Validity and reliability of a shoe-embedded sensor module for measuring foot progression angle during over-ground walking

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ABSTRACT

Wearable systems are becoming increasingly popular for gait assessment outside of laboratory settings. A single shoe-embedded sensor module can measure the foot progression angle (FPA) during walking. The FPA has important clinical utility, particularly in populations with knee osteoarthritis, as it is a target for biomechanical treatments. However, the validity and the day-to-day reliability of FPA measurement using wearable systems during over-ground walking has yet to be established. Two gait analysis sessions on 20 healthy adults were conducted. During both sessions, participants performed natural over-ground walking in a motion capture laboratory and on a 100 m linear section of outdoor athletics track. FPA was measured in the laboratory via marker trajectory data, while the sensor module measured FPA during the outdoor track walking. Validity was examined by comparing the laboratory- and sensor-measured average FPA. Day-to-day reliability was examined by comparing the sensor-measured FPA between the first and second gait analysis sessions. Average absolute error between motion capture and sensor measured FPA were 1.7° and 2.1° at session 1 and 2, respectively. A Bland and Altman plot indicated no systematic bias, with 95% limit of agreement widths of 4.2° – 5.1°. Intraclass correlation coefficient (ICC) analysis resulted in good to excellent validity (ICC = 0.89 – 0.91) and reliability (ICC = 0.95). Overall, the shoe-embedded sensor module is a valid and reliable method of measuring FPA during over-ground walking without the need for laboratory equipment.

1. Introduction

Wearable sensors are becoming an increasingly viable and popular alternative to in-lab gait analysis (Benson et al., 2018) and are growing in popularity for use in clinical populations (Kavanagh and Menz, 2008; Kobsar et al., 2014; Mannini et al., 2016; Turcot et al., 2008b, 2009). The main advantages of wearable sensors are the relatively low cost, and the potential to collect biomechanical data in many environments (Benson et al., 2018; Caldas et al., 2017; Fong and Chan, 2010; Tao et al., 2012). While relative joint angles typically require multiple sensor modules (Favre et al., 2009; Seel et al., 2014; Tadano et al., 2013; Tadano et al., 2016; van der Straaten et al., 2018), segment orientations relative to a global reference frame only require a minimum of one sensor placed on the segment of interest. For example, the orientation of the foot (projected onto the horizontal plane) relative to the direction of walking, known as the foot progression angle (FPA), needs only a single sensor module mounted on the foot (Huang et al., 2016). Modifying FPA toward toe-in or toe-out (external or internal foot rotation, respectively) can redistribute knee joint load (Simic et al., 2013), an important risk factor in knee osteoarthritis disease progression (Chang et al., 2015; Davis et al., 2019). Therefore, a sensor module capable of measuring FPA is an important development and research goal.

A shoe-worn sensor module was developed and initially validated during treadmill walking at different speeds and FPAs (Huang et al., 2016). An embedded version of the sensor in the sole of the shoe exhibited excellent validity (ICC = 0.997) during treadmill walking at varying FPAs with an absolute error of 1.7° (1.0) (Xia et al., 2017). Despite these promising results, a treadmill is a highly controlled walking environment that may not represent real-world or over-ground walking biomechanics. Furthermore, day-to-day reliability of the sensor module has not been reported.
Therefore, the objectives of this study were to examine the concurrent validity and day-to-day reliability of a shoe-embedded sensor module capable of measuring FPA during over-ground walking. Specifically, the study aimed to evaluate (i) the validity of the sensor measured FPA during over-ground walking compared to laboratory-based motion capture (gold standard) and (ii) the day-to-day reliability of both sensor and motion capture-measured FPA. It was hypothesized that the sensor-measured FPA would exhibit good validity and day-to-day reliability.

2. Methods

A convenience sample of 20 young healthy adults (Table 1) was recruited from the surrounding university and community via electronic media and word of mouth. Participants provided written informed consent prior to enrolling in the study. This study was approved by the institutional Clinical Research Ethics Board.

Participants attended two separate testing sessions. Each session consisted of two separate over-ground walking collections at (i) an outdoor athletics track (TW) first, and (ii) an indoor instrumented laboratory walkway (LW) second. For each participant, the same pair of shoe and sensor combination was used during all testing sessions, and participants were asked to walk as naturally as possible during all data collection.

2.1. Walking conditions

The TW sessions consisted of five laps along a 100 m linear section of athletics track. A single magneto-inertial sensor module (see Supplementary File 1 – Sensor Design for more details) embedded within the sole of the right shoe (Fig. 1) recorded all the steps during track walking. Participants were free to walk naturally along a single lane of track; doing so maintained a linear walking trajectory overall, while allowing for small natural variation in walking trajectory (swerving), as might be expected during daily walking activity. On the same day (within 30 min) the LW sessions took place, which consisted of 15 walking passes along an instrumented 10 m walkway. The laboratory walkway was not long enough to accommodate >7 ipsilateral steps, which is required to define a stable heading vector for FPA calculation (Huang et al., 2016). Therefore, sensor and motion capture data could not be recorded simultaneously. Accordingly, a large sample of steps for both the LW and TW were recorded to better represent the participants’ natural walking biomechanics. Fourteen high-speed cameras (Motion Analysis Corp., CA, USA) sampling at 100 Hz recorded the positions of three retro-reflective markers (calcaneus, second metatarsal, sacrum) in three-dimensions during walking.

2.2. Data analysis

Sensor data were reduced using custom MATLAB scripts (2018a, Mathworks Inc., MA, USA). For each of the five TW walking laps, 15 steps were extracted (20th from last to 5th from last) resulting in 75 total steps per TW session. Selection of these steps prevented the inclusion of any gait anomalies associated with accelerating or decelerating at the beginning or end of the walk. Marker trajectories were filtered with a 4th-order Butterworth filter (cut-off frequency = 6 Hz) prior to modeling in commercially available software (Orthotrak V6.6.1, Motion Analysis Corp., CA, USA).

Motion-capture FPA was calculated as the angle between the long axis of the foot segment (the line bisecting the second metatarsal marker and the calcaneal marker) and the x-axis of the laboratory (walking direction). FPA was then averaged between 20% and 80% of stance for all steps within the capture volume (typically 2–3) per walking pass. Sensor-measured FPA was calculated in real time as the mean over 15 consecutive data points beginning three data points after heel strike. The forward axis of the sensor and the foot segment markers may not be perfectly aligned. Therefore, an offset at each testing session was calculated using previously published methods (Xia et al., 2017). This offset value was subtracted from the mean sensor FPA from each TW session.

For comparison with Xia et al. (2017), average and absolute FPA error within walking conditions and between sessions were calculated. Validity was examined by comparing FPA values from TW and LW within each session. Motion capture measured FPA was considered the gold standard. Reliability was examined by comparing FPA values from session 1 and session 2 within the TW or LW conditions, separately.
2.3. Statistical analysis

An a priori sample size calculation was performed (Shoukri et al., 2004) estimating 15 participants. Data violations were examined, and no outcome violated any test.

Sensor and motion capture FPA and FPA error are reported as mean (SD: standard deviation), with negative values corresponding to a toe-out foot orientation. Validity was addressed via FPA errors, Bland and Altman (BA) plots, and 95% limits of agreement (LOA) (Giavarina, 2015). Systematic bias was examined using a single-factor repeated measure analysis of variance (ANOVA). Finally, to supplement these results a two-way random effects intraclass correlation coefficient (ICC(2,k)) was computed. Day-to-day reliability was examined via an ICC(2,k), the standard error of the measurement (SEM), and the minimum detectable change (MDC) as previously described (Turcot et al., 2008a; Weir, 2005). For all ICC analyses, values were interpreted as follows: <0.5 = “poor”, 0.5–0.75 = “moderate”, 0.75 – 0.9 = “good”, and >0.9 = “excellent” (Koo and Li, 2016). For more details regarding all the statistical analyses, see Supplementary File 2 – Statistics.

3. Results

Sessions 1 and 2 occurred a mean of 4 days apart (range = 1–8). Mean sensor measured FPA magnitudes during TW were –5.9° (3.7) and –5.6° (4.1), while motion capture measured FPA magnitudes during LW were –5.3° (3.9) and –5.3° (4.0) for session 1 and 2, respectively. Average and absolute errors between- and within-conditions are reported in Table 2.

The BA plots for sessions 1 and 2 (Fig. 2) illustrate the systematic bias and LOA of the sensor module (see Supplementary Table 1). There was a small, nonsignificant systematic bias in the direction of toe-out which was confirmed by the ANOVA (p > 0.23, Supplementary Table 2). Furthermore, the results of the ICC(2,k) (Table 3) indicated “good” to “excellent” validity for session 1 and “moderate” to “excellent” validity for session 2, based on the 95% CIs.

Measures of the day-to-day relative and absolute reliability of both the sensor module and motion capture FPA measurements are reported in Table 3. Sensor relative reliability was “good” to “excellent” while motion capture relative reliability was “excellent”. The SEM and MDC were both larger for the sensor module compared to motion capture (27% and 25% larger, respectively). The sensor MDC indicated that any change in FPA greater than 3.5°, as measured by the sensor, can be considered real.

4. Discussion

The first objective of this study was to examine the validity of FPA measurement using a shoe-embedded sensor module com-
pared with the gold standard of laboratory-based motion capture. The second objective was to examine day-to-day reliability of the sensor for measuring FPA. This study is the first to examine the validity and reliability of the sensor module during over-ground walking. The results suggest that the sensor is both a valid and reliable means of measuring FPA during over-ground walking. The small average and absolute errors between sensor and motion capture FPA measurements further support these results.

The results support the first hypothesis that the sensor is valid for over-ground walking measurement of FPA. Compared to the previous treadmill validation (ICC = 0.997) (Xia et al., 2017), the current results indicate “good” to “excellent” validity (ICC = 0.89 – 0.91). Though ICC and Pearson correlation coefficients (see Supplementary Fig. 1) are common in the literature, these analyses are not ideal for examining validity in this context (Bland and Altman, 1990). The BA plot is preferred (Giavarina, 2015) and these results largely agree with the current studies ICC results. Additionally, the BA plots suggest similar validity when comparable to other sensor validations of pelvis (Bolink et al., 2016) and rearfoot segment orientations (Koska et al., 2018). Finally, a small, non-significant over estimation toward toe-out was observed. It is possible that any systematic bias is a product of different heading vectors definitions for sensor versus motion capture FPA calculations. Given that the systematic bias was nonsignificant, and the magnitude was <1°, this is likely not a concern. Overall, the findings indicate that the sensor is valid for measuring FPA during over-ground walking.

Laboratory-based motion capture is currently the gold standard method of measuring FPA, which has exhibited good to excellent reliability during treadmill and over-ground walking with healthy participants (Bechard et al., 2011; Meldrum et al., 2014). The current study’s results for motion capture reliability supports this previous work (ICC = 0.97), compared to the 0.8 (Meldrum et al., 2014) and 0.95 (Bechard et al., 2011) previously observed. Expectedly, the sensor exhibited lower but still “excellent” reliability, similar to a previous study of foot inertial outcomes (Kobsar et al., 2016). Additionally, the expected between-day error in measuring FPA via the sensor (SEM = 1.3°) was comparable, if not better than previous motion capture data (Bechard et al., 2011). Given these results, it is likely that the sensor module can be used for multiday studies. This suggests the sensor is well designed for measuring FPA within a gait modification study aiming to alter FPA, such as those conducted in populations with knee osteoarthritis (Charlton et al., 2018; Hunt et al., 2018; Simic et al., 2013). The MDC suggests that changes in FPA during such an intervention must be >3.5° to be considered actual changes. This is reasonable given that changes to FPA are often 7° or more (Hunt et al., 2018; Hunt and Takacs, 2014).

The results of this study need to be interpreted with the following limitations in mind. Given that a minimum of 7 steps of linear walking were required to “calculate” valid heading vector, simultaneous FPA measurement along the 10 m walkway during the 1W sessions could not be performed. Therefore, data were compared from separate walking sessions conducted on the same day (within 30 min of one another). However, many steps were extracted for comparison to better represent the average FPA during track walking. Second, the present study was conducted in young, healthy, pain-free participants, who may have more consistent gait biomechanics compared to older adults with knee osteoarthritis (Duffell et al., 2017). Lastly, although this study examined over-ground walking, the constraints of an athletics track may not fully represent real-world walking with many stops, starts, and changes of direction.

5. Conclusion

A discrete shoe-embedded sensor module that measures FPA in real time was examined for validity and reliability during over-ground walking. The current study’s results suggest the sensor exhibits “good” to “excellent” validity and reliability for outdoor over-ground FPA measurement. However, more work is needed to examine performance during daily walking activities over multiple days.

Conflict of interest statement

The authors have no conflicts to declare.

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Appendix A. Supplementary material

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jbiomech.2019.04.012.

References


