Latex Free Balloon Catheters

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For many years, medical devices have been manufactured using components made from natural rubber latex (NRL). Recently, the FDA has required such devices to be labeled with caution statements warning of the possible serious adverse effects of such products on patients with sensitivity (allergy) to latex materials. The cause of the reaction is believed to be the result of exposure to a protein found in NRLs. We are researching the design, synthesis and processing of urethane balloon catheters. The first stage of this work focused on producing dip molded latex free polyurethane balloon catheters with the following *state of the art* requirements:

- Low modulus of elasticity. This assures that only low forces are needed to achieve high deformations.
- High percent elongation. NRL can be elongated to over 700%.
- Dramatic memory. The polymer must return to its original dimensions after it is deformed to its maximum elongation.
- Tear strength. Pli (pounds per linear inch) should be in the range of 100-190.

Figure 12

This work went along at a rapid pace; we developed light stable polyurethanes from conventional starting materials used in FDA approved polymer systems: 4,4”-methylenebis (cyclohexyl isocyanate), linear polyether glycols, 1,4-butane diol chain extender and 1,4-butene diol crosslinker. We dip coated balloons and films from tetrahydrofuran solutions (fig. 12). Crosslinked specimens were produced via UV crosslinking after dip coating. While initial mechanical property measurements are adequate, we are in the process of conducting fatigue tests.

We are beginning phase two of this research, aimed at adding bactericides which also strengthen the system. Our nanocomposite expertise is being used to developed silver nanocomposites with both desired properties. This phase of the project is of interest to us from the standpoint of characterizing the relaxation properties of the nanocomposites. We are also considering the use of bactericidal rotaxanes which impart strength to the system. This project is ready to be assigned to a Ph.D. student.