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Protective System from Medical Needle-sticks. Part II: Evaluation of Woven Structures and Bifid Needles

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Abstract: We have shown in Part I [1] of this study that medical needle-stick injuries are causing serious health problems to healthcare personnel and other professionals that require the attention of healthcare and textile researchers to develop new protective systems. Responding to such need, a needle force measurement device that is capable of measuring dynamic forces experienced by medical needles during needle penetration through protective articles was developed and described in part I. This paper reports the results of evaluation of protective woven fabrics from high performance fibers and standard and bifid medical needles using the force measurement system. The woven fabrics varied in cover factor, number of layers, and orientation angle. Standard and bifid needles with different gap widths were used to evaluate the resistance of the fabric to needle penetration.

Keywords: Medical needle-stick injuries, Bifld medical needle, Blood pathogen infection, Needle force, Medical protective system

Introduction

Healthcare workers in hospitals, dental offices, nursing homes, public clinics, and other healthcare facilities are at risk from infection by serious illnesses (such as AIDS Hepatitis B, C, D, etc.) that are caused by medical needle-sticks. Although the medical industry has the highest risk of getting such diseases, there are numerous other occupations that directly involve contact with bodily fluids [1]. The population at risk to bloodborne pathogen infections (HIV and HBV) exceeds 8.5 million. There are nearly one million needle-sticks reported annually and many cases that go unreported [2]. Many healthcare workers have lost their health and lives as a result of infection by needle-sticks despite the safety regulations set by health and safety organizations. This is because there are no effective means to stop medical needles from penetrating through the human skin and flesh.

Healthcare workers started wearing gloves in the nineteenth century to prevent passage of microorganisms from their hands to patients and vice versa. Today the use of latex gloves is the norm. While such gloves provide protection of passage of fluids, they provide little to no protection from needle-sticks. Cut-resistant gloves from high performance fibers such as Spectra are used as liners between two rubber latex gloves, over latex gloves or under latex gloves to protect physicians and staff members from cuts and slashes incurred during use of sharp instruments [3,4]. But even such composite structures do not stop needle-stick injuries due to the design nature of medical needle tip. This fact has motivated the invention of a bifid needle (Figure 1 of reference [1]). The bifid needle is designed to entangle with fibers of gloves (or other protective articles) made of composite structure (latex/textile fabric). Protective textiles need be designed to work with bifid needles to prevent needle-sticks.

Major problems arising from needle-stick injuries and the invention of the bifid needle have motivated our team to conduct research to provide healthcare workers with protective textiles. In order to achieve such a goal, it is essential to study the mechanism of medical bifid needle penetration through woven structures and understand the influence of medical needle parameters (needle gap depth and width; defined in Figure 1 of reference [1]) and the woven fabric parameters (cover factor, number of layers, and fabric orientation with respect to needle orientation) on the resistance of the fabric to needle penetration. An additional objective is

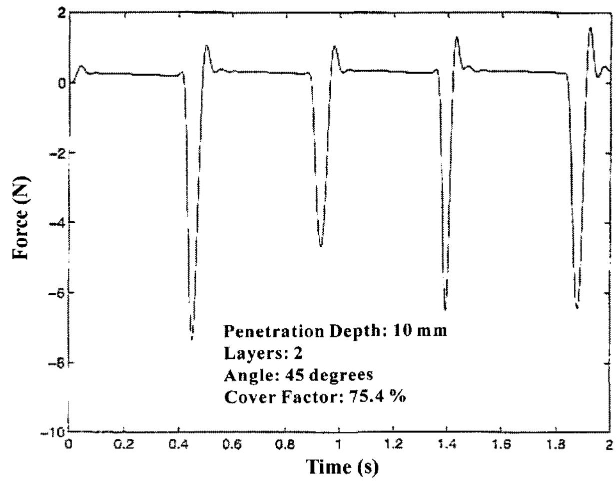

Figure 1. Filtered net forces experienced by bifid needle with 0.2974 mm gap.

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Table 1. Specifications of woven fabrics

Fabric count (threads/cm)	Yarn linear density g/9 km	Number of filaments ---	Cover factor (%)	Thickness (mm)	Weight (g/m^2)	Void area (mm^2)
13.69 × 13.69	215	63	51.8	0.1950	67.9	0.2580
17.72 × 17.72	215	56	64.6	0.2040	88.2	0.1090
22.05 × 22.05	215	54	75.4	0.2544	112.0	0.0507

to develop a technique or testing method to evaluate or characterize such resistance. In this paper we report the experimental procedure and the results of the evaluation of protective woven fabrics from high performance fibers used along with standard and bifid medical needles. The force measurement system described in Part I [1] was implemented to measure the resistance of fabrics to needle penetration (or the forces experienced by needle during penetration through the fabrics). The needle forces represent the measure of the system degree of protection.

Experimental

Woven Fabrics

Cut-resistant Spectra 1000® plain weave fabrics were utilized in this research. The specifications of the fabrics are depicted in Table 1. The fabrics are woven from flat continuous filament yarns.

Needles

Needles used in this research were 18 gauge 1 1/2 stainless steel injection needles manufactured by Becton Dickinson & Co. The diameter of 18 gauge needles is 1.2 mm. Several standard needles were converted to bifid needles using spark erosion machinery or Electrical Discharge Machinery. Etching of the bifid needle is obtained by a succession of non-stationary electrical charges. The standard needles were cut to gap widths (defined in Figure 1 of reference[1]) of 0.1778, 0.2286, and 0.2794 millimeters to produce the bifid needles. Initially, we planned to include two bifid needle parameters, namely gap width and gap depth (defined in Figure 1 of reference [1]). The nature of the cutting process and the standard needle design, however, dictated the dependency of these two parameters. The gap depths corresponding to the gap widths above are 0.8, 0.12, and 0.18 millimeters, respectively. Due to the correlation between gap width and depth, only one of bifid needle parameters need be studied. We elected to use the gap width (or shortly gap) as an independent parameter of the bifid needle. It should be noted here that needles with gap width higher than 0.2794 mm would cause pain to patients during treatment.

Needle Force Measurement System

The dependent parameter used in this study is the resistance of protective fabric to the penetration of medical needle expressed as force. A needlepunching loom was converted to a force measurement system. The force measurement system along with data acquisition and analysis hardware and software systems were developed to measure, capture, and analyze the dynamic forces experienced by the needle during its contact/penetration through the fabric. Full description of these systems is given in Part I of this series [1].

Since needle-stick injuries occur to healthcare personnel while in motion, i.e. in a dynamic mode, our force measurement system was thought to provide such a mode. To determine the needlepunching loom speed, people's movements were observed and evaluated by video recording. A device speed of 114 strokes (cycles) per minute was found to be a good average estimate of a person's speed during normal motion. Higher or lower speeds to simulate certain body part motions could be studied using our system. The data acquisition rate employed in all experimental runs was 1000 points/sec. This gave 526 data points per cycle, which is a suitable number for obtaining the needle forces details without loss of important data points.

Experimental Designs

Two full factorial experimental designs were performed for this research and referred to as Design I and II throughout the paper. The objective of these designs is to develop predictive models relating fabric resistance to needle penetration to fabric and needle parameters. Design I is 4 × 4 × 3 and Design II is 4 × 3 × 2.

Design I was structured to study the effect of needle gap, fabric orientation angle, and fabric cover factor on the resistance of fabrics to needle penetration (Table 2). The needle gap of zero value is a standard medical needle. In this design two fabric layers were used. The top fabric orientation was kept constant so that the warp yarns of the fabric were parallel to the machine direction and the bottom fabric was cut at an orientation specified by the angle given in Table 2. The bottom fabric orientation angle is defined here as the angle between the warp direction of the bottom fabric and

Table 2. Levels of the independent parameters of design I

Parameters	Levels
Needle gap (mm)	0, 0.1778, 0.2286, 0.2794
Fabric angle (degrees)	0, 15, 30, 45
Cover factor (%)	51.8, 64.6, 75.4

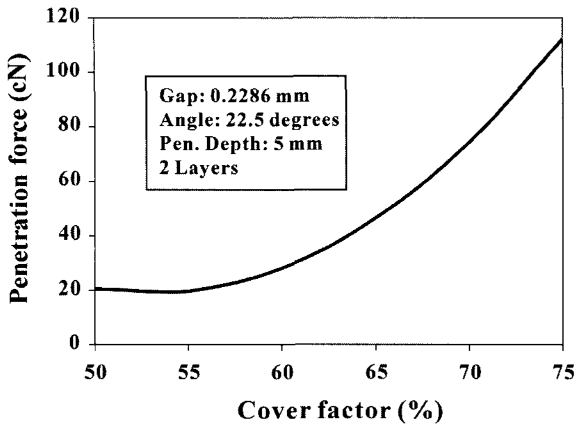

Figure 2. Fabric cover factor influence on needle force (Design I).

Table 3. Levels of the independent parameters of design II

Parameters	Levels
Needle gap (mm)	0, 0.1778, 0.2286, 0.2794
Cover factor (%)	51.8, 64.6, 75.4
Number of fabric layers	1, 2

the machine direction. The needle was fixed in the force transducer at constant orientation with the gap facing forward. All runs of Design I were conducted with constant needle penetration depth (defined in Figure 2 of reference [1]) of 5 millimeters.

Experimental Design I needed a total of 48 trials (4 x 4 x 3). For each trial two fabric samples were used. Each strip of fabric was punched 20 times at three different locations along the strip length. This gave 288 data sets (48 trials x 3 samples x 2 replications) of 20 penetration cycles each.

Design II was structured to study the effect of needle gap, fabric cover factor, and number of fabric layers on the resistance of fabrics to needle penetration (Table 3). When using two fabric layers a constant orientation angle of zero value was used. Again the needle penetration depth was kept constant at 5 millimeters for all runs of Design 2 and the needle was fixed at constant orientation with the gap facing forward. Experimental Design II needed a total of 24 trials with a total of 144 data sets (24 trials x 3 samples x 2 replications) of 20 penetration cycles each.

Additional limited trials were conducted to reveal the effect of needle penetration depth on fabric resistance to needle penetration since skin and flesh thickness vary from one person to another. The additional trials were conducted at 10 millimeters needle penetration depth.

Signal Analysis

The dependent parameter for Designs I and II is the needle peak penetration force, which is the maximum force that the needle experiences during needle penetration in each cycle. This force represents the protection provided by the fabric against needle-sticks. The signal analysis technique developed by Seyam *et al.*[5] for detecting needle forces during formation of needlepunched nonwovens was implemented in this study. The technique comprises of several steps to obtain the net forces experienced by the needle during its penetration through the fabric as a result of fabric/needle contact. The first step is to capture the raw data of the forces in time domain by the data acquisition system, then filter the data from circuit noise, force device parts noise (vibration), and needle noise (vibration) using Fast Fourier Transformation (FFT) and a suitable filter. The final step is to subtract the inertia forces caused by needle mass. The final step was not necessary in this case due to the insignificance of inertia forces because the needle mass and the needle loom speed are extremely small. Figure 1 shows an example of the net forces experienced by a bifid needle as a result of needle/fabric interaction. It can be seen that the needle experienced no forces until needle penetration through the fabric took place during descending of the needle board (Figure 2 of reference [1]). The needle force then increased at a high rate until reached maximum value after which the force is reduced rapidly due to needle withdrawal from the fabric as the needle board moves upward.

Statistical Analysis

General linear model (GLM) was used to obtain regression equations for Designs I and II. Main effects, all possible interactions, and quadratic terms were considered. Statistical Analysis System (SAS) software was used.

Results and Discussion

Design I

The GLM procedure revealed the following regression equation:

$$\begin{aligned}NPF = &-28.529249 + 1.008039(CF) - 0.009158(CF^2)\\&- 9.183086(BVSG) + 323.969093(NG)\\&- 586.928448(NG^2) + 0.333958(CF*BVSG)\\&- 11.591753(CF*NG) + 21.071646(CF*NG^2)\\&- 0.003155(CF^2*BVSG) + 0.107302(CF^2*NG)\\&- 0.196515(CF^2*NG^2)\end{aligned}$$

Where

NPF = Needle Penetration Force, N

CF = Fabric Cover Factor, %

NG = Needle Gap Width, mm

BVSG is a parameter represents needle type. It was set at −3 for standard needle and 1 for bifid needles.

Overall, this model explains a large proportion of the variability present in the observed data (since p = 0.0001, R^2 = 87.42 %). This R^2 value of 87.42 % indicates a good fitting of the observed values through the equation. Further, the model indicates that fabric cover and needle gap and their interaction have significant effect on needle penetration force while fabric orientation angle does not for the experimental range studied.

Observing the woven fabrics after each trial, we noticed that the standard needles penetrated directly through the fabrics. The standard needle caused holes through the fabrics by displacing the yarns in fabric plane. On the other hand bifid needles were entangled with the yarns/filaments and pushed them out of the fabrics plane. Thus the penetration force of a standard needle results from fiber to needle friction while the penetration forces of a bifid needle results mainly from pulling the yarns/filaments out of the fabric. In most cases standard needle force was higher than bifid needle force. This is not to say the standard needle provide better protection in these cases since this type of needle penetrates through the fabric.

Figures 2-4 are graphs of the results of Design I generated from the above regression equation. The effect of cover factor can be seen in Figure 2, which was generated using the average values of needle gap and fabric orientation angle. The data plotted in Figure 2 represent predicted averages over all needle gaps for the entire experimental range of cover factor. The increase in fabric resistance to needle penetration with cover factor is due to the increase in number of filament caught by the bifid needle as the cover increases since fabrics with high cover possess more filaments per unit fabric area. Figure 3 shows predicted averages over all cover factors for the entire experimental range of needle gap excluding the standard needle due to its penetration through the fabric as discussed above. Figure 3 shows that needle force increases with the needle gap until reaches a maximum value, after which the force tends to level off with further increase in needle gap. The increase in needle force with needle gap can be attributed to the increase of number of filaments caught by the needle as the needle gap increases.

The influence of needle gap and cover factor interaction on needle force can be assessed by observing Figure 4. The figure shows the predicted effect of varying cover factor and bifid needle gap on needle penetration when the two layers of fabric are angled at 22.5 °. The significant interaction of CF and NG implies that the differences among responses to cover factor vary with each level of needle gap and vice versa. In Figure 4, it is clearly shown that the least effective needle, in the prevention of needle-stick injuries, is the needle with the smallest gap. It is quite obvious that needle gap and cover factor are dependent on each other. The relationship describing the interaction of needle gap and cover factor for all bifid needles is of an upward quadratic form. At low cover factor, the needle force is only slightly affected by the needle gap. This is attributed to the small number of filaments that are caught by the needle, regardless of the needle gap width, when the fabric has low cover factor.

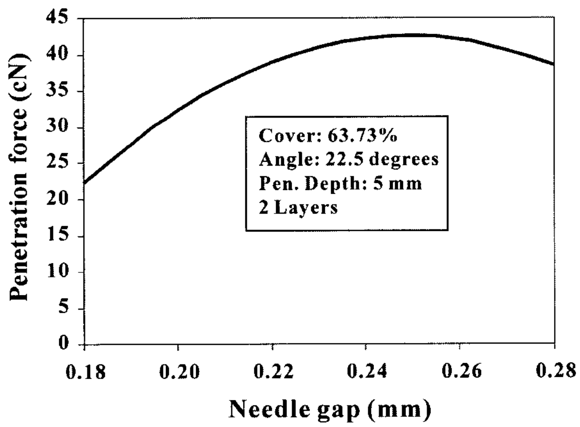

Figure 3. Needle gap influence on needle force (Design I).

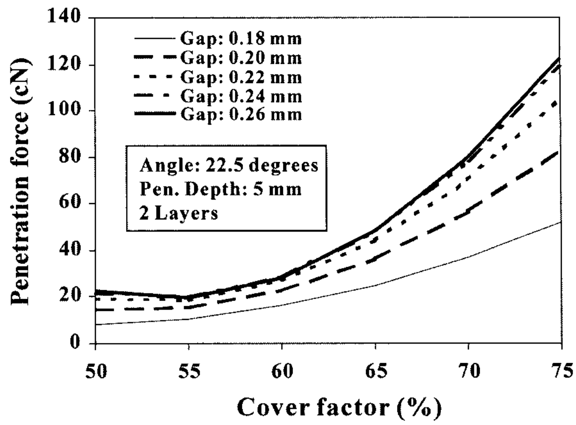

Figure 4. Influence of cover factor and needle gap interaction on needle force (Design I).

Design II

The GLM procedure revealed the following regression equation:

$$\begin{aligned} NPF = & -5.645626 + 0.187259(CF - 0.00184(CF^2) \\ & + 0.425013(BVSG) - 42.655668(NG) \\ & + 193.579346(NG^2) + 5.96543(FL) \\ & - 0.013013(CF*BVSG) + 1.52712(CF*NG) \\ & - 6.826262(CF*NG^2) - 0.000032402(CF^2*BVSG) \\ & - 0.009542(CF^2*NG) + 0.051425(CF^2*NG^2) \\ & - 0.207075(CF*FL) + 0.001788(CF^2*FL) \end{aligned}$$

Where

NPF = Needle Penetration Force, N

CF = Fabric Cover Factor, %

NG = Needle Gap Width, mm

FL = Number of Fabric Layers

BVSG is a parameter represents needle type. It was set at −3 for standard needle and 1 for bifid needles.

This regression equation is a good fitting (since R^2 =

93.59 % with p=0.0001) of the observed value. The model indicates that fabric cover, needle gap, and number of fabric layers have significant effect on needle penetration force. Additionally, there is significant interaction between cover factor and number of fabric layers and between cover factor and needle gap.

The influence of cover factor on needle force in Design II is similar to Design I as it can be seen from Figure 5. The data of Figure 5 also indicates the effect of the interaction between cover factor and number of layers. At lower value of cover factor, the effect of number of layers is insignificant while this is reversed at high levels of fabric cover. It is expected that with two layers, needle force would increase significantly at any needle gap value. This significant increase is observed in the higher levels of cover but not seen at lower extreme where there are very small differences between the one and two layer results. The data of Figure 5 suggests the use of two layers of fabric with high cover factors to cause a high number of fibers to entangle with the bifid needle and thus provide high degree of protection from needle-sticks.

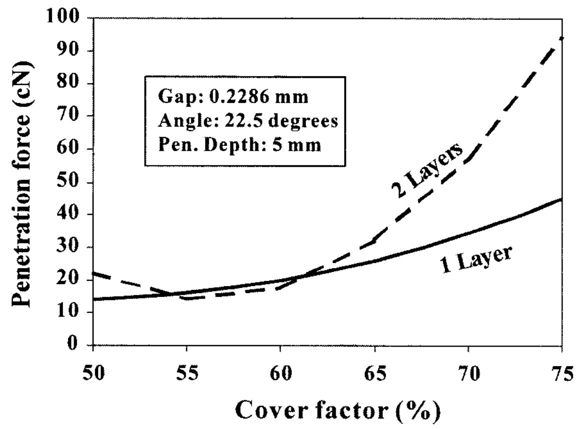

Figure 5. Effect of fabric cover factor and number of fabric layers on needle force (Design II).

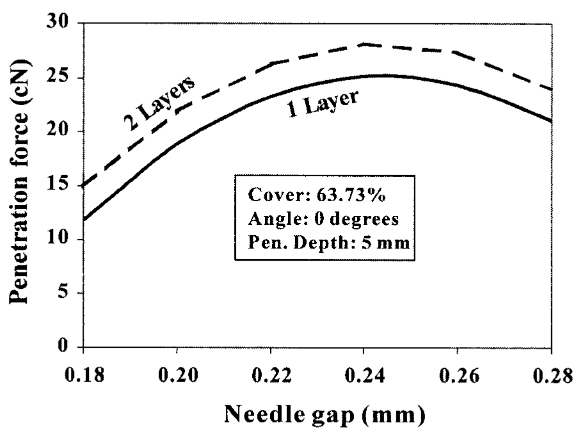

Figure 6. Effect of needle gap and number of fabric layers on needle force (Design II).

Figure 6 shows the effect of number of layers at different needle gaps. The effect of needle gap on needle force in Design II is obviously similar to Design I. Increasing the number of layers causes the needle force to increase due to the increase in number of fibers caught by the needle as it penetrates through the fabrics.

Figure 7 shows that cover factor and needle gap are dependent on one another. On the average as needle gap and cover factor increase, fabric resistance to needle penetration (or needle force) increases. The results are similar to those of Design I, which confirms the findings.

Influence of Needle Penetration Depth

Knowing that the standard and bifid needles are totally different designs, they were observed and evaluated as such. The synthetic variable, BVSG, differentiates between the two needle designs and confirms the difference through behavior. Logically, the 0.2794 mm bifid needle would catch more filaments producing a higher needle force, but at the

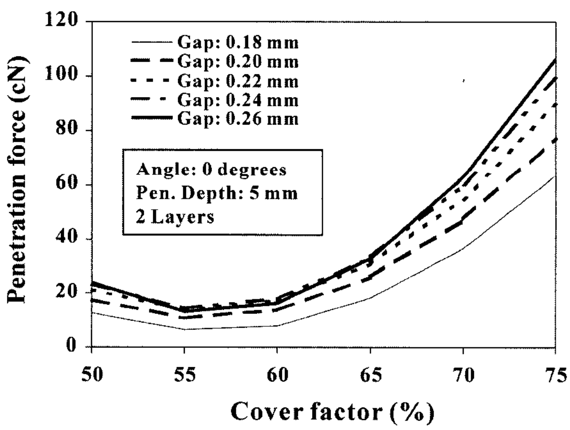

Figure 7. Influence of cover factor and needle gap interaction on needle force (Design II).

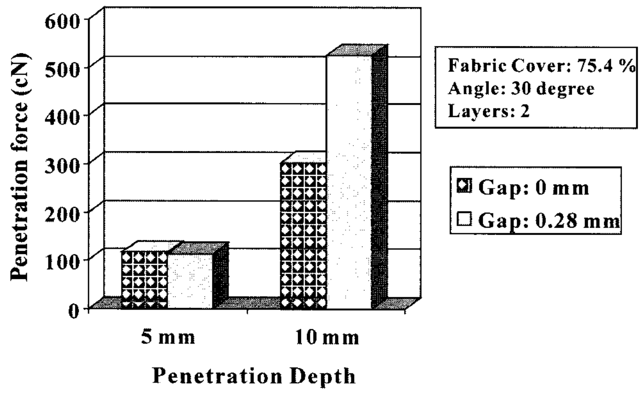

Figure 8. Effect of needle penetration depth on needle penetration force.

penetration depth used in these designs I and II (5 mm), the standard needle, on average, had a higher needle force than any bifid needle. This prompted us to carry out a limited number of trials with needle penetration depth of 10 mm to check whether a bifid needle would penetrate the fabrics by cutting through yarns/filaments.

Figure 8 shows the influence of needle penetration depth of bifid needle and standard needle on the fabric resistance to needle penetration. It should be noted that the values of needle force shown in Figure 8 are the observed (experimental) values. At 5 mm depth, standard needle force is slightly higher than bifid needle. At 10 mm depth, however, bifid needle force is much higher than the standard needle. Moreover, observation of the tested fabrics showed that the standard needle penetrated through the fabric at both penetration depths. The bifid needle entangled with the yarns/filaments of the fabrics without penetration through and there was no yarn/filament breakage at either level of penetration depths. The reason behind the increase in standard needle force with needle depth is the increase of the contact length of the needle and fabrics with increase in needle depth. Increase in contact length causes increase in friction force. The increase in bifid needle force with the penetration depth can be explained by: (1) Increase in number of filaments caught from the bottom fabric, (2) Pulling out the yarns/filaments from the fabrics further distance causes high inter yarn/inter fiber friction, and (3) After removing yarn crimp due to weave, the yarns/filaments are stretched (strained) thus developing resisting force depending on the yarns tensile behavior. While these limited trials show the effect of needle penetration depth, more elaborate statistical design (similar to Designs I and II) considering the needle penetration depth, as independent parameter would reveal its effect and possible interactions with the other independent parameters studied in this research.

Conclusions

In an effort to improve safety for medical professionals, the authors have measured the resistance forces of woven fabrics during penetration of a new bifid needle and compared it to a standard needle. The research was designed to answer the question "will the use of bifid needles combined with suitably designed protective textile articles reduce the occurrence of needle-sticks for medical professionals?" To properly answer this question the gap width in the bifid needle and fabrics with different cover factors, fabric orientation angles, and number of fabric layers were considered.

Results show that standard and bifid needles do behave differently when coming in contact with protective fabrics. It was statistically shown that fabric orientation angle did not have a significant effect on penetration force at penetration depth of 5 mm. Fabric orientation angle, however, may have significant effect on needle force at needle penetration depth of values higher than 5 mm, an issue that needs to be addressed with additional research. It was also shown statistically that fabric cover factor, needle gap width, and number of layers were significant factors in determining needle penetration force. Needle force was shown to increase as cover factor, needle gap width, and number of layers increased. The developed statistical models suggest that two fabric layers with high cover factor combined with use of bifid needle of gap of 0.28 mm will provide an excellent protection against needle-stick injuries.

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