

COMPARATIVE STUDY OF THE SENSITIVITY OF DIABETIC LOWER EXTREMITIES WITH AND WITHOUT ULCERS USING THE PSSD™

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ABSTRACT

Introduction: To determine and compare thresholds of cutaneous sensitivity of lower extremities in diabetic patients with an ulcer on only one lower extremity. **Methods and Materials:** The study group included 20 patients with mean age of 61.6 and average time with diabetes of 12.4 years. All patients were previously tested using Semmes-Weinstein monofilament 5.07. Sensitivity was evaluated using the two point discrimination test and the PSSD™ (Pressure-Specified Sensory Device) in order to assess touch thresholds in a quantitative manner, in g/mm². Three skin areas were tested: hallux pulp, dorsum of foot and medial heel, including four tests: 1 point static, 1 point

moving, 2 points static and 2 points moving. Results: Mean 2 point discrimination distance in mm was higher in feet with ulcers, but the difference between extremities was only statistically significant for the hallux. With the PSSD™, all patients had higher pressure thresholds in feet with ulcers when compared with feet without ulcers, in all tests, with statistical significance. Conclusion: The PSSD™ was able to differentiate levels of sensation between extremities with and without ulcers in diabetic patients, with statistical significance.

Keywords: Diabetic foot. Diabetic neuropathies. Foot ulcer. Sensation. Sensory thresholds.

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INTRODUCTION

Progressive loss of cutaneous sensibility on the lower limbs plays an important role in the incidence of complications and in the overall morbidity of diabetes mellitus.¹

About 15% of the diabetic population will develop ulceration on their lower extremities, usually complicated by infection and slower healing rate. This may eventually lead to amputation of parts.^{2,3}

Ulcerations are more related to the neuropathy than to peripheral vascular disease, present in 10% to 20% of patients. Neuropathy, on the other hand, is clinically diagnosed in 35% to 45% of the diabetic population,⁴ but is fairly common in patients who developed skin ulceration.⁵

Progressive loss of cutaneous sensibility is a consequence of the loss of myelin cover and of the diminished number of functioning nerve fibers caused by the accumulation of glucose degradation products.⁶ Sensibility assessment is usually performed employing non-quantitative tests, such as the Semmes-Weinstein monofilaments, tune forks and electrodiagnostic studies. These exams are subject to important variations that hamper the determination of study patterns.

The two point discrimination test, routinely used to evaluate nerve injuries in the hand, has been more recently employed in the diabetic

foot as well.⁷ The test measures the minimum distance separating two metallic prongs of a device that, when pressed to the skin, is felt by the patient as two separate points. This assesses the density of nerve fibers and of the sensitive skin receptors on a specific area.⁸

The PSSD™ (Pressure-Specified Sensory Device), introduced in 1990, aims to determine thresholds of skin sensibility with more precision; patients report whether they felt the sensation after static pressure of the prong or after dynamic pressure of the tip. The result is recorded by a computer on a continuous scale.

The device has been used previously to assess diabetic foot sensibility,⁹ but reports of correlation of the degree of sensation loss with the occurrence of ulcerations are rare.

The PSSD™ has been used by the Plastic Surgery Division of Hospital das Clínicas da Faculdade de Medicina da Universidade de São Paulo since 1999 to evaluate sensibility in areas of the body after plastic surgery procedures, such as mastoplasties,¹⁰ abdominoplasties¹¹ and after facial fractures.¹²

There is an important center for complex wounds, affiliated to the Plastic Surgery Division, and our interest was also focused on the evaluation of sensibility in diabetic lower extremities, especially in those patients that were in treatment for their wounds.¹³

All the authors declare that there is no potential conflict of interest referring to this article.

Plastic Surgery Discipline of Hospital das Clínicas da Faculdade de Medicina da Universidade de São Paulo

Study conducted in the Plastic Surgery Discipline of Hospital das Clínicas da Faculdade de Medicina da Universidade de São Paulo (FMUSP), São Paulo, Brazil.

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The purpose of this study was to compare the thresholds of sensibility on both lower extremities of 20 diabetic patients that presented ulceration on only one of them, using the PSSD™.

MATERIALS AND METHODS

We examined 20 consecutive diabetic patients at the Clinic for Complex Wounds of the Plastic Surgery Division, of Hospital das Clínicas da Faculdade de Medicina, at Universidade de São Paulo.

Fifteen patients were male, and five, female. Mean age of these patients diagnosed with diabetes type 2 confirmed and with disease clinically controlled was 61.65 years.¹⁴ The minimum time of five years since the onset of the disease was used as inclusion criterion, the average time since the onset being 12.42 years. Another inclusion criterion was the occurrence of an open or healed ulcer on only one of their lower limbs. The mean time for healing after ulceration was 3.4 years.

Major arterial disease of the limbs was discarded if the ankle-arm index was higher than 0.9.¹⁵

Neuropathic symptoms on the feet were recorded: 16 complained of paresthesia, 15 of fatigue, 10 referred to burning sensation, 8 to shock and 7, tingling sensation.

The ulcer was located on the calcaneus in four patients, the ankle in four, on the dorsum of foot in three, leg in one, sole of the foot in one and in the area of a former hallux amputation in seven.

Semmes-Weinstein monofilament 5.07/10 g was used as screening test, assessing ten points; a neuropathic foot was diagnosed if the test was abnormal in two or more points. Tinel's sign was tested over the posterior tibial nerve in all patients.

Two-point discrimination was measured in millimeters, both static and moving. More specific quantitative tests of sensibility were conducted using the PSSD™ as described below.⁶

The PSSD™ device consists of two metal prongs that are connected to a hand-held instrument and to a computer. The examiner must bring one or both of these prongs into contact with the surface of the anatomical region to be tested and exert increasing pressure. When the patients perceive the stimulus they push a button that sends a signal to the computer which records the exact pressure applied. The test is called one point or two points, accompanied by the adjectives "static" or "dynamic" or "moving", according to the number of prongs used and whether the test was performed with the prongs in movement or not.

Three skin areas on each lower extremity were assessed – the plantar surface of the hallux, the plantar aspect of the calcaneum and the dorsum of foot.

Cutaneous thresholds of pressure were assessed in g/mm², and the sensation was reported by the patient in static and dynamic test, with one and two prongs.

The statistical analysis was conducted using the Student's *t* test for paired population, comparing the results on both lower limbs. Significance was set at a *p*<0.05 level.

RESULTS

All patients reported that they felt positive sensation with the Semmes-Weinstein monofilament in both extremities. Tinel's sign was positive in six patients (30%) with ulcer and in seven (35%) without ulcer.

The results of 2PD (2 points moving) and of PSSD™ are presented in Tables 1, 2, 3, 4 and 5.

Table 1 – Two-point discrimination (2PD), expressed in mm, for hallux, dorsum of foot and heel.

discrimination (mm)	N	mean	SD	minimum	maximum
Hallux					
with ulcer	20	13.2	1.9	9	15
without ulcer	20	11.7	2.6	5	15
Dorsum of foot					
with ulcer	20	12.6	1.9	9	15
without ulcer	20	11.7	2.7	6	15
Heel					
with ulcer	20	12.6	2.3	8	15
without ulcer	20	12.6	2.1	8	15

Table 2 – Mean difference in two-point discrimination (2PD), in mm, between the foot with ulceration and without ulceration.

Discrimination (mm)	Mean difference	SD	p*
Hallux	1.50	2.80	0.027*
Dorsum of foot	0.95	2.68	0.130
Heel	0.05	2.56	0.931

Student's *t*-test *significant

Table 3 – Cutaneous pressure sensation threshold for the HALLUX in g/mm².

Pressure (g/mm ²)	N	Mean	SD	Minimum	Maximum
1-point static touch					
with ulcer	20	55.3	22.7	20.7	87.6
without ulcer	20	32.0	19.1	9.8	63.9
1-point moving touch					
with ulcer	20	44.6	23.7	12.7	82.9
without ulcer	20	25.5	15.4	3.1	54.4
2-point static touch					
with ulcer	20	58.8	24.0	17.6	96.2
without ulcer	20	36.1	17.0	6.1	56.5
2-point moving touch					
with ulcer	20	48.0	24.2	12.9	82.2
without ulcer	20	30.1	17.4	5.0	50.7

Table 4 – Cutaneous pressure sensation thresholds for the DORSUM OF FOOT in g/mm².

Pressure (g/mm ²)	N	Mean	SD	Minimum	Maximum
1-point static touch					
with ulcer	20	65.9	21.9	23.4	88.4
without ulcer	20	33.8	25.8	5.7	74.9
1-point moving touch					
with ulcer	20	50.7	25.1	16.1	88.5
without ulcer	20	21.8	16.4	4.7	54.5
2-point static touch					
with ulcer	20	65.5	28.1	20.2	99.7
without ulcer	20	32.4	20.6	7.5	68.9
2-point moving touch					
with ulcer	20	48.7	25.3	16.8	87.7
without ulcer	20	31.5	22.6	5.8	75.0

Table 5 – Cutaneous pressure sensation thresholds for the HEEL in g/mm².

Pressure (g/mm ²)	N	Mean	SD	Minimum	Maximum
1-point static touch					
with ulcer	20	64.8	23.8	22.1	94.7
without ulcer	20	35.3	18.9	10.0	70.1
1-point moving touch					
with ulcer	20	51.1	22.8	12.9	87.8
without ulcer	20	29.0	17.0	7.6	69.5
2-point static touch					
with ulcer	20	57.8	26.2	18.2	95.8
without ulcer	20	44.3	26.8	8.5	88.4
2-point moving touch					
with ulcer	20	52.2	23.5	22.6	92.5
without ulcer	20	30.6	18.9	8.0	73.4

The mean 2PD on the hallux was 13.2mm on the foot with ulcer and 11.7mm on the foot without ulcer. On the dorsum of foot the mean value was 12.6mm (with ulcer) and 11.7mm (without ulcer). On the heel the mean 2PD was the same in both feet: 12.6mm. The minimum value encountered for the 2PD test was 5mm on the hallux in one foot without ulcer and the maximum value was 15mm, found in all regions studied.

Comparing the mean difference in 2PD between the feet with and without ulceration (Table 2), the mean value in hallux was 1.50mm, in dorsum of foot 0.95mm and in heel 0.05 mm. The p value had statistical significance only in the hallux region.

The tests with PSSD™ on the hallux are presented in Table 3. The mean of one point static touch was 55.3 g/mm² on the foot with ulcer and 32 g/mm² on the foot without ulcer. In the one point moving touch test, the mean value in the foot with ulcer was 44.6 g/mm² and 25.5 g/mm² in the foot without ulcer. The mean of two-point static touch was 58.8 g/mm² in the foot with ulcer and 36.1 g/mm² in the foot without ulcer. For the two-point moving touch the mean of the foot with ulcer was 48 g/mm² and 30.1 g/mm² in the foot without ulcer. The minimum value encountered in an ulcerated foot was 12.7 g/mm² in the test with one-point moving touch and in a foot without ulcer was 3.1 g/mm² in the same test.

Comparing the mean difference in PSSD™ in the hallux between the feet with and without ulceration, the mean difference was 23.2 g/mm² in one point static touch test, 19.1 g/mm² in one point moving touch test, 22.8 g/mm² in two point static touch test and 17.9 g/mm² in two-point moving touch test. The p value was <0.001 in all these tests, demonstrating statistical significance.

Table 4 shows the PSSD™ test on the dorsum of foot. Mean one point static touch was 65.9 g/mm² on the foot with ulcer and 33.8 g/mm² on the foot without ulcer. Mean one-point moving test, was 50.7 g/mm² (with ulcer) and 21.8 g/mm² (without ulcer). The mean two point static touch was 65.5 g/mm² (with ulcer) and 32.4 g/mm² in the foot without ulcer. For the two-point moving touch the mean value was 48.7 g/mm² (with ulcer) and 31,5 g/mm² (without ulcer). The minimum value encountered in an ulcerated foot was 16.8 g/mm² (with two-point moving touch) and 4.7 g/mm² in one-point moving (foot without ulcer).

Comparing the results of PSSD™ in the dorsum of foot between the feet with and without ulceration, the mean difference was

32.2 g/mm² with one-point static test; 28.8 g/mm² in the one-point moving touch test; 33.0 g/mm² in two-point static touch test and 17.2 g/mm² with two-point moving touch test. The p value was <0.001 in all these tests and had statistical significance.

The results of the PSSD™ test on the heel are shown in table 5. The mean value for one-point static touch was 64.8 g/mm² on the foot with ulcer and 35.3 g/mm² on the foot without ulcer. One-point moving touch test had a mean value of 51.1 g/mm² in the foot with ulcer and 29.0 g/mm² without ulcer. The mean two-point static touch was 57.8 g/mm² in the foot with ulcer and 44.3 g/mm² without ulcer. For the two-point moving touch the mean value was 52.2 g/mm² in the foot with ulcer and 30.6 g/mm² in the foot without ulcer. The minimum value encountered in an ulcerated foot was 12.9 g/mm² in the one-point moving test and in the foot without ulcer, 7.6 g/mm² with the same test.

Comparing the PSSD™ in the heel between the feet with and without ulceration, the mean difference was 29.5 g/mm² in one-point static touch test, 22.1 g/mm² in one-point moving touch test, 13.5 g/mm² in two-point static touch test and 21.7 g/mm² in two-point moving touch test. The p value showed statistical significance in all these tests.

DISCUSSION

Neuropathy on sensitive fibers is responsible for progressive loss of protective sensation; associated with autonomic nerve impairment, it leads to foot ulceration and infection, eventually giving rise to amputation.^{3,4} Impairment of sensibility is not in the same degree on both affected limbs; diabetic patients normally develop ulceration on only one extremity.

Comparison between the thresholds of sensibility measured with the PSSD™ on both limbs with ulceration, when performed on just one of the limbs, would help to understand how loss of sensation can be related to the occurrence of wounds.

Stages of diabetic neuropathy, as a rule diagnosed by clinical criteria, are not precise enough to determine the progress of loss of sensation or the potential for occurrence of ulcerations.

Assessment of loss of sensibility is possible on certain aspects of cutaneous sensibility, namely touch (pressure and vibration), temperature and pain.

Touch (pressure sensation threshold), which has been classically measured using Semmes-Weinstein monofilaments, can now be measured quantitatively, on a continuous scale after the introduction of PSSD™ by Dellon and others.¹⁶⁻²²

The device provides a continuous scale for evaluation of both sensation due to static pressure (stimulation of Ruffini and Merkel receptors) and to moving pressure (Meissner and Pacini), substituting for both Semmes-Weinstein and vibrometer measurements.

The test with the PSSD™ associated with two point distance discrimination in mm has been suggested as useful to verify diabetic patients with neuropathy on lower extremities, providing a diagnosis of progression of the morbidity, and to critically study therapeutic alternatives, whether clinical or surgical.¹⁶

Pressure-Specified Sensory Device tests previously showed an association of poorer sensation in the foot and incidence of ulceration and amputation.^{16,17} Degrees of sensation were not the same in limbs with and without ulcers, but the patients in those studies were not the same either, therefore bias could not be excluded.

In this study, we selected a group of diabetic patients without vascular impairment with ulcer in just one lower limb. The average age was around 61 years old, with mean time of 12 years since disease diagnosis, which is in line with literature – a mean time of more than 10 years for appearance of complications and with the study of Barber *et al.*⁸ where the time of disease was 10.5 years for patients with no ulcers and 11.8 for those with ulcers.

The patients were selected as a part of the population with sensation thresholds lower than 100 g/mm², tested with monofilament 5.07. Therefore the patients with insensitive feet were excluded from this study; neuropathy symptoms were present but we attempted to correlate them with the level of sensation.

Mean thresholds for the four tests (one-point static, one-point moving, two-point static, and two-point moving) were significantly higher on the foot with ulcer, in all three lower extremity anatomical areas tested.

In the study published by Tassler *et al.*¹⁶, comparing two groups of patients with and without ulcers, and assessing sensibility using the PSSD™, the differences between groups were statistically significant for the hallux plantar surface, in the one-point static and dynamic and two-point moving tests. On the dorsum of foot, the results were significant for two-point static, as well as for the moving points.

Their results could not be compared with those from our study as we conducted the tests on the same patient. We discovered significantly lower mean thresholds in the non-ulcerated group, clearly showing that in extremities with ulceration there is a more advanced degenerative process, preventing the patient from defending himself against aggressions. Differences in sensation between the lower limbs were significant for the four tests used.

It would be very important to determine at which threshold there is potential for ulceration to appear. It is clear that the PSSD™ can be more precise than the Semmes-Weinstein monofilaments test. The continuous scale can be easily reproduced as a screening test to evaluate the progress of loss of sensation. In this series all the patients had a positive response to 5.07 SW – approximately

95 g/mm², but the variance of values with the PSSD™ was much greater.¹⁸ Semmes-Weinstein tests did not differentiate extremities with and without ulcers as the PSSD™ did.

Differences of values of two-point discrimination tests in mm were not significant, but were consistently higher in the group with ulcer. Both groups presented higher 2PD values than those described in the non-diabetic population both in Brazil and in the USA.^{13,16} These patients underwent an important reduction of sensitive fiber numbers (fiber density).

The minimum values obtained for the 2PD were comparable to our previous study in a smaller population,¹³ 13.2mm on the hallux in feet with ulcer and 11.7mm in feet without ulcer. In a study by Dellon, the minimum value was 9.2 mm for patients with ulcer. Previous studies showed that a 99% confidence limit exists for two-point discrimination in the hallux pulp at 8mm in individuals over 45 years of age.¹⁶ Worse discrimination suggests axonal loss and therefore the patients should be referred for specialized treatment. Our data may indicate that the 2PD around 10mm would be the limit value in our population for the patient to still be sensitive and protected against trauma.

The population studied exhibited a variable stage of diabetic complications, with feet ulcers, incidence of symptoms and altered tests. The natural history of diabetic neuropathy can perhaps be changed with the introduction of new treatment options.^{23,24} The earlier the patient is evaluated the better the chances of prevention of complications.

CONCLUSION

The PSSD™ was able to document and distinguish differences between perception of cutaneous pressure on the feet with and without ulcers. Mean thresholds were significantly higher on extremities with ulcer (less sensation) compared with the other extremity, without ulcer. The PSSD™ was a reliable and useful device for making accurate diagnosis of the loss of sensation in diabetic patients in a quantitative and demonstrable manner.

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