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The relationship between hallux grip force and balance in people with diabetes

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ABSTRACT

Background: Diabetes accelerates the decline in muscle strength in older people and substantially increases the risk for fall and injury. Weakening of lower extremity muscles, in particular, is a strong predictor for falls, but currently there is no established method for its assessment in clinics. The paper grip test (PGT) offers a qualitative assessment of hallux plantar flexor strength and its usefulness for predicting falls has been demonstrated in non-diabetic populations.

Research question: The aim of this study is to test whether the PGT can be used for a quantitative assessment of lower-extremity strength and to investigate its relationship with isometric muscle strength and balance in people with diabetes and peripheral neuropathy.

Methods: Isometric muscle strength of all muscle groups of the foot-ankle was assessed using a dynamometer in sixty-nine people with diabetes and neuropathy. Postural sway and the gripping force exerted by the participants during the PGT was measured for the same participants using a plantar pressure assessment system. These measurements were repeated in regular intervals for 18 months in a longitudinal observational cohort study.

Results: Cross-sectional analysis of baseline data showed that people who failed the PGT swayed more. Analysis of longitudinal data showed that increasing hallux grip force is significantly associated with reduced postural sway. No significant association was found between dynamometry-based measurements of strength and postural sway. Hallux grip force was significantly correlated to the strength of all muscle groups of the foot-ankle complex.

Significance: These results indicate that hallux grip force can assess the strength of the foot-ankle muscles and could potentially be used to identify people at risk of falling. This sets the basis for the development of new screening protocols to assess weakening of the muscles of the foot-ankle and to enhance risk assessment for falls in people with diabetes and peripheral neuropathy.

1. Introduction

Maintaining balance is a complex process that depends on the interaction between the sensory and musculoskeletal systems. As a person ages there is a series of physiological changes which impair the intricate function of these systems. Over time, age-related changes are combined with the cumulative effect of various clinical conditions, leading to a fall [1].

One of the conditions that significantly affects the risk for falls is diabetes [2]. Diabetes accelerates the decline in strength of lower-limb muscles which makes it more difficult to maintain balance [3]. Another diabetes-related contributor to falls is peripheral neuropathy (PN). PN is a common complication of diabetes that leads to gradual loss of somatosensory information at the foot level and contributes to increased postural instability [4] which is also a strong predictor for falls [5,6]. People with diabetes and PN are 15 times more likely to sustain an injury as a result of a fall compared to people without PN [7]. The prevalence of falls in older people (> 65y) with diabetes is as high as 43% which makes this population a key target group for testing methods that aim to prevent falls [2].

Overall, more than 25 individual risk factors for falls have been identified to date and muscle weakening is recognised as one of the

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most important [1,8,9]. A recent systematic review and meta-analysis of evidence on the relationship between muscle weakness and the risk of falls [9]; concluded that muscle weakening, especially of the lower extremity muscles, was a strong predictor for falls and it should be assessed in older individuals at risk [9].

Currently the most commonly used method for the measurement of muscle weakening in older populations is the hand-grip test [10]. The hand-grip test is a very simple, safe and clinically applicable test that can significantly enhance clinical assessment in cases where whole-body strength is important (e.g. screening for frailty). However, this measurement is not specific to the task of balance recovery which reduces its validity as a predictor for falls [8–10]. A recent longitudinal cohort study clearly highlighted that hand-grip strength was not associated with the risk of injury from falling [10]. In addition, the previous review, whilst comparing the predicting ability of muscle strength measurements of the upper-extremities against ones for the lower-extremities, concluded that measurements of lower-extremities' strength is a stronger predictor for falls and for recurring falls [9].

However, in contrast to upper-extremities, no specific quantitative measurement is currently used in clinical care for lower-extremity assessment. The most commonly used measurements of leg muscle strength are the measurements of knee extension and ankle dorsiflexion strength using complex and expensive isokinetic dynamometers [9]. Even though the isometric strength of other muscle groups can be assessed using simpler and less expensive hand-held dynamometers, all these measurements require highly trained examiners, which significantly limits their use outside a research setting [11].

The paper grip test (PGT) was developed in the 1990s by W.J. Theuvenet and P.W. Roche as a screening tool for muscle paralysis in the intrinsic muscles of the foot of people with leprosy [12] and previous research has found that it can accurately detect muscle weakness in people without diabetes [13]. Research involving people with diabetes has shown that it could be useful as an early-stage screening tool for muscle weakening [14]. During the PGT, the examiner places a small piece of cardboard (size of a standard business card) under the hallux distal to the metatarsophalangeal joint. The examiner then pulls the card away with gradually increasing force while the participant offers resistance. The participants pass the test if they can successfully hold the cardboard or fail if they fail to grip it.

A recent study by Healy et al. [15] validated PGT as a measurement of muscle strength in people with diabetes and PN and clearly indicated that the PGT offers an indirect assessment of the gripping force a person exerts during testing (i.e. hallux grip force). Although, this can reliably predict whether the strength of the hallux plantar flexion muscles is above or below a threshold, the threshold itself appeared to depend on the examiner's technique and experience [15]. Considering the importance of the hallux during gait and its role in maintaining balance [16] these results might indicate that the PGT could be used to assess muscle weakening as part of a falls risk assessment.

In this context, the aim of this study was to test whether failing the PGT is also associated with poorer balance and to investigate whether changes in hallux grip force could be a marker for deteriorating balance or muscle weakening in people with diabetes and peripheral neuropathy. The ability to maintain balance was assessed by measuring postural sway. Visual impairment or wearing footwear with cushioning insoles is known to affect balance [6,17–19], therefore postural sway was also measured under these conditions.

2. Methods

2.1. Participants

Sixty-nine people with type-2 diabetes and PN were recruited from a diabetes hospital in Chennai, India (Table 1). Institutional Ethics Committee approval was obtained prior to the start of the study and written informed consent was obtained from each participant before any testing was performed.

The inclusion criteria were: a) Age between 18–80 years, b) diagnosis of Type-2 diabetes, c) lack of sensation in both feet, d) existence of at least one palpable pedal pulse on each foot. The exclusion criteria were: a) Inability to walk independently for at least 10 m, b) active foot ulcer or history of foot ulceration, c) active foot infection, d) history of foot surgery, e) severe foot deformity/ Charcot foot, f) chronic kidney disease or g) diagnosis for a condition that affects cognitive function (e.g. Alzheimer's, dementia etc.).

During screening, vibration perception threshold (VPT) was measured at the hallux, 1st metatarsal, 3rd metatarsal, 5th metatarsal, medial arch, heel, dorsum and ankle areas of both feet using a biothesiometer (Kody Medical Electronics Private Ltd, Chennai, India). Only people with VPT values > 25 V in all tested areas of both feet were included in the study. An average VPT score was calculated for each participant by averaging all measurements.

2.2. Biomechanical measurements

Postural balance parameters related to centre of pressure (COP) were measured using a plantar pressure assessment system (Matscan,Tekscan Inc., USA). The participants stood barefoot on the pressure mat with their feet apart at a self-selected distance and with their arms hanging at their sides in a comfortable position. They were asked to stand still and to look at a visual target while pressure distribution was recorded for 30s [18]. The visual target was placed at a relatively short distance (50 cm) to enhance the contribution of vision to postural stability [20]. After a short break of ≈3 min the participants repeated the same tests but this time with their eyes closed. The entire process was then repeated for shod conditions with the participants wearing the same type of sandal. These sandals had a thick (10 mm), soft (Shore A hardness = 11), flat insole and were routinely provided to people with diabetes and neuropathy (Fig. 1a).

The area of COP sway (S_Area), the maximum antero-posterior excursion (AP_ Exc) and the maximum medio-lateral excursion (ML_Exc) were calculated for eyes open and eyes closed, barefoot and shod conditions (Fig. 1b). All postural sway parameters were calculated using the Sway Analysis Module within the Matscan software (FScan Clinical 6.62, Tekscan Inc., USA). The reliability of this method for studying balance has been previously established [21] and it has been routinely used to measure postural sway both in barefoot or shod conditions [18,19,22,23].

Isometric muscle strength of all major muscle groups of the foot was assessed using a hand-held dynamometer (500 N Cytec, C.I.T. Technics, Centre for Innovative Technics, Netherlands) following the "make technique" [24]. During testing the examiner held the dynamometer stationary and asked the participant to exert a maximal force against it. Muscle strength measurements were performed in both feet following a previously published testing protocol [11].

The muscle groups tested were the ones responsible for: a) Ankle dorsi-flexion, b) ankle plantar-flexion, c) ankle inversion, d) ankle eversion, e) hallux plantar-flexion, f) hallux dorsi-flexion, g) lesser toe plantar-flexion and h) lesser toe dorsi-flexion. Each measurement was repeated three times. At the end, a single value of muscle strength was calculated for each muscle group as the average of all measurements [24]. A detailed description of the testing protocol for isometric muscle strength can be found in Supplementary Material S1.

The PGT was also performed for all participants, and the actual gripping force exerted by the hallux during testing was directly measured using the same plantar pressure assessment system [15]. Hallux grip force was defined as the maximum net force underneath the hallux area during the PGT. Two measurements were performed for each participant (one for each foot) and their average was calculated.

During testing, the examiner placed a small piece of cardboard (size of a business card) under the participants' hallux distal to the metatarsophalangeal joint. The participants were seated with their hip, knee

Table 1
The profile of the overall recruited population and of those that passed and failed the paper grip test.

		Overall	Pass	Fail	p
N (M/F)		69 (42/27)	34 (27/7)	35 (15/20)	
Age (y)		58 (± 8)	58 (± 8)	58 (± 8)	0.909
BMI (kg. m^{-2})		28 (± 5)	27 (± 5)	28 (± 5)	0.362
Duration of diabetes (y)		12 (1-31)	10 (1-25)	12 (3-31)	0.253
VPT (V)		80 (32-82)	80 (36-82)	80 (32-81)	0.870
Hallux grip force (N)		36 (11-164)	46 (17-164)	28 (11-64)	< 0.001*
Muscle strength (N)	**Ankle dorsi-flexion**	116 (54-235)	125 (72-235)	102 (54-203)	0.024*
	Ankle plantar-flexion	146 (68-272)	159 (96-272)	138 (68-200)	0.011*
	Ankle inversion	83 (36-148)	105 (40-148)	68 (36-112)	< 0.001*
	Ankle eversion	88 (34-147)	102 (62-147)	83 (34-122)	< 0.001*
	Lesser toe plantar-flexion	92 (33-203)	108 (44-203)	83 (33-141)	0.004*
	Lesser toe dorsi-flexion	71 (32-142)	87 (42-142)	65 (32-104)	0.003*
	Hallux plantar-flexion	101 (21-209)	124 (60-209)	92 (21-137)	< 0.001*
	Hallux dorsi-flexion	66 (24-128)	82 (36-128)	57 (24-108)	0.003*

The total number of people in each group (N) and the number of male/ female (M/F) participants is presented. Normally and non-normally distributed data are represented by their average (± STDEV) or median (min-max) respectively. All values correspond to measurements at baseline. BMI = Body Mass Index, VPT = Vibration Perception Threshold. The significance of difference (p) between those who passed and those who failed the PGT is also shown (Mann-Whitney U test). Statistically significant correlations ($p < 0.05$) are noted with *.

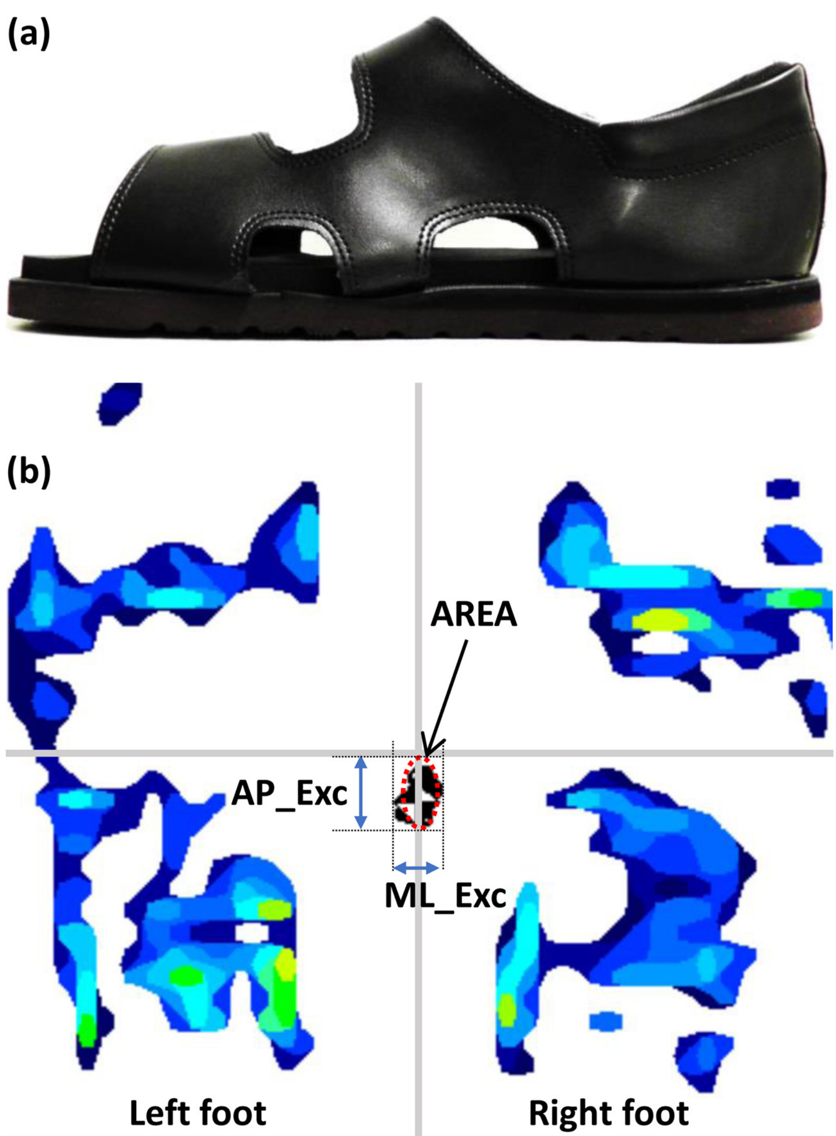

Fig. 1. The sandal used for balance measurements in shod conditions (a) and a typical centre of pressure COP excursion plot for shod conditions (b). The maximum anteroposterior COP excursion (AP_Exc), maximum mediolateral COP excursion (ML_Exc) and the area of COP excursion (S_Area) are also presented.

and ankle joints at 90 ° and with their hands hanging on their sides. The participants were instructed to grip the card with their hallux by pushing against the floor while keeping their feet flat on the ground. The examiner then pulled the card away with gradually increasing power while the participant offered resistance. The participants passed the test if they could successfully hold the cardboard or fail if they failed to grip it. No external support was applied to the foot during testing [15].

The participants were asked to return for five follow-up visits after three, six, nine, twelve and eighteen months from baseline. All clinical and biomechanical assessments were repeated during each follow-up visit.

2.3. Statistical analysis

The normality of collected data was assessed using the Shapiro-Wilk test. The average (± standard deviation) or median (range) was calculated respectively for normally or non-normally distributed data.

2.3.1. Cross-sectional analysis of baseline measurements

Baseline measurements were analysed using Spearman's rank-order correlation to assess the association between hallux grip force, postural sway and muscle strength. Finally, Mann-Whitney U test was used to investigate if people who failed the PGT had higher postural sway compared to people who passed the PGT. For this analysis failing the PGT in at least one foot at baseline was considered as an overall “fail”. Differences between these two groups were assessed separately for baseline and for each follow-up visit.

2.3.2. Associations between hallux grip force, muscle strength and postural sway

The method of generalized estimating equations (GEE) was used to investigate whether changes in hallux grip force over time were associated with changes in postural sway or muscle strength. Apart from hallux grip force, the effect of age and duration of diabetes at baseline and the effect of average VPT were also included in the analysis. Considering possible differences in muscle strength between men and women, the effect of gender on the association between hallux grip force and isometric strength was assessed using a separate set of GEE models. The relationship between the dynamometry-based measurements of isometric hallux and lesser toe plantar flexion strength with postural sway was also investigated.

Goodness of fit was assessed by calculating the marginal R^2 (R^2m) which is an extension of R^2 statistics for GEE models [25]. In the calculation of marginal R^2 the fit of the GEE model to the data is compared against a simple intercept-only model with positive values of marginal R^2 indicating a better fit by the GEE model (Supplementary material S2). All statistical analyses were performed using IBM® SPSS®v.25.

3. Results

Out of the 69 participants (Table 1) only nine attended all five follow-up sessions. The total number of participants that returned for their three-, six-, nine-, twelve- and eighteen-month assessment was 50, 44, 29, 16 and 29 respectively.

3.1. Cross-sectional analysis of baseline measurements

Grouping the participants based on the results of the PGT showed that 34 passed and 35 failed the test. Both groups had the same average age and median VPT and very similar durations of diabetes and BMI scores. As expected, the group that failed the PGT had significantly lower hallux grip force and lower isometric muscle strength (Table 1).

Spearman's rank-order correlation revealed that hallux grip force was significantly correlated to the dynamometry-based isometric strength of all muscle groups of the foot-ankle with higher hallux grip force being consistently associated with higher muscle strength (Table 2). No strong or moderate correlation was found between hallux grip force and postural sway measurements. Only one weak negative correlation was found between hallux grip force and S_Area in shod eyes closed conditions (Table 2).

Mann-Whitney U test revealed that people who failed the test at baseline swayed significantly ($p < 0.05$) more than people who passed the PGT in shod conditions (Table 3). More specifically S_Area, AP_Exc and ML_Exc in eyes open conditions was 46% (Z = 2.563, p = 0.010), 21% (Z = 2.154, p = 0.031) and 13% (Z = 2.304, p = 0.021) higher, respectively, in people who failed the test than those who passed. When the same measurements were repeated with eyes closed these differences were even higher, with people failing the PGT having S_Area, AP_Exc and ML_Exc 97% (Z = 3.493, $p < 0.001$), 57% (Z = 3.241, p = 0.001) and 15% (Z = 2.497, p = 0.013) higher respectively than those who passed. Even though the same trend was observed in the case of barefoot conditions and the median of all postural sway parameters was higher for the “fail” group compared to the “pass” group, none of these differences was statistically significant (Table 3).

Differences between these two groups were maintained throughout the follow-up period. In barefoot conditions, people who failed the PGT had significantly higher S_Area and ML_Exc at month three and significantly higher S_Area at month six. In shod conditions people who failed the PGT had significantly higher S_Area at month six. All differences with regards to muscle strength were preserved in the three- and six-month visit. Finally, hallux dorsi flexion strength was significantly lower in the group that failed the PGT at month eighteen. Detailed descriptive statistics for the results for each follow-up visit can be found in Supplementary material S3.

3.2. Associations between hallux grip force, postural sway and muscle strength

The GEE analysis of longitudinal data indicated that hallux grip force was significantly correlated with eight out of the twelve measured parameters for postural sway (Table 4) and with the strength of all eight tested muscle groups (Table 5). In the case of postural sway, the regression coefficients (B) were consistently negative (Table 4) while in the case of muscle strength they were consistently positive (Table 5). This means that increasing hallux grip force over time was associated with increased isometric muscle strength and decreased postural sway. Similarly, decreasing hallux grip force over time was associated with decreased muscle strength and with increased postural sway. In all cases where the effect of hallux grip force was significant, marginal R^2 was higher than zero which means that the GEE models were capable of predicting changes in the mean values for this population better than an intercept-only model [25]. Adding gender to the parameters of the GEE models did not affect the significance of hallux grip force for predicting changes in the mean value of isometric muscle strength but it substantially reduced the model’s goodness of the fit. The marginal R^2 of the models that included gender information was always negative indicating that a simple intercept-only model could offer better a fit to the data (Supplementary material S4). No significant association was found between changes in isometric muscle strength of the hallux or lesser toe plantar flexors and any postural sway parameter.

4. Discussion

In this study the PGT was used to record one qualitative (i.e. pass/fail) and one quantitative measure of strength (i.e. hallux grip force) and to investigate their relationship with the isometric strength of the foot-ankle complex and with postural sway.

The simple pass/fail output of the PGT was used to separate the participants into two groups with very different strength and balance characteristics. People who failed the PGT at baseline had significantly lower isometric strength in all foot-ankle muscle groups and lower

Table 2
Significant correlations between hallux grip force and the isometric strength of different muscle groups and between hallux grip force and postural sway.

			Muscle group	r_s	N	p
Hallux grip force	vs	Isometric strength	Hallux plantar-flexors	0.544	54	< 0.001
			Hallux dorsi-flexors	0.574	54	< 0.001
			Lesser toe plantar-flexors	0.505	54	< 0.001
			Lesser toe dorsi-flexors	0.574	54	< 0.001
			Ankle evertors	0.562	54	< 0.001
			Ankle invertors	0.549	54	< 0.001
			Ankle plantar-flexors	0.456	54	< 0.001
			Ankle dorsi-flexors	0.440	54	0.001
		Postural sway	S_Area (Shod/Eyes closed)	−0.268	69	0.026

Hallux grip force is measured using the PGT while isometric strength using a hand-held dynamometer. Postural sway is measured using a plantar pressure assessment system. The correlation coefficient (r_s), sample size (N) and the significance level ($p < 0.05$) of the Spearman's rank-order correlation are presented. In the case of postural sway, significant correlation was found only for the area of COP sway (S_Area) in shod, eyes closed conditions.

Table 3
The postural sway measurements for the overall recruited population and the difference between those that passed or failed the paper grip test.

			Overall	Pass	Fail	p
Barefoot	EO	Area	1.36 (0.1-9.3)	1.2 (0.4-6.7)	1.6 (0.1-9.3)	0.108
		AP_Exc	2.14 (1.0-4.4)	2.1 (1.2-4.3)	2.4 (1.0-4.4)	0.160
		ML_Exc	1.82 (0.8-8.3)	1.7 (0.8-2.8)	1.9 (1.0-8.3)	0.069
	EC	Area	1.66 (0.2-14.4)	1.5 (0.2-8.5)	1.9 (0.6-14.4)	0.110
		AP_Exc	2.49 (1.3-5.6)	2.4 (1.3-4.6)	2.7 (1.7-5.6)	0.089
		ML_Exc	1.82 (0.5-9.5)	1.8 (0.5-3.7)	1.9 (1.0-9.5)	0.212
Shod	EO	Area	1.7 (0.6-9.1)	1.4 (0.7-5.9)	2.1 (0.6-9.1)	0.010*
		AP_Exc	2.5 (1.5-6.5)	2.3 (1.5-4.1)	2.8 (1.5-6.5)	0.031*
		ML_Exc	2.0 (1.0-7.9)	1.9 (1.0-3.7)	2.2 (1.2-7.9)	0.021*
	EC	Area	2.0 (0.5-12.2)	1.6 (0.5-3.4)	3.3 (0.7-12.2)	< 0.001*
		AP_Exc	2.9 (1.5-8.9)	2.5 (1.5-4.6)	4.0 (1.9-8.9)	0.001*
		ML_Exc	1.8 (0.7-5.7)	1.8 (0.7-2.8)	2.1 (1.0-5.7)	0.013*

Postural sway is quantified by the centre of pressure (COP) sway area (S_Area), the maximum COP antero-posterior excursion (AP_ Exc) and the maximum COP medio-lateral excursion (ML_Exc). Results for eyes open (EO), eyes closed (EC), barefoot and shod conditions are presented. All values correspond to measurements at baseline. The significance (p) of the difference between those that passed or failed the paper grip test at baseline is also presented (Mann-Whitney U test). Statistically significant differences ($p < 0.05$) are noted with *.

hallux grip force (Table 1). With regards to balance, people who failed the PGT also had significantly higher postural sway in shod conditions at baseline (Table 3). Similar differences were also observed for barefoot balance in the results of the follow-up visits highlighting a link between the PGT and the act of maintaining balance.

Studying postural sway in shod conditions is particularly relevant in the case of people with diabetes and neuropathy. According to standard clinical practice, people with diabetes and PN are advised to avoid barefoot walking at all times (outdoors or indoors) and are routinely provided with footwear with thick cushioning foot-beds or insoles [18]. These cushioning supplements, which redistribute the plantar load to protect the foot, also affect balance and can increase the risk for falling [17]. Specifically, wearing footwear with thick and soft insoles has been found to increase postural sway [18,19]. This observation was also

Table 4
The results of the longitudinal GEE analysis on the correlation between hallux grip force and measurements of postural sway.

			N	B	95% Wald Confidence Interval Lower	95% Wald Confidence Interval Upper	Sig.	R^2m
Barefoot	EO	Area	196	−0.001	−0.006	0.004	0.762	−0.250
		AP_Exc	196	0.000	−0.002	0.003	0.736	0.006
		ML_Exc	196	−0.003	−0.005	0.000	0.030*	0.023
	EC	Area	196	−0.005	−0.009	−0.001	0.019*	0.031
		AP_Exc	196	−0.002	−0.004	0.000	0.099	0.031
		ML_Exc	196	−0.001	−0.004	0.002	0.389	0.021
Shod	EO	Area	196	−0.009	−0.014	−0.005	< 0.001*	0.045
		AP_Exc	196	−0.003	−0.005	−0.001	0.001*	0.029
		ML_Exc	196	−0.004	−0.006	−0.002	< 0.001*	0.037
	EC	Area	196	−0.009	−0.014	−0.003	0.001*	0.075
		AP_Exc	196	−0.003	−0.005	0.000	0.020*	0.063
		ML_Exc	196	−0.005	−0.008	−0.002	0.003*	0.028

Postural sway in eyes open (EO), eyes closed (EC), barefoot and shod conditions is quantified by the centre of pressure (COP) sway area (S_Area), the maximum COP antero-posterior excursion (AP_ Exc) and the maximum COP medio-lateral excursion (ML_Exc). The total number of observations (N) used for each application of the GEE model is presented along with the resulted regression coefficient (B), its confidence intervals and significance level (sig.). Significant correlations (i.e. sig. < 0.05) are noted with *. The values of marginal R^2 (R^2m) which offer an assessment of goodness of fit of the final GEE model are also presented. Besides hallux grip force, the GEE models also accounted for the effect of age and duration of diabetes at baseline and of the effect of average VPT.

Table 5
The results of the longitudinal GEE analysis on the correlation between hallux grip force and the dynamometry-based isometric strength of the muscles of the foot and ankle complex.

	N	B	95% Wald Confidence Interval		Sig.	R^2m
			Lower	Upper		
Ankle dorsi-flexion	190	0.004	0.002	0.005	< 0.001*	0.133
Ankle plantar-flexion	190	0.003	0.002	0.004	< 0.001*	0.143
Ankle inversion	190	0.005	0.003	0.006	< 0.001*	0.144
Ankle eversion	190	0.005	0.003	0.007	< 0.001*	0.202
Lesser toe plantar-flexion	190	0.004	0.002	0.006	< 0.001*	0.195
Lesser toe dorsi-flexion	190	0.005	0.003	0.006	< 0.001*	0.156
Hallux plantar-flexion	190	0.004	0.002	0.005	< 0.001*	0.184
Hallux dorsi-flexion	190	0.006	0.004	0.008	< 0.001*	0.168

The total number of observations (N) used for each application of the GEE model is presented along with the resulted regression coefficient (B), its confidence intervals and significance level (sig.). Significant correlations (i.e. sig. < 0.05) are noted with *. The values of marginal R^2 (R^2m) which offer an assessment of goodness of fit of the final GEE model are also presented. Besides hallux grip force the GEE models also accounted for the effect of age and duration of diabetes at baseline and of the effect of average VPT.

confirmed by the results of the present study where people consistently swayed more in shod conditions compared to barefoot (Table 3).

The use of the PGT as a qualitative tool for assessing balance has been demonstrated previously in non-diabetic populations [26]; however the present study offers the first evidence that this relationship is maintained in people with diabetes and PN. Previous research has also proven that the simple pass/fail outcome of the PGT can identify people whose hallux strength is below or above a threshold [15]. The qualitative nature of this measurement might not pose a serious problem for detecting severe impairments in muscle function, such as paralysis [12], however it can significantly limit its use in conditions where a more deterministic assessment of strength is needed.

This limitation can be overcome by measuring the gripping force exerted by the hallux during the PGT [13,15]. To this end, Menz et al. used the PGT to assess weakening of the flexors of the hallux or lesser toes in the general older population [13,26]. In order to get a measurement of strength that is specific to these muscle groups Menz et al. suggested minimising the involvement of other muscles by manually stabilising the participant's ankle during testing [13,26].

Muscle weakening is a major contributor to increased risk for falls and previous studies have identified different muscle groups as independent predictors for falls [26–28]. A study examining a population with diabetes identified the strength of the ankle dorsiflexion muscle group as a parameter that could potentially be used to identify people with a high risk for falls [27]. At the same time studies in non-diabetic populations found the strength of the lesser toe plantar flexors [26] or of the hallux plantar flexors alone to be independent predictors of falls [28].

Considering that no muscle group can be identified from literature as the single most important predictor for impaired balance and falls, the decision was made to use the PGT in this study to assess the strength of the entire foot-ankle complex and not of the hallux or toe plantar flexors alone. To achieve that, the participants were asked to keep their foot in contact with the ground while pushing against the ground with their hallux, but no external support was applied by the examiner. It was hypothesised that, to successfully perform this task, the participants would have to assume a rigid posture which would inevitably require activation of all muscle groups at the foot-ankle level.

The validity of this hypothesis is supported by the results of this study. More specifically a cross-sectional analysis of the relationship between hallux grip force and isometric muscle strength at baseline, revealed significant correlations with all muscle groups of the foot-ankle complex (Table 2). These correlations indicated that people with higher hallux grip force also tended to have higher foot-ankle isometric strength.

A longitudinal analysis was performed to see if hallux grip force could be used to monitor changes in muscle strength; results revealed that hallux grip force was a significant predictor for changes in isometric muscle strength in the tested population. Consistent with the cross-sectional analysis this relationship was significant for all muscle groups of the foot-ankle complex (Table 5).

These findings indicate that hallux grip force, as this was assessed here, is a measurement of strength that is not specific to the hallux but is relevant to the strength of the entire foot-ankle complex. Even though quantifying the involvement of individual muscle groups during the PGT was beyond the purpose of this study, further work involving EMG is needed to fully understand the role of different muscle groups and the parameters affecting hallux grip force.

In this study isometric muscle strength was assessed using a hand-held dynamometer following an established protocol (i.e. “make” technique) with verified reliability for assessing foot-ankle weakening and the effect of exercise [24]. According to this technique the examiner manually stabilises the dynamometer and the patient's leg during testing. Inability to do so compromises the isometric nature of muscle contraction and significantly affects the reliability of the measurement [24]. This element of operator-dependency and the relevant difficulty of reliably implementing this test can limit the use of dynamometry-based measurements of foot-ankle strength in clinical practice. In contrast, the measurement of hallux grip force using the PGT is not dependent on the examiner's strength and does not require manually stabilising the foot, which can significantly enhance its viability as a clinical test.

With regards to balance, hallux grip force did not appear to be a strong indicator of poor balance at baseline. Indeed, only one weak significant correlation was found between a postural sway parameter and hallux grip force. On the contrary, GEE analysis of longitudinal data revealed that monitoring hallux grip force could be used to predict changes in postural sway over time. More specifically decreasing hallux grip force was significantly associated with increasing postural sway in the tested population (Table 4). This finding highlights the potential use of hallux grip force to identify individuals who are losing their ability to maintain balance.

In contrast to hallux grip force, no significant association was found between the dynamometry-based isometric strength of the hallux or lesser toes plantar flexors and any parameter of postural sway. This lack of significant associations was consistent between the cross-sectional and longitudinal analyses. The fact that the isometric strength of the hallux was not associated in any way with postural sway, but hallux grip force was, supports the hypothesis that the measurement of hallux grip force is not a measurement specific to the hallux. Hallux grip force appears to be a task-specific measurement of force for which the ability to activate and control all muscles of the foot-ankle to maintain contact with the ground is equally important as the ability to generate high moments around the 1^{st} metatarsophalangeal joint.

This study has employed postural sway as a measurement of the participants' ability to maintain balance; which was considered an indirect assessment for their risk for falls [4,7,29]. Future studies, which will focus on the incidents of falls as a primary outcome measure is warranted to further investigate whether hallux grip force is indeed a predictor for falls. This will help develop a simple clinical tool which can be used in any setting not only to identify people at risk of falling but also to assess the effectiveness of exercise interventions for effective clinical management.

The main limitation of the methodology presented here for measuring hallux grip force stems from the use of a pressure platform. The need for such specialised equipment can limit its clinical viability and potential value for clinical practice. Although most specialist diabetic clinics have pressure platforms, alternative ways of reliably measuring hallux grip force using equipment that can be readily available in different clinical settings are needed.

Another important determinant for clinical viability is the duration of testing. Following established clinical protocols where the study was completed, hallux grip force was assessed only once for each foot, keeping the overall duration of testing below 5 min [30]. However, in other applications of the PGT up to three trials per participant have been used [12,13]. Further studies are needed to establish the minimum number of trials that are needed to reliably assess hallux grip force.

The results of this study indicate that hallux grip force is a marker for foot-ankle strength that could be used to detect weakening and to monitor the effectiveness of strength exercise interventions. Moreover, the significant relationship between hallux grip force and postural sway highlights its potential use as a screening tool for identifying people with diabetes and neuropathy who are losing their ability to maintain balance and are at risk of falling.

Conflicts of interest

None.

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Appendix A. Supplementary data

Supplementary material related to this article can be found, in the online version, at doi:https://doi.org/10.1016/j.gaitpost.2019.02.020.

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