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

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## Summary

*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 operator-hours (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*

## Introduction

The risk of becoming infected with blood borne pathogens (hepatitis B, hepatitis C, HIV) consecutive to percutaneous injury with a contaminated instrument during surgery is real [1–3]. The individual cumulative risk of occupational viral contamination can be calculated according to the cumulated number of skin injuries, the seroprevalence of the virus in the operated population and the seroconversion rate after contaminating exposure [4]. Mucosal and cutaneous contact with patient body fluids are two further possible contamination sources [5]. The probability of transmission is highest in case of percutaneous injury: 0.1% to 0.25% for HIV [6, 7] and 0.5% to 4% for HCV [2, 8]). The probability is lower in case of mucosal contact: 0.09% for HIV [7] and 0.36% for HCV [9]. In case of skin contact, the transmission risk cannot be evaluated as no data are available. However, transmission has been reported in case of excoriated skin [6]. Surgical gowns and gloves prevent contact with blood and body fluids as long as gowns are not wet and gloves are neither breached nor porous. Hence gown and gloves constitute the surgeon-patient barrier [10], the core of both surgical team and patient protection, gloving being the main component of this barrier. Double gloving has been recommended [11] because it reduces the risk of glove barrier (GB) breaches when compared to single gloving [10, 12, 13]. However, double gloving cannot prevent all GB breaches [10]. Adding an *active* protection is the next step in the prevention of viral contamination when a GB breach occurs. This can be achieved by integrating a disin-

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fectant agent within the glove material. A solution consists of two elastomeric boundary layers between which a disinfecting liquid in a drop-like compartment is sandwiched [14]. Due to the multilayer specific design, the disinfecting liquid is squeezed out in case of accidental glove rupture [15]. Bricout used bovine viral diarrhoea virus (BVDV) and feline immunodeficiency virus (FIV) as models for HCV and HIV and showed, in vitro, with contaminated needles passed through gloves and residual virus titration an 82% (BVDV) and an 81% (FIV) reduction of transmitted viral load [16]. The aim of this study was to evaluate the tolerance, ergonomics and GB-value (mechanical resistance to breach) of such a glove during surgical practice, according to the risk linked to surgical procedures.

## Patients and methods

G-VIR® (Hutchinson Santé SNC, Paris, France) is a three layer glove composed of an external thin rubber layer, a middle layer containing a disinfecting solution of didecyl-dimethyl ammonium chloride (as the major compound), benzalkonium chloride and chlorhexidine digluconate diluted in polyethylene glycol evenly distributed as micro-droplets, and an inner mechanical layer. The rubber is a synthetic thermoplastic elastomer (SEBS, Kraton Polymers, Paris, France). The resulting thickness is 500 µm, equivalent to double gloving. As standard surgical gloves, G-VIR® is classified as IIa medical device according to European Directive 93/42/CEE.

Six surgeons (3 seniors and 3 juniors) working at the Lyon-Sud Hospital (Department of Emergency Surgery) gave their informed consent to wear G-VIR® as single gloving while performing 100 elective general and digestive surgical procedures, as first or assistant surgeon.

Out of 101 consecutive patients scheduled to undergo an elective operation from November 2003 to April 2004 by these surgeons, 100 gave their informed consent for their participation in the study. Participant inclusion criteria were: age older than 18, no pregnancy and an allergy to neither quaternary ammoniums nor chlorhexidine.

The surgical 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). Deep surgical procedures involved abdominal incisions of at least 10 cm allowing palpation of the viscera, while superficial surgical procedures did not.

The operating time was recorded for each surgeon. For each pair of gloves used, the name of the surgeon, the donning and taking-off times, as well as the perceived glove breaches during the procedure (leading to an immediate glove change) were noted by a specially trained research technician (Biomatech SA, Chasse sur Rhône, France). After use, the gloves underwent water leak test (WLT) [17] for breach detection by the same technician. A positive WLT was considered as a glove breach. This allowed determination of the frequency of glove breaches (perceived or not) for each class and subclass of procedures. In addition, as a control, 500 G-VIR® randomly assigned unused pair of gloves (1000 gloves) underwent WLT.

At the end of each procedure, the surgeons were questioned on G-VIR® gloving (general impressions, ergonomic qualities, barrier and security, and immediate side effects) (table 1). Each item was graded lower than (0), identical to (1) or superior to (2) latex double gloving. The mean grade ± SE was compared to the reference grade (= 1) using the Student's t-test. At the end of the

**Table 1**

Mean marks given on G-VIR® qualities by the 6 surgeons.

| Mark | Surg. #1 | Surg. #2 | Surg. #3 | Surg. #4 | Surg. #5 | Surg. #6 | Mean ± SE | P |
|---|---|---|---|---|---|---|---|---|
| **General Impressions** | | | | | | | | |
| Packaging | 0.91 | 1.74 | 0.80 | 0.92 | 1.03 | 1.17 | 1.09 ± 0.14 | NS |
| Feel (texture. smell) | 1.00 | 1.78 | 1.10 | 1.00 | 1.03 | 1.17 | 1.18 ± 0.12 | NS |
| **Ergonomics** | | | | | | | | |
| Donning | 0.51 | 0.57 | 0.60 | 0.24 | 0.35 | 1.17 | 0.57 ± 0.13 | <0.05 |
| Cuff length | 1.00 | 1.70 | 1.40 | 1.00 | 1.22 | 1.33 | 1.27 ± 0.11 | NS |
| Cuff tightening | 0.96 | 1.70 | 1.40 | 0.82 | 1.19 | 1.17 | 1.20 ± 0.13 | NS |
| Design / Hand fitting | 0.97 | 1.70 | 0.90 | 1.00 | 1.00 | 1.17 | 1.12 ± 0.12 | NS |
| Elasticity / Dexterity | 1.00 | 1.70 | 0.70 | 0.86 | 1.00 | 1.17 | 1.07 ± 0.14 | NS |
| Tactile feeling | 0.99 | 1.70 | 0.70 | 0.80 | 0.92 | 1.17 | 1.04 ± 0.15 | NS |
| Grip quality | 0.88 | 1.30 | 0.40 | 0.76 | 0.78 | 1.17 | 0.88 ± 0.13 | NS |
| **Barrier And Security** | | | | | | | | |
| Mechanical resistance | 1.17 | 1.87 | 1.70 | 1.31 | 1.00 | 1.33 | 1.40 ± 0.13 | <0.05 |
| Integrity feeling | 1.14 | 1.74 | 1.50 | 1.10 | 1.00 | 1.33 | 1.30 ± 0.11 | <0.05 |
| **Immediate Side Effects** | | | | | | | | |
| Moist hands | 1.00 | 1.70 | 1.00 | 1.00 | 1.03 | 1.67 | 1.23 ± 0.14 | NS |
| Skin reaction | 1.00 | 1.83 | 1.70 | 1.02 | 1.00 | 1.67 | 1.37 ± 0.16 | NS |

Each item was graded lower than (0), identical to (1) or superior to (2) latex double gloving. For each surgeon, the item grade was calculated as the mean of the marks filled in the forms. The mean grade ± SE was compared to the reference mark (=1) using the Student t test.

study, the 6 surgeons were questioned on tolerance linked to G-VIR® gloving.

All the patients underwent a daily postoperative clinical examination during hospitalization and a final control examination between the 4th and the 6th postoperative week, in order to detect eventual adverse effects related to the use of G-VIR®.

Statistical analysis was performed with the Statistical Package for the Social Sciences (SPSS, Chicago, Illinois, USA) software on a personal computer. Hypothesis test (Z test) was used to compare percentages.

This protocol was validated by the Ethics committee (CCPPRB Lyon B, July 2002).

## Results

A total of 834 G-VIR® gloves (417 pairs) were used, 456 by the first surgeon and 378 by the assistant surgeon during 100 procedures resulting in 195 exposures (involvement of first and assistant surgeon) lasting 288 operator-hours (OH) (145.5 first surgeon OH and 142.5 assistant surgeon OH). The mean duration of the procedures was 1.5 hours, 47% lasted less than 1 hour, 26% from 1 to 2 hours, 20% from 2 to 3 hours and 7% more than 3 hours.

Neither localized tolerance problems nor cutaneous irritation were reported by the six surgeons throughout the six month study. In addition, post operative follow-up of the 100 patients did not reveal any specific side effect related to the glove.

The six surgeons filled in 70, 23, 10, 49, 37 and 6 forms respectively. Donning was felt to be more difficult ($P < 0.05$) than for usual latex gloves (table 1). Tactile sensitivity, elasticity, movement fluidity, shape, hand fitting, gripping quality and surgeon hand sweating were assessed as comparable to those provided by a double latex gloving (table 1). Integrity feeling and mechanical resistance of G-VIR® were estimated as higher ($P < 0.05$) than usual double gloving (table 1).

Fifteen glove breaches were identified by WLT. The breaches were located on the finger (n = 10), the palm (n = 4) and the dorsal surface of the hand (n = 1). Breaches were more frequent on the non-dominant hand (n = 9). Of the 15 identified breaches, six were perceived by the surgeon and nine went unperceived. Five of the perceived breaches were caused by needles and one was related to stitching thread, all six leading to a percutaneous injury. Five out of six perceived breaches occurred during hernia surgery. The number of perceived breaches for the first surgeon (n = 4) was twice that of the assistant. According to the type of surgery, 11 breaches were related to deep surgery (7 hernia surgery) and 4 to superficial surgery (4 hernia surgery). No breach occurred during laparoscopy (table 2). The breach rates (i) per procedure (BRpP), (ii) per glove (BRpG), and (iii) per operator-hour (BRpOH) were calculated for each class (and subclass) of surgery (table 2). Rates were also determined for perceived breaches (PBRpP, PBRpG and PBRpOH respectively). According to increasing values of BRpOH it was possible to rank the five surgical subclasses. Couples of surgical subclasses were then compared by using a unilateral Z test (table 3). By fusion of statistically non-different subclasses, 3 statistically different ($Z > 1.645$) categories of surgery linked with low, middle and high risk of glove breach were identified (table 3).

The WLT detected no breach in the 1000 G-VIR® randomly assigned unused gloves.

**Table 2**

Breach rates according to different types of procedures.

| Type of surgery | Number of procedures | Number of exposures | Exposure duration (OH) | Number of gloves | Number of breaches | Number of perceived breaches | BRpP | PBRpP | BRpG | PBRpG | BRpOH | PBRpOH |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Laparoscopy | 28 | 55 | 90 | 194 | 0 | 0 | 0.0% | 0.0% | 0.0% | 0.0% | 0.00% | 0.0% |
| Open | 72 | 140 | 198 | 640 | 15 | 6 | 20.8% | 8.3% | 2.3% | 0.9% | 7.58% | 3.0% |
| Superficial non hernia | 9 | 16 | 12 | 58 | 0 | 0 | 0.0% | 0.0% | 0.0% | 0.0% | 0.00% | 0.0% |
| Deep non hernia | 31 | 62 | 120 | 390 | 4 | 1 | 12.9% | 3.2% | 1.0% | 0.3% | 3.33% | 0.8% |
| Superficial hernia | 24 | 47 | 47 | 130 | 4 | 1 | 16.7% | 4.2% | 3.1% | 0.8% | 8.51% | 2.1% |
| Deep hernia | 8 | 15 | 19 | 62 | 7 | 4 | 87.5% | 50.0% | 11.3% | 6.5% | 36.84% | 21.1% |
| Subtotal deep | 39 | 77 | 139 | 452 | 11 | 5 | 28.2% | 12.8% | 2.4% | 1.1% | 7.91% | 3.6% |
| Subtotal superficial | 33 | 63 | 59 | 188 | 4 | 1 | 12.1% | 3.0% | 2.1% | 0.5% | 6.78% | 1.7% |
| Subtotal non hernia | 40 | 78 | 132 | 448 | 4 | 1 | 10.0% | 2.5% | 0.9% | 0.2% | 3.03% | 0.8% |
| Subtotal hernia | 32 | 62 | 66 | 192 | 11 | 5 | 34.4% | 15.6% | 5.7% | 2.6% | 16.67% | 7.6% |
| Total | 100 | 195 | 288 | 834 | 15 | 6 | 15.0% | 6.0% | 1.8% | 0.7% | 5.21% | 2.1% |

OH = operator-hour; BRpP = breach rate per procedure; PBRpP = perceived breach rate per procedure; BRpG = breach rate per glove; PBRpG = perceived breach rate per glove; BRpOH = breach rate per operator-hour; PBRpOH = perceived breach rate per operator-hour.

**Table 3**

Categorization of surgical procedures according to risk of glove breach.

| | BRpOH | Z value | | BRpOH | Z value | Risk of glove breach |
|---|---|---|---|---|---|---|
| Laparoscopy | 0.00% | NA | Laparoscopy | 0.00% | | low |
| Non hernia superficial | 0.00% | 0.64 | | | 1.95 | |
| Non hernia deep | 3.33% | 1.41 | Non Hernia & Hernia Superficial | 4.28% | | middle |
| Hernia superficial | 8.51% | 2.80 | | | 5.10 | |
| Hernia deep | 36.84% | | Hernia Deep | 36.84% | | high |

BRpOH = breach rate per operator-hour; hypothesis test significant (confidence interval = 95%) if Z >1.645

## Discussion

The G-VIR® glove is the first device providing an active protection against blood borne pathogens in case of GB breach [16]. However, this device had never been used in surgical practice. Therefore, a clinical study was indispensable in order to answer three essential questions: (i) are there any adverse effects on surgeons and patients linked to G-VIR®? (ii) is it possible to perform surgery while gloved with G-VIR®? and (iii) is the mechanical GB provided by G-VIR® reliable?

No allergy or skin intolerance was observed, neither in the six surgeons nor in the 100 patients throughout the six months study. G-VIR® is a latex-free and powder-free synthetic glove and the main cause of skin intolerance or allergy would be the disinfectant solution. Allergies to quaternary ammoniums [18] and chlorhexidine [19] have been reported. As long as G-VIR® is not breached, the disinfectant solution is sealed between two layers of synthetic elastomer and therefore is not in contact with skin or tissues. In case of a glove breach, droplets of the solution are squeezed out, potentially allowing patient organs and/or surgeon skin to be in contact with the disinfectant. We recorded this event 15 times (BRpG = 1.8%) with no adverse effects. This is in accordance with G-VIR® mandatory biocompatibility tests (NF EN ISO 10993 part 10 – Tests for Irritation and Sensitization) conducted under "intended use glove conditions" (intact gloves) and under "maximised conditions" (pierced gloves). These biocompatibility tests have demonstrated that the intact glove presents a primary irritation index (PII) equal to 0 and does not induce delayed sensitization (grade 0). When the glove is pierced, PII remains equal to 0 without any significant local reaction with tissues or organs. However, clinical tolerance to G-VIR® must be confirmed by a larger scale trial.

Regarding ergonomics, G-VIR® has been evaluated as equivalent to standard double gloving, except for donning ($P < 0.05$). The surgeons involved in the study were used to wearing two pairs of thin latex gloves and appraised synthetic elastomer gloves donning lower. Exclusively gloved with G-VIR®, the six surgeons were however able to perform 100 varied surgical procedures without any hindrance. Once the G-VIR® glove was donned, dexterity was not impaired by the unusual glove thickness and tactile feeling was not altered. Moreover, surgeons scored G-VIR® mechanical resistance and tightness better than standard double gloving ($p < 0.05$), evaluating G-VIR® gloving as an efficient GB.

This subjective GB efficiency was confirmed *in vitro* and *in vivo*. *In vitro*, 1,000 randomly chosen gloves underwent WLT. No breach was evidenced, which is not the case for usual latex gloves where the leak rate before use varies from 0.2 to 3.3% [20, 21]. The three layer structure of the G-VIR® glove, which reduces the likelihood of encountering the same defect simultaneously in all three layers, explains its exceptional barrier quality. *In vivo*, the rates of G-VIR® glove breaches were calculated. The BRpG amounts to 1.8%, far lower than the rate observed in single gloving where up to 50% of glove breaches have been reported [12, 20, 22]. With a thickness of 500 µm and such a BRpG, G-VIR® performs better than double gloving which displays similar thickness and 0% to 30% rates of simultaneous perforation of outer and inner glove [22–25]. G-VIR® displays at least as reliable a mechanical GB as a usual double gloving.

Whenever a GB breach occurs, G-VIR® deploys a chemical second line barrier [15]. Five perceived breaches were due to needle puncture and one was due to stitching thread. Furthermore, nine breaches remained totally unperceived by the surgeons and the contact between the surgeon's skin and the patient's body fluids went on until glove change [10]. These 15 glove breaches allowed diffusion of blood and body fluids through the breached GB. However, the disinfecting liquid was simultaneously squeezed in the breach to inactivate viruses possibly crossing through the breach. *In vitro*, G-VIR® is able to significantly decrease the viral load transmitted [16]. This viral inactivation operates not only to reduce surgeons' occupational viral risk [4] but also to prevent patients being contaminated by surgeons [26, 27]. This decisive technological advantage is counterbalanced by a higher cost of production leading to more stringent recommendations for use according to the risk of GB breach. At present double gloving in a public French hospital costs approximately 5 times less than G-Vir®.

The risk of glove breach is recognized as minimal in laparoscopic surgery [28]. Glove breaches are more frequent during abdominal wall surgery and deep surgery [12, 29] with a higher risk of percutaneous accidents leading to peroperative contamination [30]. In order to identify high risk situations in our surgical practice, we have analyzed the different subclasses of surgical procedures according to BRpOH. With a BRpOH of 0%, laparoscopic surgery was identified as the category at low risk. All 15 breaches were observed during open surgery.

As the BRpOH in deep hernia (36.84%) was significantly higher than in superficial hernia (8.51%) ($Z = 2.80$; $P < 0.05$), deep hernia was identified as the category at high risk. The remaining procedures (non hernia and hernia superficial) formed the category at middle risk (BRpOH = 4.28%) significantly distinct from the other two groups ($Z = 1.95$ and $Z = 5.10$, $P < 0.05$). According to the level of protection desired, G-VIR® appears to be highly recommended in surgical procedures at high risk where we observed one perceived breach every five hours (PBRpOH = 21.1%) (table 2). However, two percutaneous accidents were observed in surgical procedures at middle risk and the use of G-VIR® should be recommended in these situations. Similar categorizations of surgical procedures according to the risk need to be conducted by other teams in other specialities. Once the risk has been evaluated, hospital management can choose the level of protection they require for their surgeons.

In conclusion, G-VIR® gloving offers an excellent mechanical protection, is suitable for daily surgical practice and, in case of percutaneous accident, has a unique device activating a chemical protection.

This study is the first clinical application of G-Vir® and must be deemed a feasibility study. Although the results are statistically weak, it is evident that 100 patients have been operated by six surgeons wearing G-Vir® without any adverse effect. A large scale multi-centre randomized trial would be required to demonstrate the viral inhibiting efficacy of the glove.

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