Natural Rubber Latex Medical Gloves: Why They Are Still The Best

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Rubber surgical gloves were first used in the healthcare sector to protect the wearer's hands from the irritating antiseptic solutions of the 1870s and 1880s. They gained popularity after their adoption in the early 20th century by surgeons at John Hopkins Medical School to protect patients from the bacteria present on ungloved hands (1). The introduction of disposable latex surgical gloves in 1952 greatly increased the number of gloves in use, replacing the daily chores of glove reprocessing, repairing and sterilising. The boom in latex glove usage came only in 1988 with the AIDS scare and the 'Universal Precautions' recommended by the US Centers for Disease Control (CDC) to treat blood and certain body fluids as potentially infectious (2). In June 1992, the US Occupational Safety and Health Administration (OSHA) introduced the Blood-Borne Pathogen Standard mandating the wearing of gloves for barrier protection when in contact with body fluids and infectious materials (3). Between 1988 and 1993, the number of gloves used in the US shot up from 1.4 billion to 8.3 billion (4).

Natural rubber latex (NRL) gloves, with a proven track record in protecting against viral transmission, were the gloves of choice before latex protein allergy became a serious 'health scare' issue. The first case of latex protein allergic reaction in the USA was reported to the FDA in 1988. The US Federal Drugs Administration (FDA) notes in its website and publications that until March 1999 it received a total of 2,330 cases of allergic reactions to medical latex gloves, including five deaths. However, in none of the cases was there any clinical verification of allergic reaction. The FDA states that the reported information "*does not necessarily reflect a conclusion by the party submitting the report or by FDA that the report or information constitutes an admission that the device caused or contributed to a reportable event*."

Nonetheless, these reported allergic reactions plus adverse media publicity have created a perception that latex protein allergy is 'life threatening', that latex gloves are 'dangerous', and that synthetic alternatives are deemed a 'safer option'. The dusting powder used in powdered gloves has also been implicated as an aeroallergen (5). The position taken by many health authorities, nursing associations and other concerned parties has been for precaution and prevention by avoiding latex gloves wherever possible.

Allergic reactions related to the use of NRL gloves fall into three types:

- Non-allergic contact dermatitis
- Type IV allergic contact dermatitis
- Type I allergy.

Irritant dermatitis is not an allergic reaction. Its causes include repeated hand washing and use of irritating soaps, cleaners and hand sanitisers. The symptoms include dry, itchy and irritated skin, redness, cracking, peeling and, occasionally, blisters.

Most Type IV latex allergies are caused by residual chemicals such as certain accelerators like carbamates, thiurams and mercaptohenzothiazoles, and antioxidants added in latex compounding during glove manufacture. Proper leaching and washing in the final manufacturing stage can wash away most of the residual chemicals from the glove surface. The same types of accelerators are also used in the manufacture of nitrile, polyisoprene and neoprene gloves, and cases of contact dermatitis and contact urticaria related to nitrile and vinyl gloves have been reported (7). As use of non-NRL gloves becomes more prevalent, Type IV allergic reactions may emerge as a problem. But while there are chemicals for latex compounding that do not cause Type IV allergy, they are more costly.

The UK Health and Safety Executive (HSE) has commissioned a literature survey on latex allergy based mainly on studies on healthcare workers in North America and Europe (8). The report concludes that non-allergic skin irritation is the most common adverse health effect associated with the use of protective gloves among health care workers, followed by Type IV skin sensitisation reactions, with Type I allergic reactions being least common.

Many of the factors thought to influence skin irritation, in particular occlusion and trapping of chemicals present on the hands prior to donning, will be similar for al types of gloves. Limited evidence from a single study suggests that powdered NRL gloves may have a greater potential for causing skin irritation than powder-free NRL gloves (8). The review also concludes that all types of non-NRL gloves are likely to present a lower risk to Type IV skin sensitisation reaction than NRL gloves. Whether or not this is due to differences in the amounts or types of chemicals used in NRL and non-NRL glove manufacture is not known. For Type I protein allergic reactions, the risk is substantially lower with powder-free NRL gloves compared to powdered NRL gloves. However, the review concludes that there is insufficient evidence that exclusive use of powder-free NRL gloves will completely eliminate the risk of developing Type I allergic conditions.

Extractable Protein Levels

The cause of Type I latex protein sensitisation among certain NRL glove users is the high protein/allergen content of early generation powdered NRL gloves, which could exceed 1000 ug/dm2. Most manufacturers of NRL gloves have taken steps to lower the protein level by leaching, chlorination or through enzyme treatment. The new generation of latex gloves have low extractable protein content, and some can better the detectable limit of 50 ug/dm2 (ASTM recommends 200 ug/dm2) (9). Changing to low-protein NRL gloves that are low-powder or powder-free can significantly reduce the incidence of latex protein sensitivity among hospital workers.

Hospital studies show that latex-sensitive individuals wearing synthetic gloves can work alongside colleagues wearing improved NRL gloves without suffering any ill effects. Tarlo et al reported that switching to low-protein low-powder NRL gloves over a period of three years dramatically reduced the incidence of latex protein allergic reactions in employees at an Ontario teaching hospital from 45 to 1 (10). Two of the three nurses who had to stop work due to latex protein allergy were able to return to work alongside co-workers who wore low-protein low-powder NRL gloves. Allmers et al also reported that replacing powdered NRL gloves with powder-free NRL gloves reduced air-borne latex allergen loads to below detectable levels, and permitted sensitised personnel to remain on the job in a Munich hospital (11,

12). After switching to low-allergen NRL gloves, Mayo Clinic in the US reported a drop in the number of new-onset cases among some 12,000 workers who regularly used gloves from 0.15% to 0.027% in one year (13).

Saary et al, in a cross-sectional study at a dental school, found a significantly lower incidence of glove-related allergic symptoms among students after high-protein powdered NRL gloves were changed to low-protein powder-free NRL gloves (14). There was also an absence of skin test reactivity in the student group tested five years earlier. Ranta and Ownby recently reported that individuals with either IgE-mediated or cell-mediated hypersensitivity to latex should be able to continue working in a healthcare environment by suitable exposure reduction (15). The study suggests that the use of low-allergen non-powdered NRL gloves substantially reduces exposure to latex in most healthcare settings.

Powdered and powder-free NRL gloves

USP-absorbable dusting powder of modified cornstarch has been used extensively to reduce the inherent tack of natural rubber and to ease the donning of gloves. The powder has been implicated as an aeroallergen as it has a propensity to bind extractable proteins from NRL gloves (5). Earlier powdered gloves not only had high protein and powder content. Recent studies have shown that improved manufacturing techniques can minimise protein uptake by the powder, thus vastly reducing the aeroallergenic potential of powdered gloves (16, 17), and low-protein powdered gloves can cause low allergenicity or none at all to NRL-sensitive individuals (16, 18).

Donning of NRL gloves can also be eased by lightly chlorinating and/or polymer-coating the glove surfaces instead of using cornstarch powder. A recent survey of polymer-coated NRL powder-free gloves showed they generally met the ASTM, Standard Malaysian Glove (SMG) and FDA requirements for tensile strength and residual power limits (19). Most contained less than 50 ug/dm2 extractable protein, and all had antigenic protein content below the ASTM recommended limit of 10 ug/dm2.

The SMG certification programme, administered by the Rubber Research Institute of Malaysia, ensures that participating manufacturers consistently produce gloves that meet requirements regarding physical properties, pin holes, and contents of powder and extractable protein (20, 21). Certified producers also must possess an internationally recognised quality management system such as ISO 9000. The upper limits for extractable protein for SMG-certified powdered and powder-free gloves are 200 ug/m2 and 50 ug/m2 respectively following a stringent Inspection Level and Accepted Quality Level (AQL). Not a single glove out of 13 test samples is allowed to exceed the set limits for protein and powder content.

The SMG certification programme does not specify the method for producing powder-free gloves. Manufacturers can adopt either the lightly surfaced chlorinating or polymer coating process. An estimated 10% of powder-free gloves produced in Malaysia are polymer-coated, and this figure is expected to grow in the coming years (22). The recent FDA proposal to impose expiration data could create a problem for powder-free gloves produced by chlorination, as they have poor thermal ageing properties.

The majority of NRL gloves used are still of the powdered kind, but the trend is towards powder-free gloves both in the US and EU countries. In 1997, 65% of the NRL gloves imported by the US from Malaysia were powdered, but in 1998 the figure had declined to 50% (23). In 2000, 60% of examination gloves and 28% of surgical gloves for the hospital and alternative care market were powder-free (24). About 20% of the total disposable gloves used in the US are of synthetic materials (mainly vinyl or PVC). In the UK and Germany, the shift is from powdered to powder-free NRL gloves with low extractable protein. In the surgical area, while there have been inroads by nitrile, polyurethane and neoprene gloves, the use of powder-free low-protein NRL gloves has remained largely unaffected. In the UK, the NHS ceased purchasing powdered latex examination gloves from 2001, and 97% of surgical gloves are NRL, while 81% of total demand for examination gloves is still for low-protein powder-free NRL gloves.

Barrier protection

NRL is the material of choice for medical gloves due to its superior barrier protection, strength and durability, puncture resistance, fit and comfort, and high elasticity. A small proportion of people may be sensitive to animal and plant proteins (including those in latex), and they are advised to use synthetic gloves -- made of neoprene, nitrile, polyurethane, polyisoprene, vinyl (PVC) or a variety of copolymers. Not all synthetic gloves, though, provide adequate barrier protection.

Although viral barrier protection is the most important function of medical gloves, the FDA does not require manufacturers to test the efficacy of gloves against viral protection. Various studies (25-33) have compared gloves for barrier resistance, typically using a standard test procedure -- the ASTM F1671 (34) -– and the water leak test. These studies show that NRL gloves consistently provide more effective barrier protection for healthcare workers than vinyl gloves, which are dogged by high leakage rates. Korniewicz et al observed that vinyl gloves were 13 times more likely to leak than NRL gloves (26). A later study showed that the failure in barrier performance during use can be as high as 50-60% for vinyl gloves, compared to only 0-4% for NRL gloves (27). A more recent study by Korniewicz, on surgical gloves collected from operating staff directly involved in the surgery, showed higher defect rates of 7.4% and 9.3% for neoprene and nitrile respectively compared to 5.6% for NRL gloves (28). Similarly high leakage rates are also reported for polyethylene gloves (29). But while nitrile gloves have better barrier performance than vinyl or co-polymer ones, their barrier integrity (as well as that of vinyl gloves) is adversely affected by contact with an alcohol-based disinfectant (35).

When needle punctures occur – which are frequent during many surgical procedures – vinyl and nitrile gloves are likewise shown to be less effective than latex ones at protecting workers against the risk of infection (36, 37). Hasma and Othman compared the leakage rates of a solution containing Phi-X174 viruses through vinyl, nitrile and NRL gloves (powdered and non-powdered). Vinyl gloves exhibited failure (leakage) rates of 78% after puncture with 0.22mm-diameter needles and 100% after puncture with all needles of >0.3mm diameter, while nitrile gloves showed failure rates of 53% after puncture with 0.22mm-diameter needles and 100% after puncture with all needles of >4mm diameter (36). In contrast, NRL gloves registered zero failure after needle puncturing with holes of 0.22mm or 0.25mm diameter, and less than 20% leaked after puncture with needles of 0.3mm and 0.35mm diameter. Punctures with 0.45mm-diameter needles resulted in >2500 uL of virus suspension

penetrating through vinyl and nitrile gloves, compared to <25 uL for NRL gloves. These findings indicate the resealing property of NRL gloves and underscore their superiority over vinyl and nitrile ones at providing effective barrier protection for glove users. NRL gloves were also found to be five times more tear-resistant than either vinyl or nitrile gloves.

In the US, both the National Institute for Occupational Safety and Health (4) and OSHA (38) have highlighted latex allergy as a hazard to workers while advising the use of low-protein powder-free NRL gloves for barrier protection against infectious materials. It is only when workers are not in contact with infectious materials that NIOSH and OSHA have recommended non-latex gloves -- in food preparation, gardening, housekeeping and the like.

Proper glove selection and use can prevent many of the infections that strike an estimated two million patients each year and result in some 80,000 deaths worldwide.

Environmental and economic factors

Materials for synthetic and vinyl gloves are derived from petroleum and are not biodegradable. Disposing of vinyl/PVC products by incineration releases harmful chemicals such as dioxin, which is classified by the World Health Organisation and the US Environmental Protection Agency as a potential human carcinogen. Incineration of nitrile and neoprene gloves can lead to the release of hazardous chemicals such as cyanide and hydrogen chloride respectively (39). Acetonitrile, a product of incomplete combustion of nitrile compounds, can enter the bloodstream through inhalation and the skin. In the blood, acetonitrile metabolises into cyanide, which in turn metabolises into thiocyanate. Cyanide gas, which is produced from the burning of plastics or polyurethane, can cause early death following smoke inhalation. A cyanide serum level of 1-3 mg/L is considered lethal.

NRL, by contrast, is an environmentally friendly material – it is derived entirely from naturally renewable resources and is fully biodegradable. After 12 months of soil burial, the mass loss for NRL gloves is 58% compared to 97% for synthetic gloves (40).

Finally, disposable NRL and vinyl medical gloves are generally more affordable compared to nitrile, polyurethane and other synthetic gloves. When selecting gloves for hand protection, though, the primary consideration should be their barrier performance. Value for money would be a bonus.

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