Trace Concentrations of Vitamin E Protect Radiation Crosslinked UHMWPE From Oxidative Degradation

+*Kurtz, S.; *Mazzucco, DC; *Siskey, RS;
**Dumbleton, J; #Manley, M; ##Wang, A

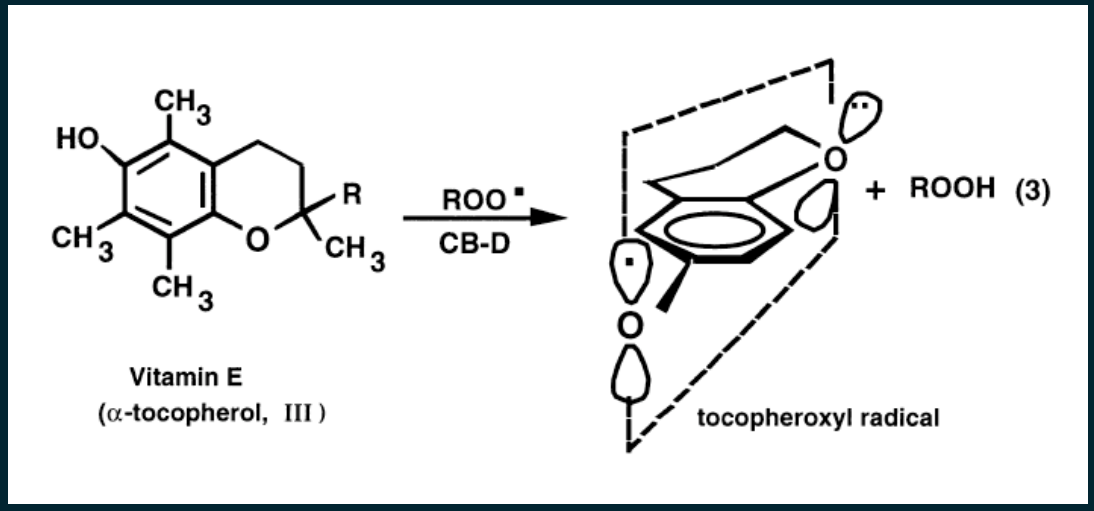
+*Exponent, Inc, Philadelphia, PA; **Consultancy in Medical Devices; #Homer Stryker Center; ##Stryker Orthopedics

Introduction

- Medical grade UHMWPE
  - No additives
  - Unstabilized
- Irradiation produces free radicals
  - Sterilization (25-40 kGy)
  - Enhanced Wear Resistance (50-105 kGy)
- Free radicals will combine with oxygen
  - Prior to implantation (“shelf aging”)
  - *In vivo*

Stabilization of UHMWPE

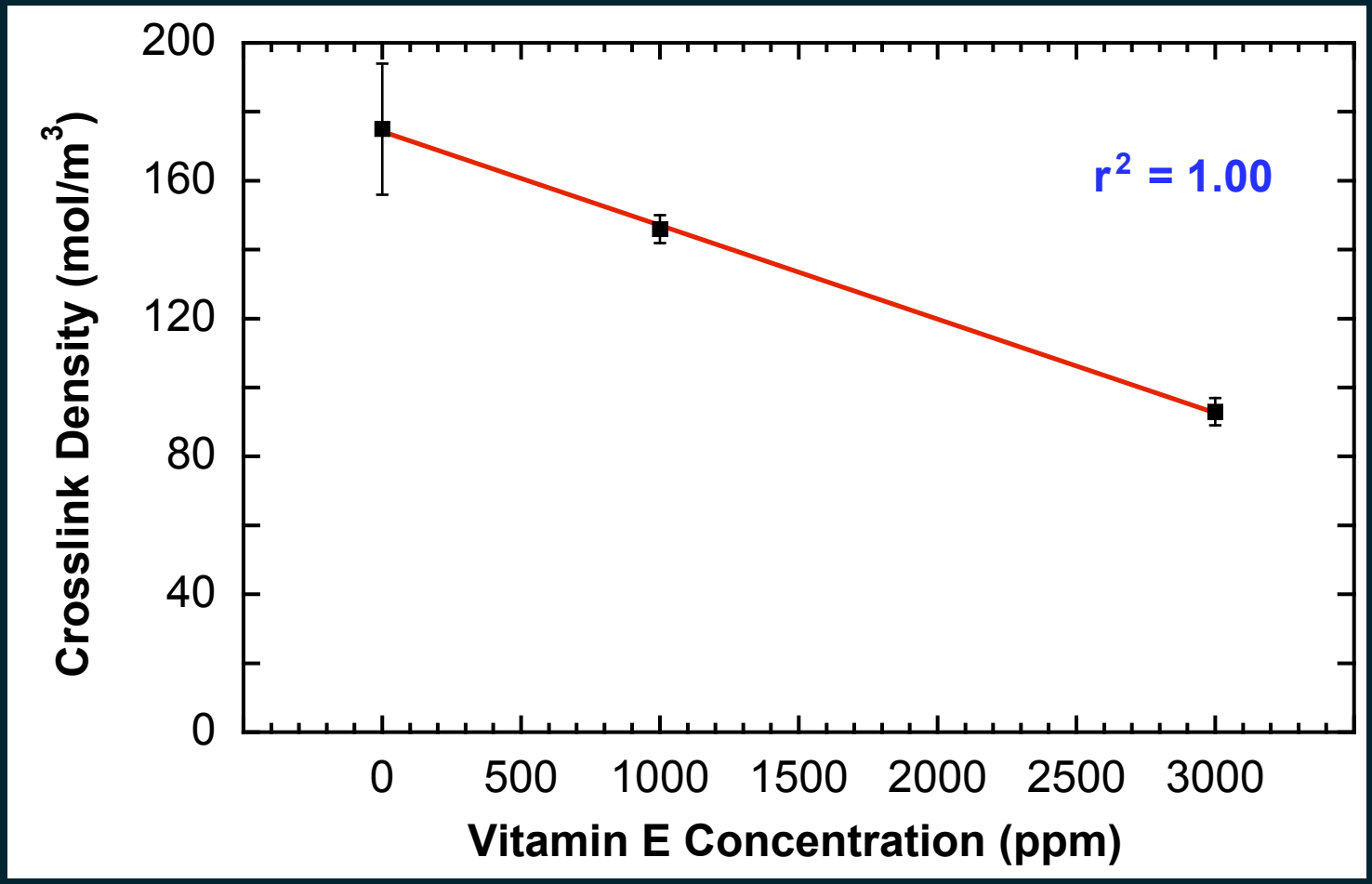
- Post-irradiation thermal treatment
  - Remelting
  - Annealing, sequential annealing
- Mechanically annealing
- Vitamin E
  - Blending
  - Doping



Vitamin E and Medical Grade UHMWPE (500-16,000 ppm)

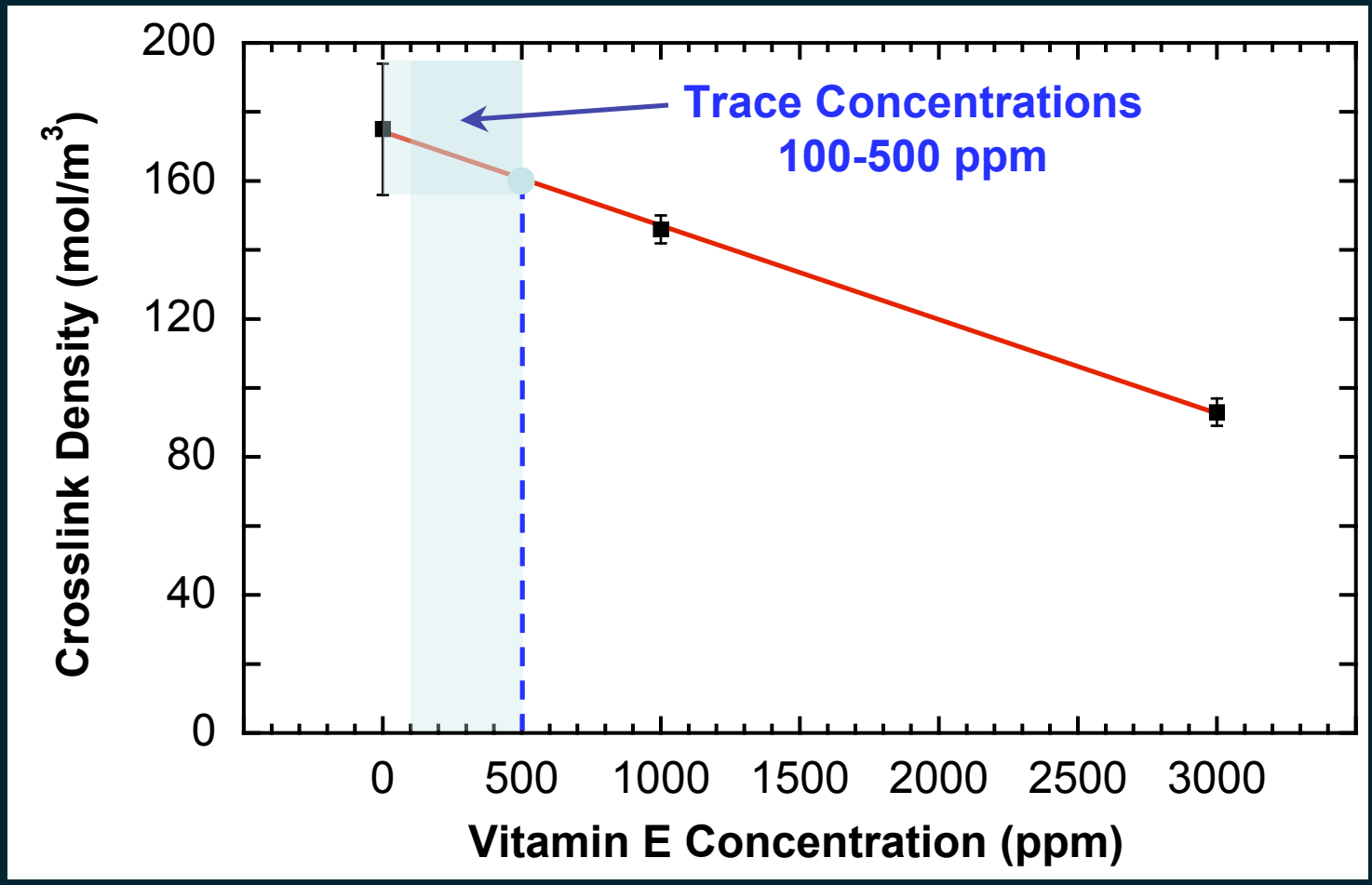
- Tomita, Shibata, Mori (1999-2005)
  - Kyoto, Japan
- Wolf, Lederer
  - Leoben, Austria (2002-2006)
- Costa, Bracco, Reno
  - Torino, Italy (2004-2007 ORS Poster 1780)
- Oral, Muratoglu
  - Boston, USA (2004-2007 ORS Poster 1626)

Vitamin E and Crosslinking



—Oral et al., *Biomaterials*, Vol. 26, 2005

Vitamin E and Crosslinking



—Oral et al., *Biomaterials,* Vol. 26, 2005

Research Objectives

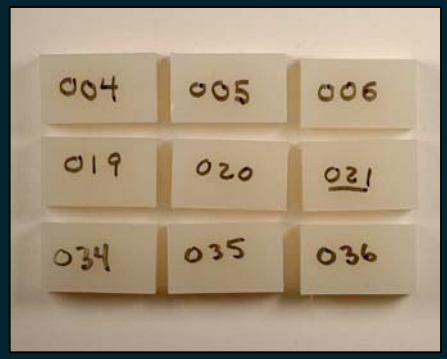
- **Goal**
  - Determine the minimum Vitamin E concentration to stabilize conventional and highly crosslinked UHMWPE
- **Hypothesis**
  - Oxidation resistance of Vitamin E blended UHMWPE is influenced by
    - Trace antioxidant concentration (≤500 ppm)
    - UHMWPE resin (GUR 1020, 1050)
    - Radiation dose (0, 30, 75 kGy)

Materials

- GUR 1020 and 1050 PE + vitamin E
  - Molded by Ticona, ~20 cm in diameter

Specimen Preparation

Machining →



Processing

None

75 kGy + machining

γ-irradiation in N_2 (30 kGy)

Accelerated Aging (ASTM F2003)

Aging →

→ None

2 weeks

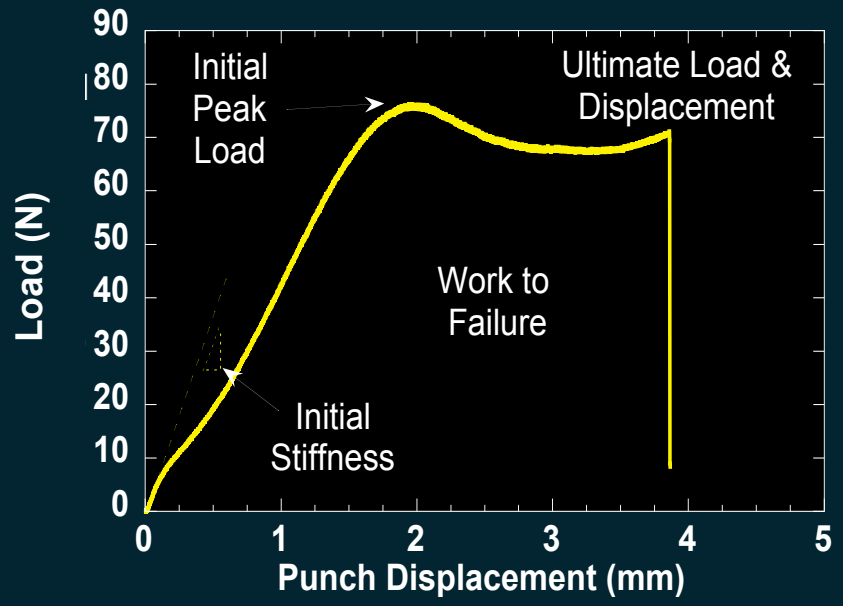
4 weeks

Tests Performed

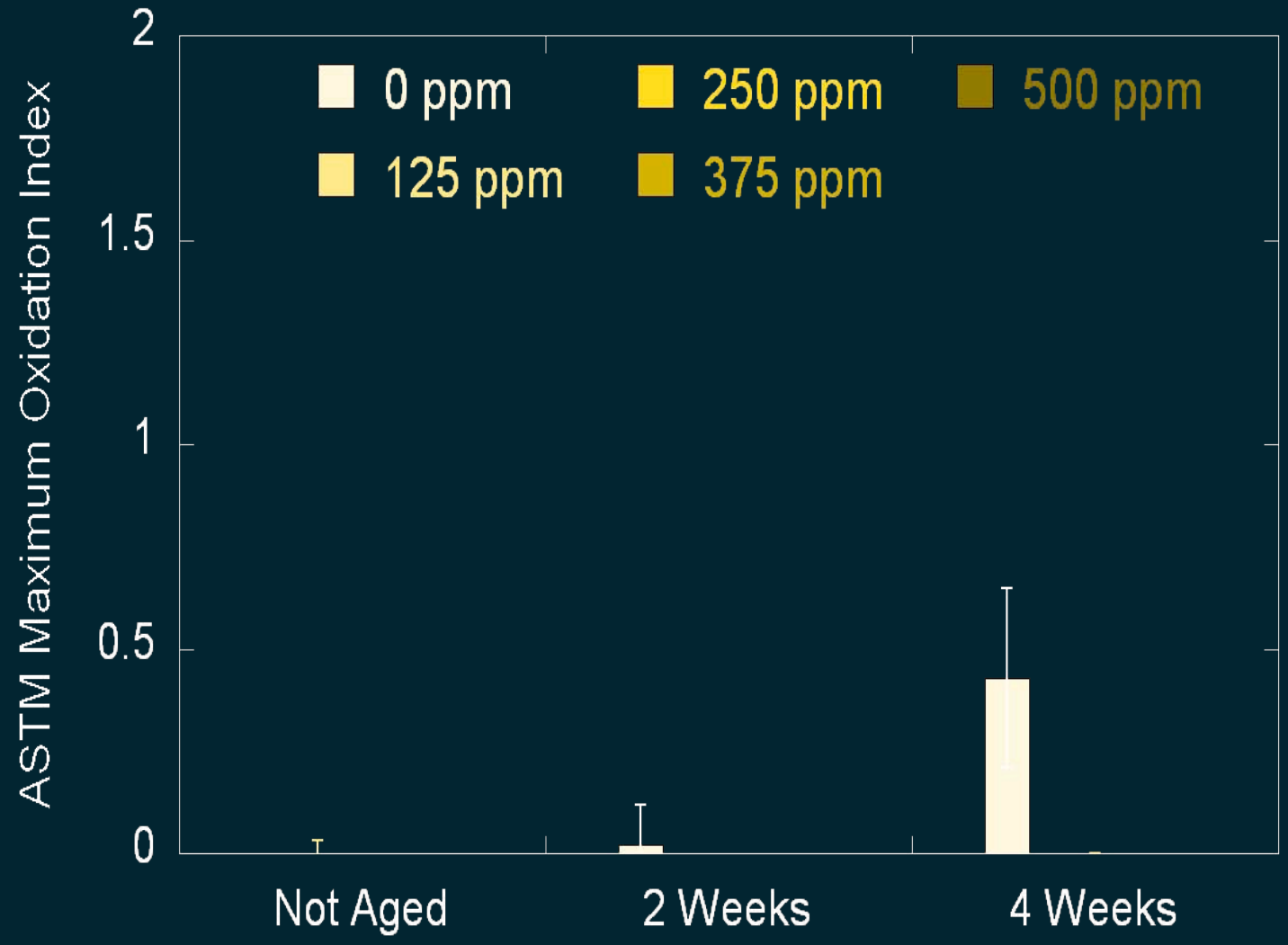
Chemical characterization → **FTIR** → **ASTM F2102 Oxidation Index**

Mechanical testing ASTM F2183 Small Punch Test

→

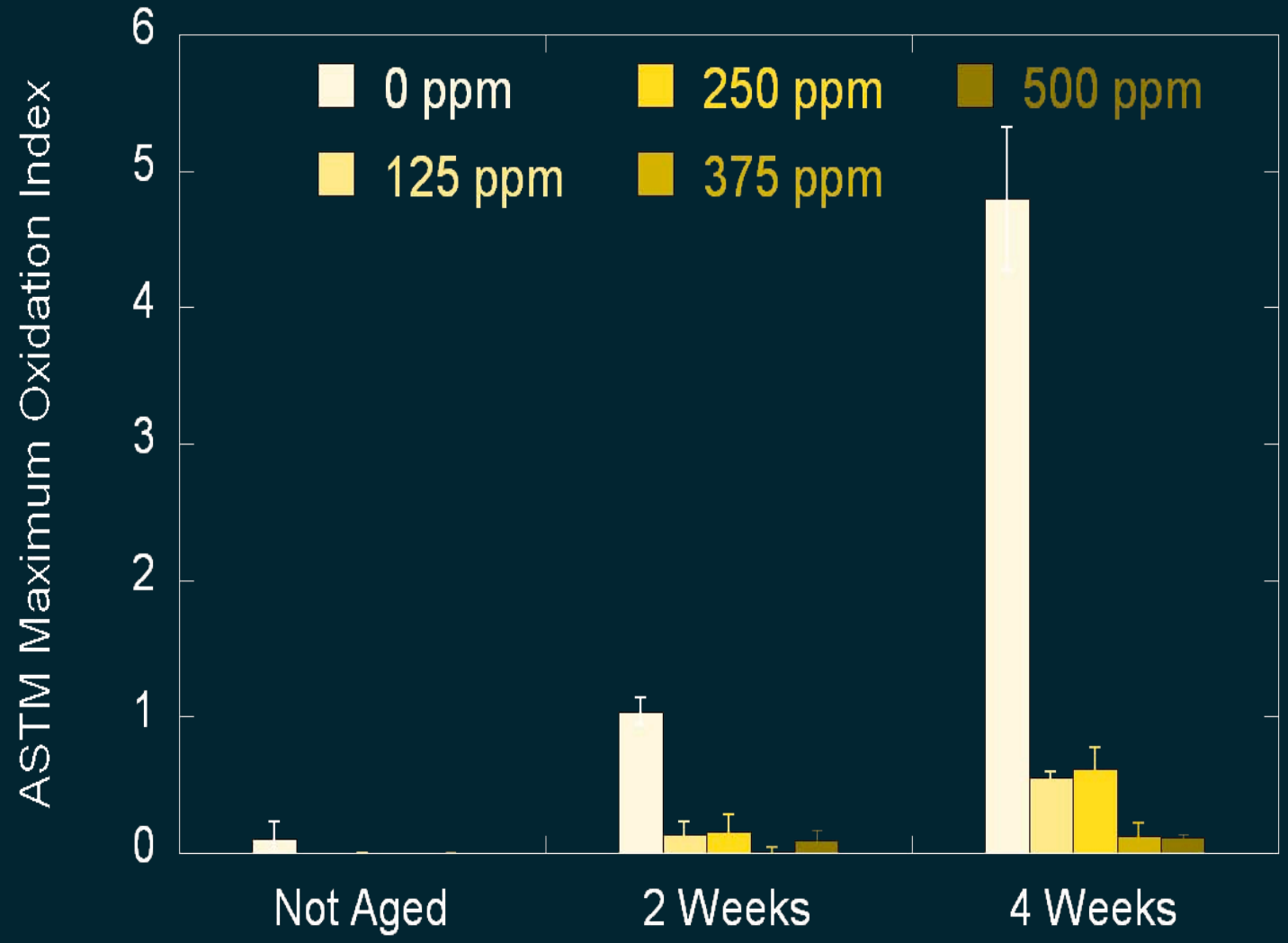


Oxidation Index, Unprocessed PE



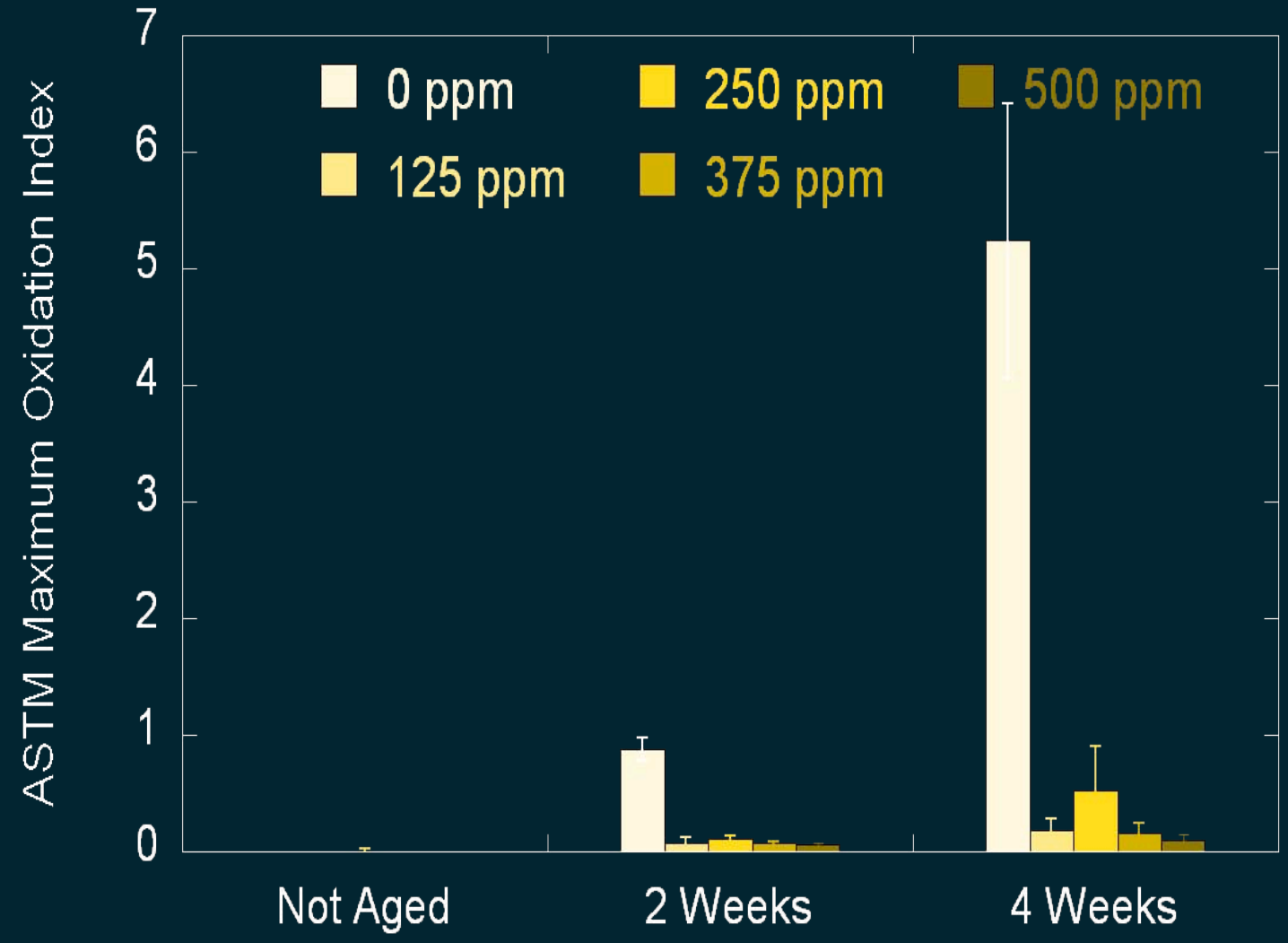
Data shown for GUR 1020; GUR 1050 data demonstrated similar trends

Oxidation Index, 30 kGy in N_2



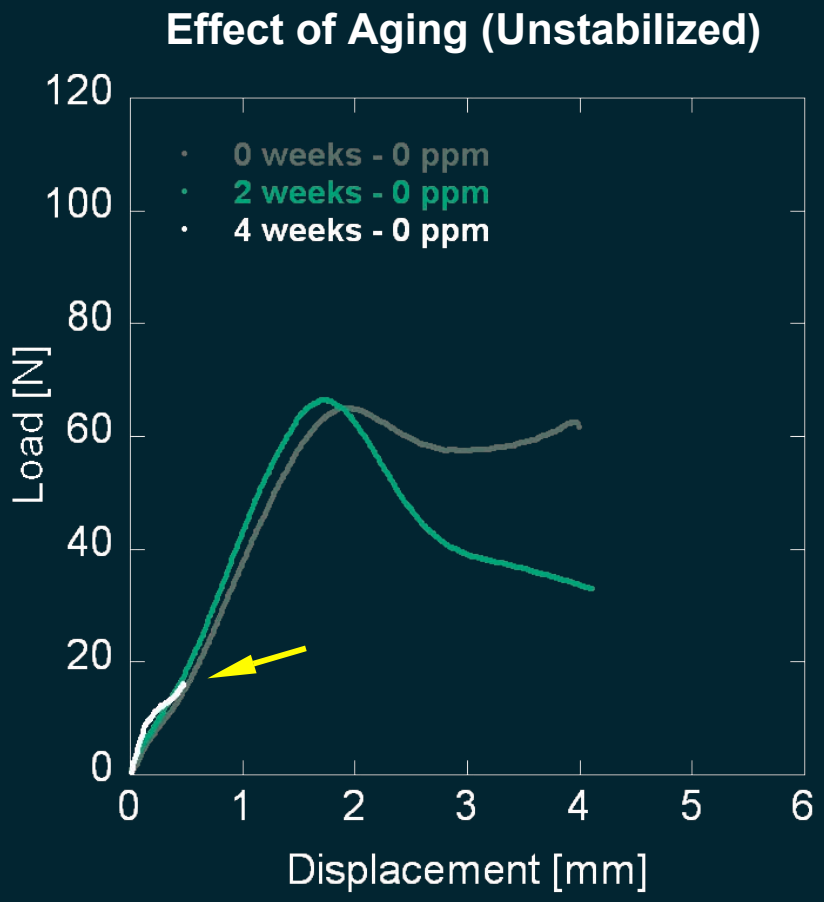
Data shown for GUR 1020; GUR 1050 data demonstrated similar trends

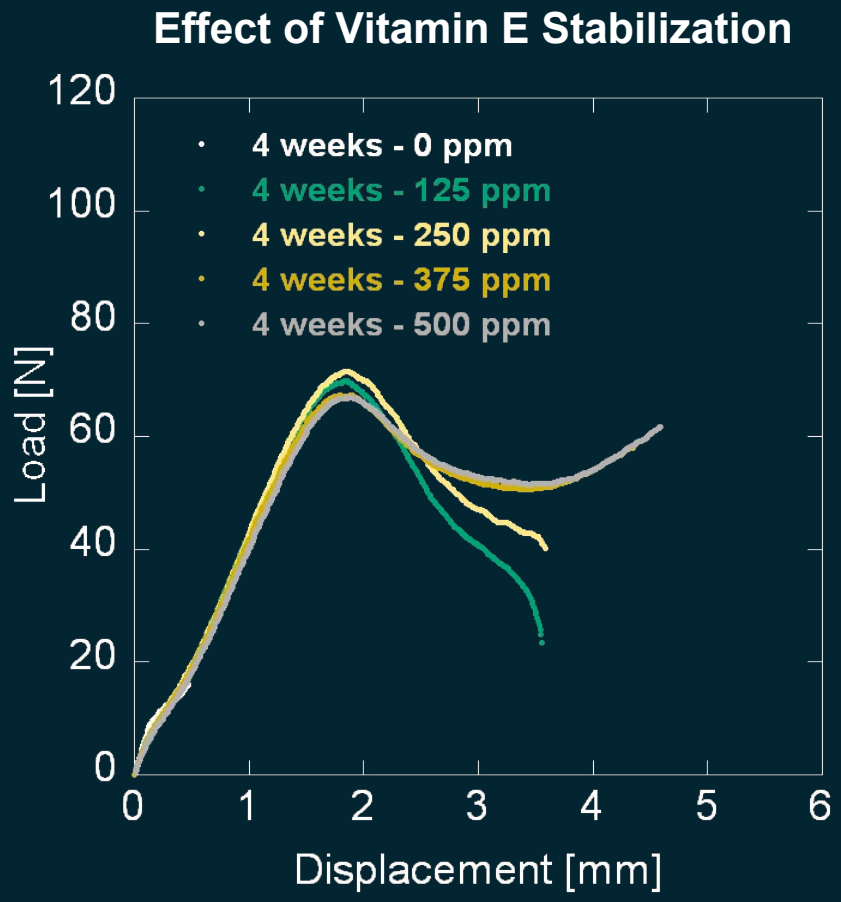
Oxidation Index, 75 kGy + Machined



Data shown for GUR 1020; GUR 1050 data demonstrated similar trends

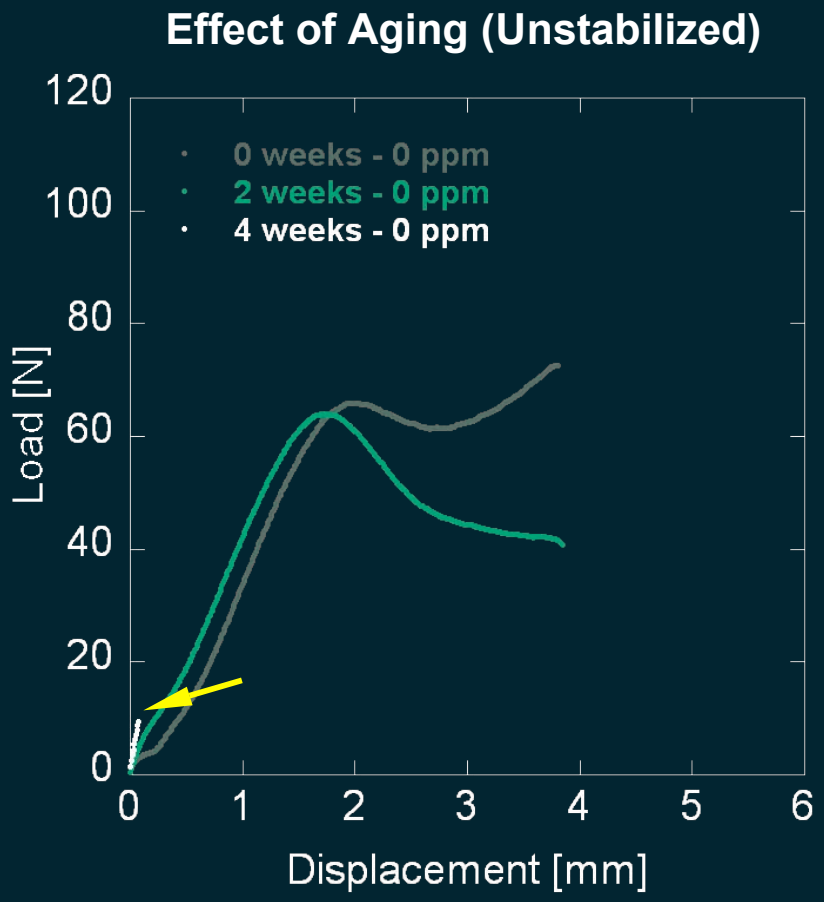
Mechanical Behavior, 30 kGy in N_2

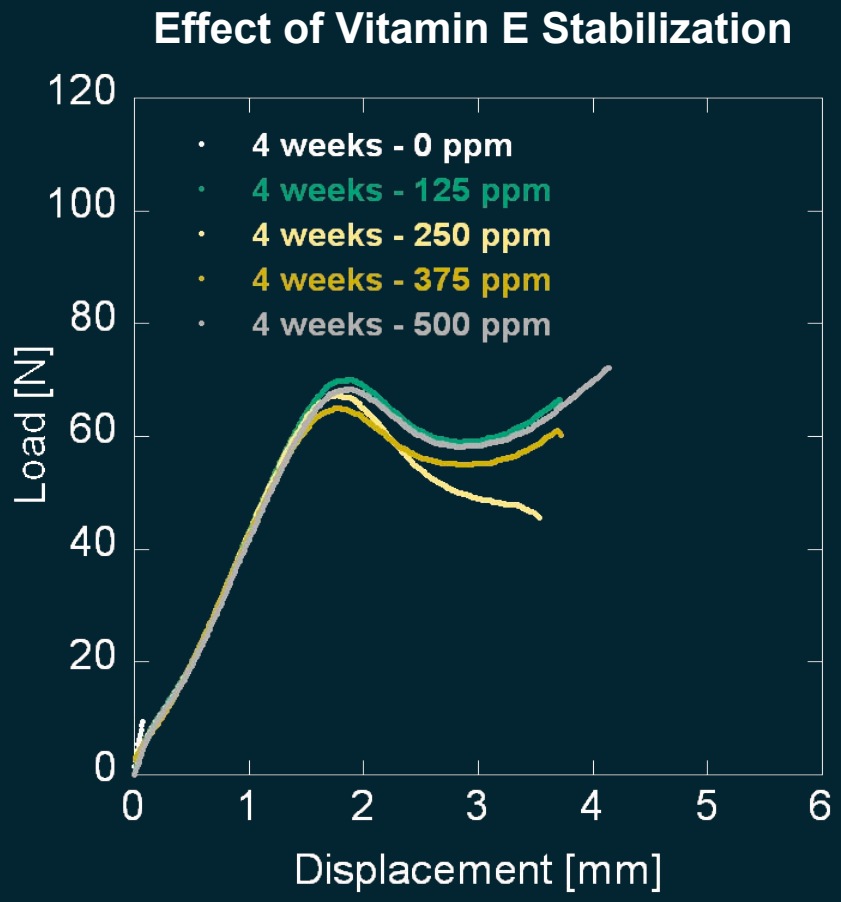




Data shown for GUR 1020; GUR 1050 data demonstrated similar trends

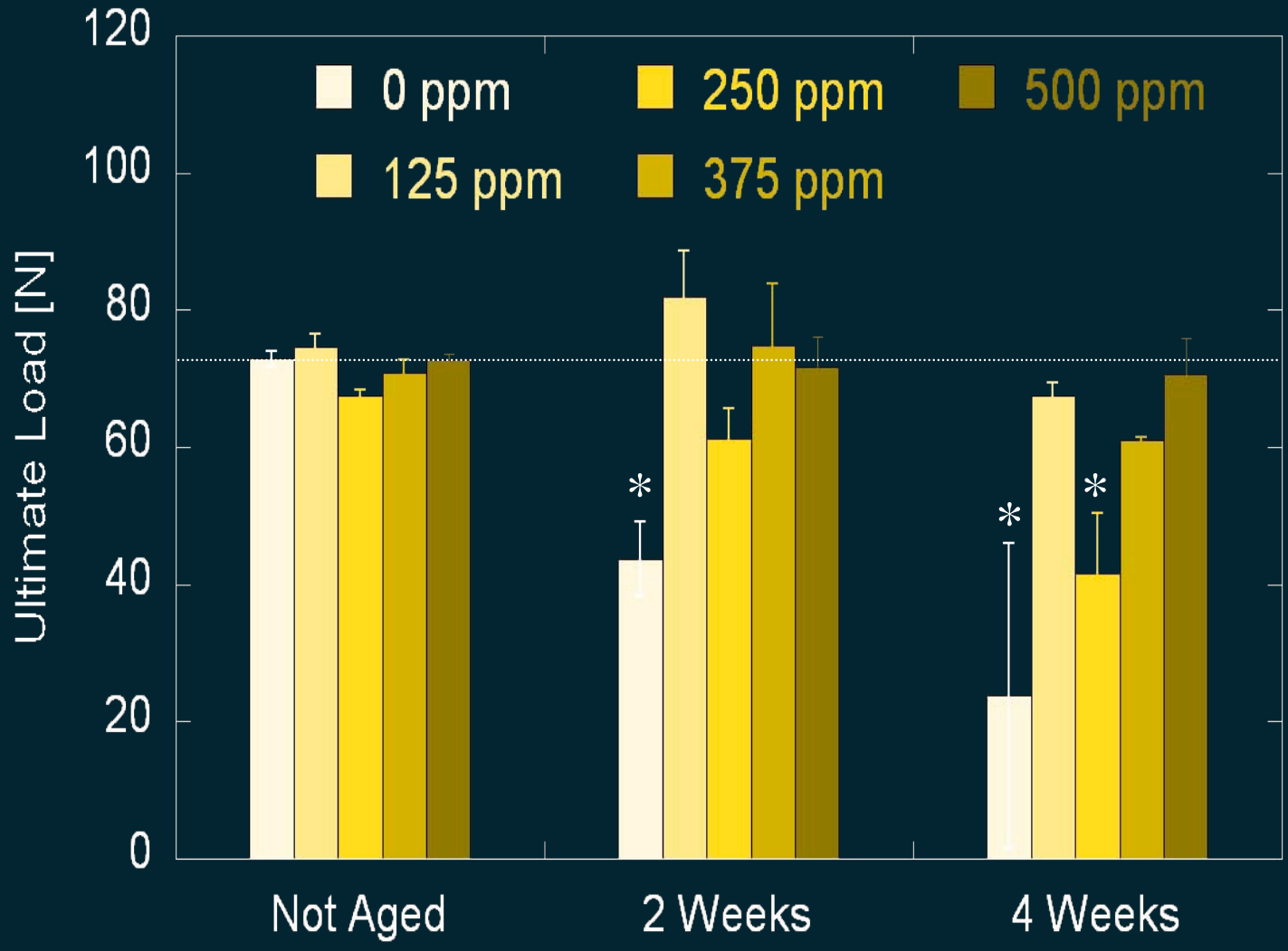
75 kGy + Machining





Data shown for GUR 1020; GUR 1050 data demonstrated similar trends

Ultimate Load, 75 kGy + Machining



* P < 0.05 when compared with non-aged

Discussion

- Only trace concentrations of Vitamin E needed to stabilize irradiated UHMWPE
- Minimum Vitamin E concentration
  - Insensitive to resin
  - Sensitive to radiation treatment
  - Sensitive to oxidative challenge

Conclusion

- High levels of Vitamin E not necessary to stabilize irradiated UHMWPE
- Trace levels of Vitamin E (≤ 500 ppm) may not substantially compromise crosslinking
  - Hardening behavior during small punch test
  - Oral et al. (2005)