Perceived Stability, Function, and Satisfaction Among Transfemoral Amputees Using Microprocessor and Nonmicroprocessor Controlled Prosthetic Knees: A Multicenter Survey

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ABSTRACT

Objective: To evaluate perceived comfort, security, maneuverability, cosmetic attributes, adverse effects, and safety of the microprocessor controlled C-Leg and nonmicroprocessor controlled passive prosthetic knees. ***Design:*** Nonrandomized pretest/posttest self-reported assessment with 50-question survey instrument. ***Setting:*** Six hundred Hanger Prosthetics and Orthotics facilities. ***Participants:*** Three hundred sixty-eight unilateral transfemoral amputees. ***Main Outcome Measures:*** Socket fit, confidence/security, gait and maneuverability, physical attributes, physical effects, and negative attributes/limiting factors of the two prosthetic technologies. ***Results:*** Participants characterized the C-Leg microprocessor controlled prosthesis as "better" according to the response percentages with regard to the following parameters: socket fit (72.9%), confidence/security (88.1%), gait and maneuverability (88.4%), physical attributes (65.8%), physical effects (61.5%), and negative attributes/limiting factors (85.3%). After use of the C-Leg, mean survey scores were significantly higher than initial responses associated with passive nonmicroprocessor controlled prosthetic knees ($p < 0.0001$). ***Conclusions:*** In comparison with their nonmicroprocessor controlled hydraulic prostheses, participants reported significant improvements with the C-Leg microprocessor controlled prosthetic knee with regard to comfort, security, maneuverability, cosmetic attributes, adverse effects, and safety. (*J Prosthet Orthot*. 2009;21:32–42.)

KEY INDEXING TERMS: amputee, prosthesis, artificial limb, microprocessor, rehabilitation

LOWER LIMB AMPUTATION AND REHABILITATION

Amputation of a lower limb is generally accepted as an event associated with poor survival. The 4-year survival rate of 22% to 76% is largely influenced by differing comorbidities of the amputee population.[1] Amputation causes a threefold loss in terms of function, sensation, and body image.[2] Negative predictors in prosthetic rehabilitation include level of amputation, comorbidity, phantom pain, skin/tissue breakdown associated with vascular incompetence, and advanced age.[3–6] In most patients, functional abilities decrease after amputation with age being a correlated factor.[7] Approximately 80% of patients with a lower limb amputation are older than 60 years of age. An older individual with a transfemoral amputation must expend an effort 68% to 100% above normal to walk, even at a reduced speed.[8] Functional outcomes in the elderly (>80 years), after lower limb amputation are associated with considerable mortality and deterioration of functional and residential status.[9]

The goal for an individual with a unilateral lower limb amputation is to be able to ambulate safely and independently on level surfaces, stairs, ramps, and curbs with or without assistive devices.[8] Secondary to safe and independent ambulation, improvement in overall health through increase in activity level is desirable. During the first year after amputation, changes in the size and shape of the residual limb affect the proper fit of a prosthesis accommodated by appropriate socket design.[10] Subsequently, appropriate clinical follow-up and ongoing socket and prosthetic monitoring and adjustments will result in the minimization or avoidance of skin breakdown (i.e., blisters, sores, and rashes).

Positive predictors for successful rehabilitation include the ability to perform activities of daily living (ADLs) before amputation, no delay for admission to a rehabilitation center, a good walking distance before amputation, a fair to good living condition, social and health status before amputation, good motivation of the patient and rehabilitation team, and good communication.[7] One of the initial challenges facing an individual after amputation is acquiring a prosthesis and becoming proficient in its use.[11] In a study by Legro et al.,[10] unilateral amputee respondents to the Prosthesis Evaluation Questionnaire (PEQ) and Short Form 36 Health Survey (SF-36®) noted that the most important function of a prosthesis was to enable walking, and the most important characteristic of a prosthesis was the way it fit the residual limb by means of an

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appropriate and comfortable socket. Other positive features of the prosthesis noted by Legro et al. included prosthetic balance, comfort while standing, texture of the prosthesis against the skin, diminished odor, cosmetic appeal, and the required energy expenditure to ambulate. Respondents also emphasized the importance of the professional and psychological support of a good prosthetist.

A number of factors must be considered in selecting the most appropriate prosthesis for an amputee. Age, physical attributes (height and weight), physical and psychological comorbid conditions, activity level, level of amputation, mobility requirements, patient preference, and motivation to learn the required skills play a major role in successful rehabilitation.[8] As a general rule, the more limited a person's walking goals, the simpler and less expensive the prosthesis.[12] In contrast, when walking/activity goals are more demanding, prosthetic requirements become more complex and expensive. However, the cost of a prosthetic device is not necessarily related to its suitability.[12]

The normal gait cycle is comprised of two parts known as stance and swing phases, which account for 60% and 40% of normal gait, respectively.[13] The stance phase constitutes the period when the leg is on the ground supporting the weight of the body, whereas the time the leg is off the ground is termed the swing phase. Correspondingly, the knee must provide stability and swing at appropriate rates to properly match an amputee's ability.[13] Patients differ in strength, balance, and overall ability. Accordingly, there are numerous knees and associated lower limb prostheses available that offer differing stance and swing phase mechanisms. An appropriate prosthetic selection, including a properly adjusted knee mechanism, is closely aligned with the patient's functional ability, therefore yielding a reliably controlled and smooth gait.

Amputees with transfemoral amputations have available prosthetic knee components, which can be classified into two groups based on how they are controlled: 1) nonmicroprocessor controlled passive devices and 2) microprocessor controlled active devices.[12]

NONMICROPROCESSOR CONTROLLED PROSTHETIC KNEE DESIGNS

Nonmicroprocessor controlled prosthetic (NMCP) knees include either single axis constant friction type of swing control mechanism or fluid control/resistance swing control mechanisms. The single axis knee is basically a "hinge" design, which is reliable mechanically but has design limitations regarding prevention of falling. In this passive knee design, the amputee is safe only if he/she has the residual muscular strength to prevent the knee from flexing at heel strike and during stance phase. This limiting safety factor can be overcome by aligning the knee posterior to the anatomical weight line; however, added stability alignment will adversely affect the ease and efficiency of initiating swing phase. In addition, the single axis constant friction mechanical swing control can only be optimally adjusted for a single fixed walking cadence, overly restricting an active amputee with the ability to ambulate with a variable cadence.

In contrast, fluid (pneumatic or hydraulic) control/resistance controlled prosthetic knees have a rotary/linear piston linked to the knee, which automatically increases or decreases the swing phase resistance as amputees speed up or slow down their walking cadence.[12] Because knee resistance responds automatically to changing walking speeds, the amputee is able to engage more freely in a range of activities with this type of knee design. Another commonly used fluid control/resistance design is the polycentric knee often referred to as the "four-bar," which has four points of rotation, each connected by a linkage bar.[13–15] The polycentric four-bar knee offers advantages, including optimization of selected stance and swing phase features, greater toe clearance at midswing, improved cosmetic appearance, and increased stance stability at heel strike combined with ease of flexion during preswing.[14] However, the increased stance stability of the polycentric knee is dependent on the knee being maintained in an extended position during stance. Therefore, the benefits of the polycentric knee are offset by the lack of stumble recovery when the knee is flexed and the inability to descend ramps and stairs step over step in a controlled manner.

MICROPROCESSOR CONTROLLED PROSTHETIC KNEE DESIGNS

The clinical application of microprocessor control (MPC) to prosthetic knee mechanisms was first proposed and demonstrated by Kobe Steel researchers in Japan in 1989[16] and reached the development stage several years later.[17] The license for this technology was obtained by Chas A. Blatchford, of the United Kingdom, who developed and first marketed a commercial product in 1993, which was known as the Endolite Intelligent Prosthesis (IP).[17,18] Improved versions referred to as the IP+ and Adaptive Prosthesis were marketed in 1995 and 1998, respectively. The IP, IP+, and Adaptive Prostheses are microprocessor controlled swing phase prosthetic knees and do not provide microprocessor controlled stance control capabilities. Therefore, stumble recovery must be initiated solely by the amputee through residual muscular strength to prevent the knee from flexing at heel strike and during stance phase.

The Otto Bock C-Leg was first introduced in 1997 during the World Congress on Orthopedics in Nuremberg, Germany. The Food and Drug Administration (FDA) approved a 510(k) application for the C-Leg in July, 1999[19] and subsequently, Otto Bock Healthcare (Duderstadt, Germany) began distributing the C-Leg in the United States.[17] Additional microprocessor controlled prosthetic knees currently marketed in the United States are the Compact Knee (Otto Bock Healthcare), the Rheo Knee (Össur, Reykjavik, Iceland), and the Agility Knee (Freedom Innovations, Inc., Irving, CA).

The C-Leg was the first microprocessor controlled knee/shin prosthesis (MPK) designed to provide amputees both hydraulic stance stability and precise electronic swing phase control.[14,20] The C-Leg has on-board sensors, which measure angles and moments every 20 millisecond (50 times/second), altering the damping of the hydraulic unit for each phase of gait.[20] Fine adjustments are made to adapt to each amputee's unique walking characteristics using special software and a personal computer (PC). Software algorithms determine the phase of gait and adjust the knee functions to compensate for the changes in gait.[20] Strain gauges in the pylon and an angle sensor in the knee provide "real-time" measurements that enable the on-board microprocessor to calculate the optimal hydraulic resistance for each phase of gait. The C-Leg microprocessor transfers information to servo-motors, which open/close the hydraulic valves enabling an immediate response to changing conditions by providing stance phase stability and cadence responsive swing phase control. In addition to pneumatic swing phase responsiveness and gait symmetry, the amputee perceives the knee as operating more consistently and reports more confidence in the prosthesis.[14] In essence, the C-Leg adjusts to varying conditions, transferring information to the hydraulic valves regarding how to react to what the amputee is doing.[20] The C-leg uses a rechargeable battery that lasts 25–30 hrs before recharging and it is feasible to remotely monitor/configure the device using Microsoft Netmeeting and Internet-based video conferencing.[21] The C-leg is suitable for lower limb amputees characterized by the following: Medicare Level K 3–4, adequate cardiovascular and pulmonary reserve to ambulate at variable cadence, adequate strength and balance to activate the knee unit, adequate cognitive ability to master technology, and patient weight not to exceed 275 pounds.[22–24]

The purpose of the current study was to evaluate perceived function, comfort, stability, and security of MPK as compared with NMCP prosthetic knees among unilateral transfemoral amputees.

METHODS

STUDY DESIGN

A nonrandomized pretest/posttest (before and after) study design was used with the microprocessor controlled prosthetic knee as the intervention. The pretest was conducted on subjects entering the study on their NMCP knees. As part of their physician's prescription, the subjects were then fitted with the microprocessor controlled knee. Posttest was conducted after a 6–9-month usage of the microprocessor controlled knee. Thus, participants served as their own control, and the comparison of treatments was not contaminated by the variability between subjects.

RECRUITMENT

Individuals who had sustained a unilateral transfemoral amputation and were prescribed a microprocessor controlled prosthetic knee were recruited from a national chain of private clinics (Hanger Orthopedic Group, Inc., Golden Valley, MN). No preference was given to gender, ethnicity, or socioeconomic status of the participants. Recruitment letters were sent to a central Hanger Orthopedic office and subsequently mailed to 725 individuals who had been recommended by their physician for microprocessor knee prostheses between January 11, 2000 and June 9, 2003. Subjects were not financially compensated for their participation in the study.

INCLUSION CRITERIA

Study participants were limited to unilateral transfemoral amputees who achieved Medicare functional level 3 (K3) as described in Table 1. Transfemoral levels of amputation included any lower limb removal between knee disarticulation to hip disarticulation. Only participants who currently wore a variable cadence NMCP knee unit were allowed in the study. No minimum timeframe for wearing the nonmicroprocessor knee device was fixed. The study participants also met specific physical and functional criteria as stipulated by the manufacturer, to be fitted with the C-Leg prosthesis system (Table 2). All participants were treated at one of 600 Hanger Prosthetics and Orthotics facilities in the United States.

PROSTHETIC KNEE DEVICES

Initial assessment with the survey instrument was conducted based on participants' experiences with their NMCP variable cadence prosthetic knee units and their existing custom socket. Subsequently, participants were fitted with the C-Leg MPK prosthetic knee (Otto Bock Healthcare, Minneapolis, MN) and a ComfortFlex Socket (Hanger Orthopedic Group, Inc.) Prosthetic System. A second assessment using the identical survey instrument was conducted after 6–9 months experience with the C-Leg prosthetic knee.

SURVEY DESIGN

A self-administered questionnaire was created to assess six dimensions of prosthetic knee rehabilitation: socket fit, confidence/security, gait/maneuverability, prosthesis attributes, physical effects of prosthesis, and safety/negative attributes of prosthesis. The 50-question survey was developed using the psychometric Likert scale methodology (a 5-point scale asking respondents to specify their level of agreement to each statement).[25] The questions were collectively grouped into six subsets for analysis and reporting purposes:

- *Socket fit*: comfort in proximal brim and distal end, suspension, ease of getting socket on/off, and overall socket comfort.
- *Confidence/security*: ability of knee to keep up with gait, ease of standing up out of chair, ease of sitting down into a chair, overall balance, confidence walking in large crowds/unfamiliar places, overall confidence, require cane/crutches to get around, being afraid knee may buckle while standing, and allowance of normal daily/special activities.
- *Gait/maneuverability with the prosthesis:* ability to walk at slow/fast pace, ability to jog/run, ability to change speeds while walking, stability on uneven surfaces, and ability to walk down stairs/ramps with confidence.

Table 1. Medicare functional levels of ambulation*

Classification	Description	Terrain/activity	Appropriate prosthesis
K-0	Nonambulator	None	None
K-1	Household ambulator	Level surfaces, single velocity cadence	Knee unit: *single axis constant friction type* of swing control mechanism (knee flexes and extends at one rate)
K-2	Limited community ambulator	Low level environmental barriers, single velocity cadence	Same as above
K-3	Unlimited community ambulator	Traverse most environmental barriers, variable cadence/multiple velocities	*Fluid control/resistance* knee unit: both hydraulic and pneumatic swing rate control mechanisms
K-4	Exceeds basic ambulation skills	Activities exhibiting variable cadence/multiple velocities, high impact, stress or energy levels (i.e., children, active adult, athletes)	Same as above

*After Romo, 2000.

Table 2. Inclusion criteria required to be fitted with a C-Leg®/ComfortFlex™ socket prosthesis system

Physical requirements	Criteria
Maximum patient weight	275 lbs
Minimum distance from heel pad to knee center	40 cm/17 in
Minimum distance from knee center to distal residual limb	38 mm/2 in
Functional requirements (adaptation of veterans administration criteria)	
Cardiovascular reserve and cognitive learning ability	Adequate to master higher level of technology and to allow faster than normal walking speed
Ability to ambulate	At faster than baseline rate using a standard prosthetic application with a swing and stance control knee
Need for long distance ambulation	At variable rates (>400 yards) on a daily basis
Need for regular ambulation	On uneven terrain or for regular use on stairs

- *Physical attributes of prosthesis:* weight, cosmetic appearance (standing/seated), resemblance to sound leg, fit of prosthetic foot in shoe, and ability/inability to wear clothing items (shorts, skirts, etc.).
- *Physical effects of prosthesis:* socket is hot/causes sweating, socket produces rash, residual limb volume fluctuates, pressure points in socket, muscle fatigue/cramps and phantom pain in residual limb, tired at end of day, and low back/hip pain/discomfort.
- *Safety/negative attributes of prosthesis:* knee buckles while standing, prosthesis feels heavy, knee does not keep up when walking fast, falling, avoidance of going up/down stairs/ramps, walking in crowds produces unstable feeling, stopping to rest when out in public, and use of disabled/handicap parking spaces.

SURVEY METHOD

Written informed consent was provided by each participant before entering the study. The 50-question survey instrument was self-administered at two assessment periods: the first, while using their NMCP knee and the second assessment, after using the C-Leg MP knee system for 6–9 months. Instructions for the first assessment included that the participant respond to their overall experience with the NMCP prosthetic knee. Subjects choosing the written option were mailed the survey, which they completed and mailed back to a central designated research office, in a self-addressed paid envelope.

The participants returned to their Hanger Orthopedic facility and were fitted with the C-Leg and ComfortFlex Socket System. Again, prosthetic alignment and socket comfort were optimized. Participants then used their C-Leg prosthetic system for 6 months before receiving the survey instrument. Although participants were encouraged to immediately complete the survey, assessing their C-Leg MPK knee experience, they were given up to 3 months to do so. If a patient did not complete and return the follow-up survey within 3 months, it was mailed to the patient a second time. If the patient did not respond within 3 months of the second request, the patient was considered nonresponsive for the outcomes study. Surveys were returned to a single Hanger Orthopedics facility (Golden Valley, MN), and the data was entered into a database by a single research assistant. The data was then analyzed by an independent statistician.

STATISTICAL METHODS

Scales were created for each survey question category by summing the responses for the questions comprising the category. Because each question was scored 1–5 (5 being the most favorable outcome) and the number of questions for each survey question category differed, the maximum value for each scale varied: socket fit (6 questions, maximum scale score 30), confidence/security in the prosthesis (11 questions, maximum scale score 55), gait and maneuverability with the prosthesis (7 questions, maximum scale score 35), physical attributes of prosthesis (7 questions, maximum scale score 35), physical effects of prosthesis (10 questions, maximum scale score 50), and negative attributes/limiting factors of prosthesis (9 questions, maximum scale score 45). Overall, the maximum of the category sums ranged from 30 to 55.

For each survey question category, participants providing both initial assessment (NMCP knee) and second assessment (C-Leg MPK knee) were classified as "Worse" if the second score was less than the initial score, "Better" if the second score was greater than the initial score, and the "Same" if the two scores were identical. The percentage of patients classified as Worse, Same, or Better were reported. In addition, the mean, median, and standard deviation for the scale scores for each survey question category were computed. Likewise, mean and standard deviation for the difference in scale scores for a survey question category were computed. To compare the mean scale score changes from the initial assessment (NMCP knee) to the second assessment (C-Leg MPK knee), the nonparametric Wilcoxon rank sum test for paired differences was computed for each survey question category. The Wilcoxon test, a robust nonparametric test, was used because of the limited range of scale score data. *p* values based on the Wilcoxon test were reported.

Table 3. Participants' demographics

Characteristic	Participant Population
Sex (n = 368)	
Male	289 (78.5%)
Female	79 (21.5%)
Age (n = 368)	
Range	15–85 yrs
Mean	54.7 ± 15.6 yrs
Experience with NMCP device (n = 342)	
Range	0.1–42.0 yrs
Mean	3.5 ± 3.7 yrs
Time from amputation to initial evaluation (n = 317)	
Range	
Mean	0.2–78.7 yrs
Side of amputation (n = 368)	
Left	197 (53.5%)
Right	171 (46.5%)
Amputation length (n = 368)	
Mid-thigh	175 (47.6%)
Long	115 (31.3%)
Short	39 (10.6%)
Knee disarticulation	4 (1.1%)
Hip disarticulation	4 (1.1%)
Short to mid-thigh	1 (0.3%)
Mid-thigh to long	1 (0.3%)
No response (listed as "transfemoral," no specific length identified)	29 (7.9%)
Cause of amputation (n = 368)	
Accident	109 (29.6%)
Trauma	54 (14.7%)
Cancer	51 (13.9%)
Vascular	41 (11.1%)
Infection/gangrene	32 (8.7%)
Gunshot/combat/explosive	22 6.0%)
Not noted	18 (4.9%)
Blood clot	15 (4.1%)
Congenital	8 (2.2%)
Medical	8 (2.2%)
Other	6 (1.6%)
Surgical	4 (1.1%)

RESULTS

SURVEY RELIABILITY

Before survey administration, the 50-question instrument was tested for reliability on 30 subjects before initiation of the study. Each subject completed the survey once and then again 2 weeks later. The results indicated that 94% of the questions were answered by the respondents with identical scores on both surveys, and the remaining 6% of the questions had a ±1 (scale of 1–5) response.

RESPONDENT DEMOGRAPHICS

Patient demographics are summarized in Table 3. The patient population included 368 unilateral amputees, of which 289 (78.5%) were men and 79 (21.7%) were women, with a mean age of 54.7 years (range, 15–85). The time from amputation to evaluation ranged from 0.2 to 78.7 years (mean, 18.5); 38 amputees had their passive variable cadence NMCP prostheses <1 year, including nine at <6 months. Unilateral amputations included 197 (53.5%) left legs and 171 (46.5%) right legs.

RESULTS

Subjects responding to both the initial NMCP surveys and C-Leg MPK surveys, 6–9 months later, numbered 368, which represented a 51% response rate to the survey. More than

60% of patients with unilateral lower limb amputations characterized the C-Leg MPC prosthesis system as better compared with their former NMCP prosthetic knees in all survey question categories. Each of the survey questions was assigned to one of six categories and comparisons of follow-up response percentage scores are presented for each survey question as being either Worse, Same, or Better and are presented by category in Table 4. For each category, the assessment factors were summed (Table 5). When amputees compared their NMCP and MPC prosthetic knees they reported that the C-Leg was better to varying degrees (percentages) in all six of the following categories: 1) socket fit (72.9%), 2) confidence/security in the prosthesis (88.1%), 3) gait and maneuverability with the prosthesis (88.4%), 4) physical attributes of prosthesis (65.8%), 5) physical effects of prosthesis (61.5%), and 6) negative attributes/limiting factors of prosthesis (85.3%). Each assessment factor was a score ranging from 1 to 5, with 5 being the most favorable outcome. The Wilcoxon rank sum test was subsequently performed to test and compare the differences in the mean patient question scores from baseline to follow-up. Comparisons of mean scores at baseline versus those at follow-up for the six question categories are presented in Table 6. Summaries noting comparisons of identified marked increases in both mean and median scores at follow-up are presented in Table 7. All assessment categories were significantly different at the alpha 0.0083 level (the standard acceptance level lowered from 0.05 to 0.0083 to account for multiple testing per Bonferroni). For all six question categories, *follow-up mean scores* were statistically significantly higher ($p < 0.0001$) than *baseline mean scores* (Table 7).

DISCUSSION

This survey study represents the largest single number of subjects whose outcomes were assessed comparing passive NMCP knee and active MPK knee use. The survey instrument incorporated 50 questions designed for the participants to rate socket fit/comfort, confidence/security, gait/maneuverability, physical/cosmetic attributes, physical effects, and negative attributes/limiting factors for both NMCP and MPK prosthetic knees. Approximately 50% of the patient population responded to the follow-up survey totaling 368 unilateral lower limb amputees (78.5% men and 21.5% women). According to the Survey Research Methods of the American Statistical Association, it is not uncommon for initial response rates in many surveys to be below 50%, and typically in self-selected opinion surveys, individuals with strong opinions (often negative) are more likely to respond.[26] Therefore, the positive outcome in favor of the C-Leg MPC knee within all survey categories suggests conservatively that microprocessor control of stance and swing phase contributes significantly to a safe, comfortable, and functional outcome for unilateral transfemoral amputees.

The unilateral amputees who participated in this survey offered positive responses when asked about their 6–9-month experience with the C-Leg prosthesis system, supported by significantly higher mean scores when C-Leg MPK assessment was compared with their NMCP knee scores ($p < 0.0001$). These positive responses and significantly higher mean scores are additionally pertinent in the presence of widely varied amputee demographics (Table 3), which can markedly impact clinical outcomes, including diversity in age among the amputees, age of the baseline passive prostheses, time from amputation to evaluation, cause and length of amputations, and the general health status of the amputees.

A five-patient study by Legro et al.[10] found that unilateral amputees reported the two most important aspects of a lower limb prosthesis were its ability to enable walking and the way the socket fit. These important functional/characteristic features of a prosthesis are strongly supported in the current survey as 88.4% of the unilateral amputees noted improvement in gait/maneuverability and 72.9% supported better socket fit when comparing C-Leg MPC prosthesis to their prior NMCP prosthetic knees. Improved gait/maneuverability included the amputees' ability to 1) walk at slow/rapid pace, 2) change speeds while walking, 3) jog/run, 4) walk down stairs (step over step)/ramps with confidence, and 5) have increased stability on uneven terrain surfaces. The amputees' perception of better socket fit included 1) comfort of the proximal brim/distal end, 2) ease of getting the socket on/off, 3) improved suspension, and 4) overall comfort of the socket.

Respondents in the previous survey conducted by Legro et al.[10] also remarked concerning additional positive features of prostheses, including balance, comfort while standing, texture of the prosthesis against the skin, cosmetic appeal, and energy expenditure requirements during ambulation. Correspondingly, participants in the current survey also responded favorably to comparable positive features associated with daily use of the C-Leg MPK prosthesis. It is relevant to identify that the cosmetic finishing techniques and prosthetic feet used with the C-Leg were similar if not identical to those used with the NMCP prosthetic devices. Yet, 65% (65.8%) of the amputees in the current survey felt that the physical attributes of the C-Leg MPC prosthesis were an improvement over their NMCP prostheses, including it's weight, cosmetic appeal (standing and seated), resemblance to the sound leg, fit of the prosthetic foot in shoes, and the ability to wear certain clothing items, (shorts, skirts, etc.). Moreover, 61.5% of the study participants noted an improvement in the physical effects, which the C-Leg MPC prosthesis system had on their bodies, including reduction in the occurrences of heat/sweating/rash production, residual limb volume fluctuation, socket pressure points, muscle fatigue/cramps and phantom pain in the residual limb, low back and hip pain/discomfort, and being tired at the end of the day. A majority of subjects (85.3%) also felt that negative prosthesis attributes/limiting factors were reduced with the use of the C-Leg MPC prosthetic system, which included such items as knee buckling while standing, heaviness of the prosthesis, the knee not keeping up with fast gait, falling, avoidance of going up/down

Table 4. Comparison of participant follow-up percentage scores (data with use of microprocessor controlled knee)

Question No.	Subset Questions	Follow-up Percentage		
		Worse	Same	Better
Socket fit/comfort				
1	Comfort in the proximal brim	18.80	24.40	56.70
2	Comfort of distal end	18.10	21.90	60.10
3	Suspension	15.70	20.80	63.50
4	Ease of getting the socket on	19.00	26.90	54.10
5	Ease of getting the socket off	19.90	28.10	52.00
6	Overall comfort of the socket	16.20	26.10	57.80
Confidence/security				
7	Ability of the knee to keep up with my walking speed	4.80	10.50	84.80
8	Ease of standing up out of a chair	10.10	19.40	70.40
9	Ease of sitting down into a chair	12.00	18.40	69.60
10	My overall balance with the prosthesis	7.00	23.20	69.80
11	My confidence walking in large crowds	5.30	18.30	76.40
12	My confidence walking in unfamiliar places	7.90	16.30	75.80
13	My overall confidence using the prosthesis	8.70	16.80	74.60
33	I require cane/crutches to get around	13.30	54.40	32.30
37	While standing, I am afraid the knee might buckle	9.40	21.30	69.40
38	My prosthesis holds me back from doing normal day to day activities	8.50	23.10	68.50
39	My prosthesis holds me back from doing special activities (sports)	13.40	29.90	56.70
Gait/maneuverability				
14	My ability to walk at slow speed	10.10	19.90	70.00
15	My ability to walk at a fast pace	7.60	14.90	77.60
16	My ability to jog/run	1.60	73.30	25.10
17	My ability to change speeds while walking	7.20	15.60	77.20
18	My stability on uneven surfaces (rocks, gravel, etc.)	5.70	15.70	78.60
19	My ability to walk down stairs step over step	2.80	28.30	68.90
20	My ability to walk down ramps with confidence	5.90	17.80	76.30
Physical/cosmetic attributes				
21	Weight of my prosthesis	10.80	24.20	65.00
22	Cosmetic look of the prosthesis	13.60	28.70	57.70
23	Cosmetic look of the knee in a seated position	27.70	25.50	46.90
24	Prosthetic shape resembles my sound side	24.90	26.60	48.40
25	Fit of the prosthetic foot in the shoe	14.90	29.70	55.50
41	I am unable to wear some clothing items because of the prosthesis	21.60	32.00	46.40
42	I wear short pants or skirt with my prosthesis	29.50	54.50	16.00
Adverse effects				
26	My socket is hot and makes me sweat	18.20	38.60	43.20
27	I get a rash with my socket	22.30	39.30	38.40
28	My residual limb volume fluctuates	32.20	39.00	28.80
29	I have pressure points in my socket	24.30	30.80	44.90
30	I have muscle fatigue in my residual limb	24.10	33.00	42.90
31	I get muscle cramps in my residual limb	20.20	37.50	42.30
32	I experience phantom pain in my residual limb	22.90	43.80	33.30
34	I get tired at the end of the day	17.80	30.10	52.20
35	I have low back pain or discomfort	24.20	36.90	38.90
36	I have pain/discomfort in my hips	26.20	33.80	40.00

(*Continued*)

Table 4. (Continued)

Question No.	Subset Questions	Follow-up Percentage Worse	Same	Better
Safety issues/limiting factors				
40	My knee buckles while I am standing	12.10	24.70	63.20
43	My prosthesis feels heavy	21.10	24.30	54.60
44	My knee does not keep up with me when I walk fast	3.00	12.10	84.90
45	I fall while wearing my prosthesis	3.20	29.70	67.20
46	I avoid going up or down stairs	10.30	28.70	61.00
47	I avoid going up or down ramps	11.00	24.90	64.10
48	I have to stop for a rest when out in public	19.80	33.40	46.70
49	I use disabled/handicap parking spaces	15.00	55.70	29.30
50	Walking in crowds makes me feel unstable	10.60	23.20	66.20

*Rating scale for questions: 1–5.
Questions 1–25: 1 = poor; 2 = fair; 3 = good; 4 = very good; 5 = excellent.
Questions 26–50: 1 = always; 2 = often; 3 = sometimes; 4 = seldom; 5 = never.

Table 5. Questionnaire subsets comparing NMCP knees with C-Leg (data with use of microprocessor controlled knee)

Survey Subsets	Survey Subset Summary No. Patients	Follow-up Response (%) Worse	Same	Better
Socket fit/comfort	361	21.3	5.8	72.9
Confidence/security in the prosthesis	363	10.5	1.4	88.1
Gait/maneuverability with the prosthesis	363	10.5	1.1	88.4
Physical/cosmetic attributes of prosthesis (weight, cosmetic appearance, resemblance to sound leg, fit of prosthetic foot in shoe, ability/inability to wear clothing items)	363	27.5	6.6	65.8
Physical effects of prosthesis (socket comfort, residual limb volume, muscle fatigue/cramps, phantom pain, low back/hip pain/discomfort)	361	33.5	5.0	61.5
Negative attributes/limiting factors of prosthesis	361	11.9	2.8	85.3

Table 6. Survey scores comparing NMCP knees with C-Leg (data with use of microprocessor controlled knee)

Survey Subset	Max Score	NMCP Devices n	Mean ± SD	Median	C-Leg n	Mean ± SD	Median
Socket fit	30	363	17.0 ± 5.3	17.0	361	21.6 ± 5.2	22.0
Confidence/security in the prosthesis	55	363	27.1 ± 7.9	27.0	363	39.8 ± 9.7	41.0
Gait and maneuverability with the prosthesis	35	363	11.8 ± 3.6	11.0	363	20.2 ± 6.6	20.0
Physical attributes of prosthesis	35	363	18.9 ± 4.9	18.0	363	22.1 ± 5.6	22.0
Physical effects of prosthesis	50	363	30.8 ± 7.3	31.0	361	33.5 ± 7.0	34.0
Negative attributes/limiting factors of prosthesis	45	363	25.2 ± 6.8	25.0	361	33.0 ± 7.0	34.0

stairs and ramps, stopping for rests/feeling unstable when out in public, and use of disabled/handicap parking spaces. In reference to all of the previously mentioned perceived prosthesis improvements when comparing the C-Leg prosthesis with NMCP prosthetic knees, 88.1% of the amputees responded with greater overall confidence/security in the C-Leg MPC prosthesis. The latter included improvements associated with the following: 1) ability of the knee to keep up with gait, 2)

Table 7. Results of survey subsets (data with use of microprocessor controlled knee)

Survey Question Category	Differences Between Means with NMCP Knees Compared with C-Leg: No. Patients	Mean ± SD Difference	*P* Value (Wilcoxon Test)
Socket fit	361	4.6 ± 7.0	<0.0001
Confidence/security in the prosthesis	363	12.7 ± 10.8	<0.0001
Gait and maneuverability with the prosthesis	363	8.4 ± 6.9	<0.0001
Physical attributes of prosthesis	363	3.2 ± 6.7	<0.0001
Physical effects of prosthesis	361	2.7 ± 8.0	<0.0001
Negative attributes/limiting factors of prosthesis	361	7.7 ± 7.9	<0.0001

ease of standing up from/sitting down into a chair, 3) balance, 4) walking in crowds/unfamiliar places, 5) requiring cane/crutches for mobility, 6) buckling of the knee, and 7) having the prosthesis impede normal daily/special (sports) activities.

Published comparative effectiveness research supports the significant scientific and clinical advantages of the C-Leg MPC knee over NMCP prosthetic knees for transfemoral amputees of various amputation etiologies, including vascular, trauma, congenital, sarcoma-related, at all levels of amputation from knee disarticulation to hip disarticulation. These studies stress the following findings concerning the C-leg as directly compared with NMCP prosthetic knees: 1) significantly reduced self-reported stumbles and falls[27,28]; 2) significantly improved gait kinematics, kinetics, peak knee extensor moment during stance, and balance as demonstrated by computerized dynamic posturography and the Sensory Organization Test (SOT), all of which supports the reduction of stumbles and falls[29]; 3) significantly higher patient satisfaction as demonstrated by the PEQ[27,28]; 4) significantly improved stair descent as demonstrated by gait analysis[30,31] and the Montreal Rehabilitation Performance Profile[27]; 5) significantly reduced overloading at the major joints of the lower limb when amputees are supported by the contralateral leg[30] 6) significant reduction in net O_2 consumption while walking[30,32–36]; 7) systematic alignment among transfemoral amputees is important and significantly reduces O_2 consumption[30] 8) significantly improved cost utility score as demonstrated by the EuroQual (EQ-5D)[37]; and 9) significant cost-effectiveness.[38]

Although the current study is based on self-reported data and does not offer direct proof for any of the previously mentioned functional advantages of the C-Leg, it lends indirect support for many of these factors based on the survey responses provided by the amputee participants. An improved gait speed range over variable terrain surfaces is supported by the current survey because 88.4% of the amputee respondents noted improvement in *gait/maneuverability*. Although the gait speed range was not quantitatively measured for this study, the amputee respondents perceived and reported an improvement in range of gait speeds and stability over uneven surfaces. The presence of additional physiological flexion when descending stairs was not questioned in the survey, however, can be indirectly inferred because survey participants noticed marked improvement in the reduction of avoiding going up/down stairs and ramps and increased ability to walk down stairs (step over step)/ramps with confidence. Although reduced energy expenditure was not scientifically measured in the current study, the survey responses lend indirect support of this occurrence because 61.4% of the participants noticed improvement in the *physical effects* of the prosthesis, including reduction in the following: 1) muscle fatigue/cramps and phantom pain in the residual limb, 2) low back/hip discomfort and pain, 3) feeling tired at the end of the day, 4) pressure points in the socket, and 5) volume fluctuation of the residual limb. Moreover, C-Leg prosthesis alignment and adjustments were made through the use of software/PC computer linkage to the microprocessor controlled prosthesis, thus enabling the prosthetist to finely tune the functional swing and stance phase parameters of the knee to provide an energy efficient gait tailored to the unique gait parameter requirements of each amputee.

CONCLUSIONS

Unilateral lower limb amputees who participated in this survey perceived that the microprocessor controlled C-Leg prosthesis system offered functional improvement over their previous NMCP prosthetic knee at 6–9 months follow-up. When comparisons were made for all six survey question categories responded to by participating amputees, marked increases were noted in both mean and median response scores. For all question categories, *follow-up mean scores* were statistically significantly higher ($p < 0.0001$) than *baseline mean scores*. Amputees viewed the C-Leg prosthesis system as better noting improvements in 1) socket fit, 2) confidence/security in the prosthesis, 3) gait/maneuverability, 4) physical attributes (8%), 5) physical effects of the prosthesis, and 6) negative attributes/limiting factors of prosthesis. In view of the responses by unilateral amputees in the current survey, the C-Leg prosthesis system offers the amputee notable functional improvements, particularly associated with the attributes of increased comfort, decreased pain/fatigue, stance stability, ability to alter gait speeds, greater agility, walking down stairs/ramps step over step with confidence, and negotiating uneven terrain surfaces. The notable improvements in confidence/security in the prosthesis and gait and maneuverability with the prosthesis are attributed to the technological advances of the microprocessor controlled C-Leg. The latter allow the prosthesis to perform automatic and continuous knee stability adjustments to accommodate the wearers changing gait patterns during normal ADLs. Concomitantly, with health insurers and third party payers increasingly looking for evidence-based substantiation of therapeutic intervention, the current C-Leg survey demonstrates the value of one particular technological innovation for improving the confidence, security, stability, and functional abilities of amputees to achieve ADLs.

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