Ionising radiation influence on the physico-chemical and functional properties of the materials

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The objects subjected to radiation sterilization or decontamination

- Medical equippment
- **medical preparations (pharmaceutical preparation)**
- **Current correspondence**
- **Cultural Heritage, Archives**
- Foodstuffs
- for agriculture (growth media)

Medical equippment and drug delivery systems predicted for radiation decontamination are often made or composed from polymers

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Radiochemistry - interaction with the atomic nuclei (radioisotopes) – not our matter

Radiation Chemistry – interaction with the valence spheres of the atoms (no radioactivity)

Gamma photons
Electron
X-ray photons

The primary effects of irradiation:

- Ionization
- Excitation
- Thermal effect

GAMMA: Photoelecric effect and Compton effect. A colision of gamma photons with an atom causes ejection of an electron from the valence shell . The excited molecule emits the photon (secondary radiation) and returns to the ground state.

Thus, both in the case of irradiation with electrons and with gamma photons, chemical processes in materials occur due to direct interaction with electrons.

Primary and secondary ionization - ejected electrons are capable to induce further ionization and excitation processes.

Radiation gradually releases energy in materials – induces on the track **reactive species** → **Chemical Reactions.**
The probability for interaction with atoms and molecules depend **only on the electron density of the material.**
However, the resistance to irradiation and the course of chemical processes depends on molecular structure

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The resistance to irradiation and the course of chemical processes depends on molecular structure

FREE RADICAL MECHANISM – THE SAME CONCERNS PROCESSES IN POLYMERS INITIALZED BY CHEMICAL METHODS

Possible free radicals formation, propagation and termination in polymers

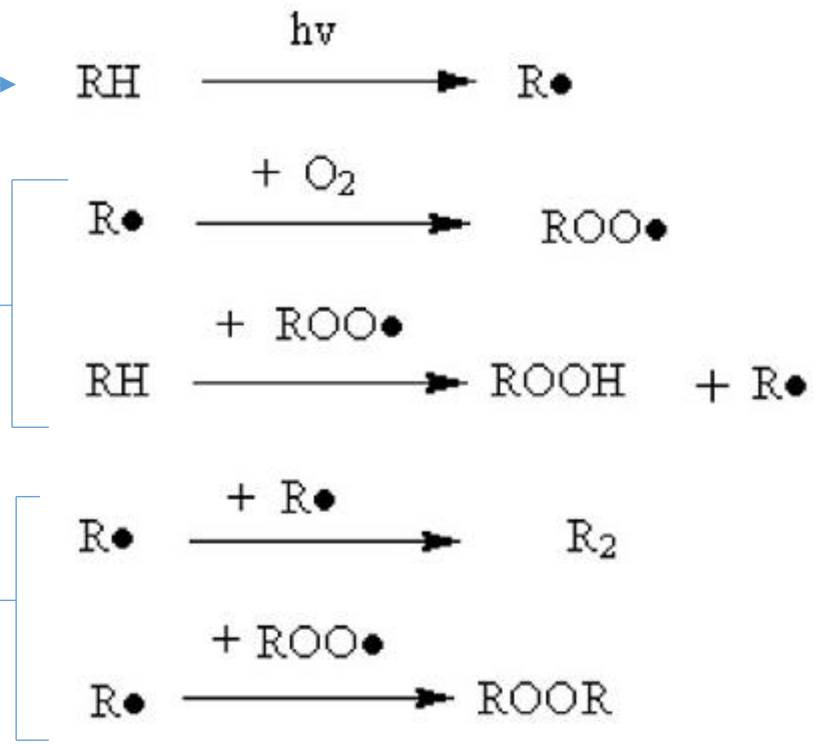
examples

Abstraction of hydrogen is an important step in free radical processes

When the process takes place in solvent: the product of **radiolysis of solvent** participate in free radical processes.
(water, alcohols, etc.)

propagation

recombination



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Polymers – resistance to irradiation

- **Highly resistant (not changed till 250 kGy (or higher**): wih aromatic groups ie aromatic polyamides and polyimides, polyphenyl ethers, polyphenyl ketones, polysulphones, polyethersulphones and polyether imides, polyphenylene oxides, polyethylene therephtalate'
- **Intermediate (100 – 250 kGy):** polyolephins (i.e. polyethylene) polyamides, aliphatic and aliphatic-aromatic polyesters.
- **Highly sensitive (changes in molecular structure below 100 kGy):** aliphatic polymers (i.e , polyethers, polysulphones) and natural polymers: polysaccharides, proteins, natural rubber)

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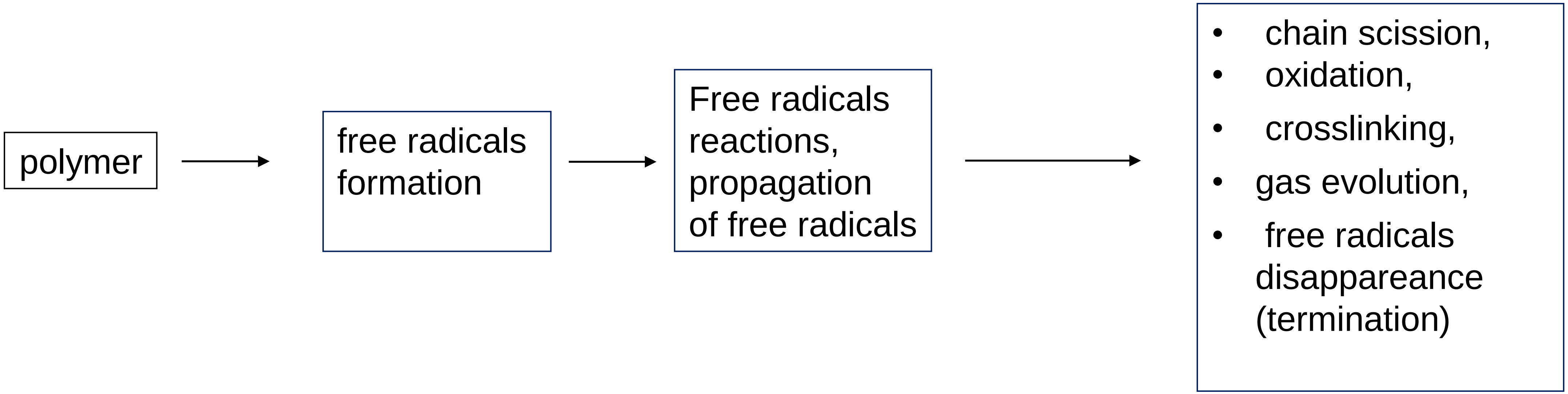
PROCESSES OCCURRING IN RESULT OF IRRADIATION



Resulting in modification of physico-chemical properties of polymers

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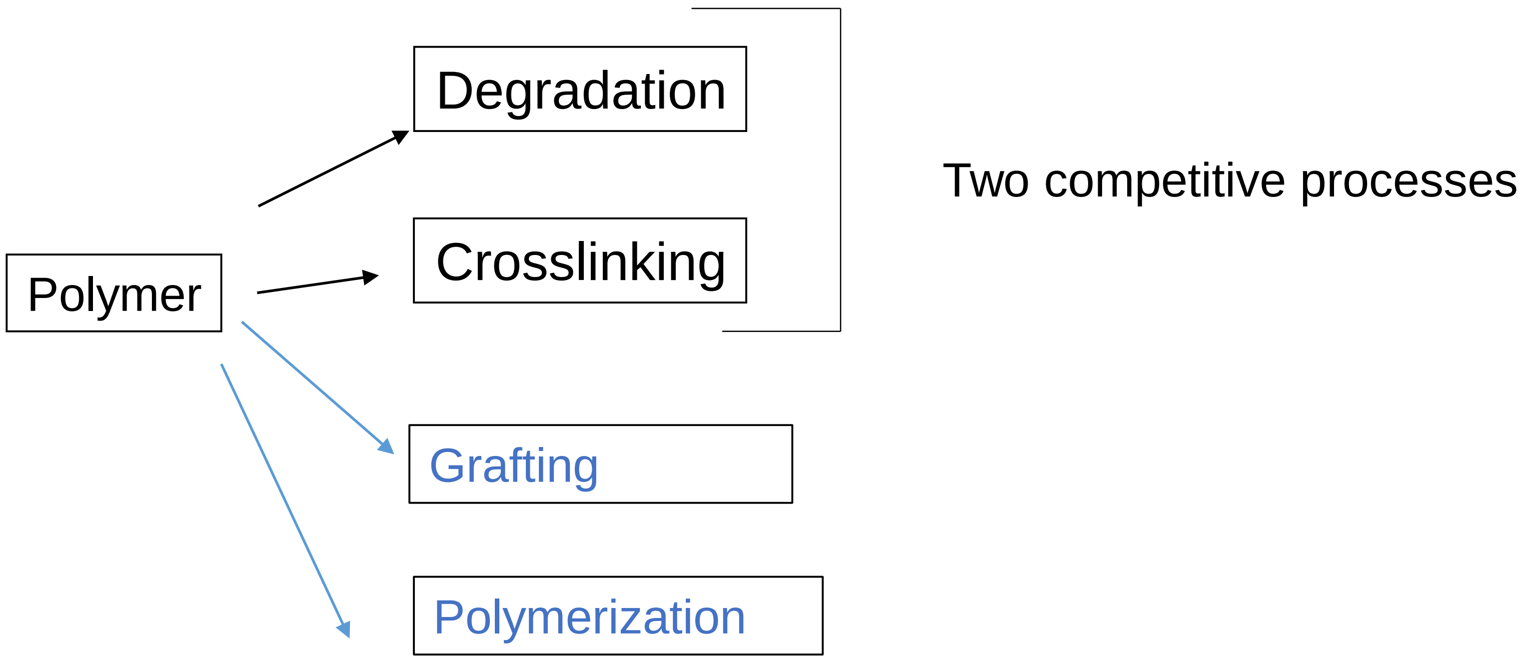
RADIATION EFFECTS IN POLYMERS



Accompanied by modification of molecular structure (i.e. double linkages number and nature), and gas evolution)

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SPECIAL FEATURE OF RADIATION PROCESS:

- Ability to limit or eliminate the chemical agents (initializing, crosslinking, etc) – clean proces
- No need for purification
- Do not need elevated temperature to initialize the proces
- Easy controlled processes
- The materials can be sterilized (and synthesized simultaneously) in the final packaging

The methods for control the radiation processes

- Type of radiation (gamma, electron, X-ray, UV), constant or pulse radiation,
- environment (solid state or solution, type of solvent, concentration, gas atmosphere);
- dose and dose rate
- temperature

In the case of new material for biomedical application, it is of high importance to consider the method of sterilization of the final product at the stage of the selection the material composition

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The following polymers are interesting in relations to medical equipment and drug delivery systems

- Polyamides
- Polystyrenes
- Polystyrene –acrylonitrile blends
- Polyethylenes
- Polypropylenes
- Polyurethanes
- Co-polymers of ethylene and vinyl acetate
- Polyvinyl pyrrolidone blends
- Polyvinyl alcohol blends
- Aliphatic polyesters
- Aliphatic-aromatic polyesters
- Poly (lactic) acid
- Poly (caprolactam)
- Poly (carbonates)
- Poly (methyl methacrylate)) PMMA
- Poly (vinyl chloride)
- polysiloxanes

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MATERIALS TO BE STERILIZED

BIOMATERIALS – THE MATERIALS PREDICTED FOR CONTACT WITH BODY

- ❖ Transplant materials
- ❖ Surgical sutures
- ❖ catheters
- ❖ Scaffolds for tissue engineering
- ❖ Cannulas
- ❖ Fillings for bone defects
- ❖ Wound dressings (hydrogels)
- ❖ Drug delivery systems
- ❖ Screws for connecting bones

Synthetic transplant materials (examples):

- Acetabulum of the hip-joint
- Knee
- Correa
- Lens
- Blood vessels
- Liver

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DISPOSABLE MATERIALS TO BE STERILIZED

(including those for analytical purposes (examples):

- bags for urine collection,
- droppers, bottles, atomizers
- surgical blades, non-woven medical devices (surgical draping),
- gynecological specula,
- the equipment for microbiological analyses (i.e Pasteur pipets, tips for pipets, Petri dishes, tubes, etc.)
- Packages for medicines, packaging films
- dressings,
- Protective clothes (one use)
- Surgical masks, gloves

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RADIATION RESISTANCE

DEGRADATION AND CROSSLINKING

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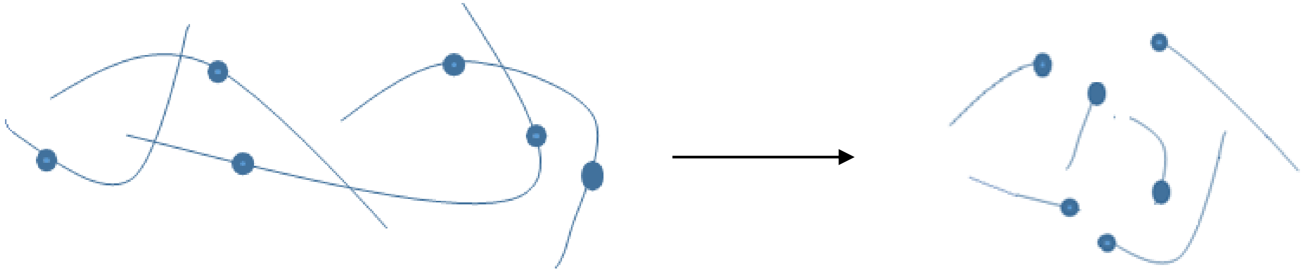
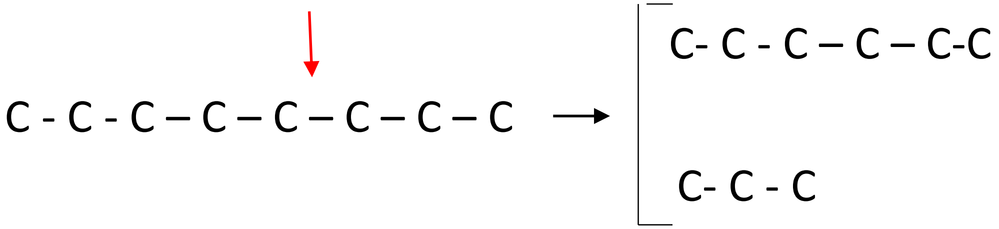
DEGRADATION OF POLYMERS



Scision of poymer chains:

- Scission of polymer chains and contineous process of **oxidative degradation**
- Formation of the **functional groups (polar groups)** in result of the reactions taking place on the end of chain (disruption)



Deterioration of

- mechanical properties (i.e. britness)
- thermal properties (→ processability, flammability, resistance to temperature)

Change in color (yellowing)

Evolution of gaseous products – not important

Degrading polymers (at standard conditions) :
Polypropylene
PLA, PLLA,
PCL,
Polysaccharides (i.e cellulose, cellulose esters)
Derivatives of acrylic acid
Fluoropolymers

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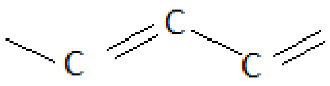
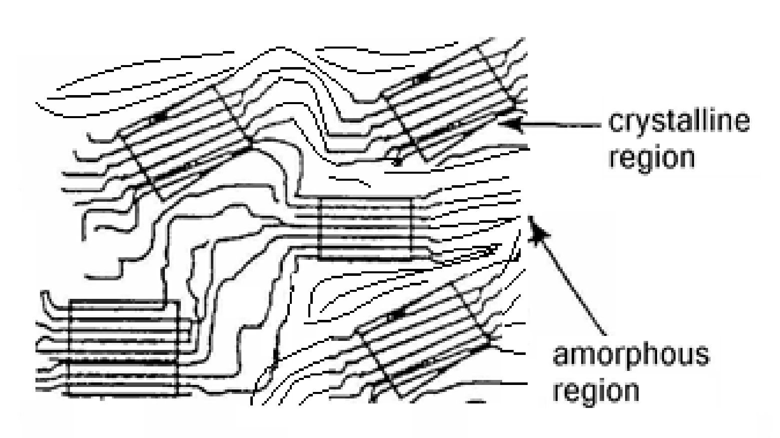
Change in color :

- Formation of the functional oxygen groups (C=O, COOH)
- Formation of the conjugated double bonds
- Formation of the chromophore groups in the additives (i.e. stabilizers, plastificators, proces-aid agents, etc)



Functional **groups:**
OH, C=O, COOH, NH_2,
OSO_3



Evolution of gaseous products

H_2, CO_2, CO, small molecular products alike: CH_4, C_2H_5
Easily leave polymer
No problem for the sterilized medical equipment

Resistance to radiation depends:

1. on the molecular structure of polymer
2. supramolecular structure (amorphous or semi-crystalline polymer

Ad 1: the type of linkages (functional groups); **aromatic segments are more resistant as compared to aliphatic segments,**

Ad 2: in general, crystalline blocks are more resistant as compared to amorphous blocks
However, post radiation effects are stronger

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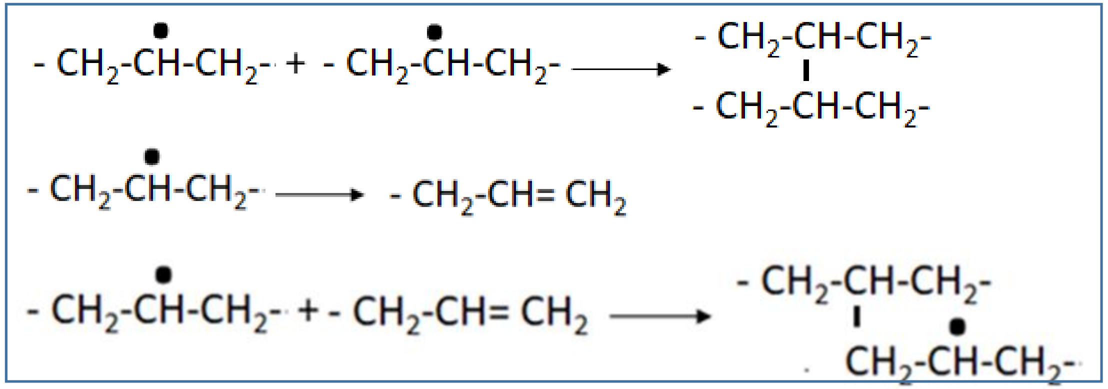
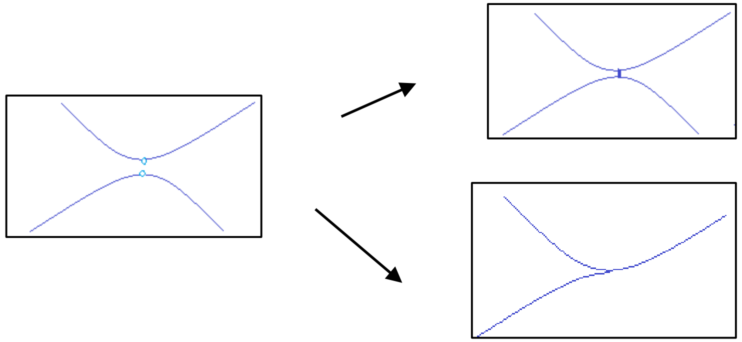
CROSSLINKING AND BRANCHING

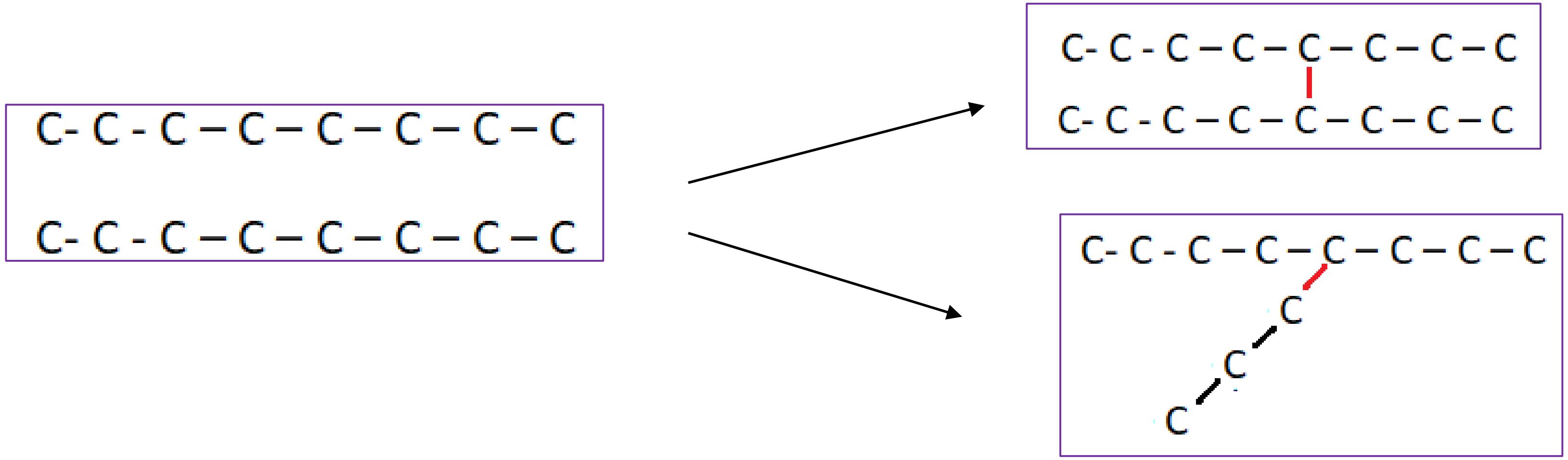
Polyethylene case (under vacuum) (molecular mass increase)





polyethylene case: Irradiation under air

Formation of the oxidized functional groups: C=O, COOH, OH, peroxide, hydroperoxide. → macromolecule chain scission (molecular mass decrease)



Crosslinking – transverse linkages (crosslinks)

Recombination of two radicals resulting from irradiation → molecular mass increase

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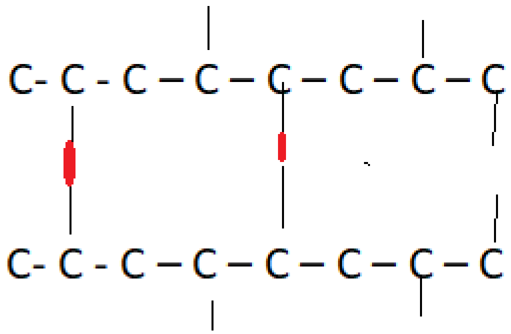
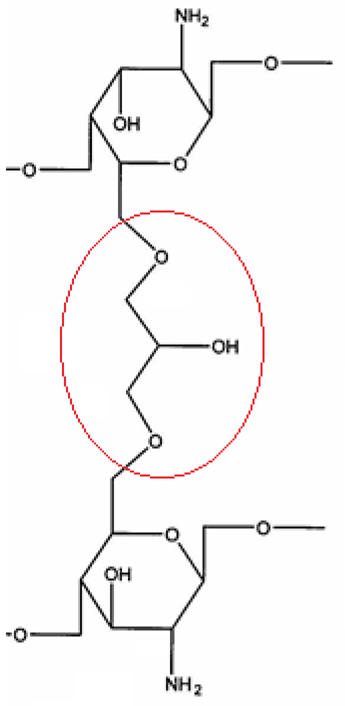
Crosslinks in the polymers with side chains



Steric restriction for crosslinking:

Addition of crosslinking agents



EPI

Chitosan - EPI

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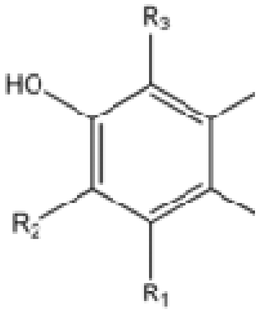
RESISTANCE TO IRRADIATION - Dependence on the molecular structure



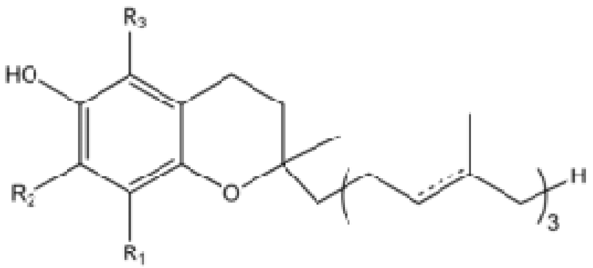
Aryl (phenyl) groups
High resistance to irradiation

Protection effect (self- protection)
Protection groups (i.e. aromatic rings) are present in the polymer molecule (co-polymer or blends). The protective effect extends over larger area of chain than neighborhood of the protection group (mer)

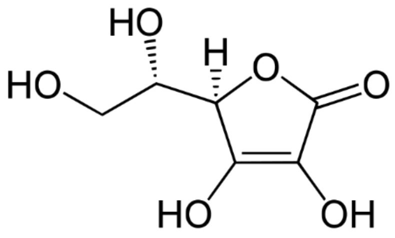
Action of antioxidants:
Dissipation of energy or charge in the chain. Effective action of aromatic compounds.

Preliminary anti-oxidants: restrict propagation stage of free radicals.
Phenyl anti-oxidants – delivery of the liable hydrogen : reacts with polymer free radical (stops propagation)

Secondary anti-oxidants: restrict decomposition of polymer (due to reactions of hydroxyperoxide radicals)



α-tokoferol
R1 = R2 = R3 = CH_3



Ascorbic acid

(also traditional (Irganoxes)

HALS antioxidants (UV stabilizers)

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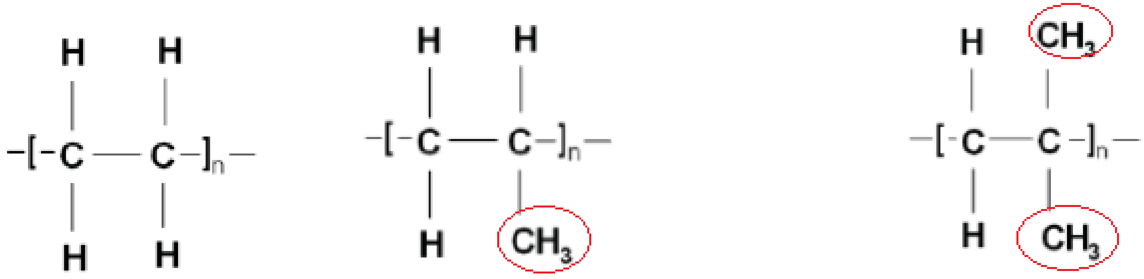
THE COURSE OF RADIATION PROCESSES - Dependence on the molecular structure

Capability for degradation depend on the energy of the dissociation of the linkage:

case C-H	(kJ/mol)
$CH_3CH_2^{\bullet}$	422
$CH_3CH^{\bullet}CH_3$	413
$(CH_3)_3C^{\bullet}$	397
$CH_2{=}CHCH_2^{\bullet}$	**357**

Abstraction o hydrogen – intial stage of free adical processes



PE PP PIB

croslinking → degradation

Poly(isobutylene)

Crosslinking – possible when each C atom in polymer chain bound at least one hydrogen

When C atoms are connected only to R groups - **only degradation**

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- **The effects of ionising radiation depend on the absorbed dose**
- For a number of polymers irradiated with a use of sterilization dose in the range up to 30 kGy the radiation effects are low and can be neglected,
- However, the influence of irradiation on each individual polymer should be checked experimentally

The change in the physicochemical and functional properties of polymer might occur due to processes involved in the polymer itself, and the processes taking place in the compounds added: plastificators, stabilizers (i.e. HALS), processing aids, etc.

HALS: Hindered Amine Light Stabilizer

POST RADIATION EFFECTS

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The strategies applied for elimination or reduction of the non-desirable degradation/ oxidative degradation

1. Irradiation at low temperature (i.e. liquid nitrogen) – reduces propagation of free radicals
2. Irradiation in the protective atmosphere (oxygen absence)
3. Modification of composition the base polymer (introduction of anti-oxidants and stabilizers)
4. Modification of composition of the base polymer: composition of aromatic-aliphatic groups, addition of crosslinkers that can enhance crosslinking processes, or addition of appropriate monomers that can be grafted in result of radiation treatment
5. Irradiation in the short time with a use of high dose (restriction for diffusion of oxygen ⟷ time of reaction)
6. *Irradiation in environment of solvent that terminates propagation of free radicals*

The effect of irradiation depends on density of the material and on the form. Thin films and fibers are more exposed to action of oxygen than thick bulk polymer.

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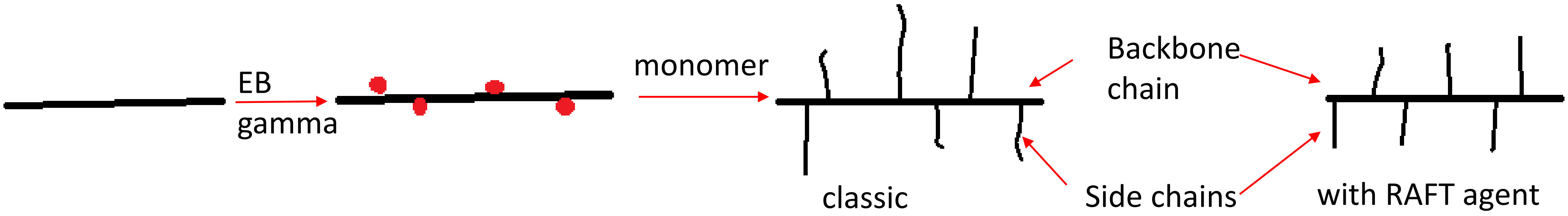
GRAFTING

Synthetic polymers for biomedical application: necessity to modify surface properties (biocompatibilty by Introduction of the functional group



Used in biomedicine for:

- To modify surface hydrophilicity
- To modify cell adhesion in tissue engineering
- To modify blood compatibility
- To modify mechanical (lubricant) properties of implants

And for:

- Improvement of membranes
- Improvement of absorbents

Procedures:

I – direct (irradiation of polymer in monomer solution)

II – non-direct (activation of polymer surface by irradiation followed by treatment with monomer solution).

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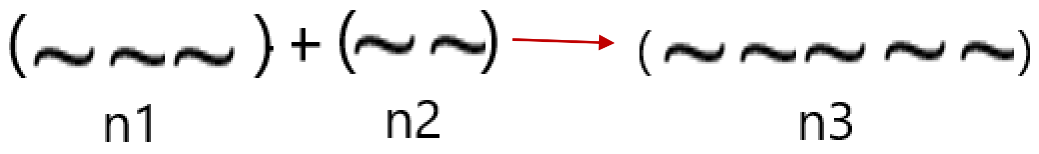
POLYMERIZATION

Commonly monomers that contain doubble linkages in moleculres (C = C) : butadiene, styrene, ethylene, methyl acrylate, methyl methacrylate, acrylonitrile, vinyl acetate, vinyl choride, octan winylu, chlorek winylu, tetrafluoretyhlene



Polymerization and Co-polymerization

Homogeneous systems

Heterogeneous systems

- Homogeneous water systems (water)
- Homogeniczne układy wodne (woda):
  low concentration
  high concentration
- Heterogeneous water systems:
  emulsions and mikroemulsions in oil in water
  dispersions

The rate and particle size depend on concentration of monomer and the irradiation conditions.

Sterilization is ussually carried out with doses till 30 kGy.

diagnostics	0.1 – 10 mGy
Anti-cancer therapy	1 – 10 Gy
Food hygenization	0.1 – 10 kGy
Radiation sterilization	**10 – 30 kGy**
Radiation technologies	1 - 200 kGy (1 – 1000 kGy)
Cultural heritage, archives	1 – 30 kGy

STERILIZATION: IRRADIATION INDUCES CHANGES IN POLYMER, THAT CAN BE DESIRABLE AS WELL AS NON-DESIRABLE

IRRADIATION CAN BE USED ALSO FOR TARGETED MODIFICATION OF THE POLYMER PROPERTIES → RADIATION TECHNOLOGIES

FOR MODIFICATION OF POLYMERS: DOSES TILL 200 kGy or even higher
For modification of natural polymers doses 1 kGy – 1000 kGy (degradation of native polysaccharides)

THE BEST – STERILIZATION DOSE IS EQUIVALENT TO THE OPTIMUM DOSE FOR DESIRED POLYMER MODIFICATION

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Ultra High Molecular Weight Polyethylene (UHMWPE)

Implants:

- Acetabulum of the hip-joint (acetabular cup)
- Knee

Exposure to high mechanical overload, particular in knee and in impulse.

Highly crosslinked PE

Made from PE. Time of usage: ca.8 years

Problems:

- wear resistance
- oxidative degradation of PE, facilitated in contact with body fluids

SOLUTION: UHMWPE - can be produced (crosslinked) by radiation technique with a use of sterilization dose or higher:

Problem: POST RADIATION EFFECT OF FREE RADICALS → **oxidative degradation in crystalline domains**

UHMWPE – semicrystalline

- Amorphous domains – fast termination of free radicals
- Crystalline domains – high stability of free radicas.

After radiation crosslinking: it is desired to remove free radicals, with preservation of the structure in crystalline domains

Appropriate procedure:

I - PE + antioxidant (α-tokoferol), irradiated. Highly effective scavenging of free radicals by α-tokoferol)

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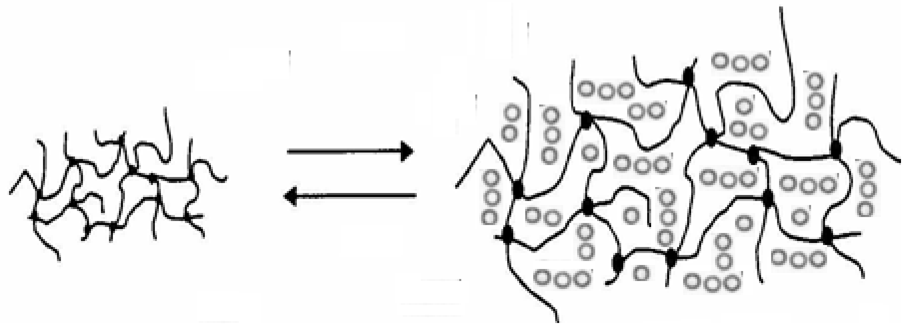
Sterile hydrogel formation by irradiation



gel swelling in water (in solvent)

Hydrogel – a tri-dimensional network formed by crosslinked hydrophilic polymer systems and capable to entrap water molecules.

Natural hydrocolloids: polysaccharides, and proteins, containing hydrophilic groups OH, COO^-, C=O, OSO_3^- .

EB   0 kGy   28 kGy

Formation of PVA hydrogel

Biodegradable water soluble synthetic polymers

Application of hydrogels:

- Medicine
  - Wound dressing
  - Carriers for active compounds (medicines)
  - Drug delivery systems (encapsulation)
  - Encapsulation of living cell (hybrid organs)
  - Cements
  - Bedsore
- Pharmacy
- Food industry
- Agriculture
- Environmental protection
- Technical Industry (Catalyzers)

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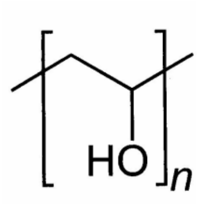
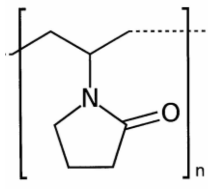
Polymerization followed by crosslinking

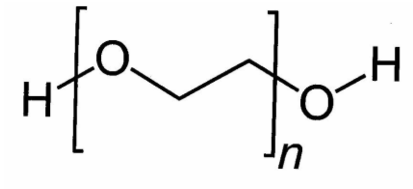
Biodegradable water soluble synthetic polymers applied for the hydrogel preparation (crosslinking)



PVA



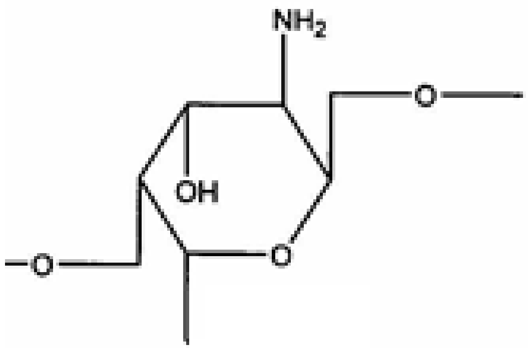
PVP



PEO

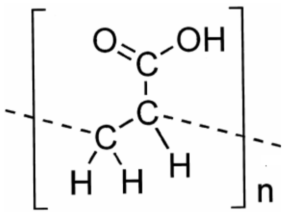
Crosslinking

Natural polymers: polysaccharides, and proteins.
Gelatin and water soluble derivatives of cellulose, starch, alginates, carrageenan, agar, etc.

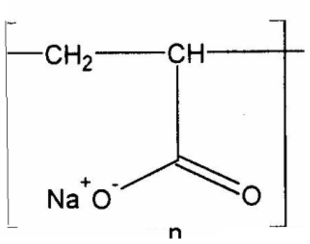


chitosan

By Grafting



Poly (acrylic acid)



Poly(acrylates) (Na-polyacrylate)

Grafting of acrylic acid derivatives onto polysaccharide backbones

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Manufacturing of the sterile hydrogel dressings by radiation technique

Composition: one or more :

- synthetic water soluble polymer;
- natural polymer
- mixed system: synthetic and natural polymer

Water dispersion of components placed the appropriate form in the package subjected to irradiation → sterile wound dressing

Standard: PVA, PVP, PEO

Components:

- base polymer: PVA, PVP, PEO
- Antioxidant (food grade): AA, polysaccharide, etc
- Biocompatible humectant: polyglicol (PEG, PPG), ethyl lactate)
- Promotor of crosslinkimng (acryl acid derivative)

Hydrogel dressings after irradiation
EB (28 kGy) (Kik-Gel, Polska)

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Manufacturing of the sterile hydrogel dressings by radiation technique

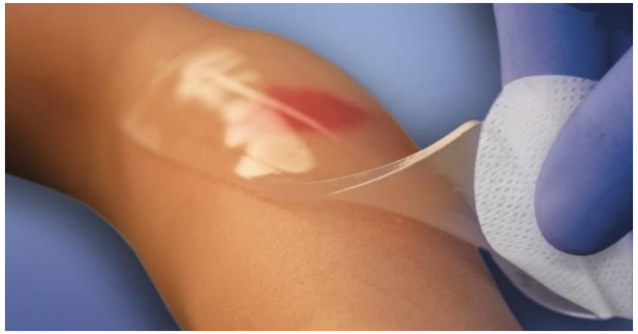
Application of the mixed systems **natural polymer-artidficial polymer** or adition of polysaccharide to the artificial polymer might result in improvement of the properties of the hydrogel in relation to those of the hydrogels composed only from the synthetic polymer (higher strength, hiher water content)

Chitosan – **antimicrobial** activity
Carrageenans – **hemostatic** activity

The example

Application for medicine and cosmetology (Kik-Gel, Poland (2020)

composition **of PVP (+ a gar and PEO)**, pseudo-gel, placed in the package, then irradiated with a sterilization dose (25 – 30 kGy) Kik-Gel Poland



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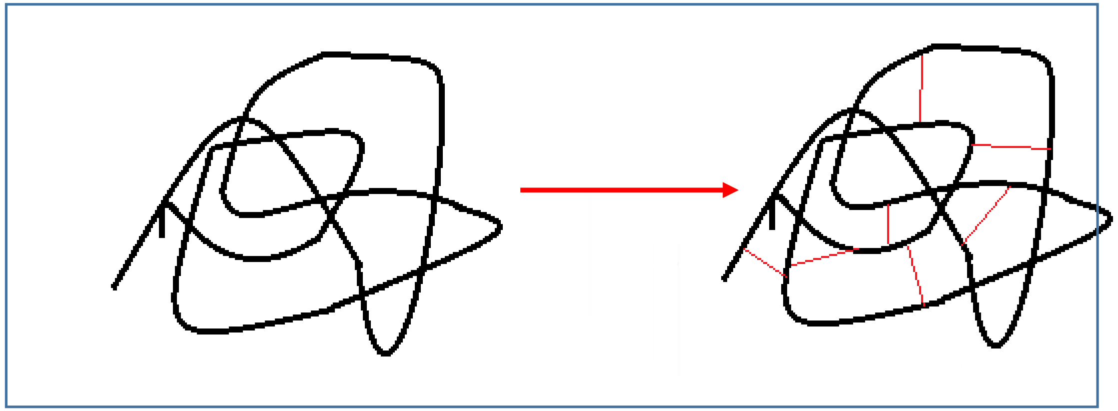
Hydrogels in medicine: Merits

Wound dressings: -he possibility of the controlled drug delivery to wound

The other drug delivery systems

Scaffolds

NANOGELS: resulting from intramolecular crosslinking



for DRUG DELIVERY SYSTEMS

HYBRID ORGANS (encapsulation of living cells) – FUTURE IN TRANSPLANTOLOGY

Inteligent hydrogels for diagnostics

Dietary fibre (i.e PVP hydrogel with chitosan)

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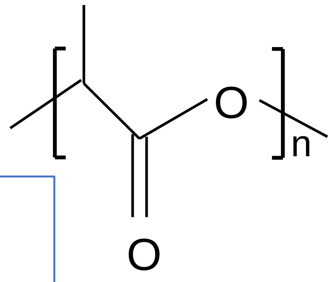
PLA (PLLA) – DEGRADING POLYMER



Biobased, biocompatible polymer, good mechanical and thermal properties, excellent processability, bioresorbable

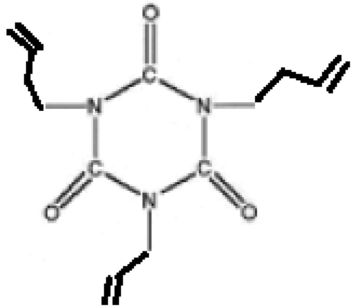
Excellent for scaffolds for tissue engineering, surgical sutures Doskonały dla skafoldów dla inżynierii tkankowej, , etc.

but **degrades under ionising radiation** , thus →

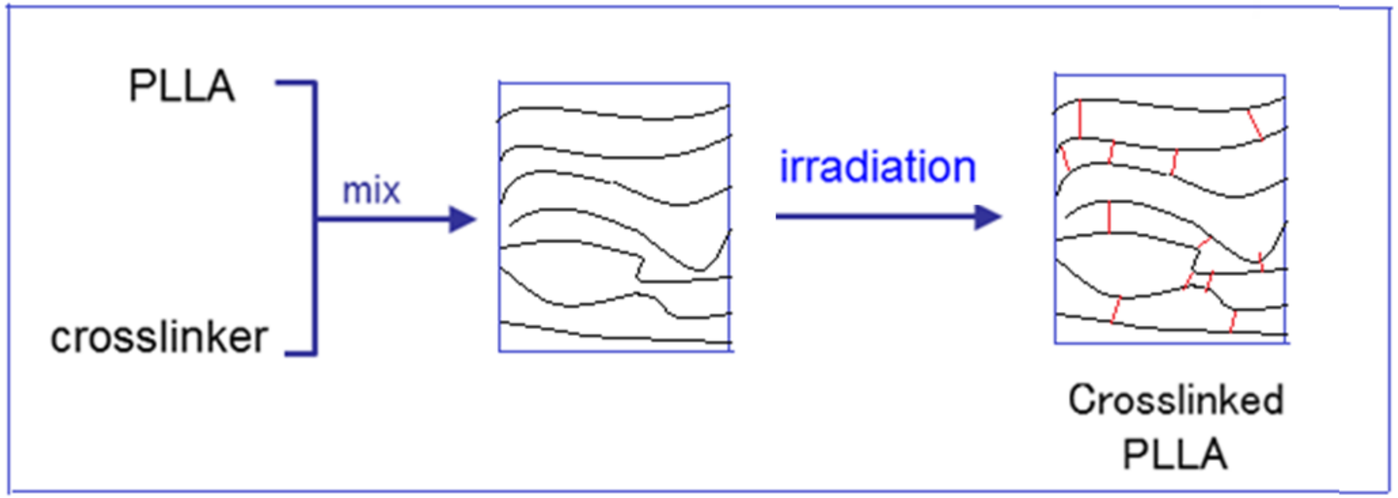
- **Not appropriate for implants**

Irradiation at -78 C limits degradation

Example crosslinker: Triallyl isocyanurate (TAIC) – biobased crosslinking agent (from gallic acid)



Solution: Addition of crosslinker



Effective crosslinking: 3 % of TAIC, 25 kGy

The process might be applied for manufacturing of contact lens

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Poly(methyl metacrylate) (PMMA)

Acrylic glass, used as the artificial cornea. Can be sterilized by gamma and electron radiation

At 25 kGy: No change in: optical transmission, mechanical properties and cel biocompatibility.

(Andrades et. Al., 2018)

Poly(methyl metacrylate) (PMMA), and Poly(caprolactone (PCL)

Highly porous scaffolds for tissue engineering (osteoblast grow) can be made with a use of radiation technique. The materials can be sterilized by ionsing radiation.

Poly(ester urethanes) – material composed from poly(urethanes) segments and PCL segments Scaffolds for tissue engineering (osteoblast) . Radiation sterilization does not influence viability and nature of the cel cultured on the surface. To limit oxidation ←→ irradiation in an inert atmosphere. (Przybytniak et.al, 2006)

Poly(aliphatic/aromatic ester)s – composed from poly(butylene therephtalate) (PBT) (hard segment) and dinoleic acid (DL, soft segment) – biocompatible. The properties and radiation resistance were modified by a change of PBT/DL ratio, as well as content of antioxidant (α-tokoferol). Good resistance to radiation sterilization) (M. El-Fray et al., 2010)

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Irradiation of scaffolds – tissue engineering

Scaffold – 1. biological material

2. polymer + biological material

Final product: ←→ Need to be sterile

STERILIZATION WITH IONISING RADIATION IS REPORTED AS SUPERIOR OVER THE OTHER METHODS OF STERILIZATION

The example (Inoue at al., 2020):

1. The scaffold (polyester, one side with high porosity)
2. Embedded subcutaneosly in an goat , left for 3 months → settling by the cells → formation of extracellular matrix (tridimensional collagen network)
3. Removed from goat muscle.
4. Decellurised - to prevent immune rejection in recipient organism
5. Sterilized using 6 methods (autoclaving, dry heat, ethylene oxide, hydrogen peroxide, **ionising radiation** → Ionising radiation- gamma- the best

<u>Polymer scaffolds</u>

- Core scaffoold from polymer
- Covered with biological network enabling better settling of cells (collagen)
- **Sterilization**
- Used to cultivate recipient tissue

<u>Important properties of scaffold</u>

- Shape, structure,
- Mechanical properties,
- Wettability,
- Cell adhesion,
- Cell proliferation,
- Cell vialability

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RADIATION DECONTATION AND CONSOLIDATION OF THE OTHER MICROBIOLOGICALLY INFECTED OBJECTS: CULTURAL HERITAGE

Archives, monumental manuscripts, wooden objects (icons, furniture), skin, biological objects (mummy, mamooth) etc

Infected by: molds, fungi, insects

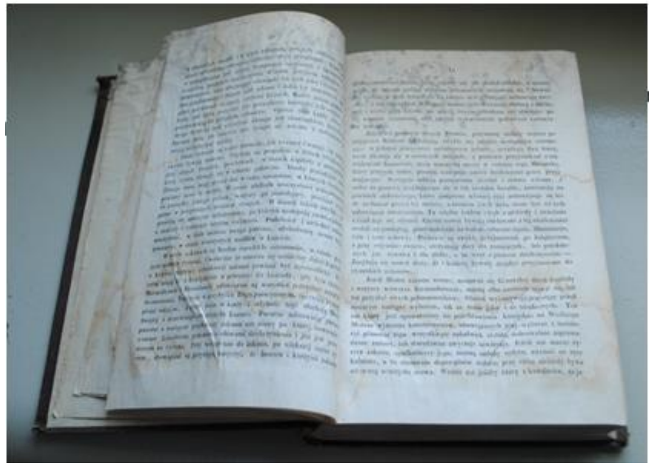

photo A. Kuberka, ALTO PROTECT, Poland

<u>The problems</u>:

1. materials based on natural polymers: mainly cellulose, collagen, that degrade under irradiation
2. Unique objects of high importance as cultural heritage

<u>Solution:</u>

1. using of the minimum doses , only in the case of strongly destroyed objects
2. Consolidation: impregnation of the object with a solution of monomer that undergo polymerization under irradiation

Irradiation of the paper with a doses till 3 kGy is considered as not significantly affecting the paper.

IAEA Technical Cooperation Project – RER 8015: Using Nuclear Techniques for the Characterization and Preservation of Cultural Heritage Artefacts in the European Region

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RADIATION STERILIZATION of the current incoming CORRESPONDENCE is used in US central Administration Offices since terroristic attack with baccillus antrax in 2001

This can be useful in present with COVID 19 pandemy

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RADIATION DECONTATION AND MODIFICATION OF THE OTHER MICROBIOLOGICALLY INFECTED OBJECTS:

Food and Food Components

- Radiation decontamination of food (standard doses till 10 kGy (dry food))

- Modification of the food additives by
  degradation
  crosslinking

Lead to modification of functional properties of food hydrocolloids
(viscosity, gelling properties, thickening agents, etc.)

- modification of the functional properties of food itself (i.e. increase in digestibility, reduction of antinutritional factors).

Food hydrocolloids: polysaccharides, proteins (gelatin, caseinates)

In general, irradiation of polysaccharide leads to reduction of viscosity water dispersions (degradation)
In some cases and at special conditions, viscosity increases (crosslinking) (Katayama et al., 20060

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CONCLUSION

- Ionising radiation induces desired and non-desired effects in material
- The effects of ionising radiation depend on the material composition and the conditions of radiation process
- For a number of polymers irradiated with a use of sterilization dose in the range up to 30 kGy the radiation effects are low and can be neglected,
- The undesired changes in polymer induced by irradiation can be avoided by modification of the polymer composition and conditions of irradiation
- These should be done for each individual composition experimentally
- In the case of new material for biomedical application, it is of high importance to consider the method of sterilization of the final product at the stage of the selection the material composition
- OPTIMALIZATION OF RADIATION STERILIZATION PROCESS IS ACHIEVED WHEN THE MATERIAL IMPROVES OR GET NEW FUNCTIONALITIES UNDER THE DOSE USED FOR STERILIZATION

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THANK YOU FOR YOUR ATTENTION

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