Effects of Sterilization on the Mechanical Properties of Silicone Rubber

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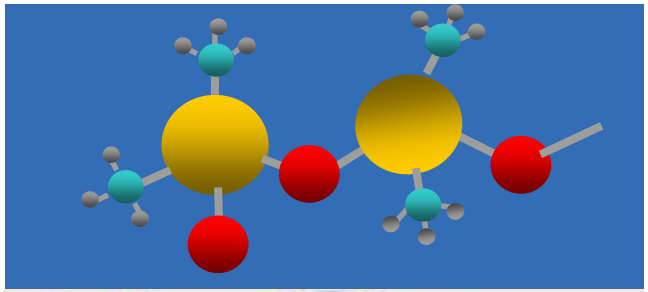
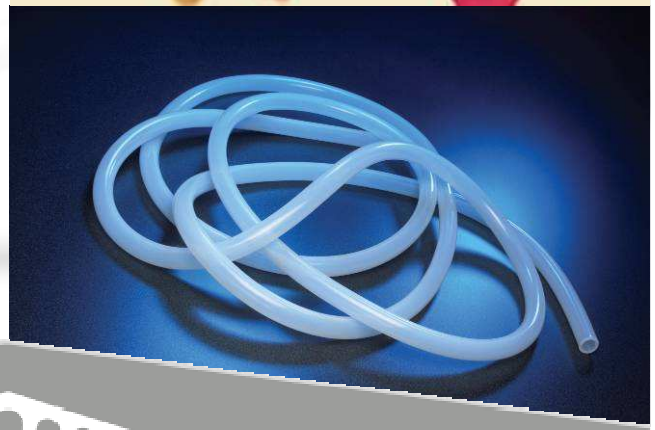
Based on a published paper authored by: Emilie Gautriaud, Keith Stafford, Jennifer Adamchuk, Mark Simon, and Danny Ou

Saint-Gobain Performance Plastics





SAINT-GOBAIN

INNOVATIVE MATERIALS

Outline

- Overview of Silicone Rubber and its Use in the Medical Industry
- Overview of Common Sterilization Methods and Their Effect on the Molecular Structure of Silicone Rubber
- Effect of Gamma Irradiation
- Effect of E-beam Irradiation
- Effect of EtO Treatment
- Conclusions and Recommendations

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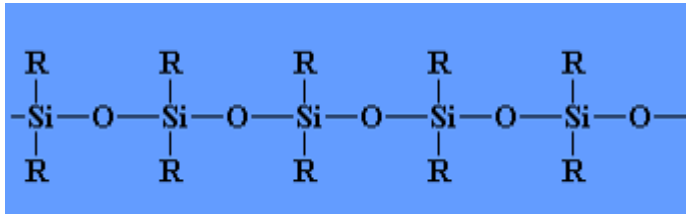
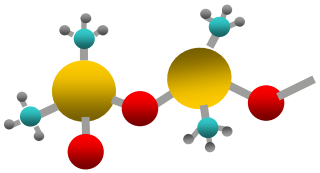
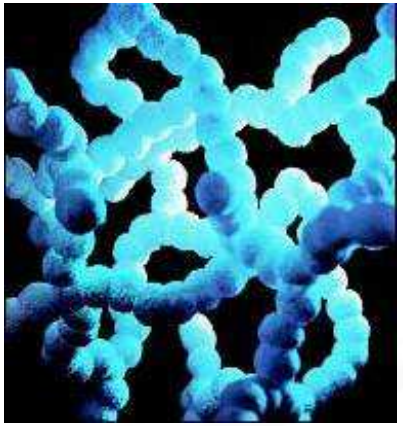
Schematic Structure of Silicone Rubber

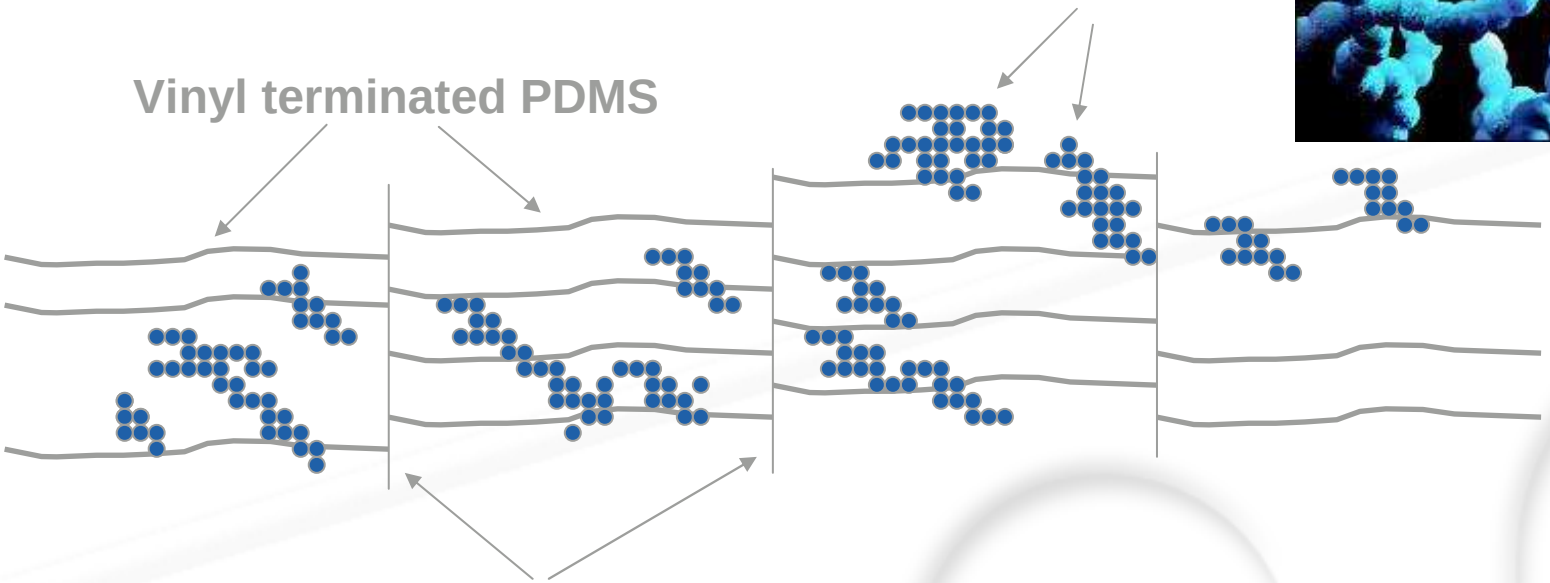






Silica filler

Vinyl terminated PDMS



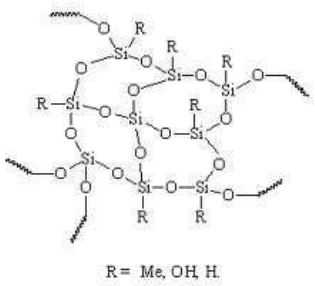
Si-H containing PDMS

- Cross-linked Polydimethylsiloxane (PDMS) Network Reinforced by Silica Filler

Silicone: Elastomer of Choice for Medical Applications

Attribute/Property	Benefit
Si-O-Si Backbone	Broad Continuous Use Temperature Range Maintains Elasticity from -65ºC to 285ºC Withstands Repetitive Steam Sterilization Cycles
Purity	Low Extractables (No plasticizers) Clarity “No” Taste or Odor
Physical Properties	Low Compression Set Low Tensile Set Broad Range of Hardnesses/Durometers
Chemical Inertness	USP Class VI Food Contact Biocompatible

The History of Silicone Rubber



Today — Elastomer of Choice for Biomedical Applications

1975 — Process for Creating Silicone Rubber using Liquid Injection Molding Techniques: The Birth of LSR

1943 — Production of the First Commercial HCR Grade - Dow Corning and GE

1940 — Industrial Scale Production Developed by Dr. E. Rochow

1908 — Invented by Prof. F. S. Kipping

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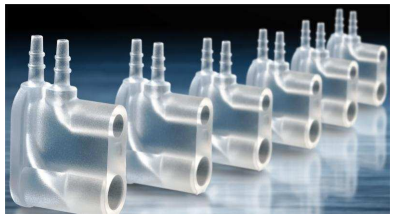
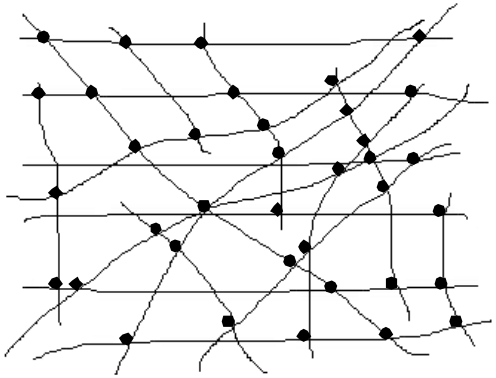
Most Common Silicone Rubbers

- **Liquid Silicone Rubber (LSR)**
  - Part A&B liquid system
  - Used for molded components



- **Platinum (Pt) Cured High Consistency Rubber (HCR)**
  - Rubber formulation using a Pt catalyst
  - Used for extruded and molded components
    - More flexible, higher tear, less extractables vs. peroxide cured rubber systems

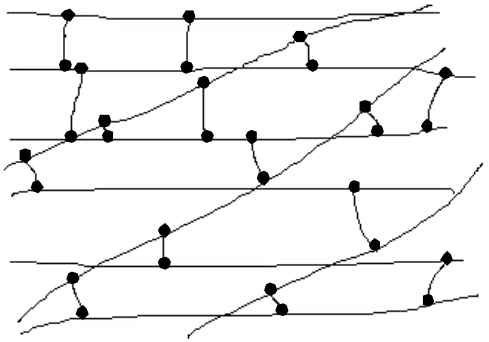
PLATINUM
Vinyl/hydride crosslinks



More flexible - Better tear

- **Peroxide Cured High Consistency Rubber (HCR)**
  - Rubber formulation using a peroxide free radical initiator
  - Used for extruded and molded components
    - More rigid, more resilient vs. Pt cured rubber systems

PEROXIDE
Methyl and vinyl crosslinks



More rigid - More resilient

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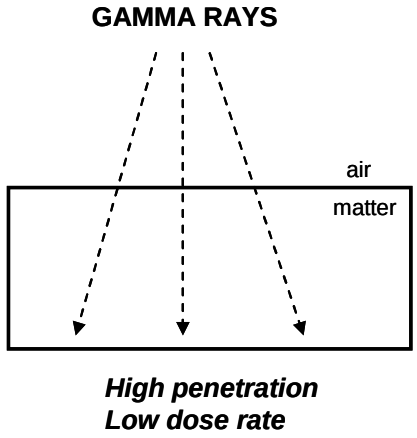
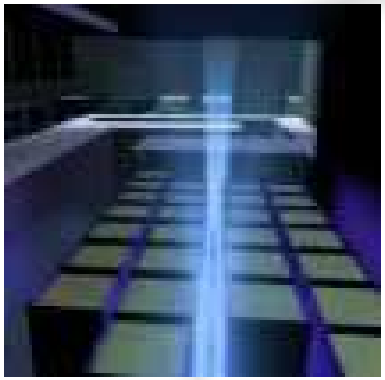
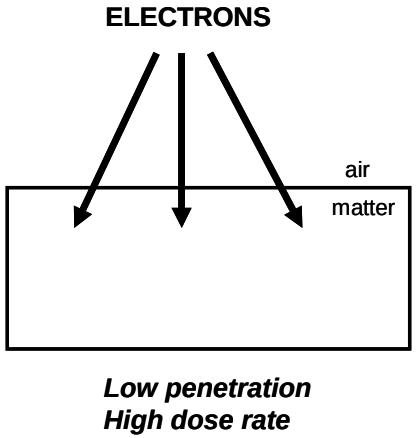
Gamma Irradiation



- Gamma radiation is commonly used to sterilize medical devices
- Gamma rays penetrate deeply into the material and are generated from a radioisotope such as Cobalt-60

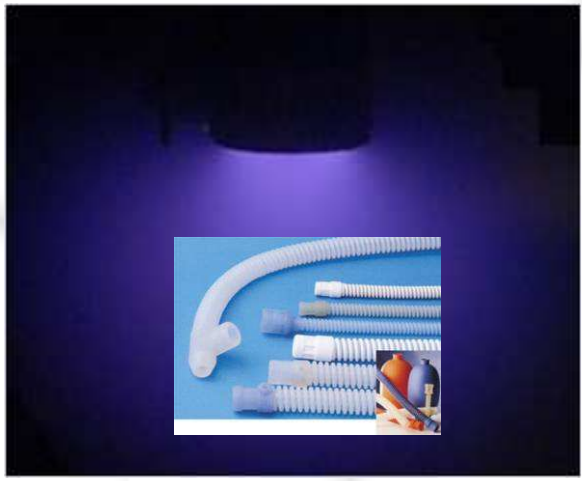


E-beam Irradiation

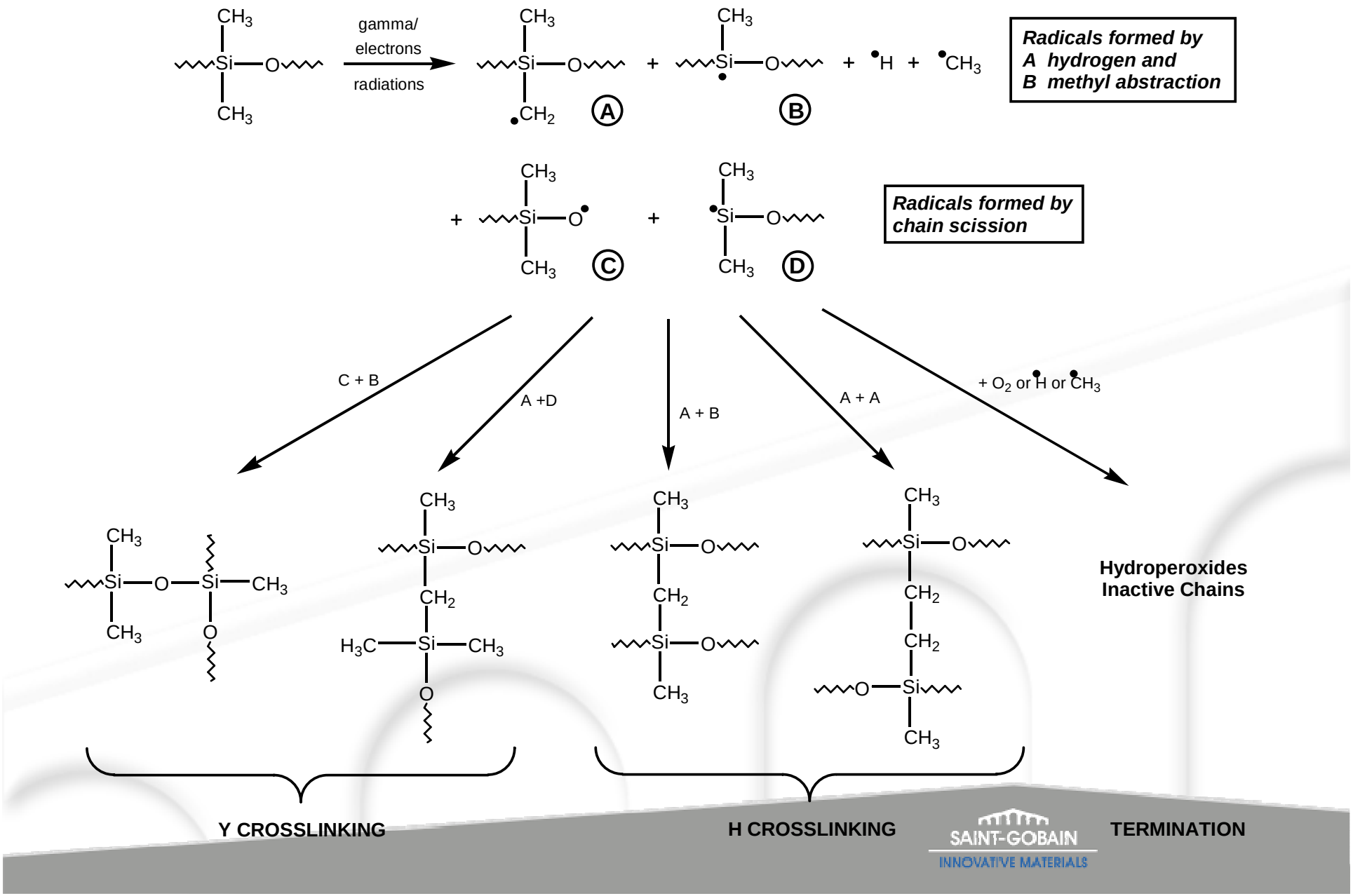


Low penetration
High dose rate

- E-beam is also commonly used for medical device sterilization
- E-beam systems use on-off technology and provide much higher dosing rates versus gamma, but with less penetration



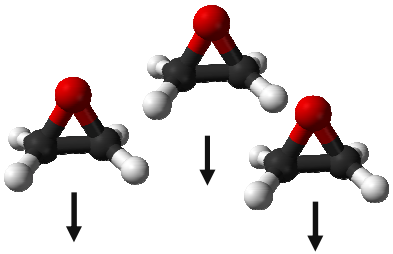
Effect of Gamma and E-beam on Polysiloxane Chains



Ethylene Oxide (EtO) Treatment

- Ethylene oxide gas is commonly used to effectively eliminate bacteria from the surface of medical parts
- EtO sterilizers are used to process sensitive instruments which cannot be sterilized by other methods
- EtO requires a longer time to sterilize and involves a period of post-sterilization aeration to remove toxic residues (namely EtO gas)

Ethylene Oxide



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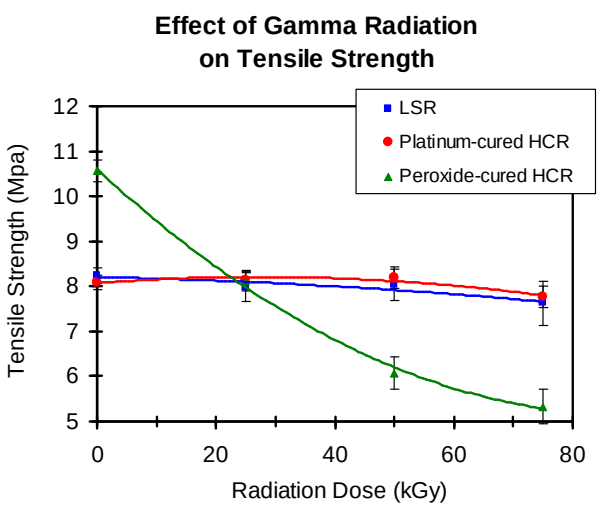
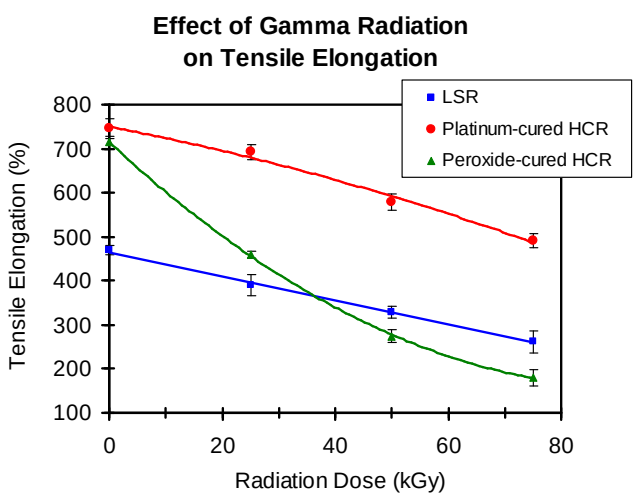
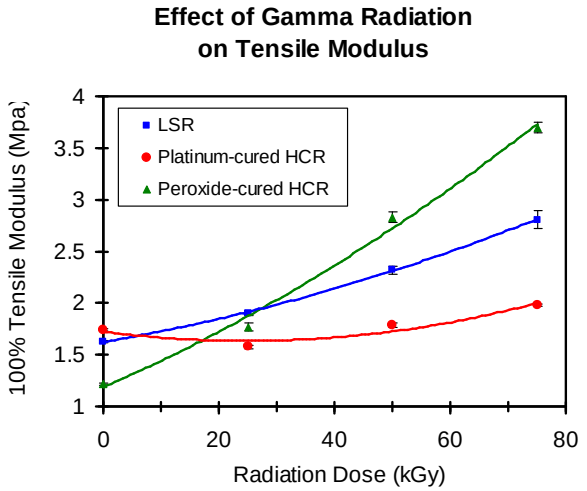
Effect of Gamma Irradiation







- Irradiation range tested: 0-75 kGy
- Tensile strength decreases in peroxide cured HCR
- Tensile elongation decreases and tensile modulus increases
  - This effect is more prominent in peroxide cured HCR

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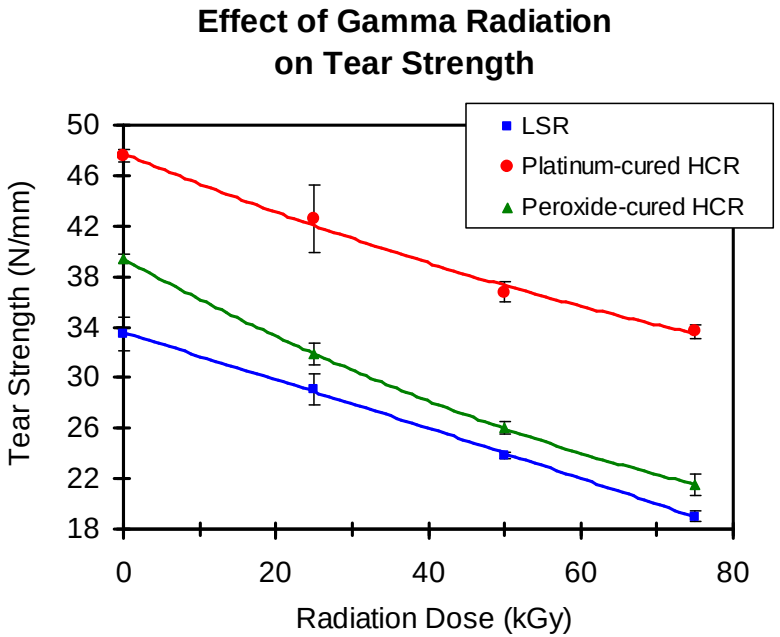
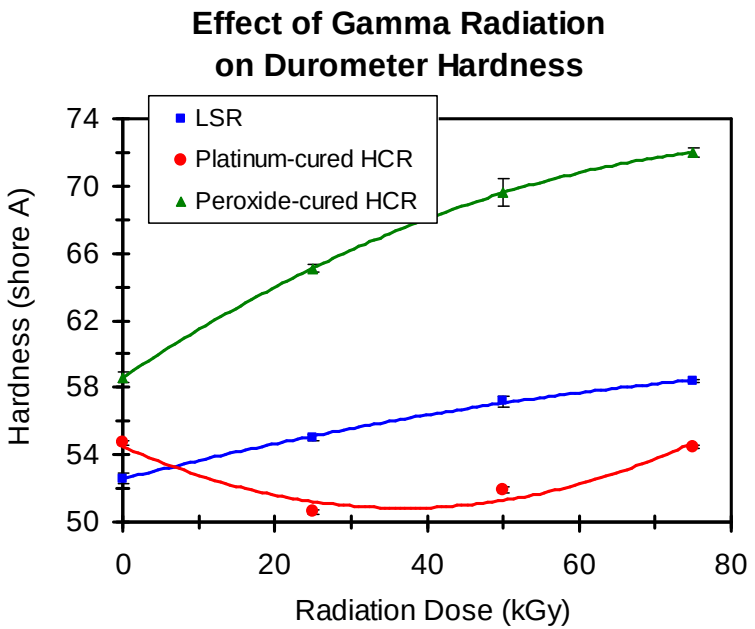
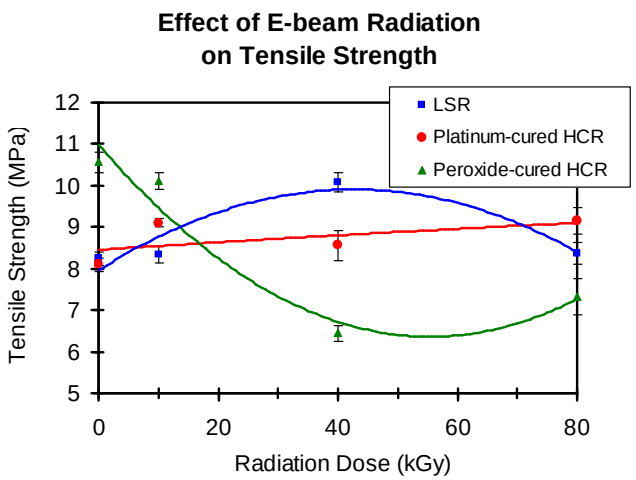
Effect of Gamma Irradiation

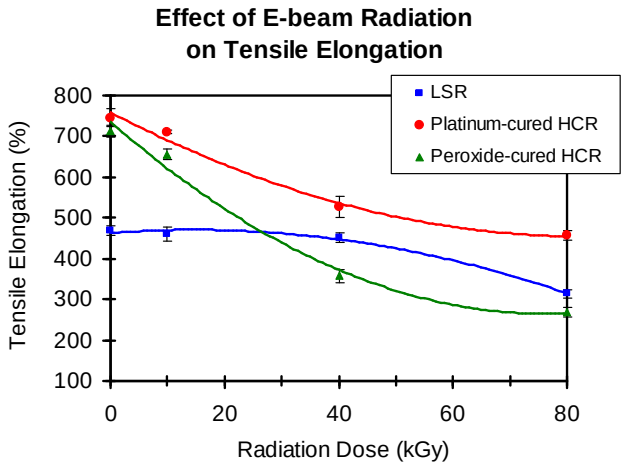


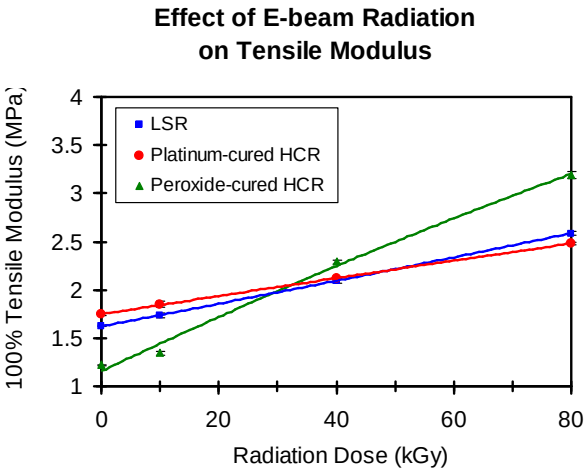


- Tear strength decreases
- Hardness increases for LSR and peroxide cured HCR

Effect of E-beam Irradiation

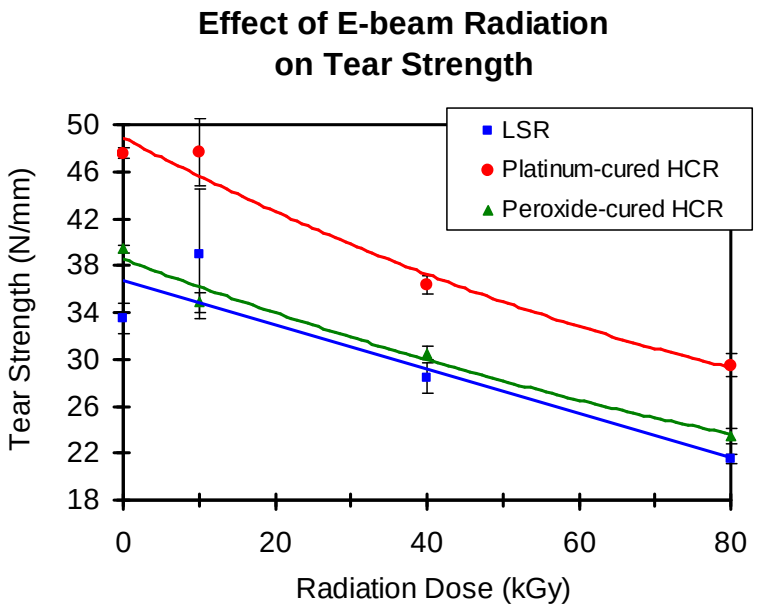


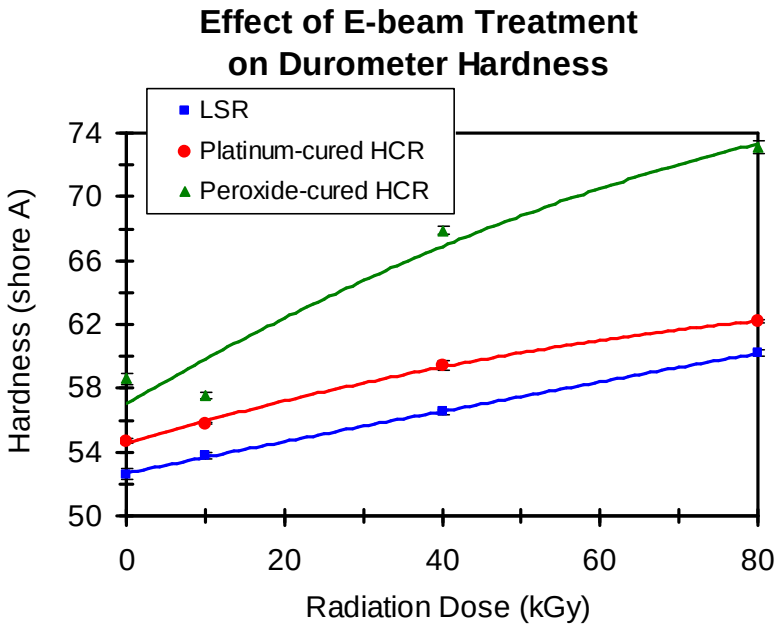




- Irradiation range tested: 0-80 kGy
- Tensile strength decreases in peroxide cured HCR
- Tensile elongation decreases and tensile modulus increases
  - This effect is more prominent in peroxide cured HCR

Effect of E-beam Irradiation





- Tear strength decreases
- Hardness increases

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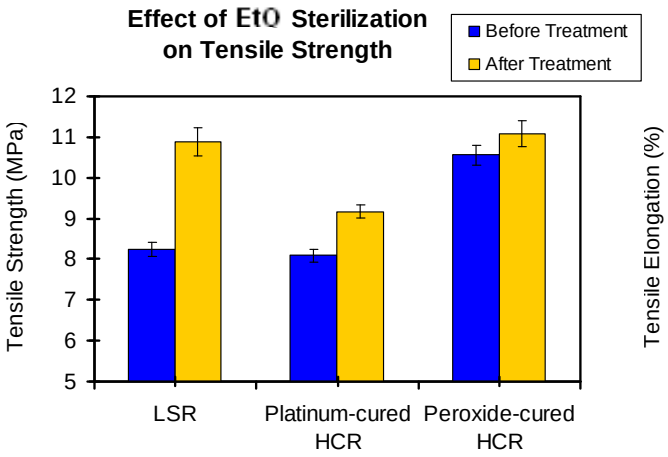
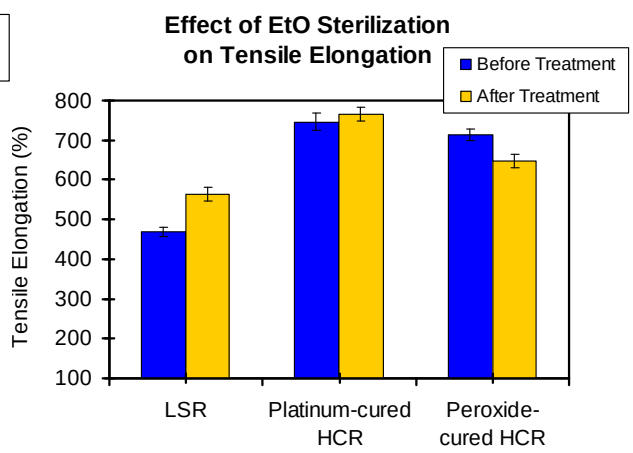
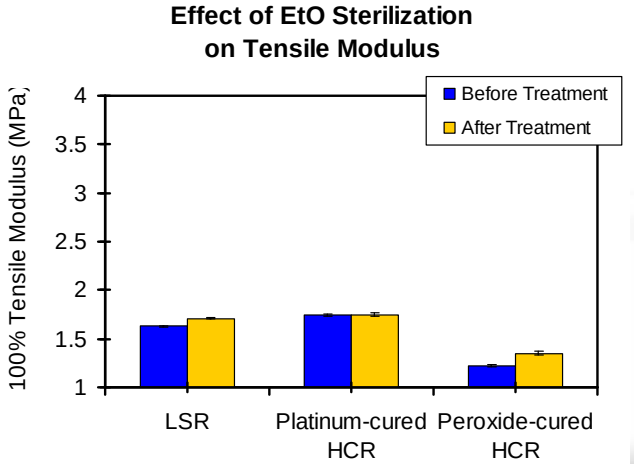
Effect of EtO Treatment







- **Overall, the effect of EtO treatment on tensile properties is minimal**
  - **The most significant effect is seen in tensile strength (increase)**

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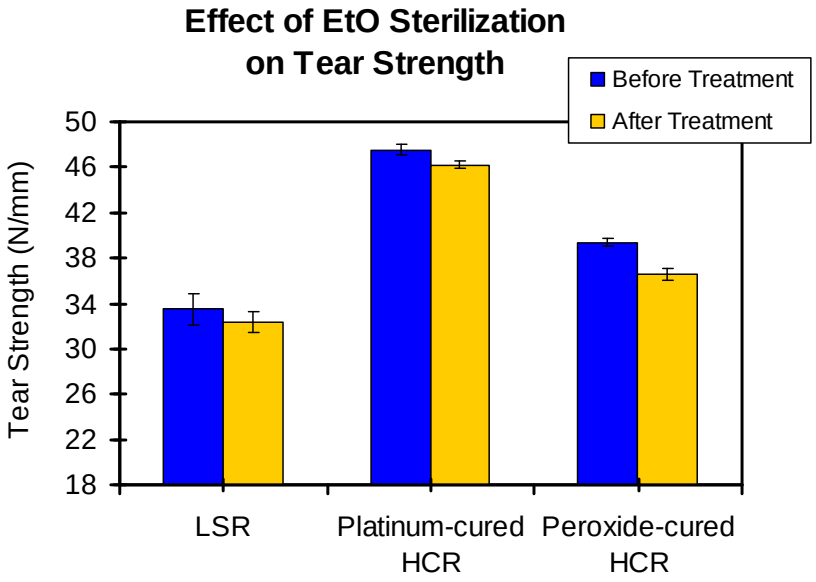
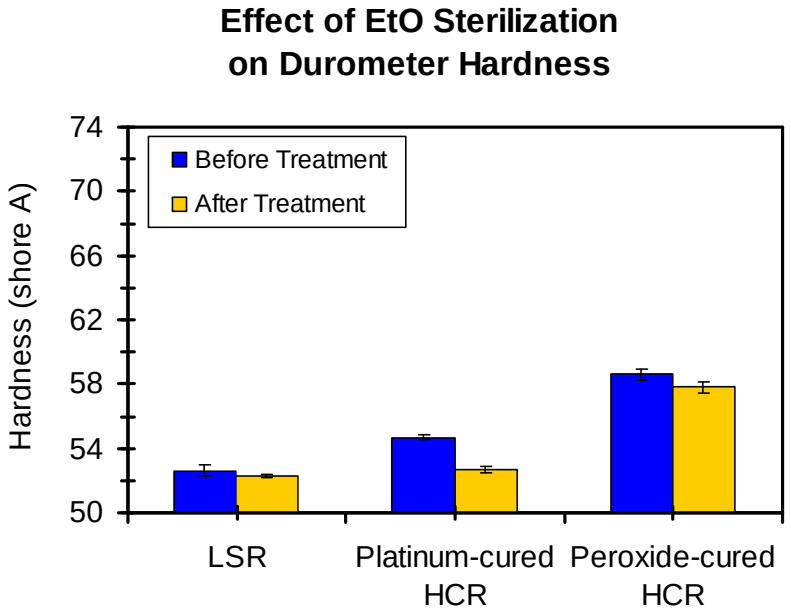
Effect of EtO Treatment





- The effect of EtO treatment on tear strength and hardness is minimal as well

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Conclusions

- Gamma and E-beam sterilization lead to an increase in tensile modulus and a decrease in tensile elongation for common silicone rubbers
- Gamma and E-beam sterilization lead to a reduction in tear strength for common silicone rubbers
- The extent of radiation deterioration is more pronounced in peroxide cured HCR
- EtO sterilization minimally impacts the physical properties of common silicone rubbers

Recommendations

- Limit Gamma and E-beam radiation sterilization of silicone medical devices if possible
  - Platinum cured silicone is less affected than peroxide cured silicone
- EtO is the preferred method of sterilizing silicone… preferred in the sense that it minimally impacts physical properties