



TITLE: Disposable Gloves for Use in Healthcare Settings: A Review of the Clinical Effectiveness, Safety, Cost-Effectiveness, and Guidelines

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CONTEXT AND POLICY ISSUES

Concerns regarding the development of latex allergy related to occupational exposure to natural rubber latex have prompted healthcare centers to look for non-latex glove products suitable for patient care. Different glove materials, such as vinyl, nitrile, and neoprene, are available on the market. This report will review the evidence on the barrier quality, durability, allergy potential, recommended duration of use, and cost effectiveness of latex and non-latex gloves.

RESEARCH QUESTIONS

1. What is the clinical effectiveness of different types of disposable gloves for use in healthcare settings?
2. What is the safety of different types of disposable gloves for use in healthcare settings?
3. What is the cost-effectiveness of different types of disposable gloves for use in healthcare settings?
4. What are the evidence-based guidelines regarding the use of different types of disposable gloves for use in healthcare settings?

KEY MESSAGE

Latex gloves may be more resistant to punctures than non-latex gloves in the surgical setting. Vinyl gloves are permeable to chemotherapy and are not suitable for use when exposure to cytotoxic agents is possible. No evidence was found that addressed the allergy potential, cost-effectiveness, effectiveness to prevent pathogen transmission, or recommended duration of use of latex versus non-latex gloves.

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METHODS

A limited literature search was conducted on key resources including PubMed, The Cochrane Library (2011, Issue 4), University of York Centre for Reviews and Dissemination (CRD) databases, Canadian and major international health technology agencies, as well as a focused Internet search. No filters were applied to limit the retrieval by study type. Where possible, retrieval was limited to the human population. The search was also limited to English language documents published between January 1, 2006 and April 21, 2011.

Studies were included if they compared latex with non-latex gloves used in a healthcare setting. Any studies comparing powdered with non-powdered latex gloves were excluded from the report (Appendix 4).

Rapid Response reports are organized so that the higher quality evidence is presented first. Therefore, health technology assessment reports, systematic reviews, and meta-analyses are presented first. These are followed by randomized controlled trials, non-randomized studies, economic evaluations, and evidence-based guidelines.

SUMMARY OF FINDINGS

The literature search identified six non-randomized studies relevant to the research questions¹⁻⁶ and two guidelines.^{7,8} No systematic reviews, meta-analyses, health technology assessments, randomized controlled trials or economic analyses were found.

Non-randomized studies

Studies in a surgical setting

A group of researchers published two prospective observational studies that evaluated the performance of latex and non-latex gloves during orthopedic surgery (Appendix 1).^{1,2} The primary knee and hip arthroplasties were performed by the same surgeons at two hospitals in the UK. One hospital had implemented a latex-free policy. Similar procedures were used in both studies during the surgery and to assess glove perforation. Double gloves were worn during the procedure and were changed at set intervals or if perforation was suspected. The first report by Aldyami et. al.¹ compared Biogel latex gloves with Synthesis Surgical latex-free gloves and found statistically significantly higher rates of perforation with the latex-free glove. In 80% of surgeries, one of the non-latex gloves were perforated compared to 34% of surgeries using latex gloves ($p < 0.0001$). The second report by Thomas et al.² compared one latex glove brand with four non-latex glove products. Gloves were assessed for resistance to perforation and general usability. The non-latex gloves (Cardinal Esteem and Biogel Skinsense) were determined to be unacceptable to surgeons because they were either too slippery or they impaired the surgeon's dexterity or tactility. The perforation rate of the latex gloves (Biogel) was statistically significantly lower than the other two non-latex gloves tested (Synthesis and Cardinal Esteem SMT). The 2011 study² failed to report the methods used to evaluate the general usability of the gloves, and neither study stated the composition of the non-latex gloves. In both reports the authors concluded that latex free gloves have an inferior clinical performance during orthopedic surgery compared to latex gloves.^{1,2}

Studies in a laboratory setting

Four laboratory based studies were found that compared latex and non-latex gloves for preventing blood contact after puncture^{3,4} and for permeability to chemotherapy.^{5,6}

Mansouri et al.³ simulated needle stick injury to test transmission of blood through gloves after puncture with straight cutting suture needles (Appendix 2). The number of red blood cells (RBCs) that were transmitted through single and double layer latex gloves were compared with single layer nitrile gloves. The study found that double layer latex offered the greatest protection. Nitrile gloves were moderately superior to single layer latex in reducing the number of RBCs carried through the glove.³

Wittmann et al.⁴ simulated glove punctures with surgical suture needles, scalpel blades, and two sizes of cannulae (20 & 23 gauge) into porcine skin samples (Appendix 2). The transmission of radiolabelled blood was measured after puncture through single and double layered latex gloves, and a non-latex glove made of thermoplastic enantiomer with a disinfectant embedded within the glove (G-Vir). Compared with single layer latex, the non-latex glove reduced the volume of blood transmitted by surgical needle, scalpel and cannulae. The authors did not report any statistical testing so it was not clear if the differences between groups were statistically significant. The study was funded by Regent Medical Overseas and Mölnlycke Health care, the manufacturer of two of the gloves tested.⁴

Boccellino et al.⁶ evaluated the permeability of latex and nitrile gloves to doxorubicin in saline and acidic solutions. Two latex gloves (Chemoprotect and Cytostatic-Protective Gloves Z+) and one nitrile glove (N-DEX Ultimate) were tested. Permeability was assessed after set up, and after 0.5, 1 and 8 hours of exposure to the drug solution. All gloves prevented the permeation of doxorubicin for up to 8 hours of exposure to the neutral pH solution. Some doxorubicin was able to penetrate the nitrile glove when it was mixed at a pH of 2. The results of this study reported were incomplete and no statistical testing was conducted to determine if differences between gloves were significant. The acidic solution of doxorubicin is not used in clinical practice. The authors concluded that the permeability of gloves to doxorubicin depends on the pH and the glove material.⁶

Wallemacq et al.⁵ conducted a study evaluating the permeability of four different glove materials to chemotherapy agents. A total of 13 glove products were tested including eight latex, two neoprene, one vinyl and two nitrile gloves. All gloves were tested for resistance to carmustine, cyclophosphamide, etoposide, irinotecan, ifosfamide, and thiotepa. The latex, nitrile and neoprene gloves were also tested for cisplatin, cytarabine, docetaxel, doxorubicin, fluorouracil, methotrexate, and vinorelbine. Permeability was measured after set up of the experiment and after 15, 30 and 60 minutes of exposure to the chemotherapy agents. Vinyl was the most permeable glove material. After 15 minutes four of six drugs had permeation rates that exceeded the American Society for Testing and Materials (ASTM) standard limit of $10 \text{ ng}/(\text{cm}^2 \cdot \text{minute})$. Five drugs exceeded the ASTM limit after 30 minutes of exposure. Carmustine permeated two latex, one nitrile and one vinyl after 15 minutes, and two other latex gloves after 30 minutes exposure. After 60 minutes, only fluorouracil, etoposide and cisplatin exceeded the ASTM standard permeability limits of the non-vinyl gloves (two latex and one nitrile). The neoprene gloves tested were the most resistant material (DermaPrene Ultra, Micro-Touch DermaPrene). The Gammex PR, EP Surgical Style, Micro-Touch PR and Perry Encore Orthopedic latex gloves, and the Nitra-Tex nitrile glove were also resistant to chemotherapy. All gloves showed a trend toward greater permeability over time. Also permeability was related to

the thickness of the glove material and chemical properties of the drug. The authors concluded that neoprene, latex and nitrile gloves are most resistant to permeation by chemotherapy agents but other factors, such as glove thickness, duration of exposure and chemical properties of the drug affect permeability.⁵

Guidelines and recommendations

In 2008, the UK Royal College of Physicians published guidelines on the occupational management of latex allergy for healthcare and other settings.⁷ The guidelines were based on a systematic review of the evidence including critical appraisal of literature identified. Expert consensus was used to formulate recommendations. The guidelines included a review of published cost analyses. The following recommendations were made on the use of gloves:

Statements and Recommendations (Grade of Recommendation*)⁷

- “If latex products are used in the workplace, employers should provide powder-free latex products, if such alternatives exist. Employers should particularly ensure that powdered latex gloves are not used in the workplace.” (Grade C) page 12
- “Users of latex gloves and purchasers should be aware that the risk of developing latex allergy is highest with the use of powdered latex gloves, and that examination gloves may contain more latex allergen than surgical gloves.” (Grade D) page 12
- “Those concerned with glove purchasing policy should be aware that alternatives to latex gloves may have other associated problems, particularly with failure rates, user satisfaction, and barrier effectiveness.” (Grade B) page 12
- “Some other materials may be better than latex for protection against certain chemicals.” (no supporting evidence available) page 12
- “Both non-latex and latex gloves should be changed after two to three hours of use because the barrier of either type of glove becomes compromised with extended use.” (no grade or supporting evidence listed) page 13
- “Those concerned with glove purchasing policy should be aware that latex glove protein content may be a poor guide to allergenicity.” (Grade D) page 13
- “Those concerned with glove purchasing policy should be aware that a switch to powder-free latex gloves can be cost effective (in terms of glove costs, and compensation).” (Grade D) page 13
- “Those concerned with glove purchasing policy should be aware that a switch to non-latex gloves can also be cost effective.” (Grade D) page 13

*see Appendix 3 for description of grades of recommendations

The 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings by the US Centre for Disease Control and Prevention provide some information on the selection of gloves.⁸ The guidelines were based on a systematic review of the literature. It was only in the general discussion on the use of gloves by healthcare personnel that the guidelines mention information relevant to this research question. These statements however, were not formal recommendations. They were supported by references to published studies dated prior to 2006.⁸ The authors commented that the extent to which gloves protect

from transmission of blood borne pathogens following a needle stick or other puncture, is not known. Gloves may reduce the volume of blood on the external surface of a sharp but not the residual blood in the lumen of a hollowbore needle. The barrier effectiveness among gloves varies depending on the quality of the manufacturing process and type of material used. Unused intact gloves have similar barrier effectiveness however vinyl gloves have higher failure rates than latex or nitrile gloves. For tasks that require manual dexterity or involve more than brief contact with the patient, latex or nitrile gloves may be preferable to vinyl. Selection of gloves should consider the potential for contact with chemicals or chemotherapeutic agents, sizing, latex sensitivity, and task to be performed.⁸

Limitations

The number of relevant studies recently published was limited. Data on the durability of different gloves were limited to use during orthopedic surgery, which may not be applicable to daily patient care. Surrogate outcomes, such as the volume of RBCs transmitted through a simulated glove puncture^{3,4} does not address which type of glove best protects against transmission of infectious agents in clinical practice. The properties (for example, durability, resistance to chemotherapy) of a specific glove type was not always consistent across all brands tested. Thus, the findings based on one nitrile glove product may not be generalizable to a different nitrile product. Some studies did not perform statistical tests to determine if the differences between gloves tested were statistically significant or due to chance.^{4,6}

CONCLUSIONS AND IMPLICATIONS FOR DECISION OR POLICY MAKING:

Few studies are available that compare the safety and efficacy of non- latex and latex medical gloves. We found no studies that addressed the allergy potential, cost-effectiveness, or recommended duration of use of gloves.

Based on two prospective studies, non-latex surgical gloves were shown to be inferior to latex gloves for their resistance to punctures during orthopedic surgery. In laboratory testing, vinyl gloves were highly permeable to chemotherapy agents and are not suitable for preparing or administering cytotoxic agents. Latex, nitrile and neoprene gloves were resistant to permeation by chemotherapy agents. Permeability was affected by the duration of exposure, the chemical properties of the cytotoxic drug, and the thickness of the glove material.

Compared with single layer latex glove, nitrile gloves reduced the number of RBCs transmitted through the glove after a simulated suture needle puncture. No studies assessed if gloves reduced the risk of transmission of blood borne infectious agents.

The evidence based guidelines suggest that selection of gloves should consider the task to be performed, sizing, durability, latex sensitivity, and the potential for contact with chemicals or chemotherapeutic agents.

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APPENDIX 1. Study characteristics of perforation of latex and latex-free gloves during surgery

Study, design	Setting, population	Glove types (manufacturer)	Outer glove perforation*	Inner glove perforation*†
Thomas 2011 ² Prospective observational study	Orthopedic surgery Double gloves worn during surgery and changed at set times during procedure 2 hospitals in UK N=241 arthroplasty patients	Latex: Biogel (Mölnlycke Health Care AB Göteborg, Sweden)	Perforation rate per surgery† 34% (24/70)	Perforation rate per surgery† 0% (0/70)
		Latex-free: Synthesis (BM Polyco Ltd, UK)	80% (56/70) P<0.0001 vs latex	6% (4/70) P=0.042 vs latex
		Cardinal Esteem (Cardinal Health Inc)	Rejected glove as too slippery	NE
		Cardinal Esteem SMT (Cardinal Health Inc.) (textured surface)	54% (54/101) P=0.013 vs latex	18% (18/101) P<0.001 vs latex P=0.2 vs Synthesis
		Biogel Skinsense (Mölnlycke Health Care AB Göteborg, Sweden)	Rejected as inner glove affected dexterity and tactility	NE
Aldlyami 2010 ¹ Prospective observational study	Orthopedic surgery Double gloves worn during surgery and changed at set times during procedure 2 hospitals in UK N=120 arthroplasty patients	Latex: Biogel and Biogel Indicator Underglove (Mölnlycke Health Care AB Göteborg, Sweden)	Proportion of gloves perforated 8%	Proportion of gloves perforated 0%
		Latex-free: Synthesis Surgical and Synthesis Blue Surgical gloves (BM Polyco Ltd, UK)	22% P<0.0001	6% P=0.04

* Perforation tested using validated water distension test (each glove filled with 1 L water for 2 minutes and perforations recorded).

† Gloves were changed during the procedure at set time points. If any gloves were perforated during the surgery then entire procedure was deemed to be compromised. Data reported reflects the proportion of surgeries considered to be compromised.

NE=not evaluated

APPENDIX 2. Characteristics of laboratory-based studies

Study	Laboratory test	Glove types (brand name, manufacturer)	Outcomes	Conclusions
Mansouri 2010 ³	<p>Simulated needle stick injury to test blood transmission after puncture with straight cutting suture needle</p> <p>A testing machine was used to drive needles through the blood specimen and then through the glove into a microbiology cell plate containing normal saline.</p> <p>After puncture, cell plates were analyzed for RBC quantity by a blinded observer.</p>	<p>Single layer latex (Bodyguard examination glove)</p> <p>Double later latex (Bodyguard examination glove)</p> <p>Single later nitrile (Bodyguard blue exam glove)</p> <p>Control (no glove barrier)</p> <p>50 needle stick punctures were completed for each glove type 25 control punctures. All gloves were powder free.</p>	<p>RBC count, median (IQR) 230 (64, 443)</p> <p>3 (0, 57) [p value <0.001 vs single latex]</p> <p>34 (7, 157) [p value <0.001 vs single latex, double latex and control]</p> <p>1288 (1081, 1432)</p>	<p>Double later latex offered the greatest protection followed by nitrile and then single later latex gloves.</p> <p>Nitrile gloves were modestly superior to single layer latex.</p>
Wittmann 2010 ⁴	<p>Simulated glove puncture with surgical suture needles, scalpel blades and two cannulae (20 & 23 gauge).</p> <p>Gloves were placed over porcine skin samples and standardized punctures made with the needles, scalpels or cannulae contaminated with radiolabelled blood.</p> <p>The volume of blood transferred through the glove was estimated based on the radioactive decay 1 minute after cut.</p>	<p>Latex: Biogel-Eclipse (Mölnlycke) Biogel Eclipse Indicator double glove (Mölnlycke) Gammex PF double glove (Ansell)</p> <p>Latex-free: G-Vir, thermoplastic enantiomer glove with integrated disinfectant on inside (Hutchinson Santé)</p> <p>40 punctures per devices</p>	<p>Relative to the single latex glove the latex-free glove reduced the mean volume of blood transferred by a factor of 1.6 after puncture with the needle, by 1.4 with the scalpel, and by 1.2 with the cannulae.</p> <p>Double gloving further reduced the volume of blood transferred. No statistical testing of differences was reported.</p>	<p>Single layer gloves with integrated disinfectant (G-Vir) reduced the volume of blood transferred after puncture relative to single layer latex gloves however it is not clear if the differences were statistically significant.</p>

IQR=interquartile range; RBC=red blood cell

APPENDIX 3: Grade of evidence⁷

Grade	Description
A	Based on a meta-analysis, systematic review or RCTs rated as very low risk of bias, and directly applicable to the target population, or a systematic review or a body of evidence of RCTs rated as low risk of bias, directly applicable to the target population, and demonstrating overall consistency of results. ⁷
B	A body of evidence including systematic reviews of high quality cohort or case control studies directly applicable to the target population, and demonstrating overall consistency of results; or extrapolated evidence from studies rated as RCTs with a low risk of bias. ⁷
C	A body of evidence including studies rated as well-conducted case control or cohort studies directly applicable to the target population and demonstrating overall consistency of results; or extrapolated evidence from systematic reviews of high quality cohort or case control studies. ⁷
D	Evidence based on case reports or case series or extrapolated evidence from well conducted cohort or case control studies. ⁷

RCTs=randomized controlled trials

APPENDIX 4: Other references

Systematic reviews (powdered versus non-powdered latex gloves)

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Non-randomized studies (powdered versus non-powdered latex gloves)

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Non-randomized studies (other outcomes)

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