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Research Paper

The permeation and concentration of chemicals in medical gloves used by healthcare workers

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ABSTRACT

Some healthcare workers, such as pharmacists and nurses are sometimes exposed to chemicals and pathogens in their jobs and use medical gloves, gowns, and masks to protect themselves. Many studies have assessed permeation of chemicals through medical gloves, but few have quantified parameters like permeation rates or glove concentrations. In this study, either glove sheet made of three different materials (nitrile, polyvinyl chloride (PVC), and latex) was set in a vertical-type diffusion cell, and the glove sheet permeability of four model chemicals (pyridoxine, antipyrine, ethyl 4-hydroxybenzoate, and butyl 4-hydroxybenzoate) was tested. Pyridoxine did not permeate any gloves, while lipophilic chemicals showed higher permeability. PVC gloves had the highest permeation rates, while latex showed the fastest diffusion but lowest membrane concentration. Nitrile gloves had the lowest permeation but retained more residual chemicals. These findings highlight the need for caution in handling and disposing of contaminated gloves.

Key words: medical gloves, glove sheet permeation, glove concentration, permeation parameter, chemical exposure

1. Introduction

Some healthcare workers such as pharmacists and nurses are sometimes exposed to many pathogens and chemicals. When working in their jobs with a risk of exposure, precautions are taken to prevent them by using medical gloves, gowns, masks, and other protective gears (Falck et al., 1979; McDiarmid et al., 2010; Sessink et al., 1995; Sugiura et al., 2011; Vandenbroucke et al., 2001; Yoshida et al., 2008). It is recommended to wear medical gloves especially when preparing and administering anticancer drugs, transporting and storing medications, disposing of leftover anticancer drugs and materials that have come into contact with anticancer agents, and managing linens (Burgaz et al., 1999; Lawson et al., 2012). Chronic exposure to anticancer drugs has been reported to increase the risk of carcinogenesis, teratogenesis, organ damage, acute symptoms, chromosomal aberrations, and miscarriages (Fairchild et al., 1979; Lawson et al., 2012; Thiede et al., 1964). Even in this current situation, the demand for anticancer therapies continues to grow. In response, Japan revised the requirements for additional payments for sterile drug processing in 2024, and these services are now subject to formal evaluation.

Common materials for medical gloves include nitrile, polyvinyl chloride (PVC), and latex. It is recommended to wear two pairs of gloves made of different materials during the anticancer drug preparation. This is attributed to the fact that permeability of chemicals varies with glove materials. Numerous studies have examined the effect of different materials on the permeability of medical gloves to chemical compounds (Connor et al., 1995; Wallemacq et al., 2006). However, most studies only assess permeability at an early single point in the exposure, with few evaluating permeability over time. To prevent contamination of chemicals, it is important to evaluate the permeation parameters such as diffusion coefficient in the medical glove, partition coefficient from the chemical solution to the glove, and permeability coefficient through the glove sheet (Arce et al., 2020; Flynn et al., 1974; Sugibayashi et al., 2010; Uchida et al., 2015) as well as the cumulative amount of chemicals permeated through the glove sheet. In general, membrane permeation of chemicals can be expressed by Fick's diffusion

Table 1. Physicochemical properties of model chemicals.

Model chemical	Abbreviation	*M.W.*	clog*P* *
Pyridoxin	VB_6	169.2	–0.35
Antipyrine	ANP	188.2	0.20
4-Hydroxybenzoic acid ethyl ester	EP	166.1	2.51
4-Hydroxybenzoic acid butyl ester	BP	194.2	3.57

* clog*P* was calculated by Chem Draw Professional.

law, and the membrane permeation rate can be expressed as DK/L, where D, K, and L are the diffusion coefficient of chemicals in the membrane, partition coefficient of chemicals from the chemical solution to the membrane and thickness of the membrane, respectively. Even when a chemical compound has high glove sheet permeability, contamination can be prevented by changing the gloves before the chemical reaches the skin surface of healthcare workers. Conversely, even if a chemical has low glove penetration, contamination can still occur quickly if the K value is low and the D value is high. Therefore, if we can clarify the differences in permeation parameters of chemicals by glove material, it will be possible to accurately select medical gloves according to the purpose of use, maximize the effectiveness of PPE (Personal Protective Equipment), and enhance the safety of healthcare workers. It is known that the permeation parameters through general diffusion membranes, not only glove sheets, depend on the physicochemical properties of the chemicals (Hatanaka et al., 1990; Potts et al., 1992; Uchida et al., 2015). Therefore, such simple diffusion can be evaluated using model drugs with known physicochemical properties but anticancer drugs.

In this study, four model chemicals with different clog*P* values (a measure of hydrophilicity and lipophilicity); pyridoxine (VB_6; hydrophilic compound), antipyrine (ANP; amphoteric compound), and ethyl 4-hydroxybenzoate and butyl 4-hydroxybenzoate (EP and BP, respectively; lipophilic compound) were used to evaluate the sheet permeability of three types of gloves (nitrile, PVC, and latex). The concentration of the chemical compounds in each glove was also measured after the permeation test.

2. Material and Methods

2.1. Medical Gloves

Medical gloves worn during medical procedures or chemical preparation; Sanifoods Nitrile Gloves Economy® (nitrile glove), Thoma Plastic Gloves® (PVC glove), and Microflex® Diamond grip™ plus (latex glove) were purchased from As One Corp. (Osaka, Japan), Utsunomiya Seisaku Co, Ltd. (Osaka, Japan), and Ansell Co, Ltd. (Richmond, Victoria, Australia), respectively. The thickness of each glove sheet was determined to be 53.1 ± 3.1 μm, 90.7 ± 11.1 μm and 123.9 ± 8.1 μm (mean ± S.D., n = 10), for nitrile, PVC, and latex gloves, respectively.

2.2. Chemicals and Reagents

Model chemicals; pyridoxine (vitamin B_6; VB_6) and antipyrine (ANP) were purchased from Sigma Aldrich (St. Louis, MO, U.S.A.) and Fujifilm Wako Pure Chemical Corporation (Osaka, Japan), respectively. Two more chemicals; 4-hydroxybenzoic acid ethyl ester (ethyl paraben; EP) and 4-hydroxybenzoic acid butyl ester (butyl paraben; BP) were purchased from Tokyo Chemical Industry Co., Ltd (Tokyo, Japan). Other reagents and solvents were of HPLC quality or special grade products and used without purification. Table 1 shows the molecular weights and clog*P* of the model chemicals used to evaluate glove sheet permeability and concentration in the gloves.

2.3. Glove sheet permeation experiment of model chemicals

Figure 1 shows the vertical-type diffusion cell used in this experiment (effective diffusion area is 3.14 cm^2). Each glove was cut with scissors to fit the diffusion cell and placed in the cell with the outside facing up. The receiver cell (maximum volume, approximately 15 mL) was filled with phosphate buffer (pH 7.4 PB). Glove sheet permeation experiments were initiated by adding 2.0 mL of each model chemical (VB_6; 100 mg/mL, ANP; 50 mg/mL, EP; 700 μg/mL, BP; 100 μg/mL) dissolved in PB in the donor cell. The dry glove fabric was used without any pre-treatment for hydration. During the permeation experiment, the receiver solution was stirred with a magnetic stirrer and heated to 37°C. At regular intervals, 1.0 mL of the receiver solution was sampled, and an equal volume of PB was returned to the receiver cell to continue the experiment.

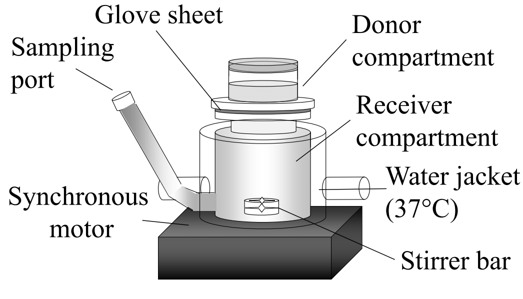

Figure 1. Schematic representation of permeation experiment through each glove sheet using vertical diffusion cell.

2.4. Determination of glove concentration of model chemicals

After determining the approximate time needed to reach steady-state conditions from the data on the time course of the cumulative amount of chemicals through the medical glove sheet, the permeation experiment was conducted again. This experiment was terminated at the appropriate time after obtaining a steady state permeation, the donor and receiver solutions were removed, and the glove surface was washed with 1.0 mL PB. The effective diffusion area of the glove sheet was then cut out using scissors, placed in a microtube (maximum volume of approximately 1.5 mL), and the cut glove sheet was weighed. After that, 1.0 mL of PB or methanol was added to the microtubes and shaken for 1 h, and the concentration of model chemicals in the extract was determined using HPLC (Shimadzu Corp., Kyoto, Japan). This extraction procedure was repeated until the concentration of each chemical was below the limit of quantification.

2.5. Analytical methods of each chemical

VB_6, ANP, EP, and BP concentrations were measured using HPLC (Shimadzu Co., Kyoto, Japan). The column temperature was maintained at 40°C and the injection volume was 20 µL. The column used to assess the concentration of VB_6 was Inertsil® NH_2, 5 µm 4.6 × 250 mm (GL Sciences, Tokyo, Japan) and the mobile phase was 50:50 solution of acetonitrile : 0.1% phosphoric acid solution. The flow rate was 1.0 mL/min and the measurement wavelength was 290 nm. The column used to measure ANP, EP, and BP concentrations was TSKgel ODS-80Ts QA, 5 µm 4.6 × 250 mm (Tosoh, Tokyo, Japan). The mobile phase for ANP was 30:70 solution of acetonitrile : 0.1% phosphoric acid solution containing tetrabutylammonium hydrogen sulfate at a concentration of 5 mM. The mobile phase for EP was 45:55 solution of acetonitrile : 0.1% aqueous phosphoric acid. That for BP was 50:50 solution of acetonitrile : 0.1% aqueous phosphoric acid. Flow rates and measurement wavelengths were 1.0 mL/min and 290 nm for ANP, 1.2 mL/min and 260 nm for EP, and 1.0 mL/min and 260 nm for BP.

2.6. Analysis of the permeation parameters (Arce et al., 2020; Flynn et al., 1974; Sugibayashi et al., 2010; Uchida et al., 2015)

Permeation parameters were calculated from the steady-state permeation rate and glove sheet thickness. The glove sheet permeation behavior of chemicals is a physicochemical phenomenon that can be explained mainly by Fick's 1st law of diffusion as shown in eq. 1.

$$J = -D\frac{dc}{dx} \tag{1}$$

where J is the steady-state glove sheet permeation rate of the chemical (*flux*; µg/cm^2/s), D is the diffusion coefficient in the glove sheet (cm^2/s), C is the concentration of chemicals in the gloves, and dc/dx is the concentration gradient in the glove sheet. In addition, x indicates the position of the glove sheet ($0 < x < L$; L is the glove sheet thickness). Assuming that the sink condition on the receiver side ($C = 0$) is maintained, the primary determinants of the cumulative amount (Q) and rate (J) of chemicals permeated through the glove sheet are the concentration of chemicals in the applied solution (C_v), the partition coefficient (K) of chemicals from the solution to the glove, the diffusion coefficient (D) of chemicals within the glove sheet, and the L of the glove sheet as shown in eqs. 2 and 3.

$$Q = \frac{KDC_v}{L}\left(t - \frac{L^2}{6D}\right) \tag{2}$$

$$J = \frac{KDC_v}{L} = PC_v \tag{3}$$

where P is the permeability coefficient, which can be expressed as $\frac{KD}{L}$. P is defined as the migration distance of a chemical through the glove sheet per unit of time (cm/s). The permeability coefficient can be calculated by dividing the flux by the applied concentration (eq. 3). The higher the value of K, the greater the permeation through the glove sheet and the higher the concentration within the glove (Arce et al., 2020; Oshizaka et al., 2014; Sugibayashi et al., 2010). The lag time (T_{lag}) until the steady state is reached can be expressed by the following eq. 4. When drawing a graph with time on the horizontal axis and cumulative permeation amount on the vertical axis, the lag time is where the steady state line is extrapolated to the x-axis. First, the data point showing the maximum flux was determined from the time curve of the cumulative amount of chemical compound through the grove sheet. Each flux was determined, the flux at 1.5 h was calculated from the data at 1 h and 2 h, and that at 2 h was calculated from the data at 1.5 h and 2.5 h, and so on, to obtain the maximum flux. Then, one data point showing the maximum flux and its before and after data points (i.e., three points) were selected to make the linear least squares regression line of the cumulative amount of chemical compound through the grove sheet versus the time curve. The permeability coefficient was determined by the maximum flux divided by the CV, and the lag time was the time-axis intercept, respectively, determined using the obtained linear least squares regression line.

$$T_{lag} = \frac{L^2}{6D} \tag{4}$$

2.7. Statistics

Statistics for each data set were done by paired *t*-test.

3. Results

Figure 2 shows the time course of the cumulative amount of each chemical that permeated through the nitrile, PVC and

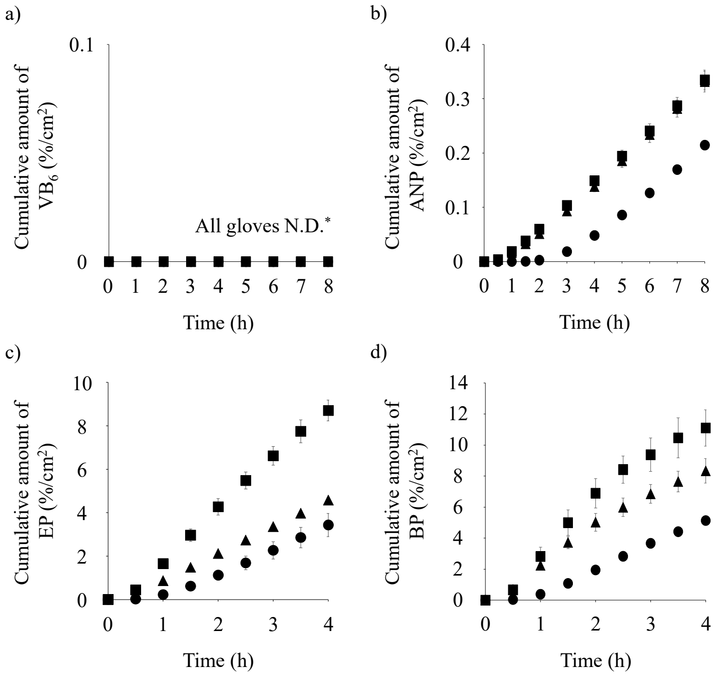

Figure 2. Time course of the cumulative amount of model chemicals that permeated through each glove sheet.
The data were normalized by the application amount of model chemicals.
Fig. 2a, b, c, and d show for VB_6, ANP, EP, and BP, respectively. Symbols: ●; nitrile glove, ■; PVC glove, and ▲; latex glove. Each data point represents the mean ± S.D. (n = 3). *N.D.: not detected.

latex glove sheets. Values were shown as %/cm^2 normalized to the applied chemical amount. The hydrophilic chemical VB_6 did not penetrate any glove over 8 h of experiment (Fig. 2a). However, in model chemicals with clog*P* values greater than 0.2, penetration was observed in all gloves (Fig. 2b–d). The permeation behavior in Fig. 2b–d shows the lag time and subsequent steady-state permeation rate observed in general membrane permeation. However, especially for the permeation of BP through the PVC glove sheet (Fig. 2d, ■), the cumulative amount-time curve tended to become convex upward approximately 2 hours after the start of the experiment. This was presumably due to a significant decrease in BP concentration on the donor side by rapid glove sheet permeation. It was also found that the greater clog*P* value showed the higher the glove sheet permeability of the chemicals ($p < 0.05$). Furthermore, for each model chemical, the cumulative amount through the nitrile glove sheet (●) was lower than through the PVC (■) and latex glove sheets (▲) ($p < 0.05$).

Table 2 shows the relationship between the permeation parameters and the type of glove. In addition, Figure 3 shows the relationship between the permeation parameters (lag time, *D*, *K*, *P*) calculated from the cumulative amount at steady state (Fig. 2b–d) and clog*P* of the model chemicals. The logarithm of the lag time (see Fig. 3a) tends to shorten as the clog*P* of the model chemical increases for all glove sheets. The lag time for the nitrile glove sheet was longer than that for PVC and latex glove sheets ($p < 0.01$). The *D* values (see Fig. 3b) also tended to increase as an increase in the clog*P* of the model chemicals in nitrile and latex glove sheet ($p < 0.05$). The *D* values (see Fig. 3b) also tended to increase as an increase in the clog*P* of the model chemicals in PVC glove sheet. However, the *D* through PVC sheet showed no difference between the lipophilic EP and BP. The *D* value of each chemical in the glove sheet was highest for the latex sheet and lowest for the nitrile sheet ($p < 0.01$). On the other hand, the *K* values (see Fig. 3c) also tended to increase as an increase in the clog*P* of the model chemicals in all gloves. However, the *K* showed no difference between the lipophilic EP and BP in all gloves. The *K* values for each chemical were highest for the nitrile gloves and lowest for the latex gloves ($p < 0.05$). Similarly, the *P* values (Fig. 3d) increased for all gloves as the clog*P* of the model chemicals rose ($p < 0.05$). The *P* value of lipophilic chemicals EP and BP for PVC gloves was higher than for nitrile and latex gloves ($p < 0.05$).

Table 3 shows the relationship between the concentrations in the glove sheets and the type of glove. In addition, Figure 4 shows the relationship between the concentrations in the glove sheets and the clog*P* of each model chemical. The hydrophilic compound VB_6 was present in small amounts in all glove sheets. The concentration in the glove sheets was significantly higher for model chemicals with higher clog*P* across all glove types ($p < 0.05$). Additionally, the concentration of ANP, EP, and BP in the glove sheets was highest in nitrile gloves, followed by PVC gloves, and lowest in latex gloves ($p < 0.01$).

Table 2. The relationship between the permeation parameters and the type of glove.

a) Lag time

Chemical	Nitrile glove The mean ± S.D. (h)	PVC glove The mean ± S.D. (h)	Latex glove The mean ± S.D. (h)
VB_6	N.D.	N.D.	N.D.
ANP	3.14 ± 0.09	0.87 ± 0.02	1.22 ± 0.15
EP	1.06 ± 0.08	0.37 ± 0.05	0.31 ± 0.02
BP	0.88 ± 0.02	0.30 ± 0.10	0.18 ± 0.02

b) Diffusion coefficient

Chemical	Nitrile glove The mean ± S.D. (cm^2/s)	PVC glove The mean ± S.D. (cm^2/s)	Latex glove The mean ± S.D. (cm^2/s)
VB_6	N.D.	N.D.	N.D.
ANP	$4.16 \times 10^{-10} \pm 1.21 \times 10^{-11}$	$4.38 \times 10^{-9} \pm 1.06 \times 10^{-10}$	$5.88 \times 10^{-9} \pm 7.89 \times 10^{-10}$
EP	$1.23 \times 10^{-9} \pm 8.96 \times 10^{-11}$	$1.03 \times 10^{-8} \pm 1.29 \times 10^{-9}$	$2.29 \times 10^{-8} \pm 2.07 \times 10^{-9}$
BP	$1.49 \times 10^{-9} \pm 3.81 \times 10^{-11}$	$1.34 \times 10^{-8} \pm 4.20 \times 10^{-9}$	$4.01 \times 10^{-8} \pm 3.71 \times 10^{-9}$

c) Partition coefficient

Chemical	Nitrile glove The mean ± S.D.	PVC glove The mean ± S.D.	Latex glove The mean ± S.D.
VB_6	N.D.	N.D.	N.D.
ANP	3.04 ± 0.18	0.54 ± 0.04	0.57 ± 0.08
EP	28.0 ± 6.08	12.6 ± 1.10	3.77 ± 0.36
BP	32.3 ± 2.77	16.3 ± 3.33	4.99 ± 0.72

d) Permeation coefficient

Chemical	Nitrile glove The mean ± S.D. (cm/s)	PVC glove The mean ± S.D. (cm/s)	Latex glove The mean ± S.D. (cm/s)
VB_6	N.D.	N.D.	N.D.
ANP	$2.39 \times 10^{-7} \pm 9.79 \times 10^{-9}$	$2.60 \times 10^{-7} \pm 1.37 \times 10^{-8}$	$2.70 \times 10^{-7} \pm 1.38 \times 10^{-8}$
EP	$6.41 \times 10^{-6} \pm 9.00 \times 10^{-7}$	$1.42 \times 10^{-5} \pm 9.70 \times 10^{-7}$	$6.92 \times 10^{-6} \pm 1.13 \times 10^{-7}$
BP	$9.03 \times 10^{-6} \pm 5.41 \times 10^{-7}$	$2.31 \times 10^{-5} \pm 2.67 \times 10^{-6}$	$1.61 \times 10^{-5} \pm 1.83 \times 10^{-6}$

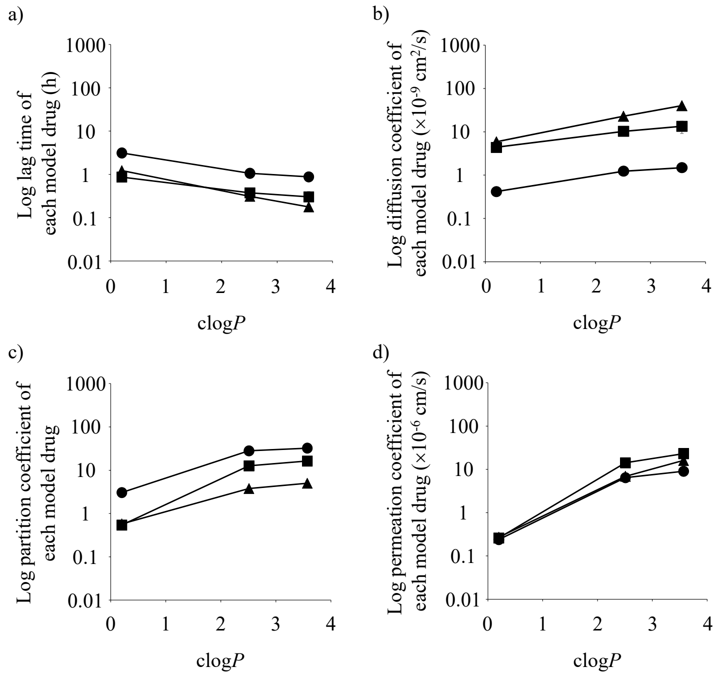

Figure 3. Relations between permeation parameters calculated from the glove sheet permeation profiles and clog*P* of model chemicals.
Fig. 3a, b, c, and d show relations between clog*P* versus lag time, *D*, *K*, and *P*, respectively. Symbols: the same as in Fig. 2. Each data point represents the mean ± S.D. (n = 3). The error bars are contained within the symbols.

Table 3. The relationship between the concentrations in the glove sheets and the type of glove.

Chemical	Nitrile glove The mean ± S.D. (%/g)	PVC glove The mean ± S.D. (%/g)	Latex glove The mean ± S.D. (%/g)
VB_6	0.004 ± 0.0003	0.0008 ± 0.0004	0.0009 ± 0.0002
ANP	0.039 ± 0.002	0.011 ± 0.0003	0.004 ± 0.0001
EP	1.17 ± 0.26	0.41 ± 0.009	0.087 ± 0.006
BP	3.24 ± 0.12	1.21 ± 0.08	0.35 ± 0.10

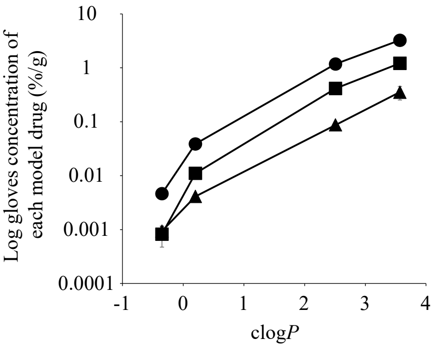

Figure 4. Relationship between clog*P* and glove sheet concentration of model chemicals.
These data were normalized by the application amount of model chemicals. Symbols: the same as in Figs. 2 and 3. Each data point represents the mean ± S.D. (n = 3). The error bars are contained within the symbols.

4. Discussion

Figure 2a shows that the hydrophilic chemical VB_6 did not permeate through any of the glove sheets for at least 8 h. However, a small amount of VB_6 was detected in the gloves after they were exposed to a VB_6 solution for 8 h (Fig. 4). Hydrophilic chemicals may eventually permeate through the glove sheets when applied for extended periods, despite each glove's high protective capacity against hydrophilic chemicals. Conversely, lipophilic chemicals tend to show a greater amount of permeation through the glove sheets. Therefore, it is recommended to frequently replace or double up gloves when handling lipophilic chemicals. Based solely on the cumulative amount, PVC gloves provided the least protection, followed by latex gloves, and then nitrile gloves.

As shown in eq. 4, lag time is a function of only L and D. The D value is generally influenced by the molecular size or weight of the chemicals. Since the molecular weights of the four chemicals used in this experiment are nearly identical, D should not change significantly even if the clog$P$ values of the chemicals differ. However, the D values for each glove sheet (Fig. 3b) were higher for chemicals with greater lipophilicity in these results. It is generally believed that the partition phenomenon from the applied solution to the membrane occurs instantaneously during membrane permeation. However, the partition of chemicals may take time, particularly when the partition rate is very low, and interfacial transfer resistance must be considered (Kokubo et al., 1992). Thus, the relationship between lag time or D and clog$P$, as observed in Figures 3a and 3b, can be explained by interfacial resistance. In addition, since the wettability of applied formulations on the skin was found to affect skin permeability (Azarbayjani et al., 2010), it is necessary to discuss the wettability of the applied formulations and glove materials, as well as their permeability, in the future.

These results suggest handling hydrophilic chemicals first and lipophilic chemicals last, and disposing of gloves immediately after contact with lipophilic substances. Additionally, the D value for latex gloves was the highest among the glove materials selected for this study, indicating that chemicals permeate through latex glove sheets faster than through those made of other materials. However, the K values for latex gloves (Fig. 3c) and the concentration of chemicals within the gloves were the lowest among the different materials (Fig. 4). These findings indicate that chemicals may begin to contaminate the fingers quickly through latex gloves, despite the small amount transferred. Caution is advised when working with anticancer drugs for extended periods while wearing latex gloves.

In contrast, nitrile gloves exhibited the lowest D (Fig. 3b) and the lowest cumulative amount of permeation through the nitrile glove sheet (Fig. 2). Thus, nitrile gloves are considered more suitable for long-term use compared to PVC or latex gloves. However, the K values for nitrile gloves (Fig. 3c) and the concentration of chemicals within these gloves (Fig. 4) were the highest. Depending on the chemical's lipophilicity, the permeability of chemicals through nitrile glove sheets reached a steady state within 1 to 3 h (Fig. 3a), making it advisable to replace gloves before reaching a steady-state permeation of chemicals. Furthermore, while nitrile glove sheets exhibited the lowest D (Fig. 3b) and P (Fig. 3d), they showed the highest protective ability among the materials studied. However, the K (Fig. 3c) and concentration within these gloves (Fig. 4) were also the highest. It has been suggested that prolonged use of nitrile gloves (when chemical permeation reaches a steady state) may result in a significantly higher permeation rate compared to other materials. Additionally, the chemicals penetrated in the glove material may be released, potentially exposing the user to these chemicals without their awareness when resuming work after a break.

The permeation parameters for PVC gloves (D in Fig. 3b and K in Fig. 3c) were intermediate between those of latex and nitrile gloves. However, their *P* (Fig. 3d) and cumulative amounts of chemicals were high, indicating that PVC gloves provided the least protective capacity among the gloves studied. These results suggest that wearing latex gloves over nitrile gloves when handling hazardous chemicals, such as anticancer drugs, can enhance protection against permeation, considering *D*, *K*, *P*, and the concentration within the gloves. Additionally, identifying glove materials with low permeation rates and low partition coefficients will be an important issue for future research.

5. Conclusion

This study demonstrates that each glove material has its own advantages and disadvantages: nitrile gloves exhibit a low diffusion coefficient (*D*) but a high partition coefficient (*K*), latex gloves have a high *D* but a low *K*, and PVC gloves show intermediate values for both *D* and *K*, along with high cumulative amounts of chemicals.

The permeation of various chemicals through a medical glove occurs by simple diffusion. The partition coefficient is determined by the physicochemical properties of the chemical and the glove material, and the diffusion coefficient varies depending on the physicochemical properties of the glove material. Therefore, it is desirable to develop glove materials with low *D* and *K* to effectively prevent contamination of healthcare workers. One potential solution is two-layer gloves with a nitrile outer layer and a latex inner layer. Furthermore, understanding the characteristics of the permeation parameters outlined in this study is essential for developing protective equipment such as gloves. Furthermore, it was considered that comparing the physicochemical properties of glove materials with drug permeability would enable a simpler selection and development of medical gloves in the future.

The data presented here will serve as a valuable reference for enhancing exposure capacity, usability, and safety in future glove development.

Conflicts of Interest

The authors declare that they have no known competing interests.

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