

Different latex aeroallergen size distributions between powdered surgical and examination gloves: Significance for environmental avoidance

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Background: Proactive medical institutions implement latex allergen avoidance to protect workers and patients with latex allergy and to prevent latex sensitization in these groups by creating latex-safe environments that include replacement of natural rubber latex examination and surgical gloves, especially those that are powdered, with synthetic alternatives. We have hypothesized that an apparent decreasing trend in new latex allergy cases in hospitals using only synthetic examination gloves but the occasional powdered latex surgical glove might result from constitutive differences in allergen content (particle size distribution and quantity) between powdered surgical gloves and examination gloves.

Objective: Because aerodynamic particle size determines where inhaled airborne allergen deposits in the airway, the aim of this study was to investigate the differential particle size distribution of latex allergen released from powdered latex examination and surgical gloves.

Methods: Powdered and nonpowdered latex examination and surgical gloves were processed to create an aerosol in a glove box equipped with air sampling equipment capable of total particle number and mass measurements. Air particulate generated in the glove box was collected on impactors with less than 2.5- μ m, 2.5- to 10- μ m, and greater than 10- μ m particle size limits (4 L/min for 4 hours). All filters were extracted, and latex allergen was quantified by using a latex-CAP inhibition assay with a human IgE anti-latex serum pool.

Results: Latex aeroallergen on powdered sterile surgical gloves resided primarily on particles greater than 10 μ m in size ($P < .006$). In contrast, powdered examination gloves released the highest total latex aeroallergen content, with 68% of the particles sized in the respirable 2.5- to 10- μ m range and carrying 56% of the airborne latex allergen.

Conclusions: Significantly lower quantities and larger sizes of latex allergen-containing particles released from surgical gloves provides one potential explanation as to why an apparent

decrease in new cases of latex allergy can occur in hospitals that successfully replace latex examination gloves with synthetic gloves but continue occasional use of powdered surgical gloves. (*J Allergy Clin Immunol* 2004;114:358-63.)

Key words: Latex allergy, allergen, particle size, avoidance therapy

Institution of universal precautions in 1987¹ was the seminal event that led to an almost 10-fold increase in nonsterile examination glove (but not sterile surgical glove) use in the United States.² This increase in examination glove use occurred along with a failure by regulatory agencies to set standards for the maximal amount of releasable latex allergen from medical gloves. These concurrent events, together with a general lack of recognition for the role for cornstarch donning powder as a vehicle for transporting latex allergen in the air, were largely responsible for the epidemic in respiratory allergic responses to natural rubber latex that occurred among health care workers in the 1990s.³

Presently, the management of individuals with latex allergy is difficult because latex immunotherapy is not an option, and pharmacotherapy has not always reduced the risk of systemic allergic symptoms associated with latex allergen exposure. Thus the avoidance of exposure to latex allergen-containing products has by default become the primary method for management of latex allergy for patients and health care workers. To promote avoidance, a number of health care institutions have established latex task forces and have proactively worked to create latex-safe environments.⁴⁻⁶ The major step in this process has been the removal of latex gloves, especially those that are powdered, from the health care setting.^{7,8}

For convenience, medical gloves can be divided into nonsterile examination gloves and sterile surgical gloves. Moreover, within these categories, the gloves can be manufactured with natural rubber latex or synthetic materials, and they can be powdered with a fine layer of cornstarch or oat starch or not powdered at all, typically after chlorination. Although there have been exceptions, in general, powdered examination and surgical latex gloves have been reported to contain the highest levels of extractable allergen.⁹ Because extractable levels of latex allergen can vary widely among different glove sources, no practical distinction has been made by hospital administrators between the importance of removing powdered

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Abbreviation used
AU: Allergen unit

examination gloves and surgical gloves. Most proactive institutions have begun creating a latex-safe environment by first replacing nonsterile powdered latex examination gloves and in some cases nonpowdered latex examination gloves with nonpowdered synthetic examination gloves made of nitrile, vinyl, or synthetic polyisoprene. They have, however, found it more difficult to convince surgeons to replace their powdered latex sterile gloves with either nonpowdered latex sterile gloves or, ideally, nonpowdered sterile synthetic gloves. The cited reasons are almost always cost and personal preference.

Interestingly, despite the continued occasional use of sterile powdered latex surgical gloves, hospitals that have successfully replaced latex examination gloves with synthetic alternatives appear to perceive a reduced incidence of newly sensitized patients and health care workers with latex allergy and a reduced prevalence of reactions associated with latex allergen exposure in hospitals. The generalized perception, unsupported by data, of a stabilization or possibly even a reduction in latex sensitization and symptom induction rates despite continued use of powdered latex sterile surgical gloves led us to hypothesize that there might be a constitutive difference in allergen content (specificity, particle size distribution, and quantity) on powdered surgical and examination gloves. Because the particle size of the allergen determines whether the allergen remains airborne and where it deposits in the human airway, we have chosen to study the particle distribution of powdered sterile surgical and nonsterile examination gloves. In this article we demonstrate that the latex aeroallergen on clinically used powdered surgical gloves resides primarily on particles larger than 10 μm in size, whereas latex allergen on widely used powdered examination gloves is predominately in the 2.5- to 10- μm range. This particle size distribution difference between powdered latex surgical and examination gloves might provide a rationale for why hospitals still using powdered latex surgical gloves experience reduced symptoms and fewer new cases of latex allergy when they are only able to eliminate the use of powdered latex examination gloves.

METHODS

Glove particle size distribution

Several widely used natural rubber latex medical gloves were selected for this investigation. These included powdered latex surgical gloves (Triflex; Allegiance Healthcare Corp, McGaw Park, Ill; manufactured in Malaysia), powdered latex examination gloves (Royal Med; Redline Healthcare Corp, Golden Valley, Minn; manufactured in Thailand), and nonpowdered latex surgical gloves (Biogel; Regent Medical, Norcross, Ga; manufactured in Malaysia). Particulate-containing aerosols were generated in a glove box containing a working space of 210 L. In addition, the box had 2 arm-length nonpowdered synthetic gloves (right and left) extended

through sealed portals into the box that allowed the contents of the box to be handled. One of the investigators (KT) snapped the study gloves through these synthetic gloves. A high-efficiency particulate air filter was mounted at the air inlet of the glove box to prevent contamination of the working space from room air. Fresh air was drawn into the box through a high-efficiency particulate air filter, and the air in the box was sampled with an Aerodynamic Particle Sizer (TSI model 3320; TSI, Inc, St Paul, Minn). After the box was closed, any particulate in the air was allowed to settle for 30 minutes. One glove was turned inside out and then snapped once. Snapping of the glove consisted of holding the glove by the fingers and the cuff, stretching it 20 inches, and releasing one end. The Aerodynamic Particle Sizer flow rate was 5 L/min, and sampling was performed for 2 hours. A total of 4 separate particle distributions were collected for each of the 3 glove types, and total particle number, surface area, and mass distribution were measured. The particle sizes collected ranged from 0.5 to 19.9 μm . Background particle levels observed before testing were subtracted from all particle counts measured after the introduction of the latex glove into the glove box.

Latex aeroallergen—particle size distribution studies

Collection of particles for aeroallergen analysis was performed by placing 10 pairs of powdered latex surgeon gloves, 10 pairs of powdered latex examination gloves, or 20 pairs of nonpowdered latex surgeon gloves into the glove box at a time. The background particles were allowed to settle, and the gloves were then snapped once each in the uniform manner described above. Impactors (MSP, St Paul, Minn) were used to collect particles on the basis of their aerodynamic diameter. A PM2.5 impactor collected particles greater than 2.5 μm (PM2.5) on its impaction plate and particles less than 2.5 μm on its downstream filter (37 mm, 2.0- μm Teflon filters; TEFLO, Pall Corporation, Ann Arbor, Mich). The PM10 impactor functioned similarly but with a 10- μm particle classification. Both the PM2.5 and the PM10 filters and their associated impactor surfaces were analyzed for latex allergen content residing on particles less than 2.5, 2.5 to 10, and greater than 10 μm in diameter. Filters and their associated impactor surfaces were analyzed for latex allergen content residing on particles less than 2.5, 2.5 to 10, and greater than 10 μm in diameter. A personal sampling pump (SKC Aircheck Model 224-PCXR8; SKC Inc, Eighty-Four, Pa) was used to pull a 4 L/min flow rate for 4 hours (total of 960 L of air sampled). Four separate aeroallergen particle collections per glove type were performed, and the data were combined to compute the aeroallergen variance for the 3 particle size ranges.

Latex allergen extraction and assay analysis

All filters and cassettes were extracted separately with 2 mL of buffer (PBS containing 1% BSA). The latex allergen levels present on each cassette-filter combination were quantified by using a Pharmacia CAP competitive inhibition assay. The Pharmacia CAP System is a US Food and Drug Administration–cleared solid-phase enzyme immunoassay that uses nonammoniated latex allergen on a sponge CAP matrix to bind latex-specific IgE.¹⁰ In the inhibition assay 0.1 mL of test or reference latex allergen extracts were individually preincubated in separate tubes with 0.1 mL of the latex-specific IgE serum pool (1 hour at 23°C). The extract-IgE antibody mixture was then added to the respective latex allergosorbent in duplicate and incubated for 1 hour. A buffer wash then removed unbound protein, and in a second incubation, enzyme-labeled anti-human IgE Fc was added to stoichiometrically detect IgE antibody bound to the latex allergosorbent. An adult human IgE anti-latex serum pool prepared from serum from 10 individuals with latex allergy (positive skin test response, positive IgE anti-latex serologic results) was used in this assay. Direct binding studies with purified and recombinant allergens have demonstrated that this serum pool contains IgE antibody to all

TABLE I. Total allergen and aerosol measurements for the 3 glove types

	Powdered latex examination	Powdered latex surgical	Nonpowdered latex surgical
Extractable allergen (AU/g)	23,865	3593	1573
Particle counts (particles/m ³)	6.6×10^6	1.4×10^6	0.55×10^6
Particle mass (μg/m ³)	250	40	14
Airborne allergen (AU/cm ³)	3077	531	20

identified major *Hevea brasiliensis* allergens.¹¹ Results of the allergen analyses were reported in allergen units (AUs) per milliliter by using the E8-FDA nonammoniated latex as a reference that had been assigned a value of 100,000 AU/mL (3.89 mg/mL total protein) when undiluted. The results were reported in AU per filter or cassette and AU per gram of glove.

Statistical analyses

The measurements for the nonpowdered gloves were divided by 2 to account for the use of twice as many nonpowdered compared with powdered gloves to normalize for the different number of nonpowdered gloves snapped. Data were analyzed by means of ANOVA (StatView 4.51; Abacus Concepts, Berkeley, Calif) with the Scheffe correction for pairwise comparisons and a significance level of *P* less than .05.

RESULTS

Levels of extractable latex allergen from test gloves

The extractable allergen content was measured in a single glove from each glove type tested. The extractable allergen contents for the various gloves tested were 23,865 AU/g, 3593 AU/g, and 1573 AU/g (Table I) for the powdered latex examination gloves, the powdered sterile latex surgical gloves, and the nonpowdered sterile latex surgical gloves, respectively.

Particle size generation and distribution of airborne latex allergen from the different latex gloves tested

Before the gloves were snapped, there were no differences among the total background levels of particles. The baseline total particle counts before snapping the gloves were $1.6 \times 10^7 \pm 7.6 \times 10^8$ particles/m³ (mean $\pm$ SEM), $2.9 \times 10^7 \pm 1.6 \times 10^7$ particles/m³, and $1.0 \times 10^7 \pm 3.4 \times 10^8$ particles/m³ for the powdered examination gloves, the sterile powdered latex surgical gloves, and the sterile nonpowdered surgical gloves, respectively (*P* = .44).

After the gloves were snapped, the powdered latex examination gloves generated significantly more total airborne particles per cubic meter ($6,644,380 \pm 2,221,699$ particles/m³; Table I; Fig 1, A) and a total particle mass of 250 ± 230 μg/m³ (Table I; Fig 1, B) compared with either

the powdered latex sterile surgeons gloves ($1,407,570 \pm 795,979$ particles/m³ [*P* = .007; Table I; Fig 1, A] and 40 ± 15 μg/m³ [*P* = .0006; Table I; Fig 1, B], respectively) or the nonpowdered sterile surgical gloves ($555,322 \pm 104,320$ particles/m³ [*P* = .002; Table I; Fig 1, A] and 14 ± 4 μg/m³ [*P* = .0002; Table I; Fig 1, B], respectively). Similarly, the powdered latex examination gloves generated significantly more total airborne allergen (3077 ± 424 U/m³; Table I; Fig 1, C) compared with either the powdered latex sterile surgical gloves (531 ± 88 U/m³; *P* = .003; Table I; Fig 1, C) or the nonpowdered sterile surgical gloves (20 ± 13 U/m³; *P* = .0008; Table I; Fig 1, C). Surprisingly, there was no significant difference in the total aerosol latex values generated between the powdered and the nonpowdered latex sterile surgical gloves (*P* = .81). In addition, for the examination gloves, there were significantly more particles generated in the 2.5- to 10-μm strata compared with the greater than 10-μm range (*P* = .04; Table II; Fig 1, A). For the surgical powdered gloves, there were no significant differences in the number of particles generated among the different size strata (Table II; *P* > .18). For the nonpowdered gloves, there were significantly more particles generated in the less than 2.5-μm strata compared with the greater than 10-μm range (*P* = .007; Table II; Fig 1, A).

Moreover, the distribution of airborne allergen was markedly different among the 3 glove types. The largest fraction (68%) of particles generated by the powdered latex examination gloves were in the 2.5- to 10-μm range, and these particles carried 56% of the airborne allergen (1729 ± 520 U/m³; Table II; Fig 1, C). In contrast, the largest fraction (66%) of particles generated by the sterile powdered latex surgical gloves was in the less than 2.5-μm range, but these particles carried only 4% of the airborne allergen (20 ± 12 U/m³; Table II; Fig 1, C). Similar to the powdered latex surgical gloves, the largest fraction (66%) of particles generated by the sterile nonpowdered latex surgical gloves were in the less than 2.5-μm range, but these particles also carried only 4% of the airborne allergen (0.8 ± 0.2 U/m³; Table II; Fig 1, C). Also, in the powdered latex surgical gloves the highest amount of airborne allergen (502 ± 134 U/m³; Table II; Fig 1, C) was carried in the particles greater than 10 μm in size (*P* < .006; Table II; Fig 1, C). For the examination and the surgical nonpowdered gloves, there were no differences in the amount of latex aeroallergen generated among the 3 particle size strata (*P* > .05; Table II; Fig 1, C). However, for the surgical powdered gloves, there was significantly more latex aeroallergen generated in the greater than 10-μm strata compared with either the less than 2.5-μm (*P* = .005; Table II; Fig 1, C) or the 2.5- to 10-μm (*P* = .006; Table II; Fig 1, C) ranges.

Furthermore, when examined on the basis of total mass for each particle size strata, there were also interesting differences among the 3 glove types. For both the powdered examination gloves and the nonpowdered sterile latex surgical gloves, the greatest particle mass was in the 2.5- to 10-μm fraction (238 ± 53 μg/m³ [94% of the total mass, *P* < .005] and 11 ± 4 μg/m³ [78% of the total

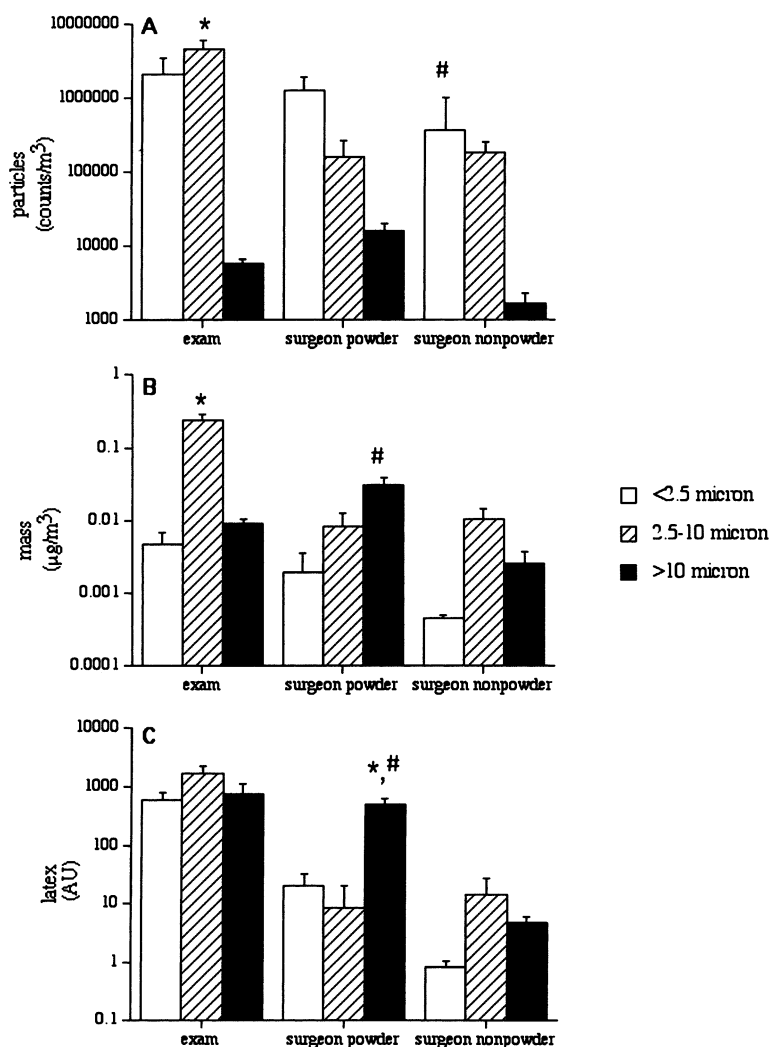


FIG 1. **A**, The aerosol particle levels in the 3 particle size ranges for the 3 latex glove types: powdered latex examination glove (*exam*), sterile powdered latex surgical glove (*surgeon powder*), and sterile nonpowdered surgical glove (*surgeon nonpowder*). See text for explanation (# $P = .007$). **B**, The particle mass released in the 3 particle size ranges for the 3 latex glove types. See text for explanation. **C**, The latex aeroallergen levels released in the 3 particle size ranges for the 3 latex glove types. See text for explanation.

mass, $P = .06$], respectively; Table II; Fig 1, B), and these size fractions accounted for the majority of the airborne allergen ($1729 \pm 520 \text{ U/m}^3$ [56% of the total airborne allergen] and $15 \pm 12 \text{ U/m}^3$ [72% of the total airborne allergen], respectively; Table II; Fig 1, C). However, for the powdered sterile latex surgical gloves, the greatest mass of aerosol was in the greater than 10- μm fraction ($30 \pm 4 \text{ } \mu\text{g/m}^3$ [72% of the total mass; $P < .04$; Table II; Fig 1, B] and $502 \pm 134 \text{ U/m}^3$ [95% of the total airborne allergen; Table II; Fig 1, C]).

DISCUSSION

Charous et al² have summarized the thoughts of many by stating that the cornerstone of successful management of latex allergy and asthma depends on the institution of cessation of exposure. Because powdered latex medical

gloves have been identified as the primary source of that exposure, their elimination is vital. Many hospitals have worked toward the goal of a latex-safe environment by attempting to eliminate all powdered and in some cases nonpowdered latex medical gloves.^{4-6,12,13} Although most have been successful with conversion of powdered nonsterile latex examination gloves to synthetic alternatives, it has been more difficult to get surgeons to convert from powdered sterile surgical gloves to nonpowdered or synthetic alternatives.¹⁴ The cited reasons for this include barrier protein concerns, leakage rates, undesirable tactile characteristics, and cost. Despite this resistance by surgeons, the prevalence rates for latex sensitization and latex allergy symptoms appear to be diminishing or at least reaching a plateau. We hypothesized that this might be the result of a constitutive difference in the particulate latex allergen released from

TABLE II. Allergen and aerosol measurements for the 3 glove types by particle size

	Powdered latex examination	Powdered latex surgical	Nonpowdered latex surgical
Airborne allergen (AU/g)			
<2.5 μm	600.6	20.3	0.8
2.5-10 μm	1729.2	8.4	14.6
>10 μm	748.0	502.3	4.9
Particle counts (particles/ m^3)			
<2.5 μm	2.07×10^6	1.2×10^6	0.4×10^6
2.5-10 μm	4.6×10^6	0.15×10^6	0.19×10^6
>10 μm	0.006×10^6	0.016×10^6	0.002×10^6
Particle mass ($\mu\text{g}/\text{m}^3$)			
<2.5 μm	4.7×10^{-3}	2.0×10^{-3}	0.45×10^{-3}
2.5-10 μm	238×10^{-3}	8.3×10^{-3}	10.6×10^{-3}
>10 μm	9.0×10^{-3}	29.9×10^{-3}	2.6×10^{-3}

the examination and surgical gloves because there are certain steps in their manufacturing that are different.

It is important to emphasize that we did not simply see a greater amount of aeroallergen from the examination gloves compared with the surgical gloves. If it were simply a matter of the total amount of allergen, then we would have expected that the distributions of the size of the particle that carried latex allergen between the examination gloves and the surgical gloves would have been similar. From this, we would have concluded that the aerosol exposure risk is simply related to the total amount of latex found on a given glove. However, we observed that the size of the particles that carried the latex allergen was significantly different between the examination and the surgical gloves. For the powdered examination gloves, the majority of the allergen was on the 2.5- to 10- μm particles, whereas for the powdered surgical gloves, the majority of the latex allergen was on particles greater than 10 μm in size. Therefore this study demonstrated not only differences in the total amount of allergen on the gloves but also in the size of the particles that carry the majority of the latex allergen.

Investigating the literature, we found a number of reports that showed medical glove donning powders were able to bind and transport latex allergen into the air.¹⁵⁻¹⁹ Extractable and aerosolizable latex allergen have also been identified as a dried soluble protein present on gloves that is not attached to donning powder.⁶ Some of these studies also investigated latex airborne allergen levels in various medical and dental environments.^{17,18,20,21} For instance, Heilman et al¹² monitored air in a hospital operating room on 52 consecutive days during which surgical gloves with high extractable allergen content (2075-31,673 AU/mL) were used on 18 days and gloves with low extractable allergen content (<75-953 AU/mL) were used on an alternative 15 days. They observed that latex aeroallergen levels detected by means of RAST inhibition in extractions of air filter cassettes equipped

with Teflon filters correlated with the total number of gloves used on designated high-allergen glove days ($r = 0.66$, $P = .003$). Moreover, substitution of low-allergen surgical gloves for high allergen-containing latex gloves reduced levels of latex allergen by more than 10-fold in the operating room (mean, 13.7 ng/ m^3 [high] to 1.1 ng/ m^3 [low]). This study, however, did not investigate examination gloves or the particle distribution of latex allergen.

Swanson et al²² studied latex allergen levels across different particle size ranges by measuring the airborne concentrations and aerodynamic particle size distributions of latex allergen in areas of a medical center. Latex allergen was quantified by means of RAST inhibition analysis of extractable particulate on 5 stages of an Anderson sampler. They detected latex allergen across all particle ranges, with the majority of the recovered allergen (>80%) associated with particles greater than 7 μm in their mass median aerodynamic diameter. Because this article does not indicate what types of gloves were used in the Anderson cascade impactor studies, we do not know whether surgical or examination gloves were used to investigate the particle size distribution for the different glove types.

The data in the present study diverge from those reported by Swanson in that 80% of latex allergen released from powdered examination gloves was detected in the 2.5- to 10- μm respirable particle range. In contrast, approximately 80% of the latex allergen released from sterile surgical gloves was detected in the greater than 10- μm range, which settles rapidly and is not readily inhaled. In addition, it is important to emphasize that even the nonpowdered latex gloves release latex allergens into the air. The nonpowdered label only refers to donning powder. Coagulant, such as calcium carbonate particulate, is still used in this manufacturing process and might account for the particulate that was measured in the current study.

We acknowledge several limitations to this study that include the investigation of a small number and manufacturer sources of gloves from each glove type and the production of latex particulate aerosols in an artificial glove box that might not represent particle generation by users in actual health care environments. However, these data suggest that the elimination of examination gloves will possibly have the greatest effect on reducing respirable latex allergen in a health care setting and thus promoting the creation of a latex-safe environment. We conclude that the goal of any avoidance program should be the total removal of all powdered latex gloves from the facility. However, when it is not possible to remove all the powdered latex surgical gloves, progressive reductions in sensitization and elimination of latex allergen-induced allergic symptoms might still be possible with their occasional use.

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