Putting the best foot forward

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

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IPC VISTA2019 Conference, Amsterdam
4-7 September 2019
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!

Prevention of secondary conditions

BIG 4

150 min/wk

ACSM, 2014; Anderson et al, 2000; Lollgen et al, 2009; Lachat et al, 2013
Lower exercise capacity in amputees

Sedentary lifestyle

The at-risk unilateral amputee

52.4% prevalence of falling

Physical activity = QOL

>2 health conditions

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

The type of foot matters

Gait asymmetries
Sound side loading

South African context

Energy storage and return properties
Reduced ability of prosthesis = reduced PA?

Secondary effects
+ injury risk

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

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

Covered more distance from 1st minute

End-spurt

Distance (meters)

Minutes

90.0 92.0 94.0 96.0 98.0 100.0 102.0 104.0 106.0

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?

**Variable performance over the trial**

Effect size
0.86 (large effect)

- P = 0.98
- Groups interaction
- P < 0.05
- Time main effect

**Smoother (efficient?) performance over the trial**
Performance during the OBST

<table>
<thead>
<tr>
<th>Speed</th>
<th>Accuracy</th>
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<tbody>
<tr>
<td>85%</td>
<td>87% *</td>
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<td></td>
<td>73%</td>
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* P = 0.005
Groups interaction
Relative differences per task

Different task- different requirement!
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!

This project was funded by the following grants

Össur research grant
IOC Research Centre, South Africa research grant
Stellenbosch University Postdoctoral Research Fellowship
Claude Leon Foundation Postdoctoral Research Fellowship

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