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# STERILIZATION AND ITS *EFFECTS ON* BULK ADHESIVES

**Scott D. Anderson**

# Executive summary

Throughout the medical industry, medical devices require sterilization to protect the patient. Some of the most common methods are autoclave, ethylene oxide, and gamma irradiation. Depending on the sterilization method selected, the sterilization conditions can greatly influence the integrity of a medical device. This can be especially true of medical devices bonded with adhesives. As a result, selecting the appropriate adhesive for the materials of construction, end use, and preferred sterilization method is critical early in the design process to minimize the impact on the bond strength after sterilization.

Henkel has previously published data on the effects of sterilization methods on bonded assemblies. This published data in various marketing literature, technical papers, and technical data sheets assist design engineers by providing results on adhesive performance after various sterilization methods on identical substrates or combinations of substrates for instance stainless steel cannula to plastic hubs.

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**Henkel has published the following data in their “Needle Bonding Design Guide”. The data below is on a 22 gauge cannulas with either polycarbonate and plasma treated polypropylene hubs. The silicones were not used in the needle bonding study, as they are not typically used for bonding needles.**

*Figure 1*

**22 ga needle pull strength on polycarbonate**

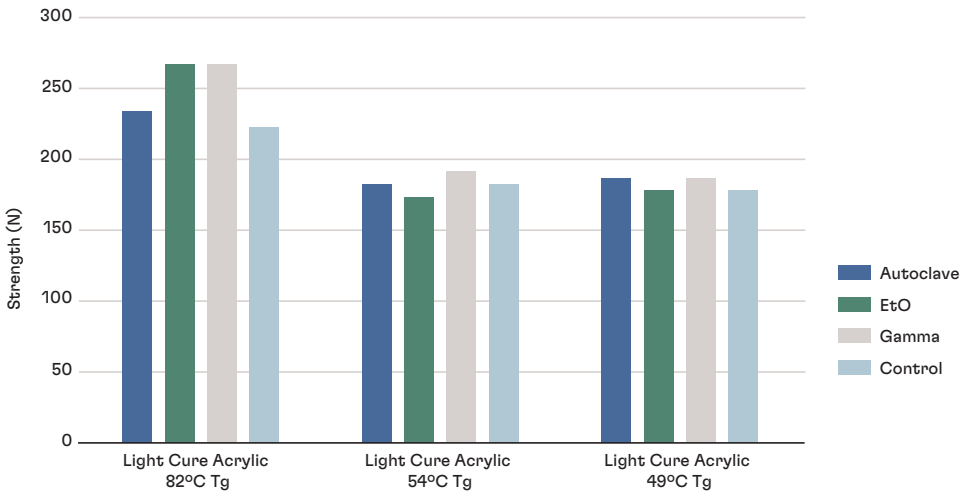
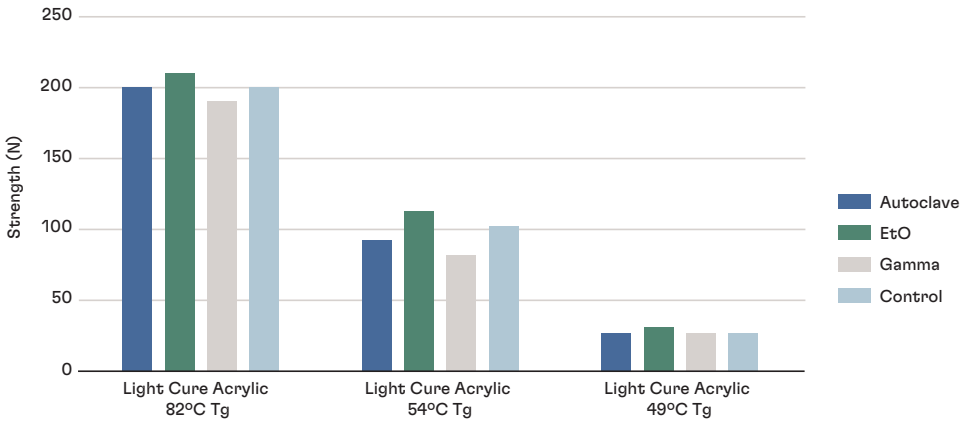



*Figure 2*

**22 ga needle pull strength on plasma treated polypropylene**




The data from “Needle Bonding Design Guide” shows similar results to unsterilized assemblies. Most of the time there is actually an improvement in strength. Theories on the reasoning behind the increase include the elevated temperature improve the ability for the adhesives to cross link, a relaxing of stress in the components by annealing, etc. This paper eliminates the substrate and joint design from the equation by looking only at the bulk properties of the adhesive and the changes that occur after sterilization. The data presented will include data on typical light cure acrylics and light cure silicone adhesives. The specific properties investigated include elongation, modulus, and tensile strength.

The light cure acrylic adhesives selected for this study primarily looked at the glass transition temperature (Tg). The three light cure adhesives have a Tg of 49°C, 54°C and 82°C. The reasoning for focusing on Tg was to evaluate the temperature effects if any during the various sterilization processes. The silicones selected were selected based upon their cure mechanism, a UV cure only and a dual cure UV and moisture cure silicone.

To perform the bulk properties testing, bubble free films were made of all the adhesives. The adhesives were then cut into either dog bones or tensile bars depending on whether they were silicones (elastomeric) or acrylic based materials (non-elastomeric). Once the specimens were prepared, the gamma and ethylene oxide sterilization specimens were sent off site for sterilization. The autoclave was done at Henkel. The gamma irradiation Strength (N) was for a duration of 108 minutes between 27.3 kGy to 30.5 kGy. The ethylene oxide specimens were exposed to sterilant for 6 hours at 15.2 in Hg absolute at 54.4°C. The autoclave samples were exposed to 6 minutes of 120°C at 0.103 MPa.

Once the dog bones or tensile bars were sterilized, they were tested in a mechanical properties tester for modulus, tensile strength at break and elongation. The basis of the testing was from ASTM standards. For the elastomeric materials, ASTM D412 “Rubber Properties in Tension” was the standard used for this paper. The non-elastomeric materials used ASTM D882-09 “Tensile Properties of Thin Plastic Sheeting”. The results of these studies can be shown in the following figures. *Figure 3* shows the modulus results.

*Figure 3*

**Modulus results**

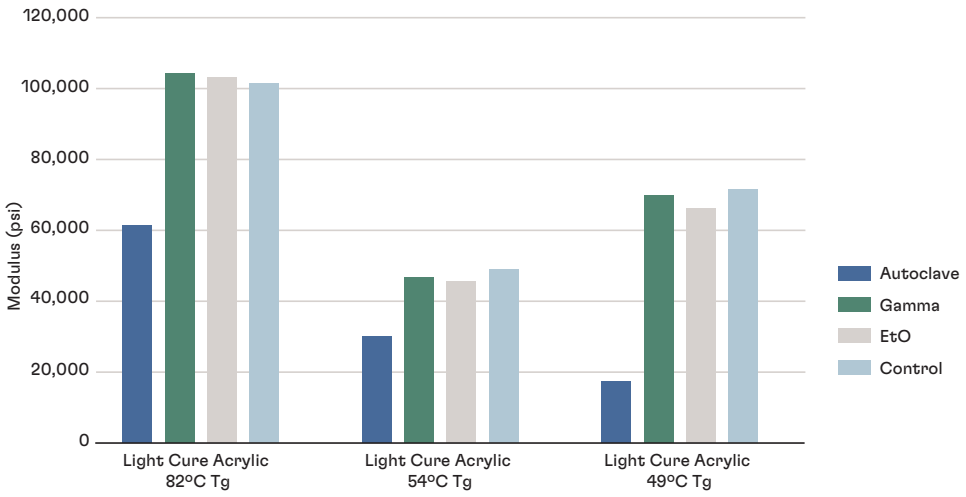


*Figure 4* shows the tensile strength at break.

*Figure 4*

**Tensile strength at break**

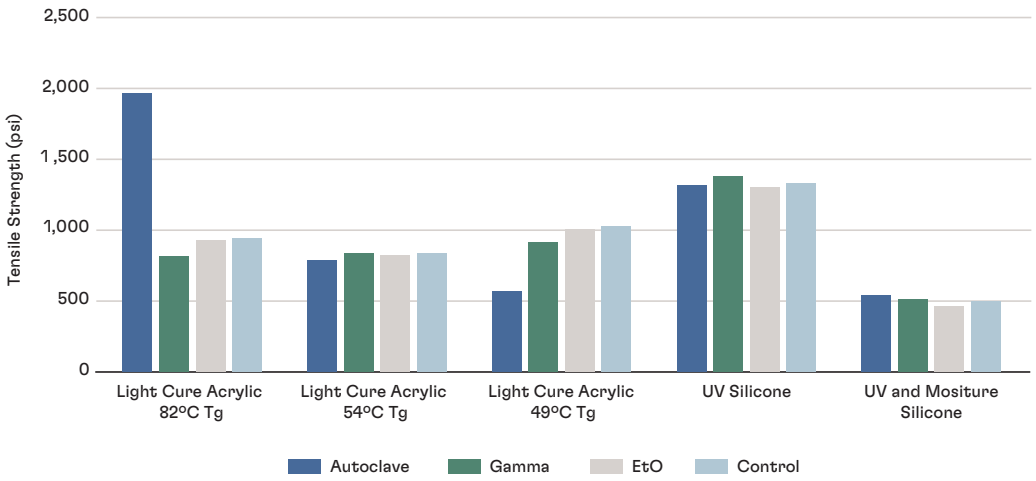
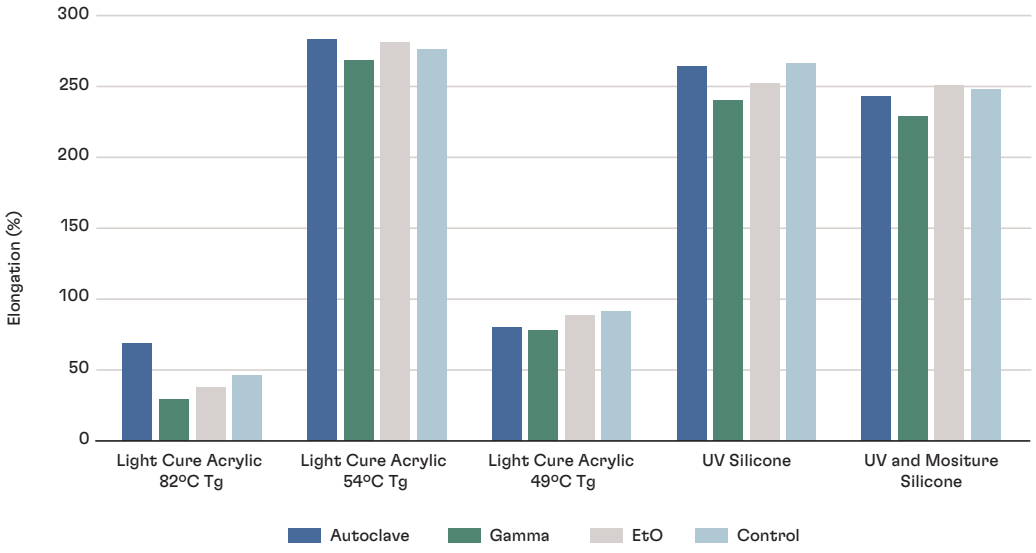



*Figure 5* shows the elongation results.

*Figure 5*

**Elongation results**



**A statistical analysis of the data showed that the data for the light cure acrylics were not significantly different, at a 95% confidence level, when the autoclave results were removed from the analysis. The silicone showed that even with the autoclave results the data was not statistically different, at a 95% confidence level.**

Depending on the chemistry selected and sterilization method selected, the resulting data shows the results are similar to the results prior to sterilization. This should provide a level of comfort for the design engineer in a disposable medical device company that the adhesive’s bulk properties are not changing significantly when sterilized via EtO or Gamma.

Design engineers in a non-disposable medical devices need to be aware of the difficulties that autoclave presents to the light cure acrylic adhesives. Although the silicones faired well in this study, this study only looked at one single exposure for the autoclave. Regardless of the medical device, the interaction between the adhesive, bond joint design, end use, and substrates can yield different results and will still require thorough testing of the assembly under manufacturing conditions and the preferred sterilization method to ensure a robust design.

# Author’s Bio

**Scott Anderson** is currently an Engineering Manger at Henkel Corporation. Previously he was the Lead Market Application Engineer supporting the medical device industry throughout North America for Henkel. Scott has worked at Henkel in the engineering department for almost 6 years and has an additional 12 years of other industrial experience. Scott has both a Bachelors and Masters degree in chemical engineering from the University of Massachusetts (Lowell) and is pursuing his MBA at the University of Connecticut.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