Disinfectants may cause adverse effects directly on the skin or systemically by permeating through the skin. In this study breakthrough times were measured for surgical gloves with chemicals which are commonly used in healthcare. Classical methods of analytical chemistry were tailored for the permeation tests, which were carried out according to the European standard EN 374 and the American standard ASTM F739. An exception to the EN 374 standard was made by using a 4 h testing time instead of 8 h. The gloves did not exhibit permeation of potassium hydroxide (45%), sodium hypochlorite (13%) or hydrogen peroxide (30%). Furthermore, neither glutaraldehyde (2%) nor chlorhexidine digluconate (4%) in the commercial disinfectant solutions studied exhibited permeation. Slight permeation of peracetic acid (0.35%) and acetic acid (4%) from a disinfectant agent was observed through single layered natural rubber materials. Clear evidence of formaldehyde permeation was detected through single layered natural rubber gloves, where the ASTM breakthrough times were 17–67 min, but the permeation rates were not high enough for breakthrough to have occurred according to the EN standard. The gloves in this study which offered most protection from chemical permeation were the chloroprene gloves and the thick double layered natural rubber gloves.

Keywords: chemicals; disinfectants; gloves; permeation; surgical

INTRODUCTION

Gloves are used in healthcare mainly to prevent the spread of infectious diseases (Rabussay and Korniewicz, 1997), but their use is also important for protection against hazardous chemicals. Gloves were first used in surgery in 1889 after a nurse had developed an allergy to a disinfectant used during surgical procedures (Burman and Fryklund, 1994). At present, the protective gloves have been divided according to European directives into two categories: medical devices and personal protective equipment (Council of the European Communities, 1989b, 1993). Individual glove brands cannot be certified according to both directives (D. Goltz, a representative of the glove distributor Kimberly Clark, Finland, personal communication 2002; T. Laatikainen, a representative of the glove distributor Tamro MedLab, Finland, personal communication 2002). The gloves used in patient care are medical gloves and therefore it is important to also test their protection efficiency against chemicals. According to the occupational safety regulations (Council of the European Communities, 1989a), workers handling hazardous chemicals should wear chemical protective gloves conforming to the personal protective equipment directive.

In healthcare use there are four types of common disposable gloves, surgical, sterile examination, non-sterile examination and non-sterile unclassified gloves. Surgical gloves are usually made from natural rubber (NR), but there are also gloves made from plastic materials (e.g. polyvinyl chloride, vinyl, PVC) and synthetic rubber materials [e.g. chloroprene rubber (CR), styrene-butadiene rubber] (Mellström and Boman, 1994; Douglas et al., 1997; Korniewicz and Rabussay, 1997). In Finland the examination gloves in use are usually either PVC or NR, but other materials such as nitrile rubber also exist (Palosuo et al., 1998). Examination gloves appear to be made of thinner materials (0.1–0.18 mm) than surgical gloves (0.17–0.3 mm) (Forsberg and Keith, 1999). The
group of non-sterile unclassified gloves includes the thin transparent gloves that are made by joining two flat polyethylene films. These seamed gloves have seldom been classified for either healthcare or occupational safety purposes. The rubber materials have better tensile strength and elasticity than plastic materials. In everyday use during high stress applications vinyl gloves often break (Korniewicz et al., 1989, 1993; Douglas et al., 1997; Neal et al., 1998).

One unique class of gloves are those gloves with thick fingertips meant for the handling of cytotoxic drugs (Mellström and Boman, 1994).

Chemical permeation is the diffusion of chemicals through intact materials. Many chemicals permeate gloves without visibly affecting the materials and thus gain access to the skin in an insidious manner. If a chemical permeates through the glove, it may cause adverse effects to the skin or it can be absorbed through the skin and cause exposure effects elsewhere in the body (Leinster, 1994). Even normally quite harmless chemicals can damage the skin if the exposure is frequent or prolonged (Mansdorf, 1994b). Furthermore, the inertness of the glove material to the chemical in use is important, because if one chemical degrades the glove material, it can aid in the permeation of other chemicals (Sansone and Tewari, 1978; Castegnaro et al., 1982; Stampfer et al., 1984) or microorganisms (Klein et al., 1990; Richards et al., 1993). It is crucial to be aware that chemical permeation through disposable gloves can sometimes be efficient and rapid (Mansdorf, 1987; Endicott, 1998; Blayney, 2001).

Composite resin materials, cytotoxic drugs and disinfectants have previously been shown to permeate through medical gloves and these studies have been reviewed by Mellström et al. (1996). Methyl methacrylate used in orthopaedic surgery is the best known chemical against which rubber surgical gloves fail to offer protection (Pegum and Medhurst, 1971; Waegemaekers et al., 1983; Darre et al., 1987; Jensen et al., 1991). It has also been shown that examination gloves do not provide adequate protection against many cytotoxic drugs, and thus surgical gloves have been examined to identify which of these gloves acts as an adequate barrier to these agents (Connor et al., 1984; Laidlaw et al., 1984; Slevin et al., 1984; Colligan and Horstman, 1990; Dinter-Heidorn and Carstens, 1992; Connor, 1995, 1999; Klein et al., 1999; Singleton and Connor, 1999). A study by Connor and Xiang showed that a 5 min contact with 70% isopropyl alcohol does not increase the permeation of cytotoxic drugs through NR or nitrile rubber material. Thus, disinfection with isopropyl alcohol solution does not enhance the exposure of healthcare workers to these agents (Connor and Xiang, 2000).

The use of disinfectants is important in surgical settings and some chemical permeation studies have been performed on disposable gloves with disinfectants and cleansing agents (Mellström et al., 1992; Lehman et al., 1994; Monticello and Gaber, 1999). However, only three studies which included surgical gloves have been found (Nelson et al., 1981; Schwoppe et al., 1988a; Jordan et al., 1996). These studies describe permeation tests against glutaraldehyde, ethanol and formaldehyde and they indicate that surgical gloves can sometimes safeguard the user when examination gloves would fail.

In this communication we offer guidance for selecting gloves against chemicals, while it is appreciated that the task in hand together with the properties of the chemical in use must play an important role in any choice of gloves (Berardinelli, 1988; Calmacher, 1993; Curtis et al., 1993; Mansdorf, 1994a).

Providing recommendations without accurate knowledge of the task in question can be misleading, but since interpretation of permeation data (Schwoppe et al., 1988b; Jamke, 1989; Leinster, 1994) has been considered to be 'state-of-the-art' or at least difficult in work places, some guidance does not seem amiss.

In this study the permeability of surgical gloves to disinfectants and components commonly present in cleansing agents was measured. The test chemicals were formaldehyde (37%), potassium hydroxide (45%), sodium hypochlorite (13%) and hydrogen peroxide (30%) and the three commercial disinfectant solutions Dialox™, Cidex Long Life™ and Hibiscrub™. The surgical gloves studied included four NR single layered brands, two NR double layered brands and one CR brand. The chemical permeation tests were carried out using the current American and European standards for permeation testing, ASTM F739 and EN 374 (European Committee for Standardization, 1994; ASTM, 1999). These define the test conditions and a two-chambered test cell for measuring chemical permeation through a flat protective material. In most of the tests, an automated valve system was used to sample the collection medium (water) outflow of the test cell. Analytical methods that have not previously been reported for use in permeation testing were tailored to the tests. The applied methods were based on ion chromatography, liquid chromatography and automated spectrophotometry.

MATERIALS AND METHODS

Seven brands of surgical gloves were studied (Table 1). One of the glove materials was CR, the rest were NR gloves. Six of the gloves came from the same factory and they had a polymeric Biogel® inner coating. Two of the glove brands were double layered gloves with a dark green glove worn underneath a pale yellow glove, which allows holes in the material created during surgical operations to be seen (Laine and Aarnio, 2001). The supplier of the gloves was SSL International plc (Oldham, UK). According to
the supplier, these products conform to the requirements for surgical gloves according to the Council Directive for Medical Devices and their acceptable quality level (AQL) is 1.5.

The chemicals tested were common hospital disinfectants or substances present in disinfectants or in other cleansing agents. Hydrogen peroxide (30%), potassium hydroxide (45%) and sodium hypochlorite (13%) were studied in more concentrated forms than the products in common use. Dialox™ is a 0.35% peracetic acid solution that contains 3–5% acetic acid and hydrogen peroxide. Cidex Long Life™ is a glutaraldehyde solution (2%). Peracetic acid solutions are gradually displacing glutaraldehyde as instrument disinfecting agents. Hibiscrub™ is a common disinfectant for skin and contains chlorhexidine gluconate (4%) as the active agent. The formaldehyde solution (37%) had methyl alcohol as the stabilizing agent. Hibiscrub™ and Dialox™ were ready-made solutions whereas for Cidex Long Life™ the accompanying activating agent was added as per the manufacturer’s instructions. The tests were carried out well before the expiry dates of the test solutions. The chemicals and their descriptions, which are required to be reported by the standard methods, are detailed in Table 2.

The permeation test method standards ASTM F739 and EN 374 were followed, except that the maximum testing time used was 4 instead of the 8 h stated by the EN standard. The glove samples were clamped

<table>
<thead>
<tr>
<th>Name</th>
<th>Material</th>
<th>Thickness (mm)</th>
<th>Weight per unit area (g/m²)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skinsense™ N</td>
<td>CR+ + BC</td>
<td>0.19</td>
<td>255</td>
</tr>
<tr>
<td>Biogel® Super Sensitive</td>
<td>NR+ + BC</td>
<td>0.22</td>
<td>197</td>
</tr>
<tr>
<td>Regent Surgical</td>
<td>NR</td>
<td>0.28</td>
<td>220</td>
</tr>
<tr>
<td>Biogel® Orthopaedic</td>
<td>NR + BC</td>
<td>0.27</td>
<td>244</td>
</tr>
<tr>
<td>Biogel® Indicator</td>
<td>NR + BC</td>
<td>0.37</td>
<td>302</td>
</tr>
<tr>
<td>Inner glove</td>
<td>0.22</td>
<td>199</td>
<td></td>
</tr>
<tr>
<td>Outer glove</td>
<td>0.22</td>
<td>202</td>
<td></td>
</tr>
<tr>
<td>Biogel® Orthopaedic</td>
<td>NR + BC</td>
<td>0.31</td>
<td>251</td>
</tr>
<tr>
<td>Biogel® Orthopaedic</td>
<td>NR + BC</td>
<td>0.29</td>
<td>241</td>
</tr>
</tbody>
</table>

Table 1. Glove materials

<table>
<thead>
<tr>
<th>Name</th>
<th>Supplier</th>
<th>Nominal concentration</th>
<th>Measured concentration</th>
<th>Other components</th>
</tr>
</thead>
<tbody>
<tr>
<td>Formaldehyde solution, A.C.S. reagent</td>
<td>Aldrich Chemie GmbH, Steinheim, Germany</td>
<td>37% (w/v)</td>
<td>38.8% (w/v)</td>
<td>Methyl alcohol 10–15%, water</td>
</tr>
<tr>
<td>Dialox™</td>
<td>Seppic, Paris, France</td>
<td>Peracetic acid 0.35% and acetic acid 3–5%</td>
<td>4.0% (w/v)</td>
<td>Hydrogen peroxide, water</td>
</tr>
<tr>
<td>Cidex Long Life™</td>
<td>Johnson &amp; Johnson Medical, Sollentuna, Sweden</td>
<td>Glutaraldehyde 2.0%</td>
<td>2.1% (w/v)</td>
<td>Peppermint oil, surfactant, potassium acetate, potassium phosphate, colour, water</td>
</tr>
<tr>
<td>Hibiscrub™</td>
<td>Zeneca Ltd, Macclesfield, UK</td>
<td>Chlorhexidine gluconate 4% (w/v)</td>
<td></td>
<td>Polyoxyethylene polyoxypropylene block co-polymer, lauryl dimethyl amine oxide, ponceau 4R, isopropyl alcohol, perfume, d-glutanolactone and water</td>
</tr>
<tr>
<td>Potassium hydroxide solution</td>
<td>Aldrich Chemical Co., Milwaukee, WI</td>
<td>45% (w/v)</td>
<td></td>
<td>Water</td>
</tr>
<tr>
<td>Sodium hypochlorite solution</td>
<td>BDH Laboratory Supplies, Poole, UK</td>
<td>Available chlorine ≥ 12%</td>
<td></td>
<td>Sodium hydroxide, water</td>
</tr>
<tr>
<td>Hydrogen peroxide solution, Reag. ISO, Reag. Ph. Eur.</td>
<td>Riedel-de Haen, Seelze, Germany</td>
<td>30%</td>
<td>33.0% (w/v)</td>
<td>Stabilizer, water</td>
</tr>
</tbody>
</table>

Table 2. Test chemicals
between the chambers of the test cells. The collection medium (water) was pumped through one chamber by a peristaltic pump (model 505S, Watson-Marlow Ltd, Falmouth, UK) and the test chemicals were injected into the other chamber. Open loop methods were used, i.e. fresh HPLC grade water was passed through the cell at a steady rate during the whole test. Appropriate flow rates (Table 3) for each analytical method were used, since the test standards do not require any specific flow rates. These flow rates were checked at the beginning of the tests and during each test. Magnetic stirrers made from polytetrafluoroethylene (PAM Solutions Ltd, Helsinki, Finland) were used to achieve adequate mixing levels in the test cells. The collection medium outflow was sampled periodically in order to measure the permeation rates of the test chemicals through the glove materials.

The ion chromatographic, liquid chromatographic and spectrophotometric test methods for measuring the test chemical in the collection medium are summarized in Table 3. The instruments were calibrated daily and checked after and during the tests when applicable. Calibration was performed with appropriate chemicals in the concentration range covering the concentrations at which the breakthrough times (BTTs) were detected. The test temperature was $23.0 \pm 1.0^\circ C$. The temperature of the test chemicals and the water used as the collection medium were regulated using a water bath. The thickness measurement was carried out according to the standard ISO 4648. The glove samples were prepared and the results were calculated as described in standards ASTM F739 and EN 374 and as reported elsewhere in detail (Mäkelä et al., 2003).

BTT is the time between application of the test chemical into the test cell and the time when the permeation rate exceeds a level of 0.1 (ASTM) or 1.0 $\mu g/cm^2/min$ (EN). The results of the tests are given as arithmetic means of three BTT measurements.

Three different glove materials were tested for all seven chemicals: the thinnest NR glove (Biogel® Super Sensitive), the NR glove without the Biogel® coating (Regent® Surgical) and the CR glove (Skin-sense™ N). The rest of the NR gloves were not tested for those chemicals which did not show any permeation through the thinnest NR glove material.

Formaldehyde was measured by HPLC/UV after derivatization (Levin et al., 1996; Priha, 1996). The collection medium flow rate was $20.6 \pm 0.6$ ml/min. Manual sampling from the outlet of the test cells was started for each test with a sampling rate of 1 sample/5 min, and was gradually reduced to 1 sample/20 min. The 1 ml liquid samples were added directly into mixtures of 2 ml of 0.3 g/l 97% 2,4-dinitrophenyl hydrazine (DNPH) (Aldrich) in acetonitrile (HPLC far UV grade; LabScan Analytical Sciences) and 0.5 ml of 4 M hydrochloric acid. After gentle mixing and keeping the samples for 2 h at room temperature, they were analysed using a HPLC system consisting of two Waters 510 pump units, a Waters 717 plus autosampler and a Waters 996 photodiode array detector (Waters, Milford, MA). A Spherisorb S5 column (ODS 2, 250 × 4.6 mm) and acetonitrile/water eluent (65:35) were used. The calibration samples were prepared by dissolving formaldehyde 2,4-DNP hydrazone (European Community Bureau of Reference BCR, reference material no. 546) into acetonitrile/water solutions at concentrations equivalent to the breakthrough detection levels. For the

### Table 3. Test methods

<table>
<thead>
<tr>
<th>Test chemical</th>
<th>Analyte</th>
<th>Collection medium flow rate (ml/min)</th>
<th>Sampling</th>
<th>Parallel tests at a time</th>
<th>Sampling frequency from one test cell (min)</th>
<th>Analytical method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Formaldehyde 37% (w/v) solution</td>
<td>Formaldehyde</td>
<td>20.6 ± 0.6</td>
<td>Manual</td>
<td>2</td>
<td>5–20</td>
<td>HPLC/UV, 2,4-dinitrophenyl hydrazine derivatives</td>
</tr>
<tr>
<td>Dialox™</td>
<td>Peracetate and acetate</td>
<td>8.3 ± 0.3</td>
<td>Automated</td>
<td>3</td>
<td>21.2</td>
<td>Anion chromatography</td>
</tr>
<tr>
<td>Cidex Long Life™</td>
<td>Glutaraldehyde</td>
<td>19.8 ± 0.8</td>
<td>Manual</td>
<td>2</td>
<td>5–20</td>
<td>HPLC/UV, 2,4-dinitrophenyl hydrazine derivatives</td>
</tr>
<tr>
<td>Hibiscrub™</td>
<td>Chlorhexidine digluconate</td>
<td>9.4 ± 2.5</td>
<td>Automated</td>
<td>3</td>
<td>16</td>
<td>HPLC/UV</td>
</tr>
<tr>
<td>Potassium hydroxide 45% (w/v) solution</td>
<td>Potassium</td>
<td>13.0 ± 2.5</td>
<td>Automated</td>
<td>3</td>
<td>13</td>
<td>Cation chromatography</td>
</tr>
<tr>
<td>Sodium hypochlorite 13% solution</td>
<td>Sodium</td>
<td>14.0 ± 1.3</td>
<td>Manual</td>
<td>2</td>
<td>5–20</td>
<td>Cation chromatography, reduction</td>
</tr>
<tr>
<td>Hydrogen peroxide 30% solution</td>
<td>Hydrogen peroxide</td>
<td>6.1 ± 0.3</td>
<td>Automated</td>
<td>2</td>
<td>17</td>
<td>Automated spectrophotometry, iodide reagent as an eluent</td>
</tr>
</tbody>
</table>

The ion chromatographic, liquid chromatographic and spectrophotometric test methods for measuring the test chemical in the collection medium are summarized in Table 3. The instruments were calibrated daily and checked after and during the tests when applicable. Calibration was performed with appropriate chemicals in the concentration range covering the concentrations at which the breakthrough times (BTTs) were detected. The test temperature was $23.0 \pm 1.0^\circ C$. The temperature of the test chemicals and the water used as the collection medium were regulated using a water bath. The thickness measurement was carried out according to the standard ISO 4648. The glove samples were prepared and the results were calculated as described in standards ASTM F739 and EN 374 and as reported elsewhere in detail (Mäkelä et al., 2003).

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recovery measurements, the concentration of the test chemical was determined using an iodometric method (Finnish Standards Association, 1981). The test chemical (~37%) was found to contain 38.8% (w/v) formaldehyde. The recoveries were 89.0 ± 6.3 (ASTM) and 93.2 ± 1.6% (EN).

The permeation of peracetic acid and acetic acid from Dialox™ was measured by ion chromatography. An automated valve system (six port valve V340 with V1001 electric actuator; Upchurch Scientific, Oak Harbor, WA; valve actuator program IC version 1.0 by Matti Jussila) was used to direct the collection medium flow into the injector valve of the ion chromatograph (DX-100; Dionex Corp., Sunnyvale, CA). The valve program also actuated the anion chromatographic run every 5.3 min. The collection medium flow rate was 8.3 ± 0.3 ml/min. Three parallel glove samples were tested simultaneously. Dionex AS14 analytical (4 × 250 mm) and AG14 (4 × 10 mm) guard columns and an ASRS-I anion self-regenerating suppressor (4 mm) were used with the eluent 3 mM Na₂CO₃/1 mM NaHCO₃, the flow rate being 0.91 ml/min. The acids eluted with the same retention time. The response was measured against calibration samples in the range 0.19–2.7 mg/l and in which the ratio of peracetic acid to acetic acid was 39:61. The permeation of hydrogen peroxide contained in the Dialox™ solution was not measured.

Only the permeation of glutaraldehyde was studied for Cidex Long Life™ solution. The test arrangement was the same as in the testing of formaldehyde. The collection medium flow rate was 19.8 ± 0.8 ml/min. Glutaraldehyde 2.4-DNP hydrazone (European Community Bureau of Reference BCR, reference material no. 550) calibration samples were in the concentration range 0.039–1.43 mg/l. A cubic through zero curve fit was used which resulted in R² values of 0.998. The HPLC eluent flow rate was 1.3 ml/min and the ratio of acetonitrile and water 70:30. Glutaraldehyde (Aldrich) at p.a. grade 50% was used to test the recovery of the method. The solution was measured titrimetrically and found to contain 53.0% (w/v) glutaraldehyde. The recoveries for samples equivalent to the breakthrough detection levels were 66 ± 13 (ASTM) and 97 ± 1% (EN). In Cidex Long Life™ 2.1% (w/v) glutaraldehyde was found, whereas it nominally contained 2.0% (w/v).

Tests studying the permeation of chlorhexidine digluconate from Hibiscrub™ were carried out with the same equipment as for Dialox™ with the exception of using the ion chromatograph as a liquid chromatograph. A UV/VIS detector (259 nm, SPD-250; Shimadzu Corp.) was connected to the outlet of the analytical column, which was Supelcosil LC-18-DB (4.6 × 250 mm). Eluent consisting of 50% (v/v) acetonitrile and water 70:30. Glutaraldehyde. The recoveries for samples equivalent to the breakthrough detection levels were 66 ± 13 (ASTM) and 97 ± 1% (EN). In Cidex Long Life™ 2.1% (w/v) glutaraldehyde was found, whereas it nominally contained 2.0% (w/v).

Potassium hydroxide testing was carried out with the same equipment as for Dialox™ but using cation exchange columns (Ionpac CS12A 4 × 250 mm and CG12A 4 × 50 mm; Dionex), a CSRS-Ultra self-regenerating suppressor (4 mm) and 15 mM sulphuric acid (diluted from 0.5 M sulphuric acid, Titrisol®; Merck) eluent at a flow rate of 1.5 ml/min. The collection medium flow rate was 13.0 ± 2.5 ml/min. Three parallel tests were carried out simultaneously. The chromatogram analysed a sample (50 µl) from every cell every 13 min. Commercial potassium hydroxide volumetric standard (0.1025 M; Aldrich) was diluted to five concentrations ranging from 0.092 to 1.84 mg/l for calibration of the cation chromatographic analysis. The response was linear.

Sodium from sodium hypochlorite was measured using ion chromatography following manual sampling and reduction of the hypochlorite. Samples (4.9 ml) were pipetted from the collection medium flow (rate 14.0 ± 1.3 ml/min) from the test cells and 100 µl of 15 mM sulphuric acid was added to liberate the oxygen from the hypochlorite. The samples were sonicated for 15 min prior to analysis. At the beginning of the tests the sampling rate was every 5 min; at the end of the tests it was prolonged to every 15 min. The same ion chromatographic conditions were used as for potassium hydroxide analysis except for the eluent flow rate, which was 1.3 ml/min. Calibration samples were dissolved and diluted from dried sodium sulphate (p.a. grade; Merck). Five concentrations were used containing sodium sulphate from 0.11 to 1.76 mg/l and the response was linear.

Hydrogen peroxide was detected using an automated spectrophotometric method based on oxidation of iodide by hydrogen peroxide. The same automated sampling system was used as in the Dialox™, Hibiscrub™ and potassium hydroxide testing. The ion chromatography column was replaced by a coiled reactor and restrictor tubing, which consisted of 6 cm polyetheretherketone (PEEK) (i.d. 0.5 mm), 16 cm polyethene (i.d. 1 mm), 97 cm PEEK (i.d. 0.5 mm), 216 cm PEEK (i.d. 0.25 mm). The UV/VIS detector was set to a wavelength of 350 nm. The injector loop was 25 µl. The eluent was prepared by adding 20 ml of sodium iodide (10 g/l in water), 5 ml of sulphuric acid (96%), 5 ml of ammonium heptamolybdate (3 g/l in water) and 250 µl of iodine solution (0.05 M Titrisol®; Merck) to water and concentrated phosphoric acid. The eluent flow rate was 1.05 ml/min. The method was an in-house modification of a method reported for amines (Vainiotalo, 1993; Vainiotalo and Matveinen et al., 1993). The collection medium flow rate from the test cells was 9.4 ± 0.6 ml/min and three parallel tests were carried simultaneously. A sample (10 µl) from each cell was analysed every 16 min. The results were calculated from calibration standards of commercial chlorhexidine gluconate (20% w/v; Sigma).
adjusting the volume to 500 ml. In the analysis the hydrogen peroxide oxidized iodide to iodine and tri-iodide. Iodine was added to the eluent as a stabilizer and ammonium heptamolybdate catalysed the reaction. The eluent flow rate was 0.34 ml/min. The sample concentrations of iodine were lower than the eluent concentrations and thus negative peak detection was used. The concentration of the commercial 30% (w/v) hydrogen peroxide was determined by an iodometric method using sodium thiosulphate. The result was 33.0% (w/v). The concentration levels of hydrogen peroxide (0.330 and 3.30 mg/l) for BTT determination corresponded to 0.58 ± 0.03 and 15.0 ± 0.2 mg/l iodine in the test system. Calibration samples were diluted from a 0.05 M Titrisol® iodine solution. Iodine concentrations between 1.2 and 15 mg/l resulted in a linear fit. The detection limit of the method was 0.33 mg/l hydrogen peroxide in water. The collection medium flow rate was 6.1 ± 0.3 ml/min. All the samples from the collection medium flow were programmed to be analysed between a sample of pure water and a solution containing 0.57 mg/l iodine. The injection frequency to the ion chromatograph was 4.2 min and two glove samples were tested simultaneously. This meant that a sample was taken from each test cell outflow every 17 min.

RESULTS

Description of the materials

The standardized methods require that glove thicknesses and the weight per unit area values must be reported; these are shown in Table 1. The test chemical information is presented in Table 2.

Potassium hydroxide (45%), sodium hypochlorite (13%), hydrogen peroxide (30%), Cidex Long Life™ and Hibiscrub™ permeation

The gloves did not show any permeation of potassium hydroxide, sodium hypochlorite or hydrogen peroxide. Neither did the glutaraldehyde nor the chlorhexidine gluconate present in the commercial disinfectant solutions show any permeation through the gloves under the conditions used (Table 4).

Formaldehyde permeation

Formaldehyde permeation of the single layered NR gloves was first detected within 4–20 min at a level of 0.03 µg/cm²/min. The thinner double layered glove, the Biogel® Indicator, showed permeation initially at 75 min and the thicker Biogel® Revealed glove at 100 min. The CR glove, the Skinsense™ N, first showed permeation at a test time of 140 min. The BTTs according to the standard ASTM F739 were 17, 38, 37 and 67 min for the Biogel® Super Sensitive, Regent® Surgical, Biogel® and Biogel® Orthopaedic, respectively (Table 4). The Biogel® Indicator, Biogel® Revealed and Skinsense™ N gloves did not reach the permeation rate required for a BTT to be assigned. A graphical presentation of the BTTs is shown (permeation rate 0.1 µg/cm²/min) in Fig. 1. For the BTTs in the EN tests the same raw data could have been utilized, but in none of the tests did the permeation rate exceed the limit of 1.0 µg/cm²/min.

If the permeation rate reaches a steady-state level (a constant rate of permeation), the ASTM standard requires that this must be reported. In the test for permeation of formaldehyde through the Biogel Super-Sensitive glove a level of 0.5 µg/cm²/min was reached, that being the only steady-state permeation rate attained in these tests.

Dialox™ permeation

The single layered NR gloves allowed slight permeation of peracetic acid and acetic acid from the Dialox™ solution. The total permeation of peracetic and acetic acids at the ASTM level of 0.1 µg/cm²/min was exceeded in only one sample of the thinnest NR, Biogel® Super Sensitive glove. The permeation rate was first detected 2 h after insertion of the test chemical and the permeation rate stayed near the level of 0.1 µg/cm²/min until the end of the test (Fig. 2). The Regent® Surgical and the Biogel® gloves and the two other samples of the Biogel® Super Sensitive glove were also permeable to the acids in the Dialox™ solution, but in the 4 h test they never reached a high enough level to permit BTT determination.

DISCUSSION

Potassium chloride and sodium hypochlorite

The test results with the concentrated solutions of potassium chloride and sodium hypochlorite show that the NR and CR gloves studied are able to protect against these two chemicals in conventional hospital work where there is usually contact with less concentrated chemicals and where contact is for short periods of chemical usage. However, should these chemicals be used in mixtures with highly glove-permeable or glove-degrading chemicals or the mechanical stress is greater than the gloves can stand, then the results will be not applicable. The results found for thin NR gloves in the compendium of permeation indices (Forsberg and Keith, 1999) agree with the study results.

Hydrogen peroxide

The concentrated hydrogen peroxide did not permeate through the studied NR and CR surgical gloves. Previously permeation of hydrogen peroxide (7.5%) through PVC and NR examination gloves has been reported to occur in <30 min. The testing of NR gloves had been stopped after 3 h, because the permeation rate had been accelerating at a rate too high to be meaningful (Monticello and Gaber, 1999). The ASTM standard with a closed loop system had been
Table 4. BTTs (min) of surgical gloves measured according to the standards EN 374 and ASTM F739

<table>
<thead>
<tr>
<th>Glove</th>
<th>Formaldehyde 37%</th>
<th>Peracetic acid and acetic acid in Dialox</th>
<th>Glutaraldehyde in Cidex Long Life</th>
<th>Chlorhexidine gluconate in Hibiscrub</th>
<th>Potassium hydroxide 45%</th>
<th>Sodium hypochlorite 13%</th>
<th>Hydrogen peroxide 30%</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>EN</td>
<td>ASTM</td>
<td>EN</td>
<td>ASTM</td>
<td>EN</td>
<td>ASTM</td>
<td>EN</td>
</tr>
<tr>
<td>Skinsense™ N</td>
<td>*</td>
<td>*</td>
<td>–</td>
<td>–</td>
<td>–</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>Biogel® Super Sensitive</td>
<td>*</td>
<td>17 (16–19)</td>
<td>*</td>
<td>&gt; 233 (189–240)</td>
<td>–</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>Regent Surgical</td>
<td>*</td>
<td>38 (33–47)</td>
<td>*</td>
<td>*</td>
<td>–</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>Biogel®</td>
<td>*</td>
<td>37 (29–43)</td>
<td>*</td>
<td>*</td>
<td>–</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>Biogel® Orthopaedic</td>
<td>*</td>
<td>67 (49–88)</td>
<td>–</td>
<td>–</td>
<td>–</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>Biogel® Indicator</td>
<td>*</td>
<td>*</td>
<td>–</td>
<td>–</td>
<td>–</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>Biogel® Reveal</td>
<td>*</td>
<td>*</td>
<td>–</td>
<td>–</td>
<td>–</td>
<td>–</td>
<td>–</td>
</tr>
</tbody>
</table>

Only the Skinsense N, Super Sensitive and the Regent Surgical were tested with all the chemicals. It was assumed that if the chemical did not permeate the thinnest natural rubber gloves (Super Sensitive) neither would it permeate the thicker gloves made from the same material. Numbers in parentheses indicate the range of the three parallel BTT results.

–, no permeation was observed during the 4 h test.

*, permeation under the limit of breakthrough detection was observed in the test.
used in the tests. One of the probable reasons for the differences between those results and the results of this study may be the glove thicknesses and materials, because the thinnest gloves used in this study still have double the thickness of the gloves examined in the Monticello and Gaber study. The compendium of permeation indices (Forsberg and Keith, 1999) presents one BTT of 150 min for NR gloves with a thickness of 0.15 mm; the other BTTs for NR gloves (0.15–0.73 mm) are >360 or >480 min, which means that permeation has not been detected. In the compendium there is no published data for CR surgical gloves, but for industrial CR glove materials BTTs of 5–>480 min are reported. The conclusion drawn for those situations in which examination gloves must be used for protection against concentrated hydrogen peroxide is that only gloves which have been determined to provide the required protection should be used.

Peracetic acid and glutaraldehyde solutions

No difficulties should arise in finding protective gloves against either of these dilute solutions. Nonetheless, only gloves that have been shown to provide protection should be used. The gloves used in this study, even the thinnest NR gloves, should provide protection in direct contact with Dialox™ solution for 1 h, if the mechanical stress on the glove is kept to a minimum. Peracetic acid and glutaraldehyde can also be used at higher concentrations. Due to the low permeation of Dialox™, the permeation data for those concentrated solutions must be used when
selecting gloves against them. Although the Dialox™ solution also contains hydrogen peroxide, testing of the permeation of hydrogen peroxide from Dialox™ was considered unnecessary, because the 30% hydrogen peroxide did not permeate the gloves and the permeation of peracetic acid and acetic acid was minor. Lehman et al. (1994) earlier noted that the permeation of dilute glutaraldehyde through NR or Tactylon® examination gloves is nil or very low after 4 h of testing if the glove samples are not stretched. Permeation of Cidex™ has also been tested through thin NR, PVC and polyethylene gloves and no evidence of glutaraldehyde permeation was detected (Mellström et al., 1992). On the other hand, Jordan et al. (1996) have reported that a 2% glutaraldehyde solution can permeate through rather thin NR gloves in 45 min.

Chlorhexidine

Chlorhexidine is used in various disinfectant products. It is unlikely thatchlorhexidine, which is polar and of large molecular size, would be able to permeate through rubber gloves unless there are chemicals in the product that degrade the glove material. Solvents, e.g. alcohols, could aid chlorhexidine permeation.

Formaldehyde

Formaldehyde is a clear risk chemical and it should not be allowed to gain access to the skin frequently or to any great extent. Thus, double gloving is recommended because of the risk of pinholes in the glove material and because of the reduced chemical permeation. The thinner double layered glove in this study, the Biogel Indicator, would provide a relatively safe period for working with formaldehyde of 30 min at a mechanically light task, even if the job included continuous contact with the chemical.

It is typical that the permeation of formaldehyde increases very slowly during the permeation tests resulting in a low steady-state permeation rate. This type of permeation rate profile makes the test results difficult to reproduce with the different methods in use in separate laboratories. Even small changes in test conditions can cause major differences. In the case of formaldehyde we will list a few of the critical test parameters. The collection medium can be either gaseous or liquid and the detection limit of the analytical method may be higher than the formaldehyde concentration corresponding to a permeation rate of 0.1 µg/cm²/min. In such a case, the permeation can be extrapolated backwards from the higher detected concentrations. There may also be difficulties due to the volatility and polymerization properties of formaldehyde. When these facts are added to the differences in glove materials, the wide range of BTTs (from 4 to >360 min) in the permeation index compendium should not come as a surprise (Forsberg and Keith, 1999). A previous study into formaldehyde permeation describes methods that were applied to three brands of NR and one type of CR gloves (Schwope et al., 1988a). The results for 0.17 mm thick NR surgical gloves ranged from 1 to 15 min and the steady-state permeation rates from 0.1 to 1.0 µg/cm²/min. Thus, our data are consistent with the data of Schwope et al. taking into consideration the differences in the materials and the non-standardized methods.

Chloroprene rubber

The CR gloves were the thinnest gloves in our study and clearly offered the best protection against formaldehyde. It is unfortunate that this brand is planned to be sold only as single-packed sterilized surgical, and thus high priced, gloves. These CR gloves also offered good protection performance against 70% isopropyl alcohol (Mäkelä et al., 2003). Additionally, a previous CR surgical glove material has proved to be an effective barrier against a mixture of methacrylates (Mäkelä et al., 1999). Schwöpe et al. (1988a) have also concluded that CR gloves are superior to NR and PVC gloves as a barrier against formaldehyde.

Glove thickness

The thicker the NR gloves, the better barriers they provided against formaldehyde as well as isopropyl alcohol (Mäkelä et al., 2003). The results for the Regent® Surgical glove were consistent with the others, although it had no Biogel® coating and was from a different production unit. The choice of not testing all the gloves for all the test chemicals proved reliable. The thick or double layered NR gloves which were not tested for all the chemicals can be safely used for protection against chemicals that did not permeate through the thin NR gloves.

Different permeation levels for BTT determination of the standards

The level of the ASTM standard, 0.1 µg/cm²/min, yields shorter BTTs than the EN standard under the same test conditions. For the user of the gloves this is naturally safer: witness that formaldehyde did not result in a BTT at all using the EN standard in this study. On the other hand, the ASTM standard requires low detection limits for the test chemicals, which complicates the testing methods for some chemicals. In the case of gaseous collection media, the flow rate is different in these two standardized methods and this sometimes affects the results (Mäkelä et al., 2003). Thus, even though there is a need for uniform standards, it is difficult to state which kind of test conditions should be selected for the harmonized standard.
Improving the safety of gloves used in the medical health services

To protect healthcare workers from the hazardous effects of chemicals, the regulations should be altered and the testing of medical gloves should be mandatory against chemicals and medical substances. Since permeation depends on both the test chemical and the glove brand, all the brands that are used in the handling of chemicals need to be tested.

The present practice of glove certification with different categories either for medical or other protective purposes should be abandoned and the same glove brands should be certified for both uses.

The goal of standardization should be the harmonization of test methods for all leak-tight gloves that are used to protect against chemicals, microbes or medications. Uniform tests would facilitate the interpretation of the results, make the selection of gloves easier and keep the testing costs reasonable.

Even if chemical permeation tests are not required of the manufacturers of medical gloves at present, the test data may be produced and provided as additional information. The healthcare personnel handling hazardous chemicals and medications must be trained to find and to know how to use this information. Furthermore, detailed studies on chemical, bacterial and viral protection provided by disposable gloves in everyday use are clearly needed.

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REFERENCES


