



Original research article

Evaluation of long cuff nitrile examination gloves' resistance to chemotherapy drug permeation

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ABSTRACT

Nitrile examination gloves with a long cuff are frequently used in healthcare settings considering their superior durability and resistance to punctures, tears, and chemicals. Many toxic substances, including chemotherapy medications, can be effectively protected against by wearing nitrile gloves. Following established standards, this study evaluated long-cuff nitrile gloves against chemotherapy drug permeation. These tests involved exposing the gloves to 11 different chemotherapy drugs and measuring the permeation rate over a specified duration. Powder-free nitrile exam gloves and extended cuff methods of chemical analysis with regards to standard practice permeation testing for assessing the resistance of medical gloves to permeation by chemotherapy drugs (ASTM D 6978-05). The EN455 Part 1: 2000 were used to test for single-use medical gloves. The testing of chemotherapy drugs and UV/ NIS absorption spectrometry were used to measure the absorbance of test chemicals, testing how much of each chemical permeated through the specimens into the collection medium. The collection medium was circulated in a closed loop at an 11 ml/minute flow rate through the testing period. It is clear that glove users must protect against the specific chemicals or chemical mixtures they are exposed to during chemotherapy. However, the results show that long cuff 400mm full finger textured 6mil nitrile gloves protected against chemotherapy drugs during working at the point of use.

Keywords: efficacy, nitrile examination gloves, resistance, chemotherapy drug, permeation

1. Introduction

Drug formulation and administration both pose unknown dangers in terms of occupational exposure to chemotherapy drugs.¹⁻⁴ Environmental investigations of chemotherapy drug handling have found detectable quantities of drug contamination, even in institutions that follow approved handling parameters.⁵ Pharmaceutical exposure can occur at any point in the supply chain, from production to distribution to administration, patient care, and final disposal. Connor et al. (2016) estimate that over 5.5 million American workers are at risk of exposure to potentially harmful medications.⁶ Since avoiding skin contact with these substances is vital for safe handling, it is essential that as little of these compounds as possible seep through protective medical gloves to the wearer's skin. Guidelines and international standards should be as stringent as possible under these conditions to ensure the safety of healthcare professionals. As such, over the last thirty years, rules and guidelines have been formed for the safe administration of potentially dangerous medications.

To ensure the highest level of safety for healthcare professionals and that proper and proven processes are used while handling dangerous pharmaceuticals, the European Union has encouraged the use of administrative and engineering controls among its member states since 2004. The European Parliament accepted revisions to the Carcinogenic and Mutagenic Substances Directive 2004/37/CE in February 2019.⁷ A more recent update (European et al., 2019) suggested a surface threshold contamination for chemotherapy drugs of 0.1 ng/cm² be used. Exposure to chemotherapy drugs is most commonly achieved by cutaneous absorption.⁶⁻⁷ Therefore, direct contact (manipulate vials producers and/or pharmacological solutions in intravenous bags) and indirect contact (due to touching contaminated surfaces) are the primary modes of cutaneous exposure to pharmaceuticals that should be considered. The guidelines outlined in "Preventing Occupational Exposure

to Cytotoxic and Other Hazardous Drugs" were published in 2016. European policy recommendations aimed to implement environmental monitoring techniques to trace any given drug's initial release and subsequent distribution and to track and enhance the performance of safety gear and procedures. Additionally, a new limit value for surface contamination was announced in January 2019 by the American Conference of Governmental Industrial Hygienists called the Threshold Limit Value (TLV) – the Surface Level (SL). Safety cabinets, closed-circuit transfer devices, and personal protective equipment (PPE) should be used when handling chemotherapy drugs because of the significant danger of occupational exposure. Regarding the latter, medical gloves are the most crucial piece of PPE because they offer immediate protection to the hands, which are particularly vulnerable to exposure to chemotherapy drugs.⁸ In the presence of cytotoxic medications, they are the first line of defense, so it is important to choose safer gloves based on the physical-chemical qualities of the chemotherapy drugs being handled and the duration of the handling. Legally, medical gloves in Europe are governed by European Council Directive 93/42/EEC, European Standard (EN) 455 (European Committee for Standardization, CEN, 2002), and UNI EN 16523-1:2019 (UNI EN, 2019), which continues the preceding UNI EN ISO 374-1:2018 (UNI EN, 2019).^{9,10} EN 455 specifies certain quality tests to determine physical qualities, visible material flaws, and minimum protective properties. Performance criteria of gloves for protection against chemicals are defined in UNI EN 16523-1:2019.⁹ However, permeability testing for chemotherapeutic medications is not required. The American Society for Testing and Materials (ASTM) D 6978-05 (ASTM International, 2005) is the current gold standard for testing protective gloves used in handling chemotherapy drugs,¹¹ and their guidelines should be utilized to test gloves in the United States.

Several studies on the permeability of gloves with regards to chemotherapy drugs were published between 1975 and 1999.^{11,12} The most comprehensive of these studies was conducted by Connor in 1999, who tested 18 different chemotherapy drugs on four different glove materials (nitrile rubber, latex, polyurethane, and neoprene).⁶ The risks associated with chemotherapy drugs and their safe handling in healthcare settings were outlined, emphasizing the role that personal protective equipment (PPE), especially medical gloves, plays. Permeation testing of medical drugs with regards to chemotherapy drugs, chemotherapy drug manipulation, and the exposed population of chemotherapy drugs were the three key themes.

Based on the above information, no studies in Thailand regarding nitrile gloves have previously been carried out in connection with chemotherapy drug permeation. Therefore, this study aims to evaluate long cuff nitrile examination gloves' resistance to chemotherapy drug permeation. In order to assess the occupational risk connected to chemotherapy drug manipulation and to minimize it, beginning with the correct choice of gloves, this data is an effective tool for industrial hygienists and environmental specialists.

2. Methods

Powder-free, non-sterile 6.0 mil, long cuff (400 mm) and finger textured Healthmedic nitrile examination gloves (Acrylonitrile-butadiene) were sent to the SGS and Akron Rubber Development Laboratory, Inc. for international standard laboratory testing. The evaluation of nitrile gloves involved two methods for chemical analysis. Permeation testing of standard practice for assessment of resistance of medical gloves to permeation by chemotherapy drugs (ASTM D6978-05: 2019) . The thickness of the test specimen sample had to be taken from either the palm or the cuff of the glove, whichever was thinner. The test temperature was 35°C (+ /- 2°C), which is a test temperature 2°C below core body temperature. This meant that the

gloves were tested at a temperature similar to that of a human hand. Permeation breakthrough of the test chemical was deemed to have occurred when the permeation rate reached $0.01\mu\text{g cm}^{-2}/\text{min}^{-1}$. The test time was defined as 240 minutes. In this study, 11 Chemotherapy Drugs were used: Carmustine (BCNU), 3.3 mg/ml (3,300 ppm), Cisplatin, 1.0 mg/ml (1,000 ppm), Cyclophosphamide (Cytoxan), 20 mg/ml (20,000 ppm), Dacarbazine (DTIC), 10.0 mg/ml (10,000 ppm), Doxorubicin Hydrochloride, 2.0 m/ml (2,000 ppm), Etoposide (Toposar), 20.0 mg/ml (20,000 ppm), Fluorouracil, 50.0 mg/ml (50,000 ppm), Methotrexate, 25 mg/ ml (25,000 ppm) , Mitoxantrone, 2. 0 mg/ml (2,000 ppm) , Paclitaxel (Taxol), 6.0 mg/ml (6,000 ppm), and Thiotepea, 10.0 mg/ml (10,000 ppm). UV/VIS absorption spectrometry was used to measure the absorbance of test chemicals, which permeated through the specimens into the collection medium. The collection medium was circulated in a closed loop at an 11 ml/ minute flow rate through the testing period. Data were collected according to the programmed schedule using UV Winlab software from the Perkin Elmer Corporation. EN455 Part 1: 2000 content 200 pieces were used to test for the absence of holes for specifying the criteria and testing for hole-free gloves. The standard employs a water leak test that uses AQL statistical sampling techniques. The EN455 Part 2: 2015 of force at break & elongation (Before & After Ageing) test methods, dimensions, and powder content - 13 pieces were used to test the test method for single-use medical gloves, dimensions, and powder content.

3. Results

The characteristics of powder-free, non-sterile 6.0 mil, long cuff (400 mm) and finger textured Healthmedic nitrile examination gloves (Acrylonitrile-butadiene) are as follows: the small size has the product code 101124414 (81 – 90 mm) , the medium size has the product code 101124415 (90 – 100 mm), the large size has the product code 101124416

(100 – 110 mm), and the extra-large has the product code 101124417 (110 – 120 mm), as shown in Table 1. Table 2 shows the minimum finger thickness of 0.17 mm (15 mm from the extreme tip) and the minimum palm thickness of 0.14 mm (in the middle of the palm) . Table 3 shows the physical parameters of tensile strength before and after the aging of 14 MPa, as well as elongation before and after the aging of 500 min. and 400 min., and force at a break of 6 N. Test results from international standard laboratories found characteristic wavelengths of Healthmedic Examination Gloves, and extended cuffs used in the UV/ VIS absorption spectrometry list are shown in Table 4. Thickness characteristics for the tested specimens of nitrile exam

gloves and extended cuff are shown in Table 5. The EN455 Part 1: 2000 content 200 pieces were used to test the test on freedom from holes following results obtained an acceptable quality limit (AQL) of 1.5 except 7 found 0 within AQL. The EN455 Part 2: 2015 force at break & elongation (Before & After Ageing) test methods, dimensions, and powder content 13 pieces were used to test the test method for single-use medical gloves, dimensions, and powder content shown in Table 6. The result of the permeation testing from 11 chemotherapy drugs with regards to powder-free nitrile exam gloves with extended cuffs are shown in Table 7.

Table 1. Characteristics of Healthmedic Examination Gloves.

Size	Palm Width (mm)	Length (mm)	Product Code
Small	81 - 90	400 (min.)	101124414
Medium	90 - 100	400 (min.)	101124415
Large	100 - 110	400 (min.)	101124416
Extra-Large	110 - 120	400 (min.)	101124417

Table 2. The thickness of Healthmedic Examination Gloves.

Point of Thickness Measurements	Single Wall (mm)
Finger (at 15mm from the extreme tip)	0.17 (min.)
Palm (at center of palm)	0.14 (min.)

Table 3. The physical properties of Healthmedic Examination Gloves.

Criteria	Before Aging	After Aging
Tensile Strength (MPa)	≥ 14	≥ 14
Elongation (%)	500 (min.)	400 (min.)
Force at Break (N)	≥ 6	≥ 6

Table 4. Characteristic wavelengths used in UV/VIS absorption spectrometry.

Testing Chemotherapy Drugs	Wavelength (nm)
Carmustine (BCNU), 3.3 mg/ml (3,300 ppm)	229
Cisplatin, 1.0 mg/ml (1,000 ppm)	199
Cyclophosphamide (Cytosan), 20 mg/ml (20,000 ppm)	200
Dacarbazine (DTIC), 10.0 mg/ml (10,000 ppm)	320
Doxorubicin Hydrochloride, 2.0 mg/ml (2,000 ppm)	232
Etoposide (Toposar), 20.0 mg/ml (20,000 ppm)	205
Fluorouracil, 50.0 mg/ml (50,000 ppm)	269
Methotrexate, 25 mg/ml (25,000 ppm)	303
Mitoxantrone, 2.0 mg/ml (2,000 ppm)	242
Paclitaxel (Taxol), 6.0 mg/ml (6,000 ppm)	231
Thiotepa, 10.0 mg/ml (10,000 ppm)	199

Table 5. The thickness characteristics test report for the tested specimens.

Testing Chemotherapy Drugs	Thickness (mm)			Average (mm)	Weight/Unit Area (g/m ²)
	Sample 1	Sample 2	Sample 3		
Carmustine (BCNU)	0.122	0.108	0.116	0.115	117.1
Cisplatin	0.117	0.113	0.118	0.116	
Cyclophosphamide (Cytosan)	0.116	0.117	0.118	0.117	
Dacarbazine (DTIC)	0.113	0.113	0.115	0.114	
Doxorubicin Hydrochloride	0.121	0.117	0.111	0.116	
Etoposide (Toposar)	0.117	0.116	0.123	0.119	
Fluorouracil	0.128	0.121	0.115	0.121	
Methotrexate	0.120	0.111	0.112	0.115	
Mitoxantrone	0.119	0.120	0.117	0.119	
Paclitaxel (Taxol)	0.114	0.123	0.112	0.116	
Thiotepa	0.113	0.130	0.108	0.117	

Table 6. The EN455 Part 2: 2015 force at break and elongation test report.

Sample No.	Before Ageing		After AgeinG	
	Force (N)	Ultimate Elongation (%)	Force (N)	Ultimate Elongation (%)
1	21.3	620	17.4	560
2	20.0	600	16.4	560
3	20.5	620	16.2	560
4	18.4	600	13.0	520
5	20.3	600	14.4	520
6	17.9	580	18.2	560
7	19.9	600	13.5	540
8	21.4	620	16.2	560
9	20.1	620	16.9	560
10	21.9	640	18.2	580
11	18.7	580	15.4	540
12	20.1	620	17.0	560
13	19.3	580	13.5	520

Table 7. Permeation test results of powder-free nitrile exam gloves, extended cuff.

Test Chemotherapy Drug and Concentration	Minimum Breakthrough Detection Time (Specimen 1/2/3) (minutes)	Steady State Perm. Rate (Specimen 1/2/3) ($\mu\text{g}/\text{cm}^2/\text{minute}$)	Other Observations
Carmustine (BCNU) 3.3 mg/ml (3,300 ppm)	40.4 (40.4, 60.4, 53.7)	0.3 (0.3, 0.2, 0.4)	Moderate swelling and no degradation
Cisplatin 1.0 mg/ml (1,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Cyclophosphamide (Cytosan) 20 mg/ml (20,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Dacarbazine (DTIC) 10.0 mg/ml (10,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Doxorubicin Hydrochloride 2.0 mg/ml (2,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Etoposide (Toposar) 20.0 mg/ml (20,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Fluorouracil 50.0 mg/ml (50,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Methotrexate 25 mg/ml (25,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Mitoxantrone, 2.0mg/ml (2,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Paclitaxel (Taxol) 6.0 mg/ml (6,000 ppm)	No breakthrough up to 240 min.	N/A	Moderate swelling and no degradation
Thiotepa 10.0 mg/ml (10,000 ppm)	60.6 (60.6, 70.6, 70.7)	0.02 (0.02, 0.02, 0.03)	Slight swelling and no degradation



Fig. 1. Healthmedic long cuff nitrile examination gloves, 6.0 mil (400 mm) and finger textured.



Fig. 2. Healthmedic long cuff nitrile examination gloves box.

4. Discussion

The evaluation of long cuff nitrile examination gloves' resistance to chemotherapy drug permeation is crucial in ensuring the safety of healthcare professionals who come into contact with these drugs. Chemotherapy drugs are potent and potentially hazardous substances, and the gloves used must provide an effective barrier to protect against permeation and subsequent exposure. This study found that the efficacy of powder-free, non-sterile 6.0 mil, long cuff (400 mm) and finger textured Healthmedic nitrile examination gloves (Acrylonitrile-butadiene) was determined by ASTM D6978-05:2019 and EN 455,^{9,11} in accordance with the European Medical Device Directive 93/42/EEC (CE Class 1).

The epidermis's corneal layer acts as a primary barrier preventing compounds from entering the body.¹³ The hydrophobicity of the stratum corneum makes it more permeable to lipid-soluble molecules than water-soluble ones. The pores of sweat glands and hair follicles may be accessible to hydrophilic molecules.¹⁴ The skin can absorb medications with a molecular weight (MW) of less than 500 Daltons.⁶ However, their penetration rates are drastically different, most likely because of their molecular weights.¹⁵⁻¹⁷ The predictability of chemical-physical constants may now support permeation investigation and chemotherapy drugs' risk assessment, especially in light of the arrival of new medications on the market.¹⁸⁻¹⁹

Permeation testing can now be used to assess the level of chemotherapy drug personal protection provided by medical gloves, with limits set at 10 ng/ (min cm²) and 1,000 ng/ (min cm²) by the American Society for Testing and Materials (ASTM) D-6978-05,^{9,11} respectively. The penetration limit in the United States is one-hundredth of the European standard, indicating the greater concern over the possible risks posed by chemotherapy drugs.^{20,21} Contrary to European Standards, which evaluate the

material's resistance to permeation by liquid chemicals (no chemotherapy medicines), the ASTM evaluates the permeation resistance of medical gloves to chemotherapy medications using a minimum of 9 chemotherapy drugs, which is consistent with this study that used 11 chemotherapy drugs.²²⁻²⁵ Another major distinction is that the ASTM test is conducted at a temperature similar to that of the body and samples from multiple locations on the glove, including the thinnest component, the cuff.^{16,26} The US ASTM D6978-05 standard, approved in 2019, details the experimental conditions that must be followed when using the static method.^{8,27-28}

This study is consistent with the use of nitrile gloves for procedural protection following ASTM D6978-05 standard in the healthcare industry in Thailand.^{25,29-30} Therefore, it can be concluded that nitrile gloves that have been tested according to these standards can be used in pharmaceutical chemotherapy drug preparation or general medical and offer excellent chemical protection.

5. Conclusion

The healthcare industry is one of the most important industries in the 21st century in developing the concept of chemical penetration through personal protective equipment (PPE), especially through protective gloves. Regarding PPE, medical gloves are the most likely to be contaminated by chemotherapy drugs during normal use. Medical gloves with minimal permeability to chemicals are recommended to protect healthcare practitioners from accidental exposure; this highlights the critical relevance of selecting the correct gloves. Permeation tests show that nitrile and chloroprene rubber is superior to vinyl and NLR for protection. Furthermore, abrasion, bending, contact time, and temperature all impact the breakthrough periods of different materials, leading to varying degrees of permeation. In the United States, medical gloves must comply with ASTM standard D

6978-05. However, in the European Union, the permeation test is optional for gloves used in Chemotherapy drug handling, indicating a significant need for improvement. Therefore, broad guidelines to evaluate acceptable materials and specify quality requirements for PPE must be introduced and standardized, with regular updates to account for new chemicals and PPE materials to promote safer handling of chemicals and to avoid potential risks and late sequelae.

Limitations of the Study

Recovery factors, such as contact time, measurement technique, and process activities, may have led to inaccuracies in this study's evaluation of the long cuff nitrile examination gloves' resistance to chemotherapeutic drug absorption. Furthermore, the comparison research between latex examination gloves and nitrile examination gloves did not include such investigations.

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Conflicts of Interest

There is no conflict of interest, according to the authors.

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