

CLINICAL

Avoiding problems: evidence-based selection of medical gloves

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For the past 18 years, there has been debate about problems arising from contact with potentially allergenic proteins in natural rubber medical gloves. This problem increased when latex glove use became more widespread following the human immunodeficiency virus (HIV) pandemic. There is also the problem of delayed allergic contact (DAC) reaction to residual chemicals in natural and synthetic rubber gloves. A literature search has not disclosed any fatality from DAC reaction to medical gloves, but its persistent effect has curtailed the careers of some healthcare workers; medical work offers few opportunities that do not involve wearing gloves. This article compares medical glove materials, in terms of reliability and allergy, and reveals a hitherto unrecognized factor that may explain why reports of reaction to latex gloves significantly increased from 1980 onwards. It will also help to choose suitable alternatives if the glove currently used causes an adverse reaction.

THE LATEX PROTEIN PROBLEM

Type I sensitivity to latex gloves is termed an 'immediate' contact urticaria (CU), and is an allergic contact reaction to various proteins in natural latex rubber. Atopic individuals are more likely to have it or acquire it (Moneret-Vautrin et al, 1993) but non-atopic people are also potentially at risk. Turjanmaa and Renuala (1988) in Finland demonstrated a 3% incidence of CU among local healthcare staff (HCS), rising to over 6% in operating unit personnel. However, Scandinavian countries are stated to have relatively large populations of atopic people (Lammintausta and Kalimo, 1981; White, 1995, personal communication, Senior Consultant Dermatologist, St John's Contact Dermatitis Clinic, London) so the Finnish study may not indicate the incidence elsewhere.

Until recently, there was little information on the incidence of latex protein sensitivity among healthcare staff in Britain. Johnson (1999), in a study of an overall level of

Abstract

Allergic contact reaction to glove proteins and residual chemicals increased from 1980 onwards; circumstantial and technical evidence indicates that change from reusable to disposable latex gloves was a causative factor. Several protein fractions are potentially allergenic; if low protein gloves contain a dominant protein fraction, people with sensitivity may still have an adverse reaction. Use of chlorinated powder-free gloves reduces risk of allergic reaction; other powder-free gloves may still pose a contact risk to patients. Adverse comparative tests of vinyl vs latex medical gloves may, in some cases, have used non-medical gloves without assessment of initial quality or involved an unrealistic test method; these have discouraged use of a non-allergenic alternative to latex gloves. Vinyl medical glove properties are reviewed. Nitrile examination gloves offer better protection than latex types when handling lipid-soluble substances and chemicals. Properties of medical gloves made from other materials are described.

adverse reaction to rubber medical products, showed that around 10% of 7436 NHS staff had experienced CU reaction, and 43% experienced either irritant or delayed allergic contact (DAC) skin reaction to chemicals in the rubber. In an earlier study, Vandenplas et al (1995) revealed that 4.7% of Belgian hospital staff were allergic to contact with latex rubber. From that, it is reasonable to assume that a similar percentage of British HCS are potentially at risk of reaction.

The estimated incidence of CU in the general population of Britain is less than 1% (Turjanmaa, 1993). So, an apparently higher level among HCS can reasonably be attributed to their repetitive contact with latex gloves and exposure to glove powder (including by inhalation) on which rubber proteins are absorbed.

Natural latex rubber is a variable raw material but its composition has not significantly changed in the past 100 years, and powdered latex rubber gloves have been widely used in hospitals for over 60 years. DAC reaction to residual chemical accelerators in rubber gloves was recognized as a problem and a few studies of it were published from 1950 onwards, yet there were none about urticarial contact reactions to CU

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medical glove proteins until 1980 (Forstrum, 1980). The number of subsequent studies of CU hypersensitivity to latex proteins, and DAC reaction to glove chemicals, makes it reasonable to assume that levels of both were previously low. For some reason sensitivity had begun to significantly increase before the HIV pandemic causing wider use of gloves. A previously overlooked factor may explain why (Table 1).

The significance lays in the technology of latex glove manufacture. Thin latex products heated in a non-enclosed process rapidly become weakened by the rubber's reaction with oxygen (in air) at temperatures above 120°C, so disposable gloves are not heated above 115°C during manufacture, and are not cleansed after use. In the earlier steam sterilizations, a 135°C temperature was applied, and latex glove strength was unaffected by it because air is excluded during the heat stage of steam autoclaving.

Current manufacturing practice illustrates that the protein content of latex gloves can be substantially reduced by successive washings. Repetitive cleansing of the earlier reusable gloves, combined with initial reesterilization at 135°C, would have similarly reduced the extractable protein content and the heat

probably denatured much of the remainder. Illustration of its beneficial effect is that latex rubber products heated at 150°C in enclosed metal moulds have been shown to have a negligible level of residual protein (Yip et al, 1995). Apart from tending to confirm that sterilization of rubber by heat affects its protein content, such information may be of help to infection control staff who have to establish if any moulded rubber item in theatre poses a potential risk of causing patients to experience CU reaction.

Autoclaving at 135°C would also explain the earlier, lower incidence of reported DAC reaction to glove chemicals. The potentially allergenic rubber accelerators function by progressive decomposition during heat vulcanization, but are not completely decomposed at the 120°C temperature restriction necessary in dipped, disposable latex glove manufacture. Further accelerator decomposition occurs, however, if latex gloves are experimentally exposed to heat above 120°C, or undergo chemical halogenation as part of a process used to render gloves powder-free and easy to don. It has been the author's experience that reduction of a glove's residual dithiocarbamate accelerator content to below 0.20% w/w lowers its potential to trigger DAC reaction, demonstrated by the apparent ability of many (but not all) sensitized HCS who have no problem with gloves that achieve that or lower levels.

The conclusion is that the change from thicker, reusable latex medical gloves to the modern disposable type during 1965–1975 was a significant cause of the increase in allergic reactions among HCS.

Autoclaving disposable gloves in packs is not an option as unlike earlier packs, disposable glove packs would rupture during the vacuum stage of autoclaving. Manufacturers should consider using a similar, autoclave-based process for their non-chlorinated gloves in unpacked form, to reduce the rubber's allergenic content before packing and subsequent irradiation.

PROTEINS IN LATEX GLOVES

The total extractable protein in latex gloves can be measured and reduced, but it is not possible to alter the (varying) proportion of individual proteins present. Several potentially allergenic fractions have been identified (Palosuo, 1996), but a person's sensitization may be only one or

Table 1. Factors associated with increased CU* and DAC contact reaction to latex medical gloves**

Pre-1965	Latex surgical and examination gloves required to withstand six episodes of reuse [BS 1803 and BS 1883, 1954]. Gloves repetitively cleansed and reesterilized in steam autoclaves at 135°C, after vulcanization heat of 120°C
1965–1975	Use of thinner, single-use disposable latex gloves, sterilized by gamma-irradiation. Disposable gloves exposed to only 115–120°C heat at vulcanization stage and no longer cleansed or autoclaved before use
1975 onwards	In Europe and USA, reusable, reesterilized latex glove use almost entirely discontinued and replaced by use of disposable gloves
1980	First study of CU reaction to latex medical glove proteins published, followed by considerable number of further studies in subsequent years. Also, increase in published studies of DAC reaction to latex glove chemicals
1991	American FDA† publish medical alert about potentially fatal (anaphylactic) type I allergic contact reactions to latex-containing medical devices

*CU = contact urticaria; ** = delayed allergenic contact;

† = Food and Drug Administration

‘Contact urticaria reaction of staff and patients by contact (particularly via inhalation) with glove powder on which rubber proteins become adsorbed is well recognized and documented... That problem can be greatly reduced and the inhalation danger eliminated if gloves are rendered powder-free by chlorination.’

two of the fractions present. For example, a latex protein of 46 kiloDaltons (kDa) molecular weight has been associated with CU reaction to latex gloves in a number of medical staff (Heese et al, 1996). If a ‘low protein’ glove contains a dominant fraction to which the wearer has sensitivity, he/she will probably react to it. Conversely, gloves with a higher total protein but with little of the dominant fraction may leave the wearers unaffected. It is therefore impossible to establish a ‘safe’ threshold level for protein content; low protein latex gloves may still cause reaction but should, nonetheless, be used wherever possible to reduce the risk of reaction.

‘Low protein’ is taken to mean less than 50 micrograms of protein per gram of rubber (50mcg/g), illustrated by the Medical Device Agency’s permissible wording (O’Gilvie, 1996) for glove packs claiming that feature. As 50 mcg/g represents 50 parts of protein per million parts of rubber, and levels vary between gloves from a single batch, test results below 20 mcg/g should be viewed with caution. Also, one batch of gloves with an ultra-low protein content is no guarantee that subsequent batches will be the same. In the USA and Malaysia, 20 mcg/g is taken as the bottom limit of analytical accuracy in protein measurement (Modified Lowry Test). Today’s single-use medical gloves have to comply with national and international standards of performance (British and European Standard BS EN 455, 1995), and acceptably low residual protein and accelerator levels can be achieved by quality control during manufacture and by effective halogenation (chlorination) of the rubber (Philips, 1998).

GLOVE CHLORINATION

CU reaction of staff and patients by contact (particularly via inhalation) with glove powder on which rubber proteins become adsorbed is well recognized and documented (Baur et al, 1993; Kaezmarek et al, 1996). That problem can be greatly reduced and the inhalation danger eliminated if gloves are rendered powder-free by chlorination. Chlorination is a well-known process applied to make glove donning easy without use of powder, and has the beneficial side-effect of extracting much of the residual protein from the glove’s inner and outer surface (Melstrom et al, 1994). Efficient chlorination also reduces rubber accelerator residues to lower levels than would be found in

powdered (or polyurethane-coated) gloves made from the same rubber.

Contrary to popular belief, chlorination does not weaken gloves if correctly carried out. Study of the initial and artificially aged properties of medical gloves shows that if the rubber is properly formulated, the manufacturing process correctly carried out and the chlorination process carefully monitored, the strength of the resulting gloves will be virtually identical to unchlorinated versions. Users also have the safeguard that all surgical, procedural and examination gloves in Britain and throughout the EU — whether chlorinated or not — meet the requirements of BS EN 455. This standard sets a minimum breaking strength for all medical gloves, and a similarly specified minimum strength for artificially ageing samples (heat at 70°C for 168 hours). The standard also stipulates that all medical gloves must have the same freedom from holes, whether made from natural or synthetic rubber, vinyl or any other material.

Not all powder-free latex gloves are chlorinated. A coating of polyurethane polymer allows for easy donning and is used by some manufacturers as a cost saving. The polyurethane coating may afford the wearer some (as yet not quantified) protection against potential allergens in the rubber, but leaves the patient exposed to the latex non-extracted, non-coated outer surface.

Wrangso et al (1994) and Lagier et al (1992) suggest that latex protein hypersensitivity is more common, and the incidence of anaphylactic reaction is higher among medical staff than patients. However, patients are potentially at risk.

Hospitals must ensure that patients and staff are protected from the potential risks encountered with glove usage. Staff who experience adverse reactions to powdered latex gloves are advised to initially switch to powder-free latex gloves and observe if their symptoms disappear. If the problem persists, switching to a non-latex, i.e. vinyl, glove is recommended (O’Gilvie, 1996).

REACTION TO RESIDUAL RUBBER ACCELERATORS

Reaction to residual accelerators (present in natural and synthetic rubber but not in vinyl) is termed a type IV delayed allergic contact response or DAC. Its ‘delayed’ prefix indi-

Examination gloves that are made from medical grade polyvinyl chloride plastisols and meet the requirements of medical glove standard [BS EN 455, 1994], although unsuitable for surgery, offer inexpensive, non-allergenic hand protection for staff with contact urticaria sensitivity to proteins or delayed allergic contact sensitization to rubber chemicals.

cates that, unlike type I reactions, it can commence some hours after contact with the allergenic substance has ceased. DAC accounts for most contact reactions to medical gloves (Kaezmarek et al, 1996). It can occur without prior warning after months or even years of medical rubber glove use, and few British hospitals have not had at least one member of staff affected by this condition.

Contact sensitivity extends to the whole external skin, so people sensitized by rubber gloves may also react to elasticated parts of their underwear. As underwear waistband and bra strap elastic can also contain high accelerator residues, in some cases that may cause sensitization and a subsequent reaction to contact with medical gloves. Reaction to elastic diminishes after the garment has had several launderings, but multiple-laundering of single-use gloves is not an option. Some proprietary garden sprays also contain dithiocarbamates, so people with DAC sensitivity to rubber accelerators may also react to contact with those sprays.

EVIDENCE-BASED ALTERNATIVES

Nitrile (*acrylonitrile-butadiene*, NBR)

Synthetic rubber gloves contain no proteins, and achieve relatively lower residual accelerator levels than powdered latex gloves. This is because NBR withstands higher heat than natural rubber and can be vulcanized at higher temperature during manufacture. However, some nitrile gloves may still contain enough residual accelerator to provoke DAC reactions in sensitized people. The main advantage of nitrile medical gloves is a greater resistance to permeation by dangerous lipid-soluble liquids, by comparison with gloves made of natural rubber. Nitrile examination gloves are a relatively recent product, but thicker industrial gloves made from it have been available for over 40 years. Its vulnerable point, however, is that it has low permeation resistance to ketones, e.g. acetone (Marigold Industrial Gloves catalogue, 1991).

Polychloroprene (CR)

Rubber surgical gloves, better known under the material's brand name Neoprene, are available from various companies but to the best of the author's knowledge not in examination glove form, as the high cost of this synthetic rubber would cause the glove to be non-competitive against natural latex or equivalent vinyl products. Neoprene latex rubber has low modulus,

conferring less hand fatigue during prolonged use and gloves made from it can also have low residual accelerators content because (like nitrile rubber) it can withstand the higher vulcanization temperature needed to effectively decompose them. Neoprene gloves, however, have less resistance to tearing, in comparison with natural latex rubber (Carl, 1962).

Elastyren

These surgical gloves are made in Denmark (Danpren A/S, Copenhagen) in relatively small numbers, from a synthetic, styrene bloc-copolymer elastomer. These gloves contain no accelerators or protein, and have a record of virtual non-allergenicity, and are available for staff whose hypersensitivity extends even to those of low allergen content. However, they have been found too expensive for general use in hospitals.

Vinyl

Examination gloves that are made from medical grade polyvinyl chloride plastisols and meet the requirements of medical glove standard [BS EN 455, 1994], although unsuitable for surgery, offer inexpensive, non-allergenic hand protection for staff with CU sensitivity to proteins or DAC sensitization to rubber chemicals. Vinyl gloves have for many years been (and increasingly are) used in hospitals throughout Britain and America, although some published studies challenge their reliability (Korniewicz et al, 1990, 1993).

It is necessary to examine this challenge to the properties of vinyl medical gloves, to see if their reliability is based on adequate evidence or, possibly, arises from (i) evaluation of cheap 'industrial' vinyl gloves or (ii) insufficient knowledge of those made to meet a stringent British and European medical glove standard [BS EN 455, 1994]. A recent article (Parker, 1999) erroneously stated 'the weakness of vinyl gloves is the welded seam', but vinyl gloves do not have seams. The writer possibly had in mind thinner, seamed copolymer or polythene gloves that are superficially similar to vinyl in appearance but now seldom used because of the seams' unreliability.

STRENGTHS AND WEAKNESSES OF VINYL GLOVES

The following should correct an apparent but largely unfounded bias against a useful alterna-

tive hand protection for HCS who have CU or DAC sensitivity to natural or synthetic rubber.

Vinyl gloves as a viral barrier

Except at ultra-high viral concentrations — likely to occur only invitro — each (intact) medical glove material prevents passage of viruses, whether it is made of natural latex rubber, vinyl or even polythene (Klein, 1990). At in-vitro concentration of 10^{11} plaque-forming units (pfu) of λ -bacteriophage, levels of viral penetration were low and broadly equal for natural latex and vinyl medical gloves. At 10^8 pfu, no penetration was found with either.

Freedom from holes

Small to minute holes can occur during manufacture of thin latex rubber or vinyl gloves, and a skilled manufacturer can prevent such mishaps. An often quoted study (Korniewicz et al, 1993) states more holes were found in *used* vinyl gloves than those made of latex, but it is not clear if any physical assessment was made of holes possibly present in either type *before use*. Plenty of low-grade vinyl gloves were primarily manufactured for food handling and had a few small holes that were no problem; doubtless some of these were sold for medical use in earlier years. However, it is not commonly realized that the British/European Standard for single-use medical gloves [BS EN 455 1994] requires *all* gloves to have the same level of freedom from holes, irrespective of glove material or design. Vinyl medical gloves that conform to the BS EN 455 standard must be as hole-free as latex surgical gloves.

Vinyl glove strength and comfort

Vinyl examination gloves are thinner than those made from natural or synthetic rubber, but under the now mandatory Standard BS EN 455, must meet specified minimum strength requirements; good quality vinyl gloves have a breaking strength twice the specified minimum (Committee European Norme Technical Committee 205, WG 3 Report N 113, 1995). Although not elastic, vinyl gloves can be extended (up to 500%) and the material's thinness confers good touch sensitivity and reasonable comfort for a wide range of hospital tasks. Its inert character makes it suitable for sensitized staff and patients alike.

Reliability of vinyl gloves

Another study (Korniewicz et al, 1989) claims breakdown occurred in two thirds of vinyl gloves during an in-use comparison with latex rubber gloves. However, that study involved repetitive use of each glove, beyond reasonable expectation of glove life or normal practice (Table 2).

Allergy potential

A search of the dermatological literature reveals no reports of allergenic or other skin reactions in vinyl medical glove users, and very few among people who handle the 'raw' non-reacted liquid plastisol from which these gloves are produced. Reports of skin reaction to other vinyl hand protection involved repetitively used, fabric-lined vinyl gloves, and bacterial decomposition or contamination of linings was the cause (Melstrom et al, 1994). Vinyl medical gloves are exposed to 170°C heat during the manufacturing process, removing any volatiles at that stage and leaving a virtually inert finished product.

Incineration

An unfounded, but common, belief is that incineration of vinyl gloves pollutes the environment and releases carcinogens (Philips, 1997). This might happen if all the waste vinyl in hospitals, such as drip and urinary bags, aprons, tubing and so on were put into landfill sites and then caught fire. However, all hospital waste has by law now to be burnt in highly efficient incinerators whose waste gases are drawn through chemical solutions to neutralize and remove any contaminants in outgoing vapour. These plants have fail-safe controls that ensure no toxic material leaves the site, and it is worth keeping in mind that natural, nitrile or Neoprene rubber gloves

Table 2. Sequence of vinyl glove tests in Korniewicz et al's (1989) study

Each 'pair' of vinyl gloves was used after donning, washing and wiping with a washcloth to:

Make 30 attachments and removals of a Luer-Lok needle to a syringe*

Connect and disconnect medical tubing eight times to a stopcock — opening and closing the stop-cock each time*

Unwrap and rebandage a simulated amputation stump twice*

*An unrealistic assessment in relation to existing, everyday use of vinyl gloves on wards and in clinics. More surprising is that over 30% of the vinyl gloves were still intact after such prolonged use

KEY POINTS

- Lack of published research on incidence of contact urticaria (CU) reaction to latex protein in gloves before 1979 indicates that incidence was low, but it increased significantly before the HIV pandemic caused wider use of medical gloves.
- The increase, since 1980, in the number of studies of adverse reaction to residual rubber chemicals in gloves indicates a higher incidence of delayed allergic contact reaction than before.
- The manufacture of medical gloves, considered in relation to the increase in reactions to residual proteins and chemicals, shows a hitherto overlooked causative factor may have been the change from reusable, resterilized latex gloves to the disposable types used from 1965–1975.
- Users should always make a risk assessment that includes allergic potential, and ensure that gloves comply with BS EN 455.

would similarly pose an environmental hazard unless burned in these approved, licensed incinerators.

Economy

British hospitals have used vinyl gloves for more than 30 years and continual improvement has been made in the material and glove quality. As with any medical glove, a risk assessment must be made where these can be routinely used or introduced as an alternative when a problem of an allergenic nature arises. To the best of the author's knowledge, current cost of vinyl medical gloves is similar to that of natural rubber equivalents and less than those made from nitrile rubber.

POLYTHENE OR COPOLYMER MEDICAL GLOVES

Welded seam polythene gloves, and similar gloves made from a copolymer called ethylene-methyl methacrylate (EMA, usually provided on a backing paper) are still available, but now restricted to non-medical tasks because of potential failure of the welded seams. Copolymer gloves were previously used by physicians for rectal or vaginal examinations but were shown to be unreliable. A danger exists in use of natural rubber gloves for anal examinations because of rapid absorption of potentially allergenic proteins by rectal tissue. It was the series of fatal, anaphylactic reactions to latex cuffs used in the USA for administration of barium enemas (Ownby et al, 1991) that focused attention on the fact that latex gloves might have the same potential to produce similar allergic reaction. Vinyl gloves are now sometimes reserved for those examinations because of the material's virtual non-allergenic nature and reasonable touch sensitivity.

CONCLUSIONS

A wealth of information is now available about gloves. With fully informed choice, and adequate risk assessment of the circumstances of use, problems arising from gloves can be greatly reduced. It is hoped this article, based upon 40 years experience of development, manufacture and improvement of medical glove quality, will help readers to understand and avoid problems in choice and use of their gloves. **BJN**

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