Using embedded prosthesis sensors for clinical gait analyses in people with lower limb amputation

A feasibility study

Manz, Sabina; Seifert, Dirk; Altenburg, Bjoern; Schmalz, Thomas; Dosen, Strahinja; Gonzalez-Vargas, Jose

Published in:
Clinical Biomechanics

DOI (link to publication from Publisher):
10.1016/j.clinbiomech.2023.105988

Publication date:
2023

Document Version
Publisher's PDF, also known as Version of record

Clinical Biomechanics 106 (2023) 105988

Contents lists available at ScienceDirect

Clinical Biomechanics

journal homepage: www.elsevier.com/locate/clinbiomech

Using embedded prosthesis sensors for clinical gait analyses in people with lower limb amputation: A feasibility study

Sabina Manz [a,c], Dirk Seifert [b], Bjoern Altenburg [a], Thomas Schmalz [a], Strahinja Dosen [c], Jose Gonzalez-Vargas [a,*]

[a] *Ottobock SE & Co. KGaA, Duderstadt, Germany*
[b] *Ottobock Healthcare Products, Vienna, Austria*
[c] *Department of Health Science and Technology, Aalborg University, Aalborg, Denmark*

ARTICLE INFO

Keywords:
Gait analysis
Embedded sensors
Prosthesis
Microprocessor-controlled knee

ABSTRACT

Background: Biomechanical gait analyses are typically performed in laboratory settings, and are associated with limitations due to space, marker placement, and tasks that are not representative of the real-world usage of lower limb prostheses. Therefore, the purpose of this study was to investigate the possibility of accurately measuring gait parameters using embedded sensors in a microprocessor-controlled knee joint.
Methods: Ten participants were recruited for this study and equipped with a Genium X3 prosthetic knee joint. They performed level walking, stair/ramp descent, and ascent. During these tasks, kinematics and kinetics (sagittal knee and thigh segment angle, and knee moment) were recorded using an optical motion capture system and force plates (gold standard), as well as the prosthesis-embedded sensors. Root mean square errors, relative errors, correlation coefficients, and discrete outcome variables of clinical relevance were calculated and compared between the gold standard and the embedded sensors.
Findings: The average root mean square errors were found to be 0.6°, 5.3°, and 0.08 Nm/kg, for the knee angle, thigh angle, and knee moment, respectively. The average relative errors were 0.75% for the knee angle, 11.67% for the thigh angle, and 9.66%, for the knee moment. The discrete outcome variables showed small but significant differences between the two measurement systems for a number of tasks (higher differences only at the thigh).
Interpretation: The findings highlight the potential of prosthesis-embedded sensors to accurately measure gait parameters across a wide range of tasks. This paves the way for assessing prosthesis performance in realistic environments outside the lab.

1. Introduction

Lower limb amputation significantly impacts the physical abilities and quality of life of those affected and can require substantial adjustments to their daily activities (Jordan et al., 2012). One of the most frequently used outcomes to measure the progress in the rehabilitation of people with lower limb amputations is the evaluation of mobility, as restrictions in mobility are good predictors of the quality of life (Pell et al., 1993). While the usage of prosthetic devices can improve gait performance or participation in everyday life activities, it can also result in altered movement patterns (Winter and Sienko, 1988). The continuous development of more advanced prosthetic legs, such as microprocessor-controlled and powered systems (e.g., Genium X3 by Ottobock SE & Co. KGaA or Power Knee by Össur) has already led to numerous improvements in gait kinematics and kinetics compared to purely passive systems, including increased walking speed (Kahle et al., 2008; Segal et al., 2006), reduced energy expenditure (Kahle et al., 2008; Seymour et al., 2007), and better walking symmetry (Kahle et al., 2008; Kaufman et al., 2012; Segal et al., 2012). However, the studies demonstrating such improvements were conducted in controlled laboratory environments, or they used users' self-reports to obtain an indirect insight in the performance of prosthetic limbs outside the lab. A more relevant evaluation of prosthesis performance would be an objective assessment while the device is used in the real world, but this

Abbreviations: OMCS, optoelectronic motion capture system; IMU, inertial measurement unit; TO, toe-off; RMSE, root mean square error; IQR, interquartile range.

* Corresponding author.
E-mail addresses: sabina.manz@ottobock.de (S. Manz), jose.gonzalez@ottobock.de (J. Gonzalez-Vargas).

https://doi.org/10.1016/j.clinbiomech.2023.105988
Received 30 January 2023; Accepted 10 May 2023
Available online 12 May 2023

requires the development of measurement methods that can be applied outside of a laboratory.

The golden standard for the evaluation of prosthetic devices includes clinical gait analyses performed using optoelectronic motion capture systems and force plates (OMCS) (Bellmann et al., 2010; Cutti et al., 2015; Dumas et al., 2009; Dumas et al., 2017; Ernst et al., 2017; Esposito et al., 2015; Fradet et al., 2010; Frossard et al., 2011; Herr and Grabowski, 2011; Koehler et al., 2014; Perry et al., 2004; Rusaw and Ramstrand, 2011; Schmalz et al., 2019; Seel et al., 2014). These measurement techniques provide the highest accuracy, but they also suffer from limitations including errors due to marker placement (Gorton et al., 2009), marker occlusion and unwanted reflections (spurious markers) from objects present in the capture volume (Cuadrado et al., 2021), soft tissue artifacts (Camomilla et al., 2017) and limited measurement volume. Therefore, only a limited number of activities (depending on the size of the laboratory) which are not necessarily representative of the real-life tasks can be recorded (e.g., 1–2 walking strides over perfectly flat ground). Furthermore, the equipment (cameras and force plates) is usually not portable and hence the measurement is bound to the gait laboratory. Due to this, the clinical gait analyses using OMCS might provide an assessment of participant's performance that is not representative of the daily life prosthesis use. This is especially because the use of a prosthesis can change substantially across different activities (e.g., walking vs. stair climbing). In addition, during lab recordings, the participants know that they are being watched and therefore try to give their best, or they might not act naturally (Cutti et al., 2015).

To overcome these limitations, researchers used inertial measurement units (IMUs) and wearable force transducers to replace OMCS and force plates, enabling them to conduct gait analyses in participants with amputation outside of a laboratory environment (Seel et al., 2014; Bolink et al., 2016; Clemens et al., 2020; Paradisi et al., 2019; Frossard et al., 2011; Dumas et al., 2009; Dumas et al., 2017; Fiedler et al., 2014; Frossard et al., 2003; Koehler et al., 2014; Simonetti et al., 2021). The reported error of these systems when measuring kinematics is $<1^{\circ}$ from the gold standard (OMCS) (Seel et al., 2014). The use of IMUs, however, is also associated with some challenges. They are external sensors that have to be placed and fixed on the participant as well as properly aligned to the limb segments. This requires an extra effort from the wearer or researcher and can result in positioning errors that can translate into over- or underestimation of the recorded movement variables (Bolink et al., 2016). Furthermore, only kinematic and spatio-temporal variables can be assessed using IMUs, while gait kinetics are not measured.

Importantly, advanced mechatronic lower limb prostheses are equipped with embedded sensors for control purposes that can measure different quantities, such as orientation, acceleration, angular velocity, joint angles, and loads (Bellmann et al., 2019). The internal sensors are advantageous as they do not need to be manually positioned and they improve wear compliance, as the prosthesis users do not have to remember to mount the sensors, because they are embedded in the prosthesis (Chadwell et al., 2020). Therefore, such sensors can collect valuable data during the activities of daily living without any extra effort. So far, the embedded sensors have been primarily used for the control of prostheses and during the development of a new device or controller, alone or in combination with IMUs (Diaz et al., 2018; Duraffourg et al., 2019; Gao et al., 2020; Pew and Klute, 2018; Stolyarov et al., 2018; Stolyarov et al., 2020; Su et al., 2019; Wentink et al., 2014; Zhang et al., 2019). Importantly, they could be also leveraged to bring the clinical gait analyses outside of a laboratory, thereby capturing the performance of prosthetic systems in a setting representative of the real world.

The validity and potential usage of these sensors for clinical gait analyses are, however, still not clear. Therefore, the aim of the present study was to investigate whether it is possible to accurately measure gait performance using the embedded device sensors. To this aim, kinematic and kinetic variables were measured by embedded device sensors while prosthesis users performed a comprehensive set of activities and the measured variables were then compared to those obtained using the golden standard of clinical gait analyses (OMCS).

2. Methods

2.1. Participants

Ten participants with transfemoral (above-knee) amputation were recruited for this study. All gave written informed consent to participate in the study. Ethics approval was granted by the Ethics Committee of the Medical University of Göttingen (Germany, no. 12/9/21). The demographics of the participants are shown in Table 1. During this study, a certified prosthetist set the participants up with a Genium X3 knee joint and a mechanical foot (Triton ($n = 7$), Taleo ($n = 2$), and Challenger ($n = 1$) from Ottobock SE & Co. KGaA, Duderstadt, Germany) according to the manufacturer's information and biomechanical guidelines (Bellmann et al., 2010). All participants were users of a microprocessor-controlled knee joint and a mechanical foot at the time of the study. Nine participants currently used a Genium (or Genium X3) device and one (participant 10) used a C-leg (all Ottobock SE & Co. KGaA, Duderstadt, Germany), but was also familiar with the use of a Genium X3. The participants did not have any other health conditions that could have affected their participation in this study (i.e., residual limb pain, unstable cardiovascular conditions, etc.)

2.2. Test setup

Thirty-four retroreflective markers were attached to anatomical landmarks on the participants' body and prosthetic limb to calculate joint angles and moments (Fig. 1 (c and d)). The marker set was developed specifically for gait analyses with transfemoral amputees. The measures obtained during this study were based on a subset of the attached markers (mostly on the prosthetic side, red markers in Fig. 1 (c and d)).

At the beginning of the session, a static trial on the force plate was recorded (while also recording the embedded sensors data). The participants were then asked to perform different tasks representative of everyday life in a laboratory environment (Fig. 1 (a)). The first task was over-ground level walking on a 10 m walkway at three self-selected walking speeds (normal, fast, and slow). The participants were asked to walk at their comfortable walking speed (normal), a slightly slower speed (e.g., as if they were strolling through the city), and a slightly faster speed (e.g., when being in a rush). The average walking speeds (mean ± standard deviation) were 0.94 ± 0.14 m/s, 1.28 ± 0.18 m/s, and 1.67 ± 0.17 m/s for slow, normal and fast walking, respectively. The second task consisted of ramp ascent and descent at 10° and 15° inclines. Lastly, the participants were asked to ascend and descend a set

Table 1
Participant demographics.

Participant	Age (years)	Weight (kg)	Height (cm)	Time since amputation (years)
1	51	79.5	169	44
2	56	85	178	41
3	54	75.5	178	31
4	32	85	190	15
5	48	96	182	40
6	32	74.5	177	5
7	58	92.5	185	39
8	31	83.5	198	5
9	62	63.5	167	30
10	51	74.5	186	27
Average ± SD	**47.50 ± 11.61**	**80.95 ± 9.54**	**181.00 ± 9.35**	**27.70 ± 14.64**

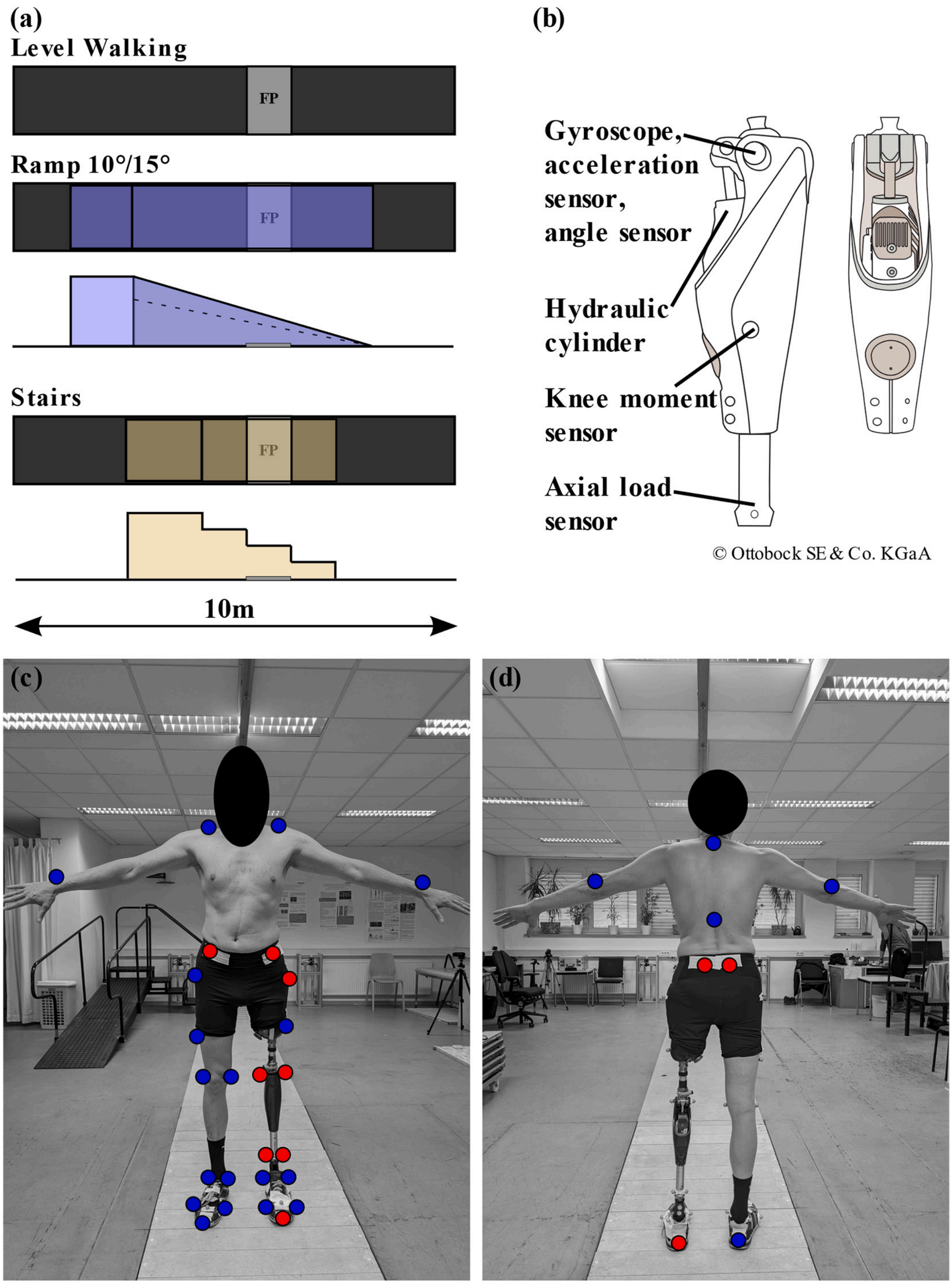

Fig. 1. Top left (a): Schematic of the test setup. From top down: Level walking top view, ramp top view, ramp side view (15° incline, dashed line represents 10° incline), stairs top view, stairs side view (FP: force plate). Top right (b): Schematic of the prosthesis-embedded sensors. Bottom (c-d): Overview of marker placement (front view - left, and back view - right). The markers were attached to the following landmarks: 7th cervical vertebrae, 10th thoracic vertebrae, left and right shoulder, elbow and wrist, anterior superior iliac spine, posterior superior iliac spine, trochanter major, thigh, medial and lateral knee joint, medial and lateral ankle joint, 1st and 5th metatarsal heads, heel, and toe. Two additional markers were placed on the prosthesis shank tube, one medially and one laterally (more proximal compared to the ankle markers). The motion tracking markers used in this study are indicated in red. (For interpretation of the references to colour in this figure legend, the reader is referred to the web version of this article.)

of stairs. The stairs consisted of four steps with heights of 17 cm each. The participants were asked to ascend and descend the stairs if possible in an alternating manner, i.e., by placing the foot directly on the next stair. Four out of the 10 participants were unable to ascend the stairs in an alternating manner, and no stair ascent data was collected in these cases, because the prostheses remains fully extended throughout the gait cycle. The tasks on the ramp and stairs were performed at a comfortable, self-selected walking speed. Each task was repeated until at least five valid trials were completed. Sufficient breaks during the trials were offered to the participants to reduce fatigue.

2.3. Sensor data acquisition and processing

The sensors embedded in the prosthetic knee joint included an axial encoder at the joint, a three degree of freedom IMU (one gyroscope and two accelerometers), a strain gauge in the hydraulics system and one in the distal shank pylon (Fig. 1 (b)). The data recorded by the prosthesis' embedded sensors included the knee moment, angle of the prosthesis' shank, and knee joint angle. The data was sampled by the internal prosthesis controller at 100 Hz and streamed via Bluetooth to a computer. The knee angle was measured using a magneto resistive axial encoder at the joint, while the shank angle was calculated by using the data from the three degree of freedom IMU and a sensor fusion algorithm. The loading of the knee joint was measured using the strain gauge based force sensor on the distal end of the hydraulics. The knee moment was calculated during post-processing from the hydraulic force, the knee angle and the kinematics of the three-bar linkage. Axial loading was measured via the strain gauge based sensor in the distal shank pylon (Fig. 1 (b)) and was only used for gait segmentation. In post-processing, the knee moment was filtered using a 4th order zero-phase Butterworth filter with a cut-off frequency of 15 Hz. The thigh segment angle was calculated from the shank angle and knee angle under the assumption of an ideal hinge joint. The angle data (both knee angle and thigh segment angle) were low-pass filtered using a 4th order zero-phase Butterworth filter with a cut-off frequency of 6 Hz. Heel strikes were derived from the axial loading of the prosthesis with a threshold of 20 N and used for gait cycle segmentation of the embedded sensor data. The acquisition and processing of the OMCS data are explained in supplementary material A.

2.4. Outcome variables

2.4.1. Deviation with respect to the benchmark

To synchronize the OMCS and the embedded sensor data, the signals computed from the motion capture system and force plates were down-sampled to match the sampling frequency of the embedded sensors (100 Hz). A cross-correlation was then used to determine the time lag between the motion capture and embedded sensor knee angle signals. The lag was defined as the time point of the maximum value of the cross-correlation function and was used to synchronize all the other signals. The time-synchronized signals were then used for comparison of the two systems. Pilot tests demonstrated that the knee and thigh segment angles obtained with the embedded sensors exhibited an offset. The offset was removed using the difference between the two systems in the static calibration trial.

The quality of measurements obtained by the embedded system with respect to the benchmark was assessed by computing Pearson correlation coefficients, root mean square errors (RMSE), and relative errors between the signals recorded by the embedded system and those measured by the OMCS. The relative error was calculated as a percentage relative to the range of motion obtained using the OMCS. The outcome variables were computed across one stride (from heel strike to heel strike of the same leg) for the knee and thigh segment angle, and across the stance time of one step (heel strike to toe-off (TO)) for the knee moment. The RMSE, relative errors and correlation coefficients obtained when measuring knee angle, thigh segment angle, and knee moment were compared between the three variables to assess if the accuracy of the embedded sensors depended on the variable of interest. More specifically, the RMSE for knee angle and thigh segment angles was compared using a Wilcoxon signed-rank test. The relative errors and the correlation coefficients were compared between the three variables using a Kruskal-Wallis test and then post-hoc pairwise comparisons with Bonferroni correction. Non parametric tests were employed as the data were not normally distributed (Shapiro-Wilk test). All tests were performed with a significance level of 0.05.

For each of the tasks and participants, five valid trials were processed and compared between the OMCS and the embedded sensors, resulting in 450 trials in total (10 participants, 9 tasks, 5 trials each). From this number, 28 trials (6.2%) had to be excluded from the data analysis. The majority of these trials were missing data because only six out of the 10 participants were able to ascend the stairs in an alternating manner (4.4% of the total trials). The remaining trials were discarded because of data processing issues (1.8% of the total trials), such as marker occlusions. The outcome variables were averaged for each participant across all nine tasks to obtain an overall estimate of the measurement quality.

2.4.2. Clinical variables

Additional comparison between the two systems was performed by computing the four clinical measures that have been frequently used in the literature to quantify gait biomechanics in a population with lower limb loss, namely, the peak knee flexion angle, peak thigh flexion angle at initial contact during all nine tasks, the peak thigh extension angle during level walking (at all three speeds) and ramp and stair ascent, and the peak knee flexion moment during level walking (in early stance, at all three speeds) and ramp and stair descent (Andrysek et al., 2020; Bellmann et al., 2010; Eberly et al., 2014; Fradet et al., 2010; Gates et al., 2013; Lura et al., 2015; Prinsen et al., 2017; Schmalz et al., 2014; Schmalz et al., 2019). In this case, the comparison was performed task-by-task by computing the average value over the task trials for each participant. The data was tested for normality using a Shapiro-Wilk test. The values obtained by the two measurement systems were then compared using a paired *t*-test when the data were normally distributed, or Wilcoxon signed-rank tests otherwise. The significance level was set to 0.05. The analysis was conducted using IBM SPSS Statistics for Windows, version 27 (IBM Corp., Armonk, N.Y., USA).

3. Results

The data recorded by the embedded sensors and OMCS from the amputated side while the participant performed level walking at normal speed, and ramp descent at 10° decline are shown in Fig. 2. There is an excellent agreement in the profiles of the knee angle while there are some deviations in the thigh segment angle and knee moment curves. The profiles match the expected normative profiles that characterize walking with a prosthesis (Burnfield et al., 2012; Segal et al., 2006; Vickers et al., 2008).

3.1. Average errors

Fig. 3 (a) shows the overall RMSE, relative error, and correlation coefficients between the OMCS and embedded sensors for the knee angle, thigh angle, and knee moment across all tasks included in the study. The average RMSE (median and interquartile range (IQR)) were 0.6° (IQR: 0.3), 5.3° (IQR: 3.1) and 0.08 Nm/kg (IQR: 0.01), for the knee angle, thigh segment angle, and knee moment, respectively. The average relative errors (median and IQR) were 0.75% (IQR: 0.38) for the knee angle, 11.67% (IQR: 8.25) for the thigh angle, and 9.66% (IQR: 2.07), for the knee moment. The summary results therefore agree with the observations from the representative profiles (Fig. 2), and the RMSE for the knee angle was significantly lower ($P < 0.001$) compared to that obtained for the thigh segment angle. The relative errors were significantly lower for the knee angle compared to the thigh segment angle ($P < 0.001$) and the knee moment ($P = 0.004$). Finally, the correlation coefficients showed strong correlations for all three variables (i.e., above 0.97 on average). Nevertheless, the correlation coefficients for the thigh segment angle ($P < 0.001$) and knee moment ($P = 0.004$) were significantly lower than for the knee angle (Fig. 3 (a)). These differences show that the performance of the embedded sensors in estimating the OMCS data varies depending on the variable of interest (i.e., knee angle, thigh angle, or knee moment).

3.2. Clinical variables

Regarding the clinically relevant variables (see Fig. 3 (b)), there were

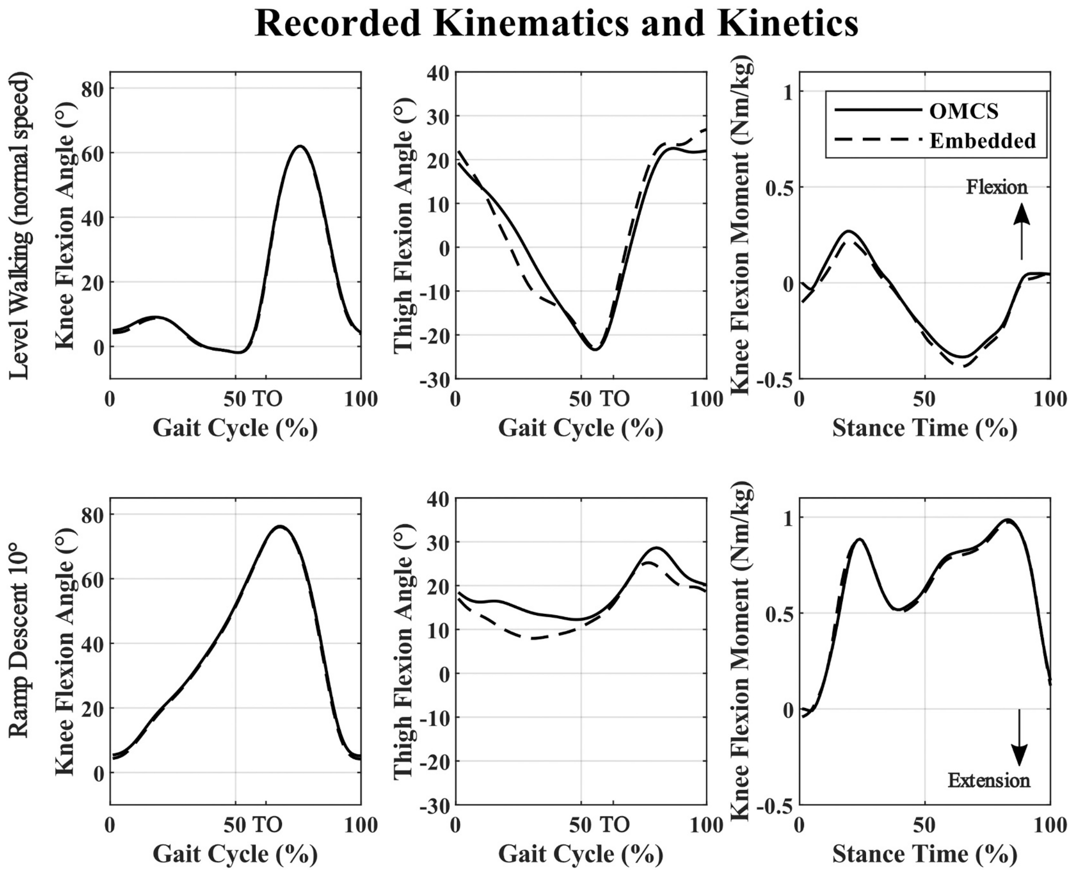

Fig. 2. Knee flexion angles, thigh flexion angles, and knee flexion moments for two representative gait cycles of participant 1 (top: during level walking at normal speed, bottom: during ramp descent at 10° decline). The solid and dashed lines represent the data recorded by the OMCS and the embedded prosthesis sensors, respectively. TO indicates toe off of the prosthesis side.

no significant differences between the values obtained by OMCS and the embedded sensors for the peak knee flexion angles during all tasks included in this study. However, the peak thigh flexion angle at initial stance during level walking at normal ($P < 0.017$, effect size: 0.76), fast ($P < 0.008$, effect size: 1.07), and slow speeds ($P = 0.013$, effect size: 0.97), during ramp descent at 10° ($P = 0.005$, effect size: 0.89) and 15° ($P = 0.022$, effect size: 0.73), and during stair ascent ($P = 0.009$, effect size: 1.70) and descent ($P = 0.001$, effect size: 1.66) was significantly higher (on average 5.3°) when measured by OMCS compared to the embedded sensors. Furthermore, the peak thigh extension angle during level walking at fast speed ($P = 0.005$, effect size: −0.89) was significantly lower (4.6°) when using OMCS compared to embedded sensors. Lastly, the peak knee flexion moment measured by the two systems also showed significant differences (on average 0.03 Nm/kg) during level walking at normal ($P < 0.001$, effect size: 2.26), fast ($P < 0.001$, effect size: 3.23), and slow speeds ($P < 0.001$, effect size: 3.03), and during ramp descent at 10° ($P = 0.035$, effect size: 0.78) and stair descent ($P < 0.001$, effect size: −2.91). Not all clinical outcome variables were assessed in all tasks as explained in the Methods section, which resulted in gaps for some tasks in Fig. 3 (b).

4. Discussion

This study aimed to determine whether it is possible to accurately measure gait performance using the sensors embedded in a prosthetic knee joint, to assess the feasibility of using prosthesis-embedded sensors for clinical gait analyses. Therefore, we have compared the kinematic and kinetic signals as well as clinically used discrete outcome variables estimated using embedded sensors to those computed by the reference measurement system (i.e., OMCS with force plates) across an extensive set of clinically relevant tasks. Overall, the results showed that the internal sensors can provide highly accurate estimates of the knee angle, and less accurate estimates for the thigh segment angle and knee moment. Furthermore, we found good estimations of the clinically relevant parameters for the peak knee flexion angle and peak thigh extension angle, small but statistically significant differences compared to the reference measurement for the peak knee flexion moment and larger statistically significant differences in the peak thigh flexion angle. A possible explanation for the larger deviaitons of the peak thigh flexion angle from the reference could be that the embedded sensors lack the information about the true hip joint center, defining the thigh segment. Furthermore, the relative movement of the residual limb inside the socket of the prosthesis cannot be assessed with the embedded sensors nor the OMCS. In both cases, it is assumed that the thigh segment was a rigid body.

Overall, the deviations in the knee angle profiles obtained by the embedded sensors were small (< 1%), and the correlations were high with respect to the gold standard (OMCS). The values reported in the present study are in accordance with previously published data obtained by externally placed sensors. Wearable sensors have been shown to accurately measure foot kinematics during gait with an average RMSE of 2.7° compared to motion capture data (Bidabadi et al., 2018). The RMSE when measuring the knee angle of a person with transfemoral amputation using IMUs and an OMCS during walking at a self-selected speed was on average 0.7° on the prosthesis side, and 3.3° on the unaffected side (Seel et al., 2014). A study comparing shank orientation angles during gait obtained using IMUs and an OMCS reported an RMSE of 2.4° on average in the sagittal plane (Duraffourg et al., 2019). Importantly, the accuracies reported in the present study originated from a variety of motor tasks (level walking at different speeds, ramp and stair ascent, and

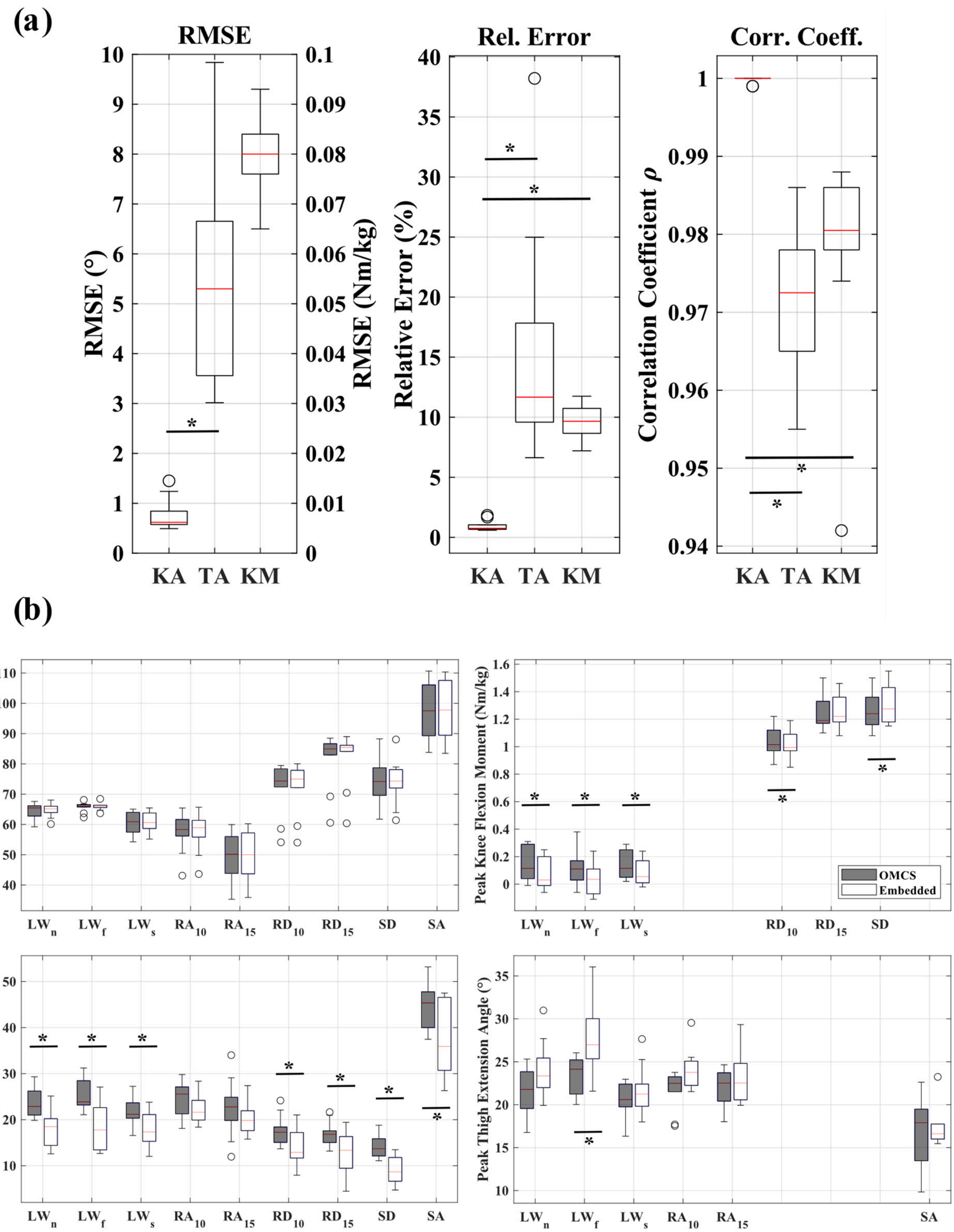

Fig. 3. (a) Box plots of average errors and correlation coefficients between the OMCS and embedded sensors for knee angle (KA), thigh angle (TA), and knee moment (KM) across all tasks. (b) Box plots of clinical outcome variables obtained using OMCS and embedded sensor data, grouped by tasks (LW_n, LW_f, and LW_s: level walking at normal, fast and slow speed, respectively; RA_{10}, RA_{15}: ramp ascent at 10° and 15°, RD_{10}, RD_{15}: ramp descent at 10 and 15°; SA, SD: stair ascent and descent). The circles indicate outliers in the data set, and the asterisks indicate statistically significant differences ($P < 0.05$).

descent), while the majority of the current literature focused on level walking only. Overall, the embedded sensors provided an accurate estimate of sagittal plane knee angles in the analysed tasks compared to the OMCS. The higher thigh segment angle RMSE could be due to the relative movement of residual limb and prosthetic socket, as already noted above. Furthermore, for some participants an offset between the embedded sensor and the OMCS thigh angle data could not be fully removed using the information from the static trials. The deviations between embedded sensors and OMCS seemed to have increased in the dynamic trials, compared to the static trial.

Previously reported average correlation coefficients between stance phase sagittal ankle and knee moments computed by inverse dynamics and those measured by a prosthesis integrated load cell in people with transtibial amputation were 0.95 and 0.79, with an RMSE of 8.16% and 16.98%, respectively (Fiedler et al., 2014). A deviation of 16% was still considered a small error in the literature, when studying the effect of mass and inertia on inverse dynamics calculations (Narang et al., 2016). The accuracy in estimating the knee moment using embedded sensing obtained across different motor tasks in the present study (average relative error < 10%) is therefore similar to that published by (Fiedler et al., 2014). In the present study inertia effects in the OMCS analysis were neglected (ground reaction force vector technique). This approach has been used in the literature (Dumas et al., 2009; Fantozzi et al., 2012) and it has been recognized as a good clinical estimate, especially at the knee and ankle during lower walking speeds (Wells, 1981). Nevertheless, the ground reaction force vector technique prevented the study of the knee moment during the swing phase. To perform the full inverse dynamics analysis, the mechanical and inertial properties of the specific prosthesis would need to be estimated. Even when those properties are considered in the literature, they are simplified by assuming uniform adjustments on segment mass and simple shifting of the center of mass location without taking into account damping or friction in the prosthetic joint (Dumas et al., 2017; Gaffney et al., 2017).

Finally, the analysis of the discrete clinically relevant variables (peak knee and thigh flexion angle, peak thigh extension angle, and peak knee flexion moment) revealed few cases with significant differences between the embedded and OMCS system. Most of the differences were found when comparing the knee moment and thigh flexion angle, and this could be due to several factors (e.g., the accuracy of the center of pressure data, limitations of ground reaction force vector technique, offset removal using static trials, etc.). Nevertheless, as stated earlier, the errors in the knee flexion moment were overall small. The largest differences in the peak knee flexion moment were detected during the stance phase of level walking. However, the flexion moments during this gait phase were generally very low in absolute numbers (< 0.4 Nm/kg), compared to those obtained during other tasks. Therefore, it is likely that the obtained differences in clinically-relevant gait parameters do not have a significant clinical impact, but this still needs to be confirmed in dedicated tests.

4.1. Study limitations

The sample of ten participants does not reflect a wide spectrum of the lower limb prosthetic users, especially because only male participants were included. A larger participant sample with an added focus on the unaffected limb and other biomechanical outcome variables (e.g., gait symmetry, or hip moments) should be included in future research to increase the generalizability of the results.

As explained in the methods and supplementary materials, the detection of heel strike and TO was conducted using force thresholds (for the embedded sensors data and the first heel strike of the OMCS) and the position and velocity of the heel marker (for the second heel strike of the OMCS) because force plate data were not available for two consecutive heel strikes of the same leg. Although the heel strike and TO was inspected visually and corrected accordingly, in some cases, this procedure introduced a slight uncertainty, i.e., a potential 1-frame shift (i.e. 10 ms) between the data obtained by the OMCS and the embedded sensors. Therefore, some of the observed errors in the present study might have been introduced due to this unprecise detection of heel strike and TO.

The analysis was further limited by the available embedded sensor outputs, which were all in the sagittal plane. In the future, it would be interesting to include three dimensional kinematic outputs as well, for example, the three dimensional orientation of the thigh, which is indeed relevant in certain clinical applications (Bae et al., 2007). The comparison of the axial load to the measured ground reaction forces was not performed in this study, because this sensor is not a standard part of the system but is only available in this specific prosthetic knee joint.

4.2. Real-life application

The results of the present study are encouraging for the potential use of the embedded sensors to assess and evaluate gait parameters in the everyday lives of people with lower limb amputation. The use of embedded sensing would enable overcoming many of the limitations of the current state-of-the-art systems for clinical gait analyses, which rely on costly equipment that cannot be easily used outside of a laboratory. The sensors embedded in prosthetic devices could assess the effectiveness of the device in realistic scenarios, track changes in the gait patterns over time and provide objective data that could complement the subjective information from self-reported questionnaires. Importantly, the sensors could be used for either short-term (clinical) or long-term (daily-life) recordings outside of a laboratory. In the former case, the embedded sensors enable recording of many steps in a realistic environment as the subject is not confined to the limited space of a human performance lab. Moreover, the setup time will decrease, as the users do not have to undergo a potentially time-consuming preparation because the sensors are embedded in the device, and the recording can start right away. Long-term recordings allow the tracking of gait pattern changes over time and day-to-day variances, for example due to the individual's daily condition. In the case of long-term recordings, interpretation of the measurement can be a challenge as the data are not labelled (e.g., the context is not known). However, microprocessor-controlled prosthetic devices are able to recognize gait phases and modalities which can help with the labelling. Finally, even without labelling and in both short and long-term recordings, the embedded sensors can be used to assess the effect of an intervention (e.g., enhancing a prosthesis with feedback, or a new control method) or accommodation to a new prosthetic device on gait kinematics and kinetics (e.g., an increase in range of motion of a joint).

5. Conclusions

The present study demonstrated that embedded prosthesis sensors can be used to estimate several kinetic and kinematic variables across a wide range of tasks within an accuracy reported in previous literature for wearable systems. However, the accuracy of the embedded sensor estimates compared to the benchmark with respect to discrete clinically relevant variables showed a decrease in the accuracy for the peak knee flexion moment (small but statistically significant differences) as well as the peak thigh flexion angle (larger differences). The embedded sensors can be therefore employed to collect comprehensive gait data on prosthesis use outside of the lab, but some discrete outcomes should be handled with care. In the future, a larger study including a more diverse sample of prosthetic users with measurements outside of the laboratory environment (e.g., continuous tracking in their daily life) should be conducted in order to validate the findings in this study.

Declaration of Competing Interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests:

Sabina Manz reports a relationship with Ottobock SE & Co KGaA that includes: employment. Dirk Seifert reports a relationship with Ottobock Healthcare Products GmbH that includes: employment. Bjoern Altenburg reports a relationship with Ottobock SE & Co KGaA that includes: employment. Thomas Schmalz reports a relationship with Ottobock SE & Co KGaA that includes: employment. Jose Gonzalez-Vargas reports a relationship with Ottobock SE & Co KGaA that includes: employment.

Acknowledgements

This work is supported by the Marie Skłodowska-Curie Actions (MSCA) Innovative Training Networks (ITN) H2020-MSCA-ITN-2019 - 860850 – SimBionics (Neuromechanical Simulation and Sensory Feedback for the Control of Bionic Legs).

We thank Dr. Roland Auberger (Ottobock Healthcare Products) for his support during the creation of this manuscript.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.clinbiomech.2023.105988.

References

Andrysek, Jan, García, Daniela, Rozbaczylo, Claudio, Alvarez-Mitchell, Carlos, Valdebenito, Rebeca, Rotter, Karin, et al., 2020. Biomechanical responses of young adults with unilateral transfemoral amputation using two types of mechanical stance control prosthetic knee joints. Prosthetics Orthot. Int. 44 (5), 314–322. https://doi.org/10.1177/0309364620916385.

Bae, Tae Soo, Choi, Kuiwon, Hong, Daehie, Mun, Museong, 2007. Dynamic analysis of above-knee amputee gait. Clin. Biomech. (Bristol, Avon) 22 (5), 557–566. https://doi.org/10.1016/j.clinbiomech.2006.12.009.

Bellmann, Malte, Schmalz, Thomas, Blumentritt, Siegmar, 2010. Comparative biomechanical analysis of current microprocessor-controlled prosthetic knee joints. Arch. Phys. Med. Rehabil. 91 (4), 644–652. https://doi.org/10.1016/j.apmr.2009.12.014.

Bellmann, Malte, Köhler, Thomas Maximilian, Schmalz, Thomas, 2019. Comparative biomechanical evaluation of two technologically different microprocessor-controlled prosthetic knee joints in safety-relevant daily-life situations. Biomed Tech (Berl) 64 (4), 407–420. https://doi.org/10.1515/bmt-2018-0026.

Bidabadi, Sharif Shiva, Murray, Iain, Lee, Gabriel Yin Foo, 2018. Validation of foot pitch angle estimation using inertial measurement unit against marker-based optical 3D motion capture system. Biomed. Eng. Lett. 8 (3), 283–290. https://doi.org/10.1007/s13534-018-0072-5.

Bolink, S.A.A.N., Naisas, H., Senden, R., Essers, H., Heyligers, I.C., Meijer, K., Grimm, B., 2016. Validity of an inertial measurement unit to assess pelvic orientation angles during gait, sit-stand transfers and step-up transfers: comparison with an optoelectronic motion capture system. Med. Eng. Phys. 38 (3), 225–231. https://doi.org/10.1016/j.medengphy.2015.11.009.

Burnfield, Judith M., Eberly, Valerie J., Gronely, Joanne K., Perry, Jacquelin, Yule, William Jared, Mulroy, Sara J., 2012. Impact of stance phase microprocessor-controlled knee prosthesis on ramp negotiation and community walking function in K2 level transfemoral amputees. Prosthetics Orthot. Int. 36 (1), 95–104. https://doi.org/10.1177/0309364611431611.

Camomilla, Valentina, Dumas, Raphaël, Cappozzo, Aurelio, 2017. Human movement analysis: the soft tissue artefact issue. J. Biomech. 62, 1–4. https://doi.org/10.1016/j.jbiomech.2017.09.001.

Chadwell, Alix, Diment, Laura, Micó-Amigo, M., Ramírez, Morgado, Dafne, Z., Dickinson, Alex, Granat, Malcolm, et al., 2020. Technology for monitoring everyday prosthesis use: a systematic review. J. Neuro Eng. Rehabil. 17 (1), 93. https://doi.org/10.1186/s12984-020-00711-4.

Clemens, Sheila, Kim, Kyoung Jae, Gailey, Robert, Kirk-Sanchez, Neva, Kristal, Anat, Gaunaurd, Ignacio, 2020. Inertial sensor-based measures of gait symmetry and repeatability in people with unilateral lower limb amputation. Clin. Biomech. 72, 102–107. https://doi.org/10.1016/j.clinbiomech.2019.12.007.

Cuadrado, Javier, Michaud, Florian, Lugrís, Urbano, Pérez Soto, Manuel, 2021. Using accelerometer data to tune the parameters of an extended Kalman filter for optical motion capture: preliminary application to gait analysis. Sensors (Basel, Switzerland) 21 (2). https://doi.org/10.3390/s21020427.

Cutti, Andrea G., Raggi, Michele, Andreoni, Giuseppe, Sacchetti, Rinaldo, 2015. Clinical gait analysis for amputees: innovation wishlist and the perspectives offered by the outwalk protocol. G Ital Med. Lav. Ergon. 37.

Diaz, Jean P., Silva, Da, Rafael, L., Zhong, Boxuan, Huang, He Helen, Lobaton, Edgar, 2018. Visual terrain identification and surface inclination estimation for improving human locomotion with a lower-limb prosthetic. In: Annual International Conference of the IEEE Engineering in Medicine and Biology Society, pp. 1817–1820. https://doi.org/10.1109/EMBC.2018.8512614.

Dumas, R., Cheze, L., Frossard, L., 2009. Loading applied on prosthetic knee of transfemoral amputee: comparison of inverse dynamics and direct measurements. Gait Posture 30 (4), 560–562. https://doi.org/10.1016/j.gaitpost.2009.07.126.

Dumas, Raphael, Branemark, Rickard, Frossard, Laurent, 2017. Gait analysis of transfemoral amputees: errors in inverse dynamics are substantial and depend on prosthetic design. IEEE Trans. Neural Syst. Rehabil. Eng. Publ. IEEE Eng. Med. Biol. Soc. 25 (6), 679–685. https://doi.org/10.1109/TNSRE.2016.2601378.

Duraffourg, Clément, Bonnet, Xavier, Dauriac, Boris, Pillet, Hélène, 2019. Real time estimation of the pose of a lower limb prosthesis from a single shank mounted IMU. Sensors (Basel, Switzerland) 19 (13). https://doi.org/10.3390/s19132865.

Eberly, Valerie J., Mulroy, Sara J., Gronley, JoAnne K., Perry, Jacquelin, Yule, William J., Burnfield, Judith M., 2014. Impact of a stance phase microprocessor-controlled knee prosthesis on level walking in lower functioning individuals with a transfemoral amputation. Prosthetics Orthot. Int. 38 (6), 447–455. https://doi.org/10.1177/0309364613506912.

Ernst, Michael, Altenburg, Björn, Bellmann, Malte, Schmalz, Thomas, 2017. Standing on slopes - How current microprocessor-controlled prosthetic feet support transtibial and transfemoral amputees in an everyday task. J. Neuro Eng. Rehabil. 14 (1), 1–16. https://doi.org/10.1186/s12984-017-0322-2.

Esposito, Elizabeth Russell, Whitehead, Jennifer, Aldridge, M., Wilken, Jason M., 2015. Step-to-step transition work during level and inclined walking using passive and powered ankle-foot prostheses. Prosthetics Orthot. Int. 40 (3), 311–319. https://doi.org/10.1177/0309364614564021.

Fantozzi, Silvia, Garofalo, Pietro, Cutti, Andrea G., Stagni, Rita, 2012. 3D Joint moments in transfemoral and transtibial amputees: when is the "ground reaction vector technique" an alternative to inverse dynamics? J. Mech. Med. Biol. 12 (04), 1250061 https://doi.org/10.1142/S0219519412004983.

Fiedler, Goeran, Slavens, Brooke, Smith, Roger O., Briggs, Douglas, Hafner, Brian J., 2014. Criterion and construct validity of prosthesis-integrated measurement of joint moment data in persons with transtibial amputation. J. Appl. Biomech. 30 (3), 431–438. https://doi.org/10.1123/jab.2013-0309.

Fradet, Laetitia, Alimusaj, Merkur, Braatz, Frank, Wolf, Sebastian I., 2010. Biomechanical analysis of ramp ambulation of transtibial amputees with an adaptive ankle foot system. Gait Posture 32 (2), 191–198. https://doi.org/10.1016/j.gaitpost.2010.04.011.

Frossard, Laurent, Beck, Jim, Dillon, Michael, Evans, John, 2003. Development and preliminary testing of a device for the direct measurement of forces and moments in the prosthetic limb of transfemoral amputees during activities of daily living. J. Prosthet. Orthot. 15 (4), 135–142. https://doi.org/10.1097/00008526-200310000-00005.

Frossard, Laurent, Cheze, Laurence, Dumas, Raphael, 2011. Dynamic input to determine hip joint moments, power and work on the prosthetic limb of transfemoral amputees: ground reaction vs knee reaction. Prosthetics Orthot. Int. 35 (2), 140–149. https://doi.org/10.1177/0309364611409002.

Gaffney, Brecca M.M., Christiansen, Cory L., Murray, Amanda M., Myers, Casey A., Laz, Peter J., Davidson, Bradley S., 2017. The effects of prosthesis inertial parameters on inverse dynamics: a probabilistic analysis. J. Verific. Validat. Uncertainty Quantific. 2.

Gao, Fei, Liu, Gaoyu, Liang, Fengyan, Liao, Wei-Hsin, 2020. IMU-based locomotion mode identification for transtibial prostheses, orthoses, and exoskeletons. IEEE Trans. Neural Syst. Rehabil. Eng. Publ. IEEE Eng. Med. Biol. Soc. 28 (6), 1334–1343. https://doi.org/10.1109/TNSRE.2020.2987155.

Gates, Deanna H., Aldridge, Jennifer M., Wilken, Jason M., 2013. Kinematic comparison of walking on uneven ground using powered and unpowered prostheses. Clin. Biomech. 28 (4), 467–472. https://doi.org/10.1016/j.clinbiomech.2013.03.005.

Gorton, George E., Hebert, David A., Gannotti, Mary E., 2009. Assessment of the kinematic variability among 12 motion analysis laboratories. Gait Posture 29 (3), 398–402. https://doi.org/10.1016/j.gaitpost.2008.10.060.

Herr, Hugh, Grabowski, Alena M., 2011. Bionic ankle-foot prosthesis normalizes walking gait for persons with leg amputation. Proc. R. Soc. B Biol. Sci. 279 (1728), 457–464. https://doi.org/10.1098/rspb.2011.1194.

Jordan, Robert Warner, Marks, Avi, Higman, Daniel, 2012. The cost of major lower limb amputation: a 12-year experience. Prosthetics Orthot. Int. 36 (4), 430–434. https://doi.org/10.1177/0309364612441489.

Kahle, Jason T., Highsmith, M., Jason; Hubbard, Sandra L., 2008. Comparison of nonmicroprocessor knee mechanism versus C-Leg on Prosthesis Evaluation Questionnaire, stumbles, falls, walking tests, stair descent, and knee preference. J. Rehabil. Res. Dev. 45 (1), 1–14. https://doi.org/10.1682/jrrd.2007.04.0054.

Kaufman, Kenton R., Frittoli, Serena, Frigo, Carlo A., 2012. Gait asymmetry of transfemoral amputees using mechanical and microprocessor-controlled prosthetic knees. Clin. Biomech. 27 (5), 460–465. https://doi.org/10.1016/j.clinbiomech.2011.11.011.

Koehler, Sara R., Dhaher, Yasin Y., Hansen, Andrew H., 2014. Cross-validation of a portable, six-degree-of-freedom load cell for use in lower-limb prosthetics research. J. Biomech. 47 (6), 1542–1547. https://doi.org/10.1016/j.jbiomech.2014.01.048.

Lura, Derek J., Wernke, Matthew M., Carey, Stephanie L., Kahle, Jason T., Miro, Rebecca M., Highsmith, M. Jason, 2015. Differences in knee flexion between the Genium and C-Leg microprocessor knees while walking on level ground and ramps. Clin. Biomech. 30 (2), 175–181. https://doi.org/10.1016/j.clinbiomech.2014.12.003.

Narang, Yashraj S., Arelekatti, V.N., Murthy; Winter, Amos G., 2016. The effects of prosthesis inertial properties on prosthetic knee moment and hip energetics required to achieve able-bodied kinematics. IEEE Trans. Neural Syst. Rehabil. Eng. Publ. IEEE Eng. Med. Biol. Soc. 24 (7), 754–763. https://doi.org/10.1109/TNSRE.2015.2455054.

Paradisi, Francesco, Di Stanislao, Eugenio, Summa, Aurora, Brunelli, Stefano, Traballesi, M., Vannozzi, Giuseppe, 2019. Upper body accelerations during level walking in transtibial amputees. Prosthetics Orthot. Int. 43 (2), 204–212. https://doi.org/10.1177/0309364618792745.

Pell, J.P., Donnan, P.T., Fowkes, F.G.R., Ruckley, C.V., 1993. Quality of life following lower limb amputation for peripheral arterial disease. Eur. J. Vasc. Surg. 7 (4), 448–451. https://doi.org/10.1016/S0950-821X(05)80265-8.

Perry, Jacquelin, Burnfield, Judith M., Newsam, Craig J., Conley, Phil, 2004. Energy expenditure and gait characteristics of a bilateral amputee walking with C-leg prostheses compared with stubby and conventional articulating prostheses. Arch. Phys. Med. Rehabil. 85 (10), 1711–1717. https://doi.org/10.1016/j.apmr.2004.02.028.

Pew, Corey, Klute, Glenn K., 2018. Turn intent detection for control of a lower limb prosthesis. IEEE Trans. Biomed. Eng. 65 (4), 789–796. https://doi.org/10.1109/TBME.2017.2721300.

Prinsen, E.C., Nederhand, M.J., Sveinsdóttir, H.S., Prins, M.R., van der Meer, F., Koopman, H.F.J.M., Rietman, J.S., 2017. The influence of a user-adaptive prosthetic knee across varying walking speeds: a randomized cross-over trial. Gait Post. 51, 254–260. https://doi.org/10.1016/j.gaitpost.2016.11.015.

Rusaw, David, Ramstrand, Nerrolyn, 2011. Motion-analysis studies of transtibial prosthesis users: a systematic review. Prosthetics Orthot. Int. 35 (1), 8–19. https://doi.org/10.1177/0309364610393060.

Schmalz, Thomas, Bellmann, Malte, Proebsting, Eva, Blumentritt, Siegmar, 2014. Effects of adaptation to a functionally new prosthetic lower-limb component: results of biomechanical tests immediately after fitting and after 3 months of use. J. Prosthet. Orthot. 26 (3), 134–143. https://doi.org/10.1097/JPO.0000000000000028.

Schmalz, Thomas, Altenburg, Björn, Ernst, Michael, Bellmann, Malte, Rosenbaum, Dieter, 2019. Lower limb amputee gait characteristics on a specifically designed test ramp: preliminary results of a biomechanical comparison of two prosthetic foot concepts. Gait Posture 68, 161–167. https://doi.org/10.1016/j.gaitpost.2018.11.017. March 2018.

Seel, Thomas, Raisch, Jörg, Schauer, Thomas, 2014. IMU-based joint angle measurement for gait analysis. Sensors (Basel, Switzerland) 14 (4), 6891–6909. https://doi.org/10.3390/s140406891.

Segal, Ava D., Orendurff, Michael S., Klute, Glenn K., McDowell, Martin L., Pecoraro, Janice A., Shofer, Jane, Czerniecki, Joseph M., 2006. Kinematic and kinetic comparisons of transfemoral amputee gait using C-Leg and Mauch SNS prosthetic knees. J. Rehabil. Res. Dev. 43 (7), 857–870. https://doi.org/10.1682/jrrd.2005.09.0147.

Segal, Ava D., Zelik, Karl E., Klute, Glenn K., Morgenroth, David C., Hahn, Michael E., Orendurff, Michael S., et al., 2012. The effects of a controlled energy storage and return prototype prosthetic foot on transtibial amputee ambulation. Hum. Mov. Sci. 31 (4), 918–931. https://doi.org/10.1016/j.humov.2011.08.005.

Seymour, Ron, Engbretson, Brenda, Kott, Karen, Ordway, Nathaniel, Brooks, Gary, Crannell, Jessica, et al., 2007. Comparison between the C-leg microprocessor-controlled prosthetic knee and non-microprocessor control prosthetic knees: a preliminary study of energy expenditure, obstacle course performance, and quality of life survey. Prosthetics Orthot. Int. 31 (1), 51–61. https://doi.org/10.1080/03093640600982255.

Simonetti, Emeline, Bergamini, Elena, Vannozzi, Giuseppe, Bascou, Joseph, Pillet, Hélène, 2021. Estimation of 3D body center of mass acceleration and instantaneous velocity from a wearable inertial sensor network in transfemoral amputee gait: a case study. Sensors (Basel, Switzerland) 21 (9). https://doi.org/10.3390/s21093129.

Stolyarov, Roman, Burnett, Gary, Herr, Hugh, 2018. Translational motion tracking of leg joints for enhanced prediction of walking tasks. IEEE Trans. Biomed. Eng. 65 (4), 763–769. https://doi.org/10.1109/TBME.2017.2718528.

Stolyarov, Roman, Carney, Matt, Herr, Hugh, 2020. Accurate heuristic terrain prediction in powered lower-limb prostheses using onboard sensors. IEEE Trans. Biomed. Eng. https://doi.org/10.31224/osf.io/7mut6.

Su, Ben-Yue, Wang, Jie, Liu, Shuang-Qing, Sheng, Min, Jiang, Jing, Xiang, Kui, 2019. A CNN-based method for intent recognition using inertial measurement units and intelligent lower limb prosthesis. IEEE Trans. Neural Syst. Rehabil. Eng. Publ. IEEE Eng. Med. Biol. Soc. 27 (5), 1032–1042. https://doi.org/10.1109/TNSRE.2019.2909585.

Vickers, Deborah R., Palk, C., McIntosh, A.S., Beatty, K.T., 2008. Elderly unilateral transtibial amputee gait on an inclined walkway: a biomechanical analysis. Gait Posture 27 (3), 518–529. https://doi.org/10.1016/j.gaitpost.2007.06.008.

Wells, Richard P., 1981. The projection of the ground reaction force as a predictor of internal joint moments. Bull. Prosthet. Res. 18 (1), 15–19.

Wentink, E.C., Schut, V.G.H., Prinsen, E.C., Rietman, J.S., Veltink, P.H., 2014. Detection of the onset of gait initiation using kinematic sensors and EMG in transfemoral amputees. Gait Posture 39 (1), 391–396. https://doi.org/10.1016/j.gaitpost.2013.08.008.

Winter, David A., Sienko, Susan E., 1988. Biomechanics of below-knee amputee gait. J. Biomech. 21 (5), 361–367. https://doi.org/10.1016/0021-9290(88)90142-x.

Zhang, Kuangen, Xiong, Caihua, Zhang, Wen, Liu, Haiyuan, Lai, Daoyuan, Rong, Yiming, Fu, Chenglong, 2019. Environmental features recognition for lower limb prostheses toward predictive walking. IEEE Trans. Neural Syst. Rehabil. Eng. Publ. IEEE Eng. Med. Biol. Soc. 27 (3), 465–476. https://doi.org/10.1109/TNSRE.2019.2895221.