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Assessing plantar sensation in the foot using the FOot Roughness Discrimination Test (FoRDT™): a reliability and validity study in stroke

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Declaration of Interest**:**

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Abstract

Background: The foot sole represents a sensory dynamometric map and is essential for balance and gait control**. S**ensory impairments are common, yet often difficult to quantify in neurological conditions, particularly stroke. A functionally oriented and quantifiable assessment, the Foot Roughness Discrimination Test (FoRDT™), was developed to address these shortcomings.

Objective: To evaluate inter- and intra-rater reliability, convergent and discriminant validity of the Foot Roughness Discrimination Test (FoRDT™).

Design: Test-retest design**.**

Setting: Hospital Outpatient.

Participants: Thirty-two people with stroke (mean age 70) at least 3 months after stroke, and 32 healthy, age-matched controls (mean age 70).

Main Outcome measures: Roughness discrimination thresholds were quantified utilising acrylic foot plates, laser-cut to produce graded spatial gratings. Stroke participants were tested on three occasions, and by two different raters. Inter- and intra-rater reliability and agreement were evaluated with Intraclass Correlation Coefficients and Bland-Altman plots. Convergent validity was evaluated through Spearman rank correlation coefficients (rho) between the FoRDT™ and the Erasmus modified Nottingham Sensory Assessment (EmNSA).

Results: Intra- and inter rater reliability and agreement were excellent (ICC =.86 (95% CI .72-.92) and .90 (95% CI .76 -.96)). Discriminant validity was demonstrated through significant differences in FoRDT™ between stroke and control participants ($p< .001$). Stroke fallers had statistically significant higher FoRDT™ scores compared to non-fallers ($p=.01$). Convergent validity was demonstrated through significant and strong correlations (rho) with the Erasmus MC Nottingham Sensory Assessment ($r=.69$, $p<.01$). Receiver Operator Curve analysis indicated the novel test to have excellent sensitivity and specificity in predicting the presence of self- reported sensory impairments. Functional Reach test significantly correlated with FoRDT™ ($r=.62$, $p< .01$) whilst measures of postural sway and gait speed did not ($r=.16-.26$, $p>.05$).

Conclusions: This simple and functionally oriented test of plantar sensation is reliable, valid and clinically feasible for use in an ambulatory, chronic stroke and elderly population. It offers clinicians and researchers a sensitive and robust sensory measure and may further support the evaluation of rehabilitation targeting foot sensation.

Level of Evidence: III

Introduction

The foot represents the only interface between the ground and the person. It is a highly specialised and dynamic unit, vital for sensing and responding to relative ground/body motion and changes in support surface properties. The plantar aspect of the foot is thus suggested to be a sensory ‘dynamometric map’ for human balance control [1,2] where enhanced or reduced tactile sensory inputs to the sole of the foot impact standing postural control [3], gait kinematics [4] and foot placement [5].

Sensory impairment to this functionally important unit is characteristic of several neurological populations and is associated with reduced standing balance, increased falls, slower gait speed, and altered postural control [6-8]. Following stroke, impairment of tactile sensation in the lower limb affects 30-56% of people [9,10], with lower limb tactile sensation showing less recovery compared to proprioception and upper limb somatosensation [9]. Reduced sensation in the foot is reported by people with stroke to impact walking, balance and is implicated in falls [7,11] whilst somatosensory deficits and motor weakness result in worse functional outcomes than motor weakness alone [12].

Evidence from cross-sectional studies of stroke populations, however, does not demonstrate strong associations between lower limb tactile sensation and functional outcomes [10,13]. Moreover, retraining of sensory impairments tend to be largely overlooked in favour of motor rehabilitation [14,15]. One interpretation contributing to this position may lie with the methods of tactile sensory assessment utilised in research and clinical settings.

Clinicians widely acknowledge the clinical importance of sensory assessment and its prognostic value following stroke [14]. The clinical evaluation of sensation following stroke, however, is typically undertaken in a subjective, non-standardized and unreliable manner with low proportions of clinicians using standardised methods [14]. Whilst standardised measures of sensation have been developed and evaluated in stroke and neurological populations [16], they are for the most part largely based on the clinical neurological examination. They are entrenched in providing clinical utility so are primarily screening tools which use ordinal scales to categorise individual tactile sensory modalities as absent, impaired or normal, making the clinical interpretation of the results difficult. They are administered passively to the patient in sitting or supine targeting the detection of stimuli; the lowest level of sensory processing [17]. This has led to several concerns: they may be insufficient to identify and uncover the presence, severity or complexity of sensory performance following CNS injury, they do not provide functionally meaningful somatosensory data, and they lack responsiveness to detect change [16-18].

Discriminating the textural qualities of a surface through touch is proposed to test the limits and capabilities of the tactile system [17,18]. Psychometrically robust and functionally oriented texture discrimination tests targeting the hand [19-21] and foot [22] have been developed and evaluated. Most adopt an active or haptic sensation paradigm, that is, they involve the manual exploration of a surface for the express purpose of obtaining somatosensory information. The movements selected optimize the relevant somatosensory receptors to gather the pertinent sensory qualities of the surface being explored. The manual exploration of a stimulus for the purpose of sensory information thus combines tactile and proprioception inputs to form a sensory perception [23], and is more strongly associated with measures of motor function in the upper limb and hand [24,25]. Such tests have been shown to possess greater sensitivity, uncovering greater proportions of sensory impairments and may better reflect sensorimotor system functioning [18,24].

To the best of our knowledge, however, no study to date has established the reliability or validity of using a roughness discrimination test, using active sensation, to quantify plantar sensory ability in people with stroke.

The aim of this study was to develop a functionally oriented, standardised test of foot sensation and evaluate its psychometric properties. Specific objectives were to evaluate intra- and inter-rater reliability, discriminant validity and convergent validity.

Methods

This is a reliability and validity study. Ethical approval was obtained from the NHS Health Research Authority NRES - Committee South Central – Berkshire B (15/SC/0191).

Participants

Participants were recruited from a convenience sample identified through UK NHS community services and stroke support groups. Eligibility criteria were: aged ≥ 18, stroke diagnosis confirmed via CT scan and clinical presentation, >3months post-stroke, able to independently stand (with or without walking aid), and able to independently walk at least 10m indoors. Potential participants were excluded if they had other neurological disease or co-morbidities/injuries that would affect mobility and/or foot sensory function.

Sample size calculations were based on the work of Shoukri et al [26]. For a 95% CI of 0.25 and a planned ICC of 0.8 (α=0.05), 32 participants were required. For inter-rater reliability, a study sample of 20 with two raters and a planned ICC of 0.8 (α=0.05) provides sufficient power for establishing a 95% CI of ~0.4 [27]. A sample size of 32 was sufficient for the test of convergent validity to detect a correlation coefficient of 0.3 (power=0.85, α=0.05) and for discriminant validity to detect an effect size of 0.86 (power=0.85, α=0.05).

The Foot Roughness Discrimination Test (FoRDT™)

This novel test was developed to assess sensory ability of the plantar aspect of the foot. It comprised 10 grated acrylic foot plates, machine laser cut to provide a range of standardised, quantifiable and graded stimuli of roughness using standardised ratio measurements (Fig 1a). The gratings run 90° to the long axis of the foot (Fig 1b). Spatial interval (SI) and dimensions are measured in micrometres (µm) (1µm = 1/1000 millimetre (mm)). The larger the spatial interval, the rougher the surface texture is perceived to be up to a point of between 3000 - 3500µm [28]. The spatial interval of the base stimulus is 1.5mm (1500µm) meaning it is the smoothest, increasing to 3.5mm for the roughest plate (3500µm). Comparator plates increase (in roughness) from the base stimulus by spatial intervals ranging from 50µm up to a maximum of 2000µm. This represents a spatial interval change or just noticeable difference (JND) from the base stimulus of between 3.3% and 133% respectively. A JND between 5-19% is considered the discrimination threshold in the fingertips of unimpaired older adults [18,28] but can be as high as 100% in stroke patients [18]. No normative data exists for the foot.

(insert fig 1 around here)

A two-alternative forced choice design (2AFC) in combination with a "one-up, three-down" staircase procedure [29] was employed. The 2AFC staircase task is a psychophysical method where the aim is to determine at what point two (different) stimuli, cannot be accurately and consistently discriminated. The 2AFC aspect attempts to eliminate inconsistencies that can otherwise arise from different observers being more or less conservative when making subjective reports about ambiguous, near threshold stimuli. It is a fundamental methodology used in sensory science [30].

Applying the 2AFC design to this test involved presenting two textured plates at a time in a series of increasingly difficult trials. Each trial included a base stimulus (A), and a changeable comparator stimulus (B). A and B were presented randomly (i.e. AB or BA) over the course of up to 11 trials. Stimuli were presented in a way that participants were unable to rely on any visual or auditory clues. The plates were presented in quick succession (within 5 seconds of each other) with participants required to discriminate between base and comparator stimuli, indicating which felt the roughest. The staircase approach to the 2AFC design involved the systematic updating of the comparator plate depending on whether the participant was able to discriminate between the plates. The task became more difficult after three correct responses (i.e. participants could tell the difference) or became easier after one incorrect response. This procedure is designed to converge over time on the threshold value that yields 79% correct performance. The discrimination threshold was calculated from the average of four reversals (i.e. changes from a series of correct to a series of incorrect responses, or vice versa), triggered by the first incorrect response. A greater discrimination threshold indicates worse somatosensory ability.

Procedures

Data collection was conducted in an outpatient hospital setting. Stroke participants (n=32) were tested with the FoRDT™ on two occasions, between one week and up to two weeks apart. The primary researcher (TG) was the rater on test session 1 and test session 2. A third testing session, involving 20 stroke participants, was completed by a physiotherapy assistant practitioner (PAP) trained in the test administration three days to one week after test session 2. Control participants (n=32) were tested on just one occasion.

The FoRDT™ was undertaken in standing with full weight bearing important to reflect real life foot-ground sensorimotor interactions and enhance ecological validity. Concentration, working memory and attention were key requirements of the test so the testing environment was an enclosed, quiet room on each occasion. A small pilot study confirmed the FoRDT™ took a maximum of 10 minutes to complete and was well understood by people with stroke.

For the purposes of validity testing, in addition to the FoRDT™, further data was collected. This included: participant demographics and stroke characteristics, self-reported falls in the previous 3 months, subjective reporting of lower limb sensory changes, Erasmus MC version of the Nottingham Sensory Assessment (EmNSA) [31], 10 metre timed walk test at fastest speed [32], standing Forward Reach Test (FRT) [33], and postural sway (COP velocity) recorded using a Tekscan pressure mat (Matscan, Biosense medical, Essex, UK).

Statistical analysis

Statistical analyses were performed using SPSS version 22.0. Data were summarised using frequencies and percentages, mean and standard deviation (SD) or median and inter-quartile range (IQR) as appropriate. Data presented for the FoRDT™ represents the roughness discrimination threshold, expressed in the original measurement unit (μm) and the Just Noticeable Difference (JND) between base and comparator stimuli, expressed as a percentage (%).

Necessary assumptions in reliability testing were accounted for [34]. Both inter- and intra-rater reliability and agreement were analysed using intra class correlation coefficient ($ICC_{2,1}$) and Bland –Altman plots in line with recommendations [35]. Standard error of measurement (SEM) provided an indication of the score likely due to measurement error. Coefficient of repeatability (CoR), provided a score change (in the original measurement scale) which included random and measurement error and was likely reflective of a true/real change [36].

FoRDT™ performance of the paretic stroke foot and matched healthy control foot allowed for an evaluation of discriminant validity. Stroke fallers/non-fallers were also compared. A Mann Whitney U test was used to determine statistical significance ($p<.05$) as data was not normally distributed as indicated by Shapiro-Wilks test ($p<0.05$). Receiver Operator Characteristic (ROC) analysis was used to generate the area under the curve (AUC) or concordance (c-statistic) to give a direct quantitative measure of the ability of FoRDT™ scores to discriminate between the respective groups (i.e. control/stroke and stroke fallers/stroke non-fallers). Stroke participants were categorised as fallers if they reported at least one fall within the previous three-month period [37].

There is no "gold-standard" measure of tactile sensation, although the EmNSA is considered a robust and clinically usable measure of sensation in neurological populations [16]. The magnitude of the relationship between the EmNSA and the FoRDT™ was determined using a Spearman's rank order correlation (rho). To provide evidence of convergent validity it was anticipated that roughness discrimination thresholds would have a moderate, negative correlation with the tactile sub-score of the EmNSA. The magnitude of the relationship between stroke participants' FoRDT™ performance and measures of gait speed, FRT, falls and COP velocity were evaluated using Spearman and Pearson correlational analysis where appropriate. Strength of correlations were interpreted using the classification where ≤ 0.29 = weak, 0.30- 0.49 = moderate and, ≥ 0.50 = strong [38].

Sensitivity and specificity was used to quantify diagnostic ability, with sensitivity indicating the proportion of true positives that are correctly identified, and specificity, the proportion of true negatives correctly identified [34]. The sensitivity and specificity of the novel test was evaluated using Receiver Operator

Characteristic (ROC) curve analysis against the dichotomous variable of stroke participant self-report sensory impaired/not impaired.

Results

Thirty-two people with chronic stroke and 32 healthy age matched controls participated in the study (table 1). Mean age (SD) for stroke participants was 70 ± 9 years and for control participants 70 ± 7 years.

(Insert table 1 here)

Scores for stroke participants on the FoRDT™ were not normally distributed, as indicated by the Shapiro-Wilks test ($p<0.05$). The distributional properties of the FoRDT™ is illustrated in Fig 2.

(insert Fig.2 around here)

Reliability

Intra- and inter-rater reliability data are presented in table 2. Figures are expressed in micrometers (µm) which represents the groove width difference between the base stimulus and comparator stimulus (i.e the point at which stimuli could not be discriminated). Both intra-and inter rater reliability was good-excellent (ICC = 0.86, 95%CI .72-0.92; ICC=0.90, 95%CI 0.76-0.96) respectively.

(insert table 2 here)

Bland-Altman plots demonstrated no significant anomlies across both inter and inter rater agreement (Figures 3 and 4). The line of equality/zero was within the 95% CI of the mean of the differences (*d)* for both inter- and intra –rater testing indicating no systematic bias. Intra rater testing indicated that eight of the 32 participants scored the same in testing session 1 and testing session 2.

(insert fig 3 and 4 around here)

Discriminant validity

Roughness discrimination threshold scores of the stroke foot (median = 750µm, JND= 50%) were significantly higher than the matched control foot (median=300µm, JND=20%, $U=267$, $z=-3.313$, $p=.001$, $r=0.58$, c-statistic 0.74, 95% CI 0.61-0.86, $p<0.01$). Stroke fallers also had significantly higher roughness discrimination thresholds (median 1200µm, JND=80%) than stroke non- fallers (median 400µm, JND=26.6%, $U=268$, $z=-2.41$, r=.43; c-statistic 0.78, 95% CI 0.61-0.94, p=0.01). In contrast, EmNSA tactile scores were not significantly different between stroke fallers and non-fallers (table 3). Roughness discrimination thresholds strongly correlated with the measure of balance, the FRT (r=.62, p<.01) but not gait speed (r=.26, p>.05) or COPvelocity (r=.17; p>.05)

(insert table 3 around here)

The FoRDT™ had strong and statistically significant correlation with the total tactile score of the EmNSA (r=0.69; p<0.01) and its constituent tactile parts (r=0.43-0.67) (table 4)

(insert table 4 here)

Sensitivity and specificity

The sensitivity and specificity of the FoRDT™ and the EmNSA against the dichotomous variable of stroke participant self-report sensory impaired/not impaired was analysed using ROC analysis. The area under the curve (AUC) c statistic for the FoRDT™ was 0.92 (SE 0.057, 95% CI 0.83-1.00, p = .001). AUC statistic for the tactile component of the EmNSA was 0.78 (SE=0.085, 95%CI 0.61-0.92, p=.05). The optimal cut off point to predict subjectively reported sensory impairment using the FoRDT™ was a roughness discrimination threshold of 500µm or JND of 33% (Youden index 0.67). At this level, our novel test demonstrated a sensitivity of 83% and a specificity of 87%.

Discussion:

Since it is the Central Nervous System rather than the peripheral sensory transducer that is affected after stroke, there is a clear rationale that any measure designed to evaluate somatosensory ability in stroke populations should attempt to assess 'higher level' processing of somatosensory perception [17]. This study evaluated the psychometric properties of the FoRDT™: our novel test of active tactile sensation targeting roughness discrimination in the sole of the foot. Our study provided data to support the feasibility, reliability and validity of the FoRDT™. Our novel test demonstrated superior sensitivity and specificity over the EmNSA in predicting self-reported sensory changes in chronic stroke and stronger associations with dynamic balance and reported falls in stroke participants.

The FoRDT™ evaluates tactile sensation in the whole of the foot sole in full weight-bearing. Our test utilises an established and robust psychophysical testing approach to evaluate somatosensory discrimination. The FoRDT™ utilises an interval measurement scale rather than a coarse ordinal scale and in this study sample, has no floor or ceiling effects. Our test provides an indication of impairment severity which may show greater responsiveness to change following intervention with further investigation. The FoRDT™ is feasible to administer, shows excellent reliability, and is strongly correlated with clinical measures of dynamic balance and reported falls. To our knowledge, this is the first study to evaluate active sensation in foot sole during full weight bearing.

This study further demonstrates that textured gratings provide a feasible, standardised and graded stimulus to evaluate roughness perception in the sole of the foot. The use of commonly found textures such as sand, gravel and turf have been recently used to assess discriminative ability in the foot of elderly and stroke subjects [38]. Whilst test-retest reliability and validity was demonstrated, such textures, whilst ecologically valid, were not quantifiably graded stimuli. A tactile test in which the stimulus is quantifiably graded is important and a feature of the FoRDT™. The grading and quantification of sensory ability along a continuous or interval scale provides a potential indicator of impairment severity so is of potential use in monitoring change. Textured gratings also produce the best match to psychophysical data of roughness perception [39] and multiple cortical and sub cortical neural correlates have been identified during texture discrimination tasks using gratings [40, 41].

Reliability and agreement of the FoRDT™ was excellent and evaluated in accordance with recommendations [35]. Inter-rater reliability of an outcome measure is crucial, particularly in long-term neurological populations who may have multiple interactions with different health-care professionals during the course of their rehabilitation. Poor or lower inter-rater reliability is commonly reported in standardised measures of sensation [16] so these data are encouraging. Coefficient of repeatability (CoR) data from this study also provide an indication of true real change. For example, a discrimination threshold change above 438μm (JND of 29%) is likely to indicate real change in sensation between testing occasions. Such a change could be due to recovery and/or therapeutic intervention, so this information is critical for the monitoring of recovery and the development of more effective interventions that target sensory impairment following stroke.

Convergent validity is supported by the strong and significant correlations with tactile scores of the EmNSA although this study contributes to the ongoing discussion as to whether individual sensory modalities (i.e. light touch, pressure, pinprick, sharp-blunt discrimination) which comprise the tactile component of several measures need to be assessed individually. Previous research in this area has demonstrated variable correlations between tactile sensory modalities [9,31,42] and hence the data from this study supports the need for further research in this area. Roughness discrimination thresholds may provide an alternative, appropriate and feasible method of determining the limits and capabilities of the tactile system in those with CNS lesions.

The FoRDT™ was also able to discriminate between stroke and control participant sensory ability. The median roughness discrimination threshold of stroke participants in this study was significantly higher than controls. Higher threshold scores, and therefore a greater JND indicate poorer discriminatory ability. There are no other studies in the foot to compare these data, although Carey et al,[18] found a mean JND of 17%-19% in the fingertips of control participants, and a modal JND of 100% in the fingertips of stroke participants; data that is comparable to our findings. One might expect healthy control discrimination thresholds in the hand to be much lower than in the foot given the increased sensory acuity of the hand and greater cortical representation compared with the foot [43], which was not the case. One explanation may be the surface areas of cutaneous skin being stimulated. The greater number of peripheral mechanoreceptors activated, equates to greater central processing of that activity [39]. Discrimination thresholds may be influenced by cutaneous-surface contact area. It also suggests that sensory ability of the hand and feet may not be as different as generally considered, at least with regard to this aspect of sensory discrimination, and supports that the foot is a complex sensory organ [1,2]. Further studies in the foot would be required to validate this.

Validity was further supported by the ability of the FoRDT™ to discriminate between stroke participants who reported falling compared to those who did not, and the strong correlations demonstrated between roughness discrimination thresholds and dynamic balance. With respect to this, our novel measure performed favourably compared to a range of other sensory measures, including the EmNSA, Q-tip cotton bud [44] and pin-prick detection as part of the National Institutes of Health Stroke Scale (NIHSS) [37], all of which showed weak and non-significant correlations with falls incidence or balance disability. This suggests that existing measures of sensory detection, widely used in clinical practice, may be inadequate for uncovering the complexities of sensory performance following CNS injury; and that novel measures such as the FoRDT™ are required to further elucidate our understanding in this area.

ROC curve analysis demonstrated that the FoRDT™ was better able to predict self-reported sensory impairments compared to the EmNSA. The data indicate that a discrimination threshold in stroke participants ≥500μm (JND 33%) is indicative of the presence of reported sensory impairments. Of note, the lower discrimination threshold of healthy controls (300μm - JND 20%) indicate that stroke participants not reporting impairment still performed worse than healthy, age matched controls. Several interpretations, which require further evaluation through future work, may account for these. Motor weakness in some stroke participants for example may have limited full active exploration of the gratings, resulting in increased threshold scores. However, textures with spatial intervals greater than 100μm are encoded spatially through the firing of slow adapting mechanoreceptors, so roughness perception is largely independent of movement, speed of movement or direction of movement [39].

Neither gait speed nor postural sway were significantly or strongly associated with roughness discrimination thresholds suggesting foot tactile discrimination may not be important during certain gait or balance tasks. Sensory reweighting in which altered or unreliable somatosensory information can be compensated for through increased use of visual and/or vestibular information [45, 46], may, however, explain these findings. Moreover, challenging locomotor tasks involve greater somatosensory cortical activity compared to more simple walking tasks [47, 48] suggesting clinical measures, such as the 10 metre walk, often used for its clinical utility, may not capture the sensorimotor interactions necessary for “real life” walking.

To develop targeted rehabilitation interventions, greater understanding of how somatosensory function maps onto participation function, is critical [49]. A key component to this is the availability and use of appropriate, sensitive and valid assessment tools. The development and use of sensory measures which are more closely aligned with the sensori-motor function of the foot may enhance understanding in this relatively understudied area. Our intention in developing the FoRDT™ was to address the issue that most standardised sensory measures are geared toward identifying the presence of impairment. In rehabilitation, however, the presence of an impairment is not necessarily important. Clinicians, and in particular patients, are most concerned with addressing the factors which impede function. Qualitative and laboratory based studies suggest foot sensation to be functionally important, and preliminary exploration of the psychometric qualities of the FoRDT™ suggests this test holds promise in corroborating this position. Sufficiently sensitive and robust measures such as the FoRDT™ which demonstrate associations between balance and mobility function and foot sensation may further support the evaluation of rehabilitation efforts which target foot sensation. It is hoped that this study provides further insight and opens up dialogue into quantifying the complex tactile sensory inputs that enable individuals to recognise and respond to variable foot-ground interactions during functional, weight bearing activities such as walking and balance.

Study limitations

This study recognises the testing of somatosensory discriminative ability, through its very nature, places greater demands than tests of detection on cognitive functions such as attention and working memory; functions which may also be impaired post stroke [50]. Discriminative ability may be further confounded by factors such as fatigue and motivation – known sequelae of stroke [51. Formal assessment of cognitive functions were not undertaken in this study sample, so the extent to which they influenced test outcome cannot be quantified. That these tests were evaluated in a cohort of chronic stroke also limits their generalisability to the wider stroke population. Symptoms of stroke, their recovery and potential compensations that occur over time, suggest further evaluation of these tests is required in other phases of stroke and across settings.

Conclusion

The FoRDT™ provides clinicians and researchers with a novel test of active tactile sensation for the foot, which has demonstrated good intra and inter-rater reliability and validity in a chronic stroke sample. It has several advantages over existing measures in terms of the sensitivity to detect somatosensory impairment, the ability to quantify impairment severity, and associations with functional measures of balance and reported falls in chronic, ambulatory stroke survivors. Such a measure has the potential to inform the development of targeted tactile rehabilitation of lower limb somatosensory impairments following stroke.

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