The Impact of Aging Environment on the Oxidation of Stabilized and Unstabilized Crosslinked Polyethylenes

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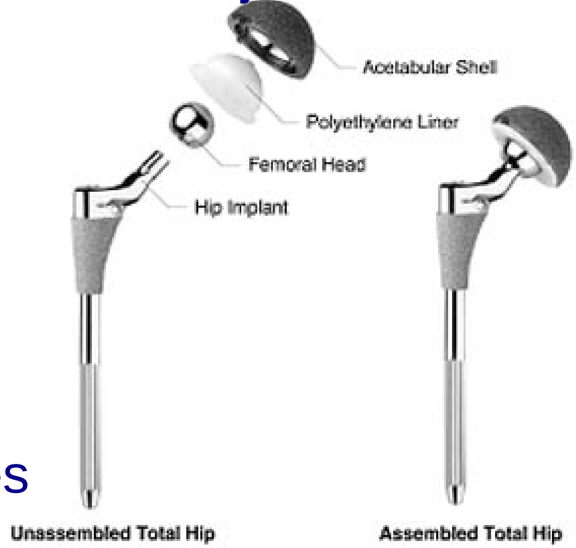
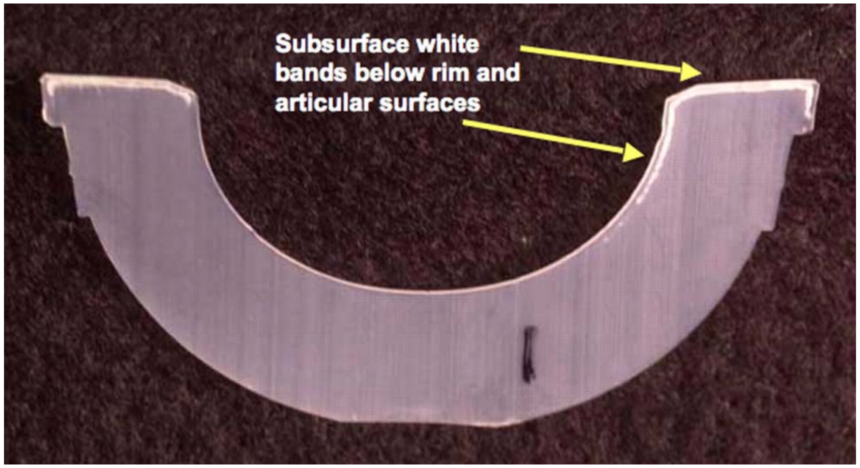
Polyethylene as a bearing surface

- UHMWPE has become the standard counterface for total joint replacements
  - Modern materials give 20+ year wear
  - Biologically inert
  - Easily handled
- Potential oxidation is one of the few weaknesses
  - Excessive wear
  - Particle generation
  - Osteolysis and implant loosening
- New materials and formulations require validation

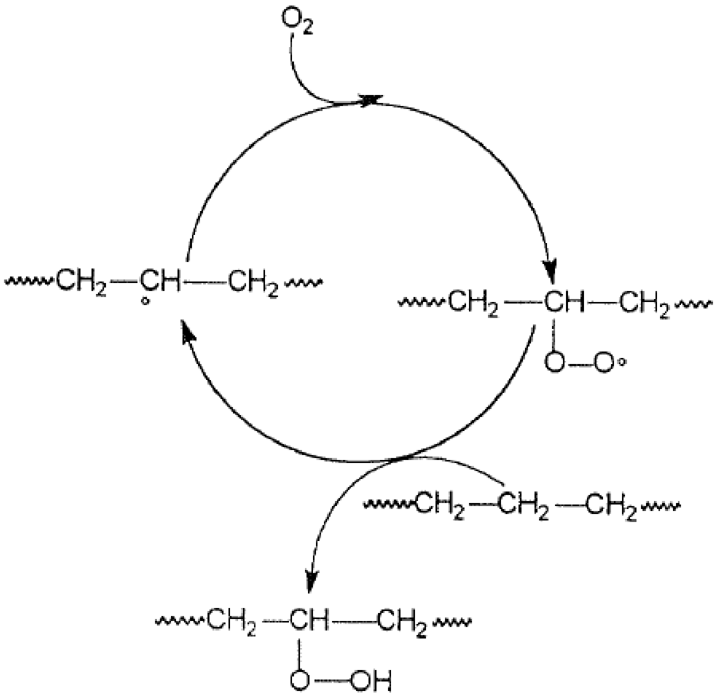


Oxidation in Polyethylene

- Modern highly crosslinked polyethylene has potential for oxidation if care is not taken
  - Residual free radicals from the crosslinking process remain active
  - Often described by the Bolland cycle
  - Can drive oxidation and degradation



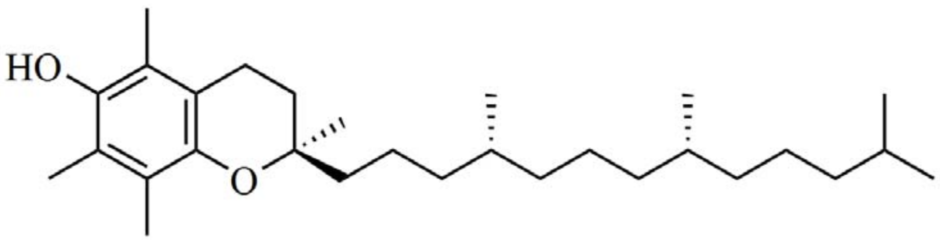
Currier et al. JBJS 2007



Costa et al. Biomaterials 1998

Stabilized polyethylene

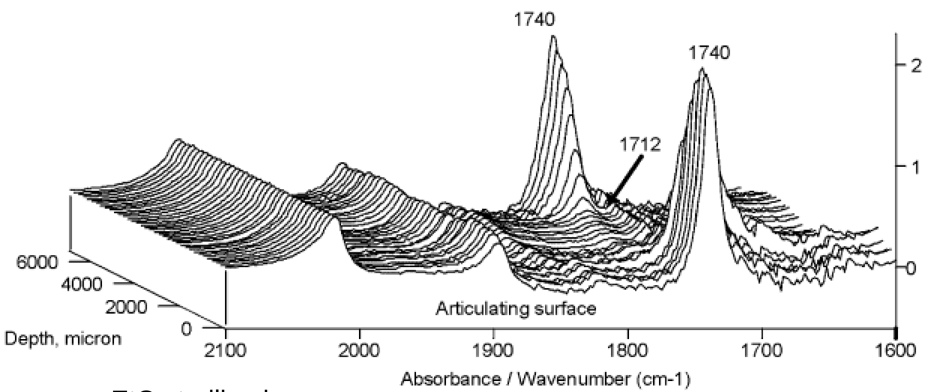
- Recent advances have begun to utilize oxidatively stabilized polyethylenes
  - Help reduce risk of oxidation
- Usually result from additional component added to system
  - α-tocopherol



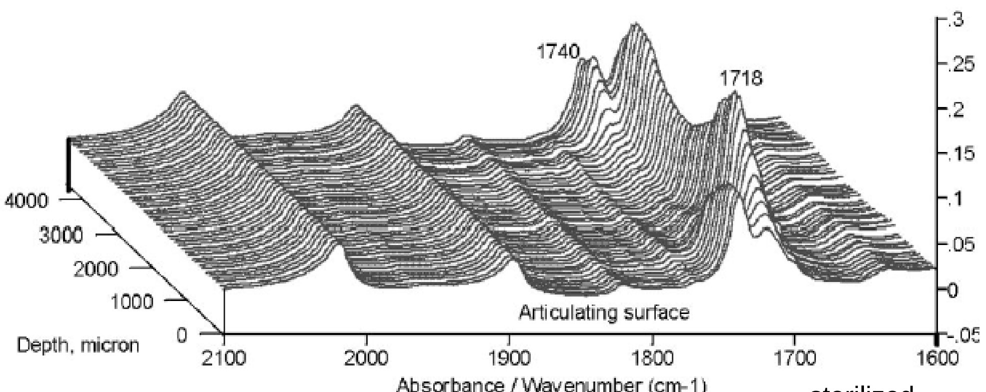
- The addition of secondary species raises questions about how accelerated aging occurs and if physiological fluids interact with the materials differently

The importance of environment

- Costa reported in 2001 that the absorption of media species may also play a role
  - Synovial fluid a complex mixture
    - Cholesterol, proteins, fatty acids
  - Post-implant
    - Surface adsorbed proteins
    - Apolar materials diffused in to bulk
      - Cholesterol and esters, with fatty acids and squalene
  - Crosslinking does not prevent absorption



EtO sterilized



γ sterilized

Costa et al. Biomaterials 2001

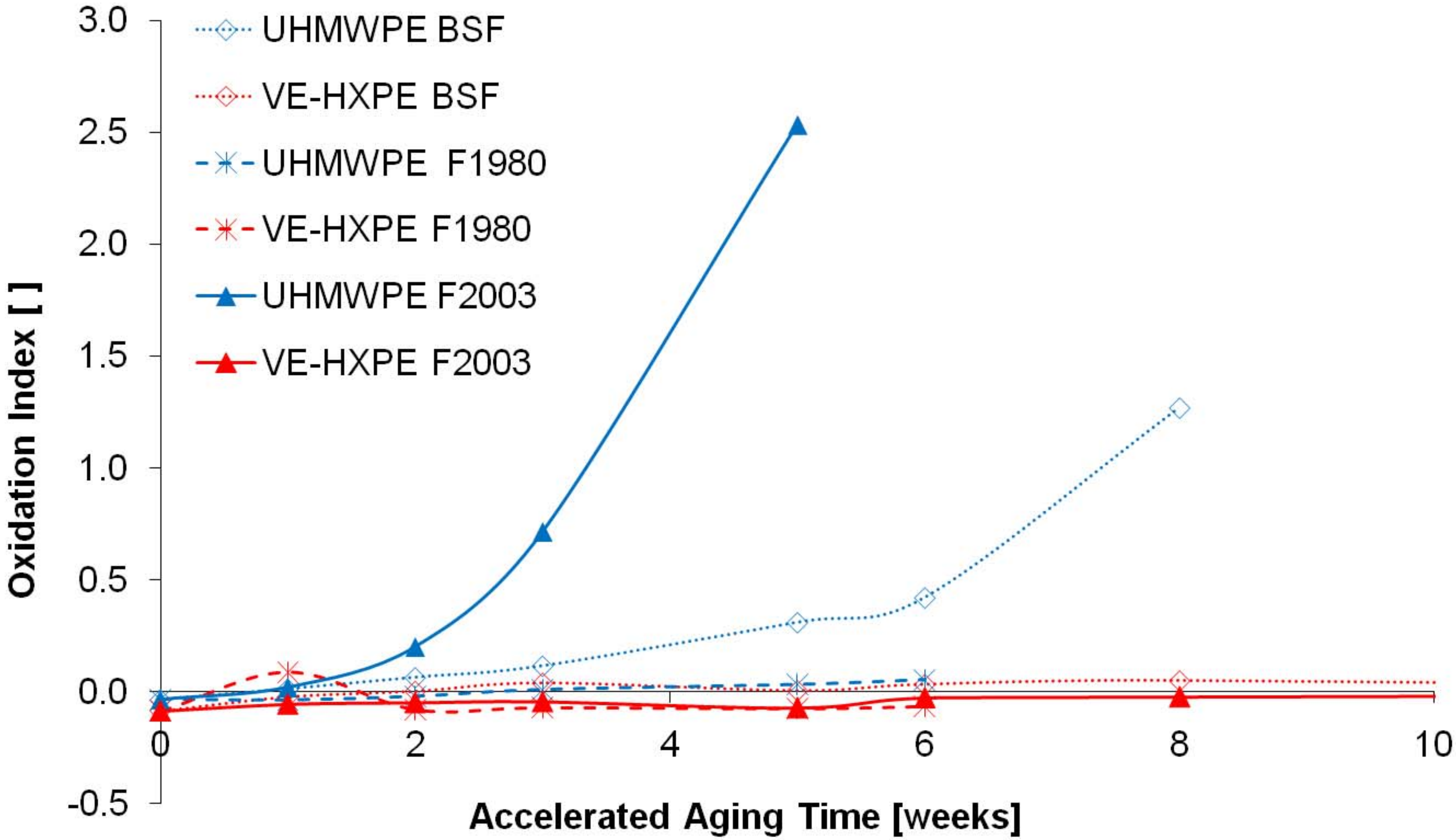
In vitro testing for oxidative stability

- Ambient, or “real-time” conditions
  - “shelf aging”
    - Room temperature and pressure
  - “fish tank”
    - Water, often at physiological temperatures, non-standard
- Accelerated
  - F 1980
    - Ambient atmosphere, 80 ºC
    - “Q10”, 1 week is considered to be 1 year equivalent
  - F 2003
    - Five atmospheres, oxygen at 70 ºC

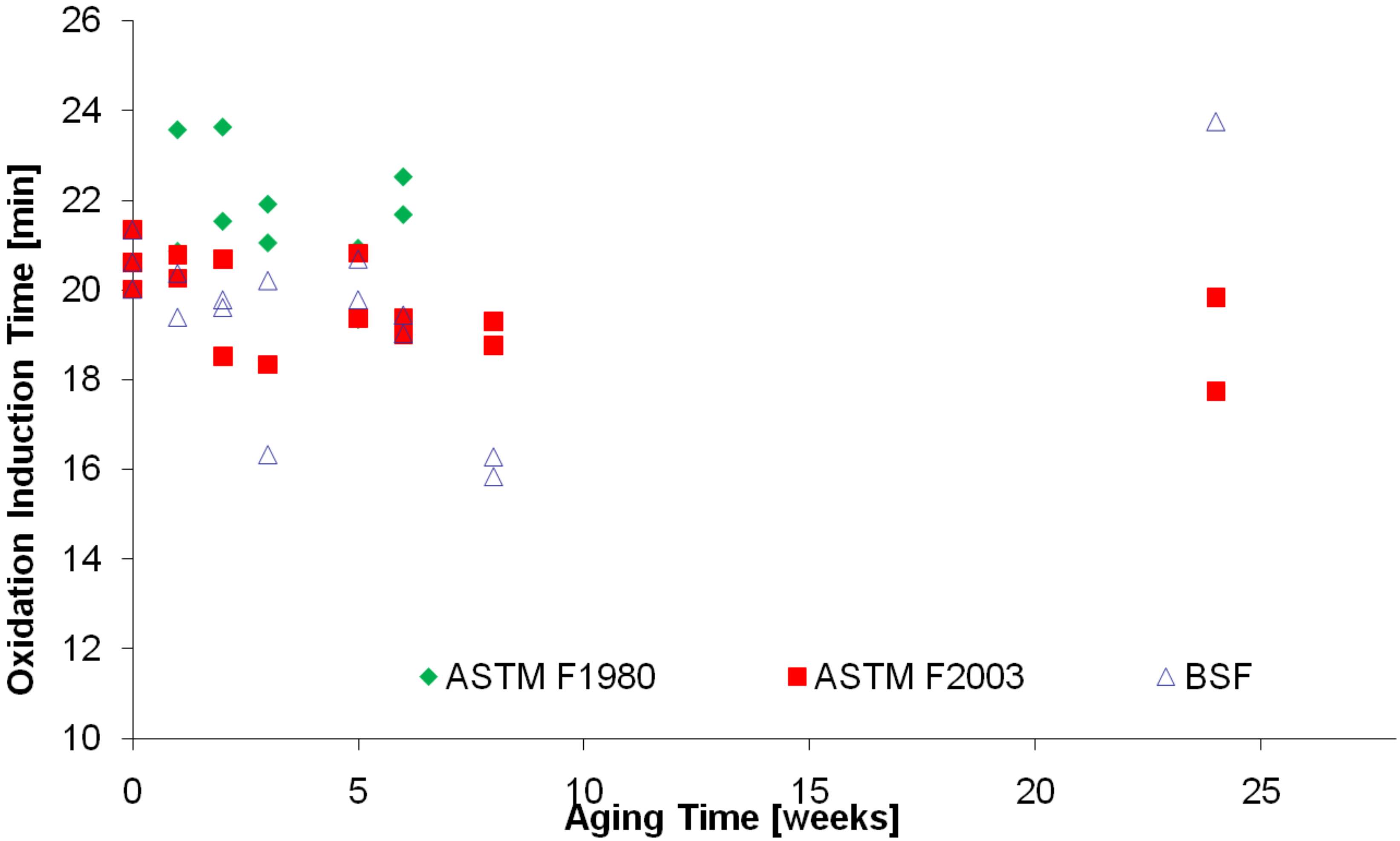
Materials and environments

- Materials
  - Consolidated GUR 1050
    - γ-sterilized (25-37 kGy) “UHMWPE”
    - Vitamin E blended, consolidated and e-beam crosslinked “VE-PE”
  - 1 cm cubes cut from each consolidated puck
- Environments
  - ASTM F1980-99 (ambient atmosphere, 80 ºC)
  - ASTM F2003-02 (5 atmospheres oxygen, 70 ºC)
    - Oxygen 99.994% ultra high purity, Air Gas
  - Bovine Synovial Fluid (5 atmospheres oxygen, 60 ºC)
    - BSF Animal Technologies Inc.
    - Oxygen 99.994% ultra high purity, Air Gas
    - Dissolved oxygen ~4.41 mmol O_2/L H_2O (c.f. 1.07 mmol O_2/L H_2O)
- Samples in BSF were refluxed against hexane for three days
  - Verify that FTIR spectra due to immobile species

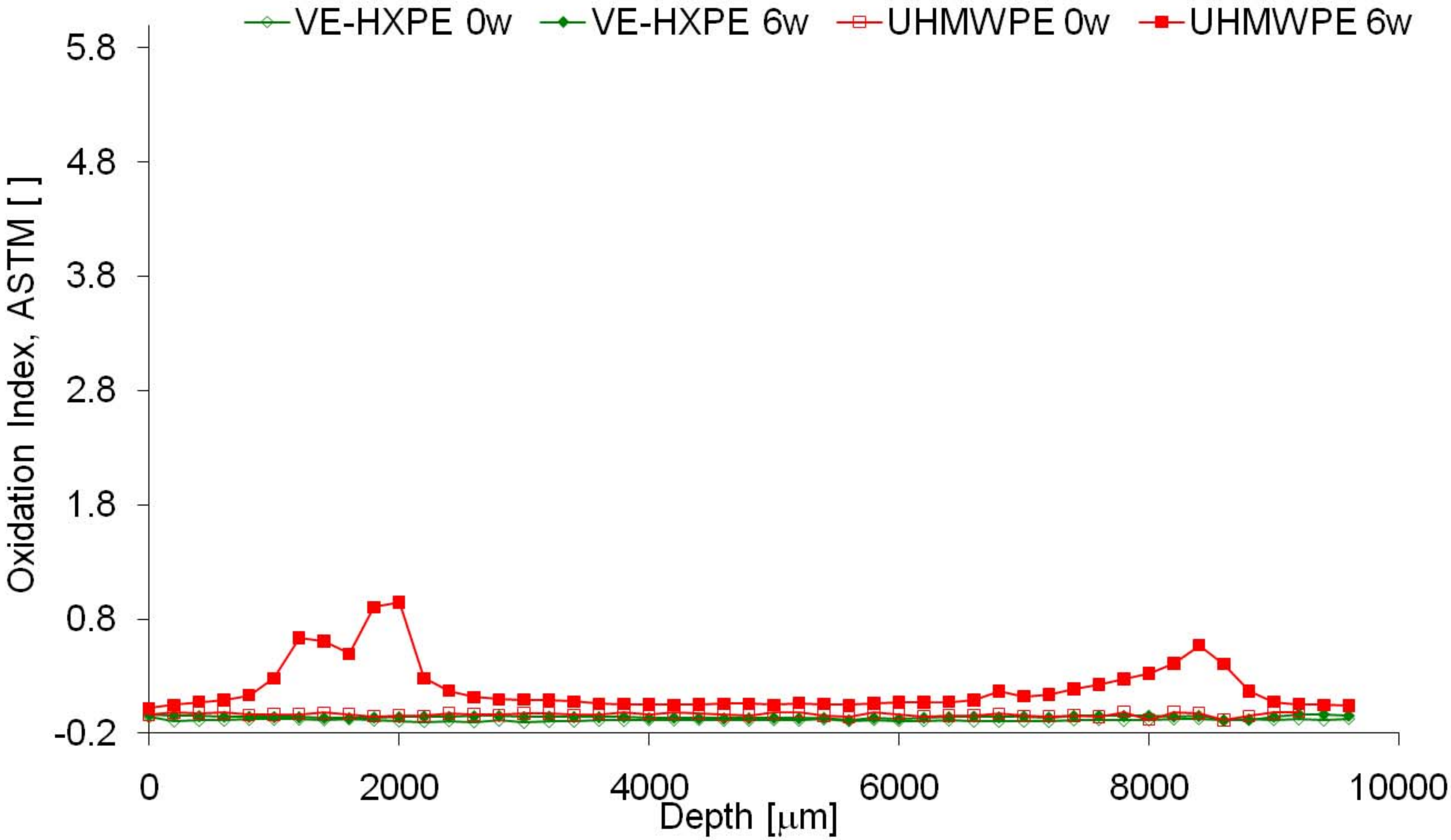
Bulk Oxidation



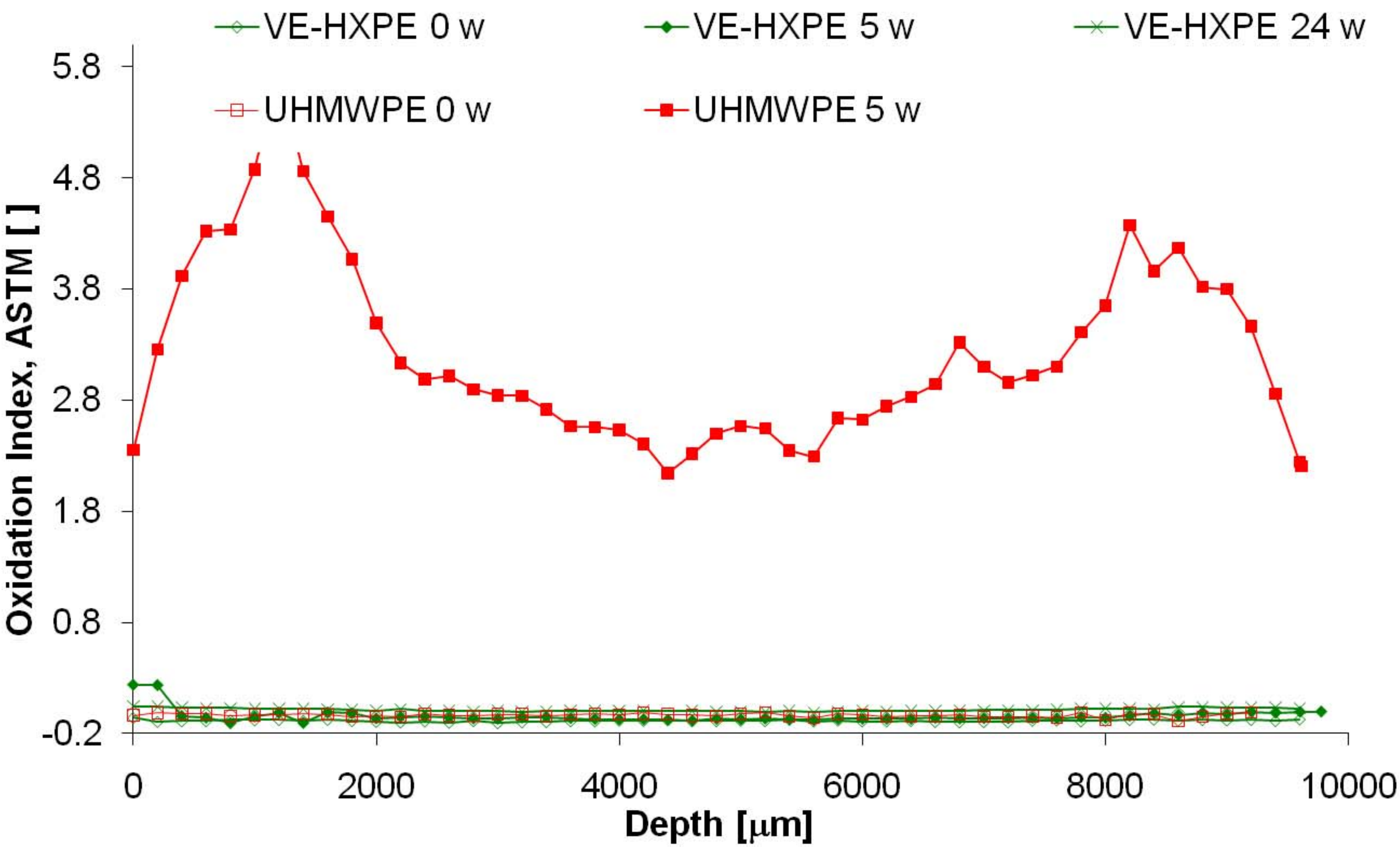
Antioxidant potential of VE-PE (OIT)



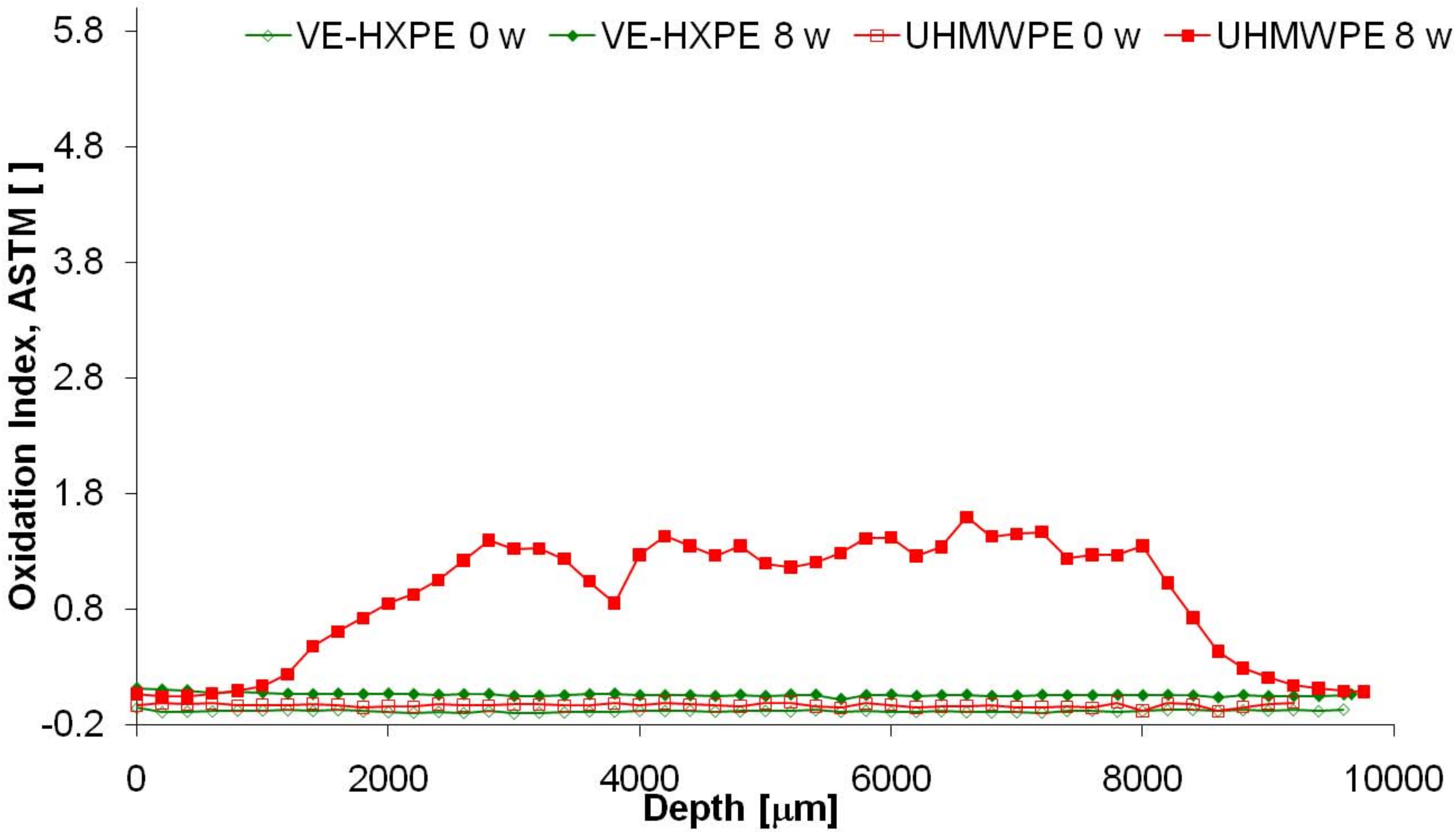
F1980 (ambient air)



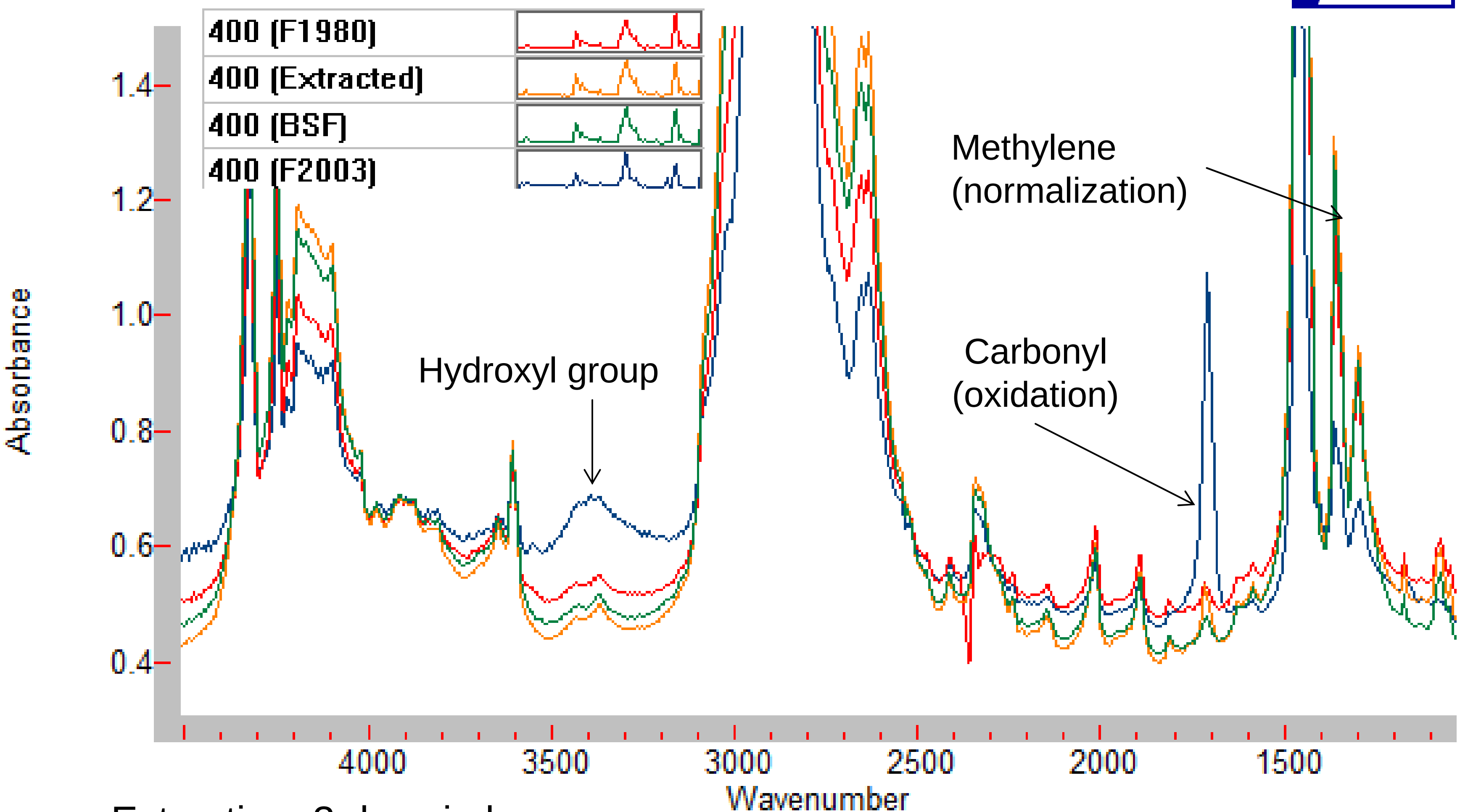
F2003 (Oxygen Bomb)



Synovial Fluid



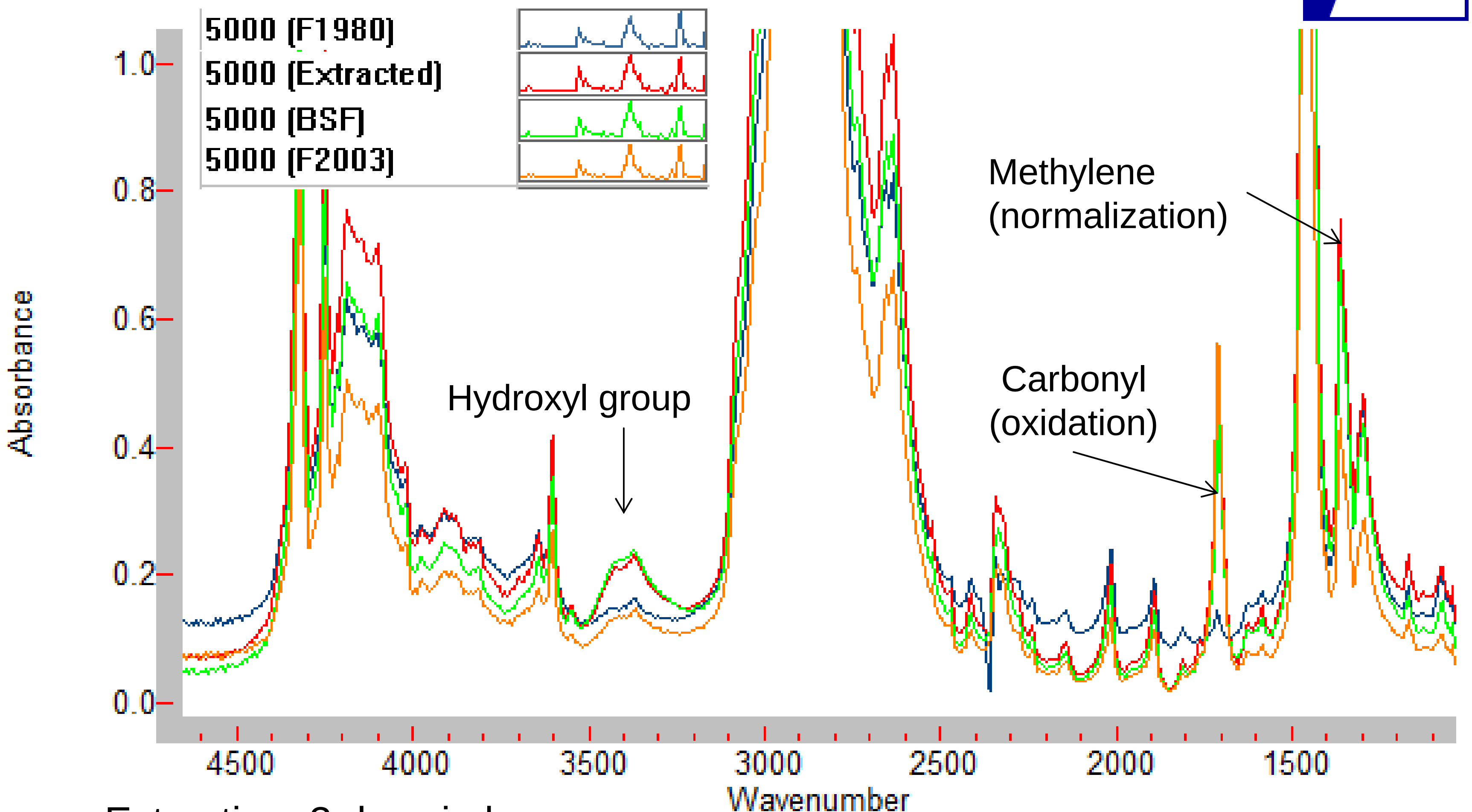
Surface Oxidation Spectra (UHMWPE)



Extraction: 3 days in hexane

BSF at 8 weeks, F2003 at 5 weeks, F1980 at 6 weeks

Bulk Oxidation Spectra (UHMWPE)



Extraction: 3 days in hexane

BSF at 8 weeks, F2003 at 5 weeks, F1980 at 6 weeks

Conclusions

- VE-PE exhibits excellent long-term stability in these accelerated environments
  - Evenly in highly demanding oxygen bomb, OI is negligible out to 24 weeks
- OIT suggests that stability is not lost as VE-PE is aged, even out to 24 weeks
  - However, very different measure of stability
- BSF is less demanding than oxygen bomb
  - Lower temperature
- BSF has different OI distribution in uncrosslinked materials
  - Bulk OI is higher – unique profile inconsistent with retrievals
    - Higher than F1980 (air) but lower than F2003 (bomb)
  - Surface OI falls off rapidly near surface
    - Possible indicator of protective effect of BSF constituents?
  - Oxidation profile still present after hexane extraction