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TITLE:	Do microprocessor knees improve outcomes in early prosthetic rehabilitation compared to non-microprocessor knees?
PRINCIPAL INVESTIGATOR:	Sara J. Morgan, PhD, CPO
CONTRACTING ORGANIZATION:	University of Washington Seattle WA 98195-0001
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13. SUPPLEMENTARY NOTES

14. ABSTRACT
Microprocessor knees have great potential to improve rehabilitation following transfemoral amputation. However, there is little evidence to direct prosthetic care, including prosthetic knee prescription, in the early stages of rehabilitation. The goal of this project is to evaluate the effect of microprocessor and non-microprocessor knees on overall function, health, and quality of life following amputation. A pilot randomized controlled trial is underway to compare falls, step activity, balance confidence, mobility, health-related quality of life, and community integration of people with recent transfemoral amputation in two prosthetic knee conditions: a microprocessor knee with control of stance phase and a non-microprocessor knee that is appropriate for people in early rehabilitation. Through this pilot study, we will better understand prescription criteria for use of MPKs in early rehabilitation, and identify characteristics of patients who are most likely to benefit from different knee technologies.

15. SUBJECT TERMS
Amputation, rehabilitation, prosthesis, artificial limb, prosthetic knee, microprocessor knee, microprocessor-controlled knee, mobility

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1. **INTRODUCTION:**

Microprocessor-controlled knees have great potential to improve the rehabilitation process and ensure that people with recent amputation are optimally prepared for a full and active life with a prosthetic limb. In principle, microprocessor knees are ideal initial prosthetic knees; they provide maximum safety and adapt their function to promote mobility following amputation. Further, these knees are intuitive for new prosthetic users, promote natural gait biomechanics, and have the potential to reduce the need for walking aids and compensatory movements in early rehabilitation. However, research on prosthetic interventions, including MPKs, in the early stages of prosthetic rehabilitation is extremely limited. The long-term goal of this line of research is to better understand prescription criteria for use of MPKs in early rehabilitation, and identify characteristics of patients who are most likely to benefit from this knee technology. The purpose of this study is to evaluate the potential for different prosthetic knee technologies to promote function, health, and quality of life following amputation. A pilot randomized controlled trial is currently underway to compare falls, step activity, balance confidence, mobility, health-related quality of life, and community integration of people with recent transfemoral amputation in two randomly-assigned prosthetic knee conditions: a microprocessor knee with control of stance phase and a non-microprocessor knee that is appropriate for people in early rehabilitation. Study participants are assessed monthly for three months after the delivery of the study prosthesis.

2. **KEYWORDS:**

Amputation, rehabilitation, prosthesis, artificial limb, prosthetic knee, microprocessor knee, microprocessor-controlled knee, mobility

3. **ACCOMPLISHMENTS:**

- **What were the major goals of the project?**

The major goals of the project, associated milestones, target dates (modified to include the no-cost extention), and percent of completion are included in the table below.

Major Goal	Milestone	Target Date	% Completed
Obtain and Maintain Human Subjects Approval	Approvals obtained from UW and ORP/HRPO	12/15/17	100%
Study Preparation	Recruitment, consent, and data collection materials; databases; and equipment ready for data collection	1/15/18	100%
Participant Recruitment (aim n=24 total)	24 participants enrolled into the study	3/15/19	67%
Data Collection	3 months of data collection completed for 24 participants	5/15/19	47%
Data Analysis	Data entered, processed, and analyzed to address study hypotheses	9/14/19	40%

Dissemination	Abstracts presented at a minimum of 2 scientific conferences; manuscripts prepared and submitted for publication	9/14/19	25%

- **What was accomplished under these goals?**

  Major activities and progress on specific objectives: In the past two years, our research team has obtained and maintained approvals from the University of Washington Institutional Review Board (IRB) and the UWAMRMC Human Research Protection Office (HRPO) to conduct the research, finalized study protocols and consent materials, purchased research supplies, prepared databases, trained research staff in data collection and data entry protocols, provided recruitment materials to clinical sites, presented study updates to a Harborview Medical Center PM&R and vascular physicians, enrolled and completed baseline data collection for 16 (of the total 24) participants in the study, provided study prostheses to 3 of the 12 enrolled participants. In addition, additional recruitment sites were contacted to expand enrollment, data collection activities are underway for all enrolled participants, and collected data is being processed and double-entered into databases as it is collected.

  Significant results or key outcomes: Nothing to report at this time.

  Other achievements: The study PI (Morgan) described study aims and methods for this research at two national prosthetic and orthotic conferences (the American Academy of Orthotists and Prosthetists Annual Meeting and Scientific Symposium; and the American Orthotic and Prosthetic Association National Assembly).

  Dr. Morgan also has additional funding from Ottobock Healthcare to extend the data collection period from 3 months of follow-up to 6 months of follow-up for each study participant. This extended follow-up period will enable further understanding of how prosthetic knee interventions may differ in their effect on health outcomes over time in early rehabilitation. The study extension is optional for all participants and requires an additional consent process prior to continued data collection activities.

- **What opportunities for training and professional development has the project provided?**

  Professional Development: The prosthetists who collaborate with the research team on this study were all provided additional training in the prosthetic knees that are used for this study. They were asked to complete in-person training with the principal investigator as well as online training that focused on the knee functions and alignment. This professional development increased competency in prosthetic knees and their use in early rehabilitation.

  Research Training: Rachael Rosen, CPO, is a trained, licensed clinician who was hired as a research assistant for the study. In this role, she has received training in performance-based data collection, GAITRite Mat and StepWatch data processing, and database management. This experience and training in human subjects research has led her to pursue a PhD in Rehabilitation Science. She is currently applying to doctoral programs for entry in the fall of 2020.

- **How were the results disseminated to communities of interest?**

  Study aims and protocols were disseminated to practitioners and researchers in the field of prosthetics at two clinical/scientific meetings: the American Academy of Orthotists and Prosthetists Annual Meeting and Scientific Symposium in New Orleans (February, 2018) and the American Orthotic and Prosthetic Association National Assembly in Vancouver, Canada (September, 2018). These presentations served to encourage conversation among the clinicians and researchers in the field about the need for research in the early rehabilitation period to guide decisions about prosthetic prescriptions.

- **What do you plan to do during the next reporting period to accomplish the goals?**

  Prior to the next report (quarterly report for Y3Q1, end date 12/14/19), the research team plans to continue with recruitment and data collection activities. The principal investigator, Dr. Morgan, will continue to reach out to recruitment sites with study numbers to encourage physicians and prosthetists to discuss the study with eligible patients.

  Dissemination of study results in the form are planned for the end of 2020. With this in mind, Dr. Morgan will also begin to plan out dissemination activities including conferences for presentations, and identifying a journal for the written publication.

4. **IMPACT:**

- **What was the impact on the development of the principal discipline(s) of the project?**

  While we do not yet have results for this research due to ongoing data collection, we anticipate that this research will fill a gap in the literature about prosthetic prescription during the earliest phases of rehabilitation. It will also inform future studies that assess interventions during the critical phase of early rehabilitation when participant outcomes (e.g., mobility, psychosocial health, etc.) have not yet plateaued.

- **What was the impact on other disciplines?**

  Nothing to report.

- **What was the impact on technology transfer?**

  Nothing to report.

- **What was the impact on society beyond science and technology?**

  Nothing to report.

5. **CHANGES/PROBLEMS:**

- **Changes in approach and reasons for change**

In the first year of the study, we received additional funding to allow study participants the option to extend their time in the study, from 3 months of follow-up to 6 months of follow-up for each participant. The reason that we were interested in extending the time in the study is to observe the continued trajectory of rehabilitation beyond the first three months, where we may begin to see some stabilization of performance. Extending time in the study is optional for all participants, is not covered under Department of Defense Grant funds, and requires participants to sign an additional consent form prior to continued data collection. IRB approval has been received and maintained for the extended data collection timepoints.

In the second year of the study, we expanded the microprocessor knee option to include the Ottobock C-Leg. The reason that we included the Ottobock C-Leg as another option (in addition to the Ottobock Kenevo) is because we had some study participants who were very quickly increasing their walking speeds in the earliest phases of rehabilitation. At speeds over 0.8m/s, the Kenevo does not function as well as the C-Leg. The C-Leg was thus introduced as a higher-activity option, similar to the 3R60 in the comparison (non-microprocessor knee) condition.

- **Actual or anticipated problems or delays and actions or plans to resolve them**

  We need to identify an additional eight participant in order to meet our recruitment goals. We anticipate that we will be able to recruit until May of 2020, which would require us to identify one participant per month. This is about the rate that we have identified participants over the past year, so our research team feels optimistic about meeting this goal. The study team will continue to closely monitor recruitment and enrollment for this study.

- **Changes that had a significant impact on expenditures**

  Study expenditures were below projected numbers in year 1 due to (1) reduced effort of the principal investigator and other investigators/staff to accommodate unanticipated commitments unrelated to the project and to reflect the lower than anticipated participant enrollment in the second quarter of the project, (2) a member of the study team taking a long-term leave, and (3) lower participant fees in year 1. Study expenditures not spent in year 1 have been allocated to the no-cost extension period for the project.

- **Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents**

  - **Significant changes in use or care of human subjects**

    Nothing to report

  - **Significant changes in use or care of vertebrate animals.**

    Not applicable/nothing to report

  - **Significant changes in use of biohazards and/or select agents**

    Not applicable/nothing to report

6. **PRODUCTS:**

- **Publications, conference papers, and presentations**
  - **Journal publications.**

    Nothing to report

  - **Books or other non-periodical, one-time publications.**

    Nothing to report.

  - **Other publications, conference papers, and presentations.**

    Kaufman K, Domaier S, **Morgan S,** Hahn A, Kannenburg A. Update on the evidence for benefits of microprocessor-controlled knees in limited community ambulators: Review of the literature, results of current studies, and future research projects. American Academy of Orthotists and Prosthetists (AAOP) 44th Annual Meeting and Scientific Symposium, New Orleans, LA, February 14-17, 2018.

    Kaufman K, Domaier S, **Morgan S**, Hahn A, Kannenburg A. Update on the evidence for benefits of microprocessor-controlled knees in limited community ambulators: Review of the literature, results of current studies, and future research projects. American Orthotics and Prosthetics Association (AOPA) National Assembly, Vancouver, Canada, September 26-29, 2018.

- **Website(s) or other Internet site(s)**

  Nothing to report.

- **Technologies or techniques**

  Nothing to report.

- **Inventions, patent applications, and/or licenses**

  Nothing to report.

- **Other Products**

  Nothing to report.

7. **PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS**

- **What individuals have worked on the project?**

Name:	Sara Morgan, PhD, CPO
Project Role:	Principal Investigator
Researcher Identifier:	ORCID: 0000-0001-8059-3659

Nearest person month worked:	3
Contribution to Project:	Dr. Morgan planned and coordinated all research activities (e.g., obtained human subjects approvals, prepared and delivered DOD status reports, finalized study protocols, trained research staff, coordinated recruitment efforts, participated in data collection, prepared presentations, led project meetings, and supervised staff and budget).
Funding Support:	N/A

Name:	Ian Nelson
Project Role:	Research Coordinator
Researcher Identifier:	N/A
Nearest person month worked:	1
Contribution to Project:	Mr. Nelson designed and maintained the research database, enrolled and scheduled participants, and entered study data as it was collected. He also assisted with human subjects approvals.
Funding Support:	N/A

Name:	Rachael Rosen, CPO
Project Role:	Research assistant/prosthetist
Researcher Identifier	N/A
Nearest person month worked:	1
Contribution to Project:	Ms. Rosen assisted with data collection as a blinded assessor. She also completes data processing and entry for data that does not unblind her (eg, GAITRite and StepWatch data).
Funding Support:	N/A

- **Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?**

  Sara Morgan, PhD, CPO: Dr. Morgan ended effort on one project (Pilot and Feasibility Award, PI: Morgan). With this change, Dr. Morgan's total effort is 6.0 calendar months.

  Brian Hafner, PhD: Dr. Hafner decreased effort on the current project (W81XWH-17-1-0617, PI: Morgan) and on another project (W81XWH-16-1-0569, PI: Morgenroth. Dr. Hafner also received funding for a new project (industry sponsored, PI: Sawers). With these changes, Dr. Hafner's total effort is 11.4 calendar months.

- **What other organizations were involved as partners?**

- **Organization Name:** Ottobock Healthcare LP
- **Location of Organization:** Austin, Texas 78758
- **Partner's contribution to the project**
  - **Financial support:** Our research team received additional funding from Ottobock Healthcare that supports an increase in the follow-up time for each participant from a total of 3 months to a total of 6 months.
  - **In-kind support:** Ottobock Healthcare provided the prosthetic components (microprocessor and non-microprocessor knees, feet, structural components) for the study.
  - **Facilities:** N/A
  - **Collaboration:** N/A
  - **Personnel exchanges:** N/A
  - **Other:** N/A

8. **SPECIAL REPORTING REQUIREMENTS**

   - **COLLABORATIVE AWARDS:**

     N/A

   - **QUAD CHARTS:**

     Updated Quad Chart attached

9. **APPENDICES:**

   N/A