Original Investigation

Intuitive Control of a Powered Prosthetic Leg During Ambulation
A Randomized Clinical Trial

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IMPORTANCE Some patients with lower leg amputations may be candidates for motorized prosthetic limbs. Optimal control of such devices requires accurate classification of the patient's ambulation mode (eg, on level ground or ascending stairs) and natural transitions between different ambulation modes.

OBJECTIVE To determine the effect of including electromyographic (EMG) data and historical information from prior gait strides in a real-time control system for a powered prosthetic leg capable of level-ground walking, stair ascent and descent, ramp ascent and descent, and natural transitions between these ambulation modes.

DESIGN, SETTING, AND PARTICIPANTS Blinded, randomized crossover clinical trial conducted between August 2012 and November 2013 in a research laboratory at the Rehabilitation Institute of Chicago. Participants were 7 patients with unilateral above-knee (n = 6) or knee-disarticulation (n = 1) amputations. All patients were capable of ambulation within their home and community using a passive prosthesis (ie, one that does not provide external power).

INTERVENTIONS Electrodes were placed over 9 residual limb muscles and EMG signals were recorded as patients ambulated and completed 20 circuit trials involving level-ground walking, ramp ascent and descent, and stair ascent and descent. Data were acquired simultaneously from 13 mechanical sensors embedded on the prosthesis. Two real-time pattern recognition algorithms, using either (1) mechanical sensor data alone or (2) mechanical sensor data in combination with EMG data and historical information from earlier in the gait cycle, were evaluated. The order in which patients used each configuration was randomized (1:1 blocked randomization) and double-blinded so patients and experimenters did not know which control configuration was being used.

MAIN OUTCOMES AND MEASURES The main outcome of the study was classification error for each real-time control system. Classification error is defined as the percentage of steps incorrectly predicted by the control system.

RESULTS Including EMG signals and historical information in the real-time control system resulted in significantly lower classification error (mean, 7.9% [95% CI, 6.1%-9.7%]) across a mean of 683 steps (range, 640-756 steps) compared with using mechanical sensor data only (mean, 14.1% [95% CI, 9.3%-18.9%]) across a mean of 692 steps (range, 631-775 steps), with a mean difference between groups of 6.2% (95% CI, 2.7%-9.7%] (P = .01).

CONCLUSIONS AND RELEVANCE In this study of 7 patients with lower limb amputations, inclusion of EMG signals and temporal gait information reduced classification error across ambulation modes and during transitions between ambulation modes. These preliminary findings, if confirmed, have the potential to improve the control of powered leg prostheses.

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Major lower limb amputation due to trauma or cancer[1] affected an estimated 115 000 patients in the United States in 2005 and accounted for up to 76% of amputations sustained by US service personnel from 2001 to 2011.[2] Most prosthetic lower limbs are mechanically passive (ie, cannot provide power) and so do not restore full function. Leg prostheses that provide power are becoming available; however, different ambulation modes—such as level-ground walking, ramp ascent and descent, and stair ascent and descent—require fundamentally different control sequences for operating powered prosthetic limbs. Transitioning currently available powered limbs between different ambulation modes requires patients to slow down, stop, press buttons on an electronic key fob, or perform unrelated body movements (eg, exagerrated hip extension; rocking forward and backward on the prosthesis).[3,4] To maximize benefit from these devices and ensure patient safety, control systems must automatically identify which ambulation mode the patient is using and provide the correct prosthesis response.

Electromyographic (EMG) signals—electrical signals generated during muscle contractions—are routinely used to control powered arm prostheses.[5] Advanced pattern recognition algorithms can decode the unique EMG signal patterns generated by multiple muscles during specific movements, thus determining user intent and providing intuitive prosthesis control. EMG signal patterns from leg muscles are highly variable during ambulation,[6] but they provide information that may complement data from the mechanical sensors on the prosthesis.[7,8]

The objective of this study was to assess the effect of including EMG data from residual muscles with mechanical sensor data in a real-time control system on ambulation performance, using a powered prosthetic leg capable of level-ground walking, stair ascent and descent, ramp ascent and descent, and natural transitions between these ambulation modes.

Methods

Patients provided written informed consent for participation in this study, which was approved by the Northwestern University institutional review board and conducted from August 2012 to November 2013 at the Rehabilitation Institute of Chicago. A convenience sample was recruited from patients who met the following eligibility criteria: (1) a unilateral above-knee or knee-disarticulation amputation and (2) ability to ambulate with a prosthesis, consistent with the Centers for Medicare & Medicaid Services K3- or K4-level designation[9] (ie, using their passive prostheses they were able to ambulate freely in a variety of environments within the community, able to traverse most environmental barriers, and had the potential for active ambulation).

For each patient, surface EMG was recorded from 9 residual limb muscles (semitendinosus, biceps femoris, tensor fasciae latae, rectus femoris, vastus lateralis, vastus medialis, sartorius, adductor magnus, and gracilis) (**Figure 1**). These muscles normally contract during ambulation, and, although the signals are complex, pattern recognition may be used to extract important information relating to how the person intends to move. Patients were fitted with a powered knee-ankle prosthesis designed by the Center for Intelligent Mechatronics at Vanderbilt University.[10] Thirteen mechanical sensors—including a 6-axis inertial measurement unit, a vertical-axis load cell, and sensors that provided the position, velocity, and torque of the knee and ankle joints—are integrated into the device. The mechanical response of the prosthesis was adjusted as necessary for each patient during several sessions, before the experiment, in which the patient learned to use the prosthesis.[11]

Ambulation Mode Training Data Collection

Each patient used the knee-ankle prosthesis to complete an experiment comprising 20 circuit trials—involving level-ground walking, ramp ascent and descent, and stair ascent and descent (**Figure 2**). These data were intended for use by a pattern recognition algorithm to learn how to interpret each type of signal pattern. Transitions between ambulation modes were controlled by a member of the research team using a remote control: transitions between level-ground walking and stair ascent were triggered at toe-off (ie, the initiation of swing phase); transitions between level-ground walking and stair descent, ramp descent, and ramp ascent were triggered at heel contact (ie, the initiation of stance phase) (**Video 1**). Data from 20 transitions between level-ground walking and each of the other 4 locomotion modes were collected. Additional level-ground walking trials that included variable speeds (fast and slow), starting and stopping, and turning were performed to obtain a rich training data set for level-ground walking.

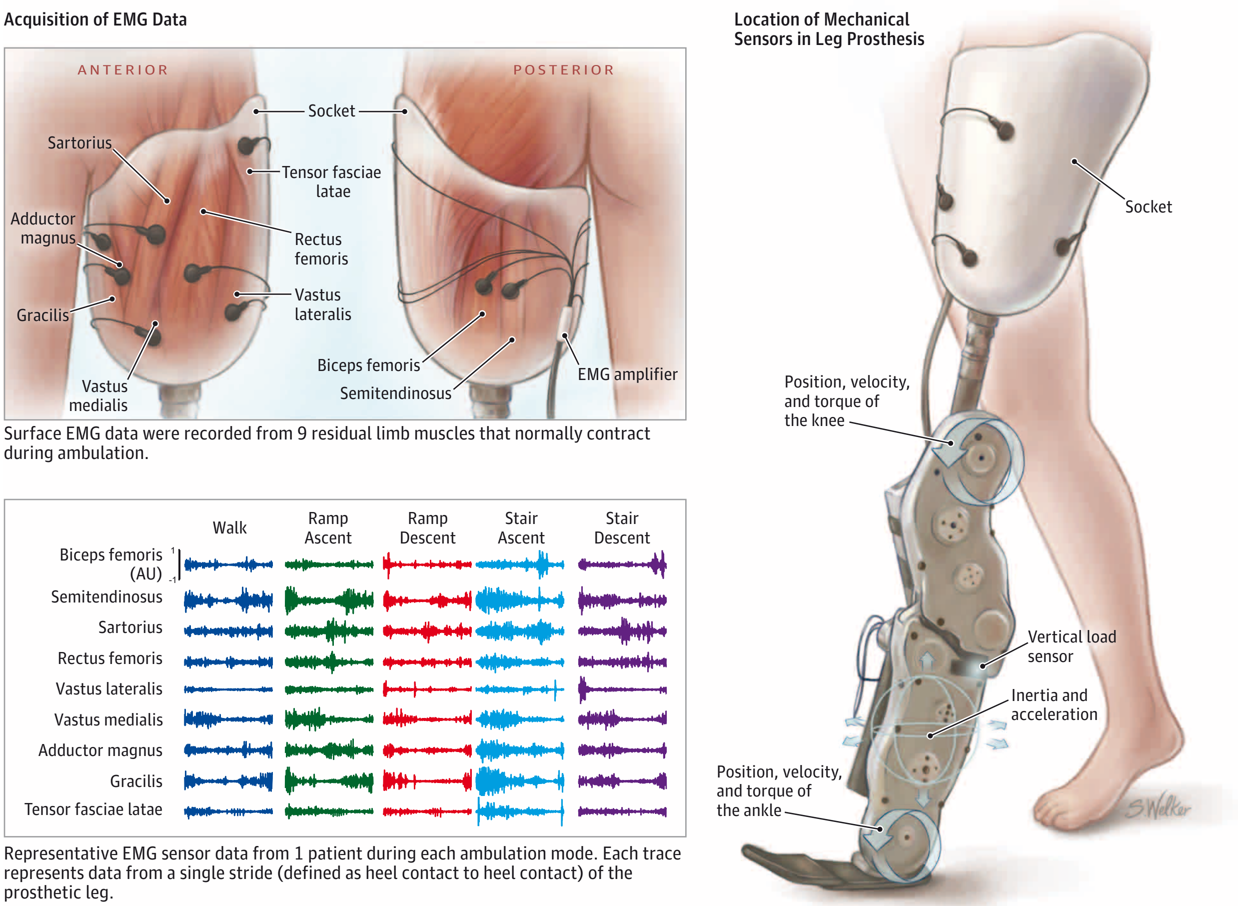
Control System Training

Thirteen mechanical signals and 9 EMG signals (Figure 1; eFigure in the Supplement) were processed and used to create and test pattern recognition systems for each patient. Because the signals are complex, we tested 2 pattern recognition algorithms to interpret the data: linear discriminant analysis (LDA) and a dynamic Bayesian network (DBN). LDA uses a weighted average of an instantaneous snapshot of the sensors to predict how the person is ambulating. The DBN is able to interpret the trajectories, rather than an instantaneous snapshot of the sensors, which is beneficial because gait has stereotypical trajectories that are consistent within an ambulation mode but different across ambulation modes. Four different control systems could be configured: (1) data from only prosthesis mechanical sensors used with an LDA pattern recognition system (Mech + LDA), (2) data from only mechanical sensors used with a DBN system (Mech + DBN), (3) data from both mechanical and EMG sensors used with an LDA system (Mech + EMG + LDA), and (4) data from both mechanical and EMG sensors used with a DBN system (Mech + EMG + DBN).

Classification Error

The primary performance outcome of this study was classification error—the percentage of steps incorrectly identified by

Figure 1. Electromyographic (EMG) and Mechanical Sensor Placement and Example EMG Data Used for Intuitive Prosthetic Leg Control



Surface EMG data were recorded from 9 residual limb muscles that normally contract during ambulation.

Representative EMG sensor data from 1 patient during each ambulation mode. Each trace represents data from a single stride (defined as heel contact to heel contact) of the prosthetic leg.

The data from EMG and mechanical sensors are sampled simultaneously, and the patient's ambulation mode intent is decoded using algorithms programmed onto an embedded microprocessor within the EMG amplifier. Movement commands are then sent to the motors at the knee and ankle to allow the patient to move naturally and also allow intuitive transitions between movements. AU indicates arbitrary units.

the control system while patients walked in different ambulation modes (eg, level-ground walking or stair ascent) and transitioned between these modes. Classification error can be calculated offline, where the predicted mode does not actually affect the control, or in real time, when the prediction changes the behavior of the prosthetic leg and consequently influences the user.

Offline Classification Error

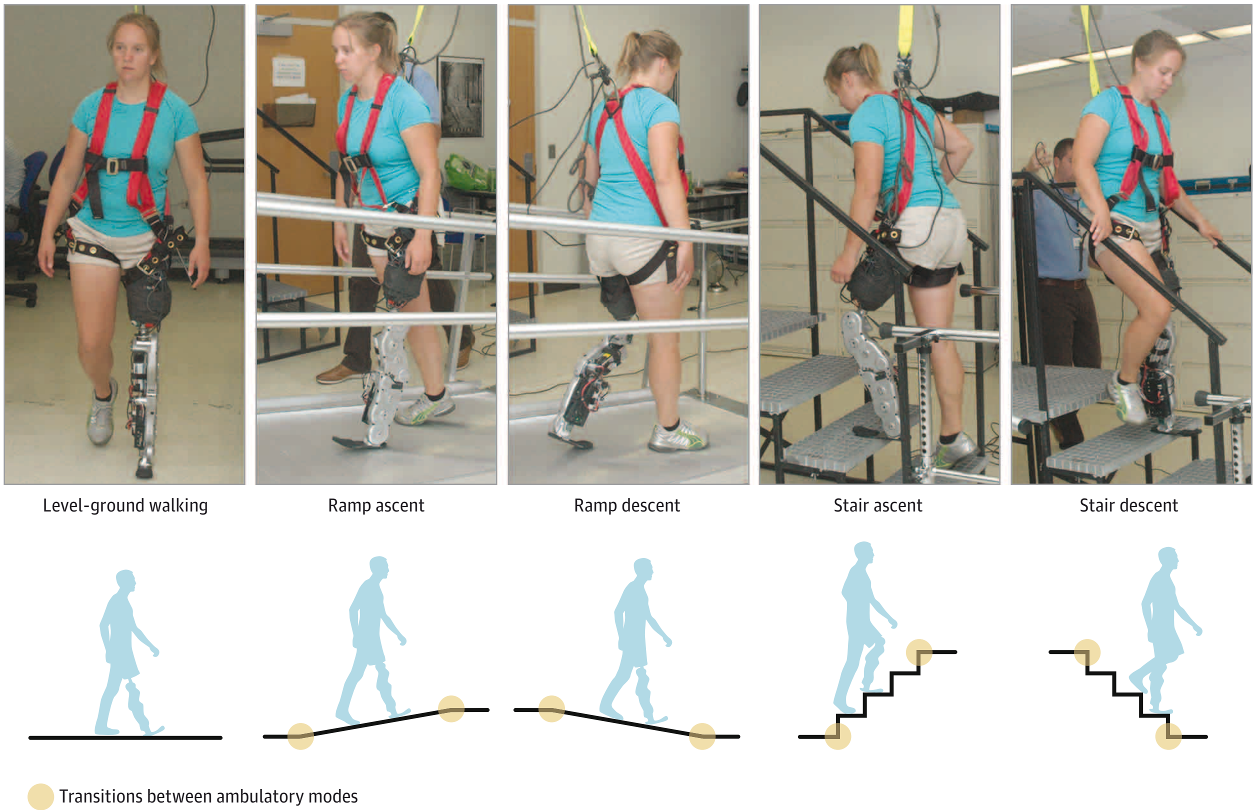
Offline classification error can provide insight into how well a pattern recognition system will perform when it is used in real time to control the prosthesis. All errors generated in the offline trials are strictly attributable to the inability of the pattern algorithms to predict the correct mode. To determine classification error, each system was trained using sensor data (Mech or Mech + EMG) from all the trials except one. Data from the remaining trial were used to test the system, ie, to determine the ability of the trained control system to correctly identify ambulation mode and mode transitions in that trial. This was repeated 19 times, such that each of the trials served as the test trial once. The average classification error for all trials of each control system was then calculated.

Evaluation of Real-Time Control

Only the Mech + LDA and Mech + EMG + DBN control system configurations were evaluated in real time. The Mech + LDA control system was evaluated because it was the only real-time pattern recognition control system for a powered leg prosthesis previously reported in the literature[12]; the Mech + EMG + DBN control system was evaluated because we hypothesized it would provide the best performance of the 4 systems under consideration. Evaluating these 2 conditions required 4 to 6 hours of ambulation, and many of the patients would have had difficulty completing 2 additional configurations because of fatigue. Comparison between these systems was selected a priori.

For each online configuration, patients completed 10 additional ambulation circuits and level-ground walking trials. In these trials, transitions between ambulation modes were performed by the control system, which predicted the

Figure 2. Ambulation Modes and Transitions Investigated in the Study



ambulation mode intended by the patient at each toe-off and heel-contact event and actively changed the mechanical response of the powered knee-ankle prosthesis in real time, based on this prediction. An experimenter labeled the data with the patient's intended ambulation mode. The order in which patients used each configuration was randomized (1:1 blocked randomization using a computerized random number generator) and double-blinded such that the patient and the research team members who provided instructions to the patients did not know which control configuration was being used.

After the ambulation circuits were completed, real-time classification error was determined by comparing the ambulation mode predicted by the control system, with the correct mode identified by the ambulation mode label assigned by a member of the research team observing the experiment. Additionally, the classification error for steps after a correct or an incorrect classification was calculated for both configurations. The relationship between the real-time classification error after a correct classification and the offline classification error (calculated as described in the previous section) was determined using a correlation analysis. Offline and real-time performance was also compared with a previously published case study with a male patient (31 years old, 3 years postamputation, 1.8 m tall, 77.1 kg) who had targeted muscle reinnervation (TMR) surgery to restore EMG signals corresponding to below-knee muscles following a traumatic right knee disarticulation amputation.[8]

A post hoc exploratory analysis was performed after data collection was completed. Classification errors were grouped into 3 categories according to the patient's subjective assessment of the effect of the control system on ambulation: (1) whether classification errors were unnoticeable to the patient, (2) whether errors resulted in a moderate perturbation that was noticeable but did not impede ambulation, and (3) whether errors caused a substantial perturbation that required the patient to stop and an experimenter to manually correct the error by safely transitioning the prosthetic leg to level-ground walking using a remote control. This extension of the error categories proposed by Zhang et al[13] was performed to evaluate the clinical effects of different classification errors.

Statistical Analyses

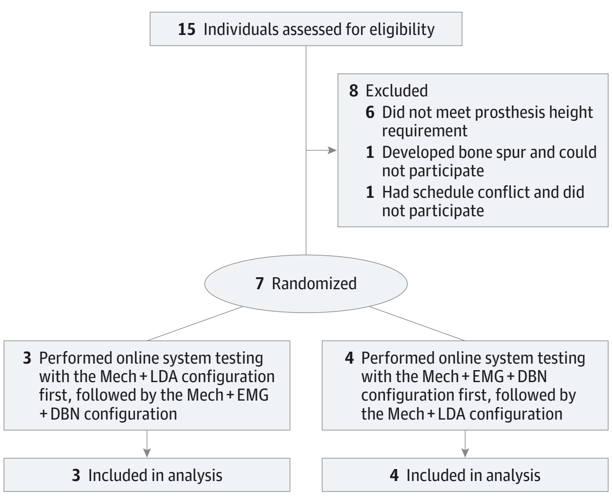
Based on a power analysis completed on closely related data[7] with type-1 error (α) set to .05, type-2 error (β) set to .20, and a minimally important difference of 5% classification error, 7 patients were recruited. An offline classification error rate of approximately 7% was expected.[7] Offline classification errors from each of the 4 control configurations were compared in a 1-way analysis of variance performed with MiniTab version 16 and using a post hoc Bonferroni correction to determine pairwise differences between conditions (α = .05). Differences between the overall error rates of the 2 conditions tested in real time were evaluated using a 2-sided paired t test (α = .05). For the 2 real-time conditions, 2-sided paired *t* tests (α = .05) were conducted on the 3 categories of error based on the effect of the perturbation (unnoticeable, moderate, substantial). A Pearson correlation test was performed to quantify the relationship between offline error and real-time classification error to determine the Pearson correlation coefficient (r)[14] and its associated *P* value (α = .05).

Results

Patient Recruitment

Six patients with above-knee amputations and 1 patient with a knee disarticulation amputation were enrolled in the study (**Figure 3**, **Table**). Five patients used a suction socket, 1 used a locking liner, and 1 used a belt suspension system. All patients were classified as community ambulators (Centers for Medicare & Medicaid Services designated K3 or K4 level). Among the 7 study participants, age ranged from 21 to 65 years, weight ranged from 62 to 112 kg, and height ranged from 1.60 to 1.87 m.

Figure 3. Study Participation for Intuitive Control of a Powered Prosthetic Leg During Ambulation



Description of patients screened and recruited into the study.

Offline Classification Error

During the offline portion of the experiment, patients took a mean of 1215 steps (range, 1104-1427). Inclusion of EMG signals and time history information (Mech + EMG + DBN) resulted in the most accurate control system and significantly ($P < .001$) reduced mean classification error from 6.3% (95% CI, 5.5%-7.1%) to 2.9% (95% CI, 2.5%-3.3%) compared with using mechanical sensors only (Mech + LDA) (**Figure 4**). The Mech + DBN system had a mean error of 4.2% (95% CI, 3.7%-4.7%) and the Mech + EMG + LDA system had a mean error of 3.8% (95% CI, 2.8%-4.8%]; these errors were significantly lower than for the Mech + LDA system ($P = .002$ and $P < .001$, respectively).

Real-Time Classification Error

All patients successfully completed the real-time ambulation circuit trials using the powered knee-ankle prosthesis (**Video 2**). Patients took a mean of 692 steps (range, 631-775) to complete real-time ambulation circuits using the Mech + LDA system and a mean of 683 steps (range, 640-756) to complete real-time ambulation circuits using the Mech + EMG + DBN system (Figure 4). Compared with the baseline Mech + LDA configuration, adding EMG signals and time-history information (Mech + EMG + DBN) significantly ($P = .01$) reduced overall real-time mean error rates from 14.1% (95% CI, 9.3%-18.9%) to 7.9% (95% CI, 6.1%-9.7%) and median error rates from 14.0% (interquartile range, 6.1%-21.8%) to 7.6% (interquartile range, 6.0%-9.2%) (Figure 4). When steps were correctly classified, the mean error for the next step was 10.4% (95% CI, 7.7%-13.1%) for the Mech + LDA configuration and 5.7% (95% CI, 4.4%-7.0%) for the Mech + EMG + DBN configuration. In contrast, after a classification error, the mean classification error for the subsequent step was 26.5% (95% CI, 14.6%-38.4%) for the Mech + LDA configuration and 24.3% (95% CI, 15.0%-33.6%) for the Mech + EMG + DBN configuration. For both real-time control conditions, errors were reduced when the previous step was correctly classified. When a step was inaccurately classified, the error was propagated such that subsequent steps were more likely to be classified incorrectly.

Effect of Classification Errors on Real-Time Ambulation

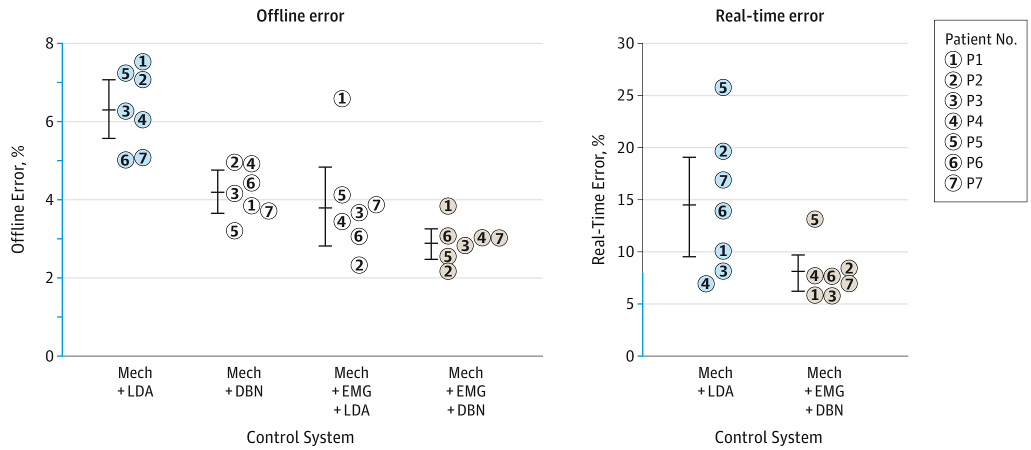
Classification errors that occurred between level-ground walking and ramp ascent were always unnoticeable to the patient (**Video 3**). Classification errors between level-ground walking

Table. Patients Enrolled in Study

Patient No.	Age, y	Sex	Time Since Amputation, y	Weight With Prosthesis, kg	Height, m	Etiology	Amputation Level	Suspension Type[a]	Previous Powered Prosthesis Experience, h
P1	56	Male	43	81.7	1.80	Left traumatic	Above-knee	Suction	16
P2	65	Male	38	90.0	1.75	Right traumatic	Above-knee	Suction	35
P3	21	Female	6	61.7	1.60	Left sarcoma	Above-knee	Suction	11
P4	50	Male	16	87.7	1.87	Right traumatic	Above-knee	Liner-lock	14
P5	52	Male	38	112.3	1.86	Left traumatic	Above-knee	Sock and belt	17
P6	43	Male	18	100.2	1.82	Left traumatic	Above-knee	Suction	8
P7	28	Male	15	90.7	1.87	Left sarcoma	Knee disarticulation	Suction	11

[a] Method by which the prosthesis is "suspended" from (ie, attached to) the residual limb.

Figure 4. Mean Offline and Real-Time Classification Error for All Control Systems



A 1-way analysis of variance using a post hoc Bonferroni correction revealed a significant reduction in offline classification error between the control system using mechanical sensors only (Mech + linear discriminant analysis [LDA]) and the other 3 control systems (Mech + dynamic Bayesian Network [DBN], *P* = .002; Mech + electromyographic [EMG] + LDA, *P* < .001; Mech + EMG + DBN, *P* < .001). Individual data points for each patient indicate the mean offline error across all ambulation modes and all steps (P1, 1211 steps; P2, 1210 steps; P3, 1427 steps, P4, 1144 steps; P5, 1182 steps; P6, 1230 steps; P7, 1104 steps) for each control system. Y-axes shown in blue indicate range from 0% to 8%.

and ramp or stair descent caused moderate perturbations that were noticeable and slightly disruptive to the patient but did not cause the patient to stop ambulating or to use the safety harness. Any classification error while ambulating on stairs, or any step that was classified as stair ascent while the patient was not climbing stairs, caused a substantial perturbation such that the patient had to stop ambulating. The Mech + EMG + DBN configuration significantly (*P* = .01) reduced the number of classification errors that caused moderate perturbations compared with only the Mech + LDA configuration, with a mean difference of 4.5% (95% CI, 2.0%-7.0%) (**Figure 5**).

Comparison of Offline and Real-Time Classification Error

The Pearson correlation coefficient between offline and real-time error rates for the 2 configurations tested in real time (Mech + LDA and Mech + EMG + DBN) was 0.6 (*P* = .02), indicating that offline error rate was significantly associated with real-time classification error (**Figure 6**). All patients reported that they preferred the Mech + EMG + DBN system. Using this system, patients indicated that they were more confident when ambulating and appreciated the reduced number of noticeable perturbations, resulting from fewer classification errors.

Effect of TMR Surgery on Prediction of Ambulation Mode

In our previous study, the offline mean classification error for a knee disarticulation patient after TMR surgery[8] was within 1 standard deviation of the patients who participated in this study and did not have TMR surgery (Mech + LDA, 5.9%; Mech + DBN, 4.8%; Mech + EMG + LDA, 2.1%; and Mech + EMG + DBN, 1.8%). The real-time performance of the patient with TMR using only mechanical sensors (Mech + LDA) had a mean error of 12.9%, which was comparable with the mean error of 14.1% for the patients in this study without TMR. The mean error for the patient with TMR decreased to 1.8% using the real-time Mech + EMG + DBN system, which was markedly (2.5 SDs) below the mean error rates (7.9%) for patients without TMR in this study.

Discussion

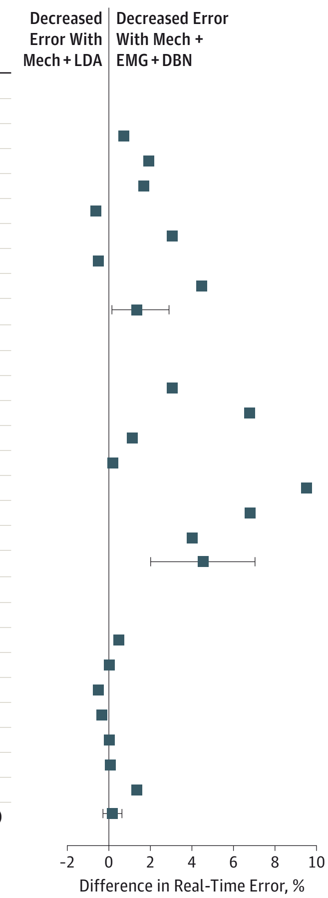
This preliminary study is, to our knowledge, the first clinical evaluation of the ability of individuals with above-knee amputations to control a powered knee-ankle prosthesis across different ambulation modes and the first time EMG signals have been incorporated into a real-time control system for a powered lower limb prosthesis. We used pattern recognition algorithms that incorporated information from many different sensor sources to predict ambulation mode for the next stride. Inclusion of EMG and time-history information (Mech + EMG + DBN) reduced classification errors by 6.2% (*P* = .01). This control system allowed for automatic, natural transitions between ambulation modes, in contrast to current control systems that require the patient to use an electronic key fob or perform a set of exaggerated movements to transition between modes.[3,4]

Previous work has shown that EMG patterns can be used to predict ambulation modes in a passive prosthesis.[6,7] However, in those studies, the patient had to make abnormal gait adaptations, such as ascending stairs using a step-by-step gait pattern. We have previously shown that EMG pattern recognition techniques can be used to predict ambulation modes of individuals using a powered knee-ankle prosthesis,[15] but in that study the experimenter controlled the prosthesis remotely. In the present study, use of pattern recognition in real time enabled a true test of control system performance and clinical feedback from patients on their experience of the control systems.

The offline performances of the patient with TMR described in a previous study[8] were consistent with those of the

Figure 5. Mean Real-Time Classification Errors Grouped by the Perturbation to the Patient

Impact Caused to Patient	Mech + LDA No. of Errors	Mech + LDA No. of Steps	Mech + LDA Real-Time Error, %	Mech + EMG + DBN No. of Errors	Mech + EMG + DBN No. of Steps	Mech + EMG + DBN Real-Time Error, %	Difference in Real-Time Error, %
Unnoticeable perturbation							
Patient No.							
1	17	716	2.37	11	664	1.66	0.71
2	20	649	3.08	8	640	1.25	1.83
3	27	775	3.48	14	756	1.85	1.63
4	10	667	1.50	15	678	2.12	-0.62
5	22	631	3.49	3	675	0.45	3.04
6	15	709	2.12	19	721	2.64	-0.52
7	61	694	8.79	28	649	4.31	4.48
Mean (95% CI)			3.54 (1.75 to 5.34)			2.05 (1.15 to 2.95)	1.50 (0.11 to 2.88)
Moderate perturbation							
Patient No.							
1	42	716	5.87	19	664	2.86	3.01
2	90	649	13.87	45	640	7.03	6.84
3	33	775	4.26	24	756	3.17	1.09
4	33	667	4.95	32	678	4.72	0.23
5	137	631	21.71	82	675	12.15	9.56
6	82	709	11.57	34	721	4.72	6.85
7	40	694	5.76	11	649	1.69	4.07
Mean (95% CI)			9.71 (4.95 to 14.49)			5.19 (2.59 to 7.79)	4.52 (2.01 to 7.03)
Substantial perturbation							
Patient No.							
1	13	716	1.82	9	664	1.36	0.46
2	1	649	0.15	1	640	0.16	-0.01
3	3	775	0.39	7	756	0.93	-0.54
4	3	667	0.45	5	678	0.74	-0.29
5	3	631	0.48	3	675	0.44	0.04
6	2	709	0.28	2	721	0.28	0
7	16	694	2.31	6	649	0.92	1.39
Mean (95% CI)			0.84 (0.21 to 1.47)			0.69 (0.39 to 1.00)	0.15 (-0.31 to 0.61)



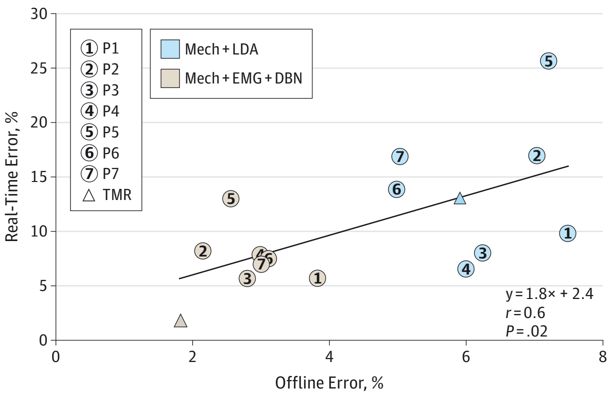
A post hoc test conducted to determine pairwise differences between the 2 control systems for each of the perturbation types revealed that inclusion of electromyographic (EMG) signals and time-history information (Mech + EMG + dynamic Bayesian network [DBN]) significantly ($P = .01$) reduced classification errors that caused moderate perturbations compared with only using mechanical sensor data (Mech + linear discriminant analysis).

patients in this study, although the patient with TMR did have markedly lower error rates than patients without TMR when using the Mech + EMG + DBN system in real time. It is likely that by transferring severed nerves to functional muscle, TMR enabled access to additional EMG control information intended for the amputated distal limb, which enabled improved control of the prosthesis. However, the patient with TMR in the previous reports had more experience walking with the powered knee-ankle prosthesis than all but 1 of the patients without TMR in this study, which could also have affected this result. Even if TMR only marginally improves control of a powered lower limb prosthesis during ambulation, the previous report describing 1 patient with TMR suggested that TMR improved intent recognition for non-weight-bearing movements such as repositioning the knee and ankle while seated and preparing to stand.[8] A laboratory investigation in an animal model and retrospective analysis of recipients of upper limb TMR suggested that TMR may also be useful for amputation-related neuromas.[16,17]

Studies evaluating upper limb pattern recognition control strategies have shown only a weak correlation between offline error rates and real-time control capability.[18,19] However, we found a significant correlation between the offline and real-time control error rates during ambulation for the lower limb. The offline error rates were lower than the real-time error rates primarily because steps after a real-time classification error generated data patterns not present in the training data (ie, training data only contained patterns from when the patient was ambulating correctly). Additionally, because the real-time experiment was conducted after the training session, factors such as fatigue or sweating may have caused signal changes that resulted in additional classification errors. Many previous offline studies showed promising results when using pattern recognition to determine user intent during ambulation[6,7,20,21]; the results of this study extend these studies to real-time control of a powered leg.

The primary performance metric used in this study was classification error. Patient safety is of paramount importance, and classification errors occurring during ambulation could cause patients to stumble or fall; an ideal control system would be error free. The powered knee-ankle prosthesis uses an impedance control model to generate the knee and ankle torques,[22] and the impedance parameters are similar for some ambulation modes. Thus, as shown in post hoc

Figure 6. Relationship of Offline Error to Real-Time Error and a Best-Fit Line of the Pooled Data



Blue data points represent individual patients using the Mech + linear discriminant analysis (LDA) system and green data points represent individual patients using the electromyographic (EMG) + Mech + dynamic Bayesian network (DBN) system. Each point for each patient indicates the mean error across all ambulation modes and all steps for the offline Mech + LDA and Mech + EMG + DBN classification error rate (P1, 1211 steps; P2, 1210 steps; P3, 1427 steps; P4, 1144 steps; P5, 1182 steps; P6, 1230 steps; P7, 1104 steps; targeted muscle reinnervation [TMR], 1240 steps), the real-time Mech + LDA classification error rate (P1, 716 steps; P2, 649 steps; P3, 775 steps; P4, 667 steps; P5, 631 steps; P6, 709 steps; P7, 694 steps; TMR, 719 steps) and real-time Mech + EMG + DBN classification error rate (P1, 664 steps; P2, 640 steps; P3, 756 steps; P4, 678 steps; P5, 675 steps; P6, 721 steps; P7, 649 steps; TMR, 660 steps). A Pearson correlation test was run to quantify the relationship between offline and real-time classification error to determine the Pearson correlation coefficient[14] and its associated *P* value (α = .05).

analyses, many classification errors, such as those between walking and ramp ascent, did not produce noticeable disturbances to the patient, resulting in a relatively forgiving control system (Figure 4). Other classification errors caused moderate disturbances that the patient noticed but could tolerate and continue walking, such as those occurring between walking and ramp descent (**Video 3**). In addition, incorrect classification of any step as stair ascent caused substantial perturbations from which it was difficult for the patient to safely recover without stopping. Another particularly critical transition was between level-ground walking and stair descent, which required patients to stop and reattempt the stairs; the Mech + EMG + DBN system performed with 0% error for this transition, whereas the Mech + LDA system had 5.4% error. Further control improvements could be achieved by collection of a more robust training data set, use of additional sensors, or implementation of a stumble-recovery mode. It may also be possible to statistically weight the classifier to avoid the most substantial errors.

This study was preliminary and had limitations that should be considered. The sample size was small, and experiments were only performed by patients who could already ambulate freely in a variety of environments. Additional work needs to be completed to determine if patients with more limited ambulation capabilities could benefit from the proposed system. The control system testing was completed in the laboratory over a short time frame (1 experimental session) rather than in a real-world setting, which would have less controlled variables. Additional studies are required to determine the system performance over multiple days or months. Incorporation of EMG electrodes into the patient's socket is nontrivial, and care must be taken so that the electrodes do not interfere with residual limb skin health. Last, system configuration must be further simplified so that clinicians can comfortably fit the device after receiving a reasonable amount of training.

Conclusions

In this study of 7 patients with lower limb amputations, inclusion of EMG signals and temporal gait information reduced classification error across ambulation modes and during transitions between ambulation modes. These preliminary findings, if confirmed, have the potential to improve the control of powered leg prostheses.

ARTICLE INFORMATION

Author Contributions: Dr Hargrove had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.
Study concept and design: Hargrove, Young, Simon, Fey, Kuiken.
Acquisition, analysis, or interpretation of data: Hargrove, Young, Simon, Fey, Lipschutz, Finucane, Halsne, Ingraham.
Drafting of the manuscript: Hargrove, Young, Simon, Fey, Kuiken.
Critical revision of the manuscript for important intellectual content: Young, Simon, Fey, Lipschutz, Finucane, Halsne, Ingraham.
Statistical analysis: Hargrove, Young.
Obtained funding: Kuiken.
Administrative, technical, or material support: Hargrove, Young, Simon, Fey, Lipschutz, Finucane, Halsne, Ingraham, Kuiken.
Study supervision: Hargrove, Simon.

Conflict of Interest Disclosures: All authors have completed and submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest. Drs Hargrove and Young reported submitting a patent, US Patent Application No. 13/925 668, describing the control system. Dr Hargrove reported ownership in a closely-held small company, Coapt LLC, that has licensed intellectual property from the Rehabilitation Institute of Chicago for upper-limb prosthetic limbs (application of any of the licensed technology to the closely-held company for lower limb prosthetic limb applications is expressly prohibited in the license agreement). Drs Simon and Fey reported submitting a patent, US Patent Application 2014/063469, describing the method for controlling stair ascent. Dr Kuiken reported ownership in a closely held small company, Coapt LLC, that has licensed intellectual property from the Rehabilitation Institute of Chicago for upper-limb prosthetic limbs (application of any of the licensed technology to the closely held company for lower limb prosthetic limb applications is expressly prohibited in the license agreement); having a patent issued, US8828093 B1, related to using EMG to predict ambulation; and having a patent pending (13/925,668). None of the patents cited have been licensed to industry. No other authors reported disclosures.

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REFERENCES

1. Ziegler-Graham K, MacKenzie EJ, Ephraim PL, Travison TG, Brookmeyer R. Estimating the prevalence of limb loss in the United States: 2005 to 2050. *Arch Phys Med Rehabil*. 2008;89(3):422-429.

2. Krueger CA, Wenke JC, Ficke JR. Ten years at war: comprehensive analysis of amputation trends. *J Trauma Acute Care Surg*. 2012;73(6)(suppl 5):S438-S444.

3. Bionic Technology. The Power Knee. ÖSSUR website. http://www.ossur.com/prosthetic-solutions/bionic-technology. Accessed April 17, 2015.

4. Bellmann M, Schmalz T, Ludwigs E, Blumentritt S. Immediate effects of a new microprocessor-controlled prosthetic knee joint: a comparative biomechanical evaluation. *Arch Phys Med Rehabil*. 2012;93(3):541-549.

5. Parker P, Englehart K, Hudgins B. Myoelectric signal processing for control of powered limb prostheses. *J Electromyogr Kinesiol*. 2006;16(6):541-548.

6. Huang H, Kuiken TA, Lipschutz RD. A strategy for identifying locomotion modes using surface electromyography. *IEEE Trans Biomed Eng*. 2009;56(1):65-73.

7. Huang H, Zhang F, Hargrove LJ, Dou Z, Rogers DR, Englehart KB. Continuous locomotion-mode identification for prosthetic legs based on neuromuscular-mechanical fusion. *IEEE Trans Biomed Eng*. 2011;58(10):2867-2875.

8. Hargrove LJ, Simon AM, Young AJ, et al. Robotic leg control with EMG decoding in an amputee with nerve transfers. *N Engl J Med*. 2013;369(13):1237-1242.

9. Gailey RS, Roach KE, Applegate EB, et al. The amputee mobility predictor: an instrument to assess determinants of the lower-limb amputee's ability to ambulate. *Arch Phys Med Rehabil*. 2002;83(5):613-627.

10. Goldfarb M, Lawson BE, Shultz AH. Realizing the promise of robotic leg prostheses. *Sci Transl Med*. 2013;5(210):210ps15.

11. Simon AM, Ingraham KA, Fey NP, et al. Configuring a powered knee and ankle prosthesis for transfemoral amputees within five specific ambulation modes. *PLoS One*. 2014;9(6):e99387.

12. Varol HA, Sup F, Goldfarb M. Multiclass real-time intent recognition of a powered lower limb prosthesis. *IEEE Trans Biomed Eng*. 2010;57(3):542-551.

13. Zhang F, Liu M, Huang H. *Preliminary study of the effect of user intent recognition errors on volitional control of powered lower limb prostheses*. Presented at: 34th Annual International Conference of the IEEE EMBS; 2012; San Diego, CA.

14. Katz M. *Multivariable Analysis: A Practical Guide for Clinicians and Public Health Researchers*. 3rd ed. Cambridge, United Kingdom: Cambridge University Press; 2011.

15. Young AJ, Kuiken TA, Hargrove LJ. Analysis of using EMG and mechanical sensors to enhance intent recognition in powered lower limb prostheses. *J Neural Eng*. 2014;11(5):056021.

16. Kim PS, Ko JH, O'Shaughnessy KK, Kuiken TA, Pohlmeyer EA, Dumanian GA. The effects of targeted muscle reinnervation on neuromas in a rabbit rectus abdominis flap model. *J Hand Surg Am*. 2012;37(8):1609-1616.

17. Souza JM, Cheesborough JE, Ko JH, Cho MS, Kuiken TA, Dumanian GA. Targeted muscle reinnervation: a novel approach to postamputation neuroma pain. *Clin Orthop Relat Res*. 2014;472(10):2984-2990.

18. Kuiken TA, Li G, Lock BA, et al. Targeted muscle reinnervation for real-time myoelectric control of multifunction artificial arms. *JAMA*. 2009;301(6):619-628.

19. Lock BA, Englehart K, Hudgins B. *Real-time myoelectric control in a virtual environment to relate usability vs accuracy*. In: MyoElectric Controls Symposium; 2005 August; New Brunswick, Fredericton; 2005. p. 122-7.

20. Young AJ, Simon AM, Fey NP, Hargrove LJ. Intent recognition in a powered lower limb prosthesis using time history information. *Ann Biomed Eng*. 2014;42(3):631-641.

21. Young AJ, Simon AM, Hargrove LJ. A training method for locomotion mode prediction using powered lower limb prostheses. *IEEE Trans Neural Syst Rehabil Eng*. 2014;22(3):671-677.

22. Sup F, Varol HA, Mitchell J, Withrow T, Goldfarb M. Design and control of an active electrical knee and ankle prosthesis. *Proc IEEE RAS EMBS Int Conf Biomed Robot Biomechatron*. 2008:2008;523-528.