The Clinical Significance of Hydration in Natural Rubber Latex Gloves

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In Brief

- *Hydration*, the absorption of fluid into the interstitial areas of a glove once it is wetted, adversely affects the clinical performance of natural rubber latex gloves.
- These effects potentially include increased conductivity, changes in tensile and tactile properties, and increased chemical and viral permeability.
- All of our data indicate that significant hydration is an undesirable property, and that gloves that hydrate slowly are clinically superior to gloves that hydrate quickly.

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Summary

Increasing health concerns in the last decade, exemplified by the "Universal Precautions" promulgated by the U.S. Center for Disease Control [6], have resulted in a dramatic increase in the use of natural rubber latex (NRL) surgical and examination gloves. Health concerns have also elevated the importance of these gloves as reliable biological barriers. The risk of disease transmission via blood-borne pathogens has raised the level of concern of both health care providers and patients. One response to this concern has been a dramatic increase in the use of NRL surgical and examination gloves. Although NRL gloves have been routinely used during medical procedures for decades, the physical properties of NRL gloves have only recenting become a significant research focus outside of the community of NRL product manufacturers. The organic origin of NRL gloves gives them a variety of intrinsicly interesting properties, most of which have clinical significance.

One of these properties, *Hydration* (the absorption of fluid into the interstitial areas of the glove once it is wetted), affects the clinical performance of NRL gloves in several ways. Possible adverse effects include increased electrical conductivity (which affects the reliability of electronic "hole detectors"), degraded glove tactile and tensile properties, increased chemical and viral permeability, and a higher concentration of latex-related allergens. This article begins with a brief discussion of how NRL gloves are made and tested, and then describes the impact of glove hydration on some of these properties as they relate to glove performance during use. Our data indicate that significant hydration is an undesirable property, and that gloves that hydrate slowly are clinically superior to those gloves that hydrate quickly.

Manufacturing and Testing of NRL Gloves

Natural rubber latex gloves are produced from a fluid extract of the *Hevea Brasiliensis* tree. This fluid is collected, blended, preserved, and concentrated prior to storage or shipment. Glove dipping consists of depositing a film of concentrated liquid latex on a hand-shaped metal or ceramic mandrel. Prior to dipping, the latex concentrate is "compounded", in which chemical additives are mixed with the latex for the purpose of improving the gloves' physical characteristics. These additives include stabilizers and vulcanizing agents, as well as various compounds specific to the intended end-use of the glove. Dipping is followed by "leaching", where undesired material is removing by washing, then drying and curing.

Natural rubber gloves manufactured in the U.S. must currently meet or exceed the requirements of ASTM Standard D 3577-88 "Standard Specification for Rubber Surgical Gloves" [2]. This test requires gloves to be filled with 1000 ml of water, and then visually inspected for seepage. Current acceptable quality levels (AQL's), using the ASTM 1000 ml test, are a 2.5% failure rate for surgical gloves, and a 4% failure rate for examination gloves [2]. Many glove manufacturers and health care professionals consider the ASTM 1000 ml test to be inadequate in light of the current risk of infection to both health care provider and patient [5, 13, 14, 16, 11]. Additionally, we have found that many factors affecting NRL glove barrier integrity degrade during use, and that this degradation is the result of glove hydration.

What is Hydration?

Hydration is the absorption of fluid into the interstitial areas of the glove once it is wetted. The interstitial areas exist because natural rubber latex is a coagulation of many small rubber particles. These particles range in size from about .1 to 5 microns, with an average size of about .5 microns. A latex film is a very large number of these particles held in close proximity. Most NRL gloves are about 200 to 400 microns in thickness. Imagine a large aquarium filled with marbles of various sizes. Small, very convoluted channels will exist from one end of the aquarium to the other, provided that these interstitial areas are empty, as would be the case with marbles. In latex however, these interstitial areas are (at least initially) filled with proteins and their decomposition products, fatty acid soaps, ammonia, water, and a number of organic and inorganic salts. Also present are the chemical additives that were not leached out of the latex during manufacturing.

When an NRL glove is exposed to fluids, the material in these interstitial areas is partially dissolved. This exposes more of the interstitial areas to fluid, leading to additional material being dissolved, etc. The rate at which hydration occurs is determined by the initial density of the dry latex film (dense latex hydrates more slowly), as well as by the amount of glove surface that is wetted (gloves will hydrate more slowly if they are relatively dry), and by temperature (heat increases the rate of hydration). The presence of surfactants in the fluid, as would be found in various bodily fluids, also increases the rate of hydration. Finally, the presence of material in the interstitial areas that is strongly hydrophilic (such as water soluble proteins) will dramatically increase the rate of hydration. Figures 1 through 4 attempt to illustrate what happens when a latex film hydrates.

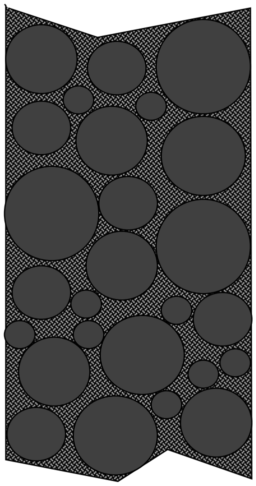

Figure 1: Dry Latex

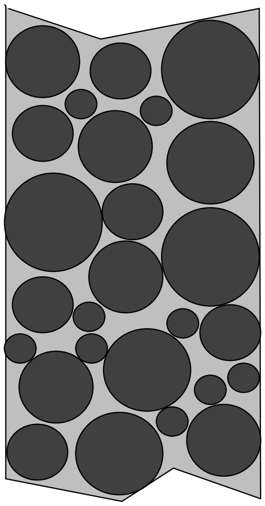

Figure 2: Partially Hydrated Latex

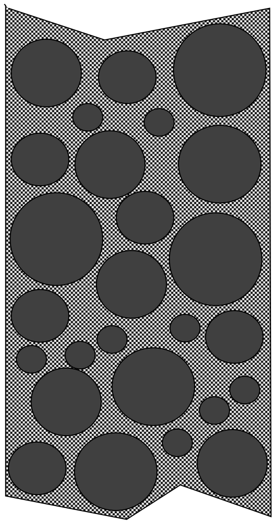

Figure 3: Significantly Hydrated Latex

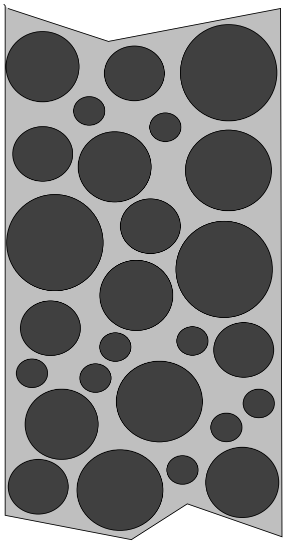

Figure 4: Fully Hydrated Latex

All natural rubber latex gloves hydrate to some extent, although gloves from different manufacturers, and different glove styles from the same manufacturer, hydrate at widely varying rates. Some gloves may hydrate significantly in just a few minutes of exposure to fluids, others may not exhibit significant hydration after several hours of exposure.

Clinical Issues Related to Glove Hydration

Basic Hydration-Related Issues A severely hydrated glove with very high conductivity may expose its wearer to increased risk of shock or burn from electrocautery procedures [19]. Hydration can also cause gloves to swell, degrading their tensile and tactile properties [10]. Exposure to fat and body fluids exacerbates this problem. Hydrated gloves will often be more susceptible to tearing or puncture, as well as feeling "tacky" [30, 1]. In addition, a severely hydrated glove may be less effective as a chemical barrier [9]. Finally, a recent pilot study observed viral penetration in one third of the gloves tested after 50 minutes of hydration, and no penetration in non-hydrated gloves [27].

Monitoring Glove Integrity During Use Current clinical guidelines mandate the "scrupulous monitoring" of adherence to Universal Precautions during actual glove use [7]. This monitoring currently consists of the periodic or incidental visual inspection of gloves by the glove wearer, and the wearer's colleagues, during clinical procedures. The many reports of undetected glove failure in the literature indicate that this practice, by itself, is inadequate to detect all breaches in glove barrier integrity, [30, 22, 1, 15].

The likelihood of undetected glove failure has generated renewed interest in the possibility of electrical monitoring of glove barrier integrity. Devices intended for this purpose were first developed over thirty years ago by Penikett and Gorrill [21] and Beck [3]. Since then, many similar devices have been developed, e.g., [17, 1]. These devices function by treating the glove barrier as a resistor. The theory is that an intact glove will always have a high resistance, and that a hole will appear as a lower resistance than an intact glove.

Hydration and Conductivity *Conductivity* refers to the ability of the glove to permit or impede the flow of electric current. We explored the validity of the simple resistor model for conductivity in NRL gloves by examining the electrical properties of gloves representing the product lines of most major U.S. and international manufacturers. Approximately 2000 gloves, representing a total of 85 glove styles, were tested. Test conditions were designed to simulate a worst-case operating room environment, i.e., fluid exposure to both sides of the glove. This would be the situation in a long procedure (due to perspiration of the glove wearer) that involved the deep abdomen, obstetrical procedures, or orthopedic repair or replacement (that exposed the exterior of the glove to large quantities of blood or other fluid). We also validated our results concerning glove hydration under laboratory conditions by monitoring changes in glove conductivity (and therefore rate of hydration) under conditions of actual use during approximately 100 surgical procedures. Finally, we explored the effect of varying wetted surface area and temperature on the rate of hydration.

Measuring the Rate of Hydration We found that the dominant factor affecting the electrical properties of latex rubber gloves is their hydrophilic tendency, as exhibited by a decrease in resistance (and associated increase in conductivity) over time, once the glove is wetted. Thus the rate of hydration can be directly measured by observing this increase in conductivity.

Several factors may influence this effect to varying degrees, including temperature and salinity of the wetting solution, glove storage time prior to use, and conditions of storage (all of which increase the rate of hydration). The presence of surfactants, heat, humidity, and ozone may also increase the rate of hydration. All natural rubber gloves tested were observed to hydrate once wetted, but to dramatically different degrees. Synthetic rubber gloves did not appear to exhibit this phenomenon. The tendency of a glove to hydrate, and the resulting increase in conductivity, varies widely among manufacturers and glove styles. The "best" gloves typically increase in conductivity by no more than a factor of ten over an hour of exposure. The "worst" gloves may increase in conductivity by several orders of magnitude in less than 10 minutes of exposure to bodily fluids or saline solution, then rapidly taper off. Figures 5 through 10 depict the test results for six representative classes of glove type. In each of these figures, the dark black line represents the mean resistance of the glove over time, and the error bars indicate the range of observed values at each sample point.

Figure 5 depicts a hydration-induced resistance curve representative of gloves of the "slowest hydration" variety (Glove A), and Figure 10 depicts a hydration-induced resistance curve representative of gloves of the "fastest hydration" variety (Glove F). Figures 6 through Figure 9 depict similar curves for glove styles whose hydration behavior ranges between that shown in Figures 5 and 10 (Gloves B – E, respectively).

The conductivity of synthetic (non-natural-rubber) gloves does not change appreciably over time, but the (nearly constant) degree of fairly high conductivity allows these gloves to be grouped with latex gloves in the intermediate hydration range. Data for a representative synthetic glove is depicted in Figure 11 (Glove G).

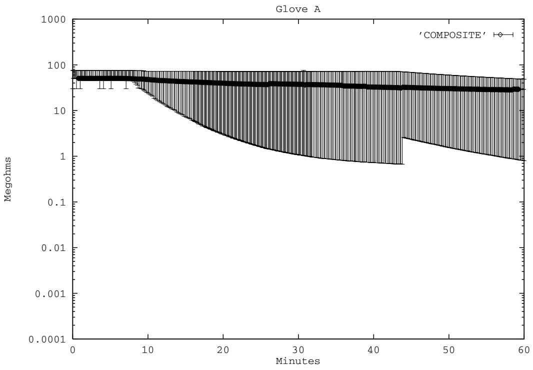

Figure 5: Glove A

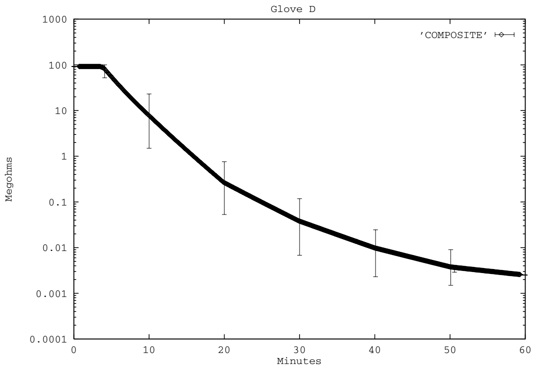

Figure 8: Glove D

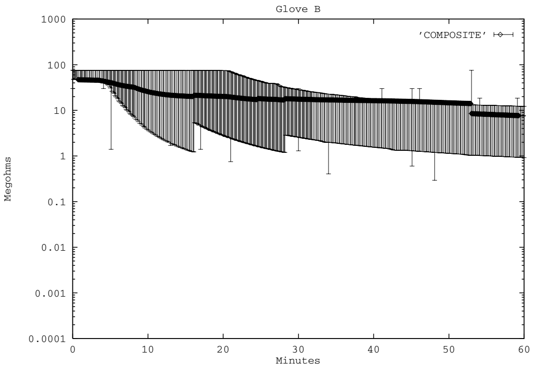

Figure 6: Glove B

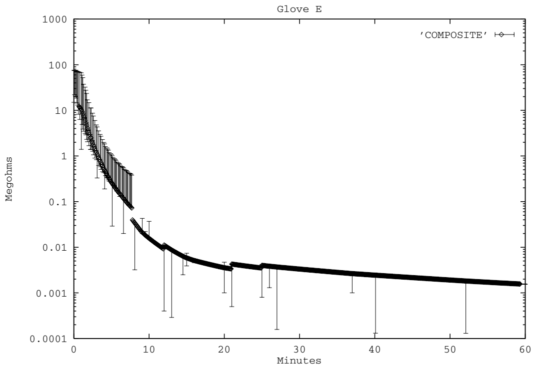

Figure 9: Glove E

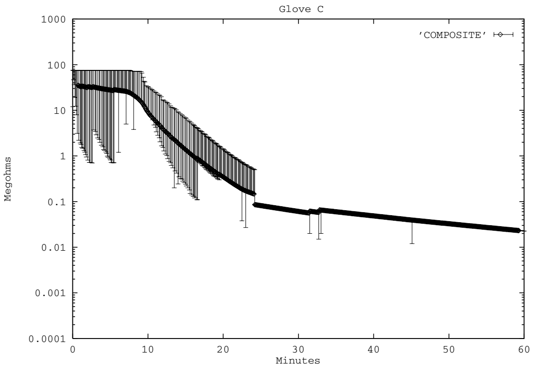

Figure 7: Glove C

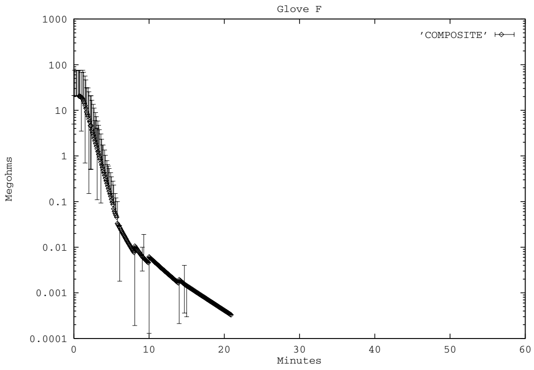

Figure 10: Glove F

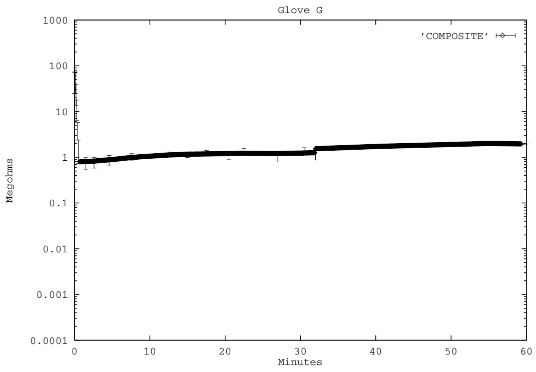

Figure 11: Glove G

Clinical Implications of Hydration and Conductivity While it is difficult to establish with certainty whether a glove with low electrical resistance (high conductivity) has failed, or is simply hydrated, the converse is easy to establish. Thus, a glove that exhibits high resistance (low conductivity) is necessarily a "good" biological barrier. For the health care professional, this suggests that gloves styles with high initial resistance, and that hydrate slowly, may offer superior protection, particularly when these gloves are used in conjunction with some form of reliable barrier monitoring mechanism.

Hydration and Latex Hypersensitivity Associated with the increased use of NRL gloves has been a dramatic increase in the number of health care professionals and patients who exhibit latex allergy [29, 25, 20, 23, 24]. Latex allergy can be a career-ending or even life-threatening disability for health care workers [28, 8], and a significant health care risk for patients [12, 18]. The appears to be a clear relationship between glove hydration and the release of water-soluble glove proteins, including those responsible for human latex hypersensitivity [4]. Although a strong corollation between allergen content and total extractable (water-soluble) protein content has not been established, reducing total protein content will also tend to reduce the levels of those proteins responsible for latex hypersensitivity. Our data indicate that the total amount of water-soluble protein present in an NRL glove is a good predictor of glove hydration and conductivity behavior. Conversely, hydration and conductivity data can be used to estimate the total amount of water-soluble protein [4]. These data suggest that a glove with high extractable protein content will hydrate more quickly, and its conductivity will increase more rapidly, than a similar glove with less extractable protein. This means that efforts to reduce glove extractable protein levels should yield gloves that have improved hydration and conductivity properties as well. Similarly, choosing an existing glove with observed high resistance and slow hydration is likely to yield a glove with lower levels of all water-soluble proteins, including those causing latex sensitivity.

Summary of Clinical Implications

All of our data suggest that gloves that hydrate slowly are clinically superior to gloves that hydrate quickly. We have described several reasons supporting this conclusion. These reasons are summarized below:

1. Hydration may degrade desirable glove tensile and tactile properties.
2. Hydration may increase the risk of electrical shock or burn.
3. Hydration may increase the risk of allergic reaction due to latex hypersensitivity.
4. Hydration may increase glove chemical permeability.
5. Hydration may increase glove viral permeability.
6. Hydration may preclude electronic monitoring of glove barrier integrity.

Not all gloves that hydrate rapidly exhibit all of these characteristics. However, gloves that hydrate very slowly tend not to exhibit *any* of these characteristics. Since on-going efforts by glove manufacturers to reduce allergen content in NRL gloves will tend to produce gloves that hydrate more slowly, the availability of glove styles that hydrate slowly is increasing. There appears to be a compelling clinical argument in favor of choosing these gloves.

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