Polymer Testing 54 (2016) 244–249

Contents lists available at ScienceDirect

Polymer Testing

journal homepage: www.elsevier.com/locate/polytest

Test method

Quantitative leak test for microholes and microtears in whole gloves and glove pieces

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A R T I C L E I N F O

Article history:
Received 27 April 2016
Accepted 20 July 2016
Available online 22 July 2016

Keywords:
Quantitative glove leak test
Vacuum glove leak test
Glove
Nitrile
Penetration

A B S T R A C T

The current leak tests for gloves are qualitative. The developed quantitative leak test uses vacuum pressure to draw measured volumes of water to detect microholes/tears in whole gloves and glove pieces. A modified plastic vacuum desiccator interfaced with a Frazier air permeability tester allowed exposure of disposable unsupported/unlined/powderless Kimtech Blue nitrile to 50 mL of water for glove pieces or to 600 mL within a whole glove at vacua of 8–9 in. (20–23 cm) and 11–12 in. (28–30 cm) water gauge, respectively. Punctures of known dimensions were made before testing in specific glove areas using 21-, 22-, 26-, 30-, and 33-gauge needles (outer/inner diameters in micrometres of 873/514, 794/413, 635/311, 476/127, 318/159 and 238/133, respectively). The length of the punctures varied from 0.13 ± 0.01 to 0.80 ± 0.11 mm. Flow rates of water through the holes/tears ranged from 2.5 ± 0.4 to 106 ± 7 mL/min for glove pieces. For whole gloves, the ranges were from 31 ± 9 to 543 ± 110 mL/min in the palm area; and 0.23 ± 0.06 to 82 ± 18 mL/min in the finger/fingertip area. The method quantified tear lengths as short as 0.13 ± 0.01 mm.

1. Introduction

The methods used for the detection of holes/tears in glove materials range from leak tests to electronic detection. All are qualitative in nature.

The ASTM D5151-06 1-L leak test [1], also recommended for examining medical gloves [2] by the U.S. Food and Drug Administration for both medical personnel and patients, calls for the pouring of 1.0 L of water at room temperature into a glove held from the wrist, glove fingers down, to see if any leaks occur within 2 min using gravity. Micro-size holes/tears may not be detected however. The airburst leak test [3] involves inflating a glove with air and holes are deemed present if the glove partially deflates. This test has also been used to assess condom integrity. It may not detect microholes because the air loss through such holes is very low, the glove still appearing inflated.

The electronic methods are usually based on the behavior of an intact latex glove as an insulator with the presence of holes allowing the detection of a current. Thus, the Fluid Alarm System (FAS) works by generating a very small electrical current to activate a warning system after being conducted by moisture in the holes [4]. The Barrier Integrity Monitor (BIM) and the Surgic Alert Monitor (SAM) are similar devices [5]. The FAS system cannot detect holes and tears in synthetic rubbers, a major disadvantage [4]. Microholes in latex material have also been missed.

The transmission of viruses through glove microholes has been a concern during the HIV/AIDS [6] and Ebola [7] epidemics, as has the transmission of nanoparticles [8]. The penetration of viruses and nanoparticles through gloves is always higher with liquid vehicles like water, buffers and body fluids than under dry conditions. Hygienic practices and wearer training are also important. However, there is still no quantitative leak test for gloves or protective materials available to evaluate such situations.

The technique of pre-puncturing gloves with a 30-gauge (318 μm outer diameter/159 μm inner diameter) acupuncture needle has been used in conjunction with the 1-L water leak test to test for the glove penetration of the non-infectious ϕX174 virus, a small virus of 27 nm [9]. The usual leak test without glove puncturing detected leaks only 20% of the times that virus penetration was detected, whereas the punctured glove facilitated 91%. This also varied with glove type. Allowing leak tests of 60 min increased the accuracy of the leak test for unpunctured gloves to 66%.

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http://dx.doi.org/10.1016/j.polymertesting.2016.07.018
0142-9418/

The current research has developed a quantitative leak test for liquids for the first time by using pre-punctured glove materials and by determining the method's lower limit to detect holes/tears with a Frazier air permeability tester used as a negative pressure source connected to a modified vacuum desiccator and an inexpensive visualization system to assess tear/hole dimensions.

2. Methods

2.1. Equipment

Unsupported/unlined/powderless Blue disposable nitrile gloves were from Kimtech Science, Kimberly-Clark Professional, Roswell, GA. A laptop (Fujitsu Lifebook E series with Microsoft Windows 7 operating system, Sunnyvale CA) processed the digital images captured from an electronic Mighty Scope of 200× magnification power (Aven, Ann Arbor MI). Software from Microviewer, Carlstadt NJ was used for imaging and to measure samples. Metal hub sharp non-coring needles (Hamilton Company, Reno NV) were used to puncture glove materials. The gauges used were 21, 22, 24, 26s, 30, and 33 (respective outer/inner diameters in micrometres of 873/514, 794/413, 635/311, 476/127, 318/159 and 238/133).

A 1-L Room Essentials plastic storage bowl captured any water that flowed through tears in the gloves or glove materials. A cork ring of dimensions 6 in. (15 cm) inner diameter x 8.3 in (21 cm) outer diameter supported the plastic container inside the dome to capture water.

The vacuum generated was by a Frazier Air Permeability tester (FAP-HP-C) high pressure compact model from Frazier Instruments, Hagerstown, MD. This instrument is capable of pulling a vacuum between the ranges of 1–21 in. (2.5–53 cm) water gauge.

The testing dome was retrofitted from a Bel-Art Scienceware Transparent Vacuum Desiccator (Fisher Scientific, Pittsburgh PA). The vacuum desiccator was modified by drilling two holes in the top and bottom that were 2.75 in. (7.0 cm) in diameter (Fig. 1 a & b).

Dome hole linings were made using two 2.0 in. (5.1 cm) x 4 in. (10 cm) black polyvinyl chloride (PVC) flexible rubber couplers (Fernco, Sparks NV) cut to be 1.0 in. (2.4 cm) tall to fit around the holes to avoid damage to the glove material for the top of the dome, and the other was cut to be 3 in.(7.6 cm) tall for the dome bottom (Fig. 2).

One 2.0 in (5.1 cm) x 0.75 in (1.9 cm) solid PVC reducer bushing (Dura, Brackley Northamptonshire, UK) was used inside the whole glove cuff area to hold it in place during testing (Fig. 3). Two Dura 2.0 in.(5.1 cm) x 1.5 in. (3.8 cm) solid PVC bushings were used for glove pieces. They were modified to create an adapter to hold a glove piece in place. Two holes were drilled in opposite ends of the bushings. Water gaskets were super-glued to the bottom of each reducer to prevent water leaks (Fig. 4).

Fig. 2. (Left) PVC flexible rubber coupler was cut to be 1.0 in. tall for the top of the dome (Right) PVC flexible rubber coupler was cut to be 3.0 in. tall for the bottom of the dome.

Two flush valve gaskets (Danco Emergency Equipment, Snyder NE) were cut and super-glued to the bottom of two reducer bushings to hold samples in place and to minimize water leakage. A 2 in. (5.1 cm) zinc plate (Everbilt, The Home Depot, Los Angeles CA) was used with two 0.25 in (0.64 cm) x 2.5 in. (6.4 cm) zinc-plated flat-head Phillips drive machine screws to tighten all parts together to ensure no water leaks.

The assembled interface is presented in Fig. 5.

2.2. Procedures

2.2.1. Test dome manufacture

The vacuum desiccator was modified by drilling two holes in the top and bottom that were 2.75 in. (7.0 cm) in diameter. The holes were smoothed with a metal file. For the top of the dome, a 2.0 in. (5.1 cm) polyvinyl chloride (PVC) flexible rubber coupler 1.0

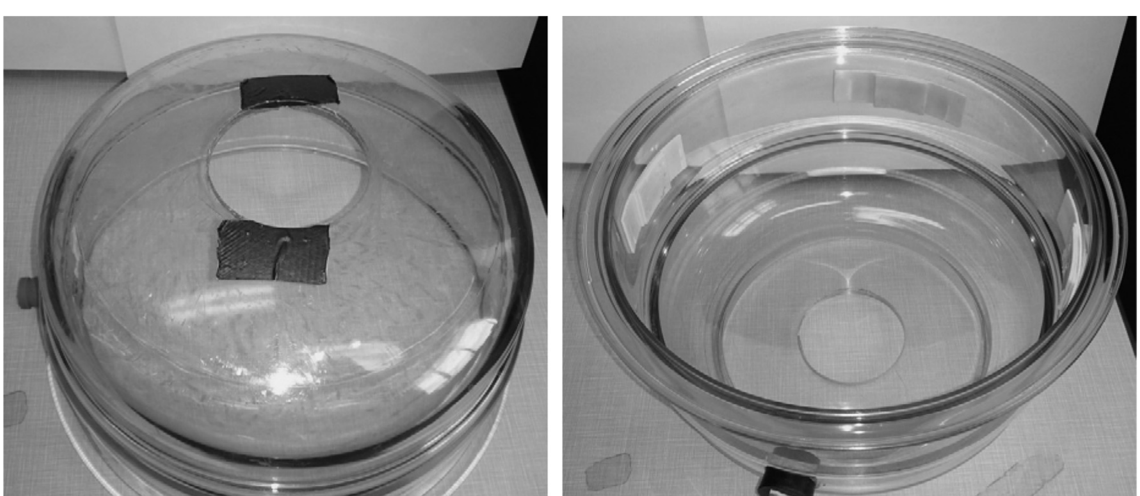

Fig. 1. (a) Left Side is top of dome with 2.75 in. hole cut out (b) Right side is the bottom of the dome with the 2.75 in. hole cut out.