Which prosthetic foot to prescribe? Biomechanical differences found during a single session comparison of different foot types hold true one year later.

Abstract

Introduction: Clinicians typically use findings from cohort studies to objectively inform judgements regarding the potential (dis)advantages of prescribing a new prosthetic device. However, before finalising prescription a clinician will typically ask a patient to 'try out' a change of prosthetic device while the patient is at the clinic. Observed differences in gait when using the new device should be the result of the device's mechanical function, but could also conceivably be due to patient related factors which can change from day-to-day and can thus make device comparisons unreliable. To determine whether a device's mechanical function consistently has a more meaningful impact on gait than patient-related factors, the present study undertook quantitative gait analyses of a trans-tibial amputee walking using two different foot-ankle devices on two occasions over a year apart. If the observed differences present between devices, established using quantitative gait analysis, were in the same direction and of similar magnitude on each of the two occasions, this would indicate that device-related factors were more important than patient-related factors.

Methods: One adult male with a unilateral trans-tibial amputation completed repeated walking trials using two different prosthetic foot devices on two separate occasions, 14 months apart. Walking speed and sagittal plane joint kinematics and kinetics for both limbs were assessed on each occasion. Clinically meaningful differences in these biomechanical outcome variables were defined as those with an effect size difference (d) between prosthetic conditions of at least 0.4 (i.e. 'medium' effect size).

Results: Eight variables namely, walking speed, prosthetic 'ankle' peak plantar- and dorsi-flexion and peak positive power, and residual knee loading response flexion, peak stance-phase extension and flexion moments and peak negative power, displayed clinically meaningful differences ($d > 0.4$) between foot devices during the first session. All eight of these showed similar effect size differences during the second session despite the participant being heavier and older.

Conclusions: Findings suggest that a prosthetic device's mechanical function consistently has a more meaningful impact on gait than patient-related factors. These findings support the current clinical practice of making decisions regarding prosthetic prescription for an individual, based on a single session evaluation of their gait using two different devices. However, to confirm this conclusion, a case series using the same approach as the present study could be undertaken.

Keywords

Gait analysis, Lower-limb amputation, Methodology, Prosthetics, Foot device

Introduction

Within a research setting, the efficacy of a particular prosthetic device is typically determined by comparing group mean biomechanical outcome variables (e.g. peak residual knee flexion during stance) from a cohort of lower-limb amputees performing locomotor tasks when using one device versus using a different device, typically with differing design features[1-8]. Findings from such research is used by clinicians to objectively inform judgements regarding the potential (dis)advantages of prescribing one prosthetic device compared to another. Interpreting the findings from research in this way is based upon the assumption that the differences in biomechanical outcome variables between prosthetic conditions are solely a result of the prosthetic components and that the observed effect would be present for any patient with a similar level of amputation, activity level and health status as those reported in the research. However, this assumption may not necessarily be valid and even if it is, the applicability of such research findings to a clinical setting, where decisions regarding prosthetic prescription are made on a patient by patient basis, is questionable. For example, in a cohort study comparing the efficacy of one prosthetic device versus

another, it is entirely possible that group mean biomechanical outcome variables may indicate a statistically significant effect in one direction, even though some members of the group display minimal changes, or even changes in the opposing direction. Based on the findings from such studies, a clinician could make an evidence-based decision regarding prosthetic prescription that may have a negative outcome for a patient. Accordingly, before finalising prosthesis prescription, clinicians will typically ask a patient to 'try out' any recommended change in prosthetic device while the patient is at their clinic, with the necessary adjustments to alignment and the like being made with a view to optimising the device's function during gait. Any differences in gait observed at the clinic when the patient switches to using the new device are expected to, and may indeed, be a result of the function of the new prosthetic device. However, it is possible that evaluation of a patient's gait made on any day can also be affected by patient-related factors (e.g. weight, physical condition, motivation) rather than soley device-related factors alone.

Therefore, in order to investigate the efficacy of carrying out such single-session evaluations, the current study undertook quantitative gait analyses of an individual with a trans-tibial amputation when using two different foot-ankle devices, on two separate occasions 14 months apart. It was reasoned that if quantitative gait analysis showed that the differences observed when using one device compared to the other were in the same

direction and of similar magnitude on each of the two occasions, this would indicate that device-related factors were more important than patient-related factors. This would highlight that a single-session qualitative comparison of an amputee's gait using two different foot-ankle devices, as typically occurs in a clinic, is a valid approach in finalising descisions regarding prosthetic prescription, and, furthermore, that prosthetic prescription decisions should not be made solely using evidence from research evaluating group mean response to using a new device.

Methods

One healthy adult male (age 35.8 years, mass 90.4 kg, height 1.86 m at the time of the first data collection session) with a unilateral trans-tibial amputation, and described as being K4 on the Medicare Scale by his prescribing clinician, participated. Amputation of the right limb had been conducted, as a result of trauma, 9.2 years prior to the first data collection session. The habitual prosthetic foot device (at the time of both data collection sessions) was an Echelon VT (Chas. A Blatchford and Sons Ltd., Basingstoke, UK). The participant had used a full-contact, suction socket with silicon liner for 12 months prior to the first data collection session, and was using the same at the time of the second data collection session. Data were recorded while the participant completed repeated walking trials using two different types of prosthetic feet. A second,

identical data collection session was conducted 14 months later (at which time the participant's mass had increased by 6.0 kg). The study gained ethical approval from the University of Bradford's bioethics committee, with written informed consent being obtained from the participant prior to participation.

In the present study, the protocol, trial order, laboratory set up, experimenters and prosthetist were identical for both data collection sessions. Segmental kinematic and ground reaction force data were recorded at 200 Hz using a ten camera motion capture system (Vicon MX, Oxford, UK) and two floor mounted force platforms (AMTI, Watertown, MA, USA) while the participant completed overground walking trials along a flat and level 8 m walkway (full details of the marker configuration used to determine segmental kinematics are reported in De Asha et al., [9]). The participant completed 12 walking trials at a self-selected walking speed, using each of two prosthetic foot devices (details below) with stance phase kinetic data being recorded for the intact and prosthetic limbs (six trials for each limb in each prosthetic condition; 24 trials in total).

To avoid habituation affecting the comparisons made between prosthetic feet, during both data collection sessions the participant used foot devices (an Elan and

Epirus; both Chas. A Blatchford and Sons Ltd., Basingstoke, UK) which were different from his currently prescribed foot. Both the Elan and Epirus feet incorporate a dynamic-response foot base with the same shape and design of heel and fore-foot keels and both have an ankle device that passively articulates during stance. In both feet, deflection of the heel and forefoot keels provides simulated 'ankle' motion, with actual articulation occurring at the ankle device, which in the Elan is governed by a microprocessor controlled hydraulic unit, while in the Epirus it is governed by the elastic resistance offered by a rubber ball-joint. The overall prosthesis length, socket and suspension were unchanged between devices. However, as it was impossible to replicate exactly the foot alignment of the first data collection during the second, it was decided to use the same approach to obtain ‘optimal’ alignment for each foot at each session. Thus, as is common practice clinically, foot alignment was decided upon by a mixture of feedback regarding perceived function and comfort from the participant and the expertise of the prosthetist. After each foot device had been fitted the participant walked on it for a period of approximately 20 minutes prior to data collection to enable the participant to become accustomed to it.

Initial processing of marker trajectories were undertaken within Nexus software (Vicon, Oxford, UK). Marker trajectory and ground reaction force data were then exported in C3D format to Visual 3D software (C-Motion, Germantown, MD, USA),

where it was then filtered using a fourth-order, zero-lag Butterworth filter with a 6 Hz cut-off, and all further processing was completed (for more details regarding data processing see De Asha et al. [9]). Walking speed and sagittal plane joint kinematics and kinetics for both limbs have been shown by previous research to be important outcome variables in unilateral amputee gait[10]. Therefore we assessed; average walking speed, positive and negative peaks in sagittal plane joint moments and powers, peak flexion and extension at hips, knees and ankles (dorsi- and plantar-flexion) and the joint angle at specific gait events (e.g. initial contact, peak loading response, toe-off). Clinically meaningful differences in these biomechanical outcome variables were defined as those with an effect size difference (d) between prosthetic conditions of at least 0.4 ('medium' effect size)[11]. No inferential statistical tests were applied.

Results

In total, there were eight biomechanical variables where clinically meaningful differences ($d > 0.4$) were evident between foot types during the first data collection session. These variables were walking speed, peak plantar- and dorsi-flexion at the prosthetic 'ankle', residual knee loading response flexion, peak positive power during early stance at the prosthetic 'ankle', peak negative residual knee power during late stance, and peak stance-phase extension and flexion moments at the residual knee

(direction and magnitude of differences are shown at Table 1 and Figures 1 and 2). The mean (SD) effect size difference between foot types was 0.99 (0.48). During the second data collection session, differences between foot types in the same eight variables were in the same direction and had much the same effect size, mean 0.89 (0.51), as those determined during the first session (Table 1).

INSERT TABLE 1

INSERT FIGURE 1

INSERT FIGURE 2

Discussion

The aim of the current study was to investigate the efficacy of making decisions regarding prosthetic foot prescription for an individual patient, based on a single session comparison of their gait using two different foot-ankle devices. To fulfil this aim we undertook quantitative gait analyses of a an individual with a trans-tibial amputation, using two different foot-ankle devices, on two separate occasions 14 months apart.

171 The results indicated that eight biomechanical variables had ‘medium’ or ‘large’
172 effect size differences between prosthetic foot types (d > 0.4) during the first data
173 collection session. All eight of these variables had the same directional and comparable
174 effect size differences between prosthetic conditions during the second data collection
175 session, which was conducted 14 months after the initial session with the participant
176 now older and heavier by 6kg, indicating an increase in body mass index from 26.1 to
177 27.9 (implying his physical conditioning had altered). The average effect size difference
178 between prosthetic foot types was slightly greater in the first session than the second
179 (session 1, d = 0.99; session 2, d = 0.89), although average effect sizes were similarly
180 ‘large’ for both data collection sessions. Therefore, these results suggest that a single
181 session comparison of the gait of an individual with unilateral trans-tibial amputation
182 using two different foot-ankle devices, as is typically undertaken in a clinical setting
183 (albeit in a qualitative manner), is appropriate for identifying biomechanical differences
184 between prosthetic devices. Hence it is a valid type of evaluation to conduct when
185 finalising decisions about prosthetic prescription.

186

187 Despite an increase in participant mass of 6kg between sessions, both feet had
188 the same category of heel and forefoot keel stiffness on both occasions. With such an
189 increase in body mass, absolute joint kinetic values would have increased between
190 testing sessions, so in order to ensure comparisons were valid all joint kinetic

parameters were normalised to body mass. These normalised values, which had comparable magnitudes between sessions, showed meaningful effect size differences between prosthetic foot types in both data collection sessions; suggesting the change in foot type was the main cause of such differences, not patient-related factors. These findings support our stated supposition.

Self-selected walking speed was higher during both sessions ('medium' effect sizes) when the participant used the Elan, compared to the Epirus foot device. Increased self-selected walking speed can be considered a global descriptor of improved gait function.[12] Thus speed increases when using a particular foot device provide an indication that any accompanying changes in other parameters when using the new device may also be beneficial. Thus in the present study, the reduction in peak negative residual knee power during late stance when using the Elan compared to the Epirus foot device, for example, can be interpreted as a beneficial change.

Generally, the magnitudes of effect size differences between prosthetic conditions appear to reflect relatively low inter-trial variability rather than large changes to average values (see Figures 1 and 2). This is likely due to the participant, who was assessed as being K4 on the Medicare scale, having excellent gait function. Whilst data

from such a participant may be limited in terms of its generalisibility to the wider population group, such a participant would be better able to adjust to using different, non-habitual feet than a participant with a lower level of function. It is quite possible that the differences between prosthetic conditions observed in the present study may well be amplified in an individual with a lower Medicare classification due to them being more affected by the function and/or design features of a particular prosthetic device, compared to an individual with higher levels of function.

In conclusion, the findings of this study indicate that the direction and effect sizes of differences in biomechanical outcomes when using one prosthetic foot versus another remained more or less constant when such assessment was conducted 14 months later, even though certain participant specific parameters (e.g. body mass, age) were different between sessions. These findings support our stated (*a priori*) supposition and lends support to the current clinical practice of finalising decisions regarding prosthetic prescription for an individual, based on a single session comparison of their gait using two different devices (typically, new device compared to habitual device). Potentially, future studies could undertake a case-series using the same approach as the present study to support, or refute, the findings of this study.

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Declaration of Conflicting Interests

The authors declare that there is no conflict of interest.

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Figure legends

Figure 1 Mean (SD) sagittal plane angular displacement at the prosthetic ‘ankle’ (top) and residual knee (bottom) using Elan (dashed lines) and Epirus (solid lines) foot devices. Data collection session one is on the left and session two on the right.

Figure 2 Mean (SD) sagittal plane prosthetic ‘ankle’ joint rotation power (top; power generation is positive, absorbtion is negative) and residual knee joint moment (bottom; internal extension moment is positive, flexion moment is negative) using Elan (dashed lines) and Epirus (solid lines) foot devices. Data collection session one is on the left and session two on the right.

Table 1. A list of mean (SD) variables with clinically meaningful inter-foot differences.