Shell Chemicals

THE EFFECT OF STERILIZATION PROCESSES ON CARILON* POLYMERS

By Keith Stone and Anne Lacroix

INTRODUCTION

CARILON Polymers, a revolutionary new class of semi-crystalline thermoplastics also referred to as aliphatic polyketones, offer a unique balance of processing and performance properties which, when combined, can satisfy a very broad range of applications, including those where sterilization is required on a once-only or repetitive basis.

This paper examines the effect of steam sterilization on the mechanical properties of two grades of CARILON Polymers, both recommended for general-purpose injection molding. It also considers the materials' hydrolytic stability and examines the effect of Gamma ϒ and Beta β sterilization and Ethylene Oxide sterilization (EtOx) upon test specimens of these grades.

TESTING

The grades tested include CARILON Polymer D26HM100 and CARILON Polymer DB6G3A10. CARILON Polymer D26HM100 is a general-purpose injection molding grade with mechanical properties that classify it as an engineering thermoplastic. This material shows excellent impact resistance at room temperature and lower temperatures, high resilience and good creep performance. It can withstand short-term exposure to elevated temperatures and also exhibits excellent resistance to hydrocarbons, solvents, salt solutions, weak acids and weak bases.

CARILON Polymer DB6G3A10 is a 15% short glass fiber-reinforced general-purpose injection molding grade with mechanical properties that classify it as an engineering thermoplastic. It shows a unique balance of toughness and high modulus combined with good creep performance, strength and elevated temperature performance. It also exhibits excellent resistance to hydrocarbons, solvents, salt solutions, weak acids and weak bases.

RESULTS AND DISCUSSION

Steam Sterilization

For the purposes of comparison with other sterilization processes, a process consisting of five autoclave cycles[†] at 134 °C followed by drying and conditioning at 50% RH before testing was selected as a "typical" example.

Steam sterilization of CARILON Polymer D26HM100 caused a small increase in stress at yield, strain at yield and impact strength. Plasticization of the polymer by water absorbed during sterilization is the most likely explanation for these changes.

Steam sterilization of CARILON Polymer DB6G3A10 caused a small increase in break stress. In tests, a decrease in the modulus and impact strength was observed. The most likely explanation for these changes is plasticization of the polymer matrix by water absorbed during sterilization, with the additional effect of changes to the fiber matrix interface.

CARILON Polymer D26HM100 absorbs approximately 3.5% of water at 100 °C. The water absorption for CARILON Polymer DB6G3A10, under similar conditions, is estimated to be approximately 2.5%. It can be assumed that the test specimens absorb at least this amount of water during steam sterilization. It also can be assumed that this water would remain in the specimens for a considerable amount of time if they were not subject to vacuum drying at an elevated temperature.

Multiple Steam Sterilization Cycles

The effect of multiple steam autoclave cycles is of interest for a number of applications where repeated exposure to steam or hot water is required.

Figures 1 and 2 demonstrate the effect of multiple autoclave cycles on the modulus and impact strength of CARILON Polymers D26HM100 and DB6G3A10, respectively. Polymer specimens were dried and conditioned before testing. In the case of CARILON Polymer D26HM100, an increase in impact strength and decrease in modulus were observed as the number of cycles increased. The most likely explanation for this change remains plasticization by water. In the case of CARILON Polymer DB6G3A10, there was a decrease in both modulus and impact strength as the number of cycles increased. While plasticization is likely to play a role, moisture may also affect the fiber matrix interface, leading to the decrease in toughness, which was observed in testing.

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[†] 12-minute vacuum – 12-minute steam – 12-minute vacuum.

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FIGURE 1: INFLUENCE OF STEAM STERILIZATION ON MECHANICAL PROPERTIES OF CARILON POLYMER D26HM100

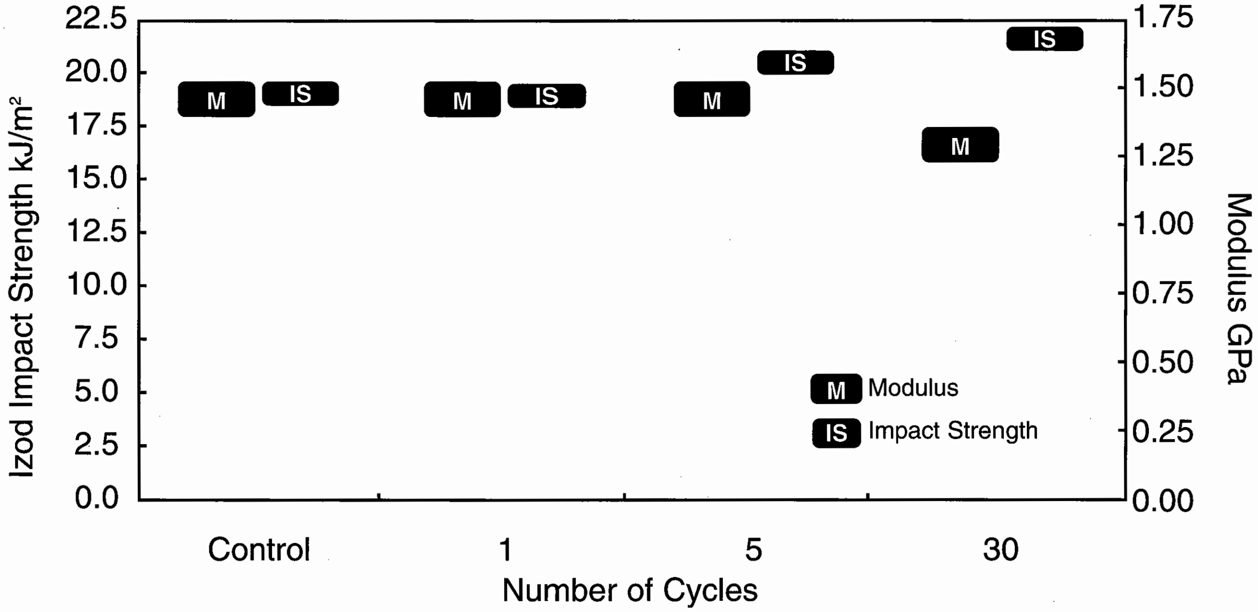
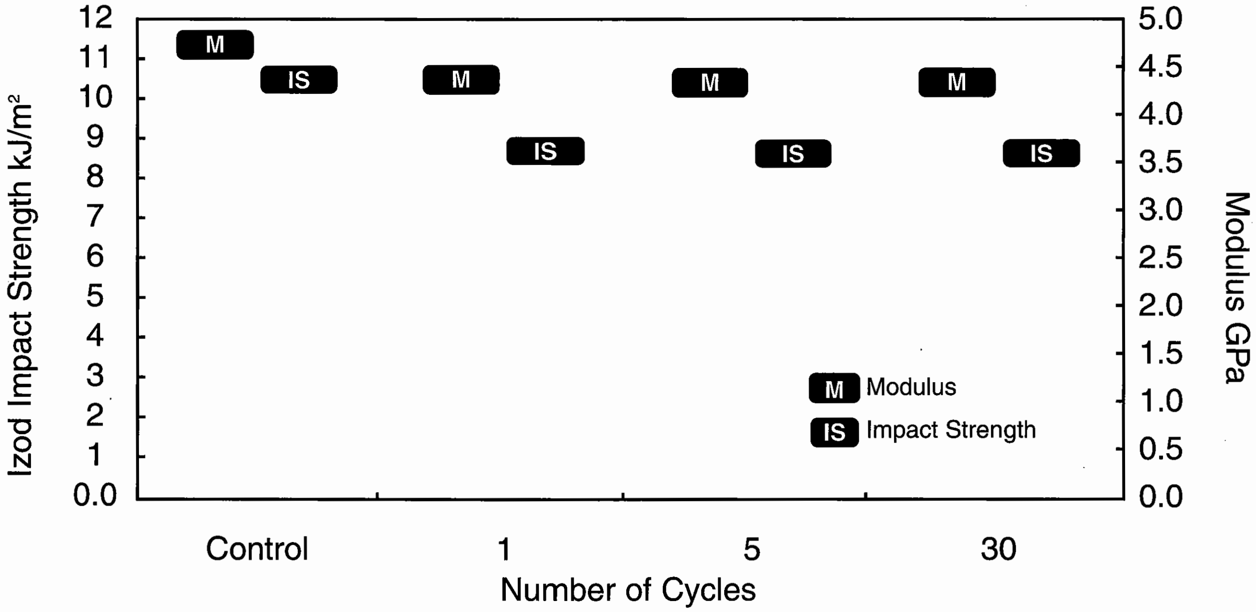


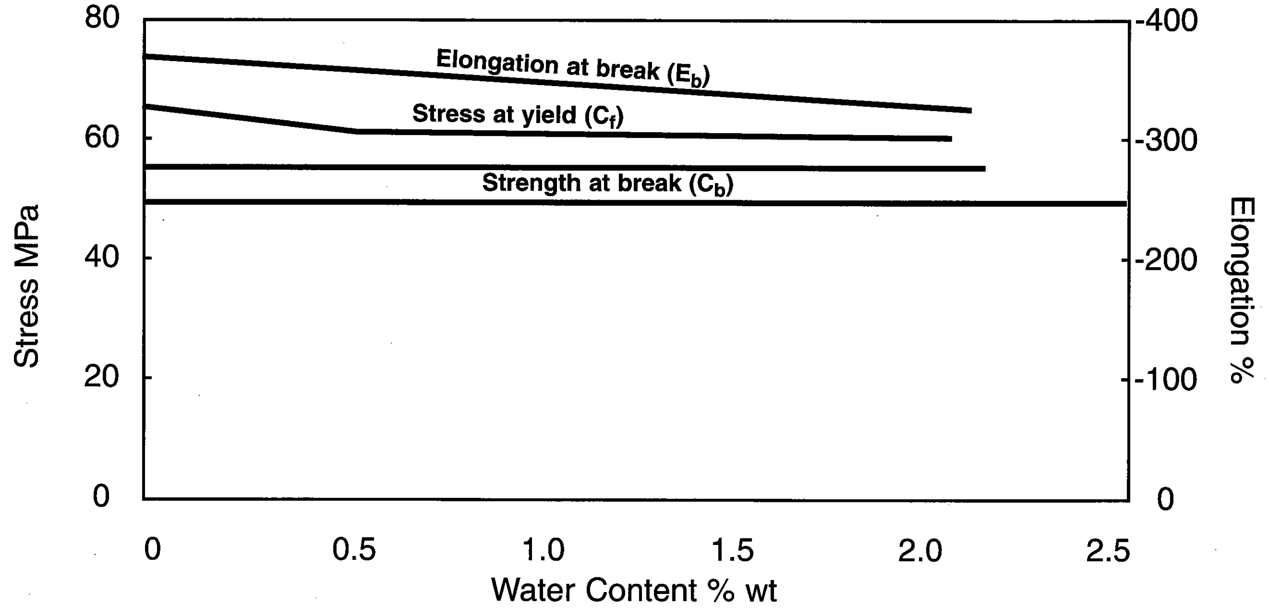
FIGURE 2: INFLUENCE OF STEAM STERILIZATION ON MECHANICAL PROPERTIES OF CARILON POLYMER DB6G3A10



Hydrolytic Stability

CARILON Polymers exhibit excellent hydrolytic stability and low moisture absorption, which means they are not susceptible to hydrolysis upon processing, exhibit resistance to hydrolysis in a broad range of aqueous environments (temperature, pH, salts, etc.) and absorb small amounts of water (0.5% at 50% RH) resulting in a mild plasticizing effect on stiffness but almost no effect on strength (Figure 3).

FIGURE 3: LOW WATER SENSITIVITY



Gamma Υ and Beta β Sterilization – CARILON Polymer D26HM100

Neither Υ nor β sterilization caused significant short-term change in the tensile properties of CARILON Polymer D26HM100 (Figures 4, 5 and 6).

Both of these sterilization processes did, however, cause yellowing of the polymer (Figure 7).

The toughness of the polymer was affected by both Υ and β sterilization, as demonstrated by a reduction in impact strength (Figure 8).

After storage of the Υ sterilized polymer, significant increase in the tensile modulus and decrease in impact strength were observed.

NOTE: The mechanical properties of many polymers change as a result of exposure to high-energy radiation. These changes are symptomatic of structural alterations within the polymer backbone occurring as a result of chain scission. When irradiated in the absence of oxygen, chain scission may be followed by "cross linking" or other similar modifications to the polymer (e.g. branching), resulting in an increase in molecular weight. When irradiated in the presence of oxygen, photo oxidative degradation occurs in competition with the "cross linking" process, resulting in an overall decrease in molecular weight and a consequent reduction in associated mechanical properties, such as toughness.

FIGURE 4: INFLUENCE OF STERILIZATION PROCESSES ON THE MODULUS OF CARILON POLYMER D26HM100

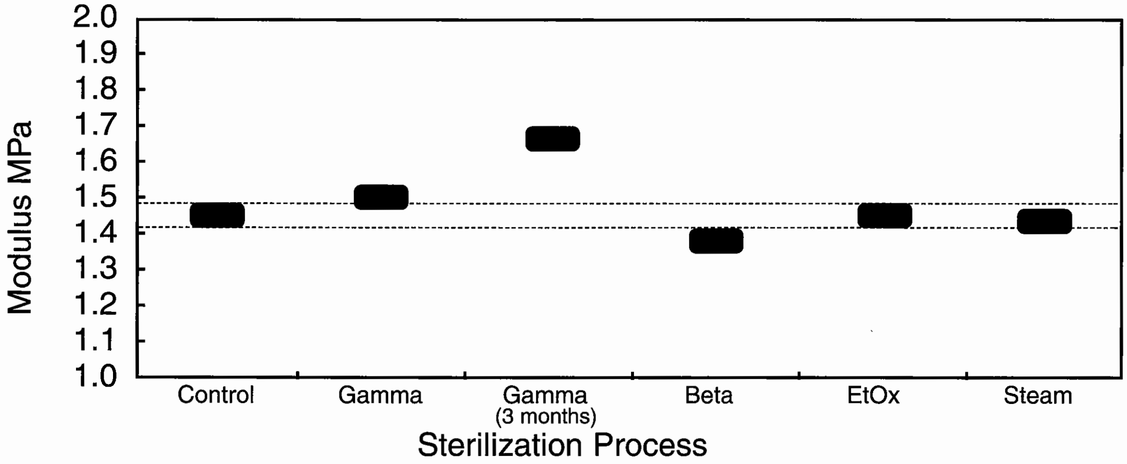


FIGURE 5: INFLUENCE OF STERILIZATION PROCESSES ON THE STRESS AT YIELD ON CARILON POLYMER D26HM100

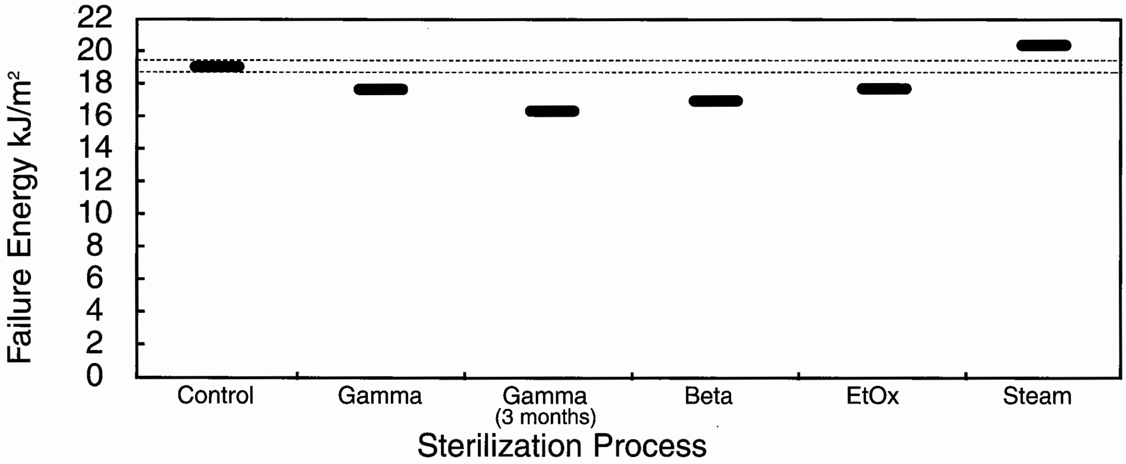


FIGURE 6: INFLUENCE OF STERILIZATION PROCESSES ON THE STRAIN AT YIELD ON CARILON POLYMER D26HM100

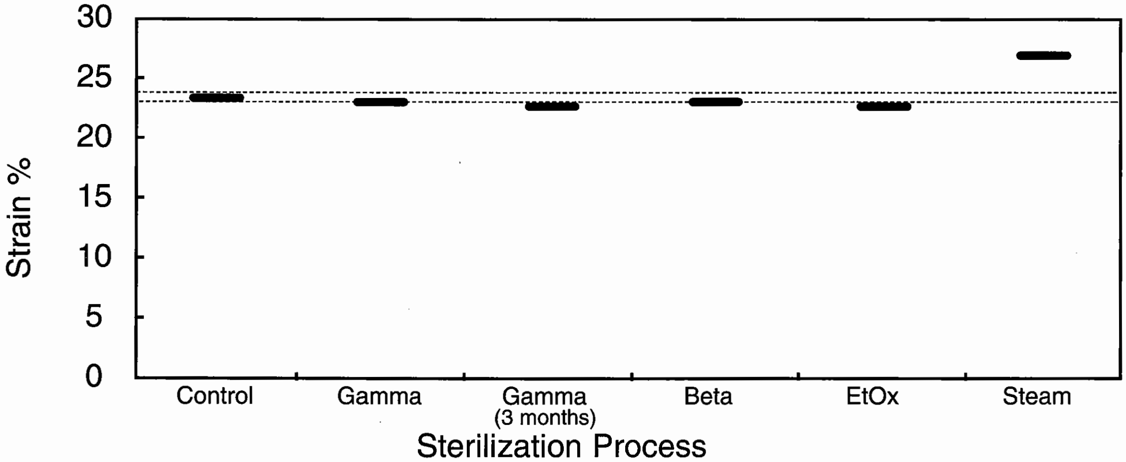


FIGURE 7: DISCOLORATION OF CARILON POLYMER D26HM100 AS A RESULT OF STERILIZATION PROCESSES

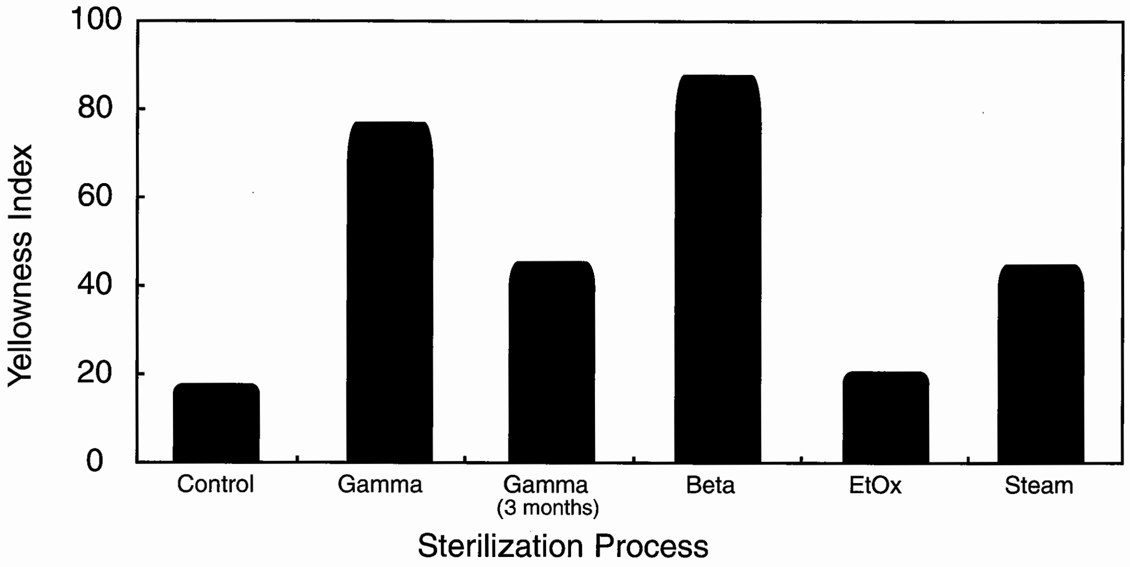
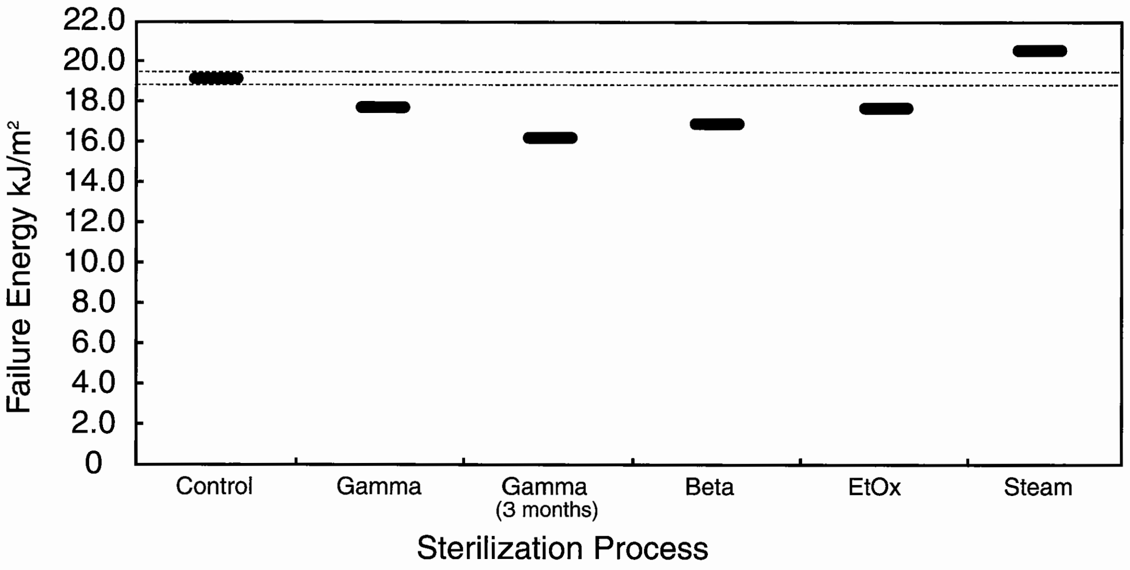


FIGURE 8: INFLUENCE OF STERILIZATION PROCESSES ON NOTCHED IZOD IMPACT STRENGTH OF CARILON POLYMER D26HM100



Gamma Υ and Beta β Sterilization – CARILON Polymer DB6G3A10

The changes in properties of CARILON Polymer DB6G3A10 on Υ or β sterilization followed similar trends to those observed for CARILON Polymer D26HM100. However, the changes to the polymer matrix were substantially masked by the reinforcing effect of the glass fiber.

Neither Υ nor β sterilization caused significant short-term change in the tensile properties of CARILON Polymer DB6G3A10 (Figures 9, 10 and 11).

The impact strength of the polymer was also unaffected by either Υ or β sterilization (Figure 12).

After storage of the Υ sterilized compound, significant increase in the tensile peak stress and decrease in toughness were observed. This is associated with continuing free radical degradation of the polymer matrix.

FIGURE 9: INFLUENCE OF STERILIZATION PROCESSES ON THE MODULUS OF CARILON POLYMER DB6G3A10

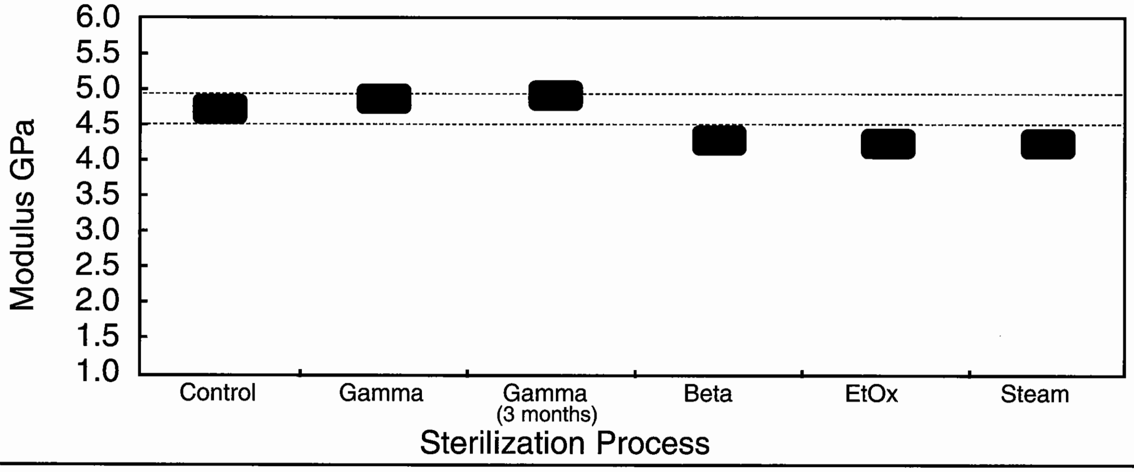


FIGURE 10: INFLUENCE OF STERILIZATION PROCESSES ON BREAK STRESS OF CARILON POLYMER DB6G3A10

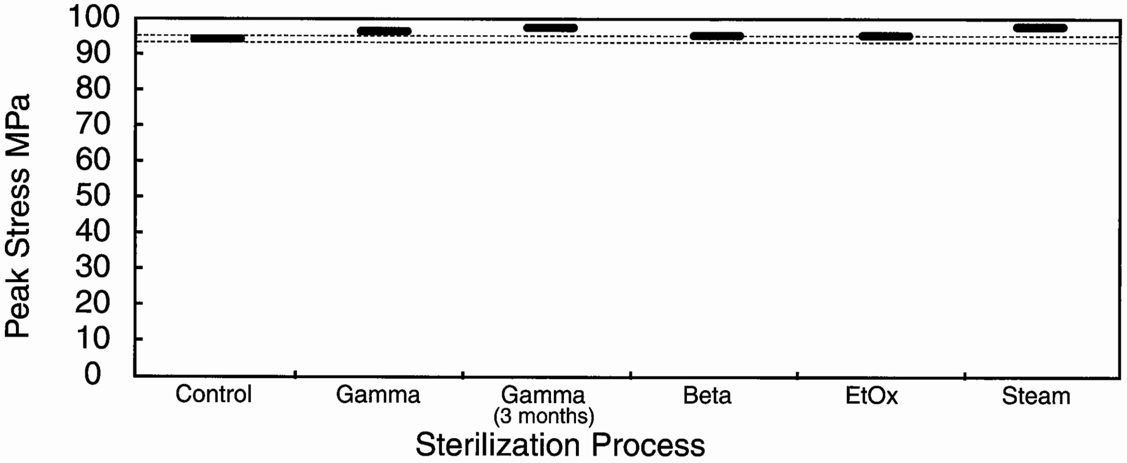


FIGURE 11: INFLUENCE OF STERILIZATION PROCESSES ON STRAIN AT BREAK OF CARILON POLYMER DB6G3A10

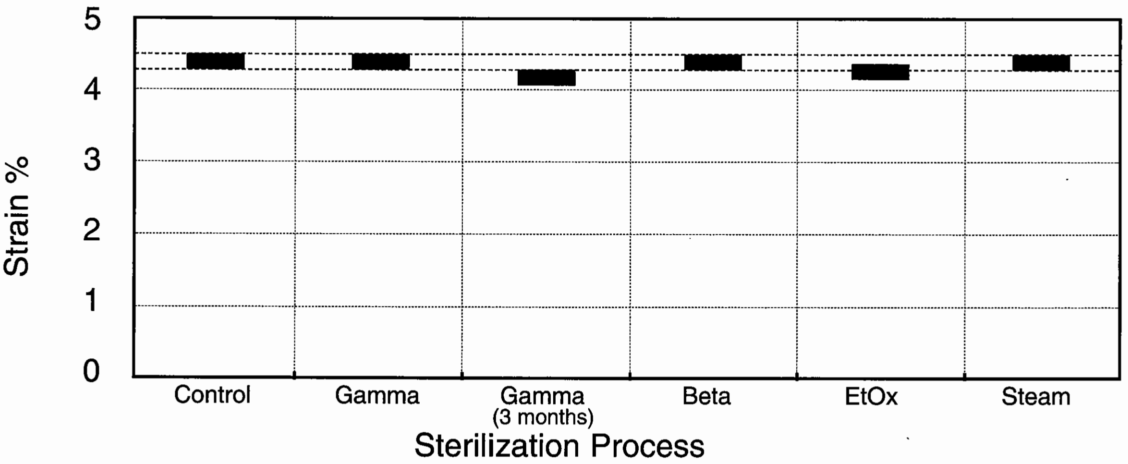
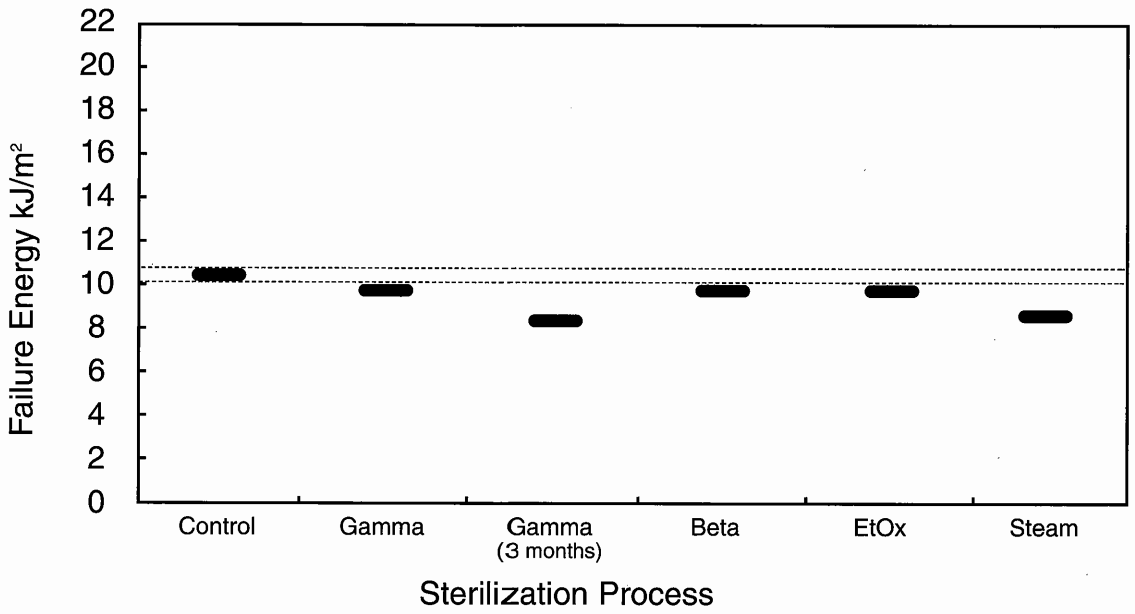


FIGURE 12: INFLUENCE OF STERILIZATION PROCESSES ON THE NOTCHED IZOD IMPACT STRENGTH OF CARILON POLYMER DB6G3A10



Ethylene Oxide Sterilization (EtOx) – CARILON Polymer D26HM100

As can be seen from Figures 4, 5 and 6, EtOx sterilization had no significant effect upon the tensile properties of CARILON Polymer D26HM100.

There was a reduction in toughness and impact strength following EtOx sterilization (Figure 8), but this change is judged not to be of practical significance.

Ethylene Oxide Sterilization (EtOx) – CARILON Polymer DB6G3A10

As can be seen from Figures 10, 11 and 12, EtOx sterilization had no effect on the break stress, strain at break or impact strength of CARILON Polymer DB6G3A10.

There was a reduction in modulus after EtOx sterilization (Figure 9), but this change is judged not to be of practical significance in the context of fiber-reinforced materials.

NOTE: The EtOx concentrations in 4mm samples of CARILON Polymer D26HM100 were observed to reach a value of 17 ppm after a five-day degassing phase. The EtOx concentrations in 4mm samples of CARILON Polymer DB6G3A10 were observed to reach a value of 20 ppm after a five-day degassing phase. It is important to determine minimum degassing times for individual applications in order to comply with regulations that specify the maximum level of residual EtOx.

CONCLUSION

CARILON Thermoplastic Polymers can withstand different widely used sterilization processes. Unlike some other materials, their excellent hydrolytic stability makes them of special interest for steam sterilization. Even after multiple steam sterilization cycles, the tested materials still demonstrated an attractive balance of mechanical properties, making them materials to consider for end uses requiring reusable sterilized injection-molded parts. Additional development work is under way.

Shell has assembled a global sales and technical support team that is ready to assist you, anywhere in the world.

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Or contact your local Shell Chemicals company

Shell strongly suggests that all those who come in contact with CARILON* Polymers and compounds read and follow all information presented in the Material Safety Data Sheet (MSDS) for this product. Also refer to all safety information provided with processing equipment.

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