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Health Considerations of Synthetic Alternatives to Natural Rubber Latex

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Considerable criticism has been made against the use of natural rubber latex for the manufacture of elastic medical goods due to allergic reactions that can be caused. An analysis of published data reveals that the proportion of the population affected by latex proteins is small, and that the effects are usually not serious. Consideration of the four main groups of alternative materials, namely PVC, polyurethane, nitrile and neoprene, and styrene copolymers concludes that the inferior performance of these materials can lead to increased health and safety risks, and that they have also been known to cause toxic and allergic effects.

The latex protein allergy problem has received a great deal of attention during the past few years. It is now well established that extractable proteins from some latex products can trigger allergic reactions to sensitive individuals. To those deeply involved in the natural rubber latex industry, this problem could appear to be at best a cause for concern, and at worst a cause for panic. At this time it may be worthwhile to take a step back and consider how serious the threat to the latex industry really is.

How Serious is the Problem?

The first point that needs to be made is that allergic reactions are very common, particularly amongst European and North American populations. This fact may not be appreciated by people in parts of the world where allergies are less common. The list of substances or materials that have been shown to illicit allergic reactions is almost endless, and certainly too long to present here. Most cases of allergic reaction result only in localised skin conditions and are considered a source of discomfort rather than a serious medical problem. However, even the Type I reactions, which are considered to be the most severe type of allergic response have been shown to be caused by a wide range of substances, including potato[1], fruit and vegetables[2], eggs[3], fish, nuts, silk[4], teak (wood)[5], insect repellant[6] and cephalosporins[7]. Most of these substances, but by no means all, are derived from living matter and therefore contain proteins. In this context, it should have come as no surprise that natural rubber, which is also derived from a living organism, causes allergic responses in certain individuals. The surprise is perhaps that it was so long before any significant numbers of reactions were reported.

The incidence of latex protein allergy is difficult to ascertain from the literature. One analysis of a large random sample in Finland indicated a general prevalence of between 0.04% and 0.12% for latex protein allergy[8]. This figure can increase to as much as 10% for the so-called high risk groups such as healthcare workers[9,10] and atopic individuals[11], but even in these groups it is still very much the minority that is affected. Spina bifida sufferers, who are particularly susceptible to the allergy must be considered a special case. Amongst those individuals that are affected, by far the most common symptom of the allergy

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is urticaria or nettle rash. It appears that only about 10% of latex allergy sufferers exhibit the more worrying symptoms of anaphylaxis[8].

Anaphylaxis is invariably described in the non-medical literature, and sometimes in the medical literature, as 'life-threatening'. A rational study of the data, however, reveals that the threat to life may not be as great as some people seem to think. For example, not a single fatality has been reported anywhere in the world due to anaphylactic shock caused by latex gloves. This is in spite of an annual consumption in the United States alone of about 8 billion pieces per year, equivalent to 30 gloves for every man, woman and child. So whilst anaphylaxis is not a condition to be taken lightly, it would appear that established medical treatment, such as administration of adrenalin, is sufficient to overcome the problem. Even where anaphylaxis has occurred outside a hospital or medical environment, patients have recovered with no long-term ill effects[12]. In fact the only fatalities ever to be linked to latex protein allergy were caused by a single supply of barium enema catheters. In this case it would appear that poor manufacturing practice, contact of the article with a particularly receptive part of the body, and lack of awareness of a potential problem by medical staff, combined to cause the tragic loss of life of a number of patients[13]. This unfortunate combination of circumstances does not appear to have been repeated elsewhere. In view of the isolated nature of these deaths, and the fact that latex products are used so extensively in the medical environment, the threat to life from latex products can only be described as minimal. Patients undergoing surgery or other medical procedures are subjected to much more significant risks. For example, the probability of an allergic reaction to anaesthetic is three times greater than that of a reaction to latex.

Although the threat to life from latex medical products may be extremely small, the other symptoms, such as urticaria, conjunctivitis and rhinitis are unpleasant and need to be avoided as far as possible. Those individuals who are known to suffer from latex allergy should avoid latex products, just as someone who is allergic to fish avoids fish and one who is allergic to silk does not buy silk dresses. The question with regard to medical products is what are the alternatives? One alternative could be not to use rubber articles at all, but even the fiercest critic of natural rubber would concede that rubber gloves and other medical devices have prevented more illness and suffering than they have caused. The question then becomes what are the alternative rubber materials available and how do they compare to natural latex rubber?

Alternative Rubber Materials

A wide variety of elastomeric materials is now available to product manufacturers, ranging from synthetic 'imitations' of natural rubber to thermoplastic rubbers and plasticised PVC. Many of these are available in latex form and others can be used in solution. In spite of this, natural rubber latex accounts for more than 99% of surgical gloves, 85% of examination gloves and also dominates in other medical devices. The reason is not primarily cost, or some kind of affection for the traditional material, but simply that natural rubber is the best material for the job. Its combination of high strength with high elasticity and softness gives it ideal properties for many medical products. Another important feature is the excellent film-forming properties of natural latex which allows thin films to be formed free of holes.

Any consideration of safety of elastomers for medical products must take into account the performance of the material as well as its

inherent toxicological properties. For example, a comparison of natural rubber and silicone baby feeding teats should consider the fact that silicone teats can be bitten off, due to their inferior tear and tensile strengths, and this has led to a number of babies chocking. So although natural rubber teats present a potential allergy hazard (no cases of protein allergy from rubber teats has been reported) this is probably outweighed by the chocking hazard of silicone teats.

The alternatives to natural rubber latex for medical product manufacture will now be considered individually.

Plasticised Poly(vinyl chloride)

This material, also known as PVC or vinyl is used to make medical examination gloves. The polymer PVC is itself not rubbery, but rigid. The flexibility is imparted by the plasticiser which becomes an integral part of the material. Vinyl gloves account for about 14% of the market in the United States, but their main attraction appears to be cost. Vinyl gloves have tensile strengths only about half that of typical latex gloves and the elongation at break is also substantially lower. This means that the chance of perforating a vinyl glove is considerably greater than with a comparable latex glove. It is also less comfortable to wear and dexterity can be impaired.

There are numerous health hazards associated with PVC. The monomer from which it is made, vinyl chloride, is a human carcinogen. Following a precedent set by several countries, the European Community has recently issued a directive limiting exposure to vinyl chloride of 3 p.p.m. Although vinyl products do not contain the free monomer, hazards exist during the manufacturing stages of the product and in disposal. The only safe method for disposing of used medical devices is burning or incineration and this would certainly cause the release of vinyl chloride from PVC products. Furthermore, due to the nature of the polymer, the overall level of chemical additives which are a potential source of hazard, particularly plasticiser, is much higher than in latex gloves. These problems of vinyl chloride and high plasticiser levels are inherent to the material and cannot be overcome by changes in processing. They have led Greenpeace to describe PVC as 'an environmental poison', a claim which was upheld by the Vienna High Court when challenged by manufacturers[14].

In addition to toxicity and environmental deficiencies, vinyl materials are not free from allergy problems. One study reported five cases of allergic eczema from PVC gloves[15] and anotherreported an urticarial reaction to PVC in household items[16]. In both cases the cause of the allergy was put down to additives in the PVC. In another case, an allergic reaction to a PVC identity band was attributed to the plasticiser di-ascetical phthalate[17].

Polyurethanes

Polyurethanes are a particular group of thermoplastic rubbers made from isocyanates with other components. They are used in some medical devices and have been suggested as a more general alternative for latex. Polyurethane can have very high tensile strength, higher than latex rubber, but its modulus is also high and it has lower elongation at break. These last two properties tend to make polyurethane gloves uncomfortable to wear. Polyurethane is also considerably more expensive than any of the other materials considered here.

Like PVC, polyurethane is constructed from inherently toxic substances, namely isocyanates. This presents dangers during manufacture and disposal. Many incidents of workers in polyurethane factories suffering

from toxic and allergic effects are known. Burning polyurethane can also release cyanide which is even more toxic than isocyanates.

In order to ascertain the likelihood of polyurethane medical devices causing allergic-type reactions one has to look at the experience with polyurethane-coated breast implants. This is probably the most significant application of polyurethane materials in the medical contact field. Many cases of complications arising after implantation of these prostheses have been reported[18,19]. In one report, complications were observed in seven out of 54 patients, ranging from an itching rash of the chest to persistent pain and temperature, necessitating removal of the implant.

There are also reports of allergic reactions to polyurethane elastic thread, which is already widely used. These effects have usually been traced to additives such as a light stabiliser[20]. In one case of contact dermatitis from a polyurethane watch strap, the polymer itself was found to be the cause of the problem[21]. More precisely, it was postulated that sweat-induced hydrolysis of a polyurethane component released the allergen diphenylmethane. Clearly, in materials as chemically complex as polyurethanes, the potential for secondary and side-reactions leading to trace amounts of unwanted chemicals will always exist.

Nitrile and Neoprene

Both of these materials are true rubbers and can be processed in their latex forms into medical gloves. They do account for a very small portion of the market. The physical properties of these rubbers when vulcanised are comparable to those of natural rubber but tensile strengths tend to be lower and moduli higher. Nitrile is a copolymer of acrylonitrile, a proven carcinogen, and butadiene which is a suspected human carcinogen. Commercial grades of nitrile do contain acrylonitrile residues in varying concentrations. One manufacturer specifies a maximum concentration of 100 p.p.m., but this should be compared against a TLV (maximum acceptable daily exposure level) of 2 p.p.m. Neoprene is a polymer of chloroprene which is a toxic substance. The TLV for chloroprene is 10 p.p.m. but for some Neoprene latices, the raw material for manufacturing Neoprene gloves, have been reported to contain up to 0.5% (5000 p.p.m). Burning of both Neoprene and nitrile materials is hazardous, with nitrile liberating cyanide and Neoprene evolving hydrogen chloride.

Few reports can be found of allergic reactions to these materials but that must be at least in part due to the fact that they have been little used in medical applications. There has been a case of allergic dermatitis from Neoprene gloves which was attributed to an antioxidant and/or accelerator in the material[22] Also, a more serious, anaphylactoid reaction to Neoprene in the form of a wetsuit has been reported[23]. It was speculated that a non-protein chemical in the wetsuit was responsible. This isolated case may be a freak combination of a particular additive with a particular individual, but it is impossible to assess what the incidence of such occurrences would be if Neoprene materials were used as widely as natural latex in applications involving intimate body contact.

Styrene Copolymers

Styrene-butadiene rubber (SBR), and particularly the carboxylated form of it, is used in large quantitites in the latex state. Its main applications are in the paper coating and carpet backing industries where physical strength of the polymer is not of primary importance. SBR has not been used to any significant extent in medical products because of its inferior

physical properties. Some block copolymers of styrene, however, can meet the physical requirements of medical gloves and have been used to a limited extent in this application. Examples are styrene-butadiene-styrene (SBS), styrene-isoprene-styrene (SIS) and styrene-ethylene-butylene-styrene (SIBS) copolymers which are produced under trade names such as *Kraton, Vector DPG* and *Tactylon*. The nature of these polymers is such that their physical properties depend on exactly how the films are made. Films produced from emulsions generally do not possess adequate properties for medical gloves. High strength products can be made from polymer solutions, but even these tend to have high permanent set which means that their ability to revert to the original shape after repeated stretching is lower than that of a corresponding latex film.

Little is known about the toxicity or allergic effects of styrene block copolymers. The one study which has been carried out found that *Tactylon* gloves produced allergic responses in as many patients as latex rubber gloves did[24]. It could be argued that at least with natural latex the allergy problems are well known and documented. The same cannot be said of these newer materials which are still in a state of evolution, and also vary in composition between different manufacturers.

Whilst little is known about these block copolymers, considerable data has been accumulated on styrene itself and on SBR. Styrene is not a particularly toxic chemical, but several incidents of immediate asthmatic responses to styrene inhalation have been reported[25,26]. These reports provide further proof that hypersensitivity leading to Type I allergic responses can be induced by relatively simple molecules such as monomers, and not only by proteins. Many of the toxicity problems encountered by SBR in carpet backing, for example, have been attributed to styrene and benzene residues producing emissions from the finished product[27]. Whilst more care will almost certainly be taken to minimise residues in materials for medical use, no guarantees on the absence of styrene or other monomer residues can be given.

CONCLUSIONS

The dominant position of natural rubber in the medical glove market means that any ill-effects caused by natural rubber are certain to be more widely experienced and studied than any problems which might exist with other materials.

Alternative materials to natural rubber should be available to people who are sensitive to the latex protein allergy.

For the general population, any possible benefits obtained by changing to other materials would probably be outweighed by the inferior performance of the alternative material.

It is by no means clear that the overall health risks imparted by any of the alternative materials is less than that caused by natural latex. Allergic reactions are a risk to health for which the effects are well known, easily treatable, and are life-threatening in only an extremely small proportion of cases. Health problems caused by other rubber materials include allergic reactions but also include risks of carcinogenesis and acute toxicity for which cures are not so readily available.

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