STERILIZING RADIATION EFFECTS ON SELECTED POLYMERS

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INTRODUCTION

MASTER

Sterilization of plastic medical devices and supplies by ionizing radiation is increasingly being employed as an alternative to gaseous ethylene oxide sterilization. In many cases, plastic materials cannot be sterilized by techniques which require heat--dry heat, steam (or moist heat) sterilization--nor is sterilization by cold (aqueous) sterilants satisfactory in many instances. Radiation sterilization, therefore, is becoming a more and more viable method for sterilization of many medical products, and indeed, is well on the way to becoming a well established industrial process. Although this technique is not limited to the sterilization of polymeric materials, it is probably the most applicable method for these materials.

Polymers as discussed here are organic materials made up of a specific type of molecule joined together in multiple repeat (monomer) units to form a high molecular weight material (macromolecule). They may be either synthetic or natural materials, although generally only synthetic or modified natural polymers will be discussed here. These materials are frequently separated into three types as a result of their final properties--thermoplastics, thermosets and elastomers. All three types of materials are capable of being shaped into a desired product at some stage of their processing.

The arrangement of molecules in macromolecules may be very regular or completely random, thus providing zones of potentially high crystallinity or those with little or no apparent crystallinity. The degree of crystallinity is highly dependent not only on this molecular makeup, but also frequently upon the processing conditions used to form a polymeric material. In addition

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to the polymer molecules themselves the materials usually contain varying (usually small) amounts of other components to aid in processing or provide particular desirable properties to the finished product.

The additives are generally small molecules which function in the polymer matrix as antioxidants, ultra-violet light stabilizers, plasticizers, inert fillers, processing aids, etc., usually in low concentrations (1% or less), although such additives as fillers may be put in in quantities up to 30-40%.

Polymers vary greatly in their interaction with ionizing radiation and thus the dose necessary to produce similar significant effects in two different polymers may vary from values as low as about 4×10^4 rads in polytetrafluoroethylene to 5×10^9 rads in styrene or polyimides. These effects, however, can be quite profound with regard to the mechanical and physical properties of the polymer. For instance, in a typical polyethylene of about 100,000 weight average molecular weight and readily soluble in a solvent such as decalin (weight to number average molecular weight ratio of about 10), only one cross link for 14,400 monomer (ethylene) units can cause gelation (insolubility).⁽¹⁾ It is often very difficult to predict behavior of a polymer as a result of ionizing radiation. Certain additives have very distinctive protective actions in preventing radiation damage to plastics. In some instances, these compounds are called "antirads" and frequently they are materials which are also good antioxidants for polymeric materials. The action of these additives can be that of a reactant which combines rapidly with radiation generated free radicals in the polymer, or as primary energy absorbers themselves.

Radiation generally interacts with polymers in two ways, both resulting from energy being dissipated by the radiation and causing excitation or ionization of the atoms or molecules of the material concerned. Alterations in molecular structures of the material then appear as changes in the chemical and physical properties of the polymers. Two major mechanisms of degradation or changes take place in a polymer as it is subjected to radiation. These are 1) chain scission occurring as a random rupturing of bonds which reduce the molecular weight of the polymer or 2) crosslinking occurs which results in the formation of large three-dimensional networks. Usually both of these

mechanisms occur as a polymeric material is subjected to ionizing radiation, but frequently (depending on condition and polymer) one mechanism predominates with a specific polymer. As a result of chain scission very low molecular weight fragments, gas evolution and unsaturation may occur. Crosslinking generally results in increased tensile strength, while impact strength decreases and the polymer becomes increasingly brittle with increased dose. For polymers with carbon-carbon chains or backbones it is observed that crosslinking generally will occur if the carbons have one or more hydrogens attached to them, whereas scission occurs at a tetra substituted carbon. Polymers containing aromatic molecules generally are much more resistant to radiation degradation than purely aliphatic chain polymers. This is true whether or not the aromatic group is directly in the chain backbone or not. Thus, both polystyrene, with a pendant aromatic group and/or polyimides, with an aromatic group directly in the polymer backbone, are relatively resistant to high doses (10^9 - 10^{10} rads) of radiation. From a product/use viewpoint, the most important characteristic of polymers affected by ionizing radiations are the mechanical properties. These properties include tensile strength, elastic modulus, impact strength and shear strength as well as the elongation. Embrittlement may occur even though irradiated polymers drop in hardness. Crystallinity and hence density characteristics may also change as chain scission continues.

Another important factor often resulting from the irradiation of polymers is the development of color. This is usually an undesirable development whether the change results in only yellowing or browning the product or complete opacity. These changes which usually occur at widely differing doses in various polymers are affected by the presence of oxygen and may either diminish or develop with storage after irradiation.

A great deal of the information available from government reports, industrial literature and scientific publications concerning radiation effects on polymers deals with their properties after exposure to extremely high doses and frequently little data is available in the range of interest for sterilization.

Radiation dose conditions used for sterilization, although varying significantly from process to process or device to device, generally appear to be in the 1-5 Mrad range. The higher values might also apply to situations where repeated sterilization of a plastic material might occur. It is assumed that the effects of radiation on polymers are cumulative (additive) with each subsequent sterilization of a device or product.

The information detailed here regarding a variety of polymers has been obtained from a wide range of sources which are generally referenced. The polymers described here are divided into the three major types, thermoplastics, thermosets and elastomers, with some additional remarks concerning fibers, and adhesives, coatings and potting compounds which, although generally polymeric in nature, frequently have a somewhat different function than the normal biomedical plastics.

The conditions under which irradiation occurs can significantly affect the final material. The presence of oxygen or air frequently makes a difference in the interaction of radiation with polymers. Free radicals produced in polymers by radiation are rapidly converted into peroxidic radicals.⁽²⁾ The fate of these radicals is dependent both upon the nature of the irradiated polymer and on other parameters such as temperature, total dose, dose rate and sample size. Conditions may also effect the interaction of radiation with polymer additives resulting in gas evolution and other degradation products from these small molecules with the possibility of producing irritants or other undesirable products.

THERMOPLASTICS

This large group of polymers constitutes the most widely used variety in medical devices and supplies. The most widely used of these materials are briefly described in the following paragraphs.

ABS (ACRYLONITRILE/BUTADIENE/STYRENE)

Although ABS materials are less radiation resistant than styrene or styrene/acrylonitrile polymers, they are easily processed by standard polymer

fabrication techniques and will withstand one or more radiation sterilization procedures with no observable effect on properties.⁽³⁾

POLYACETALS

Homopolymers and copolymers making up the polyacetals are derived from formaldehyde as the primary monomer. Both the copolymers and homopolymers are relatively sensitive to radiation. Radiation doses exceeding 1.0 Mrad appear to cause undesirable changes in these materials and although they have many desirable properties as structural plastics, they should be used with caution where they may be expected to receive radiation doses in excess of 1 Mrad.⁽³⁾ The radiation damage threshold is estimated at 0.5 Mrads with 25% damage at 1.1 Mrads.⁽⁴⁻⁶⁾

POLYACRYLICS

This important group of materials consist of a number of commercially available polymers and copolymers with a wide range of uses and properties. The most commonly used acrylic polymer, polymethyl methacrylate (PMMA), has relatively poor ionizing radiation resistance.⁽⁷⁻⁹⁾ It is certainly capable of withstanding at least one sterilizing radiation procedure in most of its finished product forms without noticeable effect, however, multiple doses in the megarad range may be expected to affect its mechanical properties significantly. Irradiation degrades this polymer to produce an unacceptably brittle product in the 10^7 rads dose range.⁽¹⁰⁻¹⁴⁾ Perhaps more importantly one of PMMA's most desirable properties, optical clarity, is considerably affected. Discoloration may occur at doses as low as 0.5 Mrad and light transmission can decrease by more than 50% after a 5 Mrad exposure. Some recovery of transmission occurs during storage in oil and certain additives help protect the polymer against damage.

Other acrylic polymers such as polyacrylonitrile, polyacrylates, polyhydroxyacrylates and polycyanoacrylates appear to have somewhat better resistance to radiation than PMMA, but none of these materials should be sterilized by radiation many times.⁽¹⁵⁾

POLYAMIDES

These polymers commonly referred to as nylons, or in some cases aramids, are among the most commonly used polymers for many applications. The aliphatic polyamides, nylons 6, 66, 6/10, 12 show little difference in their stability to radiation. Nylons of this type generally crosslink under the influence of irradiation and show an increase in tensile strength and hardness, but decrease in elongation to break and impact strength.^(16,17) Thus, these materials can readily withstand single radiation sterilizations, but the advisability of multiple sterilizations should be questioned depending upon the use and the particular polymer.

The aromatic family of polyamides called aramids, although most frequently appearing in fiber form, have very excellent radiation (10^9 rads) and thermal stability and can be expected to retain all their properties after multiple sterilizations by radiation or other techniques.⁽¹⁸⁾

Most recently some new transparent (amorphous) polyamides have been made available and may be very useful in some application, but may be expected to be sensitive to multiple sterilizations.

CELLULOSICS

The cellulosic polymers considered in this application are comprised primarily of the cellulose esters or mixed esters together with ethyl cellulose. They exhibit fair radiation resistance and, although they vary considerably from material to material, an average dose value at which significant (~25%) degradation takes place in cellulose acetate is about 20 Mrads. Thus, these materials appear to be able to withstand a single sterilization without significant effect on their properties.^(19,20)

FLUOROPOLYMERS

Fluorinated polymers and particularly tetrafluoroethylene (TFE) are renowned for their chemical stability and their high temperature use characteristics. However, these materials are extremely sensitive to radiation and are among the poorest known polymers in terms of radiation stability. TFE (Teflon), perhaps the best known and used of the group, shows significant radiation damage at exposures as low as 0.04 Mrads⁽²¹⁾ and is unsuitable

for radiation sterilization. TFE does not crosslink on irradiation, but instead liberates fluorine atoms which in turn react to break carbon-carbon bonds in the polymer, thus reducing molecular weight.

Other fluoropolymers have somewhat better resistance to radiation. Polychlorotrifluoroethylene (PCTFE) reportedly shows threshold radiations damage at about 1 Mrad and 25% damage at 20 Mrads.⁽⁴⁾ FEP (copolymer of hexafluoropropene and tetrafluoroethylene) polymer is considerably more radiation resistant than TFE and can be sterilized satisfactorily. Other fluoropolymers such as polyvinyl fluoride, polyvinylidene fluoride, and copolymers of ethylene and tetrafluoroethylene (ETFE) show much less sensitivity to radiation (100 Mrads), tend to crosslink on exposure and are capable of multiple sterilizations by radiations.⁽³⁾

POLYCARBONATE

The commercial polycarbonate polymers contain aromatic rings in their main chain structure and as might be predicted show quite good resistance to radiation.⁽⁴⁾ Their strength is retained well after exposures up to 800 Mrads. Polycarbonates have excellent impact strength and resist thermal oxidation degradation up to 150°C. They are readily molded, extended or machined to desired shapes.

POLYESTERS (AROMATIC)

Aromatic thermoplastic polyesters for use as structural polymers have been increasingly popular in recent years. The most common type of polyester is the polyethyleneterephthalate which shows fairly good radiation resistance (25% damage at ~90 Mrads).⁽³⁾ Recently these materials have appeared in a variety of filled and unfilled as well as transparent (amorphous) products that should find a range of applications in medical devices and packaging. These materials, of course, can withstand multiple radiation sterilization without serious degradation.

POLYOLEFINS

These materials are among the most commonly used thermoplastic materials. They are widely used in medical devices and packaging. They are divided into broad groups as discussed briefly.

Polyethylene. Polyethylene is produced in differing types known as low density, high density and ultrahigh molecular weight varieties by modifying the processes by which the monomer ethylene is polymerized. All forms are reasonably resistant to radiation and can withstand without significant change in properties doses up to 100 Mrads. Polyethylene reacts with ionizing radiation generally to crosslink the polymer. Charlesby and Pinner⁽²²⁾ have obtained a value of 0.3 for the ratio of chain scission to crosslinking in irradiated polyethylene, thus indicating that although crosslinking predominates as a mechanism, considerable carbon-carbon bond cleavage also occurs. With irradiation the average molecular weight increases and the degree of crystallinity decreases.⁽²³⁾ The mechanical properties show increases in tensile strength and other values up to about 10 Mrad and then gradually decreases. The modulus of elasticity reacts oppositely, first falling, and then increasing, while the impact strength falls continuously after about 50-80 Mrad.

Polypropylene. Both chain scission and crosslinking are observed to occur in irradiated polypropylene in about equal amounts.^(24,25) This is perhaps not surprising due to the fact that polypropylene has a structure intermediate between that of polyethylene, which primarily crosslinks, and polyisobutylene (quaternary carbon atom) which degrades by scission on exposure to radiation. Radiation doses that cause only 25% damage to polyethylene make polypropylene completely useless.⁽⁴⁾ Impact strength continues to decrease slowly after irradiation indicating additional crosslinking. Polypropylene therefore is probably suitable only for single dose radiation sterilization. Polypropylene, an extremely useful polymer for medical applications, is discussed much more fully in a paper devoted exclusively to it in this symposium.

Polymethylpentene. This transparent polyolefin material has a number of desirable properties and although not a great deal of information is known concerning its radiation behavior, it is expected to have stability between that of polyethylene and polypropylene. Information from its manufacturer⁽²⁶⁾ states "polymer is stable against electron and gamma radiation, and can be

subjected to such radiation, as required by sterilization procedures, without discoloration or embrittlement even on prolonged exposure."

Copolymers - Polyallomers are copolymers of ethylene and propylene and in some cases a third monomer. They are relatively crystalline block copolymers which exhibit many of the same properties as polyethylene and polypropylene and, indeed, show some of the best properties of both, such as stress-crack resistance, low brittleness temperatures and ease of processing. These copolymers have good radiation resistance with the primary effect being cross-linking. These copolymers are easily processed by common plastic molding and extrusion techniques and may be multiply sterilized by radiation without effect.⁽³⁾ Poly(ethylene-vinyl acetate) and poly(ethylene-acrylate) are ethylene copolymers normally containing relatively large ratios of ethylene and are reasonably stable to radiation (similar to polyethylene) and therefore are suitable for multiple sterilization procedures. Some of these materials, being almost elastomeric in nature, widen the selection of properties available in polyethylene type polymers.

POLYSTYRENE

This well known polymer is the most radiation stable of the common and inexpensive molding and extrusion materials. Its properties remain unaffected and gas evolution is insignificant to a higher radiation dose than any other plastic in its class. Its stability is believed to be due to the protective action of the pendant benzene rings.⁽²⁷⁾ Cross linking of styrene occurs almost to the total exclusion of chain scission and a radiation dose of about 4000 Mrads is necessary to cause any significant damage.⁽¹⁹⁾

Poly(styrene acrylonitrile) - SAN. Copolymers of styrene, although not exhibiting the same degree of radiation stability as polystyrene itself, nevertheless, have reasonably good resistance and may be expected to withstand multiple sterilizations without damage.

POLYSULFONES

This is a relatively new group of sulfur-containing, aromatic-backbone polymers which in general have very promising thermal and radiation resistance properties. There are at least three commercial products available:

(polysulfone, polyethersulfone and polyphenylsulfone), all of which reportedly can withstand radiation doses of greater than 1000 Mrads without significant damage.⁽²⁸⁻³⁰⁾ These polymers also have good chemical and thermal stabilities as well as mechanical properties and appear useful for multiple sterilization in a range of applications.

One other similar polymer of interest, although not a sulfone, is polyphenylene sulfide, another new and promising sulfur-containing material. This is another in the group of aromatic, high-temperature thermoplastics with good radiation stability. Technical representatives of the manufacturer report little change in tensile strength and flexural modulus of this material after exposure to 5000 Mrads.

POLYVINYLS

Polyvinyl chloride (PVC) is the most widely used vinyl polymer in medical products and finds application in many products, both as a plasticized and as an unplasticized material. PVC is found to crosslink to a considerable extent under irradiation^(7,31-33) Its stability to radiation is reported to be very similar to polyethylene--at least regarding the dose at which significant damage begins to appear (~100 Mrads).⁽³⁾ Plasticizers have some effect on the radiation sensitivity and hydrochloric acid is one product of irradiation which should be considered as PVC is used. However, PVC is certainly suitable for single and in most instances multiple radiation sterilizations.

Other vinyl polymers - Copolymers of PVC such as vinyl chloride-vinyl acetate as well as other polymers polyvinylidene chloride, polyvinylformal and polyvinylbutyral all appear to be more sensitive to radiation than PVC. Damage with these polymers begins in the range of 1-4 Mrads and 25% damage is observed at about 10-40 Mrads.⁽⁴⁾ It is therefore probable that these materials can be used in single sterilization, but may not be suitable for multiple procedures.

There are many additional thermoplastic polymers which have not been mentioned in this review. The attempt was made to include the major families of thermoplastics and the most commonly used polymers in these groups. There are certainly many other potentially useful materials which might be very applicable for specific purposes.

Table 1 summarizes the affects of radiation on thermoplastics and estimates their ability to be used in radiation sterilization procedures.

THERMOSETS

Although most of the thermoset polymers can generally be sterilized by such techniques as heat or steam sterilization, they will be briefly mentioned here as frequently useful polymeric medical products materials that might in most cases also be radiation sterilized.

PHENOL OR UREA FORMALDEHYDES

These formaldehyde resins are almost invariably used as filled or reinforced materials. Generally, the addition of mineral fillers increases the radiation stability of these polymers significantly--frequently by as much as 100 fold.^(3,4) Filled resin of this type usually show good radiation resistance up to 500 Mrads or higher. They can therefore be expected to be suitable for multiple sterilizations by radiation.

EPOXIES

These resins find wide use in many adhesive, potting, coating and encapsulating uses in medical products. These materials are above average in radiation resistance for polymers, although this may be varied somewhat depending upon the hardners (curing agent) used--resins produced utilizing aromatic curing agents generally are more stable than those using aliphatic hardners. These polymers are stable to radiation doses above 1000 Mrads and are therefore fully capable of surviving any number of radiation sterilization procedures without significant damage.

POLYESTERS (UNSATURATED)

Thermoset polyesters, of which there is a large group, represented by such polymers as styrene or diallyl phthalate modified alkyds, have quite good radiation resistance especially if they contain mineral fillers or glass fibers. Like the phenolic resins they can be expected to withstand radiation doses of more than 1000 Mrads before evidencing significant damage.⁽⁴⁾

TABLE 1. Effects of Radiation on Selected Thermoplastic Polymers

<u>Polymer</u>	<u>Radiation Stability</u>	<u>Radiation Dose to Produce Significant Damage (Mrads)</u>	<u>No. of Potential Sterilizations*</u>
ABS	Good	100	M
Acetals	Poor	1-2	0
Acrylics		5	
PMMA	Fair	5	1
Others	Fair	10	1-2
Amides			
Aliphatic	Fair	50-100	1-2
Aromatic	Excellent	1000	M
Cellulosics	Fair	20	1-2
Fluoroplastics			
TFE	Poor	1	0
PTFE	Fair	10-20	1-2
FEP	Fair	20	M
PVF, PVF ₂ , ETFE	Good	100	M
Polycarbonate	Good	100 ⁺	M
Polyesters (aromatic)	Good	100	M
Polyolefins			
Polyethylene	Good	100	M
Polypropylene	Fair	10	1
Polymethylpentente	Good	30-50	M
Copolymers	Good	50	M
Polystyrene	Excellent	1000	M
SAN	Good	100-500	M
Polysulfones	Excellent	1000	M
Polyvinyls			
PVC	Good	50-100	M
Copolymers	Fair	10-40	1-2

* Sterilization potential of polymers divided into four categories:
0 - non-sterilizable, 1 - one procedure, 1-2 - somewhat more than one, M - multiple sterilization possible.

This potential is based primarily on the mechanical properties of the polymers and for other reasons such as optical clarity or gas evaluation the material may not be suitable for the noted number of sterilizations.

Allyl diglycol carbonate, although listed as a polyester, is quite different in structure from most of the other polyesters and quite distinct in properties and uses. It has good optical qualities and good radiation stability. Exposures to nearly 100 Mrads are required to produce significant damage (25%) to this material.⁽¹⁹⁾ Its radiation resistance together with its optical properties make it a prime candidate for uses in medical devices requiring lenses or viewing windows.

POLYIMIDES

Polyimides are generally classified as thermosets, although some thermoplastic polyimides are now also available. These materials are well known for their very high thermal and radiation resistance. They can be expected to withstand radiation doses well about 1000 Mrads at high temperatures (500°F).

POLYURETHANES

The polyurethanes represent a wide variety of polymeric materials with properties dependent upon the monomers, and their ratios used in preparation. The most common products are called polyester- or polyetherurethanes and generally have very good resistance to radiation. The urethane's properties vary from those of an elastomer to that of hard, rigid crosslinked polymer whose mechanical properties showed no reduction after an exposure to 1000 Mrads.

These and other thermoset materials offer a wide variety of properties for a host of applications in the medical area. The polymers listed describe only a few of the most common materials available. A brief summary of the average expected radiation sensitivity of a number of these materials is summarized in Table 2.

TABLE 2. Radiation Sensitivity of Selected Thermoset Polymers

<u>Material</u>	<u>General Radiation Resistance</u>	<u>Radiation Dose For Significant Damage, Mrads</u>	<u>Suitable for Sterilization*</u>
Epoxies	Excellent	1000-10,000	M
Phenol (or Urea) formaldehyde	Good	500	M
Polyesters (unsaturated)	Good	1000	M
Polyimides	Excellent	1000-10,000	M
Polyurethanes	Excellent	1000+	M

*This data indicates when the polymer as generally used (formulated) is suitable for: 0-no sterilizations, 1-single sterilizations, or M-multiple sterilizations.

ELASTOMERS

The elastomers (rubbers) represent a large group of polymeric products which have some unique properties quite distinct from those of the thermoplastic and thermoset materials. They have a variety of applications in the area of medical products. Their resistance to radiation varies over a considerable range, although generally not as greatly as with the thermoplastic polymers. Table 3 lists a selected group of elastomers and compares the average radiation resistance of one of each of these types of rubbers. It suggests radiation doses at which threshold damage occurs (at least one physical property begins to change) and values at which about 25% damage occurs (represented by a 25% change in one property). Although this gives only a brief insight into the radiation stability of these materials, it does permit some selection of those materials for use in applications where radiation sterilizations may be used.

TABLE 3. Radiation Sensitivity of Selected Elastomers^(3,4,34)

<u>Material (Rubbers)</u>	<u>Radiation Threshold Damage Mrads</u>	<u>Dosage ~25% Damage Mrads</u>
Polyacrylic	2-4	10-15
Butyl	2-3	10
Chlorosulfonated polyethylene	--	30
EPDM	10	100 ⁺
Fluoro	5	50-70
Natural	10	100-200
Nitrile	--	100
Polychloroprene (Neoprene)	6	50
Silicones	--	50-100
Styrene-butadiene	6-8	100 ⁺
Urethane	20	600-800

The figures given in Table 3 are only meant to be average figures and it must be pointed out that fillers, plasticizers, etc. and the polymers themselves can have a very substantial influence on the radiation stability of these elastomers. For instance, the addition of aromatic plasticizers to neoprene compositions make these rubbers much more stable to radiation.⁽⁴⁾ The partial substitution of phenyl groups for methyl groups in silicone rubbers increase the radiation stability considerably.⁽³⁵⁾ Most of the elastomers listed, with the possible exception of the first two (polyacrylic and butyl), are certainly capable of being radiation sterilized one or more times.

FILMS AND FIBERS

The effects of radiation on thin plastic films and organic synthetic fibers (textiles) may in some cases differ from effects noticed in bulk products manufactured from the same or similar polymers. These variations may be due to differences resulting from processing of these materials. For

polymers which may be in the questionable range for the use of radiation sterilization techniques, only testing will determine their applicability.

ADHESIVES, COATINGS AND POTTING COMPOUNDS

These materials generally react to radiation in much the same manner as the plastics or elastomers from which they are derived. Generally, those containing aromatic compounds show good resistance to radiations. In general, fillers and reinforcing materials improve the radiation stability of these products substantially while also improving other properties.

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