ORIGINAL ARTICLE

Glove Leakage Rates as a Function of Latex Content and Brand

Caveat Emptor

Carlene A. Muto, MD, MS; Maria G. Sistrom, MSN; Barbara A. Strain, MA; Barry M. Farr, MD, MSc

Hypothesis: That water leakage rates and protection against blood-borne pathogens should not vary as a function of latex content among Food and Drug Administration–approved gloves, allowing avoidance of unnecessary latex exposure.

Design and Methods: Eighteen different glove types were purchased and tested using the American Society for Testing Methods Standard Test for Detecting Holes in medical gloves, which involves mounting the glove on a plastic tube, pouring a liter of tap water into the glove, and visually inspecting the glove initially and after 2 minutes. Half of the gloves were tested straight from the package and half after a standardized manipulation.

Setting: A university hospital.

Results: Eleven sterile glove types (5 high latex content, 4 low latex content, and 2 nonlatex content), and 7 nonsterile examination glove types (2 high latex content, 2 low latex content, and 3 nonlatex content) were tested (total tested, 3720 gloves). Leakage rates were greater for examination than for surgical gloves (relative risk [RR], 1.41, 95% confidence interval [CI], 1.01-1.96), for manipulated than for unused gloves (RR, 2.89, 5% CI, 1.98-4.22), and for low latex content surgical gloves (RR, 2.58, 95% CI, 1.35-4.92) or nonlatex content surgical gloves (RR, 4.93, 95% CI, 2.35-10.32) than for high latex content surgical gloves. Significant differences were observed among low latex content surgical gloves ($P \leq .001$) and all types of examination gloves ($P = .0015$) especially after the standardized manipulation (leakage rates ranging from 0%-30%).

Conclusions: Food and Drug Administration approval should not be interpreted as suggesting equality of different manufacturers' products. Some low latex and nonlatex content gloves are very resistant to leakage and should provide an effective barrier for preventing exposure to blood-borne pathogens, while others may not.

Arch Surg. 2000;135:982-985

From the University of Virginia Health System, Charlottesville.

In 1987 the Centers for Disease Control and Prevention issued guidelines for preventing spread of blood-borne pathogens using Universal Precautions, which included wearing gloves to prevent contact with human blood or body fluids.[1] The Departments of Labor, and of Health and Human Services issued a joint advisory notice 5 months later requiring implementation of these guidelines. The Occupational Safety and Health Administration Bloodborne Pathogens Standard became a federal regulation in 1991 continuing these requirements.[2]

Multiple studies of glove leakage rates were conducted with the advent of Universal Precautions to determine optimal gloves for use as barriers against blood-borne pathogens.[3-5] These studies showed that sterile surgical gloves were significantly less likely to leak than nonsterile examination gloves and that latex gloves were less likely to leak than vinyl gloves. Glove use increased from 1 billion pairs per year in the United States in 1987 to 10 billion pairs in 1996 with latex gloves accounting for a large majority of the increase.[6]

Between 1988 and 1992 there were more than 1000 reports to the Food and Drug Administration (FDA) of allergic reactions to latex-containing products that included 15 deaths.[7] Due to concern about the risk of allergic reactions and concern that the increased use of latex gloves could have resulted in increased rates of sensitization, the National Institute for Occupational Safety and Health published an alert in June 1997 recommending the use of nonlatex gloves for activities unlikely to involve contact with infectious materials, the use of powder-free latex gloves with reduced latex protein content if latex gloves were chosen for protection against potentially infectious materials, and of nonlatex gloves for patients or health care workers with latex allergy.[8]

As our hospital prepared to comply with the National Institute for Occupa-

METHODS

SETTING

The University of Virginia is a 600-bed teaching hospital with 31 nursing units, including 9 intensive care units. The hospital provides both primary and tertiary care, admitting 28 000 patients each year. In 1997 the hospital purchased over 15 million pairs of gloves at a cost of $921 151 ($86 491 for surgical gloves and $834 660 for examination gloves).

LATEX ENZYME-LINKED IMMUNOASSAY FOR ANTIGENIC PROTEIN (LEAP) AND MODIFIED-LOWRY ASSAYS

The American Society for Testing and Methods (ASTM) modified-Lowry assay has been used by glove manufacturers to determine total residual protein levels in gloves. This test is approved by the FDA.[9] Another protein quantification test considered to be more sensitive and specific for antigenic protein,[10] the Guthrie LEAP assay, has also been used. A high latex concentration has been defined in one publication as a LEAP value of 11 µg/g or higher or a modified-Lowry value higher than 50 µg/g.[11] Modified-Lowry and LEAP values provided by the manufacturers were used to categorize gloves as having high or low latex content for all but 2 of the brands tested in this study. Two brands were tested by Donald H. Beezhold, PhD, at the Guthrie Research Institute, Sayre, Pa.

STANDARD TEST FOR DETECTION OF HOLES

The ASTM Standard Test for Detection of Holes in Medical Gloves (ASTM D 5151-92)[12] was used to detect holes in gloves that compromised their usefulness as a barrier to blood as in previous studies.[4,5] Each glove was mounted on a 38-cm-long plastic tube with a 6-cm outer diameter and 5-cm inner diameter. One liter of tap water was poured into each glove followed by immediate visual inspection of the glove and then reinspection at 2 minutes. Half of the gloves were tested straight from the package. Because loss of barrier integrity has been correlated with duration of use, the other half of the gloves were tested after a standardized manipulation developed by Korniewicz et al.[3] This manipulation involved removing and reapplying a luerlock needle to a syringe 30 times, twisting a stopcock 8 times, connecting and reconnecting a luerlock stopcock to intravenous tubing 8 times, and wrapping, taping, and unwrapping an elastic bandage (Ace; Beckton Dickinson and Company, Franklin Lakes, NJ) on a blunt object 2 times wearing the test gloves. These activities were conducted wearing 2 gloves. All activities were divided equally among left- and right-hand gloves.

STATISTICAL METHODS

The frequency of leakage was compared for different types of gloves using χ^2 or a 2-tailed, Fisher's exact test as appropriate. Differences associated with a probability value $<.05$ were considered statistically significant.

Table 1. Leakage Rates for Sterile Surgical Gloves*

Glove Brand (Sterile), Manufacturer	Not Manipulated	Manipulated	Total
High latex			
Microtouch, Johnson and Johnson, Arlington, Tex	0/102 (0.0)	2/132 (1.5)	**2/234** (0.9)
Ultraderm, Baxter, Deerfield, Ill	0/110 (0.0)	2/102 (2.0)	**2/212** (0.9)
MicrOptic, Ansell Perry, Massillion, Ohio	1/100 (1.0)	0/100 (0.0)	**1/200** (0.5)
Custom dip, Ansell Perry	7/169 (4.0)	1/100 (1.0)	**8/269** (3.0)
Total	**8/481** (1.7)	**5/434** (1.2)	**13/915** (1.4)
Low Latex			
Eudermic, Maxxium Medical, Clearwater, Fla	5/100 (5.0)	10/100 (10.0)	**15/200** (7.5)
Bio-Gel, Regent Medical, Norcross, Ga	0/100 (0.0)	1/100 (1.0)	**1/200** (0.5)
Dextren, Maxxium Medical	0/92 (0.0)	1/100 (1.0)	**1/192** (0.5)
Ultrafree, Baxter	1/100 (1.0)	11/100 (11.0)	**12/200** (6.0)
Total	**6/392** (1.5)	**23/400** (5.8)	**29/792** (3.7)
Nonlatex			
Neolon Neoprene, Maxxium Medical	7/100 (7.0)	7/100 (7.0)	**14/200** (7.0)

**All values are expressed as number/total (percentage).*

tional Safety and Health alert, published data regarding leakage rates as a function of latex content were sought but not found by searching the MEDLINE database or by contacting officials at the Centers for Disease Control and Prevention, Atlanta, Ga. Because gloves are usually worn for infection control and because low latex content (hereafter, low latex) and nonlatex content (hereafter, nonlatex) gloves were significantly more expensive than high latex content (hereafter, high latex) gloves, it seemed important to know whether low latex and nonlatex gloves provided as much protection against blood-borne pathogens as high latex gloves, which had been the accepted infection control standard for a decade. Leakage rates of high latex, low latex, and nonlatex surgical and examination gloves were therefore assessed.

RESULTS

Eighteen different types of gloves were purchased and tested, 9 sterile surgical gloves (**Table 1**), 2 sterile procedure gloves (**Table 2**), and 7 nonsterile examination gloves (**Table 3**). The 11 types of sterile gloves tested included 5 high latex, 4 low latex, and 2 nonlatex. The 7 types of nonsterile examination gloves tested included 2 high latex, 2 low latex, and 3 nonlatex. In all 3720 gloves were tested.

The level of acceptable quality established by the FDA allows a glove leakage rate of 2.5% or less for surgical gloves and 4% or less for examination gloves[12] as determined using the ASTM Standard Test. Three of the 9 surgical gloves, neither of the 2 sterile procedure gloves, and 1 of the 7 nonsterile examination gloves exceeded these failure rates in testing straight from the package. Leakage rates were greater for manipulated vs unused gloves (relative risk [RR], 2.89, 95% confidence interval [CI],

Table 2. Leakage Rates for Sterile Procedure Gloves*

Glove Brand (Sterile), Manfacturer	Not Manipulated	Manipulated	Total
High latex			
Triflex, Baxter	1/104 (1.0)	1/102 (1.0)	**2/206** (1.0)
Nonlatex			
Sensicare (vinyl), Maxxium Medical	4/100 (4.0)	9/100 (9.0)	**13/200** (6.5)

**All values are expressed as number/total (percentage). See Table 1 for manufacturer information.*

Table 3. Leakage Rates for Nonsterile Examination Gloves*

Glove Brand (Examination), Manufacturer	Not Manipulated	Manipulated	Total
High latex			
X-AM, Ansell Perry	0/99 (0.0)	0/97 (0.0)	**0/196** (0.0)
Low latex			
Best Touch Vi B, Best, Menlo, Ga	0/93 (0.0)	14/97 (14.4)	**14/190** (7.4)
Derma-Clean X-AM (powder free), Ansell Perry	4/89 (4.5)	2/104 (1.9)	**6/193** (3.1)
Best Touch ViB (powder free)	1/100 (1.0)	2/118 (1.7)	**3/218** (1.4)
Total	**5/282** (1.8)	**18/319** (5.6)	**23/601** (3.8)
Nonlatex			
Sensicare (vinyl), Maxxium Medical	3/121 (2.5)	28/94 (29.8)	**31/215** (14.4)
N-Dex (nitrile), Best	1/94 (1.0)	3/101 (3.0)	**4/195** (2.0)
Featherweight (vinyl), Maxxium Medical	0/100 (0.0)	6/100 (6.0)	**6/200** (3.0)
Total	**4/315** (1.3)	**37/301** (12.3)	**41/610** (6.7)

**All values are expressed as number/total (percentage). See Table 1 for manufacturer information.*

1.98-4.22, $P<10^{-7}$ (Tables 1, 2, and 3). Examination gloves were significantly more likely to leak than surgical gloves (RR, 1.41, 95% CI, 1.01-1.96, $P=.05$)

High latex surgical gloves generally provided an excellent barrier as demonstrated a decade ago, but one brand was associated with a leakage rate of 4% prior to manipulation, which was significantly higher than leakage rates for the other 3 types of high latex surgical gloves tested (RR, 12.92, 95% CI, 1.60-104.16, $P=.003$). Significant differences were observed in leakage rates among 4 low latex surgical gloves, with 2 exhibiting satisfactorily low rates (0.5%) and 2 significantly higher rates (6.0%-7.5%) (RR, 13.23, 95% CI, 3.17-55.26, $P=7.3\times10^{-6}$). The low latex surgical gloves showed significantly higher leakage rates than the high latex surgical gloves (RR, 2.58, 95% CI, 1.35-4.92, $P=.0047$). Nonlatex surgical gloves tested were also associated with leakage rates that significantly exceeded those of high latex surgical gloves (RR, 4.93, 95% CI, 2.35-10.32, $P=.00005$). Nevertheless, some low latex surgical gloves were associated with acceptably low leakage rates (Table 1). A high latex, sterile procedure glove had a significantly lower leakage rate (1.0%) than did a vinyl sterile procedure glove (6.5%) (RR, 0.15, 95% CI, 0.03-0.65, $P=.0072$).

Examination gloves showed considerable variability in water leakage rates. One brand of high latex examination gloves tested provided excellent protection (0/196 [0%], 95% CI, 0%-1.86%). Among nonsterile examination gloves there were significant differences in overall leakage rates among high latex (0%), low latex (3.8%), and nonlatex gloves (6.7%) ($P=.0015$), which were largely because of even bigger differences after manipulation (high latex, 0%; low latex, 5.6%; and nonlatex gloves, 12.3% [$P=7.5\times10^{-5}$]). The worst performance was by a vinyl examination glove; 30% of which leaked after the standardized manipulation. Nevertheless, some low latex and nonlatex examination gloves exhibited satisfactorily low leakage rates (Table 3).

COMMENT

This study demonstrated superior quality of high latex gloves for preventing leaks as compared with low latex and nonlatex gloves currently on the market. Nevertheless some low latex surgical gloves and some low latex and nonlatex examination gloves performed in a satisfactory manner using the ASTM water leakage test. Overall 4 of 18 brands of gloves tested had leakage rates straight out of the package that exceeded the level of acceptable quality established by the FDA. While it is possible that high failure rates straight from the package could occasionally be due to a bad lot, the frequency of failures observed in this evaluation would suggest a disturbingly high frequency of bad lots. Perhaps more importantly, some gloves performed significantly worse than others after the standardized manipulation giving some idea of the frequency of failure during use, including 2 examination gloves that met FDA criteria straight from the package but showed leakage rates of 14% and 30% after the standardized manipulation, significantly exceeding the leakage rates of many other brands.

A more cumbersome test method assessing viral penetration of gloves has been studied and shown to correlate highly with the results of the water leakage test (97.4%-100% concordance for vinyl gloves and 100% for high latex gloves).[5] The authors of that study concluded that their approach was comparatively labor intensive and expensive, and that it was unlikely to be adopted for use as part of a manufacturing quality-control process.

Latex glove use significantly increased after the Centers for Disease Control and Prevention published guidelines to prevent transmission of blood-borne pathogens,[13] and the Occupational Safety and Health Administration implemented requirements that employers provide gloves for employees.[2] Changes in raw materials, processing, and/or manufacturing procedures to meet the increased demand for latex gloves may have resulted in production of more allergenic gloves.[14] These production changes may also have accounted in part for the 3000-fold variation in the concentration of extractable latex proteins reported among different brands of latex gloves.[10,15] Significant variation also could exist among different lots produced by the same manufacturer.

Allergen levels have been considerably lower in powder-free gloves as a result of the washing and chlorination steps involved in their production (**Table 4**). When patients with documented latex allergy were tested by skin-prick test, 68% tested positive to powdered latex gloves whereas only 11% of latex-allergic patients reacted with a positive skin test to low latex gloves (<0.2 μg/g by the LEAP assay).[16]

Table 4. Latex Protein Content of Selected Powdered and Powder-Free Latex Gloves*

Glove Type	Lowry Range, µg/g	Lowry Median, µg/g	LEAP† Range, µg/g	LEAP Median, µg/g
Powdered latex	<20-1039	191	<0.1-193	26
Powder-free latex	<20-108	33	<0.1-21	0.9

*Data are given adapted from Meyers and Beezhold.[16]
†LEAP indicates latex enzyme-linked immunoassay for antigenic protein.

Latex allergy in regularly exposed health care workers has been reported to range from 8% to 12% as compared with 1% to 6% in the general population.[8,17-20] While latex products are ubiquitous in modern households (eg, adhesive bandages, balloons, rubber bands, chewing gum, pencil erasers, diapers, and computer mouse pads), health care workers are considered to be at increased risk for developing latex allergy because of their frequent exposure to latex gloves. Most latex allergies have been manifested by irritant contact dermatitis and allergic contact dermatitis. Type 1 hypersensitivity reactions such as urticaria and anaphylaxis have occurred but much less frequently.

Food and Drug Administration approval should not be interpreted as suggesting equality of different manufacturers' products. While high latex gloves were associated with significantly lower leakage rates than the low latex and nonlatex brands tested, some nonlatex and low latex gloves were very resistant to leakage and should provide an effective barrier for preventing exposure to blood-borne pathogens. Lot to lot variation in leakage within individual brands was not assessed in this study and should be the subject of further investigation.

The authors wish to acknowledge Donald H. Beezhold, PhD, for determining the latex concentration of 2 brands of latex gloves.

Reprints: Barry M. Farr, MD, MSc, Box 473, University of Virginia Health System, Charlottesville, VA 22908 (e-mail: bmf@virginia.edu).

REFERENCES

1. Centers for Disease Control. Recommendations for prevention of HIV transmission health-care settings. *MMWR Morbid Mortal Wkly Rep.* 1987;36(suppl):1S-18S.
2. Occupational Safety and Health Administration. Occupational Exposure to Bloodborne pathogens: final rule, 29 *Federal Register* 1910.1030 (1991).
3. Korniewicz DM, Laughon BE, Cyr WH, Lyttle CD, Larson E. Leakage of virus through used vinyl and latex gloves. *J Clin Microbiol.* 1990;28:787-788.
4. Olsen RJ, Lynch P, Coyle MB, Cummings J, Bokete T, Stamm WE. Examination gloves as barriers to hand contamination in clinical practice. *JAMA.* 1993;270:353.
5. Kotilainen HR, Brinker JP, Avato JL, Gantz NM. Latex and vinyl examination gloves: quality control procedures and implications for health care workers. *Arch Intern Med.* 1989;149:2749-2753.
6. Edlich R. *Medicine's Deadly Dust.* Arlington, Va: Vandamere Press; 1997.
7. Tomazic VJ, Withrow TJ, Fisher BR, Dillard SF. Latex-associated allergies and anaphylactic reactions. *Clin Immunol Immunopathol.* 1992;64:89-97.
8. National Institute of Occupational Safety and Health. *NIOSH Alert: Preventing Allergic Reactions to Natural Rubber Latex in the Workplace.* Washington, DC: Dept of Health & Human Services (National Institute of Occupational Safety and Health); 1997. Publication 97-135.
9. Beezhold DH. Measurement of latex proteins by chemical and immunological methods: from latex protein allergy: the present position. Paper presented at: Proceedings of the International Conference by European Rubber Journal and Rubber Consultants; 1993; Amsterdam, the Netherlands.
10. Beezhold D. LEAP: latex ELISA for antigenic protein. *Guthrie J.* 1992;61:77-81.
11. Beezhold D. Determining the allergenic potential of latex gloves. *Surg Serv Manage.* 1997;3:35-41.
12. American Society for Testing Materials. Standard Test Method for Detection of Holes in Medical Gloves: D5151-92. In: *Annual Book of ASTM Standards.* Philadelphia, Pa; 1992:190.
13. Centers for Disease Control. Guidelines for prevention of transmission of human immunodeficiency virus and hepatitis B virus to health-care and public-safety workers. *MMWR Morbid Mortal Wkly Rep.* 1989;38(suppl 6):1-37.
14. Hunt L, Fransway A, Reed C, Miller L, Jones R, Swanson M. An epidemic of occupational allergy to latex involving health care workers. *J Occup Environl Med.* 1995;37:1204-1209.
15. Yunginger J, Jones R, Frasway A, Kelso J, Warner M, Hunt L. Extractable latex allergens and proteins in disposable medical gloves and other rubber products. *J Allergy Clin Immunol.* 1994;93:836-842.
16. Meyers K, Beezhold D. Latex allergy: how safe are your gloves? [editorial]. *Bull Am Coll Surg.* 1997;82:13-15.
17. Kelly KJ, Sussman G, Fink J. Stop the sensitization. *J Allergy Clin Immunol.* 1996; 98:857-858.
18. Katelaris C, Widmer R, Lazarus R. Prevalence of latex allergy in a dental school. *Med J Aust.* 1996;164:711-714.
19. Liss GM, Sussman GL, Desal K, et al. Latex allergy: epidemiological study of hospital workers. *Occup Environ Med.* 1999;54:335-342.
20. Sussman G, Beezhold D. Allergy to latex rubber. *Ann Intern Med.* 1995;122:43-46.

Invited Critique

Muto and associates present an elegant and simple study of water leakage rates as a function of latex content among FDA-approved sterile and nonsterile gloves. They demonstrated consistent superior performance of both high-latex surgical and examination gloves, and wide variability in water leakage rates of low-latex and nonlatex surgical gloves in both categories. The superiority of gloves with high latex content for protection from blood-borne pathogens would be the straightforward and indisputable conclusion from this study were it not for the increasing incidence of latex allergies among health care workers. This study unveils the variability of protection provided by FDA-approved low-latex and nonlatex surgical and examination gloves. Workers with latex allergies, and those wishing to avoid latex exposure, should choose carefully among the alternative low-latex and nonlatex gloves. Without this study, the choice among nonlatex and low-latex gloves, given their comparatively high costs, might otherwise be made on the basis of acquisition costs alone without regard for the protection afforded by individual gloves. Clearly, cost should not be the only consideration given to the purchase of these special products.

This study does not address how double gloving, a standard practice among surgeons, affects the water leakage rates observed. Whether individuals with latex allergies can effectively avoid latex exposure and optimize barrier protection by double gloving using low-latex or nonlatex gloves covered by a high-latex glove is also of interest. These questions will undoubtedly be addressed in future investigations of this subject.

This study by Muto and associates is of widespread importance to health care workers. Universal precautions are the standards of protection from blood-borne pathogens. However, many of us don surgical and examination gloves without considering the level of protection provided. This study adds an important dimension to our understanding of the protocol and its practical application.

Vernon J. Henderson, MD
Atlanta, Ga