

Non-Latex Residual Force Testing

Testing Performed by Mike Anderson and Joel Thornton at Glenroe Technologies Research Facility, Bradenton, Florida

Overview

The following is an informative report that encompasses the 4-year development by Glenroe Technologies of the Ultra Non-latex Elastics. The initial focus was to develop a material that would have comparable tear strength and strength properties of latex without any of the health hazards that are associated with using latex as a medical device such as allergic reactions. Over the last 4 years Glenroe technologies has developed a material that not only meets but exceeds all of these requirements. To date this is the only FDA approved material that can make this claim. The data in figure 1 illustrates extensive testing data, which quantifies the strength to elongation characteristics.

Material Strength Comparison

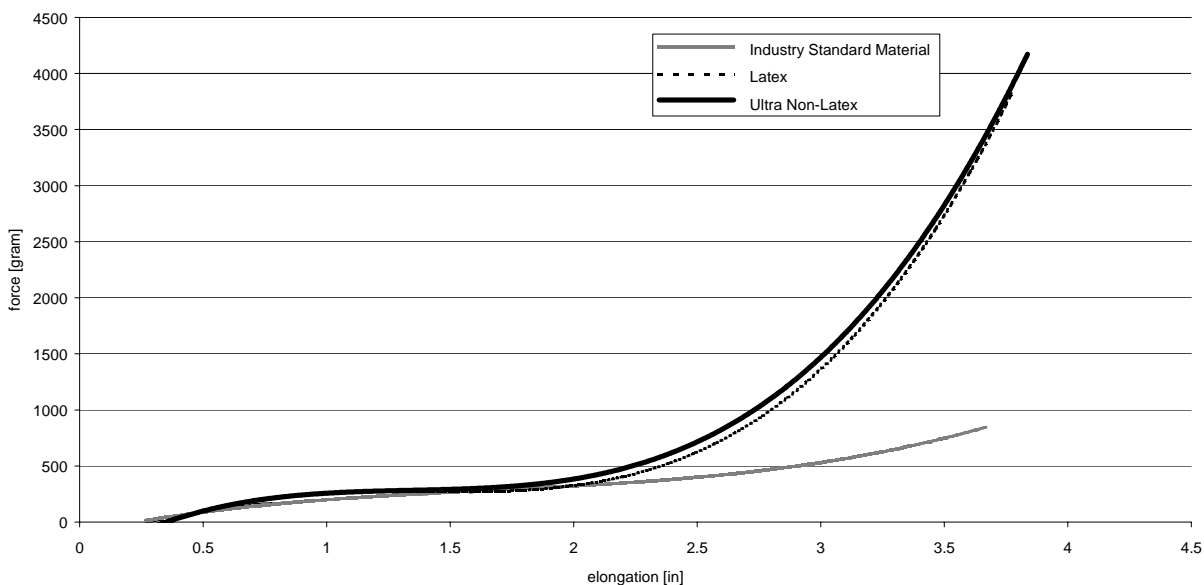


Figure 1: Graph of strength to elongation properties of latex, Ultra-Non latex, and the industry standard non-latex.

Specifications and Standards

Elastics manufactured by Glenroe technologies are produced using the industry standard measurements. All elastics are specified by the Inner Diameter and the force required to stretch the elastic three times the inner diameter (shown below in figure 2). For example all of the elastics that were used for this report were ¼ 4.5 [oz] elastics. This standard test is not indicative of the range of use. The actual range of use will vary from as little as 3 (190% elongation) to as much as 10 (600%) times the inner diameter.

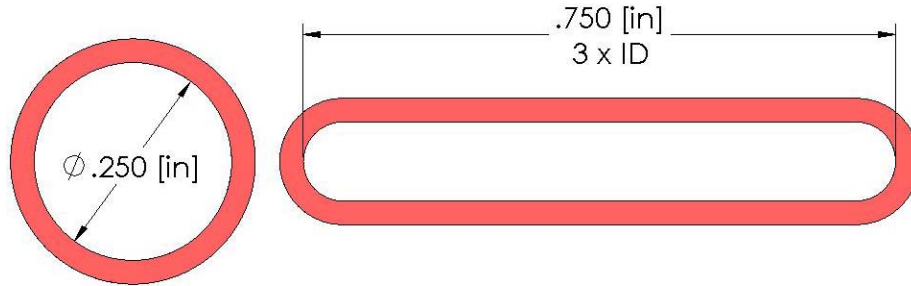


Figure 2: Standard measurement procedure for elastics specification

Testing Procedures and Results

Two tests were conducted to demonstrate over all superiority of Glenroe Technologies Ultra Non-Latex. The first test measured range of use. This test identified both overall endurance and maximum tear strength of the Ultra Non-Latex against that of Latex both of which are far superior to the industry standard non-latex. To simulate the range of use condition, samples were submerged in a 98 [°F] saline rich environment in order to mimic oral conditions. The samples were stretched 6 times the inner diameter repeatedly for 2500 cycles, each sample was tested every 330 cycles to determine loss of force. As shown below in figure 3 the Latex began to significantly degrade after 1600 cycles (6-8 hours of use) with an over all degradation of 80-100%. The Ultra Non-Latex proved to maintain an over all fatigued of less than 22%. The test results concluded that the Ultra Non-Latex possessed superior force retention and greater tear strength. This test was comparable to a 12 hour period of use.

Force Degradation Report

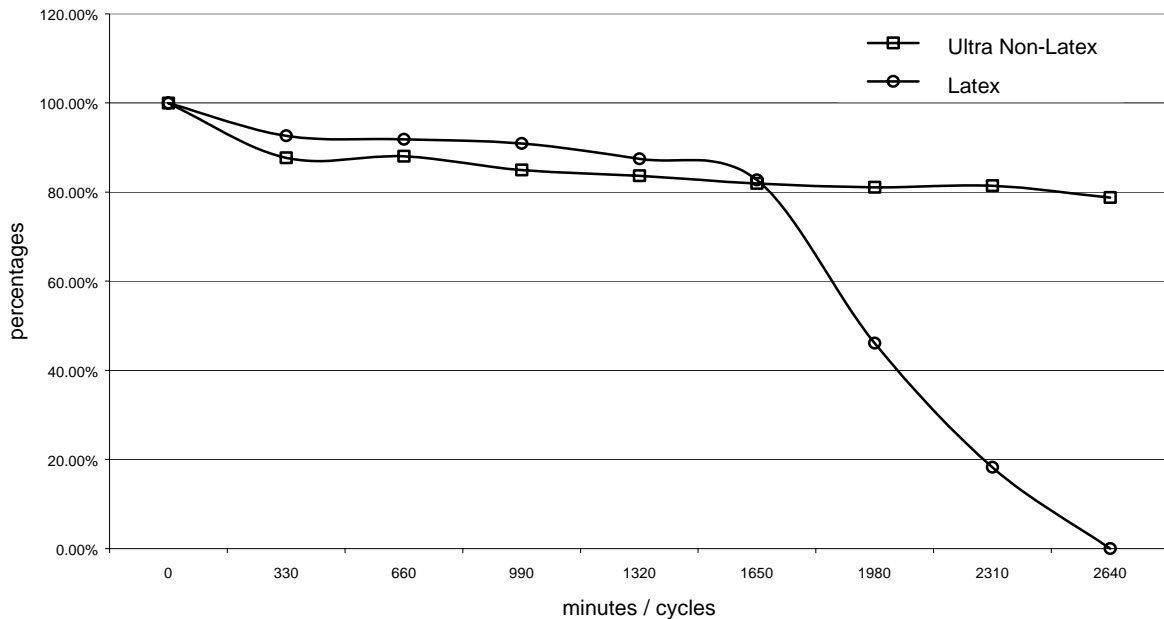


Figure 3: Retention Percentages

The second test was to elongate the elastics 10 times the inner diameter and record the force on elongation and relaxation. The results of which are displayed on the chart in figure 4. From figure 4 it is important to note that the Ultra Non-latex displays much less force differential than Latex when comparing elongation and relaxation cycles. This is significant in the fact that a more consistent force is provided during the overall cycle. This is technically known as Hysteresis.

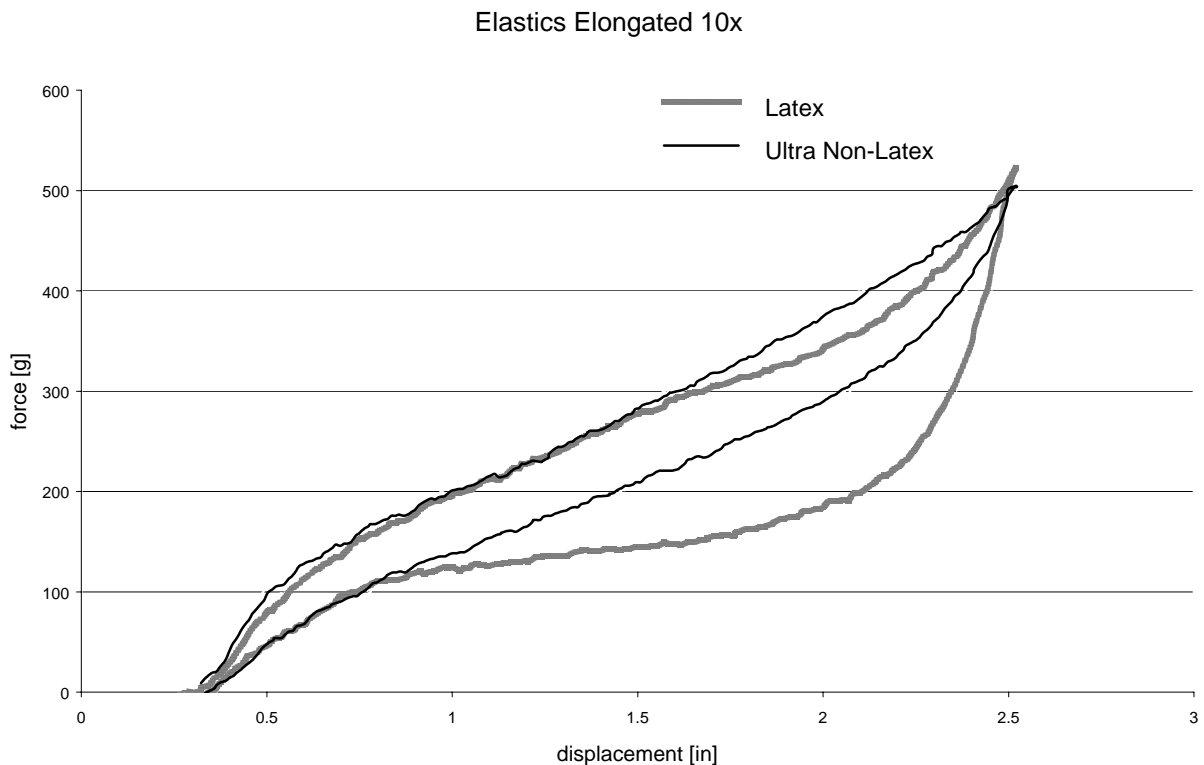


Figure 4: Ultimate Force Comparison

Non-latex elastics of leading competitors require twice the volume of material to achieve comparable retention forces of latex. The material in Glenroe Technologies Ultra Non-Latex requires less to equal the material of latex to achieve comparable to equal force retention (as shown in figure 5). Lower volumes of material used in the Ultra Non-Latex elastic increase ease of application and reduces patient irritation. Both of which increase Patient compliance.

Volume Required to Provide Equal Force

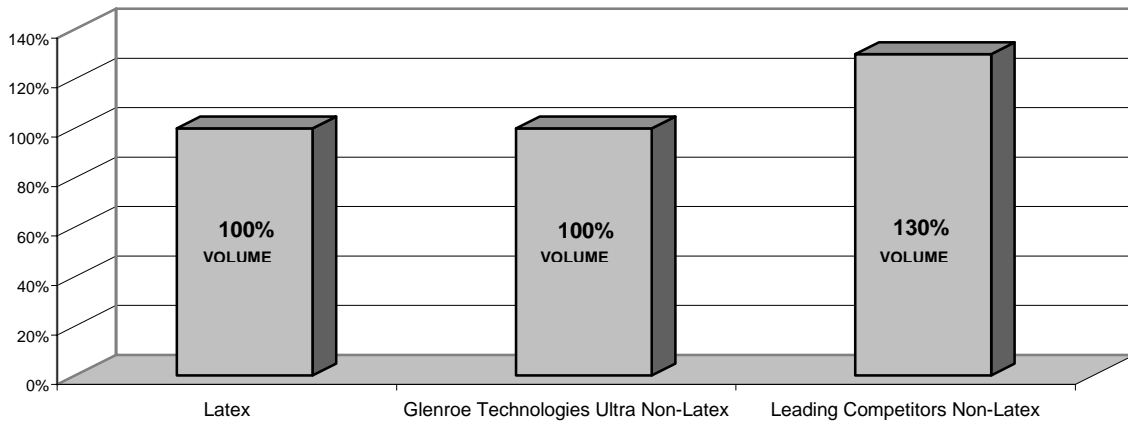


Figure 5: Material Volume

Summary

The Data provided in this report was produced by Glenroe Technologies Research and Development Group. Numerous studies have been conducted in the development of this new and exciting material. With the improved tear and fatigue strength, Glenroe Technology's Ultra Non-latex is not only the solution to the problem of safety it also surpasses the function of latex and standard non-latex elastics.

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