A new device for foot sensory examination employing auto-presentation of shear force stimuli against the skin

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Abstract

A new plantar foot sensation-testing instrument (PFS Tester) was developed for the practical screening of diabetic neuropathy and the prediction of fall risk for frail elderly people. Human plantar sensation may play an important role in many processes, including postural control, walking, and the clinical testing of diabetic peripheral neuropathy. The PFS Tester uses shear force on the skin as the mechanical stimulus, unlike any existing devices or tools for sensory examination, and it automatically provides the test site on the plantar foot with a pre-programmed sequence of stimuli. Although the PFS Tester uses two factors to distinguish stimulus intensity (a variable range and the speed of the shearing movement), measurements of the shear force on a material that simulates a human body showed that only a range of the probe movement affected the stimulus intensity. Also, the increment profiles of twenty-grade stimulus of the PFS Tester were similar to those of the Semmes-Weinstein (SW) monofilament, which is the most typical sensory exam tool. In addition, repetitive measurements of the force using the PFS Tester and the SW monofilament showed that the stimulus intensity of the PFS Tester had better reproducibility than that of the SW monofilament. To verify the validity of the sensory examination’s results of the PFS Tester, sensory thresholds on three sites of the plantar foot in nineteen subjects with diabetes mellitus were measured using the SW monofilament test and the PFS Tester. The sensory thresholds obtained by the PFS Tester had a favorable correlation to those obtained by the SW monofilament test. The results of this study demonstrated that a PFS Tester could be used as a simple sensory examination machine with good reliability, simplified operation, and a high compatibility with the SW monofilament test.

Key words: Foot sensation, Neurological evaluation, Semmes-Weinstein monofilament test, Mechanical stimulus, Fall prevention, Diabetic peripheral neuropathy, Health screening

1. Introduction

A sensory examination is one of the most common parts of the clinical neurological evaluation. It is generally accepted that there are five sensory modalities: vision, hearing, taste, smell, and touch. The main elements in the
sensory examination consist of segmental and peripheral nerve testing of the cutaneous sensibility, including sense of light touch, pain, temperature, vibration, and proprioception (Haerer, 1992, LeBlond, et al., 2008). The purpose of the sensory examination is to localize neurologic pathology by looking for characteristic distributions of sensory loss.

While the target sites of sensory exams generally spread into the whole body, the sensory exam for a particular part of the body contributes to a diagnosis of a specific pathology or the assessment of a specific physical performance. Plantar sensation appears to play an important role in regulating stepping during human gait and is also known to contribute to certain aspects of postural control, such as rapid stepping reactions evoked by a sudden unexpected loss of balance (Perry, et al., 2000). Because the foot is, in general, the only point of direct contact between the body and the external environment, sensory feedback originating from cutaneous receptors in the foot must have a role in the regulation of normal gait patterns (Nurse and Nigg, 2001). Additionally, age-related decline in plantar sensation has been related to both increased falls and impairment in compensatory stepping responses (Perry, 2006). A somatosensory exam for the plantar surface of the foot will prove to be very useful in predicting the risk of falling and will make a contribution to preventive care for frail elderly people.

The sensory exam for the plantar surface of the foot is also useful in the screening process of diabetic peripheral neuropathy (DPN), which is one of main long-term complications of diabetes. The Semmes-Weinstein (SW) monofilament test, which is a somatosensory examination method used to indicate protective sensations evoked by pressure stimulation of a nylon filament on the skin, is a sensitive screening tool for DPN. The SW monofilament, which have been manufactured with longitudinal buckling forces of twenty-grade ranging from 0.008 to 300 g, are applied to the test site perpendicularly until they bend for about one second. Patients are instructed to say “yes” each time they sense the monofilament on their skin. (Feng, et al., 2009). Because DPN is associated with the risk for foot ulceration and lower extremity amputation, the SW monofilament test on the foot surface is also recommended to detect DPN and enable earlier medical intervention for ulcers and leg amputations (National Institute for Health and Clinical Excellence, 2004, World Health Organization, 2006, American Diabetes Association, 2008).

Despite the utility of the test, the sensory examination is the most subjective, difficult and tedious part of the neurologic examination (Bigley, 1990, Haerer, 1992). Sensory tests, which rely upon a subjective response depending on the patients’ understanding of what they are being asked to do, may have high inter-measurer variability and poor reproducibility (Gelb, 2010, Krishnan, et al., 2009). For example, the SW monofilament test needs to be performed with repeated of stimuli of various intensities via manual operation. A slight change in the buckling strength of the SW monofilaments can also produce misleading results and affect the workload. Consequently, clinical assessment of neuropathy relies upon the skill and interpretation of the individual clinician; discrepancies could lead to confusion in the estimation of health care requirements (McGill, et al., 1999).

This study describes the development of a plantar foot sense-testing instrument (PFS Tester) for practical screening of DPN and for the prediction of fall risk of frail elderly people. The PFS Tester can automatically apply stimuli of homogeneous intensity to testing sites on the plantar surface of the foot. By automating the examination process, a PFS Tester provides the ability to carry out examinations of high reliability, even by an inexperienced person. The goal of this research is to confirm the validity of the mechanical stimuli of the PFS Tester by comparing the measurements of the force applied to a testing object and the sensory thresholds on the plantar foot of individuals to those of the SW monofilament.

2. An outline of the PFS Tester

Many types of stimuli are employed for the sensory examination, including a light touch, pinprick, vibration, thermal stimulation, and electrical stimulation (Bigley, 1990, Haerer, 1992). The SW monofilament is classified as a tool using a stimulus of mechanical strain for non-invasive evaluation of the cutaneous sensation threshold by applying pressure perpendicular to the skin layer. Although the PFS Tester confines measurable sites to a plantar foot, it is also classified as a tool using a stimulus of mechanical strain for non-invasive evaluation of the cutaneous sensation threshold. It employs a single shear movement horizontal to the surface of the skin to provide shear deformation of the skin layer automatically.

The PFS Tester consists of three parts as shown in Fig. 1A, including a measuring platform with a mechanical probe, a command-control-record (CCR) device (notebook PC) and a pushbutton switch for a response to the stimulus perception. The measuring platform, which measures 500 mm in width and length, and 75 mm in height, contains a
linear actuator controlled by pulses from the CCR device to drive the mechanical probe with a positioning error of less than 3 µm under vertical load of 100 N. The mechanical probe, which contacts the testing site and applies the stimuli, is made of polyether ether ketone resin (PEEK) with good abrasion and chemical resistant property and without biological toxicity and allergy inducibility. The probe measures 10 mm in width and length. Because a probe with the whole flat top so easily slipped on the skin of testing site, the top of the probe has nine flattop projections, which are 2 mm in width and length, to provide shear force to the skin of testing site in proportion to the probe movement without slipping on the skin. The tops of projections are arranged on the same level as that of the platform top (see Fig. 1C). The probe is driven by the linear actuator with variable ranges and speeds of the shearing movement from 10 µm to 2000 µm and from 0.1 mm/s to 250 mm/s, respectively. One movement of the mechanical probe in one direction is considered a single stimulus, and both the variable range and the speed of the probe movement can affect the definition of the mechanical stimulus intensity. The experiments mentioned later in this study will investigate which of the ranges and speeds of the probe movement contribute to the mechanical stimulus intensity of the PFS Tester. A series of probe movements can be freely pre-programmed into the CCR device to provide various stimulus sequences such as an ascending sequence in which the stimulus intensity increases stepwise from a subthreshold level to an easily detectable intensity level; a descending sequence in which the stimulus intensity decreases stepwise from suprathreshold to barely detectable intensity; and an adaptive method in which the stimulus intensity is varied both upward and downward according to the subject’s response (Gescheider, 1985).

Preparation for the measurement is finished if a testing site of the foot is placed at the probe on the measuring platform. Clicking the “Start” button on the CCR display automatically presents the pre-programmed stimulus sequence for the testing site of the plantar foot. A history of the applied stimulus intensity and the presence or absence of the pushbutton response is recorded by the CCR device. When the prescribed number of responses has been acquired, the PFS Tester will automatically cease presenting the stimuli and estimate a threshold of the tested site.
3. Research Design and Methods

3.1 Experiment 1: Stimulus intensity measurement of the PFS Tester and SW monofilament

To define which range and speeds of the probe movement contributed to the mechanical stimulus intensity of the PFS Tester, the probe was driven at various ranges and speeds and the amounts of shear force applied to an aspect of the target site were measured at that time. In these experiments, silicone rubber (hardness A50, 5 mm thickness) that simulates the sole of a human foot was fixed on the probe at the top of the platform. The shear forces applied by the probe of the PFS Tester to the silicone rubber were measured. The peak values of the shear forces applied to the object were measured at various speeds (1.0, 5.0, 10, and 50 mm/s) and various ranges (100 to 500 μm). In addition, because the probe slipped on the surface of the silicone rubber when driven to a range of 500 μm or above, shear forces applied by the probe of the PFS Tester to the plantar foot of the total number of four healthy subjects (age 27-66 years, all male) were also measured using the standard examination protocols for neuropathy screening, which consist of twenty-level ascending stimuli sequence. Those examination protocols had ranges from 10 to 2000 μm and successive stimulus presentation with exponentially increasing magnitude that obeyed the Weber-Fechner law (Hecht, 1924). Because the existing methods for sensory examination such as the SW monofilament test adopted constant presentation time for different intensities of stimuli, those protocols were prescribed higher speeds of the probe movement depending on the increments of the movement range. In consequence, constant presentation times of 20 and 50 ms were adopted as shown in Table 1. The peak values of the shear forces applied by the probe to the testing object at each twenty-grade stimulus were measured three times by a digital push-pull gauge (RX-2: AIKOH Engineering CO., LTD. Osaka, Japan). The digital push-pull gauge was coupled dynamically with the thin rod extending from the probe in the direction of the movement. To cancel the force caused by the probe movement and to measure only the reaction force from the plantar skin, the digital push-pull gauge was mounted on a platform moving with a sliding table of the linear actuator, or moved with the probe.

Furthermore, dynamic forces produced by the full set of the twenty SW monofilaments kit were also measured using an electronic analytical scale (GR120: A&D CO., LTD. Tokyo, Japan), whose weighing dish was covered by the silicone rubber (hardness A50, 5 mm thickness). The means and SDs were determined by three times measurements of the peak force when each filament was applied to the silicone rubber on the weighting dish using a medically prescribed method.

3.2 Experiment 2: Measurement of the thresholds obtained by the PFS Tester and SW monofilament

To verify whether the stimulus of the PFS Tester is compatible with the SW monofilament test, sensory thresholds on the plantar foot of subjects with neurological disorder were measured using both devices. A total of nineteen diabetic patients (age 35-80 years, four females) participated in this study. Individuals with a history of neurological disorders (except for DN) were excluded from the diabetic patient group. Individuals having corns or visible skin induration in the testing sites on the plantar skin were also excluded. Two testing sessions were performed on all subjects. In each test, the PFS Tester and the SW monofilament (North Coast Medical, Inc., Gilroy, CA, USA) were used on three sites on the right and left of plantar feet: (1) great toe, (2) first metatarsal head (ball of the hallux), and (3) heel.

Cutaneous sensation thresholds obtained with the SW monofilament were tested such that the 0.07 g monofilament was initially applied to the testing site. When the participant could detect the 0.07 g stimulus, the stimulus levels were decreased until it was below perception (descending sequence). The minimum stimulus at which the participant reported feeling a sensation was designated as the threshold. If the participant could not detect the initial stimulus, the stimulus levels were increased until they were above perception (ascending sequence). The minimum stimulus at which

Table 1 Movement ranges and speeds of the probe of the PFS Tester in the twenty-grade stimulus sequence employed in this study.

| 20ms const. duration | Stimulus grade | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 |
|-----------------------|----------------|---|---|---|---|---|---|---|---|---|-----|----|----|----|----|----|----|----|----|----|----|----|
| Range [μm]            |                | 10| 14| 18| 25| 33| 45| 60| 80| 105| 140| 180| 240| 330| 430| 550| 700| 920| 1200| 1550| 2000|
| Speed [mm/s]          | 0.5            | 0.7| 0.9| 1.25| 1.65| 2.25| 3.0| 4.0| 5.25| 7.0| 9.0| 12| 16.5| 21.5| 27.5| 35| 46| 60| 77.5| 100|
| 50ms const. duration | Stimulus grade | 10| 14| 18| 25| 33| 45| 60| 80| 105| 140| 180| 240| 330| 430| 550| 700| 920| 1200| 1550| 2000|
| Range [μm]            |                | 0.2| 0.28| 0.36| 0.5| 0.66| 0.9| 1.2| 1.6| 2.1| 2.8| 3.6| 4.8| 6.6| 8.6| 11| 14| 18.4| 24| 31| 40|

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the participant reported feeling a sensation was designated as the threshold (Enders, 2013). Thresholds obtained by the PFS Tester were determined with the standard protocol consisting of an ascending stimuli sequence at a constant duration of 50 ms. The PFS Tester continued to present successive stimuli until the participant reported feeling a sensation three times. The minimum stimulus at which the participant reported feeling a sensation was adopted as a threshold of the testing site.

A full explanation was made about the purpose and procedure of the experiment to all subjects. An informed consent was signed by all subjects. The research protocol was approved by the Ethics Committee of the Showa University Hospital.

3.3 Data analysis

Means and SDs of the dynamic force in Experiment 1 were obtained by the three times measurements at each stimulus. For comparison of each value among the three testing sites, analysis of variance (ANOVA) and Student’s t-tests were performed. To evaluate the equivalence of the threshold values between those obtained by the PFS Tester and the SW monofilament test, Pearson’s correlation coefficients were calculated. Coefficients of variation for each threshold were used to compare the inter-measurer difference between the two testing tools. Paired Student’s t-tests were used for all other comparisons, and p values of less than 0.05 were considered significant. All of the analyses were performed using the JMP 10.0 software package (SAS Institute Inc., Cary, NC, USA).

4. Results

4.1 Results of Experiment 1: Stimulus intensity measurement of the PFS Tester and SW monofilament

Actual measurement values of the peak shear force applied to the aspect of the silicone rubber by the PFS Tester at various speeds (1.0, 5.0, 10, and 50 mm/s) are shown in Fig. 2. It was found that the shear force varied solely with the range of the probe because there were little practical differences between the applying shear forces of the four speeds at every moving range. Fig. 3a shows actual measurement values of the shear force applied to the aspect of the plantar foot by the PFS Tester when using the twenty-grade examination protocols with constant presentation times of 20 and 50 ms shown in Table 1. There was little difference of the shear forces between constant presentation times of 20 and 50 ms, although every stimulus in both protocols had the same ranges but different speeds of the probe movement. The probe did not slip until 2000 µm of the movement range in the results of Fig. 3a, though the increase rates of the shear forces to the silicone rubber at 500 µm or more of the movement range were reduced due to the probe slipping on the surface of the object. Profile of the shear forces in the twenty-grade stimulus of the PFS Tester shown in Fig. 3a resembled the measured normal forces in the twenty-grade of the SW monofilament full set (Fig. 3b) in spite of the difference in the scale of the forces.

![Fig. 2 Shear forces to a silicone rubber that simulates a human body applied by the PFS Tester at various speeds of the probe movement.](image-url)
Variations of shear forces obtained by the PFS Tester and the SW monofilament when the twenty-grade stimulus was applied to the silicon rubber repeatedly are shown in Fig. 4. The coefficients of variations, which indicate the degree of variation of a data set obtained by the PFS Tester (50 ms const. duration) in the three times measurements of the applied shear forces, were significantly smaller than those obtained by the SW monofilament. This result demonstrates that the stimulus of the PFS Tester has a better reproducibility.

4.2 Results of Experiment 2: Measurement of sensory thresholds by the PFS Tester and the SW monofilament

Distributions of thresholds on the great toe, first metatarsal head, and heel of nineteen diabetic patients using the PFS Tester are shown in Fig. 5a. Some of the diabetic patients without diagnosis of DPN were able to detect the minimum stimulus of the PFS Tester, which was the movement range of 10 µm, whereas other patients with DPN were able to detect stimuli of 1000 µm or more of the PFS Tester. A significant difference was not found between the two examination protocols of 20 ms and 50 ms, as well as between the three tested sites, when using the PFS Tester. The distributions of thresholds of the three tested sites of nineteen diabetic patients using the SW monofilament are shown in Fig. 5b. The heel thresholds measured by the SW monofilament were significantly higher than at the other two sites.

The correlation coefficients and p-values between the thresholds measured by the PFS Tester and the SW monofilament are shown in Fig. 6. The correlations were statistically significant with p-values less than 0.05.

Fig. 3  a: Shear forces to a plantar foot applied by each twenty-grade stimulus of the PFS Tester with constant duration protocols. b: Normal forces to a testing object applied by each twenty-grade stimulus of the SW monofilament (twenty full set).

Fig. 4  Coefficient of variations at each twenty-grade stimulus in the three times measurements of forces to the object using the PFS Tester (50ms const. duration) and SW monofilament. * indicates p<0.05.
monofilament at the three tested sites are shown in Table 2. There are high positive correlations at the plantar surface of the great toe and the first metatarsal head; however, there was low positive correlation at the plantar surface of the heel. Fig. 6 shows scatter plots of the thresholds on the first metatarsal head and the heel measured for the PFS Tester and the SW monofilament. Subjects with high threshold on the first metatarsal head measured by the SW monofilament had a pronounced tendency to indicate high thresholds on the first metatarsal head measured by the PFS Tester. This tendency is essentially similar to the thresholds on the great toe. However, in the heel, there were a numbers of high-threshold subjects measured by the SW monofilament without elevation of the threshold measured by the PFS Tester.

![Graphs showing thresholds](image)

Fig. 5  a: Thresholds at the three testing sites obtained by the PFS Tester. b: Thresholds at the three testing sites obtained by the monofilament. * indicates \( p < 0.05 \). n.s. indicates no significant difference.

**Table 2** Correlation coefficients and \( p \)-values between the thresholds obtained with the PFS Tester and the SW monofilament.

| Tested site           | Correlation coefficient | \( p \)   |
|-----------------------|-------------------------|-----------|
| Great toe             | 0.806                   | < 0.001   |
| First metatarsal head | 0.954                   | < 0.01    |
| Heel                  | 0.367                   | < 0.001   |

![Graphs showing thresholds](image)

Fig. 6  Scatter plot of the thresholds acquired from nineteen diabetic patients measured by the PFS Tester and the SW monofilament. a: First metatarsal head. b: Heel.
5. Discussion

5.1 Sensory stimulus intensity of the PFS Tester

The PFS Tester has adopted a novel stimulus, consisting of a one-way horizontal movement of the small mechanical probe on the surface of the skin, as a sensory cue. In Experiment 1, when the mechanical probe of that device was driven at various ranges and speeds, the peak values of the shear forces on the testing object were measured. Though movement ranges and speeds of the probe varied independently with each other, it became clear based on the results of Fig. 2 and Fig. 3a that the factor affecting the peak shear force was only the range of the probe movement. Any existing devices or tools for sensory examination, including an SW monofilament tool prescribe sensory stimulus intensity to a target site of the skin, independently of the impressed speed of the applied force (Levin, et al., 1978). Therefore, it is proper, for the estimation based on the peak value of the applied force in this study, to verify consistency with the existing devices of the sensory testing. As the physical stimulus intensity for sensory testing is defined only by the movement range of the probe, prehension of the stimulus intensity is easier than in the case when the movement speed of the probe affects the stimulus intensity. Therefore, in the twenty-grade stimulus protocol shown in Table 1, it is correct to consider the stimulus range to be the stimulus intensity in itself. The results in Fig. 5a, for which identical ranges of the probe movement generated equivalent sensory thresholds in spite of the different speed of the probe, also support this conclusion from the mechanical and stimuli cognition perspectives.

Although the peak values of the shear forces on the silicone rubber shown in Fig. 2 decreased at movement ranges of 500 \( \mu \text{m} \) or more, slipping of the probe on the testing site caused the insufficient stimulus intensity. The testing target of cutaneous sensation intended by the SW monofilament is not sense of touch but protective sensation to noxious stimulation with skin deformation (Abdulkader, et al., 2008). The slip of the PFS Tester probe on the testing site reduces the peak shear force of the stimulus and the expected skin deformation. Moreover, it will transform a shear force stimulus into a stimulus for the sense of touch. Because the emergence of the probe slip depends on the coefficient of friction due to the condition of the surface of the objects, it is difficult for shear force applied to the testing site to be mathematically represented. However, the twenty-grade stimulus protocol increasing the movement range with a power function, which obeyed the Weber-Fechner law, showed a similar force profile of the normal force of the SW monofilament with the twenty-grade stimulus (Fig. 3). This indicates the possibility that the PFS Tester supplies examination results are similar to those of the SW monofilament from the mechanical properties perspective. It also suggests that the probe slip did not appear in the movement range from 10 to 2000 \( \mu \text{m} \) when the PFS Tester was employed on the plantar foot. Also, the probe provided proper deformation for measurement of the protective sensation of the skin layer on the testing site. These results indicate that the probe of the PFS Tester has an appropriate surface shape for the sensory testing of the skin on the plantar surface. However, optimal shape of the top of the probe will be determined entirely by diagnostic capability of certain neurological disorders. Further clinical data are needed to assess the top shape of the probe.

The range of distribution of the shear forces shown in Fig. 3a will reflect cutaneous conditions of the plantar foot, such as hardness or perspiration. The profile of the distribution area of the shear forces in twenty-grade stimulus of the PFS Tester is also similar to the profile of measured normal forces in the SW monofilament (Fig. 3a, b). This result shows that the difference in the shear force caused by the cutaneous conditions of the plantar foot will fall within a tolerance for sensory examination.

5.2 Consistency of examination results between the PFS Tester and other existing devices

The horizontal movement stimulus of the PFS Tester on a target site of the plantar foot differs from existing devices, which apply a normal force to a testing site to deform the skin layers. It is not clear whether shear force causes a similar activation status in mechanoreceptors to that caused by normal force. Furthermore, it is not clear whether the sensory thresholds measured by the PFS Tester and the SW monofilament from testing sites on the plantar foot are equivalent. As shown in Table 2, high correlations in testing results of the PFS Tester and the SW monofilament on the great toes and the first metatarsal head, where sensory deficit due to DPN will emerge at a very early stage, suggest that shear and normal forces on those sites will induce equivalent perceptions arising from the activation of the cutaneous mechanoreceptors in plantar skin. The mechanoreceptors that respond to both shear and normal forces are found in the plantar foot (Kennedy and Inglis, 2002). Existence of those receptors may contribute to the equivalent perception between different styles of skin deformation. The high correlations of thresholds from the great toes and the first
metatarsal head (Table 2) showed that the difference in scale of the applied mechanical forces of both devices (Fig. 3) would be proper from the stimulation cognition perspective.

At the other extreme, the correlation of the heel thresholds obtained by both devices was lower than the correlation between those of the great toe and the first metatarsal head. Previous studies that examined thresholds around the plantar foot with the SW monofilament test reported that the heel threshold of healthy subjects showed higher values than other sites on the plantar foot (Bell-Krotoski, et al., 1995, Jeng, et al., 2000). In cases where sensory thresholds of the plantar foot were measured by vibration stimuli; in contrast, the threshold of the heel was lower than or equal to those of other plantar foot sites (Nurse and Nigg, 1999, Perry, 2006). These findings suggest that the SW monofilament with an extremely small cross section used to apply mechanical stimulus to the target site (cross section of the widest twentieth filament is approximately 0.7 mm²) cannot provide sufficient mechanical stimulation for the surface of the heel, which has significantly thicker skin and fat layers compared to the rest of the sole of the foot (Frahm, et al., 2013).

In this study also, the heel thresholds measured by the SW monofilament shown Fig. 6b appear to be somewhat higher than the first metatarsal head measured by the SW monofilament shown Fig. 6a. By way of contrast, the heel thresholds measured by the PFS Tester shown Fig. 6b were lower than or equal to the first metatarsal head measured by the PFS Tester shown Fig. 6a. Because the sensory deficit in the early stage of DPN will appear from a forefoot to a rear foot, the heel thresholds obtained by the PFS Tester are likely to be more appropriate than those obtained by the SW monofilament. Because the mechanical probe of the PFS Tester has relatively wide cross section of 100 mm² it has the potential to apply an effective stimulus and provide an adequate testing result even on a target site with thick skin, such as the heel. Therefore, the insufficient correlation of the thresholds on the heel in this study is considered to be caused by a property peculiar to the SW monofilament. Because the heel must initially strike the ground during walking or running, the skin layer of the heel acts as a shock absorber, involving substantial connective tissue (Frahm, et al., 2013). If the heel slips when it contacts the ground, mechanical perception of the shear force at the heel plays an essential role in carrying the sensory signals of such an event to the brain. Therefore, the perception of shear force at the heel is not less important to dynamic gait control than that at the forefoot. Thus, it is reasonable that the threshold level of shear force stimulation at the heel measured by the PFS Tester in this study is as good or better than those at the great toe or the first metatarsal head. From the perspective of motor control, the PFS Tester’s use of the stimulus of shear force is very likely to provide a physician or a researcher with an unprecedented method that is useful in understanding sensory function.

5.3 Functional superiority of the PFS Tester

The SW monofilament can be easily applied to somatosensory testing because of its low cost and ease of operation. It also remains the only handheld instrument specifically designed to control the applied force (Birke and Rolfsen, 1998). Some medical agencies and academic associations with global influence have recommended the use of the SW monofilament to provide an optimal choice for objective sensory testing in a variety of clinics. However, it was reported that a variation of more than 50 % was found in the buckling stress of the SW monofilament, which is difficult to avoid with differences in handling (Bell-Krotoski, et al., 1995). The National Institute for Health and Clinical Excellence of England (2004) recommends that the SW monofilament should not be used to test more than ten patients in one session and that it should be left unused for at least 24 hours to recover buckling strength. The PFS Tester is designed for a simplified operation based on an automatic stimulus presentation that differs from existing devices such as the SW monofilament. Shear forces applied to the testing object by the PFS Tester showed some variability in the same way as the SW monofilament. The degree of variability in the shear force is less than that of the SW monofilament (Fig. 4). Because, at least in principle, there is no way that the stimuli retains residual effects of force shifting caused by successive use, the PFS Tester possesses an additional advantage when many hours of use are required. The PFS Tester has an adequate ability to reduce variability of the measured thresholds, which is a fault in the existing devices using manual operation. However, it is recommended to perform additional measurements of thresholds from conceivable subjects using both devices for a more favorable verification of reproducibility.

The new sensory testing device mentioned in this study could be available as a simple sensory examination tool with favorable performance, including better reproducibility of the stimulus intensity, simplified operation with automatic stimulus presentation, and a high compatibility with the SW monofilament test, which is the most frequently executed tactile examination. The designed measuring platform, which is more compact and thinner than those devices in current use, has good portability that gives enhanced measurement performance in community-based health
screening. However, there is a need to have some form of semi-quantitative screening that can be used by the most inexperienced and the most highly specialized health professional in the community-based screening (McGill et al., 1999). Though measurable sites are confined almost exclusively to a plantar foot, the PFS Tester can function effectively as a new screening method for DPN or a fall-prevention screening tool used in the community. Additional measurements on such persons or acquisition of standard values for each age group are considered necessary to confirm the usefulness and validity of the PFS Tester.

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