

PERMEATION MEASUREMENTS OF 27 CHEMOTHERAPY DRUGS AFTER SIMULATED DYNAMIC TESTING ON 15 SURGICAL AND EXAMINATION GLOVES: A KNOWLEDGE UPDATE

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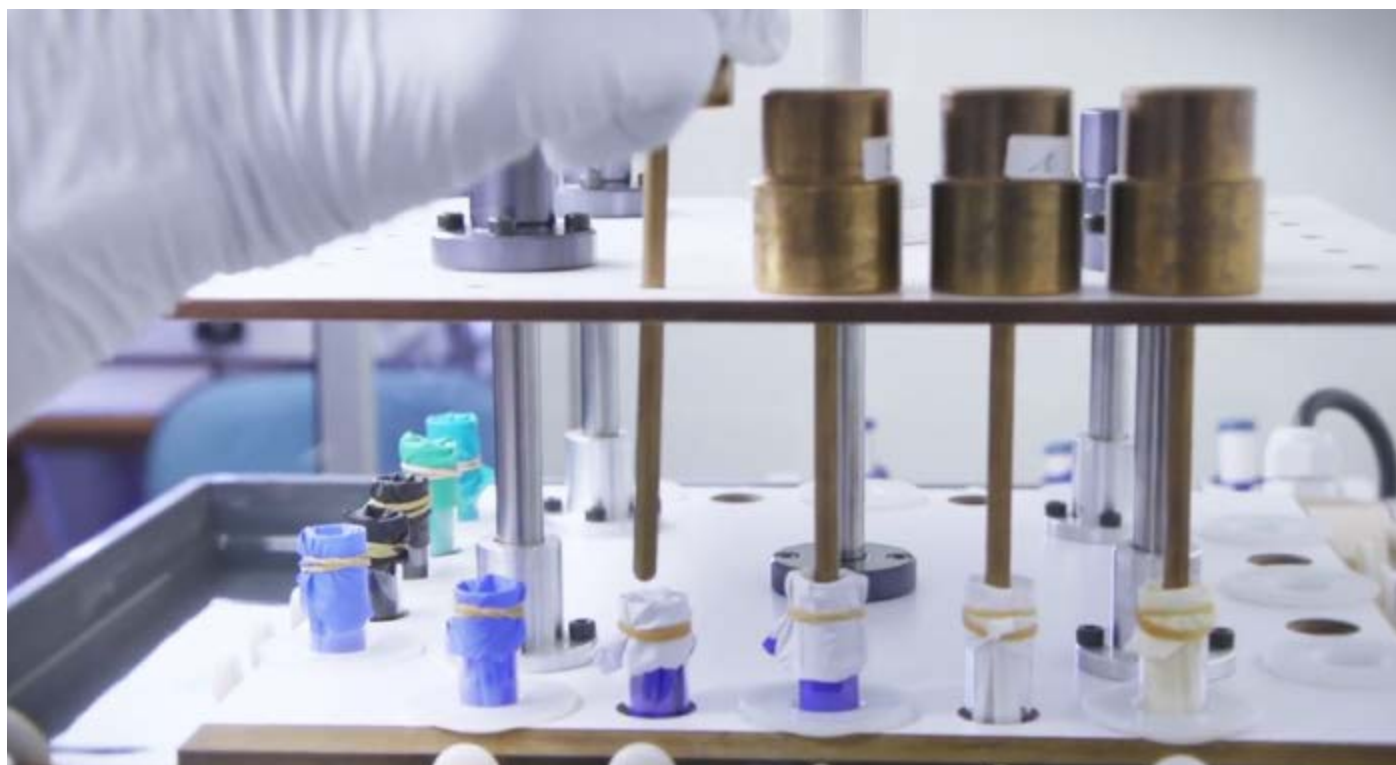
BACKGROUND

The authors introduced this article as worldwide cancer rates are expected to continue to increase, cytotoxic drugs will be at the forefront of treating this disease. As a result, safety concerns regarding preparing and handling antineoplastic agents are likely to grow. Exposure to anticancer drugs is a known risk for people working in specialty oncology units or having to compound chemotherapy drugs. Frequent exposure might lead to side effects like headaches, irritation of the eyes/skin, hair loss, and dizziness. It might also lead to more severe adverse outcomes; including genetic damage leading to infertility, cancer, and miscarriages. Though healthcare workers' exposure to hazardous compounds results from multiple factors, wearing gloves is one of the vital components of personal protection.

Since the 1990s, several studies have been published to measure glove barrier protection on permeation of drugs used in chemotherapy per recognized ASTM (American Society for Testing and Materials) standard. Permeation is the process by which the drug passes through the glove at a molecular level. Before 2005, permeation result testing relied on ASTM F739 methodology, a reliable test method for chemical permeation testing but is not specific to chemotherapy drugs. Which is why in 2005, the ASTM D6978 methodology was developed using a higher sensitivity threshold and specifically described the concentration and type of chemotherapy drugs to be tested. However, the current internationally recognized standards methodology from the European norms (EN-16523) and the American standards (ASTM D6978-05) for chemotherapy drug testing utilizes static and control permeation testing, which is not indicative of workplace reality. In 2006, for the first time, a new dynamic permeation assessment protocol was published in the American Journal of Health-System Pharmacy (AJHP). Ansell, in partnership with the Université Catholique de Louvain, Brussels, Belgium, developed a **unique** dynamic permeation device. The device allowed for the simulated dynamic chemotherapy permeation of glove fingers. Thereafter, permeation results were obtained via mass spectrometry (LSCMS-MS) or HPLC-DAD quantification methods.

OBJECTIVES AND METHODS

Using realistic dynamic conditions, this study assessed the permeability of 15 surgical and examination gloves made from different materials when exposed to 27 anticancer drugs. These gloves were tested using controlled dynamic conditions, duplicating flexion and extension movements simulating typical clinical applications. The cytotoxic drugs and concentration defined in the ASTM D6978 and EN1653-1 were used identifying differences in permeation rate and threshold sensitivity during the stretch and flex motion. Ansell Cytotoxic Permeation Program quantified the results with mass spectrometry methodology at different times to a maximum of 30 minutes.



ACPP offers an opportunity to provide better protection advice through evidence-based dynamic permeation testing data.

How ACPP Increases Healthcare Worker Safety

- 1** Helps select the right glove for the job.
- 2** Delivers a practical perspective of the impact of permeation on gloves to correspond to real life working conditions.
- 3** Mimics user and usage temperatures:
 - Temperatures are known to influence the rate of permeation. The higher the temperature the faster the permeation
 - Temperature set at 37°C
 - Testing under specialized usage conditions for cancer treatment:
 - » Only ACPP tests for permeation at Hyperthermic Intraperitoneal Chemotherapy (HIPEC)
 - » Chemotherapy drug heated at 43°C (109.6.4°F) is delivered directly into the abdomen during surgery
 - » Cisplatin, Doxorubin Hydrochloride, Mitomycin C and Oxaliplatin, drugs commonly used for HIPEC treatment, were tested

RESULTS

After testing 27 anticancer drugs on 15 different gloves in dynamic conditions for 30 minutes:

91.4 % gloves	96.5% Gloves	Busulfan, Carmustine and Thiotepa	100 % Gloves
• Met the D6978 standard	• Met the EN16523-1 European standard	• Permeation rate above ASTM D6978-05 for both sterile surgical and medical examination glove • Permeated through thinner gloves where permeation was no longer observed in thicker gloves of the same material	• Met the D6978 standard when double gloved

Finally, it has been found that Polysorbate 80 excipient added in the manufacturing of Docetaxel and Etoposide compounds and not the anti-cancer chemical itself could directly impact glove material integrity.

CONCLUSION

While ASTM and EN standards determine glove permeation under static test conditions, ACPP mimics everyday use in your workplace through controlled dynamic conditions. Current testing standards do not consider all working conditions that may influence the permeation of your glove's protective barrier. Such influencing factors include the concentration and exposure time of the chemotherapy drug being handled, glove properties such as thickness, the stretching and flexing motion of the task, and both body and workplace temperatures. Dynamic (ACPP) testing presents a comprehensive view of how the permeability of a glove to a chemotherapy drug is affected under these different conditions. This study has provided significant additional information on drug permeation volume on different surgical and examination glove types. ACPP offers greater sensitivity and selectivity of the method used. Finally, ACPP Liquid Chromatography - Mass Spectrometry (LC-MS) or Inductively Coupled Plasma - Mass Spectrometry detection limits of drug permeation can guide the end-user on glove choices to minimize or reduce the risk of exposure.

APPLICATION FOR PRACTICE

Increase safety by:

1



Practicing double gloving

2



Change both pairs of gloves every 30 minutes and after contact with heated chemotherapy drugs during HIPEC sterile procedure

3



Following National & International recommendations and guidelines when handling chemotherapy drugs

Note: This clinical summary is written by clinicians at Ansell Healthcare Products LLC. Please refer to the actual study for full text information.

Nalin M, Hug G, Boeckmans E, Machon C, Favier B, Guittton J. Permeation measurement of 27 chemotherapy drugs after simulated dynamic testing on 15 surgical and examination gloves: A knowledge update. J Oncol Pharm Pract. 2021; 27(6) 1395-1408

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