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TITLE: Do Microprocessor Knees Improve Outcomes in Early Prosthetic Rehabilitation Compared to Nonmicroprocessor Knees?

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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, 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	25%
Data Collection	3 months of data collection completed for 24 participants	5/15/19	12%
Data Analysis	Data entered, processed, and analyzed to address study hypotheses	9/14/19	5%

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: Over the first year of the project, our research team has obtained 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, prepared data collection files and databases, purchased research supplies, trained research staff, provided recruitment materials to clinical sites, enrolled and completed baseline data collection for 6 (of the total 24) participants in the study, provided test prostheses to 3 of the 6 enrolled participants (the 3 remaining enrolled participants are scheduled to receive their prosthesis in the next month). In addition, data collection activities are underway for all enrolled participants and collected data is being processed and double-entered into databases as it is collected. While we are behind our projected enrollment numbers for Year 1, we are enrolling new participants on a regular basis and are providing recruitment materials to additional recruitment sites to address enrollment concerns.

  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 a national prosthetic and orthotic conference (the American Academy of Orthotists and Prosthetists Annual Meeting and Scientific Symposium) and was invited to give a similar presentation at another prosthetic and orthotic conference in late September, 2018.

  Dr. Morgan also received notice of 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. Funds are anticipated in Autumn of 2018.

- **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.

- **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 the American Academy of Orthotists and Prosthetists Annual Meeting and Scientific Symposium in New Orleans (February, 2018). This presentation 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 Y2Q1, end date 12/14/18), the research team plans to continue with recruitment and data collection activities. In addition, the principal investigator will follow enrollment rates closely and expand recruitment sites as needed.

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**

     Study participants will have 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. We were not able to support a 6-month follow-up period in the original two-year grant period, but the research team did acquire additional funding from Ottobock Healthcare to support additional timepoints and associated costs for the additional 3-months for each participant. 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 for the extended data collection timepoints.

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

  The study team is closely monitoring recruitment and enrollment for this study. The principal investigator has already approached additional clinics about posting flyers and she will continue to identify other clinics as needed.

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

  Study expenditures are below projected numbers for several reasons: (1) effort of the principal investigator and other investigators/staff was reduced slightly in Year 1 to accommodate unanticipated commitments unrelated to the project and to reflect the lower than anticipated participant enrollment in the second quarter of the project (note that effort for the PI was not reduced more than 25% over the reporting period), (2) the graduate research assistant (Ms. McDonald) went on maternity leave and the interim staff hired to cover for her position did not require tuition reimbursement, and (3) participant fees were less than anticipated due to lower participant enrollment than was projected for Year 1. Due to the increase in participant enrollment over recent quarters and the return of Ms. McDonald, we anticipate that carryforward funds will be spent in Year 2.

- **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.

- **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:	N/A
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:	Julie Schaar, CPO
Project Role:	Research assistant/prosthetist
Researcher Identifier	N/A
Nearest person month worked:	1
Contribution to Project:	Ms. Schaar assisted with the design of study materials, including forms and blinding materials for the prosthetic knees. She attended all study trainings and assisted with data collection sessions as the blinded assessor. She was hired for the project while the graduate research assistant (Cody McDonald, CPO) was on maternity leave.
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 added effort on one new project (W81XWH-17-1-0551, PI: Hafner), reduced effort on one other project (Pilot and Feasibility Award, PI: Morgan), and ended effort on one project (W81XWH-15-1-0458, PI: Hafner). With these changes, Dr. Morgan's total effort is 7.2 calendar months.

  Brian Hafner, PhD: To accommodate effort on the current project (W81XWH-17-1-0617, PI: Morgan) and two other new projects (W81XWH-17-1-0547, PI: Sawers and W81XWH-17-1-0551, PI: Hafner), Dr. Hafner ended effort on one project (R01HD060585, PI: Sanders) and reduced effort on other projects (R01HD065340, PI: Hafner; W81XWH-15-1-0458, PI: Hafner; W81XWH-16-1-0585, PI: Sanders; W81XWH-16-C-0020, PI: Sanders). 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 is finalizing a contract with Ottobock Healthcare for additional funding that will support 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

Do microprocessor knees improve outcomes in early prosthetic rehabilitation compared to non-microprocessor knees?

PI: Sara Morgan, PhD, CPO **Org:** University of Washington **Award Amount:** $300,000

Study/Product Aims

• Aim 1: Evaluate falls, physical activity, and mobility in people with recent transfemoral amputation walking with a NMPK and a MPK.

• Aim 2: Compare self-reported balance confidence, health-related quality of life, and community integration in participants between the MPK and NMPK conditions.

Approach

A randomized controlled trial will be conducted 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 stance-controlled MPK and a comparison NMPK that is appropriate for each participant's predicted functional level. 24 total participants will be assessed multiple times over a 3-month period following the fitting of the initial prosthesis.

Microprocessor knee (MPK, left) and non-microprocessor knee (NMPK, right)

Accomplishments: 6/24 participants enrolled, enrollment and longitudinal data collection ongoing.

Timeline and Cost

Activities CY	17	18	19
Recruit 24 participants			
Data collection			
Process and analyze data			
Prepare manuscripts and disseminate study results			
Estimated Budget ($K)	**$10K**	**$165K**	**$125K**

Updated: 06/26/2018

Goals/Milestones

CY17 Goals – Study preparation

☑ Prepare study protocols

CY18 Goals – Participant recruitment and data collection

☑ Obtain institutional review board approvals

◉ Recruitment of participants

◉ Collect longitudinal data

CY19 Goals – Analysis and dissemination

☐ Continue recruitment and data collection efforts

☐ Analyze study data

☐ Disseminate results

Budget Expenditure to Date

$96,000