

MEASUREMENT OF NEEDLE PUNCTURE RESISTANCE USING AN ELECTRONIC PUNCTURE DETECTION SYSTEM

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ABSTRACT

Standard puncture test methods fulfill a key role in assisting workers with the selection of equipment to protect against occupational needle injuries. Existing test methods assign a puncture resistance based on the maximum force recorded as a needle is lowered through the specimen at a fixed rate. However, a portion of the needle may defeat the material and place a wearer at risk of injury well before this maximum force is reached. Puncture tests were performed on neoprene rubber and woven Kevlar® using a new conductive, carbon-fiber filled, silicone rubber backing with electronic detection of the point at which the needle first penetrates the specimen. The tests were performed using 21 and 25 gauge hypodermic needles as the puncture probes. Puncture tests were also repeated with the specimens mounted in a holder with no backing material, as in the current standard test method. There was no significant difference in the measured puncture resistance of the neoprene sheets between the two configurations. The puncture resistance of woven Kevlar® as measured with the electronic detection method is only 23-32% of the puncture resistance determined based on the maximum force in the unbacked test. The results indicate that the puncture resistance measured by existing standard test methods may significantly overestimate the protection from needle injury that a consumer can expect, particularly for textile-based protective materials. The variety of materials used in personal protective equipment and the complexity of needle-specimen interactions leads to force-displacement curves with widely varying shapes, some with multiple peaks. Puncture test methods should use positive detection of the puncture point in order to provide a reliable estimate of the level of puncture protection offered by a material.

1. INTRODUCTION

Sharps injuries are a threat to workers in a number of industries, including healthcare, law enforcement and waste handling. Percutaneous injuries caused by blood-contaminated needles place the worker at risk of contracting bloodborne diseases such as HIV or hepatitis. Protective gloves and garments can mitigate some of the risk of injury and disease transmission from contaminated sharps. A medical worker must weigh factors such as performance, cost and comfort in order to select appropriate personal protective equipment (PPE) to protect against the sharps hazards that are present in the workplace. While comfort and cost factors are relatively easy for the consumer to evaluate, it is more difficult for the end user to determine whether an article of PPE provides sufficient puncture protection for their needs. Standard test methods provide well-defined test protocols and performance comparisons that manufacturers can use to aid users in the selection of PPE. From a consumer's perspective, it is important that these test results correlate with the "real world" protection offered by such products.

ASTM F-1342 and EN 388 are two test methods used to evaluate PPE resistance to puncture (ASTM F-1342, 2005; EN 388, 2003). Both methods use a load frame to record the maximum force acting to resist a round-point probe as it is lowered through the test specimen. However, the results of these tests are generally not representative of needle puncture. The probes used in these tests lack the sharp point and cutting edge of a hypodermic needle and the results do not correlate with needle resistance (Jackson et al., 1998). The text of the EN 388 standard clearly states: “Gloves meeting the requirements for resistance to puncture may not be suitable for protection against sharply pointed objects such as hypodermic needles”. The need for an improved method for measuring the true level of needle protection to aid in the selection of appropriate PPE has been noted by multiple authors (Jackson et al., 1998; Dolez et al., 2008). ASTM F-2878 Standard Test Method for Protective Clothing Material Resistance to Hypodermic Needle Puncture was recently published to address the need for a standard method to evaluate the needle resistance of PPE (ASTM F-2878, 2010). The F-2878 method is similar to F-1342, except with the round-point probe replaced by a 21-, 25- or 28-gauge hypodermic needle. The use of actual needles as the puncture probes improves the evaluation of the level of needle puncture protection as compared to the rounded probe tests. While the test does not capture puncture by all of the different sharps that cause injuries, hypodermic needles are involved in a majority of sharps injuries hospital-wide (Jagger and Balon, 1995).

Surgical and examination gloves made from latex and synthetic rubbers are ubiquitous in occupations where exposures to blood and bodily fluids are expected. Although primarily intended to serve as a barrier against such fluids, these rubber gloves are typically the only puncture protection that a medical worker has. Rubber gloves typically offer very little resistance to needle puncture, but techniques such as double gloving do provide some extra protection against needle injury or blood exposure (Edlich et al., 2003). Understanding the puncture properties of surgical and examination gloves therefore has a high degree of clinical relevance. The puncture mechanism of rubber has been modeled and understood using fracture mechanics (Nguyen et al., 2003; Nguyen et al., 2009a; Nguyen et al., 2009b). The monolithic nature of rubbers typically leads to reproducible puncture measurements and makes them appropriate choices as calibration materials for puncture tests (ASTM F-2878). While the needle puncture testing of rubbers has value due to the above noted clinical relevance and reproducibility, it is important that a standard test method is robust enough to evaluate all types of materials that may be used to construct the PPE.

Densely woven textiles consisting of performance fibers such as Kevlar®, Spectra® and Vectran® have been developed to provide protection from a range of puncture threats. Examples include the range of Turtleskin® needle-resistant products from Warwick Mills (Turtleskin Safety Brochure 2011) and finger guards incorporating Spectra® (Leslie et al., 1996). Correctional Kevlar®, which is intended to stop improvised sharp weapons, has been shown to exhibit some resistance to needle puncture and is further enhanced by the addition of shear-thickening fluids to the textile (Houghton et al., 2007). To defeat the protective textile either the sharp edge of the needle cuts fibers or the pointed tip forces fibers apart in a process termed windowing. The needle and textile geometries are exceedingly important since a large needle will be forced to cut or displace yarns to penetrate, whereas a finer threat may be able to slip between yarns with little or no resistance (Decker et al., 2007). This complexity of probe-textile interaction during a puncture test introduces potential pitfalls in the interpretation of test results.

The standard methods use the maximum force during a test as an indication of puncture resistance. While having the advantage of being easy to determine from a force-displacement curve, the maximum force does not necessarily correspond to a clinically relevant level of protection against needle injury. Previous studies have indicated that the maximum force during the puncture of woven Kevlar® does not occur until well after the needle tip has breached the back plane of the textile (Termonia, 2000; Houghton et al., 2007). Thus, the protective barrier properties of PPE with textiles may be compromised well before the maximum force is achieved. Wearers of the PPE may have cuts or abrasions on their hands that could facilitate disease transmission as soon as the contaminated needle contacts the hand. Any additional needle displacement beyond this initial skin contact will quickly lead to penetration of the skin. Consequently, the puncture resistance currently assigned to the material based on the maximum force criterion would clinically correspond to a point at which the needle has been driven well into the wearer's skin. In limited cases, such as the puncture testing of some rubbers, the maximum force does correspond to initial barrier breach (Dolez et al., 2008). Factors affecting the relationship between the force at barrier breach and the maximum force include the needle size, needle sharpness, specimen thickness, specimen structure (e.g. monolithic, woven, knit, etc.) and specimen fracture energy.

In this paper we investigate a new method for measuring the true needle puncture resistance of rubber and textile materials. A test method incorporating electronic detection of the point at which the needle breaches the material is used to evaluate the puncture protection offered by an article of PPE. Similar electrical methods have been used to detect the point at which a metal probe breaches a geotextile membrane (Puhlinger, 1990) or when a blade defeats an article of PPE in cut-resistance testing (ASTM F-1790, 2005). Typically, a conductive foil is placed on the backside of the specimen and a lead is connected to the foil and to the metal puncture probe. When the probe breaches the material the circuit is completed and an electronic signal gives clear indication of the puncture point. In this study, the relationship between the puncture force from standard methods and the electronically detected puncture force is analyzed and results are interpreted in the context of previously published puncture mechanisms for rubbers and textiles.

2. EXPERIMENTATION

2.1 Puncture Testing Apparatus

Puncture testing was performed on an Instron 5565 load testing frame using a 100N load cell and controlled with Bluehill 2 software. A probe displacement rate of 10 mm/min was used. The sample holder was made from two aluminum plates, each having three, 6.4 mm puncture guide holes as specified for the Probe A configuration in ASTM F-1342-05. Test samples were securely clamped between the plates and attached to the machine interface plate. Since the specimen is free to deform in the direction of probe travel, this configuration will be referred to as the “unbacked” test configuration.

PrecisionGlide® 21 and 25 gauge hypodermic needles were used as puncture probes (Part Nos. 305167 & 305127, Becton-Dickinson, Franklin Lakes, NJ, USA). To avoid potential effects of needle blunting during the tests, a new needle was used for each puncture. Needles were securely mounted in a chuck attached to the load cell. The test was commenced by lowering the needle into the sample starting from a non-contact position approximately 2-3 mm above the

sample surface to eliminate the possibility of damaging the sample or needle tip during surface detection. The position of the sample surface was determined by analysis of the force-displacement curve and was defined as the point at which the force first exceeded and remained above 0.01 N. Twelve puncture tests were performed for each material/needle combination.

2.2 Electronic Puncture Detection

The electronic detection circuit was assembled in a 25-pin D-plug to interface with the Strain 1 channel of the load frame. In the puncture experiments using electronic detection, the bottom plate of the sample holder was replaced by a conductive elastomer. The test specimen was fixed between the top plate and conductive elastomer backing, which was then secured to the test frame using the same machine interface plate as used for the unbacked tests. One test lead from the D-plug was connected to the conductive elastomer backing and the second was connected to the needle. When the needle penetrated the specimen and touched the conductive backing the circuit was completed and there was a sharp increase in the electronic signal indicated by the Strain 1 channel.

The conductive elastomer backing material was prepared by filling a two-part poly(dimethyl siloxane) (PDMS) rubber kit (Sylgard® 184, Dow-Corning) with chopped carbon fibers (Fortafil 341, Toho-Tenax). The conductive PDMS was prepared by thoroughly mixing 30 weight % of carbon fibers into the base polymer of the PDMS kit. Once the fibers were thoroughly dispersed, the curing agent was mixed in a ratio of 1 part curing agent to 10 parts base, by mass. The carbon fiber/poly(dimethyl siloxane) (CF-PDMS) mixture was poured into a dish to yield a thickness of approximately 6 mm. Air bubbles were removed under vacuum at room temperature. The degassed, fiber-filled rubber was finally cured at 50° C for 3 hours. A digital multimeter was used to confirm that the surface and bulk of the filled elastomer were electrically conductive.

2.3 Test Specimen Materials

Neoprene rubber with a Shore hardness of 50A was obtained in 1.59 and 0.4 mm thick sheets from McMaster-Carr (Robbinsville, NJ). Style 779 woven Kevlar® (200 denier Kevlar 159, 70x70 yarns per inch, 132 g/m², 0.18 mm thickness) was obtained from JPS Composite Materials, Anderson, SC. All materials were tested both in the unbacked configuration and on top of the CF-PDMS with the electronic puncture detection circuit.

3. RESULTS

3.1 Puncture of Rubbers and Textiles in Unbacked Configuration

Example force displacement curves from the unbacked puncture of the 1.59 mm neoprene by a 21G (gauge) needle are shown in Figure 1 (a). The curves have a highly reproducible triangular shape with a single maximum, followed by a gradual decrease in force. The decreasing portion of the curve exhibits two general regions – an initial convex portion up to shoulder at a probe displacement of about 4 mm followed by a second downward sloping region. The offset between the peak and the shoulder on the decreasing portion of the curve averages 1.5 mm, which is approximately equal to the 1.4 mm distance from the needle tip to the facet transition.

The maximum force is attributed to the initial penetration of the needle tip through the back of the sample and the shoulder corresponds to the widest portion of the needle cutting edge penetrating the back plane of the sample. Testing with the 25G needles produced similar triangle-shaped puncture curves with a single maximum (Figure 1 (b)).

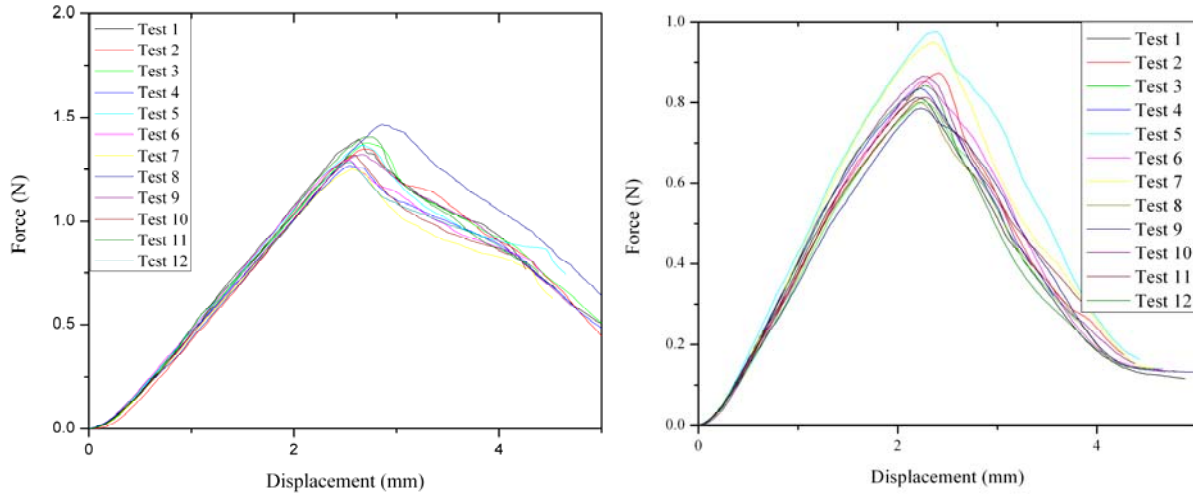


Figure 1. Examples of puncture curves of 1.59 mm thick neoprene (a) 21G needle (b) 25G needle.

The 1.59 mm rubber is significantly thicker than medical gloves, which are typically only 0.22 to 0.55 mm thick (Makela et al., 2003; Bricout et al., 2003). The puncture testing was repeated on 0.4 mm thick neoprene rubber to investigate the effects of sample thickness in the unbacked configuration. Example force-displacement curves for the puncture of the 0.4 mm rubber with each needle are shown in Figure 2. Unlike the smooth, triangular curves obtained for the thicker rubber, the curves for the 0.4 mm rubber typically exhibited two distinct peaks. In some tests a third peak was observed in the decreasing portion of the curve. These curves are characterized by the peak force and corresponding probe displacement if the first two peaks. The results of the puncture testing are summarized in Table 1.

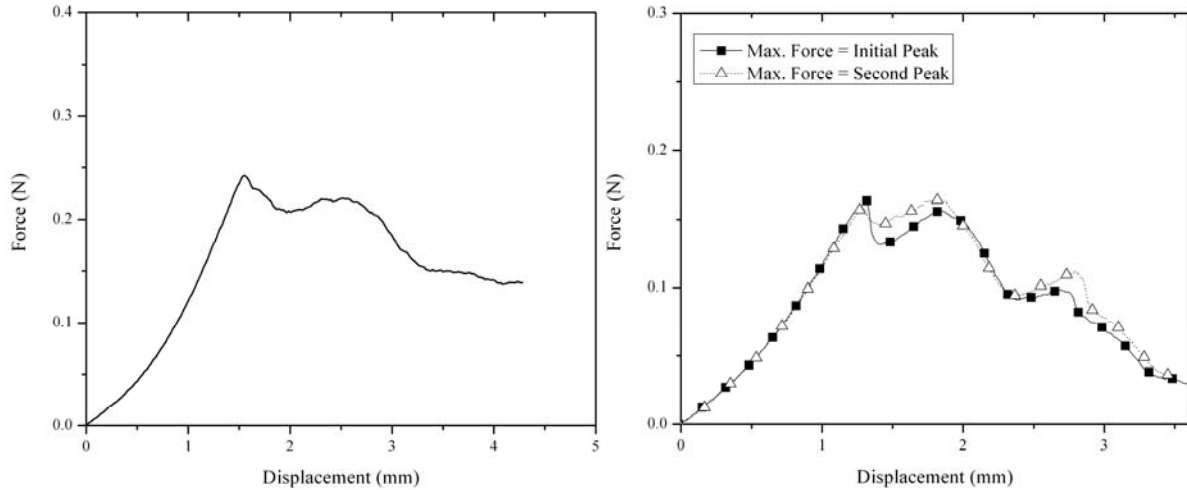


Figure 2. Example force-displacement curves from puncture testing of 0.4 mm thick neoprene with (a) 21G needle (b) 25G needle.

Table 1. Summary of puncture testing results for 0.4 mm thick neoprene

Puncture Probe	Peak 1		Peak 2		Pk. 2 Disp. – Pk. 1 Disp. (mm)	$w-h$ (mm)
	Force (N)	Probe Displacement (mm)	Force (N)	Probe Displacement (mm)		
21 G	0.26 +/- 0.03	1.59	0.23 +/- 0.02	2.57	0.98	0.97
25 G	0.18 +/- 0.03	1.45	0.17 +/- 0.01	1.93	0.48	0.51

Curves having the same general “initial peak – trough – second peak” shape as those shown in Figure 2 have been previously observed for the puncture of 3.2 mm thick neoprene sheets by medical needles (Dolez et al., 2008). The authors did test thinner rubbers, but indicated that the multi-peak curves were only observed for the thick samples. The puncture measurements on the 0.4 mm neoprene shown here indicate that the occurrence of multiple peaks is not limited to very thick specimens. The mechanism of puncture is illustrated in Figure 3. The first peak in the curve corresponds to the point at which the needle tip breaches the bottom plane of the specimen. The second peak is generated when the widest part of the needle cutting edge (the transition between facets) passes through the rubber. Based on this mechanism, one would expect that the difference in the positions of the two peaks would correspond to $w - h$, where h is the specimen thickness and w is the distance from needle tip to the facet transition. As shown in Table 1, the measured distance between peaks is almost exactly equal $w - h$ for both the 21 and 25 gauge needle tests. This mechanism suggests that as either the thickness of the specimen is increased or the needle

size is decreased the quantity $w - h$ will decrease and the two peaks will converge, consistent with the single peak observation in the tests on the 1.59 mm thick samples.

The mechanism illustrated above indicates that the maximum force criterion can provide a good estimate of puncture protection for *some* combinations of needle and specimen. Tests on needle-rubber combinations that produce multiple peaks with the second peak higher than the first will lead to overestimation of the clinically relevant puncture protection. Figure 2 (b) shows an example of a test in which the second peak exceeds the first. In one-sixth of the 21G needle tests and one-third of the 25G needle tests on the 0.4 mm neoprene, the second peak force exceeded the first peak force. However, for the particular case of the neoprene rubbers the error will not be very large since the magnitudes of the two peaks are approximately equal. We now turn to the puncture testing of textiles, where these peaks can occur at very different forces.

Examples of the force-displacement curves from the unbacked puncture tests on the 779 Kevlar® are shown in Figure 4. Unlike the highly consistent curve shapes obtained in rubber puncture tests, the Kevlar® tests produce a variety of curve shapes with multiple large and small peaks. The Kevlar® puncture curves typically have multiple peaks with some “sawtooth” oscillations in the increasing portion of the force curve, such as the small peak at about 0.5 mm on the solid curve in Figure 4 (a). The tests with the 21G needle had similar loading portions of the curve up to a displacement of about 1 mm, with differences in peak height at higher displacements. The 25G tests showed two general shapes of loading curves – 7 tests showed shallower loading similar to the solid curve in Figure 4 (b) and 5 showed a more rapid increase similar to the dashed curve. The measured peak force ranged from 1.18 to 2.11 N with the 21G needle and from 0.51 to 1.22 N with the 25G needle.

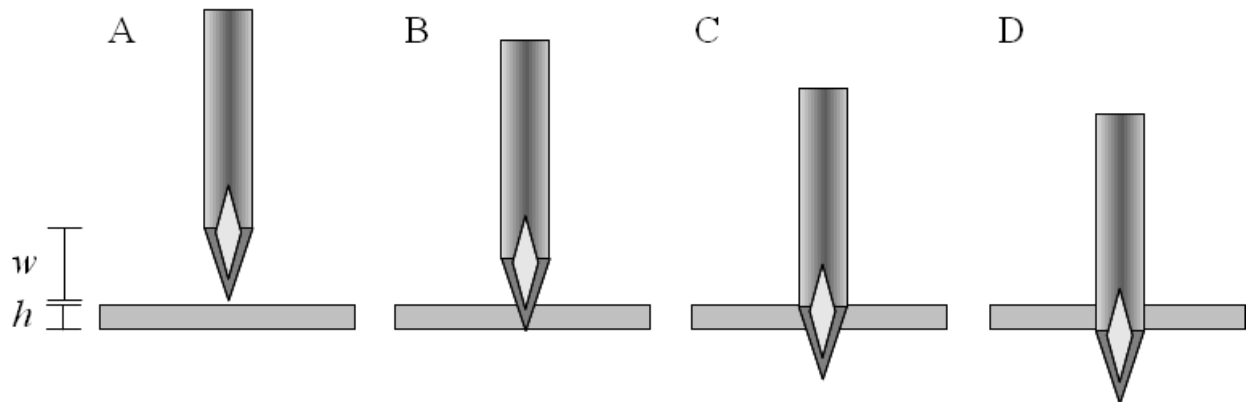


Figure 3. Illustration of the mechanism of a needle puncturing a thin rubber membrane that leads to the generation of multiple peaks. The tip initially penetrates the back plane of the rubber at point B, creating the first peak as the needle is displaced a distance h into the specimen. The needle continues to pass through the specimen until the widest part of the cutting portion of the needle (the facet transition) enters the specimen at point C, which also corresponds to the second peak. The force acting on the needle decreases between points C and D as the force acting on the needle gradually shifts from cutting of the specimen to friction on the needle barrel.

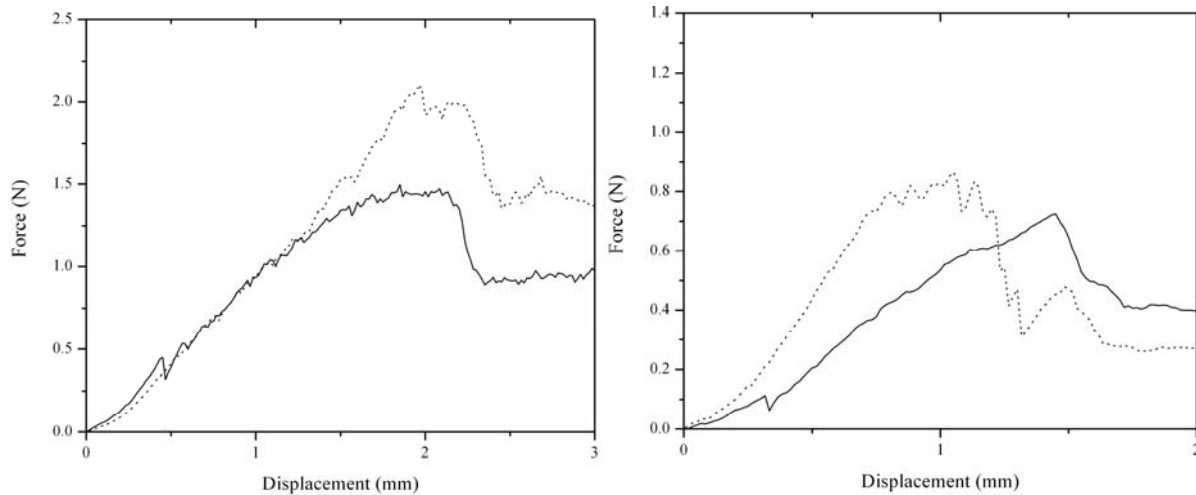


Figure 4. Force-displacement curves for the puncture of 779 Kevlar® by (a) 21G needle (b) 25G needle illustrating the typical curve shapes that were observed during testing

The increased variability in the Kevlar® puncture curves as compared to the rubber puncture curves stems from both the heterogeneity of the woven fabric on the scale of the needle diameter and the presence of multiple relaxation mechanisms during textile puncture. The puncture of a rubber material by a needle proceeds by a crack initiation and crack growth mechanism (Nguyen et al., 2009a). This mode of material failure leads to the smooth, generally triangular puncture curves that are typically observed for rubber. In contrast, the multiple peaks and features in the textile puncture curves correspond to the different textile puncture mechanisms. Stages of textile loading and puncture have been shown to include yarn tensioning, yarn slippage/rearrangement, pullout and yarn breakage (Sun et al., 2011). These mechanisms may be broadly classed as windowing (any movement of the yarns out of the path of the probe without yarn breakage) and cutting (or breakage). Real protective equipment often uses multiple layers of textiles and/or different materials in each layer, which can lead to even more complex puncture curves as the needle sequentially defeats the topmost layers and loads subsequent layers (Termonia, 2000; Houghton et al., 2007). In addition to the multiple failure modes, variability also arises from the non-uniform surface of woven textiles such that the needle point may initially engage zero yarns (when the point hits an open space in the weave), one yarn or two yarns (when the point hits a yarn crossover). When the needle impacts inter-yarn space the dominant puncture mechanism is windowing and the maximum force typically corresponds to the widest portion of the needle passing through the textile (i.e., well after the tip has penetrated). For the case of direct needle-yarn impact, cutting or yarn breakage becomes the dominant failure mechanism. When these more catastrophic failure modes dominate, it is more likely that the maximum force will correspond to initial tip puncture. Although these discretized cases are illustrative, real puncture testing will sample a continuous range of needle textile interactions ranging from direct yarn impacts to “glancing blows”, leading to a distribution of force-displacement curve shapes. The complexity and distribution of curve shapes make it difficult or impossible to definitively identify the point at which the needle breaches the back of the textile from the force-displacement curve without additional evidence. We now consider the electronic puncture detection method to eliminate the uncertainty in determining the initial puncture point.

3.2 Puncture of Rubbers and Textiles with Electronic Puncture Detection

Testing of the neoprene rubbers was repeated with the CF-PDMS backing and puncture detection circuit connected as described in the Materials and Methods section. Figure 5 shows a typical result of a puncture test on the 1.59 mm neoprene using the 21G needle with the force and electronic detection signals plotted simultaneously. The force increases smoothly up to an inflection point at approximately 1 mm of probe displacement. The force signal continues to increase and is accompanied by increasing noise as the wider portion of the needle cuts through the specimen. The point at which the needle tip penetrates the back plane of the specimen is clearly indicated by the sharp spike in signal from the puncture detection circuit at 2 mm of probe displacement. Although the force curve does have small features and increased noise when the needle penetrates the specimen, the electronic detection signal is essential for conclusive determination of the puncture point.

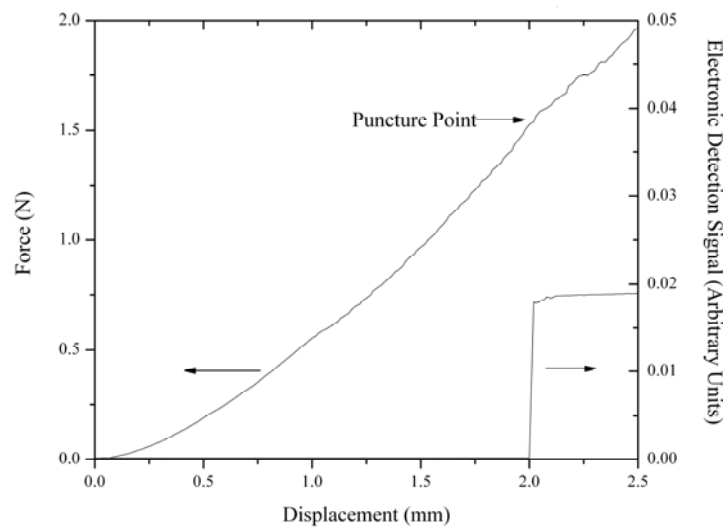


Figure 5. Sample puncture test on 1.59 mm neoprene using a 21G needle with the CF-PDMS and electronic detection circuit.

Twelve puncture tests were performed using the CF-PDMS backing for each of the four needle/rubber combinations. Figure 6 compares the average puncture forces from the tests on the CF-PDMS backing (determined from the electronic detection circuit) with the previous results of the peak puncture force (Figure 1 and 2) for the unbacked tests. The average puncture force for the 1.59 mm thick neoprene was slightly higher for the CF-PDMS backed test, but the difference is within the experimental variability. There is no significant difference in the measured puncture force of the 0.4 mm thick neoprene rubber between the different test configurations.

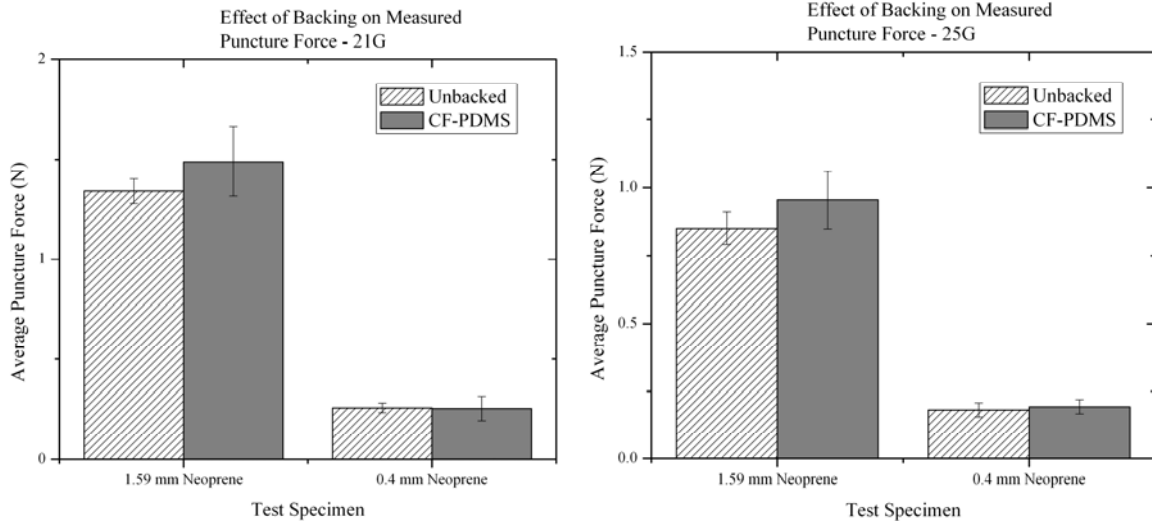


Figure 6. Comparisons of the average puncture force for neoprene rubbers in the different test configurations (a) 21G needle (b) 25G needle.

Figure 7 shows a typical force-displacement curve for the 779 Kevlar® on top of the CF-PDMS, with the unbacked result from Figure 4 (a) shown as comparison. The initial loading portion of the test is nearly identical for both configurations up to a needle displacement of approximately 0.4 mm. In the CF-PDMS backed test, puncture is electronically detected at the point indicated by the arrow in Figure 7. There is also a small feature on the curve at the indicated puncture point, but the presence of the backing prevents a sharp drop in force as observed in the unbacked test. Note that the electronically detected puncture point occurs at almost exactly the same force and displacement as the first small peak in the unbacked test. This is consistent with the mechanism of textile puncture proposed by Termonia and Houghton et al. that suggested that this initial peak corresponds to the first breach of the textile by the needle tip.

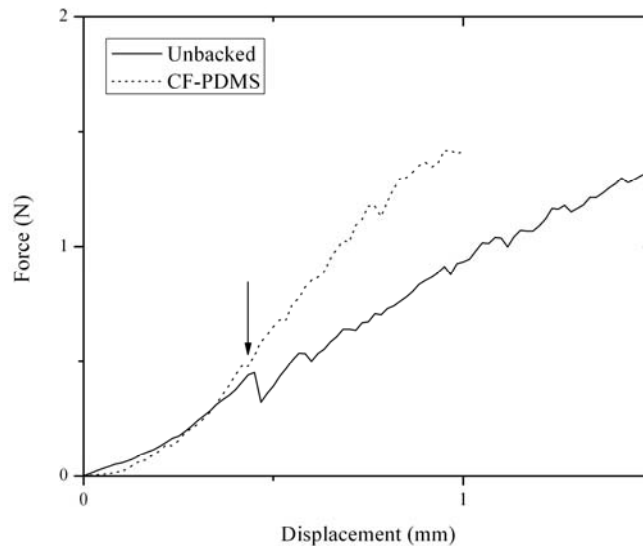


Figure 7. Comparison of the force-displacement curves from puncture testing of 779 Kevlar® with a 21G needle in the two experimental configurations. The arrow shows the point at which the electronic detection circuit indicated puncture in the CF-PDMS test.

Figure 8 summarizes the results for the Kevlar® maximum puncture force from the unbacked tests and the electronically detected puncture force on the CF-PDMS backing. Unlike the rubber puncture testing, the puncture force and displacement for the Kevlar® were significantly lower in the CF-PDMS backed test. The force to puncture the Kevlar® as determined using the electronic detection method was only 23 and 32% of the peak force measured in the unbacked test for the 21 and 25 G needles, respectively. The displacement at the puncture point is also reduced in the CF-PDMS backed test configuration. Based on the test results and the understanding of the puncture mechanism, we can conclude that the unbacked test is measuring an increasing force well after the needle has already defeated the sample. Puncture detection is an integral part of textile puncture testing and these results demonstrate that puncture protection cannot be determined using methods that solely rely on a force-displacement curve.

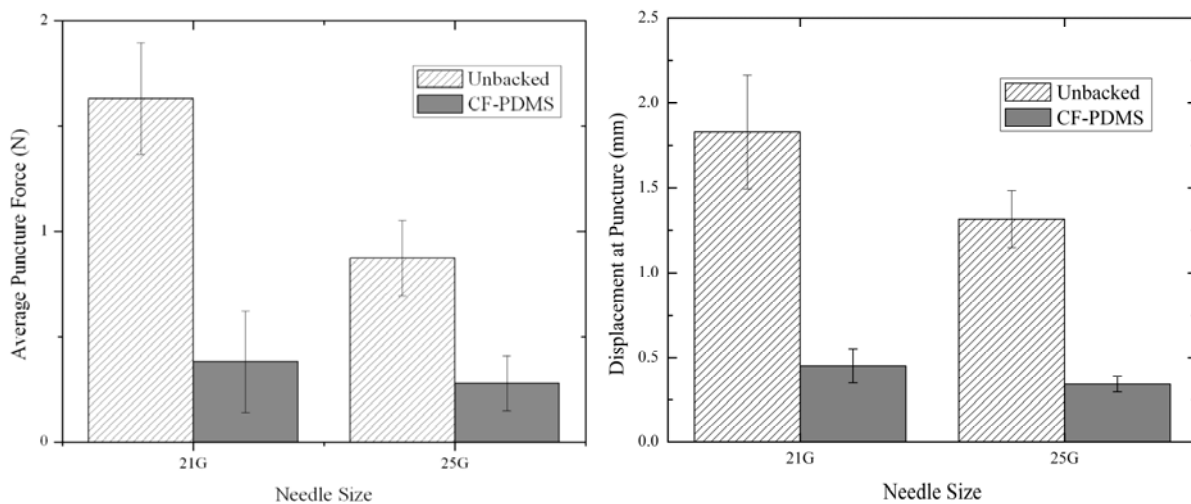


Figure 8. Effect of test configuration on the measured puncture (a) force and (b) displacement for 779 Kevlar®.

4. CONCLUSIONS

Standard test methods used to evaluate the puncture resistance of different PPE products should provide an estimate of the realistic protection from injury that a wearer could expect. Due to the variety of PPE materials that are used when needle hazards are present, the test method must be robust enough to evaluate the puncture protection offered by different materials on a consistent basis. The test results shown here indicate that although the maximum force achieved in an unbacked test does provide a reasonable estimate of puncture protection for some rubber materials, particularly those in which the thickness of the specimen is on the order of the characteristic dimension of the needle cutting edge, the sensitivity of the puncture curve shapes to a number of experimental parameters means that the results of unbacked puncture tests must be interpreted with caution.

The mechanisms of textile puncture by a medical needle are complex and the force-displacement curve alone does not provide enough information to reliably evaluate puncture protection offered by textiles. The electronic puncture detection method demonstrated here provides unequivocal indication of the point at which the needle would contact the wearer's body during puncture. The puncture testing of woven Kevlar® indicates that current unbacked test methods measure the

puncture resistance well beyond the point at which injury would occur. The observed discrepancies in the puncture resistance between the different methods are consistent with textile puncture methods that have previously been proposed in the literature. Unbacked tests may overestimate the puncture protection offered by textiles by up to a factor of 4 and may lead to unnecessary injuries due to the selection of PPE having insufficient protection against workplace hazards.

The CF-PDMS used as the backing material supports the test specimen in a manner similar to the body supporting the PPE during use. The current CF-PDMS has a higher modulus than the fleshy portions of the hand, arms and legs. The accuracy of the puncture test may be further improved by identifying or developing a conductive backing material with compressive properties that are closer to the properties of the human body.

5. ACKNOWLEDGEMENTS

This study was supported by funding from Mölnlycke Health Care AB, Göteborg, Sweden.

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