

Validation of a Corona Discharge Technique to Test Male Latex Condoms for Pinhole Defects

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ABSTRACT: The Center for Devices and Radiological Health, Food and Drug Administration, evaluated a prototype device using novel technology to detect pinholes in male latex condoms. This device uses multiple electrodes, maintained at high positive voltage, which interrogate a latex condom placed on a conducting mandrel. An electric discharge occurs only when a small hole is present in the condom and is sensed by the device. The mandrel is rotated to map out the entire surface of the condom. Using latex condoms with laser-drilled holes ranging from approximately 1 to 30 μm in diameter, we examined the sensitivity of this device. The smallest holes were detected, and the overall false negative rate was 2%.

KEYWORDS: latex, condoms, holes, electrical discharge

It is well recognized that latex condoms play an important role in preventing the spread of acquired immune deficiency syndrome (AIDS) and other sexually transmitted diseases (STDs) [1,2]. Studies have shown that the use of these devices by a partner testing positive for human immunodeficiency virus (HIV) substantially reduces, but does not eliminate, the possibility of seroconversion by an initially HIV-negative partner [3,4]. It is unclear whether the predominant reason for seroconversion is improper use of the latex condom, breakage during use, or leakage due to pinholes or defects in the condom itself.

Several methods to test for holes in condoms have been developed. The Food and Drug Administration (FDA) specifies use of a water leak test [5] to examine manufactured lots of latex condoms before allowing them to be sold. The technique used is similar to one (D 3492: Specification for Rubber Contraceptives (Male Condoms)) developed by the American Society for Testing and Materials (ASTM), which fills the condom with 300 mL of fluid. Theoretically, the FDA test, under ideal conditions, is able to detect a hole 3 μm in diameter [6], but, in practice, the sensitivity (diameter of the smallest hole reliably detectable) is approximately 15 μm . Water leak tests do not have the capability of being used on-line in a manufacturing setting.

Since relatively large quantities of fluid can be transferred through 15- μm -diameter holes, other more sensitive, albeit more complicated, tests have been devised by the FDA to examine latex condoms for pinholes. One protocol [7] determines whether 110-nm fluorescent beads have been transferred from the interior to

the exterior of a condom. The size of the beads was chosen to mimic that of HIV particles (90 to 130 nm). The sensitivity of this method is approximately 4 μm in diameter. Another technique [8] determines the penetration of a bacteriophage, ϕX174 , through a latex condom. The ϕX174 , having a diameter of 27 nm, is smaller than either the HIV or the hepatitis B viruses. The sensitivity of this test is approximately 1 to 2 μm in diameter. Since these last two techniques determine the total fluid transferred across the condom barrier, neither is capable of determining hole location. Therefore, the sensitivity refers to that size hole observable if all fluid came through a single hole.

Studies [9,10] using both of these more sensitive tests, and off-the-shelf latex condoms, have shown that insofar as intrinsic holes are concerned, and undersimulated "physiologic" conditions, those manufactured lots of condoms that have passed the water leak tests, while not perfect, offer, statistically, a high degree of barrier effectiveness for viruses associated with STDs, i.e., they do not exhibit large numbers of holes with sizes below the sensitivity of the water leak test. In light of these results and the epidemiological studies referenced above, the monitoring of condom lots with the water leak test is deemed appropriate by the FDA to characterize, or to determine any degradation in a company's manufacturing process.

As part of FDA's continuing effort to evaluate new methods for assuring the adequacy of medical devices, a device was purchased and evaluated that uses a novel method for detecting holes in latex condoms. This apparatus, named the ViruShield™ Test System², uses an electric discharge to detect small holes in the condom material. The developer's claim is that this device can detect, non-destructively, submicron-sized holes in latex condoms, either in a laboratory or an on-line manufacturing environment. Our study examined the device only in a laboratory setting. Also, since even nominal 1- μm -sized holes were very hard to produce and difficult to distinguish as to actual size or shape under a microscope, we limited this study to holes no smaller than 1 μm in diameter.

Description and Methodology of Apparatus

The ViruShield test method utilizes an aluminum mandrel 4.2 cm in diameter and 23.5 cm in length and shaped such that the latex condom to be tested fits snugly over it. This means that to adequately examine the end of a reservoir-tipped condom, the mandrel must be shaped specifically for a particular model. The mandrel sits in open atmosphere. Sixteen electrodes are positioned in a plane and along the length of the condom to be tested. Spacing

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² Manufactured by the ConverTec Corp. (Newtown, PA).

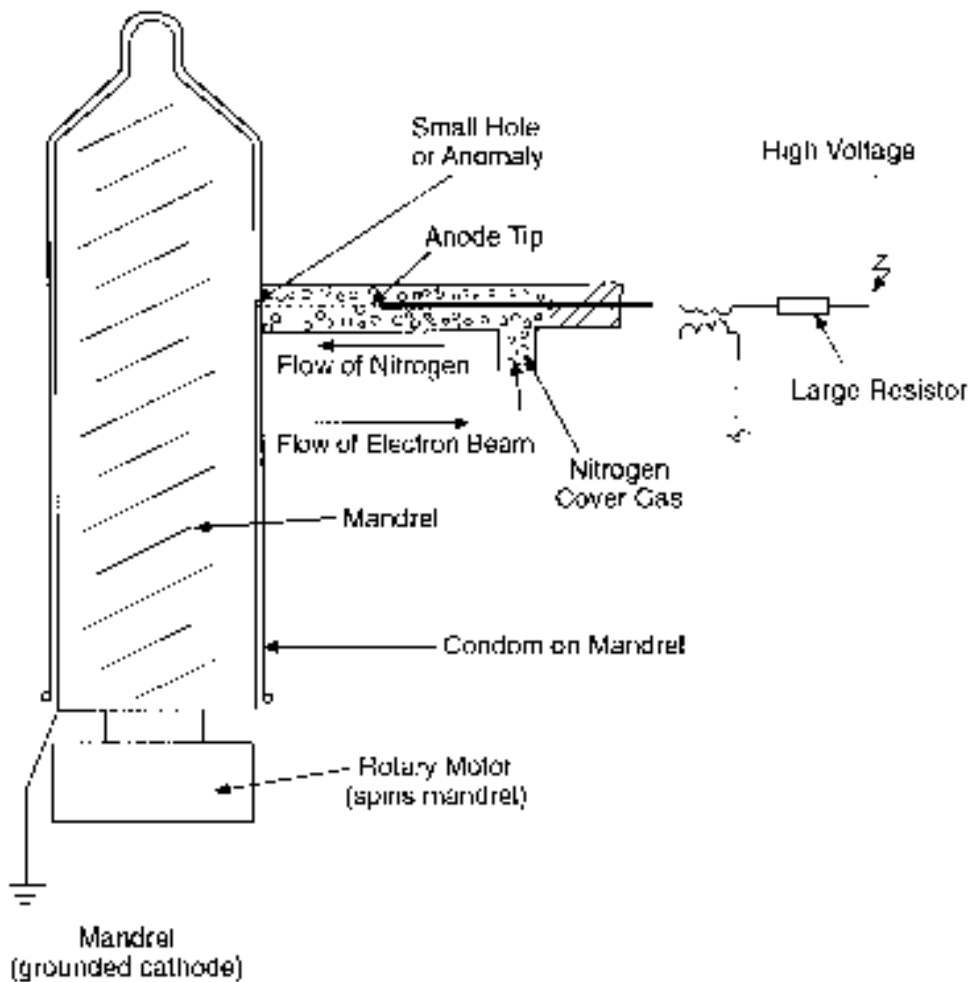


FIG. 1—Schematic of device depicting one representative sensor.

between sensors is approximately 1.3 cm. Figure 1 is a schematic showing one representative electrode assembly, and Fig. 2 is a photograph showing all 16 sensor elements. Each electrode is maintained at a high positive voltage relative to the aluminum mandrel. This voltage is pulsed, with a frequency in the low kHz range. Surrounding each electrode is a tube through which is delivered nitrogen cover gas. The distance of the electrodes to the mandrel, the voltage, the frequency, and the rate of flow of the nitrogen are all adjustable. A 3-G Ω -high impedance resistor is placed in series with each sensor.

According to the manufacturer, if the voltage is adjusted correctly, very little, if any, current flows unless there exists a hole in the latex condom covering the mandrel, and then a corona discharge completes the electrical circuit. When this occurs, the change in current in any of the 16 sensor circuits can be analyzed by a data acquisition system or noted by a light-emitting diode (LED) located on each of the 16 sensors (or the sound made by a small speaker). All are inductively coupled to the main circuit. The electrode geometry, voltage, frequency, resistor impedance, electrode distance, rate of flow, and type of cover gas all affect the nature and duration of the discharge and hence the current. The mandrel can be automatically or manually rotated such that virtually all of the condom surface, including the tip, can be mapped out by the sensor bank.

Validation Study

Holes of known size, utilizing an excimer laser, were drilled for the FDA by an outside contractor³ in nonlubricated, reservoir-tipped latex condoms. The hole is actually a pore through the latex, and the nominal size given is that of the exit diameter. The exit is the narrowest part of the pore. The location was marked with a red circle (0.3 mm in diameter) surrounding the hole. Figure 3 shows a representative 4- μ m hole as seen under X600 light microscope magnification. Hole sizes ranged in diameter from approximately 1 to 30 μ m. The holes, particularly the smaller ones, were often irregular and slightly elliptical, with the dimensions of the major and minor axes within 1 μ m of each other. The diameter sizes given above are therefore the mean value of the two axes, rounded to the nearest micron. The distributions of hole diameters (see Table 1) and locations were not specifically planned since the condoms tested were excess devices, originally intended as part of another study. Hole locations ranged from along the shaft between 2 to 8 cm from both the open and closed ends and at the closed reservoir tip of the condom. Additional identical red circles were also placed on many of the condoms at positions where there was no known hole. Furthermore, as controls, condoms with no known holes were also given identical markings. Ten out of 43

³ Resonetics, Inc. (Nashua, NH).

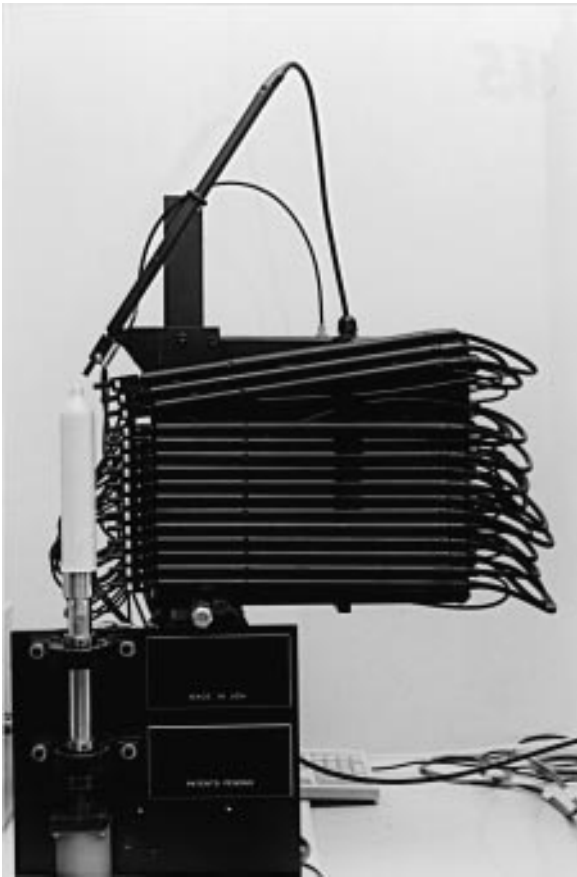


FIG. 2—Photograph of device.

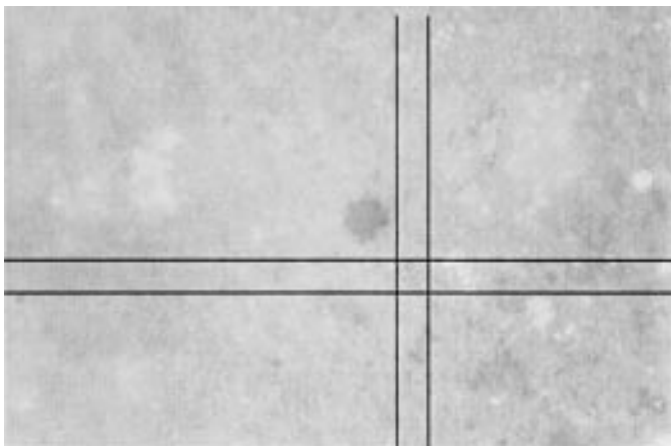


FIG. 3—Photograph of laser-drilled 4- μm hole in condom under magnification. Hole is just outside of cross-hair box.

condoms with holes had only the single original red circle; the rest had two. Ten out of the 22 controls (no holes) had a single red circle; the rest had two.

All condoms were examined by testers who had no knowledge as to the actual hole sizes or locations. Detection was indicated by the lighting of the LEDs on the sensors, and the particular sensor(s) lit were noted. For the device to have been deemed to have detected any particular hole, sensors close to the actual hole position must have lit up. Indications of holes where there were no nominal holes were also noted.

TABLE 1—Hole detection results.

Hole Diameter, μm	No. Condoms Tested	No. Correctly Identified
No holes	22	21
1	2	2
2	10	9
3	2	2
4	6	6
6	2	2
7	2	2
8	1	1
10	5	5
15	5	5
20	4	4
30	4	4

At the instruction of the manufacturer of the ViruShield, the study was performed at 7.5-kV, 21.5-kHz settings. Nitrogen was delivered at the rate of 2 L/min total for the entire sensor bank. The sensor-mandrel spacing distance was 0.7 cm. The mandrel was rotated such that the entire condom was examined in approximately 30 s.

Results

Out of 43 condoms with holes, 42 were correctly identified by the Convertec device. Out of 22 condoms without holes, 21 were correctly identified as being intact. The distribution of condoms as a function of hole diameter in microns and results is shown in Table 1. The ten condoms having 2- μm holes included five condoms that had a 2- μm hole at the tip. One of the 1- μm holes was also at the tip.

As Table 1 shows, one nominal 2- μm hole, near the open end of a condom, was undetected. The hole was confirmed, after the ViruShield test, by filling the condom with water, greatly pressurizing and expanding the area (and the hole) around the nominal hole location by manually squeezing the latex, and observing water leaking through the hole. This is an unquantitative and destructive test, but it is more sensitive (in the low micron range) than the standard FDA water leak method [5]. It is also useful only if one knows the location of the hole to be tested.

One condom without a nominal hole was incorrectly identified as having a hole. The same squeeze water leak test was performed in the area denoted by the ViruShield test (near the open end of the condom), but no water was detected.

Discussion

This study was limited by two factors: the expense and difficulty of making and characterizing small holes in latex condoms, and the lack of a standard method against which to compare the ViruShield technique. For example, even though the study showed a false negative rate at 2 μm of 10%, the small sample size at this hole diameter precludes attaching much significance to this number. The overall false negative rate was 2% (the rate was 0% for holes greater than 2 μm), but it is conceivable that the one hole missed by the ViruShield technique could have been blocked by a piece of foreign matter that might have been forced out under the pressure of our squeeze confirmation test. In any case, these percentages compare favorably with other tests used. The fluorescent bead test, while not validated in this manner, cannot detect any hole smaller than 4 μm . The bacteriophage technique has shown a 6% false

negative rate [11]. It should also be mentioned that it is virtually impossible to find a several-micron-sized hole in latex under a microscope unless the exact location is known, so that microscopy is not useful, in general, to detect and characterize pinholes.

The ViruShield's ability to detect holes at the closed reservoir tip is important for two reasons. First, due to the changing contour in this area, we believed this would be the most challenging pinhole location for the device. Second, in actual use, a pinhole at this location would tend to allow the greatest transfer of bodily fluids across the latex barrier.

The false positive rate was 5%. It is possible, however, that the one hole detected in the nominally intact condom actually existed, but was too small or in the wrong location to be confirmed by our squeeze test.

Several aspects of this device were not tested in this study. The claimed ability of the device to characterize the size of the hole by noting the value and frequency of the discharge current was not examined. Also, the possibility that localized material characteristics such as thickness, contamination, and structure could be determined by this technique will have to be left to future studies.

The electrode geometry, voltage, frequency, resistor impedance, electrode distance, and rate of flow and type of cover gas are all important to the acceptable performance of this device in assessing a particular condom material. In preliminary studies, many spurious readings were noted and holes were even burned into condoms by the measuring device when the above-listed device parameters were not adjusted optimally. Since the exact formulation for latex condoms may differ among manufacturers, ViruShield would have to be calibrated for each formulation.

While we did not quantitatively examine the ability of ViruShield to localize a hole, this and other preliminary studies indicate that in most cases the position of a hole could be determined within approximately 1.5 by 1.5 cm. It might be possible to localize holes better by noting the relative currents in several adjacent sensors as well as the current variation as the mandrel is rotated. Performance changes due to mandrel rotation speed were not specifically studied, but occasional repeat mapping of selected condoms in times as short as 1 s did not seem to affect the outcome.

Conclusion

While our validation study did not prove that the ViruShield device is infallible, it does seem a good laboratory tool, with sensi-

tivity at least as good as, and ease of use better than, anything else available. Indeed, the sensitivity might be much greater than our tests showed. Considering its capabilities and characteristics, it also seems probable that the ViruShield Test System has potential as an on-line test in a manufacturing setting for determination of pinhole defects in latex condoms.

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