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Aging of γ-sterilized UHMWPE: Influence of oxygen on the oxidation and the oxidative potential

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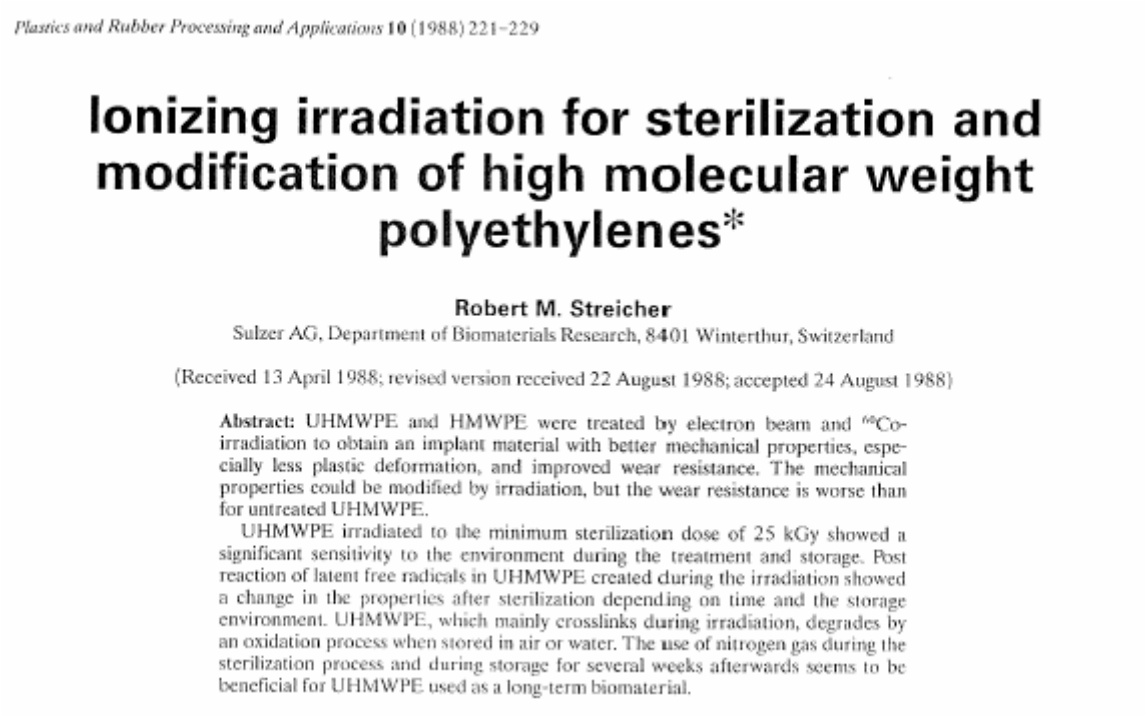
History

- γ- Sterilization of UHMWPE implants packaged in air
- Severe oxidation of the shelf
- Delamination / mechanical failure

History

- One of the alternatives: Packaging under inert atmosphere



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Ionizing irradiation for sterilization and modification of high molecular weight polyethylenes*

Robert M. Streicher
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(Received 13 April 1988; revised version received 22 August 1988; accepted 24 August 1988)

Abstract: UHMWPE and HMWPE were treated by electron beam and ^{60}Co-irradiation to obtain an implant material with better mechanical properties, especially less plastic deformation, and improved wear resistance. The mechanical properties could be modified by irradiation, but the wear resistance is worse than for untreated UHMWPE.

UHMWPE irradiated to the minimum sterilization dose of 25 kGy showed a significant sensitivity to the environment during the treatment and storage. Post reaction of latent free radicals in UHMWPE created during the irradiation showed a change in the properties after sterilization depending on time and the storage environment. UHMWPE, which mainly crosslinks during irradiation, degrades by an oxidation process when stored in air or water. The use of nitrogen gas during the sterilization process and during storage for several weeks afterwards seems to be beneficial for UHMWPE used as a long-term biomaterial.

„the use of nitrogen gas during the sterilization process and during storage for several weeks afterwards seems to be benefical for UHMWPE as a long-term biomaterial

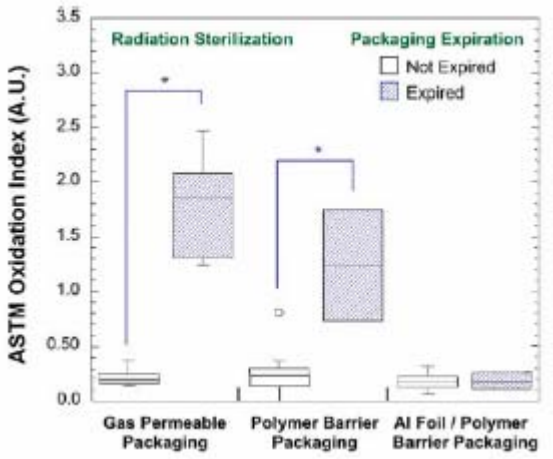
History

- 2nd UHMWPE meeting in Torino

Oxidation and Oxidation Potential in Contemporary Packaging for Polyethylene Total Joint Replacement Components

Luigi Costa,[1] Pierangiola Bracco,[1] Elena Maria Brach del Prever,[2,3] Steven M. Kurtz,[4,5] Paolo Gallinaro,[2,3]

Abstract: The packaging and chemical stability of both conventional and highly crosslinked polyethylene (PE) components available for clinical use in Italy were analyzed. A total of 100 sterilized PE components were entered by 18 orthopedic manufacturers into the study. Six of the manufacturers were Italian and the remaining were based in Europe or America. Hydroperoxide, oxidation, and *trans*-vinylene levels within the PE components were characterized using Fourier-transform infrared spectroscopy (FTIR). None of the 31 gas-sterilized components had detectable free radicals, hydroperoxide content, or oxidation. Among radiation-sterilized inserts, the highest oxidation and hydroperoxide levels were associated with gas-permeable and polymer-barrier packaging. To the authors' knowledge, this is the first study that relates elevated oxidation and hydroperoxide content in γ-sterilized PE components to certain types of contemporary, polymeric barrier packaging. © 2006 Wiley Periodicals, Inc. J Biomed Mater Res Part B: Appl Biomater 78B: 20–26, 2006



-> Inert atmosphere and the quality of the packaging play a crucial role

Goal

- The influence of the oxygen concentration in the packaging on the oxidation (and oxidative potential) by selecting different diffusion rates for the oxygen

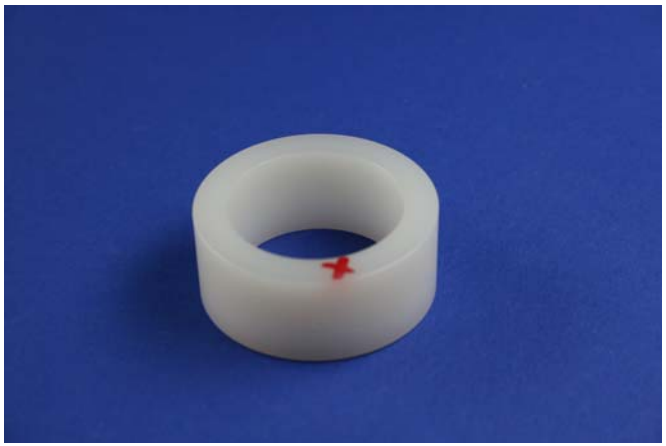
- Threefold peel polymeric pouches either with standard or barrier film

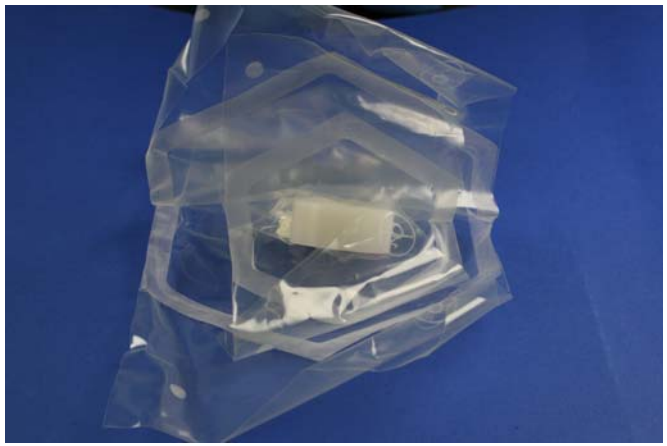
Experimental

- 4 packaging systems
- Barrier films with 70 fold reduction in oxygen transmission rate (cm^3/m^2 x d x P) compared to standard films
- Threefold peel pouches with
  - A -> 0 Barrier / 3 Standard
  - B -> 1 Barrier / 2 Standard
  - C -> 2 Barrier / 1 Standard
  - D -> 3 Barrier
- Packaged, flushed with nitrogen and gamma sterilized (3 Mrad)

Experimental

- 400 PE Rings, GUR 1020 CMS
- Diameter 36 mm, wall-thickness 3mm
- Accelerated + real time ageing
- Ageing after ASTM F1980:
  55°C / 50% RH (acceleration factor 9.3: 6wks ~ 1 yr)

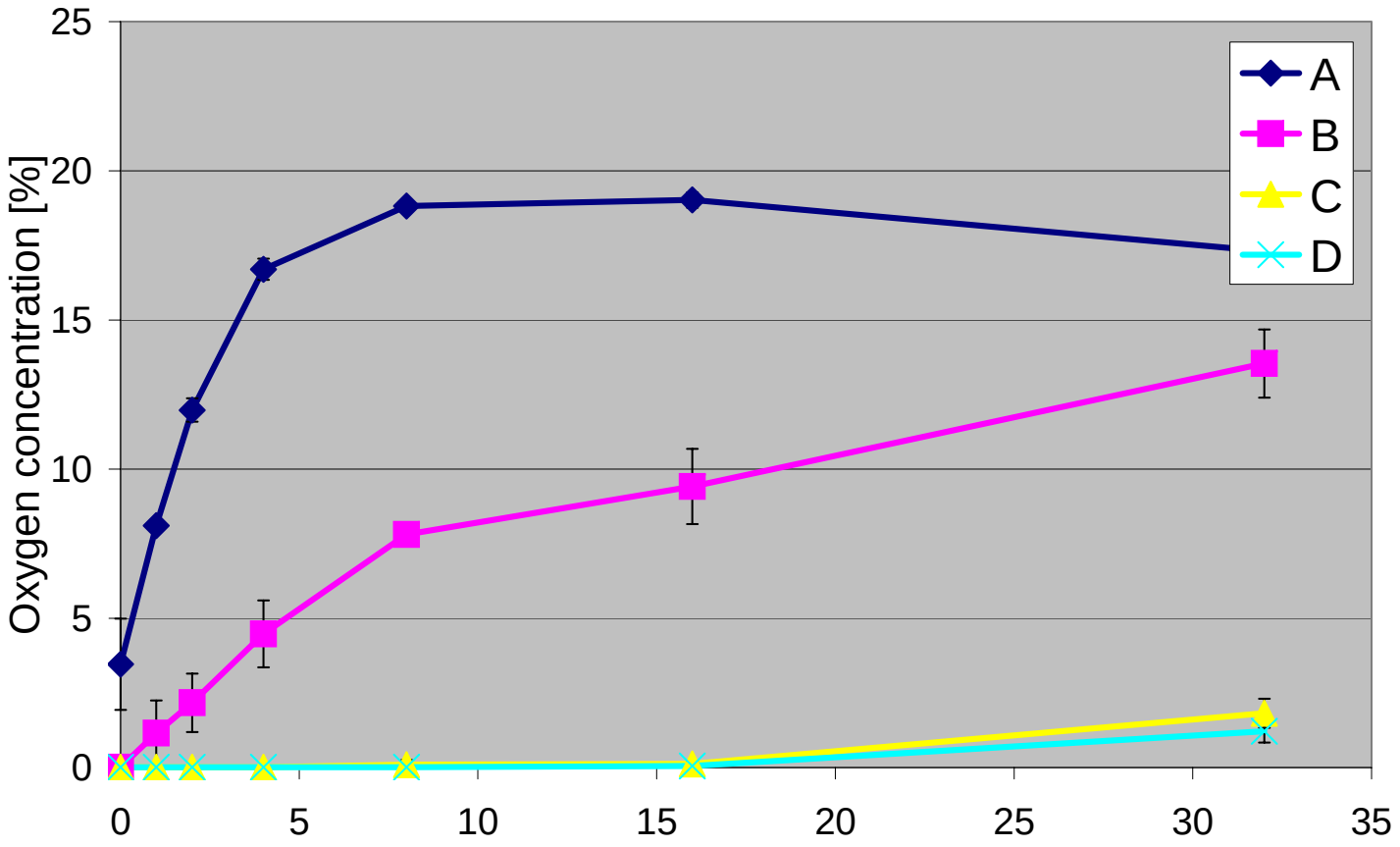




Experimental

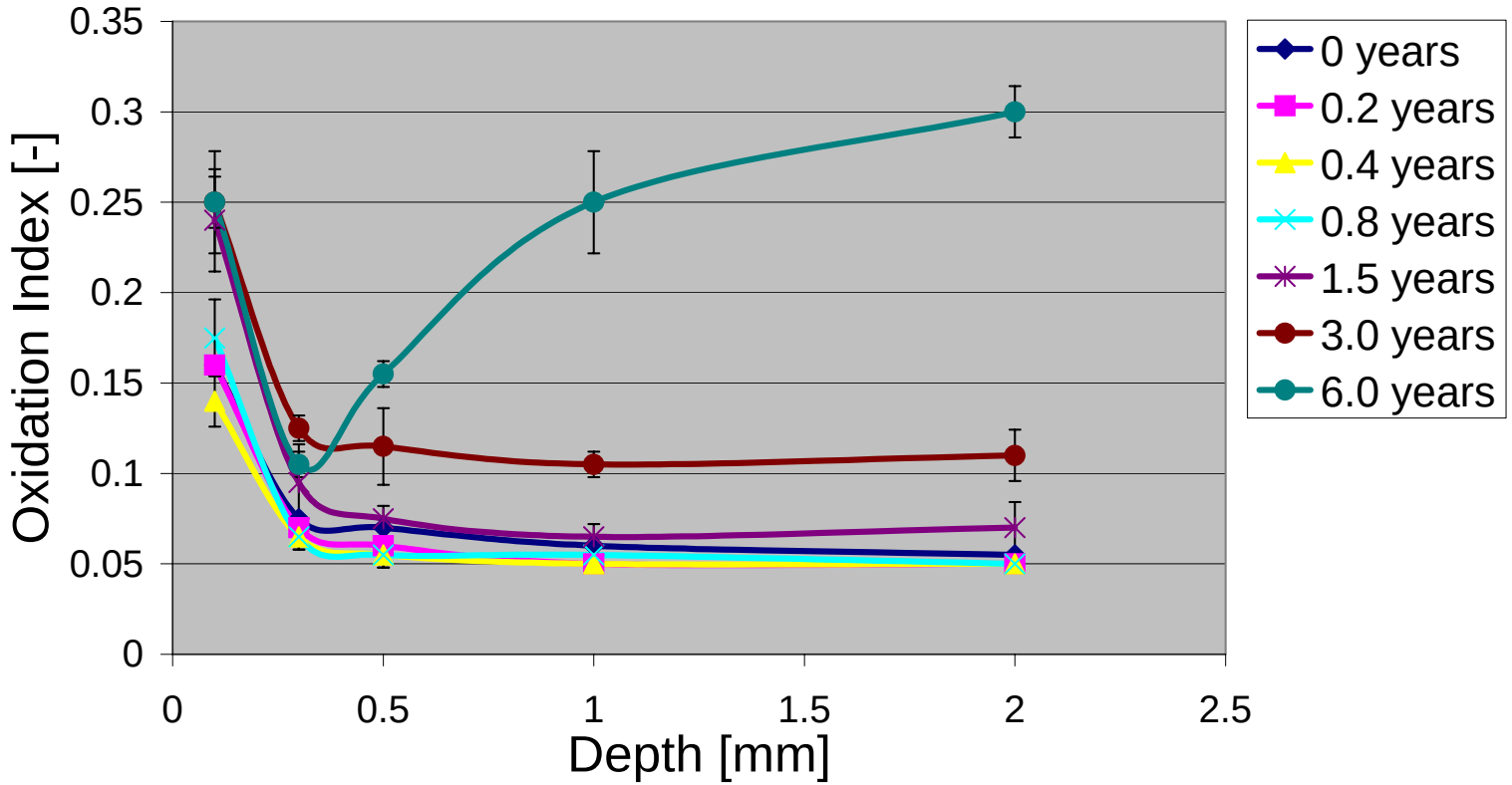
- Residual oxygen concentration (n = 5)
- Dimensions (n = 3)
  - Height /diameter / roundness
- Oxidation profiles (n = 2, FTIR, ASTM F2101)

Results: Oxygen concentration

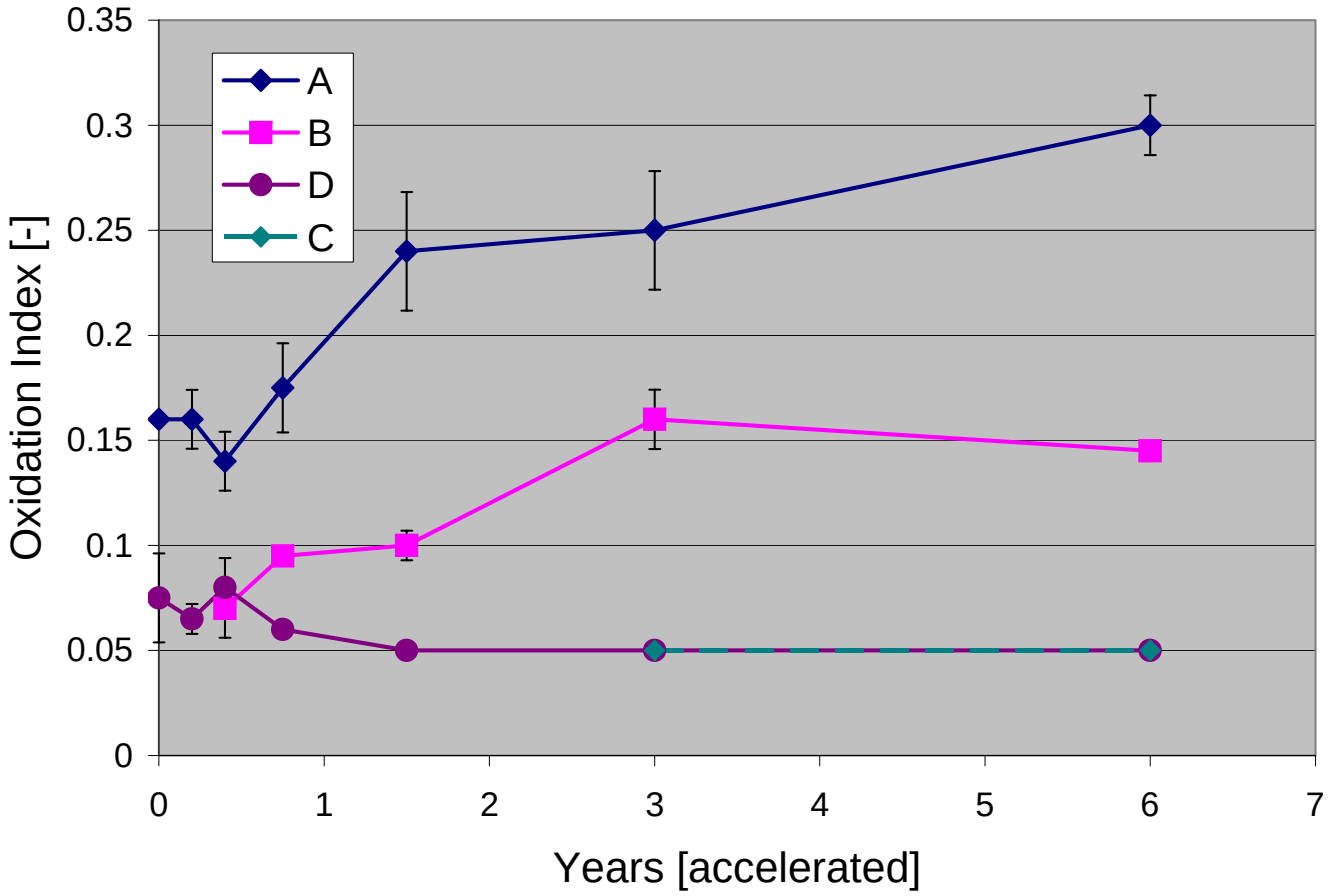


Results: Oxidation vs Depth

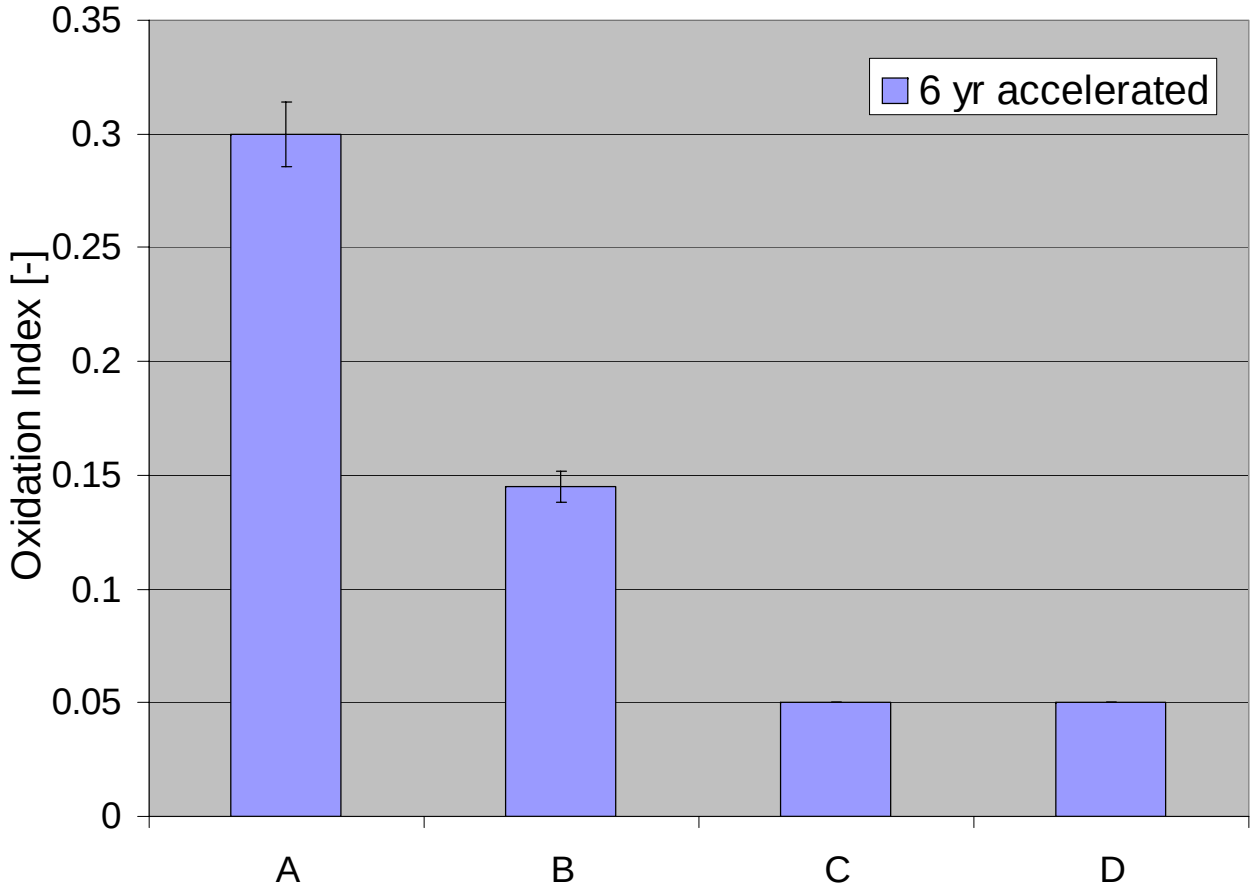
- System A / Yrs accelerated



Results: Max oxidation vs. time



Results: Max oxidation vs. time



Oxidative potential

Mild ageing in the packaging at 55°C (ASTM F1980)

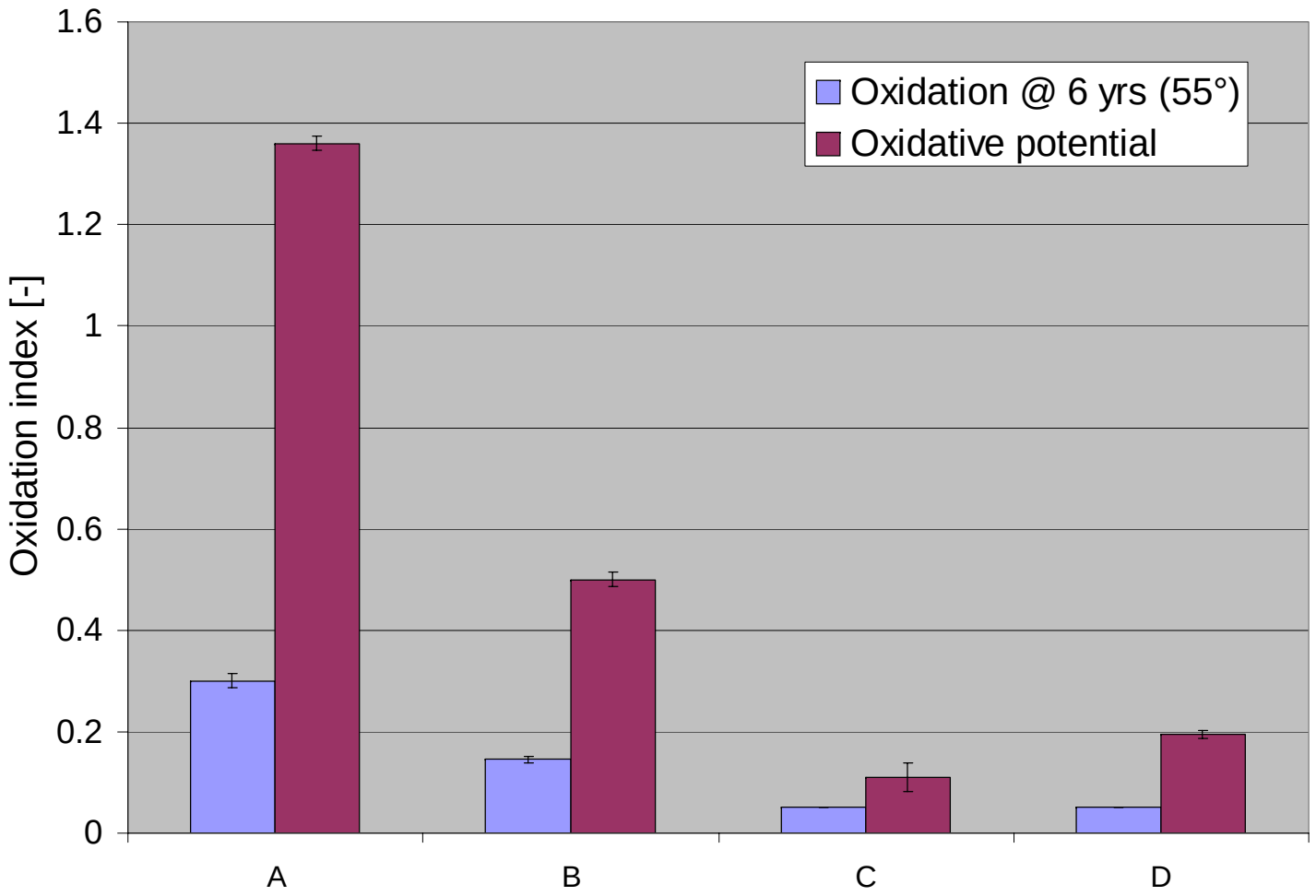
Carbonyl groups / Hydroperoxides (3 + 6 yrs accelerated)

Remove from packaging

Ageing at 70°C/5atm O2 / 2wks after ASTM F2003

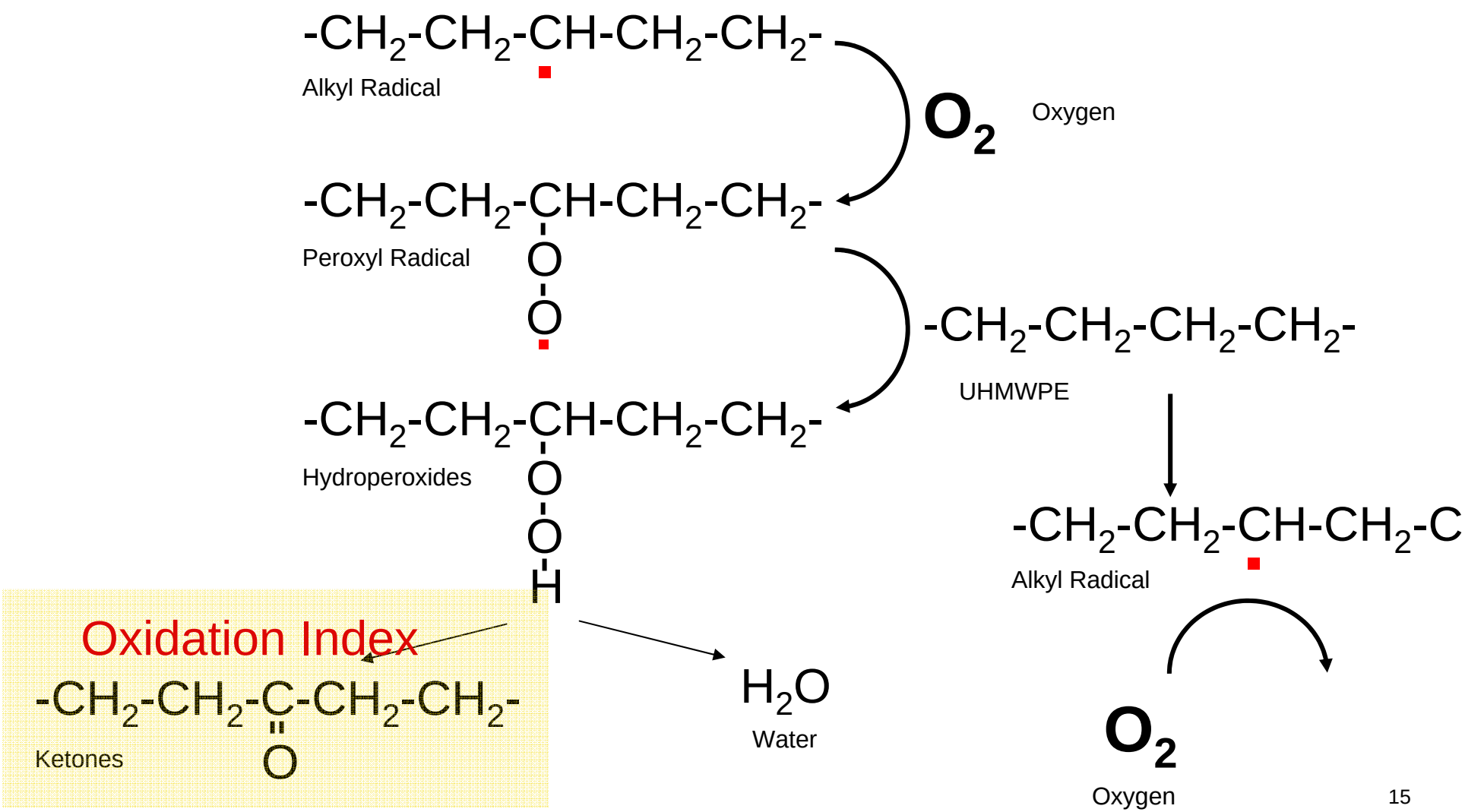
Carbonyl groups (~ 5 yrs shelfageing gamma-air)

Oxidative potential

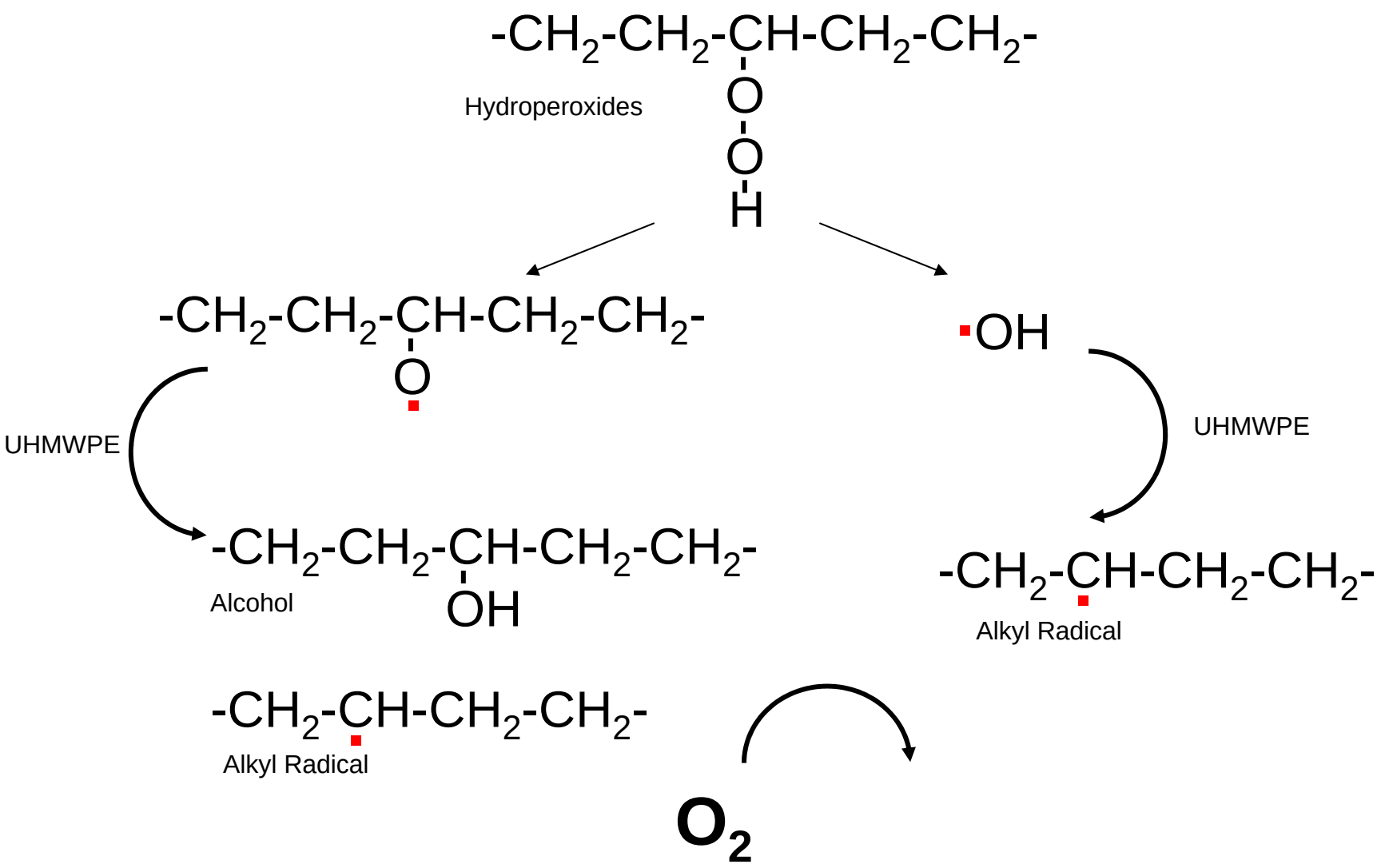


Reaction with oxygen I: Linear

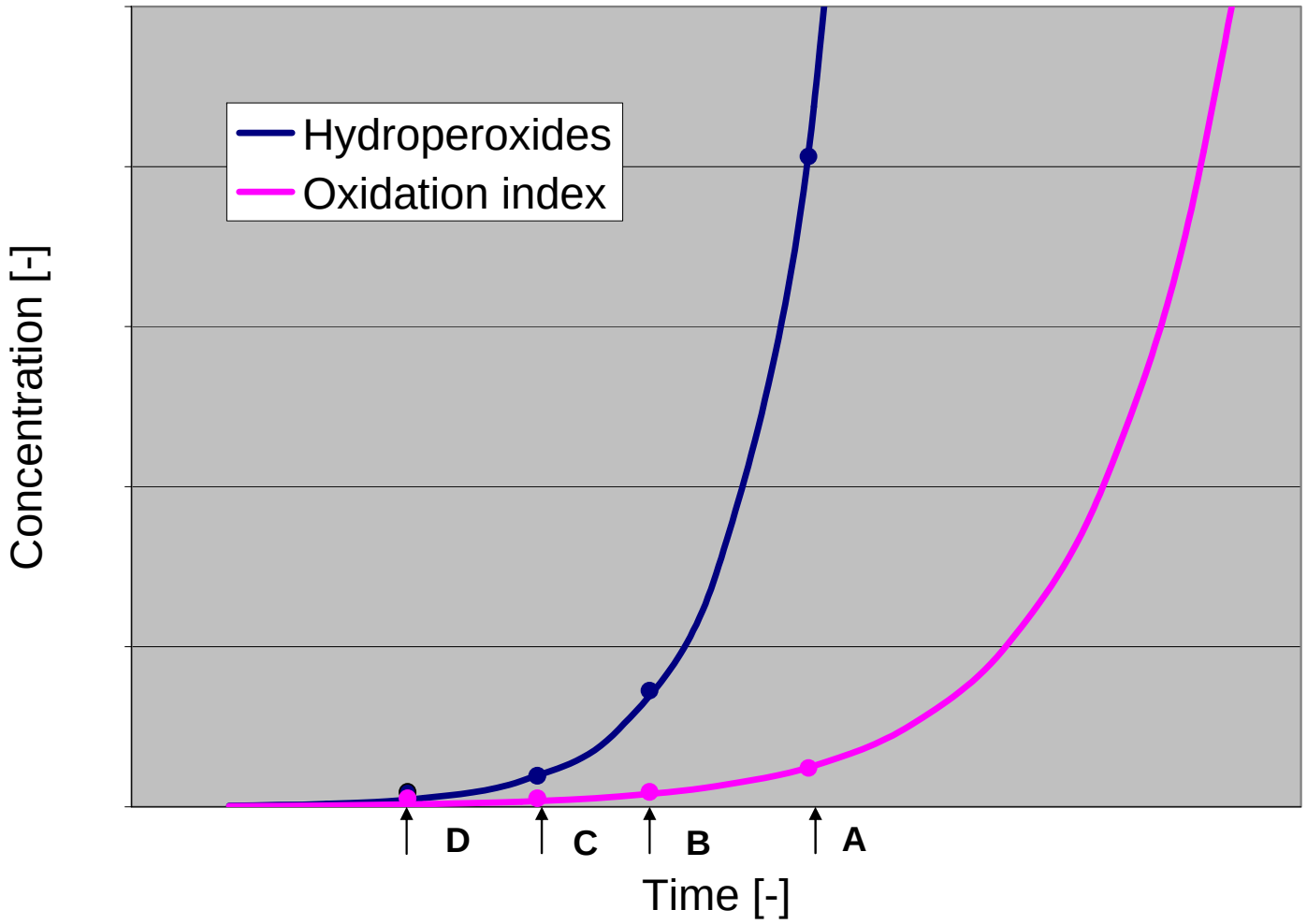
Premnath V. et al. Biomaterials 17, 1741, 1996
Costa L., Polym. Degr Stab 58, 41, 1997



Reaction with oxygen II: Exponential



Oxidative potential



Limitations

- Accelerated aging
  - Elevated temperatures (55°C /70°C)
  - Acceleration of chemical oxidation vs. decrease in radical content
  - Must be verified using real time ageing
- Oxidative potential /Hydroperoxides can also be measured using NO treatment

Conclusions

- Oxygen concentration important during gamma steri but also afterwards during storage
- Oxygen concentration can be controlled by selecting the packaging materials
- Oxygen has a strong influence on the oxidative potential
- Small differences in the oxidation index still can have huge differences in oxidative potential

Thank you !

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