## Biocide squirting from an elastomeric tri-layer film

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### **Abstract**

Protective layers typically act in a passive way by simply separating two sides. Protection is only efficient as long as the layers are intact. If a high level of protection has to be achieved by thin layers, complementary measures need to be in place to ensure safety, even after breakage of the layer – an important issue in medical applications.

Here, we present a novel approach for integrating a biocide liquid into a protective film (about 300-500  $\mu$ m thick), which guarantees that a sufficient amount of biocide is rapidly released when the film is punctured. The film is composed of a middle layer, containing the liquid in droplet-like compartments, sandwiched between two elastomeric boundary layers. When the film is punctured, the liquid squirts out of the middle layer.

A theoretical model was used to determine the size and density of droplets that are necessary to ensure a sufficient quantity of biocide is expelled from an adequately elastic matrix to provide protection at the site of damage. We demonstrate the utility of this approach for the fabrication of surgical gloves. Journal of Medical Virology, 69 : 538-545 (2003)

# Virus-Inhibiting Surgical Glove to Reduce the Risk of Infection by Enveloped Viruses

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### Abstract

Needle puncture and other accidents that occur during surgery and other procedures may lead to viral infections of medical personnel, notably by hepatitis C (HCV) and human immunodeficiency virus (HIV), now that hepatitis B can be prevented by vaccination.

A new surgical glove called G-VIR, which contains a disinfecting agent for enveloped viruses, has been developed. Herpes simplex type 1 (HSV) was used as a standard enveloped virus in both in vitro and in vivo tests of the virucidal capacity of the glove. Bovine viral diarrhea virus (BVDV) and feline immunodeficiency virus (FIV) were used as models for HCV and HIV, respectively.

For in vitro study, a contaminated needle was passed through a glove and residual virus was titrated; for in vivo studies, animals were stuck with a contaminated needle through a glove.

Despite variation in virus enumeration inherent in the puncture technique, statistical evaluation showed that infection was reproducibly and substantially reduced by passage through the virucidal layer.

For BVDV, the amount of virus passing through the virucidal glove was reduced in 82% of pairwise comparisons with control gloves that lacked the virucidal agent; when plaque counts were adjusted to a common dilution, the median count for the virucidal glove was on the average reduced > 10-fold.

In experiments in which the proportion of wells infected with FIV was measured, the ratio of TCID50 values (control glove to G-VIR) was > 15, and probably much higher.

For HSV, the amount of virus passing through the virucidal glove was reduced in 81% of comparisons with control gloves; the median of adjusted plaque counts was reduced on the average approximately eightfold or ninefold.

In vivo tests with FIV and HSV in cats and mice, respectively, found smaller percentage reductions in infection than the in vitro tests but confirmed the virucidal effect of the gloves.

Key Words : gloves, surgical infection; hepatitis B, blood-borne viruses; HIV

# Standardization of needlestick injury and evaluation of a novel virus-inhibiting protective glove

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#### Abstract

Rubber surgical gloves worn as a barrier to prevent contamination from body fluids offer relative protection against contamination through direct percutaneous injuries involving needles, scalpel blades or bone fragments.

To determine the main experimental parameters influencing the volume of blood transmitted by a hollow-bore needle (worst case scenario) during an accidental puncture, we designed an automatic puncture apparatus. Herpes simplex type 1 virus (HSV1), a model for enveloped viruses, was used as a 'marker' in an in-vitro gelatine model. Of the experimental parameters studied, the most critical influences were found to be needle diameter and puncture depth, whereas puncture speed, puncture angle and glove-stretching feature appeared to be less influential.

A single glove reduced the volume of blood transferred by 52% compared with no glove, but double gloving offered no additional protection against hollow-bore needle punctures. Using 'standardized' puncture conditions, the virus-inhibiting surgical glove G-VIR® elicited an 81% reduction in the amount of HSV1 transmitted as compared with single or double latex glove systems.

Keywords: Blood exposure accident; Needle puncture; Viral contamination; Glove; Protection

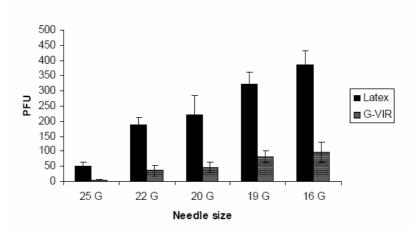


Figure. Influence of needle diameter on the protective effect of G-VIR<sup>®</sup>. The histogram represents the number of viruses passing through G-VIR<sup>®</sup> versus latex for hollow-bore needles varying from 25G to 16G. Puncture parameters were set as: 15 cm/s speed, 90° angle, 6 mm depth, 10% glove tension. The titre of the HSV1 suspension in blood was 2.1 ~ 10<sup>6</sup> plaque-forming units (pfu)/mL. *N* = 45 for each experimental condition.

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### First clinical study of a new virus-inhibiting surgical glove

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### Abstract

Question under study: Prospective clinical study to evaluate the tolerance, ergonomics and glove barrier value (mechanical resistance to breach) of a new surgical glove sandwiching droplets of a disinfecting agent between two layers of a synthetic elastomer (G-VIR®) able to inactivate viruses when breached.

Methods: 100 surgical procedures were performed by six surgeons wearing G-VIR® on 100 patients included after informed consent. Procedures were classified into laparoscopic (n = 28) or open surgery (n = 72); open surgery being subdivided either into superficial (n = 33)and deep (n = 39) or into hernia (n = 32) and non hernia (n = 40). The ergonomics and tolerance of the glove were evaluated by the surgeons using a questionnaire. Patients were clinically evaluated daily during hospitalization and once between the 4th to 6th postoperative week. All used gloves underwent a water leak test to detect any breach.

Results: 834 G-VIR® gloves were used, 456 by the first surgeon and 378 by the assistant surgeon, resulting in 195 exposures, lasting 288 operatorhours (OH). No adverse effect on patients and/or surgeons linked to G-VIR® could be observed. Ergonomics of G-VIR® has been evaluated as equivalent as standard double gloving, excepted for donning which was more difficult (P <0.05). The breach rate per glove (BRpG) amounted to 1.8%. According to breach rate per operator-hour (BRpOH), surgical procedures could be categorized in low (laparoscopy), middle (non hernia and hernia superficial) and high (hernia deep) risk procedures.

Conclusions: G-VIR® gloving offers an excellent mechanical protection, is suitable for daily surgical practice and maybe recommended in high risk surgical procedures.

*Key words*: *HIV/HCV*; protection; surgical glove; blood exposure accident