

# The Feasibility of Using Electrical Means for Monitoring Barrier Integrity in Natural Rubber Latex Gloves: Hydration, Conductivity, and Protein Content in Natural Rubber Latex Gloves

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## Background

Increasing health concerns in the last decade, exemplified by the “Universal Precautions” promulgated by the U.S. Center for Disease Control, 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. NRL 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”. 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. 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 practitioner and patient. Several manufacturers have instituted other test methods that provide superior AQL’s over ASTM testing, in addition to testing a larger product sample.

Current clinical guidelines (MMWR-7-91) also mandate the “scrupulous monitoring” of adherence to Universal Precautions during actual glove use. 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 medical literature indicate that this practice, by itself, is inadequate to detect all breaches in glove barrier integrity.

About three years ago, we began an investigation of the physical properties of NRL gloves in an effort to develop improved methods for monitoring glove barrier integrity. Initially, we focused primarily on hydration and conductivity. The results of this early work are in-

corporated into the hardware and software design of the Novatec “Surgic-Alert Monitor”, which was designed by the author. More recently, we have continued our investigation of the physical properties of NRL gloves in order to develop an improved understanding of their observed complex behavior. Our recent results suggest a relationship between extractable protein content and electrical behavior that may have both clinical and manufacturing implications. This work is not supported by Novatec, nor does Novatec hold any business interest in the results.

## **Work to Date**

### **Hydration and Conductivity**

The electrical properties of natural rubber latex (NRL) gloves have been of clinical interest since the concept of using an electrical device to monitor glove barrier integrity was introduced over thirty years ago by Dr. William Beck. Beck’s monitoring device, and other similar devices, function by treating the glove barrier as a resistor. The theory is that a hole will appear as a lower resistance than an intact glove.

We have performed a series of tests designed to explore the validity of this theory. We examined the electrical properties of gloves representing the product lines of most major U.S. and international manufacturers. Our principal result is that most natural rubber latex gloves have dynamic electrical behavior that precludes the use of the simple resistor model for monitoring glove barrier effectiveness. The dynamic electrical behavior of NRL is due primarily to the fact that, as a glove absorbs fluid over time, its resistance decreases. This absorption of fluid into interstitial areas within the glove is called *hydration*. Hydration causes gloves to swell, degrading their tensile and tactile properties. Hydrated gloves will often be more susceptible to tearing or puncture, as well as feeling “tacky”. In addition, a heavily hydrated glove may be less effective as a chemical barrier, but a hydrated glove is not necessarily a less effective biological barrier. 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.

Closely related to hydration is the electrical *conductivity* of the glove. Conductivity refers to the ability of the glove to permit or impede the flow of electric current. A glove with very high conductivity (low resistance) may expose its wearer to increased risk of shock or burn from electrocautery procedures. Very high conductivity may also preclude the monitoring of glove barrier integrity by electrical means. This is because it is very difficult to distinguish between a glove with very high conductivity, and a low conductivity glove with a barrier breach. Since most bodily fluids and irrigating solutions are themselves electrically conductive, electrical conductivity and hydration are closely related. A heavily hydrated glove will have much higher conductivity than a glove that is less hydrated. The variability of conductivity over glove manufacturer and style correlates strongly with the degree of hydration.

**Materials and Methods:** In order to explore the feasibility of monitoring glove barrier integrity using electrical means, we examined the electrical properties of a large and representative sample of glove types. Approximately 1200 gloves, representing a total of 60 glove types, were tested. Gloves were obtained either from supply shelves of Houston area hospitals, or, in cases where particular glove types were locally unavailable, directly from the manufacturer. An effort was made to test as many different glove types as possible, including glove types not in common use. Most of the gloves tested were sterile gloves intended for surgical use. A small number of non-sterile exam gloves were also 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).

This environment was simulated by filling the glove under test with isotonic saline solution (750ml of .9% NaCl) and immersing the glove in a non-conductive plastic tank containing the same isotonic (.9% NaCl) saline solution (total volume of solution in the tank was approximately 12 liters) to a point where the solution in the glove had a 1 cm (above the solution in the tank) static head of pressure over the solution in the tank. This ensured that fluid would flow if a path for such flow existed in the glove. Water temperature was

varied between 25 and 40 degrees Celsius. Non-polarizing electrodes were placed in the tank and glove and resistance measurements were taken repeatedly using an instrument designed for that purpose. The time of measurement was also recorded. These measurements were repeated until the glove resistance had decreased to below approximately 10000 ohms, or one hour had elapsed, whichever occurred first. This experiment was repeated many times for each glove type tested. The resulting resistance versus time data was plotted for each glove type. This data was time-step averaged to produce a mean composite “characteristic” curve for each glove type, and standard deviations were calculated from this mean. For each glove type, the number of samples tested was sufficient to obtain a statistically significant mean.

**Test Results:** 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. Several factors influenced this effect, including temperature and salinity of the wetting solution, glove storage time prior to use, and conditions of storage (all of which increase the rate that resistance decreases). Heat, humidity, and ozone appear to also increase the rate that resistance decreases. All natural rubber gloves tested were observed to exhibit this tendency, but to dramatically different degrees. Synthetic rubber gloves did not appear to exhibit this phenomenon. This increase in conductivity due to glove hydration is the primary reason that barrier monitors based on simple resistance will be less effective with gloves that hydrate quickly. The tendency of a glove to hydrate, and the resulting increase in conductivity, varies widely among manufacturers and glove styles. The electrically “best” gloves typically increase in conductivity by no more than a factor of ten over an hour of exposure. The electrically “worst” gloves may increase in conductivity by three orders of magnitude in less than 10 minutes of exposure to bodily fluids or saline solution, then rapidly taper off. Figures 1 through 6 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 1 depicts a hydration-induced resistance curve representative of gloves of the “slowest hydration” variety (Becton Dickinson Eudermic in this case), and Figure 6 depicts a

hydration-induced resistance curve representative of gloves of the “fastest hydration” variety (Johnson & Johnson Microtouch Surgical in this case). Figure 2 through Figure 5 depict similar curves for glove styles whose hydration behavior ranges between that shown in Figures 1 and 6 (Regent Biogel, Baxter Ultraderm, Ansell Fitted Procedure, and Johnson & Johnson Neutrolon, 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 7 (Becton Dickinson Neolon in this case).

### **Hydration, Conductivity, and Protein Content**

While investigating the origin of the observed electrical behavior, we observed a surprising correlation between our data on hydration rate, and other researchers data on extractable protein content. We have initiated an effort to confirm this apparent relationship. Our preliminary results indicate that the water-soluble proteins, found to varying degree in NRL gloves, strongly influence NRL glove hydration and conductivity. These proteins may in fact be the primary causal agent for glove hydration and increased conductivity. Since some number of these proteins are associated with latex product hypersensitivity in humans, an understanding of the electrical behavior of NRL gloves has both clinical and manufacturing implications beyond barrier integrity monitoring.

Various chemicals added to raw latex during the manufacturing process have been reported to interfere with many of the standard analytical techniques for total protein assay based upon the methods of Lowry and Bradford. More reliable immunoassay techniques are typically slow. We are exploring the feasibility of a variety of protein assay methods based upon absorbance of the sample in the ultraviolet range at several wavelengths between 200nm and 280nm. Preliminary results using these methods are promising.

**Materials and Methods:** Gloves were cut into small pieces, weighed, and placed in a beaker, to which 200ml of .9% NaCl solution was added. Care was taken to minimize extraneous protein contamination. All equipment coming in contact with the glove material under test was cleaned with 100% ethyl alcohol to remove protein residue. Non-latex gloves

were worn by laboratory personnel during the experiment. After saline solution was added, the mixture was periodically stirred, and whatever cornstarch powder that was present was allowed to settle out. Increased turbidity from starch powder did not prove to be a concern. Four ml of solution was removed at 1 minute, 5 minutes, 10 minutes, 20 minutes, 30 minutes, 60 minutes, and 120 minutes after addition of the saline solution, and placed in a methacrylate cuvet. Absorbance readings were taken at 280nm, 260nm, 235nm, 234.5nm, 233.3nm, 230nm, 228.5nm, 225nm, 224nm, 215nm, 210nm, 209nm, 207nm, 205nm, and 203nm, and protein concentrations were separately determined using the methods of Warburg and Christian, Kalchkar, Kalb and Bernlohr, Scopes, Tombs, Waddell, Whittaker and Granum, and van Iersel, Frank, and Dunne.

**Test Results:** Figures 8 through 11 depict the observed logarithmic relationship between increased conductivity and rate at which protein elutes in two glove styles, the Smith and Nephew Style 42 and the Regent Biogel. Figure 8 depicts a hydration-induced resistance curve representative of the S&N Perry Style 42, while Figure 9 depicts the observed rate at which protein elutes from this glove over the same time period (total protein determined according to the method of van Iersel, Frank, and Dunne). Figure 10 depicts a hydration-induced resistance curve representative of the Regent Biogel, while Figure 11 depicts the observed rate at which protein elutes from this glove over the same time period (determined as before).

## **Clinical Implications**

### **Monitoring Barrier Integrity**

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 resistance, and that hydrate slowly may offer superior protection, particularly when these gloves are used in conjunction with some form of reliable electrical barrier monitoring device.

## Latex Product Hypersensitivity in Humans

A second reason for choosing gloves styles with high resistance and a slow hydration rate is the apparent relationship between glove conductivity and soluble protein content. The *allergenicity* of natural rubber latex medical products is of increasing concern to health care professionals, since they are regularly exposed to these products, especially examination and surgical gloves. At the 1992 AORN conference, 30% of the 1738 respondents to a AORN/CDC survey reported some latex allergy. Of the 1133 reports to the FDA of severe latex allergic reactions (including anaphylaxis) that occurred between 10/1/88 and 9/30/92, 408 of the injuries reported involved examination gloves, and 77 involved surgical gloves. Approximately 68% of the injuries reported involved health care workers, and 65% of this group were patients at the time of injury. Other studies have confirmed that health care workers, particularly females, with a prior history of latex sensitivity are among those more likely to experience a more severe latex allergic reaction upon additional exposure. The result of these concerns is that many glove manufacturers have undertaken to reduce the allergen content of their products. These allergens are believed to be found in some of the naturally occurring proteins in the latex itself. Efforts are underway, with some initial success, to identify the specific proteins that are responsible for causing allergic reactions. In the meantime, those glove manufacturers seeking to reduce the allergen content of their gloves are taking steps to reduce the total extractable protein content. Allergen content and total extractable protein content have not been shown to be strongly correlated, but reducing the total protein content should tend to reduce the allergen content as well.

Some of our recent results indicate that the extractable (water-soluble) proteins in latex gloves are one of the primary causal agents of glove hydration and increased conductivity. 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 a 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.

## **Manufacturing Implications**

### **Non-Destructive Testing**

Low voltage electrical test methods afford the opportunity to non-destructively test gloves and condoms prior to stripping. Such testing can be used to signal to either automated stripping machinery or hand-stripping personnel that particular gloves or condoms should be discarded prior to further processing steps.

Low voltage test methods are particularly appropriate for use during condom manufacturing, where it is estimated that approximately 2% of the manufactured product is needlessly destroyed *by the test method itself* using high voltage test methods. In addition, high voltage testing produces significant quantities of ozone, which is known to have a deleterious effect on all NRL products.

### **Measuring Extractable Proteins**

The apparent link between the electrical behavior and extractable protein content in NRL products suggests the possibility of directly measuring the soluble protein content of gloves and condoms on-line during the manufacturing process. In theory, such measurements could be used to vary process control parameters, e.g., line speed and leach tank turnover rate, in order to ensure a product of consistent and verifiable extractable protein content. Rapid, on-line measurement of extractable protein content could also significantly improve yield by eliminating the potential waste associated with the time between when product is sampled and when it is known whether or not the product meets production standards.

## **Research Objectives**

The overall objective of our work at Rice University is to develop an understanding of the relationship between the electrical, chemical, and biological properties of natural rubber latex, and to develop the technology to exploit this understanding during the manufacture and use of NRL products. Our focus to date has been primarily on gloves that are used for medical applications.







