

A 15-years experience in analyses of UHMWPE prosthetic components: state of the art and future perspectives.

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3rd UHMWPE INTERNATIONAL MEETING

"Polyethylene in total joint replacement systems: Concerns and solutions"

FACTS AND FIGURES

Starting in 1992, in the last 15 years, we collected:

KNEE

131 retrieved

69 new

200 TOT

HIP

388 retrieved

108 new

496 TOT

SHOULDER

10 new



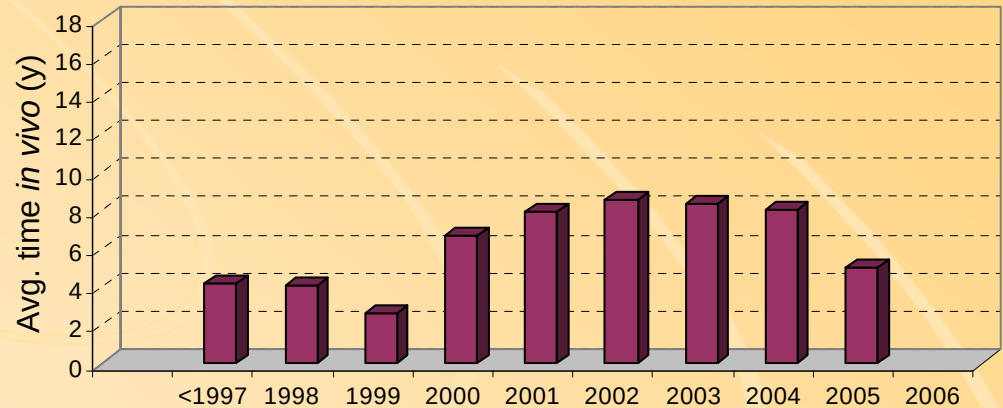
706 TOT

(519 retrieved
187 new)

RETRIEVED UHMWPE

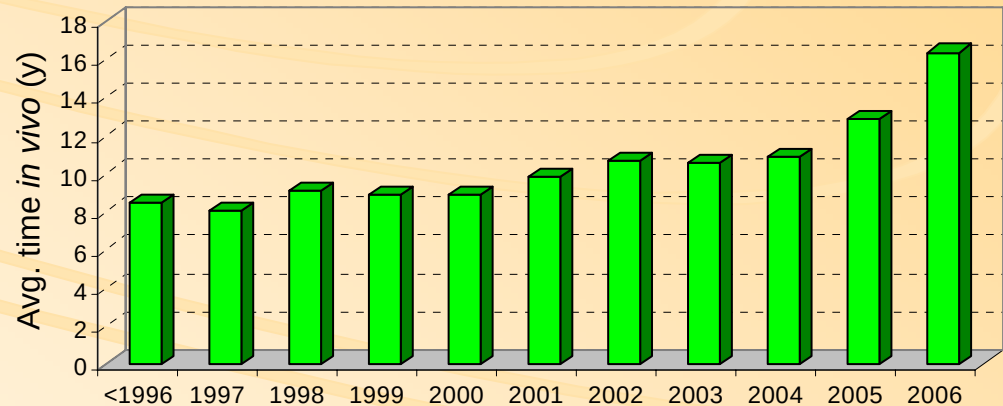
KNEE

100% radiation sterilized



HIP

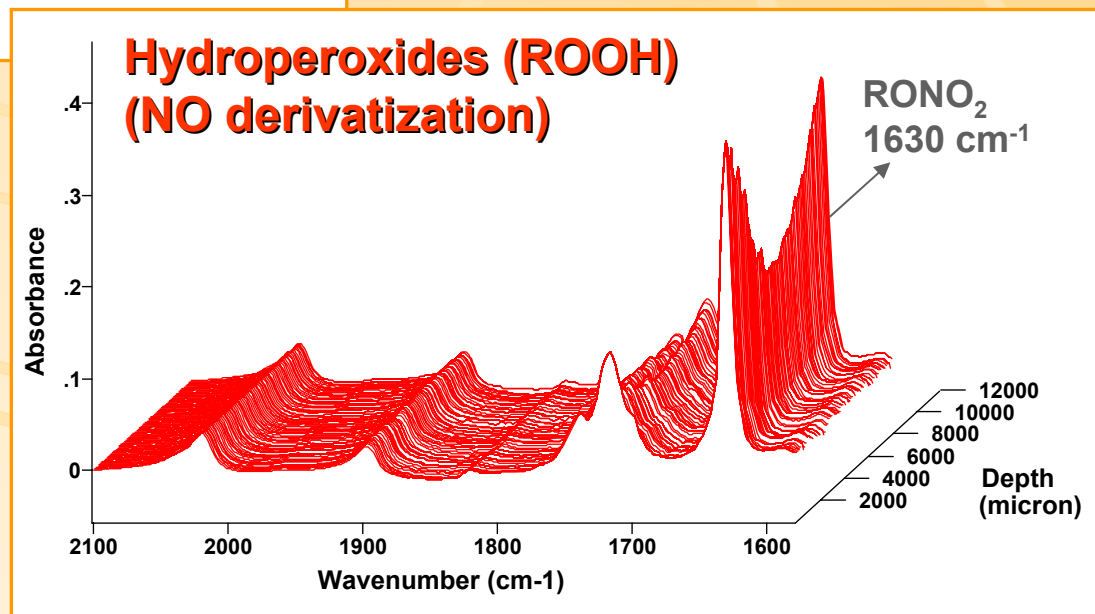
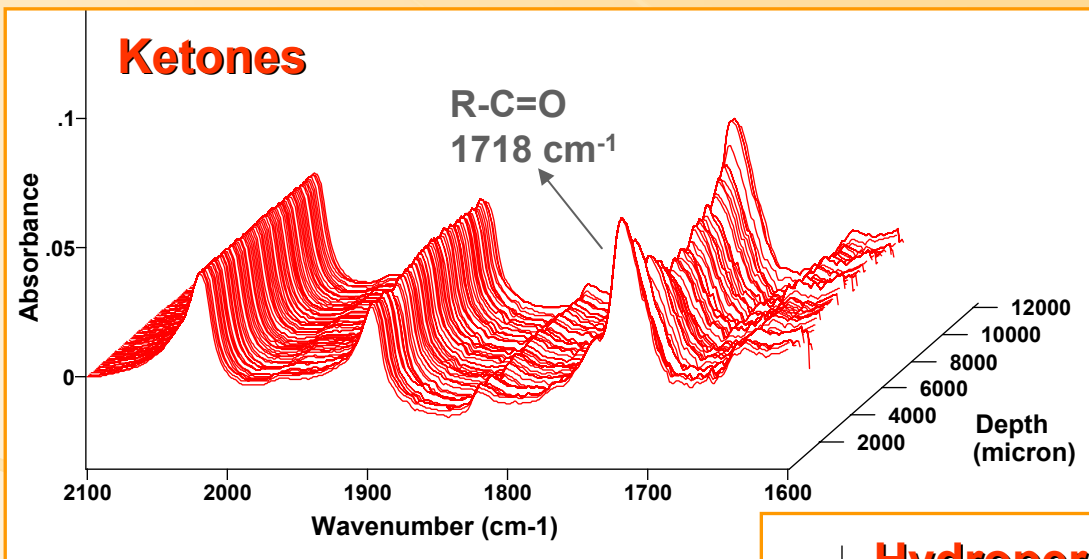
**94% radiation sterilized
6% EtO, other**



RETRIEVED UHMWPE

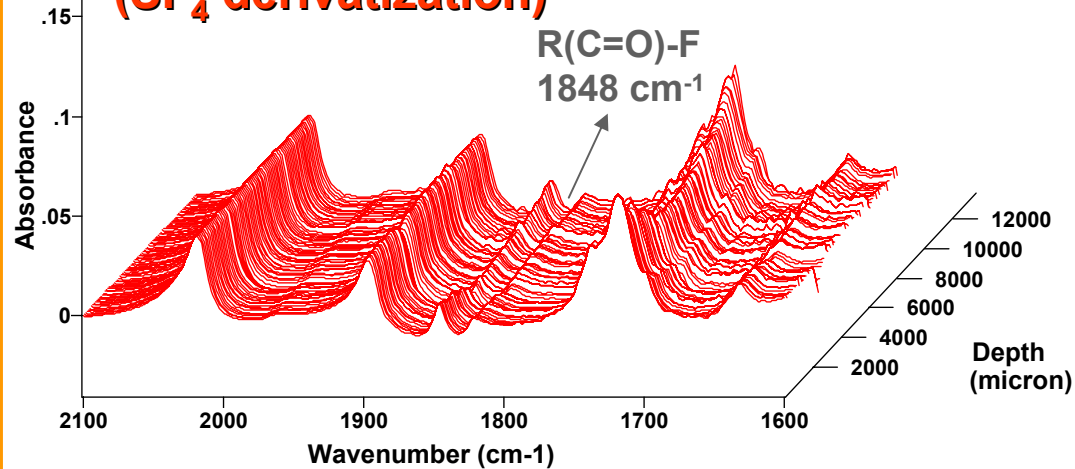


FTIR studies of oxidative degradation



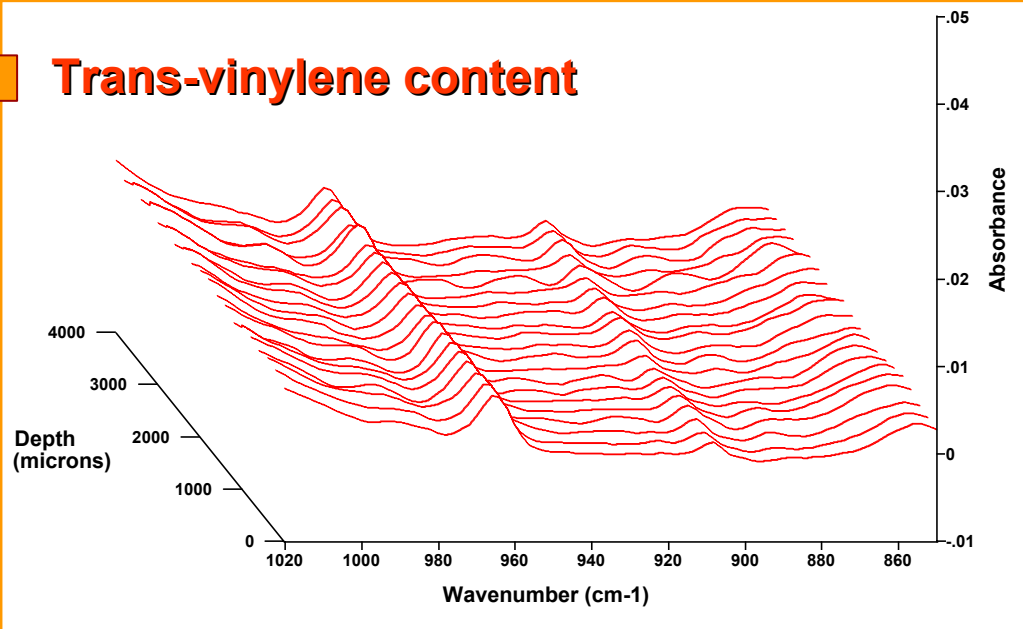
Costa L, Luda MP, Trossarelli L, Brach del Prever E, Crova M, Gallinaro P. Oxidation in orthopaedic UHMWPE sterilised by gamma-radiation and ethylene oxide. *Biomaterials*, 1998; 19: 659-668

Carboxylic acids ($\text{RC}=\text{O}-\text{OH}$) (SF_4 derivatization)



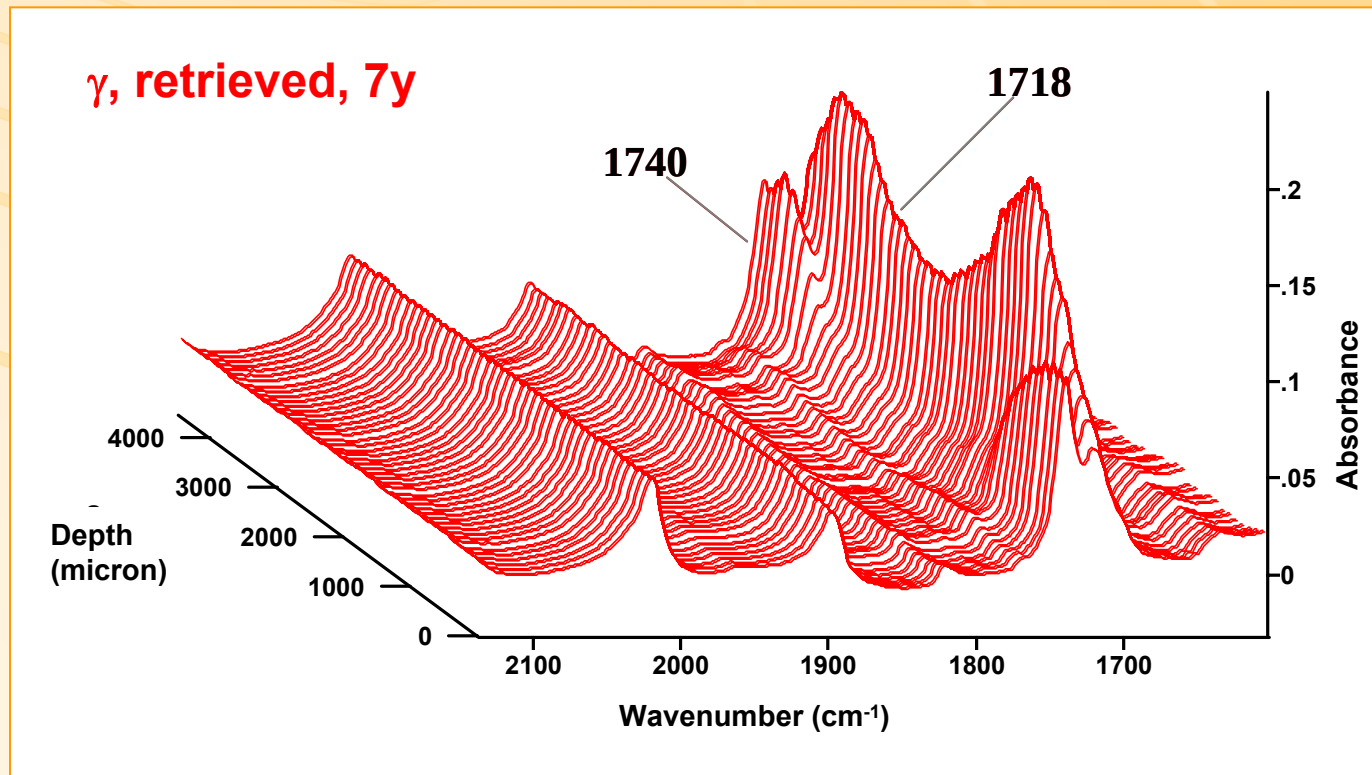
Dose assessment

Trans-vinylene content



L. Costa, M.P. Luda, P. Bracco and L. Trossarelli. *Oxidation of UHMWPE during sterilisation by gamma and beta ray*. Macro 98, 37th International Symposium on Macromolecules Gold Coast, Australia. 12th –17th July 1998

RETRIEVED UHMWPE - Typical FTIR analyses

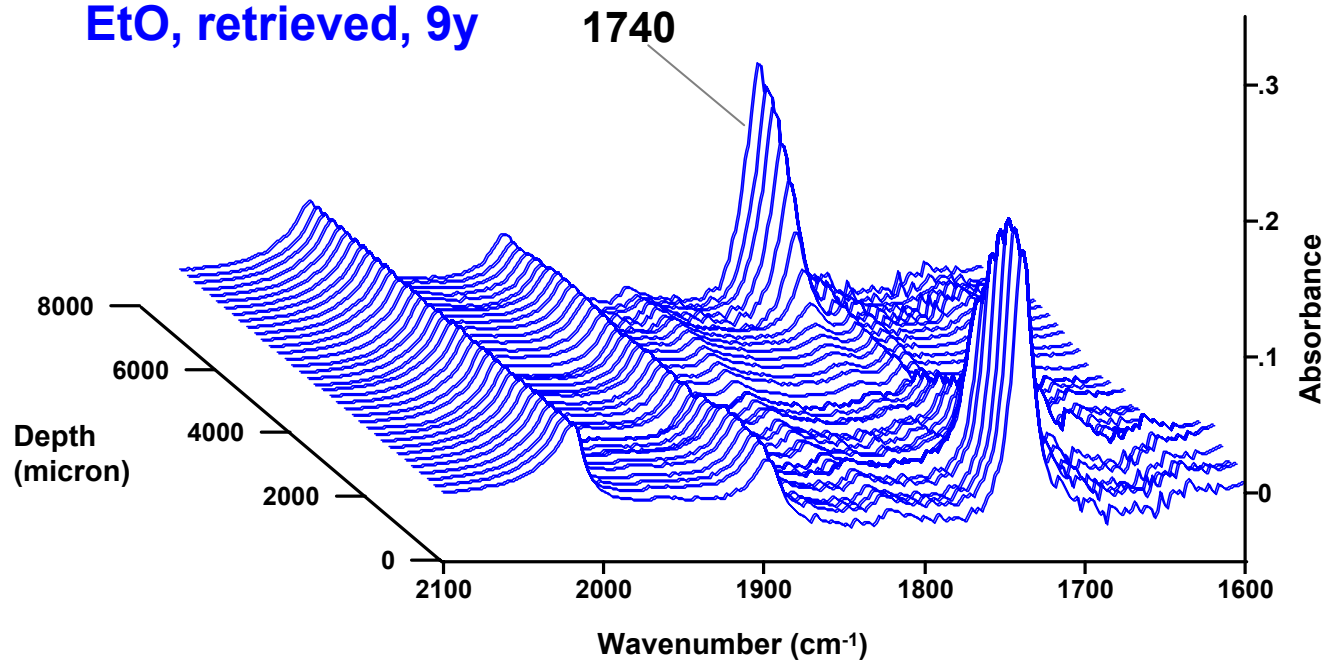


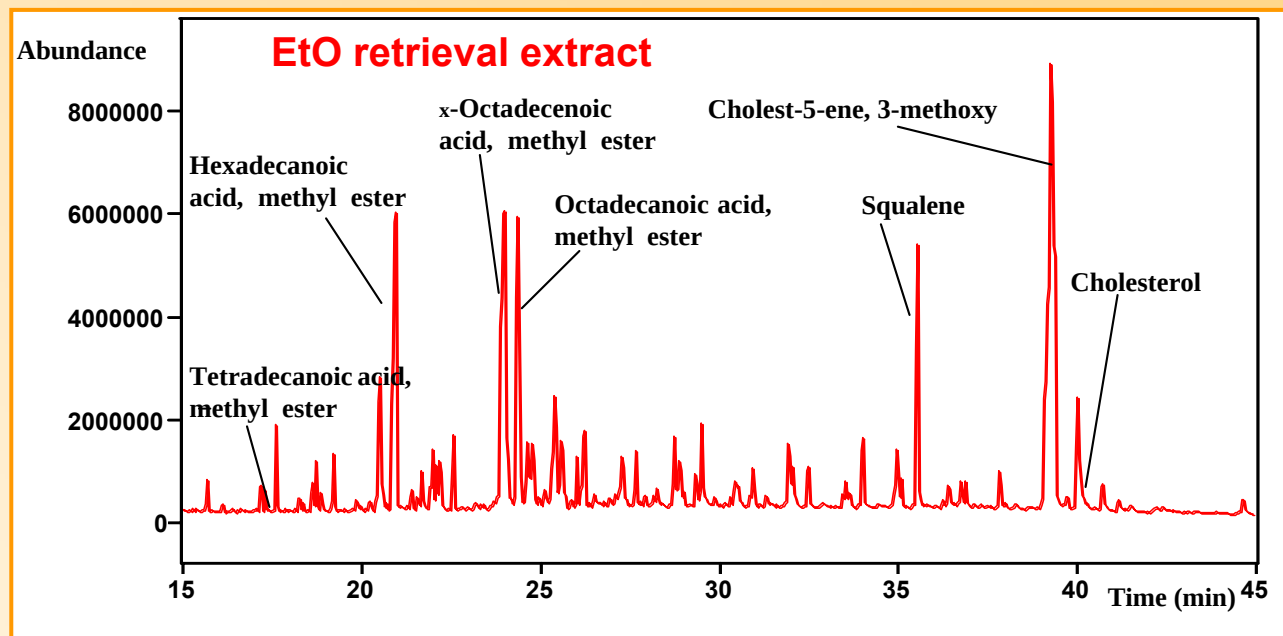
EtO sterilized



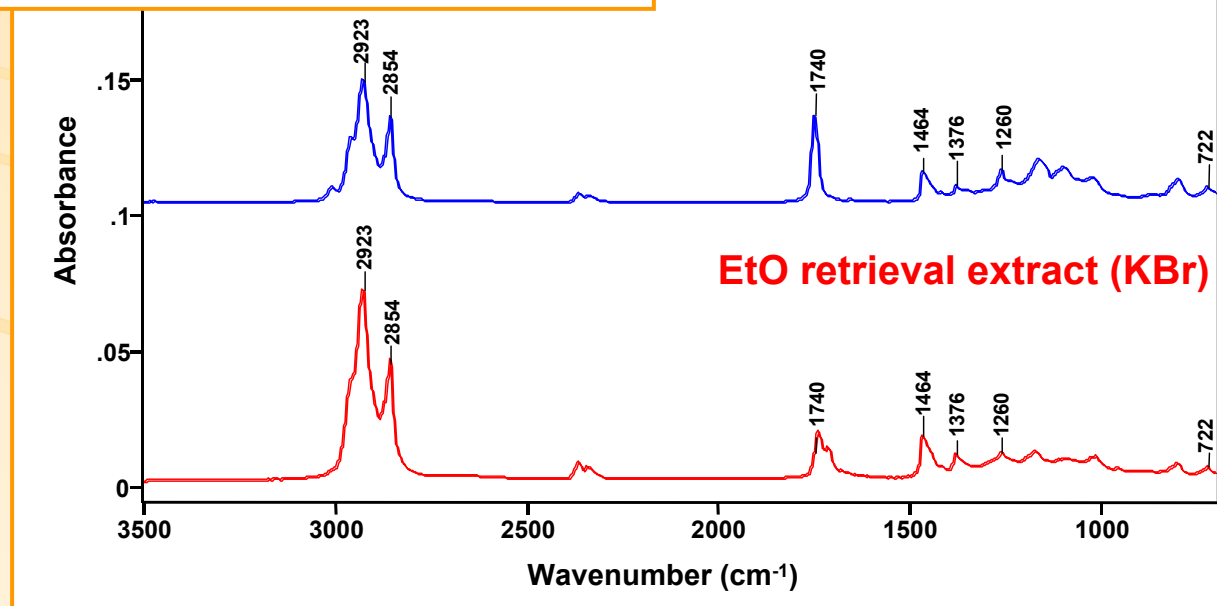
EtO, retrieved, 9y

1740



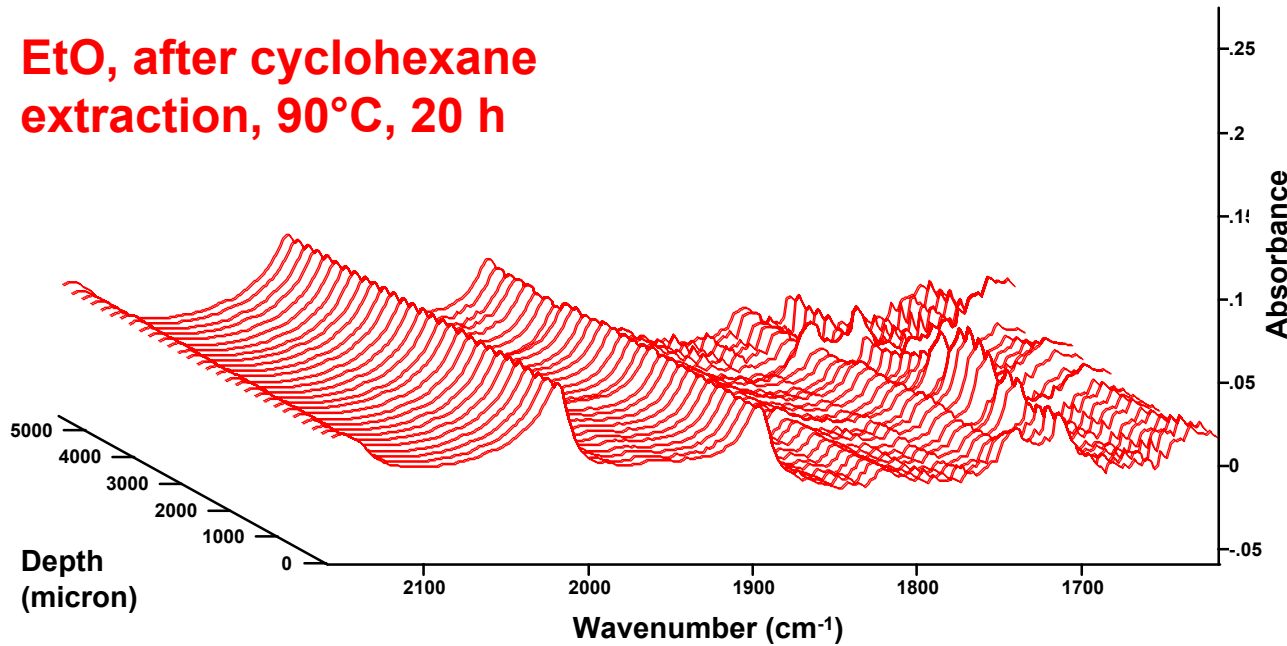


Synovial fluid extract (KBr)



L. Costa, P. Bracco, E. Brach del Prever, M.P. Luda and L. Trossarelli. *Analysis of products diffused into UHMWPE prosthetic components in vivo*. *Biomaterials*, 2001; 22(4): 307-315

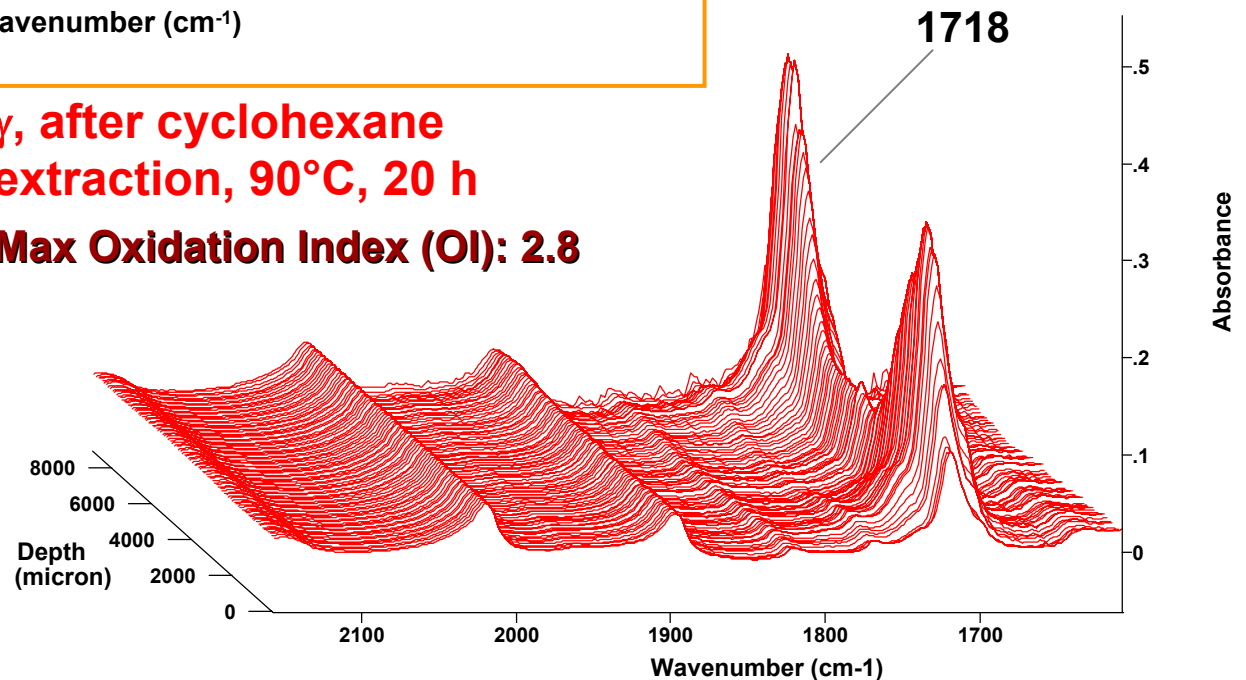
**EtO, after cyclohexane
extraction, 90°C, 20 h**



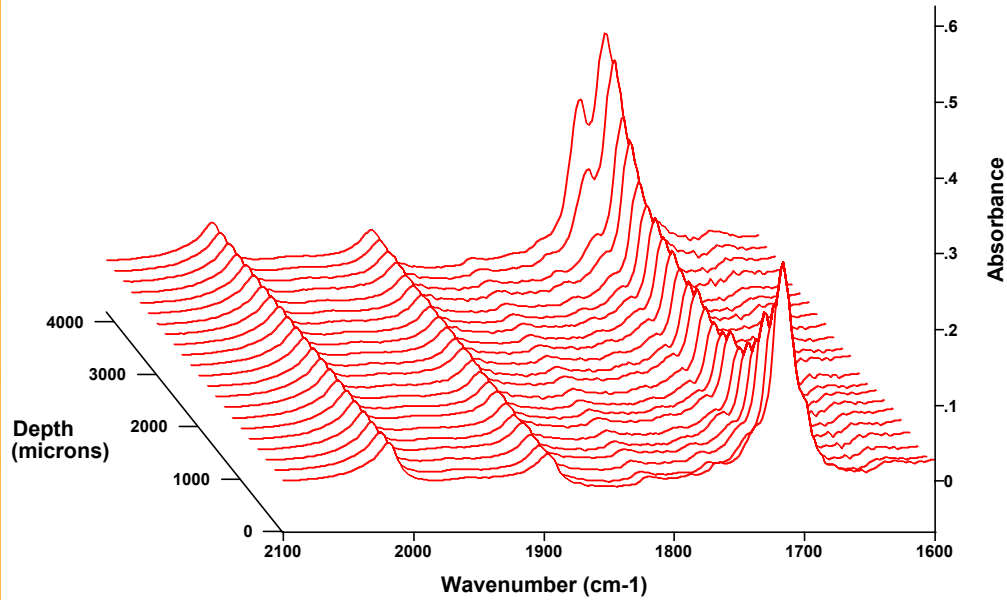
**Oxidative
degradation does
not start *in vivo***

**γ, after cyclohexane
extraction, 90°C, 20 h**

Max Oxidation Index (OI): 2.8

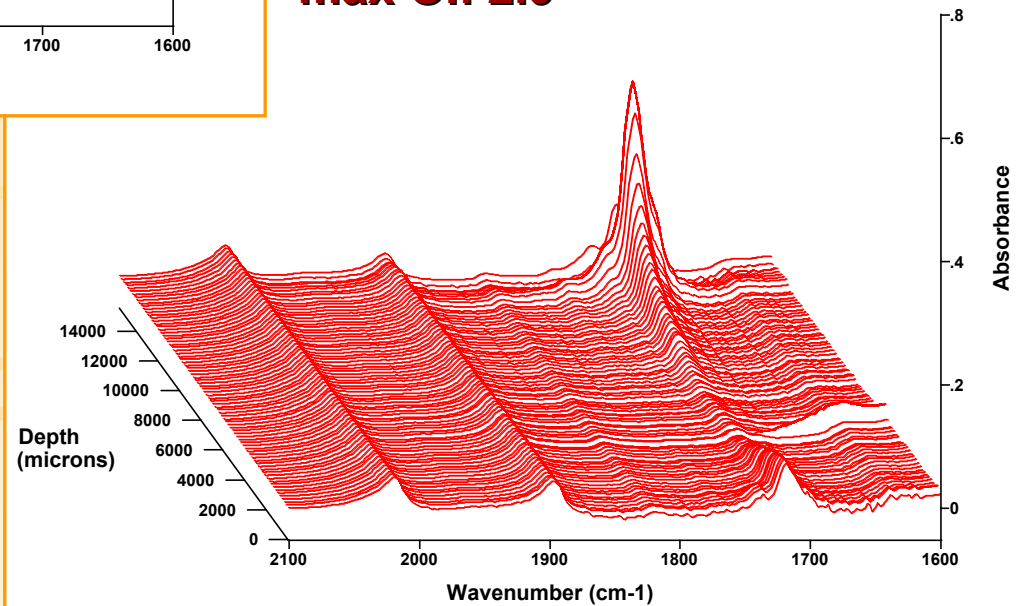


max Ol: 2.7



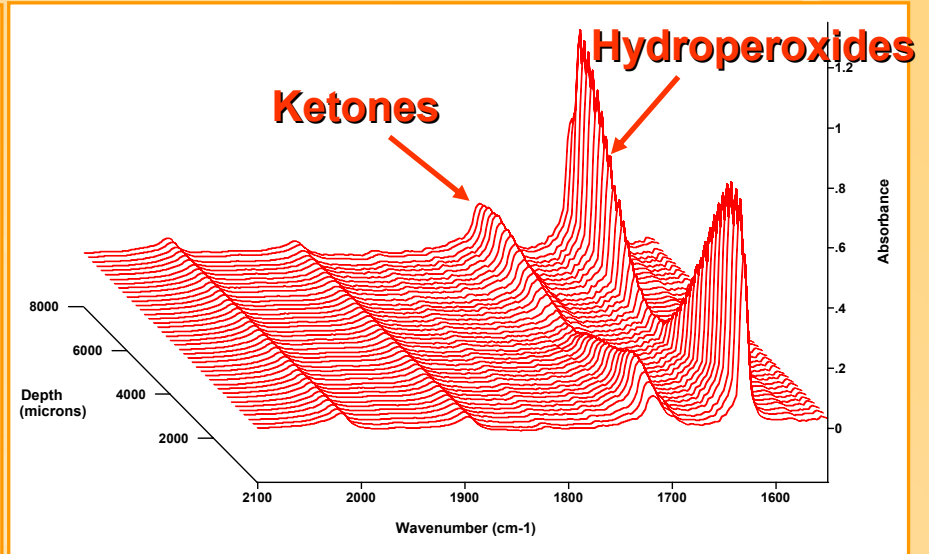
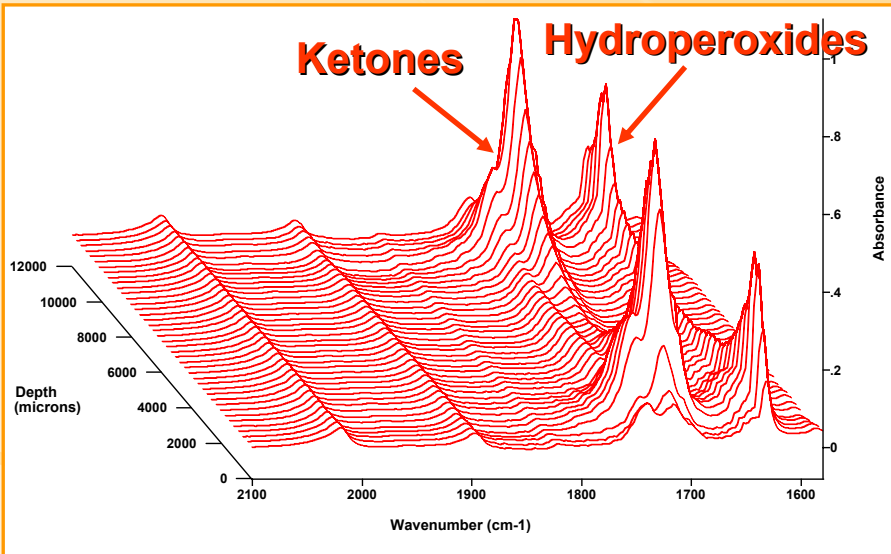
12 y

max Ol: 2.9



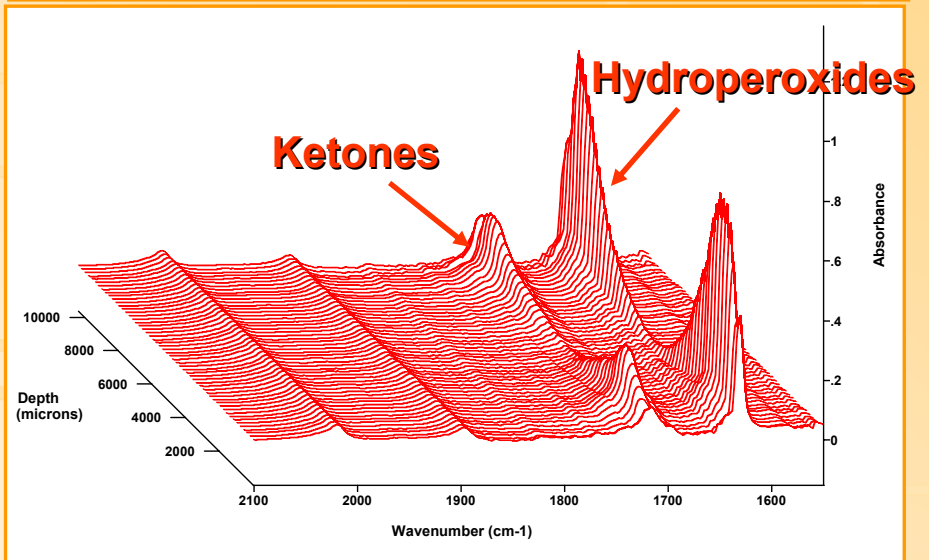
8 y

NEW, READY TO IMPLANT UHMWPE



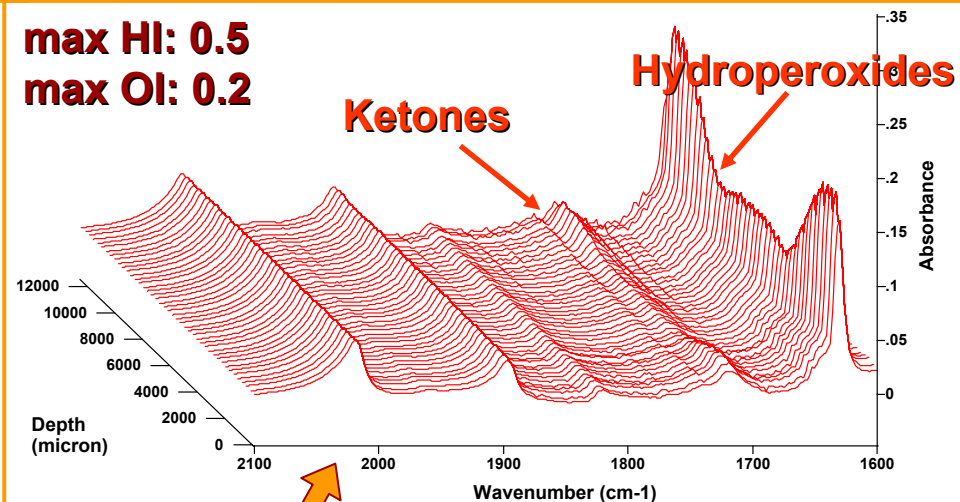
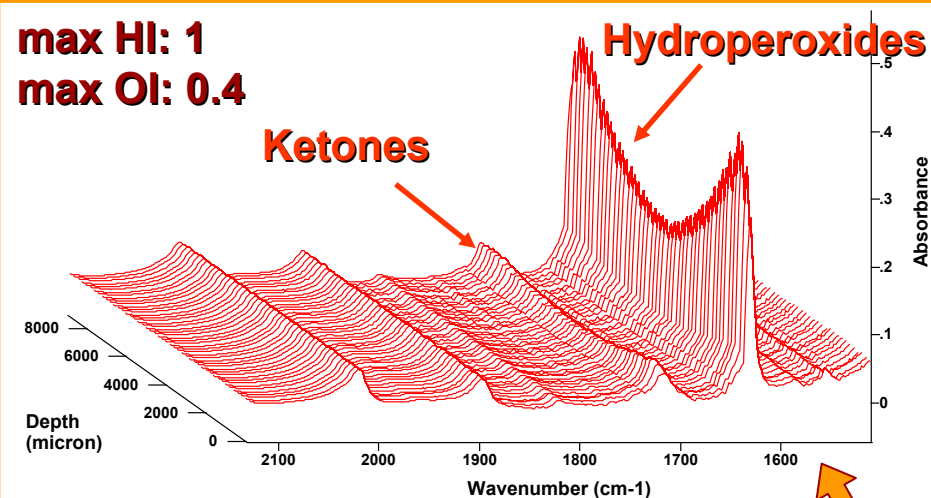
**Before 2000
(55 samples)**

**Radiation sterilized:
Oxidation index ca. 2 (up to 6)
Hydroperoxide index ca. 2**



Bracco P, Brunella V, Luda MP, Brach del Prever EM, Zanetti M, Costa L. "Oxidation behaviour in prosthetic UHMWPE components sterilised with high energy radiation in the presence of oxygen" *Polymer Degrad. Stability* 2006, 91: 3057-3064

100 (69 radiation sterilized), new, ready-to-implant UHMWPE hip, knee and shoulder components, submitted in 2003-2004 by 19 manufacturers (6 Italian, 8 European, 5 US).



L Costa, P Bracco, EM Brach del Prever, SM Kurtz, P Gallinaro. A survey of oxidation and oxidation potential in contemporary packaging for polyethylene total joint replacement components. J Biomed Mater Res 2006; 78B (1):20-26

Variables involved in OXIDATION:

- **Oxygen availability (oxygen is always present into UHMWPE)**
- **Purity of the inert gas**
- **Actual impermeability of the packaging**
- **Shelf-life**
- **Radiation dose and dose rate**
- **Temperature**

ABSORBED DOSE AND RADICALS

**Out of 79 irradiated samples
(69 radiation sterilized + 10 highly crosslinked):**

32 → 25 - 30 kGy

27 → 30 - 35 kGy

9 → >35 kGy

11 → ≥ 50 kGy highly crosslinked (5 manufacturers)

- **Out of 69 radiation sterilized samples, ALL showed a measurable ESR signal!**
- **None but one (not remelted, gamma sterilized) of the highly crosslinked samples show any measurable ESR signal**

CONCLUSIONS

- Residual radicals are **always** found in radiation-sterilized UHMWPE
- Residual radicals can react with **oxygen**, triggering the oxidation process
- Given the high number of variables involved, the prediction of the level, distribution and evolution of oxidation is, generally, **not** a successful activity!

ACKNOWLEDGEMENTS

This study could not have been possible without the cooperation of the CTO Hospital (Torino).

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THANK YOU FOR YOUR ATTENTION!