Surgical glove powder: 
An unnecessary hazard

Chapter one: 
Introduction
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

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.

WARNING

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.

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.
Chapter two: History of powdered gloves
**Powder concerns are old news**

Over half a century of concern.1-5

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**1950’s**

- FDA issues warning about washing powdered gloves.

**1971**

- Edlich petitioned FDA to ban powdered Latex Gloves (PLG).

**1990’s**

- Occupational Health concerns.

**1995**

- FDA Glove Report.

**1997**

- UK ceases purchase of powdered gloves.

**1998**

- Public Citizen petitioned FDA for ban. Germany bans surgical glove powder.

**2000**

- FDA recommends stronger warning. Public Citizen issues a 3rd letter to FDA.

**2008**

- Public Citizen issues 2nd letter to FDA.

**2011**

- FDA issues intent to ban most powdered medical gloves.

**2013**

- FDA recommends using powder-free gloves.

**2016**

- AORN; 2015 Guideline for A Safe Environment of Care, Part 1. 239-263.

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Dusting powders: from talc to cornstarch

Powders developed as lubricant to help don gloves.¹

<table>
<thead>
<tr>
<th>Mixture of dusting powers</th>
<th>Talcum power</th>
<th>Cornstarch</th>
</tr>
</thead>
<tbody>
<tr>
<td>1889</td>
<td>1930’s</td>
<td>1970’s</td>
</tr>
<tr>
<td>Mix of lycopodium spores (ground pines or club moss) and talc, talcum powder alone, calcium carbonate, different types of starch products.</td>
<td>Talcum powder (hydrous magnesium silicate) predominately used. Quickly recognized to be the cause of postoperative adhesions and granuloma formulation in the ‘40’s²</td>
<td>Modified cornstarch glove introduced in 1947. Cornstarch predominantly used as dusting powder.</td>
</tr>
</tbody>
</table>

USP “absorbable” cornstarch

Reasons for use:

- 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:
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...

**Operation theater**

...spread into the environment.

Powder, powder everywhere

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

- Surgical tools
- Equipment
- Patient tissue
- Clothing
- Hair
- Bed rails
- Keyboards
- Dressings
- Air ducts
Routes of exposure to powder

**Direct contact**¹
- 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.”

- 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 bacteria\(^1\). Interferes with immunological defense mechanisms, allowing microorganisms to multiply.\(^2\)

References:

Corstarch can cause foreign body reactions and delayed wound healing.\(^3\)
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 gloves\(^2\)
- Ophthalmic granulomas\(^3\)

References:
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

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

**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

**OPHTHALMICS**⁴
- 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

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:
SURGICAL GLOVE POWDER

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

# Glove associated skin reactions

<table>
<thead>
<tr>
<th>Category</th>
<th>Condition</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>IRRITANT CONTACT DERMATITIS</strong></td>
<td>Toxic chemicals, excessive perspiration, irritating chemicals used in hand products and glove manufacture</td>
</tr>
<tr>
<td><strong>ALLERGIC CONTACT DERMATITIS (TYPE IV) DELAYED HYPERSENSITIVITY</strong></td>
<td>Accelerators and other chemicals used in glove manufacture, sterilants and disinfectants, bonding agents, local anesthetics</td>
</tr>
<tr>
<td><strong>LATEX ALLERGY (TYPE I) IMMEDIATE OR NATURAL RUBBER LATEX PROTEIN ALLERGY</strong></td>
<td>Latex proteins</td>
</tr>
</tbody>
</table>

## Causative Agents

- **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

## Reactions

- **Skin reactions usually confined to the area of contact**
  - **Actue**: 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**
  - **Actue**: Hives, swelling, runny nose, nausea, abdominal cramps, dizziness, low blood pressure, bronchospasm, anaphylaxis
  - **Chronic**: as above, increased potential for extensive more severe reaction

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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.

Risks with powdered gloves:

Respiratory complications
Respiratory complications

Inhalation of cornstarch glove powder can lead to the development of subclinical inflammation in the airways\(^1\) such as:

- Accumulation of eosinophilic granulocytes
- Respiratory allergic reactions and asthma-like attacks\(^2\)

**Estimated roughly 30% of latex sensitive individuals develop respiratory problems\(^2\)**

The problems include:

- Rhinitis
- Conjunctivitis
- Dyspnea

References:
Aeroallergens increase asthma risk

Latex aeroallergens dispersed during glove donning 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.

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

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

References:
Risks with powdered gloves: Laboratory interference
SURGICAL GLOVE POWDER

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

**Socio-Economic Components.**

<table>
<thead>
<tr>
<th>Direct Medical Costs</th>
<th>Indirect Costs</th>
<th>Intangible Costs</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Cost of SSIs and post-op complications</strong></td>
<td><strong>Indirect costs include:</strong></td>
<td><strong>Psychological costs (i.e. anxiety, grief, disability, job loss)</strong></td>
</tr>
<tr>
<td>• Additional surgical procedures and hospitalizations</td>
<td>• Lost wages</td>
<td>• Healthcare workers who demonstrated latex sensitization were 3 times more likely to leave their job³</td>
</tr>
<tr>
<td><strong>Procedures and treatments for:</strong></td>
<td>• Diminished worker productivity</td>
<td><strong>Pain and suffering</strong></td>
</tr>
<tr>
<td>• Latex allergy sensitization</td>
<td>• Short and long term morbidity</td>
<td><strong>Change in social functioning/daily activities</strong></td>
</tr>
<tr>
<td>• Hypersensitivity reactions</td>
<td>• Mortality</td>
<td></td>
</tr>
<tr>
<td>• Asthma</td>
<td>• Decrease in insurance reimbursement</td>
<td></td>
</tr>
</tbody>
</table>

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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 intensify the tissue reaction.

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

**Washing wastes time and money**

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

- 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.**

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References:
Risks with powdered gloves: Effective solutions
Surfical Glove Powder

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

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

- Switzerland
- Austria
- Sweden
- Denmark
- Finland
- Norway

Europeans advocate

Many organizations advocate for a powder-free environment:\(^1\)

- American Chemical Society
- National Institute for Occupational Safety and Health
- American Nurses Association
- Health & Safety Executive
- American College of Allergy, Asthma & Immunology
- Association of Perioperative Registered Nurses

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**

- **Pre-conversion (Powdered, latex gloves)**: 42%
- **Post-conversion (Powder-free latex gloves)**: 29%

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:

- **16-FOLD DECREASE IN RATE OF NEW LATEX SENSITIZATIONS**
- **25 PERCENT OF PREVIOUSLY SENSITIVE EMPLOYEES 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. turn downs.

**SYNTHETIC GLOVES OFFER:**

- **SAFETY FOR BOTH PATIENT AND WEARER**
- **GREAT COMFORT**
- **MAY BE TAILORED FOR SPECIFIC NEEDS (DIFFERENT THICKNESSES OR GRIPS)**
- **EASE OF DONNING**
- **OVERALL COST IN-USE**
**Surgical Glove Powder**

**Powdered glove usage trend**

<table>
<thead>
<tr>
<th>Year</th>
<th>&lt; 10%</th>
<th>&lt; 11% - 25%</th>
<th>&lt; 26% - 49%</th>
</tr>
</thead>
<tbody>
<tr>
<td>2013</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2014</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2016 Q1</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

References: GHX Glove Market Data, Q1 2016.
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”.

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”

FDA has only banned one other medical device: prosthetic hair fibers.


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

1. EDUCATE STAFF on the clinical risks associated with powdered gloves.

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.

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.

4. SUPPORT OCCUPATIONAL HEALTH as the move will benefit patient and employee outcomes.