Northumbria Research Link

Are Accelerometer-based Functional Outcome Assessments Feasible and Valid After Treatment for Lower Extremity Sarcomas?

Running title: Balance and Gait Assessment in Sarcoma

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Abstract

Background Aspects of physical functioning, including balance and gait, are affected after surgery for lower limb musculoskeletal tumors. These are not routinely measured but likely are related to how well patients function after resection or amputation for a bone or soft tissue sarcoma. Small, inexpensive portable accelerometers are available that might be clinically useful to assess balance and gait in these patients, but they have not been well studied.

Questions/purposes In patients treated for lower extremity musculoskeletal tumors, we asked: (1) Are accelerometer-based body-worn monitor assessments of balance, gait, and timed up and go tests (TUG) feasible and acceptable? (2) Do these accelerometer-based body-worn monitor assessments produce clinically useful data (face validity), distinguish between patients and controls (discriminant validity), reflect findings obtained using existing clinical measures (convergent validity) and standard manual techniques in clinic (concurrent validity)?

Methods This was a prospective cross-sectional study. Out of 97 patients approached, 34 adult patients treated for tumors in the femur/thigh (19), pelvis/hip (3), tibia/leg (9), or ankle/foot (3) were included in this study. Twenty-seven had limb-sparing surgery and seven underwent amputation. Patients performed standard activities while wearing a body-worn monitor on the lower back, including standing, walking, and TUG tests. Summary measures of balance (area [ellipsis], magnitude [Root Mean Square (RMS)], jerkiness [jerk], frequency of postural sway below which 95% of power of acceleration power spectrum is observed [f95 of postural sway], gait [temporal outcomes, step length and velocity], and TUG time were derived. Body-worn monitor assessments were evaluated for feasibility by investigating data loss and patient-reported acceptability and comfort. In addition, outcomes in patients were compared with datasets of healthy controls collected in parallel studies using identical methods as in this study to assess discriminant validity. Body-worn monitor assessments

26 were also investigated for their relationships with routine clinical scales [Musculoskeletal

27 Tumour Society Scoring system (MSTS), Toronto Extremity Salvage Score (TESS), Quality

28 of life-Cancer survivors [QoL-CS)] to assess convergent validity and their agreement with

29 standard manual techniques (video and stopwatch) to assess concurrent validity.

30 *Results* Although this was a small patient group, there were initial indications that body-worn

31 monitor assessments were well-tolerated, feasible to perform, acceptable to patients who

32 responded (19 of 20 [95%] found the body-worn monitor acceptable and comfortable and 17

33 of 20 [85%] found it user-friendly), and produced clinically useful data comparable to the

34 evidence. Balance and gait measures distinguished patients and controls (discriminant

35 validity), for instance balance outcome (ellipsis) in patients (0.0475; 95% confidence interval

36 [CI] 0.0251–0.0810 m^2/s^4) was affected compared with controls (0.0007; 95% CI, 0.0003–

37 0.0502 m^2/s^4; p = 0.001). Similarly gait outcome (step time) was affected in patients (0.483;

38 95% CI, 0.451–0.512 seconds (s)) compared with controls (0.541; 95% CI, 0.496–0.573 s; p <

39 0.001). Moreover, body-worn monitor assessments showed significant relationships with

40 existing clinical scales (convergent validity), for instance ellipsis with MSTS (r = -0.393; p =

41 0.024). Similarly, manual techniques showed excellent agreement with body-worn monitor

42 assessments (concurrent validity), for instance stopwatch time 22.28 +/- 6.93 s with iTUG time

43 21.18 +/- 6.23 s (ICC agreement = 0.933; p < 0.001). P < 0.05 was considered statistically

44 significant.

45 *Conclusions* Although we had a small, heterogeneous study patient population, this pilot

46 study suggests that body-worn monitors might be useful clinically to quantify physical

47 functioning in patients treated for lower extremity tumors. Balance and gait relate to

48 disability and quality of life. These measurements could provide clinicians with useful novel

49 information on balance and gait, which in turn can guide rehabilitation strategies.

50 *Level of Evidence* Level III, diagnostic study.

51 **Introduction**

52 Surgical resection or amputation, chemotherapy, and radiotherapy for musculoskeletal tumors

53 in the pelvis and lower extremity have a detrimental impact on the locomotor system [5]. The

54 impaired balance and gait that result [9, 11] often lead to reduced mobility, lack of

55 confidence, loss of adaptive mechanisms to maintain the body in space, and falls [45, 57].

56 Despite this, balance and gait assessments are not part of routine clinical practice [19].

57 Balance and gait can be clinically assessed by visual examination or patient-completed scales

58 [20, 52]. However, these methods are subjective, may not detect subtle abnormalities, and

59 some have ceiling effects [25]. Furthermore, difficulties in interpreting results can complicate

60 rehabilitation delivery [25]. Objective functional assessments are therefore potentially useful

61 after sarcoma treatment [19]. Simple tests of balance, gait, or other composite measures, such

62 as the timed up and go (TUG) test, may reflect objective physical capability and fall risk [29,

63 37, 56].

64 Despite this, there remains a deficit of valid and reliable objective balance and gait

65 assessments for these patients [19]. A low-cost, accelerometer-based, body-worn monitor has

66 been able to provide valid objective balance and gait data in other patient cohorts [13, 23, 27,

67 42] and could be of value for monitoring and guiding rehabilitation of sarcoma patients.

68 Different outcome measures are often used to capture outcomes, however, good measures are

69 those that demonstrate accuracy and validity [34, 47, 51]. Body-worn monitors have been

70 sensitive to disability and could detect mild balance differences between patients and controls

71 in diabetic neuropathy [54] and untreated Parkinsonism [37]. Hence, these could be

72 particularly useful in patients treated for a musculoskeletal tumor with mild function

73 abnormalities. Furthermore, it is key to understand whether body-worn monitors are able to

74 satisfy other indicators of validity [34, 47, 51], for example provide clinically useful data,

75 distinguish sarcoma patients from controls, capture disease-specific outcomes and agree with

76 standard clinic assessments.

77 Therefore, in patients treated for lower extremity musculoskeletal tumors, we investigated:

78 (1) Are accelerometer-based body-worn monitor assessments of balance, gait, and timed up

79 and go tests (TUG) feasible to use and acceptable? (2) Do these accelerometer-based body-

80 worn monitor assessments produce clinically useful data (face validity), distinguish between

81 patients and controls (discriminant validity), reflect findings obtained using existing clinical

82 measures (convergent validity) and standard manual techniques in clinic (concurrent

83 validity)?

84 **Patients and Methods**

85 The study was approved by the National Research Ethics committee (NREC) (Reference:

86 13/NE/0296) and the Newcastle upon Tyne Hospitals NHS Foundation Trust, Research and

87 Development department (Reference: 6801). The study was conducted according to Ethical

88 Standards of Helsinki declaration and good clinical practice guidelines.

89 *The Patient Group*

90 We recruited a convenience sample of 34 adult patients (age ≥ 18 years) from the North of

91 England Bone and Soft Tissue Tumor Service, which is located in Newcastle upon Tyne

92 Hospitals NHS Foundation Trust. A convenience sampling of patients was performed to

93 enroll patients who were treated for lower extremity sarcomas. We used this type of sampling

94 in this study to establish proof of concept of the use of body-worn assessments in this clinical

95 group. We included patients if they had undergone treatment, including limb-sparing surgery

96 or amputation and/or radiotherapy, for a lower extremity bone or soft tissue tumor at the iliac

97 crest or below. We excluded patients if they were undergoing active treatment, had benign

98 bone or soft tissue tumors, were unable to take part because of cognitive or physical

99 incapacity, or refused to participate (Fig. 1). All patients provided written informed consent.

100   We collected demographics and clinical characteristics, including diagnosis, treatments, and

101   time since surgery.

102   *Assessments Using Existing Clinic Measures*

103   Patients completed established measures of disability (Toronto Extremity Salvage Score

104   [TESS]) [8], impairment (Musculoskeletal Tumor Rating System [MSTS] [14, 15]), and

105   quality of life (Quality of life-Cancer survivors [QoL-CS] [16]) at their point of assessment

106   (Table 1).

107   *The Healthy Control Group*

108   Healthy controls from other parallel studies (NREC: 12/NE/0319 and NREC: 09-H0906-82/

109   08-H0906-147) provided age-matched references for comparison [33, 61]). Healthy control

110   data, collected by research staff using the same body-worn monitor assessments as our study

111   (described in sections below) were used to compare against the patient group. The healthy

112   control data was collected in the following parallel studies: (1) Pilot work exploring the

113   potential use of the XSens and Open Movement Sensor Device for the Assessment of

114   Osteoarthritis (Osteoarthritis study) which included young healthy control data (age, 19-35

115   years) (for balance and gait outcomes). (2) Incidence of Cognitive Impairment in Cohorts

116   with Longitudinal Evaluation—GAIT (ICICLE-GAIT) study. This study was a collaborative

117   project with ICICLE-PD, an incident cohort study (Incidence of Cognitive Impairment in

118   Cohorts with Longitudinal Evaluation — Parkinson's disease) that was conducted between

119   June 2009 and December 2011 [33, 61]. It included middle-aged and elderly healthy control

120   data (age, 36-90 years) (for balance and gait outcomes).

121   To ensure unbiased comparisons, healthy controls were randomly selected from the control

122   datasets. The protocols for body-worn monitor assessment and data processing in patients and

123   controls were identical. We compared demographics such as age, gender, and BMI between

124   patient and control groups to ensure no differences were present between groups ($p > 0.05$).

125   This was performed to eliminate the confounding effect of demographics on outcomes.

126   *Assessment of Activities Using Manual Techniques*

127   Stopwatch

128   We assessed the amount of time it took patients to complete 7-meter TUG test with a manual

129   technique (stopwatch) [59]; this test was referred to as "Stopwatch TUG time." We started

130   the stopwatch with the patient sitting upright on a chair and tracked the time it took for the

131   patient to complete five components: standing up, walking 7 meters, and turning around,

132   walking back 7 meters, and returning to a seated position in the chair. The subject wore their

133   usual footwear, and they could use their usual walking aids if required but could not be

134   assisted by another person.

135   Video

136   Step count from fast walk test was assessed using observational video analysis. This was

137   referred to as "Video step count."

138   *Equipment*

139   Study participants were asked to wear a triaxial accelerometer-based, body-worn monitor

140   (Axivity AX3, Newcastle-upon-Tyne, UK; dimensions 23.0, 32.5 and 7.6 mm; weight: 11.0 g,

141   sampling frequency 100 Hz, range $\pm$ 8 g, Fig. 2A), which has been validated for human

142   movement analysis [6]. The sensor was located on the lower back (over the fifth lumbar

143   vertebrae) within the pocket of a lumbar belt (Fig. 2B). This is close to the center of mass,

144   where readings can quantify a range of physical functioning tasks [24]. The patients wore the

145   device in the clinic for approximately 2 hours and for 7 days in their homes. However, the 7-

146   day data is beyond the remit of this study article. No repeated measures were performed.

147 *Body-worn Monitor Protocol and Data Collection*

148 Participants wore the body-worn monitor in the clinic and underwent standard tests to assess

149 balance, gait, and timed up and go (TUG) outcomes (also referred to as body-worn monitor

150 outcomes).

151 *Test 1: Standing (Balance) Test*

152 Participants were asked to stand upright on a level surface wearing their own footwear, feet

153 slightly apart, hands by their side and eyes open [41] for 120 seconds [38].

154 *Test 2: Intermittent Fast Walk (Gait) Test*

155 Participants were asked to complete three intermittent fast walks; they were instructed to

156 walk as fast as possible without running along a 7-meter walkway [17].

157 *Test 3: 7-meter Instrumented Timed Up and Go (iTUG) (Physical Capability) Test*

158 This test involved standing up from a chair, walking 7 meters at a regular pace, turning

159 around, walking back to the chair and sitting down [62]; participants repeated this test three

160 times. Participants completed feedback forms about acceptability, comfort and user-

161 friendliness of monitors at the end of the assessment.

162 *Data Processing Using an Established Algorithm*

163 Raw data downloaded from the body-worn monitor (using the OMGUI 1.0 Configuration and

164 Analysis software; Axivity, OpenMovement) were processed using established algorithms

165 [12, 13, 24] (Fig. 2C) to derive balance (Supplemental Fig. 1; supplemental materials are

166 available with the online version of *CORR*®), gait (Supplemental Fig. 2; supplemental

167 materials are available with the online version of *CORR*®) and iTUG outcomes

168 (Supplemental Figs. 3; supplemental materials are available with the online version of

169 *CORR*®) using MATLAB® (R2012a, Mathworks, Cambridge, UK).

170 *Algorithm 1# Derivation of Balance Outcomes*

171 We used raw acceleration signals in the AP and mediolateral planes to assess standing balance

172 in these directions [12, 37, 38]. We captured four balance measures in this study; area,

173 magnitude, jerk and f95 (the highest frequency of sway comprising 95% of the power) of

174 postural sway [12] (Table 1). Area refers to the amount of postural sway, including 95 % AP

175 and ML direction of the acceleration trajectories, and is measured using ellipsis (an elliptical

176 area of postural sway). An ellipsis calculates the scatter of center of mass data and represents

177 the extent to which an individual sways during upright standing. Magnitude of postural sway

178 refers to the root mean square (RMS) of the acceleration signal and is positively related to the

179 metabolic energy cost during upright standing [31]. A low magnitude of postural sway and

180 therefore a low metabolic cost is an optimisation criterion used to set postural control [31].

181 Jerk, on the hand refers to the 'smoothness of sway' and highlights the postural control of an

182 individual to maintain their balance in an upright position. It is calculated as the rate of change

183 of acceleration signals over time, essentially a time derivative of acceleration. The fourth

184 balance outcome, frequency of sway refers to how often an individual sways in space (number

185 of postural oscillations) whilst in upright standing. f95 is defined as the frequency below which

186 95% of power of acceleration power spectrum is observed (f95%) [37]. Balance outcomes were

187 normalized over time (120 seconds) for comparison with controls.

188 *Algorithm 2# Derivation of Fast Gait (Gait) Outcomes*

189 Initial contact/final contact events identified from the body-worn monitor vertical

190 acceleration were used to extract gait measures: (1) temporal characteristics, which included

191 individual step, stride (combined left and right step), stance and swing time to complete a fast

192 walk (total gait time) [40] (2) spatial characteristics, such as step length, which were

193 estimated using the inverted pendulum model [63] and (3) spatiotemporal characteristic step

194 velocity calculated as step length/step time. The other gait outcome captured using a body-

195 worn monitor adopting existing algorithms [22] was "step count," also referred to as "body-

196 worn monitor step count" [22].

197 *Algorithm 3# Derivation of iTUG Outcome*

198 Time taken to complete the 7-meter iTUG time was the primary outcome, estimated from raw

199 accelerometer signals using established algorithms [4].

200 *Clinical Interpretation of Normal Versus Impaired Body-worn Monitor Outcomes*

201 Using support from previous evidence, we classified patients with a very high postural sway

202 compared with healthy controls as impaired (poor function) [9] and those with lower values

203 or comparable to healthy controls as unimpaired (good function) (Fig. 3A-D). We classified

204 patients with high temporal values of gait, small step length and reduced step velocity as

205 impaired. Low iTUG time indicated better function (unimpaired) while high iTUG time

206 suggested poorer function (impaired) [62].

207 **Study Outcomes**

208 Our primary study outcome was to investigate whether accelerometer-based, body-worn

209 monitor assessments of balance, gait, and timed up and go tests (TUG) were feasible to use

210 and acceptable. The primary study outcome was evaluated by assessing the number of

211 datasets successfully obtained from patients, data loss during data processing, and

212 acceptability collected through feedback forms. Our secondary outcomes were to study

213 whether accelerometer-based, body-worn monitor assessments showed indicators of face

214 validity, discriminant validity, convergent validity and concurrent validity. The secondary

215 outcomes were assessed by comparing body-worn monitor outcomes to reference values in

216 the evidence, between patients and healthy controls to assess discriminant validity, body-

217 worn monitor outcomes to established clinical scales data to assess convergent validity, and

218 body-worn monitor outcomes to standard manual techniques to assess concurrent validity,

219 respectively.

220 **Statistical Analysis**

221 Parametric data were expressed using means and SDs (min–max) and nonparametric data

222 using medians with interquartile ranges (IQR). Body-worn monitor outcomes were compared

223 between patients and controls, and tumor subgroups using independent t or Mann-Whitney U

224 tests (to assess convergent validity). Bonferroni correction was used to address correction for

225 multiple measures for the between group comparisons. For the related gait variables (step

226 time, step length and step velocity) as the three tests were undertaken, the Bonferroni

227 correction was applied and alpha level was set at $0.05/3 = 0.016$. Only those tests showing

228 p values less than 0.016 for the three tests were considered as a significant difference.

229 Pearson's and Spearman's rho correlations were used to assess relationships between body-

230 worn monitor outcomes and clinic measures (for convergent validity). Correlations were

231 classified as strong (-1.0 to -0.5 or 0.5–1.0), moderate (-0.5 to -0.3 or 0.3–0.5) or weak (-0.3

232 to -0.1 or 0.1–0.3). Significance was defined at .05 level. ICC agreement and Bland Altman

233 analysis tested agreement between body-worn monitor measures and standard manual

234 techniques (for concurrent validity). ICC agreements were interpreted as: poor (< 0.5),

235 moderate (between 0.5 and 0.75), good (0.75 to 0.9) and excellent (> 0.9) [35, 46].

236 **Results**

237 In all, 34 adults with a mean age 43 ± 20 years participated (Fig. 1). Recruited patients

238 included those who were treated for bone (21) or soft tissue tumors (13) in the femur/thigh

239 (19), pelvis/hip (3), tibia/leg (9), or ankle/foot (3). Twenty-seven had limb-sparing surgery

240 and seven patients underwent amputation and median time from surgery was 79 months

241 (minimum – maximum, 33–108 months). Fifteen of 34 patients received chemotherapy, and

242 13 of 34 received radiotherapy (Table 2). Details of Individual patients are presented in Table

243 3.

244 *Feasibility, Data Loss and Acceptability of a Body-worn Monitor in the Clinic*

245 The body-worn monitor was feasible to use and quick to set up. Data downloading,

246 processing and derivation of outcomes took approximately 10 minutes. However, it took an

247 additional 10 to 20 minutes to tackle problems if they were encountered during data

248 processing. Of 34 adults who attended the laboratory assessment, one who was wheelchair

249 bound, reported a high level of disability and was unable to participate in any of the

250 laboratory tests, as this patient could not stand and perform transfers. We obtained balance

251 and iTUG data from the remaining 33 adult patients. Three adult patients did not participate

252 in the intermittent fast walk test due to fatigue or lack of time, leaving 30 gait patients for

253 analysis. In addition, one patient's step length outcome could not be calculated as the height

254 of the sensor from the floor was not available. There was minimal data loss; of 34 adult

255 assessments, 33 balance, 29 gait and 33 iTUG datasets were available for final analysis. A

256 larger data loss was seen due to patient not completing the test as opposed to the data been

257 lost during analysis process. Of 20 participants who returned feedback forms, 19 of 20 (95%)

258 found the body-worn monitor acceptable and comfortable, and 17 of 20 (85%) found it user-

259 friendly.

260

261 *Indicators of Face Validity, Discriminant Validity, Convergent Validity, and Concurrent*

262 *Validity by Accelerometer-based Body-worn Monitor Assessments*

263 Body-worn Monitor Balance, Gait and iTUG Outcomes in Patients Versus Healthy Controls

264 and Tumor Subgroups

265 Patients demonstrated alterations of balance and gait compared with controls. Patients

266 presented with higher ellipsis, RMS, and jerk than controls ($p < 0.05$), but with the numbers

267 available, we could not show a difference in frequency of sway ($p > 0.05$) (Table 4). For

268 instance, when comparing patients with controls, ellipsis was 0.0475 (95% CI, 0.0251–0.0810)

269 m^2/s^4 versus 0.0007 (95% CI, 0.0003–0.0502) m^2/s^4 ($p = 0.001$), RMS was 0.0020 (95% CI,

270 0.0016–0.0036) m/s^2 versus 0.0010 (95% CI, 0.0007–0.0042) m/s^2 ($p = 0.009$) and jerk was

271 0.0910 m^2/s^5 versus 0.0513 m^2/s^5 ($p = 0.004$). A p value is < 0.05 was considered statistically

272 significant. Patients presented with a large spread of in the above knee tumour groups, showed

273 trends towards a higher ellipsis and jerk (Fig. 4 A-B), compared to the below knee tumour

274 groups.

275 Patients also presented with higher step time, stance time, swing time, shorter step length and

276 lower step velocity than controls ($p < 0.05$) (Table 4). For instance, on comparing patients with

277 controls; step time was 0.483 (0.451–0.512) seconds (s) versus 0.541 (0.496–0.573) s; $p <$

278 0.001), stance time was 0.630 (0.576–0.672) s versus 0.680 (0.630–0.724) s ($p = 0.001$), swing

279 time was 0.328 (0.311–0.365) s versus 0.383 (0.348–0.424) s; $p < 0.001$), step length was 0.695

280 +/- 0.106 m versus 0.641 +/- 0.092 m; p=0.044, not significant after Bonferroni correction for

281 multiple measures was applied; step velocity 1.468 +/- 0.242 m/s versus 1.196+/-0.189; $p <$

282 0.001. There was also a wide spread of patients' gait values; in step time and step velocity

283 variables (Fig. 5 A-B) (With the numbers available, we could not detect a difference between

284 tumor subgroups ($p > 0.05$) (Table 4).

285   Patients had a mean iTUG time of 19.49 s (16.61–24.28). No differences were seen between

286   groups; those in the BT group showed values for iTUG time (19.82 s [95% CI, 16.93–24.95])

287   and the STS group (17.97s [95% CI, 15.86–24.03]) [p value = 0.889]. Patients in the limb-

288   sparing surgery group showed values of iTUG time (19.48 s [95% CI, 16.45 - 24.37]) and the

289   amputation group (19.34 s [95% CI, 16.52–23.79]) [p value = 0.203].

290   *Relationships Between Body-worn Monitor Balance, Gait and iTUG Outcomes and Existing*

291   *Clinical Scales*

292   Median TESS score was 83.6 (IQR, 62.1–93.8; range, 8.3–100.0), mean MSTS score 24.5 (SD

293   7.9; range, 5.0–35.0), median 3-meter TUG time 10.8 seconds (IQR, 8.5–12.7; range, 7.9–32.3)

294   s and median QoL-CS total score 7.1 (IQR, 6.1–7.8; range, 2.7–9.1).

295   Strong or moderate negative correlations were observed between MSTS, TESS, QoL-CS and

296   postural sway (Table 5), for instance ellipsis with MSTS ($r = -0.393$; $p = 0.024$), between MSTS

297   and total gait time ($r = -0.424$; $p = 0.022$) and MSTS and step velocity ($r = 0.424$; $p = 0.022$)

298   and between MSTS, TESS, and iTUG time ($p < 0.05$) (Table 5). This indicates that more

299   structural impairment is associated with impaired balance, gait, and reduced physical

300   capability. A p value < 0.05 was considered significant.

301   *Agreement of Body-worn monitor Measures with Manual Techniques*

302   Gait (Total Steps Measured by Body-worn monitor Versus Gold Standard Video): ICC showed

303   excellent agreement between techniques ($p < 0.05$) (Table 6), for instance stopwatch time 22.28

304   +/- 6.93 s with iTUG time 21.18 +/- 6.23 s (ICC agreement = 0.933; $p < 0.001$). Similarly step

305   counts recorded by body-worn monitors 13 +/- 3 showed an excellent agreement with step

306   count recorded by video 14 +/- 3 (ICC agreement 0.909; $p < 0.001$). Bland-Altman analysis

307   (Fig. 6) indicated that the body-worn monitor under-estimated step counts by 2 to 5 steps in

308   five patients. Bland-Altman analysis (Fig. 6) confirmed that in a small number of patients, poor

309 agreement was seen, predominantly in elderly patients who used their hands as support during

310 "sit to stand" and "stand to sit."

311 **Discussion**

312 Assessing patients treated for a bone or soft tissue tumors of the lower extremity is difficult

313 and often subjective. Gait labs can provide some useful information, but they are not

314 commonly available and not used routinely even for research investigations of tumor patients.

315 We therefore wanted to test a body-worn device to assess its potential value and relationship

316 to known clinical assessments of patients with lower extremity sarcomas. This is the first

317 study to our knowledge investigating body-worn monitor assessments of balance and gait

318 after sarcoma treatments. We showed that we could measure several parameters of gait and

319 function with this device and that it could discriminate between different patient groups.

320 *Limitations*

321 One major limitation of this study is that as a pilot study with multiple comparisons and a

322 small sample size the possibility of a Type 1 and Type 2 sampling error respectively, cannot

323 be eliminated. Bonferroni corrections could potentially be used as a solution to correct Type

324 1 sampling errors related to multiple comparisons [2]; however, these can increase the

325 chances of Type 2 errors [44]. Therefore, the sensitivity of measures to characterise outcomes

326 needs to be assessed in a larger study with a higher power. The heterogeneous sample also

327 makes it challenging to draw robust conclusions for distinct clinical subgroups. The use of

328 healthy controls recruited from different studies introduces potential sources of investigator

329 and selection bias, which are difficult to eliminate from the analysis. Body-worn monitor

330 clinic measures do not necessarily reflect behaviour in the real-world environment, and this

331 needs to be captured separately. Another key limitation is that although most responder

332 patients found this device acceptable; our response rate to the survey was low (59%). Further

333 larger studies are therefore needed.

334 *Feasibility, Data Loss and Acceptability of a Body-worn monitor in the Clinic*

335 We showed that body-worn monitors are feasible and straightforward to use, and at least in

336 those who answered our survey, were acceptable and user-friendly for patients. Clinically

337 useful outcomes could be obtained promptly, with minimal data loss. It was feasible to

338 capture postural control measures characterized by four relatively independent

339 characteristics: area, magnitude, frequency and jerk of sway; rhythm and pace domains of

340 gait and iTUG time. The feasibility of obtaining outcomes in a short time scale, minimal data

341 loss, acceptability, comfort in the clinic and user-friendliness of the device supports the

342 clinical usefulness of the device. As body-worn monitors are portable, functional evaluations

343 could also be performed at in the community, which may be helpful for remote patient

344 assessment. The strengths of the algorithms were that minimal data loss was encountered, and

345 they appeared effective across a range of age groups and functional characteristics [43, 60].

346 *Indicators of Face Validity, Discriminant Validity, Convergent Validity, and Concurrent*

347 *Validity by Accelerometer-based Body-worn Monitor Assessments*

348 Body-worn Monitor Outcomes in Tumor Patients Versus Controls, Evidence and Across

349 Tumor Subgroups

350 In our study, patients demonstrated altered balance and gait outcomes compared with healthy

351 individuals, which supports published studies [3, 9, 10]. These results contraindicated De

352 Visser et al. [9] in which no differences were detected between patients and controls by the

353 force platform for the standing (balance) test. This could be because our study included

354 patients after amputation; additionally, triaxial accelerometers may be more sensitive than

355 force platforms [39]. The increased step time, swing time, and reduced step velocity in

356 patients compared with controls also agrees with published reports [3, 10]; however, the

357 higher stance phase and shorter step length in our patients compared with controls contrasts

358 with published studies [10, 48]. This could be because our study used a combined value that

359 included the affected and unaffected limbs. Differences in step length in our study may also

360 reflect the inclusion of patients with limb-sparing surgery and amputation in different

361 anatomical locations, whereas Rompen et al. [48], only included patients with a femoral

362 endoprosthesis.

363 After resection of major bone and soft tissues for a lower extremity sarcoma, the loss of

364 sensory [58], motor [7], and proprioceptive [18] systems may disrupt physiological systems,

365 delaying the transmission of sensory data to the central nervous system. Therefore, an

366 appropriate timely response to activate postural muscle groups and maintain balance and

367 posture may not be formulated [28-30]. This might impact gait and performance tests (TUG),

368 explaining a higher iTUG time (poor physical capability) in our study patients [19.486s

369 (16.610 – 24.280)] compared with controls in the literature [14.3 ± 0.5 s] [62] although we do

370 not know if this is a true difference since we cannot directly compare. .

371 With the numbers we had, we could not detect a difference between BT and STS subgroups,

372 however, and more numbers of patients are needed to determine if our findings will support

373 the findings of others that BTs perform worse than STS and amputation patients perform

374 worse than limb-sparing surgery agrees with the evidence [1, 53]. It also makes clinical sense

375 because BT treatment generally needs more extensive surgery, including bone reconstruction;

376 and after amputation, major limb loss and disrupted sensory and proprioceptive input may

377 lead to poorer function [1, 36]. We could not demonstrate differences (for RMS_ML) until

378 categorized into homogenous groups, which highlights the importance of subgrouping in this

379 heterogeneous patient group.

380 *Body-worn Monitor Measures Against Existing Clinical Measures*

381 In our study, higher impairments (measured by MSTS) related to poor balance, gait, and

382 TUG outcomes. Furthermore, poor balance, gait, and TUG outcomes relate to greater

383 disability and reduced QoL (physical and social components). Relationships between balance

384   and QoL agree with findings in other clinical conditions [50, 55]. Therefore, simple clinic

385   tests can indicate which patients are at risk of higher disability and reduced QoL. When

386   outcomes in our study were mapped to the widely recognised International Classification of

387   Functioning, Disability and Health (ICF) framework [21], relationships were found to be

388   sensible between the body-worn monitor measures and existing clinic measures (an indicator

389   of convergent validity) and this information could be vital in informing rehabilitation.

390   *Agreement of Body-worn Monitor Measures with Manual Standard Techniques in Clinic*

391   Body-worn monitor measures demonstrated good or excellent agreement with standard

392   techniques, but some instances underestimated step counts. For example, in patients with

393   obvious gait deviations while walking, such as heel drag or low gait velocity (< 1.4 m/s),

394   some steps may not be detected. Slower gait speeds are known to cause step underestimation

395   [32, 49]; synchronization (communication of data) between devices at the start of assessment

396   might help.

397   Although an excellent agreement was observed between devices, stopwatch time was 1.1 s

398   higher than iTUG time, possibly due to errors in manual timing [26]. The body-worn monitor

399   time starts when the L5 monitor moves upwards during "sit to stand," whereas the stopwatch

400   runs between the command "Go" and "Stop." Poorest agreement appeared to be for slower

401   patients in whom the stopwatch had started before the body-worn monitor acceleration

402   threshold was reached, therefore showing body-worn monitor was late in capturing the initial

403   and final phases of the activity. Although the initial and final phases are important to capture,

404   a clear advantage of using a body-worn monitor is that a range of additional measures of

405   postural transitions and gait could be derived [62]. A single body-worn monitor can capture

406   multiple attributes of physical functioning quickly, which is advantageous in busy clinics.

407   **Conclusion**

408   This pilot study supports the feasibility, acceptability, and validity indicators for an

409   accelerometer-based BWM assessment of balance, gait, and iTUG outcomes in patients

410   treated for lower extremity musculoskeletal cancer. Structural impairments are associated

411   with poor balance, gait, and TUG outcomes, which in turn are associated with greater

412   disability and reduced QoL. Body-worn monitor measures demonstrated excellent agreement

413   between measurements, but in some instances, did not agree with standard techniques. In

414   summary, a laboratory assessment using a body-worn monitor can offer an alternative to

415   cumbersome systems for quantifying balance, gait, and iTUG outcomes.

416

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579

580 **Legends**

581 **Fig. 1** Flowchart of recruitment

582 **Fig. 2** (A) Photograph of a body-worn monitor device, the Axivity AX3, a triaxial

583 accelerometer that captures acceleration in vertical (X axis), mediolateral (Y axis) and AP (Z

584 axis) directions. (B) Body-worn monitor on the low back at fifth lumbar vertebra (L5) level

585 for laboratory testing. (C) Raw acceleration signal obtained from a body-worn monitor during

586 an activity. The orange line is the acceleration signal measured in the AP direction, the

587 yellow line is the acceleration signal measured in the mediolateral direction, and the blue line

588 is the acceleration signal measured in the vertical direction.

589 **Fig. 3** Examples of normal balance outcome versus impaired balance outcomes in patients are

590 shown here. (A) Normal ellipsis outcome in a 19-year-old male treated with above-knee

591 limb-sparing surgery (excision plus proximal femoral reconstruction) for a bone tumor in the

592 thigh demonstrates a low ellipsis $= 0.0113$ m^2/s^4, or a small area of postural sway. (B)

593 Impaired ellipsis outcome in a 22-year-old male treated with an above-knee amputation for a

594 bone tumor in the thigh demonstrates a high ellipsis $= 0.5890$ m^2/s^4, or a large area of

595 postural sway. (C) Normal f95 outcome in a 19-year-old female in the above-knee limb-

596 sparing surgery group (resection of adductor compartment of thigh for a soft tissue tumor)

597 demonstrates a low frequency of sway in the mediolateral direction $= 1.160$ Hz. (D) Impaired

598 outcome in a 22-year-old male treated with an above-knee amputation for a bone tumor in the

599 thigh demonstrates a high frequency of sway in the mediolateral direction, with a f95_ML $=$

600 3.140 Hz.

601 **Fig. 4** Jitter plots to show an increased postural sway in tumor patients compared with

602 healthy controls ($p < 0.05$). (A) Higher ellipsis in patients compared with heathy controls. (B)

603 Higher jerk in patients compared with healthy controls.

604   **Fig. 5** Jitter plots demonstrate an altered gait in tumor patients compared with healthy

605   controls ($p < 0.05$). (A) A higher step time is seen in patients compared with heathy controls.

606   (B) A lower step velocity is seen in patients compared with heathy controls.

607   **Fig. 6** Bland-Altman plots for body-worn monitor measures versus standard manual

608   techniques are shown here. (A) This figure shows the video step count versus body-worn

609   monitor step count. (B) The stopwatch TUG time versus the iTUG time is shown here.

610

611   **Supplemental Fig. 1**

612   This figure demonstrates the derivation of balance outcomes from the standing (balance) test

613   in a tumor patient. (A) Ellipsis derived from an accelerometer signal: On the y–z [(ML)-

614   (AP)] axis plane, the blue lines are the acceleration signal from BWM and red is the elliptical

615   area which includes 95 % acceleration trajectories in the AP and ML directions. The area of

616   sway was assessed using MATLAB® (R2012a) functions. (B) Frequency in mediolateral

617   direction (f95_ML) derived from an accelerometer signal. The power spectrum is represented

618   in red and final result below which 95% of the accelerations are present are represented by

619   the black dotted line. ML = mediolateral.

620   **Supplemental Fig. 2**

621   This image depicts the derivation of gait outcomes from the intermittent fast walk test in a

622   tumour patient. (A) The raw vertical acceleration signal during a fast walk trial is represented

623   by blue lines, which were used for data processing. (B) In this Zoomshot of initial contact

624   (IC) and final contact (FC) events, the pink diamond dots represent the initial contact and the

625   red dots represent the final contact and are used to derive temporal gait measures (step time,

626   stride time, stance time, swing time).

627   (C) We used the Inverted Pendulum Model to derive step length. The leg movement reflects

628   an inverted pendulum model, where l denotes the leg length, h denotes the vertical

629   displacement of L5 level, and step length is calculated. Reprinted with permission from

630   SAGE from Zhao Q, Zhang B, Wang J, Feng W, Jia W, Sun M. Improved method of step

631   length estimation based on inverted pendulum model. Int J Distrib Sens Netw. [Published

632   online ahead of print April 10, 2017]. doi: 10.1177/1550147717702914. Link to the article:

633   http://journals.sagepub.com/doi/abs/10.1177/1550147717702914

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636

637   **Supplemental Fig. 3**

638   This figure shows the iTUG time from the iTUG test in a tumour patient and the method of

639   iTUG time calculation of iTUG time. The algorithm uses the vertical acceleration to detect

640   the first crest representing "sit to stand component" and last crest representing "stand to sit"

641   component. Duration taken to complete iTUG test, also termed as iTUG time was calculated

642   as the time between two crests.