

Dangers of Cornstarch Powder on Medical Gloves

Seeking a Solution

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Abstract: This article reviews information on the hazards of cornstarch powder on medical gloves. Dusting powders were first applied to latex gloves to facilitate donning. After 1980, manufacturers devised innovative techniques without dusting powder. It has been well documented that these powders on gloves present a health hazard to patients and health care workers by 5 different mechanisms. First, the glove cornstarch has documented detrimental effects on wound closure techniques. Second, this powder potentiates wound infection. Third, cornstarch induces peritoneal adhesion formation and granulomatous peritonitis. Finally, these powders serve as carriers as latex allergen and they precipitate a life-threatening allergic reaction in sensitized patients. These well-documented hazards of glove powder have caused the United Kingdom and Germany to ban cornstarch powder on medical gloves over 10 years ago.

Key Words: Citizen's Petition, Food and Drug Administration, cornstarch ban, latex, synthetic, examination, surgical gloves

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Examination and surgical gloves are worn by all health care providers. When surgical gloves were introduced at the turn of the century, they were sterilized by boiling and it could only be done by pulling the rubber gloves over wet hands because the wet hands of the surgical staff became macerated under the occlusive cover of the rubber gloves predisposing them to severe dermatitis. By the 1950s cornstarch powder became the lubricant on most surgical gloves. Because of the dangers to patients and health care professionals from cornstarch powder, numerous manufacturers have developed powder-free latex and synthetic examination and surgical gloves.¹ This collective review has 4 important components: overview of scientific studies on glove powder, governmental and institutional regulations of cornstarch on medical gloves, organizations highlighting the dangers of cornstarch powder, and discussion.

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OVERVIEW OF SCIENTIFIC STUDIES ON GLOVE POWDER

The following section is an overview of scientific studies related to the dangers of cornstarch on surgical and examination gloves.

Influence of Glove Cornstarch on Wound Closure Techniques

Tape closure is ideally suited for lacerations because it avoids the use of foreign bodies (eg, sutures, staples, tissue adhesives) in the wound that can damage host defenses and invite the development of infection. Consequently, contaminated wounds closed by tape exhibit the lowest incidence of infection as compared with staples and the least reactive suture. Despite the obvious benefits, tape closure has had limited use in many Emergency Departments because many Emergency Physicians use sterile, cornstarch-coated surgical gloves. In the study by Pavlovich et al, they measured the magnitude of tape adhesion to a dry powder-free skin compared with that of a dry glove covered by cornstarch.² In addition, they examined the influence of temporarily wetting and then drying the glove surfaces on the adhesion of the tape to the glove. This study showed that the skin closure tapes adhered aggressively to cornstarch-coated latex gloves. Consequently, it was difficult to separate the tape from the glove and apply the tape to the skin. The advent of a new powder-free glove allowed Emergency Physicians to handle the tapes and accomplish successful tape wound closure.

Potential of Wound Infection

Ruhl et al demonstrated in an experimental study in guinea pigs that cornstarch enhanced the development of wound infection.³ The bacterial concentration in cornstarch contaminated wounds was significantly greater than in control wounds without cornstarch. In wounds subjected to cornstarch, the indurated wound margins were significantly wider than those of the control wounds. As a result of these investigations, the scientists indicated that gloves with cornstarch powder should not be used.

Holmdahl reviewed the evidence that cornstarch glove powder plays an important role in adhesion formation and has adverse effects on the healing of abdominal incisional wounds.⁴ Holmdahl indicated that the underlying mechanisms leading to these adverse effects were beginning to be revealed. By affecting the mesothelial cell function, cornstarch powder contamination disrupted the delicate balance of fibrin deposition and degradation, provoking adhesion formation in the abdominal cavity, and interfering with wound healing. Studies in this report showed that cornstarch impairs incisional wound healing by its effect on the T cell-mediated immune system. In addition, cornstarch powder may act as a vector for endotoxin. Holmdahl concluded that cornstarch powder is harmful and its use in a hospital setting can no longer be supported.

In another experimental study, Odum et al reported the results of their experimental study that documented that cornstarch potentiated infection in guinea pig wounds and enhanced the wound's

inflammatory response.⁵ With the advent of powder-free gloves, the authors concluded that cornstarch powder should be banned from use in the health care setting.

In a 1999 report by Dave et al from the United Kingdom, they provided documentation that powdered glove wearers have an increased risk of latex allergy, and there is circumstantial evidence that the examination and surgical glove powders may increase bacterial environmental contamination.⁶ They also noted that cornstarch glove powder promoted infection in animal models. The authors concluded that infection control teams need to be aware of this evidence and should support switching from the use of powdered to powder-free gloves.

Cornstarch-Induced Peritoneal Adhesion Formation

Clinical and experimental studies document that cornstarch powder promotes the development of peritoneal adhesions in the abdominal cavity after surgery. In 1977, Cooke and Hamilton examined the significance of cornstarch powder contamination in the etiology of peritoneal adhesions.⁷ In their study, they examined the presence or absence of starch granulomas on the peritoneal surface or within peritoneal adhesions in 20 patients subjected to a second laparotomy. They presented evidence to show that cornstarch granuloma formation was common in the early months after operation, and that adhesions associated with cornstarch granulomas cause intestinal obstruction. They pointed out that although cornstarch is usually absorbed within 2 years, associated band adhesions may persist. Consequently, glove powder contamination of the peritoneal cavity may be a common cause of band adhesion intestinal obstruction.

In a report by Luijendijk et al in Göteborg, Sweden, they studied the presence of foreign material and postoperative adhesions.⁸ Cornstarch granulomas were found in 14 of 309 patients (5%) with a history of being operated on with cornstarch-coated gloves. The authors concluded that intra-abdominal contamination with foreign material, like cornstarch, should be minimized.

In 2001, van den Tol et al performed an experimental study that demonstrated that cornstarch glove powder promoted adhesion formation and facilitated tumor cell adhesion and growth.⁹ They developed a reproducible model that allowed semiquantitative scoring of adhesion formation or tumor load in rats. On the basis of these studies, they found that application of cornstarch on minimally and severely traumatized peritoneum gave rise to significantly greater adhesion formation and intra-abdominal tumor load than peritoneal trauma alone. On the basis of this experimental study, the authors concluded that cornstarch-induced peritoneal trauma led not only to more adhesion formation, but also to increased adhesion and growth of tumor cells. Because good quality powder-free surgical gloves are available, they believed that there was no longer any justification for the use of cornstarch powdered gloves during intra-abdominal surgery.

In 2004, Dwivedi et al pointed out that postoperative intra-peritoneal adhesions were a major cause of morbidity.¹⁰ They studied the effects of synthetic and latex gloves and their powders on postoperative adhesions and cytokine expression in rat models. In their study, rats underwent laparotomy and cecal abrasion. Rats were grouped based on glove type used: synthetic powder-free, synthetic powdered, latex powder-free, and latex powder. Serum cytokine and interleukin-1 levels were measured in the animals and the peritoneal adhesions were graded. The synthetic powder-free group had no adhesions! Adhesions were increased similarly in the synthetic powder and latex powder-free groups and further increased in the latex powdered glove group. Postoperative serum cytokine levels reveal a similar pattern of increases. The authors included that the presence of latex or cornstarch powder on surgical gloves promoted adhesions. The authors concluded strategies to use latex-free, powder-free gloves will reduce peritoneal adhesions in the clinic setting.

Glove Cornstarch-Induced Granulomatous Peritonitis

In 1976, Berkow discussed granulomatous peritonitis due to cornstarch from surgeon's gloves.¹¹ Berkow indicated that granulomatous inflammation of the peritoneal surfaces resulting from exposure to cornstarch granules from surgical gloves produced a syndrome of abdominal pain, adynamic ileus, fever, peritonitis, variable white blood cell count, and inflammatory ascites. Berkow indicated that symptoms developed 3 to 4 weeks after a routine abdominal surgical procedure. It was pointed out that recognition of this entity by nonsurgical means is necessary to avoid reoperation. Paracentesis with examination of the fluid by polarized light offers the best method of nonsurgical diagnosis. Berkow recommended treatment with steroids or indomethacin or conservative measures. To prevent this disease, gloves coated with cornstarch must be washed effectively before starting the operation. When this article was reported, it is important to emphasize that there were no commercially available powder-free surgical gloves.

In 1994, Giercksky et al described patients with multiple cornstarch powder granulomas that were assumed to be peritoneal carcinomatosis.¹² In their report, they registered 10 cases of multiple powder granulomas, believed by the surgeon to represent tumor dissemination, but diagnosed by the pathologist as glove powder granules with the typical Maltese cross pattern viewed under polarized light. The authors concluded that routine pathologic documentation of all peritoneal nodules appearing to be tumor dissemination should be undertaken. If the results influence the surgical procedure, frozen sections should always be performed. To minimize the risk of powder-induced complications, the authors recommended the use of powder-free sterile surgical gloves for all operative procedures in the abdominal cavity.

In 2001, Winkler et al evaluated the use of magnetic resonance imaging in a differential diagnosis between cornstarch and fecal peritonitis.¹³ They reported that magnetic resonance imaging of the starch peritonitis was remarkable for a diffuse pathologic process with enhancement of the omentum and the peritoneum after gadolinium injection. In contrast, the magnetic resonance imaging of the fecal peritonitis group showed a localized process with no diffuse enhancement of the peritoneum. This initial study was done in rats. They are currently investigating the use of magnetic resonance imaging in suspected cornstarch peritonitis in humans. The obvious solution is to ban the use of cornstarch on surgical gloves.

In another case report by Juaneda et al, they described a 54-year-old woman admitted with abdominal pain, fever, and an unusually prolonged ileus in the postoperative period after a laparotomy.¹⁴ Conventional hysterectomy was undertaken 3 months before. At admission, exploratory video laparoscopy was undertaken, in which the distal jejunum was accidentally perforated which required laparotomy for enterorrhaphy. One month later, she was subjected to another laparotomy due to the persistence of ileus. Granulomatous peritonitis was confirmed by histopathology. Endovenous hydrocortisone was given during 2 weeks and changed to oral prednisone during 4 weeks with gradual diminution until suppression. The authors concluded that prevention was crucial and would not have occurred if the surgeons had worn cornstarch-free surgical gloves.

Cornstarch-Induced Latex Hypersensitivity

In 1997, National Institute for Occupational Safety and Health published a working document on preventing allergic reactions to natural rubber latex in the workplace.¹⁵ In their document, it is emphasized that workers exposed to latex gloves and other products containing natural rubber latex may develop allergic reactions such as skin rashes, hives, nasal, eye, or sinus symptoms,

asthma, and (rarely) shock. They made the following recommendation: if you have a latex allergy, consult your physician regarding the following precautions: avoid contact with latex gloves and products; and avoid areas where you might inhale the cornstarch powder from latex gloves worn by others.

In 1999, the American Dental Association Council on Scientific Affairs wrote a landmark report on latex hypersensitivity.¹⁶ The report summarizes the signs and symptoms of natural rubber latex protein allergy, allergic contact dermatitis, and irritant dermatitis. It also offers information on the means to diagnose these conditions definitively and suggests means of reducing occupational exposure to the causative allergens and irritants in the dental office. In their report, they pointed out that latex antigens can bind to cornstarch and aerosolization of cornstarch powder when donning or removing gloves can precipitate a heightened latex protein exposure. In addition to the use of synthetic or powder-free latex gloves, dental personnel can further reduce occupational exposure by using low-protein, powder-free latex gloves.

In 2002, Truscott of the Kimberly-Clark Corporation, Roswell, Georgia wrote another important article on glove powder reduction and alternative approaches.¹⁷ Her article addressed the role of glove powder in facilitating allergic reactions to natural rubber latex and to the chemical additives in synthetic gloves and its role in eliciting post surgical complications. She pointed out that various dusting powders have been used historically to prevent gloves from sticking to each other, to facilitate donning, and that all glove powders have manifested adverse consequences for health care professionals and patients. She presented important manufacturing methods for powder elimination from gloves and reviewed the American Society for Testing Materials (ASTM) methods for the measurement of powder on powder-free and powdered gloves along with the new ASTM maximum powder limits for all medical gloves. Her most important message was that it is imperative to eliminate powder from any surgical and examination glove.

In another report published in 2002 in Sweden, Edelstam et al reviewed glove powder in the hospital environment.¹⁸ The authors made the following strong recommendations: "It is not acceptable to use powdered medical gloves within health care. In spite of the risk of allergy and impairment of the working environment from powdered gloves, there is still only a minority of hospitals working according to a strict general powder-free policy in Sweden." The study further pointed out that the reduced cost resulting from fewer absences due to sickness further adds an argument for omitting glove powder, and justifies the higher cost of using powder-free medical gloves.

In another study by Barbara et al, they pointed out that cornstarch powder present in medical gloves plays an important role in latex-induced hypersensitivity as an allergen carrier either by the inhalation route, by skin contact, or by direct contact with mucous membranes.¹⁹ Their study demonstrated that cornstarch powder enhanced antigen-induced bronchoconstriction and antibody production. This role of immunoadjuvant is not antigen specific. The authors concluded that cornstarch powder used as a donning agent in latex gloves is an allergen carrier and it can enhance latex-induced hypersensitivity.

In another study reported in *Morbidity and Mortality Weekly Report*, the authors made the following comment: "because of the role of glove powder in exposure to latex protein, NIOSH recommends that if latex gloves are chosen, health care personnel should be provided with reduced protein, powder-free gloves."²⁰ They also pointed out that nonlatex (eg, nitrile or vinyl) powder-free and low protein gloves are also available.

In the book written by Edlich et al entitled, "Medicine's Deadly Dust: A Surgeon's Wake-Up Call to Society," they indicated

that cornstarch-coated gloves should not be used in hospitals in the United States.²¹ They emphasized that cornstarch is a substance recognized by all surgeons, doctors, nurses, and hospital administrators. It is a substance that has outlived its benefits. It is a substance that should be eliminated immediately by the Food and Drug Administration (FDA).

This information in this collective review should be included in all health care professionals' training until the FDA bans the dangerous cornstarch powder from examination and surgical gloves that risk the lives of patients and health care workers. It is a crisis in health care that can be easily stopped by banning the use of powder on surgical and examination gloves. In addition, the authors of this Citizen's Petition believe that the scientific evidence supporting the need to ban the use of glove powder for the protection of all Americans is overwhelming and indisputable. The authors call upon the FDA to take immediate action to exercise its authority and end the menaces of cornstarch.

Realizing the scientific and clinical studies that have documented the dangerous effects of cornstarch powder on synthetic and latex examination and surgical gloves, the authors of this report will now review the governmental and institutional regulations of cornstarch on medical gloves.

GOVERNMENTAL AND INSTITUTIONAL REGULATIONS OF CORNSTARCH ON MEDICAL GLOVES

Dr. Henning Allmers, Director of the Department of Occupational Medicine, Head of the Occupational Medicine Laboratory at the Department of Dermatology, Environmental Medicine, and Health Sciences at the University of Osnabruck in Germany described the educational and regulatory measures in the German health care system to prevent natural rubber latex allergy through education and intervention.²²

"In December 1995, an interdisciplinary work group from the Departments of Dermatology, Allergy, and Occupational Medicine of 7 German universities met in Bochum, Germany, to decide on recommendations concerning the prevention of natural rubber allergy in health care workers and allergic patients. Those guidelines for hospital administrators and personnel were published in several scientific journals and were also distributed by the BGFA."²³

Recognizing the dangers of natural rubber latex allergy, a regulation banning natural rubber latex gloves was implemented in Germany in 1998. A study by Allmers et al assessed the effects of this regulation on the development of occupational skin disease caused by natural rubber latex in health care personnel working in facilities insured by the German statutory accident insurance company covering some 1.8 billion insured health care workers.²⁴ They reviewed the annual numbers of reported suspected cases of natural rubber latex-induced occupational allergies (mainly contact urticaria) from 1996 to 2002, as well as the number and type of gloves purchased in acute-care hospitals from 1986 to 2002. They reported that the number of purchased nonsterile examination gloves increased by 1387% from 1986 to 2002. The purchase of powder-free natural rubber latex examination gloves exceeded that of powdered gloves in 1998. The incidence of suspected cases of natural rubber latex allergy increased until 1998 and has since decreased by 79.9%. They reported that most suspected cases (67.9%) were identified as occupationally caused. The authors concluded that reducing the purchase of powdered natural rubber latex gloves was associated with a decrease in suspected and proven cases of occupational contact urticaria caused by natural rubber latex. Consequently, the development of occupationally caused contact urticaria by natural rubber latex can be significantly reduced by eliminating the use of powdered natural rubber latex gloves.

In 2000, in response to the enormous scientific information about the dangers of cornstarch on gloves, the Purchasing and Supply agency responsible for purchasing health care supplies to be used in the National Health Service of the United Kingdom ceased to purchase any gloves lubricated with USP cornstarch (ie, all gloves in the National Health Service of the United Kingdom became powder-free).²³

The University of Virginia Healthcare System was the first health care system in the United States to ban cornstarch from all surgical and examination gloves.¹ The basis for this decision was outlined in this collective review of the hazards of cornstarch powder on surgical and examination gloves. In addition, a team of scientists documented that powder-free latex gloves have been designed so that they have the same donning forces as gloves with cornstarch powder.²⁵

Some major hospitals, including Johns Hopkins Hospital in Baltimore and the Cleveland Clinic's network of 9 hospitals have switched entirely to synthetic surgical gloves. These 2 health care facilities converted their hospital and clinics to powder-free, nonlatex surgical, and examination gloves.²⁶

In 2000, Jackson et al conducted a global inventory of hospitals using powder-free gloves.²⁷ Their study, using a global internet search, identified 70 hospitals in the United States that use only powder-free gloves. This survey did not include hospitals in the Legacy Healthcare System in Washington and Oregon that have banned the use of cornstarch gloves in their hospitals and hospice under the leadership of Dr. William B. Long III, Director of Trauma Specialists LLP., Legacy Emanuel Hospital, Portland, Oregon in 2001.

An extensive survey of second quarter 2008 market research data showed the following for the total examination glove market (physician offices, surgery centers, and hospitals): percent powder-free examination gloves (units) 94.4%; percentage powdered examination gloves (units) 5.6%. In the second quarter 2008, market research shows the following for total surgical glove market: percent powder-free surgical gloves (units) 64.6%; percentage powdered surgical gloves (units) 35.4%.

ORGANIZATIONS HIGHLIGHTING THE DANGERS OF CORNSTARCH POWDER

American College of Allergy, Asthma, and Immunology,^{28–35} American College of Surgeons,³⁶ and American Nurses Association³⁷ all share a common belief. All agree that cornstarch powder should be banned from all medical gloves. They base their decision on the wide range of comprehensive scientific studies that have documented the dangers of cornstarch powders on all medical gloves. In a recent collective review by Ellis, he has documented the evolution of the surgical gloves as well as the need to ban cornstarch powder from medical gloves.³⁸

DISCUSSION

On September 24, 2008, the authors of this report submitted a Citizen's Petition to the FDA to immediately eliminate the use of cornstarch powder in the manufacture of natural rubber latex surgical and examination gloves as well as synthetic surgical and examination gloves due to the serious and widespread dangers that these gloves coated with cornstarch cause to medical personnel and patients. An acceptable substitute—latex and synthetic nonpowdered gloves—is available and has already been implemented in many hospitals in our country and hospitals in Europe. In 1998, Germany's regulations of personal protective equipment banned the use of surgical glove powder (cornstarch).²⁴ In 2000, the Purchasing and Supply Agency responsible for purchasing health care supplies to be used in the national health care service sought to purchase any

gloves lubricated with cornstarch.²³ The continued use of powdered latex gloves is unacceptable and the FDA must act to eliminate these dangerous cornstarch powdered latex and synthetic glove products.

It has been well documented that cornstarch powder on examination and surgical gloves enhances the incidence of wound infection, causes peritoneal adhesions and granulomatous peritonitis in the abdominal cavity, and is a vector for the latex allergy epidemic in our country. Realizing the dangers of cornstarch on latex and synthetic examination and surgical gloves, Germany and the United Kingdom have banned the use of this dangerous powder on all synthetic and latex examination and surgical gloves used in their countries. In recognition of the dangers of cornstarch to the patients and health care workers, many hospitals in the United States have banned the use of cornstarch on synthetic and latex examination and surgical gloves. In addition, some of the leading health care organizations, including the American College of Allergy, Asthma and Immunology, the American College of Surgeons, and the American Nursing Association, have recommended a ban on the use of cornstarch in latex and synthetic examination and surgical gloves. Since the Citizen's Petition was filed on September 24, 2008, it has been posted on the FDA website for comments by health professionals and the general public.

It will come to no surprise to the reader that the FDA website has received 210 favorable comments from health professionals encouraging the FDA to ban cornstarch on examination and surgical gloves in the United States. The only unfavorable comment was made by the Malaysian Rubber Export Promotion Counsel who manufactures the dangerous cornstarch coated examination and surgical gloves. This company obviously had a significant conflict of interest because it is making financial profit from the manufacturing and sales of these dangerous cornstarch coated examination and surgical gloves.

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