

In-use barrier integrity of gloves: Latex and nitrile superior to vinyl

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Background: Although gloves manufactured with different materials have comparable barrier properties when removed directly from the box and tested, their actual on-the-job barrier performance may be extremely different. Although effective in static, pre-use conditions, barrier properties may be compromised once challenged by the rigorous hand and finger movements associated with many health care procedures. Gloves are meant to act as barriers, protecting persons by reducing the risk of exposure to bloodborne pathogens. Ineffective barriers or barriers that are easily breached during risk-associated procedures have the potential to place health care professionals at risk. Multiple studies attesting to the barrier attributes of vinyl and latex gloves during varied controlled clinical situations are available. Studies are available that address the permeation characteristics of nitrile, but no studies document the effectiveness of nitrile as a barrier to bloodborne pathogens or compare the barrier effectiveness of nitrile to gloves made of other materials during simulated use or clinical situations.

Objective: This study was undertaken to compare the barrier integrity of latex, vinyl, and nitrile gloves during controlled, simulated clinical use conditions that were specifically designed to mimic patient care activities. This study compares the performance of gloves made of natural rubber latex, long considered the gold standard; polyvinyl chloride (vinyl), a synthetic copolymer; and nitrile (acrylonitrile butadiene), a recently available synthetic for use in the health care environment.

Methods: A total of 2000 gloves (800 latex gloves, 800 vinyl gloves, and 400 nitrile gloves) were evaluated for baseline determinations in unused gloves and for failure rates after specific simulated use conditions. Potential bias was avoided through strict control of all actions and manipulations. Gloves were graded on a pass or fail system for leaks as defined by American Society for Testing and Materials D5151, *Standard Test Method for Detection of Holes in Medical Gloves*. To more fully characterize the gloves evaluated, individual products were also tested for physical dimensions (finger and palm thickness), powder levels, total protein (Modified Lowry), and antigenic protein (Latex ELISA [enzyme-linked immunosorbent assay] for Antigenic Proteins).

Results: With the exception of one vinyl glove brand with a 12% failure rate, no significant differences in failure rates were detected among the 3 types of gloves when tested directly out of the box with no manipulation. However, after manipulation intended to simulate in-use conditions, vinyl gloves failed 12% to 61% of the time. Latex and nitrile performed significantly better, with failure rates of only 0% to 4% and 1% to 3%, respectively. All latex gloves, with one exception, tested at less than 50 µg/g of total water extractable protein. The antigenic protein levels, with one exception, tested from less than 0.2 µg/g to 5.5 µg/g. The one latex product that fell outside these values had 154 µg/g of total protein and 105.7 µg/g of antigenic protein.

Conclusions: This study indicates that the latex and nitrile gloves evaluated were comparable in terms of barrier performance characteristics both unused and during manipulations mimicking patient care procedures. Whereas stretch vinyl exhibited lower failure rates than standard vinyl, the higher in-use leakage rates associated with all vinyl gloves tested indicate decreased durability and, potentially, compromised barrier protection when this synthetic is used. Careful consideration to the degree of barrier effectiveness should be given before glove selection when the potential exposure to bloodborne pathogens or biohazard risks is a concern. (AJIC Am J Infect Control 1999;27:405-10)

Glove use in the health care setting has risen dramatically since 1987, when the advent of AIDS and potential contact exposure to hepatitis strains and other bloodborne pathogens became a concern.¹ The introduction of Universal Precautions in 1989 and the subsequent introduction of the Bloodborne Pathogen ruling by the US Occupational Health and Safety Administration in 1991 heralded a significant increase in the use of personal pro-

TECTIVE equipment. The Occupational Health and Safety Administration estimated at this time that 4.9 million health care workers would be affected by this standard, and 200 deaths and 9000 infections would be prevented annually.² In 1995, 31,582 cases of hepatitis A, 10,805 cases of hepatitis B, and 4576 cases of hepatitis C were reported to the Centers for Disease Control and Prevention.³ The estimated number of annual acute infections is considerably higher, and potential exposure to these bloodborne pathogens is extremely high.

The barrier effectiveness and performance criteria of gloves and other protective devices used in occupations in which contact with contaminated blood or other bodily fluids is possible is a serious concern. Gloves must protect both health care professionals and patients from transmission of pathogens during use. Gloves must

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Table 1. Comparison of baseline and simulated use performance rates for latex, nitrile, standard vinyl, and "stretch" vinyl gloves

Code*	Material	Manufacturer/brand	Lot No.	BL		SU	
				Rate	Percent failure	Rate	Percent failure
A	Latex	Baxter Flexam Latex	PGE6A822	98/2	2	99/1	1
B	Latex	J&J Micro-Touch Latex	081627A	95/5	5	96/4	4
C	Latex	Safeskin Lightly Powdered Latex	T085349	100/0	0	98/2	2
D	Latex	Safeskin Powder Free Latex	6288-T24	99/1	1	100/0	0
Total tested				400		400	
E	Nitrile	Safeskin Powder Free Nitrile	29A6010C	97/3	3	99/1	1
F	Nitrile	THC Pure Advantage Nitrile	N125008	97/3	3	97/3	3
Total tested				200		200	
G	Vinyl	B-D Tru-Touch Vinyl†	No lot number	99/1	1	88/12	12
H	Vinyl	Maxxim SensiCare Vinyl†	63932N	97/3	3	80/20	20
I	Vinyl	Baxter Triflex Vinyl	N6H019	97/3	3	39/61	61
J	Vinyl	Medline Vinyl	B540017	88/12	12	74/26	26
Total tested				400		400	

BL, Baseline determination (out-of-box failures); SU, simulated use determination

*A: Baxter Healthcare Corporation, McGaw Park, Ill; B: Johnson & Johnson Medical Inc, New Brunswick, NJ; C: Safeskin Corporation, San Diego, Calif; D: Safeskin Corporation, San Diego, Calif; E: Safeskin Corporation, San Diego, Calif; F: Tillotson Healthcare Corporation, Bedford, NH; G: Becton Dickinson & Company, Franklin Lakes, NJ; H: Maxxim Medical Inc, Clearwater, Fla; I: Baxter Healthcare Corporation, McGaw Park, Ill; J: Medline Industries, Inc, Mundelein, Ill.

†Stretch vinyl.

Table 2. Simulated-use conditions applied to gloves in this study

Manipulation	Repetition
1. Attach and remove a capped needle to a Luer-Lok syringe	30 times
2. Connect and disconnect a Luer-Lok syringe to intravenous tubing	8 times
3. Manipulate a stopcock	8 times
4. Wrapping, taping, and unwrapping a blunt object (simulate bandaging and amputation stump)	2 times

maintain this protective 2-way barrier while providing the wearer tactile sensitivity, flexibility, comfort, and fit to ensure optimum on-the-job performance.

Whereas glove-associated irritation and type IV hypersensitivity have been reported since the 1930s, only sporadic reports of type I were noted through 1986.^{4,5} Currently, the increased frequency of reported incidences of type I immediate hypersensitivity associated with latex proteins has spawned an interest in the development of synthetic alternatives that exhibit barrier protection comparable to latex but without the accompanying latex proteins associated with type I hypersensitivity.

Latex has long been the glove material of choice in health care settings. However, persons with type I hypersensitivity to natural rubber latex must use latex-free alternatives and need to be aware of the potential for barrier-integrity limitations with the various synthetic material choices. Evaluation of glove durability is necessary before the use of any synthetic glove, especially in high-risk situations in which the potential for exposure to bloodborne pathogens exists.

MATERIALS AND METHODS

Gloves tested

A total of 2000 gloves of varying types (800 latex, 800 vinyl, and 400 nitrile) were obtained from multiple manufacturers. One hundred gloves of each brand were tested for baseline determinations and 100 for simulated use evaluation for a total of 200 gloves from each of 7 different manufacturers (2 latex, 4 vinyl, and 1 nitrile), with 3 glove types from one manufacturer (2 latex and 1 nitrile). All gloves were commercially purchased for this evaluation and used as received for the study. Gloves were designated code letters of A through J (Table 1). To limit potential observational bias, gloves were not identified as to the material type (vinyl, latex, or nitrile) during the study. Gloves were randomly evaluated to ensure nonbias, experimental design, and statistical considerations. Data was statistically evaluated by using χ^2 and the Fisher exact (2-tailed) tests.

Baseline determination of leaks

To establish a comparative baseline (control) for determination of leaks, 100 gloves of each brand and type were subjected to the standard test method for determining glove leaks, the 1000 mL water leak test.⁶ Gloves were taken directly from the original box or individual packages and tested immediately without further manipulation.

Simulated use determination of leaks

One hundred gloves of each brand and type were subjected to level III simulated use conditions designed to mimic the rigorous patient care activities published in

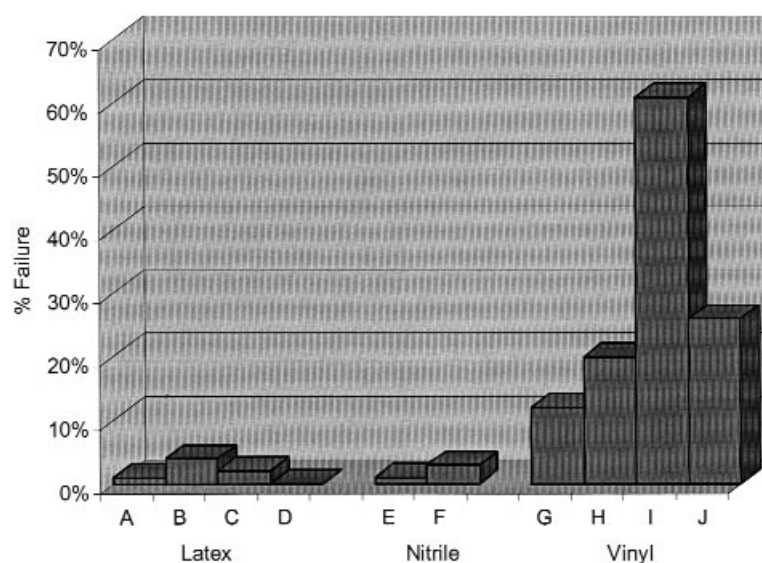


Fig 1. Comparison by product of simulated use failure rates for latex, nitrile, and vinyl gloves.

Table 3. Profile of gloves used in this study

Manufacturer/ brand	Material	Powdered	Finger thickness (mm)	Tensile (MPa)	Elongation (%)	Total powder (mg per glove)	Lowry (μg/g)	LEAP (μg/g)
Baxter Flexam	Latex	Yes	0.22	26.7	828	79.3	154	105.7
J&J Micro-Touch	Latex	Yes	0.21	26.6	871	89.9	<30	5.5
Safeskin Lightly Powdered	Latex	Yes	0.20	27.0	775	79.3	35	3.2
Safeskin Powder Free	Latex	No	0.20	21.0	759	1.9	<28	<0.2
Safeskin Powder Free	Nitrile	No	0.17	22.7	607	0.4	N/T	N/T
THC Pure Advantage	Nitrile	Yes	0.12	26.0	610	29.8	N/T	N/T
B-D Tru-Touch	Vinyl*	Yes	0.13	12.9	436	209.5	N/T	N/T
Maxxim SensiCare	Vinyl*	No	0.16	11.3	493	0.2	N/T	N/T
Baxter Triflex	Vinyl	Yes	0.12	12.0	357	33.1	N/T	N/T
Medline	Vinyl	Yes	0.25	8.8	411	41.0	N/T	N/T

N/T, Not tested.

*Stretch vinyl.

the Journal of Clinical Microbiology (1990).⁷ Manipulations took approximately 20 minutes to complete for each glove tested in simulated use (Table 2).

Size medium glove samples were subjected to each of the manipulations in the same chronologic order and in a single session. The glove simulated use regimens were performed by one person to avoid any potential bias in manipulation. This person wore no rings or nail polish, and all fingernails were filed short and smooth. All manipulations were performed with the right hand to avoid strength and manipulation differences between the left and right hand. To determine whether simulated use had an effect on the barrier material, failure rates were assessed by using the American Society for Testing and Materials (ASTM) D5151 1000 mL water leak test.⁶

Additional testing

Physical testing. A total of 24 gloves of each manufacturer's brand were used for physical testing (thickness and tensile strength) and powder levels (inside and out). Physical dimensions were determined by using ASTM D3578, Standard Specification for Rubber Examination Gloves. Thickness was based on single thickness measurements by using a dial micrometer. All tests for physical requirements were performed in accordance with ASTM D412, Standard Test Methods for Vulcanized Rubber and Thermoplastic Rubbers and Thermoplastic Elastomers-Tension.

Protein levels. No studies conducted have correlated the durability of gloves with reduced levels of latex pro-

Table 4. A comparison of barrier performance studies: vinyl versus latex versus nitrile gloves

Author	Date published	Results (%)		
		Vinyl	Latex	Nitrile
Historial data				
Korniewicz ¹¹	1989	53	3.3	—
Korniewicz ⁷	1990	63	7	—
Klein ¹⁶	1990	22*	<1*	—
		56†	<1†	
Olsen ¹⁷	1993	43	4.2-7.9	—
Douglas ¹²	1997	22-27‡ 25-32§	1.1	—
Current study				
Rego	1999	12-20‡ 26-61§	0-4	1-3

*No alcohol contact.

†Pretreatment with 70% alcohol.

‡Stretch vinyl.

§Standard vinyl.

||Latex powder-free.

teins. To determine whether manufacturing processes used to reduce protein levels can affect durability, 30 gloves were tested by Guthrie Research Institute, Sayre, Pa, for total⁸ and antigenic protein levels.⁹ Total protein levels were determined by ASTM D5712, *Standard Test Method for Analysis of Protein in Natural Rubber and its Products (Modified Lowry method)*. Antigenic protein was determined by the Guthrie LEAP Assay, an antibody-based enzyme-linked immunosorbent assay specific for immunogenic proteins in latex products.⁹

Powder levels. Determination of powder levels was made by using the gravimetric method as described by the US Food and Drug Administration.¹⁰

Results of the evaluation of physical properties, powder levels, and total and antigenic protein determinations are summarized by product in Table 3.

RESULTS

Out-of-box failure rates

Significant differences in failure rates (χ^2 , $P < .05$; Fisher exact (2-tailed), $P < .05$) were detected with 1 of the 4 vinyl brands tested (Fig 1). One of the two brands of stretch vinyl gloves exhibited a baseline failure rate of 12%.

Simulated use determination of leaks

After level III manipulations intended to simulate in-use conditions, the 2 brands of standard vinyl gloves tested exhibited significantly decreased durability (χ^2 , $P < .05$; Fisher exact (2-tailed), $P < .05$), with failure rates ranging from 26% to 61%. The 2 brands of stretch vinyl gloves tested exhibited failure rates ranging from 12% to 20%, indicating that stretch vinyl had increased durability when compared with standard vinyl but a high failure rate when compared with latex or nitrile.

The 4 brands of latex and 2 brands of nitrile tested performed significantly better than all vinyl gloves, with failure rates ranging from 0% to 4% and from 1% to 3%, respectively (Table 1). Although a difference was noted in the performance rates between standard and stretch vinyl, all vinyl gloves performed poorly. This increased glove failure rate among vinyl gloves is consistent with previous observations.^{7,11-13}

DISCUSSION

Multiple published studies evaluate the barrier properties of vinyl and latex gloves. To date no studies evaluate the performance of nitrile gloves. This study evaluates barrier characteristics of vinyl, latex, and nitrile before and after rigorous manipulations. Previous studies highlight the inferior durability of vinyl gloves during use. The current study supports this history but also defines the barrier characteristics of nitrile gloves. The current study and several previous studies are summarized in Table 4.

Physical characteristics of gloves

When choosing a glove for barrier protection, strength, durability, and glove thickness are primary factors to consider. Tensile strength, a measurement that reflects the amount of stretch or pull required to rupture the glove material, is measured in megapascals. Elongation, the length a glove material can be stretched before it breaks, is expressed as a percentage of the original length at the time the glove ruptures.

As a result of differences in the chemical composition and molecular structure, the minimal requirements for strength and durability for each of the glove materials differ, and the inequities are reflected in material-specific glove standards. The minimum ASTM glove standard durability requirements are summarized in Table 5.

The performance characteristics of gloves are based on the molecular composition and structure of the material from which they are manufactured. Latex gloves are manufactured by using expandable 1-4 poly-cis-isoprene particles obtained from the cytosol of the rubber tree *Hevea brasiliensis*. This natural product has a “coiled” molecular structure that allows for rigorous manipulation activities while maintaining integrity and supporting the return (or rebound) to the original shape.

Vinyl gloves are made of polyvinyl chloride. This synthetic polymer has a rigid, highly branched brittle molecular backbone that is easily broken. To facilitate the movement of these branches over each other and to provide a degree of flexibility, vinyl gloves must be compounded with large amounts of phthalates or other plasticizers at volumes of approximately 50% of the total compound.¹⁴ However, vinyl still lacks the ability to stretch when stressed or snagged, and readily fractures, tears, or separates at the molecular level resulting in barrier loss. The “stretch” vinyls use more or different forms of plasticizers but are unable to overcome the fracture weakness.

Nitrile gloves are generally manufactured from a synthetic polymer that exhibits rubberlike characteristics such as elasticity and tensile strength when vulcanized. Three major components are used in the production of nitrile gloves, each of which performs a unique role and contributes to the overall characteristics of the glove. Acrylonitrile provides permeation resistance characteristics. Butadiene contributes to the modulus of the glove, affecting elasticity, flexibility, and feel. The third major component, carboxylic acid, contributes to physical characteristics such as tensile strength and tear resistance.

Glove failure rate results in this study demonstrate that both nitrile and latex gloves are far less susceptible to material breakdown and leakage than vinyl during in-use conditions. There is a correlation between tensile strength, elongation, and durability. Vinyl gloves, with a required tensile strength almost 40% lower than latex, do not maintain durability under stresses of use conditions.

Allergy and barrier protection

With increased reports of allergic reactions to latex products and the corresponding concern that persons potentially may develop type I immediate type hypersensitivity, many health care facilities are turning to vinyl gloves for use in situations in which latex was previously used or highly recommended. This growing concern regarding the effects that glove-associated reactions may have on the health care provider is driving facilities to focus on vinyl as a less expensive synthetic alternative to latex. However, the repercussions from use of inappropriate glove materials that compro-

Table 5. Physical performance inequities for latex, nitrile, and vinyl gloves

	Latex	Nitrile	Vinyl
ASTM standard	D 3578	D 0000*	D 5250
Tensile strength	14 MPa	12.5 MPa	9 MPa
Elongation	700%	500%	300%
Finger thickness	0.08 mm	0.08 mm	0.05 mm

*Proposed standard.

mise barrier protection and place the end-user at risk are often not being considered.¹⁵

Latex gloves, manufactured to reduce the levels of extractable proteins and chemical sensitizers, maintained their barrier properties under the conditions of this study, which indicates that postcure processing does not have an effect on glove durability and supports the use of latex gloves with reduced levels of extractable proteins and chemicals as an appropriate barrier to bloodborne pathogens.

Use of vinyl gloves

Large differences exist among all the vinyl glove brands tested. Comparison of direct “out-of-the-box” testing with in-use testing provides some indication of durability. When tested directly out of the box with no manipulation, a new vinyl glove may pass the 1000 mL leak test, but degradation with use indicates that out-of-box studies are not predictive of barrier durability during in-use conditions. The Maxxim Medical SensiCare (Maxxim Medical Inc, Clearwater, Fla) and the B-D Tru-Touch (Becton Dickinson & Company, Franklin Lakes, NJ) brands, both stretch vinyl, and the Baxter standard vinyl examination gloves (Baxter Healthcare Corporation, McGaw Park, Ill) had low leakage rates when tested directly out of the box with no manipulation, but all degraded quickly during use. The Medline (Medline Industries, Inc, Mundelein, Ill) vinyl had a high failure rate when tested directly out of the box as well as after simulated use.

Whereas barrier integrity is a concern, nitrile would provide appropriate protection while affording the latex-sensitive person with a necessary synthetic alternative. Although stretch vinyl gloves performed better than the standard vinyl gloves tested in this study, their in-use barrier integrity was still far below that of nitrile or latex, which is consistent with a previous study in which the observed leakage rates of used gloves for the BD Sencare stretch vinyl was 24%.¹²

CONCLUSION

Previous studies exposed the weaknesses of vinyl gloves during use. The 61% in-use failure rate demonstrated in this study for standard vinyl gloves is consis-

tent with these previous studies. The barrier protection afforded by standard and "stretch" vinyl gloves is compromised more often during use (12% to 61%) than is either latex (with a failure rate ranging from 0% to 4%) or nitrile gloves (with a failure rate ranging from 1% to 3%). These data indicate that an equally effective non-latex glove alternative is nitrile, a synthetic polymer that exhibits rubberlike characteristics and barrier properties comparable with latex.

On the basis of the results of this study, nitrile and latex gloves provide better barrier protection than vinyl gloves. The barrier protection afforded by vinyl gloves is compromised more often during use than is either latex or nitrile. Whereas vinyl is an appropriate barrier for nonrigorous, low-risk procedures of short duration, nitrile or latex should be the glove of choice for high-risk situations, including exposure to bloodborne pathogens.

It should be emphasized that glove material selection should include the assessment of material durability during use, the rigorousness and duration of the procedures being performed, the potential of exposure to infectious microorganisms or other hazardous substances, and, ultimately, the safety of the user.

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