INSTRUCTIONS FOR AOPA AND CENTER FOR LEARNING PROGRESS REPORT ON RESEARCH PROJECT

Recipient Name Nicoleta Bugnariu, PhD, PT

Original Study Name Functional Performance and Evaluation of Dynamic Response Feet

Institution Name University North Texas Health Science Center

General Items:

1. If human subjects or patient information is used – please provide IRB number/certification and any forms/documents approved by the IRB for use with patients.

   UNTHSC, IRB # 2013-184

2. How have funds been used to date?

   Funds were used for M&O: development of software and maintenance of hardware equipment in the laboratory, subject compensation and miscellaneous supplies for the laboratory. Salary support for clinical project coordinator for scheduling during data collection testing, and research assistant for data analysis.

3. How will remaining funds be used?

   There are no remaining funds.

4. Please provide a 2 to 3 page description of the accomplishments of the project to date including where the work is being conducted, who the participants are, what progress has been made to date and what work remains until the project due date.

Signed N Bugnariu Date 09/03/2014
Grant Recipient

Signed [signature] Date 09/03/2014
Grant Recipient's Immediate Superior

September 4, 2014

Kendra Calhoun, President
The Center for Orthotics and Prosthetics
Learning and Outcomes/Evidence-based Practice

Thomas Kirk, PhD, President
American Orthotic and Prosthetic Association

Re: Interim report for grant "Functional Performance and Evaluation of Dynamic Response Feet" from AOPA 2013-2014

PI: Nicoleta Bugnariu
University North Texas Health Science Center

Our grant aims to determine the clinical appropriateness and efficacy of dynamic response feet. We proposed to recruit transtibial amputees currently ambulating with either a K3 or K2 level foot. Through the use of virtual environments that allow testing of balance and gait in realistic complex real life situations, this study will provide information regarding the function of the K2 level prosthetic foot in comparison to the K3 level foot.

Specific Aim 1: to evaluate immediate effects of wearing two types of prosthetic feet (K2- short, lower functioning foot and K3- longer, higher functioning dynamic response foot) on balance and walking performance in amputees classified at either the K2 or K3 functional level.

Specific Aim 2: to evaluate short-term effects (after a 2-week accommodation/training period) of wearing a prosthetic foot (K2 or K3) that is either at, above or below the functional level of the amputee.

Final report:

1: Personnel hired on grant

- Katelyn Rockenback, MSc, Project Coordinator
- Joe Hidrago, TCOM Student, Research Assistant
- Lindsay Appleby, Master in Research Management, Research Assistant

2: Institutional Review Board for Human Research

- Initial approval was obtain on September 13, 2013 and was transmitted to AOPA as requested
- An addendum to include software analysis and video recordings were approved in January 9, 2014

3: CPO collaborators

- Gordon Steven, CPO/LPO from Baker Orthotics has secure all K2 / K3 feet that were tested in this grant.
- Elizabeth Ginzel CPO/LPO from Baker Orthotics has participated in data collections and performed the switch of prosthetic foot for participants going from K2 to K3, or K3 to K2.

4. Results

We completed the grant and presented our results to the AOPA National Assembly, in September 2014. The presentation won the Thranhardt Lecture Award. (see attached abstract and .pdf of presentation including results).
The team is collaborating and responsive and we will pursue this line of research in the future.

Thank you very much for supporting this work,

Sincerely,

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FUNCTIONAL PERFORMANCE AND EVALUATION OF DYNAMIC RESPONSE FEET

Nicoleta Bugnariu, PT PhD[1], Rita M. Patterson PhD[1], Gordon Stevens CPO/LPO [2],

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INTRODUCTION

The K-Level classification of prosthetic feet is used in conjunction with a similar classification of functional level of amputees to determine the prosthetic feet that will be prescribed and reimbursed. Individuals classified as level 2 ambulatory, receive a K2 prosthetic foot and not the higher functioning K3 prosthetic. This provides less technology to the patients who need it most, limiting them in their current and potential abilities. We aimed to evaluate gait and balance in transtibial amputees ambulating with either a K2 prosthetic foot or the more functional dynamic response K3 prosthesis. We hypothesized that K3 prosthesis will show immediate improvements in gait and balance, and a 2- week trial with a K3 would increase functional level and quality of life.

METHODS

Research participants with transtibial amputations secondary to diabetes, vascular disease or trauma, fitted by a CPO with either K2 or K3 prosthesis and currently ambulating with their prosthesis were enrolled in the study after they gave informed consent. On the initial study visit the quality of life baseline were established using standardized questionnaires (SP 36, and the Reintegration to Normal Living Index). A battery of clinical tests (Timed Up and Go, Short Physical Performance Battery, Dynamic Gait Index and Activity Specific Balance Confidence Scale) routinely performed by physical therapists to assess balance, mobility and risk for falls were also administered. The V-gait CAREN (Computer Assisted Rehabilitation Environment Network) system was used to measure standing balance sway during double limb support and one foot, as well as gait speed, kinematics and kinetics during level walking and on an 4.8 degrees ramp. The Physiological Cost Index was calculated for level and ramp walking. These tests were repeated after the CPO fitted the participant with a different foot (either a K2 or K3) to determine immediate effects of switching type of prosthesis. The participants were then randomized into groups for a 2-week trial period of wearing a prosthetic foot that was either *at, above or below* the current functional level of the amputee. Post-trial measurements of balance, gait, and quality of life were reassessed. A repeated measure ANOVA was performed for each dependent variable of balance, gait and quality of life measures with respect to: patient's level status and prosthesis type (K2 or K3).

RESULTS

Baseline quality of life, balance and gait measures were significantly lower for patients currently ambulating with K2 vs. K3 feet ($p<0.05$). All subjects had significant difficulties walking up and down ramps illustrated by slower gait speed and changes in lower limb kinematics. The Physiological Cost Index increased 20% from level ground to ramps. Majority of subjects currently ambulating with K2 feet were not able to complete walking on ramp trials. Switching from K3 to K2 resulted in significantly increased sway during standing balance and decreased functional limits of stability (area that the patient can safely reach in multiple directions). When tested with K2 prosthetics, subjects that otherwise ambulated with K3 feet were unable to maintain baseline gait velocity even on level ground and displayed loss of balance and changes in lower limb kinematics and kinetics (increased hip abduction and rotation angles and hip moments suggesting compensatory strategies) . Switching from K2 to K3 resulted in significantly improved standing balance and increased gait velocity on level ground ($p<0.5$). Immediate effects of switching from K2 to K3 foot were: decreased sway in standing balance, improved functional stability limits and increased gait velocity. After a 2 week trial period, subjects wearing a prosthetic foot above their current functional level improved walking kinematics and were able to perform ramp trials and reported increased quality of life.

DISCUSSION

Preliminary results confirm that K3 prosthetic foot provides additional benefits for balance and gait function and quality of life compared to K2. Providing higher level prosthetic feet to patients who are classified at lower functional level could improve their balance, prevent serious costly injuries caused by trips and falls, and facilitate transition to higher functional status.

REFERENCE

1. Resnik L et al., *Physical Therapy*. 2011;91(4):555-565.
2. Vanicek N et al., *Prosthetics & Orthotics Intern. 2010:34(4):399*

DISCLOSURE

Authors have no conflicts of interest in their abstract.

ACKNOWLEDGEMENTS

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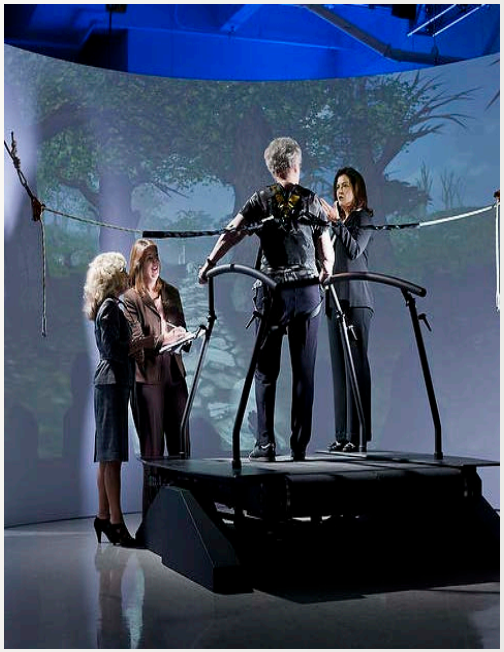
AOPA's national assembly '14
The premier meeting for orthotic, prosthetic, and pedorthic professionals
Sept. 4–7, 2014
Mandalay Bay, Las Vegas

Functional Performance and Evaluation of Dynamic Response Feet

Nicoleta Bugnariu, PT, PhD
Rita M. Patterson PhD,
Gordon Stevens CPO/LPO

Acknowledgements

AOPA Research Award administered by the Center for Orthotics and Prosthetics Learning and Outcomes/ Evidence-based Practice



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Human Movement Performance Laboratory
motek medical
improving human performance

Introduction

Classification Functional level / Classification prosthetic feet		Functional level 2	Functional level 3
K 2		✓	?
K 3		?	✓

Purpose

- We aimed to evaluate the immediate and long term effects on gait and balance function in transtibial amputees ambulating with K2 / K3 prosthetic feet.

- We hypothesized that switching from K2 to K3 prosthesis will show immediate improvements in gait and balance, and a 2- week trial with a K3 would increase functional level and quality of life.

Methods: Research design

V 1

- Patients with transtibial amputation ambulating with either K2 or K3, informed consent
- Establish baseline values for all outcome measures with their own prosthetic foot
- Evaluate immediate effects of switching prosthetic feet (K2 to K3, or K3 to K2), CPO

Trial

- Randomize participants to 2-week trial period of wearing a prosthetic foot that was either ***at, above or below*** the current functional level of the amputee.
- K2→K2, K3→K3; or K2 → K3; or K3 →K2 ;

V 2

- Evaluate long term effects of switching prosthetic feet
- Test all outcome measures with the trial prosthesis and then CPO put back the participant own prosthesis

Methods: Outcomes Measures

Balance measure : COP sway (RMS)

Gait velocity, kinematics and kinetics and Physiological Cost Index

- on level ground
- on 4.8 degrees ramp

Quality of life: SF36, Reintegration to Normal Living Index

Battery of PT clinical tests:

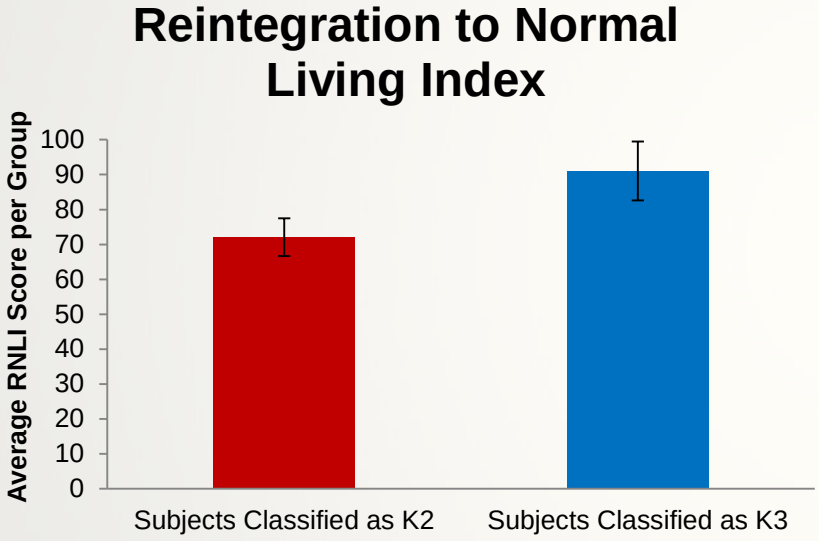
Timed Up and Go
Short Physical Performance Battery
Dynamic Gait Index
Activity Specific Balance Confidence Scale

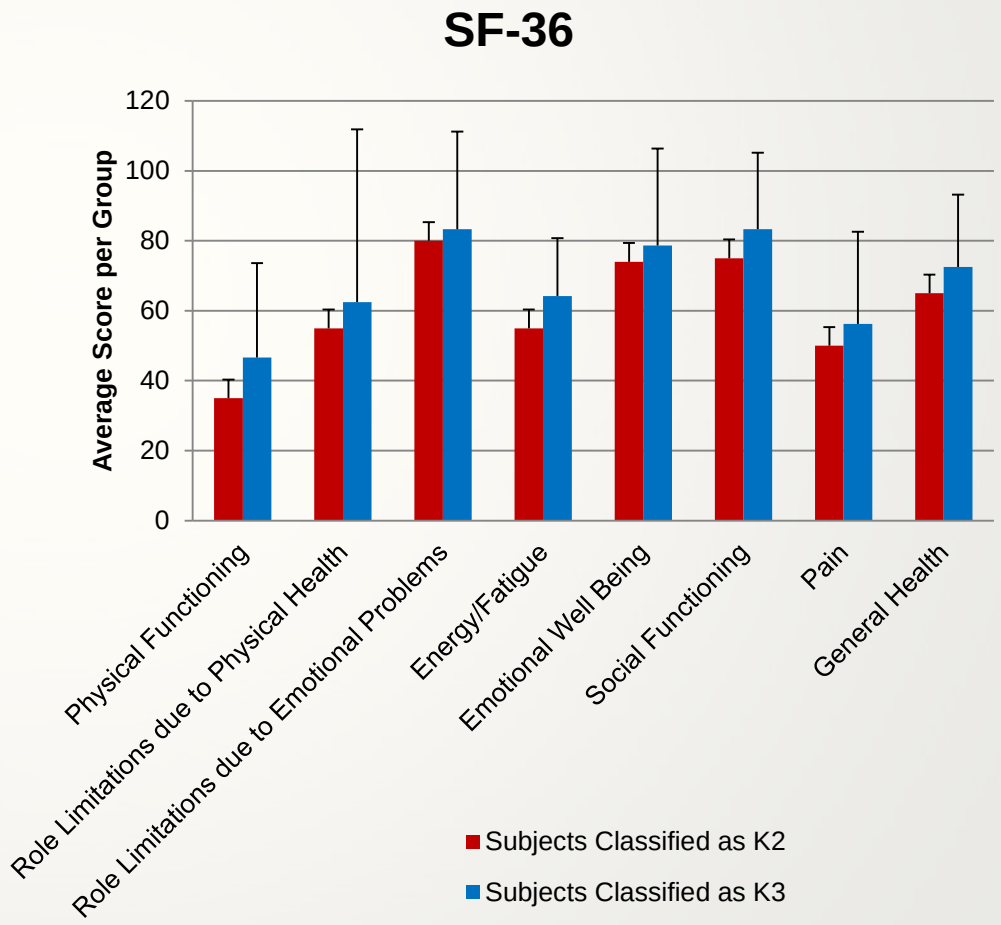
The V-Gait CAREN System, by Motek Medical

Participants

Subject ID	Ethnicity	Gender	Age	Weight (lbs)	Height (cm)	Left or Right Foot Prosthesis	Functional Classification	Initial Prosthesis Type
AOPA01	Hispanic	Male	59	193	180	Right	K3	Kinterra
AOPA02	Caucasian	Male	52	308	188	Left	K2	OSSUR Ceterus
AOPA03	Afrian American	Male	59	193	180	Left	K3	Kinterra
AOPA04	Caucasian	Male	69	243	178	Right	K2	Freedom Highlander
AOPA05	Hispanic	Male	62	170	174	Left	K3	Kinterra
AOPA06	Caucasian	Male	48	273	172	Right	K3	OSSUR
AOPA07	Caucasian	Female	51	172	168	Left	K3	Kinterra
AOPA08	Caucasian	Female	66	190	157	Left	K2	OSSUR
AOPA09	Caucasian	Female	51	198	164	Right	K3	OSSUR

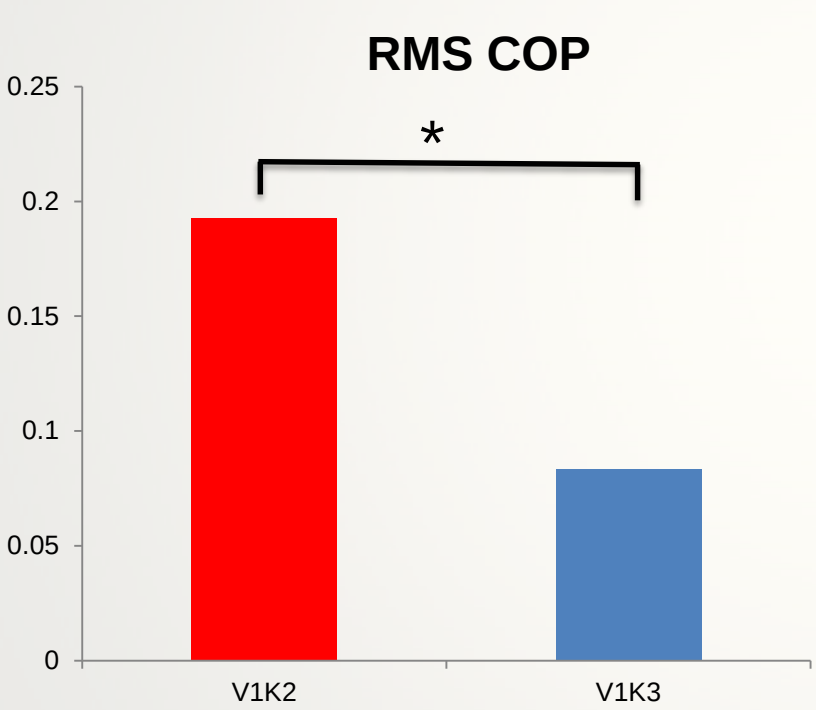
Results:

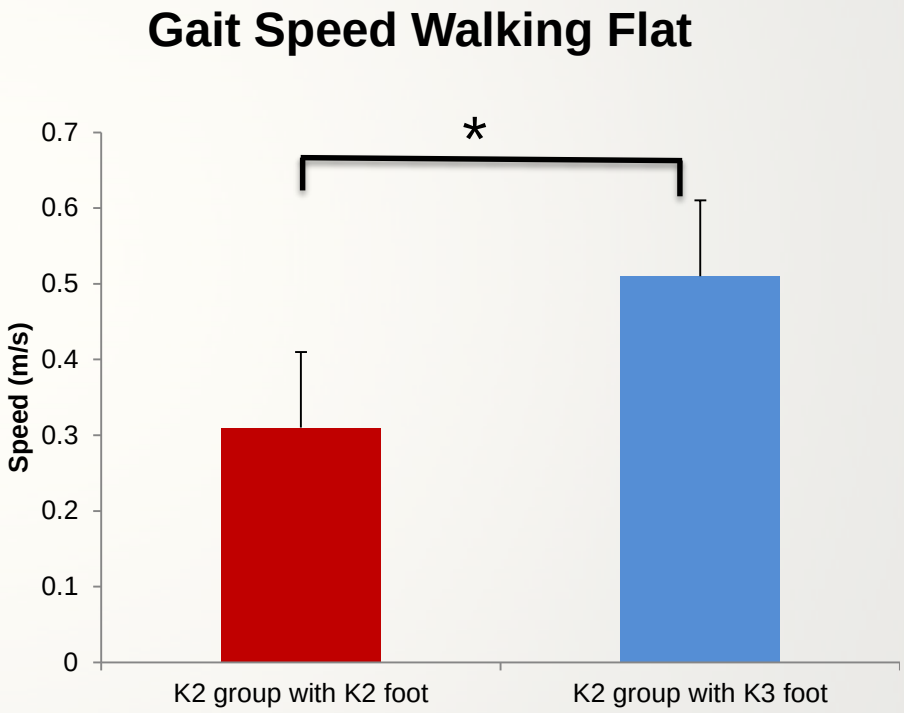




Lower Quality of Life at baseline in K2 vs. K3 participants

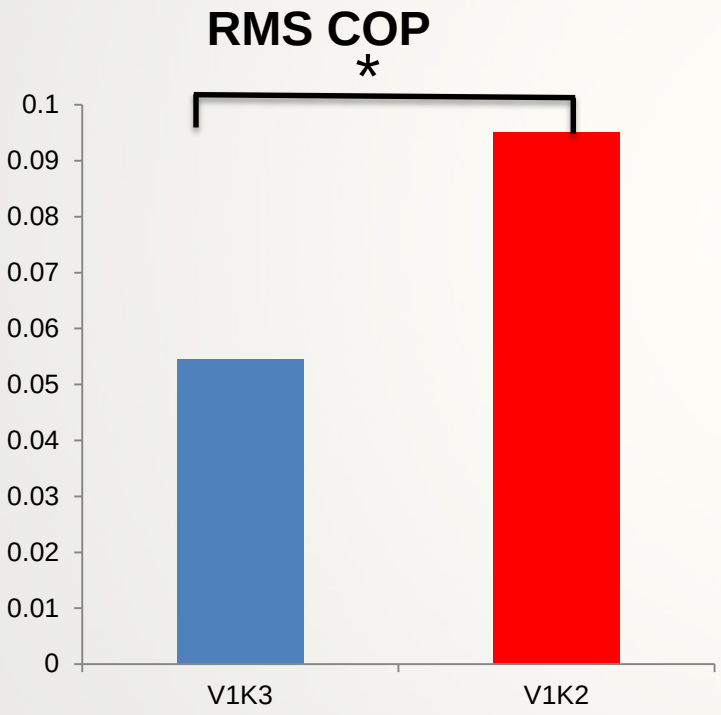
Results: immediate effects K2→K3

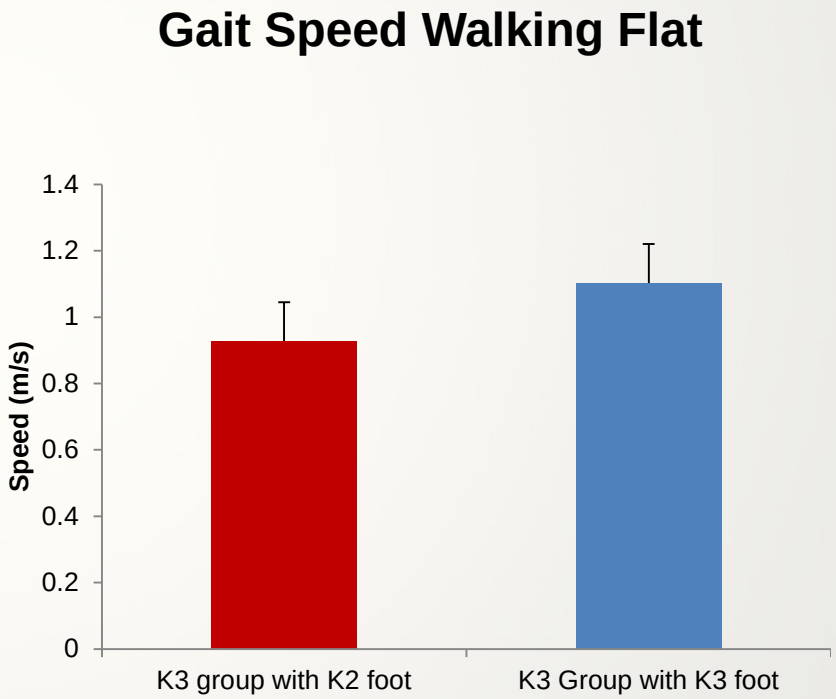




Improved standing balance, increased gait speed

Results: immediate effects K3→K2



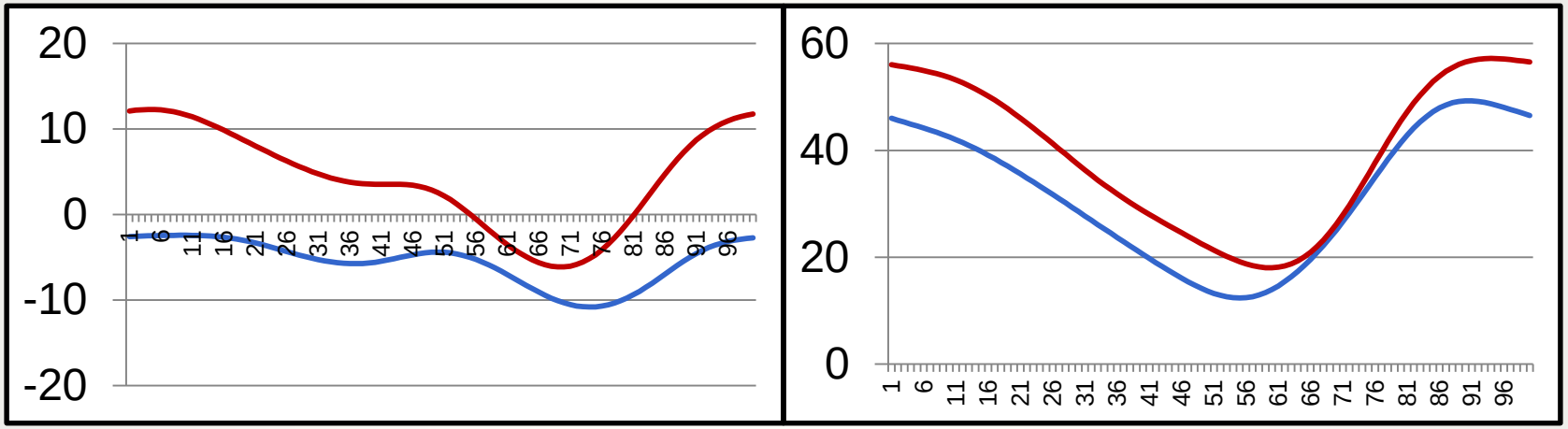


Worse standing balance, decreased gait speed

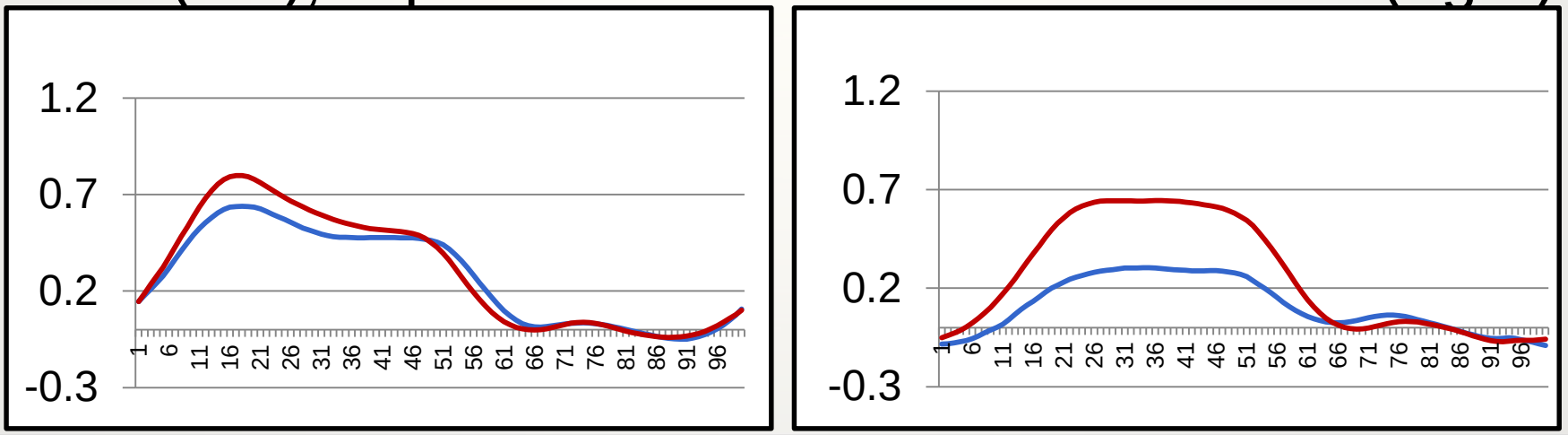
Results: immediate effects

K3	K2

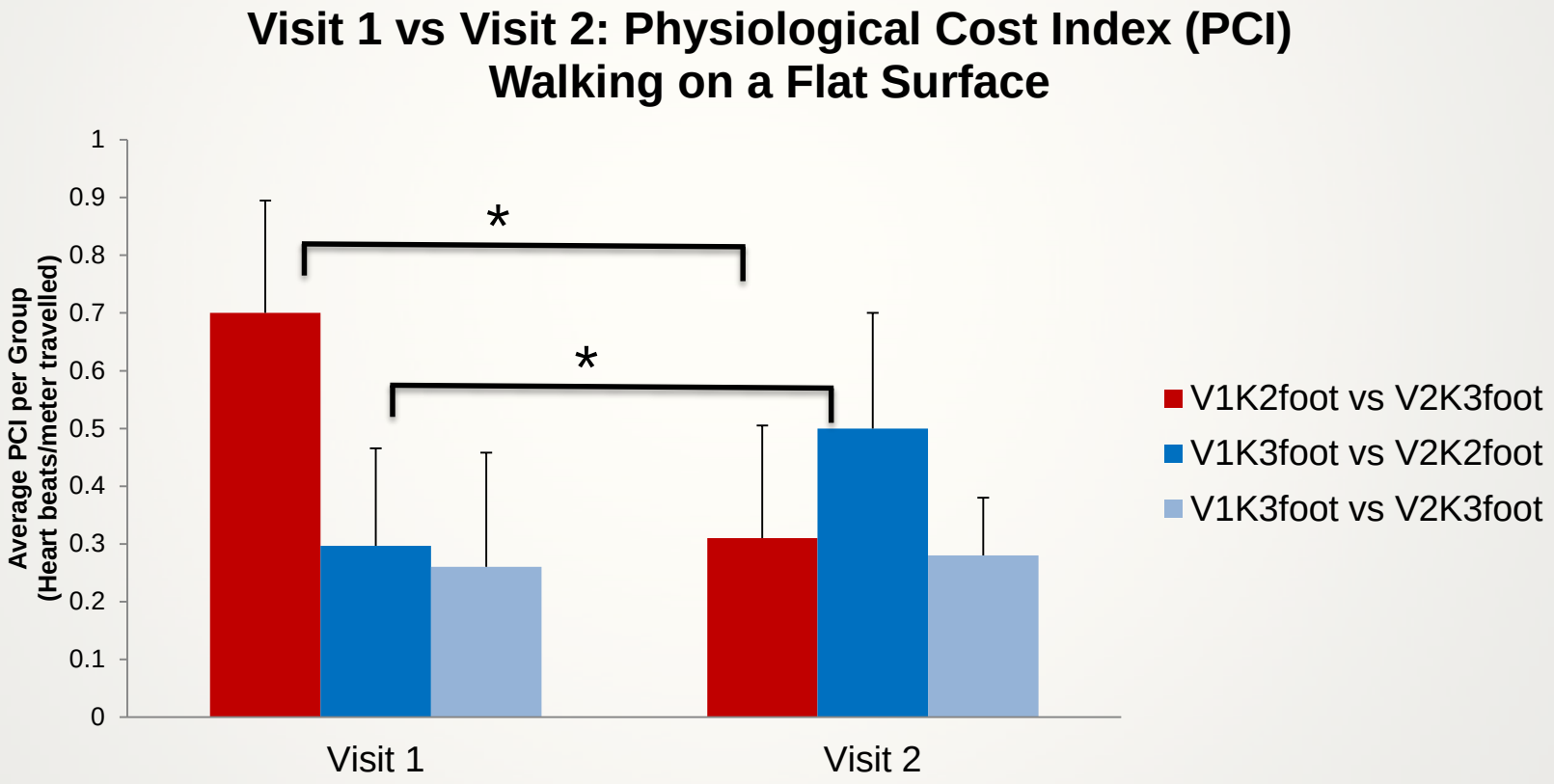
Kinematics: Hip abduction/adduction (left); Hip flexion/extension (right) while walking on Flat surface.



Kinetics: Moment Hip abduction/adduction on flat surface (left); Hip abduction/adduction on incline (right).

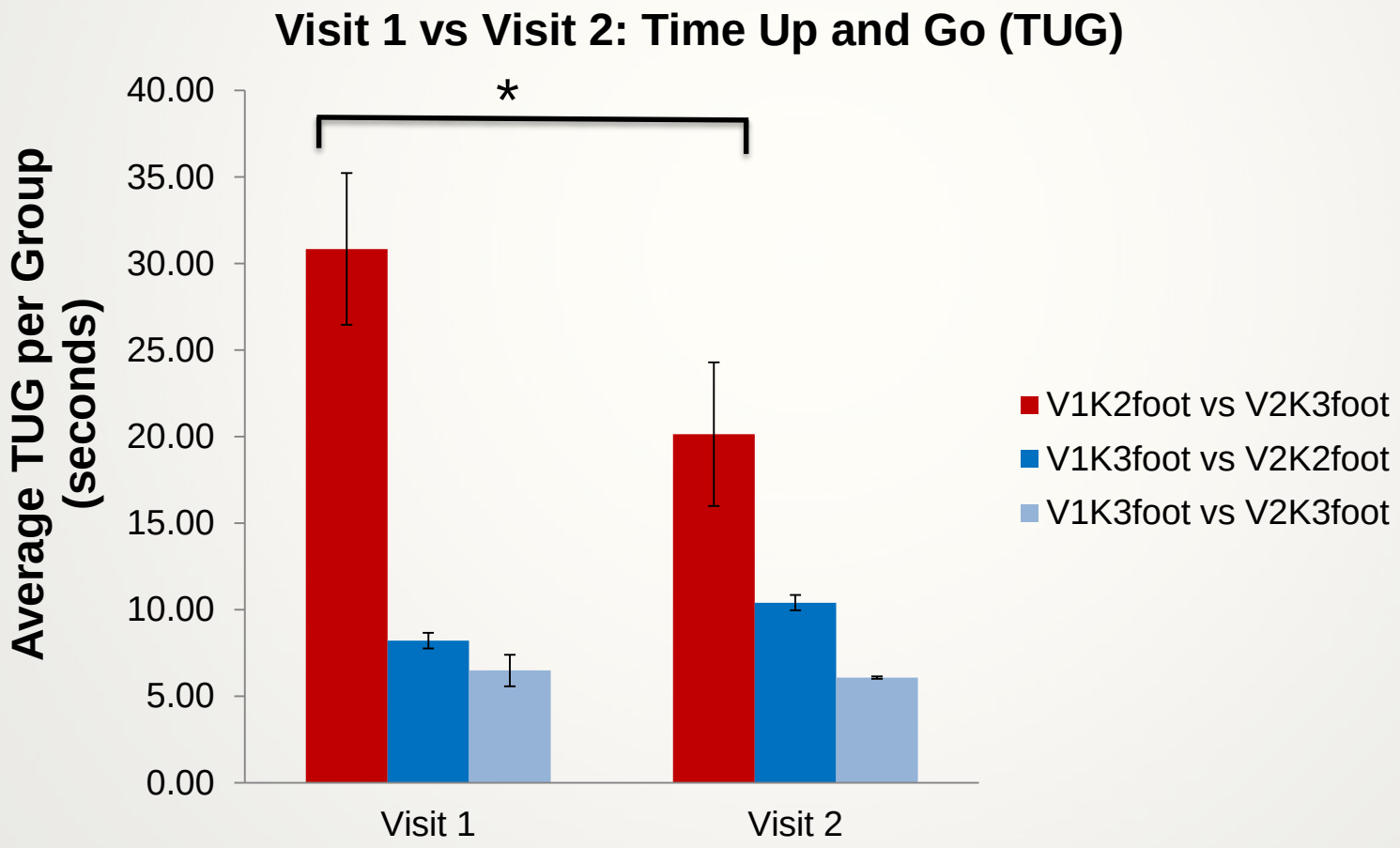


Results: post 2-weeks trial effects

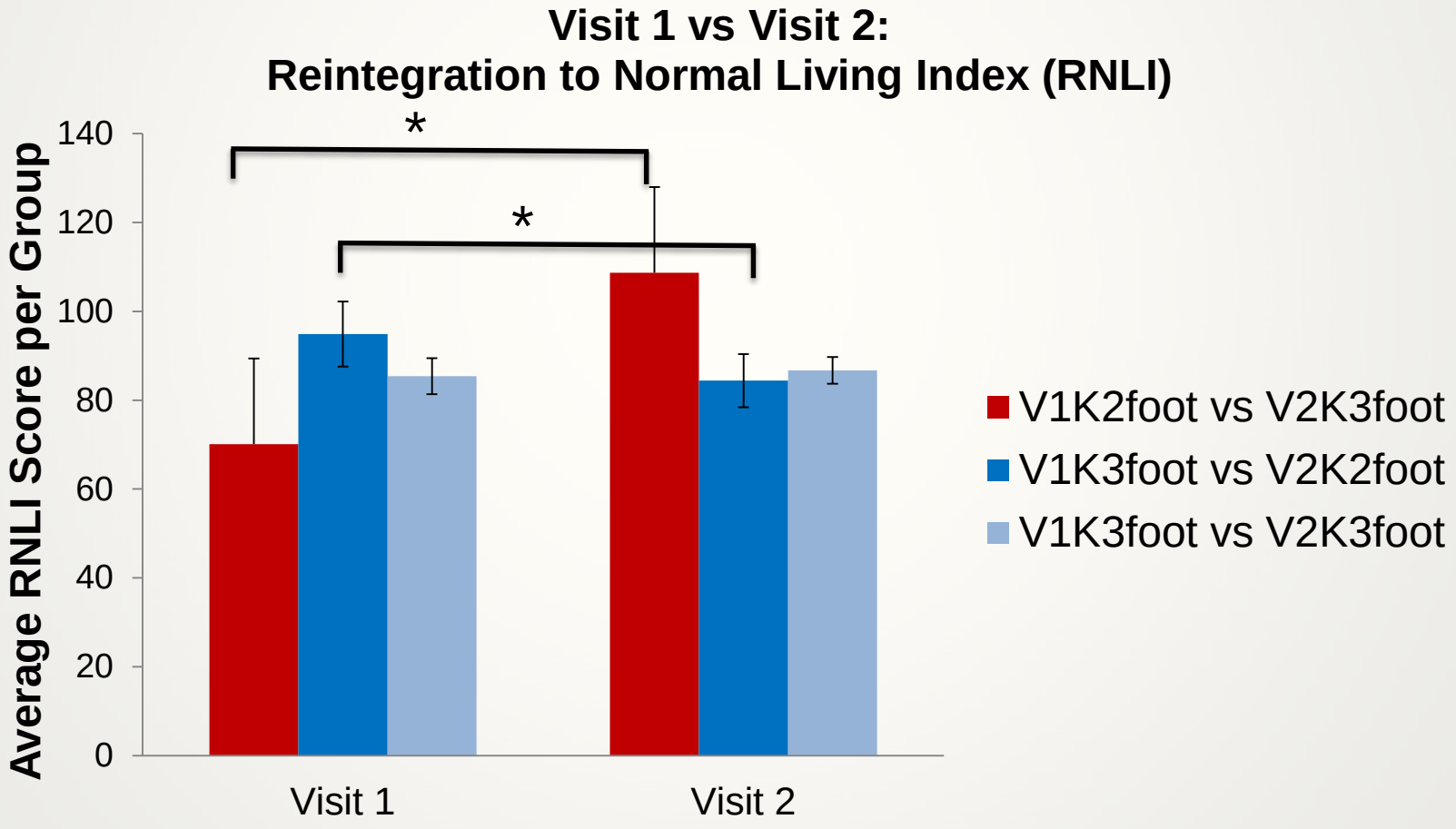


PCI = (HR (w) - HR(r)) / Speed of walking

Results: post 2-weeks trial effects



Results: post 2-weeks trial effects



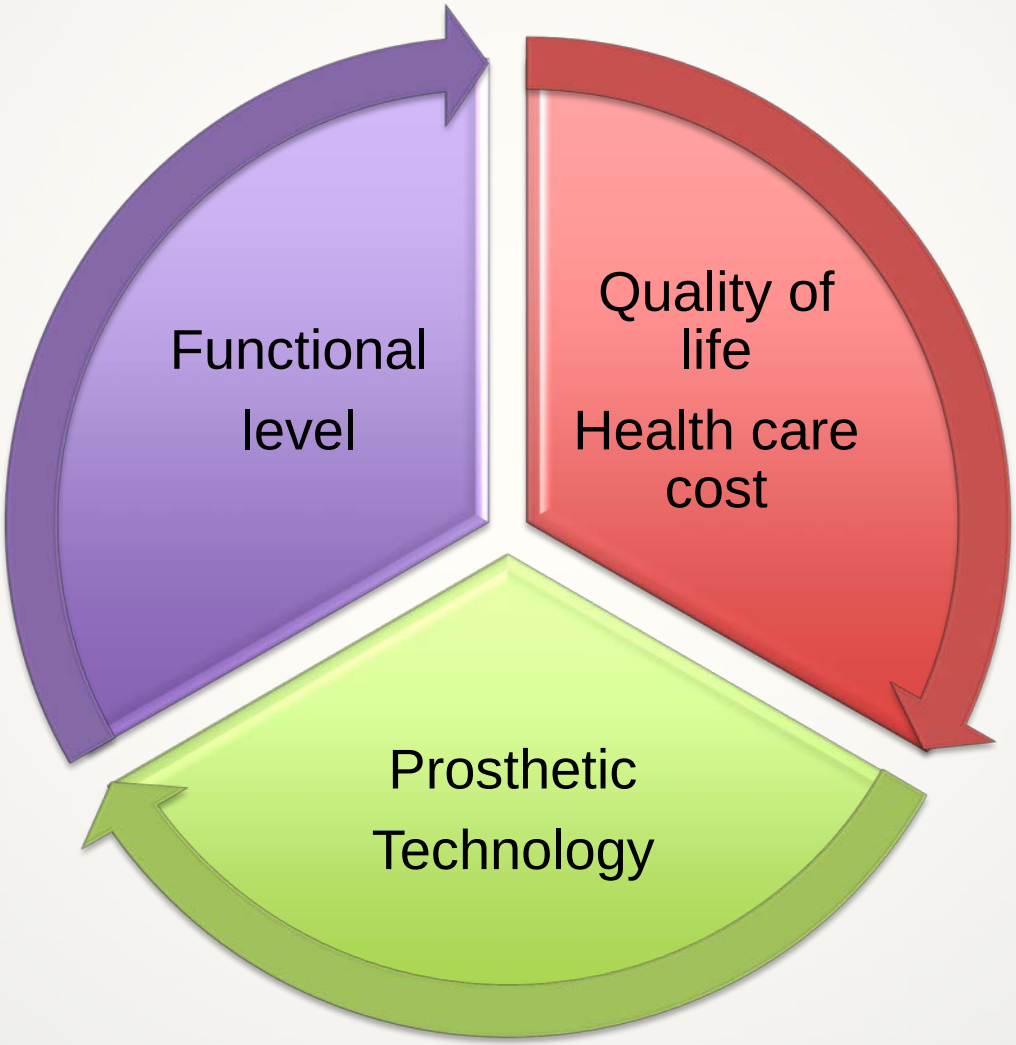
Results: Participants' self report

- **K2 → K3**
  - "I feel more stable with this foot"
  - "I can walk and turn around easier"
  - "I was able to walk up the ramp at the restaurant"
  - "I think I can get rid of my walker with this foot"
- **K3 → K2**
  - "It did not bother me"
  - "I had to work harder at walking"
  - "I feel less stable"
  - "I fell twice in 24 hours after switching"

Conclusions

- K3 prosthetic foot provides additional benefits for balance and gait function and quality of life compared to K2.

- Providing higher level prosthetic feet to patients who are classified at lower functional level (K2 →K3) could improve balance, prevent serious costly injuries caused by trips and falls, and facilitate transition to higher functional status, resulting in lower health care costs in the long term.


Functional level
Quality of life
Health care cost
Prosthetic Technology