1   Which prosthetic foot to prescribe? Biomechanical differences found during a single

2   session comparison of different foot types hold true one year later.

3

4   Abstract

5   *Introduction:* Clinicians typically use findings from cohort studies to objectively inform

6   judgements regarding the potential (dis)advantages of prescribing a new prosthetic

7   device. However, before finalising prescription a clinician will typically ask a patient to

8   'try out' a change of prosthetic device while the patient is at the clinic. Observed

9   differences in gait when using the new device should be the result of the device's

10 mechanical function, but could also conceivably be due to patient related factors which

11 can change from day-to-day and can thus make device comparisons unreliable. To

12 determine whether a device's mechanical function consistently has a more meaningful

13 impact on gait than patient-related factors, the present study undertook quantitative gait

14 analyses of a trans-tibial amputee walking using two different foot-ankle devices on two

15 occasions over a year apart. If the observed differences present between devices,

16 established using quantitative gait analysis, were in the same direction and of similar

17 magnitude on each of the two occasions, this would indicate that device-related factors

18 were more important than patient-related factors.

19   *Methods*: One adult male with a unilateral trans-tibial amputation completed repeated

20   walking trials using two different prosthetic foot devices on two separate occasions, 14

21   months apart. Walking speed and sagittal plane joint kinematics and kinetics for both

22   limbs were assessed on each occasion. Clinically meaningful differences in these

23   biomechanical outcome variables were defined as those with an effect size difference

24   (d) between prosthetic conditions of at least 0.4 (i.e. 'medium' effect size).

25   *Results*: Eight variables namely, walking speed, prosthetic 'ankle' peak plantar- and

26   dorsi-flexion and peak positive power, and residual knee loading response flexion, peak

27   stance-phase extension and flexion moments and peak negative power, displayed

28   clinically meaningful differences (d > 0.4) between foot devices during the first session.

29   All eight of these showed similar effect size differences during the second session

30   despite the participant being heavier and older.

31   *Conclusions*: Findings suggest that a prosthetic device's mechanical function

32   consistently has a more meaningful impact on gait than patient-related factors. These

33   findings support the current clinical practice of making decisions regarding prosthetic

34   prescription for an individual, based on a single session evaluation of their gait using

35   two different devices. However, to confirm this conclusion, a case series using the same

36   approach as the present study could be undertaken.

37

38   Keywords

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

40

41   **Introduction**

42   Within a research setting, the efficacy of a particular prosthetic device is

43   typically determined by comparing group mean biomechanical outcome variables (e.g.

44   peak residual knee flexion during stance) from a cohort of lower-limb amputees

45   performing locomotor tasks when using one device versus using a different device,

46   typically with differing design features[1-8]. Findings from such research is used by

47   clinicians to objectively inform judgements regarding the potential (dis)advantages of

48   prescribing one prosthetic device compared to another. Interpreting the findings from

49   research in this way is based upon the assumption that the differences in biomechanical

50   outcome variables between prosthetic conditions are solely a result of the prosthetic

51   components and that the observed effect would be present for any patient with a similar

52   level of amputation, activity level and health status as those reported in the research.

53   However, this assumption may not necessarily be valid and even if it is, the

54   applicability of such research findings to a clinical setting, where decisions regarding

55   prosthetic prescription are made on a patient by patient basis, is questionable. For

56   example, in a cohort study comparing the efficacy of one prosthetic device versus

57   another, it is entirely possible that group mean biomechanical outcome variables may

58   indicate a statistically significant effect in one direction, even though some members of

59   the group display minimal changes, or even changes in the opposing direction. Based on

60   the findings from such studies, a clinician could make an evidence-based decision

61   regarding prosthetic prescription that may have a negative outcome for a patient.

62   Accordingly, before finalising prosthesis prescription, clinicians will typically ask a

63   patient to 'try out' any recommended change in prosthetic device while the patient is at

64   their clinic, with the necessary adjustments to alignment and the like being made with a

65   view to optimising the device's function during gait. Any differences in gait observed at

66   the clinic when the patient switches to using the new device are expected to, and may

67   indeed, be a result of the function of the new prosthetic device. However, it is possible

68   that evaluation of a patient's gait made on any day can also be affected by patient-

69   related factors (e.g. weight, physical condition, motivation) rather than soley device-

70   related factors alone.

71

72   Therefore, in order to investigate the efficacy of carrying out such single-session

73   evaluations, the current study undertook quantitative gait analyses of an individual with

74   a trans-tibial amputation when using two different foot-ankle devices, on two separate

75   occasions 14 months apart. It was reasoned that if quantitative gait analysis showed that

76   the differences observed when using one device compared to the other were in the same

77   direction and of similar magnitude on each of the two occasions, this would indicate

78   that device-related factors were more important than patient-related factors. This would

79   highlight that a single-session qualitative comparison of an amputee's gait using two

80   different foot-ankle devices, as typically occurs in a clinic, is a valid approach in

81   finalising descisions regarding prosthetic prescription, and, furthermore, that prosthetic

82   prescription decisions should not be made solely using evidence from research

83   evaluating group mean response to using a new device.

84

85   **Methods**

86   One healthy adult male (age 35.8 years, mass 90.4 kg, height 1.86 m at the time

87   of the first data collection session) with a unilateral trans-tibial amputation, and

88   described as being K4 on the Medicare Scale by his prescribing clinician, participated.

89   Amputation of the right limb had been conducted, as a result of trauma, 9.2 years prior

90   to the first data collection session. The habitual prosthetic foot device (at the time of

91   both data collection sessions) was an Echelon VT (Chas. A Blatchford and Sons Ltd.,

92   Basingstoke, UK). The participant had used a full-contact, suction socket with silicon

93   liner for 12 months prior to the first data collection session, and was using the same at

94   the time of the second data collection session. Data were recorded while the participant

95   completed repeated walking trials using two different types of prosthetic feet. A second,

96   identical data collection session was conducted 14 months later (at which time the

97   participant's mass had increased by 6.0 kg). The study gained ethical approval from the

98   University of Bradford's bioethics committee, with written informed consent being

99   obtained from the participant prior to participation.

100

101   In the present study, the protocol, trial order, laboratory set up, experimenters

102   and prosthetist were identical for both data collection sessions. Segmental kinematic

103   and ground reaction force data were recorded at 200 Hz using a ten camera motion

104   capture system (Vicon MX, Oxford, UK) and two floor mounted force platforms

105   (AMTI, Watertown, MA, USA) while the participant completed overground walking

106   trials along a flat and level 8 m walkway (full details of the marker configuration used

107   to determine segmental kinematics are reported in De Asha et al., [9]). The participant

108   completed 12 walking trials at a self-selected walking speed, using each of two

109   prosthetic foot devices (details below) with stance phase kinetic data being recorded for

110   the intact and prosthetic limbs (six trials for each limb in each prosthetic condition; 24

111   trials in total).

112

113   To avoid habituation affecting the comparisons made between prosthetic feet,

114   during both data collection sessions the participant used foot devices (an Elan and

115   Epirus; both Chas. A Blatchford and Sons Ltd., Basingstoke, UK) which were different

116   from his currently prescribed foot. Both the Elan and Epirus feet incorporate a dynamic-

117   response foot base with the same shape and design of heel and fore-foot keels and both

118   have an ankle device that passively articulates during stance. In both feet, deflection of

119   the heel and forefoot keels provides simulated 'ankle' motion, with actual articulation

120   occurring at the ankle device, which in the Elan is governed by a microprocessor

121   controlled hydraulic unit, while in the Epirus it is governed by the elastic resistance

122   offered by a rubber ball-joint. The overall prosthesis length, socket and suspension were

123   unchanged between devices. However, as it was impossible to replicate exactly the foot

124   alignment of the first data collection during the second, it was decided to use the same

125   approach to obtain 'optimal' alignment for each foot at each session. Thus, as is

126   common practice clinically, foot alignment was decided upon by a mixture of feedback

127   regarding perceived function and comfort from the participant and the expertise of the

128   prosthetist. After each foot device had been fitted the participant walked on it for a

129   period of approximately 20 minutes prior to data collection to enable the participant to

130   become accustomed to it.

131

132   Initial processing of marker trajectories were undertaken within Nexus software

133   (Vicon, Oxford, UK). Marker trajectory and ground reaction force data were then

134   exported in C3D format to Visual 3D software (C-Motion, Germantown, MD, USA),

135   where it was then filtered using a fourth-order, zero-lag Butterworth filter with a 6 Hz

136   cut-off, and all further processing was completed (for more details regarding data

137   processing see De Asha et al. [9]). Walking speed and sagittal plane joint kinematics and

138   kinetics for both limbs have been shown by previous research to be important outcome

139   variables in unilateral amputee gait[10]. Therefore we assessed; average walking speed,

140   positive and negative peaks in sagittal plane joint moments and powers, peak flexion

141   and extension at hips, knees and ankles (dorsi- and plantar-flexion) and the joint angle

142   at specific gait events (e.g. initial contact, peak loading response, toe-off). Clinically

143   meaningful differences in these biomechanical outcome variables were defined as those

144   with an effect size difference (d) between prosthetic conditions of at least 0.4 ('medium'

145   effect size)[11]. No inferential statistical tests were applied.

146

147   Results

148   In total, there were eight biomechanical variables where clinically meaningful

149   differences (d > 0.4) were evident between foot types during the first data collection

150   session. These variables were walking speed, peak plantar- and dorsi-flexion at the

151   prosthetic 'ankle', residual knee loading response flexion, peak positive power during

152   early stance at the prosthetic 'ankle', peak negative residual knee power during late

153   stance, and peak stance-phase extension and flexion moments at the residual knee

154 (direction and magnitude of differences are shown at Table 1 and Figures 1 and 2). The

155 mean (SD) effect size difference between foot types was 0.99 (0.48). During the second

156 data collection session, differences between foot types in the same eight variables were

157 in the same direction and had much the same effect size, mean 0.89 (0.51), as those

158 determined during the first session (Table 1).

159   INSERT TABLE 1

160   INSERT FIGURE 1

161   INSERT FIGURE 2

162

163

164 **Discussion**

165   The aim of the current study was to investigate the efficacy of making decisions

166 regarding prosthetic foot prescription for an individual patient, based on a single session

167 comparison of their gait using two different foot-ankle devices. To fulfil this aim we

168 undertook quantitative gait analyses of a an individual with a trans-tibial amputation,

169 using two different foot-ankle devices, on two separate occasions 14 months apart.

170

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

191 parameters were normalised to body mass. These normalised values, which had

192 comparable magnitudes between sessions, showed meaningful effect size differences

193 between prosthetic foot types in both data collection sessions; suggesting the change in

194 foot type was the main cause of such differences, not patient-related factors. These

195 findings support our stated supposition.

196

197 Self-selected walking speed was higher during both sessions ('medium' effect

198 sizes) when the participant used the Elan, compared to the Epirus foot device. Increased

199 self-selected walking speed can be considered a global descriptor of improved gait

200 function.[12] Thus speed increases when using a particular foot device provide an

201 indication that any accompanying changes in other parameters when using the new

202 device may also be beneficial. Thus in the present study, the reduction in peak negative

203 residual knee power during late stance when using the Elan compared to the Epirus foot

204 device, for example, can be interpreted as a beneficial change.

205

206 Generally, the magnitudes of effect size differences between prosthetic

207 conditions appear to reflect relatively low inter-trial variability rather than large changes

208 to average values (see Figures 1 and 2). This is likely due to the participant, who was

209 assessed as being K4 on the Medicare scale, having excellent gait function. Whilst data

210 from such a participant may be limited in terms of its generalisibility to the wider

211 population group, such a participant would be better able to adjust to using different,

212 non-habitual feet than a participant with a lower level of function. It is quite possible

213 that the differences between prosthetic conditions observed in the present study may

214 well be amplified in an individual with a lower Medicare classification due to them

215 being more affected by the function and/or design features of a particular prosthetic

216 device, compared to an individual with higher levels of function.

217

218 In conclusion, the findings of this study indicate that the direction and effect

219 sizes of differences in biomechanical outcomes when using one prosthetic foot versus

220 another remained more or less constant when such assessment was conducted 14

221 months later, even though certain participant specific parameters (e.g. body mass, age)

222 were different between sessions. These findings support our stated (*a priori*)

223 supposition and lends support to the current clinical practice of finalising decisions

224 regarding prosthetic prescription for an individual, based on a single session comparison

225 of their gait using two different devices (typically, new device compared to habitual

226 device). Potentially, future studies could undertake a case-series using the same

227 approach as the present study to support, or refute, the findings of this study.

228

Declaration of Conflicting Interests

The authors declare that there is no conflict of interest.

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281

282   **Figure legends**

283   Figure 1 Mean (SD) sagittal plane angular displacement at the prosthetic 'ankle' (top)

284   and residual knee (bottom) using Elan (dashed lines) and Epirus (solid lines) foot

285   devices. Data collection session one is on the left and session two on the right.

286

287   Figure 2 Mean (SD) sagittal plane prosthetic 'ankle' joint rotation power (top; power

288   generation is positive, absorbtion is negative) and residual knee joint moment (bottom;

289   internal extension moment is positive, flexion moment is negative) using Elan (dashed

290   lines) and Epirus (solid lines) foot devices. Data collection session one is on the left and

291   session two on the right.

292

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

294