BRIEF COMMUNICATIONS

Integrity of Powdered and Powder-free Latex Examination Gloves

Andrew J. Calhoun, BS, MS; Gary E. Rodrick, PhD; Frederic H. Brown, DMD, MS

Abstract

Objectives: *The difference in permeability between one brand of powdered and another of powder-free latex examination gloves was evaluated to determine leak rates.* ***Methods:*** *Thirty-one of each type of glove were tested for each of three different conditions: usage by dental personnel (1) for 15 minutes or longer, (2) for less than 15 minutes, and (3) directly from the manufacturer's packaging (zero usage time). Each glove was evaluated in the fingers and the palm. The phiX-174 viral solution in the glove was allowed to penetrate for 15 minutes. Powder (cornstarch) was subsequently added to 20 powder-free gloves, and 15 of these were pierced with a 30-gauge needle.* ***Results:*** *Powdered gloves showed no leakage rates. Because of this, 30-, 27-, and 25-gauge needles were used to pierce five gloves each. One glove with 27- and 25-gauge needle holes showed leakage. Leakage rates for powder-free gloves: 45.1 percent for more than 15 minutes of use, 25.8 percent for less than 15 minutes of use, and 16.1 percent for zero minutes of use. Two of the 20 pierced and one of the five unpierced powder-free gloves with added cornstarch leaked.* ***Conclusion:*** *Significant differences in leak results between powdered and powder-free gloves suggest further study is needed. [J Public Health Dent 2002;62(3):170-72]*

Key Words: gloves, protective; latex; permeability; virus; bacteriophage phiX-174.

Latex gloves are used worldwide for protection of the wearer and patient against contamination. Glove use has risen dramatically since 1987, when the Centers for Disease Control and Prevention (CDC) recommended use when chance of contact with blood or body fluids was anticipated (1). There is concern among health care personnel regarding the use of vinyl and latex gloves as barriers against microorganisms, particularly viral pathogens (2). There are few data on the effectiveness of latex and vinyl gloves as barriers (3). These gloves, if ineffective, may be breached during procedures and can place the health care professional at risk (4). Other studies maintain that gloves do provide an adequate barrier, but they are not completely impermeable, especially under in-use conditions (3).

There are no regulatory standards for testing viral penetration of latex exam gloves. The FDA recommends that gloves be tested with the 1,000 ml pinhole leak test (5,6). That test does not sufficiently test the penetration of latex examination gloves because hole diameters are not known and pathogens are not used during testing.

The major bloodborne pathogens of concern to health care professionals are the hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV) (7-9). HBV is spherical, enveloped, and 42 nanometers (nm) in size. HCV is enveloped, and is 40–50 nm in size. HIV is spherical, enveloped, and 80–100 nm in size (10). Evaluating the effectiveness of examination gloves as a barrier to bloodborne pathogens is important in reducing the risk of exposure by health care workers. Utilizing actual bloodborne pathogens to test barrier effectiveness poses difficulties. HBV and HCV cannot be produced in a laboratory (1), and HIV is highly infectious and requires special safety considerations and conditions.

To evaluate barrier effectiveness, an appropriate surrogate virus must be used. The surrogate virus must have certain qualities that will make testing faster, less expensive, and more effective (11). PhiX-174 exhibits many qualities that make it an excellent candidate to evaluate latex glove penetration. PhiX-174 is a spherical bacteriophage that has a diameter of 27 nm. Phi-X174 is similar in morphology to the viral pathogens mentioned. This virus is easy and inexpensive to use, and is environmentally stable under most test conditions (11). Also, the test material does not need to be sterile before the challenge because it can be assayed in as little as four hours (11). Because phiX-174 is a bacteriophage, it is noninfectious to humans. The objective of this study was to assess the integrity of powdered and unpowdered latex examination gloves under varying periods of clinical use. PhiX-174 was used to simulate viral pathogens, to test barrier penetrance, and to evaluate the potential for viral infection across a contact surface.

Methods

This study was conducted in three parts. The first part of the experiment compared the ability of phiX-174 to penetrate powdered and powder-free latex exam gloves. The second part of the experiment forced leakage of powdered gloves by piercing them. The third part of the experiment determined whether cornstarch added to powder-free latex exam gloves would impede leakage through intentionally pierced holes.

All gloves used in this study were commercially available. The powder-

Send correspondence and reprints to Dr. Rodrick, University of Florida, Department of Food Science and Human Nutrition, Gainesville, FL 32611-0370. E-mail: ger@gnv.ifas.ufl.edu. Mr. Calhoun is a dental student at the University of Florida College of Dentistry. Dr. Brown is with the Department of Periodontics, University of Florida College of Dentistry. Manuscript received: 5/1/01; returned to authors for revision: 10/2/01; final version accepted for publication: 12/17/01.

free gloves were Tekmedic textured latex medical exam gloves (Henry Schein Inc., Melville, NY). The powdered gloves were Color Touch color-coded latex exam gloves (MicroFlex Medical Corp., Reno, NV).

Gloves collected for testing were used in clinical procedures by dental students and faculty from the periodontology clinic at the University of Florida College of Dentistry. Gloves were collected in four different plastic biohazard bags according to type (powdered/unpowdered) and usage time (less than or greater than 15 minutes). Glove users reported time of use to the glove collector and gloves were placed in appropriate bags. Samples of 31 powdered and 31 powder-free latex examination gloves were evaluated under three test conditions: directly from the manufacturers' packaging, after less than 15 minutes of wear, and after 15 minutes or more of wear. Thus, a total of 93 powdered and 93 powder-free gloves were tested.

Initial Production of phiX-174. Triptic Soy Broth was autoclaved and inoculated with *E. coli* KC (ATCC 13607), which was grown for 8 hours at 31.8°C in an incubator shaker. Subsequently, 100 µl of 10^{-8} phiX-174 (ATCC 13706-B1) was added to the broth and incubated while shaking at 80 rpm at 31.8°C for 16–20 hours. The phage solution was stored at 4°C until use; 31.8°C was used for incubating and shaking because that was the temperature limit of the machine. A virus titer of 10^{9} plaque-forming units (pfu)/ml was used during all glove testing.

Initial Preparation of Triptic Soy Agar Plates. Triptic Soy Broth was autoclaved and inoculated with *E. coli* KC. This was allowed to grow overnight. Triptic Soy Agar was autoclaved, poured into plates, and allowed to harden. *E. coli* KC was then spread plated and incubated at 37°C for 2–3 hours. This was done to start the *E. coli* KC growing and to reduce the moisture on each plate.

The ability of phiX-174 to penetrate powdered and powder-free latex examination gloves was tested by filling them with 40–50 ml of phiX-174 solution. The open end of each glove was then twisted, folded back, and tied with a twist-tie to seal in the phiX-174 solution. Each glove was then placed on two plates with the fingers on one and palm on the other. Gloves remained in contact with the agar for 15 minutes. The plates were then incubated at 37°C overnight. Positive controls were prepared by piercing the glove with a 30-gauge needle.

The second part of the experiment was initiated after it was discovered that there was no penetration of powdered glove samples (used gloves) or controls (unused gloves). Perforations were made on unused powdered gloves to force leakage of the gloves. Five unused powdered gloves were pierced with a 30-gauge needle, five with a 27-gauge needle, and five with a 25-gauge needle; 40–50 holes were made in each glove. Gloves were then filled and tested as described above.

In the third part of the experiment, 20 unused gloves were tested to determine if cornstarch added to powder-free latex exam gloves would impede leakage. Each glove was dusted internally with cornstarch. This was done by coating a hand with cornstarch and donning the glove. The hand was moved inside the glove to ensure an even coating. Fifteen gloves were pierced with a 30-gauge needle and five were not. Gloves were then filled and tested as described above.

The bacteriophage titer was determined by plaque formation using the top agar layer method (12). A chi-square test was used to compare leakage rates under the three different usage times.

Results

No powdered gloves showed penetration by phiX-174. The penetration rates for powder-free gloves varied by duration of use (Table 1). There was a 16.1 percent penetration rate on gloves that were not used clinically. A 29.0 percent penetration rate was found on gloves used for less than 15 minutes, and a 45.1 percent penetration rate was found for gloves used more than 15 minutes. Powder-free gloves that were used for 15 minutes or longer were significantly more likely to leak than gloves that were not used clinically ($P<.05$). Other comparisons were not statistically significant.

The powdered gloves that were pierced with the 30-gauge needle to force leakage showed no penetration of phiX-174. The gloves pierced with the 27-gauge and 25-gauge needles each allowed virus penetration in one of five gloves tested.

When the cornstarch was added to five powder-free latex exam gloves, one glove showed penetration in the palm. Of 15 gloves pierced with the 30-gauge needle with cornstarch added, one glove failed in the fingers and one failed in the palm.

Discussion

This study examined a novel method of testing viral penetration through latex gloves. The methods of testing that were used in this study may better simulate the contact barrier of the glove on the dentist's hand than other methods of testing. Placing the phage-filled glove directly on the agar produced a wet surface on one side of the glove barrier and a moist surface on the other. This is a close simulation of glove, hand, and mouth. Another advantage of this study is that there was no simulated glove use because gloves used were actually worn during dental procedures. Gloves were gathered after timed use during procedures performed by dental personnel. This method was limited in that there was no way to survey both sides of the glove. Variables that may have inhibited the penetration of phiX-174 such as fat, saliva, or blood products were

TABLE 1
Number and Leak Location of Powder-free Latex Gloves that Showed Penetration by phiX-174, by Duration of Glove Use

	Duration of Use (N=31)					
	0 Minutes		1–15 Minutes		≥15 Minutes	
Location of Leak	*n*	(%)	*n*	(%)	*n*	(%)
Fingers	4	(12.9)	4	(12.9)	7	(22.6)
Palm	1	(3.2)	6	(19.4)	7	(22.6)
Total	5	(16.1)	10	(32.3)	14	(45.2)

not fully tested. No data exist for or against phiX-174 inhibition by blood products or other used glove contaminants. Had phiX-174 been inhibited by a contaminant, the problem would have manifested itself in all samples of powdered and unpowdered gloves. Other studies use a penetration test that involves a liquid-filled glove suspended in liquid, whereas this study uses a liquid-glove-agar penetration test (13).

It was found that as the usage time of powder-free latex gloves increased, the chance for leakage also increased. The glove barrier may break down with use and time. Another important aspect of this study is that it looked at the effect of powder (cornstarch) on the penetration rates of gloves. Although our study was limited due to sample size and brand used, powdered latex gloves had less viral penetration than powder-free latex gloves. Perhaps phiX-174 adhered to the cornstarch molecule, thus allowing fewer viral particles to pass through the latex barrier. Further laboratory testing may be needed to confirm our results.

In contrast to our findings, another study using a solution-filled glove found no penetration through any powder-free gloves (13). This discrepancy may be because different brands of gloves were used, or that the testing method used liquid-filled gloves suspended in liquid. In another study, it was recommended that hospitals use only powder-free latex gloves because the powdered gloves promote disease by acting as a reactive foreign body in tissue and powder serves as a vector for latex allergen (14). Our findings suggest, however, that powder (cornstarch) may reduce the penetration of latex gloves by potentially pathogenic viruses. Further research may be needed to confirm these findings. Another study concluded that, "intact gloves act as effective barriers to the transmission of viral particles, including HIV in the health care setting" (15).

The small sample size, the inability to sample both sides of the glove, and a limited number of brands are the main limitations of this study. In future studies, a larger sample size may be needed to increase statistical power. Also, more comparisons of powder-free gloves with those that have been freshly powdered may yield more data is this area. This study provides some support for establishing more adequate standards and testing procedures for viral penetration of gloves (16).

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References

1. DeGroot-Kosolcharoen J, Jones JM. Permeability of latex and vinyl gloves to water and blood. Am J Infect Control 1989;17:196-201.
2. Korniewicz DM, Laughon BE, Cyr WH, Lytle D, Larson E. Leakage of virus through used vinyl and latex examination gloves. J Clin Microbiol 1990;28:787-8.
3. Korniewicz DM, Laughon BE, Butz A, Larson E. Integrity of vinyl and latex procedure gloves. Nurs Res 1989;38:144-6.
4. Rego A, Roley L. In-use barrier integrity of gloves: latex and nitrile superior to vinyl. Am J Infect Control 1999;27:405-10.
5. Food and Drug Administration. Medical glove guidance manual. Draft guidance—not for implementation. Rockville, MD: US Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health, Division of Small Manufacturers Assistance, Office of Health and Industry Probrams, 1999. Accessed Feb 1, 2001 at http://www.fda.gov/cdrh/dsma/gloveman/gloveman99.pdf.
6. American Society for Testing and Materials. Standard test for detection of holes in medical gloves—D 5151- 99. West Conshohocken, PA: American Society for Testing and Materials, 2001.
7. Centers for Disease Control and Prevention. Hepatitis B fact sheet. URL: www.cdc.gov/ncidod/diseases/hepatitis/b/fact.htm (accessed Feb 1, 2001).
8. Centers for Disease Control and Prevention. Hepatitis C fact sheet. URL: www.cdc.gov/ncidod/diseases/hepatitis/c/fact.htm (accessed Feb 1, 2001).
9. Centers for Disease Control and Prevention. HIV/AIDS surveillance report, 1998;10(2):1-43.
10. White D, Fenner F. Medical virology. 4th ed. San Diego, CA: Academic Press, 1994.
11. Lytle CD, Truscott W, Budacz AP, Venegas L, Routson LB, Cyr WH. Important factors for testing barrier methods with surrogate viruses. Appl Environ Microbiol 1991;57:2549-54.
12. Snustad DP, Dean DS. Genetics experiments with bacterial viruses. San Francisco, CA: W. H. Freeman and Co., 1971.
13. Edlich RF, Suber F, Neal JG, Jackson EM, Williams FM. Integrity of powder-free examination gloves to bacteriophage penetration. J Biomed Materials Res 1999;49:755-8.
14. Jackson EM, Arnette JA, Martin ML, Tahir WM, Frost-Arner L, Edlich RF. A global inventory of hospitals using powder-free gloves: a search for principled medical leadership. J Emergency Med 2000;18:241-6.
15. Zbitnew A, Greer K, Heise-Qualtiere J, Conly J. Vinyl verses latex gloves as barriers to transmission of viruses in the health care setting. J Acquired Immune Deficiency Syndrome 1989;2:201-4.
16. Klein RC, Party E, Gershey EL. Virus penetration of examination gloves. Biotechniques 1990;9:196-9.