**Title:** Reliability and validity of an enhanced paper grip test; a simple clinical test for assessing lower limb strength

**Running title**: Enhanced paper grip test

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**Abstract:**

**Background:** The paper-grip-test (PGT) involves pulling a small card from underneath the participant's foot while asking them to grip with their hallux. The PGT is shown to be effective in detecting foot muscle-weakening but its outcome is operator-dependent. To overcome this limitation, an enhanced PGT (EPGT) is proposed that replaces the pass/fail outcome of the PGT with a continuous measurement of the pulling force that is needed to remove the card (EPGT-force).

**Research question:** Is the EPGT-force an accurate, reliable and clinically applicable measurement of strength?

**Methods:** Reliability and clinical applicability were examined in two ways. Firstly, two examiners measured EPGT-force for twenty healthy volunteers in a test/retest set-up. EPGT force was measured using a dynamometer, the hallux grip force was measured using a pressure mat. The clinical applicability of the EPGT was tested in ten people with diabetes. Postural sway was also measured.

**Results:** Interclass correlation coefficients (ICC) revealed excellent inter-rater reliability (ICC>0.75). Intra-rater reliability was excellent for the first examiner (ICC=0.795) and good for the second (ICC=0.703). Linear regression analysis indicated that hallux grip force accounted (on average) for 83%±4% of the variability in EPGT force. This strong relationship between EPGT force and hallux grip force remained when the test was performed in a clinical setting with the latter accounting for 88% in EPGT force variability. Spearman rank order correlation showed that people with diabetes with a higher difference in EPGT force between limbs swayed more.

**Significance:** EPGT force is a reliable and accurate measurement of hallux grip force. Hallux grip force was previously found to be strongly correlated to the strength of all muscle groups of the foot and ankle and to the ability to maintain balance. The proposed EPGT could be used to monitor muscle weakness in clinics for better falls-risk assessment.

## 1. Introduction

Thirty percent of the general population over the age of 65 have at least one fall every year[1] and this figure is even higher in people with diabetes[2–4]. Strong evidence suggests that access to preventative care for falls, including multifactorial falls risk assessment and targeted strength and balance training, could lead to a substantial reduction in falls and savings for national health systems[5–8]. Falling for the first time sets in motion a cycle of increased fear of falling, reduced activity and loss of strength leading to a higher risk for further falls. Hence, preventing the first fall from happening is crucial.

Muscle weakening as a result of ageing or pathologies like diabetes is a major risk factor for falls[1,9,10] which should be considered when assessing falls risk[9]. Indeed numerous studies have demonstrated that measurements of foot and ankle muscle strength can enhance the prediction of falls[9–15]. Even though a range of different methods to reliably measure foot and ankle muscle strength in the lab can be found in the literature, to the authors knowledge, none of these methods are as yet widely adopted as part of standard clinical practice. Among the limiting factors for measuring foot and ankle strength in clinics, is the need for specialised measurement devices such as pressure platforms[13–15] or specialised dynamometers[16–18].

The paper grip test(PGT) is a simple, clinically applicable test to detect muscle weakness in the foot. This test involves the examiner placing a piece of cardboard (the size of a business card) under the patient's hallux and asking them to grip it with their hallux. The examiner then pulls the card away with gradually increasing power while the participant offers resistance. The participant passes the test if they can successfully grip the card. This test 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[19]. In recent years, it has also been proven that the PGT is capable of detecting muscle weakness in the general older population[12,20], and in people with diabetes and sensory loss in their feet[21,22].

More specifically the PGT was shown to be capable of detecting whether the strength of the hallux plantar flexors is above or below a certain threshold[21]. However, this threshold could strongly depend on the examiner's own strength and technique. A possible way of overcoming this limitation is to replace the simple pass/fail outcome of the conventional PGT with a continuous measurement of strength. This can be achieved by performing the PGT on a pressure mat[20,21,23]. The use of a pressure mat enables the direct measurement of the force that is applied by a person's hallux during the PGT (i.e. hallux grip force). Hallux grip force is significantly correlated to dynamometry-based measurements of all muscle groups of the foot and ankle and to the ability to maintain balance[23].

These findings highlight the potential value of hallux grip force as a measurement of foot and ankle strength that can be used to detect people that start losing their ability to maintain their balance. However, the use of a pressure mat or any other specialised equipment to measure hallux grip force can significantly undermine the clinical applicability of this measurement. In this context, the purpose of this study is to propose a simple method to measure hallux grip force in clinics without the use of expensive specialised equipment. It is hypothesised that measuring the pulling force that is needed to pull the card from underneath the patient's hallux is a reliable measurement of hallux grip force. The inter-/intra-rater reliability and clinical applicability of this enhanced paper grip test(EPGT) will be assessed.

## 2. Enhanced paper grip test

Similar to the conventional PGT, the proposed EPGT requires the participant to take off their shoes and socks and to sit on a sturdy chair (preferably a chair without arm rests). The plantar surface of each hallux is wiped clean using a wet wipe. Once the skin is dry again the card is placed underneath the hallux. Unlike the conventional PGT, in this case, the card is linked to a dynamometer(Figure 1). The examiner asks the patient to start gripping the card and then starts pulling the dynamometer until the card is fully removed from underneath the hallux. The participant is gripping the card by pushing downwards with their hallux while also trying to keep their foot flat on the ground. They should also resist any forward sliding of the foot during testing. The test is repeated three times/foot, alternating between feet to allow at least 30 s of rest for each foot between tests. For each test, the maximum pulling force is recorded by the dynamometer with the three tests averaged to provide a single value for each foot. For simplicity, from this point on this force will be referred to as EPGT force. In this study, the card was connected to a 100N handheld dynamometer (Omega engineering, UK) using a 3D-printed attachment. A 3D-printable file for this attachment can be found in Supplementary Material A.

## 3. Inter-/intra-rater reliability

### 3.1 Methods

A convenience sample of twenty healthy participants (Female:7/ Male:13) was recruited at Staffordshire University to test the inter- and intra-rater reliability of the proposed EPGT (age: 34y±11y, BMI: 28kgr/$m^2$±6kgr/$m^2$). Inclusion criteria: Aged ≥18y. Exclusion criteria: history of structural surgery in the foot, lower limb musculoskeletal injury in the last 6 months, any musculoskeletal/neurological condition that would make them unable to plantar-flex their hallux.

Ethical approval was sought and granted by Staffordshire University's Research Ethics Committee. Written informed consent was obtained from each participant before testing.

Each participant attended two separate testing sessions within 48h and during each session, they were tested by two independent examiners (one male, one female)[24]. The participants were tested with the examiners taking turns at being the first to perform the test. The order of testing was reversed in the second testing session. The participants and examiners were blinded to all measurements.

The two examiners had different educational backgrounds and, at recruitment, they also had very different levels of exposure to the PGT or the proposed EPGT. More specifically, one examiner had a biomechanics background and was involved in the development of the EPGT (examiner-1). The second examiner had a clinical background and had never before performed either test (examiner-2). Both examiners were given a detailed step-by-step protocol to follow which included the exact instructions to participants (Supplementary Material B). The only deviation from this protocol was that for the purpose of this test only the left foot was tested. Also, testing was performed on a pressure mat (Matscan, Tekscan Inc., USA) to directly measure the hallux grip force.

The normality of recorded data was tested using the Shapiro Wilk test. Normally distributed data will be represented using their average(±STDEV) while non-normally distributed with their median (min:value, max:value). Bland-Altman's limits of agreement[25] and intraclass correlation coefficients(ICC) were calculated for: a) the data recorded by the two examiners for the same participant (inter-rater reliability) and b) for the data recorded by the same examiner on two different testing sessions (intra-rater reliability). Linear regression analysis was performed to see whether EPGT force is a strong predictor for the hallux grip force.

Bland-Altman's limits of agreement (LoA) are calculated based on the mean difference (Md) and the standard deviation (Sd) of differences between two paired measurements as follows[25]:

LoA =Md±2Sd.

When the difference between paired measurements is plotted over their average for each participant then 95% of data points should fall between the lower LoA and the upper LoA[25]. The values of ICCs (absolute agreement, two-way random, single measures) were interpreted as follows: ICC<0.40= poor, 0.40≤ICC< 0.60= fair, 0.60≤ ICC<0.74= good and ICC≥0.75 = excellent reliability[26].

For the proposed EPGT to be a viable test for clinical use it will need to have a good to excellent reliability. The inclusion of two examiners and twenty participants enables the reliable calculation of ICC between 0.7 and 0.9 (α=0.05. β=0.20)[24].

**3.2 Results**

Measurements from all twenty participants for both testing sessions and both examiners were included in the analysis. The recorded forces were not normally distributed but the calculated differences for the Bland-Altman analysis were normally distributed. The median of EPGT force for test/retest was 17N(8N,45N)/15N(4N,52N) for examiner-1 and 20N(4N,71N)/18N(8N,52N) for examiner-2, respectively.

The Bland-Altman plots for between-examiner (Figure 2a) and within-examiner (Figure 2b,c) comparisons verified that in all cases ≥95% of measured differences are within the respective LoA indicating satisfactory levels of agreement.

ICC for intra- and inter-rater reliability was calculated using the natural logarithm transformation of recorded forces. Inter-rater reliability was excellent for both the test and retest (Figure 3a). In both cases ICC was equal to 0.762 with 95% confidence intervals between 0.487/ 0.472 and 0.899/ 0.900 for the test/retest respectively. Intra-rater reliability was excellent for examiner-1 (ICC=0.795, 95% confidence interval 0.558 - 0.913) and good for examiner-2 (ICC=0.703, 95% confidence interval 0.392 - 0.870)(Figure 3b).

Regression analysis indicated that the hallux grip force can be predicted based on EPGT force(Figure 4). Hallux gripping force accounted for 79% to 88% of the variability in EPGT force(Table 1). A detailed table with all measurements can be found in Supplementary Material C.

## 4. Clinical applicability

### 4.1 Methods

Ten people (Female:5/Male:5) with diabetes and peripheral neuropathy(PN) were recruited from a diabetes hospital in Chennai, India (age: 58y±14y, BMI: $28kgr/m^2$±$4kgr/m^2$, duration of diabetes: 17y±14y). Institutional Ethics Committee approval was obtained prior to the start of the study and written informed consent was obtained from each participant before testing.

Inclusion criteria: a) Age>18y, b) diagnosis of diabetes (Type-1/2), c) lack of sensation in both feet. Exclusion criteria: a) Inability to walk independently for at least 10m, b) active foot ulcer, c) active infection, d) active/history of Charcot osteoarthropathy. Lack of sensation was determined by measuring the vibration perception threshold(VPT) at the hallux[27] using a biothesiometer (Kody Medical Electronics Private Ltd, Chennai, India). Three VPT measurements were performed for each hallux and only people with average VPT >25 V in both feet were included in the study[28]. Across all participants, the median of VPT score was 42V(26V,49V).

EPGT force and hallux grip force were recorded for both feet using the same protocol as outlined above. Measurements were averaged between limbs to produce a single EPGT force and hallux grip force per participant. To provide a measurement of imbalance in strength between limbs, the normalised difference between limbs ($NF_{dif}$) was also calculated as follows: $NF_{dif}=abs(F_L-F_R)/F_{Avg}$, where $F_L$, $F_R$ are the forces measured for the left and right foot respectively and $F_{Avg}$ their average (i.e. $(F_L+F_R)/2$).

In addition, postural balance parameters related to centre of pressure (CoP) were measured in barefoot standing (eyes open and eyes closed conditions) using a pressure mat (Matscan,Tekscan Inc.,USA) and a previously presented testing protocol[23]. The area of CoP sway, the maximum antero-posterior excursion (AP_ Exc) and the maximum medio-lateral excursion (ML_Exc) were calculated using the Sway Analysis Module within the Matscan software (FScan Clinical 6.62,Tekscan Inc.,USA).

The normality of recorded data was tested using the Shapiro Wilk test and linear regression analysis was performed to see whether the EPGT force remains a strong predictor for hallux grip force when the test is performed in a diabetic population in a clinical setting. The possible associations between VPT, force and balance measurements were tested using a Spearman rank order correlation analysis.

### 4.2 Results

One participant had to be excluded from the analysis because his EPGT force exceeded the capacity of the dynamometer(i.e. >100N). Regression analysis indicated that the hallux grip force can be predicted based on EPGT force (Figure 5); with hallux gripping force accounting for 88% of the variability in EPGT force(Table 1). Spearman rank order correlation showed that higher values of VPT were moderately[29] correlated with higher sway area (rs(9)=0.667,p=0.049) in the eyes closed conditions. Higher normalised difference between limbs in EPGT force was strongly[29] correlated to higher sway area (rs(9)=0.800,p=0.010), and moderately correlated to higher AP_Exc (rs(9)=0.667,p=0.049) and ML_Exc (rs(9)=0.667,p=0.007) in the eyes open conditions. In the eyes closed conditions, a higher EPGT force difference between limbs was strongly[29] correlated to higher sway area (rs(9)=0.700,p=0.036) and AP_Exc(rs(9)=0.800,p=0.010). A detailed table with all measurements can be found in supplementary material C.

## 5. Discussion

This study proposes an enhanced version of an established test (i.e. PGT) for the quantitative assessment of lower limb strength as part of clinical practice. In the conventional PGT muscle weakness is detected based on whether the examiner is able (or not) to pull a small piece of cardboard from underneath the participant's hallux. To enhance the reliability and reduce the operator-dependency of this test, its simple pass/fail outcome is replaced by a continuous measurement of force. In previous studies, this has been achieved by measuring the compressive force applied by the hallux during testing (i.e. hallux grip force) using plantar pressure assessment systems. Although hallux grip force can be reliably measured using plantar pressure assessment systems the need for such specialised equipment significantly reduces the clinical applicability of this measurement. At the same time, calculating the hallux grip force from pressure distribution data also requires identifying and isolating the hallux area and extracting the maximum net force for this area. The need for data extraction/postprocessing increases the time burden of the test reducing even further its clinical applicability.

To overcome these challenges, thereby improving the clinical applicability of the test, the proposed EPGT indirectly assesses the hallux grip force from the pulling force that is needed to pull the card from underneath the participant's hallux. In this case, the only device that is needed is a hand-held dynamometer which is substantially less expensive than plantar pressure assessment systems. These dynamometers can be digital, or mechanical and are easily available from various commercial sources. At the same time, this test does not require any data extraction or postprocessing. When this test was used in people with diabetes and PN in a diabetes clinic, calculating EPGT force for both feet took around 5 minutes; including the time spent explaining the test to the participants. The simple nature of the EPGT, combined with its low cost and low time burden indicates that it could be implemented as part of standard clinical practice as a screening tool for foot and ankle muscle weakening. Early detection of foot and ankle weakness could lead to timely initiation of an exercise program to improve strength, balance and to prevent falls [15,30]. However, before exploring the possible clinical use of the EPGT, its reliability and accuracy must be established first.

The reliability of the measurement of EPGT force was assessed by having two examiners performing this test on the same group of people. The examiners had very diverse backgrounds and one of them (examiner-2) had not performed this test before. However, when the two examiners were provided with step-by-step instructions (see supplementary material B) they were both able to successfully perform the test with excellent consistency between them (ICC≥0.75).

A comparison between the test/retest results for each examiner showed that both examiners were also very consistent within themselves (Figures 2,3). More specifically the intra-rater reliability for examiner-1, who had previous experience with this test, was excellent (ICC≥0.75). For examiner-2, who had not performed this test before, the intra-rater reliability was good (ICC=0.703). Even though this is still a positive outcome, it also points to a possible learning curve.

The accuracy of EPGT force as an indirect measurement of the hallux grip force was assessed in a series of linear regression analyses. These analyses indicated that EPGT force is a strong predictor of hallux grip force with the latter accounting for 79% to 88% of the variability of EPGT force. This strong relationship between EPGT force and hallux grip force was maintained when the test was performed in a clinic in people with diabetes and PN, where hallux grip force accounted for 88% of the variability in EPGT force. Based on that it can be concluded that EPGT force can be a valid indirect measurement of hallux grip force. However clearly this measurement is also affected, to a lesser degree, by parameters other than hallux grip force.

The remaining 12% to 21% of the variability in EPGT force could be attributed to differences in the friction coefficient between the skin and the card and differences in the examiners' technique. Probably the most important parameter with regards to this technique is the speed with which the examiner pulls the dynamometer. In this study, the examiners were asked to pull the dynamometer approximately by one cm/second, but no aid or feedback was given with regards to the actual pulling speed. The use of distance markings on the testing surface combined with a metronome could help reduce the effect of different pulling speeds.

The testing surface is also expected to play a very important role in the outcome of the test. More specifically the testing surface needs to be flat and rigid with frictional properties that are uniform across its surface. In the present study, all tests were performed on a pressure mat. Moving forward, the use of a standardised surface will enable a comparison between different applications of the test. This standardised surface could simply be a sheet of paper taped on a flat firm floor.

The proposed test is focused on the indirect measurement of the hallux grip force because previous research has shown that this measurement is strongly related to balance[23]. This link was further explored here, and strong associations were found between the imbalance in EPGT force between limbs and postural balance both in eyes open and eyes closed conditions. Even though the sample size in this study is too low to enable drawing any definitive conclusion, these findings reinforce the potential value of EPGT force in assessing a person's ability to maintain their balance.

**6. Conclusions:**

The results of this study indicate that the EPGT force is a reliable and accurate indirect measurement of the hallux grip force and opens the way for its wider use in research and clinical practice. Further research will be needed to assess the clinical value of this measurement for the prevention of falls in people with diabetes as well as in the general older population.

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**Tables:**

Table 1: The outcome of the linear regression analyses on the relationship between hallux grip force and EPGT force. The assumed relationship is as follows: y= x*B + Intercept, where x is the hallux grip force and y the EPGT force. Values of B and of Intercept that are significantly different to zero are indicated with (**) or (*) for p<0.001 or p<0.05 respectively. Multiplying the Adjusted $R^2$ value by hundred gives the percent of variation in EPGT force that can be explained by variation in hallux grip force.

| Examiner | Condition | n | Adjusted $R^2$ | F | B | Intercept |
|---|---|---|---|---|---|---|
| 1 | Healthy-Day1 | 20 | 0.79 | 71.77 | 0.260** | 9.074** |
| 2 | Healthy-Day1 | 20 | 0.88 | 134.74 | 0.316** | 8.169** |
| 1 | Healthy-Day2 | 20 | 0.83 | 91.11 | 0.358** | 5.985* |
| 2 | Healthy-Day2 | 20 | 0.82 | 87.72 | 0.372** | 8.45** |
| 1 | People with diabetes | 9 | 0.88 | 61.61 | 0.433** | -0.093 |

**Figure legends:**

Figure 1: The testing set up for the EPGT.

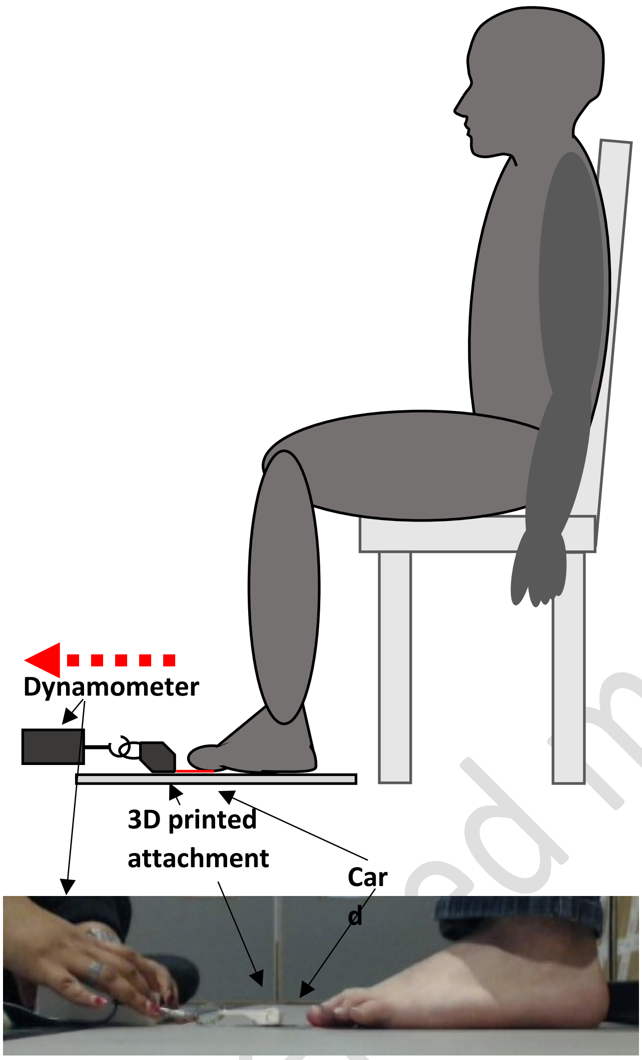

Figure 2: The Bland-Altman graphs of differences between examiners (a) and between test/retest for examiner-1 (b) and examiner-2 (c). In each case the respective average difference (Md) and limits of agreement (LoA) are also shown. Within-examiner differences are assessed relative to the average EPGT force for test/retest. Between-examiner differences are assessed relative to the average EPGT force for both examiners and for test/retest. In this case, repeated measures have been considered in the calculation of LoA[25].

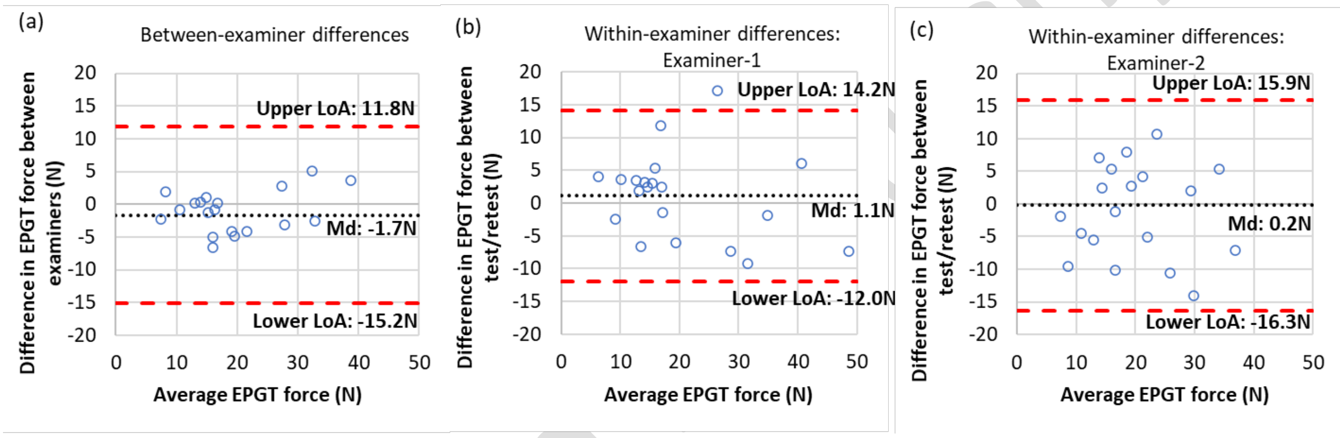

Figure 3: A graphic representation of (a) inter- and (b) intra-rater reliability. The relationship between the measured EPGT force by examiner-1 and examiner-2 for the first and second day of testing (a). The relationship between the measurements taken for the same participants on two different days by the two examiners (b). The natural logarithm transformation of measurements is presented to account for the non-normal distribution of EPGT force data.

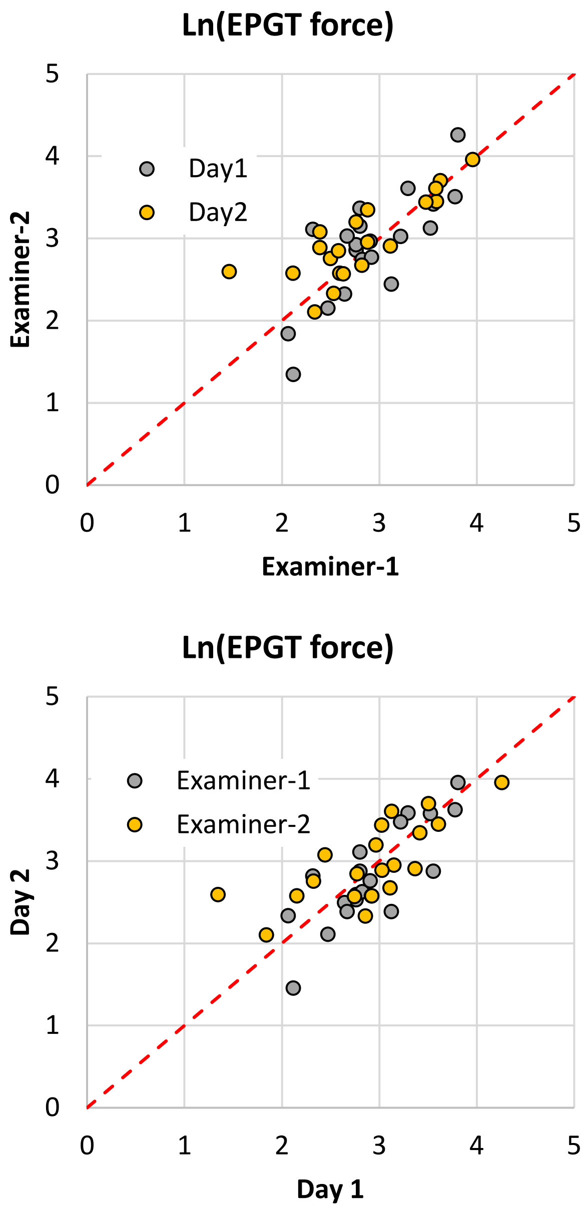

Figure 4: The relationship between hallux grip force and EPGT force in non-diabetic participants.

Results from both examiners as well as from test (Day 1) and retest (Day 2) are presented.

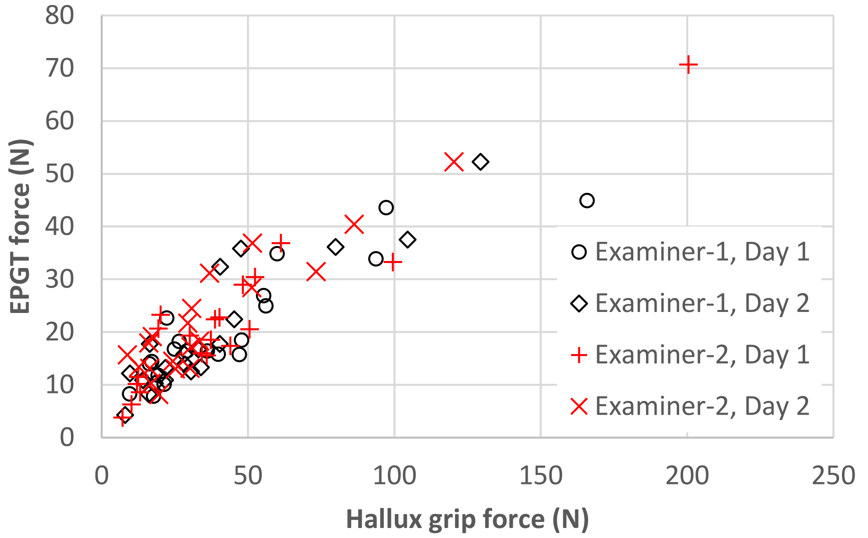

Figure 5: The relationship between hallux grip force and EPGT force in people with diabetes and PN participants. The equation of the linear relationship between the two is also shown; y: EPGT force, x: Hallux grip force.