Surgical glove powder: An unnecessary hazard

Chapter one: Introduction

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Objectives

The objectives of this training about surgical glove powder are to:

- Review the recent FDA proposed ban on most powdered medical gloves
- Highlight the history and role of powdered gloves
- Discuss how powder is transferred in a hospital setting
- Uncover the risks and economic implications associated with powder
- Identify the success of powder-free glove solutions
- Discuss the ethical considerations in using powdered gloves

FDA proposal: ban on most powdered medical gloves

March 21, 2016

Food and Drug Administration (FDA) proposed a ban on most powdered medical gloves in the United States.





The FDA acknowledged powdered gloves pose an unreasonable and substantial risk of illness or injury to both healthcare providers and patients.¹

FDA proposed ban on most powdered medical gloves

"This ban is about protecting patients and healthcare professionals from a danger they might not even be aware of. We take bans very seriously and only take this action when we feel it's necessary to protect the public health."

Jeffrey Shuren, M.D. Director of FDA's Center for Devices and Radiological Health

If finalized, the ban will remove powdered surgical and exam gloves from the marketplace completely.¹

Gloves that will be impacted include:

- Powdered surgical gloves
- Powdered patient examination gloves
- Absorbable powder for lubricating medical gloves

Current FDA warning label on powdered gloves

The FDA glove report (1997) outlined risks and issues with powdered gloves.¹ Recommended a warning label on powdered gloves outlining the risks.

Powdered gloves may lead to foreign body reactions and the formulation 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.²

Warning label text found on boxes containing powdered medical gloves.

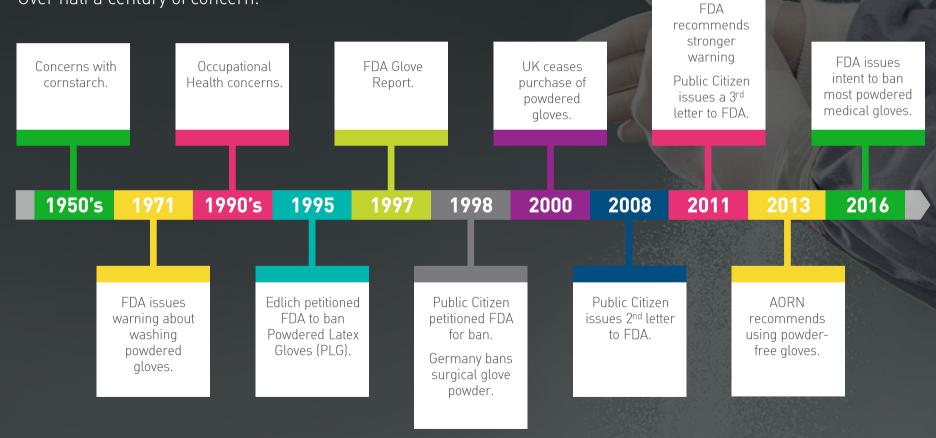
The Warning label touted as useless. A "Waste of time" and would require an "8-10 page warning" to list all the possible complications and risks.³

References: 1. FDA Staff. Medical glove powder report. FDA. September 1997. Available at http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm113316.htm. Accessed April 26, 2016. 2. Infection Control Today Staff. FDA Issues Warning About Powdered Gloves. Infection Control Today. February 15, 2011. Available at http://www.infectioncontroltoday.com/news/2011/02/fda-issues-warming-about-powdered-gloves.aspx. Accessed May 10, 2016. 3. Hospital Employee Health. June 2011;30(6):61-72

Chapter two: History of powdered gloves

Powder concerns are old news

Over half a century of concern.¹⁻⁵



References: 1. Hospital Employee Health. June 2011;30(6):61-72. 2.Edlich RF, Long WB, Gubler DK, et al. Dangers of Cornstarch Powder on Medical Gloves: Seeking a Solution. Ann Plast Surg. 2009; 63: 822-826. .. 3. FDA Staff. Medical glove powder report. FDA. September 1997. Available at http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm113316.htm. Accessed April 26, 2016. 4. Srejic, E. Evidence, Experts' Campaigning May Convince FDA to Finally Ban Powdered Medical Gloves. Infection Control Today. December 4, 2015. Available at: http://www.infectioncontroltoday.com/articles/2015/12/evidence-experts-campaigning-may-convince-fda-to-finally-ban-powdered-medical-gloves.aspx. Accessed 5/20/16. 5. AORN; 2015 Guideline for A Safe Environment of Care, Part 1. 239-263.

Dusting powders: from talc to cornstarch

Powders developed as lubricant to help don gloves.¹_____

Mixture of dusting powers	100	Talcum power	Cornstarch	
1889	SIE.	1930's	1970's	
Mix of lycopodium spores (ground pines or club moss) and talc, talcum powder alone, calcium carbonate, different types of starch products.		Talcum powder (hydrous magnesium silicate) predominately used. Quickly recognized to be the cause of postoperative adhesions and granuloma formulation in the '40's ²	Modified cornstarch glove introduced in 1947. Cornstarch predominantly used as dusting powder.	
1890 1900 1910 19	20	1930 1940 1950 1960		

References1, FDA Staff. Medical Glove Powder Report. FDA. September 1997. Available at http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm113316.htm. Accessed April 26, 2016. 2. The Federal Register. Banned Devices; Proposal to Ban Powdered Surgeon's Gloves, Powdered Patient Examination Gloves, and Absorbable Powder for Lubricating a Surgeon's Glove. 3/22/2016. Available at: https://www.federalregister.gov/articles/2016/03/22/2016-06360/banned-devices-proposal-to-ban-powdered-surgeons-gloves-powdered-patient-examination-gloves-and. Accessed 5/5/16.

USP "absorbable" cornstarch

Reasons for use:¹

- Lubricant to aid in donning gloves
- Aid to removing gloves from the manufacturer's mold
- Aid to prevent glove decay while in storage

Irradiation sterilization makes powder less absorbable when in contact with tissue. Allows the starch molecule to remain intact, smooth and circular rendering the molecule less absorbable and more likely to cause a foreign body reaction.



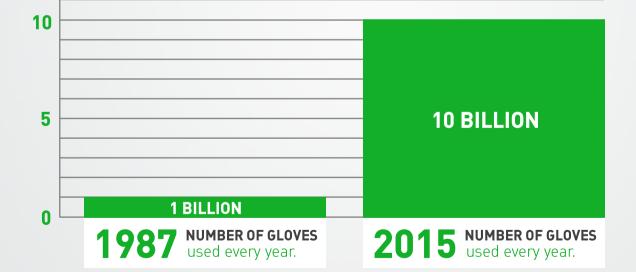
Increased demand for gloves = increased powder exposure

1980's

AIDS became a global health agenda. The Centers for Disease Control and Prevention (CDC) recommended healthcare workers protect themselves by using appropriate barrier precautions.¹

Increased glove use coincides with:

- Elevated adverse events
- Elevated costs
- Issues related to waste disposal



References: 1. The Federal Register. Banned Devices; Proposal to Ban Powdered Surgeon's Gloves, Powdered Patient Examination Gloves, and Absorbable Powder for Lubricating a Surgeon's Glove. 3/22/2016. Available at: https://www.federalregister.gov/articles/2016/03/22/2016-06360/banned-devices-proposal-to-ban-powdered-surgeons-gloves-powdered-patient-examination-gloves-and. Accessed 5/5/16. 2. . Infection Control Today Staff. Is it Time to Stop Using Powder as a Donning Agent for Gloves? Infection Control Today. February 1, 2001. Available at: http://www.infectioncontroltoday.com/articles/2016/03/22/2016-06360/banned-devices-proposal-to-ban-powdered-surgeons-gloves-powdered-patient-examination-gloves-and. Accessed 5/5/16. 2. . Infection Control Today Staff. Is it Time to Stop Using Powder as a Donning Agent for Gloves? Infection Control Today. February 1, 2001. Available at: http://www.infectioncontroltoday.com/articles/2001/02/is-it-time-to-stop-using-powder-as-a-donning-agen.aspx. Accessed May 11, 2016.

Chapter three: Powder dispersion

Powdered glove to powdered air

The chart below explains the powder's route from glove to air:

Manufacturing process



Powder is applied to glove as cornstarch slurry when glove is in mold.



Water-soluble proteins leach from surface of glove onto the cornstarch particles.

Glove in use



When dry, glove powder acts as a vector



Latex proteins from the glove...



....spread into the environment.

References: 1. AORN Latex Guideline. Perioperative Standards and Recommended Practices. Association of periOperative Registered Nurses. 2012:605-620.

Powder, powder everywhere

Powder is released into the air when donning gloves and can settle on¹:



Routes of exposure to powder

Direct contact¹

- From hands of wearer when donning gloves, onto exposed tissue in surgical site
- Torn or punctured gloves

Indirect transfer

- Powder from glove deposits on an object which later contacts patient; i.e. surgical instruments or suture, ducts, clothing, hair
 - Aerosolization²

Chapter four: Risks with powdered gloves

Risks associated with powdered gloves

Powdered gloves pose "an unreasonable and substantial risk of illness or injury to healthcare providers, patients, and other individuals who are exposed to them." ¹

Post operative complications

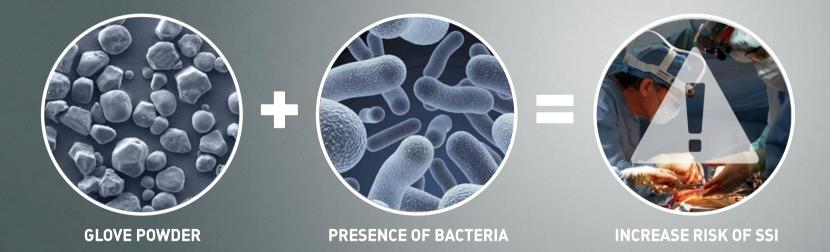
Latex allergy sensitization

Respiratory complications

Risks with powdered gloves: Post operative complications

Risk of surgical site infections (SSI)

Surgical glove powder can increase the likelihood of abscess formation in the presence of bacteria¹. Interferes with immunological defense mechanisms, allowing microorganisms to multiply.²



Cornstarch can cause foreign body reactions and delayed wound healing.³

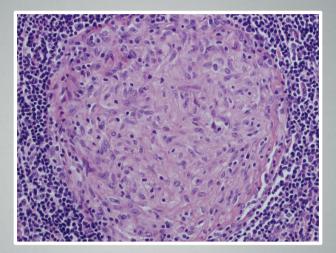
References: 1. Suding P, Nguyen T, Gordon I, Wilson SE. Glove powder increases Staphylococcus aureus abscess rate in a rat model. Surg Infect (Larchmt). 2010 Apr; 11(2): 133-5. 2. Eye Bank Association of America. INFORMATIONAL ALERT: Potential Consequences of Use of Powdered Gloves. March 16, 2012.3. Bosco JA, Slover JD, Haas JP. Perioperative Strategies for Decreasing Infection. A Comprehensive Evidenced-Based Approach. The Journal of Bone & Joint Surgery. 2010 Jan; 92 (A-1); 232-239.

Post-Operative Granulomas

Surgical granulomas are small area of inflammation in tissue.¹ Glove powder induces an inflammatory reaction causing risk of forming granulomas.

Most frequently occur in lungs, but can occur in other parts of the body:

- Peritoneal granulomas linked to operations with powdered gloves²
- Ophthalmic granulomas³



Picture of a granuloma (without necrosis) as seen through a microscope on a glass slide.

Swedish study found cornstarch granulomas in 5% of patients post-operatively.⁴

Granulomas often misdiagnosed as carcinomas, leading to unnecessary testing.⁴

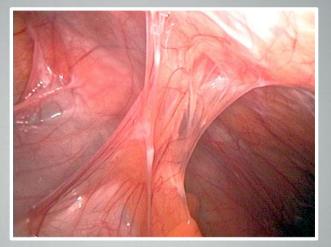
References: 1. Steckelberg.James M. Granuloma:what does it mean. Mayo Clinic. October 10, 2015. Available at http://www.mayoclinic.org/granuloma/expert-answers/fag-20057838. Accessed April 27, 2016. 2. FDA Staff. Medical glove powder report. FDA. September 1097. Available at http://www.fda.gov/medicaldevices/devicerggulationandguidance/guidance/guidancedocuments/ucm113316.htm. Accessed April 26, 2016. 3. Eye Bank Association of America. INFORMATIONAL ALERT: Potential Consequences of Use of Powdered Gloves. March 16, 2012. 4. Edlich RF, Long WB, Gubler DK, et al. Dangers of Cornstarch Powder on Medical Gloves: Seeking a Solution. Ann Plast Surg. 2009; 63: 822-826.

Post-Operative Adhesions

Powdered gloves increase risk of post-operative adhesions.¹ Adhesions can occur due to irritation by infection or surgical trauma.²

Adhesions cause morbidity and complications such as:

- Pain
- Bowel obstruction
- Infertility



Picture of adhesions after appendectomy.

Peritoneal adhesions costs the U.S. \$1.3 billion each year in hospital and surgical expenditures²

References: 1. Edlich RF, Long WB, Gubler DK, et al. Dangers of Cornstarch Powder on Medical Gloves: Seeking a Solution. Ann Plast Surg. 2009; 63: 822-826. 2. Arung W, Meurisse M, Detry O. Pathophysiology and prevention of postoperatie peritoneal adhesions. World Journal of Gastroenterology. 2011;17(41):4545-4553.

Systemic complications

Surgical complications due to powdered gloves have been seen in:



ORTHOPAEDICS

Increased and prolonged inflammation with swelling and delayed healing during joint surgery. ¹



OPHTHALMICS⁴

- Inflammation
- Toxic lens syndrome
- Chronic granulomas
- Fibrosis and adhesion formation
- Sterile endophthalmitis



GYNAECOLOGICS

Post-surgical adhesions can lead to infertility.

Retrograde migration of powder from gloves after gynaecologic examination and surgery to other parts of the body and reproductive system. ^{2,3}



CARDIOVASCULAR

Granulomatous myocarditis.⁵

References: 1. Edlich, Deadly Powder on Medical Gloves; A Wake-Up Call To The FDA. Page 70. https://books.google.com/books?id=92M71zEaH3QC&pg=PA79& lpg=PA79& lpg=PA79

Wound healing and scar formation

Cornstarch can delay wound healing, increasing risk of infection¹.

Wound margins are significantly wider²

Powder can also increase scar formation³.



References: 1. Bosco JA, Slover JD, Haas JP. Perioperative Strategies for Decreasing Infection. A Comprehensive Evidenced-Based Approach. The Journal of Bone & Joint Surgery. 2010 Jan; 92 (A-1); 232-239. 2. Edlich RF, Long WB, Gubler DK, et al. Dangers of Cornstarch Powder on Medical Gloves: Seeking a Solution. Ann Plast Surg. 2009; 63: 822-826. 3. Eye Bank Association of America. INFORMATIONAL ALERT: Potential Consequences of Use of Powdered Gloves. March 16, 2012.

Risks with powdered gloves: Latex allergy sensitization

Latex allergy sensitization

Cornstarch can bind natural latex proteins and become airborne.¹

Powder can cause irritation to the wearer through both direct and indirect contact.

Powdered, natural latex gloves are a key agent responsible for the sensitization of healthcare workers to latex, with resulting morbidity and economic costs.²



One study found switching to powder-free latex gloves not only reduced sensitization rates, but some healthcare workers actually lost their sensitivity.²

References: 1. FDA Staff. Medical glove powder report. FDA. September 1997. Available at <u>http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm113316.htm. Accessed April 26</u>, 2016. 2. Kelly KJ, Wang ML, Klancnik M, Petsonk EL. Prevention of IgE Sensitization to Latex in Health Care Workers after Reduction of Antigen Exposures.JOEM. 2011; 53(8):934-940.

Glove associated skin reactions¹

	IRRITANT CONTACT DERMATITIS	ALLERGIC CONTACT DERMATITIS (TYPE IV) DELAYED HYPERSENSITIVITY	LATEX ALLERGY (TYPE I) IMMEDIATE OR NATURAL RUBBER LATEX PROTEIN ALLERGY
	Toxic chemicals, excessive perspiration, irritating chemicals used in hand products and glove manufacture	Accelerators and other chemicals used in glove manufacture, sterilants and disinfectants, bonding agents, local anesthetics	Latex proteins
REACTIONS	Skin reactions usually confined to area of contact Actue: red, dry itchy irritated areas Chronic: Dry thickened skin, crusting, deep painful cracking, scabbing sores, peeling	Skin reactions usually confined to the area of contact Acute: Itchy, red rash, small blisters Chronic: Dry thickened skin, crusting, scabbing sores, vesicles, peeling (appears 4-96 hrs. after exposure)	 Skin and systemic reactions can occur as soon as 2-3 minutes, or as long as several hours after skin or mucous membrane contact Acute: Hives, swelling, runny nose, nausea, abdominal cramps, dizziness, low blood pressure, bronchospasm, anaphylaxis Chronic: as above, increased potential for extensive more severe reaction

NIOSH recommendation

Surgical 1997 National Institute of Occupational Safety and Health (NIOSH) published a document on preventing allergic reactions to natural rubber latex in workplace.¹

It emphasized that workers exposed to latex may develop allergic reactions:

- Skin rashes
- Hives
 - Nasal, eye or sinus symptoms
 - Shock (rarely)

Recommend employees with latex allergy to avoid contact with latex gloves and avoid areas where you might inhale cornstarch powder from latex gloves worn by others.

Dangers of Cornstarch Powder on Medical Gloves Seeking a Solution

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Abstract: This article reviews information on the hazards of cornstarch nowder on medical gloves. Dusting nowders 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 (Ann Plast Surg 2009;63: 822-826)

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.

Received April 22, 2009, and accepted for publication, after revision, April 22,

2009.
From the "Departments of Plastic Surgery, 'Biomedical Engineering, and 'Emergency Medicine, University of Virginia Health System, Charlottesville, VA; Bicgay Verhal Level Slock-Tamas Centre for Polarisa and Adaha, Legory Emanael Hospital, Portland, OR, "Department of Mechanical and Accounce (reirred, Waschese PA, "Viceps"), "Department of Plastic Surgery and Pediatrics, Charlottesville, VA; "Ely Physicans of Southern Viceps", Dake University Medical Center, Duban, Nc.

Reprints: Richard F. Edlich, MD, FACEP, PHD, FACS, FASPS, 22500 NE 128th Circle Brush Prairie, WA 98606. E-mail: richardedlich@gmail.com. Copyright © 2009 by Lippincott Williams & Wilkins ISSN: 0148-7043/09/6301-0822 DOI: 10.1097/SAP.0b013e3181ab43ae

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

Tane 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 tane 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 Paylovich 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.

Potentiation 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

References: 1. Edlich RF, Long WB, Gubler DK, et al. Dangers of Cornstarch Powder on Medical Gloves: Seeking a Solution. Ann Plast Surg. 2009; 63: 822-826.

Risks with powdered gloves: Respiratory complications

Respiratory complications

Inhalation of cornstarch glove powder can lead to the development of subclinical inflammation in the airways¹ such as:

- Accumulation of eosinophilic granulocytes
- Respiratory allergic reactions and asthma-like attacks²

Estimated roughly 30% of latex sensitive individuals develop respiratory problems²

The problems include:

- Rhinitis
- Conjunctivitis
- Dyspnea



Aeroallergens increase asthma risk

Latex aeroallergens dispersed during glove donning¹ and powdered gloves are the worst offenders.

Concentration of airborne latex aero-allergens can be 5-10 times higher in areas where powdered gloves are used.²

Aerosolized latex is a leading cause of occupational asthma among healthcare workers.³

For every year of exposure to latex within the workplace, there is a 5% incremental increase in the risk of developing asthma⁴



References: 1. Elliot Beth A. Latex allergy: The perspecitve from the surgical site. The Journal of Allergy and Clinical Immunology. 2012;110(2):117-120.

2. Filon FL, Radman G. Latex allergy: a follow up study of 1040 healthcare workers. Occup Environ Med. 2006;63:121-125.

3. Hospital Employee Health. June 2011:;30(6):61-72.

4. Hoy RF. Occupational exposures and the development of new-onset asthma. JOEM. 2013;55(3): 235-239.

Risks with powdered gloves: Laboratory interference

Laboratory interference



LABORATORY ENVIRONMENTS Glove powder can fall into assays and cultures, which can thereby alter the results.¹



RADIOLOGY DEPARTMENTS Glove powder can affect radiographic films, thereby altering the images.²



References: 1. Hamlin CR, Black AL, Opalek JT. 1991. Assay Interference Caused by Powder from PrePowdered Latex Gloves. Clin Chem 37(8):1460 . 2. Hubar JS, Etzel KR, Dietrich CB. 1991 Oct. Effects of Glove Powder on Radiographic Quality. J Can Dent Assoc 57:790.

Risks with powdered gloves: Economic impact of powdered glove-related complications

Impact of powdered glove-related complications

Socio-Economic Components.^{1,2}

Direct Medical Costs

Cost of SSIs and post-op complications

• Additional surgical procedures and hospitalizations

Procedures and treatments for:

- Latex allergy sensitization
- Hypersensitivity reactions
- Asthma

Indirect Costs

Indirect costs include:

- Lost wages
- Diminished worker productivity
- Short and long term morbidity
- Mortality
- Decrease in insurance reimbursement
- Legal considerations
- Forgone leisure time
- Travel costs

Intangible Costs

Psychological costs (i.e. anxiety, grief, disability, job loss)

 Healthcare workers who demonstrated latex sensitization were 3 times more likely to leave their job³

Pain and suffering

Change in social functioning/daily activities

References: 1. Scott RD. Costpaper. The Direct Medical Costs of Infections in U.S. Hospitals and the Benefits of Prevention. March 2009.

2. Arung W, Meurisse M, Detry O. Pathophysiology and prevention of postoperatie peritoneal adhesions. World Journal of Gastroenterology. 2011;17(41):4545-4553.

3. Kelly KJ, Wang ML, Klancnik M, Petsonk EL. Prevention of IgE Sensitization to Latex in Health Care Workers after Reduction of Antigen Exposures. JOEM. 2011; 53(8):934-940.

Risks with powdered gloves: Ineffective solutions

Washing powdered gloves proven ineffective

The FDA's warning on powdered gloves cautions the wearer to remove powder after donning the glove:¹

- Washing with sterile water in a basin
- Sterile gauze or lap sponge

Washing or wiping gloves does not effectively remove powder.²

Washing can cause clumping of the powder and can intensity the listue reaction.

Study found that only 17% of the surgeons and 21% of the surgical nursing staff washed their gloves after donning³

References: 1. FDA Staff. Medical glove powder report. FDA. September 1997. Available at http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm113316.htm. Accessed April 26, 2016. 2. Jaffray D C, Nade S Does Surgical Glove Powder Decrease the Inoculum of Bacteria Required to Produce an Abscess? Journal of the Royal College of Surgeons 1983; Edinburgh 28(4): 219-222 3. Friedman, M. Public Citizen Petition letter to FDA. Petition to Ban Cornstarch Powder on Latex Gloves. January 7, 1998. Available at http://www.citizen.org/documents/1432.pdf. Accessed May 19, 2016.

lt's a wash-out



THE POWDER REMAINS

Even after the usual 1-2 minute rinse, powder can still appear on gloves 10-30 minutes later.²

References: 1. Hospital Employee Health. June 2011;30(6):61-72. 2. Infection Control Today Staff. Is it Time to Stop Using Powder as a Donning Agent for Gloves? Infection Control Today. February 1, 2001. Available at: http://www.infectioncontroltoday.com/articles/2001/02/is-it-time-to-stop-using-powder-as-a-donning-agen.aspx. Accessed May 11, 2016.

Washing wastes time and money

Effectively removing powder from gloves is both a time consuming and complex process:¹

- Washing with detergent
- Cleansing with povidone-iodine scrub followed by rinsing in sterile water

The cost of washing gloves has been reported as being at least 7 times higher than using powder-free gloves.²

COST OF POWDER-FREE GLOVES

COST OF

WASHING POWDERED GLOVES $\langle \mathfrak{S} \rangle$

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References: 1.Jaffray D C, Nade S Does Surgical Glove Powder Decrease the Inoculum of Bacteria Required to Produce an Abscess? Journal of the Royal College of Surgeons 1983; Edinburgh 28(4): 219-222. 2.Edelstam G, Arvanius L, Karlsson G. Glove powder in the hospital environment – consequences for healthcare workers. Int. Arch. Environ. Health 2002; (75): 267-271.

Risks with powdered gloves: Effective solutions

Join the movement: Ban powdered gloves

The shift to powder-free gloves has already begun. In 2000, 70 hospitals in the U.S. were reported to be registered as "Powder-Free".¹

Healthcare institutions that have restricted or banned powdered gloves include:



Johns Hopkins Hospital



Cleveland Clinic



University of Virginia

References: 1. The Federal Register. Banned Devices; Proposal to Ban Powdered Surgeon's Gloves, Powdered Patient Examination Gloves, and Absorbable Powder for Lubricating a Surgeon's Glove. 3/22/2016. Available at:https://www.federalregister.gov/articles/2016/03/22/2016-06360/banned-devices-proposal-to-ban-powdered-surgeons-gloves-powdered-patient-examination-gloves-and. Accessed 5/5/16.

Europeans advocate

1998

Germany banned powdered gloves.¹

2000

Purchasing department in the United Kingdom ceased purchase of powdered medical gloves. Currently, even more European countries have joined the powder-free movement:²



Europeans advocate

Many organizations advocate for a powder-free environment:¹



AMERICAN CHEMICAL SOCIETY



NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH



HEALTH & SAFETY EXECUTIVE



AMERICAN COLLEGE OF ALLERGY, ASTHMA &IMMUNOLOGY



ASSOCIATION OF PERIOPERATIVE REGISTERED NURSES

References: 1. The Federal Register. Banned Devices; Proposal to Ban Powdered Surgeon's Gloves, Powdered Patient Examination Gloves, and Absorbable Powder for Lubricating a Surgeon's Glove. 3/22/2016. Available at:https://www.federalregister.gov/articles/2016/03/22/2016-06360/banned-devices-proposal-to-ban-powdered-surgeons-gloves-powdered-patient-examination-gloves-and. Accessed 5/5/16.

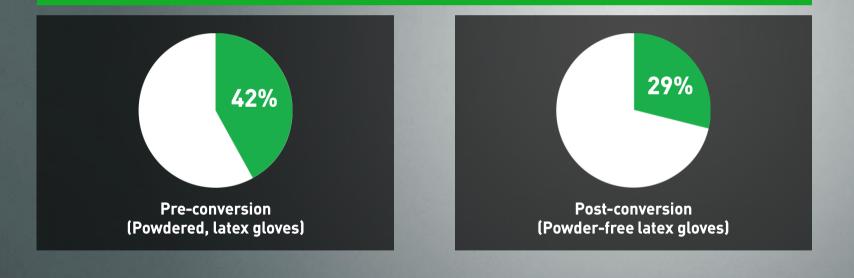


AMERICAN NURSES ASSOCIATION

Impact of switching to powder-free gloves

1-year longitudinal study designed to assess the impact of switching to powder-free latex gloves on latex sensitization of O.R. personnel.¹

Report of latex symptoms



What would the impact be if switching to synthetic gloves?

Impact of switching to powder-free gloves

Prospective, 4.5 year study of two hospitals to determine impact of switching to powder-free latex gloves.²

The switch resulted in:



25 PERCENT OF PREVIOUSLY SENSITIVE EMPLOYEES DEVEDTED TO

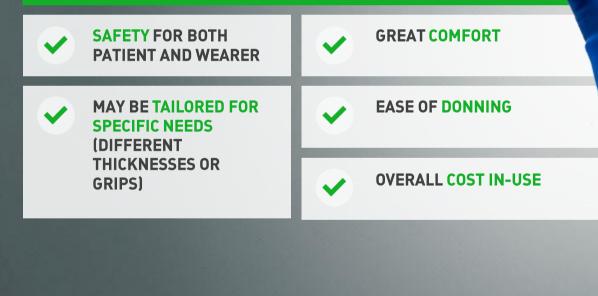
REVERTED TO NEGATIVE SKIN TESTS

What would the impact be if switching to synthetic gloves?

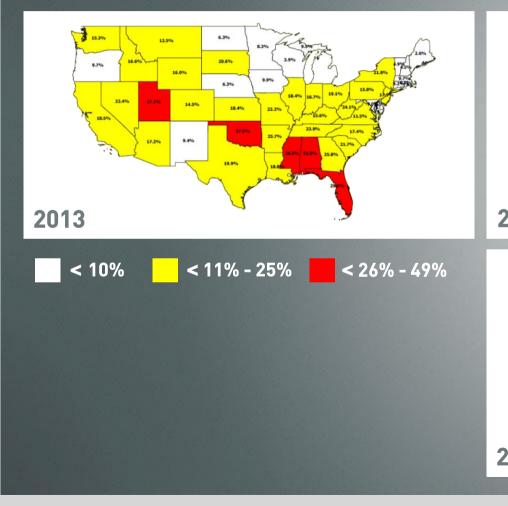
Powder is out, synthetic is in.

Synthetic gloves offer safety for both patients as well as healthcare workers. Consistent use avoids confusion for latex-sensitive patients and potential O.R. turndowns.

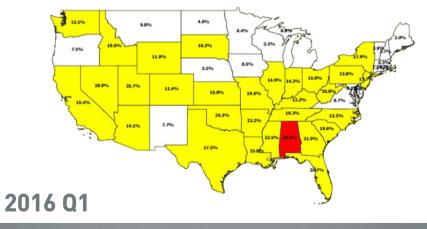
SYNTHETIC GLOVES OFFER:



Powdered glove usage trend







Powdered gloves don't add Up

Well-documented risks to both patients and healthcare workers

Costs of complications resulting from powdered glove use outweigh cost of powder-free gloves

FDA has proposed a ban

Why use them?

FDA bans are rarities

For the FDA to "ban" a product/device it must "present substantial deception" or an "unreasonable and substantial risk of illness or injury"¹

FDA concluded that powdered gloves now lag behind the state of the art.

 State of art: i.e, the "state of technical and scientific knowledge and modern practices of medicine" [Code of Federal Regulations] [Title 21, Volume 8] [Revised as of April 1, 2015] [CITE: 21CFR895.101]

> TITLE 21--FOOD AND DRUGS CHAPTER I--FOOD AND DRUG ADMINISTRATION DEPARTMENT OF HEALTH AND HUMAN SERVICES SUBCHAPTER H--MEDICAL DEVICES

PART 895 -- BANNED DEVICES Subpart B--Listing of Banned Devices

Sec. 895.101 Prosthetic hair fibers.

Prosthetic hair fibers are devices intended for implantation into the human scalp to simulate natural hair or conceal baldness. Prosthetic hair fibers may consist of various materials; for example, synthetic fibers, such as modacrylic, polyacrylic, and polyester; and natural fibers, such as processed human hair. Excluded from the banned device are natural hair transplants, in which a person's hair and its surrounding tissue are surgically removed from one location on the person's scalp and then grafted onto another area of the person's scalp.

[48 FR 25136, June 3, 1983]

FDA has only banned one other medical device: prosthetic hair fibers²

References: 1. The Federal Register. Banned Devices; Proposal to Ban Powdered Surgeon's Gloves, Powdered Patient Examination Gloves, and Absorbable Powder for Lubricating a Surgeon's Glove. 3/22/2016. Available at:https://www.federalregister.gov/articles/2016/03/22/2016-06360/banned-devices-proposal-to-ban-powdered-surgeons-gloves-powdered-patient-examination-gloves-and. Accessed 5/5/16.

Eliminate the dinosaur from your facility

Cornstarch is not benign

Exposure to powder from surgical gloves can accompany serious health risks and complications for both healthcare workers and patients

Initially used to aid in glove donning, with current advances in synthetic gloves, the glove powder is no longer necessary...

IT'S A DINOSAUR!



So how do you make the switch to be powder-free?

Moving to a safe environment

FOUR STEPS TO A SAFER ENVIRONMENT

EDUCATE STAFF

on the clinical risks associated with powdered gloves.

3

CONSIDER ONLY LOW PROTEIN POWDER-FREE GLOVES, OR...

...MAKE THE DECISION TO MOVE TO A SYNTHETIC ENVIRONMENT

- Make it convenient for staff and surgeons to use latex-free.
- Have good latex-free surgical gloves available for use.

2 FACILITATE A MEETING WITH YOUR GLOVE MANUFACTURER

to determine potential powder-free glove options.

• Staff can evaluate different options to find a suitable alternative



SUPPORT OCCUPATIONAL HEALTH as the move will benefit patient and

employee outcomes.