Putting the best foot forward

a randomised controlled cross-over trial investigating functional capacity in lower limb amputees

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Institute of Sport and Exercise Medicine
UNIVERSITEIT STELLENBOSCH UNIVERSITY

Dr Phoebe Runciman
Prof Wayne Derman
Stellenbosch University
South Africa

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Sportwetenskap Sport Science STELLENBOSCH 80 years of excellence

Conflict of interest statement

- This project was partly funded by Össur and the products used in the study have been provided by Össur.

- The Institute of Sport and Exercise Medicine and Department of Sport Science are independent entities within Stellenbosch University, South Africa, and Össur has not had any influence over the data collection or analysis in any way.

Physical activity as a risk modifier

All cause mortality

Do more physical activity!

150 min/wk

Prevention of secondary conditions

BIG 4

ACSM, 2014; Anderson et al, 2000; Lollgen et al, 2009; Lachat et al, 2013

Lower exercise capacity in amputees

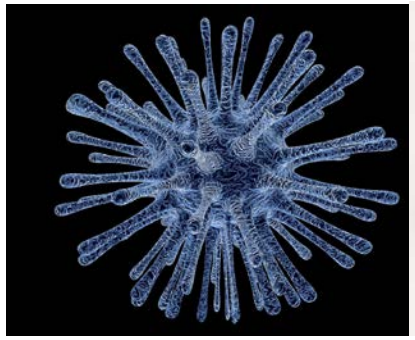
Sedentary lifestyle

52.4% prevalence of falling

The at-risk unilateral amputee

Physical activity = ↑ QOL

>2 health conditions



Farrokhi, 2016; Houdijk et al, 2018; Hak et al, 2014; Schafer et al, 2018;

Prosthetic considerations

Gait asymmetries
Sound side loading

Secondary effects
+ injury risk

OA 17x

The type of foot matters

South African context

Energy storage and return properties

Reduced ability of prosthesis
= reduced PA?

Morgenroth, 2011; Mengelkoch, Kahle and Highsmith, 2014, Struyf, 2001; Heitzmann DWW, 2015; Childers W, 2018

Aims of this study

1) To determine the functional capacity and physiological response of 19 unilateral transtibial amputees, using a 6-minute walk test and 6-item obstacle course

2) To assess the differences in functional capacity whilst the amputees used 3 prosthetic feet

Prosthetic feet used in this study:

SACH

Gold standard ESAR

Novel pivot ESAR

3 bladed foot
Pivot linkage system
- btw forefoot + pylon
Increased flexibility + power

The Randomised Controlled Cross-over Trial

Participants

- Participants (Aged 40 ± 16 years) (20-6MWT; 19-OBST)
- Unilateral transtibial amputees
- Time from amputation: 2 – 30 years (Mean 9.6 years)
- Sex: 17 male, 3 female
- BMI: 24.7 ± 3.6
- Cause: 18 traumatic, 2 medical
- No sig. stump pathology (> 5 SFCS score)

All participants completed informed consent

- IRB number N/16/032

Statistical analyses

- Repeated measures ANOVA
- Cohen's d effect size of magnitude

2 week cross over

Acclimatisation to foot

Same methodology every 2 weeks

Random foot order

double-blind foot sock

Functional testing methodology

Functional exercise performance

6 MINUTE WALK TEST
5m markers
Distance (m)
Heart Rate
Ratings of perceived exertion 6-20

OBSTACLE COURSE
Time per task (s)
Completeness
Heart Rate

1) Walk the line

2) Sit- to- stand- to- sit

3) Stair climbing

4) Pick up the box

5) Cone walk

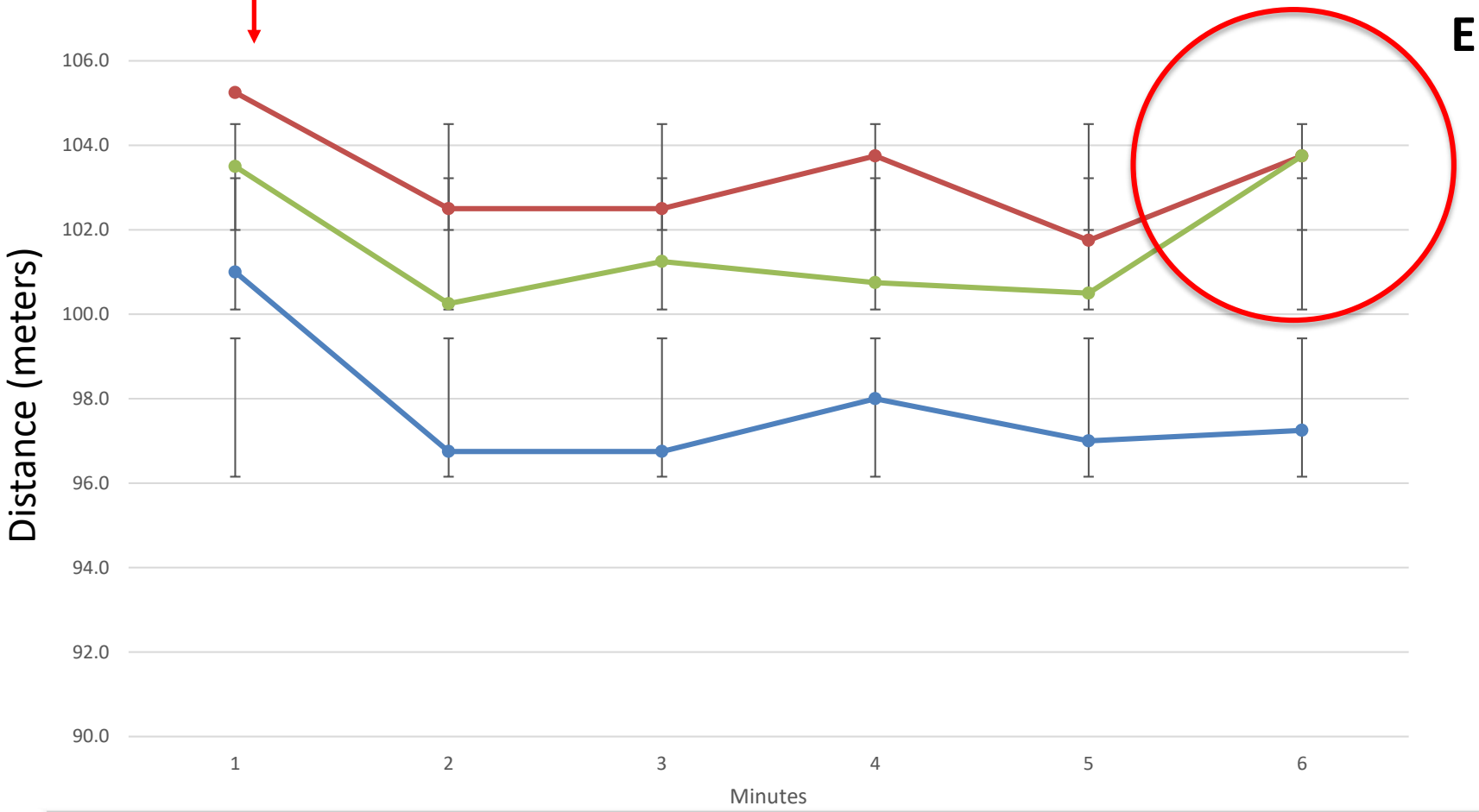
6) Step over the box

Distance covered during the 6MWT

SACH
NOVEL
ESAR

Covered more distance from 1st minute

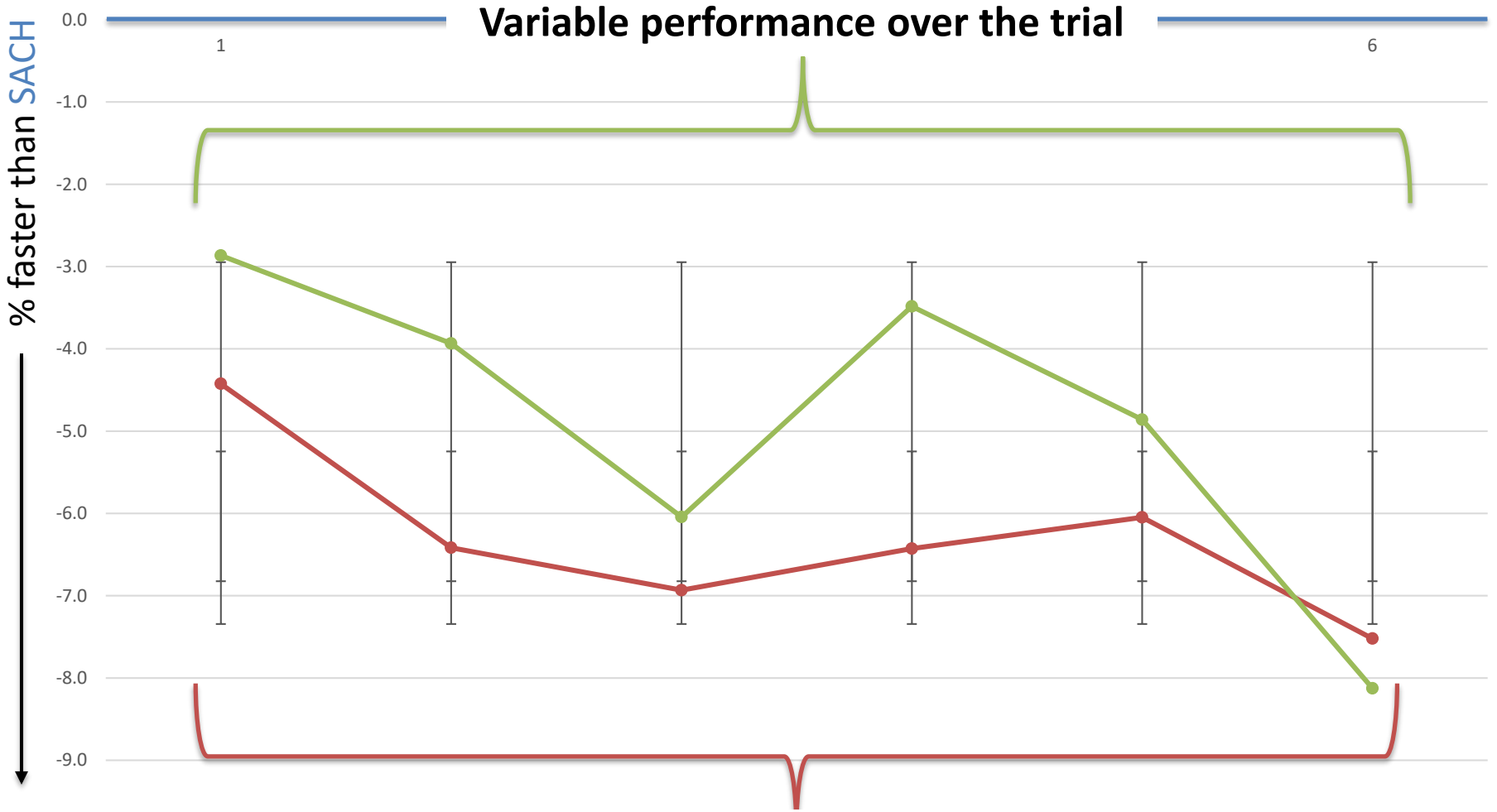
End-spurt



P = 0.75
Groups interaction

P < 0.01
Time main effect
HR time main effect
RPE time main effect

But **HOW** was the distance covered?



SACH
NOVEL
ESAR

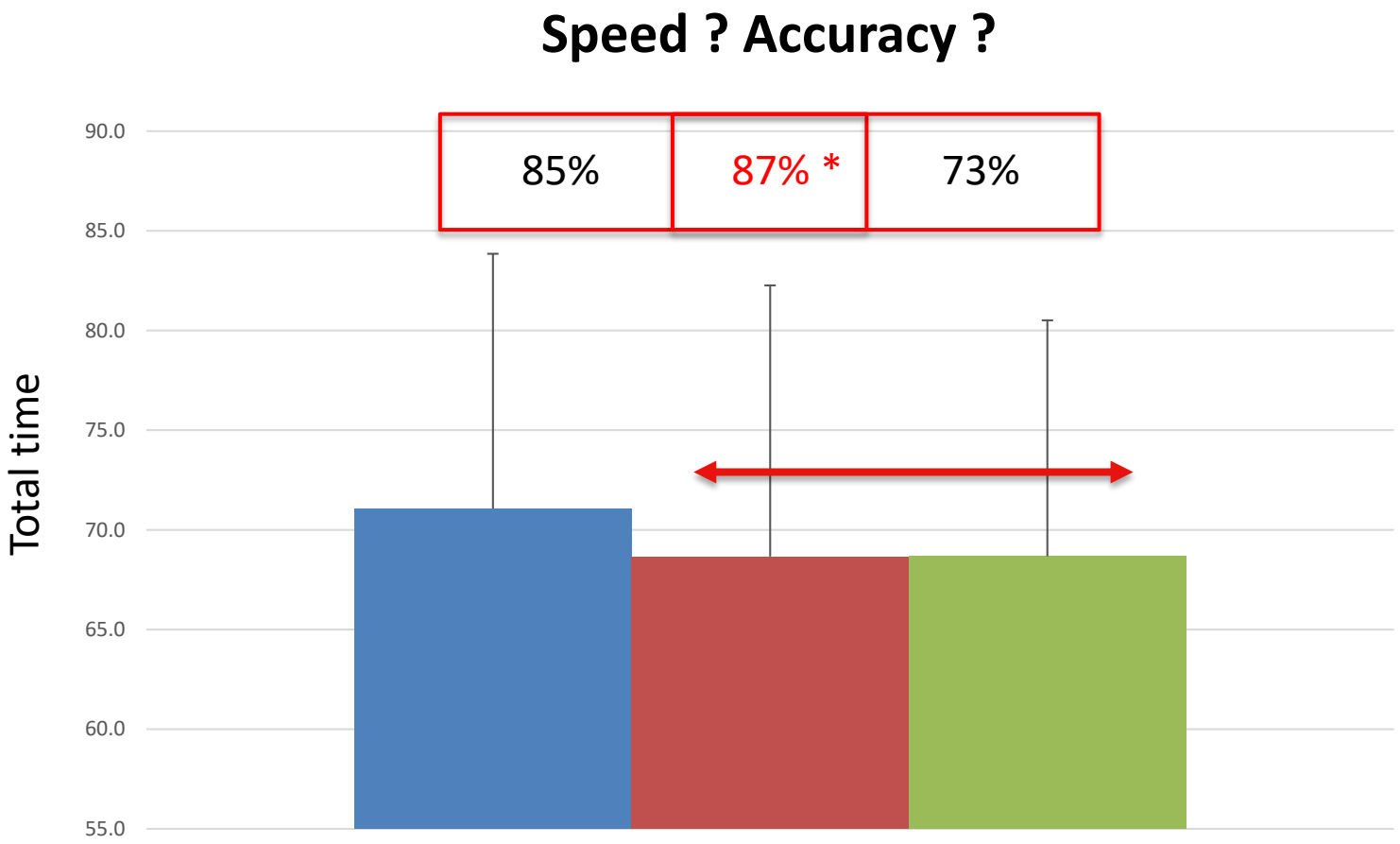
Effect size
0.86 (large effect)

P = 0.98
Groups interaction

P < 0.05
Time main effect

Performance during the OBST

SACH
NOVEL
ESAR



* P = 0.005
Groups interaction

Relative differences per task

SACH
NOVEL
ESAR

Conclusions & implications

- There was a clear increase in 6 Minute-Walk-Test performance whilst the participants were wearing the NOVEL pivot foot, compared with the ESAR and SACH (ES 0.86)
- There was also a higher accuracy of tasks completed correctly during the Obstacle Course whilst the participants were wearing the NOVEL, compared with the ESAR
- Furthermore, we provide insight into the specific tasks in which the amputees gained functional performance gains from the NOVEL and ESAR feet
- **The use of an advanced carbon foot prosthesis increases volitional functional capacity and accuracy – long-term consequences**
- Limitation: Functional performance tests may lack sensitivity required to see large differences between the groups (high clinical magnitude remains)

Thank you!

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Dr Phoebe Runciman
para@sun.ac.za
@PhoebeRunciman

Dr Phoebe Runciman
1. Department of Sport Science, Stellenbosch University
2. Institute of Sport and Exercise Medicine, Stellenbosch University

Prof Wayne Derman
1. Institute of Sport and Exercise Medicine, Stellenbosch University
2. IOC Research Centre, South Africa