In-Use Barrier Performance Studies

Due to the differences in the material performance capabilities of glove materials, the American Society of Testing and Standards (ASTM), the International Organization for Standardization (ISO) and the European Committee for Standardization (CEN) have all developed physical performance requirements for medical gloves. It should be noted that requirements for vinyl gloves are consistently far below those for natural rubber latex.

Although such standards identify basic physical capability differences between glove material types and establish minimal acceptable standards, the real relevance to the healthcare professional is whether or not the glove is protective in use. Both simulated in-use studies and actual clinical studies have been performed to evaluate glove durability. NRL and vinyl have been the primary materials used in the medical glove industry and thus constitute the bulk of independent research testing to date. Data summaries of several studies are provided below.

Physical Barrier Performance Studies

Author	Date	Durability Challenge		Leakage Percentage Rates (a, b)		
		Simulated Use	Clinical Use	Vinyl	Latex (NRL)	Nitrile
Kerr[1]	2002	X		35.0 %	9.0 %	
Korniewicz[2]	2002	X		8.2 %	2.2 %	1.3 %
Rego[3]	1999	X		30.0 %(c)	2.0 %(f) 0.0 %(g)	2.0 %
Douglas[4]	1997		X	28.0 %(c)	10.0 %(f) 6.0 %(g)	-
Korniewicz[5]	1994	X		51.0 %	4.0 %	-
Korniewicz[6]	1993		X	85.0 %	18.0 %	-
Olsen[7]	1993		X	43.0 %	9.0 %	-
Merchant[8]	1992		X	83.0 %	35.0 %(f) 5.0 %(g)	-
Klein[9]	1990	X		22.0 %(d)	1.0 %(d)	-
				56.0 %(e)	1.0 %(e)	-
Korniewicz[10]	1990	X		63.0 %	7.0 %	-
Korniewicz[11]	1989	X		53.0 %	3.0 %	-

Footnotes

(a) All percentages were rounded to the nearest whole number
(b) When more than one brand of a particular material was evaluated, failure rates were averaged
(c) There did appear to be a difference in performance between standard and stretch vinyl
- Rego study: Standard vinyl exhibited failure rates ranging from 26-61%; stretch vinyl failed at 12-20%
- Douglas study: standard vinyl failed at 25-32%; stretch vinyl failed at 22-27%

(d) Without first contacting ethanol
(e) After contact with 70% ethanol
(f) Powdered latex
(g) Powder-free latex

In-Use Barrier Performance Studies

Summaries of Individual Studies

1. Kerr LN, Boivin WS, Chaput MP, et al. 2002 Sep. The Effect of Simulated Clinical Use on Vinyl and Latex Exam Glove Durability. Journal of Testing and Evaluation 30(5): 415-420.

A 12 minute simulated use study was performed on 100 vinyl and 100 latex gloves by ten analysts after which leak rates were determined. Failure rates: 35% vinyl, 9% latex.

2. Korniewicz DM, El-Masri M, Broyles JM, et al. 2002 Apr. Performance of Latex and Nonlatex Medical Examination Gloves during Simulated Use. American Journal of Infection Control, 30(2): 133-8.

1,988 vinyl, 1,006 vinyl/copolymer (base material is vinyl), 1,052 latex and 1,464 nitrile gloves were worn during a simulated use study. Failure rates: 8.2% vinyl and vinyl/copolymer, 2.2% latex and 1.3% nitrile.

3. Rego A, Roley L. 1999 Oct. In-Use Barrier Integrity of Gloves: Latex and Nitrile Superior to Vinyl. American Journal of Infection Control 27(5): 405-410.

400 vinyl, 300 powdered latex, 100 powder-free latex and 200 nitrile gloves were evaluated for leaks after simulated use activities. Failure rates: 29.8% vinyl, 2.3% powdered latex, 0% powder-free latex, 2% nitrile.

4. Douglas A, Simon R, Goddard M. 1997. Barrier Durability of Latex and Vinyl Medical Gloves in Clinical Settings. American Industrial Hygiene Association Journal 58: 672-676.

This was a Canadian multi-hospital clinical use study. 816 non-sterile vinyl, 640 powdered latex and 674 powder-free latex gloves were evaluated after use in various departments of the hospitals. Failure rates: 28% vinyl, 10.2% powdered latex, 5.9% powder-free latex.

5. Korniewicz D, Kirwin M, Cresci K, Tian Sing S, Tay Eng Choo J, Wool M, Larson E. 1994. Barrier Protection with Examination Gloves: Double Versus Single. APIC, American Journal Infection Control 22: 12-15.

This study was designed to evaluate single vs. double glove usage of vinyl and latex exam gloves. 385 vinyl (199 single & 186 double) and 501 latex (290 single & 211 double) were subjected to simulated in-use activities designed to mimic patient care activities. Failure rates: 51.3% single vinyl, 19.7% double vinyl, 4.1% single latex and 3.8% double latex.

6. Korniewicz D, Kirwin M, Cresci K, Larson E. 1993 Jan. Leakage of Latex and Vinyl Exam Gloves in High and Low Risk Clinical Settings. Am Ind Hyg Assoc Journal 54(1): 22-26.

4,838 latex and 1,008 vinyl gloves were collected after hospital use, filled with 1,000 mL of water and observed for leaks. Failure rates: 85.3% vinyl, 18.4% latex.

7. Olsen R, Lynch P, Coyle M, Cummings J, Bokete T, Stamm W. 1993 Jul 21. Examination Gloves as Barriers to Hand Contamination in Clinical Practice. JAMA 270(3): 350-353.

This study evaluated the hands of health care professionals and glove leakage rates after use in routine hospital procedures in which exposure to large numbers of pathogenic organisms was anticipated. Procedures included the care of endotracheal tubes, oral examinations and digital rectal stimulation. Microbial examination of health care professionals' hands revealed 11% gram negative microbial contamination with vinyl glove use compared to 2.3% with latex. Similarly, glove leaks were discovered in 42.6% of the post-use vinyl gloves and 8.6% of the latex gloves. Participants reported awareness of the presence of leaks in only 22% of the 32 events in which leaks were later demonstrated.

8. Merchant V, Molinari J, Pickett T. 1992 Apr. Microbial Penetration of Gloves Following Usage in Routine Dental Procedures. American Journal of Dentistry 5(2): 95-96.

24 vinyl, 40 powdered latex and 40 powder-free latex gloves were worn throughout a variety of dental procedures. Gloves were then evaluated for leaks. Failure rates: 83.3% vinyl, 35% powdered latex and 7.5% powder-free latex.

9. Klein R, Party E, Gershey E. 1990 Aug. Virus Penetration of Examination Gloves. BioTechniques 9(2): 196-199.

In addition to being ineffective barriers, this study found vinyl (polyvinyl chloride – PVC) and polyethylene (PE) gloves were not compatible with alcohol. Failure rates: 22% for PVC and 44% for PE rose to 56% and 94% respectively after contact with 70% ethanol. Only 0.8% of the latex gloves (1 out of 130) failed both prior to and after contact with alcohol.

10. Korniewicz D, Laughon B, Cyr WH, Lytle CD, Larson E. 1990 Apr. Leakage of Virus through Used Vinyl and Latex Examination Gloves. Journal of Clinical Microbiology 28(4): 787-788.

This study inflicted stress on 240 vinyl and 240 latex examination gloves by using manipulations designed to mimic four levels of patient care. Viral leak assays utilizing the virus PhiX174 demonstrated failure rates of 63% vinyl and 7% latex.

11. Korniewicz D, Laughon B, Butz A, Larson E. 1989 May/Jun. Integrity of Vinyl and Latex Procedure Gloves. Nursing Research 38(3) 144-146.

315 vinyl and 330 latex gloves were subjected to a series of manipulations designed to simulate approximately 15 minutes of clinical activity in an intensive care unit at John Hopkins University. Before removing the gloves, clinicians immersed their hands in liquid containing cultured Serratia marcescens. Their hands were then cultured to determine if the organisms passed through the used gloves. A statistically significant difference was demonstrated. Failure rates: 53% vinyl, 3% latex.

Glove Durability Needs Assessment

Durability Catagory	Criteria: Consider Each One Seperately	Examples	Glove Selection
Low	• No risk of infection • Only patient contact is intact skin • Chemicals contacted are not harmful and do not breakdown the glove material • Low levels of twisting, abrasion, or other glove stress • Short-term use	• Food handling • Dispensing general medications • Transporting patients • Routine oral care • Non-invasive general physical examinations • Specimen container transport	• Vinyl • Gloves of higher calibre may also be selected (e.g. nitrile, latex)
Moderate	• Twisting, torquing, abrasion, snagging • No emersion in potentially harmful chemicals • Risk of cross-infection	• Wound care • General surgery • Vaginal and C-section deliveries • Sigmoidoscopy • Rectal exams • Ostomy care • Staple removal • Changing infectious incontinent patients • Catheter insertion • Handling liquid sterilants and harsh disinfectants	• Natural Rubber Latex (NRL) • Nitrile • Tactylon® • Neoprene • Polyurethane • Ask manufacturer for information regarding resistance to specific chemicals when contact is anticipated
High	• Greater than normal physical or chemical challenges • High risk of infection or highly lethal communicable disease • If procedures are extremely long • Chemotherapy procedures • Contact with sharps, wires, bone fragments, etc.	• Orthopedic and thoracic surgical cases • Bone marrow biopsies requiring a high degree of rigorous hand manipulation • Contact with bone fragments, wires, sharp objects • Preparing and administering chemotherapeutic agents	• Identified on the label as: - Ortho, Orthopedic, - Chemo, Chemotherapeutic. • X-ray gloves • Hazardous chemical handling gloves • Can be: - NRL - Nitrile - Neoprene - Tactylon® - Others may qualify Ask manufacturer for appropriate test data and/or FDA clearance at this level

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