Ann. Occup. Hyg., Vol. 56, No. 4, pp. 450–457, 2012
Published by Oxford University Press
on behalf of the British Occupational Hygiene Society [2011]
doi:10.1093/annhyg/mer116

Tensile Properties and Integrity of Clean Room and Low-Modulus Disposable Nitrile Gloves: A Comparison of Two Dissimilar Glove Types

ROBERT N. PHALEN[1]* and WENG KEE WONG[2]

[1]*Department of Health Science and Human Ecology, California State University San Bernardino, 5500 University Parkway, San Bernardino, CA 92407-2397, USA;* [2]*Department of Biostatistics, UCLA School of Public Health, University of California, Los Angeles, Los Angeles, CA 90095, USA*

Received 23 August 2011; in final form 11 November 2011; published online 26 December 2011

Background: The selection of disposable nitrile exam gloves is complicated by (i) the availability of several types or formulations, (ii) product variability, and (iii) an inability of common quality control tests to detect small holes in the fingers. Differences in polymer formulation (e.g. filler and plasticizer/oil content) and tensile properties are expected to account for much of the observed variability in performance.

Objectives: This study evaluated the tensile properties and integrity (leak failure rates) of two glove choices assumed to contain different amounts of plasticizers/oils. The primary aims were to determine if the tensile properties and integrity differed and if associations existed among these factors. Additional physical and chemical properties were evaluated.

Methods: Six clean room and five low-modulus products were evaluated using the American Society for Testing and Materials Method D412 and a modified water-leak test to detect holes capable of passing a virus or chemical agent.

Results: Significant differences in the leak failure rates and tensile properties existed between the two glove types ($P \leq 0.05$). The clean room gloves were about three times more likely to have leak failures (chi-square; $P = 0.001$). No correlation was observed between leak failures and tensile properties. Solvent extract, an indication of added plasticizer/oil, was not associated with leak failures. However, gloves with a maximum modulus <4 MPa or area density (AD) <11 g cm^{-2} were about four times less likely to leak.

Conclusions: On average, the low-modulus gloves were a better choice for protection against aqueous chemical or biological penetration. The observed variability between glove products indicated that glove selection cannot rely solely on glove type or manufacturer labeling. Measures of modulus and AD may aid in the selection process, in contrast with common measures of tensile strength and elongation at break.

Keywords: chemical protective clothing; exam gloves; penetration; PPE; water-leak test

INTRODUCTION

The selection of disposable nitrile exam gloves can be a complicated matter and one not well supported by current consensus standards. Much of this is due to product variability and a lack of available manufacturing standards or certifications that address critical issues such as polymer, filler, and plasticizer content. In addition, several types or classes of gloves are available, such as accelerator free, controlled environment (i.e. clean room), general duty, industrial, low modulus, and medical grade. Potential certification of gloves, similar to what exists for respiratory protection devices, for protection against chemical and biological agents would likely require careful considerations of product formulation.

*Author to whom correspondence should be addressed.
Tel: +1-909-537-5393; fax: +909-537-7037;
e-mail: phalen@csusb.edu

A recent study showing the disparities in physical integrity of disposable nitrile gloves indicated that polymer formulations vary significantly among manufacturers and glove types (Phalen and Wong, 2011). A number of additional glove integrity and composition studies also support this notion that nitrile glove formulations are variable among similar brands or types (Zinner, 1994; Muto *et al.*, 2000; Phalen *et al.*, 2007; Phalen and Que Hee, 2008). In light of the current consensus standards for these products, product variability complicates the glove selection process, especially when protection against biological or chemical agents is critical.

Within the healthcare setting, the National Fire Protection Agency (NFPA) and various consensus standards provide guidance on the proper selection of emergency medical examination gloves (Edlich *et al.*, 2004, 2005). However, product formulation and variability are not addressed in these standards. This is further complicated by indications that the existing 1-l water-leak test for watertightness, which is a basis of many standards such as American Society for Testing and Materials (ASTM) D 5151, EN 455-1, and NFPA 1999, does not adequately detect small holes in the fingers and thumb that could pass a virus (Kotilainen *et al.*, 1992; Phalen and Wong, 2011). The ASTM has a test method for evaluating viral penetration (ASTM International, 2007), ASTM F 1671, which is also used in the NFPA 1999 Standard (NFPA, 2008), but it is not designed for post-production quality control and quality assurance testing. Only a limited number of gloves can be tested using this method. Current consensus standards do not address the above-mentioned disparities regarding product variability.

Differences in plasticizer content, especially waxy hydrocarbons and oils, among glove brands or types are expected to account for a portion of the observed variability in glove integrity (Phalen and Wong, 2011). Added non-polar and hydrophobic plasticizers are likely to repel water and result in a favorable water resistance, which would help protect users from aqueous solutions and biological fluids. Conversely, the absence of plasticizers is expected to produce a stiffer and less hydrophobic polymer, which may be more prone to leakage and affected by movement or stretching of the material. Current manufacturing standards and certifications do not address plasticizer content nor is there sufficient data to support this notion.

This study evaluated the tensile properties and physical integrity of two different disposable nitrile glove choices, most likely to have different amounts of plasticizers/oils. First, clean room gloves make up a class of gloves that must minimize surface residues. Therefore, it is less likely that clean room gloves would contain significant amounts of oil or plasticizer, which could contaminate surfaces within a controlled environment. In contrast, low-modulus gloves are expected to have a higher amount of plasticizer, which is used to reduce tensile strength and modulus. Low-modulus implies a lower ratio of stress to applied strain, thus the polymer stretches easier with less resistance.

The primary aims were to determine if the tensile properties and integrity differed and if associations existed among these factors. In addition, a solvent extraction of free hydrocarbons and oils was performed to determine if this was associated with improved water resistance. This information will aid in our understanding of the role of polymer formulation and properties in barrier protection, as well as help in the glove selection process for protection against aqueous chemical and biological agents.

MATERIALS AND METHODS

Gloves

Six clean room and five low-modulus disposable nitrile glove products were evaluated. All gloves were medium size with a reported palm thickness of 4–5 mil. Table 1 provides the glove manufacturer/brand, number of gloves tested, and glove type. From a previous study (Phalen and Wong, 2011), half of the gloves were exposed to simulated movement for 2 h prior to water-leak testing. However, there was no significant effect of movement on glove integrity ($P > 0.05$). Movement was not evaluated in this study. A total of 2360 gloves were tested.

Area density

Thickness and density data were used to calculate the mass-to-area ratio (grams per square centimeter), termed area density (AD), a variable more closely associated with glove performance when thicknesses are similar (Phalen *et al.*, 2007). Glove thickness and density were measured using a previously described method (Phalen *et al.*, 2007). Prior to analysis, glove samples were conditioned overnight at 51 ± 4% relative humidity (RH) and 21.1 ± 0.5°C.

Tensile testing

Tensile strength (units of megapascal) and percent elongation at break were measured using the ASTM Method D 412 *Standardized Test Methods for Vulcanized Rubber and Thermoplastic Elastomers—Tension* (ASTM International, 2002). A specialized die (W.R. Sharples, North Attleboro, MA, USA) was used

Table 1. Glove brand, number of gloves tested, and type (label claim).

Glove ID	Manufacturer/brand	Number of gloves tested	Type
1	Ansell Nitrilite® (low filler)	320	C
2	Best® Clean-Dex®	320	C
3	Cardinal Health Esteem® Tru-Blu™ Stretchy	160	L
4	High Five® Cobalt®	160	L
5	High Five® Softwear™	160	L
6	Kimberly Clark Kimtech G5	160	C
7	Microflex® CE4 System	160	C
8	Microflex® Ultrasense™	180[a]	L
9	North® Chem Soft CE™	340[a]	C[b]
10	Prima Pro Gentle Guard	240	L
11	QRP® Q095 Qualatrile™ XC (low filler)	160	C

C, clean room; L, low-modulus.
[a]These gloves were used to establish the feasibility of the modified water-leak test and sampling protocol. The initial sample sizes were $n = 100$.
[b]The glove was also a reported low-modulus product but treated as a clean room glove because the likelihood of excess non-polar plasticizers was low.

to collect 1.27 cm by 7.62 cm samples from the gloves. For each glove product, 20 vertical and 20 horizontal swatches were cut from the palm region to account for the effects of bidirectional stretching and polymer grain direction. All samples were conditioned for at least 24 h at 51 ± 4% RH and 21.1 ± 0.5°C. Tensile testing was conducted using an ADMET (Norwood, MA, USA) eXpert 7601 tensiometer with 1-kN vice grips. From the tensile test data, the elastic modulus between 50 and 100% elongation (hereby termed modulus 50–100%) and the maximum modulus were also calculated for each sample. Elastic modulus is a measure of stress (in megapascal) versus strain (percent elongation) and is defined as the slope of the stress–strain curve in the elastic region (Askeland and Phulé, 2006). It is a measure of the stiffness or resistance to stretching of an elastic material. It is probable that modulus may be a better indicator of polymer performance than tensile strength. The modulus 50–100% represents the stress versus strain more closely related to normal use conditions (i.e. hand movement), whereas tensile strength, maximum modulus, and elongation at break are measures associated with extreme conditions (near or at complete material failure) well beyond normal use.

Glove integrity

A previously described modified water-leak test (Fig. 1) was used to detect small holes capable of passing a virus (Phalen and Wong, 2011). The standardized method was developed to reliably detect a 0.15 ± 0.05 mm hole (crescent-shaped) in the finger, thumb, and palm regions.

The water volumes used to test gloves for defects/leaks ranged from 1 to 2 l. The low-modulus gloves required no added water to detect known holes; whereas 50% of the clean room gloves required additional water. These results indicated that disparities in glove formulation/properties existed between the two glove types and even among individual clean room products.

The sampling protocol for water-leak testing was performed using the U.S. Food and Drug Agency (U.S. FDA) guidance on *Patient examination gloves and surgeons' gloves; sample plans and test method for leakage defects; adulteration* (21 CFR 800.20) (U.S. FDA, 2000). An adulteration level of 4.0 was used to detect defective gloves on a pass or fail basis. The newer adulteration level of 2.5 was not used because some gloves were manufactured prior to the change and the larger sample sizes were prohibitive.

Solvent extract

A modified solvent extraction was performed consistent with the guidelines provided by ASTM Method D 297 *Standard Test Methods for Rubber Products—Chemical Analysis* (ASTM International, 2006). A 0.1 g sample was cut from the palm and dried in a desiccator overnight prior to all weighing, with an analytical balance. Serial extractions with 5 ml of ACS Grade acetone (Fisher Scientific, Pittsburgh, PA) was performed within an ultrasonic bath at 35 ± 2°C for at least 4 h until no further weight loss was observed. In all cases, no weight loss was observed after the fifth extraction. Six extractions were conducted. In addition to waxy hydrocarbons

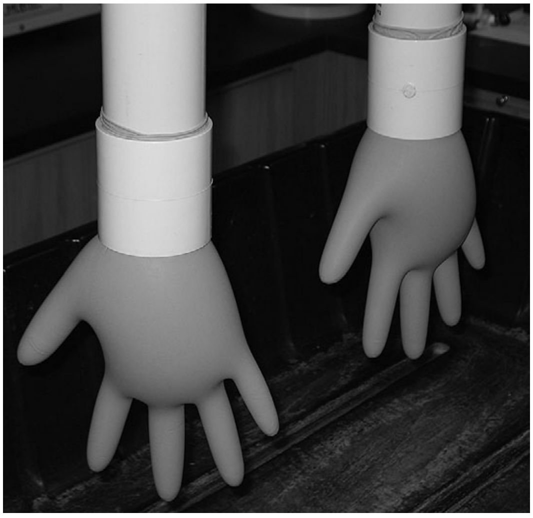

Fig. 1. Modified water-leak test apparatus. A specialized adapter was used to restrict glove expansion in the cuff region. Water columns were 2 ft long to hold added volumes of water.

and oils, small amounts of free sulfur were expected to be present in the extracts. Thus, this test was only an indicator of added oils/plasticizers. Further testing of the extracts was not performed in this study but planned for in subsequent studies.

Statistical analyses

Shapiro–Wilks, Shapiro–Francia, and skewness/kurtosis normality tests were used to test for the normal distribution of individual variables. Student's *t*-test, analysis of variance (ANOVA), correlation, and regression analyses were used and, when appropriate, non-parametric methods. The results were deemed significant if the P value was ≤ 0.05. Logistic regression, correlation, and ANOVA analyses were performed using Stata version 11 (StataCorp, College Station, TX, USA). Chi-square analysis was used to compare the failure rates between the two glove types.

RESULTS

Physical and mechanical properties

Table 2 summarizes the AD and tensile testing results. Student's t and Wilcoxon rank sum-tests were used to compare the data. For tensile strength, on average, a significant difference ($P \leq 0.05$) existed between the clean room gloves (21.3 ± 5.1 MPa) and low-modulus gloves (15.4 ± 3.8 MPa). Similar results were observed for the modulus 50–100%, which were, on average, 2.1 ± 0.9 MPa for the clean room gloves and 1.3 ± 0.3 MPa for the low-modulus gloves. There was a significant difference ($P \leq 0.05$) in AD between the clean room gloves (12.0 ± 1.8 g cm^{-2}) and low-modulus gloves (10.2 ± 0.8 g cm^{-2}). The lower AD for low-modulus gloves was an indicator of an increased amount of, often less dense, oily plasticizers. No significant differences in thickness (data not shown), elongation at break, or maximum modulus were observed between the two glove types ($P > 0.05$).

Leak failures and glove type

On average, the leak failure rates (Table 2) were variable for the clean room gloves (2.6 ± 2.5%)

Table 2. Physical and mechanical glove properties plus leak failure and solvent extraction results.

ID	Area density (g cm^{-2})	Tensile strength (MPa)	Elongation at break (%)	Modulus 50–100% (MPa)	Maximum modulus (MPa)	Leak failures (%)	Amount of extractable content (%)
Clean room gloves							
1	11.1 ± 1.2	29.4 ± 5.2	544 ± 96	4.0 ± 0.9	8.6 ± 2.2	5.9	5.9
2	14.1 ± 1.9	22.9 ± 3.1	785 ± 68	1.5 ± 0.3	5.1 ± 1.0	3.7	9.2
6	9.2 ± 0.6	23.9 ± 9.1	710 ± 159	2.1 ± 0.4	4.7 ± 2.3	0.0	4.7
7	13.9 ± 0.5	17.3 ± 3.7	712 ± 114	1.7 ± 0.1	3.4 ± 1.1	0.6	5.6
9	12.1 ± 1.6	15.5 ± 3.8	647 ± 93	1.9 ± 0.4	4.4 ± 0.6	4.7	5.6
11	11.7 ± 1.2	18.9 ± 2.8	868 ± 97	1.7 ± 0.2	3.1 ± 1.4	0.6	4.6
Group average	12.0 ± 1.8	21.3 ± 5.1	711 ± 111	2.1 ± 0.9	4.9 ± 2.0	2.6 ± 2.5	5.9 ± 1.7
Low-modulus gloves							
3	11.1 ± 1.2	20.6 ± 6.0	681 ± 135	1.8 ± 0.3	5.1 ± 1.4	0.6	6.2
4	9.4 ± 1.0	16.7 ± 4.4	766 ± 145	1.1 ± 0.1	3.5 ± 0.9	0.6	12.9
5	9.8 ± 0.6	10.8 ± 3.3	724 ± 128	0.99 ± 0.04	2.5 ± 0.8	1.2	12.7
8	9.7 ± 1.0	16.4 ± 5.1	656 ± 118	1.2 ± 0.1	3.4 ± 1.5	1.1	6.8
10	11.0 ± 1.0	12.6 ± 5.0	665 ± 143	1.4 ± 0.2	2.4 ± 1.1	1.2	12.2
Group average	10.2 ± 0.8	15.4 ± 3.8	698 ± 46	1.3 ± 0.3	3.4 ± 1.1	1.0 ± 0.3	10.2 ± 3.4

and ranged from 0 to ~6%. Two of the clean room glove products failed the water-leak test (failure rates >4.0%), whereas none of the low-modulus products had leak failures >1.25%. On average, the low-modulus leak failures were lower than the clean room gloves. However, half of the clean room gloves had low-leak failure rates ranging from 0 to 0.625%. In summary, significant variation existed among the different glove products, mostly among the clean room products.

Table 3 shows the results of the chi-square analysis of glove type versus observed leaks. A significant difference in leaks was observed between the different glove types (chi-square; $P = 0.001$). On average, the clean room gloves had the highest number of leaks (3.1%), compared to the low-modulus gloves (1.0%). Glove integrity was significantly different between the two glove types.

Solvent extraction

Table 2 summarizes the solvent extraction data. Student's *t* and Wilcoxon rank-sum tests were used to compare the data. On average, a significant difference ($P \leq 0.05$) existed between the clean room gloves (5.9 ± 1.7%) and low-modulus gloves (10.2 ± 3.4%). As expected, the low-modulus gloves had a larger amount of extractable content, on average. However, Gloves 3 and 8 had lower amounts of extractable compounds than the other low-modulus products.

Table 3. Chi-square glove type versus glove leaks (with row percentages).

Glove type	No leaks	Leaks	Total
Clean room	1415 (96.92%)	45 (3.08%)	1460 (100%)
Low-modulus	891 (99.00%)	9 (1.00%)	900 (100%)
Total	2306 (97.71%)	54 (2.29%)	2360 (100%)

Pearson chi-square = 10.797 ($P = 0.001$).

Correlation analysis

Table 4 summarizes the results of the correlation analysis. Little to no association was observed between leak failures and the physical, chemical, or mechanical properties of the gloves. The Spearman's rank order correlation coefficient (rho) ranged from −0.07 to 0.09, indicating no association, for leak failures versus glove type, AD, and various tensile properties ($P \leq 0.05$). The results for leak failure versus solvent extract were not significant ($P > 0.05$).

There were weak to strong correlations ($P \leq 0.05$) between glove type and the physical and mechanical properties of the glove. The modulus 50–100% exhibited the best correlation with glove type, the Spearman's rho was −0.71. Similar correlations were exhibited between glove type and tensile strength (rho −0.56), maximum modulus (rho −0.54), and AD (rho −0.63). In general, the following all decreased going from the clean room to the low-modulus glove type: tensile strength; modulus 50–100%; maximum modulus; and AD.

The associations between AD and tensile properties were weak, with little to no association. The Spearman's rho ranged from 0.17 to 0.31 ($P \leq 0.05$).

Strong associations were observed between solvent extract and both glove type (rho 0.71) and modulus 50–100% (rho −0.74). This indicated that increased plasticizer content was associated with the low-modulus classification and tensile properties (modulus 50–100%). However, as with the physical and mechanical parameters, solvent extract was not associated with leak failures.

The correlations between the different measures of tensile properties were strong to moderate and

Table 4. Correlation analysis.

	Glove type	Leak failures	Tensile strength	Modulus 50–100%	Maximum modulus	AD	Solvent extract
Glove type	—	−0.07	*−0.56*[a]	**−0.71**[b]	*−0.54*[a]	*−0.63*[a]	**0.71**[b]
Leak failures		—	0.05	0.08	0.09	0.05	[c]
Tensile strength			—	*0.62*[a]	**0.83**[b]	0.17	−0.34
Modulus 50–100%				—	*0.65*[a]	0.25	**−0.74**[b]
Maximum modulus					—	0.31	−0.19
AD						—	−0.25
Solvent extract							—

Values shown are Spearman's rank order correlation coefficient (rho) with all $P \leq 0.05$. Even though many of the correlations were weak to moderate, the large sample size contributed to the low-observed probabilities.
[a]Italic values indicate weak to moderate association.
[b]Bold values indicate strong association.
[c]Not significant ($P > 0.05$).

positive associations ($P \leq 0.05$). The correlation between tensile strength and maximum modulus was the strongest with a Spearman's rho of 0.83. For modulus 50–100%, moderate associations were observed between tensile strength (rho 0.62) and maximum modulus (rho 0.65).

Overall, the correlation analysis confirmed the previously reported results (see Table 2) on the differences in AD and tensile properties between the two glove types. However, no correlation between leak failures and glove type, or any other variable, were observed. This was likely due to the fact that three (50%) of the clean room gloves had low-leak failure rates.

Logistic regression

Table 5 shows the results of the logistic regression analyses of glove leaks by the experimental variables. The results are consistent with the chi-square results: glove type was found to have a significant effect on glove leaks ($P = 0.002$). On average, the clean room gloves [odds ratio (OR) = 3.15; 95% confidence interval (CI) 1.53–6.47] were about three times more likely to have leaks than the low-modulus gloves. Logistic regression analysis of the individual glove products revealed that only one glove product (Glove 1) had significantly higher leak failures than the other gloves. For Glove 1, a clean room product, the odds of experiencing a leak was ~10 times the odds of another glove experiencing a leak ($P = 0.025$). For Glove 9, also a clean room product, there was an indication that the odds of experiencing a leak was about seven times the odds of another glove experiencing a leak ($P = 0.065$). The overall variability in failure rates was low between glove products, with the exception of Glove 1.

Table 5. Logistic regression of glove failure by experimental variables.

Variable	Odds ratio (95% confidence interval)	*P* value
Glove type		
Low-modulus[a]	1.00	
Clean room	**3.15 (1.53–6.47)**	**0.002**
Glove product (ID)		
Glove 11[a]	1.00	
Glove 1	**10.04 (1.33–75.66)**	**0.025**
Glove 9	**6.83 (0.89–52.39)**	**0.065**
Tensile strength ≥ 18 MPa	1.50 (0.87–2.60)	0.14
Elongation at break	0.99 (0.99–1.00)	<0.001
Modulus 50–100% ≥ 1.7 MPa	**2.00 (1.14–3.52)**	**0.016**
Maximum modulus ≥ 4 MPa	**3.68 (1.84–7.34)**	**<0.001**
AD ≥ 11 g cm^{-2}	**3.89 (1.54–9.80)**	**0.004**
Solvent extract ≤ 8%	1.42 (0.79–2.57)	0.24

Bold values indicate significantly more leaks than the reference category ($P \leq 0.05$).
[a]Reference category.

For those physical, chemical, and mechanical properties shown to be significantly different between the two glove types, the average of the two group means (a mid-point) was used for the logistic regression. For modulus 50–100% ≥ 1.7 MPa, the odds of experiencing a leak were about two times the odds of those gloves <1.7 MPa (OR = 2.00; 95% CI 1.14–3.52). Similar, but more compelling, results were found for maximum modulus ≥4 MPa (OR = 3.68; 95% CI 1.84–7.34) and AD ≥11 g cm^{-2} (OR = 3.89; 95% CI 1.54–9.80). The results for tensile strength ≥18 MPa and solvent extract ≤8% were not significant ($P > 0.05$).

DISCUSSION

Physical and mechanical properties

On average, significant differences ($P \leq 0.05$) in the tensile strength, modulus 50–100%, and AD existed between the two glove types. As expected, the low-modulus gloves had lower modulus 50–100%. Previous studies have indicated significant differences in tensile strength or stiffness between manufacturers or brands (Fisher *et al.*, 1999; Rego and Roley, 1999); however, glove type was not identified as a contributing factor. In general, the physical and mechanical properties were significantly different between the two glove types, which indicate that, on average, the formulations are significantly different.

Based on the statistical comparison and correlation analyses, the AD, solvent extraction, and modulus 50–100% were the strongest indicators of glove type between the two formulations. As mentioned earlier, lower AD can be an indicator of an increased amount of oily plasticizers, which are often less dense than the base polymer. However, the correlation between AD and solvent extract was weak (rho −0.25). Further determination of specific plasticizer and oil content is needed. Aside from this, measures of AD and modulus 50–100% may aid in the designation and selection of low-modulus glove products.

Glove integrity

The glove integrity results were different than the leak failure rates observed in comparable studies, which ranged from 0 to ~3% (Rego and Roley, 1999; Korniewicz *et al.*, 2002; Patel *et al.*, 2003). In this study, the variability was higher for the clean room gloves, ranging from 0 to ~6%. The higher leak failure rates are likely due to the increased sensitivity of the modified water-leak test. However, the variability was lower for the low-modulus gloves, ranging from 0 to 1.25%. The addition of oils and/or plasticizers may in fact improve the watertightness of disposable nitrile gloves. Further determination of specific plasticizer and oil content is needed. Hydrophobic releasing agents, such as silicone oil, may also play a role in improved watertightness.

On average, the leak failure rates were significantly different between the two glove types. The clean room gloves were about three times more likely to have leak failures than the low-modulus gloves. About 30% of the clean room glove products failed the glove integrity tests, whereas none of the low-modulus gloves failed the test. These results indicated prominent differences in glove integrity, even among the clean room gloves. From a watertightness and infection control standpoint, the low-modulus gloves appear to be a better choice for barrier protection. It must be noted that clean room gloves are not specifically intended for infection control; however, the observed variability between glove products and brands indicate that glove selection cannot rely solely on glove type nor label claims.

The results of the correlation and logistic regression analyses clearly indicate that the tensile properties measured in this study are not associated with leak failures. Current standards and guidance for disposable gloves commonly address physical dimensions (e.g. widths and thicknesses), tensile strength, elongation at break, and performance on the 1-l water-leak test (U.S. FDA, 1999, 2000; ASTM International, 2002; ASTM International, 2003; U.S. FDA, 2008). Thus, selection of disposable gloves resides primarily on the 1-l water-leak test results, which has been shown to not adequately protect against viral penetration (Kotilainen *et al.*, 1992). Alternative standards and guidance do evaluate viral penetration, namely ASTM F 1671 (ASTM International, 2007). However, further developments of whole-glove quality control methods that can address large batches of gloves post-production are needed.

Based on the logistic regression analyses in this study, it appears that modulus and AD may help significantly in the glove selection process. Most notably, the odds of a leak were about four times higher when either the maximum modulus was $\geq$4 MPa or the AD was $\geq$11 g cm^{-2}. Fortunately, AD can be easily measured using an analytical balance and precision micrometer and modulus can be determined from ASTM D412 tensile strength test run data. Future standards or certifications may include these important parameters.

Limitations

The fact that only two dissimilar glove types were evaluated in this study is an acknowledged limitation and the results should not be applied to all disposable nitrile glove types. The intent was to uncover disparities in the physical, chemical, and mechanical properties that may lead to the improvement of whole-glove integrity and worker protection. As a starting point, this study achieved this goal, with the determination that AD and modulus are important considerations regarding glove integrity. Future research is needed, and currently underway, to broaden the narrow scope of application exhibited in this study.

CONCLUSIONS

It was apparent that glove formulation played a role in glove integrity; however, solvent extract was not found to influence leak failure rates. The AD and maximum modulus were better indicators of watertightness and glove integrity. Both of these properties are affected by the glove formulation, which indicates that polymer formulation should be considered in the establishment of disposable glove standards and certifications. Future research needs to investigate the influence of specific plasticizer/oil content and inorganic filler content on glove integrity. At the same time, caution must be applied regarding the use of known allergens and less well-understood phthalates in glove products (Rose *et al.*, 2009) to improve integrity. This information will provide necessary guidance for improved disposable nitrile glove standards and certifications, which would address the observed disparities in performance between glove brands and types.

FUNDING

Centers for Disease Control and Prevention (CDC), National Institute for Occupational Safety and Health (NIOSH) (1R21OH009327-01A2). Funding for preliminary results and equipment was also provided by the National Institutes of Health (HD052368).

Acknowledgements—Special thanks go to students Thi Le, Chima Metu, Hou Ung, Jesus Gaeta, Lan Nguyen, Catherine Tran, Yanet Melgarejo, Gloria Serrano, and Yvette Velasquez for their work on this project.

Disclaimer—Its contents are solely the responsibility of the authors and do not necessarily represent the official views of the Centers for Disease Control and Prevention or National Institute for Occupational Safety and Health.

REFERENCES

Askeland DR, Phulé PP. (2006) The science and engineering of materials. 5th edn. Toronto, Canada: Nelson/Thomson Learning. ISBN 0 534 55396 6.

ASTM International. (2002) D 412. Standardized test methods for vulcanized rubber and thermoplastic elastomers—tension. Philadelphia, PA: American Society for Testing and Materials International.

ASTM International. (2003) D 5151–99. Standard test method for rubber detection of holes in medical gloves. Philadelphia, PA: American Society for Testing and Materials International.

ASTM International. (2006) D 297. Standard test methods for rubber products—chemical analysis. Philadelphia, PA: American Society for Testing and Materials International.

ASTM International. (2007) F 1671–07. Standard test method for resistance of materials used in protective clothing to penetration by blood-borne pathogens using Phi-X174 bacteriophage penetration as a test system. Philadelphia, PA: American Society for Testing and Materials International.

Edlich RF, Taylor CC, Winters K *et al*. (2004) Scientific basis for selection of emergency medical examination gloves for emergency medical technicians, paramedics, firefighters, and emergency department personnel. J Long Term Eff Med Implants; 14: 51–66.

Edlich RF, Winters KL, Martin ML *et al*. (2005) Scientific basis for the selection of emergency medical examination gloves for emergency medical technicians, paramedics, firefighters, and emergency department personnel. An update. J Long Term Eff Med Implants; 15: 161–83.

Fisher MD, Reddy VR, Williams FM *et al*. (1999) Biomechanical performance of powder-free examination gloves. J Emerg Med; 17: 1011–18.

Korniewicz DM, El-Masri M, Broyles JM *et al*. (2002) Performance of latex and nonlatex medical examination gloves during simulated use. Am J Infect Control; 30: 133–8.

Kotilainen HR, Cy WH, Truscott W *et al*. (1992) Ability of 1000 ml water leak test for medical gloves to detect gloves with potential for virus penetration. In McBriarty JP, Henry NW, editors. Performance of protective clothing. Vol. 4, ASTM STP 1133. Philadelphia, PA: American Society for Testing and Materials International. pp. 38–48. ISBN 0-8031-1430-3.

Muto CA, Sistrom MG, Strain BA *et al.* (2000) Glove leakage rates as a function of latex content and brand—caveat emptor. Arch Surg; 135: 982–5.

NFPA. (2008) NFPA 1999. Standard on protective clothing for emergency medical operations. Quincy, MA: National Fire Protection Agency.

Patel HB, Fleming GJP, Burke FJT. (2003) A preliminary report on the incidence of pre-existing pinhole defects in nitrile dental gloves. Br Dent J; 195: 509–12.

Phalen RN, Que Hee SS. (2008) A moving robotic hand system for whole-glove permeation and penetration: captan and nitrile gloves. J Occup Environ Hyg; 5: 258–70.

Phalen RN, Que Hee SS, Xu W *et al*. (2007) Acrylonitrile content as a predictor of the captan permeation resistance for disposablenitrile rubber gloves. J Appl Polym Sci; 103: 2057–63.

Phalen RN, Wong WK. (2011) Integrity of disposable nitrile exam gloves exposed to simulated movement. J Occup Environ Hyg; 8: 289–99.

Rego A, Roley L. (1999) In-use barrier integrity of gloves: latex and nitrile superior to vinyl. Amer J Infect Control; 27: 405–10.

Rose RF, Lyons P, Horne H *et al*. (2009) A review of the materials and allergens in protective gloves. Contact Dermatitis; 61: 129–37.

U.S. FDA. (1999) Medical glove guidance manual, document shelf number 852. Rockville, MD: U.S. Food and Drug Administration, Department of Health and Human Services.

U.S. FDA. (2000) Patient examination gloves and surgeons' gloves; sample plans and test method for leakage defects; adulteration. Rockville, MD: U.S. Food and Drug Administration, Department of Health and Human Services.

U.S. FDA. (2008) Guidance for industry and FDA staff: medical glove guidance manual (document 1661). Rockville, MD: U.S. Food and Drug Administration, Department of Health and Human Services.

Zinner NL. (1994) How safe are your gloves? A study of protective barrier properties of gloves. AORN J; 59: 876, 879–82.