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

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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
- 187 new
- 519 retrieved
- 706 TOT
RETRIEVED UHMWPE

KNEE
100% radiation sterilized

HIP
94% radiation sterilized
6% EtO, other
RETRIEVED UHMWPE

3rd UHMWPE INTERNATIONAL MEETING

“Polyethylene in total joint replacement systems: Concerns and solutions”
FTIR studies of oxidative degradation

Ketones

R-C=O

1718 cm\(^{-1}\)

Hydroperoxides (ROOH) (NO derivatization)

RONO\(_2\)

1630 cm\(^{-1}\)

RETRIEVED UHMWPE - Typical FTIR analyses

\[ \gamma, \text{retrieved, 7y} \]

Absorbance

Wavenumber (cm\(^{-1}\))

Depth (micron)

4000
3000
2000
1000
0

2100
2000
1900
1800
1700
EtO sterilized

EtO, retrieved, 9y

Absorbance

Wavenumber (cm⁻¹)

Depth (micron)

0 2000 4000 6000 8000
0 1 2

3rd UHMWPE INTERNATIONAL MEETING
“Polyethylene in total joint replacement systems: Concerns and solutions”
Oxidative degradation does not start \textit{in vivo}.

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

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

Max Oxidation Index (OI): 2.8
max OI: 2.7

max OI: 2.9

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NEW, READY TO IMPLANT UHMWPE

Before 2000 (55 samples)

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


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  $\rightarrow$ 25 - 30 kGy
-  27  $\rightarrow$ 30 - 35 kGy
-  9   $\rightarrow$ >35 kGy
-  11  $\rightarrow$ $\geq$ 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!
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