Performance of the Locally Made Disposable 10-gram Semmes-Weinstein Monofilament Compared to the Commercially Available Monofilament

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ABSTRACT

Objective: The aim of this study was to find a technique to make a disposable monofilament which is accurate and affordable for Thailand context. A prototype of local made monofilament was developed and tested with the calibrated universal machine test to evaluate its performance compared with the commercial monofilament. Effect of the uncontrolled humidity condition on the performance of the commercial monofilament was also studied.

Methods: Review of literatures showed no published specifications of the monofilament. The investigators set the concepts that materials must be locally available and affordable. Also the unit cost must be affordable for primary care units in Thailand. Monofilament's fabrication technique was developed and the accuracy test of monofilament force was performed and compared with the commercially available monofilament.

Results: The specification of locally made disposable 10-gram Semmes-Weinstein monofilament was identified. The force of the monofilaments developed was in an acceptable range for a standard clinical practice and comparable to the commercially available monofilament. From the study, the effect of Thailand's humidity conditions can deteriorate the performance of the monofilament. The investigators decided to use a disposable monofilament one to ensure its hygiene and accuracy.

Conclusion: The local made disposable 10-gram Semmes-Weinstein monofilament was developed. The material is available and affordable for Thailand context. The accuracy of the monofilament's force was measured by a calibrated testing apparatus. Availability, durability, and cost are important issues to be concerned for medical tools that have been recommended to use worldwide. The result from this study could be applied to other countries that have similar conditions as Thailand.

Keywords: Monofilament; disposable; specification; humidity (Siriraj Med J 2018;70: 22-27)

INTRODUCTION

Diabetes Mellitus is one of the top ten causes reducing the disability adjusted life years (DALYS) of Thai population.[1] The National Health Examination Survey (NHES) conducted in 2009 found an overall diabetes prevalence of 7.5% in Thailand and 31% of them were undiagnosed.[2] According to International Diabetes Federation (http://www.idf.org/membership/wp/thailand), there were more than 4 million people with diabetes in Thailand in 2015. Diabetes can lead to several complications e.g. Retinopathy, Nephropathy, and Neuropathy. Peripheral neuropathy is a complication in approximately 50% of patients with diabetes, and up to 50% of patients with peripheral neuropathy may not have symptoms.[3] Neuropathy usually leads to loss of protective sensation at foot, chronic and infected wounds at foot and finally foot amputation. The rate of foot amputation of people with diabetes is up to 13.7 per 1,000 people

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per year, which is 10-times higher than healthy people.[4] Thus, a routine diagnosis foot protective sensation is crucial. Various methods may be employed to test for neuropathy such as temperature differentiation, pin-prick test, vibration perception threshold and the 10-g monofilament.[5] One of the widely used foot diagnoses for foot protective sensation is using Semmes-Weinstein monofilament or 10-g monofilament. It has become popular because it is easy to use, reliable and lower cost than other methods. The criteria of the monofilament test to determine the loss of foot protective sensation is using the monofilament no. 5.07. If the person does not respond to the test by monofilament no. 5.07, the person is considered to have lost their foot protective sensation. However, the genuine Semmes-Weinstein monofilament has to be imported and is unaffordable by most public hospitals in Thailand. Currently, public healthcare practitioners have to use home-made monofilament or free monofilament from pharmaceutical companies. The quality and reliability of these monofilaments are sometimes questionable. The monofilament no. 5.07 must accurately apply 10 grams force to the patient's foot to diagnose the patient's foot protective sensation. However, Booth and Young found that only 70% of commercial Semmes–Weinstein monofilaments they have tested were accurate (buckling force within +/- 1 g of 10 g).[6] There are many factors that affect the performance of the monofilament including the environmental condition. The durability of the monofilament is also sceptical after repeated usage. Yong et al., reported a reduction in average buckling force by 0.8 g and 1.2 g after 200 and 500 cycles of compression respectively.[7] Therefore, we decided to develop the disposable monofilament to avoid the aforesaid problems. Our disposable monofilament is made of locally available materials in order to be accessible and affordable. The prototype of locally made monofilament was tested with the calibrated universal machine test to evaluate its performance compared to the commercial monofilament. Effect of the uncontrolled humidity condition on the performance of the commercial monofilament was also studied.

MATERIALS AND METHODS

A set of forty commercial monofilaments (two packages with twenty monofilaments a package) was put in indoor humidity condition (uncontrolled humidity condition), while another set of forty of the same commercial monofilaments was put in controlled condition with fixed humidity at 45%. A set of forty prototype monofilaments was also prepared from a roll of nylon fishing line 0.5 mm in diameter, cut into 35 mm lengths measured from a fixed point by fixing a stamp paper clip to the end, and then put it in controlled condition with fixed humidity at 45%. With a universal testing machine (Instron 5943, Norwood, MA, USA) at polymer physics and rheology laboratory, National Metals and Materials Technology Center, 10 N load cell was used to measure compressive forces on all monofilaments. Load pattern began with 1 mm/s with 10 mm downward loading, 3 mm/s with 10 mm upward to original point of unloading, and 2 seconds of holding, respectively, and then repeated those three back and forth for 16 times. Testing time was 2 days.

For statistical analysis, statistic t-test was used to check, whether in this case, the humidity condition affected the average forces of 16 consecutive compressions by comparing their averages and assuming homogeneity of variance between groups. Therefore, the null hypothesis (H0), was that difference between two average forces of 16 consecutive compressions, was zero and the alternative hypothesis (H1) was that difference between two average forces of 16 consecutive compressions was not zero. However, to check if disposable monofilament, was is accurate and affordable, the commercial and prototype monofilaments were compared. Before using statistic t-test to test the difference between two average forces, statistic F-test of difference of two variance between groups of samples had to be tested. Therefore, the null hypothesis (H0) was that standard deviation of force of commercial monofilaments equalled standard deviation of force of prototype monofilaments and the alternative hypothesis (H1) was that standard deviation force of commercial did not equal standard deviation force of prototype monofilaments. If the result of H1 was rejected, the commercial and prototype monofilaments could be compared and then concluded which one was better using statistic t-test.

RESULTS

First of all there was a failed test on a commercial monofilaments in controlled condition with fixed humidity at 45%, then the sample size was reduced to 39 in this condition. The average forces of 16 consecutive compressions of commercial monofilaments put in indoor humidity condition and controlled condition with fixed humidity at 45% were 8.29 and 9.23 grams, respectively. The standard deviation forces of 16 consecutive compressions of commercial monofilaments put in indoor humidity condition and controlled condition with fixed humidity at 45% were 0.22 and 0.20 grams, respectively. Figs 2 and 3 were testing results of the commercial monofilaments with different humidity conditions. They were comparable patterns for both graphs, which were very high forces at first compression and then decreased over time. Their average forces were different by about a gram. Therefore, statistic t-test was used to check whether their averages were different or not by assuming the same variance of those groups. The p-value of statistic t-test was zero, which came from t-value of 21.262 and degrees of freedom of 77. The null hypotheses were rejected which meant their averages were different. Therefore, the forces of commercial monofilaments put in indoor humidity condition was lower as shown in Table 1.

The average and standard deviation forces of 16 consecutive compressions of prototype monofilaments put in controlled condition with fixed humidity at 45% were 9.19 and 0.37 grams, respectively. As shown in Fig 4,

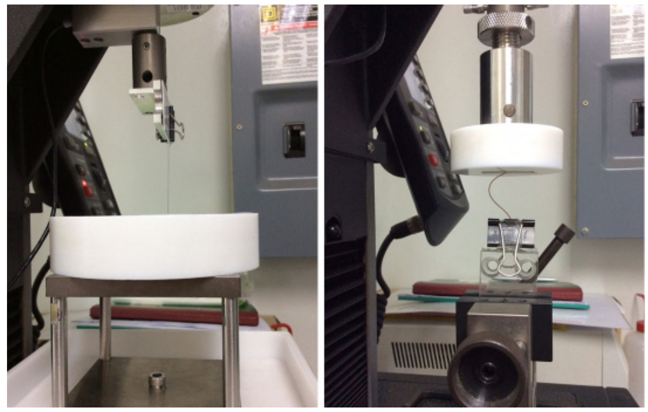

Fig 1. Commercial monofilament (left) and prototype monofilament (right) on a universal testing machine for compression test to simulate sensation testing on the patient's foot.

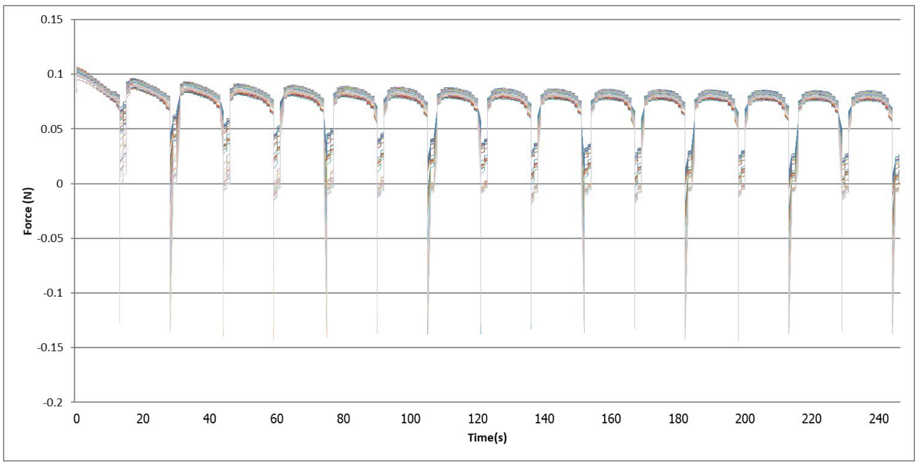

Fig 2. Forces of 16 consecutive loading, unloading, and resting pattern of commercial monofilaments put in indoor humidity condition.

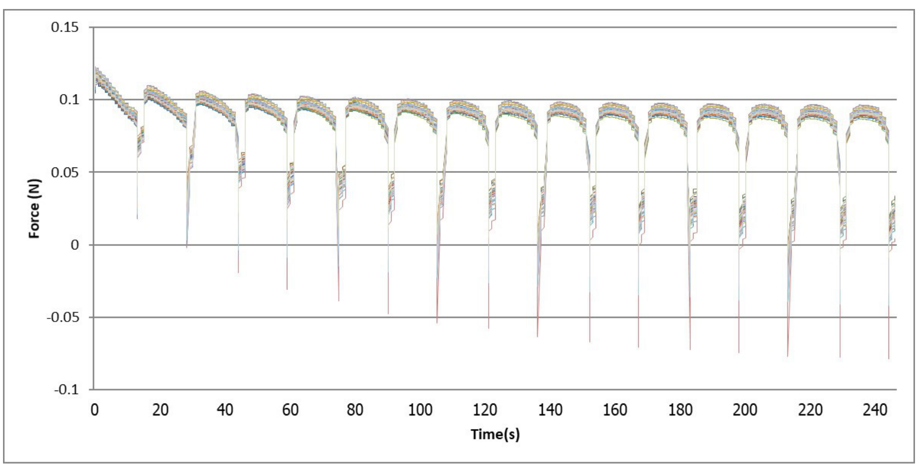

Fig 3. Forces of 16 consecutive loading, unloading, and resting pattern of commercial monofilaments put in controlled condition with fixed humidity at 45%.

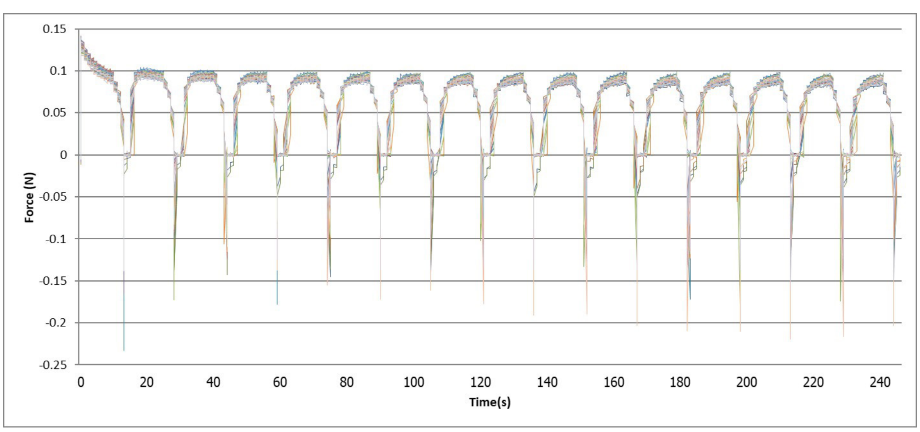

Fig 4. Forces of 16 consecutive loading, unloading, and resting pattern of prototype monofilaments put in controlled condition with fixed humidity at 45%.

they were also comparable patterns compared with commercial ones, which were very high forces at first compression and then decreased over time. However, they were different groups, thus two variances had to be checked. The p-value of statistic F-test was 0.0001, which came from F-value for a left-tailed test of 0.2840 and both degrees of freedom of 39 and 38 for commercial and prototype monofilaments, respectively. Thus, the null hypotheses were rejected. Therefore, average difference between commercial and prototype could not be compared because the two variances were different as shown in Table 2. Even though both the average peak forces could not statistically be compared. as shown in Fig 5, the average peak forces of commercial monofilaments and prototype in controlled condition with fixed humidity at 45% after 16 consecutive compressions were slightly higher than the average peak force of commercial monofilaments in indoor humidity condition in Fig 5.

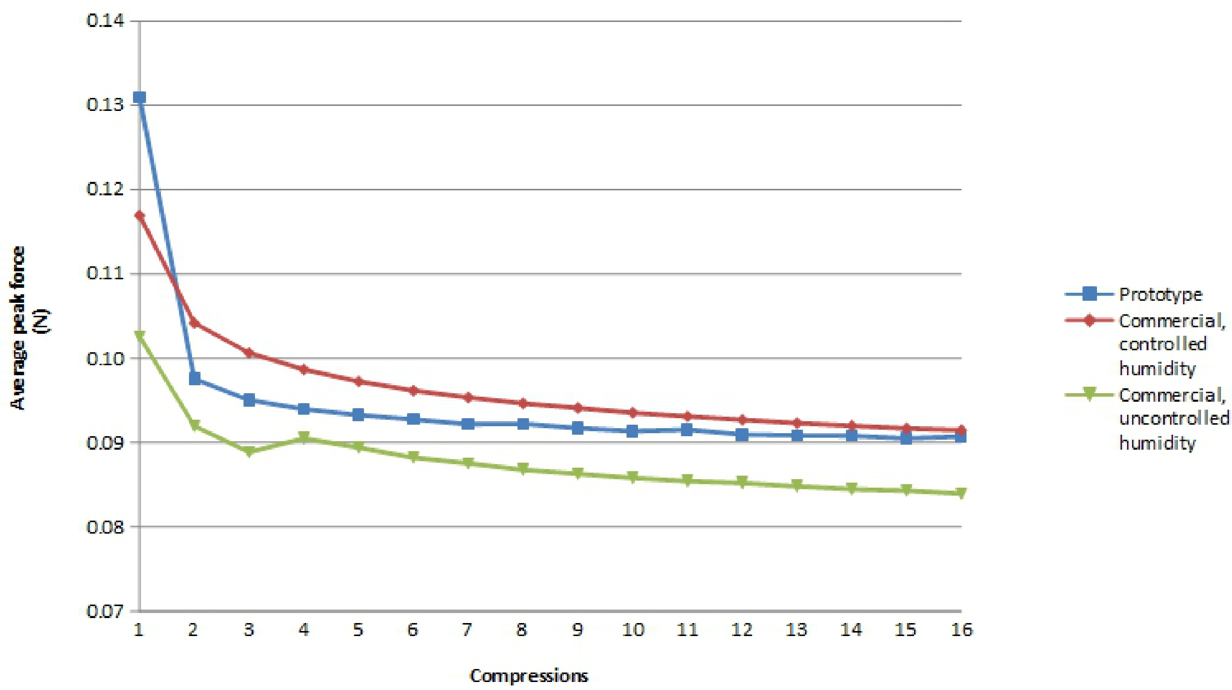

Fig 5. Average peak forces of commercial monofilaments in both indoor humidity condition and controlled condition with fixed humidity at 45% and prototype monofilaments in controlled condition with fixed humidity at 45% after 16 consecutive compressions.

TABLE 1. The average forces and their standard deviations of 16 consecutive compressions of commercial monofilaments put in indoor humidity condition and controlled condition with fixed humidity at 45%, and to compare the effect of humidity condition, the statistic t-test was used to check whether their averages were different or not with the same variance of those groups.

Average peak forces of	Average (N)	Standard deviation (N)	Sample size	Statistic t-test	Statistic F-test
Commercial monofilament in indoor humidity condition	8.29	0.22	40	t-value of 21.262, degree of freedom of 77, p-value = 0, then the averages are different	Same source of population, then assumed no difference of variance
Commercial monofilaments in controlled condition with fixed humidity at 45%	9.23	0.20	39		

TABLE 2. The average forces and their standard deviations of 16 consecutive compressions of commercial and prototype monofilaments commercial monofilaments put in indoor humidity condition and controlled condition with fixed humidity at 45%, and to compare between commercial and prototype monofilaments at fixed 45% humidity condition the statistic F-test was used to check whether two variance were different or not between groups before using the statistic t-test.

In controlled condition with fixed humidity at 45% average peak forces of	Average (N)	Standard deviation (N)	Sample size	Statistic t-test	Statistic F-test
Commercial monofilaments	9.23	0.20	39	Could not be compared because two variances were different	F-value of left tailed test of 0.2840, degree of freedom of 39 and 38, p-value = 0.0001, and then two variances were different
Prototype monofilaments	9.19	0.37	40		

DISCUSSION

After testing on commercial monofilaments, it was statistically confirmed that the null hypotheses was rejected, which means that humidity condition to store monofilaments is the primary concern. Max HH et al.,[8] also found that there were significant changes in buckling force of the Semmes-Weinstein monofilaments in different temperature and humidity conditions. The calibrated monofilament may have deteriorated performance if it is stored in the high humidity condition. Thailand has an average relatively high humidity with high temperature. Therefore, there is a high chance of misdiagnosis if a monofilament is stored in uncontrolled condition as shown in our study. Therefore, using monofilaments and storing them in the uncontrolled humidity condition and then reusing them is not recommended. Our suggestion is that the monofilaments should be disposable, calibrated from the manufacturers and packed in the moisture barrier packaging to ensure their performance. Moreover, the disposable monofilaments tend to be more hygienic than the reusable ones.

For prototype monofilaments, it was shown that monofilament can be possibly made with lower cost with an example of a simple holder like a stamp paper clip as shown in Fig1. The crucial point is the quality control of the manufacturing process to ensure the force of the monofilament and the packaging process to ensure the moisture protection before the use. The buckling force of the monofilament depends on the diameter, length and elastic modulus of the monofilament. These three parameters can be adjusted as appropriate. A holder of the monofilaments can be customized as shown in Fig 6.

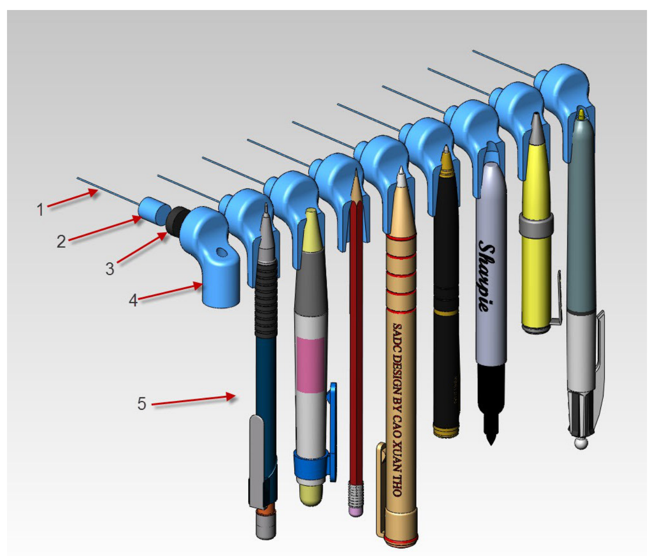

Fig 6. Design examples of local made disposable monofilament.

The effects of the diameter, length of monofilament, elastic modulus of the monofilament and moisture barrier of the package on the performance of the monofilament will be studied in further work.

CONCLUSION

The local made disposable 10-gram Semmes-Weinstein monofilament was developed and tested. Its performance is comparable to the commercial one. However, Thailand's ambient humidity may deteriorate the performance of the calibrated monofilament after storing for a while as shown in our study. Therefore, an affordable and disposable monofilament seems appropriate to Thailand's context. The disposable monofilaments in the sealed packages with good quality control process can ensure their reliable performance to the users.

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