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Greater Sensitivity of Detecting Glove Defects Using Soap Solution and the Role of Non-rubber Constituents in Needle Puncture Tear

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The higher percentage of failure in the palm region of commercial gloves than in the fingers was partly attributed to the sensitivity of the 1 litre water leak test rather than merely to the higher number of defects in the palm. Incorporating 0.1% sodium dodecyl sulphate, Teepol®, Triton X-100® or Tween-80® in water increased the sensitivity of detecting finger defects. The smallest leak detectable by the 1 litre soap leak test was equivalent to 2 µL virus ΦX174 penetration.

Needle punctured NR gloves exposed to cyclic stress offered a better protection than vinyl and nitrile gloves under similar conditions. The non-rubber constituents present in NR gloves were shown to have some effect on the amount of virus penetrating through the punctured tear.

Key words: NR gloves; penetration; soap solution; non-rubber; needle puncture; tear; sensitivity; defects; vinyl; nitrile; virus ΦX174

Currently *ASTM D5151*[1] is the standard method to evaluate the barrier integrity of latex gloves. The test involves filling the glove with 1 litre of water and examining the leak after 2 min. Any appearance of water on the outside of the glove is considered a leak and the glove fails. The test, however, fails to detect smaller defects in the fingers than in the palm: an evaluation[2] on laser-made holes in surgeon's gloves showed that the test could reliably detect palm holes >20 µm and finger holes of >40 µm. This poses a disadvantage to the test as fingers are the parts of gloves frequently exposed to body fluid when the gloves are used in clinical procedures. A more sensitive method of detecting smaller holes in the fingers is essential for greater protection against transmission of infectious micro-organisms.

Needle puncture is known to be one of the major causes of glove perforation in surgery and obstetrics. Punctured NR gloves have been demonstrated[3] to possess superior barrier integrity than vinyl and nitrile gloves. For the same needle puncture, NR leaked significantly lower virus suspension than the latter two gloves. This has largely been attributed to the 're-sealing' ability of NR gloves[4] which could be partly contributed by the non-rubber constituents such as proteins and lipids. So far no attempt has been made to elucidate the latter effect.

The present paper evaluates the incorporation of soap/surfactant into the 1 litre water leak test (WLT) to increase the sensitivity of detecting failures in the glove fingers and to relate the amount of ΦX174 virus penetrating

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through puncture tear with the level of non-rubber constituents present.

MATERIALS AND METHODS

Gloves and Films Containing Different Levels of Non-rubber Constituents

The gloves tested were of commercially available examination gloves from NR latex, vinyl and nitrile synthetic polymer.

Films containing different levels of non-rubber constituents were prepared from lattices described as purified rubber particle (RP), unpurified RP and high ammoniated (HA) latex concentrate in an earlier publication[5]. Cast films were from latex cast on glass plate and dried at room temperature while dipped films were from sulphur-vulcanised latex processed through the normal procedures of preparing commercial NR gloves[5].

Water/Soap Leak Test on Punctured Glove Fingers and Palm

The 1 litre WLT was carried out as specified in the *ASTM D 5151*[1]. A similar procedure was adopted for the 1 litre soap/surfactant leak test (SLT) except that 0.1% surfactant was added to the water. The surfactants tested were sodium dodecyl sulphate (SDS), Teepol®, Triton X-100® and Tween-80® obtained commercially.

A circle of 1 cm diameter was drawn in the middle part of the glove palm and 2 cm from the tip of the finger. Acupuncture needles (made in Suzhou, China) of diameters 0.22 mm to 0.4 mm and syringe needles (from Terumo, Belgium) of size 27 G (0.4 mm) and 26 G (0.45 mm) were used to puncture the middle of the circle from both sides of the gloves. The gloves were then filled with 1 litre water or soap solution and any visible leak within the punctured region after 2 min was recorded.

Virus Penetration Test

Challenge virus. The bacteriophage ΦX174 of diameter 27 nm was chosen as a surrogate for human pathogenic virus. The virus culture and bioassay utilising *Escherichia coli C* as the host were as previously reported[6]. For the experiment, the virus was suspended in a solution of 0.1% Tween-80® (v/v) in sterile deionised water.

Penetration of ΦX174 through punctured whole glove fingers. The test as described in an earlier publication[3] involved puncturing the glove fingers with acupuncture needles or syringe needles, filling the glove with 1 litre of virus suspension containing about 1×10^6 plaque forming unit (pfu)/mL and checking the extent of water leak after 2 min. The extent of the water leak was labeled as 0: no visible leak; 1+: small bead of water; 2+: large bead of water and 3+: trickle to free flowing of water. The virus leak was then collected with 5 mL of 0.1% Tween-80® and an aliquot of the collection fluid was assayed for virus ΦX174 infectivity.

Penetration of ΦX174 through punctured latex films: cyclic stressed and non-stressed. The cyclic stress test was carried out on an apparatus designed to simulate stresses that may occur during use. A piece of glove or latex film punctured with an acupuncture needle was subjected to 2000 cycles of 20% elongation for 33 min by cyclically inflating the specimen with compressed air.

The stressed sample was then placed over the open top of a 25 mm diameter glass tube, with the punctured tear in the middle. The sample was then fastened in place with a tight-fitting rubber band. Parafilm was wrapped

around the fastened area to prevent leaks from the sides of the latex piece. Twenty three mL of ΦX174 suspension of 1×10^6 pfu/mL in 0.1% Tween-80® was then placed in the tube. After 1 min the tube was checked for any leak outside the puncture region. The tube was suspended in 5 mL collection fluid of 0.1% Tween-80® for 12 min. An aliquot of the fluid was then assayed for virus infectivity.

RESULTS AND DISCUSSION

Location of Commercial Glove Defects by WLT

A survey on 29 commercial examination gloves failing the 1 litre WLT showed that 82.7% of the defects were from the palm region compared to a lower incidence of failure in the calf, web and fingers (*Figure 1*). Failure at the finger-tips was the least detectable. The results could not merely indicate high manufacturing defects in the palm but could also imply that the test was more sensitive to defects in the palm than in the other parts of the gloves. Under the weight of 1 litre water, the palm region expanded more than the other regions which could partly explain the observation[2] that the WLT could detect a smaller hole in the palm than in the fingers. In fact, when the fingers and palm were deliberately punctured with acupuncture syringe needles of diameters varying from 0.22 mm to 0.45 mm, the test could detect all the puncture tears in the palm but not in the fingers (*Table 1*). Only finger tears induced by needles of ≥0.4 mm diameter were detectable.

Comparison between the SLT and WLT

The sensitivity of detecting glove defects in fingers could be enhanced by using 0.1% soap. *Table 2* shows that 1 to 2 of the 13 forefingers punctured with a 0.22 mm needle could be detected by incorporating 0.1% of Tween-80®, Teepol®, SDS or Triton X-100® in the test solution whereas WLT could only detect fingers punctured with a needle of greater than

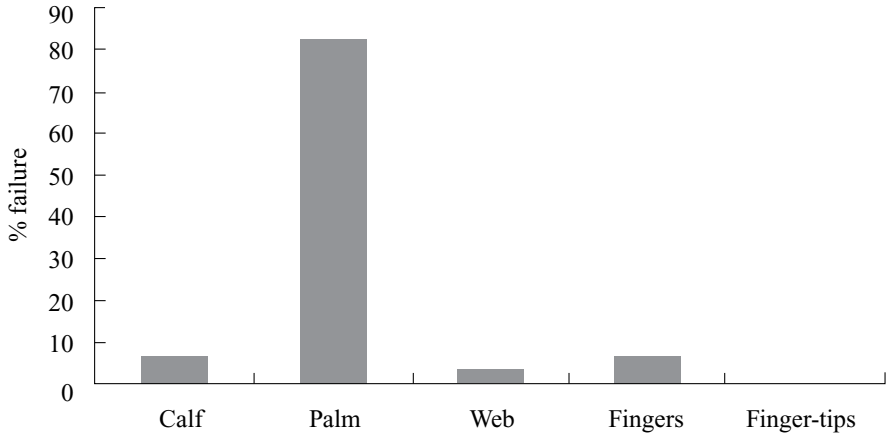

Figure 1. Percentage failure at different parts of the commercial examination gloves detected by 1 litre of water leak test.

TABLE1. DETECTION OF LEAK BY 1 LITRE OF WLT THROUGH GLOVE FINGERS AND PALM PUNCTURED BY NEEDLES OF DIFFERENT DIAMETERS

Glove parts	0.22 mm	0.25 mm	0.30 mm	0.35 mm	0.40 mm (27 G)	0.45 mm (26 G)
Thumb	–	–	–	–	–	–
2nd Finger	–	–	–	–	+	+
3rd Finger	–	–	–	–	+	+
4th Finger	–	–	–	–	+	+
5th Finger	–	–	–	–	–	+
Palm	+	+	+	+	+	+

– : Non-detectable water leak
+ : Detectable water leak.

TABLE 2. PERCENTAGE OF 13 FOREFINGERS PUNCTURED WITH NEEDLES OF DIFFERENT DIAMETERS THAT FAILED THE WLT AND SLT

Soap in 1 litre water	0.22 mm	0.25 mm	0.30 mm	0.35 mm	0.40 mm	27 G	26 G
None (WLT)	0	8	31	23	38	62	77
0.1% Tween-80®	8	38	77	100	100	100	100
0.1% Teepol®	8	23	85	100	100	100	100
0.1% SDS	15	23	100	100	100	100	100
0.1% Triton X-100®	8	15	62	100	100	100	100

0.25 mm diameter. The higher sensitivity of the SLT could also be seen by its ability to detect all fingers punctured with needles ≥0.35 mm diameter. In the case of SDS, all punctures caused by needles as small as 0.3 mm diameter could be detected. On the other hand, the WLT could only detect 77% of fingers punctured with a 0.45 mm needle (26 G). The function of the soap was presumably to reduce the surface tension of the water which enabled the water to penetrate through small holes onto the outside of the glove[7].

Correlation of the Amount of Virus Penetration with the Extent of the Soap Leak

The extent of soap leak from punctured fingers in a 2 min SLT was correlated with the amount of virus suspension penetrating the tear in the same time. *Figure 2* shows that when no visible leak was detected in the SLT(O), the amount of virus suspension penetrating through the puncture tear was below the detection limit of the test of 0.02 μL[8]. A small bead of water (1+) indicated a virus leak of 0.1 μL to 5.7 μL with 4/7 of the fingers leaked ≥2 μL. A large bead of water leak (2+) showed a higher virus leak of 2.4 μL to 4.1 μL. However, the amount of virus leak was greater than 10 μL when a trickle of water or free flowing of water passed through the puncture tear (3+).

The results indicated that the minimum amount of ΦX174 virus suspension penetrating through the punctured fingers which failed the 1 litre of SLT, was 2 μL. Although a similar amount of ΦX174 virus suspension penetrated

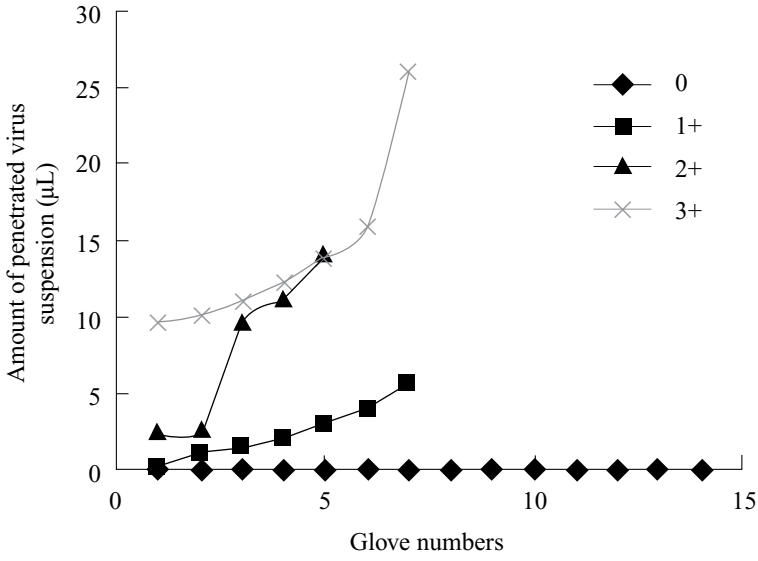

Figure 2. Correlation of the amount of virus suspension penetrating the punctured fingers of NR gloves with the extent of leakage in the SLT.

through a punctured NR glove forefinger, which failed the 1 liter of WLT[8], the SLT could detect the leak from smaller holes/tear than the WLT. A 2 µL leak is a significant amount for certain pathogens such as hepatitis B virus which has high infectivity and high titre in the blood.

Role of Naturally Occurring Non-rubbers in Puncture Tear

It was observed that NR gloves leaked markedly less than nitrile and vinyl gloves when the gloves were punctured with a 0.25 mm acupuncture needle before being stressed (*Table 3*). The contributing factor could be the polymeric material or the non-rubbers, which are present in NR but not in non-NR gloves. When HA, RP and purified RP dipped films were punctured with a 0.35 mm needle and subjected to similar cyclic stress conditions, the HA films with the highest amount of non-rubbers leaked the least while the purified RP film with the least non-rubbers leaked the most (*Figure 3*). The difference was more pronounced with cast films. This again could be due to the presence of more non-rubbers in HA cast films than in the RP cast films. Interestingly, dipped films though subjected to cyclic stress showed lower leakage than cast films which were not stressed (due to film tackiness). This shows that non-rubber constituents and vulcanisation of the rubber chain play some role in controlling the aperture of the tear slit which was reported[9] to affect the level of virus leak.

CONCLUSION

The 1 litre of WLT was shown to be less sensitive to needle puncture tear in glove fingers than in the palm. Addition of 0.1% SDS, Teepol®, Triton X-100® or Tween-80® increased the sensitivity of the test. All fingers punctured with a 0.35 mm needle failed the SLT, compared to only 23% failing the WLT.

TABLE 3. VIRUS PENETRATION THROUGH GLOVES THAT HAD BEEN PUNCTURED WITH 0.25 MM NEEDLE BEFORE BEING STRESSED

Powder-free NR gloves		Non-NR gloves	
Glove (brand)	Virus leak (μL)	Glove (brand)	Virus leak (μL)
I	0.16	Nitrile glove 1	4.80
II	0.29	Nitrile glove II	9.97
III	0.37	Vinyl glove I	20.25
IV	0.41	Vinyl glove II	123.90

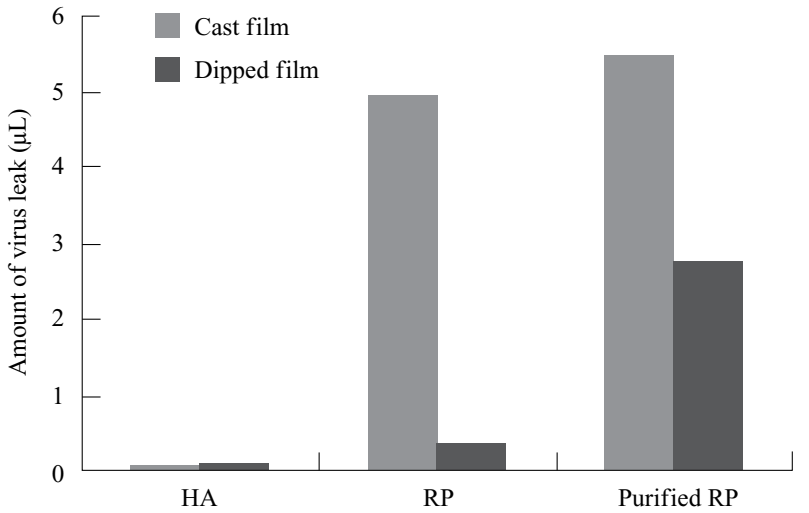

Figure 3. Virus penetration through films of different amount of non-rubber constituents punctured with 0.35 mm acupuncture needle.

The minimum leak detectable by the 1 litre SLT was equivalent 2 μL of ΦX174 virus suspension penetrating through the defect.

Punctured NR gloves exposed to cyclic stress exhibited a better barrier performance than nitrile and vinyl gloves under similar conditions. This was partly attributed to the non-rubber constituents present in NR gloves.

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