

ANTIMICROBIAL SURGICAL GLOVES:

INTRIGUING NEW DEVICE THAT COULD PREVENT SURGICAL SITE INFECTIONS

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Over the past few years, use of antimicrobial medical devices has increased. A key driver for the adoption of antimicrobial products is the need to eliminate healthcare-associated infections (HAIs) particularly surgical site infections (SSIs) and their associated grievous outcomes.

Healthcare-associated infections (infections acquired in healthcare settings) are the most frequent adverse event in healthcare. Hundreds of millions of patients are affected by HAIs worldwide each year, leading to significant mortality and financial losses for health systems. Of every 100 hospitalized patients at any given time, 7 in developed and 10 in developing countries will acquire at least one HAI.¹

The endemic burden of healthcare-associated infection is also significant. The prevalence of HAIs in developed countries varies between 3.5% and 12%. The European Centre for Disease Prevention and Control reports an average prevalence of 7.1% in European countries. The estimated incidence rate in Canada is 11.6% and in the US is 4.5%, corresponding to 2 million affected patients annually.¹ It has been estimated that overall prevalence of HAIs in Australia is 9.7%, affecting as many as 150,000 patients each year.²

Impact of Healthcare-Associated Infections

Healthcare-associated infections create suffering and come at a high cost for patients, their families and the healthcare system. Infections prolong hospital stays, create long-term disability, increase resistance to antimicrobials, impact both work life and family life, and represent massive additional financial burdens.

Such infections account for 37,000 deaths in Europe³, 8,500-12,000 deaths in Canada⁴⁻⁵ and 99,000 deaths in the USA annually.⁶ This equates to approximately 270 deaths per day in the US alone! Further, in Europe annual financial losses due to healthcare-associated infections are estimated at approximately €7 billion in direct costs only and reflect 16 million extra days of hospital stay.⁴ In US hospitals, annual direct medical costs of HAIs range from \$28.4 to \$33.8 billion.⁷

Surgical Site Infections

A recent prevalence study found that SSIs were the most common healthcare-associated infection, accounting for 31% of all HAIs among hospitalized patients globally.⁸⁻⁹ Infections develop in about 1 to 3 out of every 100 patients.¹⁰ Surgical site infections are a common complication of care, occurring in 2-5% of patients after clean extra-abdominal surgeries (e.g., thoracic and orthopedic surgery)¹¹ and in up to 20% of patients undergoing intra-abdominal procedures.¹²⁻¹⁸ Studies following patients into the post-discharge period have reported even higher rates of postoperative infection.¹⁹⁻²² These complications increase morbidity for patients and consume substantial additional resources.²³⁻²⁷

Statistics

US

- 780,000 out of 30 million surgical procedures performed annually result in SSI.²⁸
- SSIs result in \$10 billion in direct and indirect medical costs each year.²⁹

UK

- The estimated direct costs for a patient who develops a surgical site infection are between €2,265 and €2,518.³⁰
- SSIs accounted for 14% of HAIs.³¹
- Nearly 5% of patients who had undergone a surgical procedure were found to have developed an SSI.³¹

Europe

- Incidence of SSI range from 1.5% to 20%.³²
- SSIs contribute greatly to the economic costs of surgical procedures - estimated range: €1.47-19.1 billion.³²

Australia

- The Australian Council for Safety and Quality in Health Care suggests that 2% to 13% of patients suffer from SSIs.³³
- SSIs increased length of stay by six days at cost of A\$12,419 - A\$40,940 per patient.³⁴
- Total costs for SSIs are estimated at A\$268 million per year.
- SSI's account for 7000 deaths annually.³⁵

Canada

- Minor post-surgical infections add an additional \$5,000-\$10,000 per case, while major procedures (e.g. orthopedic or cardiac) increase the patient cost of care by well over \$100,000 per case.³⁶

Prior to Ignaz Semmelweis and Joseph Lister introducing antiseptic surgery in the 19th century, most wounds became infected. In response, surgeons started to use various protective and preventive means, such as surgical gloves, pathogen killing disinfectants for their hands and their instruments, masks, sterile gowns and drapes, improved surgical technique, and the use of antimicrobial prophylaxis.

With the advanced technologies used for today's surgical procedures, these various protective devices no longer provide all the protection required. We need more proactive medical devices to suppress and kill germs, particularly during surgical procedures. One method now being used in the fight against infections is the use of medical devices exhibiting antimicrobial capabilities. By definition, an antimicrobial agent is one that is capable of destroying or inhibiting the growth of microorganisms.

Surgical Gloves

Antimicrobial surgical gloves could serve as a second line of defense against disease causing microbes. This type of technology would not be a replacement for today's best practices such as surgical scrubs, double gloving, skin preps,

prophylaxis antibiotics, etc., but would be an added level of protection.

Due to innovation from manufacturers, products are constantly being improved, not only in healthcare, but in all industries, as new technology is developed. Take a more commonplace example into consideration; today's automobiles. Innumerable safety features have been integrated for an added level of protection: safety glass, seat belts, head restraints, antilock brakes, airbags, backup sensing system, energy absorbing steering, automatic dimming mirrors and the list goes on. Vehicle safety features reduce the effect of collision impacts on your car and save lives. Many of these safety devices have become not only expected, but standard, in most new vehicles.

Additional protection should be expected from other types of products, like surgical gloves. It is time for an upgrade. Antimicrobial surgical gloves have the potential to reduce the transmission of bacteria and viruses, reducing SSIs and potentially saving lives.

Surgical Scrub

Healthcare providers wear gloves not only to protect the patient, but to protect themselves from any potential bacteria or viruses that could be transmitted via the patient's blood and body fluids. Bacteria on the hands of surgeons can cause wound infections if introduced into the operative field during surgery.³⁷⁻³⁸ Antiseptics for surgical hand preparation must eliminate the transient and significantly reduce the resident flora at the beginning of an operation and maintain the microbial release from the hands below baseline until the end of the procedure. Reducing resident skin flora on the hands of the surgical team for the duration of a procedure reduces (but does not eliminate) the risk of bacteria being released into the surgical field if gloves become punctured or torn during surgery. It is still possible for re-growth of bacteria under surgical gloves during surgery, particularly when the hands become warm, moist and sweat posing risk for a SSI in the event of a glove breach.³⁹⁻⁴⁰

Surgical Glove Breaches

Although surgeons expect their gloves to serve as an effective barrier during use, products can, and do, fail. Pathogens are proven to transfer from healthcare workers to patients and from patients to healthcare workers. Bacteria pass to the healthcare worker through glove breaches resulting from normal wear.⁴¹ Members of surgical teams are known to have higher rates of percutaneous injury than individuals in other healthcare settings as surgical procedures expose the surgical team to multiple sharp instruments.⁴² This too increases potential for bacteria to pass through the glove. Glove punctures during surgical procedures have been found to occur at rates of 11% – 43%, depending on the surgical procedures being performed. Up to 83% of glove breaches go unnoticed by surgeons; therefore they do not change their gloves, further increasing the risk of contamination.⁴³⁻⁴⁵

Double gloving has been shown to be an effective method to reduce (but not eliminate) the surgeon's potential for contact with bodily fluids and the patient's exposure to microorganisms shed by the surgical team. In 18% to 48% of cases, breaches occur in both the outer and inner gloves.⁴⁶⁻⁴⁷ Glove breaches, whether with a single glove or double gloved hand, may enable bacteria from the surgical team's hands to be passed to the patient. Moreover, some surgeons are

uncomfortable with the loss of dexterity caused by the thickness of the double gloving, and by the layers slipping against each other, so they will forgo wearing a double glove.

Surgical gloves provide a protective barrier against bacteria and blood-borne pathogens both for the healthcare provider and the patient but, when the barrier is breached; risk of infection can increase, as demonstrated in the very recent case reports below.

Infection passes through surgical gloves to the patient

- **Bacteria on hands of surgeon causes SSI - Case Reported LA Times (Dec. 8th 2012)** ⁴⁸

A heart surgeon at Cedars-Sinai Medical Center in Los Angeles unwittingly infected five patients during valve replacement surgeries, causing four of them to need a second operation.

- **University of Virginia Health System published in the journal Clinical Infectious Diseases - October 2012)** ⁴⁹

A surgeon with hepatitis B who performed joint replacement surgeries unknowingly passed the virus on to at least two of his patients.

Summary

Patients entering hospitals for medical treatments and surgical procedures face the risk of potentially developing a life threatening infection during their stay. Although a number of initiatives have been implemented over the past few decades to reduce SSIs, these initiatives are not enough and SSIs continue to be a significant cause of morbidity, mortality and substantial costs.

Recent analysis from Frost & Sullivan found that the U.S. antimicrobial coatings market earned revenues of US \$175.4M in 2005 with estimates to reach US\$558.7M in 2012. ⁵⁰ Antimicrobial coatings, when used in conjunction with other sound practices, appear to have a positive impact in controlling infection rates. ⁵¹⁻⁵³

Today, a new breed of surgical gloves is being equipped with antimicrobial technology. The science of this antimicrobial technology is both theoretically and practically sound and has the potential to prevent microbial transmission due to intraoperative glove breaches. In turn, this will provide an additional level of protection to surgical staff against viruses and bacteria and increase the potential to prevent contamination of the surgical site, decrease the risk of SSI, and increase patient safety.

Increasing pressure to address surgical site infection rates will play a crucial role in the growth and adoption of antimicrobial surgical gloves.

Pending Publication

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*Dr. Assadian has performed paid consulting work for Ansell and/or its affiliates.