Evaluation of an innovative antimicrobial surgical glove technology to reduce the risk of microbial passage following intraoperative perforation

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Background: Surgical gloves provide a protective barrier for patients and members of the surgical team. Although glove integrity is important in an era of blood-borne pathogens, little data exist on bacterial passage after glove perforation. This study evaluated the impact of antimicrobial surgical gloves in reducing microbial passage after glove puncture in a model of wound contamination.
Methods: *Staphylococcus aureus* (ATCC 6538) and *Brevundimonas diminuta* (DSM 1639) were used to prepare a standardized suspension for testing bacterial passage after glove puncture in volunteers wearing single-layer gloves (group A), double-layer gloves (group B), or antimicrobial trilayer gloves (group C). After exposure periods of 5, 10, 30 and 45 minutes, the outer test gloves were removed and microbial passage was measured on the inner surface of the base gloves. Multiple repetitions (5 or 6) were performed at each sampling time.
Results: Microbial passage at 5-, 10-, 30-, and 45-minute exposures were analyzed both separately and combined (5 and 10 minutes and 30 and 45 minutes). No difference was observed in microbial passage between group A and group B at the 10-, 30-, and 45-minute exposures for *S aureus*, whereas a significant reduction in microbial passage was observed in group C compared with group A ($P \leq .05$ to $< .005$) at the 5-, 30-, and 45-minute exposures for both *S aureus* and *B diminuta*. When timed groups were combined (5 and 10 minutes and 30 and 45 minutes), a significant reduction ($P \leq .01$ to $\leq .005$) in microbial passage of *S aureus* and *B diminuta* was observed in group C compared with both group A and group B.
Conclusion: These findings represent the first evidence that microbial passage across surgical gloves can be reduced significantly using an innovative antimicrobial glove technology.
Key Words: Chlorhexidine gluconate; quaternary ammonium salts; microperforation; surgical site infection; elastomeric antibacterial surgical gloves.

Sterile surgical gloves play a dual role during the intraoperative period, protecting the patient against contaminating hand flora and members of the operative team against blood-borne fluid pathogens, such as human immunodeficiency virus (HIV) and hepatitis C virus (HCV). However, studies have suggested that glove perforation rates range from 16% to >60% in selected surgical procedures, including gastrointestinal, cardiothoracic, orthopedic, obstetric, and gynecologic.[1-5] It has been suggested that during surgery, manipulation of abrasive and cutting objects and associated mechanical stress generate damage leading to microperforations, threatening the integrity of the glove barrier and allowing bacterial migration across the composite surface of the surgical glove.[6] The rate of microperforation has been shown to increase over time, calling into question how often members of the surgical team should change gloves, especially during long complex surgical procedures.[5]

Historically, the risk of transmission of HIV and HCV after a sharps injury in the operating room has led surgical practitioners to adopt appropriate interventional strategies, such as double-gloving for high-risk cases or when exposure to blood or body fluid places the surgical team at risk. A recent Cochrane collaborative review examined 31 clinical trials involving 8 selected surgical disciplines associated with both low-risk and high-risk procedures and found that although

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double-gloving afforded greater protection to the inner layer against microperforation injury compared with single-gloving, there was no evidence that double-gloving reduced the risk of postoperative surgical site infection.[7] Given that most of the studies reviewed were not powered to discern a difference in infection rate, as well as the disparaging heterogeneity of the studies included in the analysis, it is not surprising that the authors were unable to assess the infection prevention benefit of double-gloving versus single-gloving. The relationship between glove integrity and the intraoperative passage of bacteria from patient (contaminated field) to surgeon or vice versa remains an unresolved question in terms of both risk and clinical impact. In the present investigation, we used an in vitro model of gross wound contamination to evaluate microbial passage through a conventional single-thickness latex glove, a double-thickness surgical glove, and an innovative trilayer antimicrobial surgical glove in which the middle layer contains an antimicrobial agent.

MATERIALS AND METHODS

Study subjects

The investigation was reviewed and approved by the Institutional Human Subjects Committee, and all volunteers provided informed consent before participation. A total of 34 volunteers were randomized into the 3 study groups identified below. Before donning study gloves, each participant performed skin antisepsis (for 90 seconds, in accordance with the manufacturer's recommendation) using an ethanol-based hand disinfectant (Bode Chemie Hamburg; Medline Industries, Mundelein, IL). After disinfection, skin flora of each hand (fingertips and palm) was analyzed. None of the test subjects exhibited bacterial growth on the test areas (ie, no growth after 48 hours of cultivation). Any individuals found to have a positive bacterial culture would have been excluded from the study analysis.

Surgical test gloves

Four types of sterile surgical gloves were used in the in vitro study: group A, controls (n = 10), single-layer latex, powder-free, 225 μm thick (Semperit Technische Produkte, Vienna, Austria; group B (n = 12), double-layer latex, powder-free, 450 μm thick (Hutchinson Sante, SNC, Paris, France); group C (n = 12), integrated three-layer antimicrobial synthetic (thermoplastic elastomer), 500 μm thick (Hutchinson Sante); and a conventional latex surgical glove, 340 μm thick (ANSELL, Richmond, Australia), that was used as the base glove for evaluating microbial quantitative recovery after bacterial passage. The trilayer antimicrobial glove used in group C consisted of two boundary layers separated by an antimicrobial middle layer in a drop-like compartment (Fig 1). The antimicrobial was composed of chlorhexidine digluconate, didecyl dimethyl ammonium chloride salt, and benzalkonium chloride salt in a polyethylene glycol diluent. This disinfectant solution has been shown to be active against enveloped virus particles and selective gram-positive and gram-negative bacteria. Figure 1 illustrates the structural components of the trilayer antimicrobial surgical glove.

Simulated contaminated field and test protocol

Two contaminated solutions were prepared for testing, one containing *Staphylococcus aureus* (ATCC 6538) and the other containing the test organism, *Brevundimonas* (formerly *Pseudomonas*) *diminuta* (DSM 1639). The *S aureus* is a standard laboratory reference strain used routinely for in vitro susceptibility studies, whereas because of its size, *B diminuta* is routinely used as a standard organism to validate the efficacy of sterilizing-grade membrane filters (0.2 μ). Both strains were recovered from frozen stock. After determination of purity, the organisms were inoculated to caseine peptone broth and incubated overnight at 35°C. Overnight cultures were adjusted to a concentration of 7.0 $\log_{10}$ cfu/mL in a final test volume of 3 L.

Before donning the study gloves, each participant donned a sterile latex (single-layer) indicator glove on each hand. Before the study gloves were applied, 4 punctures were made in each glove using a 20-gauge needle, 2 each (1 cm apart) in the distal medial thumb and index finger. Care was taken to avoid puncturing the base latex indicator glove. Once the study gloves were donned, both hands were immersed into a 5-L basin containing 3 L of contaminated broth (with *S aureus* or *B diminuta*) for a period of 5, 10, 30, or 45 minutes. While his or her hands were in the basin, the participant was asked to periodically (several times a minute) flex the hands, kneading the bottom of the basin to create pressure or stress on the tips of the gloved fingers. This process was repeated for all 3 study gloves at each specified time interval.

After each test period, the study gloves were carefully removed so as not to contaminate the external surface of the base latex glove. The base gloves were aseptically removed, both thumbs and index finger segments were inverted and filled with 25 mL of physiological saline and gently massaged for 30 seconds, and 100 μL of the solution was plated to Columbia agar containing 5% sheep's blood (Oxoid, Wesel, Germany) and incubated at 35°C for 48 hours. A total of 5 replicate samples were plated per sample interval for group A, whereas 6 replicate were plated for groups B and C in the *S aureus* challenge. A total of 5 replicates were plated for each time interval in groups A, B, and C