

# Evaluation of an antimicrobial surgical glove to inactivate live human immunodeficiency virus following simulated glove puncture

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**Background.** Percutaneous injuries associated with cutting instruments, needles, and other sharps (eg, metallic meshes, bone fragments, etc) occur commonly during surgical procedures, exposing members of surgical teams to the risk for contamination by blood-borne pathogens. This study evaluated the efficacy of an innovative integrated antimicrobial glove to reduce transmission of the human immunodeficiency virus (HIV) following a simulated surgical-glove puncture injury.

**Methods.** A pneumatically activated puncturing apparatus was used in a surgical-glove perforation model to evaluate the passage of live HIV-1 virus transferred via a contaminated blood-laden needle, using a reference (standard double-layer glove) and an antimicrobial benzalkonium chloride (BKC) surgical glove. The study used 2 experimental designs. In method A, 10 replicates were used in 2 cycles to compare the mean viral load following passage through standard and antimicrobial gloves. In method B, 10 replicates were pooled into 3 aliquots and were used to assess viral passage through standard and antimicrobial test gloves. In both methods, viral viability was assessed by observing the cytopathic effects in human lymphocytic C8166 T-cell tissue culture. Concurrent viral and cell culture viability controls were run in parallel with the experiment's studies.

**Results.** All controls involving tissue culture and viral viability were performed according to study design. Mean HIV viral loads ( $\log_{10}TCID_{50}$ ) were significantly reduced ( $P < .01$ ) following passage through the BKC surgical glove compared to passage through the nonantimicrobial glove. The reduction (log reduction and percent viral reduction) of the HIV virus ranged from 1.96 to 2.4 and from 98.9% to 99.6%, respectively, following simulated surgical-glove perforation.

**Conclusion.** Sharps injuries in the operating room pose a significant occupational risk for surgical practitioners. The findings of this study suggest that an innovative antimicrobial glove was effective at significantly ( $P < .01$ ) reducing the risk for blood-borne virus transfer in a model of simulated glove perforation. (*Surgery* 2013;153:225-33.)

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THE CENTERS FOR DISEASE CONTROL AND PREVENTION has estimated that more than 1,000 injuries involving sharp objects occur daily in US hospitals, placing health care workers at risk for a myriad of

blood-borne pathogens, including human immunodeficiency virus (HIV), hepatitis B virus, and hepatitis C virus (HCV).<sup>1</sup> Members of surgical teams are known to have higher rates of percutaneous injury than individuals in other health care settings: the probabilities of blood exposure are high; the natures of the surgical procedures often dictate the use of multiple sharp instruments in tight or confined quarters; sharps injuries may occur while devices such as sutures or needles are manipulated or passed among members of the surgical team; and stressful intraoperative events may occur, momentarily distracting attention from sharp objects within the surgical field.<sup>1-3</sup> Following passage of the Needlestick Safety and Prevention Act

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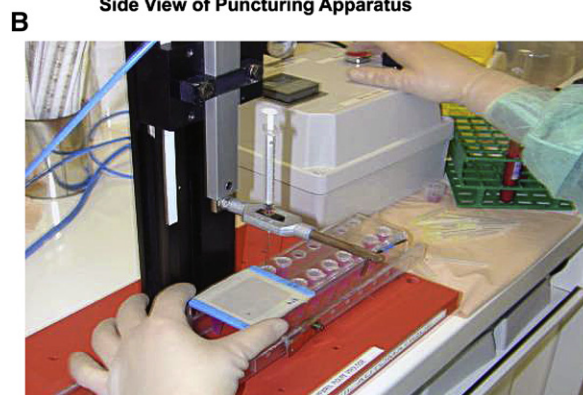
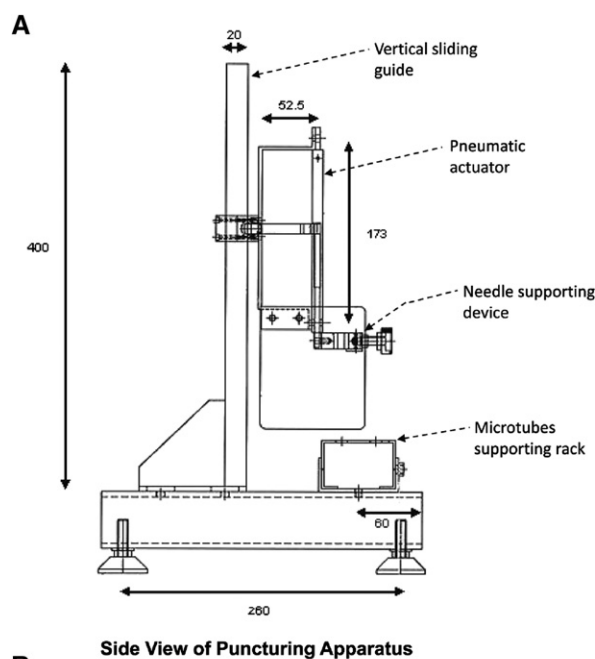
in 2001, there was a significant drop (31.6%) in the sharps injury rate within the nonsurgical setting; however, over the same time interval a 6.5% increase in sharps injuries was noted in the operating room environment.<sup>4,5</sup> The devices most often associated with injury include suture needles, scalpel blades, and syringe needles. These findings suggest that compared to other areas of the hospital, operating rooms have been less compliant in adopting engineering controls that would reduce the risk for sharps injuries.

In an effort to mitigate the risk for sharps injuries in the operating room, the American College of Surgeons (ACS) in 2005 issued a position statement supporting the adoption of blunt suture technology for fascia closure.<sup>6</sup> Although these devices have been shown to be effective in reducing sharps-related injuries, this technology has not been universally embraced by surgical practitioners, and although the devices themselves do not have cutting edges, the proximal (pointed) tip of the suture can still penetrate surgical gloves.<sup>7,8</sup> The ACS Committee on Perioperative Care has also endorsed the practice of double-gloving as a technique of reducing exposure to body fluids caused by tears in gloves caused by sharps. It has been estimated that double-gloving can reduce the volume of blood transferred when a contaminated needle or suture passes through the 2 glove layers by as much as 95%.<sup>9</sup> In spite of the data supportive of double-gloving as an effective risk-reduction strategy, many surgeons feel that double-gloving reduces hand sensitivity and dexterity, so the practice has seen limited application. A third intervention, endorsed by the Occupational Safety and Health Administration, ACS, and the Association of periOperative Registered Nurses, involves the concept of the neutral zone, or the hands-free technique, in which objects are not passed between individuals by hand during surgery but rather are placed on a designated area of the sterile field.<sup>10-12</sup> In spite of these collective endorsements, sharps injuries in operating rooms remain problematic, especially in high-volume surgical services involving high-risk patient populations.

The present *in vitro* study has been designed to evaluate the effectiveness of an innovative antimicrobial surgical glove in reducing live HIV-1 infectious viral transmission following simulated, severe percutaneous occupational injury.

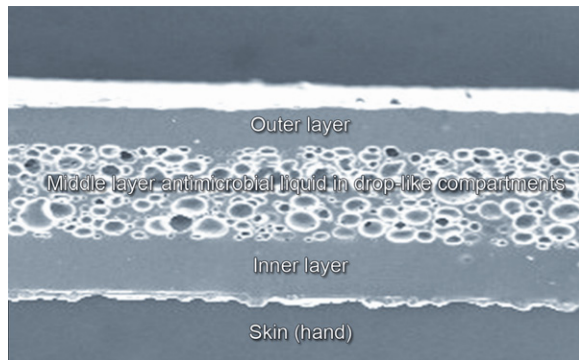
## MATERIALS AND METHODS

**Standardized puncture technique.** The test conditions were designed to simulate an accidental



**Fig 1.** (A) Side-view schematic of glove-puncturing apparatus, demonstrating vertical guide, pneumatic actuator, needle support, and microtube support rack. (B) Picture of investigator using pneumatic glove-puncturing device, demonstrating positioning of glove segments above microtube support rack. (Color version of figure is available online.)

occupational exposure involving a 6 mm–depth puncture using a 22-gauge hollow-bore needle filled with blood containing live HIV-1 virus. Briefly, the puncture apparatus consists of a pneumatic actuator, supporting a needle and syringe mounted on a vertical scale, allowing accurate control of the puncture depth and angle (Fig 1, A). Air pressure regulated by a manometer controlled the puncture speed, allowing for a high degree of reproducibility. Two different surgical gloves were tested in the apparatus; an integrated 3-layer elastomeric antimicrobial glove containing in its core homogeneously distributed micrometer-sized liquid droplets (Fig 2) composed of 30% benzalkonium chloride (BKC) in polyethylene



**Fig 2.** Cross-sectional micrograph of antimicrobial glove, demonstrating outer, inner, and antimicrobial middle layer containing benzalkonium chloride in droplet-like compartments. (Color version of figure is available online.)

glycol (G-VIR, Hutchinson Santé, Liancourt, France) and a control nonantimicrobial glove made of the same material and thickness (Hutchinson Santé). The sample gloves were prepared for testing by cutting out an  $8 \times 7$  cm rectangular segment from the planar surface of the back, which was then affixed to a rigid metal frame, simulating a 10% stretch ratio.

Prior to testing, a collection medium was prepared: RPMI 1640 medium (GIBCO, Life Technologies, Grand Island, NY) containing 4% gelatin (w/v) and 5% fetal bovine serum, which was heated to  $60^\circ\text{C}$  and swirled gently every 30 minutes for a total of 90 minutes. A 1.2 mL volume of the collection medium was added aseptically to 1.5 mL microtube collection vessels, capped, and stored in a refrigerator until use. At the time of testing, the glove samples were affixed to the puncture apparatus and the microtubes carefully positioned 3 mm below the test glove's surface. Mean resident time of the needle within the collection medium (0.387 seconds), travel time (0.217 seconds), and puncture speed (18.42 cm/sec) were determined by 10 repetitions using a reference control glove. The puncture angle was 90 degrees.

A purified viral lysate of HIV-1, strain IIIB, was used as the challenging agent (ZeptoMetrix, Buffalo, NY). This strain was stored at a temperature of  $-70^\circ\text{C}$  prior to use. Under laminar flow conditions, fresh-frozen stock was thawed on the day of the test and titrated to approximately  $8 \log_{10}$  TCID<sub>50</sub>/mL to ensure a sufficient loading dose for documenting a viral reduction of at least 15- to 100-fold. The challenge virus was then diluted 1:9 (vol/vol) in defibrinated sheep blood and loaded into a 1 mL disposable syringe containing a 22-gauge hollow-bore needle. While maintaining the tip of the needle below the surface of the

challenge medium, the viral suspension was carefully withdrawn and aspirated several times. A final sample was carefully withdrawn so that the virus-blood mixture filled the lumen of the needle.

The syringe was positioned in the apparatus above the stretched glove segments (Fig 1, B), and the pneumatic actuator was activated, allowing the viral-loaded needle to puncture the glove, allowing the collection medium to penetrate to a depth of approximately 6 mm. Any inoculate transmitted through the glove was collected in the microtubes. All punctures were performed using a reproducible resident time of the needle in the collection medium of  $<0.5$  seconds. Following puncture, the needle was immediately removed and placed in a sharps container, and a new microtube was shifted into position under the previous puncture site. A new needle was contaminated as previously described and a second puncture was performed. This process was repeated for the desired number of punctures per glove sample.

Following completion, inoculated microtubes were placed for approximately 5 minutes in a dry bath at  $37^\circ\text{C}$  to quickly liquefy the gelatin, and they were homogenized using a glass pipette. The study involved 2 separate methods to estimate the amount of viable virus that passed through the antimicrobial and control test gloves.

*Method A:* In the study, 10 punctures were performed on each glove segment, and individual collection microtubes (1.2 mL per tube) were analyzed separately to determine the number of infectious viral units transferred through the glove surface. The test was repeated twice for both antimicrobial and control gloves.

*Method B:* In the study, 10 punctures were performed on each glove segment, as previously described, and the samples from each glove were pooled in 50 mL conical tubes, and 3 aliquot samples per glove were analyzed for infectious viral units.

The residual viral load following passage through both the antimicrobial and the control gloves was determined by direct observation of the virus-induced cytopathic effects (CPEs) in a human lymphocytic T-cell line (C8166, University of Pennsylvania, Philadelphia, PA). The C8166 T cells used in this study were immortalized through transformation by the human T-cell leukemia-lymphoma virus type I.<sup>13</sup> In both methods, samples were serially diluted twofold in RPMI 1640 (with 5% fetal bovine serum) and added to the cell culture monolayer in 96-well culture plates (8 or 16 wells per dilution per sample). The inoculated plates were incubated at  $36 \pm 2^\circ\text{C}$  in  $5 \pm 1\%$  CO<sub>2</sub>

for 9 to 12 days. Several experimental controls were incorporated into the inactivation assay.

**Controls.** *Baseline glove control:* Infectious viral units were recovered from the control glove using methods A and B. The results of this assay functioned as a baseline for comparison with the antimicrobial test glove to determine the efficacy of viral reduction.

*Neutralizer effectiveness and viral interference control:* The “quench” of the microbicidal properties of the antimicrobial agent (BKC) when placed in the collecting medium was assayed to ensure there was no inactivation of the virus beyond the experimental exposure time. In general, inactivation can occur when there is a rapid quenching of antimicrobial activity either by massive dilution to subinhibitory levels or by chemical inactivation. The following neutralizer-effectiveness control test was used to document no residual activity of the BKC in the collecting medium. One set of microtubes ( $n = 10$ ) was inoculated through an antimicrobial glove segment by needles containing sheep blood without virus, depositing BKC into the collection medium. The microtubes were immediately inoculated again through the same glove but with needles now containing live HIV-1 virus, depositing virus into the collection medium containing residual BKC. As a separate control, another set of microtubes ( $n = 10$ ) was inoculated through a nonantimicrobial glove (reference control) with needles containing sheep blood without live virus and were inoculated again through the same glove with needles loaded with live HIV-1 virus, depositing live virus into the collection medium. Both sets of tubes were liquefied, pooled, divided into 3 aliquots, and assayed for infectious virus (CPEs). The viral load recovered from the antimicrobial glove and the reference control glove were expected to be similar ( $\pm 0.5 \log_{10}$ ).

*Cytotoxicity control:* This control was used to determine whether the collection medium containing residual BKC following test glove puncture was toxic to host (C8166) T cells. A total of 10 microtubes containing collection medium were inoculated through the antimicrobial glove using needles containing sheep blood without virus, depositing BKC into the collection medium. The contents of the tubes were liquefied and pooled to form 3 aliquots for dilution and inoculation into the C8166 monolayer. Following incubation, any noted CPEs should be distinct from observed viral-specific CPEs.

*No-glove-puncture control:* We made 10 separate punctures (with live virus) directly into the collection medium in the absence of a glove. The

medium was liquefied and pooled, and 3 samples were analyzed as previously described to document the viral load delivered without the protective barrier of a glove.

*Cell viability control:* We inoculated 8 wells with C8166 cells during the incubation period, documenting cell viability and the sterility of the medium employed throughout the assay period.

*Virus stock titer control:* An aliquot of the live virus was serially diluted and inoculated into the C8166 monolayer, confirming the stock virus titer and the performance of the virus-infected assay.

#### Calculation of viral titer and statistical analysis.

The 50% tissue culture infective dose per mL (TCID<sub>50</sub>/mL) was determined by the method of Spearman-Kärber, using the following formula<sup>14</sup>:

$$m = x_k + (d/2) - d \sum p_i,$$

where  $m$  = the logarithm of the titer relative to the test volume;  $x_k$  = the logarithm of the smallest dosage which induces infection in all cultures;  $d$  = the logarithm of the dilution factor; and  $p_i$  = the proportion of positive results at dilution  $i$ .

The values were converted to TCID<sub>50</sub>/mL using a sample inoculum of  $\sim 0.05$  mL.

It is to be noted that when a test sample contains a low viral load there is the possibility that a fraction of the samples will test negative due to random distribution of the virus throughout the total sample. The probability that the analyzed sample does not contain infectious virus is expressed by  $p = [(V - v)/v]^y$ , where  $V$  is the total volume of the container,  $v$  is the volume of the fraction being tested, and  $y$  is the absolute number of infectious viruses randomly distributed throughout the sample. If  $V$  is sufficiently large relative to  $v$ , the Poisson distribution can be approximated:

$$P = e^{-cv} \text{ or } c = -[\text{Ln}(P)]/v,$$

where  $c$  is the concentration of infectious virus and  $v$  is the total sample volume.

The amount of virus that would have to be present in the total sample in order to achieve a positive result with 95% confidence ( $P = .05$ ) is calculated as:

$$C = -[\text{Ln}(0.05)]/v = 3/v.$$

If selective wells ( $n$ ) are negative, the virus titer is considered to be less than or equal to this value. The total volume of sample assayed is  $v = v'nd$ , where  $v'$  is the test volume in a well,  $n$  is the number of wells per sample, and  $d$  is the sample dilution.

Statistical analysis was carried out using a paired 2-tailed student *t*-test (Windows Microsoft Excel, Redmond, WA).

## RESULTS

The assay cell line (C8166) documented viability and confluent growth throughout the study. The cytotoxicity studies documented that residual BKC inoculated into the collection media did not cause CPEs in any of the 4 test dilutions. The virus stock control titer following a 10-fold dilution in defibrinated blood was 7.55 log<sub>10</sub>TCID<sub>50</sub>/mL. The theoretical viral load in the absence of a glove barrier based on an approximate volume of blood transferred by a 22-gauge needle (~0.2-μL) was calculated to be 3.85 log<sub>10</sub>TCID<sub>50</sub>. The theoretical viral load in the presence of a glove barrier based on an approximate volume of blood transferred by a 22-gauge needle (~0.1-μL) was calculated to be 3.55. Table I documents the neutralizer effectiveness/viral interference control. There was no significant difference (*P* = .27) in viral recovery in the presence of residual BKC in the collection medium compared to the antimicrobial-free collection media. The volume of the collecting medium was approximately 1,000,000 times higher than the volume of antimicrobial agent transferred in the medium when the needle was removed. The BKC was rapidly diluted to subinhibitory levels, and its activity was quenched, as demonstrated by the neutralizer effectiveness test results. Similar results (not shown) have been observed by adding a chemical neutralizer composed of a mixture of lecithin, tamol, and polysorbate 80 to the collecting medium.

Table II (method A) reports the mean viral load following passage of an HIV-1-laden 22-gauge needle through the control and antimicrobial surgical glove. The final viral load was calculated from the viral titer and corrected for the sample volume tested in the puncture apparatus (1.2 mL). The corresponding mean viral load obtained from the duplicate test runs (10 replicates per run) using the control glove were 2.90 and 2.87 log<sub>10</sub>TCID<sub>50</sub>, respectively, compared to a recovered viral load of 0.72 and 0.88 log<sub>10</sub>TCID<sub>50</sub> following inoculation through the BKC test gloves (*P* < .01). Of note, no virus was detected in 3 of 10 samples from 1 of the antimicrobial glove runs. The viral load in this case was calculated based on a theoretical viral titer, which was determined by the Poisson distribution. The aliquot sampling data (method B) is documented in Table III. No significant difference was observed in the mean viral load between direct inoculation into collection medium or inoculation through the reference control glove. However, there was a

**Table I.** Neutralizer effectiveness and viral interference controls (method B)

	Mean viral load* (log <sub>10</sub> TCID <sub>50</sub> )
Samples ( <i>n</i> = 10) pooled to form 3 aliquots	
Control glove†	
Aliquot 1	2.74
Aliquot 2	3.11
Aliquot 3	3.11
	3.02
Antimicrobial glove‡	
Aliquot 1	2.81
Aliquot 2	2.74
Aliquot 3	2.74
	2.76 (ns)

\*The viral load was determined as follows: VL(log<sub>10</sub> TCID<sub>50</sub>) = Titer (log<sub>10</sub> TCID<sub>50</sub>/mL) + log<sub>10</sub>[Volume (mL)]; volume = 1.2 mL.

†Mean viral titer for aliquots 1, 2, and 3: 2.66, 3.03, and 3.03.

‡Mean viral titer for aliquots 1, 2, and 3: 2.73, 2.66, and 2.68.

ns, Nonsignificant.

**Table II.** Mean viral load (log<sub>10</sub>TCID<sub>50</sub>) recovery: control vs antimicrobial test gloves (method A)

	Mean viral load* (log <sub>10</sub> TCID <sub>50</sub> )
Control glove: 2 runs†	
<i>n</i> = 10	2.90
<i>n</i> = 10	2.87
Antimicrobial glove: 2 runs‡	
<i>n</i> = 10§	0.72 <i>P</i> < .01
<i>n</i> = 10	0.88 <i>P</i> < .01

\*The viral load (VL) was determined as follows: VL (log<sub>10</sub> TCID<sub>50</sub>) = titer (log<sub>10</sub> TCID<sub>50</sub>/mL) + log<sub>10</sub> [Volume (mL)]; volume = 1.2 mL.

†Mean viral titer for duplicate control runs: 2.75, 2.80.

‡Mean viral titer for duplicate antimicrobial (BKC) glove runs: 0.64, 0.75.

§No virus detected in 3/10 samples; theoretical titer determined based on Poisson distribution.

significant difference (*P* < .01) in viral load recovery in both antimicrobial aliquot runs compared to direct inoculation through the control gloves.

Table IV compares the mean viral reduction (log<sub>10</sub>TCID<sub>50</sub>) and actual mean viral units (TCID<sub>50</sub>) recovered following puncture of control and test antimicrobial gloves, using assay methods A and B. The mean viral load following puncture of the control gloves ranged from 2.89 to 3.25 (log<sub>10</sub>TCID<sub>50</sub>) in methods A and B, respectively. The actual mean viral units recovered following needle puncture ranged from 776 to 1778 TCID<sub>50</sub> in control gloves; actual mean viral units recovered following passage through the antimicrobial surgical glove ranged from 5 to 11 TCID<sub>50</sub>. The log<sub>10</sub> reduction in viral load following passage through the antimicrobial surgical glove

**Table III.** Mean viral load ( $\log_{10}$ TCID<sub>50</sub>) recovery: control vs antimicrobial test gloves (method B)

	Mean viral load* ( $\log_{10}$ TCID <sub>50</sub> )
Samples ( $n = 10$ ) pooled to form 3 aliquots	
No glove puncture†	
Aliquot 1	3.58
Aliquot 2	3.49
Aliquot 3	3.47
	3.52
Control glove‡	
Aliquot 1	3.24
Aliquot 2	3.22
Aliquot 3	3.28
	3.25 ns
Antimicrobial glove run #1§	
Aliquot 1	1.12
Aliquot 2	0.99
Aliquot 3	0.99
	1.04 $P < .01$
Antimicrobial glove run #2	
Aliquot 1	0.80
Aliquot 2	0.86
Aliquot 3	0.90
	0.85 $P < .01$

\*The viral load (VL) was determined as follows: VL ( $\log_{10}$  TCID<sub>50</sub>) = titer ( $\log_{10}$  TCID<sub>50</sub>/mL) +  $\log_{10}$ [Volume (mL)]; volume = 1.2 mL.

†Mean viral titer for no glove puncture aliquots 1, 2, and 3: 3.50, 3.41, 3.39.

‡Mean viral titer for control glove aliquots 1, 2, and 3: 3.16, 3.14, 3.20.

§Mean viral titer for antimicrobial glove run #1 aliquots 1, 2, and 3: 1.04, 0.91, 0.91.

||Mean viral titer for antimicrobial glove run #2 aliquots 1, 2, and 3: 0.72, 0.78, 0.82.

ns, Nonsignificant.

compared to the standard comparator glove ranged from 1.96 to 2.4, representing a 98.9% to 99.6% viral inactivation following passage through the antimicrobial surgical glove.

## DISCUSSION

The study identified 3 sentinel factors as being associated with increased risk for viral acquisition following percutaneous injury: (1) the presence of sharps devices (needles, sutures, etc) contaminated by blood; (2) exposure to a high viral load from a source patient; and (3) depth of injury. Implementation of the 2001 Needlestick Safety and Prevention Act mandated that “effective engineering” controls be utilized to eliminate or minimize the exposure of health care professionals to sharps injuries.<sup>15</sup> This act has had a significant impact in reducing the risk for health care professionals’ exposure to blood-borne pathogens in the nonsurgical environment, but the surgical services have been slow to embrace effective

engineering control measures specifically designed to meet the needs of surgical practitioners. Historically, sharps injuries among surgical practitioners have been under-reported, making an accurate assessment of risk difficult.<sup>16,17</sup> A pioneering study published in 1991 at the Medical College of Wisconsin found a high risk for injury and blood exposure among surgical personnel in approximately 50% of elective surgical procedures.<sup>18</sup> A study conducted in a single teaching institution between 2002 and 2005 found that approximately 50% of injuries in the operating room were caused by suture needles, whereas scalpel blades, injection needles, bone fragments, wires, and other objects were responsible for the other half of reported sharps injuries.<sup>19</sup>

Unfortunately, not all sharps injuries resulting in intraoperative blood exposure are at first glance obvious to the members of the surgical team. A study conducted 20 years ago in a tertiary care teaching institution found that in 63% of surgical glove failures, the first indication that an exposure had occurred was the observation of visible blood on the skin upon glove removal.<sup>20</sup> The frequency of glove failure due to overt or unapparent injury is quite variable; a study conducted in Germany found that surgical glove failures can range from ~9% to >35% in selected surgical procedures.<sup>21</sup> These findings suggest that a significant number of blood exposures occur daily in operating rooms in both the United States and elsewhere, leading to increase risks for members of surgical teams.

The practice of wearing 2 gloves is viewed by OSHA, ACS, and the Association of periOperative Registered Nurses as an appropriate interventional practice to reduce the risk for blood exposure during high-risk surgical cases. Mechanistically, following percutaneous injury, the rubber-like elasticity of the glove facilitates a “wiping-like” effect as the object penetrates the glove’s surface. This mechanism is likely effective for simple sharps devices such as suture needles, but more complex geometric configurations, such as scalpel blades, bone fragments, or hollow-bore needles, have surfaces that are hidden or less accessible for cleansing.<sup>22</sup> The configurations of the sharps devices can greatly influence the volume of blood transferred across the gloves’ surfaces following percutaneous injury. A minilance will harbor 0.064  $\mu$ L of blood compared to a large scalpel blade, which can sequester 0.133  $\mu$ L on its surface.<sup>23</sup> A study published in 2010 compared 4 separate surgical gloves (including the antimicrobial glove reported in this article) in terms of their abilities to inhibit the transmission of blood in a

**Table IV.** Viral reduction ( $\log_{10}$ TCID<sub>50</sub> virus units) following inoculation through antimicrobial test glove

Method	Mean viral load ( $\log_{10}$ TCID <sub>50</sub> )		$\log_{10}$ reduction*	% viral inactivation†
	Control glove	Antimicrobial glove		
A <sub>1</sub> ‡	2.89 (776)§	0.74 (5)§	2.15	99.3
A <sub>2</sub> ‡	2.89 (776)	0.93 (7)	1.96	98.9
B <sub>1</sub>	3.25 (1,778)	1.04 (11)	2.22	99.4
B <sub>2</sub>	3.25 (1,778)	0.85 (7)	2.40	99.6

\*The  $\log_{10}$  reduction was calculated as follows: LR = control-glove viral load per puncture ( $\log_{10}$ ) minus test-glove viral load per puncture ( $\log_{10}$ ).

†The percentage of virus inactivated was calculated as follows:  $[1 - \text{output viral load}/\text{initial viral load}] \times 100 = [1 - 10^{\Lambda} (-\log_{10} \text{reduction factor})] \times 100$ .

‡Mean value of 10 replicates.

§Mean viral units: TCID<sub>50</sub>.

||Mean value of 3 replicates.

porcine model of percutaneous injury using various sharp surgical devices (needle-shaped lancets, scalpel blades, and cannulas) contaminated with human blood. The integrated antimicrobial glove was equally effective in preventing the passage of blood across the glove's boundary layers as a double-layer comparator.<sup>24</sup>

The standardized test method used in this study was designed to simulate a severe scenario of occupational exposure combining 3 risk factors: a 6 mm puncture involving a 22-gauge hollow-bore needle contaminated with a  $>6.0 \log_{10}$  infectious viral units suspended in blood. The high viral suspension used in the present study corresponds to the viral load associated with HIV- or HCV-infected patients.<sup>25,26</sup> In a separate series of pilot studies (unpublished) using a lower viral load of  $6.0 \log_{10}$  ID<sub>50</sub>/mL, the average number of infectious viral units passing through a control glove ranged from 159 to 278 units (transferred blood volume, 0.15  $\mu$ L). In contrast, under the same test conditions, the number of HIV infectious units passing through the integrated antimicrobial glove was  $\leq 2$  viral units. The risk for disease transmission correlates with the number of infectious viral units delivered at the time of injury. The reduction in viral load, as documented in the present investigation (approaching 99%), should significantly reduce the risk for disease acquisition. Therefore, the viral reduction data presented in Table IV should be viewed as clinically relevant, especially in scenarios involving severe occupational exposure.

In the current study, live HIV-1 virus was chosen as the challenge agent for testing the neutralization efficacy of the antimicrobial surgical glove. In actual practice, the HCV virus poses a more problematic issue for health care professionals; however, there are currently no robust methods for propagating HCV under in vitro conditions. Bovine viral diarrhea virus (BVDV), which shares

similar structural characteristics with HCV (RNA-enveloped virus) and is responsible for causing chronic long-term infection, has been used as a surrogate test agent for HCV in laboratory studies. Developmental studies conducted almost 10 years ago, using an early prototype of the antimicrobial surgical glove, found a significant reduction in the viral titer of both BVDV and feline immunodeficiency virus (a surrogate virus for HIV) as they passed through the antimicrobial elastomeric glove, compared to a nonantimicrobial glove comparator.<sup>27</sup> In both cases, the mechanism of virucidal activity of BKC against HCV and HIV surrogate viruses is thought to involve a destabilization of the external phospholipid viral envelope.<sup>28</sup>

This article represents the first study using live HIV type 1 virus to document the in vitro efficacy of an integrated antimicrobial surgical glove to reduce ( $>99\%$ ) viral transmission following glove perforation involving a contaminated sharps device. However, a few key questions remain unresolved. For example, how likely is it that the reduction in viral load documented in this study results in a correspondingly decreased likelihood of disease (HIV or HCV) transmission (seroconversion) in the surgical practitioner following a significant sharps injury (scalpel blade, needle, etc)? The answer to this question may be somewhat elusive, but a technology that significantly lowers the probability of occupational exposure to live virus should be viewed as an effective risk-reduction intervention. The current investigation used a hollow-bore needle to deliver a high viral titer, but this mechanism of exposure probably represents less than 50% of potential occupational injuries that occur in the operating room. However, any blood-laden sharps objects, including scalpel blades, retractors, and bone fragments, would have to pass first through the antimicrobial droplet-like layer prior to penetrating the skin,

resulting in an instantaneous, localized release of virus-neutralizing fluid from the middle layer, rapidly inactivating the live virus on contact. This protective component has been documented to persist for several hours of simulated use.

Finally, in our current cost-conscious health care environment, is the use of a premium antimicrobial surgical glove to protect the surgical staff in high-risk scenarios warranted? The implementation of effective engineering controls in the health care environment, although costly, has had a measurable impact on the reduction of the incidence and morbidity associated with sharps injuries.<sup>29</sup> Given that the majority of occupational sharps injuries now occur in the operating room and that under-reporting commonly exceeds 70% in selected surgical practices, the availability of an innovative antimicrobial surgical glove technology that reduces the risk for percutaneous exposure following sharps injuries would appear to be warranted.<sup>30,31</sup>

The BKC antimicrobial glove technology (Hutchinson Santé) reported in this article is currently available in Europe, Japan, Canada, and South Korea and has been sold in 30 countries since 2011). Since 2005, the gloves have been used in orthopedic, general, urologic, cardiothoracic, and plastic surgical services. The functional design of this antimicrobial glove technology offers the same barrier protection afforded by the double-gloving process, with the addition of a virus-neutralizing antimicrobial barrier between the inner and outer layers. Surgeons who have used this technology in their practices have found the glove to be acceptable in terms of elasticity, ease of movement, grip quality, cuff tightness, and fit. A prospective study published in 2008 assessed the tolerance, ergonomics, and glove-barrier properties of this innovative technology following use in 100 consecutive general surgical procedures involving 6 surgeons. The ergonomic characteristics (tactile sensitivity, elasticity, movement, hand fitting, and gripping) of the antimicrobial glove were assessed as being equivalent to standard double-gloving. Integrity of feeling and mechanical resistance were deemed superior to double-gloving ( $P < .05$ ). In addition, no allergies or skin sensitivities were noted by the 6 surgeons who participated in the 6-month clinical trial. In cases in which there were substantial risks for blood exposure (the high-risk patient population), the BKC antimicrobial surgical glove was deemed to be an excellent replacement for double gloving.<sup>32</sup> The glove is currently under evaluation by the US Food and Drug Administration.

In conclusion, the optimal strategy for reducing the risk for percutaneous injury during surgery

involves an interdisciplinary effort, requiring education, awareness of risk, and the application of effective risk-reduction strategies. Implementation of the Needlestick Safety and Prevention Act has had a profound influence on the culture of safety in health care institutions. Selected sharps devices with effective engineering control are now routinely used on all patient-care floors for line insertions, blood draws, and wound management. This has not been the case in the operating rooms, where tradition and dogma have at times trumped innovation. A reduction in the incidence of sharps injuries in operating rooms should be considered a priority championed by surgical leadership. Adoption of an antimicrobial surgical glove technology that effectively reduces the viable viral burden following occupational exposure by a factor exceeding 99% should be viewed by surgeons as a beneficial and effective adjunctive strategy for minimizing exposure to selective blood-borne pathogens such as HIV or HCV, especially in surgical procedures involving high-risk patient populations.

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