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**Title:** Hallux plantar flexor strength in people with diabetic neuropathy: Validation of a simple clinical test.

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Hallux plantar flexor strength in people with diabetic neuropathy: Validation of a simple clinical test**.**

**Abstract**

**Aim:** To validate the paper grip test for assessing plantar flexion strength of the hallux.

**Methods:** Plantar flexor strength for 69 people with diabetic neuropathy was assessed: (a) using the paper grip test while simultaneously a plantar pressure platform quantified the force under the hallux, and (b) using a hand-held dynamometer. Following testing, participants were divided into groups: (1) passed vs. failed paper grip test (2) males vs. females. Statistical analyses determined if differences were evident between the groups and assessed the relationship between the paper grip test and the hand-held dynamometer. The discrimination ability, sensitivity, specificity, and reproducibility of the paper grip test was established.

**Results:** Participants who passed the paper grip test demonstrated greater grip force at the hallux than those who failed, and they also exhibited greater isometric maximum force during the hand-held dynamometry test (p ≤ 0.05). Grip force for males was significantly higher than for females. A moderate positive correlation between the paper grip test and the hand-held dynamometer was evident.

**Conclusions:** In the population examined the paper grip test was found to be a valid clinical tool; it offers a non-invasive, inexpensive, and quick method to assess plantar flexion strength of the hallux.

**Keywords:** Diabetes Mellitus;Diabetic Neuropathies;Foot; Hallux; Plantar pressure; Muscle weakness; Paper grip test; Muscle Strength Dynamometer

**1. Introduction**

Diabetes can lead to many long-term complications and is a major cause of lower limb amputation; people with diabetes are six times more likely to undergo an amputation than people without diabetes [1]. Approximately 85% of amputations are preceded by a foot ulcer [2] and the most common causal pathway to their development is the accumulation of trauma, neuropathy, and deformity [3].

The identification of the at-risk foot is an essential step in the prevention of foot problems, with an annual foot exanimation recommended for all people with diabetes [4]. A number of international guidelines on diabetic foot screening exist which detail the importance of determining the presence of peripheral neuropathy, peripheral vascular disease, foot deformity and limited joint mobility in this population [5]. While it was believed that foot deformity, such as claw toe, was caused by muscle atrophy or imbalance this has been shown to be incorrect [6], and therefore assessing foot deformity does not infer assessing muscular changes in the foot. However, the current foot screening guidelines do not include an examination of foot muscle strength, even though structural changes in the forefoot [7] and atrophy of the intrinsic foot muscles, which has implications for foot function [8], are evident in the neuropathic diabetic foot. Previous research has highlighted the need for the introduction of clinical guidelines with regards to the biomechanical assessment of the feet in the primary care setting, in order to reduce the incidence of diabetic foot complications [9].

The toes play an important role in gait to stabilise the foot and assist in forward propulsion [10]. The paper grip test was developed as a screening tool for muscle weakness in people with leprosy [11] and previous research has found it to be accurate in detecting muscle weakness in people without diabetes [12]. A recent paper utilised the paper grip test in a population of people with diabetes and concluded that it could add value to current foot examination procedures for patients with diabetes mellitus [13], however, the paper grip test has not previously been validated for people with diabetes. Previous research which examined toe flexor muscle strength reported strength differences between the sexes [12,14], with women exhibiting less absolute strength than men. At present, it is not known if this difference in muscle strength between the sexes is evident in people with diabetes.

Hand-held dynamometers, to measure muscle strength, has been shown to be reliable [15–17] and have been utilised in research involving people with diabetes [18,19]. While previous research has reported that the paper grip test has lower reliability than hand-held dynamometry when measuring intrinsic foot muscle strength [20], no research to date has compared results from the same participants for the paper grip test and a hand-held dynamometer.

This study investigated the validity of the paper grip test as a clinical tool for assessing plantar flexion strength of the hallux in people with diabetic neuropathy and examined the relationship between results from the paper grip test and a hand-held dynamometer. In addition, a comparison between sexes was conducted.

**2.** **Subjects, Materials and Methods**

**2.1 Study population**

Sixty-nine people (27 females and 42 males) with Type 2 diabetes were recruited from and tested at a diabetic referral centre in India (see Table 1 for participant demographics).

Inclusion criteria for participants were:

* Adult (age 18-80 years)
* Diagnosed with Type 2 diabetes
* Lack of sensation (Vibration perception threshold >25 Volts) at the hallux, 1st metatarsal, 3rd metatarsal, 5th metatarsal, medial arch, heel, dorsum and ankle
* At least one palpable pedal pulse on each foot
* Ability to walk independently for 10m

Exclusion criteria for participants were:

* Current/previous foot ulceration
* Active foot infection
* Previous foot surgeries
* Gross foot abnormality/deformity
* Alzheimer’s/dementia/impaired cognitive function
* Chronic kidney disease

Institutional Ethics Committee approval was obtained prior to the start of the study and written informed consent was obtained from participants prior to initiation of study procedures.

**2.2 Procedure**

Plantar flexion strength of the hallux was measured simultaneously using the paper grip test [11] (clinical assessment) and a plantar pressure platform (biomechanical assessment) for both feet. During the paper grip test, participants sit in a chair with their hips, knees and ankles in 90° of flexion. 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 in a horizontal direction while the participant offers resistance, ensuring the participant’s heel remains on the ground during the test. The participants were considered to have passed the paper grip test if they could successfully hold the cardboard or a fail if they failed to grip the cardboard, with one trial completed for each foot. Although previous research has utilised different scoring systems for the paper grip test [11,12], the present study employed the procedure used in common clinical practice. It was important to replicate the current clinical procedure which normally used one trial. As a part of routine clinical practice at the hospital where the study was conducted, a single examiner completed the paper grip test for all participants. Participants completed a trial run of the paper grip test to ensure they understood the procedure prior to testing. While the paper grip test was being performed the force generated under the hallux was recorded using a pressure platform (sampling at 100Hz; MatScan, Tekscan, USA). The MatScan system has a sensing area of 435.9 x 368.8 mm and a total of 2,288 sensels (resistive sensors) with a sensel density of 1.4 sensels/cm2. The system was calibrated for each participant using the “step calibration”, which uses the participant’s body weight to calibrate the system. The participant’s foot was placed on top of the pressure platform to allow the measurement of the force during the paper grip test to be recorded (Figure 1).

Hallux plantar flexion strength of both feet was assessed with a hand-held dynamometer (CITEC, C.I.T. Technics, The Netherlands) and followed the “make technique”. According to this strictly isometric technique the examiner holds the dynamometer stationary while the participant exerts a maximal force against it [21]. The testing procedure followed a previously published protocol [17]. The measurement was performed with the participants in a supine position with hips and knees extended and the foot stabilised by the examiner. The dynamometer was positioned on the plantar surface of the hallux. Three measurements of 3–5 s duration were recorded and the average of the three measurements was used for data analysis. The average of the three trials was used for analysis as previous research has shown that for this test mean values are more reliable than maximal values [22]. For a period during the study technical issues with the dynamometer resulted in an inability to record measurements for all participants. Therefore, it was only possible to record measurements for 53 of the 69 participants.

The testing procedure was repeated for 47 of the 69 participants at a follow-up session, three months after the first testing session. Follow up hand-held dynamometer measurements were recorded for 33 of the 53 participants who had measurements recorded in the first session. A flow chart of the experimental procedure is provided in Supplementary Figure 1.

**2.2** **Outcome measures**

Grip force was defined as the maximum total force value underneath the hallux during the paper grip test [12], as measured by the pressure platform. Isometric maximum force was defined as the maximal value recorded on the hand-held dynamometer during the test.

**2.3 Statistical analysis**

Participants were divided into groups for statistical analysis. Grouping one divided the participants into those who passed and those who failed the paper grip test and grouping two consisted of separate groups for males and females. Results for the left and right foot were analysed separately, as it is recommended not to pool data from both feet in foot research [22].

Data normality was assessed by Shapiro-Wilk's test (p > 0.05), with results indicating the data was not normally distributed. Distributions of the grip force and isometric maximum force results for the groups who passed and failed the paper grip test were not similar, as assessed by visual inspection.

Mann-Whitney U tests were conducted to determine if a significant difference in grip force measured at the hallux during the paper grip test, and isometric maximum force measured by the hand-held dynamometer, were evident between the participants who passed the paper grip test and those who failed the test. Mann-Whitney U tests were also performed to examine if grip force and isometric maximum force were affected by the participants’ sex, and to examine if the demographic profile (age, height, weight, BMI, duration of diabetes and HbA1c) was significantly different between (1) participants who passed and those who failed the paper grip test and (2) male and female participants. A chi-square test for homogeneity was performed to examine if a difference between the sexes existed in the groups which passed and failed the grip test. A significance level of a p-value ≤ 0.05 was used for all the analyses. Data for grip force and isometric maximum force are presented using univariate scatterplots [23] (Figures 2 and 3). To assess the relationship between the paper grip test and the hand-held dynamometer a Spearman's rank-order correlation was performed.

To determine the ability of the paper grip test to classify grip force (measured using the pressure platform) and isometric maximum force (measured using the hand-held dynamometer), receiver operating characteristic (ROC) curves were produced and the cut-off values were determined which provided the best balance between sensitivity and specificity. Using the identified cut-off value 2x2 tables were used to calculate diagnostic accuracy, sensitivity specificity and positive predictive values [24]. To examine the reproducibility of the paper grip test, this procedure was replicated for the results from the 3-month follow-up session to enable comparisons between the determined cut-off values from the two testing sessions.

**3. Results**

Out of 69 participants, 25 (36.2%) failed the grip test for both feet while 10 (14.5%) failed for only one foot. More specifically 8 participants failed the grip test for their left foot and passed for their right foot, while 2 participants failed the grip test for their right but not their left foot.

3.1 Group comparisons

Grip force for the group which passed the paper grip test was significantly higher than for the group which failed the paper grip test (left foot: U = 270, z = -3.892, p < 0.0005, r = 0.47, right foot: U = 176.5, z = -4.801, p < 0.0005, r = 0.57) (Table 1 and Figure 2). Grip force for males was significantly higher than for females (left foot: U = 304, z = -3.234, p = 0.001, r = 0.39, right foot: U = 175, z = -4.82, p < 0.0005, r = 0.58) (Table 2 and Figure 3).

Isometric maximum force for the group which passed the paper grip test was significantly higher than for the group which failed the paper grip test (left foot: U = 162.5, z = -3.341, p = 0.001, r = 0.46, right foot: U = 169, z = -3.199, p = 0.001, r = 0.44) (Table 1 and Figure 2). Isometric maximum force for males was significantly higher than for females (left foot: U = 148.50, z = -3.527, p < 0.0005, r = 0.48, right foot: U = 140.50, z = -3.671, p < 0.0005, r = 0.50) (Table 2 and Figure 3).

A Spearman's rank-order correlation was performed to assess the relationship between grip force (measured by the pressure platform) and isometric maximum force (measured by the hand-held dynamometer. Preliminary analysis showed the relationship to be monotonic, as assessed by visual inspection of the scatterplots. There was a significant moderate positive correlation between grip force (paper grip test) and isometric maximum force (hand-held dynamometer), rs = 0.533, (left) and rs = 0.540 (right), p < 0.0005. Scatterplots displaying the relationship between grip force and isometric maximum force are provided in Supplementary Figure 2.

3.2 Participant Demographics

Significant differences were evident between the group which passed the paper grip test and the group which failed for HbA1c values and height (left foot), with no differences evident for age, weight, BMI, and duration of diabetes (Table 1). In the group which passed the paper grip test the participants had lower HbA1c values (U = 420, z = -2.092, p = 0.036, r = 0.25 (left); and U = 366, z = -2.473, p = 0.013, r = 0.30 (right)). Participants who passed the paper grip test were taller than those who failed for the left foot analysis (U = 358, z = -2.572, p = 0.01, r = 0.31), however for the right foot analysis no difference in the height of the participants was evident (U = 436, z = -1.9, p = 0.057, r = 0.23).

There were significant differences between the sexes in the groups which passed and failed the grip test (left: p = 0.012; right: p = 0.006). There were more males (left: 27 (75%); right: 31 (73.8%)) in the group which passed the paper grip test compared to the group which failed (left: 15 males (45.5%); right: 11 males (40.7%)).

Significant differences were evident between male and female participants for height (U = 78, z = -6.018, p < 0.0005, r = 0.72) and BMI (U = 360.5, z = -2.55, p = 0.011, r = 0.31), with no differences evident for age, weight, duration of diabetes or HbA1c (Table 2).

3.3 Discrimination ability of the paper grip test

Regarding the ability of the paper grip test to assess grip force, the ROC curves (provided in Supplementary Figure 3) indicate fair/good discrimination ability of the paper grip test (area under the curve = 0.773 (left) and 0.844 (right) (p < 0.001)). The test exhibited 75% diagnostic accuracy (71% sensitivity, 81% specificity, 82% positive predictive value) in detecting plantar flexion muscle weakness using a cut off value of 38.81 N for the left foot; and for the right foot a 75% diagnostic accuracy (65% sensitivity, 86% specificity, 81% positive predictive value) using a cut off value of 36.74 N.

Regarding the ability of the paper grip test to classify isometric maximum force, the ROC curves (provided in Supplementary Figure 4) indicate fair discrimination ability of the hand-held dynamometer (area under the curve = 0.768 (left) and 0.757 (right) (p = 0.001)). The test exhibited 73% diagnostic accuracy (72% sensitivity, 75% specificity, 79% positive predictive value) in detecting plantar flexion muscle weakness using a cut off value of 109.5 N for the left foot; and for the right foot a 69% diagnostic accuracy (63% sensitivity, 76% specificity, 76% positive predictive value) using a cut off value of 105 N.

3.4 Reproducibility of the paper grip test

The ROC curves for the 3-month follow-up session (provided in Supplementary Figure 5) indicate good discrimination ability of the paper grip test (area under the curve = 0.873 (left) and 0.874 (right) (p < 0.001)). The test exhibited 81% diagnostic accuracy (85% sensitivity, 75% specificity, 82% positive predictive value) in detecting plantar flexion muscle weakness using a cut off value of 33.81 N for the left foot; and for the right foot a 79% diagnostic accuracy (78% sensitivity, 79% specificity, 78% positive predictive value) using a cut off value of 33.73 N.

Regarding the ability of the paper grip test to classify isometric maximum force, the ROC curves 3-month follow-up session (provided in Supplementary Figure 6) indicate fair discrimination ability of the hand-held dynamometer (area under the curve = 0.764 (p = 0.002) (left) and 0.713 (p = 0.012) (right)). The test exhibited 75% diagnostic accuracy (81% sensitivity, 67% specificity, 75% positive predictive value) in detecting plantar flexion muscle weakness using a cut off value of 101.5N for the left foot; and for the right foot a 68% diagnostic accuracy (65% sensitivity, 71% specificity, 74% positive predictive value) using a cut off value of 102 N.

**4. Discussion**

The present study is the first to confirm the validity of the paper grip test in people with diabetes, previous research has confirmed its validity in people with leprosy [9] and people without a medical condition [10].

Weakness of the plantar flexor muscles was prominent in the participants in this study with 43% of feet tested (60 of 138 feet; 47% for left foot and 39% for right foot) failing the paper grip test. Only one previous study has reported results for the paper grip test in people with diabetes [13]; in their sample of 266 people with diabetes 32% of participants failed the paper grip test. While all the participants in the present study had neuropathy only 21% of the participants in the study by Mahieu et al. [13] had neuropathy (as assessed by the Semmes Weinstein Monofilament Test 5.07/10-g), which may explain the lower percentage of people with plantar flexion muscle weakness in their study. The grip force values for participants who passed the paper grip test were similar to those reported by Menz et al. [12] for a population without a medical condition, however, the values for those who failed the test were higher (6-12 N higher) in the present study. A potential explanation for this difference may be that the forces applied by the examiners when completing the test were different across the studies. Results from this study, regarding higher HbA1c values for those who failed the paper grip test, support previous research which found that higher HbA1c values increase the risk of developing diabetes-related complications [25]. When the relationship between height and results of the paper grip test were examined a significant difference was evident for the left but not the right foot (p = 0.057), additional research is warranted to examine the effect of height on hallux plantar flexor muscle strength assessments.

This study was the first to compare grip force (paper grip test) and isometric maximum force (hand- held dynamometry testing) for the same participants, with a significant moderate positive correlation found between the tests. The paper grip test indicated fair/good discrimination ability to classify hallux plantar flexor strength, as assessed by grip force and isometric maximum force, with similar diagnostic accuracy, sensitivity, specificity, and positive predictive values. While previous research reported that the paper grip test has lower reliability than hand-held dynamometry testing when measuring intrinsic foot muscle strength [17], results from the present study support the use of the paper grip test in clinical practice. The present study also examined the reproducibility of the paper grip test with positive results; for both testing sessions, there were similar results for diagnostic accuracy, sensitivity, specificity, and positive predictive value and small differences in the determined cut-off values were evident. For grip force, there were differences of 5 N and 3 N between the testing sessions, for the left and right feet respectively. For isometric maximum force differences of 8 N and 3 N, for the left and right feet respectively, were evident.

As identified by Formosa et al. [5] there is a clear lack of evidence on which the current diabetic foot screening guidelines are based, and the paper grip test is a simple tool which can provide quantifiable information which can be utilised to inform these guidelines. Also, previous research has highlighted the importance of clinical biomechanical assessment of the feet in people with diabetes in order to reduce the incidence of diabetes foot complications [9]. There is a need for the development of evidence bases for clinical tests, like the paper grip test, to confirm the importance of their use in clinical practice. The current study offers initial evidence on the validity of the paper grip test, further larger scale studies assessing the association between passing/failing the paper grip test and the development of diabetes foot complications and the inter-tester reliability of the paper grip test are required.

4.1 Limitations

The use of one trial per participant for the paper grip test could be considered a limitation in this study. This protocol was utilised as it was clinical practice where the study was completed, however, previous research has used different protocols of up to three trials per participant [11,12].

The hand-held dynamometer has the advantage over the paper grip test of the ability to assess different muscle groups, whereas the paper grip test can only be used for assessing flexion strength of the toes. The paper grip test can also be used on the lesser toes; however, this was not examined within this study. Other limitations of the paper grip test include the effect of ankle plantar flexor muscles and considerations about inter-tester reliability and the type of paper and flooring used during the test. While the paper grip test is conducted with the heel on the floor to limit ankle plantar flexor muscles, the contribution of these muscles cannot be completely discounted. Also, the accuracy of the grip paper test is dependent on the examiner being consistent in the force that apply to move the paper, and future research to evaluate its inter-tester reliability is required. If the paper used is too thin it may tear during the test, therefore it is recommended to use a standard business card (at least a paper weight of 100 g/m2) and, as different flooring may offer different frictional properties, to standardise the testing surface flooring [11]. Having said that, the overall reliability of the grip test could be improved with the standardisation of the pulling force that is applied to the paper and of the testing surfaces. Currently, it is not possible to implement a method to consistently adjust the examiner’s applied force during the test for individuals, therefore as males in general generate a greater grip force than females, females will be more likely to fail the test (in the present study 69% of male feet passed while only 37% of female feet passed). The ability to modify the test to enable the quantification of the force needed to pull the paper from under the toe would greatly increase the usability of this test. Testing using hand-held dynamometers also have limitations; differences are evident between different dynamometers [26] and for accurate results the examiner’s strength must be greater than that of the muscle group being tested [21]. While both the paper grip test and hand-held dynamometer offer a quick assessment of muscle strength, as the paper grip test does not require specialist or expensive equipment it has an advantage over the hand-held dynamometer.

5. Conclusions

In the examined population, the paper grip test was found to be a valid and reproducible clinical tool for assessing plantar flexion strength of the hallux. This study also quantified the level of strength required to pass the paper grip test. Given that individuals with diabetes are generally required to complete a wide range of clinical tests which can be time consuming, the paper grip test can offer a non-invasive, inexpensive and quick test that provides valuable information on foot function.

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