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Assessment of the Durability of Medical Examination Gloves

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This study determined the durability of various types of medical examination gloves using a laboratory test developed by the researchers. Results of this testing are compared with a simulated clinical method, also developed by the researchers, found to produce failures at rates similar to actual clinical use. Ten types of exam gloves were tested. One set of gloves was tested using a glove durability method. A second set was worn and conditioned using a simulated clinical method for comparison. The third set consisted of a control set of gloves that were not stressed. Samples consisted of 100 gloves combined from 2 or 4 manufacturers. All gloves were water-leak tested as the last step. The glove durability method created failures at similar rates to the simulated clinical method. The majority of the defects were located in the finger regions of the gloves. Durability of powdered and powder-free vinyl gloves was inferior to that of other glove types tested, with failure rates ranging from 24% to 42%, compared with 3% to 17% for the other glove types tested. Glove durability was also affected by the powdered state of the gloves and the user having long fingernails.

Keywords glove durability, leakage, medical examination gloves, simulated clinical use

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Health care workers and patients depend on medical examination gloves to provide an effective barrier to potentially infectious materials and other contaminants. Latex, nitrile, and vinyl are the most common medical glove materials, with latex being the preferred material due to its perceived superior durability.[1] However, there is a need for an alternative to latex gloves since 15 million people worldwide and 1 million health care workers in the United States suffer from latex allergies.[2] The Food and Drug Administration (FDA) and others have been studying some aspects of medical glove durability.[3]

Several studies have examined the failure rates of different medical gloves under simulated and actual clinical use. Those studies indicate an average after-use failure rate of 41% for vinyl gloves, 10% for latex gloves, and 2% for nitrile gloves.[4–13] The majority of defects are located in the finger region of the gloves, specifically the thumb and index finger.[4,5,7–9] The duration of use also has a significant effect on the occurrence of defects.[5,7,9] Two of the studies found that health care workers are not aware of the majority of failures detected after use.[8,10] One study found that wearing rings resulted in a significantly higher rate of failures than not wearing rings.[10]

For many years, the performance of medical examination gloves has been based on conformance to ASTM International and FDA requirements.[14] However, these performance requirements only evaluate the presence of defects in unused finished product and do not address the dynamics of glove use. There is an ASTM working group currently developing a standard to assess the durability of medical gloves. This standard will be used by manufacturers to characterize the durability of their products.

The purpose of this project is to determine the durability of various types of medical examination gloves using a laboratory test that is relatively simple, eliminates user variability, and uses readily available equipment. Results of this testing are compared with a simulated clinical test method found to produce failures at rates similar to those seen in the literature.[15]

METHODS AND MATERIALS

Ten types of commercially available medium-sized medical examination gloves were tested. A single glove size was selected to standardize the tests. Size medium gloves were selected since they represent the average glove size available. The study took on a three-pronged approach. One set of gloves was tested using the glove durability method. A second set was worn and conditioned using a simulated clinical method for comparison. The third set consisted of a control set of gloves that were not stressed. One hundred gloves of each type, consisting of four brands, 25 gloves per brand, were analyzed per

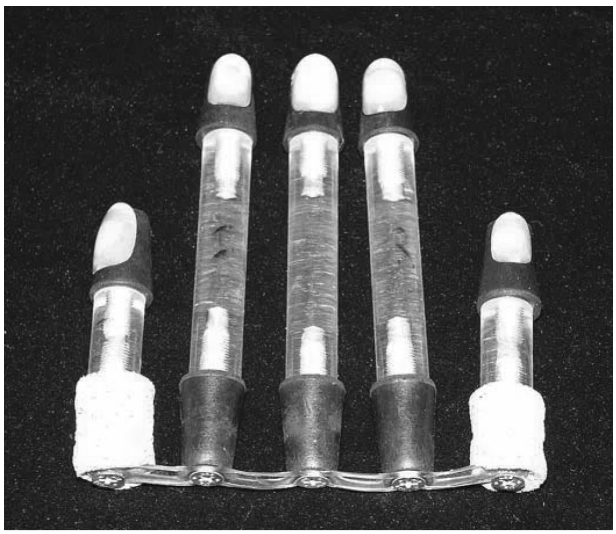

FIGURE 1. Top view of an assembled hand phantom with artificial fingernails applied to the rubber stoppers

test unit (except the chloroprene gloves for which two brands, 50 gloves per brand, were analyzed). Multiple manufacturers were selected for each material to give a representative sample of the gloves currently available. Finally, all gloves were water-leak tested using the FDA water-leak test method.[16]

Glove Durability Method

The glove durability method consisted of shaking the gloves in an abrasive medium for 10 min. First, a hand phantom with acrylic fingernails attached at a fingernail length of approximately 1/8 inch (Figure 1) was placed inside the glove. Then the glove was placed into a Fleaker™ beaker containing 250 cm^3 of Plasti-Grit® abrasive material so that the glove's fingers were hanging inside the beaker and 1–3 cm of the cuff area was stretched over the opening of the beaker. Next, a rectangular piece of medium density polyurethane foam was inserted into the glove, over the top of the hand phantom. The beaker was then capped and fixed horizontally onto a reciprocating shaker table so the glove had the palm side facing down (thumb pointing out to one side) and the fingers were parallel to the travel of the shaker table (Figure 2). The beaker was then shaken on the shaker table at a speed of 220 ± 10 rpm for 5 min. With the palm still facing down, the beaker was rotated 90° so that the direction of agitation was sideways across the surface of the glove. The beaker was fixed and then shaken for another 5 min. On completion, the gloves were removed from the test setup and collected for water-leak testing.

Simulated Clinical Method

The simulated clinical-use protocol consisted of approximately 12 min of manipulating various medical devices.[12] The manipulations included wiping the gloves with a wet towel; using a sphygmomanometer and syringe; removing and attaching a Luer-lok™ tip to a syringe; and opening and closing different sized stopcocks, clamps, and hemostats.

Pairs of gloves were packaged in resealable plastic bags and identified with a label indicating the type of glove, the glove numbers, and spaces for the analyst's initials and date tested. Glove pairs consisted of two consecutively numbered gloves, with the odd-numbered glove intended for the left hand and the even-numbered glove for the right hand. Glove

FIGURE 2. Exam glove durability test setup

TABLE I. Failure Rates Among Test Groups

Glove Type	Controls (%)	Durability Method (%)	Simulated Clinical Method (%)
Powder-free vinyl	0	42[A]	38 (n = 90)[A]
Powdered vinyl	3	24[A]	33 (n = 90)[A]
Powder-free latex	3	11[A]	4
Powder-free, textured latex	3	12[A]	5
Polymer coated, powder-free, textured latex	4	9	10[A]
Powdered latex	2	8[A]	17[A]
Powdered, textured latex	3	6	9[A]
Powder-free, textured chloroprene	4	3	8
Powder-free, textured nitrile	1	5	3
Powder-free nitrile	5	6	12[A]

Note: n = 100 unless otherwise noted.
[A]Defect rate is significantly higher than the control rate (Chi squared statistic, one-tailed test, $\alpha = 0.05$, p-value ≤ 0.05).

pairs were distributed among eight individuals. The participants were asked to record whether they wore rings and whether their fingernails extended past their fingertips. They were also asked to record any defects observed before, during, or after manipulating the gloves.

RESULTS

Table I summarizes the water-leak test failure rates for all of the test groups. The failure rates for the control gloves ranged from 0% to 5%. The glove durability method produced failures at similar rates to the simulated clinical method for all the glove types tested (Chi squared statistic, two-tailed test, $\alpha = 0.05$, p-values: 0.06–0.81; i.e., no differences were significant).

Figures 3 and 4 show the distribution of all the defects found during poststressing water-leak testing for the durability and clinical tests, respectively. Some gloves had multiple defects after stressing. The glove durability method created defects in all areas of the gloves including the fingertips and crotches. The simulated clinical method also created defects in all areas of the gloves. The majority of the defects in the

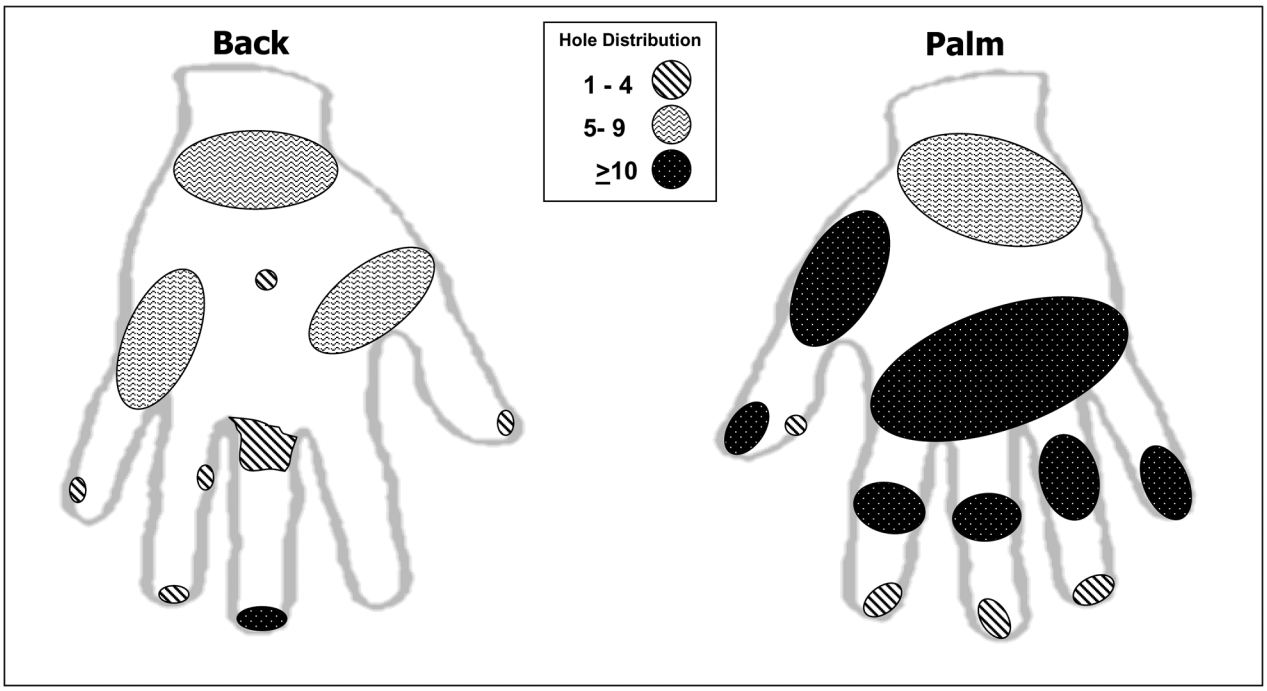

FIGURE 3. Overall defect distribution for durability method

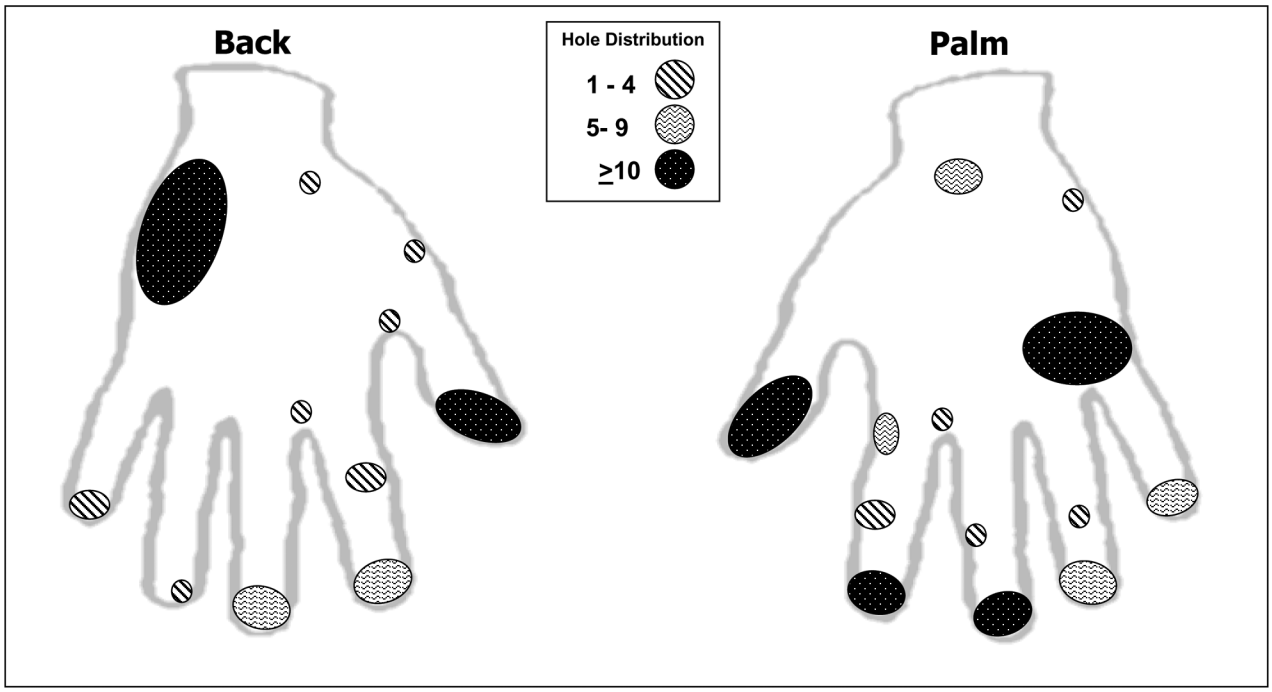

FIGURE 4. Overall defect distribution for clinical method

simulated clinical method were located in the finger regions of the gloves.

Glove Durability Method

The results of the glove durability method varied by glove type (Chi squared statistic, $\alpha = 0.05$, dof = 9, p-value < 0.001). Powdered and powder-free vinyl gloves were inferior to the other glove types tested with failure rates ranging from 24% to 42% compared with 3% to 12% for the other glove types tested. Powder-free, textured chloroprene gloves had the lowest failure rate (3%), followed by powder-free, textured nitrile gloves (5%).

When comparing latex, textured latex, and vinyl gloves, powder-free gloves had higher failure rates than the powdered gloves, but the difference was significant only for vinyl gloves (Chi squared statistic, one-tailed test, $\alpha = 0.05$, $p_{vinyl} = 0.03$; $p_{latex} = 0.31$; $p_{text.latex} = 0.15$).

There was no significant difference in failure rates between textured and nontextured gloves. This comparison was made for powder-free latex and powder-free nitrile gloves (Chi squared statistic, one-tailed test, $\alpha = 0.05$, p-$value_{latex} = 0.83$; p-$value_{nitrile} = 0.76$).

Simulated Clinical Method

Simulated clinical testing was performed to provide a reference for the durability method. Seven individuals participated in the testing (Table II). The overall (all glove types) failure rates varied significantly by analyst (Chi squared statistic, $\alpha = 0.05$, dof = 6, p-value = <0.01). The coefficient of variation among analysts was 42.7%. Of the defects detected, only 22% were visually detected before, during, or immediately after use. All others were detected using the water-leak test.

The results of the simulated clinical method also varied by glove type (Chi squared statistic, $\alpha = 0.05$, dof = 9, p-value $<$ 0.001). Powdered and powder-free vinyl gloves were inferior to the other glove types tested with failure rates ranging from 33% to 38% compared with 3% to 17% for the other glove types tested. Powder-free, textured nitrile gloves had the lowest failure rate (3%), followed by powder-free, latex gloves (4%) and powder-free, textured latex gloves (5%).

The difference in failure rates between powdered and powder-free gloves varied by glove type. The powder-free vinyl gloves had a greater failure rate than the powdered, but

TABLE II. Overall Failure Rates by Analyst for Simulated Clinical Method

Analyst	# Failures	# Tested	Failure Rate
1	12	132	9.1%
2	17	120	14.2%
3	14	130	10.8%
4	27	146	18.5%
5	34	146	23.3%
6	20	150	13.3%
7	10	164	6.1%

TABLE III. Effect of Rings and Fingernails on all Failures for Simulated Clinical Method

	Vinyl Gloves	
Test Condition	**Failure Rate**	**p-Value**
Fingernails and rings	27% (51/304)	0.02*
No fingernails and no rings	11% (28/1262)	
Fingernails	24% (22/92)	<0.001*
No fingernails	11% (28/262)	
Rings	11% (37/338)	0.46
No rings	11% (28/262)	

*Statistically significant (Chi squared statistic, one-tailed test, $\alpha = 0.05$, p-value ≤ 0.05).

this difference is not statistically significant (Chi squared statistic, one-tailed test, $\alpha = 0.05$, $p_{vinyl} = 0.23$). The failure rates for the powdered latex gloves were higher than the powder-free gloves, both textured and nontextured, but was significant only for the nontextured gloves (Chi squared statistic, one-tailed test, $\alpha = 0.05$, $p_{latex} = 0.02$; $p_{text.latex} = 0.22$).

There was a significant difference in failure rates between textured and nontextured gloves for powder-free nitrile gloves, but not for powder-free latex (Chi squared statistic, one-tailed test, $\alpha = 0.05$, p-value$_{latex} = 0.73$; p-value$_{nitrile} = 0.02$).

The effects of rings and long fingernails on failure rates were also examined. Table III shows the three test conditions that were analyzed, the failure rate, and the p-values. The test conditions were compared using the Chi squared statistic, one-tailed test, and $\alpha = 0.05$. The results indicate that having both long fingernails and rings and just long fingernails has a significant effect on the occurrence of defects in examination gloves.

DISCUSSION

The methods used in this study adequately assess the durability of various types of medical examination gloves. The results show that the glove durability method creates failures at similar rates to the simulated clinical method. The distribution of the defects for both methods correlates with the literature with the majority of the defects located in the finger regions of the gloves.[4,5,7–9]

Powdered and powder-free vinyl gloves were the least durable gloves tested in this study, confirming the findings in the literature.[5–9,11–13] The other synthetic gloves were comparable in durability to the latex gloves, also corresponding with the literature.[11–13]

Using the glove durability method, the powder-free gloves had higher failure rates than the powdered gloves, with a statistically significant difference seen in the vinyl gloves. This difference is hypothesized to be due to the chlorination process. The chlorination process consists of immersing gloves in a high-concentration chlorine bath followed by a neutralization bath, a water rinse, and then drying. The chlorine causes cross-linking of the glove material. Chlorination is used to remove powder added during the manufacturing process, to reduce the amount of extractable protein in natural rubber latex gloves and to make the surface more slippery, thereby aiding the donning process. Chlorination has also been shown to adversely affect shelf life, grip, and in-use durability in some cases.[17]

The results for the simulated clinical method were different, with the powdered latex gloves, both textured and nontextured, resulting in a higher failure rate than the powder-free gloves. The wear mechanism of the simulated clinical method differs from the glove durability method, with much more emphasis on the fingertips. Powder-free latex gloves tend to be more slippery and less likely to tear during use. In fact, several of the analysts commented that the slipperiness of these gloves made it difficult to manipulate some of the devices during the simulated clinical method.

There was no significant difference in durability between textured and nontextured gloves (with the exception of powder-free nitrile gloves tested using the simulated clinical method). This could be due to the high failure rates in the controls for the powder-free nitrile gloves.

User variability is also an important factor in the durability of exam gloves. This variability is a function of fit, individual work techniques, fingernail length, and the presence of rings. Significantly higher failure rates were seen when users had long fingernails and when users wore rings and had long fingernails. Since rings alone did not have a significant effect on the failure rate, the difference seen between fingernails and rings and no fingernails and no rings is probably due to the long fingernails alone. These results are contrary to those found by Hansen et al.,[10] in which wearing rings resulted in a significantly higher rate of failures than not wearing rings. The Hansen study conclusions are based on individual parameters and do not appear to take into consideration the confounding effect of combinations of such parameters as long fingernails, materials used, and varying procedures.

Finally, it is important to note that the glove wearers in this study were aware of only 22% of the total defects detected. This agrees with the previous studies that show that health care workers are not aware of the majority of defects detected after use.[8,10]

CONCLUSIONS

The results of this study demonstrate that all medical exam gloves are not equal in durability. The durability depends on the type of glove material. Vinyl gloves are not as durable as latex and this may be an important factor when choosing an alternative to latex. Nitrile and chloroprene gloves appear to be as durable as latex gloves and may provide a better alternative. User variability also affects the durability of gloves. To minimize the defects created during exam glove use, it is recommended that health care workers keep their fingernails short.

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