



Risks and Benefits of the Different Types of Gloves used in the Perioperative Setting

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ABSTRACT

The role of powder gloves in allergic reactions, infections, wound healing and granuloma formation has been known for many years. Despite a gradual shift away from powder gloves over the last several decades, many healthcare professionals and facilities continue to use powder gloves as the FDA has continued to refrain from issuing a comprehensive formal ban. However, recent advancements in glove technology and position statements by professional societies have continued the push for removal of powder gloves from all clinical and surgical settings and will hopefully entirely eradicate usage in the coming years.

Keywords: Glove, Infection, Operating room, Surgical glove.

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INTRODUCTION

During patient care, both the patient and members of the health care team are at risk for transmission of infectious agents from both endogenous and exogenous microorganisms. Accordingly, surgical gloves have become a universal infection precaution in the operative theater, and exam gloves have become increasingly utilized in the clinical setting for all tasks with potential exposure to bodily fluids or mucous membranes.

Since the first medical gloves were produced over a century ago, various techniques and powder lubricants

have been used to facilitate removal of gloves from formers during production and donning of gloves by users.¹ As gloves have become increasingly used in both the operative theater and clinical settings, complications of glove lubrication powders have become evident and the medical field, industry, and governmental regulators have been forced to take notice.^{2,3} As the number of reports and studies documenting increased rates of infection and allergic reactions due to powdered gloves grows,^{4,5} momentum has developed in the effort to transition completely to powder-free surgical gloves as the new standard of care.

Problems of surgical site infections and other health care-associated conditions take on greater significance today in the face of the economic incentives outlined in the Affordable Care Act (ACA), designed to improve the safety and efficiency of patient care. The ACA established the Hospital-Acquired Condition (HAC) Reduction Program to encourage hospitals to decrease HACs, which are defined as “a group of reasonably preventable conditions that patients did not have upon admission to a hospital, but which developed during the hospital stay.”⁶ Reducing the risk of infection and allergic reaction for patients as well as members of the surgical team continues to be a primary focus in today’s dynamic health care environment, as perioperative personnel face challenges presented by newly recognized pathogens and those that have become resistant to current treatment modalities.⁷

HISTORY

In 1758, Dr Johann Julius Walbaum became the first surgeon to use gloves in the operative theater when he fashioned gloves from the cecum of sheep which only covered the finger tips.⁸ However, it was not until 1893 when Dr Joseph Bloodgood recognized the need to prevent the spread of infection that gloves became popular in the operative theater.⁹ Dr William Steward Halstead introduced the first sterile, latex, reusable glove in 1894.¹⁰ In the early twentieth century, lycopodium spores mixed with talc (hydrous magnesium silicate) were introduced as a lubricant to facilitate donning of gloves but were subsequently replaced with a talc-only lubricant after a study demonstrated the toxicity of lycopodium spores and the propensity for granuloma

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formation.^{9,11} Later in 1947, talc was also found to cause surgical complications including granuloma formation and abdominal adhesions and impedes healing and was gradually replaced by modified cornstarch as an absorbable (biologically degraded), nonirritating lubricant of choice.¹¹

The first disposable gloves were introduced in 1964 and quickly became universal, demonstrating decreased incidence of postoperative infection.¹¹ During the 1970s, latex was recognized as a cause of allergic reactions and cornstarch was found to impede wound healing.¹² In August 1987, in response to concerns for health care worker safety after the emergence of human immunodeficiency virus/acquired immunodeficiency syndrome, the Centers for Disease Control (CDC) mandated that all health care workers wear gloves.¹³ In the late 1990s, glove technology continued to advance with the advent of “powderless” natural rubber latex (NRL) and synthetic materials.¹⁴ Since that time, the glove industry has continued to evolve to reduce the powder content of gloves and decrease manufacturing costs.

Currently, powders continue to be used both as dusting powders and in the manufacturing process. Cornstarch remains the most common dusting powder meeting the US Pharmacopeia definition of an absorbable dusting powder as it is absorbable through biologic degradation. Lubricants used in the manufacturing process include calcium carbonate or a mixture of cornstarch and calcium carbonate to facilitate release of latex and other tacky glove polymers from glove formers or molds. Finally, silicon and cornstarch remain common donning lubricants.

Although glove manufacturers have responded to reports of increased rates of infection and allergy, glove powders continue to be used in the manufacturing process and as donning lubricants in nonpowderless gloves. Many health care workers remain unaware of the potential health risks of powder gloves and of the recent improvement in price, availability, and handling characteristics of powderless gloves.

INFECTION, WOUND HEALING, AND GRANULOMAS

Particulates of glove powder are aerosolized when the gloves are manipulated and donned and can then subsequently settle on surgical instruments, implants, drapes, sponges, or in the wound.^{8,15} When powder is deposited in a surgical wound, it is phagocytosed and the body mounts a foreign body reaction with an exaggerated inflammatory response, interfering with the host's defenses against infection.¹⁵ This exaggerated inflammatory response has

been implicated as the cause of a wide range of complications including delayed wound healing, adhesions, joint inflammation, abdominal pain, vascular obstructions, and starch granuloma formation.^{15,16} Powder contamination has also been implicated as a cause of misdiagnosis resulting in inappropriate treatment or unnecessary surgery^{5,17} and has been shown to enhance the growth of bacteria.¹⁸

Hunt et al¹⁹ found that the number of starch granules in surgical wounds was proportional to the number of team members who wore powdered gloves and also to the proximity of the gloves from the surgical site. The starch-containing phagocytes in the tissue were surrounded by an inflammatory reaction which ultimately led to scarring in one patient. Ruhl et al¹⁸ found that cornstarch in wounds enhanced bacterial growth and elicited exaggerated inflammatory responses. Using an animal model, Dwivedi et al²⁰ found that the presence of latex or powder on surgical gloves increased the formation of adhesions and correlated with increased serum levels of tumor necrosis factor. In a 1996 retrospective study by Luijendijk et al,²¹ intraabdominal cornstarch granulomas were found in 5% (14/309) of the patients operated on by surgeons using powder gloves. A subsequent study in 2001 by van den Tol et al²² used a rat model to demonstrate that cornstarch powder promotes adhesion formation and facilitates tumor cell adhesion and growth. Additionally, in a 2010 study, Suding et al¹⁶ assessed the relationship between cornstarch and abscess formation. When methicillin-susceptible *Staphylococcus aureus* (MSSA) was injected into the subcutaneous tissue with cornstarch, both an increase in MSSA and cornstarch concentration led to increased frequency of abscess formation and the presence of high concentration of starch reduced the inoculum of bacteria needed to produce an abscess.¹⁶

Granuloma formation has been a known complication of glove powder.^{1,5} Winkler et al²³ evaluated the use of magnetic resonance imaging in a differential diagnosis between cornstarch and fecal peritonitis in rat models and they reported results that were remarkable for cornstarch peritonitis. In a case report by Juaneda et al,²⁴ they present a 54-year-old woman admitted due to abdominal pain, fever, and prolonged postoperative ileus status post hysterectomy 3 months prior. The patient had her distal jejunum accidentally perforated during exploratory video laparoscopy and required laparotomy for enterorrhaphy and then a laparotomy 30 days later for persistent ileus. Histopathology confirmed cornstarch granulomatous peritonitis. It was concluded that prevention was important and this would have been avoided if the surgeons had used cornstarch-free surgical gloves. Beyond the problem of the powder-induced granulomas, Giercksy et al²⁵

highlighted the potential diagnostic complications resulting from multifocal powder granulomas mimicking disseminated peritoneal carcinomatosis. Although studies have demonstrated that other operative materials including gauze and suture material may cause granuloma formation more commonly and the dose of cornstarch required to induce a granuloma is much higher than talc powder, cornstarch remains a clear and modifiable risk factor for granuloma formation.^{1,26} The process of sterilization of powder gloves is very important as irradiation of cornstarch can delay biological degradation from 48 hours to months, dramatically increasing the rate of granuloma formation, whereas autoclave sterilization does not delay biological degradation.²⁷

ALLERGIC REACTION

Many of the complications associated with the powder in powder gloves stem from the propensity of cornstarch powder to bind to NRL and subsequently serve as a vector for NRL allergens.^{1,4} Studies by Beezhold and Beck²⁸ and Tomazic et al²⁹ demonstrated that cornstarch not exposed to NRL had no allergenic proteins, whereas cornstarch exposed to NRL or extracted from powdered gloves has a significant amount of allergenic proteins.³⁰ Furthermore, as a powder, cornstarch has the capability to aerosolize and remain airborne for extended periods of time.^{30,31} Levels of aerosolized NRL via cornstarch powder have been analyzed in several studies. In a study by Tarlo et al,³² the allergen levels in laboratories where powder gloves were used were 2 to 15 times higher than laboratories where powderless gloves were used. Assessing the operative room specifically, Heilman et al³³ found a reduction in average allergen levels from 13.7 ng/m³ on days that powdered gloves were used down to 0.6 to 1 ng/m³ on days where powderless gloves were used.

Beyond the obvious risk of aerosolized powder contaminating wounds, aerosolized NRL has the potential to be inhaled by the patient or health care staff causing a respiratory allergic reaction. An estimated 30% of people with NRL sensitivity develop respiratory problems.³⁴ Additionally, Vandenplas et al³⁵ demonstrated that reaction to aerosolized NRL can occur not only by the direct user of powdered gloves, but also secondarily by any other user in the room. In a study by Pisati et al,³⁶ a bronchial provocation test demonstrated no bronchial reaction to clean cornstarch in NRL-sensitized patients, intermediate reaction to a nebulized powderless NRL glove, and complete reaction (bronchoconstriction) to a powdered glove.

The allergic reactions with glove powder and NRL are fundamentally separated into type I (immediate or immunoglobulin [Ig]E-mediated) hypersensitivity and

type IV (delayed or T-cell-mediated) hypersensitivity.^{37,38} Although these different reactions can produce a similar phenotype or rash, distinction of the mechanism of the reaction is important for prevention of subsequent reactions.

Type I hypersensitivity, or allergy, is due to an IgE-mediated reaction to a specific antigen, or allergen. After sensitization to an earlier exposure to an antigen, B-cells produce IgE which then binds to receptors of circulating immune cells.^{1,39} When these circulating IgE-covered immune cells encounter the same allergen, the immune cell degranulates and releases active mediators including histamine, prostaglandins, and leukotrienes, which produce a combined effect of vasodilation and recruitment of leukocytes to the area of exposure. The cutaneous manifestation of this response is urticarial but the systemic response can include rhinorrhea, generalized pruritis, wheezing, shortness of breath, and even potentially anaphylaxis.^{1,40} The importance and prevalence of type I hypersensitivity to NRL was first recognized in the early 1990s following a rapid increase in utilization of gloves as a universal precaution.^{41,42} Estimated prevalence rates of NRL allergy in health care workers have ranged 5.5 to 17% due to the discrepancy between serum IgE measurements and skin prick testing.⁴³⁻⁴⁷ However, a meta-analysis by Bousquet et al⁴⁸ showed a 4.3% prevalence of NRL allergy in health care workers and only 1.4% prevalence in the general population. As institutions began reacting to published data regarding rates of NRL allergy and limiting or eliminating NRL gloves, prevalence rates and incidence rates decreased.^{19,49-51}

Type IV, or delayed-type T-cell-mediated, hypersensitivity, is caused by the contact of an allergen with the skin following a previous sensitization to the allergen. Although allergic contact dermatitis on the hand in the health care setting is frequently attributed to NRL gloves, this reaction can be caused by numerous allergens including fabrics, cosmetics, and even soaps. However, the prolonged contact of the powder with the wearer's hand during a surgical case presents an increased risk for reaction over other potential irritants in contact with the skin only briefly. The resultant contact dermatitis is very common and is the most common occupational skin disease with numerous potential allergen causes. Allergic contact dermatitis due to one of the chemicals used to manufacture rubber gloves is not uncommon.³⁹ Symptoms include eczema and blisters and occur over the skin in contact with the allergen similar to a poison ivy rash and typically appear 1 to 3 days after glove use. The implications of this reaction are serious as dryness and cracks in the skin as well as excoriation from scratching pruritic areas compromises the protective barrier of the epithelium.

PROFESSIONAL SOCIETY POSITION STATEMENTS

The collective data regarding topical and systemic allergic reaction to cornstarch powder and NRL via cornstarch powder as a vector led to the American Academy of Dermatology to publish a position statement in 1998 recommending the exclusive use of powderless gloves with low NRL allergen levels.³⁷ Similarly, the American College of Surgeons (ACS) has stated: "The College believes there is no reason to continue the use of powdered gloves. Indeed, the elimination of powdered gloves will significantly lower the risk of allergic reactions."⁵² In their 2013 update for Recommended Practices for a safe Environment of Care, the Association of periOperative Registered Nurses (AORN) currently recommends the use of powder-free, low-protein NRL gloves or latex-free gloves in the perioperative setting.⁵³

Although the FDA continues to delay the issuance of a formal ban on powder gloves, other government agencies have released statements and regulations pertaining to powdered gloves. The CDC/National Institute for Occupational Safety and Health (NIOSH) has stated, "appropriate barrier protection is necessary when handling infectious materials. If you choose latex gloves, use powder-free gloves with reduced protein content."⁵⁴ Additionally, the bloodborne pathogens standard from the Occupational Safety and Health Administration (OSHA) specifies that employers must provide hypoallergenic gloves, glove liners, powderless gloves, or other similar alternatives if employees are allergic to the gloves that are routinely provided.⁵⁵

A citizen's petition entitled "Maltese cross birefringence" was signed and sent to the FDA on September 24, 2008, to commemorate thousands of individuals who have been seriously injured or died of powder-coated gloves that have caused wound infection and intestinal adhesions leading to intestinal obstruction, cornstarch granulomatosis, as well as allergic reactions. Edlich et al state that on July 3, 2013, Mr. Paul Gadiock of the Regulatory Affairs of the FDA Division of Devices and Radiological Health sent them a letter confirming the FDA's approval of their proposal to ban powdered examination and surgical gloves.⁵⁶ Given these complications together with the technological advancements to produce powder-free examination and surgical gloves, the United States should have enough resources to ensure that all health care workers are able to use powder-free examination and surgical gloves.⁵⁷

THE ROLE OF THE FDA

Both exam and surgical gloves are considered a medical devices in the United States and, accordingly, glove usage

is regulated by the FDA. Although many large professional societies have released unambiguous recommendations urging members to cease use of powder gloves and numerous institutions have completely eliminated powder gloves, there remain many health care practitioners and facilities that continue to use powdered gloves. Accordingly, advocates for the banning of powdered gloves have repeatedly gone to the FDA and requested review of the formidable data concerning powdered gloves and formal removal of powdered gloves from the marketplace. The timeline of the FDA's involvement is detailed herein:

1971

The FDA responded to mounting evidence regarding the harm of using cornstarch powder in gloves, issuing a caution statement in regard to reducing the amount of powder on surgeon's gloves. Either of the two following statements needed to be included on the labeling: "Caution: Powder should be removed from the gloves after donning by wiping gloves thoroughly with a sterile wet sponge, sterile wet towel, or other effective method," or "Caution: After donning, remove powder by wiping gloves thoroughly with a sterile wet sponge, sterile wet towel, or other effective method."⁵⁶ The most effective method to remove cornstarch from gloves is noted to consist of a 1-minute wash with 10 mL of povidone-iodine, followed by a 30-second rinse with sterile water.⁵⁷ This procedure, however, cannot ensure that all of the powder particles have been eliminated and is time-consuming, costly, and burdensome to the staff.⁵⁸ Studies have shown that efforts to remove the cornstarch from surgical gloves in a basin with sterile water or using a wet lap sponge are unsuccessful; moreover, reports indicate that these efforts have led to additional clumping, which results in even fewer absorbable particles.²⁷

1997

One year after the introduction of the first powderless glove into the US market, the FDA published its first report on medical glove powder, noting that at the time, it had received requests to ban the use of glove powder. The report concluded that²⁷ (i) the primary adverse effect of glove powder seems to be its contributing factor in the development of allergies to NRL, (ii) glove powder serves as an airborne carrier of natural latex proteins, and (iii) exposure to airborne NRL allergens can be most effectively decreased by taking into consideration both the level of natural latex proteins as well as the amount of glove powder on the gloves. In their critique of the literature, the FDA further concluded that many granulomas were described earlier (with talc powder) but "there are

few granulomas described in the current literature” and that although glove powder is clearly implicated in peritoneal tissue, sutures are a more common cause. In discussion of the potential economic implications of banning powdered gloves, the FDA cited a limited number of companies producing powderless gloves which would in turn lead to increased cost due to increased demand.

1998

The FDA received the first Citizen’s petition to ban the use of powder from the Public Citizen.⁵⁹ Public Citizen, founded in 1971, serves as the people’s voice in Washington, DC, advocating various citizen interests before Congress.⁶⁰ This letter, dated January 7, 1998, petitioned the FDA to “immediately ban the use of cornstarch powder in the manufacture of latex surgical and examination gloves because of the serious and widespread dangers these gloves cause to medical personnel and to patients.”⁵⁹ The letter furthermore addressed the contention of the 1997 FDA report that powderless gloves were not readily available and warned that continued use of powdered latex gloves was both harmful and unacceptable.

2008

The FDA received a second petition from the Public Citizen to again ban the use of cornstarch powder in medical and surgical gloves. This petition specifically noted that safer, powderless gloves were available and in use in many hospitals.³⁰

2011

The FDA published an updated warning statement that was required to be included on all labeling for medical gloves with powder that read: “Warning: Powdered gloves may lead to foreign body reactions and the formation of granulomas in patients. In addition, the powder used on gloves may contribute to the development of irritant dermatitis and type IV allergy, and on latex gloves may serve as a carrier for airborne natural latex leading to sensitization of glove users.”⁶¹ Soon after the public release of this updated warning statement, the Public Citizen sent a third petition to the FDA requesting the immediate, complete ban on using cornstarch powder in patient exam and surgeon gloves and also a ban on the use of all NRL patient exam and surgeon’s gloves.⁶²

2014

The FDA issued a proposed ban on powdered NRL and synthetic latex gloves in the spring of 2014.^{31,63} In the document, the FDA noted that it has identified that a

subset of powdered gloves present a substantial risk of illness that cannot be corrected by changing the labeling. As of yet, there has been no final ruling from the FDA regarding a complete ban on the use of cornstarch powder in patient gloves and also on the use of all NRL medical gloves. The current recommendations from the FDA are that glove manufacturers must label the total quantity of glove powder content for all gloves, unless there are trace amounts of powder (2 mg or less per glove) and no donning powders have been added intentionally.⁶⁴

RECENT ADVANCEMENTS

Based on the awareness of the potential complications of powdered gloves, over 60% of the surgical gloves used in US hospitals are powderless.⁶⁵ Additionally, advancements in glove technology over the last two decades have led to greater availability and acceptability of users. The current glove marketplace now includes gloves made from polyvinyl chloride, nitrile (acetonitrile butadiene), neoprene, polyisoprene, polychloroprene, polyurethane, and polyethylene, as well as NRL. The cost and handling characteristics of gloves made of the various materials differ significantly and the choice for the ideal glove is governed by the health care setting and wearer preference.

Deproteinized NRL is a relatively new glove material that results from a chemical treatment to NRL that removes the proteins which cause allergic reaction. Gloves from this material retain the tactile sensitivity and barrier integrity that many ardent NRL glove proponents demand, but reduce the risk of latex sensitization.⁶⁶

Polyisoprene, a latex-free alternative with a very similar chemical composition, has become the most popular glove material over the last decade as it provides a very similar fit and feel to latex gloves.

Although the cost of powderless gloves has decreased and availability has increased, many institutions and providers continue to cite cost as a barrier to switching from powdered NRL gloves. Multiple studies have documented a significant decrease in worker disability and missed work days after switching to powderless gloves, which led to an inherent reduction in financial losses to the institution or employer from paid sick days.

CONCLUSION

Perioperative nurses are responsible for reducing the risks of disease transmission and infection for both surgical patients and staff members. The risks associated with the use of powdered surgical gloves are well documented and include inflammation, scarring, adhesions, delayed

wound healing, wound infection, and starch granuloma formation as well as allergic reactions and sensitization. Powder contamination may also cause misdiagnosis, resulting in inappropriate treatment or unnecessary surgery and increased costs of care. Today, hospitals are not reimbursed for these costs and may receive additional payment penalties as well. For health care workers, the risks of powder-related complications, such as respiratory symptoms, asthma, and hand dermatitis – all of which lead to latex sensitization – are major concerns. Furthermore, all of these contribute to lost health care employee productivity and disability.

All of these risks can be significantly decreased with the use of powder-free gloves. Many industry and professional organizations, including the CDC/NIOSH, OSHA, AORN, and ACS, have acknowledged the risks of powder and issued recommendations for the use of powder-free gloves. Previously, the FDA has cited concern for the economic impact of changing entirely to powderless gloves due to the cost and limited availability of powderless alternatives in the late 1990s. However, to date, the FDA has recognized the dangers and has issued multiple warnings regarding the risks for powder gloves, but a formal ban is yet to be issued. Given the unnecessary danger of powdered gloves, demanded powderless alternatives, and the advancement of technology, the formal banning of powdered gloves by the FDA is seemingly inevitable. Further research is needed to evaluate the specific action steps needed to ensure a good transitioning from the powdered to powder-free examination and surgical gloves, as well as assess the financial ramifications for this transition.

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