ORIGINAL ARTICLE

Evaluation of Function, Performance, and Preference as Transfemoral Amputees Transition From Mechanical to Microprocessor Control of the Prosthetic Knee

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ABSTRACT. 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;88:207-17.

Objective: To evaluate differences in function, performance, and preference between mechanical and microprocessor prosthetic knee control technologies.

Design: A-B-A-B reversal design.

Setting: Home, community, and laboratory environments.

Participants: Twenty-one unilateral, transfemoral amputees.

Intervention: Mechanical control prosthetic knee versus microprocessor control prosthetic knee (Otto Bock C-Leg).

Main Outcome Measures: Stair rating, hill rating and time, obstacle course time, divided attention task accuracy and time, Amputee Mobility Predictor score, step activity, Prosthesis Evaluation Questionnaire score, Medical Outcomes Study 36-Item Short-Form Health Survey score, self-reported frequency of stumbles and falls, and self-reported concentration required for ambulation.

Results: Stair descent score, hill descent time, and hill sound-side step length showed significant ($P<.01$) improvement with the C-Leg. Users reported a significant ($P<.05$) decrease in frequency of stumbles and falls, frustration with falling, and difficulty in multitasking while using the microprocessor knee. Subject satisfaction with the C-Leg was significantly ($P<.001$) greater than the mechanical control prosthesis.

Conclusions: The study population showed improved performance when negotiating stairs and hills, reduced frequency of stumbling and falling, and a preference for the microprocessor control C-Leg as compared with the mechanical control prosthetic knee.

Key Words: Amputees; Artificial limbs; Knee; Patient satisfaction; Rehabilitation.

AMPUTATION OF A MAJOR extremity is a life-altering event that greatly affects a person's ability to perform many functions needed for independent living. The more proximal the level of amputation, the more impact the limb loss will have on these activities. For many amputees, rehabilitation after an amputation involves the use of a prosthetic limb as a substitute for the lost extremity. Prosthetic use can restore much of the functional ability lost because of the amputation of a limb. Selection of the appropriate prosthetic component(s) for a person is a critical factor in determining the degree to which function can be restored. For a transfemoral amputee, the prosthesis typically includes a socket, knee, pylon, and foot. The design and function of the prosthetic knee is of particular importance because it is the most proximal artificial joint that the amputee must stabilize and control to effectively ambulate. A wide variety of prosthetic knee components are available, each designed to specific users, purposes, or functions.

Prosthetic knees can be classified into 2 distinct categories: those that use exclusive mechanical control of the knee joint and those that use some form of microprocessor control to manage the swing and/or stance phases of gait.[1] Historically, transfemoral prostheses use a passive, mechanical (ie, free swing, manual lock, constant friction, weight-activated friction, fixed-aperture fluid) mechanism in the knee joint to control the swing and stance phases of gait. More recently, these prostheses have adopted active, microprocessor-controlled systems. Although mechanical and microprocessor control knees are functionally similar, microprocessor control allows dynamic management of the flexion and extension behavior of the knee joint throughout the gait cycle, providing a number of potential benefits to the amputee.

The Blatchford[a] Intelligent Prosthesis (IP) knee was the first commercially available prosthetic knee to offer microprocessor control in lieu of a mechanical control mechanism.[2] The IP knee incorporates microprocessor control of the swing phase of gait. Active management of swing phase behavior was claimed to reduce energy expenditure, adjust to a greater range of walking speeds, and provide for a more natural gait pattern. A survey of 22 IP knee users suggested that microprocessor control most influenced metabolic energy expenditure, walking at varying speeds, and distance walking.[3] The scientific research that followed the release of the IP knee attempted to measure these benefits.

Several researchers[3-8] investigated the influence of swing-phase microprocessor control on metabolic energy expenditure. A study of a single subject by Taylor et al[4] found that oxygen rate was reduced with the IP knee as compared with a mechanical knee but only at speeds in excess of 53m/min. Buckley[5] and Datta[8] and colleagues showed similar results, showing that the IP knee significantly reduced the oxygen rate and cost, respectively, at walking speeds above or below (but not at) self-selected. In a population of 3 hip-disarticulation amputees, Chin et al[7] reported a significant reduction in oxygen rate when

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using the IP knee at speeds between 30 and 70m/min. Chin et al[6] also noted a decrease in oxygen rate in transfemoral amputees using the IP knee, although the comparative mechanical control data were obtained from the literature rather than experimental trials. These results suggest that microprocessor swing control is most effective at mitigating energy expenditure when amputees walk above or below customary self-selected speeds.

The influence of microprocessor swing control on gait and cognitive demand were also investigated. Datta et al[8] measured walking speed and step symmetry in 10 transfemoral amputees by using both the IP knee and a mechanical control (ie, pneumatic) knee. No significant differences in self-selected slow, normal, or fast speed; step symmetry; or stride symmetry were reported between the different control mechanisms. Cognitive demand, or the concentration required for ambulation, was recently investigated by Heller et al[9] in 10 subjects wearing an IP and a mechanical control knee. An automation index, defined by the researchers as the ratio of total body sway measured while subjects walked and simultaneously performed a simple mental task over the sway measured while subjects walked and performed a complex mental task, was used to compare the knees. No significant difference in automation index was noted between knees, although greater total sway was recorded while subjects walked on the mechanical control knee. These results do not support those temporospatial or cognitive demand improvements reported by IP knee users.[3]

Microprocessor control of the prosthetic knee evolved to also include stance phase in the late 1990s. The Otto Bock[b] C-Leg was the first commercially available knee to use microprocessor control in both the swing and stance phases of gait. This addition provides active management of knee flexion and extension across a broad range of functional domains including level ground, stairs, slopes, and uneven terrain. The manufacturer claims that microprocessor control of both phases of gait can provide increased safety, stability, and function as well as a reduction in energy expenditure and concentration required for ambulation.

As with microprocessor swing control, microprocessor stance control research has focused largely on metabolic energy expenditure measured on level, indoor terrain. Perry et al[10] examined rate of oxygen consumption and gait biomechanics of a bilateral, knee disarticulation amputee wearing mechanical control knees and microprocessor control C-Legs. The research found that the C-Leg promoted increased speed, cadence, and stride length while requiring less oxygen, although no statistical analysis was performed. Johansson et al[11] measured oxygen rate, kinetics, and kinematics in 8 transfemoral amputees wearing mechanical and microprocessor swing and stance control knees. Results showed a decreased oxygen rate of 3% to 5% across the population when users wore the microprocessor knee as compared with the mechanical control knee. Chin et al[12] more recently assessed the impact of microprocessor control on oxygen rate and cost in 4 transfemoral amputees. This research compared the C-Leg and IP knee to able-bodied subjects and found no significant difference in the oxygen rate or cost between the knees but showed that the energy expended with either was lower than that reported in the literature for this population.

Anecdotal reports suggest that microprocessor control is most beneficial in functional activities outside of level walking. Improvement in stair descent, ramp or hill descent, and walking on uneven terrain are commonly noted by users after transitioning to microprocessor stance control. However, these conditions are rarely researched. To date, only 1 study has examined microprocessor-controlled stair descent. Schmalz et al[13] recently studied stair descent kinetics and kinematics in 12 transfemoral amputees by using both mechanical and microprocessor knee control. Results showed that kinetics and kinematics of the microprocessor control knee were closer to the normal knee and produced a significantly ($P<.01$) reduced maximum sound-side weight-acceptance force and increased ($P<.01$) maximum knee flexion moment when compared with mechanical control knees. Although this suggests that microprocessor control may be more beneficial than mechanical control for descending stairs, little is known about how microprocessor control influences function on slopes or uneven terrain, likely because of a lack of objective outcome measures that target these activities. Therefore, if these activities are to be measured, novel performance outcomes must be used in conjunction with established measures to explore the potential benefits of microprocessor control in the prosthetic knee.

The purpose of this study is to observe transfemoral amputees transitioning from mechanical to microprocessor control of the prosthetic knee and to measure subjects' functional ability, performance characteristics, and preference for each type of control mechanism. It was hypothesized that satisfaction and performance on stairs, hills, and uneven terrain would improve after users transitioned from mechanical control to microprocessor control of the prosthetic knee. Secondary hypotheses included (1) users would prefer to use the prosthesis with the microprocessor knee control, (2) users would experience a reduction in the cognitive demand required for walking, and (3) users would experience fewer stumbles and falls after the transition to microprocessor control of the prosthetic knee.

METHODS

The clinical trial was conducted as a controlled reversal design (ie, A-B-A-B) in which each subject was exposed to 2 different prosthetic limb conditions: a mechanical (ie, nonmicroprocessor) control prosthesis and a microprocessor control Otto Bock C-Leg (model 3C99) prosthesis. Subjects were exposed to each prosthetic limb condition 2 times during the trial (fig 1). Ideally, a reversal design would incorporate randomization with an equal number of crossover phases. In this

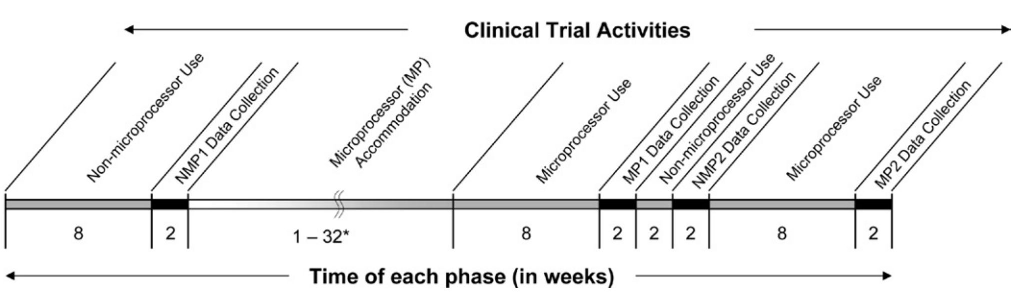

Fig 1. Study design overview. Data-collection sessions follow a period of either mechanical (ie, nonmicroprocessor [NMP]) or microprocessor (MP) control prosthetic knee use. *Time of accommodation varied among subjects.

study, the order of the tested prostheses was not randomized. Instead, subjects were enrolled only when fully accustomed to a nonspecific mechanical knee system and then transitioned to a microprocessor control system. This design was intentionally selected because it replicates common clinical practice. Typically, patients that are prescribed a microprocessor knee transition to that system from a variety of mechanical control knees. Therefore, for this study, the mechanical, nonmicroprocessor (NMP) limb configuration was the baseline (A) measure and the microprocessor (MP) knee was the intervention (B) measure for all subjects in this study design.

Recruitment and Enrollment

Volunteer subjects were recruited for participation from the local amputee population. Inclusion criteria for enrollment included ages 18 or older, unilateral transfemoral amputation, Medicare Functional Classification Level 2 or 3, a minimum of 2 years postamputation, and current use of a mechanical control knee. Exclusion criteria included chronic residual limb skin breakdown or secondary health problems that would prohibit participation in the study activities. Human subject approval was granted through the University of Washington Internal Review Board. Informed consent was obtained from all subjects.

Enrollment in the clinical trial required that candidates pass a physical assessment, functional evaluation, and prosthetic appraisal by the research prosthetist and physical therapist. These examinations ensured that subjects met inclusion and exclusion criteria; could participate in all study activities; and showed proficient use of a comfortable, stable, and well-maintained mechanical control prosthesis, respectively. The prosthetist and therapist each evaluated candidates independently by using Medicare ambulation definitions. Any discrepancies were debated until a final classification for each candidate was reached. All prostheses were evaluated to ensure comfortable, safe, and effective use during the trial. Proficient use of a mechanical control prosthesis required that each subject show the ability to ambulate without personal assistance on level ground, inclines, stairs, and uneven terrain. Candidates were enrolled only after showing proficiency in the mechanical control prosthesis.

Enrolled subjects were provided with a test prosthesis that included a duplicate socket and suspension system, an Otto Bock C-Leg, and an approved prosthetic foot that was functionally similar to each subject's previous prosthetic foot. To minimize bias, subjects were informed at the time of enrollment that they would be allowed to keep the test prosthesis whether or not they completed the trial. Subjects' existing sockets were duplicated by using either computer-aided design/computer-aided manufacturing or manual techniques, and subjects were only enrolled if both the prosthetist and subject agreed that the test socket was equivalent to their existing socket. One of the 21 recruited subjects could not obtain an equivalent socket and was withdrawn by the researchers.

Data Collection

On enrollment, subjects were asked to use the mechanical control prosthesis normally for a period of 2 months. Subjects' activity was monitored with a Cyma StepWatch 2 step activity monitor[c] to establish baseline activity and ensure each subject maintained regular activity over the initial study period. At the end of the 2-month activity assessment, subjects returned for functional, performance, and perceptive evaluation (see Outcome Measures section) of the mechanical control prosthesis (ie, the NMP evaluation).

After this NMP session, subjects were fit with the C-Leg prosthesis. Because accommodation time of a transfemoral prosthesis has not been reported in published literature, a fixed time for acclimation to the microprocessor control prosthesis was not set. Instead, users were allowed to accommodate until they (1) showed stable alignment in the test prosthesis, (2) required no additional changes to the C-Leg software settings, and (3) were able to perform those same "proficient-use" tasks (see Recruitment and Enrollment section) that each subject had previously shown in the mechanical control prosthesis. Once each subject showed this proficiency, they were asked to wear the microprocessor control prosthesis regularly for a period of 2 months. Step activity data were again acquired to document the subjects' chosen level of activity during this period. After this assessment phase, subjects returned for functional and subjective evaluation of the microprocessor control prosthesis (ie, the MP evaluation).

After the MP data collection, subjects were returned to their mechanical prosthesis for a period of 2 weeks. This shorter period of time was believed to be sufficient for subjects to functionally accommodate to a previously known prosthesis. After the 2-week activity assessment, subjects returned for a second mechanical control evaluation (ie, NMP2).

In the last phase of the study, subjects were able to use either or both the mechanical and microprocessor control prostheses over a period of 4 months. Daily use of each prosthesis and overall subject activity levels were recorded with StepWatch monitors. Subjects returned at the end of this period for a second microprocessor (MP2) evaluation. All subjects regularly used the C-Leg in their daily activity over this time, and subjects were deemed to be fully accommodated to this prosthesis before the MP2 evaluation. Additional long-term assessments are anticipated and will be reported elsewhere.

Outcome Measures

Functional, performance, and preferential outcomes were collected in the baseline (ie, NMP, NMP2) and intervention (ie, MP, MP2) activity phases and data-collection sessions. Functional outcomes were used to evaluate overall subject health and function and to isolate physical changes in the subject population from those caused by the prosthetic interventions. Performance and preference measures were used to assess differences between the prosthetic limbs.

Functional outcome measures established subjects' relative measure of potential and actual function over the duration of the trial. These included activity data, basic functional mobility, and self-reported general health. Although these measures were not expected to change over the duration of the trial, it was necessary to document these outcomes to show that changes in performance and preferential measures were the result of the prosthetic intervention (ie, microprocessor or mechanical control) and not an unrelated change in health or function. Activity was measured via step frequency and estimated daily distance traveled (ie, the product of daily step frequency and mean step length obtained in level walking at self-selected walking speed). Basic mobility was evaluated by the study therapist at all data-collection sessions by using the Amputee Mobility Predictor (AMP).[14] Subjects' health was self-assessed at each session by using the Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36).

Subject performance on level ground, stairs, decline, and uneven terrain in each prosthetic limb was assessed by the researchers during each data-collection session. Subjects' ability to ambulate on level ground was assessed by using step symmetry data recorded as subjects walked a 9-m (30-ft) carpeted floor at self-selected walking speed. The location of each heel was noted with chalk when the subject was in midstance (ie, the foot was flat on the ground). Step length,

Table 1: SAI

Score	Mobility Descriptor
0	Cannot do/refuses to do
1	Needs assist
2	With rail and assistive device, step-to pattern
3	With rail, step-to pattern
4	With assistive device, step-to pattern
5	Without rail or assistive device, step-to pattern
6	With rail and assistive device, skipping step pattern
7	With rail, skipping step pattern
8	With assistive device, skipping step pattern
9	Without rail or assistive device, skipping step pattern
10	With rail and assistive device, step-over-step pattern
11	With rail, step-over-step pattern
12	With assistive device, step-over-step pattern
13	Without rail or assistive device, step-over-step pattern

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noted as the distance between adjacent heel marks along the direction of travel, was recorded to the nearest 0.5cm by using a metric measuring tape. Stair ascent and descent ability was measured by using a custom assessment tool, the Stair Assessment Index (SAI).[15] Subjects were asked to ascend and descend a 12-step Americans with Disability Act−compliant stairwell as they were scored for functional independence and technique by using the 14-level SAI scale (table 1). Similarly, subjects' ability to ambulate a decline was measured with a custom Hill Assessment Index (HAI).[16] Subjects were asked to ambulate on a 28.2m (94-ft), 19° downgrade hill at self-selected speed. Subjects were scored for independence and technique by using the HAI (table 2), step length, and time of descent. The ability to navigate uneven terrain was assessed on a standardized, 73.2-m (244-ft) obstacle course that included level grass, wood chips, and sand as well as a cement ramp and stairs. Subjects were asked to walk at self-selected walking speed while overall time and mean speed were measured.

The cognitive demand (ie, "mental energy") of walking was also assessed as a performance measure. Subjects' concentration during ambulation was measured with a novel distracted walking test. Subjects were asked to walk 2 sides of a city block while talking on a cellular telephone with a study researcher. During the test, each subject was read 20 groups of randomized numbers in a series of 2, 3, 4, or 5 digits. Subjects were asked to repeat the numbers back to the researcher in reverse order and asked to stop walking when they had completed the verbal test. Cognitive demand was measured as the mean test speed and the test accuracy.

Subjects' self-assessed performance and perceived preference during the previous 4 weeks were measured at each session after all functional and performance tests were completed. Self-assessed satisfaction and performance were measured by using the Prosthesis Evaluation Questionnaire (PEQ).[17] Each subject's satisfaction with the tested limb was assessed with the first question of the PEQ (ie, "Over the past four weeks, how happy have you been with your prosthesis?"). Subjects were also polled as to which limb they most preferred after the MP2 data-collection session. Self-assessed performance was measured by using the 9 validated scales of the PEQ: ambulation, perceived response, sounds, appearance, residual limb, utility, frustration, social burden, and well-being. An additional 14 questions regarding subject confidence, concentration, stumbles, and falls were created and added to the PEQ as an addendum (PEQ-A) (table 3).

Statistical Analysis

Per-protocol outcomes across the study population were assessed with descriptive statistics (ie, means and standard errors) and compared between the baseline and intervention prostheses. NMP was selected as the baseline reference if the outcome was a functional or assessed performance measure. NMP2 was chosen as the baseline reference if the outcome was a self-assessed measure because self-assessment requires that both conditions receive equal experience. Population trends were noted as mean MP and MP2 outcomes that were a 5% or more improvement over the NMP or NMP2 outcomes.

Inferential statistics for ratio data (ie, time, speed) were conducted with a single-factor repeated-measures analysis of variance (α=.05). Pairwise significant differences were identified by using a Tukey honestly significant differences post hoc test with 95% confidence intervals. Inferential statistics for ordinal data (eg, SAI, HAI) were conducted with a repeated-measures Friedman test (α=.05) and a Dunn post hoc test at a 95% confidence interval. Statistical analyses were conducted by using GraphPad Prism software.[d] Significant differences were noted between the mechanical and microprocessor control knees if the mean outcome measure for sessions MP and MP2 differed significantly from the NMP or the NMP2 sessions but did not differ significantly from each other.

RESULTS

Twenty-one subjects, aged 21 to 77 (mean, 48y), were recruited for participation in the clinical trial. Two subjects withdrew because of medical complications that prevented their participation in the study activities. One additional subject voluntarily withdrew from the study for personal reasons. Demographic information and prosthetic history for the remaining 17 subjects is shown in tables 4 and 5, respectively. Subjects maintained the same style of prosthetic suspension throughout the trial (ie, 12 with suction, 2 with a pin-lock, 2 with a lanyard, 1 with a Silesian belt). The time required to show proficiency in the microprocessor control knee varied among subjects, ranging from 1 week to 33 weeks.

Activity, General Function, and Health

As expected, functional measures showed consistent behavior over the study period. The mean daily step frequency from the 2 weeks proceeding each data-collection session for the study population is shown in figure 2. Although a slight decrease in mean step frequency was noted after subjects transi-

Table 2: HAI

Score	Mobility Descriptor
0	Cannot do/refuses to do
1	Needs assist
2	Side step, with assistive device
3	Side step, without assistive device
4	Step-to with assistive device
5	Step a little past (½ foot length), with assistive device
6	Step past (more than ½ foot length), with assistive device
7	Even step with assistive device
8	Step-to, without assistive device
9	Step a little past (½ foot length), without assistive device
10	Step past (more than ½ foot length), without assistive device
11	Even step, without assistive device

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Table 3: PEQ-A Questions

	PEQ-A Question	Subject Matter
A	Over the past 4 weeks, how much mental energy was required to walk with your prosthesis?	Concentration
B	Over the past 4 weeks, how often have you "stumbled" while wearing your prosthesis?	Stumbles
B1	Over the past 4 weeks, please estimate the *number* of stumbles you have had?	Stumbles
C	Over the past 4 weeks, how often have you had a "semi-controlled" fall?	Falls
C1	Over the past 4 weeks please estimate the *number* of semi-controlled falls you have had?	Falls
D	Over the past 4 weeks, how often have you had an "uncontrolled fall"?	Falls
D1	Over the past 4 weeks please estimate the *number* of uncontrolled falls you have had?	Falls
E	Over the past 4 weeks, how confident have you felt while walking on your prosthesis?	Confidence
F	Over the past 4 weeks, how difficult has it been to complete a task while walking such as talking or reading?	Concentration
G	Over the past 4 weeks, how often has your fear of falling kept you from performing activities that you would normally do?	Confidence
H	Over the past 4 weeks, how frustrated have you been with the amount of falls you have taken?	Confidence
I	Over the past 4 weeks, how embarrassed have you been when you fall?	Confidence
J	Over the past 4 weeks, how fearful have you been about falling without your prosthesis?	Confidence
K	Over the past 4 weeks how often have you felt it was difficult to concentrate on anything other than walking?	Concentration

tioned to the microprocessor control knee, significant ($P>.05$) differences among sessions were not detected. Activity, as measured by the mean estimated daily distance traveled, showed even less difference as the reduced step frequency was countered by an increased step length while subjects wore the microprocessor knee (see Performance results). As with step frequency, significant ($P>.05$) differences among sessions were not detected (see fig 2). Similarly, assessed AMP scores and self-assessed SF-36 general health scores for the population revealed no significant ($P>.05$) differences among sessions.

Performance

Indoor walking on level ground, as measured by step length, showed a trend of increased affected side step length when subjects used the microprocessor control knee (fig 3). Sound-side step length was unchanged among sessions. These changes in sound step length produced a trend of increased asymmetry with use of the microprocessor control, but differences did not reach significance ($P>.05$) among sessions.

Subjects' stair descent SAI scores varied with the use of the prosthetic limb (fig 4). The SAI descent pattern showed both a population trend of improved SAI score and a statistically significant ($P<.001$) difference between the mechanical and microprocessor control sessions. Conversely, subjects' function in stair ascent, as measured by the SAI, showed a mean score of approximately 5 (ie, "Without rail or assistive device, step-to pattern"). Difference among the data collection sessions did not reach significance ($P>.05$).

The ability to descend a decline, as measured by both the HAI score and time (fig 5), showed trends of improved ability when users wore the microprocessor knee. Mean HAI scores for the mechanical control knee were approximately 7 and 6 for the NMP and NMP2 sessions, respectively. The mean scores increased to approximately 8 and 7 after users transitioned to the C-Leg (in the MP and MP2 sessions, respectively). The

Table 4: Subject Demographic Information

Subject	Age (y)	Sex	Time Since Amputation (y)	Etiology	MFCL	Residual Limb Length*
1	50	Female	2	Trauma	2	Short
2	46	Male	2	Trauma	3	Long
3	58	Male	21	Dysfunction†	2	Long
4	59	Male	7	Trauma	3	Short
5	62	Female	5	Trauma	2	Medium
6	77	Male	30	Trauma	2	Long
7	33	Male	3	Trauma	2	Medium
8	33	Male	33	Malignancy	3	Short
9	39	Male	2	Trauma	2	Long
10	39	Female	37	Malignancy	3	Medium
11	31	Male	3	Trauma	3	Medium
12	21	Male	12	Trauma	3	Short
13	36	Male	6	Infection	3	Medium
14	67	Male	37	Trauma	3	Medium
15	45	Female	27	Malignancy	3	Medium
16	71	Male	67	Infection	2	Long
17	67	Male	6	Vascular disease	2	Medium

Abbreviation: MFCL, Medicare Functional Classification Level.
*Short is 0 to one third of the length of the sound side femur, medium is one third to two thirds of the length of the sound side femur, and long is greater than two thirds of the length of the sound side femur.
†Amputation performed to address a physical deformity and chronic musculoskeletal weakness resulting from polio.

Table 5: Subject Prosthetic Information

	Mechanical Prosthesis		Microprocessor Prosthesis		
Subject	Knee	Foot	Knee	Foot	Accommodation Period (wk)
1	Seattle Mark V[e]	Össur Total Concept	C-Leg	1D25	28
2	Össur Mauch[f]	Össur Ceterus	C-Leg	Luxon Max	22
3	Tehlin Graph-Lite[g]	Stomper[j]	C-Leg	1D25	7
4	Össur Total 2000	Össur Vari-Flex	C-Leg	1C40	13
5	CaTech Hydraulic[h]	College Park TruStep[k]	C-Leg	1D25	11
6	Össur Mauch	College Park TruStep	C-Leg	1D25	13
7	Tehlin Graph-Lite	OWW Single Axis[l]	C-Leg	1D25	29
8	CaTech Hydraulic	Össur Ceterus	C-Leg	Luxon Max	4
9	Össur Total 2000	Össur Vari-Flex	C-Leg	1C40	4
10	Össur Mauch	Seattle Lightfoot	C-Leg	1D25	20
11	Otto Bock Active	MICA Genesis II[m]	C-Leg	1C40	1
12	Össur Mauch	OWW Single Axis	C-Leg	1D25	19
13	Ortho Ultimate[i]	Campbell-Childs Safe[n]	C-Leg	1D25	13
14	Össur Total 2000	MICA Genesis II	C-Leg	1C40	8
15	Otto Bock 3R60	Össur Vari-Flex	C-Leg	1C40	32
16	Össur Total 2000	Seattle Foot	C-Leg	1D25	11
17	Otto Bock 3R60	Seattle Lightfoot	C-Leg	1D25	1

time required for hill descent dropped from approximately 55 seconds in the mechanical control sessions to approximately 40 seconds in the microprocessor control sessions. This decrease was statistically significant ($P<.001$). The decreased time of hill descent in the microprocessor control sessions was caused by a mean increase in both the sound- and affected-side step lengths (fig 6). Furthermore, the increased affected-side step length was significantly ($P<.01$) greater in the C-Leg than in the mechanical control knee.

Functional ability on uneven terrain, as measured by the time required to ambulate the obstacle course at self-selected speed, showed a trend of decreased time in the microprocessor control sessions. Similarly, subjects exhibited a trend of increased self-selected walking speed when using the C-Leg. However, neither outcome reached statistical significance ($P>.05$) among data-collection sessions.

Cognitive Demand

The cognitive demand of walking, measured by the self-selected speed and accuracy of the cognitive test, showed trends of increased speed and accuracy when subjects wore the microprocessor control knee as compared with the first mechanical control assessment (fig 7). However, this trend did not extend to the second mechanical control assessment. In fact, closer inspection reveals that response accuracy continues to improve with time across all sessions.

Preference

Subject responses to the question "which prosthesis do you prefer?" were in favor of the microprocessor-controlled C-Leg. Of the 17 respondents, 14 subjects preferred the C-Leg, 1 preferred the mechanical control knee, and 2 subjects had no preference. Responses to the first item of the PEQ ("Over the past four weeks, rate how happy you have been with your current prosthesis") also showed a trend of increased satisfaction in the microprocessor control knee (fig 8). This result was statistically significant ($P<.001$) between the microprocessor (MP, MP2) and the mechanical control (NMP, NMP2) data-collection sessions. Last, subjects were given the choice to wear either prosthesis during their daily activity in between the NMP2 and MP2 data-collection sessions. Total step activity

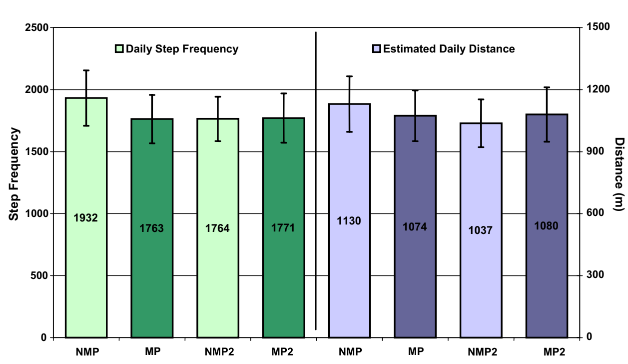

Fig 2. Daily activity as measured by the mean daily step frequency (left) and mean estimated daily distance (right). Trends were not noted, and differences did not reach significance (*P*>.05) among sessions.

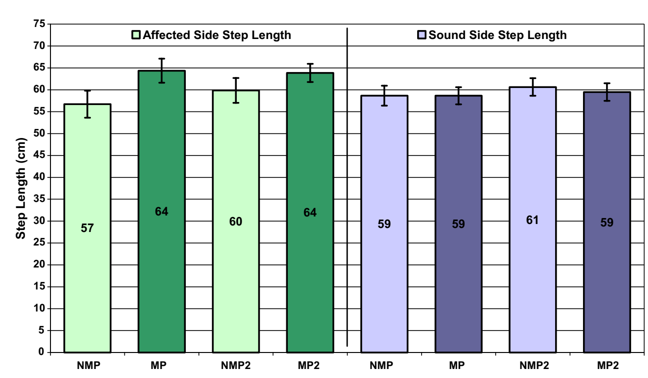

Fig 3. Performance on level ground as measured by sound- (left) and affected- (right) side step length. A trend of increased affected-side step length in the microprocessor knee (MP, MP2) was noted, but differences did not reach significance (*P*>.05) among sessions.

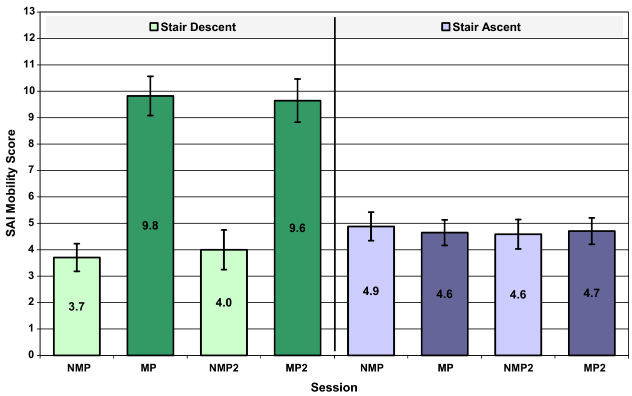

Fig 4. Assessment of stair function as measured by the SAI while subjects descend (left) and ascend (right) stairs. A trend of increased score and significant differences (*P*<.001) were noted between the microprocessor (MP, MP2) and the mechanical control (NMP, NMP2) knees in stair descent.

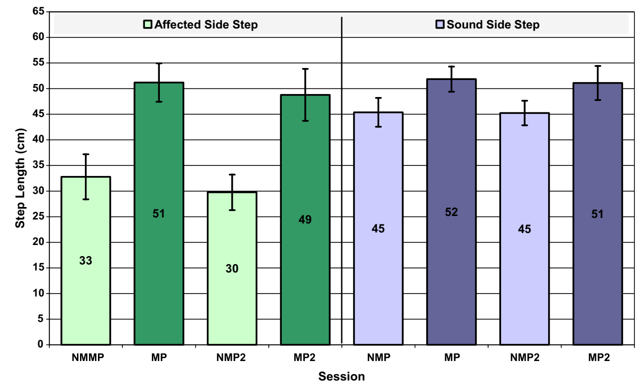

Fig 6. Assessment of hill function as measured by the sound-side (left) and affected-side (right) step length as subjects descend the hill. A trend of increased sound- and affected-side step length was noted when subjects wore the microprocessor knee. Significant differences (*P*<.001) were noted in the affected side step between the microprocessor (MP, MP2) and the mechanical control (NMP, NMP2) knees.

across the population, as measured in the 2 weeks prior to the MP2 test session revealed that 94.4% of all steps were taken on the microprocessor control prosthesis.

Self-Assessment of Performance

Perceived performance, as indicated by several of the PEQ scales, showed an increased score (ie, improvement) trend when subjects tested in the MP and MP2 sessions as compared with the NMP2 session (table 6). This was observed in the ambulation, frustration, sounds, and utility PEQ scales, although none of the differences reached statistical significance ($P>.05$) among sessions. Results of the PEQ-A questions showed a trend of improvement in the microprocessor control knee for 13 of the 14 questions. Only question J, "Over the past four weeks, how fearful have you been about falling without your prosthesis?" did not show a trend in the population responses. Because this question does not relate to a specific prosthetic component, this is not unexpected. Five PEQ-A responses showed significant ($P<.05$) improvements over the baseline response when subjects wore the C-Leg prosthesis. Responses to questions B, C, and D (ie, "Over the past four weeks, how often have you had a 'stumble,' 'semi-controlled fall,' or 'uncontrolled fall'?"), F ("Over the past four weeks, how difficult has it been to complete a task while walking such as talking or reading?"), and H (ie, "Over the past four weeks, how frustrated have you been with the amount of falls you have taken?") were significantly ($P<.05$) improved in the MP and MP2 sessions.

DISCUSSION

This research examined the influence of microprocessor and mechanical control of the prosthetic knee in functional, preferential, and performance outcomes in transfemoral amputees. Subjects in this study transitioned from a variety of mechanical control systems to the microprocessor control of the Otto Bock C-Leg. The study was designed to model a common clinical practice where a practitioner elects to transition a patient from their current prosthesis (ie, typically, a prosthetic system with a mechanical control knee) to one with a microprocessor control knee so as to provide additional, functional capabilities. Here, the microprocessor control of the C-Leg was not only expected to be preferred by the transfemoral subjects when compared with the mechanical control of each amputee's previous knee but also was expected to provide a number of

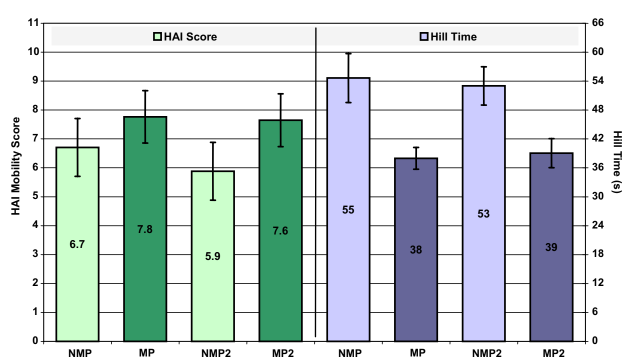

Fig 5. Assessment of hill function as measured by the HAI (left) and by time (right) as subjects descend the hill. Trends of increased score and decreased time were noted when subjects wore the microprocessor knee. Significant differences (*P*<.01) were noted in the hill time between the microprocessor (MP, MP2) and the mechanical control (NMP, NMP2) knees.

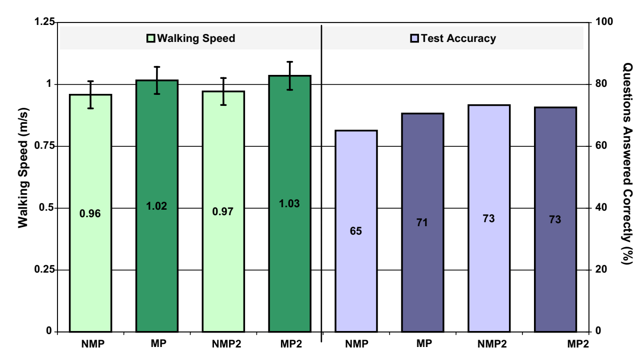

Fig 7. Concentration required for ambulation as measured by the divided attention task walking speed (left) and test accuracy (right). A trend of increased walking speed was noted when subjects wore the microprocessor knee, but differences did not reach significance (*P*>.05) among sessions.

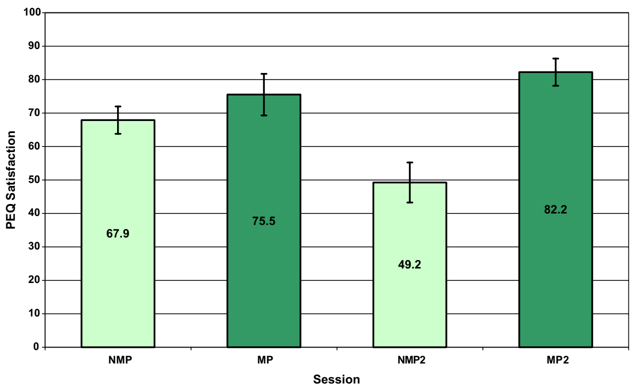

Fig 8. Amputee satisfaction as reported by the first item ("Over the past four weeks, rate how happy you have been with your current prosthesis") of the PEQ. Significant differences ($P<.001$) were noted between the microprocessor knee (MP, MP2) and the mechanical control (NMP2) knees.

functional benefits, including improvements in functional domains such as level walking, stair ascent and descent, hill descent, and uneven terrain.

A key component of this study was to establish and continuously monitor functional and health baselines. Over the duration of an extended trial, it is conceivable that changes in performance may be influenced by external factors such as health changes across the subject population. The population recruited for this study was noted to be younger (ie, mean age, 48y; median age, 45.5y) than the overall amputee population and likely less susceptible to age-related functional changes. Likewise, a traumatic etiology was more prevalent in the study population than the overall population, suggesting that health-related functional changes would be minimal. However, to isolate the effect of the prosthetic intervention from these potential changes, functional and health measures, including the step activity, the AMP, and SF-36, were monitored to assess their impact on the subjects. Although it could be argued that daily activity may increase with the use of the C-Leg, recent research by Klute et al[18] has shown microprocessor control of the knee may not influence overall patient activity. The results obtained here agree that step frequency is not influenced by the transition to microprocessor control of the knee. The population data also show no change in ability to ambulate, as measured by the AMP, or in self-assessed health, as measured by the 8 subscales of the SF-36. Although these measures are not sensitive to prosthetic intervention, the consistency of these measures over the trial period indicates that the measured changes in performance and preference are likely the result of the prosthetic intervention and not an unrelated change in activity or health.

Another way in which this study minimized the influence of confounding factors and emphasized differences between the knee control strategies was through the use of an A-B-A-B reversal design. Alternation between baseline (ie, mechanical) and intervention (ie, microprocessor) phases of the study provided several advantages. First, this design provides for 2 opportunities to assess the influence of knee control mechanisms. Because trends and significant differences required changes to the results in both the MP and MP2 data-collection sessions when compared with those obtained when subjects wore the mechanical knee, increased confidence is obtained in the benefits of microprocessor control. Differences observed in such a reversal design are more convincing than those obtained in a traditional A-B design because subjects show a repeatable pattern of change when alternating knee control methodologies. Second, repetition also allowed for the use of self-assessed measures that would not be available in a traditional A-B study design. Recall that in the initial study period (ie, NMP1), the subjects had not yet experienced the influence of microprocessor control. Only after the first intervention phase (ie, MP1) could subjects adequately compare both methods. Marked differences between self-assessed measures recorded in NMP1 and NMP2 support this belief. With only a single evaluation period, this observation would not have been possible.

Study Limitations

One limitation to the study included the reduced period of the NMP2 phase. Recall that the primary purpose of the NMP2 phase was to provide a baseline for all self-assessed outcome measures. To date, very little has been published on the time necessary to accommodate to prosthetic modifications. English et al[19] recommended an accommodation time of at least 1 week for clinical assessment and at least 3 weeks for research purposes when a new prosthetic device is used. Two weeks was therefore selected as the NMP accommodation period because it was expected that subjects would accommodate to a previously used prosthesis more rapidly than to new changes to the prosthetic limb. Although functional measures (ie, AMP score, step activity, SF-36 scores) remained constant through the NMP2 phase, a comparison of the performance measures be-

Table 6: Results of Self-Assessment Outcomes

Outcome Measure	Mean Population Scores			
	NMP	MP	NMP2	MP2
PEQ				
Ambulation	66	72	62	78
Appearance	73	78	74	78
Frustration	73	76	62	81
Perceived response	90	96	94	96
Residual limb	82	80	79	77
Social burden	86	89	90	88
Sounds	61	69	64	71
Utility	72	76	64	78
Well being	73	78	78	85
PEQ-A				
Mental energy expenditure	53	61	54	
Frequency of stumbling*	68	82	66	83
Number of stumbles	5.6	3.1	5.7	3.3
Frequency of semi-controlled falling*	87	95	81	95
Number of semi-controlled falls	1.4	0.5	3.2	0.4
Frequency of uncontrolled falling*	97	97	89	98
Number of uncontrolled falls	0.4	0.2	0.7	0.3
Confidence while walking	75	79	66	88
Difficulty multitasking while walking*	67	84	68	87
Fear of falling	80	82	77	91
Frustration with falling†	88	95	68	97
Embarrassment with falling	83	92	86	95
Fearful of falling without the prosthesis	79	88	80	83
Difficulty with concentration	78	85	74	89

NOTE. PEQ and PEQ-A scores range from 0 to 100 (larger scores represent a more positive response than lower scores). Outcomes that showed significant differences (*$P<.05$, †$P<.01$) between the microprocessor knee (MP, MP2) and the mechanical control (NMP2) knees are noted.

tween phases NMP1 and NMP2 showed significant differences in the obstacle course speed and cognitive demand task time. This suggests that the subjects may not have fully accommodated to the limb in this time. To address this limitation, the NMP2 phase was only used as a baseline assessment for the self-assessed tasks, and the NMP1 phase was used as a baseline for all performance and cognitive demand tasks. More research is clearly needed to better define the proper time of accommodation for new and previously used prostheses. In future studies, the researchers recommend that subject-specific functional criteria, like those used to determine accommodation to the microprocessor control prosthesis in the MP1 phase, be used to determine subjects' needed accommodation time each time the prosthetic configuration is changed.

Control of prosthetic components may also be viewed as a limitation to this study. Subjects were enrolled in and used their existing mechanical control prosthesis as a baseline for preference, function, and performance. No attempt was made to standardize the prosthetic knee for the baseline periods. The researchers recognize that different types of mechanical control (ie, hydraulic) knees may more closely mimic the behavior of the microprocessor control C-Leg and therefore may be less likely to promote changes in the outcomes measured. Although this may bias the population data, this decision was made to account for the broad variety of previous knees used by those who transition to a microprocessor control knee. The choice of prosthetic foot, however, was made in an attempt to standardize the foot performance for individual subjects. Subjects were each prescribed a foot for the test prosthesis that was functionally similar to the foot in their mechanical control prosthesis but was also approved for use in the C-Leg. The C-Leg uses information from the prosthetic pylon, and hence the selection of the foot is critical to optimal performance of the knee. The selection of prosthetic socket and suspension was likewise standardized in order to maintain consistency for each subject so as to best assess the impact of the knee without influence from other components.

Another limitation is the lack of blinding to the prosthetic intervention. Unfortunately, blinding subjects to the C-Leg (or any other types of microprocessor knee) is impractical in a clinical study. Unlike mechanical control knees, microprocessor knees require regular recharging and most cannot tolerate certain environmental or loading conditions (eg, submersion in water or extreme impacts). Users must therefore be instructed in proper use and maintenance of the knee. It is possible that subjects' self-assessed impressions of microprocessor control were positively or negatively influenced by their predetermined impressions of these types of prosthetic knees. This limitation, however, pertains only to those measures that were self-assessed. Assessed performance measures were likely unaffected by preconceived opinions of microprocessor control.

One critical challenge to assessing the influence of microprocessor control in the prosthetic knee is a relative scarcity of outcome measures suited to assessing prosthetic interventions in the amputee population. The vast majority of those available target quality of life and health status. Those measures available for assessing mobility, such as timed walk tests or the Timed Up & Go, are designed to assess basic function on level terrain. Existing mobility measures do not target environmental obstacles such as stairs, inclines, or uneven terrain. Here, several novel outcomes were developed to assess prosthetic performance in these situations. The SAI and HAI were applied to measure the influence of knee control on steps and inclines. It should, however, be noted that until these measures are validated for this population, results obtained by using these measures should be weighed appropriately. Here, these measures were used in conjunction with other performance outcomes to comprehensively evaluate the subjects' performance in a variety of functional situations.

It was originally hypothesized that users who transitioned to the microprocessor control of the prosthetic knee from a mechanical control knee would greatly favor the microprocessor device. Results from this study do indicate a strong preference for microprocessor control of the prosthesis. The significantly greater satisfaction score, usage during the MP2 phase, and individual preference in knee type suggest that amputees are able to discern differences in prosthetic knee components and that microprocessor control of the knee offers benefits over mechanical control. This is particularly interesting in light of the relative complexity of the device. Unlike the mechanical knee, the C-Leg requires attention to a charging cycle and environmental conditions for which it may not be suited (eg, submersion in water). Even with these potential limitations, the acceptance and preference for the device is overwhelmingly positive.

The reported satisfaction and preference for the microprocessor knee control was likely influenced by several critical self-assessed measures of function, performance, and stability. Users reported a significant decrease in the frequency of stumbles, semicontrolled falls, and uncontrolled falls. The occurrence of these events greatly impacts an amputee's ability to function and maintain confidence in the prosthesis. The decreased frequency of falling was accompanied by a significant decrease in the frustration resulting from falls. Although these outcomes have yet to be validated, they infer that stance-phase microprocessor control may provide enhanced stability and safety for transfemoral amputees.

Although the concentration required for ambulation has been speculated to be a benefit of microprocessor knee control, the results from assessed and self-assessed cognitive tests in this study are inconclusive. Subjects reported a significant increase in their ability to perform other tasks while ambulating, even though assessed differences in cognitive demand did not reach significance. However, as noted earlier, the assessed subjects showed increased accuracy with time during this test. This likely indicates that the chosen reverse numbers test was influenced by a learning effect and may not reflect subjects' perceived reduction in concentration required for ambulation. However, without further evidence to verify this perceived reduction, the effect of microprocessor control on concentration during ambulation is still unknown. The scarcity of evidence for or against a reduction in concentration with microprocessor control indicates that additional efforts should focus on the development of outcomes appropriate for the amputee population and in determining if cognitive demand is sensitive to prosthetic intervention. Because relatively few measures for cognitive demand in the amputee population have been explored, there exists a clear need for such research.

Last, it was hypothesized that microprocessor control would show improved performance over mechanical control, particularly in the functional domains of stairs, inclines, and uneven terrain. Significant improvements in the SAI descent score and time of hill descent with the C-Leg suggest that an amputee's ability to navigate in functional domains outside of level ground is noticeably improved with the use of microprocessor control. The trend of increased affected-side step length on level ground and the significantly increased affected-side step in hill descent may imply that subjects felt more stable on the microprocessor control knee, thereby stretching out farther with the sound limb in terminal swing. Because stance stability, particularly in stair or hill descent, is a noted feature of the

C-Leg, this seems a logical conclusion. Although microprocessor control did not show significant improvement in the time or average speed on uneven terrain, both outcomes showed an improving trend with use of the microprocessor control. The cumulative performance-based evidence supports the initial hypotheses that microprocessor control of the swing and stance phases of gait, as provided by the C-Leg, offers significant benefit to function, stability, and performance in functional domains aside from level walking. Given these results, the researchers believe that future efforts to evaluate the potential benefits and influence of microprocessor technology in lower-extremity prostheses should focus in areas beyond traditional, level ambulation. Although the majority of an amputee's daily life may be spent on level ground, it is in these more demanding environments that microprocessor control shows a significant benefit.

CONCLUSIONS

This study examined the functional ability, performance, and satisfaction of transfemoral amputee subjects during the transition from an established, mechanical control prosthetic knee system into a microprocessor control Otto Bock C-Leg. This transition mirrors the common clinical practice of prescribing a microprocessor control knee after demonstration of proficient and successful use of a mechanical control knee unit. Although anecdotal evidence suggests that microprocessor control of the prosthetic knee may offer increased performance in functional tasks such as stair descent, ramp and hill descent, walking on uneven terrain, a reduction in cognitive demand while walking, and increased safety, empirical evidence for such benefits has been limited. The results shown in this investigation show a statistically significant improvement in subjects' ability to descend stairs; time required to descend a slope; sound-side step length while descending a hill; preference; satisfaction; self-reported frustration with falling; and self-reported frequency of stumbles, semicontrolled falls, and uncontrolled falls while wearing the microprocessor control knee and population trends of 5% or more improvement in a number of other functional categories. The results of this investigation not only highlight measured differences between the microprocessor and mechanical control of a knee component but also offer several new techniques and associated outcome measures for assessing function in the transfemoral amputee population. Because it is in functional areas beyond level walking that the benefits of microprocessor control are most observed, the development and standardized use of tools to assess function in these domains is critical to our understanding of real-world amputee ability, performance, and preference. This research has shown that microprocessor control provides significant benefit over mechanical control of the prosthetic knee. It is hoped that this information encourages and promotes additional research in these and other potential benefits of microprocessor stance-phase control in lower-limb prosthetics.

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Suppliers

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