The Semmes Weinstein monofilament examination as a screening tool for diabetic peripheral neuropathy

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Objective: The purpose of this systematic review is to evaluate current evidence in the literature on the efficacy of Semmes Weinstein monofilament examination (SWME) in diagnosing diabetic peripheral neuropathy (DPN).

Methods: The PubMed database was searched through August 2008 for articles pertaining to DPN and SWME with no language or publication date restrictions. Studies with original data comparing the diagnostic value of SWME with that of one or more other modalities for DPN in patients with diabetes mellitus were analyzed. Data were extracted by two independent investigators. Diagnostic values were calculated after classifying data by reference test, SWME methodology, and diagnostic threshold.

Results: Of the 764 studies identified, 30 articles were selected, involving 8365 patients. There was great variation in both the reference test and the methodology of SWME. However, current literature suggests that nerve conduction study (NCS) is the gold standard for diagnosing DPN. Four studies were identified which directly compared SWME with NCS and encompassed 1065 patients with, and 52 patients without diabetes mellitus. SWME had a sensitivity ranging from 57% (95% confidence interval [CI], 44% to 68%) to 93% (95% CI, 77% to 99%), specificity ranging from 75% (95% CI, 64% to 84%) to 100% (95% CI, 63% to 100%), positive predictive value (PPV) ranging from 84% (95% CI, 74% to 90%) to 100% (95% CI, 87% to 100%), and negative predictive value (NPV) ranging from 36% (95% CI, 29% to 43%) to 94% (95% CI, 91% to 96%).

Conclusions: There is great variation in the current literature regarding the diagnostic value of SWME as a result of different methodologies. To maximize the diagnostic value of SWME, a three site test involving the plantar aspects of the great toe, the third metatarsal, and the fifth metatarsals should be used. Screening is vital in identifying DPN early, enabling earlier intervention and management to reduce the risk of ulceration and lower extremity amputation. (J Vasc Surg 2009;50: 675-82.)

Diabetic peripheral sensory neuropathy (DPN) is a significant independent risk factor for diabetic foot, which is a major cause of foot ulcers and lower extremity amputations in patients with diabetes mellitus. Diabetic foot ulcers have a lifelong incidence in patients with diabetes mellitus of approximately 15% and are responsible for more than 50% of nontraumatic lower limb amputations. Following the diagnosis of diabetes, strict glucose control can be employed to prevent or delay the development of DPN. An effective screening instrument is then required to diagnose DPN early in high risk patients to prevent future ulceration and amputation. 4.

While physicians may use many quantitative methods to detect peripheral neuropathy, the Semmes Weinstein monofilament examination (SWME) is a noninvasive, low-cost, rapid, and easy-to-apply test often used in clinical testing and routine self assessment. The monofilaments are applied to the test site perpendicularly until they bend for about one second. Patients are instructed to say "yes" each

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time they sense the monofilament on their foot. If patients fail to sense the monofilament after it bends, the test site is considered to be insensate. Currently, Medicare only reimburses SWME as a part of the foot examination for the loss of protective sensation, for which Medicare reimburses \$44.72.^{5,6} SWME is not reimbursed as a separate service, often hindering accessibility to the test. The cost of disposable monofilaments is merely around \$0.50 each when purchased from an independent supplier.⁷

The SWME has become closely associated with the detection of DPN in both primary and specialty care over the past five decades since its invention. In 1960, psychologists Florence Semmes and Sidney Weinstein developed a set of nylon monofilaments to measure sensory loss in the hand of patients with brain injury. Currently, the general consensus regarding the definition of loss of protective sensation involves inability to sense the 5.07/10 g Semmes Weinstein monofilament. The gauge of this monofilament is 5.07, a number derived from the logarithm of the applied force in milligrams. The buckling force for the 5.07 monofilament is 10 grams, which is also the force felt by the patient when the monofilament bends. However, in the literature, the SWME test sites on the feet vary widely in number and location.

Current literature has not integrated original data on the diagnostic value of SWME. This systematic review summarizes and critically evaluates evidence on the efficacy

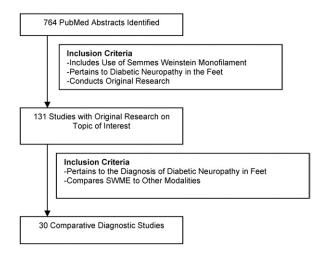


Fig 1. Summary of the article selection process.

of SWME as an instrument for diagnosing diabetic peripheral neuropathy in the clinical setting.

METHODS

Article selection. The search sequence was performed in the Back66 file of the Medline Database via PubMed on August 31, 2008 for titles and abstracts, resulting in 764 articles (Appendix, online only). All of these articles were subsequently searched by two independent investigators (Y.F. and F.S.) for relevance. The inclusion criteria for selection of articles were: (1) domain of the study consisted of patients with diabetes mellitus, (2) articles presented original data on the application of the 5.07/10 g SWME for diagnosis of DPN of the foot, and (3) the monofilament test results were compared with one or more other modalities in the diagnosis of DPN. No language restrictions were applied. No publication date restrictions other than the 1966 starting date criterion were applied. Through this process, 30 relevant articles were selected for analysis as shown in Fig 1. The validity of the data in the selected articles was determined according to the Oxford Center For Evidence-Based Medicine's levels of evidence. 10

Statistical analysis. Data regarding the diagnostic value of the 5.07/10 g SWME from each article were collected. The sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), true positives, false positives, true negatives, and false negatives were obtained or calculated from the original data of each selected study. After grouping the data by the presented reference test, sub-classifications were created with the methods of SWME application and the diagnostic thresholds of SWME. If more than one study presented data with the same reference test, method of application, and diagnostic threshold, meta-analyses were performed for the diagnostic values of SWME from these articles. This calculation was done by adding the crude number of patients that were true positives, false positives, true negatives, or false negatives for each combination and then calculating the sensitivity, specificity, PPV, and NPV.¹¹ This calculation was done only two times in lines F and I of Fig 2. All other diagnostic values presented were derived from individual studies.

RESULTS

The final selection process yielded 30 articles that matched all of the inclusion criteria, involving a total of 8365 patients and 10 different reference tests. All selected studies met the Oxford Center for Evidence-Based Medicine's evidence level¹⁰ of 2b or higher. There was a lack of consensus in both the reference test used and the methodology of SWME in the identified studies. From these 30 articles, 16 provided sufficient original data, comparing SWME with a reference test, to calculate the sensitivity, specificity, PPV, NPV, true positives, false positives, true negatives, and false negatives. 12-27 While the other 14 studies fulfilled the inclusion criteria, they did not provide enough data to calculate all of the above values.²⁸⁻⁴¹ For this reason, only the 16 studies with sufficient data were used for data analysis while all 30 were used for qualitative analysis. Fig 2 lists the quantitative data, including the reference test, the articles, the study domain, the testing methods, and the results of these studies. The 95% confidence intervals for the sensitivity of SWME were calculated for all 16 studies and graphed in Fig 3. Fig 4 shows the same calculations for the specificity of SWME for the 16 studies.

To assess the accuracy of SWME in diagnosing DPN, the results of SWME needed to be compared with a reference test. NCS was chosen as the most valid reference test based on current literature. 14,34 In the 16 studies with sufficient data, the most frequent reference tests were history of ulceration with eight articles, and nerve conduction study (NCS) with four studies. For each of these two reference tests, five different methods of SWME application and their associated sensitivity and specificity were presented. SWME was compared with the other four reference tests by only one article each. The studies with NCS as the reference test encompassed 1065 subjects with diabetic mellitus along with 52 nondiabetic subjects. In two of the studies, subjects without diabetes were used as controls and were also listed in Fig 2. However, these subjects did not contribute to the diagnostic values in the studies.

Considering all different methods and thresholds of SWME that were described in these studies, SWME had a sensitivity ranging from 57% (95% confidence interval [CI], 44% to 68%) to 93% (95% CI, 77% to 99%), specificity ranging from 75% (95% CI, 64% to 84%) to 100% (95% CI, 63% to 100%), PPV ranging from 84% (95% CI, 74% to 90%) to 100% (95% CI, 87% to 100%), and NPV ranging from 36% (95% CI, 29% to 43%) to 94% (95% CI, 91% to 96%) compared with NCS. The most sensitive method involved testing the third and fifth metatarsal heads on each foot with a positive test defined as the inability to sense either site, resulting in a sensitivity of 93% (95% CI, 77% to 99%).

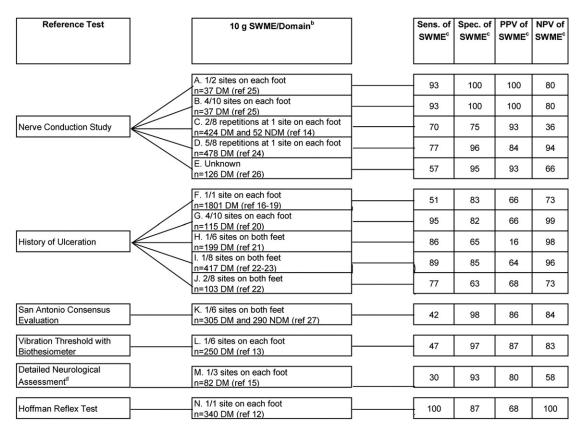


Fig 2. The sensitivity, specificity, PPV, and NPV of SWME were compared with different reference tests as presented in the literature. The first column shows the reference test that was used for the comparisons. The second column shows specific descriptions of the study populations and detailed information regarding the methodology of SWME in the identified articles. Articles with identical methods of SWME and reference tests were grouped. The last four columns present the sensitivity, specificity, PPV, and NPV for each method of SWME given a specific reference test. *SWME*, Semmes Weinstein monofilament examination; *DM*, diabetes mellitus; *NDM*, patients without diabetes mellitus in the reference group; *Sens.*, sensitivity; *Spec.*, specificity; *PPV*, positive predictive value; *NPV*, negative predictive value; *VPT*, vibration perception threshold. "The fractions in the SWME column show the threshold for diagnosis/the number of sites tested. Ex: 1/2 sites on each foot means the inability to detect one site out of two sites on each foot was considered DPN. The calculations necessary for rows F and I were done by combining the crude number of subjects from all studies in the specific category. Two positive out of the three tests: numbness in both legs; diminished reflex in both legs; VPT score below 4.

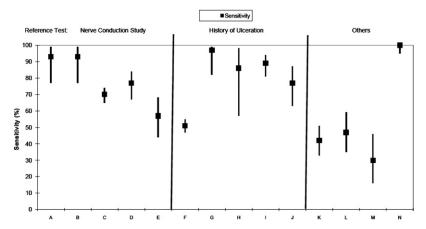


Fig 3. The sensitivities of SWME as indicated in Fig 2 are shown along with 95% CI. Letters in the horizontal axis correspond to the "10 g SWME/Domain" column in Fig 2.

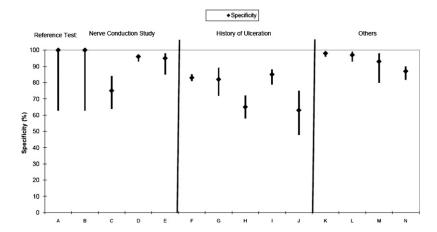


Fig 4. The specificities of SWME as indicated in Fig 2 are shown along with 95% CI. Letters in the horizontal axis correspond to the "10 g SWME/Domain" column in Fig 2.

DISCUSSION

Clinical relevance and main findings. Early identification and management of DPN may reduce the risk of ulceration and lower extremity amputation. Screening for DPN in feet should be done on a regular basis with a noninvasive semiquantitative examination by the patients and their caretakers. ¹⁵ The Center for Medicare and Medicaid Services, the International Diabetes Federation, and the World Health Organization recommend that this testing on the feet should be done by SWME. ^{7,42-43}

The quantitative analysis of the 16 studies with sufficient data revealed that SWME is both fairly sensitive and highly specific when compared with the gold standard of NCS. Current literature on diagnosing DPN suggests that NCS is the gold standard. NCS is used to identify patients with peripheral neuropathy because it is objective and sensitive. The test also measures quantitative neurophysiologic changes, and appears to be a reasonable surrogate marker for neuropathy. 34,44 In addition, the Diabetes Control and Complications Trial Research Group has demonstrated that NCS can be successfully used in large, multicenter clinical investigations of diabetic neuropathy. 45 NCS also is noted as the prima facie measure used for diagnosing DPN. 14 However, the clinical uses of NCS is limited due to its expense and limited availability. Based on the Medicare Fee Schedule for the nation in 2009, the global fee for each NCS procedure is \$61.31.46 In addition, the cost of obtaining the electromyography equipment and supplies make the procedure impractical for patients and physicians alike.

Diagnostic values of SWME vary significantly with different reference tests as the reference tests themselves vary in effectiveness. This lack of consensus regarding the reference test was evident in the data collected. The second most frequently used reference test, history of ulceration, yielded lower sensitivity and specificity for SWME. For these results to be valid, it was a necessary precondition that history of ulceration be 100% indicative of DPN. This reference test, however, did not meet this criterion since some cases were

secondary to vascular insufficiency without neuropathy. Therefore, the lower diagnostic values revealed a worse correlation between SWME and the history of ulceration, but not necessarily a worse correlation between SWME and DPN. The diagnostic values created by comparison of SWME with the other four reference tests were only supported by one study each. Therefore, these correlations did not reflect the relationships between SWME and DPN as the diagnostic values of these references tests were unknown. Different reference tests may classify patients in different ways as their diagnostic powers vary. Therefore, it is vitally important to select the most effective reference test for comparison purposes.

SWME as a screening tool for **DPN**. While the use of 5.07/10 g SWME is widespread and generally accepted, there is still no standard method for the application of SWME. The large variation in diagnostic value in the data showed that many factors of SWME still need to be standardized in order to create a test that is highly reproducible. Therefore, based on the current literature, we sought to address the size of the monofilament, the testing sites, the diagnostic threshold, and the accuracy of the test.

Regarding the size of the monofilament that is used in SWME, all 30 selected articles used the 5.07/10 g monofilament to determine the loss of protective sensations. Birke and Sims were the first to establish the threshold of the 10 g monofilament in 1985.47 They used size 4.17, 5.07, and 6.28 monofilaments to detect sensation in 72 patients with leprosy and 28 patients with diabetic mellitus. They concluded that the 5.07 monofilament is the threshold for detecting protective sensation as no patients with ulceration could sense the monofilament. Olmos et al tested 199 patients with diabetic mellitus with monofilaments ranging from 0.0045 g to 447 g, concluding that the 5.07 monofilament is also the best predictor of foot ulcer in patients with diabetes mellitus.²¹ However, Sosenko et al tested 314 patients using monofilaments ranging from 1.65 g to 6.16 g, concluding that the 4.21 monofilament

should be the threshold.²³ This conclusion raised the question of whether the 4.21 monofilament could be more sensitive; however, further testing by many others determined that the 5.07 monofilament best correlated with DPN. The buckling force of the 4.21 monofilament is normally considered to be within the range of normal perception, not as the threshold. Holewski et al, 48 Mueller et al,28 and Kumar et al18 all obtained the same conclusion that the 10 g buckling force of the 5.07 monofilament is the best threshold. Lastly, Rith-Najarian et al⁴⁹ and Boyko et al⁵⁰ conducted large scale prospective studies to determine that insensitivity to the 5.07 monofilament is an independent predictor for foot ulceration. Several of the above articles were not included in the final selection as they did not meet the criterion of comparing the 10 g SWME with other modalities of sensory testing.

The 30 selected studies used a variety of techniques to detect neuropathy with SWME. Wide variation existed in the number and location of the sites for testing. In the original studies, selecting the number of sites for testing seemed mostly arbitrary as most of these articles lack detailed information on this aspect of the test. Without a consensus on technique, number of testing sites varied from one to ten. Lee et al evaluated the impact of each of the ten possible sites in addition to combinations of sites.²⁵ The sites included the dorsal surface between the base of the first and second toes, the plantar aspect of the first, third, fifth toes, the first, third, and fifth metatarsal heads, the medial and later midfoot, and the heel. They found that testing on all 10 sites and testing on the plantar aspects of third and fifth metatarsal heads yielded the same sensitivity of 93% and specificity of 100%. Throughout all studies, all examinations were preformed on the plantar aspect of the foot except for the one dorsal site in testing with ten sites. Another study on the diagnostic values of different sites by McGill et al recommended that testing be done on the first and fifth metatarsal heads. The sensitivity and specificity for this combination of sites were 80% and 86% respectively. 51 In another study, Smieja et al concluded that a four-site examination involving the first toe, the third metatarsal head, and two other toes or metatarsal heads produces 90% to 93% sensitivity.³² Mueller and Holewski et al suggested that SWME should be performed in regions at highest risk for skin breakdown, including the plantar aspects of the metatarsal heads and the first toe. 47,52

One point of consensus among all the studies is that all SWME was carried out on the plantar aspect of the first toe. Studies testing more than one site proceeded to test mostly other toes and metatarsal heads. The number of sites tested had an observable effect on the sensitivity of SWME. In the group with history of ulceration as the reference test, the four studies that used only one site 16-19 had a sensitivity of around 50%, considerably lower than other studies that tested more than one site. 20-23 In the NCS reference test group, the two studies that only tested one site 14,24 also had sensitivities about 15% lower than methods that tested more than one site. Testing more sites allowed the SWME to be more sensitive in identifying patients with DPN. How-

ever, testing more sites also has the consequence of taking more time. The data showed that the number of sites tested does not have the same effects on specificity. Considering the need for both efficiency and efficacy, it is recommended that SWME be done at least three sites on the plantar aspects of the great toes, third and fifth metatarsal heads. This recommendation derives from the highly sensitivity as described in Lee et al, McGill et al, and Smieja et al.^{25,51,32}

Another uncertainty in SWME involves the diagnostic threshold, the number of incorrect responses necessary to produce a positive test. In the selected studies, there was no consensus for this threshold. The diagnostic threshold is closely related to the sensitivity and specificity of the test. As the number of incorrect answers necessary increases, the sensitivity of the test decreases while the specificity increases.²² In 16 of the 30 selected studies, the diagnostic threshold was set as one incorrect answer or inability to detect one site. 12,16-18,21,23,25,28-36 This conservative approach shows that the foot is at risk of DPN if any region cannot sense the 5.07 monofilament. In the groups with history of ulceration as the reference test, two categories both tested eight sites with different thresholds as shown in Fig 2. The test with one insensitive site as the threshold was a more conservative approach and had a higher sensitivity than the test with two sites as the threshold. Therefore, to have the most sensitive screening, the most conservative approach, with one insensitive site threshold should be used. When considering specificity of these two categories, the results were unexpected. The 1/8 sites method with a more conservative threshold had a higher specificity than the 2/8 sites method. The expected result was that the conservative method would have a lower specificity as it would have a higher false positive rate. This anomaly may be due to the studies testing two different cohorts of patients. In the groups with NCS as the reference test, two of the categories both included one site with eight repetitions. The more conservative threshold was the inability to feel two repetitions while the other threshold was the inability to feel five repetitions. In this case, the threshold with inability to feel five repetitions was more sensitive. While this result was somewhat counterintuitive, it showed that repetitions at any one site were not as effective in diagnosing DPN as using multiple different sites. This data shows that testing one site multiple times is more subjective as the patients expect the feeling at that site. This explanation can also account for the very low specificity of the 2/8 site threshold in the NCS reference test group. Ultimately, the most conservative thresholds with multiple site testing are recommended to maximize sensitivity of SWME.

One great disadvantage of other modalities such as pinprick and light touch is that the application of the stimulus may be inconsistent, thus introducing possible bias.³² Therefore, SWME, which applies a constant pressure, is a more objective examination for the diagnosis of DPN. Another one of the widely accepted modalities is detection by vibration perception threshold (VPT) with biothesiometer as it is objective and provides quantitative measurements. However, poor repeatability of VPT test

results on the same patient has been reported.⁵³ This test is also impractical for widespread use as it is expensive, needs calibration and a power source.¹⁸ Therefore, SWME is a very practical screening instrument for the diagnosis of DPN as its results are well correlated with NCS results if the most sensitive methodology is applied.

The qualitative analysis of all 30 selected studies focused on the specific process of SWME testing. The 5.07/10 g Semmes Weinstein monofilament assesses the integrity of Merkel touch domes and Meissner's corpuscles and their associated large diameter fibers.³³ Sensitivity of the test and the number of sites tested has positive correlation. While more sites increases sensitivity, practical aspects regarding the length of the examination also need to be taken into consideration. Studies showed that three well chosen test sites had close if not the same sensitivity as more sites.⁵¹ Lastly, the diagnostic threshold for SWME should be set as one or more insensate sites to maximize sensitivity. With this threshold, any foot with any insensate regions should be labeled as being at risk of DPN. From a public health perspective, there is more to lose by failing to initiate preventive interventions in those who would benefit than the alternative.

GENERAL RECOMMENDATIONS

This meta-analysis serves as a comprehensive review of all the studies performed on the diagnostic properties of SWME throughout the world. While many discrepancies exist in the current literature regarding SWME, this review seeks to present one standardized method of SWME with the greatest sensitivity. Based on the current literature on SWME, the optimal method is to use the 5.07/10 gmonofilament to test the plantar aspects of the great toe, third, and fifth metatarsal heads. Patients unable to detect one or more sites should be classified as at risk in order to maximize sensitivity. Performed with this methodology, the SWME can achieve sensitivity of 90% or above. In this case, SWME can be an inexpensive, accurate, and painless way for primary and specialty care physicians to identify patients with DPN during a physical examination. The SWME allows DPN to be diagnosed before obvious visual signs such as foot deformities and calluses. We recommend that SWME be used to identify DPN early on during routine diabetic care. Once loss of protective sensation at any site is identified by SWME, patients should be provided with an intensive foot-care education program in addition to appropriate therapeutic footwear. Medicare currently covers one pair of therapeutic shoes per year if there are documented signs of nerve damage with calluses.⁵⁴ It should be emphasized, however, that foot examinations are adjuncts and cannot replace early detection of diabetes partnered with strict glycemic control and close monitoring of hemoglobin A1c.

One possible deficiency is that this study did not report the prevalence of DPN in the sample vs the population for the domain of each study, which could affect the external validity of the reported PPV and NPV. In addition, publication bias was not accounted for in this review. However, for the purposes of this review, the main goal of assessing whether SWME can be an effective tool in diagnosing DPN was accomplished.

The variability in the methodology of SWME could greatly limit the effectiveness of the test as a diagnostic tool. However, this review found explanations that would account for these variations. It is possible that early DPN can affect sensory nerves differently in different regions of the foot, thus leading to variation in the data from the studies. Another cause of variation might have been testing on sites with callus. These calluses should be avoided when performing the SWME in order to standardize results. Because more testing sites on the foot and lower diagnostic thresholds lead to higher sensitivity, variation in these two factors would lead to different results in studies comparing different modalities. However, more research is necessary in many areas of SWME to produce data for quantitative analysis, specifically regarding the number of sites, location of sites, and the diagnostic threshold. In addition, further experimentation is needed to compare the diagnostic accuracy of SWME with that of other modalities such as the tuning fork or the pinprick test given the gold standard of NCS. A large cross-sectional study should also be performed with the currently recommended SWME method to validate its diagnostic value. This method of SWME has great potential to be the first alternative to NCS in the initial evaluation for clinically significant neuropathy in patients with diabetes mellitus.

AUTHOR CONTRIBUTIONS

Conception and design: YF, FS, BS Analysis and interpretation: YF, FS, BS Data collection: YF, FS Writing the article: YF, FS Critical revision of the article: FS, BS Final approval of the article: YF, FS, BS Statistical analysis: YF, FS, BS Obtained funding: Not applicable

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Overall responsibility: BS

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Appendix, online only. Search terms for the use of SWME for the diagnosis of diabetic peripheral neuropathy^a

Diabetes			Neuropathy			SWMF	
Title/Abstract	MeSH terms		Title/Abstract	MeSH terms		Title/Abstract	MeSH terms
sorbitol* "glucose intolerance" diabet* hyperglyc*	"Diabetes Mellitus" "Diabetes Mellitus, Type 2" "Diabetes Mellitus, Type 1" "Diabetes Complications" "Diabetes Complications" "Glucose Intolerance" "Sorbitol"	AND	neuropath* amyotroph* neuralg* polyneuropath* mononeuropath* pals* ischemi* angiopath* microvasc* (endotheli* AND hyperplas*) atherosclero* (periph* AND vasc*) foot feet plantar callus ulcer* cellulitis osteomyelitis streptococc* staphylococc* aureus	"Diabetic Neuropathies" "Vascular Diseases" "Peripheral Vascular Diseases" "Foot diseases" "Foot Ulcer" "Diabetic Foot" "Diabetic Angiopathies"	AND	frey* semmes* weinstein* filamen* monofilam* aesthesiometer "touch assessment" esthesiometer "threshold detection" "sensory testing" "mechanical sensitivity" "touch test" "cutaneous touch pressure"	"Microfilaments" "Sensory Thresholds"

^aThe search terms in the above three categories were connected by AND. All terms within each of the three categories, title/abstract terms and MeSH Terms, were all connected by OR.

^{*}The asterisks ("*") was used to truncate search terms (e.g., diabet* will retrieve diabetes, diabetic, etc.).