Position Paper

Vinyl Gloves: Facts you should know

Background

Polyvinyl Chloride (PVC) gloves, more commonly known as vinyl exam gloves, are sometimes provided by hospitals as a less expensive choice for examination gloves.

While hospitals sometimes want gloves with a synthetic origin to avoid concerns about the risk of natural rubber latex (NRL) allergy, vinyl gloves have several elements that limit their performances in terms of protection and safety. Therefore, vinyl gloves should not be used in all situations due to the potential risk they can present for patients and healthcare workers.

The objective of this paper is to review these limitations in the light of recent studies and publications in order to provide guidance and risk assessment to support end users and purchasing decision makers.

Classification of Examination and Surgeon Gloves

In the 1980s, the Food and Drug Administration (FDA) classified surgeon and patient examination gloves into Class I. At the time of classification, patient examination gloves were exempt from pre-market notification and certain requirements of the Good Manufacturing Process (GMP) regulation. Following the emergence of AIDS as a major public health concern, the FDA needed greater assurance that cross-contamination be prevented between healthcare workers and patients. The FDA subsequently revoked the exemptions for patient examination gloves in order to obtain more information about gloves before they were marketed and to ensure that manufacturers complied with appropriate manufacturing practices. Thus, both surgeon gloves and patient examination gloves must comply with all FDA pre-market notification and GMP requirements.

ASTM

The American Society of Testing and Materials organized in 1898. The ASTM is a not-for-profit organization that provides a forum for the development and publication of voluntary consensus standards for materials, products, systems and services in various industries. The FDA adopted and enforces the examination glove standards and specifications developed by the ASTM.

Strength & Elongation Standards

The ASTM developed specific glove standards based on tensile strength and elongation performance specifications. The ASTM states how well the exam glove can stretch by measuring tensile strength and elongation.

- Tensile Strength is a measure of how much force is required to break the glove. Defined as the "load on specimen glove when it breaks divided by the cross section of the area." Stated in lbs/square inch (psi). This is a measurement of how strong a glove is when stretched. The heavier the weight used to break the cross-sectional area, the stronger the glove is. Tensile strength is an important measure of barrier protection, in that a glove that breaks easily does not provide effective barrier protection.

Ansell follows stringent ASTM and FDA standards in the design of every glove.

KEY POINT

- Elongation is a measure of how far a glove film can stretch before it breaks. A material's elongation limit is quantified as the percentage of its length the material can be stretched without breaking. For example, an elongation of 500% means the material can be stretched 5 times its original length before breaking. Elongation can be considered another measure of barrier protection, because gloves are routinely stretched during donning and use, and they must withstand this stretching without breaking.

The longer a medical glove can stretch/elongate generally the better the protection. Latex, nitrile and vinyl have different strength and elongation criteria which demonstrate how different they are from each other.

Table 1 for ASTM exam performance requirements

	Latex	Nitrile	Vinyl
Tensile Strength	18MPa	14MPa	11MPa
Elongation	650%	500%	300%
AQL Holes	2.5	2.5	2.5

AQL Standard

Acceptable Quality Level is a quality specification that the FDA and the manufacturers use to specify the pinhole rate in surgical and exam gloves. The FDA specifies an AQL of 2.5 for exam gloves. AQL 2.5 means the defect level from a very large numbers of gloves out of the box (e.g. one million pieces) will not be more than 2.5%.

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Vinyl Gloves and Barrier Integrity

Medical gloves must provide a continuous and durable layer of material between the clinician's hand and the patient's bodily fluids or tissue specimens. This layer should be flexible, free from holes, breaches and cracks, and strong enough to prevent breakage during normal use. When selecting a medical glove, an important consideration should be the barrier requirement related to the procedure or task at hand. Be aware of the level of exposure risk that the patient-care activities will require. Procedures that involve exposure to hazardous chemicals, blood, bodily fluids, and other potentially infectious material require a glove material that provides appropriate barrier protection. While there is little difference in the barrier properties of unused intact gloves, studies have shown repeatedly that vinyl gloves have higher failure rates than latex or nitrile gloves when tested under simulated and actual clinical conditions. For this reason either latex or nitrile gloves are preferable for clinical procedures that require manual dexterity and/or will involve more than brief patient contact[28]. The failure of an exam glove depends on gloving material and stress placed on the glove during patient care activities.

PVC is a petroleum-based film which is not molecularly cross-linked, in contrast to NRL or other types of synthetic latex such as nitrile. Because of this lack of cross-linking, the individual molecules of vinyl tend to separate when the film is stretched or flexed. This relative weakness of the vinyl film means that manufactured vinyl medical gloves do not have comparable resistance to stretch and elongation than that offered by NRL or nitrile gloves. **This is reflected in the ASTM Standards Table 1.** This specifies a minimal force at break before ageing for vinyl gloves at a level significantly lower than for natural rubber and nitrile gloves. This difference is not known by many healthcare workers who believe that vinyl examination medical gloves offer the same features as those made of NRL and nitrile.

The lower resistance of vinyl, due to the lack of cross-linking, may cause small holes and breaches to form during use or make the gloves liable to puncture and tear easily on extension. In addition, vinyl does not return to its original shape after stretching, which means that glove fingers sag and can easily get caught. Furthermore, due to the lack of elasticity, vinyl gloves have baggy cuffs, compromising barrier integrity.

Many studies have been published during the past 20 years (1989-2007) that have clearly shown the inferior barrier integrity and shorter durability of vinyl gloves by comparison with natural rubber latex gloves or nitrile gloves. These poorer features of vinyl gloves were shown whether the gloves were tested under simulated conditions or clinical conditions[1-5], as well as in situations involving double-donning[6].

Natural rubber latex and nitrile gloves offer greater barrier protection than vinyl.

KEY POINT

Other publications have also highlighted the greater permeability of vinyl gloves to bacteria and virus than natural rubber latex or nitrile gloves during use[7-12]. Such permeability increases the risk of cross-contamination for both patients and healthcare workers.

Data from these studies on leakage of vinyl gloves compared with natural rubber latex are summarized in Table 2. In each study, vinyl gloves demonstrated a barrier performance significantly lower than that of natural rubber latex gloves.

Barrier Performance Studies

Vinyl gloves have, in general, a poor resistance to many chemicals, including glutaraldehyde based products[13] and alcohols used in formulation of disinfectants for swabbing down work surfaces or in hand rubs, which use has recently expanded greatly with the implementation of best practice recommendations for hand hygiene[14]. Vinyl gloves, compared with other types, have also been shown to be the most permeable to antineoplastic cytotoxic drugs[15-17]. Therefore, they are not recommended for any use in relation to chemotherapy.

Table 1: Barrier Performance Studies

Author (Reference)	Date of Publication	Type of Use		Leakage Rate (*)		Leakage Ratio (*)	Specific Conditions
		Simulated	Clinical	Vinyl	NR Latex		
Korniewicz[1]	1989	X		53%	3%	18	
Korniewicz[2]	1990	X		63%	7%	9	
Klein[14]	1990	X		22% 56%	1% 1%	22 56	Without contact with Ethanol After contact with Ethanol 70%
Korniewicz[3]	1993		X	85%	18%	5	
Olsen[4]	1993		X	43%	9%	5	
Korniewicz[5]	1994		X	51% 20%	4% 4%	13 5	Single gloving Double gloving
Douglas[7]	1997		X	26%	8%	3	Standard Vinyl: 25% to 32% Stretch Vinyl: 22% to 27%
Rego[8]	1999	X		30%	2%	15	Standard Vinyl: 26% to 61% Stretch Vinyl: 12% to 20%
Korniewicz[9]	2002	X		8%	2%	4	
Kerr[10]	2004	X		33%	10%	3	

Vinyl Gloves and Comfort

Vinyl is less flexible and elastic than latex, resulting in vinyl gloves not fitting well and becoming uncomfortable during prolonged use. In addition, sensitivity is reduced and some studies have shown that tactile sensitivity of vinyl is appreciably lower than natural rubber latex gloves[18].

Because of the reduced flexibility and sensitivity, several guidelines recommend either latex or nitrile gloves for clinical care and procedures that require manual dexterity and/or that involve patient contact for more than a brief period[19-21].

Vinyl Gloves and Allergic Reactions

Several publications have highlighted cases of skin reactions due to chemical additives used in the manufacturing process of vinyl gloves:

- Bisphenol A, which is used as an antioxidant in PVC plastics and as an inhibitor of end polymerization in PVC, has been identified as a cause of some cases of allergic contact dermatitis[(22,23)].
- Exacerbation of hand dermatitis while using PVC gloves was noted in 8 patients who were allergic to benzisothiazolinone, a biocide widely used in the manufacture of disposable PVC gloves[24].

In Finland, benzisothiazolinone in powder-free PVC gloves caused a small epidemic of allergic contact dermatitis in dental personnel and other healthcare workers, and 1/3 of disposable PVC gloves marketed in Finland contained some benzisothiazolinone[25].

Other studies identified additional chemical agents, such as an adipic polyester[26], propylene glycol compound and ethylhexylmaleate[27], as a cause of allergic contact dermatitis in vinyl gloves.

Conclusion

The failure of an exam glove depends on gloving material and stress placed on the glove during patient care activities. Vinyl gloves raise several issues in terms of protection for end users and patients.

- Vinyl medical gloves do not have comparable resistance to stretch and elongation than that offered by NRL or nitrile gloves
- More holes occur in vinyl gloves than other gloves during routine use
- Higher permeation of bacteria and virus in vinyl gloves
- Poor resistance to many chemicals and highest permeation of cytotoxic drugs
- Vinyl gloves do not fit well as they are less flexible and elastic

Use of vinyl gloves in any healthcare setting should be properly assessed and not offered as the only choice.

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