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Chemical Resistance of Disposable Nitrile Gloves Exposed to Simulated Movement

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Abstract

Large discrepancies between laboratory permeation testing and field exposures have been reported, with indications that hand movement could account for a portion of these differences. This study evaluated the influence of simulated movement on chemical permeation of 30 different disposable nitrile glove products. Products were investigated out-of-box and with exposure to simulated whole-glove movement. Permeation testing was conducted using ethanol as a surrogate test chemical. A previously designed pneumatic system was used to simulate hand movement. *No movement* and *movement* tests were matched-paired to control for environmental conditions, as were statistical analyses. Permeation data were collected for a 30-min exposure period or until a breakthrough time (BT) and steady-state permeation rate (SSPR) could be determined. A third parameter, area under the curve at 30 min (AUC-30), was used to estimate potential worker exposure. With movement, a significant decrease in BT ($p < 0.05$), ranging from 6–33%, was observed for 28 products. The average decrease in BT was 18% ($p < 0.001$). With movement, a significant increase in SSPR ($p < 0.05$), ranging from 1–78%, was observed with 25 products. The average increase in SSPR was 18% ($p < 0.001$). Significant increases in AUC-30 ($p < 0.05$), ranging from 23–277%, were also observed for all products where it could be calculated. On average, there was a 58% increase ($p < 0.001$). The overall effect of movement on permeation through disposable nitrile gloves was significant. Simulated movement significantly shortened the BT, increased the SSPR, and increased the cumulative 30-min exposure up to three times. Product variability also accounted for large differences, up to 40 times, in permeation and cumulative exposure. Glove selection must take these factors into account. It cannot be assumed that all products will perform in a similar manner.

Keywords

chemical protective clothing; dermal protection; exam gloves; permeation; personal protective equipment

INTRODUCTION

Workplace protection factors and certifications have been developed and established for respiratory protection devices but not for chemical protective clothing (CPC) such as gloves.⁽¹⁾ The National Institute for Occupational Safety and Health (NIOSH) has recognized CPC and exposure control technologies as research priorities in addressing this

issue.^(2,3) NIOSH has also identified the need for the development of whole garment tests for the performance of protective clothing used by first responders.⁽³⁾ Determination of those factors affecting whole-glove performance under work-use conditions will aid in the development of improved materials performance and possible certification of disposable gloves. In addition, simulated worker-use tests can facilitate the development of work protection factors, similar to those used with respirators,^(4,5) for the selection of appropriate dermal protection. This would improve the protection provided to workers using disposable gloves as a barrier against chemical, physical, and biological hazards.

One critical gap in the current knowledge is the protection afforded by protective clothing under worker-use conditions.⁽³⁾ As an example, up to a 100-fold increase in field exposures through gloves relative to laboratory-based permeation data have been reported.^(2,6,7) Previous studies have identified whole-glove movement as accounting for some of this variation.^(8,9) Additional studies have indicated that polymer content and product variability can account for a significant portion of the variation.⁽¹⁰⁻¹²⁾ More research is needed to assess the influence of glove composition and whole-glove movement on the permeation of chemicals through gloves.

The purpose of this study was to evaluate the influence of simulated movement on the chemical permeation of different disposable nitrile glove products/brands. Glove products were investigated both out-of-box and with exposure to simulated whole-glove movement. An array of commercially available product formulations was evaluated under the broad classifications of general duty, medical grade, low-modulus, and cleanroom (controlled environment) gloves. The classifications, which were not evaluated in this study, were based on manufacturer label claims, and they represent a general indication of glove design, quality, or polymer formulation modification to meet a specific customer need. Whole-glove permeation testing was conducted using ethanol as a surrogate test chemical, and a previously designed pneumatic system was used to simulate hand movement.⁽¹³⁾ This study was designed to address the following questions:

1. What are the effects of whole-glove movement on chemical permeation through disposable nitrile gloves?
2. How do different disposable nitrile glove products perform under conditions of whole-glove movement? Are there significant differences between the different products?

MATERIALS AND METHODS

Gloves

Thirty different disposable nitrile glove products were tested that included gloves classified as general duty, medical grade, cleanroom, and low-modulus. A broad spectrum of glove brands and formulations was represented. Gloves were medium size with a reported palm thickness of 0.10 to 0.13 mm (4 to 5 mil). Thickness measurements were performed using a previously described method.⁽¹³⁾ Table I summarizes the glove manufacturer, brand, and thickness information.

Simulated Movement

Air inflation with a pneumatic controller (Figure 1a) (Geocontrol Pro, Geotech, Denver, Colo.) was used to simulate whole-glove movement, as previously described.⁽¹³⁾ The gauge pressure was closely matched to approximate glove stretching during hand extension and flexion. An inflation gauge pressure of 0.08 inches water was optimal,⁽¹³⁾ but 0.10 inches of water gauge pressure was a limitation of the available pneumatic controller. Thus, the

movement exposures were slightly higher than those consistent with a properly sized and fitted glove. In comparison, the worst case scenario of an improperly fitted medium glove to a large-sized hand resulted in a gauge pressure of about 0.2 inches water. The gauge pressure used in this study (0.10 inches of water) was conservative, but not extreme.

Gloves were attached to the air line for the pneumatic controller using 1/4-inch (I.D.) tygon tubing and a previously described glove adapter (Figure 1d) that precluded movement in the cuff region.⁽¹³⁾ The inflation and deflation cycle time was 30 sec, which included a 5-sec stationary time at the end of each cycle to ensure complete deflation. During simulated movement exposures, the gloves were in continual movement greater than 80% of the time. A default exposure time of 30 min, equivalent to 60 cycles, was used to evaluate the effect of simulated movement on chemical permeation. Only one glove (Glove 3) required greater than 30 min to provide the necessary permeation data.

Permeation Testing

Whole-glove permeation testing was conducted using a specially designed system that allowed simulated movement during the permeation run. The main components of the system, shown in Figure 1, include (a) a pneumatic controller; (b) a magnehelic pressure gauge; (c) an intermediate chamber; (d) an environmental chamber with glove adapter and installed glove; and (e) a datalogging photoionization detector, in a closed loop.

A Boekel Model 1340 environmental chamber (Figure 1d) (Fisher Scientific, Pittsburgh, PA), with chamber dimensions of 29.2 cm × 25.4 cm × 30.5 cm, was fitted with two connected 1/4-inch hose barbs (outside and inside) at the top center to accommodate instillation of the glove adapter with 1/4-inch (I.D.) tubing. Two 1/8-inch hose barbs were installed at opposite ends (diagonally) and 1/8-inch (I.D.) teflon tubing was used to connect the PID for closed-loop, continuous monitoring of the chamber. A datalogging MiniRae2000 PID (Figure 1e) (Rae Systems, San Jose, Calif.) with 10.6 eV lamp and internal pump (0.50 ± 0.01 L/min) was used to collect air concentrations within the chamber. The PID was calibrated before each permeation run, checked after each run (zero and span), and recalibrated if the accuracy was off by more than ± 3%. Results were invalidated if the accuracy exceeded ± 5% of the true value. The chamber was regularly checked for leaks, and testing was performed inside an enclosed fume hood for added safety. For safety reasons a fan was not used inside the chamber. During validation, using a PID with an attached moveable probe, it was determined that no concentration gradient existed at the low ethanol concentrations evaluated in this study. A concentration gradient was observed when there were visible leaks or penetration, but these were not evaluated in this study. Validation tests with nitrile and latex gloves indicated that glove movement alone did not change the internal chamber concentrations. There were no significant changes ($p > 0.05$) in concentration with movement for the latex glove. This method was well suited for permeation of ethanol through disposable nitrile and latex gloves; however, less volatile agents, higher permeation rates, and chemical degradation may affect the utility of this method.

The intermediate chamber was a modified pelican case (Figure 1c) with internally installed 5-L tedlar bag connected to the glove adapter via connection to the environmental chamber. The tedlar bag was connected to the environmental chamber using installed 1/4-inch hose barbs and 1/4-inch (I.D.) tygon tubing. The bag was filled with about 3 L air and enclosed within the airtight case. The pneumatic pump controller (Figure 1a) pressurized and depressurized the case, thereby moving air from the tedlar bag into and out of the glove assembly (Figure 1d). This system was designed to protect the pneumatic pump from contact with chemical vapors and facilitate depressurization of the glove assembly.

The glove was turned inside out using light air pressure (lab air) and installed on the 2-inch diameter PVC coupling (cuff) so that the base of the thumb was even with the bottom edge of the cuff. The glove was filled with 200 mL ethanol, denatured (Fisher Scientific A407P) and then fitted with the top adapter. The adapter and glove were installed within the chamber (butt-to-butt connection), the door sealed shut, and datalogging was promptly initiated.

The pneumatic controller was used for movement exposures. Inflation and deflation gauge pressures were monitored using a Dwyer 2301 magnehelic gauge (Figure 1b) (Dwyer Instruments, Inc., Michigan City, Ind.). Initial adjustments were made as necessary. Glove samples with detectable leaks or holes, which rarely occurred, were removed from study. Only viable permeation parameters, associated with the molecular movement of ethanol through the glove material, were evaluated in this study.

The movement exposures were matched and paired with no movement exposures, at equivalent ambient temperature and relative humidity (RH) conditions. Ambient temperature ($21.4 \pm 1.0^\circ\text{C}$) and RH ($35 \pm 15\%$) were recorded during all experiments. Preliminary investigations determined that temperature had a significant effect ($p > 0.05$) on permeation results. Relative humidity did not have a significant effect ($p > 0.05$) on permeation between about 15–65%. Both temperature and RH were effectively accounted for by matching the ambient conditions during no exposure and exposure runs. Similarly, all data analyses were for matched-pairs.

Permeation data were collected for a simulated 30-min exposure period, or until a breakthrough time (BT) and steady-state permeation rate (SSPR) could be determined. The datalogger recorded the average chamber concentration at 30-sec intervals. The BT was determined as the first significant increase of $0.4 \mu\text{g}/\text{cm}^2$, where subsequent readings continued to increase. The increase in $\mu\text{g}/\text{cm}^2$ was evaluated by subtracting the previous reading from the current reading, which provided a measure of concentration change that could be used to determine a reliable BT. The critical value $0.4 \mu\text{g}/\text{cm}^2$ was a limitation of the PID, which is less sensitive to ethanol than a flame ionization detector. The PID was more reliable, efficient, and cost-effective for this study design. In addition, PIDs are non-destructive detectors,⁽¹⁴⁾ and better suited for closed-loop permeation testing. The SSPR, in units of $\mu\text{g}/\text{cm}^2/\text{min}$, was calculated from the linear portion of permeation curve using at least 10 sequential readings. The Pearson correlation coefficients (r) were all well above an established criterion of 0.95 ($p > 0.05$); most were > 0.99 . Figure 2 illustrates exemplary permeation curves showing no movement and movement exposures for permeation of ethanol through Glove 14.

A third parameter, area under the curve at 30 min (AUC-30), was used to evaluate the combined effects of BT and SSPR on potential worker exposure. The AUC-30 was calculated from the height (in $\mu\text{g}/\text{cm}^2$) of the permeation curve at 30 min, also known as the cumulative permeation at 30 min,⁽¹¹⁾ and the base (in min) from BT to 30 min. The basic shape was triangular, and the formula for the area of a triangle was used to estimate the area under the curve. The units were $\text{min} \cdot \mu\text{g}/\text{cm}^2$. The AUC-30 represented the relative cumulative exposure after 30 min. Cumulative permeation has been used with permeation studies⁽¹¹⁾ but represents an end-point exposure that does not fully take into account the important issue of exposure duration.^(15, 16) Figure 3 illustrates the potential added value of AUC-30 over a cumulative permeation at 30 min. For Glove A, the BT is 10 min and the SSPR is $3 \mu\text{g}/\text{cm}^2/\text{min}$, which results in an estimated cumulative permeation at 30 min of $60 \mu\text{g}/\text{cm}^2$.

$$\begin{aligned} \text{Estimated cumulative permeation at 30 min} &= (30 \text{ min} - \text{BT}) \times \text{SSPR} \\ &= (30 \text{ min} - 10 \text{ min}) \times 3 \mu\text{g}/\text{cm}^2/\text{min} \\ &= 60 \mu\text{g}/\text{cm}^2 \end{aligned} \quad (1)$$

Glove B, has a longer BT of 25 min but 4-fold higher SSPR at 12 $\mu\text{g}/\text{cm}^2/\text{min}$. Gloves A and B have the same estimated cumulative permeation at 30 min and would be judged as providing equal protection. As stated earlier, both exposure and duration are critical factors when evaluating toxicity potential or hazard. The calculated AUC-30, which uses the above cumulative permeation at 30 min value, for Glove A is 600 $\text{min}\cdot\mu\text{g}/\text{cm}^2$.

$$\begin{aligned} \text{AUC-30} &= 0.5 \times (30 \text{ min} - \text{BT}) \times (\text{Cumulative permeation at 30 min}) \\ &= 0.5 \times (30 \text{ min} - 10 \text{ min}) \times 60 \mu\text{g}/\text{cm}^2 \\ &= 600 \text{ min} \cdot \mu\text{g}/\text{cm}^2 \end{aligned} \quad (2)$$

The AUC-30 for Glove A is four times higher than Glove B at 150 $\text{min}\cdot\mu\text{g}/\text{cm}^2$. Thus, when taking into account the duration of exposure over a 30-min period, Glove B would be a better overall choice, especially for chemical agents that illicit a dose-response effect or are likely to permeate the underlying skin. The AUC-30 introduced here provides added value in the selection of chemical protective clothing (CPC), as it provides an estimate of hazard or toxicity. Industrial hygienists can estimate the cumulative permeation (Eq. 1) and AUC-30 (Eq. 2) based on available BT and SSPR data. The time period could also be changed to fit a specific duration of CPC use.

Statistical Analyses

Sample sizes (Table I), ranging from 26 to 90, were adjusted for product variability to ensure at least a 10% change in the permeation parameters could be determined statistically. Statistical analyses were performed using Stata version 11 and 12 (StataCorp, College Station, Texas). Shapiro-Wilks, Shapiro-Francia, and skewness/kurtosis normality tests were used to test the normal distribution of individual variables. From these results it was determined that non-parametric tests were required to best evaluate the influence of movement on chemical permeation parameters. Not all permeation results were normally distributed. Because the no movement and movement tests were matched and paired, to account for variations in ambient conditions, a Wilcoxon matched-pairs signed-rank test was used. The results were considered significant if the *p* value was not larger than 0.05.

RESULTS

Breakthrough Time

Table II shows the BT data for no movement and movement exposures, plus a statistical comparison of the percent change for each glove product and all gloves combined. With exposure to movement, a significant decrease in BT was observed for all gloves except two (Gloves 5 and 21). For Glove 5, the change was less than 10% and the *p* value was 0.06. The same was true for Glove 21 with a change less than 10% and a *p* value of 0.07. For the remaining gloves, the decrease in BT ranged from 6 to 33% (all *p* < 0.05). The average decrease in BT for all gloves combined was about 18% (*p* < 0.001), 13.7 \pm 6.4 min without movement, and 11.3 \pm 5.1 min with movement. On average, movement significantly lowered the BT to about 35%.

Without movement, the average BTs varied between the glove products and ranged from 6.6 min (Glove 1) to as high as 47.5 min (Glove 3). A 7-fold difference in average BT was observed between the glove products. With movement, a 7-fold difference was also

observed. In general, significant variation in breakthrough protection existed between the glove products.

Steady-State Permeation Rate

Table III shows the SSPR data for no movement and movement exposures, plus a statistical comparison of the percent change for each glove product and all gloves combined. With exposure to movement, a significant increase in SSPR was observed for 25 of the 30 glove products. For the 25 glove products, the increase in average SSPR for individual products ranged from 1–78% (all $p < 0.05$), and the average increase in SSPR was 18% ($p < 0.001$). For all glove products combined, the average SSPR was $12.6 \pm 5.6 \mu\text{g}/\text{cm}^2/\text{min}$ without movement and $14.9 \pm 6.4 \mu\text{g}/\text{cm}^2/\text{min}$ with movement. On average, simulated movement significantly increased the SSPR to about 80%.

Without movement, the average SSPRs varied between the glove products and ranged from as high as $25 \mu\text{g}/\text{cm}^2/\text{min}$ (Glove 11) to as low as $3.2 \mu\text{g}/\text{cm}^2/\text{min}$ (Glove 3). An 8-fold difference in average SSPR was observed. Conversely, with movement, there was a 7-fold difference. Significant variation in the permeation rates existed between the glove products.

Area Under the Curve at 30 Minutes

Table IV shows the AUC-30 data for no movement and movement exposures, plus a statistical comparison of the percent change for each glove product and all gloves combined. Because a significant change in either BT (decrease) or SSPR (increase) was observed for each glove product, significant increases ($p < 0.05$) in the AUC-30 were observed for all glove products where the AUC-30 could be calculated. The BT for Glove 3 was greater than 30 min, thus an AUC-30 could not be calculated. On average, there was a 58% increase in the AUC-30 ($p < 0.001$). The increase in AUC-30 for individual products ranged from 23% (Glove 6) to as high as 277% (Glove 19). On average, movement significantly increased the AUC-30 up to about three times.

Without movement, the average AUC-30 varied between the glove products and a 40-fold difference was observed between them. With movement, a 20-fold difference in average AUC-30 was observed. Significant variation in cumulative exposure existed between them.

DISCUSSION

Simulated Movement

The results summarized in Tables II, III and IV indicated that simulated movement had a significant effect on chemical permeation. On average, movement resulted in a decrease in BT of about 18%, an increase in SSPR of about 18%, and an overall increase in cumulative exposure (AUC-30) of about 58%. Individual results for glove products varied considerably and in some cases cumulative exposure increased by as much as three times with movement. Unlike the effects of simulated movement on glove integrity, which have been shown to be minimal in similar glove products,⁽¹³⁾ permeation occurred both sooner and at a faster rate with movement. In two cases (Gloves 5 and 21) movement did not significantly affect BT. However, with both of those glove products the SSPR was significantly higher ($p < 0.01$) with movement. The same was true for those gloves (Gloves 13, 15, 16, 20 and 25) where the SSPR was not significantly affected by movement; the BTs for those gloves were all significantly lower ($p < 0.01$) with movement. Thus, the overall effect of movement was a significant increase in the cumulative exposure to ethanol. For the purpose of assigning a workplace protection factor, at least a 3-fold increase (worst-case) in worker exposure should be assumed with exposure to normal hand movements over a 30-min period.

In a related study by Perkins and Rainey,⁽⁸⁾ which evaluated the effect of whole-glove flexure on permeation of thicker glove materials (20–30 mil), both a decrease in BT and increase in SSPR were detected in neoprene and polyvinyl chloride (PVC) gloves. In contrast, a rapidly moving human hand, about 30–50 flexes per min, was used as the movement exposure. On average, the BT decreased about 20–45% with movement. The average SSPR increased about 30–55% with movement. The results were consistent with those discovered in this study with disposable nitrile gloves. The percent decrease in BT was slightly more in the abovementioned study. Further evaluation of the effect of movement using different glove types and multiple solvents is suggested.

Colligan and Horstman conducted a study on the effect of flexure on the permeation of antineoplastic drugs through latex and PVC gloves.⁽¹⁷⁾ A modified Franz diffusion cell was used and a syringe pump displaced a volume of air, at a rate of 16 cycles per minute. As with the American Society for Testing and Materials Method F 739,⁽¹⁸⁾ the diffusion cell accommodates a swatch of glove material from the palm region. No significant differences in NBTs between static and flexed conditions were found. The NBTs were often greater than 4 h, which was likely due to the low volatility of the challenge solutions. Although, the antineoplastic drugs are typically solid and crystalline in structure; the method of preparation for permeation testing was not disclosed. For one antineoplastic drug, with the lowest BT, the permeation rate was twice as high with movement through a disposable latex exam glove. This finding was consistent with the indications that the effect of movement on permeation is more pronounced with the permeation rate than the breakthrough time.

In comparison with other factors likely to influence permeation, temperature has been shown to dramatically decrease the BT (up to 3-fold) and increase SSPR (up to 2.5-fold) going from 25°C to 37°C (body temperature).^(2,19) For permeation data collected under ambient conditions (20–25°C), increased temperature is more likely to have a greater effect on in-use chemical permeation than movement. However, the combined effect of increased temperature and movement on chemical permeation should be evaluated. Applying the area under the curve concept of increased worker exposure with changes in BT and SSPR, these combined effects may account for some of the observed discrepancies between laboratory permeation tests and in-use exposures. As previously mentioned, up to a 100-fold increase in field exposures through gloves relative to laboratory-based permeation data have been reported.^(2,6,7) Additional factors not assessed may include abrasion, perforation during use, improper doffing procedures, and cross contamination. The combined effects of temperature and movement are likely to account for a significant portion of these observed discrepancies.

Product Variability

Individual glove products responded differently to simulated movement. Seven- to 8-fold differences in the BT and SSPR were observed between the glove products. The average BTs ranged from 6.6 (Glove 1) to 47.5 min (Glove 3), a difference of about 7 times. The average SSPRs ranged from 3.2 (Glove 3) to 25 $\mu\text{g}/\text{cm}^2/\text{min}$ (Glove 11), a difference of about eight times. Mickelsen and Hall⁽¹²⁾ reported similar discrepancies with BTs, up to 10-fold differences, between thicker nitrile glove products exposed to perchloroethylene. Similarly, Phalen et al.⁽¹⁰⁾ discovered up to a 12-fold difference in NBT between disposable nitrile glove products exposed to the pesticide captan. Up to a 200-fold difference in the SSPR was observed between the glove products. A cleanroom glove, with high reported acrylonitrile content, accounted for these large discrepancies in permeation parameters for captan. In this current study, Glove 3 (a cleanroom product) was similar, as it had the lowest SSPR ($3.2 \pm 0.5 \mu\text{g}/\text{cm}^2/\text{min}$) and highest BT ($47.5 \pm 3.4 \text{ min}$), which was more than twice any other glove product. Similar variability in permeability of cytotoxic agents through various glove products and types exposed to movement has also been reported, with increased differences observed after 15-, 30-, and 60-min periods.⁽²⁰⁾

Polymer formulation, such as acrylonitrile content, is likely to influence chemical resistance and account for a significant portion of these observed discrepancies. A better understanding of the factors associated with these differences in permeation performance and chemical resistance will aid in the development of improved glove standards and possible certification. Currently, industrial hygienists must rely on manufacturer-supplied permeation data (which is sometimes qualitative), non-specific or qualitative chemical resistance charts and guides,⁽²¹⁾ or expensive laboratory permeation testing to select an appropriate protective glove product. Because batch-lot variability in performance has also been observed,⁽¹¹⁾ industrial hygienists must assume that the selection criteria are primarily useful for selecting a glove or material type based on general compatibility but not regarding in-use performance. The implications for certification of gloves and the establishment of minimum BT and SSPR standards for surrogate chemicals, in a similar manner to respiratory protection,⁽²²⁾ are evident in this study.

Limitations of the Study

It must be noted that only one test chemical was evaluated in this study, which limits the application to different chemical classes with nitrile gloves. Ethanol was selected because it is known to permeate nitrile products rapidly without significant degradation and can be used to evaluate natural rubber and neoprene glove products.⁽¹⁸⁾ The ACGIH[®] threshold limit value (TLV[®]) is also high in comparison with other alternatives.⁽²³⁾ While the findings are relevant to similar aliphatic hydroxyl compounds, they may not necessarily apply to different chemical classifications. Finally, it would have been optimal to control temperature (at body temperature) and relative humidity more closely; however, this study design required a large number of test runs for statistical significance and future analyses related to chemical and physical composition. The presence of a heating element near a flammable solvent posed an additional safety issue.

CONCLUSIONS

The overall effect of movement on the permeation parameters of disposable nitrile gloves was significant. Simulated movement significantly shortened the BT to about 30%, increased the SSPR to about 80%, and increased the cumulative 30-min exposure by as much as three times. These results were consistent with previous studies with different glove types. In addition, there was no strong indication that nitrile gloves were affected by movement more or less than other glove types and thicknesses. Equally important, product variability accounted for large differences, up to 40 times, in permeation and cumulative exposure. Glove selection must take movement and product variability into account. It cannot be assumed that all products will perform in a similar manner. This study provides impetus for the development of workplace protection factors and certification of disposable nitrile gloves for improved protection of workers. Future studies should investigate the influence of product formulation and properties on chemical resistance, which would help address the observed disparities in performance between glove brands.

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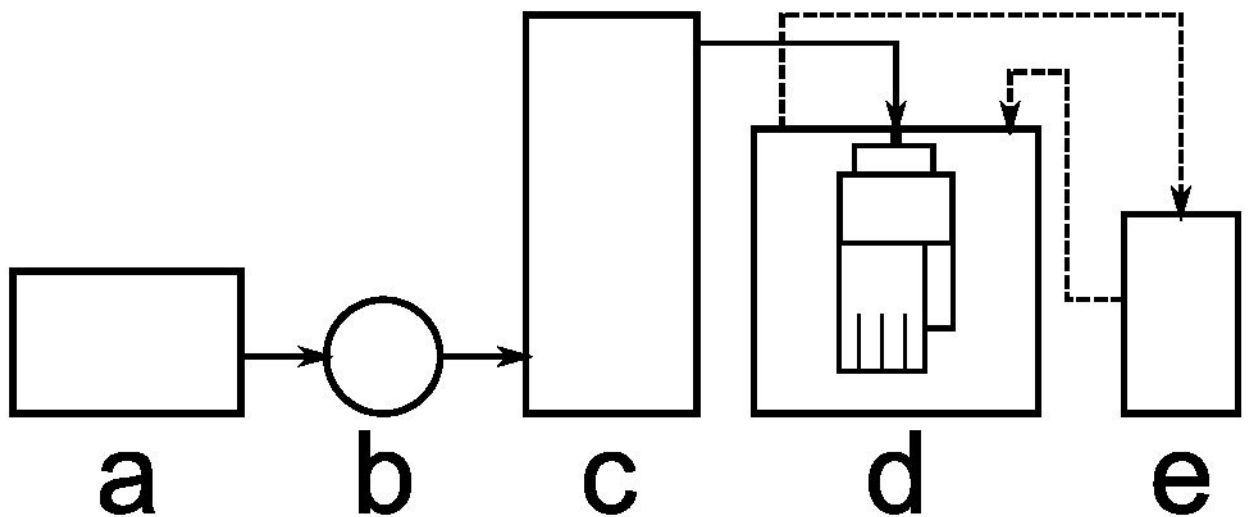
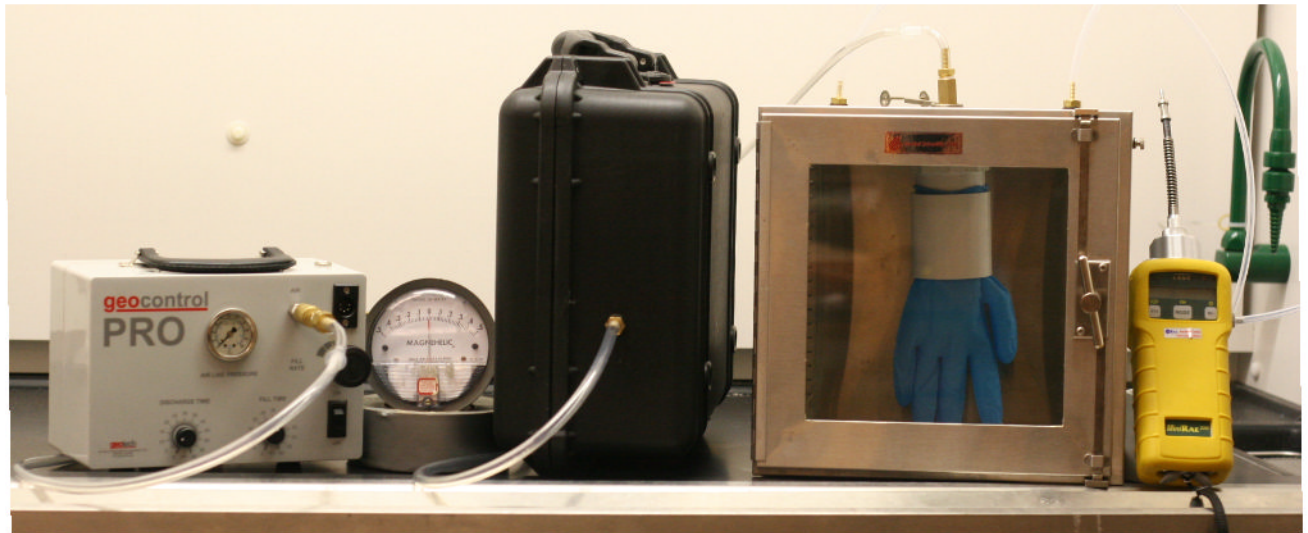


FIGURE 1. Whole-glove permeation test system. The main components of the system include: (a) pneumatic controller; (b) pressure gauge; (c) intermediate chamber; (d) environmental chamber, glove adapter, and installed glove; and (e) photoionization detector, in a closed-loop.

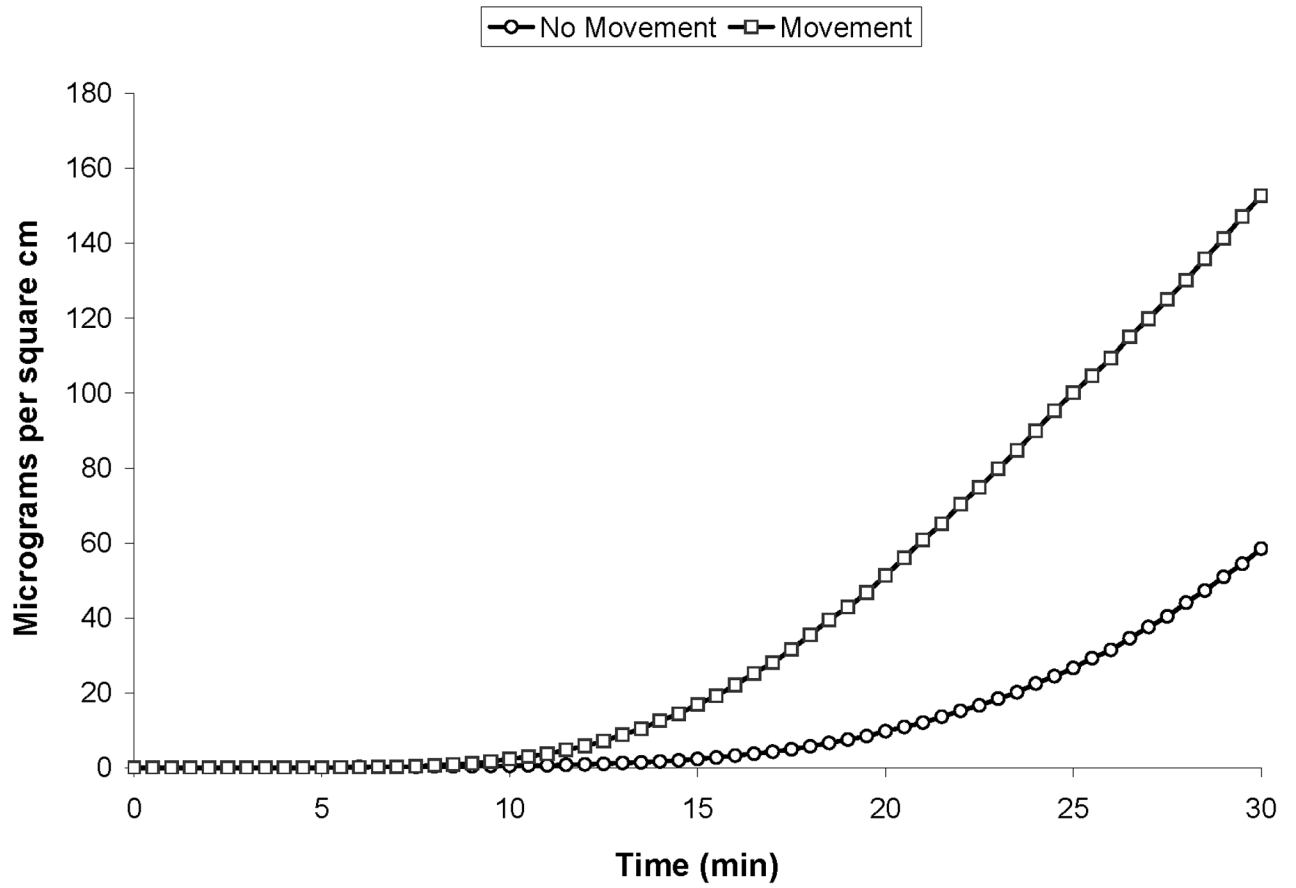


FIGURE 2.

Exemplary permeation curves showing no movement and movement exposures for permeation of ethanol through a disposable nitrile glove product

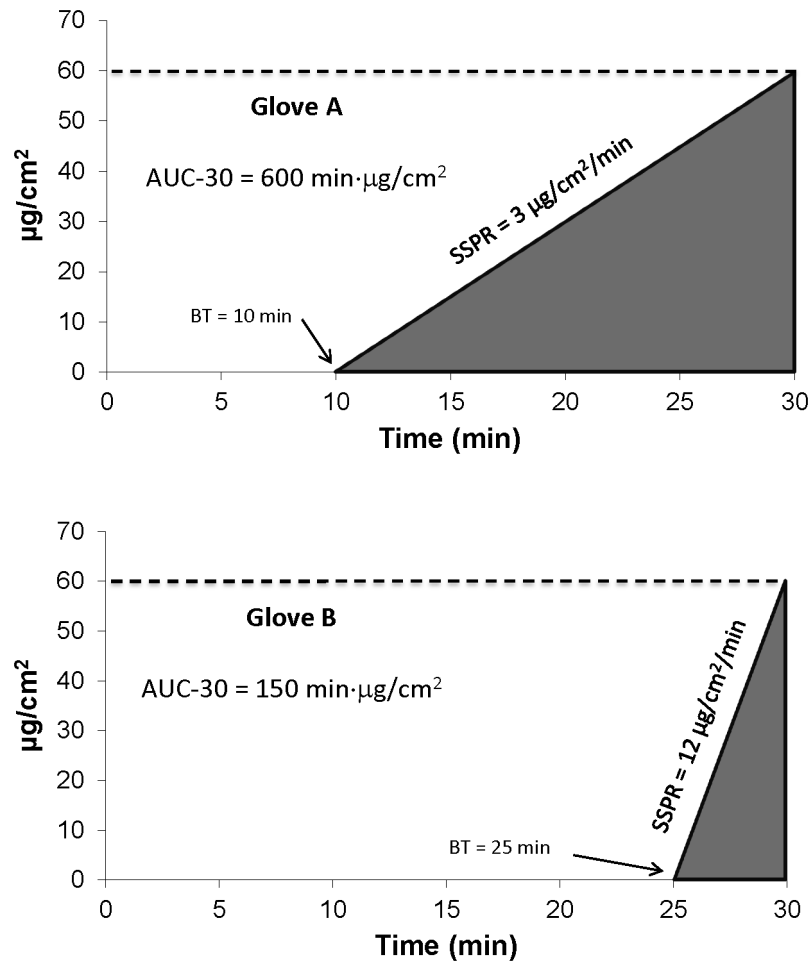


FIGURE 3.

Comparison of cumulative permeation at 30 min (dotted line) vs. area under the curve at 30 min (AUC-30) for two scenarios where the permeation parameters are different, but the cumulative permeation amounts are the same. Based on the AUC-30, Glove B represents a 4-fold lower hazard potential for a 30-min exposure. BT = breakthrough time (min). SSPR = steady-state permeation rate ($\mu\text{g}/\text{cm}^2/\text{min}$).

TABLE I

Glove Brand and Thickness Information

Glove ID	Manufacturer/Brand	Average Glove Thickness (mm ± SD)	Number of Permeation Tests Performed ^A
1	Ammex Xtreme X3	0.08 ± 0.02	40
2	Ansell Micro-Touch NitraFree	0.103 ± 0.006	40
3	Ansell Nitrilite	0.11 ± 0.01	26
4	Ansell Touch N Tuff	0.109 ± 0.007	48
5	Best Clean-Dex	0.15 ± 0.03	48
6	Best N-Dex 6005	0.123 ± 0.007	36
7	Best N-Dex Free	0.12 ± 0.01	34
8	Cardinal Health Esteem Tru-Blu Stretchy	0.11 ± 0.01	36
9	Fisherbrand Nitrile	0.098 ± 0.009	36
10	Henry Schein Criterion	0.083 ± 0.009	48
11	High Five Cobalt	0.10 ± 0.01	36
12	High Five Onyx	0.12 ± 0.01	48
13	High Five Softwear	0.10 ± 0.02	40
14	Kimberly Clark Kimtech G5	0.090 ± 0.006	48
15	Kimberly Clark KleenGuard G10	0.11 ± 0.02	36
16	Medline Sensicare	0.09 ± 0.02	36
17	Microflex CE4 System	0.14 ± 0.03	48
18	Microflex Midnight	0.11 ± 0.01	36
19	Microflex Supreno SE	0.13 ± 0.01	40
20	Microflex Ultrasense	0.095 ± 0.009	36
21	North Chem Soft CE	0.12 ± 0.02	48
22	North Dexi-Task	0.10 ± 0.02	48
23	Omar Nitrile	0.11 ± 0.02	36
24	PIP Ambi-dex	0.11 ± 0.01	36
25	Prima Pro Gentle Guard	0.11 ± 0.01	60
26	QRP Q095 Qualatrilite XC	0.12 ± 0.01	90
27	QRP Qualatrilite Blue 5	0.11 ± 0.02	48
28	Safety Choice Nitrile	0.11 ± 0.02	40
29	Sempermed SemperSure	0.088 ± 0.005	30
30	Tillotson True Advantage	0.096 ± 0.008	36

^ATotal number of permeation tests performed. The no movement and movement samples were paired to control for changes in laboratory conditions of temperature and relative humidity.

TABLE II

Breakthrough Time Data, No Movement vs. Movement

Glove ID	Breakthrough Time (min \pm SD)		Percent Change (%) ^A	Wilcoxon Matched-Pairs Signed-Rank Test ^B
	No Movement	Movement		
1	6.6 \pm 1.8	4.8 \pm 1.4	-27	p 0.001
2	10.8 \pm 1.5	8.5 \pm 1.0	-21	p 0.001
3	47.5 \pm 3.4	34.9 \pm 5.9	-27	p 0.01
4	19.8 \pm 2.7	18.2 \pm 2.5	-8	p 0.01
5	15.4 \pm 2.3	14.1 \pm 2.3	-8 (n.s.)	p = 0.06
6	13.5 \pm 0.7	12.7 \pm 0.5	-6	p 0.001
7	13.5 \pm 3.5	10.5 \pm 3.6	-22	p 0.01
8	15.5 \pm 1.5	12.4 \pm 1.0	-20	p 0.001
9	8.1 \pm 1.4	7.3 \pm 1.0	-10	p 0.05
10	7.1 \pm 1.4	6.2 \pm 1.1	-13	p 0.05
11	8.1 \pm 1.4	6.5 \pm 1.3	-20	p 0.01
12	12.0 \pm 1.6	9.9 \pm 1.2	-17	p 0.001
13	9.2 \pm 1.7	7.0 \pm 1.1	-24	p 0.001
14	14.6 \pm 3.1	9.8 \pm 1.7	-33	p 0.001
15	12.8 \pm 1.3	11.0 \pm 1.0	-14	p 0.001
16	12.7 \pm 1.4	9.9 \pm 1.0	-22	p 0.001
17	20.1 \pm 2.1	17.4 \pm 2.4	-13	p 0.001
18	14.3 \pm 1.7	12.4 \pm 1.3	-13	p 0.001
19	19.1 \pm 1.7	14.1 \pm 1.1	-26	p 0.001
20	15.6 \pm 2.3	13.3 \pm 1.8	-15	p 0.001
21	12.5 \pm 1.9	11.7 \pm 1.7	-6 (n.s.)	p = 0.07
22	12.0 \pm 2.6	8.5 \pm 0.9	-29	p 0.001
23	7.8 \pm 0.8	6.3 \pm 1.3	-19	p 0.001
24	15.3 \pm 1.7	12.0 \pm 2.9	-22	p 0.001
25	12.0 \pm 2.1	10.9 \pm 1.9	-9	p 0.01
26	13.7 \pm 2.8	12.2 \pm 2.5	-11	p 0.01
27	17.6 \pm 2.9	14.8 \pm 2.0	-16	p 0.01
28	11.2 \pm 2.1	7.8 \pm 1.0	-30	p 0.001
29	10.0 \pm 0.9	7.6 \pm 0.7	-24	p 0.001
30	10.9 \pm 1.0	8.5 \pm 0.8	-22	p 0.001
All Gloves	13.7 \pm 6.4	11.3 \pm 5.1	-18	p 0.001

^A n.s. = not statistically significant ($p > 0.05$).

^B $p < 0.05$ means that a statistically significant difference existed between movement and no movement exposures, whereas $p > 0.05$ indicated no statistically significant change.

TABLE III

Steady-State Permeation Rate Data, No Movement vs. Movement

Glove ID	SSPR ($\mu\text{g}/\text{cm}^2/\text{min} \pm \text{SD}$)		Percent Change (%) ^A	Wilcoxon Matched-Pairs Signed-Rank Test ^B
	No Movement	Movement		
1	24.2 ± 6.3	28.4 ± 3.7	+17	p 0.05
2	13.9 ± 2.0	19.5 ± 2.1	+40	p 0.001
3	3.2 ± 0.5	4.6 ± 1.2	+44	p 0.01
4	8.3 ± 3.2	10.0 ± 3.3	+20	p 0.01
5	8.5 ± 2.2	10.0 ± 2.0	+18	p 0.01
6	16.2 ± 0.6	17.2 ± 0.5	+6	p 0.001
7	13.8 ± 2.1	18.2 ± 1.4	+32	p 0.001
8	8.0 ± 1.3	10.0 ± 1.1	+25	p 0.01
9	17.4 ± 0.6	18.1 ± 1.1	+4	p 0.01
10	23.1 ± 2.4	31.3 ± 5.1	+35	p 0.001
11	25.0 ± 3.9	28.2 ± 1.2	+13	p 0.01
12	12.1 ± 1.6	13.2 ± 2.4	+9	p 0.01
13	13.7 ± 0.8	13.7 ± 1.0	0 (n.s.)	p = 0.79
14	5.1 ± 1.5	9.1 ± 0.8	+78	p 0.001
15	14.5 ± 2.4	15.2 ± 1.7	+5 (n.s.)	p = 0.12
16	13.7 ± 1.0	13.8 ± 0.6	+0.7 (n.s.)	p = 0.31
17	4.4 ± 1.5	6.8 ± 1.9	+55	p 0.001
18	8.8 ± 1.8	10.4 ± 1.4	+18	p 0.001
19	7.5 ± 1.6	11.9 ± 1.8	+59	p 0.001
20	11.8 ± 3.6	12.6 ± 3.0	+7 (n.s.)	p = 0.18
21	10.6 ± 1.9	11.8 ± 1.8	+11	p 0.01
22	11.0 ± 2.2	12.4 ± 1.5	+13	p 0.05
23	15.1 ± 0.5	15.3 ± 0.5	+1	p 0.05
24	9.7 ± 2.2	10.8 ± 1.5	+11	p 0.05
25	15.5 ± 2.7	15.2 ± 3.2	-2 (n.s.)	p = 0.73
26	12.5 ± 3.0	14.5 ± 2.4	+16	p 0.001
27	9.1 ± 3.0	11.7 ± 2.0	+29	p 0.001
28	11.2 ± 2.3	15.1 ± 1.0	+35	p 0.001
29	16.5 ± 2.1	25.5 ± 4.0	+55	p 0.001
30	15.4 ± 1.6	17.1 ± 2.1	+11	p 0.05
All Gloves	12.6 ± 5.6	14.9 ± 6.4	+18	p 0.001

^A n.s. = not statistically significant ($p > 0.05$)

^B p 0.05 means that a statistically significant difference existed between movement and no movement exposures, whereas $p > 0.05$ indicated no statistically significant change.

TABLE IV

Area Under Curve for 30-Minute Exposure Data, No Movement vs. Movement

Glove ID	AUC-30 (min· $\mu\text{g}/\text{cm}^2 \pm \text{SD}$) ^A		Percent Change (%)	Wilcoxon Matched-Pairs Signed-Rank Test ^B
	No Movement	Movement		
1	4860 \pm 1140	6570 \pm 1090	+35	p 0.001
2	1960 \pm 450	3480 \pm 580	+78	p 0.001
3	0 ^C	0 ^B	—	—
4	250 \pm 180	400 \pm 250	+60	p 0.01
5	520 \pm 290	780 \pm 430	+50	p 0.05
6	1300 \pm 150	1600 \pm 150	+23	p 0.001
7	1050 \pm 490	2050 \pm 670	+95	p 0.001
8	440 \pm 170	900 \pm 200	+105	p 0.001
9	3120 \pm 640	4100 \pm 550	+31	p 0.001
10	4260 \pm 790	6240 \pm 820	+46	p 0.001
11	4460 \pm 1080	6220 \pm 1260	+39	p 0.001
12	1200 \pm 460	1860 \pm 460	+55	p 0.001
13	2480 \pm 600	3830 \pm 510	+54	p 0.001
14	370 \pm 300	1360 \pm 410	+270	p 0.001
15	1270 \pm 390	1720 \pm 430	+35	p 0.01
16	1320 \pm 440	2060 \pm 450	+56	p 0.001
17	120 \pm 80	320 \pm 280	+167	p 0.001
18	600 \pm 230	930 \pm 240	+55	p 0.001
19	220 \pm 110	830 \pm 190	+277	p 0.001
20	640 \pm 390	1000 \pm 450	+56	p 0.01
21	990 \pm 370	1260 \pm 440	+27	p 0.01
22	1140 \pm 750	2310 \pm 500	+103	p 0.001
23	3630 \pm 460	4740 \pm 480	+31	p 0.001
24	560 \pm 290	920 \pm 220	+64	p 0.01
25	1650 \pm 810	2200 \pm 810	+33	p 0.01
26	1040 \pm 540	1580 \pm 790	+52	p 0.001
27	410 \pm 280	810 \pm 330	+98	p 0.001
28	1140 \pm 460	3110 \pm 630	+173	p 0.001
29	2390 \pm 340	5160 \pm 850	+116	p 0.001
30	1890 \pm 460	3250 \pm 580	+72	p 0.001
All Gloves	1470 \pm 1390	2320 \pm 1880	+58	p 0.001

^A AUC-30 min represents the relative area under the permeation curve between the initial breakthrough time (BT) and 30 min.

^B p < 0.05 means that a statistically significant difference existed between movement and no movement exposures, whereas p > 0.05 indicated no statistically significant change.

^C For Glove 3, the BT was beyond 30 min.