Reduction in falls associated with use of microprocessor-controlled prosthetic knees among community ambulators with transfemoral amputation

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Clinical Question: Will limited or unlimited community ambulators with unilateral, transfemoral amputation (TFA) experience fewer falls when using a microprocessor-controlled prosthetic knee (MPK) as compared to using a non-microprocessor controlled prosthetic knee (NMPK)?

Background: People with severe physical impairments, like TFA, have a high risk of falls. For example, nearly two-thirds of prosthesis users with TFA fall at least once per year.[8-9] Further, about 40% of these falls were reported to be injurious.[8,10,11] The high risk of fall-related injuries and subsequent outcomes (including medical care and long-term disability) implies a pressing need for interventions that reduce falls among people with TFA. One prosthetic intervention capable of mitigating fall risk in people with TFA is a MPK. Sensors in the MPK allow the computer to quickly and accurately adapt to changes in the user's gait, providing high levels of function and safety in walking. MPKs also rapidly increase knee flexion resistance in response to abnormal movements to prevent falls.[12] As such, MPKs have the potential to reduce the frequency of falls among prosthetic users**.** Although unlimited community (K3) ambulators are often candidates for a MPK, limited community (K2) ambulators are typically deemed ineligible, as they are not expected to benefit from functional capabilities of the knee.[14] However, the safety features inherent to MPKs may offer both K2 and K3 ambulators protection against falls, injury, and costs associated with fall-related events. This CAT was therefore conducted to determine if evidence exists to indicate that MPKs may reduce falls in people with TFA.

Search Strategy:
Databases Searched: PubMed, CINAHL, Web of Science
Search Terms: (microprocessor OR "microprocessor-control" OR "microprocessor-controlled" OR C-leg) AND (trans femoral OR "trans-femoral" OR "above-knee" OR "above knee") AND (fall OR falls OR falling)
Inclusion/Exclusion Criteria: English, peer-reviewed and published, original research, not grey literature

Synthesis of Results: Seven articles were reviewed that included both reported incidence and direct measurement of falls. Subjects reported significantly fewer falls[15-18, 21] and stumbles[15-16] when they used a MPK compared to when they used an NMPK. However, falls were reported using ad hoc surveys with limited evidence of reliability and validity.[15-18, 21] One study[19] examining biomechanical outcomes of three prosthetic knee users under four conditions likely to cause falls determined that the MPK was the only knee that resisted falls under all conditions. However, the small sample size and simulated conditions limit generalizability of these outcomes. Another study found that two MPK users and one NMPK user experienced a fall while ambulating over an uneven, compliant surface.[20] Thus, users may still experience falls while wearing a MPK. Additionally, although subjects in the reviewed articles were predominantly classified as K3, a subgroup analysis[17] showed K2 users reported a statistically significant reduction in uncontrolled falls.

Potential limitations to the evidence presented include: (1) lower representation of K2 ambulators and people with dysvascular TFA in many of the studies, and (2) examination of only one MPK knee (the Otto Bock C-Leg). The available evidence therefore suggests that both K2 and K3 ambulators often experience fewer falls when wearing a MPK, but these findings should be confirmed with additional research that more thoroughly assesses fall outcomes associated with MPK use in K2 and dysvascular populations and in other MPK models.

Clinical Message: Use of the Otto Bock C-leg MPK is likely to reduce the number of falls experienced by K2 and K3 ambulators with unilateral TFA. Existing evidence is of low-to-moderate quality, but predominately shows that prosthetic knee users report fewer falls and are more stable under conditions that cause falls when wearing a C-Leg compared to various, NMPKs.

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Evidence Table

	Hafner 2007[15]	Kahle 2008[16]	Hafner 2009[17]	Berry 2009[18]	Blumentritt 2009[19]	Meier 2012[20]	Wong 2012[21]
Population	Number of subjects: 17 Ages: 21-77 (mean = 49 years) Genders: male (12); female (5) Times since amputation: 2-67 years (mean = 20 years) Causes of amputation: trauma (10), vascular (1), infection (2), tumor (3), and other (1) Functional levels: 2 (8), 3 (9)	Number of subjects: 19 Ages: 22-83 (mean = 51 years) Genders: n/a Times since amputation: 9-26 years (mean = 19 years) Causes of amputation: trauma (7), vascular (7), tumor (1), congenital (4), Functional levels: 2 (9), 3 (8), 4 (2)	Number of subjects: 17 Ages: 21-77 (mean = 49 years) Genders: male (12); female (5) Times since amputation: 2-67 years (mean = 20 years) Causes of amputation: trauma (10), vascular (1), infection (2), tumor (3), and other (1) Functional levels: 2 (8), 3 (9)	Number of subjects: 368 Ages: 15-85 (mean = 55 years) Genders: male (289); female (79) Times since amputation: 0.2-79 years (mean = n/a) Causes of amputation: trauma (185), vascular (41), tumor (51), infection (32), congenital (8) and other (51) Functional levels: 3 (368)	Number of subjects: 3 Ages: 25-43 (mean = 37 years) Genders: male (2); female (1) Times since amputation: 9-26 years (mean = 19 years) Causes of amputation: trauma (2) and tumor (1) Functional levels: 3 (1) and 4 (2)	Number of subjects: 12 Ages: 46 ± 9 years Genders: male (10); female (2) Times since amputation: 21 ± 16 years Causes of amputation: trauma (7), infection (2), congenital (2), and vascular (1) Functional levels: not stated (2-4 estimated by inclusion criteria)	Number of subjects: 1 Ages: 53 Genders: male (1) Times since amputation: 1.4 years Causes of amputation: vascular (1) Functional levels: 3
Recruitment source	Convenience community sample (Seattle, WA)	Convenience community sample (Tampa, FL)	Convenience community sample (Seattle, WA)	Clinic sample (National)	Not stated	Not stated	Urban support group (New York, NY)
Study Design	Interrupted time series	Before-and-after	Secondary analysis of interrupted time series (by MFCL/K-level)	Case series	Before-and-after	Before-and-after	Case study
Intervention	Otto Bock C-Leg	Otto Bock C-Leg	Otto Bock C-Leg	Otto Bock C-Leg	Otto Bock C-Leg	Otto Bock C-Leg	Otto Bock C-Leg
Comparison	Non-microprocessor controlled prosthetic knee (various variable-cadence designs)	Non-microprocessor controlled prosthetic knee (various variable-cadence designs)	Non-microprocessor controlled prosthetic knee (various variable-cadence designs)	Non-microprocessor controlled prosthetic knee (various variable-cadence designs)	Otto Bock 3R80 (rotary hydraulic) and Otto Bock 3C1 (SNS)	Catech SNS and Otto Bock 3R60 (pneumatic polycentric)	Össur Mauch (SNS)
Relevant Outcome(s)	Self-reported stumbles, semi-controlled falls, and uncontrolled falls	Self-reported stumbles and falls	Self-reported stumbles, semi-controlled falls, and uncontrolled falls	Self-reported falls	Uncontrolled biomechanical motion of the knee joint that would suggest a fall would occur under similar conditions (users wore a safety harness to prevent falls)	Observed falls	Self-reported falls

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Outcome Measure(s)	Self-report, ad hoc questionnaire with the following questions: Stumbles questions: "Over the past 4 weeks, how often have you stumbled while wearing your prosthesis?" And "Over the past 4 weeks, please estimate the number of stumbles you have had?" Semi-controlled falls questions: "Over the past 4 weeks, how often have you had a semi-controlled fall while wearing your prosthesis?" And "Over the past 4 weeks, please estimate the number of semi-controlled falls you have had?" Uncontrolled falls questions: "Over the past 4 weeks, how often have you had an uncontrolled fall while wearing your prosthesis?" And "Over the past 4 weeks, please estimate the number of uncontrolled falls you have had?" Time period: 4 weeks Response options: visual analog scale (VAS) and direct entry of number of events	Self-report, ad hoc questionnaire with the following questions: Stumbles question: "How many times in the last 60 days did any event occur in which you felt your prosthesis became temporarily unstable and you felt you were at risk of falling but did not?" Falls question: "How many times in the last 60 days did an event occur that caused you to fall to the ground?" Time period: 60 days Response options: direct entry of number of events	Self-report, ad hoc questionnaire with the following questions: Stumbles questions: "Over the past 4 weeks, how often have you stumbled while wearing your prosthesis?" And "Over the past 4 weeks, please estimate the number of stumbles you have had?" Semi-controlled falls questions: "Over the past 4 weeks, how often have you had a semi-controlled fall while wearing your prosthesis?" And "Over the past 4 weeks, please estimate the number of semi-controlled falls you have had?" Uncontrolled falls questions: "Over the past 4 weeks, how often have you had an uncontrolled fall while wearing your prosthesis?" And "Over the past 4 weeks, please estimate the number of uncontrolled falls you have had?" Time period: 4 weeks Response options: visual analog scale (VAS) and direct entry of number of events	Self-report, ad hoc questionnaire that included safety questions: Falls question: "I fall while wearing my prosthesis" Time period: n/a (see response options) Response options: 1 = always, 2 = often, 3 = sometimes, 4 = seldom, 5 = never	Knee angle and moments under the following conditions: abrupt stopping, abrupt side-stepping, stepping onto an obstacle, and interruption of swing-phase knee extension (tripping).	Number of falls experienced while walking an indoor obstacle course	Self-report, ad hoc questionnaire (details not reported)

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	Hafner 2007[15]	Kahle 2008[16]	Hafner 2009[17]	Berry 2009[18]	Blumentritt 2009[19]	Meier 2012[20]	Wong 2012[21]
Location of Measurement	Laboratory (Note: questionnaires asked subject to reflect on community experience over an extended period of time)	Laboratory (Note: questionnaires asked subject to reflect on community experience over an extended period of time)	Laboratory (Note: questionnaires asked subject to reflect on community experience over an extended period of time)	Clinic and home (Note: questionnaires asked subject to reflect on community experience over an extended period of time)	Laboratory	Laboratory	Clinic (Note: questionnaires asked subject to reflect on community experience over an extended period of time)
Timing of Measurement	Initial questionnaire (NMPK) administered after 4 weeks use of NMPK; Follow-up questionnaire (MPK) administered after a subject-specific accommodation period; Subsequent questionnaires administered at after 2 weeks to 2 months use in each knee	Initial questionnaire (NMPK) administered at beginning of study; Follow-up questionnaire (MPK) administered after a 90-day accommodation period	Initial questionnaire (NMPK) administered after 4 weeks use of NMPK. Follow-up questionnaire (MPK) administered after a subject-specific accommodation period; Subsequent questionnaires administered at after 2 weeks to 2 months use in each knee	Initial questionnaire (NMPK) was administered at a clinical visit prior to receiving a new prosthesis; Follow-up questionnaire (MPK) administered by mail 6-9 months after receipt of a new prosthesis (with MPK)	Biomechanical measurements of all interventions was performed on a single day	Biomechanical measurements were performed after 4 weeks of use in each intervention	Initial questionnaire (NMPK) administered at beginning of study; Follow-up questionnaire (MPK) administered after a 12 months

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	Hafner 2007[15]	Kahle 2008[16]	Hafner 2009[17]	Berry 2009[18]	Blumentritt 2009[19]	Meier 2012[20]	Wong 2012[21]
Key Findings	Study subjects reported fewer stumbles, semi-controlled falls, and uncontrolled falls using both the VAS scale and report of number of events in the MPK as compared to the NMPK. However, only changes reported using the VAS scale were found to be significantly reduced. Subjects also reported fewer problems with activity restrictions, frustration, and embarrassment with the MPK. Only frustration with falling was significantly reduced with the MPK (compared to NMPK), however.	Study subjects reported significantly 59% fewer stumbles and 64% fewer falls in the MPK over the 60-day recall period ($p<0.05$). Stumbles: NMPK: 7 MPK: 3 Falls: NMPK: 3 MPK: 1	Both K2 and K3 users reported decreased stumbles, semi-controlled falls, and uncontrolled falls. Magnitude and significance of differences varied by outcome and method of measurement (VAS and number of events). Stumbles (VAS, #): K2: 16%, -33% K3: 31%, -49% Semi-controlled falls (VAS, #): K2: 11%, -63% K3: 10%, -76% Uncontrolled falls (VAS, #): K2: 4%*, -80%* K3: 5%, -20% *=$p<0.05$ K2 users reported significantly reduced uncontrolled falls via both methods of reporting. K2 and K3 users both reported improvements in activity avoidance, frustration, and embarrassment due to falls with MPK. However, none of these improvements were significantly different than the NMPK condition.	67% of respondents indicated falling less; 30% reported falling about the same; and 3% reported falling more in the MPK compared to the NMPK. Significant differences not reported for this item. However, users reported significantly improved outcomes across a group of items related to safety and limiting factors in the MPK as compared to the NMPK.	Abrupt stopping was possible with the 3R80 and C-Leg. Stance mode of the 3C1 disengaged, meaning it would not support weight (and would likely collapse). Sidestepping similarly was possible only in the 3R80 and C-Leg. The 3C1's stance mode was disengaged, putting the subjects at risk of a fall. Stepping onto a small object with the fore-, mid-, and rearfoot of the prosthetic limb often resulted led to various outcomes depending on the knee joint. Forefoot: 3C1: No adverse effect; stance mode was disengaged 3R80: No adverse effect C-Leg: No adverse effect Midfoot: 3C1: High risk of knee collapse 3R80: No adverse effect C-Leg: No adverse effect Rearfoot: 3C1:High risk of knee collapse; stance mode disengaged 3R80:High risk of knee collapse; stance mode not engaged C-Leg: No adverse effect Interruption of swing phase also produced variable results. If the knee interruption caused sufficient interruption to prevent full extension at heel strike, only the C-Leg and 3C1 allowed loading under flexed conditions. The 3R80 would collapse under such conditions. Across all four adverse conditions, only the C-Leg resisted collapse.	Two subjects experienced 1 fall each in the MPK; one subject experienced 1 fall in the NMPK (3R60); falls occurred while subjects walked over a "beanbag" portion of the course	Subject reported fewer falls in the MPK (0 over 12 months) compared to the NMPK (2 over 12 months). ABC increased from 84 to 91. BBS increased from 46 to 52.
	Hafner 2007[15]	Kahle 2008[16]	Hafner 2009[17]	Berry 2009[18]	Blumentritt 2009[19]	Meier 2012[20]	Wong 2012[21]

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Key Limitations	Questionnaire was not tested or validated; NMPK condition was not standardized (i.e., subjects wore various NMPKs); research funded by MPK manufacturer.	Questionnaire was not tested or validated; NMPK condition was not standardized (i.e., subjects wore various NMPKs).	Questionnaire was not tested or validated; NMPK condition was not standardized (i.e., subjects wore various NMPKs); data from Hafner 2007 study was pooled for secondary analysis; research funded by MPK manufacturer.	MPKs were provided in context of clinical fitting (presumably because of poor fit/performance of the NMPK); MPK was provided along with new socket and foot; Questionnaire was not tested or validated.	Small sample size; no period of accommodation provided for each intervention; simulated conditions may not represent those that cause falls; research funded by MPK manufacturer.	High attrition (4 subjects dropped out); analysis did not include dropped subjects; simulated conditions may not represent those that cause falls; potential order effect not examined	Single-subject; MPK was provided with training and may have received a new socket (potential confounding interventions)

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	Hafner 2007[15]	Kahle 2008[16]	Hafner 2009[17]	Berry 2009[18]	Blumentritt 2009[19]	Meier 2012[20]	Wong 2012[21]
Outcome Measure(s)	Self-report, ad hoc questionnaire with the following questions: Stumbles questions: "Over the past 4 weeks, how often have you stumbled while wearing your prosthesis?" And "Over the past 4 weeks, please estimate the number of stumbles you have had?" Semi-controlled falls questions: "Over the past 4 weeks, how often have you had a semi-controlled fall while wearing your prosthesis?" And "Over the past 4 weeks, please estimate the number of semi-controlled falls you have had?" Uncontrolled falls questions: "Over the past 4 weeks, how often have you had an uncontrolled fall while wearing your prosthesis?" And "Over the past 4 weeks, please estimate the number of uncontrolled falls you have had?" Time period: 4 weeks Response options: visual analog scale (VAS) and direct entry of number of events	Self-report, ad hoc questionnaire with the following questions: Stumbles question: "How many times in the last 60 days did any event occur in which you felt your prosthesis became temporarily unstable and you felt you were at risk of falling but did not?" Falls question: "How many times in the last 60 days did an event occur that caused you to fall to the ground?" Time period: 60 days Response options: direct entry of number of events	Self-report, ad hoc questionnaire with the following questions: Stumbles questions: "Over the past 4 weeks, how often have you stumbled while wearing your prosthesis?" And "Over the past 4 weeks, please estimate the number of stumbles you have had?" Semi-controlled falls questions: "Over the past 4 weeks, how often have you had a semi-controlled fall while wearing your prosthesis?" And "Over the past 4 weeks, please estimate the number of semi-controlled falls you have had?" Uncontrolled falls questions: "Over the past 4 weeks, how often have you had an uncontrolled fall while wearing your prosthesis?" And "Over the past 4 weeks, please estimate the number of uncontrolled falls you have had?" Time period: 4 weeks Response options: visual analog scale (VAS) and direct entry of number of events	Self-report, ad hoc questionnaire that included safety questions: Falls question: "I fall while wearing my prosthesis" Time period: n/a (see response options) Response options: 1 = always, 2 = often, 3 = sometimes, 4 = seldom, 5 = never	Knee angle and moments under the following conditions: abrupt stopping, abrupt side-stepping, stepping onto an obstacle, and interruption of swing-phase knee extension (tripping).	Number of falls experienced while walking an indoor obstacle course	Self-report, ad hoc questionnaire (details not reported)

Reduction in falls associated with use of microprocessor-controlled prosthetic knees among community ambulators with transfemoral amputation

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Location of Measurement	Laboratory (Note: questionnaires asked subject to reflect on community experience over an extended period of time)	Laboratory (Note: questionnaires asked subject to reflect on community experience over an extended period of time)	Laboratory (Note: questionnaires asked subject to reflect on community experience over an extended period of time)	Clinic and home (Note: questionnaires asked subject to reflect on community experience over an extended period of time)	Laboratory	Laboratory	Clinic (Note: questionnaires asked subject to reflect on community experience over an extended period of time)
Timing of Measurement	Initial questionnaire (NMPK) administered after 4 weeks use of NMPK; Follow-up questionnaire (MPK) administered after a subject-specific accommodation period; Subsequent questionnaires administered at after 2 weeks to 2 months use in each knee	Initial questionnaire (NMPK) administered at beginning of study; Follow-up questionnaire (MPK) administered after a 90-day accommodation period	Initial questionnaire (NMPK) administered after 4 weeks use of NMPK. Follow-up questionnaire (MPK) administered after a subject-specific accommodation period; Subsequent questionnaires administered at after 2 weeks to 2 months use in each knee	Initial questionnaire (NMPK) was administered at a clinical visit prior to receiving a new prosthesis; Follow-up questionnaire (MPK) administered by mail 6-9 months after receipt of a new prosthesis (with MPK)	Biomechanical measurements of all interventions was performed on a single day	Biomechanical measurements were performed after 4 weeks of use in each intervention	Initial questionnaire (NMPK) administered at beginning of study; Follow-up questionnaire (MPK) administered after a 12 months

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Key Findings	Study subjects reported fewer stumbles, semi-controlled falls, and uncontrolled falls using both the VAS scale and report of number of events in the MPK as compared to the NMPK. However, only changes reported using the VAS scale were found to be significantly reduced. Subjects also reported fewer problems with activity restrictions, frustration, and embarrassment with the MPK. Only frustration with falling was significantly reduced with the MPK (compared to NMPK), however.	Study subjects reported significantly 59% fewer stumbles and 64% fewer falls in the MPK over the 60-day recall period ($p<0.05$). Stumbles: NMPK: 7 MPK: 3 Falls: NMPK: 3 MPK: 1	Both K2 and K3 users reported decreased stumbles, semi-controlled falls, and uncontrolled falls. Magnitude and significance of differences varied by outcome and method of measurement (VAS and number of events). Stumbles (VAS, #): K2: 16%, -33% K3: 31%, -49% Semi-controlled falls (VAS, #): K2: 11%, -63% K3: 10%, -76% Uncontrolled falls (VAS, #): K2: 4%*, -80%* K3: 5%, -20% *=$p<0.05$ K2 users reported significantly reduced uncontrolled falls via both methods of reporting. K2 and K3 users both reported improvements in activity avoidance, frustration, and embarrassment due to falls with MPK. However, none of these improvements were significantly different than the NMPK condition.	67% of respondents indicated falling less; 30% reported falling about the same; and 3% reported falling more in the MPK compared to the NMPK. Significant differences not reported for this item. However, users reported significantly improved outcomes across a group of items related to safety and limiting factors in the MPK as compared to the NMPK.	Abrupt stopping was possible with the 3R80 and C-Leg. Stance mode of the 3C1 disengaged, meaning it would not support weight (and would likely collapse). Sidestepping similarly was possible only in the 3R80 and C-Leg. The 3C1's stance mode was disengaged, putting the subjects at risk of a fall. Stepping onto a small object with the fore-, mid-, and rearfoot of the prosthetic limb often resulted led to various outcomes depending on the knee joint. Forefoot: 3C1: No adverse effect; stance mode was disengaged 3R80: No adverse effect C-Leg: No adverse effect Midfoot: 3C1: High risk of knee collapse 3R80: No adverse effect C-Leg: No adverse effect Rearfoot: 3C1:High risk of knee collapse; stance mode disengaged 3R80:High risk of knee collapse; stance mode not engaged C-Leg: No adverse effect Interruption of swing phase also produced variable results. If the knee interruption caused sufficient interruption to prevent full extension at heel strike, only the C-Leg and 3C1 allowed loading under flexed conditions. The 3R80 would collapse under such conditions. Across all four adverse conditions, only the C-Leg resisted collapse.	Two subjects experienced 1 fall each in the MPK; one subject experienced 1 fall in the NMPK (3R60); falls occurred while subjects walked over a "beanbag" portion of the course	Subject reported fewer falls in the MPK (0 over 12 months) compared to the NMPK (2 over 12 months). ABC increased from 84 to 91. BBS increased from 46 to 52.
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Key Limitations	Questionnaire was not tested or validated; NMPK condition was not standardized (i.e., subjects wore various NMPKs); research funded by MPK manufacturer.	Questionnaire was not tested or validated; NMPK condition was not standardized (i.e., subjects wore various NMPKs).	Questionnaire was not tested or validated; NMPK condition was not standardized (i.e., subjects wore various NMPKs); data from Hafner 2007 study was pooled for secondary analysis; research funded by MPK manufacturer.	MPKs were provided in context of clinical fitting (presumably because of poor fit/performance of the NMPK); MPK was provided along with new socket and foot; Questionnaire was not tested or validated.	Small sample size; no period of accommodation provided for each intervention; simulated conditions may not represent those that cause falls; research funded by MPK manufacturer.	High attrition (4 subjects dropped out); analysis did not include dropped subjects; simulated conditions may not represent those that cause falls; potential order effect not examined	Single-subject; MPK was provided with training and may have received a new socket (potential confounding interventions)