. Although the provision of a prosthesis is expected to allow a patient to function at a higher level than without the prosthesis, the effect of different devices on an individual's assessed MFCL has never been explored before now. Changes to a patient's MFCL are commonly expected immediately following amputation and early into a rehabilitation program [34]. Such transitions, however, are typically due to a change in a medical condition or obtained through physical therapy. Here, one could argue that the physical therapy provided to study subjects was the causal factor for the change in functional status and not the use of an active-control knee. However, the study subjects were only provided therapy during the transition period in the active-control knee in order to achieve a level of basic function and safety equivalent to that demonstrated previously in the passive-control knee. Therefore, the changes in outcome and functional status achieved here were not expected to be the result of provided therapy.

The changes in MFCL over the study period seem to indicate that the provision of advanced technology (i.e., active control of the prosthetic knee) can potentially expand the functional domain of a person with amputation. Aside from improved function and safety, such a transition may also allow patients access to a greater range of prosthetic components. These subjects might have transitioned to a higher functional level without the addition of active knee control. However, given the age and history of the subjects and the large proportion of subjects who were reclassified, this seems unlikely. A prospective cohort study of subjects receiving either passive- or active-control knees is recommended to further evaluate this potential benefit to active knee control.

One limitation to this study involves the subjective assessment of MFCL. Because the MFCL classification involves either the "ability or potential" to perform various activities, one could argue that subjects were initially classified by ability and later classified by potential. To address this concern, two members of the study team (i.e., a prosthetist and a physical therapist) evaluated subjects by "potential" rather than "ability" and obtained agreement on each subject's MFCL classification. In the future, researchers should also consider using validated, objective functional outcomes at the time of assessment, including timed tests such as the timed walk test or the timed up-and-go test.

The chosen data reduction and associated statistical analysis may present a limitation. Reduction of the data collected from the six data-collection sessions into either "active" or "passive" conditions may dampen effects to the data that may be present in the time history. As with any study design, time-dependent threats such as history, testing, and maturation exist here. While the chosen analysis technique may not reflect variations due to learning, aging, environment (weather), or testing conditions (time of day, illness, etc.), it does attempt to mitigate such influences by averaging the results of multiple data-collection sessions and alternation of the interventions over the first four sessions. Similarly, use of multiple outcome measures and extended time between assessments minimizes the threat of subjects adapting to the test procedures.

Another limitation of this study is the chosen controls in the experimental design. The study presented here did not randomize application of the interventions or control for the type of passive (i.e., mechanical) knee. Instead, we elected to begin all subjects in their familiar and prescribed prosthesis, so long as it was safe, mechanically sound, and comfortable. Given the indeterminate time required for accommodation to changes to a prosthesis, we felt that first testing subjects in their existing prosthesis was most appropriate because it established a functional baseline for the passive-control prosthesis. Once this baseline was established, the research team was able to set the functional criteria needed for accommodation to the active-control prosthesis. Other researchers have elected to control the type of knee and randomize the interventions in transfemoral amputation studies and set a fixed accommodation time anywhere from 10 hours [11] to 3 months [9–10]. However, until the acclimation period for these transfemoral devices is established, the results may be influenced by subjects unaccustomed to the intervention. The research team felt that the chosen design would most accurately reflect subjects' functional ability in and perceptions of their passive-control prosthesis. Additionally, this design most commonly reflects traditional clinical practice in which patients are prescribed an active-control knee only after they have previous experience in a passive-control knee.

This study was conducted to measure the influence of active and passive knee control in persons with transfemoral amputation. Another goal was to explore similarities and differences between subjects rated as MFCL-2 and MFCL-3 according to the CMS classification system. This work is novel in that previous research has focused on members of a single classification or has not considered these groups as individual cohorts. The results of this study have shown that, in many cases, the MFCL-2 and MFCL-3 cohorts responded similarly to the use of active knee control and passive knee control in the prosthetic knee joint. Significant changes in subjects' ability to function on inclines, stairs, and uneven terrain were observed when subjects used the active-control C-Leg prosthesis. The results also showed differences in how the cohorts responded in other areas. For example, the mean number and frequency of adverse events, including stumbles, SC falls, and UC falls improved in the active-control knee condition as compared with the passive-control knee condition for the entire study population. However, only the MFCL-2 cohort significantly benefitted (as noted from a significant reduction in the number of events and a reported reduction in the frequency using the VAS score) from active control and in only one type of adverse event—UC falls.

Although microprocessor-controlled knees are not commonly prescribed for the MFCL-2 population because of their overall level of activity and functional limitations, the research presented here suggests that provision of such devices may allow subjects to improve their functional status while reducing the frequency of adverse events. Likewise, providing such devices to new amputees may increase safety and security in the early stages of rehabilitation. Given the frequency of falls, the associated injuries, and resultant medical costs reported for the population with amputation, any device noted to significantly reduce those events should be strongly considered in these at-risk populations. The evidence here does not suggest a universal recommendation for advanced technology in prosthetic prescriptions. Indeed, patients' function may be as much impaired if they are provided with components that are either too inadequate or too complicated [35]. In the case of the microprocessor-controlled knee, the patient must be able to properly use the device, including demonstrating knowledge of the knee's safety features and need for maintenance and recharging. However, given the potential shown here for persons with amputation to transition between functional levels, the provision of advanced technology in the prosthetic prescription should be at the very least considered as an option for MFCL-2 patients rather than summarily dismissed as inappropriate.

Future research should further examine the potential for established amputees to change in functional ability over an extended period of time. The influence of prosthetic components is just one area of many that would benefit from additional research. The impact of physical therapy and exercise in the long-term functional ability of established amputees is likewise unexplored. Levine noted that "the multifaceted nature of function after amputation makes predicting outcome difficult and often subjective" [35]. Therefore, to match each individual with the appropriate medical, rehabilitation, and prosthetic care, we must understand how individuals change over time and which interventions offer individuals with lower-limb amputation the most potential to overcome the physical, functional, and psychological challenges they face.

CONCLUSIONS

This study examined the influence of active and passive knee control on the function and safety of persons with transfemoral amputation who were classified as MFCL-2 and MFCL-3. Both the MFCL-2 and MFCL-3 cohorts showed significant improvements in negotiating environmental obstacles (i.e., walking down inclines, walking downstairs, and walking over uneven terrain) while using the active-control knee as compared with the passive-control knee. Active control of the prosthetic knee also resulted in significantly fewer UC falls (MFCL-2 cohort). These benefits provided by active control of the knee allowed 50 percent of MFCL-2 subjects and 33 percent of MFCL-3 subjects to transition to a higher activity level by the end of the study. Such a transition indicates that advanced technology, typically reserved for the most active subjects, equally benefits less active subjects and may address the functional limitations that prevent them from reaching higher levels of activity. Furthermore, the reduction in adverse events obtained with active knee control may lead to fewer injuries and lowered long-term medical costs in a population that is at-risk for falls and injury.

ACKNOWLEDGMENTS

Author Contributions:
Study concept and design: D. G. Smith.
Analysis and interpretation of data: B. J. Hafner.
Drafting of manuscript: B. J. Hafner.
Critical revision of manuscript for important intellectual content: B. J. Hafner.
Statistical analysis: B. J. Hafner.
Obtained funding: B. J. Hafner, D. G. Smith.
Study supervision: B. J. Hafner, D. G. Smith.

Financial Disclosures: The authors have declared that no competing interests exist. The study sponsor, Otto Bock, had no involvement in

the study design; in the collection, analysis, and interpretation of data; in the writing of the report; and in the decision to submit the report for publication.

Funding/Support: This material was based on work supported by a research grant from Otto Bock HealthCare, LP.

Additional Contributions: We would like to thank Sharon Hubbard, MS, for assistance with grant management and manuscript preparation, Laura Willingham for project management and data entry, Kate Allyn, CPO, for prosthetic care and data collection, and Noelle Buell, MS, for physical therapy and data collection. Dr. Hafner is now with the University of Washington.

Participant Follow-Up: The authors do not plan to inform participants of the publication of this study. However, participants have been encouraged to check the Prosthetics Research Study Web site for updated publications related to the program's activities, which include the present study.

REFERENCES

1. Waters RL, Mulroy S. The energy expenditure of normal and pathologic gait. Gait Posture. 1999;9(3):207–31. [PMID: 10575082] DOI:10.1016/S0966-6362(99)00009-0
2. Sulzle H, Pagliarulo M, Rodgers M, Jordan C. Energetics of amputee gait. Orthop Clin North Am. 1978;9(2):358–62. [PMID: 662299]
3. Waters RL, Perry J, Antonelli D, Hislop H. Energy cost of walking of amputees: The influence of level of amputation. J Bone Joint Surg Am. 1976;58(1):42–46. [PMID: 1249111]
4. Traugh GH, Corcoran PJ, Reyes RL. Energy expenditure of ambulation in patients with above-knee amputations. Arch Phys Med Rehabil. 1975;56(2):67–71. [PMID: 1124978]
5. James U. Oxygen uptake and heart rate during prosthetic walking in healthy male unilateral above-knee amputees. Scand J Rehabil Med. 1973;5(2):71–80. [PMID: 4695243]
6. Schmid M, Beltrami G, Zambarbieri D, Verni G. Centre of pressure displacements in trans-femoral amputees during gait. Gait Posture. 2005;21(3):255–62. [PMID: 15760740] DOI:10.1016/j.gaitpost.2004.01.016
7. Jaegers SM, Arendzen JH, De Jongh HJ. Prosthetic gait of unilateral transfemoral amputees: A kinematic study. Arch Phys Med Rehabil. 1995;76(8):736–43. [PMID: 7632129] DOI:10.1016/S0003-9993(95)80528-1
8. Buckley JG, O'Driscoll D, Bennett SJ. Postural sway and active balance performance in highly active lower-limb amputees. Am J Phys Med Rehabil. 2002;81(1):13–20. [PMID: 11807327] DOI:10.1097/00002060-200201000-00004
9. Orendurff MS, Segal AD, Klute GK, McDowell ML, Pecoraro JA, Czerniecki JM. Gait efficiency using the C-Leg. J Rehabil Res Dev. 2006;43(2):239–46. [PMID: 16847790] DOI:10.1682/JRRD.2005.06.0095
10. Segal AD, Orendurff MS, Klute GK, McDowell ML, Pecoraro JA, Shofer J, Czerniecki JM. Kinematic and kinetic comparisons of transfemoral amputee gait using C-Leg and Mauch SNS prosthetic knees. J Rehabil Res Dev. 2006; 43(7):857–70. [PMID: 17436172] DOI:10.1682/JRRD.2005.09.0147
11. Johansson JL, Sherrill DM, Riley PO, Bonato P, Herr H. A clinical comparison of variable-damping and mechanically passive prosthetic knee devices. Am J Phys Med Rehabil. 2005;84(8):563–75. [PMID: 16034225] DOI:10.1097/01.phm.0000174665.74933.0b
12. Heller BW, Datta D, Howitt J. A pilot study comparing the cognitive demand of walking for transfemoral amputees using the Intelligent Prosthesis with that using conventionally damped knees. Clin Rehabil. 2000;14(5):518–22. [PMID: 11043877] DOI:10.1191/0269215500cr345oa
13. Kaufman KR, Levine JA, Brey RH, Iverson BK, McCrady SK, Padgett DG, Joyner MJ. Gait and balance of transfemoral amputees using passive mechanical and microprocessor-controlled prosthetic knees. Gait Posture. 2007;26(4): 489–93. [PMID: 17869114] DOI:10.1016/j.gaitpost.2007.07.011
14. Medicare region C durable medical equipment prosthetics orthotic supplier (DMEPOS) manual. Columbia (SC): Palmetto GBA; 2005. p. 53.5–6.
15. Zahedi S. Experience and future of microprocessor swing-and-stance control in lower-limb prosthetics. Proceedings of the International Society for Prosthetics and Orthotics. 1998 Jun 28–Jul 5; Amsterdam, the Netherlands; Copenhagen (Denmark): International Society for Prosthetics and Orthotics; 1998. p. 47–49.
16. Swanson E, Stube J, Edman P. Function and body image levels in individuals with transfemoral amputations using the C-Leg®. J Prosthet Orthot. 2005;17(3):80–84. DOI:10.1097/00008526-200507000-00004
17. Datta D, Howitt J. Conventional versus microchip controlled pneumatic swing phase control for trans-femoral amputees: User's verdict. Prosthet Orthot Int. 1998;22(2): 129–35. [PMID: 9747997]
18. Gauthier-Gagnon C, Grisé MC, Potvin D. Enabling factors related to prosthetic use by people with transtibial and transfemoral amputation. Arch Phys Med Rehabil. 1999; 80(6):706–13. [PMID: 10378500] DOI:10.1016/S0003-9993(99)90177-6
19. Miller WC, Speechley M, Deathe B. The prevalence and risk factors of falling and fear of falling among lower extremity amputees. Arch Phys Med Rehabil. 2001;82(8): 1031–37. [PMID: 11494181] DOI:10.1053/apmr.2001.24295

20. Miller WC, Speechley M, Deathe AB. Balance confidence among people with lower-limb amputations. Phys Ther. 2002;82(9):856–65. [PMID: 12201800]
21. Friel K. Componentry for lower extremity prostheses. J Am Acad Orthop Surg. 2005;13(5):326–35. [PMID: 16148358]
22. Gailey RS, Roach KE, Applegate EB, Cho B, Cunniffe B, Licht S, Maguire M, Nash MS. The amputee mobility predictor: An instrument to assess determinants of the lower-limb amputee's ability to ambulate. Arch Phys Med Rehabil. 2002;83(5):613–27. [PMID: 11994800]
23. Legro MW, Reiber GD, Smith DG, Del Aguila M, Larsen J, Boone D. Prosthesis evaluation questionnaire for persons with lower limb amputations: Assessing prosthesis-related quality of life. Arch Phys Med Rehabil. 1998;79(8):931–38. [PMID: 9710165] DOI:10.1016/S0003-9993(98)90090-9
24. English RD, Hubbard WA, McElroy GK. Establishment of consistent gait after fitting of new components. J Rehabil Res Dev. 1995;32(1):32–35. [PMID: 7760265]
25. Hafner BJ, Willingham LL, Buell NC, Allyn KJ, Smith DG. Evaluation of function, performance, and preference as transfemoral amputees transition from mechanical to microprocessor control of the prosthetic knee. Arch Phys Med Rehabil. 2007;88(2):207–17. [PMID: 17270519] Erratum in: Arch Phys Med Rehabil. 2007;88(4):544.
26. Chin T, Machida K, Sawamura S, Shiba R, Oyabu H, Nagakura Y, Takase I, Nakagawa A. Comparison of different microprocessor controlled knee joints on the energy consumption during walking in trans-femoral amputees: Intelligent Knee Prosthesis (IP) versus C-Leg. Prosthet Orthot Int. 2006;30(1):73–80. [PMID: 16739783] DOI:10.1080/03093640500533414
27. Datta D, Heller B, Howitt J. A comparative evaluation of oxygen consumption and gait pattern in amputees using Intelligent Prostheses and conventionally damped knee swing-phase control. Clin Rehabil. 2005;19(4):398–403. [PMID: 15929508] DOI:10.1191/0269215505cr805oa
28. Seymour R, Engbretson B, Kott K, Ordway N, Brooks G, Crannell J, Hickernell E, Wheeler K. Comparison between the C-Leg microprocessor-controlled prosthetic knee and non-microprocessor control prosthetic knees: A preliminary study of energy expenditure, obstacle course performance, and quality of life survey. Prosthet Orthot Int. 2007;31(1):51–61. [PMID: 17365885] DOI:10.1080/03093640600982255
29. Miller WC, Deathe AB. A prospective study examining balance confidence among individuals with lower limb amputation. Disabil Rehabil. 2004;26(14–15):875–81. [PMID: 15497916] DOI:10.1080/09638280410001708887
30. Williams RM, Turner AP, Orendurff M, Segal AD, Klute GK, Pecoraro J, Czerniecki J. Does having a computerized prosthetic knee influence cognitive performance during amputee walking? Arch Phys Med Rehabil. 2006;87(7):989–94. [PMID: 16813788] DOI:10.1016/j.apmr.2006.03.006
31. Tinetti ME. Clinical practice. Preventing falls in elderly persons. N Engl J Med. 2003;348(1):42–49. [PMID: 12510042] DOI:10.1056/NEJMcp020719
32. Hill SW, Patla AE, Ishac MG, Adkin AL, Supan TJ, Barth DG. Altered kinetic strategy for the control of swing limb elevation over obstacles in unilateral below-knee amputee gait. J Biomech. 1999;32(5):545–49. [PMID: 10327009] DOI:10.1016/S0021-9290(98)00168-7
33. Hofstad CJ, Van der Linde H, Nienhuis B, Weerdesteyn V, Duysens J, Geurts AC. High failure rates when avoiding obstacles during treadmill walking in patients with a transtibial amputation. Arch Phys Med Rehabil. 2006;87(8):1115–22. [PMID: 16876558] DOI:10.1016/j.apmr.2006.04.009
34. Cole ES. Training elders with transfemoral amputations. Top Geriatr Rehabil. 2003;19(3):183–90.
35. Levin AZ. Functional outcome following amputation. Top Geriatr Rehabil. 2004;20(4):253–61.

Submitted for publication January 13, 2008. Accepted in revised form September 8, 2008.