Determining validity of the PALite and ODFS PACE activity logger for measuring step count in healthy adults

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Abstract

Background: Determining adherence with orthoses is important for clinicians prescribing devices. Measuring orthotic use often relies on patient recall which has poor agreement with objective measures. Measuring step count whilst wearing an orthosis could help objectively quantifying adherence. The Odstock Drop Foot Stimulator (ODFS) Pace, used in foot drop, has an integral activity logger which provides data on step count. The PALite, an accelerometer, measures step count and can be fixed to an ankle foot orthoses (AFO). Both have the potential to provide objective measures of adherence; however, their validity for this purpose has not been determined.

Research question: To determine the validity of the PALite and ODFS Pace activity logger in measuring total step count, by exploring their level of agreement.

Methods: A convenience sample of sixteen healthy volunteers, aged 18-65, were recruited from Glasgow Caledonian University (GCU). Participants walked continuously for 5 minutes on a treadmill at three walking speeds; normal ($1.3ms^{-1}$), slow ($0.4ms^{-1}$) and fast ($1.7\text{-}2.0\ ms^{-1}$), wearing both the PALite and ODFS Pace. All walks were video recorded, viewed by 2 raters, and observed step count was determined by a click counter. Step count from both devices was validated against observed step count using video recording. The level of agreement between the three methods was established.

Results: There was no significant difference between the 3 methods of measuring step count at either walking speed (normal, p=0.913; slow, p=0.938; fast, p=0.566). Good levels of agreement for both devices with observed step count at all 3 walking speeds, with mean percentage differences being between -1.2 and 2.1% (maximum upper and lower levels of agreement = 19.5 and -18.8%) was detected.

Significance: Clinicians could consider both devices to objectively measure step count with people who are prescribed foot drop orthoses, thus quantifying orthotic use.

Key words: Step count, foot drop, validity, measurement, orthotic adherence.

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Ethics approval: Ethical approval was granted by GCU Health and Life Sciences ethics committee.

Introduction

Orthotic devices such as ankle foot orthoses (AFO) and functional electrical stimulation (FES) are prescribed in the management of foot drop [1, 2]. Adherence with such devices is an important consideration for prescribing clinicians especially where the cost benefit of interventions needs to be justified. Non-compliance with lower limb orthotic devices can be high (6-80%) [3]. A small number of AFO [4, 5] and FES [6, 7] studies have investigated orthotic adherence using questionnaires and interviews. Such methodology relies on patient recall where there is poor agreement with objective measures [8]. Jarl [9] suggests that objective measurement, such as using accelerometers to measure step count, should be considered where possible when considering adherence.

Accelerometry devices such as the ActivPAL and PALite (PALTechnologies, Glasgow) approximate activity through measurement of step counts [10] and have been validated for activity monitoring and measure free-living sedentary, upright, and walking activities [11]. When attached to an AFO the PALite can measure steps taken and thus has the potential to afford valuable information around AFO adherence. The Odstock Dropped Foot Stimulator (ODFS) Pace (OML, Salisbury), a FES device, has a built-in activity logger which records steps as detected via a pressure sensitive foot switch placed in the heel of the shoe.

To better understand adherence with foot drop orthoses, one must first determine whether the PALite and the ODFS Pace activity logger devices can provide valid and accurate data on step count. Demonstrating a relationship between the recorded step count from these devices with a gold standard measure of step count would help to determine their validity, thus supporting their ability to quantify orthotic adherence.

The aim of this study is thus to validate these devices, against observed step count when walking at slow, normal, and fast walking speeds, thus reflecting a range of patient populations, in healthy volunteers. A secondary aim was to determine the level of agreement of the two devices.

Methods

Participants and setting

The study was granted ethical permission from the Glasgow Caledonian University (GCU), School of Health and Life Sciences Ethics committee. A convenience sample of sixteen healthy adult volunteers was recruited from GCU. Participants were aged between 18 and 65, had no gait impairments or significant cardiac history and were able to sustain a fast walking pace for 5 minutes. Interested volunteers consented to participate in the study and wore both devices on their dominant leg. The activPAL (PALite3c LT, Figure 1) was placed on the lateral aspect of the lower leg with a hypoallergenic waterproof dressing to replicate where it would be attached if an AFO was worn. The ODFS Pace (Figure 2) was worn on the participant's waistband and set up in dropped foot mode, but without stimulation being delivered. A pressure sensitive switch was taped to the heel of an insole which was inserted into the participant's shoe. Participants walked for 5 minutes at three different walking speeds on a treadmill: normal (1.3ms^{-1}), slow (0.4ms^{-1}) and fast (1.7-2.0 ms^{-1}) [12, 13]. Each walk test was videoed using a digital camcorder. Participants were afforded a 2-minute rest between each walk test [8].

Data collection and Analysis

Each video sequence recorded was viewed independently by two members of the research team (AL, RH). A click counter, the current gold standard for measuring step count [14], recorded the number of steps taken. Data was downloaded from the PALite3c using PALconnetx software and analysed using PALanalysis (PAL technologies, Glasgow). The total number of steps for each walk test was recorded. The ODFS Pace activity logger menu screen was accessed and the total number of steps on each walk was recorded before resetting the logger for the next test.

Statistical analysis

Data was tested for normality and a one-way ANOVA (Factor – device) tests were employed to explore difference between the PALite, ODFS Pace and video analysis methods at each walking speed. The level of agreement between the PALite and ODFS Pace were established against video step count (Bland and Altman) [15].

Results

Sixteen subjects were recruited (M: F, 9:7; mean age 34.9 ±3.36 years; mean BMI 23.7±3.36 kgm^{-2}). All PALite and ODFS Pace data were successfully recorded. Data

from two subjects from the video analysis was unusable due to a video SD card error. A further three tests at different speeds for two subjects were omitted for the same reasons. A further two subjects had missing data for some trials for the same reason thus 12 complete data sets were included in the final analysis. All data was normally distributed (Shapiro Wilk - $p>0.05$).

Both assessors agreed on the numbers of observed steps in all the videoed walk tests. There was no significant difference between each method for counting steps at Normal, Slow, and Fast walking speeds respectively ($p=0.913$, 0.938, 0.566) were found.

Good levels of agreement for both the ODFS Pace activity logger and the PALite with video analysis was found at all three gait speeds. Upper and Lower levels of agreement ranged from -18.8 (ODFSvsPALite, slow speed) to 19.5% (Video vs ODFS, slow speed).

	Normal ($1.3ms^{-1}$)			Slow ($0.4ms^{-1}$)			Fast ($1.7ms^{-1}$)		
	Video	ODFS	PALite	Video	ODFS	PALite	Video	ODFS	PALite
Mean step count SD	586.2 (44.4)	579.4 (42.0)	580.5 (48.1)	284.3 (18.6)	285.8 (25.2)	287.3 (22.6)	625.3 (36.5)	631.6 (29.7)	637.9 (28.5)
Bland & Altman Comparison	Video vs ODFS	Video vs PALite	ODFS vs PaLite	Video vs ODFS	Video vs PaLite	ODFS vs PaLite	Video vs ODFS	Video vs PaLite	ODFS vs PaLite
Difference & SD (%)	-1.2 (5.4)	0.0 (3.0)	-0.1 (5.9)	1.0 (9.4)	1.4 (3.3)	-0.6 (9.2)	1.8 (4.6)	2.1 (5.9)	-1.0 (5.2)
ULA (%) (95% LoA)	9.3	5.8	11.5	19.5	7.9	17.5	10.8	13.8	9.3
LLA (%) (95% LoA)	-11.6	-5.8	-11.7	-17.4	-5.1	-18.8	-7.2	-9.5	-11.3

Table 1: Mean step count for the 3 walk speeds ($0.4ms^{-1}$, $1.3ms^{-1}$, $1.7ms^{-1}$). Upper level of agreement (ULA) and lower level of agreement (LLA) are expressed as a percentage of the step count as obtained from video analysis (n=12)

Discussion

This small study found good levels of agreement for both the PALite and the ODFS Pace activity logger in comparison to video analysis, demonstrating sound validity for both devices measuring step count in healthy adults.

The low percentage difference between the two devices suggests no systematic differences were present. However, the limits of agreement between the ODFS Pace and PALite, particularly at normal and slow walking speed indicated a greater variation between the devices at these speeds [15]. Although people who are prescribed a foot drop device walk at a range of walking speeds, previous research suggests that people with MS walking a slower walking speeds (<0.8ms^{-1}) may gain most benefit form FES [16], therefore it may be more pertinent to focus on these results. At the slow walking speed (0.4ms^{-1}) the PALite demonstrates tighter levels of agreement with the video step count analysis in comparison to the ODFS Pace suggesting the PALite may provide a more accurate measure of step count. These results may be explained by the different methods used to count steps. The ODFS Pace activity logger measures heel pressure contacts at heel strike, whereas the PALite uses accelerometery signalling to detect movement of the leg shank through the whole step cycle.

This study recruited healthy adults and examined the validity of these devices during treadmill walking which unlike community ambulation is of a fixed pace, direction, and surface. Treadmill walking has been found to be unequal to over ground walking in terms of smoothness and rhythmicity of gait in older adults [17]; therefore, further work to explore their ecological validity in specific patient groups is needed.

This study has demonstrated good validity for both the PALite and the ODFS Pace activity logger in measuring step count, thus highlighting their potential to monitor orthotic adherence in people presenting with foot drop. The PALite also has the potential to help inform adherence with a range of other orthotic and prosthetic applications. Being able to accurately quantify adherence will create opportunities for the exchange of meaningful health information between patients and health care providers and inform future prescribing and treatment decisions of orthoses.

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