



Original Article

Can a Smartphone be used for Balance Assessment during Walking in Lower Limb Amputees?

Mohammad Reza Rezaie¹, MSc; Tahmoures Tahmasebi^{1*}, PhD; Akbar Hassanzadeh², MSc

¹Department of Orthotics and Prosthetics, School of Rehabilitation Sciences, Isfahan University of Medical Sciences, Isfahan, Iran

²Department of Epidemiology and Biostatistics, School of Health, Isfahan University of Medical Sciences, Isfahan, Iran

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ABSTRACT

Background: Nowadays, smartphones are equipped with an accelerometer module that can measure and record the body linear accelerations during walking. The aims of this study were: 1) reliability assessment of smartphone accelerometer for trunk accelerometry; 2) comparison of stability indices based on trunk accelerometry between the amputee and able-bodied subjects; and 3) comparison between energy storage and release (ESR) and multi-axis prosthetic feet users.

Methods: Eleven below-knee amputees (5 multi-axis and 6 ESR prosthetic feet) and 11 able-bodied subjects enrolled in this comparative study. The dynamic stability was assessed using a smartphone attached to their back through an elastic belt during walking in a 6-m walkway. Also, normalized root mean squares (nRMS) of mediolateral (ML) and anteroposterior (AP) directions were calculated as stability indices. The intraclass correlation coefficient (ICC), standard error of measurement (SEM), SEM%, and Bland-Altman plots were used for reliability analysis. The Independent T-test was also used to compare the healthy and amputee subjects as well as ESR and multiaxis prosthetic feet users. The critical alpha was set at 0.05.

Results: The results showed that the accelerometer has the ICC values more than 0.97 and 0.89 for test-retest and inter-session, respectively. Amputees had significantly higher trunk accelerations in ML direction compared to able-bodied subjects ($P=0.023$) but not in AP direction ($P=0.496$). Although the results were not significant between ESR and multi-axis prosthetic feet (AP $P=0.16$, ML $P=0.44$), the AP stability index was higher in ESR users (AP Multi-axis=117.45, ESR=127.38).

Conclusion: The smartphone can be used as a reliable measurement tool in clinical environments to assess the stability indices based on trunk accelerometry in transtibial amputees. More studies should be conducted to obtain more reliable results.

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Introduction

Amputation is the surgical removal of an extremity. In this regard, there are 3.9 times more amputations in the lower limb than the upper limb. There are nearly 2 million amputees in the USA caused by vascular diseases (54%)

like diabetes, trauma (45%), cancer (less than 2%), and congenital anomalies (less than 1%) [1]. A pitfall in any amputation is falling and as Ulger said, 80% of lower limb amputees believe that their falls are due to losing balance [2].

In literature, balance has been defined as the ability to maintain the body center of mass (COM) within the base of support (BOS) which happens by a complex contribution of sensory and motor control systems [3]. In

*Corresponding author: Tahmoures Tahmasebi, PhD; Tahmoures Tahmasebi, 2nd floor, School of Rehabilitation Sciences, Isfahan University of Medical Sciences, Isfahan, Iran. Tel: +98 9131121953; Email: t_tahmasbi@yahoo.com

healthy subjects, two main hip and ankle joint strategies exist to control the frontal and sagittal movements, respectively [4]. The balance control can be disturbed by lower limb amputation. Due to losing the ankle joint and lower leg muscles and lack of ankle joint strategy in below-knee amputees, sufficient ankle moment and power cannot be generated and the body mass is not transformed properly during gait [5]. In this condition, some compensatory mechanisms will be developed in upper joints [6].

Lack of proprioception receptor and somatosensory feedback in lower limb amputees can also influence the balance [7]. The prevalence of falling in community ambulator amputees is 52.4% and regardless of the falling complications such as bone fracture and bleeding in lower limb amputees [8], the frequent experience of falling can influence the balance confidence and leads to fear of falling, worsening the individuals' mobility and their community participation. Moreover, muscle length, endurance, and coordination can also be deteriorated and cause more disability [9].

There are many types of clinical tests such as Berg Balance Scale (BBS), Timed Up and Go test (TUG), Functional Reach Test (FRT), 6-minute walk test (6MWT), and also many questionnaires developed to evaluate the stability, mobility, and risk of falling in lower limb amputees. However, these tests are limited due to ceiling effects and lack of sufficient precision to detect the small changes in gait and balance [10]. These tests were first developed for the elderly and became validated for community-dwelling amputees [11], not active subjects. On the other hand, there are some sophisticated methods such as 3D gait analysis for the assessment of gait and balance using high-speed infrared cameras and force platforms which are quite expensive and are not available in clinical environments.

Body-worn inertial sensors are a substitution for motion-capture cameras that can evaluate the gait and balance in clinics [12]. There are commercially and stand-alone 3d accelerometer sensors that are sensitive to changes in gait and balance in different patients and conditions but the problem is that both hardware and software are expensive too [10]. Fortunately, in recent years smartphones have been equipped with inertial measurement units (IMU) consisting of 3 axial accelerometers, gyroscope, and magnetometer, and based on this functionality of smartphones, many applications were developed to detect and screen the falls in elderly.

Although many studies assessed the stability of different patients during walking, little is known about the stability of amputees based on body accelerations. Therefore, this study was conducted to 1) assess the reliability of the smartphone accelerometer for trunk accelerometry; 2) compare the stability indices based on trunk accelerometry in able-bodied and amputee subjects, and 3) evaluate the effect of different prosthetic feet on the stability of transtibial amputees. It is necessary to evaluate and compare the different prosthetic feet both clinically and biomechanically to better address the patients' needs.

Methods

Participants

Eleven amputees (6 Energy storage and release (ESR) and 5 Multi-axis prosthetic feet users) and 11 able-bodied subjects participated voluntarily in this study and before their participation, written informed consent was obtained from all of them. This comparative study was approved by the ethics committee (IR.MUI.RESEARCH.REC.1397.382) and the research committee (397550) of the Isfahan University of Medical Sciences.

Amputees were selected based on the following criteria: 1) unilateral transtibial amputees due to trauma; 2) ESR or Multi-axis prosthetic feet users with at least 6 months of experience with the current prosthesis; 3) standard stump length (12.5 – 17.5 cm); 4) functional mobility K3; 5) lack of stump pain; 6) lack of any orthopedics or neurological conditions. In terms of reducing the confounding factors related to prostheses, all subjects had TSB (Total Surface Bearing) socket with Shuttle lock and silicon liner as suspension system. The proper prosthetic alignment was also verified by certified prosthetists before data collection. Moreover, the ESR and Multi-axis prosthetic feet users were selected with the same baseline characteristics to ensure that there are no confounding factors between the two groups of amputee subjects.

Prosthetic Feet

Two types of prosthetic feet were compared in this study; the Trustep (College Park Industries, USA) is a multi-axis foot that moves in three directions (dorsi/ plantar flexion, in/eversion, and int/external rotation) similar to human feet. It also has two bumpers in the posterior and anterior side of the ankle joint that can help absorb shocks in heel strikes and foot propelling in the push-off phase of gait, respectively. Another foot was a carbon J shape prosthetic foot manufactured by CGS Co., Iran, with special flexibility in the heel, bottom, and leg that helps to store the energy in early stance and releases it in the late stance.

Equipment and Data Acquisition

The reliability of the trunk accelerometry method was evaluated by Moe-Nilssen during walking and standing [13]. In this study, a smartphone with MPU-6500 module manufactured by Invensense Inc., USA, was used as a triaxial accelerometer and attached to the individuals back between the 2nd and 3rd lumbar spinous processes through an elastic belt. Subjects walked at a regular pace in a 6-m walkway and the linear acceleration of body movements in 3 directions (anterior-posterior (Z-axis), medial-lateral (X-axis) and vertical (Y-axis)) was recorded at the sampling frequency of 119Hz by an Android application named Physics Toolbox Suite v.1.8.7 (Vieyra Software, USA) (Figure 1). The free version of this application was used to save the raw data containing time, x, y, z, and total columns in .csv file format.

Data Analysis

The data were filtered using 2nd order zero-lag phase Butterworth low-pass filter with a cut-off frequency of

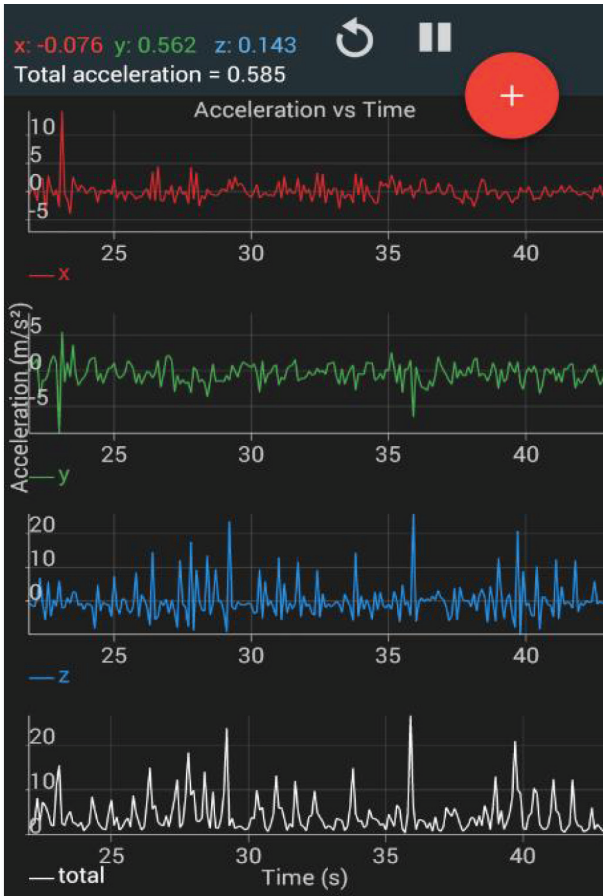


Figure 1: A screenshot of Physics Toolbox Suite Android application (Vieyra Software, USA)

20HZ [14] in MATLAB v. 2013a (Mathworks, Inc., Natick, MA, USA). The peaks of forward acceleration (Z-axis) were detected and set as heel strikes akin to the Zijlstra method [15] (Figure 2). Four gait cycle times were extracted from the data and RMS (Root Mean Square) of each axis was then calculated. As trunk acceleration highly correlated with walking speed, the mediolateral and anteroposterior direction were normalized by Y-axis. Finally, the stability indices in AP and ML directions were calculated by the following equations [16]. The higher values represent higher stability and fewer trunk movements (accelerations) during walking.

Equation 1

$$ML \text{ upright stability} = \frac{RMS_V}{RMS_{ML}} \times 100$$

$$AP \text{ upright stability} = \frac{RMS_V}{RMS_{AP}} \times 100$$

AP=Anteroposterior (Z axis), ML=Mediolateral (X axis), V=Vertical (Y axis), RMS=Root Mean Square

Statistical Analysis

Statistical analysis was conducted by SPSS v.23 (IBM Corp, NY, USA). Initially, the test-retest and inter-sessions reliability of the smartphone accelerometer was evaluated by ICC (intraclass Correlation Coefficient), SEM (Standard Error of Measurement), SEM%, and Bland-Altman plots. In this regard, the ICC values of more than 0.75 are considered as excellent reliability [17]. SEM value assesses the difference between actual measured and estimated true values [18]. Based on the SEM Formulation (Equation 2), the higher values of standard deviation and the lower values of ICC make a higher value for SEM. After ensuring the normal distribution of all parameters by the Kolmogorov-Smirnov test, the Independent Samples T-test was used to compare the normalized RMS of ML and AP accelerations between able-bodied and amputee subjects and also between different prosthetic feet users. The significance level was set at P<0.05.

Equation 2

$$SEM\% = \frac{SEM}{Mean} * 100$$

$$SEM = SD * \sqrt{1 - ICC}$$

SEM=Standard Error of Measurement, SD=Standard Deviation, ICC=Intraclass Correlation Coefficient

Equation 3

$$LoA = Mean \pm 1.96 * SD$$

LOF=Limits of agreement, SD=Standard Deviation

Results

The baseline characteristics of healthy subjects, ESR, and multi-axis prosthetic feet users are reported in Table 1. The average values of age, weight, and height of the overall amputee subjects were 51.69±5.78 (years), 81.69±7.78 (kilograms), and 174.73±9.98 (centimeters), respectively. Moreover, the mean age and BMI in able-bodied participants were 27.33±4.84 years and 23.07±2.63 (kg/m2), respectively.

The results of test-retest and inter-sessions reliability

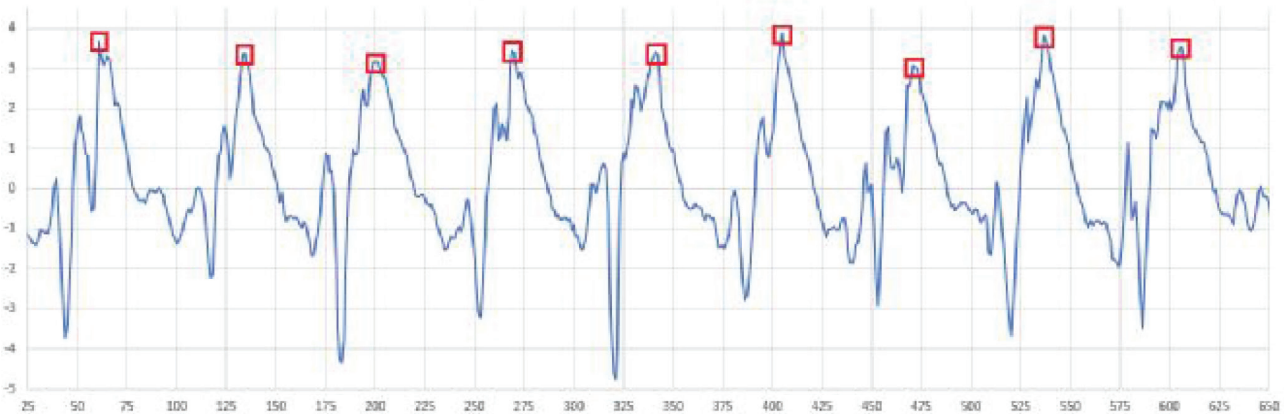


Figure 2: Peaks of anterior-posterior acceleration shown with red boxes as heel strikes

Table 1: Baseline characteristics of healthy subjects and ESR and multi-axis prosthetic feet users

	Multi-axis Mean±SD	ESR Mean±SD	Healthy Mean±SD
Age (years)	51.50±8.5	51.86±2.54	27.33±4.84
Weight (kg)	82.33±9.04	81.07±7.21	70.33±9.78
Height (cm)	177.67±11.15	172.21±8.91	174.44±6.16
BMI (kg/m ²)	26.21±3.26	27.63±4.33	23.07±2.63
Amputation years	29.67±12.94	31.57±3.26	---
Stump length (cm)	22.33±3.92	18.21±4.83	---

BMI=Body Mass Index, ESR=Energy Storing and Release

Table 2: The results of test-retest and inter-sessions reliability analysis of smartphone accelerometer

		Mean±SD	ICC	95% CI	SEM	SEM%
Test-retest	nRMS-ML – day 1	149.102±31.53	0.984*	0.961 – 0.995	3.9883	2.67
	nRMS-AP – day 1	118.01±17.7	0.975*	0.941 – 0.992	2.7986	2.37
	nRMS-ML – day 2	155.96±34.33	0.989*	0.970 – 0.997	3.6006	2.31
	nRMS-AP – day 2	117.93±20.06	0.984*	0.959 – 0.996	2.5374	2.15
Inter-sessions	nRMS-ML	155.47±31.60	0.899*	0.550 – 0.997	10.0426	6.46
	nRMS-AP	118.44±19.20	0.939*	0.731 – 0.986	4.7421	4.00

nRMS-ML=Normalized Root Mean Square of Mediolateral, nRMS-AP=Normalized Root Mean Square of Anteroposterior, ICC=Intraclass Correlation Coefficient, CI=Confidence Intervals, SEM=Standard error of measurement, *=Excellent Reliability

Table 3: Statistics required for Bland-Altman plots

	Mean Differences±SD	P value	95% CI	LOA
nRMS-ML	-0.97±22.37	0.773	-7.69 – 5.75	-44.81 – 42.87
nRMS-AP	1.01±12.36	0.585	-2.70 – 4.73	-23.21 – 25.23

nRMS-ML=Normalized Root Mean Square of Mediolateral, nRMS-AP=Normalized Root Mean Square of Anteroposterior, CI=Confidence Intervals, LOA=Limit of Agreement

of the smartphone accelerometer are shown in Table 2. The mean value of the mediolateral stability index is higher than the anteroposterior direction in all trials and sessions. The ICC values of test-retest and inter-sessions reliability analysis are excellent and equal to more than 0.975 and 0.899, respectively. The SEM and SEM% values are less than 3.99 (2.67%) for test-retest and 10.04 (6.46%) for inter-session reliabilities.

The mean difference of measurements between two sessions is -0.97 and 1.01 for ML and AP directions, respectively (Table 3). The one-sample t-test results do not show any significant difference between the mean differences of the two sessions and the zero value is not within the 95% CI.

Figure 3 shows the Bland-Altman plots for ML and AP stability indices and represents the consistency

of measurement between the two sessions. The mean differences for both ML and AP are near the zero value and within the 95% CI and almost all points are within the LOA.

Table 4 represents the results of the stability indices based on trunk accelerometry comparison between able-bodied and amputee subjects. There is a significant difference between these two groups in ML direction (P=0.023) with a mean difference of 25.41. However, in AP direction, the difference is not significant (P=0.469) and the mean values are relatively the same.

As represented in Table 5, there is no significant difference in AP and ML stability indices between ESR and multi-axis prosthetic feet users. Regardless of the ML accelerometry, the mean value of AP accelerometry in ESR foot is higher than the multi-axis foot (mean difference=9.93).

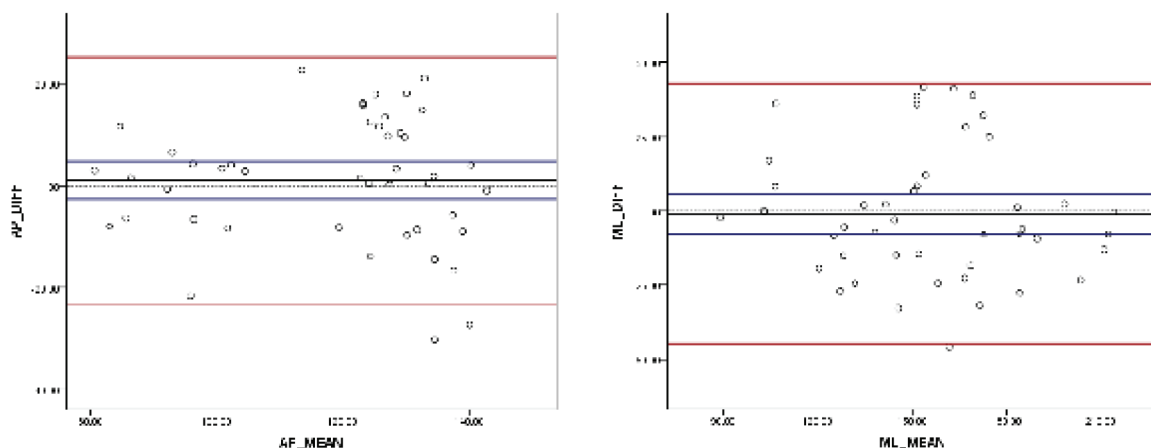


Figure 3: Bland-Altman plots for AP (left) and ML (right) . Black lines=mean, dot lines=zero value, upper and lower blue lines=95% CI, upper and lower red lines=limits of agreement

Table 4: The comparison results of AP and ML accelerometry between healthy and amputee subjects

	Amputees Mean±SD	Healthy Mean±SD	Difference Mean±SD	P value	95% CI
nRMS-AP	121.89±17.39	122.61±14.77	0.72±7.22	0.496	-14.44 – 15.88
nRMS-ML	131.81±20.47	157.21±31.48	25.41±11.87	0.023*	-50.36 – -0.46

nRMS-ML=Normalized Root Mean Square of Mediolateral, nRMS-AP=Normalized Root Mean Square of Anteroposterior, CI=Confidence Intervals

Table 5: The comparison results of AP and ML accelerometry between ESR and multi-axis prosthetic feet users

	Multi-axis Mean±SD	ESR Mean±SD	Difference Mean±SD	P value	95% CI
nRMS-AP	117.45±1.76	127.38±22.20	9.93±9.10	0.162	-33.85 – 38.69
nRMS-ML	137.95±33.64	135.53±18.89	2.42±16.03	0.441	-32.66 – 12.80

nRMS-ML=Normalized Root Mean Square of Mediolateral, nRMS-AP=Normalized Root Mean Square of Anteroposterior, ESR=Energy Storing and Release, CI=Confidence Intervals

Discussion

Nowadays, smartphones with many applications have been used extensively in healthcare as measurement toolmaking it is necessary to ensure the consistency of measured parameters by these devices. As every device has a different IMU module with different technical specifications, it needs to be checked before any measurement. The novelty of this study is that a smartphone has never been used to assess the dynamic stability in lower limb amputees, and we checked the feasibility and sensitivity of the device in this regard.

The results of test-retest and inter-session reliability of the smartphone accelerometer showed that this device can be used as a highly reliable tool for measuring the trunk acceleration in both clinics and research because of the high ICC values (more than 0.975 and 0.899 for test-retest and inter-session, respectively). The same procedure was also conducted by Kosse et al. on iPod touch which revealed high validity and reliability for clinical gait and posture assessment [10]. Besides, the same MPU-6500 module and Physics toolbox suite Android application was used by Procházka et al. for assessing the symmetry of motions in athletes [19]. The tricky parts of this procedure are the data pre-processing and the calculation of stability indices carried out here by MATLAB with a little programming. Developing an application for clinicians to process the signals and calculate the indices without any extra software directly on that smartphone could be an asset.

The one-sample t-test results showed that there are not any significant differences between the two sessions because of the low mean difference in both ML and AP directions (-0.9 and 1 respectively) which are close to zero. Nevertheless, the SEM and SEM% showed that the errors were less than 3.99 (2.67%) and 10.04 (6.46%) for test-retest and inter-session reliability assessment, respectively. These values are relatively high because of the large standard deviation values. On the other hand, the points in Bland-Altman plots are scattered and are not centralized to a specific region, and the upper and lower limits of agreements are relatively large (ML=-44.81 – 42.87, AP=-23.21 – 25.23).

Able-bodied subjects had a significantly lower trunk acceleration in ML direction compared to amputees (P=0.023). Paradisi [12] also reported the same result

for the comparison of trunk accelerometry between these groups, with a more advanced device (Opal, USA). However, in our study, there is not any significant difference for AP direction (P=0.496) which might be due to the low number of participants in our study. A study conducted by Isoa also reported a significant difference and higher trunk accelerations in both ML and AP direction in transtibial subjects [16]. Despite that, the sample size, activity level, and the cause of amputation in the Isoa study are not identical to those in our study (8 transtibial, one crutch user, and 5 vascular diseases). These baseline characteristics of participants can tell us the lower stability of amputees compared to able-bodied subjects and also the significant difference in AP direction in that study. Lamoth [20] also reported the significant ML acceleration difference between healthy and transfemoral amputees with the same P-value compared to our study, and also a non-significant difference for AP direction. This comparison shows that the results of the current study are consistent in previous works.

Prescribing the prosthesis is one of the rehabilitation services. Below-knee amputees have to use the prosthetic foot to simulate the function of the sound foot during standing and walking, and that is selected based on several influential factors such as functional levels, activities of daily living, and work requirements, environmental stresses, etc. [21]. There is a variety of commercially available prosthetic feet in clinics ranging from conventional SACH (Solid Ankle Cushion Heel) and single-axis feet to ESR (Energy Storing and Release) and more advanced power ones. Due to the absence of the ankle joints, below-leg muscles, sensory feedback, and also lack of ankle strategy in below-knee amputees, they are susceptible to lose balance and also fall during daily activities [6]. In this study, the stability of ESR and multi-axis prosthetic feet users were also compared by AP and ML accelerometry.

It is stated that some demographics of amputees such as age, stump length, and cause of amputation can influence the balance control [6, 22-25]. The baseline characteristic of ESR and multi-axis prosthetic feet users (Table 1) showed that the amputees were almost the same in terms of age, BMI, amputation years, and stump length. Indeed, we tried to find similar participants to reduce confounding factors.

The results of AP and ML accelerometry in amputees did not show a significant difference between ESR and multi-axis prosthetic feet users similar to the findings by Paradisi [14]. In our study, however, the AP stability index of ESR prosthetic foot was more than the other one. In healthy individuals, the plantar flexor muscles play an important role in reducing and controlling the whole-body angular momentum in the sagittal plane. Indeed, this moment is regulated by the muscles that contribute to the external moment generated about the center of mass [26]. Based on the kinetic studies, it is stated that in amputees, more whole-body angular momentum is generated compared to able-bodied subjects because of lack of plantar flexor muscles and finally increasing the risk of falling and dynamic instability [26]. Because of the flexible structure of ESR foot which is made of carbon fiber and its ability to store the energy and release it in late stance, it can simulate the plantar flexor muscles like a spring. Thus, the higher stability index in AP direction based on trunk accelerometry can be due to this feature of ESR foot, as evident in our results. More studies with a higher sample size are needed to validate this result.

It is highlighted that trunk accelerometry is a suitable method for the assessment of general stability in different subjects as it is near the whole-body COM. Neither Paradisi [14] nor the current study detected any significant difference between different prosthetic feet, while other sensor placements (on leg or foot [27]) might detect the differences based on acceleration data. In the literature, there are other parameters calculated from acceleration signals [20, 28] which might be better than RMS equations which were used here and which might better address the differences of the prosthetic components. Moreover, body accelerometry can be used simultaneously for different segments and also with other clinical tests (e.g TUG and 6MWT) to collect in-depth clinical and biomechanical data regarding stability and mobility. More studies should be conducted to evaluate other parameters and sensor placements to find out the best protocol for stability analysis of different prosthetic components.

One of the limitations of this study is that although the ESR and multi-axis prosthetic feet users matched demographically, the able-bodied participants were younger than the amputees. Moreover, amputees with special amputation level, activity, and prosthesis components participated in this study and the results might not be generalized considering the low number of participants. The current study did not validate the APP and the smartphone's accelerometer with more sophisticated software and IMUs.

Conclusion

The smartphone can be used as a reliable measurement tool in clinical environments to assess the stability indices based on trunk accelerometry in transtibial amputees. While there was no significant difference between different prosthetic feet, further studies are needed to find an appropriate protocol to detect the differences between prosthetic components based on acceleration data.

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Conflict of Interest: None declared.

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