Abstract:

Objective: This study develops normalized values for sensation in the feet of healthy subjects. Knowledge relative to normal sensory perception and subsequent loss will enable clinicians to differentiate between normal and abnormal findings, especially in patients with or at risk for diabetes.

Methods: Subjects were over age 18 and without medical complications that might compromise sensory perception. Subjects were divided into three age groups: 18-34, 35-64, and 65 & older. With the subject’s eyes closed, Semmes Weinstein monofilaments were applied to 10 sites per foot and progressively lightened each time the subject correctly identified the monofilament at 10/10 sites, until the subject’s sensory threshold was reached. The threshold was defined as the lightest monofilament sensed at all 10 sites. Additionally, the researcher ranked the condition of the subject’s feet on a 1-3 scale, and the subject completed a questionnaire regarding their average weekly frequency of sandal use.

Results: The median value for the 18-34 group was 3.61(.4g), the 35-64 group was 4.31 (2g), and the 65 and older group was 4.74 (6g). The 18-34 group was significantly (40.941, df=2, p<0.001) different than the other groups. The older two groups did not significantly differ. There was a significant (-.445, n=60, p<0.0001) negative correlation between the frequency of sandal use and foot sensitivity.

Conclusions: Foot sensitivity decreases with age, but decline initiates earlier than anticipated. Loss of peripheral nerve fibers and integumentary sensory organs are implicated as the cause for sensory loss. Additionally, foot sensation decreased with increased sandal use.

Key words: LOPS, Monofilament, Neuropathy, Normative, Screening, Ulcer

Abbreviations: (LEAP) Lower Extremity Amputation Prevention Program, (LOPS) Loss of Protective Sensation, (PDGF) Platelet Derived Growth Factor

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Many disease processes lead to peripheral neuropathy and the Loss Of Protective Sensation (LOPS) in the feet. LOPS is seen in a variety of conditions and can have far reaching effects. Lost sensation is one of the early steps in the pathway that leads from foot ulceration to lower extremity amputation. Since research has indicated that 44-85% of ulcers are preventable, testing the feet for diminished sensation is a commonly recognized technique for aiding in the prediction of ulceration.\(^1,2\) However, the medical community lacks well-established research defining normal foot sensation across the lifespan. The currently accepted screening tool for loss of peripheral sensation is the 5.07 (10g) Semmes-Weinstein monofilament. All previous clinical tests for sensation have used the 5.07 monofilament as the minimum sensory threshold for all age groups.\(^3\) This value was not selected based on research; rather, it was arbitrarily selected and, over time, has become accepted as the medical standard. The 5.07 filament gained popularity as part of the Lower Extremity Amputation Prevention (LEAP) screen for lost sensation in Hansen’s Disease.\(^3\) The LEAP screen was adopted by clinicians as a general screening tool for loss of sensation from any disease process, and the 5.07 filament has survived as the cutoff for the concern without any research support suggesting that this is the normal physiologic threshold for sensation. In fact, one small study conducted on people with diabetes demonstrated that a 4g monofilament is capable of detecting neuropathy earlier than the 10g filament.\(^4\) Without thoroughly researched normative values in the genre, there is no frame of reference with which to compare the sensation values of patients with suspected peripheral neuropathy. The establishment of normative values for foot sensation in a healthy population will allow for the earlier identification of those at risk for ulceration, prior to significant comorbidity. This research presented herein attempts to define normal foot sensation. Prior to delving into our study, explanations of LOPS, the major predisposing factors leading to LOPS, and the outcome of LOPS are provided.

**Introduction**

Many disease processes degrade sensation. There exists a critical value for sensation where the individual can no longer perceive damage occurring in the feet. The critical value for sensation separates merely diminished sensation from the condition of LOPS. To further define these terms, diminished sensation is a loss of sensation that does not limit the individual from sensing damage, while LOPS is the loss of sensation that does limit the individual from sensing damage. Once LOPS is present, the individual cannot detect the damage occurring, and the stimulus for the damage (usually uneven weight bearing) remains for a prolonged amount of time. Generally, the stimulus for damage is not removed until the individual inspects their feet or, by chance, visualizes the damaged tissue. Further complicating the disease process, proprioceptive loss generally accompanies LOPS, and this loss of proprioception can lead to improper weight distribution in the feet.\(^5,6\) As discussed above, the uneven distribution of weight through the feet is a stimulus for damage. According to Levin,\(^5\) sensory and motor neuropathies can change the way patients sense various stimuli and transfer their body weight through their feet during gait, resulting in calluses and, if untreated, ulceration.
Diabetes

With 8.3% (25.8 million) of Americans affected, diabetes is currently the seventh leading cause of death in the United States and a major contributor to foot ulceration.\(^7\)\(^8\) The disease process leads to lost sensation through diabetic neuropathy. This form of neuropathy is caused by the deposition of sorbitol (a byproduct of excess glucose metabolism) on peripheral nerves.\(^9\) Once sorbitol is deposited, the conduction of the nerve is slowed and, eventually, limited by interference of the myelin sheath’s conduction of the action potential. Diabetes related vascular disease contributes to the development of ulceration by both directly impeding blood supply to the sensory nerves of the foot and occluding the microvasculature responsible for supplying the tissue of the foot. Given the large incidence and prevalence of diabetes, the majority of foot ulcerations and related complications are rightfully attributed to this disease. However, peripheral nerves can be affected by other processes, such as peripheral vascular disease (PVD).

Peripheral Vascular Disease

PVD affects peripheral nerves by limiting blood flow to the nerve. Cholesterol and other fatty plaques gradually build inside vessels, reducing the intraluminal space. As peripheral vessels lose their patency, the structures receiving their blood supply from these vessels begin to lose function. In the case of peripheral nerves, the lost blood flow caused by PVD causes avascular necrosis and lost sensation. While diabetes and PVD are largely avoidable through proper diet and exercise, the final cause for lost sensation discussed, aging, is not.

Aging

Aging causes lost sensation through a number of processes. The key changes that lead to lost sensation with age include the following: decreased Merkel cells, decreased Meissner’s/Pacinian corpuscles, decreased cross sectional area/number of peripheral nerve fibers, and decreased secretion of neurotrophins. Primarily, the loss of Merkel cells and Meissner’s/Pacinian corpuscles with aging causes lost sensation because these organs are directly responsible for sensing various stimuli, such as pressure and fine discriminative touch.\(^10\)\(^-\)\(^12\) The loss of any of these organs will immediately influence sensation because stimuli cannot be detected. Secondly, the decreased cross sectional area/number of peripheral nerve fibers causes lost sensation because these processes limit the conduction of the action potential through the nerve.\(^12\)\(^,\)\(^13\) The action potential must be conducted to the brain in an all-or-nothing fashion, or the brain will not recognize that a stimulus has been detected. With any limitation in the conduction of an action potential, the all-or-nothing signal is biased towards conducting nothing. Finally, the loss of neurotrophins with aging prevents the maintenance of peripheral nerves.\(^12\)\(^,\)\(^14\) Without maintenance, a decrease in cross sectional area and total fiber number is inevitable. As previously discussed, the disruption of peripheral nerves interferes with action potentials and, ultimately, the brain’s recognition of a stimulus. Any of the processes discussed above can cause lost sensation, which, if not monitored, can lead to LOPS.
Ulcers

Ulcers are commonly the result of continued and uneven weight distribution over an area of skin. Patients with intact sensation identify improper weight distribution through painful stimuli, calluses, and blisters prior to ulceration. Once the people identify the problem area, they seek treatment or modify their weight distribution to prevent further aggravation to the area. A person without intact sensation cannot recognize improper weight distribution because the stimulus of pain is not felt. The patient continues to apply pressure to the aggravated tissue until the skin begins to wear away and an ulcer is formed. The same diseases processes that lead to LOPS and ulceration are known to impair wound healing. When an ulcer is impaired from healing, it becomes a chronic wound. Nearly 13% of patients with diabetes develop a foot ulcer.\textsuperscript{1} The ulceration is secondary to LOPS or other diabetes-related deformities occurring within the feet.\textsuperscript{5} For the population with lost sensation, the pathologies that limit sensation will also limit healing.

Normal Healing

Healing normally occurs in four orderly phases: Hemostasis, Inflammation, Proliferation, and Remodeling.\textsuperscript{15,16} The hemostasis phase occurs at the onset of the wound and is characterized by the presence of platelets.\textsuperscript{15-18} The platelets form a clot to stop the bleeding from the wound by signaling for matrix materials such as fibrin through agents such as platelet derived growth factor (PDGF).\textsuperscript{15,19} The hemostasis phase leads to the inflammation phase.

The inflammation phase occurs 24-48 hours after the injury and is marked by the presence of neutrophils, which degrade any foreign material within the wound.\textsuperscript{15,16} This process is aided by macrophages, which help to destroy microorganisms. To perform their job properly, the two aforementioned cells must be able to move into the extra cellular space. This move is accomplished through vasodilation, which leads to the inflammation for which the phase is named. The inflammation phase generally lasts from one to four days and leads into the proliferation phase.

The proliferation phase is characterized by the presence of fibroblasts, which secrete collagen.\textsuperscript{15,17} Collagen acts to fill in the area that was damaged in the wound. The dermal layer is replaced, and new blood vessels begin to form in this phase.\textsuperscript{15,17} Angiogenesis is signaled for chemically by the hypoxic/acidotic environment within the wound. Proliferation usually lasts from the 4th day to the 21st day post-injury and leads into the remodeling phase.

The remodeling phase can last up to two years following the injury and is characterized by the break down and rebuilding of tissue in accordance with stresses placed on the tissue. For example, collagen laid down in a scar over a joint will be remodeled and realigned to correspond to the motion of the joint. When a wound fails to progress through the four phases, it becomes a chronic wound.

Abnormal Healing

Any variance from the normal wound healing model can cause a wound to heal abnormally and become chronic. Primary causes for a wound to become abnormal include the following: missing chemical messenger, infection, prolonged trauma to the wound, and other comorbidities. Some comorbidities are poor nutrition, peripheral vascular disease, improper offloading, and poor fitting orthotics. When a wound heals abnormally, it can become a chronic wound, which can lead to an amputation over time. In consequence, 60% of lower extremity amputations occur in patients with diabetes, and 85% of these amputations are preceded by foot ulceration.\textsuperscript{20}
The following will summarize the above-discussed algorithm: disease processes such as diabetes and PVD cause diminished sensation; when the sensation loss reaches a critical point, the individual can no longer sense damage to their feet (LOPS); the LOPS is accompanied by lost proprioception, which leads to improper weight bearing through the feet; improper weight bearing leads to ulceration in an individual with LOPS; individuals with diabetes or PVD that experience ulceration have impaired wound healing, which leads to chronic wounds; chronic wounds have many complications, including amputation.

MATERIAL AND METHODS

This normative data collecting study investigated the sensation of healthy subjects in three age groups: 18-34 years olds, 35-64 year olds, and 65 years old and greater. Twenty subjects were recruited for each age group, giving a total of 60 subjects combined. The data were collected in majority at Daemen College, but some individuals were met in the community. The same methods were used for each subject, regardless of the setting for collection.

Prior to the screen administration, a brief questionnaire was provided to each subject, which recorded age, medical conditions, sandal usage, and perceived ability of sensation. The inclusion criterion requires subjects over the age of 18. Since a normal value of sensation is sought, the exclusion criteria include conditions that would alter foot sensation such as diabetes, peripheral neuropathy, and peripheral vascular disease. Additionally, the administrator recorded the appearance of the feet on a 1-3 scale. A score of 1 was given to feet that were both free of dead skin and unsoiled. A score of 2 was given to feet that had either the presence of dirt or dead skin. A score of 3 was given to feet that had the presence of both dirt and dead skin.

The question regarding sandal use was included because the authors perceived that increased sandal use could potentially limit the study. Subjects who use sandals more frequently can develop thicker calluses due to the increased shear forces accompanying this type of footwear. The thicker calluses can potentially skew the results of the study. With data regarding frequency of sandal use recorded, the authors can identify any correlation between sandal use and foot sensation, and increased sandal use can be controlled.

The 1-3 scale for foot condition was included because the authors perceived another potential limit to the study. Subjects who walk barefoot with an increased frequency could potentially have thicker calluses and skew the results of the study. With the 1-3 scale, the subjects who walk barefoot with an increased frequency can be identified by the condition of their feet. With data regarding the condition of the feet, the authors can identify any correlation between foot condition and sensation, and feet with increased wear can be controlled. Semmes-Weinstein monofilaments were used in conjunction with the American Diabetes Association’s Lower Extremity Amputation Prevention Program (LEAP).

The LEAP program’s screen includes 10 testing sites for each foot. For each subject, one initial filament was chosen as an estimate for their sensation and then applied to all ten sites of the LEAP screen. If the subject could feel the initial filament at all 10 sites, the administrator progressively applied filaments of lesser weights until the subject could not identify the stimulus at all 10 sites. If the subject could not sense the initial filament at all 10 sites, the administrator progressively applied heavier filaments until the subject could identify the stimuli at all 10 sites. The lightest filament that the subject felt at all 10 sites was recorded, and the test was repeated on the other foot.
Once the other foot was tested, the data collection was concluded. Once the data were collected on all 60 subjects, non-parametric statistical analysis was conducted. The statistical analysis consisted of the following: determination of mean, determination of median, determination of mode, determination of standard deviation, Kruskal-Wallis test, Bonferroni’s test, and a Spearman’s Rho test. The Kruskal-Wallis test was used to identify the presence of a statistical difference between the age groups. The Bonferroni’s test was used to describe the relationship between the age groups. The Spearman’s Rho test was used to identify any correlation between sensation, sandal use, and foot condition.

Results

Each age group demonstrated a unique median monofilament value. The 18-34 year olds had a median value of .4 grams. The 35-64 year olds had a median value of 2 grams, and the 65 year old and older group had a median value of 6 grams (Figure 1).

![Figure 1: The relationship between foot sensitivity and age](image)
A Kruskal-Wallis test showed that the values for the three groups were significantly different (data not displayed), and a Bonferroni’s test showed that the 18-34 year old age group was unique, but the 35-64 and 65 & older groups did not significantly differ (Table 1).

Table 1. Bonferroni Test Values.

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<th>(J) age</th>
<th>Mean Difference (I-J)</th>
<th>Std. Error</th>
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Table 2. Spearman’s Rho Values

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The Critical Value when N=60 is .418 at the .0001 confidence level.

**Discussion**

The results are primarily explained by the processes discussed in the aging section above. Changes in Meissner’s/pacinian corpuscles, merkel cells, cross sectional area/number of peripheral nerves, and neurotrophins all occur with age and can account for the decreased sensation correlated with age. As reflected by the Bonferroni’s test, the 35-64 and 65 and older age groups did not significantly differ. This lack of significant difference suggests that the aging processes starts to have an effect on sensation when the subjects are in their 30’s, which could help to explain why the 35-64 and 65 and older age groups do not differ significantly. Since patients with peripheral neuropathy can be of any age, and sensory values were shown to differ
across age groups, the 5.07 monofilament is not appropriate as a threshold value for all patients. Because the LEAP screen is a well-known and thoroughly studied instrument for detecting lost sensation, we support its continued use with one important caveat: changing the value of the monofilaments used in the test to more accurately reflect the norms of sensation discussed herein. These preliminary norms suggest that the average threshold for sensation across all ages is much lower, roughly one quarter, than the value currently being used as the cut off for pathology. The age-specific thresholds identified in this study are as follows:

- 18-34 year olds: 0.4 grams
- 35-64 year olds: 2 grams
- 65 year olds and older: 6 grams

Lower thresholds are more sensitive and will identify loss of sensation earlier in the disease process. Earlier identification prompts earlier treatment and, presumably, a lower incidence of ulcers and their complications. Prior to any modification of the current screening method, a similar study to ours with a larger number of subjects is needed for validation. A validated model is applicable to the population as a whole, which would prompt the modification of the standard monofilament used during screening for loss of peripheral sensation.

When Spearman’s Rho is conducted on any of the three individual age groups, no correlation is present between foot sensation and frequency of sandal use; however, there is a negative correlation between foot sensation and frequency of sandal use when the test is applied to the population as a whole. The relationship between sandal use and sensation can be explained by the increased shear on the feet with sandal use, which results in a thicker stratum corneum. This thicker layer of skin results in callused feet and decreases sensation. Therefore, any attempts at validating the findings of this study would be strengthened by the exclusion of subjects who wear sandals frequently, as they have the potential to skew the average sensory values. Since this study demonstrated that no correlation exists between the condition of the foot and the sensation of the foot, subjects with poor foot hygiene need not be excluded. Although statistical significance was achieved in this study, a larger population is needed for each age group to lend power to the statistics and validate the findings. With further research into the normal values, a better understanding of sensory deficit can follow, and a lower threshold can be selected to identify pathology. In addition to a larger, validating study, more research is needed in the following areas to increase our understanding of the process of lost sensation: the relationship between sensory loss and gender, the relationship between sandals and sensation, and the age-specific threshold values for sensation prior to skin damage.

The Relationship between Sensory Loss and Gender

The only current research regarding normative values for foot sensation was conducted by McPoil et al. and found variation in foot sensation based on genders; however, this study did not research this relationship on different age groups. Although the study found differences in the 40 subjects’ sensations, this relationship may not remain when the study is expanded to include three age groups. The small sample size does not have statistical power, and the study should be repeated with a larger sample size. Therefore, further research is needed in this field.

The Relationship between Sandals and Sensation

Since this study established a relationship between foot sensation and frequency of sandal use, further research regarding the time of year of the study is needed. Testing immediately after summer, the time of year with the highest sandal use, may have skewed the results.
Therefore, further research is needed to distinguish if this relationship persists throughout the year. Moreover, if a relationship is present between certain months of the year and lowered sensation based on sandal use, the most critical time of year to screen for lost sensation can be identified. Different styles of sandals will fit the foot’s anatomy in differing ways, which will cause different forces on the skin. The variation in forces could stimulate different extents of stratum corneum thickness. The corneum could affect the subject’s performance on the LEAP screen; therefore, further research comparing the effect of different sandal styles on sensation is needed. Additionally, different types of footwear (not necessarily sandals) can also contribute to distinctive callus patterns. One example is orthotic footwear, which would have a higher frequency of appearance in the population of patients with diabetes secondary to the presence of deformities such as Charcot foot. A more specific study could investigate sensation within a population of subjects who wear orthotics. As previously discussed, sensation is decreased by sandal use. In older patients (with inherently lower levels of sensation to begin with), increased sandal use could result in LOPS. Therefore, further research is needed to determine if a distinct number of sandal uses per week results in LOPS over time. Because the sandal is such a popular form of footwear, insight into the safety and recommendations on use of this form of footwear in the older population as well as subjects with LOPS could have a dramatic effect on the incidence of ulceration in the overall population.

The Age Specific Threshold Values for Sensation Prior to Skin Damage

The single most important area for the conduct of follow-up research pertains to thresholds of sensation in regards to damage. Once sensory thresholds for various ages are known, thresholds for damage must be determined for each age group. Understanding the threshold for damage will enable clinicians to determine the significance of patients’ sensory deficits. As the patients’ sensations increasingly deviate from the expected value towards the threshold for damage, increased action can be taken to return sensation or protect from ulceration.
REFERENCES


