

Recent Changes In Natural Rubber Latex Medical Gloves And Comparison With Synthetic Materials

Background

Medical gloves are worn by the healthcare community in order to provide a barrier to prevent transmission of microorganism to and from patients. Natural rubber latex (NRL) has been used as the material for gloves for many years. Through the 1990s the use of NRL gloves increased dramatically due to concerns about various transmittable diseases. This increased use coincided with increasing numbers of reports of rising prevalence of allergic reactions to NRL gloves among healthcare workers. In addition to scientific papers on the topic, this negative aspect of NRL gloves

gained substantial media coverage. As a reaction to this and to compensation claims, some hospitals tried to introduce a policy of non-use of NRL gloves and only using gloves made from synthetic materials. However, in many cases this occurred without full consideration of all of the factors involved, such as glove functionality and costs, both directly and on the environment. Furthermore, following recognition of the problem of latex sensitivity, changes had been made in the production process for NRL gloves and in implementation of latex-sensitivity protocols. In particular, non-powdered

gloves were introduced and these changes have, in recent years, resulted in greatly reduced prevalence rates of allergic reactions.

Three types of reactions to NRL have been described: irritant contact dermatitis which is not mediated by the immune system, type I allergic reactions involving IgE antibodies and type IV allergic reactions due to chemical irritants¹. Irritant dermatitis and type IV allergy can occur with gloves made from any material and specific reactions to NRL are type I allergy.

Prevalence of Natural Rubber Latex (NRL) Allergy

Type I NRL Allergy

In studies conducted on healthcare workers during the late 1990s the incidence of NRL allergy was reported to be around 20%^{2,4} or even higher in some reports in the USA⁵. However, in many cases reported as NRL allergy the symptoms have been more specifically irritant contact dermatitis or a type IV reaction to chemical irritants. The gold standard for defining type I NRL allergy is considered to be skin prick testing and prevalence using this test tends to be much lower than for contact dermatitis⁶.

Epidemiological studies carried out at the time of the peak of reporting could not equate the apparent sensitization of healthcare workers to duration of exposure or use of NRL versus non-NRL gloves⁷. While other studies did show a relationship to exposure, prevalence of type I allergy was often only around 1.5%, even among workers producing the latex and the gloves^{8,9}. In addition, since 2001/2002 there have been strict policies of use of powder-free NRL gloves in many hospitals and in some countries

(Finland, Germany, UK). This has stopped the development of new cases of sensitization and has greatly reduced the reported prevalence of type I allergies¹⁰⁻¹⁴. In hospitals with a strict policy, the prevalence of type I latex allergy in healthcare workers has been reported to be less than 1%^{15,16}.

Skin irritation and irritant contact dermatitis, which do not involve an immune reaction, are frequently confused with specific NRL allergy

KEY POINT

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Use of powder-free, low-allergen gloves has greatly reduced the prevalence of NRL allergy among health care workers

With regards to the prevalence of latex allergy in the general population, few studies have been carried out. The results from control groups examined as comparators have indicated the prevalence of type I NRL allergy in Western Europe to be approximately 1%^{13,17,18}. Thus, the reported prevalence is now very similar to that reported for health care workers⁷. It should be noted, however, that the prevalence in the general population is higher in certain groups of people, specifically those who

are known to be atopic and those who have received multiple operations with implants of latex-containing materials, such as children with spina bifida or short bowel syndrome^{17,19,20}. Individuals who are highly allergic to certain fruits, such as kiwi fruit, bananas and avocados, are known to be more likely to have NRL allergy^{17,21}. By questioning patients with regard to specific allergies and medical history, those who are likely to have a type I allergy to NRL can be screened and appropriate measure taken.

In some studies, the allergenic potential of gloves has been classified according to the total protein content²². However, this is a non-specific determination and specific antigens of the class of proteins known as

heveins, have been identified in NRL^{23,24}. The allergens hevein b 1, b 3, b 5 and b 6.02 appear to be the main agents that can cause type I allergy. Using specific assays for these allergens a cut-off level for the sum of the allergens can be determined for NRL gloves. Gloves that have levels below that cut-off are considered as low allergenic potential²³. A new test, the FITkit[®] test (Quattromed Ltd), is an immunological assay being developed to determine clinically relevant levels of these specific allergens in NRL products. While initial results show strong correlation with currently available methods for measuring allergenic potential, the test is only available for research at present and not yet for diagnostic testing.

The FITkit[®] test is being developed to determine the levels of the specific hevein antigens that determine allergenic potential of NRL products

KEY POINT

Effect of post processing on allergen content

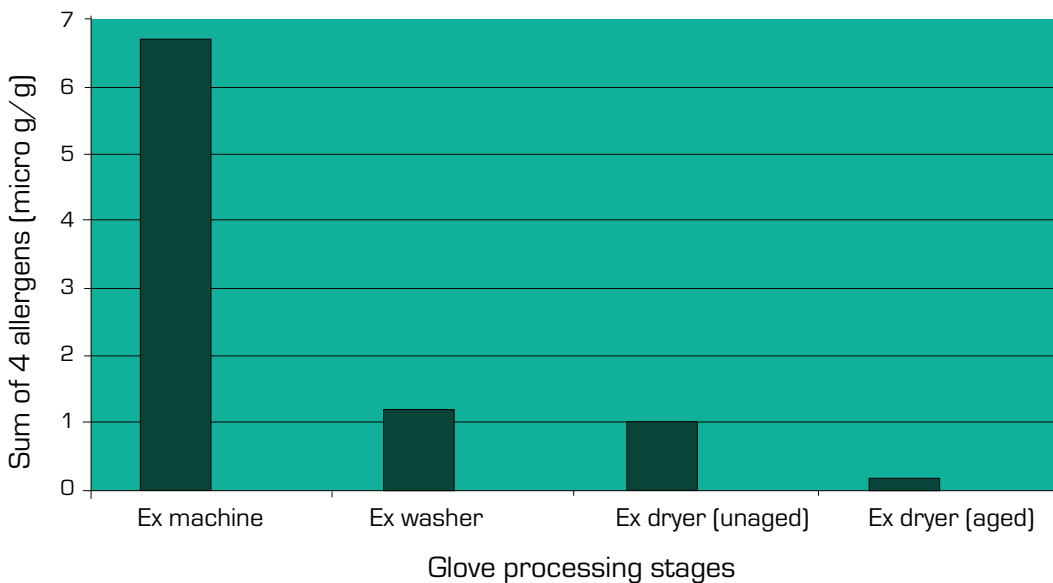


Chart 1

KEY POINT

Gloves containing casein should be avoided to reduce the risk of an allergic reaction to the casein

It should also be noted that some gloves use casein as a binding agent in the jellification of latex. Allergic reactions to gloves containing casein have been noted and so these gloves should be avoided to reduce the likelihood of allergies^{25,26}.

Using current NRL glove manufacturing processes with on-line leaching and high temperature post-washing procedures the allergen content is greatly reduced at each stage as shown in figure 1. Development of these processes has resulted in the very low prevalence of type 1 allergy currently reported^{15,16}.

Strict policies on latex safety within hospitals results in very low prevalence rates for NRL allergy

KEY POINT

Type IV Chemical Allergies

In addition to type I allergies to NRL proteins, type IV allergies to chemicals used in the manufacturing process, such as vulcanization agents, must be considered. Skin patch testing will demonstrate a response to both specific allergens and the chemicals present and so will be a combination of both type I reactions and type IV reactions. Several surveys have highlighted a high prevalence rate in healthcare workers, which can sometimes be greater than

NRL protein type I allergies²⁷⁻²⁹. In a study in Italy, skin symptoms were noted 316 of 1294 healthcare workers questioned. Among those with skin symptoms, 27 had a type I allergy to NRL and 31 had a type IV reaction²⁸. The overall prevalence of type IV reaction to NRL in 2738 patients was found to be 1%³⁰. Similar to type I allergy, prevalence was greater in patients reported to be atopic and in those with eczema.

There have not been any studies examining prevalence of type IV reactions over time. However, similar to the reductions in type I allergies with the changing processes of NRL glove manufacture, there has been a reduction in chemicals that can cause type IV reactions. It should also be noted that synthetic gloves may require chemical accelerators in the manufacturing process and the levels of chemicals in some synthetic gloves may also induce type IV reactions³¹.

Other Factors Influencing Choice of Glove Type

Barrier Integrity

The primary function of a glove is to provide an excellent two-way barrier protection against infections for both healthcare professionals and the patients. Studies have been carried out to examine durability of the barrier. The performance of NRL and non-latex surgical gloves were compared in a simulated stress protocol³². Non-latex neoprene and nitrile gloves were comparable to latex and were suggested to provide a good alternative to NRL gloves for allergic patients and health care workers; however, isoprene was found to be inferior to latex and other non latex materials. In an abrasion test study, NRL gloves were found to be better than

vinyl but not as good as nitrile or neoprene³³. However, leak and viral penetration tests after 10 months at 40°C were the same for NRL gloves compared with nitrile and neoprene. Other studies have also shown NRL gloves to provide lower rates of perforation and lower viral leakage rates than vinyl gloves¹⁴.

Environmental and Economic Costs

NRL is a sustainable and renewable resource and rubber trees are reported to remove 363 million kg of carbon dioxide from the atmosphere each year³⁴. In contrast to NRL, the raw materials for

synthetic gloves are derived from oil chemistry. These materials are not a renewable source and the costs are rising rapidly over time. In the production process for the raw materials, it requires only 16 GJ/ton in the case of NRL but estimated energy consumption ranges from 108 to 174 GJ/ton for the synthetic materials³⁵. In addition, rubber and rubber products are biodegradable, by a combination of chemical and biological attack and a number of micro-organisms are able to degrade NRL gloves³⁶. Furthermore, if NRL gloves are incinerated they do not produce toxic emissions, unlike synthetic gloves^{14,37}.

Conclusion

Increased use of latex medical gloves through the 1990s coincided with increased reporting of allergic reactions. Although many reports related to contact irritation, frequently confused with an immune response, recognition of the problem resulted in changes in production processes and protocols to minimise latex sensitivity. Reported prevalence of type I allergic reactions to NRL gloves has fallen greatly in recent years and is now considered to be less than 1% among healthcare workers, not

very different from reported prevalence in the general population. Prevalence is higher in certain groups such as those who have had multiple childhood exposures and in individuals with allergies to certain fruits. Thus, type I reactions in healthcare workers and patients can be partly anticipated by appropriate questioning. Specific heveins have been identified as allergens in NRL and tests show very low levels in modern gloves. Other allergens are chemicals used in glove manufacture, which cause type IV

allergy; such reactions can also occur with synthetic gloves and in all cases levels of chemicals are being reduced. Barrier integrity of NRL gloves is at least as good as most synthetic types and latex is a natural product from a renewable source, thus making it environmentally better than synthetic materials. Therefore, latex remains a good material for glove manufacture and should continue to be used.

Latex remains a good material for glove manufacture

KEY POINT

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