HHS Public Access
Author manuscript
J Occup Environ Hyg. Author manuscript; available in PMC 2023 March 13.

Published in final edited form as:
J Occup Environ Hyg. 2019 July ; 16(7): 498–506. doi:10.1080/15459624.2019.1600702.

Critical investigation of glove–gown interface barrier performance in simulated surgical settings

Zafer Kahveci,

F. Selcen Kilinc-Balci,

Patrick L. Yorio

Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health (NIOSH), National Personal Protective Technology Laboratory, Pittsburgh, Pennsylvania

Abstract

The barrier properties of personal protective equipment are vital to healthcare personnel to protect themselves from possible infectious body fluids. Intraoperative exposure of healthcare personnel to body fluids can be substantial in both inpatient and outpatient settings. The glove–gown interface is known as one of the weakest points of the whole personal protective equipment system. However, there is a lack of scientific research designed to investigate the problem. This paper reports the results of experiments using a new testing methodology developed to quantify fluid leakage through the glove–gown interface while simulating surgical settings in terms of operating room personnel activities, exposure types, exposure durations, and physical stresses applied on the interface. This study represents one of the first efforts investigating the amount of fluid leakage through the glove–gown interface for a number of surgical gown and glove models while considering glove material differences and single vs. double gloving. The test results showed that there is a significant difference in fluid leakage amounts between three gown models and four glove models studied. The results also demonstrated that double gloving significantly reduced the fluid leakage compared to single glove use. The mean fluid leakage was lower in the double synthetic glove configurations (M = 2.76g) compared with all other configurations (3GLV, M = 8.3g; 4GLV, M = 9.49g; 5GLV, M = 3.08g; 6GLV, M = 20.03g; double latex, M = 5.22g). Findings highlighted a significant interaction between glove and gown designs, which suggests that gown and gloves should be designed together as a system to minimize or eliminate the fluid leakage.

Keywords

Glove; gown; interface; penetration; personal protective equipment; surgical settings

---

CONTACT F. Selcen Kilinc-Balci jcq8@cdc.gov Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health (NIOSH), National Personal Protective Technology Laboratory, 626 Cochrans Mill Rd., Pittsburgh, Pennsylvania 15236.

Conflicts of Interest
The authors identify no conflicts of interest in the conduct of this study.

Introduction

During surgery, both operating room (OR) personnel and patients are at risk of exposure to contaminated body fluids. Surgical attire, such as gowns and gloves, act as a barrier to protect OR personnel and patients from infectious body fluids. There are many studies and surveys in the literature, which demonstrated that skin and blood contact is not a rare occurrence for healthcare personnel (HCP).[1–5] In addition, healthcare-associated infections (HAIs) are of concern. It is estimated that 1.4 million people worldwide suffer from HAIs at any given time. HAIs are the sixth leading cause of death in the United States, and approximately 1 in 10 hospitalized patients acquires an infection after admission.[6,7] Furthermore, recent epidemics of infectious diseases highlighted the need for more reliable personal protective equipment (PPE) with less number and leak-proof junctions.[8] Therefore, effective PPE is vital to reduce the exposure risk to both HCP and patients.

The textiles and designs used in protective surgical attire must prevent the transmission of fluids and microorganisms in the OR.[9] Significant effort has been employed to develop new materials and designs to improve the barrier protection as well as consumer satisfaction. Also, a number of standards for assessing and monitoring the performance and quality of gowns and gloves have been developed by standards development organizations (SDO). However, interface regions, particularly the glove–gown interface, received minimal attention, and, most importantly, there is no established standard test method to evaluate the barrier performance of this interface region for the surgical settings.[10]

The surgical glove–gown interface can be described as the junction between the open end of a glove and the sleeve of a gown immediately underneath the glove (Figure 1). The surgical gown sleeves are designed as wide and baggy, with approximate circumference of 12”, to provide comfort to the wearer; however, when the surgical glove with an approximate 6” circumference, is worn over the gown sleeve, the extra portion of the gown creates folds and pleats under the glove, and forms channels (Figure 1). The channels create air pockets separating the gown and the glove, where the contaminated body fluid may travel through, and thereby contact the skin of the wearer. Additionally, body fluids of the wearer could be transferred to the patient. Thus, fluid leakage through the glove–gown interface can put both OR personnel and patient at risk for transmission of pathogens.[10]

This study examines quantitative evidence of fluid leakage through the glove–gown interface using a robotic arm, which can simulate HCP activities in an OR. The fluid leakage is defined as the fluid passage through gown–glove interface and does not include penetration through the gown fabric. Test duration, exposure type, exposure duration and physical stresses that can be applied to the glove–gown interface were determined by literature review and communication with expert HCP. The primary goal of the study is to compare fluid leakage at the glove–gown interface of three surgical gown models, four surgical glove models, two glove materials (synthetic and latex), two glove layers (single and double), and the unique combinations of surgical gown and glove configurations, while exposures (spraying and soaking) and physical stresses (pressure) in surgical settings were simulated. The hypotheses of the study are listed as follows:

Hypothesis #1: There is a significant difference in the fluid leakage amounts with different gown models.

Hypothesis #2: There is a significant difference in the fluid leakage amounts with different glove models.

Hypothesis #3: There is a significant difference in the fluid leakage amounts with different glove materials (synthetic *vs.* latex).

Hypothesis #4: Amount of fluid leakage decreases with the addition of glove layers (single gloving *vs.* double gloving).

Methods

The three most widely used surgical gown models in the U.S. market were selected for the study from three major manufacturers in the marketplace: Halyard, formerly Kimberly-Clark, (Product Code #10558), Medline (Product Code #DYNJP2202), and Cardinal Health (Product Code #9010). Through direct communication, these gowns were identified among the most commonly used or ordered surgical gowns in the U.S. market by the U.S. Veterans Affairs Hospitals, U.S. Ebola Treatment Centers, and Centers for Disease Control and Prevention's Strategic National Stockpile. The gowns were identified as 7G, 8G, and 9G, respectively, for the purpose of this study. All of the surgical gown models used in this study claimed to meet the "American National Standards Institute/Association for the Advancement of Medical Instrumentation" (ANSI/AAMI) PB70[11] level 4 barrier performance, which is the highest level of protection defined in the standard. The Halyard Microcool Secure-Fit gown, 7G, was produced with a breathable film sandwiched between a soft spunbond outer layer, and a spunbond–meltblown–spunbond (SMS) inner layer. These gowns were designed with heat-sealed raglan sleeves and knit cuffs. The manufacturer claims that a special coating on the sleeves, where it connects to the knit cuff, helps reduce glove slip-down when used with surgical gloves (Figure 2). The Medline surgical gown, 8G, is manufactured with SMS fabric and poly-reinforced at the chest and sleeves and constructed with a knit cuff and heat-sealed sleeves. The manufacturer highlights its wider cut in the chest and sleeves as a comfort and mobility parameter for the wearer. The Cardinal Health Astound surgical gown, 9G, features a poly-reinforced coating at the arm sleeve, which creates a smooth surface around the sleeves, and multilayered chest area. They were also constructed with knit cuff design and heat-sealed sleeves (Figure 2). Astound gowns are claimed by the manufacturer as the leading brand of surgical gowns in the United States in terms of quantities sold in 2016.[12] The size selection of gowns in this study varied due to the sizing differences of the manufacturers. Thus, best fitting gowns were selected as x-large for 8G and large for 7G and 9G.

There were four surgical gloves selected for this study; Biogel PI OrthoPro (47675), Biogel PI Pro-Fit (47975), Biogel Optifit Orthopaedic (31075), and Biogel Indicator Underglove (31275). They were referred as 3GLV, 4GLV, 5GLV, and 6GLV, respectively, for the purpose of this study (Figure 3). All gloves were advertised as sterile, powder-free, having a beaded cuff with a special coating on the inner surface for easy donning and helping to prevent skin moisture loss. The 3GLV and 4GLV are both made from synthetic polyisoprene elastomer. The manufacturer suggests that the 4GLV can be used as a single glove or coupled with an outer one as an indicator inner glove. Indicator gloves are colored inner gloves which help to identify the punctures or failures of the outer gloves and increase the efficiency of protection. The 5GLV and 6GLV were both made from natural rubber latex, and 6GLV suggested to be used as a single or an indicator inner glove by the manufacturer. The physical properties of the gloves are summarized in the Figure 3.

The surface tensions for a number of human body fluids vary between 27–75 dynes/cm with an average of 40 dynes/cm at 20–25˚C which is normally encountered in an OR.[13] In the ASTM F1670[14] and ISO 16603,[15] synthetic blood with a surface tension of 42 ± 2 dynes/cm is used. Therefore, in this study, a challenge fluid was prepared using deionized water and surfactant (0.03% weight percent solution of Surfynol 104H, Air Products, Vandalia, IL)[16], to keep the surface tension at approximately 42 ± 2 dynes/cm (measured by du Noüy Ring Method and used for all experiments.

This study used a Johns Hopkins University Applied Physics Laboratory developed prosthetic limb.[17] The limb was developed to improve upper-extremity prosthetics in response to the growing number of military personnel injured. It is capable of effectuating almost all of the movements of a human arm. An experimental chamber, which houses the robotic arm, was designed and developed by the National Institute for Occupational Safety and Health (NIOSH). Four spraying nozzles equidistant from the robotic wrist were placed in the corners of the chamber.[10]

Simulation of surgical settings

A programmable prosthetic limb simulated OR personnel movements during the performance of healthcare tasks. The most commonly performed arm movements in surgical settings were selected based on the literature,[18,19] as well as communicating and reaching a consensus with HCP and experts in the field.[10] It is well-known that some of the surgical procedures take hours, but total test duration was kept constant at 1 hr in this study due to the complexity of the testing and the large number of experiments. Our previous findings showed that test duration does not affect the fluid leakage through the interface significantly when exposure type, duration, and amount as well as number of movements are kept constant.[10] Studies designed to investigate the manner in which HCP are exposed to potentially contaminated body fluids and the duration of that exposure are scarce. There are mainly two types of exposures that occur in surgery according to a technical report published by AAMI.[20] Those exposures are spray and soak. Additionally, Panlilio et al. identified high risk factors as those in which patients lost more than 250 mL of blood and the procedure time exceeds 1 hr.[3] Consequently, these two types of exposures were simulated by applying 5 sec of spraying and 5 sec of soaking twice in 1 hr of testing duration. The external pressure acting against the clothing is also an important parameter for fluid leakage. Jaques et al.[21] found that fluid strike-through increased with higher applied elbow pressure. Kilinc-Balci et al.[10] also reported that fluid leakage through glove–gown interface increases with the mechanical pressure applied on the wrist area. These external forces can be generated by pressing or leaning. A typical example would be when lifting a patient. In ASTM F1670 and F1671, the applied hydrostatic pressure level is 2 psi. This pressure level is supported by a few studies that suggest that common movements during surgery result in less than 2 psi pressure,[22,23] In this experimental study, 2 psi pressure for 10-sec duration was applied twice on the wrist area immediately after each exposure.

Experimental study

Each 1-hr testing procedure was divided into four 15-min intervals to introduce test fluid by spraying or soaking and to apply pressure to the interested area. To simulate the spraying as one of the exposure types, two 5-sec sprays were employed from four corner nozzles at 0 and 30 min of the testing procedure. The total fluid amount applied to the glove-gown interface was 187 mL per each spray exposure. To mimic the soaking, two 5-sec soaks were applied at 15 and 45 min of the testing procedure by immersing the arm into the container filled with challenge fluid. To simulate the physical stresses on the wrist area, two 10-sec, 2 psi pressures were employed at 15 and 30 min. The robotic arm was automated to perform an equal number of pre-programmed movements between exposure and pressure applications (Table 1). The evaluation of the total fluid leakage in grams was done by calculating the amount of fluid absorbed by the inner cotton sleeve (93/7% Cotton/Spandex, Medline, NONSLEEVE) and knit cuff of the gown through weighing the dry (pre-test) and wet conditions (post-test). The scale used in the measurements was Symmetry by Cole-Parmer model # S-PT 413E with 0.001g sensitivity.

With four distinct surgical glove models examined in this study, in total, six distinct surgical glove configurations were examined, which consisted of both single and double gloving configurations: two synthetic and two latex glove models worn individually and two configurations in which the synthetic models were worn together (i.e., 3GLV and 4GLV were combined to create a double synthetic glove configuration) and the latex models were worn together (i.e., 5GLV and 6GLV were combined to create a double latex glove configuration) according to manufacturer recommendations.

A fully-crossed experimental design was used: the average fluid leakage was derived and examined from 10 experiments for each of the three surgical gown models within each of the six glove configurations resulting in a total of 180 experiments ($10 \times 6 \times 3$). SPSS (Version 23, SPSS Inc., Chicago, IL) was used to examine the main effects of each variable; namely, surgical gown model, surgical glove model, surgical glove material, the number of surgical gloves, and their interactions through analysis of variance (ANOVA).

Results and Discussion

Hypothesis #1: Effect of gown model on the fluid leakage

Fluid leakage significantly differed among the different types of surgical gowns (7G, Mean (M) = 8.72 g; 8G M = 8.47g; 9G M = 7.25 g; $F = 8.34$, $p < 0.001$, $\eta_p^2 = 0.09$) (Figure 4). Follow-up post hoc comparisons revealed that 8G and 7G were not statistically different from each other, but both were significantly different (higher) from the fluid leakage found using gown 9G (both at the $p < 0.001$ level). When only single glove configurations were considered, the model of surgical gown significantly affected the fluid leakage (7G, M =

10.13 g; 8G, M = 11.22 g; 9G, M = 9.33 g; F = 6.59, p = 0.002, $\eta_p^2 = 0.11$). Fluid leakage also significantly differed among different types of surgical gowns when only double glove (p < 0.001), single synthetic glove (p = 0.003), and single latex glove (p < 0.001) configurations were considered. In general, fluid leakage was the least when 8G and 9G were used, followed by 7G. Among all gown models, the cuff diameter of 8G might be considered as the largest, and fabric used for the gown is the softest, therefore this may have resulted in the narrower channel formation at the glove–gown interface, thereby lower leakage (Figure 2). Partial Eta squared (η_p^2) is an estimate of effect size for effects within the ANOVA; the larger the value of η_p^2 the more fluid leakage variance that is explained by the effect in question.

Hypothesis #2: Effect of glove model on the fluid leakage

Fluid leakage also significantly differed among the different types of surgical glove configurations (3GLV, M = 8.31 g; 4GLV, M = 9.50g; 5GLV, M = 3.08 g; 6GLV, M = 20.03 g; Double Synthetic, M = 2.77 g; Double Latex, M = 5.23 g; F = 275.42, p < 0.001, $\eta_p^2 = 0.90$). When fluid leakage values were compared among all single glove models, it was found that the lowest fluid leakage was achieved when the 5GLV latex gloves were used, followed by 3GLV and 4GLV; and the highest when 6GLV latex gloves were used. When two different single synthetic gloves were compared, it was found that the fluid leakage was similar and both were significantly lower than the configurations with 6GLV (both comparisons p < 0.001) and higher than the configurations with 5GLV (both comparisons, p < 0.001). When all glove models were compared, it was observed that the 5GLV model was the most elastic model, had the smallest cuff diameter and highest grip property of all tested models and, therefore, sealed the material inside more tightly than other gloves (Figure 3). These properties could have resulted in less fluid leakage. The 6GLV has the lowest grip compared to all gloves, which may also support the same conclusion.

Hypothesis #3: Effect of glove material on the fluid leakage

No general trend in fluid leakage was observed among the different glove materials (synthetic *vs.* latex). As seen in Figure 4, while fluid leakage is highest when one latex glove model (6GLV) was used, it was the lowest when the other latex model (5GLV) was used. These results suggest that the glove model affects the fluid leakage more than the glove material. It seems apparent that certain glove characteristics (grip, elasticity, etc.) may significantly influence the fluid leakage at the glove–gown interface more than their material of construction. As was explained in Hypothesis #2 results, synthetic gloves had the same grip, cuff length, and cuff diameter properties, and the fluid leakage values for these synthetic gloves were similar. However, there was a significant difference (p < 0.001) between the amounts of fluid leakage for the two latex models as 5GLV has much higher grip while the cuff diameter is much smaller compared with 6GLV. It was also observed that the 5GLV tightly-sealed the wrist compared with the 6GLV. These parameters may have helped the 5GLV to achieve the lowest fluid leakage values. When synthetic and latex gloves (only 6GLV) were compared, it could be seen that cuff diameter, cuff length, and grip were slightly larger for synthetic gloves. However, fluid leakage was much less for the synthetic gloves as compared with the 6GLV latex gloves, and higher than the 5GLV latex gloves. This may explain why the grip and elasticity affect the fluid leakage more than the cuff diameter or the glove material. Additional synthetic and latex samples with a variety of grip and length properties should be tested to support this conclusion.

Hypothesis #4: Effect of glove configuration on the fluid leakage

Important insights can be derived by observing the pattern of mean fluid leakage between single and double gloves. The mean fluid leakage was lower in the double synthetic glove configurations (M = 2.76 g) compared with all other configurations (3GLV, M = 8.3 g; 4GLV, M = 9.49 g; 5GLV, M = 3.08 g; 6GLV, M = 20.03 g; double latex, M = 5.22 g). Post-hoc comparisons revealed that the differences between the double synthetic glove configuration and each of the other configurations was significant at the $p < 0.001$ level except the comparison with 5GLV ($p = 0.55$). In addition, the mean fluid leakage was lower in the double synthetic glove configurations when compared to each of the synthetic gloves worn individually corresponding to each of the three gown types. For example, the mean fluid leakage for the 3GLV and 4GLV was 10.35 g and 10.70 g when paired with the 7G surgical gown model. When the 3GLV and 4GLV were combined into the double synthetic glove configuration, the resulting mean fluid leakage (3.88 g) was lower than both the individual means for that gown. In other words, when fluid leakage was compared between single and double gloving, the data showed that double gloving reduced fluid leakage in the case of synthetic gloves. However, when fluid leakage with single and double gloving were compared between the latex glove configurations, the lowest fluid leakage was found with the 5GLV model, which is even lower than the double latex gloving. This may be attributed to some of the properties of the 6GLV explained previously. Although the double latex configuration yielded a higher penetration than the single 5GLV latex, double gloving still substantially reduced the penetration when compared with the worst performing single latex, 6GLV.

Interaction between glove and gown types

In addition to the main effects, the interaction between surgical glove configuration and surgical gown model was significant ($F = 19.79$, $p < 0.001$, $\eta_p^2 = 0.55$). Table 2 reports the descriptive statistics and Figure 4 shows the mean fluid leakage for each cell in the design corresponding to the significant interaction. As can be seen in Table 2, mean fluid leakage values for gowns 8G and 9G were not significantly different when coupled with the single synthetic gloves (3GLV, $p = 0.96$; 4GLV, $p = 0.82$) and both values are less than mean fluid leakage values for gown 7G. However, the same pattern was not observed for the single latex gloves as there is a significant difference between 8G and 9G fluid leakage when these gowns were used with the 6GLV single latex gloves (8G, M = 26.718 g; 9G, M = 18.161 g; contrast = 8.558, $p < 0.001$). Also, 8G and 9G were not significantly different when coupled with 5GLV (8G, M = 1.933g; 9G, M = 3.082g; contrast = 1.146, $p = 0.23$). While the fluid leakage was lowest for 8G when coupled with 5GLV, it was largest for 6GLV and significantly higher when compared with 7G and 9G ($p < 0.001$). When double gloves are considered, 9G produced the lowest fluid leakage followed by 8G in the latex glove category and both were significantly lower than the 7G (for both comparisons $p < 0.001$). In the double synthetic glove combinations, use of the 8G resulted in the lowest fluid leakage, followed by the 9G but with only the 8G significantly lower than the 7G ($p = 0.02$). In other words, use of the 8G and 9G gowns resulted in the lowest fluid leakage values as compared with the 7G in all single and double synthetic glove and double latex glove configurations. However, the 8G produced the highest fluid leakage of all three gown models when the 6GLV glove was used as a single glove. These results exemplify one of the reasons for significant interaction between gown and glove type. Therefore, it seems apparent that unique surgical glove–gown combinations can create different configurations, which influence the amount of fluid leakage possible. The evidence within the interaction and the random fluctuations that occurred in fluid leakage when different models and numbers of gloves were combined with different gowns suggests that unique glove–gown combinations are needed to minimize fluid leakage. It also points to different design and material features inherent to gowns and gloves that impede or enhance their ability to fit together to reduce fluid leakage. These results suggest that gown and gloves should be designed as a system to function together.

One of the limitations of this study was the control of the temperature and humidity in the experimental chamber, and the temperature of the challenge fluid. The other limitation of the study is the simulation of the finger joint movements as the movements of shoulder, elbow, and wrist joints clearly showed greater impact on the gown and glove interface compared to finger movements. The sizes of each wearer's hand and arms are important factors that are expected to affect the fluid leakage through glove–gown interface. This study only used the size that best fits the robotic arm. However, end users might have different body, hand, and arm sizes, which could affect the fluid leakage.

Conclusions

Fluid leakage through the glove-gown interface is an area of concern for many HCP, including surgical teams that conduct various operations, especially deep abdominal surgery, trauma cases, and labor and delivery. In contrast to the significant risks posed to HCP, there are limited research studies conducted to understand the degree of fluid leakage through the glove–gown interface. This study represents one of the first efforts to compare the amount of fluid leakage for three surgical gown models, four surgical glove models, two glove materials, and single *vs.* double gloving. A unique and state-of-the art robotic arm was utilized in this study to simulate the arm movements of OR personnel while the most frequent types of exposures were introduced.

The results showed that there is a significant difference in fluid leakage amounts between gown models, glove models, and the number of glove layers studied. Some of the differences were attributed to the design and material used in gowns as well as glove grip and elasticity properties. It was observed that the model of the glove affected the fluid leakage more than the material that the glove is made of. Also, the results demonstrated that double gloving significantly reduced the fluid leakage compared to single gloving. Findings highlighted that there is a significant interaction between glove and gown models; surgical glove-gown combinations can create different configurations, which influence the amount of fluid leakage possible. Thus, unique glove–gown combinations can be formed to minimize fluid leakage by considering design and material features. These results underline that, as gowns and gloves are intended to function together, they should be designed as a system in order to minimize or eliminate fluid leakage through the interface areas.

As a follow-up to this study, surface characteristics of gown and gloves could be analyzed to understand how these properties influence the fluid flow at the interface. Also, the impact of surface tension of the challenge fluid on the fluid flow and fluid leakage could be determined in a further study. Human subject studies that validate the test results found by the robotic arm would be helpful to explore and address the limitation of size of the robotic arm.

Acknowledgments

The authors would like to acknowledge James Beaty, Matthew Johannes, and Jared Wormley of the Applied Physics Laboratory of Johns Hopkins University for their technical support with robotic arm; Ramona Conner and Amber Wood of AORN, Wanda Folsom of AST, Jacqueline Daley, and Donna Swenson for their technical support during the design of experimental parameters. The authors are thankful to Raymond Roberge, Harold Boyles, Ronald E. Shaffer, Judi Coyne, Chris Coffey, and Maryann D’Alessandro at NIOSH for their review of the manuscript and valuable comments and suggestions.

Funding

This research was supported through the Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health (NIOSH) [CAN#93905MJ] and the National Center for Emerging and Zoonotic Infectious Diseases.

References

[1]. Tokars JI, Chamberland ME, Schable CA, et al. : A survey of occupational blood contact and HIV infection among orthopedic surgeons. J. Am. Med. Assoc 268(4):489–494 (1992).

[2]. Willy ME, Dhillon GL, Loewen NL, Wesley RA, and Henderson DK: Adverse exposures and universal precautions practices among a group of highly exposed health professionals. Infect. Control 11(07):351–356 (1990).

[3]. Panlilio AL, Foy DR, Edwards JR, et al. : Blood contacts during surgical procedures. J. Am. Med. Assoc 265(12):1533–1537 (1991).

[4]. Fischer WA 2nd, Uyeki TM, and Tauxe RV: Ebola virus disease: What clinicians in the United States need to know. Am. J. Infect. Control 43(8):788–793 (2015). [PubMed: 26116335]

[5]. Sepkowitz KA, and Eisenberg L: Occupational deaths among healthcare workers. Emerging Infect. Dis 11(7):1003 (2005).

[6]. World Health Organization (WHO): “10 facts on patient safety.” Available at https://www.who.int/features/factfiles/patient_safety/en/ (accessed March 18, 2019).

[7]. Klein E, Smith DL, and Laxminarayan R: Hospitalizations and deaths caused by methicillin-resistant Staphylococcus aureus, United States, 1999–2005. Emerg Infec. Dis 13(12):1840–1846 (2007). [PubMed: 18258033]

[8]. World Health Organization (WHO): “Preferred Product Characteristics for Personal Protective Equipment for the Healthcare Worker on the Frontline Responding to Ebola Virus and Haemorrhagic Fever Outbreaks in Tropical Climat.” Available at https://www.who.int/medical_devices/documentPPEfor_public_comment_6Sept2017.pdf?ua1 (accessed March 18, 2019).

[9]. Leonas KK: Textiles for Protection. Boca Raton, FL: Woodhead Publishing-CRC Press, 2005.

[10]. Kilinc-Balci FS, Kahveci Z, and Yorio PL: Novel test method for the evaluation of fluid leakage at the glove–gown interface and investigation of test parameters. J. Am. College Surg 227(6):573–586 (2018).

[11]. American National Standards Institute (ANSI)-Association for the Advancement of Medical Instrumentation (AAMI): Liquid Barrier Performance and Classification of Protective Apparel

and Drapes Intended for Use in Health Care Facilities (ANSI/AAMI PB70:2003). [Standard] Arlington, VA: AAMI, 2012.

[12]. Cardinal Health: "Surgical Gowns." Available at http://www.cardinalhealth.com/en/product-solutions/medical/infection-control/surgical-gowns/surgical-gowns. html (accessed March 18, 2019).

[13]. National Institute for Occupational Safety and Health (NIOSH): "Considerations for Selecting Protective Clothing Used in Healthcare for Protection against Microorganisms in Blood and Body Fluids." Available at https://www.cdc.gov/niosh/npptl/topics/protectiveclothing/default.html (accessed March 18, 2019).

[14]. ASTM International: Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Synthetic Blood (ASTM (2003a) ASTM F1670–03). [Standard] West Conshohocken, PA: ASTM, 2003.

[15]. International Organization for Standardization (ISO): Clothing for Protection against Contact with Blood and Body Fluids-Determination of the Resistance of Protective Clothing Materials to Penetration by Blood and Body Fluids-Test Method Using Synthetic Blood (ISO 16603:2004). [Standard] Geneva, Switzerland: ISO, 2004.

[16]. ASTM International: Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Liquids (ASTM F903–17). [Standard] West Conshohocken, PA: ASTM, 2017.

[17]. Johannes MS, Bigelow JD, Burck JM, et al. : An overview of the developmental process for the modular prosthetic limb Johns Hopkins APL Tech. Digest 30(3):207–216 (2011).

[18]. Nguyen NT, Ho HS, Smith WD, et al. : An ergonomic evaluation of surgeons' axial skeletal and upper extremity movements during laparoscopic and open surgery. Am. J. Surg 182(6):720–724 (2001). [PubMed: 11839346]

[19]. McAtamney L, and Nigel Corlett E: RULA: A survey method for the investigation of work-related upper limb disorders. Appl. Ergon 24(2): 91–99 (1993). [PubMed: 15676903]

[20]. Association for the Advancement of Medical Instrumentation (AAMI): "Selection of Surgical Gowns and Drapes in Health Care Facilities." In AAMI-TIR No 11–2005. Arlington, VA: AAMI, 2005. [Memo]

[21]. Jaques PA, Gao P, Kilinc-Balci S, et al. : Evaluation of gowns and coveralls used by medical personnel working with Ebola patients against simulated bodily fluids using an Elbow Lean Test. J. Occup. Environ. Hyg 13(11):881–893 (2016). [PubMed: 27171285]

[22]. Smith JW, and Nichols RL: Barrier efficiency of surgical gowns: Are we really protected from our patients' pathogens? Arch. Surg. 126(6):756–763 (1991).

[23]. Smith JW, Tate WA, Yazdani S, et al. : Determination of surgeon-generated gown pressures during various surgical procedures in the operating room. Am. J. Infect. Control 23(4):237–246 (1995). [PubMed: 7503435]

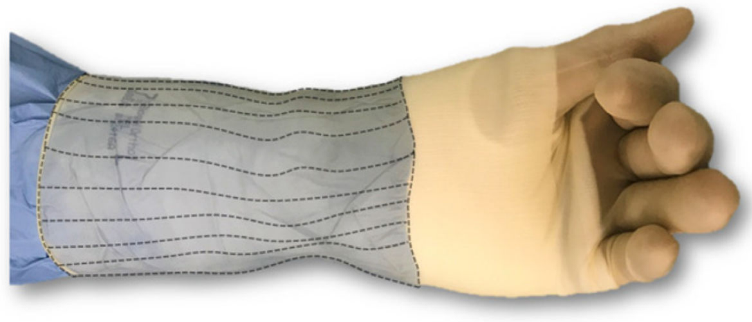

Figure 1.
The sketched area is the interface between glove and gown. The channels formed underneath the glove cuff.

		7G	8G	9G
Dimensions of Sleeve and Sleeve Cuffs (inch)*	A	14	14.22	15
	C	11.25	11	11
	D	2.75	3.25	3
	E	4.5	5.11	4.5

Figure 2.

Gown sleeve and cuff designs and dimensions. *A, C, and E are the circumference measurements at marked locations. B = 6 inches for all gown models and it is the end point for the surgical glove when donned. The best fitting gowns were selected for robotic arm as x-large for 8G and large for 7G and 9G.

Glove ID	Material Type	Cuff (cm)		Size	Grip	Thickness (mil)			Standards
		Length	Diameter			Palm	Finger	Cuff	
3GLV	Synthetic	30.7	20	7.5	1.5	12.2	13.8	9.8	ISO 9001,13485,14001 EN 455-1, -2, -3, EN 552, 556 ASTM D3577, F1671
4GLV	Synthetic	30.7	20	7.5	1.5	10.4	10.6	8.5	
5GLV	Latex	29.7	17.2	7.5	3	10.8	11.8	8.7	
6GLV	Latex	29.7	19.6	7.5	1	8.1	8.5	6.9	

Figure 3.

The physical properties of surgical gloves. 4GLV is recommended to use as inner-glove with 3GLV and 6GLV is with 5GLV by the manufacturer.

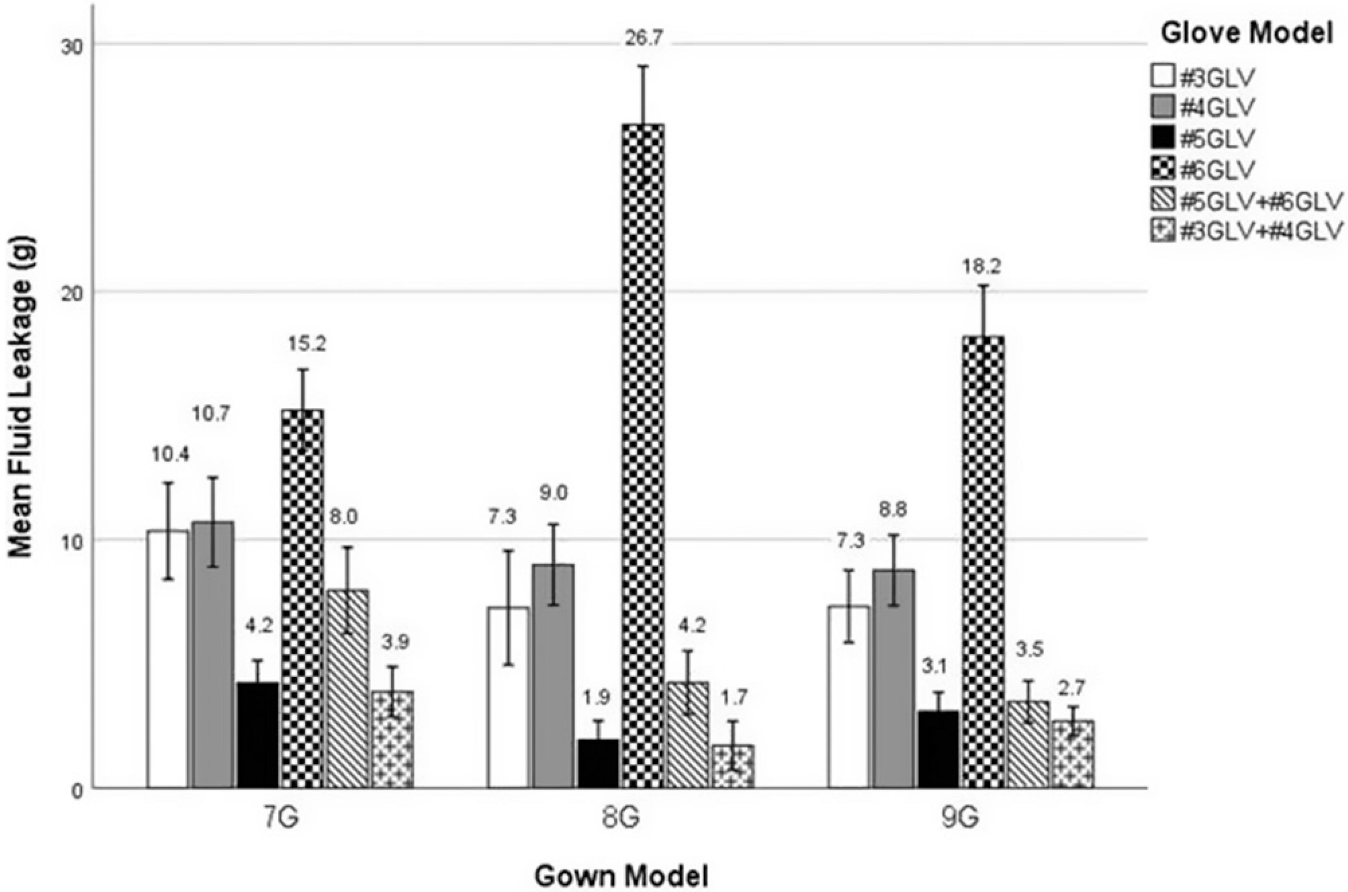

Figure 4:

Mean fluid leakage by surgical glove configuration and surgical gown model. The error bars represent the 95% confidence interval of the mean. The mean fluid leakage was derived and examined from 10 experiments for each of the three surgical gown models within each of the six glove configurations resulting in a total of 180 experiments.

Table 1.

Body part movements and total number of movements in a 1-hr procedure.[18]

Body Part	Movement	1 Hr
Shoulder	Flexion (90°)	4
	Flexion (140°)	4
	Abduction (90°)	8
	Abduction (max)*	8
	Internal Rotation	12
	Hyperextension*	4
Elbow	Flexion (45°)	12
	Flexion (90°)	12
	Flexion (Max)*	12
	Pronation	8
	Supination	8
Wrist	Flexion	8
	Extension	8
	Ulnar deviation	8
	Radial deviation	8

*Modified movements for the purpose of this study.

Table 2.

Fluid leakage descriptive statistics by glove model and gown model.

Glove Model	Gown Model	Mean Fluid Leakage (g)	Median Fluid Leakage (g)	Std. Deviation	Std. Error of Mean	95% CI for Mean Fluid Leakage (g)		Minimum and Maximum Fluid Leakage (g)		Range (g)
3GLV Synthetic	7G	10.35	10.70	2.71	0.86	8.67	12.03	6.35	13.41	7.07
	8G	7.26	6.39	3.22	1.02	5.26	9.25	3.37	12.61	9.24
	9G	7.31	7.13	2.04	0.64	6.05	8.57	4.98	10.81	5.83
4GLV Synthetic	7G	10.70	9.87	2.51	0.80	9.15	12.26	7.08	15.23	8.16
	8G	8.99	8.97	2.28	0.72	7.57	10.40	5.44	13.04	7.60
	9G	8.77	8.84	1.99	0.63	7.53	10.00	4.98	11.57	6.60
5GLV Latex	7G	4.23	4.37	1.26	0.40	3.44	5.01	1.91	5.98	4.07
	8G	1.93	1.63	1.08	0.34	1.26	2.60	1.15	4.71	3.56
	9G	3.08	3.25	1.08	0.34	2.42	3.75	1.17	4.89	3.72
6GLV Latex	7G	15.22	15.01	2.29	0.72	13.80	16.64	12.36	18.93	6.57
	8G	26.72	26.27	3.30	1.04	24.67	28.76	22.69	33.59	10.89
	9G	18.16	18.03	2.91	0.92	16.35	19.97	14.63	22.58	7.94
5GLV+ 6GLV	7G	7.96	6.69	2.43	0.77	6.46	9.47	5.19	11.64	6.45
	8G	4.24	4.42	1.79	0.57	3.13	5.35	1.38	7.70	6.31
	9G	3.47	3.35	1.18	0.37	2.74	4.20	2.03	5.60	3.57
3GLV+ 4GLV	7G	3.88	3.49	1.41	0.45	3.00	4.75	2.48	6.97	4.49
	8G	1.70	1.77	1.37	0.43	0.85	2.55	0.02	4.10	4.08
	9G	2.69	2.92	0.81	0.25	2.19	3.19	0.9	3.66	2.76