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INFORMS

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Tolerability of Medical Gloves from a Contemporary Perspective

Skin irritations, latex allergies, allergic contact eczemas: What progress has been made in reducing these potential risks for the health professions? How common are glove reactions in the medical sector today? – Sempermed informs about the latest findings and developments.

Altogether, occupational skin disorders rank first among all occupational diseases with a prevalence of about 27% (respiratory disorders rank third), whereby the health sector is affected most with almost half the cases. More than 90% of the occupational dermatoses are eczemas, especially on the hands. [1]

Skin Irritations

Irritant hand eczemas are local skin irritations caused by cleaning agents, frequent hand washing, inadequate hand drying, aggressive hand disinfection methods, glove powder, and the occlusive effect when wearing gloves. In the health sector, such hand eczemas are widespread with a prevalence of 23-44%, whereby the surgical and internal medicine areas are most commonly affected [2,3]. In the nursing profession, the prevalence is 17-30% [4].

Significantly, skin irritations can promote the development of contact and latex allergies. Therefore consistent hand care is imperative, and the use of powder-free gloves can make a major contribution towards the prevention of allergies, because glove powder not only has a frictional effect - powdered gloves almost always have an alkaline pH value [5]. This can damage the skin's acid protection layer, and damaged skin is an open door for allergens. According to one study, about every fourth individual with hand eczema developed an allergy, whilst this is only the case in 1% of individuals without hand eczema [6].

What substances can cause glove reactions?

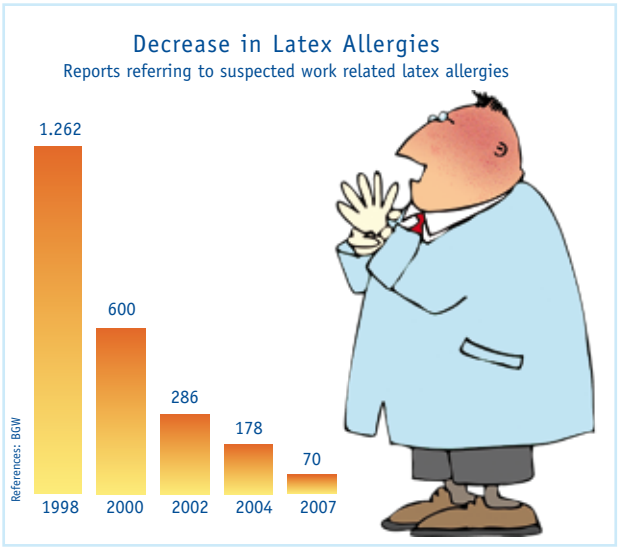
Regardless of the source material (natural latex, synthetic latex), various additives are required in the production of medical gloves, e.g. wetting agents (sulphur), vulcanisation accelerators, zinc oxide (activator for accelerators), antioxidants, anti-aging agents, surface treatment products. The type and quantity of chemicals added have a significant influence on the glove properties and quality, but also on their allergy potential. The residues of accelerators, for example, are often quite generally condemned as being the main causes of glove-related contact allergies, but there are big differences between the individual substance classes and between the so-called "older" and "newer molecules".

Latex Allergies (Type I)

The IgE-mediated, so-called immediate-type allergy against latex proteins is primarily caused by inhalation (of airborne powder particles bearing allergens). According to studies, latex sensitisation in the health sector is found mainly in places where airborne latex allergens are also detectable [7]. The bad thing about type I allergy is that it can cause life-threatening anaphylactic shock under certain circumstances. Moreover, people with latex allergy have to look out for cross-allergies (especially exotic fruits).

Prevalence in health professions

About 80% of individuals with latex allergy work in the medical professions, because a great number of articles containing latex are used in this sector [1]. In the mid-1980s the incidence of latex allergies in the medical sector increased rapidly due to increased use of gloves as a protection against AIDS and hepatitis. It peaked at the end of the 1990s with a rate of about 17%, and has been decreasing again since the turn of the millennium. In 2007 only 5% of the number of cases reported in 1998 were recorded by the statutory accident insurance agency in Germany (BGW) (cf. Fig.), which means a decrease by almost 95% within these 9 years, for example [8]. Currently it may be assumed that in the industrialised nations about every 10th person employed in the health sector is affected by latex allergy [7].



Developments: Away from powdered latex gloves to synthetic latex

The decreasing prevalence of latex allergies in the industrialised nations is due to the fact that strict guidelines for the use of powder-free, low-allergen natural latex or synthetic gloves were introduced in many hospitals around the millennium. Whereby a risk minimisation recommendation by the Landesamt für Arbeitsschutz, Gesundheitsschutz und technische Sicherheit [Land Office for Work Protection, Health Protection and Engineering Safety] in Germany defines low-allergen as having a latex protein concentration of <30 µg/g glove material and "powder-free" as having a powder content of < 2mg [9]. Aerogenic allergen contact with latex proteins is now also regulated by occupational safety law: The ambient air at the workplace must contain < 0.5 ng allergens/m³ [1].

Compliance with these measures and the two developments "away from powder" and "to synthetic latex" are also confirmed by the current sales figures for Germany: The market share for powdered gloves is now lower than 1%, whilst synthetic gloves are recording high growth rates.

Prevention

Avoiding powdered latex gloves has just recently been confirmed as the most important measure to prevent latex-mediated skin and respiratory tract allergies in health sector employees by a new study [10]: Ability to work, quality of life, allergen avoidance and symptoms have improved significantly in most of the individuals concerned in the last 7 years. 77% of individuals suffering from skin allergy and 68% of individuals suffering from respiratory tract allergy did not have any symptoms any more, and in the other individuals affects the symptom severity had decreased from 8.5 to 2.3 (scale from 0-10). The reason for the persisting symptoms is the fact that 85% were able to avoid latex contact in their private lives, but only 61% were able to avoid it successfully at work. Prior to introduction of the preventive measure, every tenth individual had to give up his profession due to latex allergy.

A similar study in the USA showed comparably good results through latex avoidance [11]: Occupational skin or respiratory symptoms could be eliminated in 90% of all latex allergy sufferers when the staff switched to low-protein, powder-free latex gloves.

Contact Allergies (Type IV)

The t-cell-mediated, so-called late-type allergy can have numerous causes, with an existing irritant hand eczema being a predisposing factor. Altogether, more than 2,800 substances are considered to be contact sensitisers, including soaps, cleaning agents and disinfectants [12]. Usually there is polysensitisation to various chemicals. 12-31% of people employed in the health sector suffer from allergic contact eczemas [13,3]. Glove-related contact allergies are triggered

mainly by chemical residues from the production process, about 80% thereof by traditional vulcanisation accelerators (e.g. thiurames, benzothiazoles, thioureas, carbamates, guanidines), but also by antioxidants (e.g. aromatic amines, phenols), softeners (e.g. phthalates), colour additives and anti-aging agents (e.g. p-phenylene diamines) [14,1]. Altogether, rubber chemical allergies account for 2% of all allergic contact eczemas [1]. The allergy potential of a chemical depends on the substance and the concentration released on the glove surface. In investigations of the chemical residues in glove extracts, 10-fold differences were measured between various manufacturers (levels of 2-15 µmol/g glove material), and powdered gloves contained significantly more chemical residues [15,16].

Technical Advances

In recent years, both the latex protein content and the chemical residues have been reduced significantly through new engineering methods in glove production. Low-allergen natural latex gloves with <10 µg protein/g (Lowry test as set out in EN 455-3) and thiurame-free gloves with low carbamate content are already available today (e.g. the new Sempermed Supreme +). New patents for linings and surface treatment methods allow powder to be wholly dispensed with. Moreover, new vulcanisation accelerators have been developed that are significantly more tolerable and do not have any residues that are difficult to release (e.g. DIXP, ZDNC – see p. 4).

Improvements have also been made to the glove materials – some of the modern synthetic latexes already have the same popular properties as natural latex, but they are free from proteins of course (e.g. the new Sempermed Syntegra IR of synthetic polyisoprene). All in all, a greater range and quality of medical gloves is available to the user today, offering a differentiated choice and better tolerability even for modern clinical demands and surgical techniques.

COMPARISON OF MATERIALS	Natural latex (NRL)	Polyisoprene (IR)	Chloroprene (CR)	Nitrile (NBR)	Vinyl (PVC)
Properties					
Comfort	+++	+++	++	++	+
Mechanical strength:					
Tear resistance	++	++	+	++	–
Perforation resistance	+	+	+	++	–
Migration	++	++	++	++	–
Skin friendliness:					
Proteins	yes	no	no	no	no
Accelerators	yes	yes	yes/no	yes	no
Environmentally friendly disposal	++	++	+	+	+
Price	++	–	–	+	+++
Use					
for surgical gloves	•	•	•	–	–
for examination gloves	•	–	•	•	•

New accelerators: Effective and safe

Many traditional vulcanisation accelerators of the thiurame, carbamate and thiazol group have been identified as potent contact sensitisers. Some of them have also been classified as harmful to health and the environment, or as producers of carcinogenic nitrosamines (nitrogen compounds that cause cancer). The identification of these risks has resulted in thiurames, for example, no longer being used in quality gloves, and new accelerators being developed that are significantly safer.

One of the best examples of this is the new accelerator system used for production of the Sempermed Syntegra IR in Austria. A synergistic combination of the two modern accelerators DIXP and ZDNC (diisopropyl xanthogen polysulphide and zinc diisononyl dithiocarbamate), which have been investigated intensively and offer a number of benefits. The environmentally friendly system is highly effective and improves the properties of the vulcanised material. The synergy of the two multi-functional accelerators results in a skin-tolerable product. Hardly any other accelerator on the market today has as much safety data as DIXP and ZDNC [17].

The multi-talents DIXP and ZDNC

The polyxanthogenate DIXP as a very fast-acting accelerator shortens the vulcanisation time, and as a sulphur donor it enables smaller quantities of sulphur to be used. DIXP is readily soluble in rubber and volatilises completely during the vulcanisation process, so that there are verifiably practically no residues in the glove and the risk of allergy is therefore excluded. [17,18,19,20]

The special zinc dithiocarbamate ZDNC is extremely effective as an accelerator and it also provides a high level of aging protection. The zinc contained in ZDNC is important for its solubility in rubber, allows the addition of less zinc oxide, supports sulphur binding, and lends the glove more tensile strength. Compared with other dithiocarbamates, ZDNC is longer-chained and therefore more readily soluble in rubber and hardly extractable – i.e. possible residues can hardly migrate from the glove, if at all, thus reducing the allergy risk to a minimum. In the contact migration test ZDNC was below the detection limit, and in clinical allergy studies no skin reactions could be observed either. [17,18,19, 21]

The latex- and powder-free surgical glove Sempermed Syntegra IR thus has virtually no allergenic potential at all, and maximum skin friendliness, comfort and safety are achieved.

What happens in the vulcanisation process?

Vulcanisation is the most important step in the rubber manufacturing process, and neither natural nor synthetic latex would be elastic without it. Thereby the long rubber molecule chains that lying next to each other are cross-linked under the influence of heat and with the help of sulphur. The number of sulphur bridges (linking density) depends on the sulphur quantity and vulcanisation time, and it is decisive for a high degree of elasticity and dimensional stability of the glove material. Accelerators function as catalysers for this cross-linking process: They increase the speed and efficiency of the net structure, and they improve the elasticity, resistance and durability of the gloves.

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