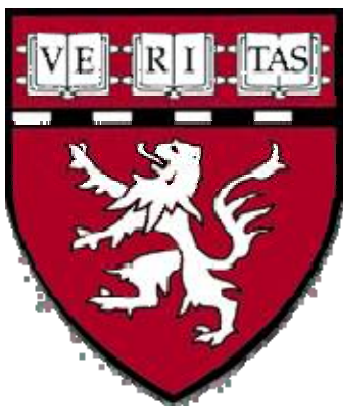


1st and 2nd Generation Highly Crosslinked UHMWPEs for Total Joints

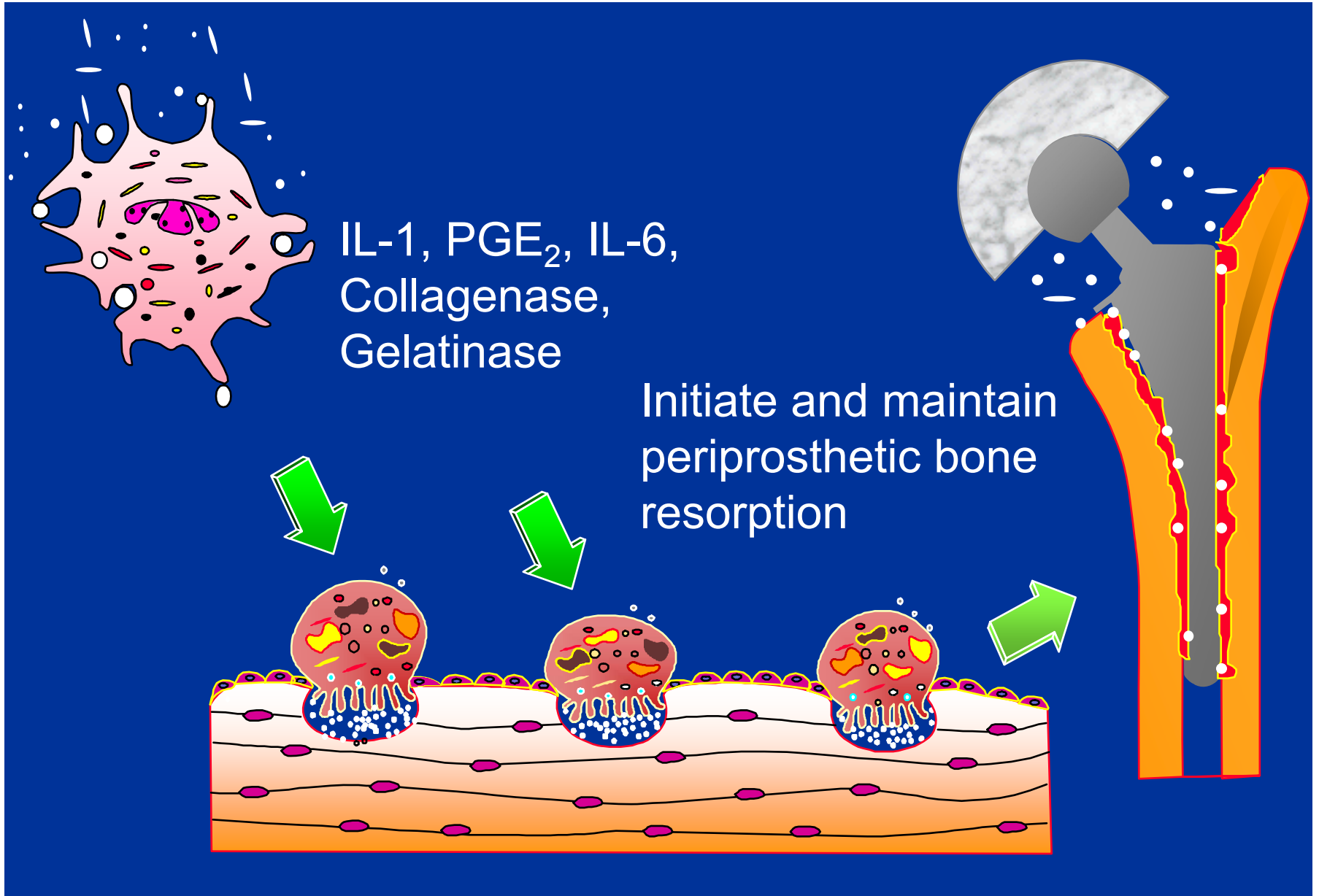
Orhun K. Muratoglu, Ph.D.

Associate Professor
Harvard Medical School

Alan Gerry Scholar
Co-Director, Harris Orthopedic
Biomechanics Biomaterials Laboratory
Massachusetts General Hospital

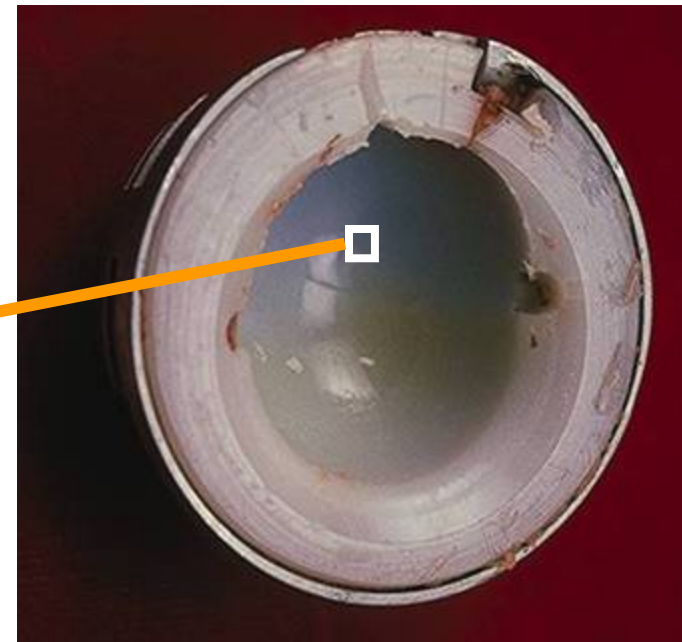
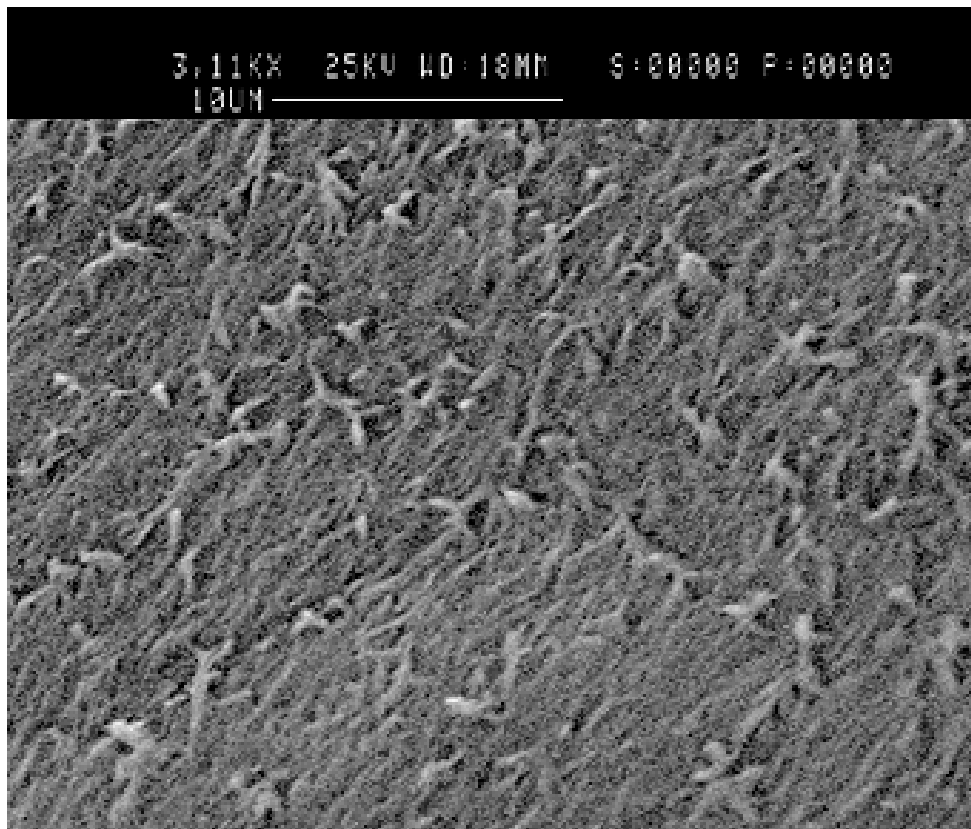


Particle Disease - Osteolysis



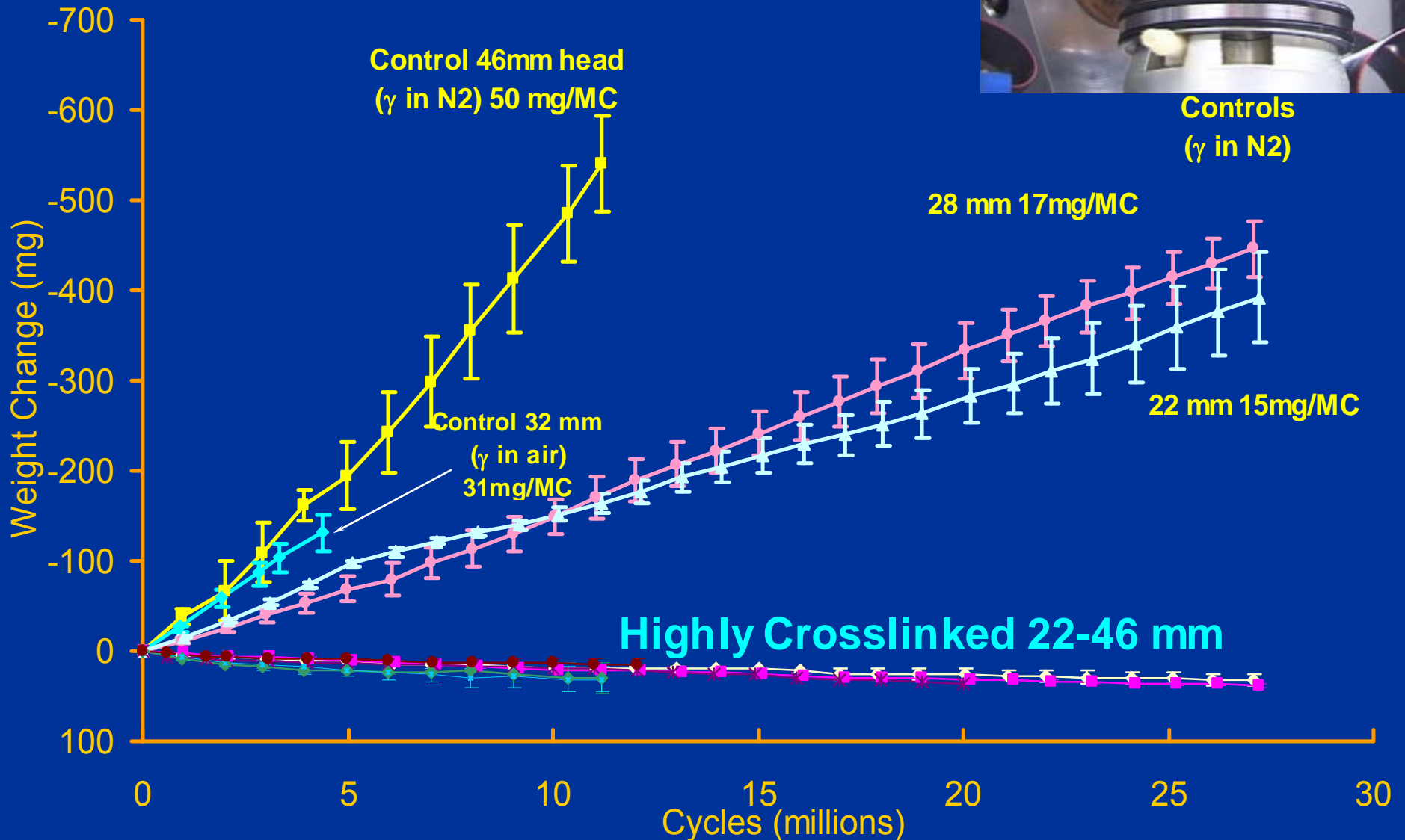
Wear Mechanisms in vivo - THR

**SEM analysis of 138 clinical
and autopsy retrieved
acetabular components**

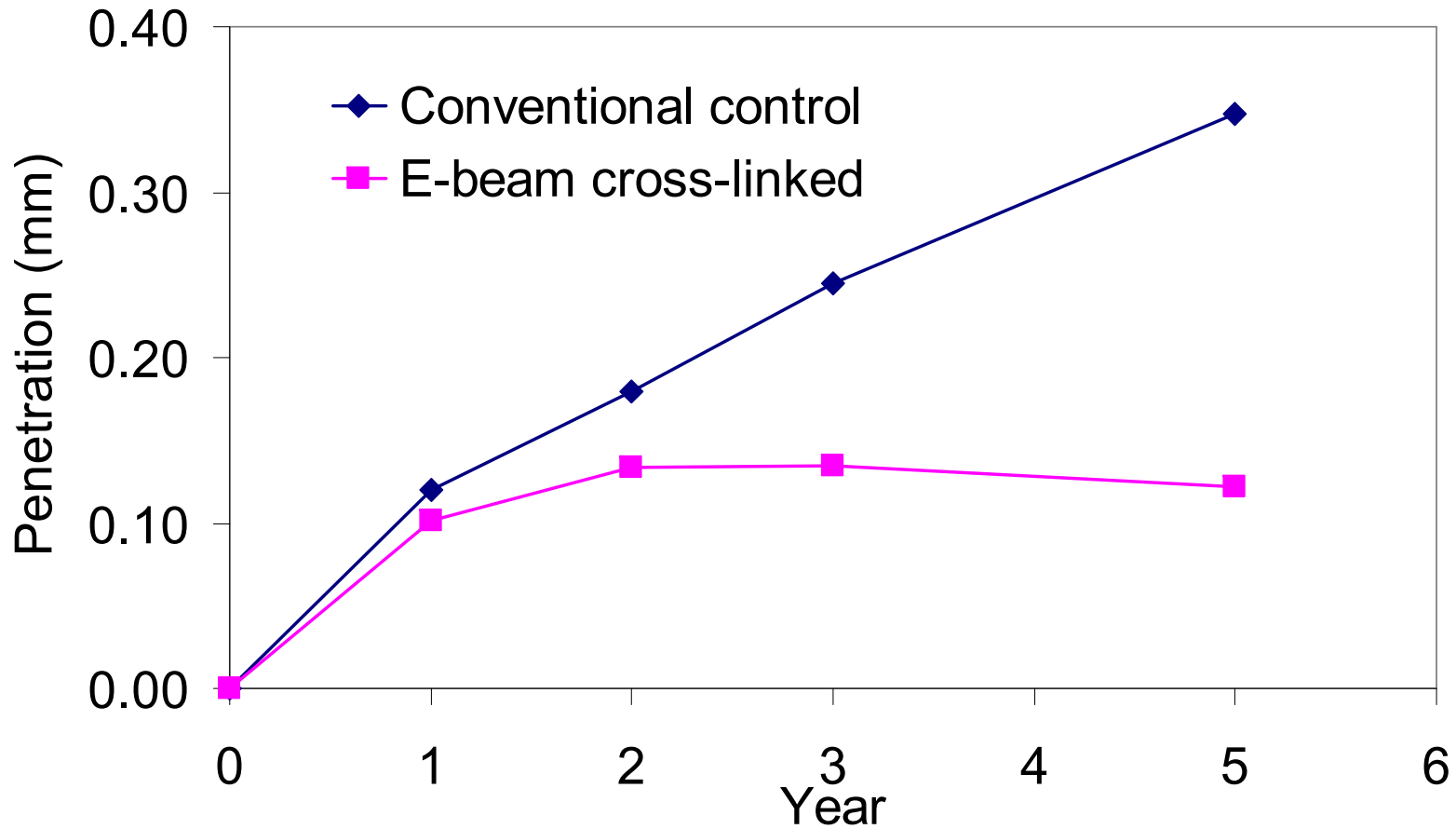


Jasty et al., JBJS 1994

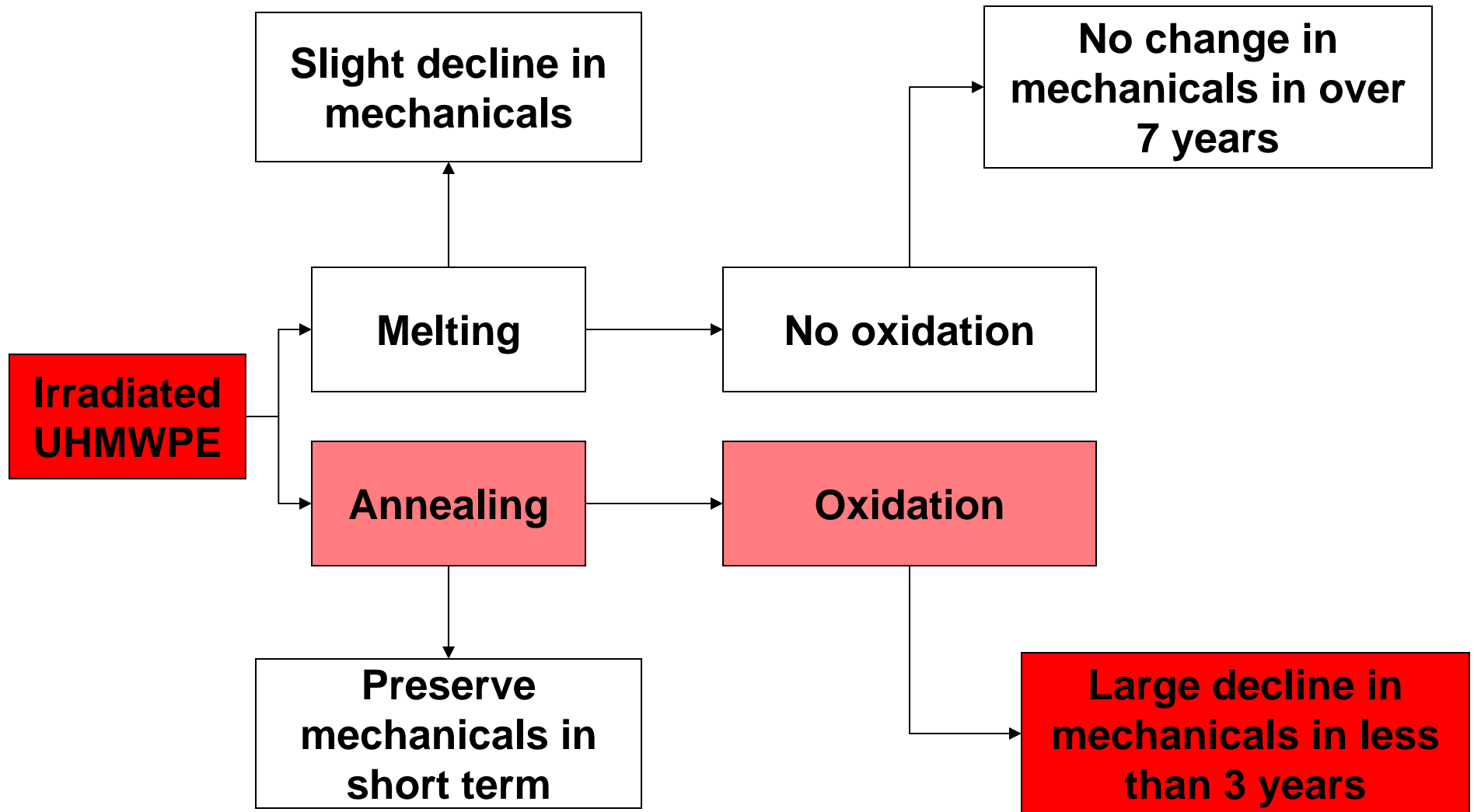
1st Generation Highly Crosslinked Polyethylene - Simulated Hip Gait



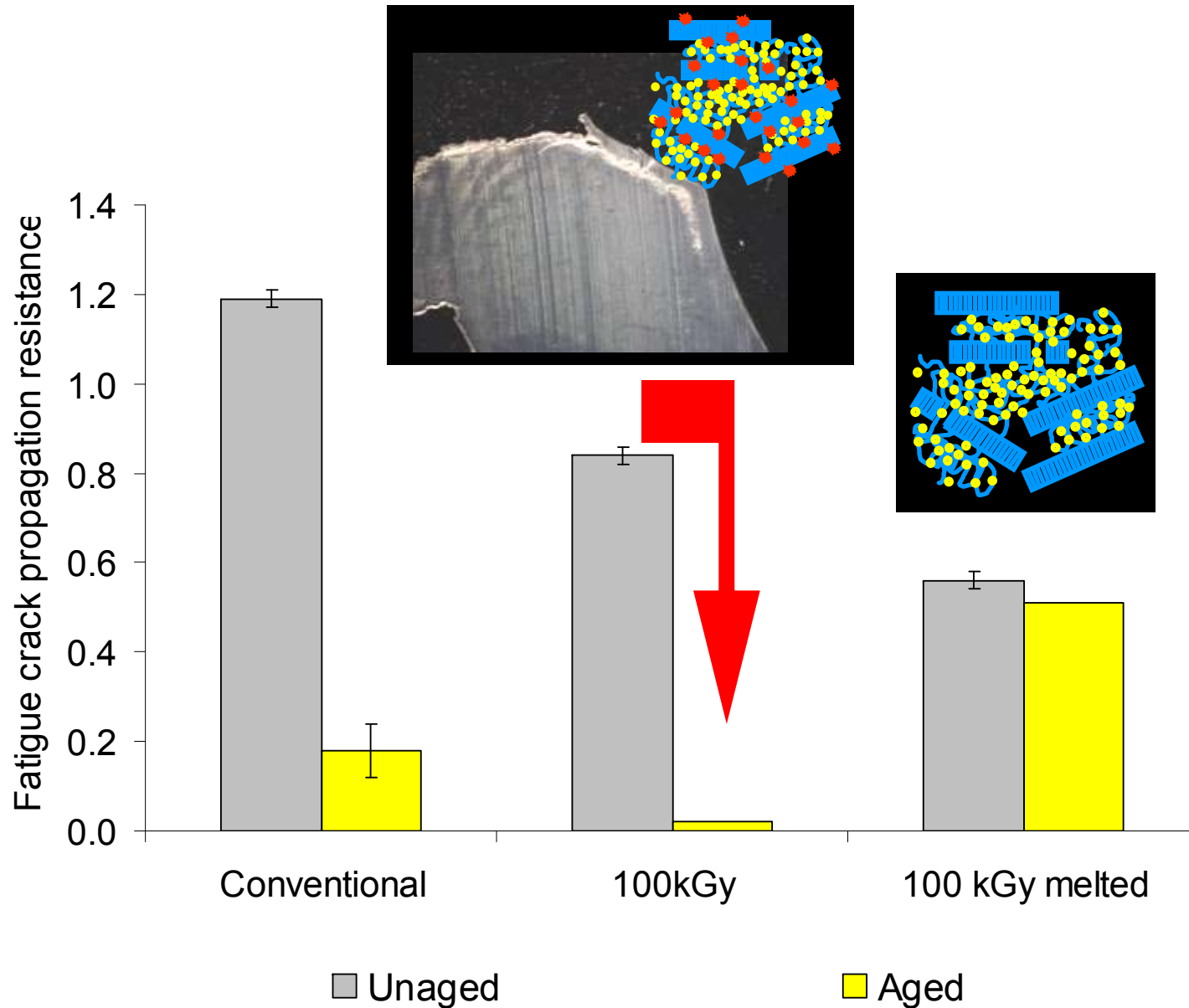
RSA 28mm Cemented all-poly; Durasul vs. Conventional – Malchau 2006 AAOS-Hip Society

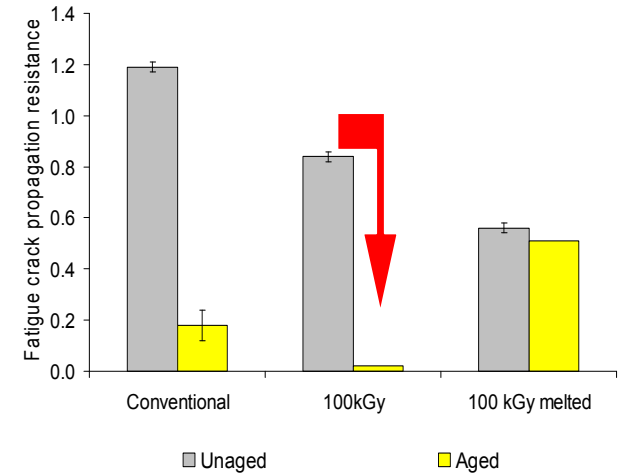
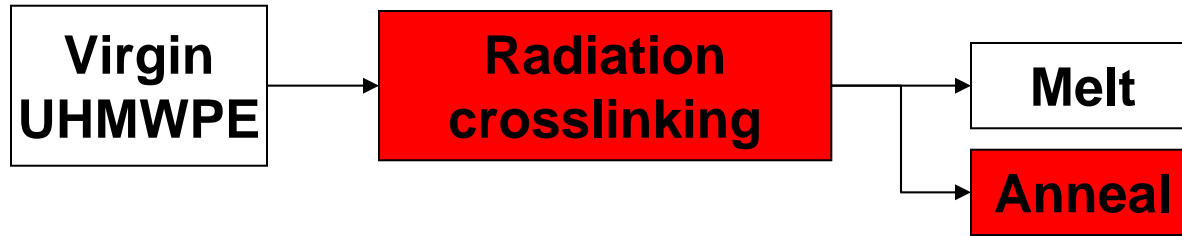


1st generation Xlinked UHMWPEs

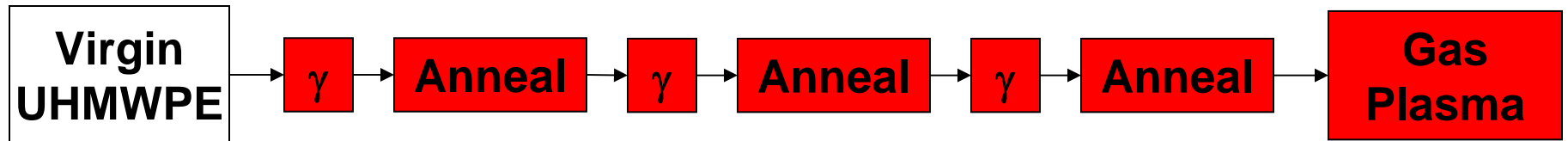


1st Generation Highly Crosslinked UHMWPEs

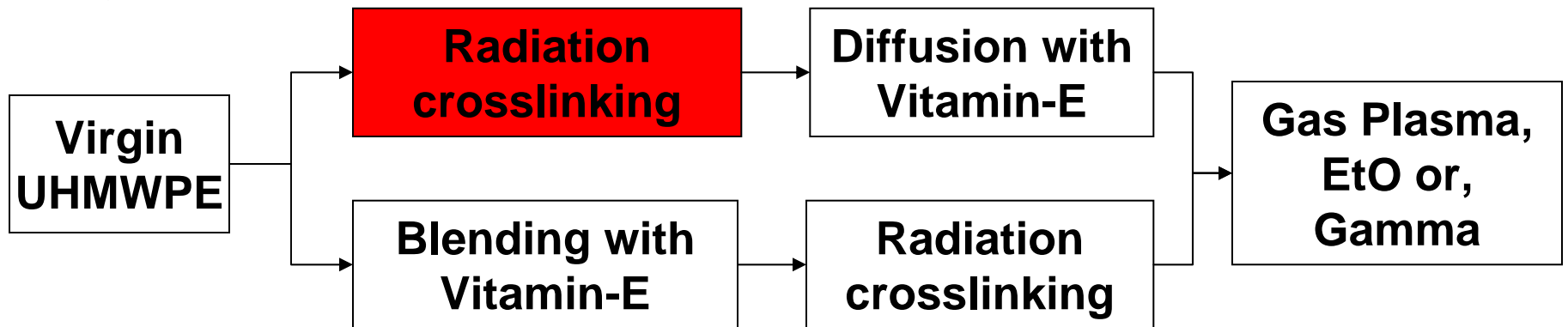




X3

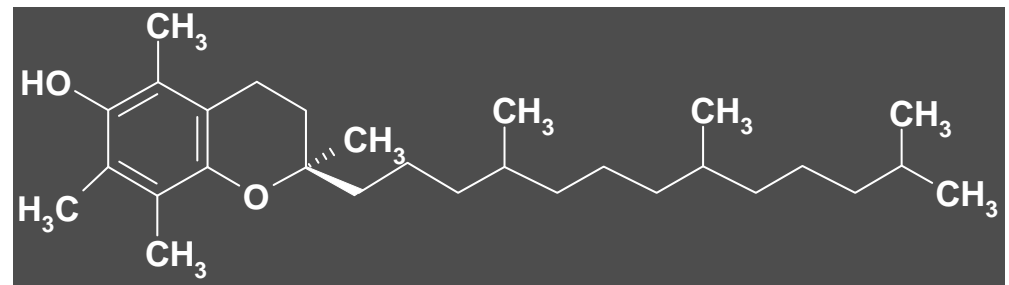
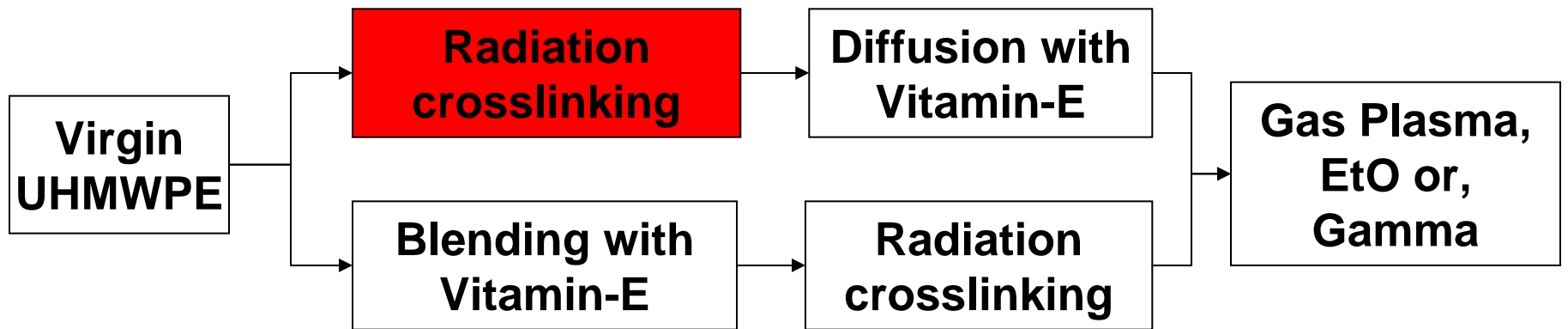


Vitamin-E

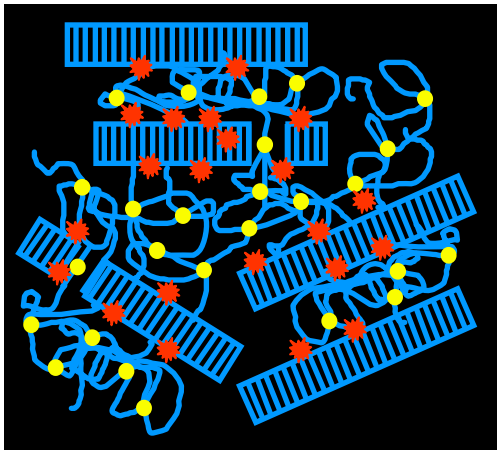
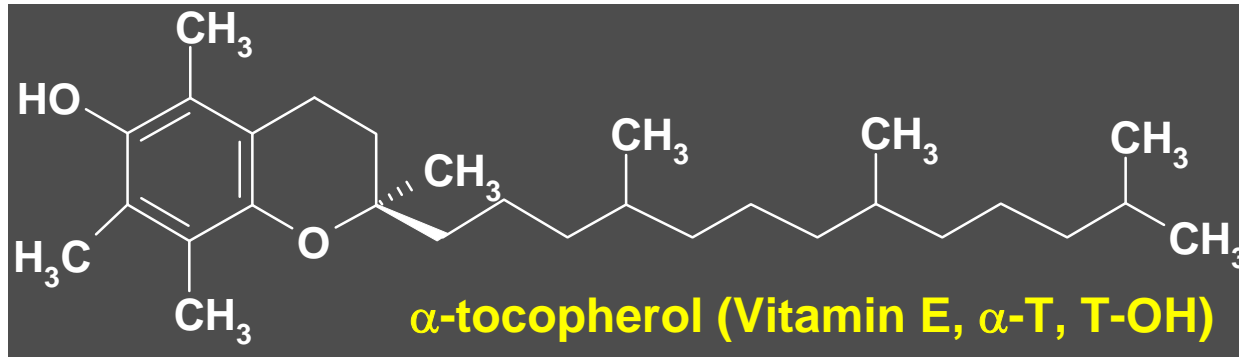




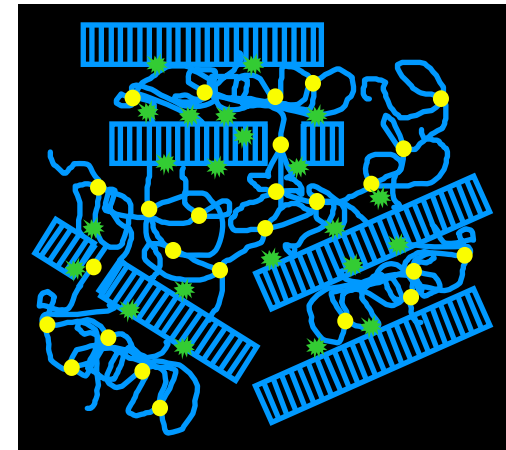
Vitamin-E



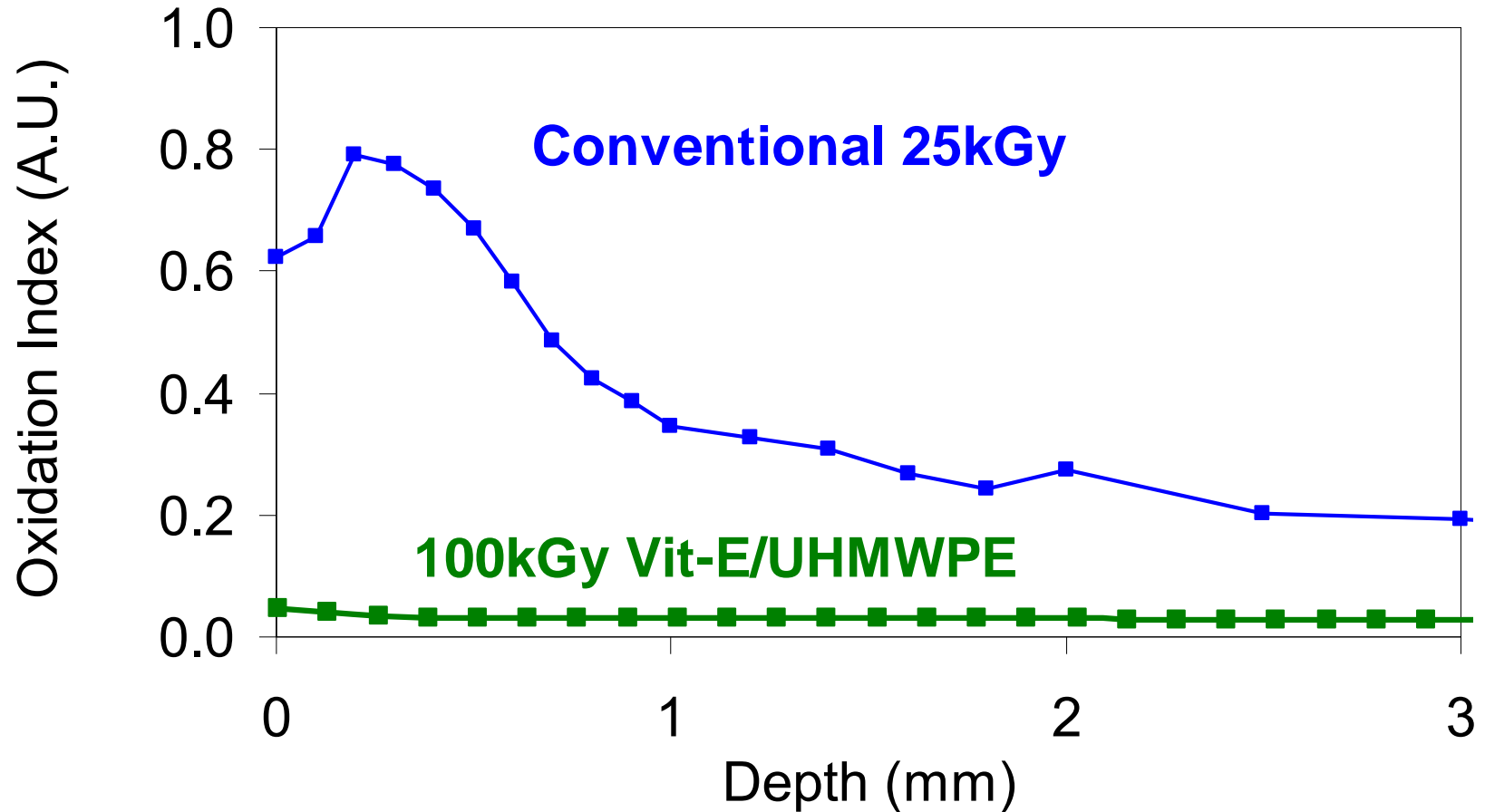
Vitamin-E Stabilization of Free Radicals



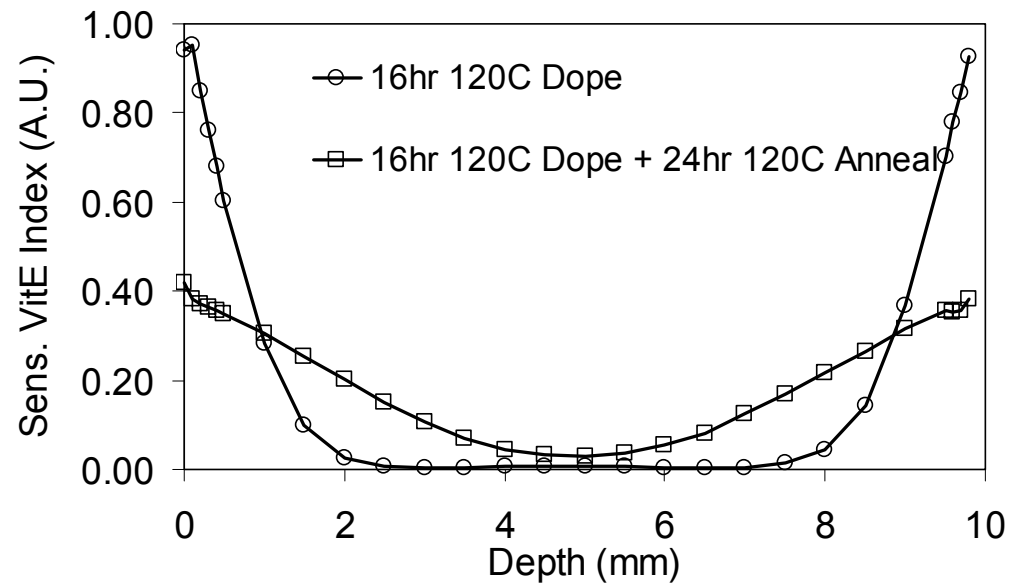
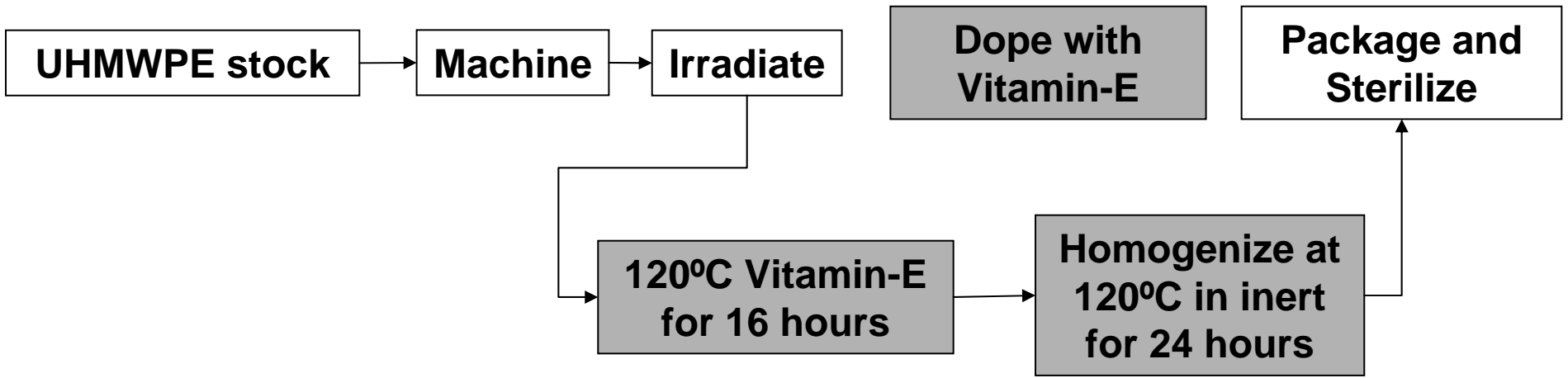
+ Vitamin-E \longrightarrow



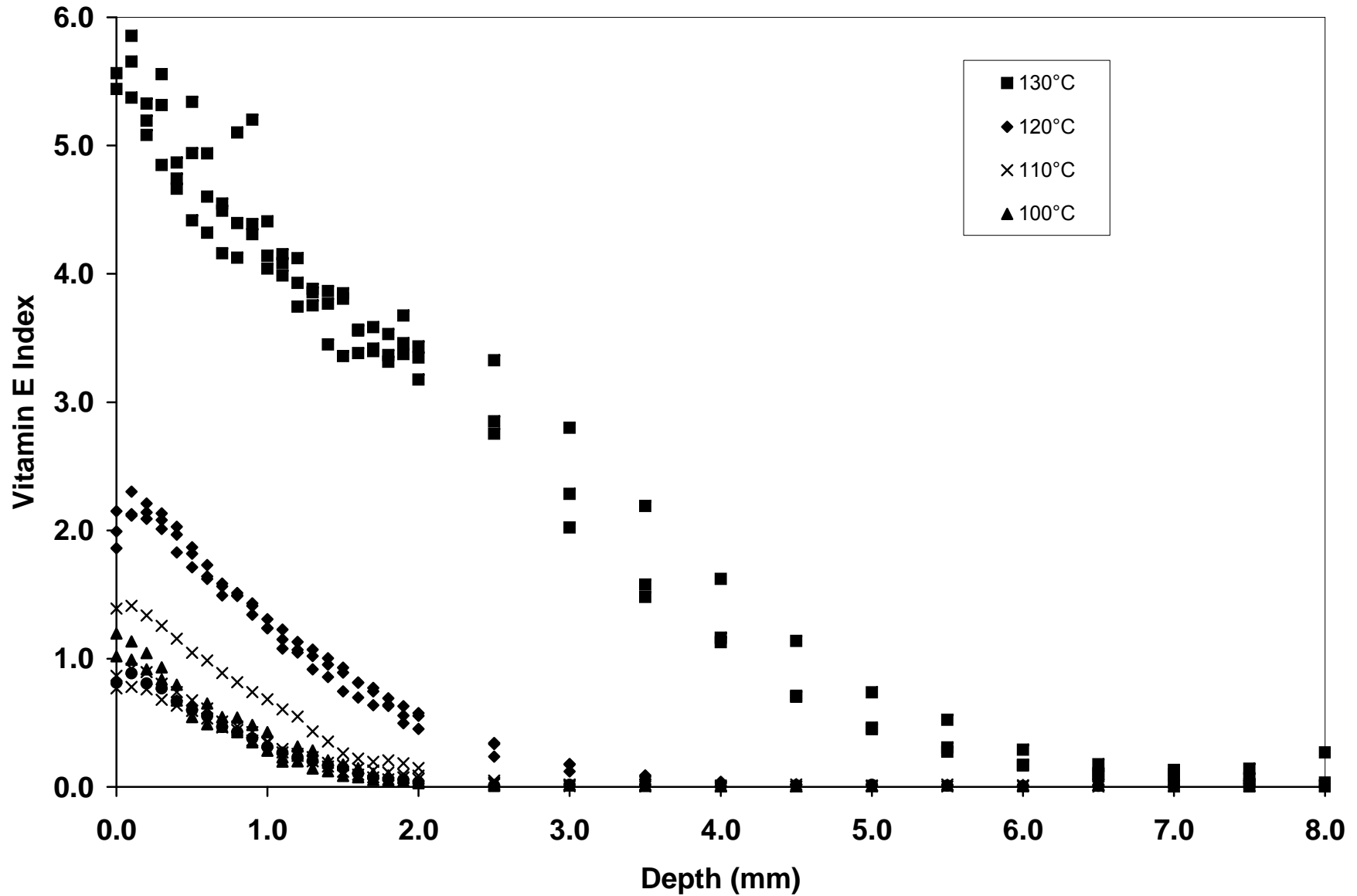
Accelerated Aging of Vit-E/UHMWPE



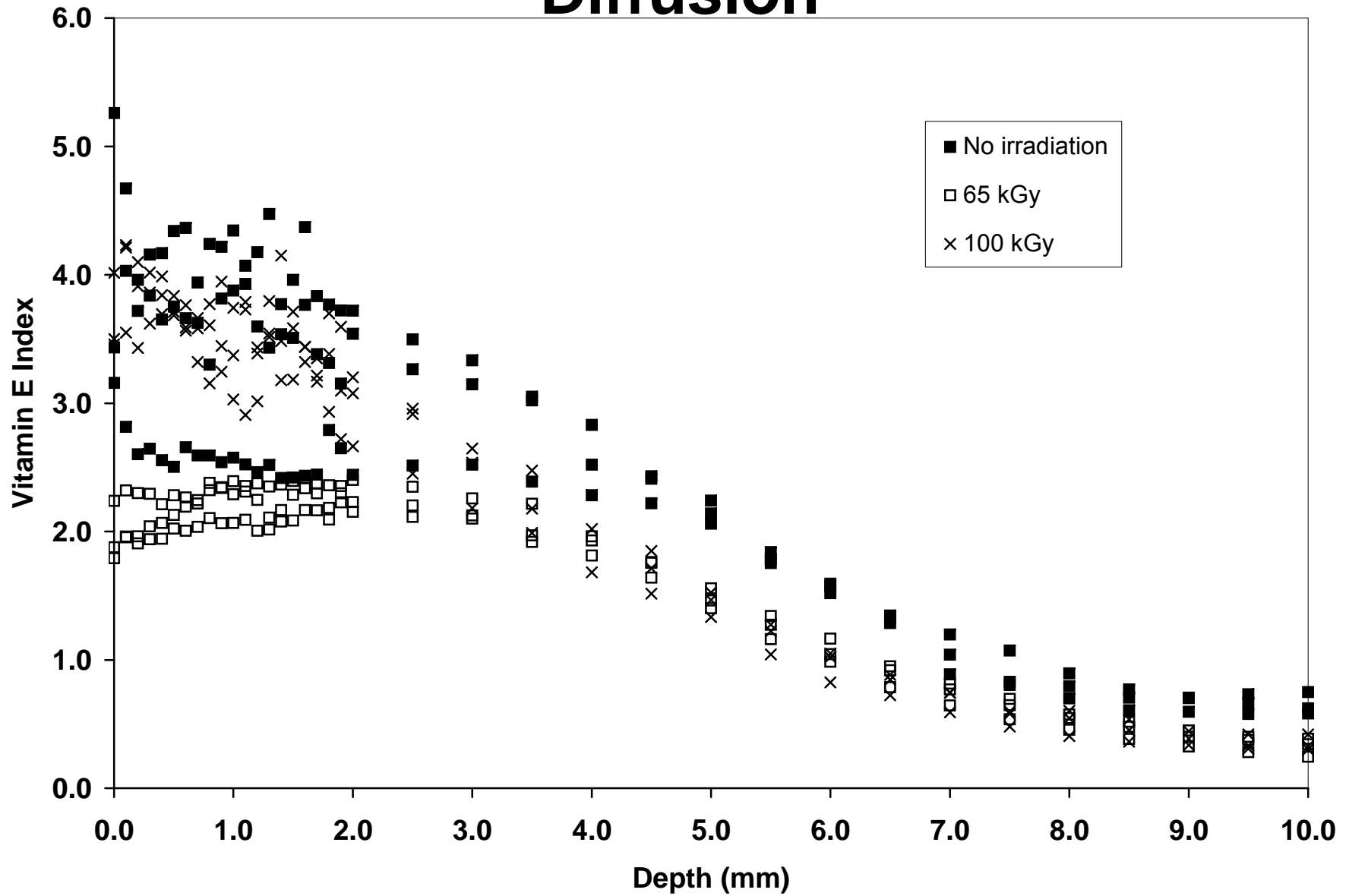
Manufacturing Scenario



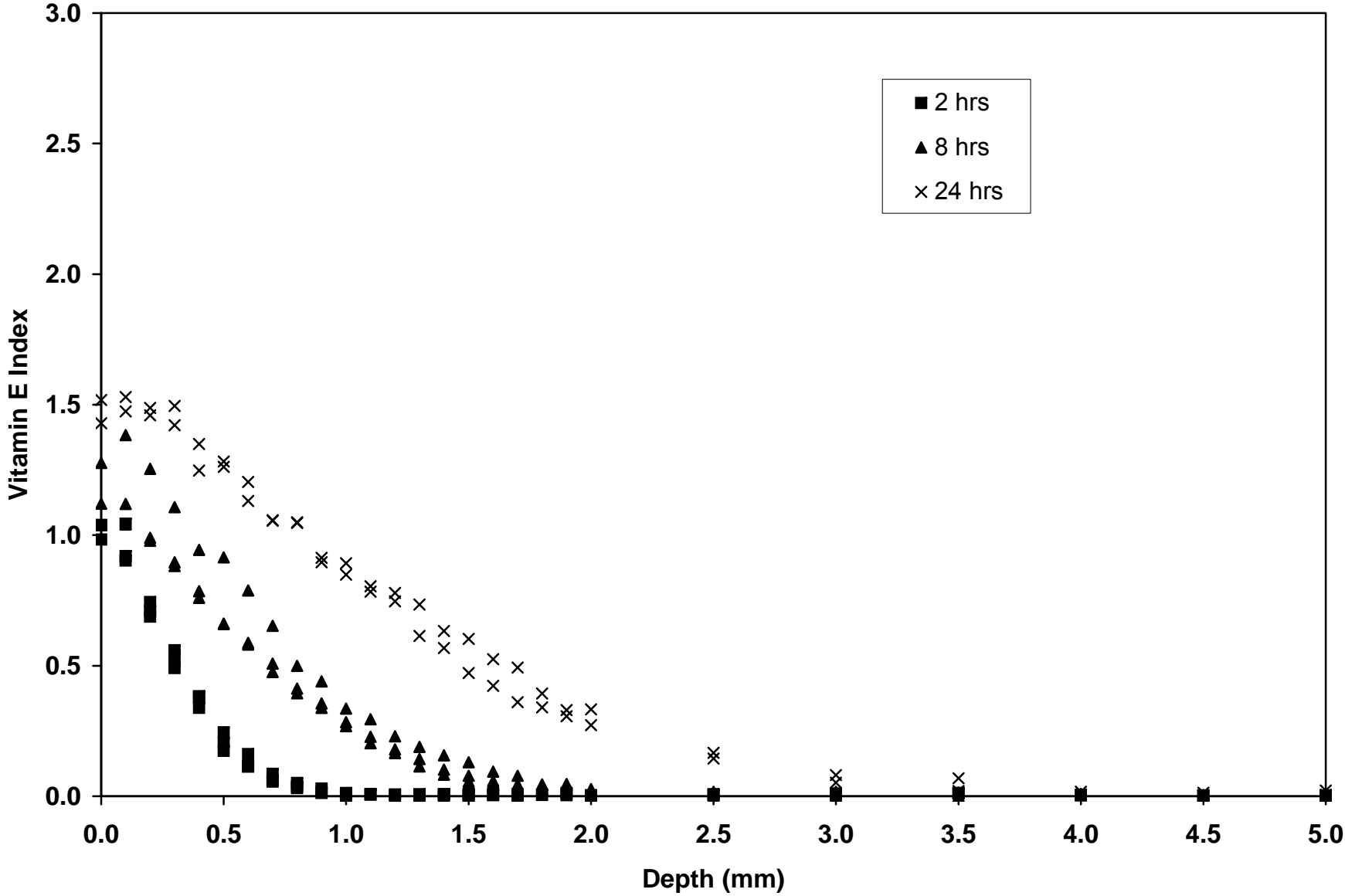
Effect of Temperature on Vitamin-E Diffusion (virgin UHMWPE)



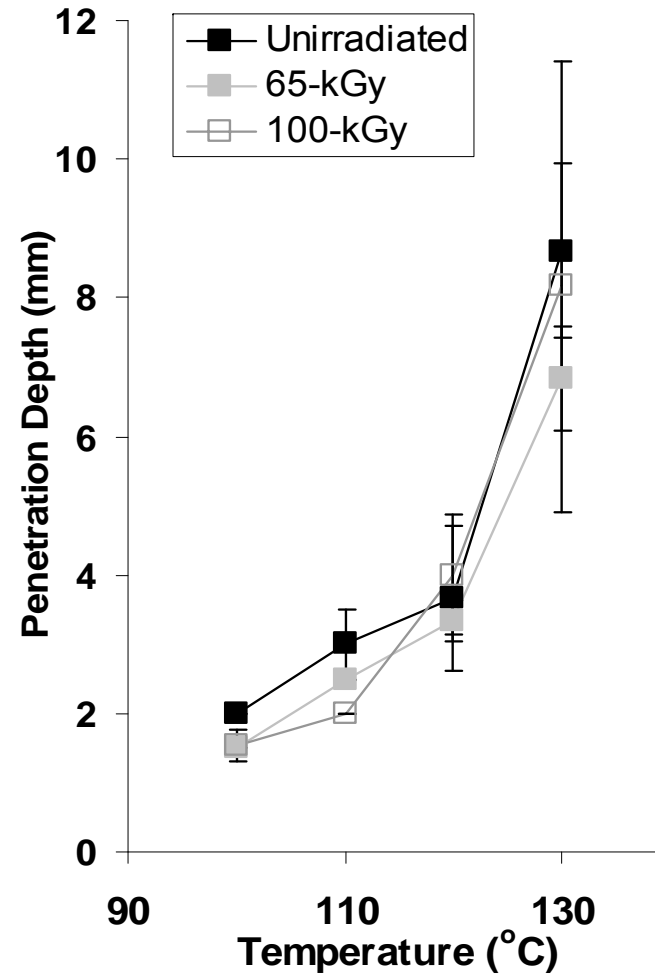
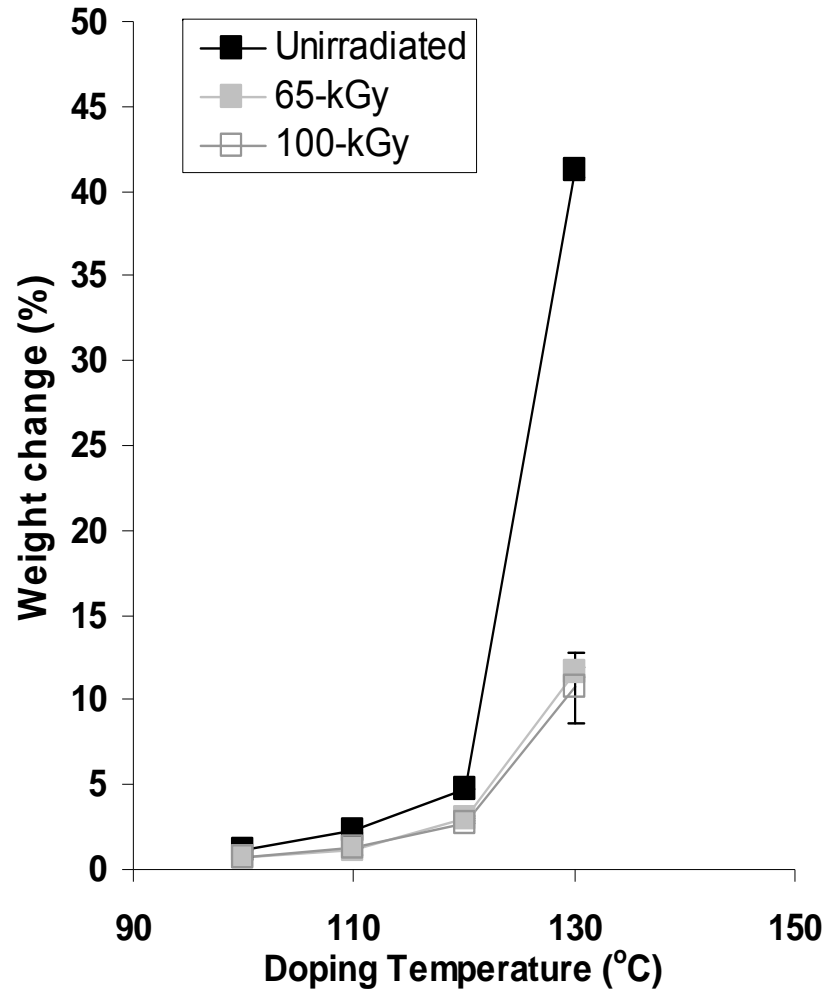
Effect of Radiation Dose on Vitamin-E Diffusion



Effect of time on Vitamin-E Diffusion – (100kGy UHMWPE at 120C)



24 h Doping – Weight Change vs. Temperature

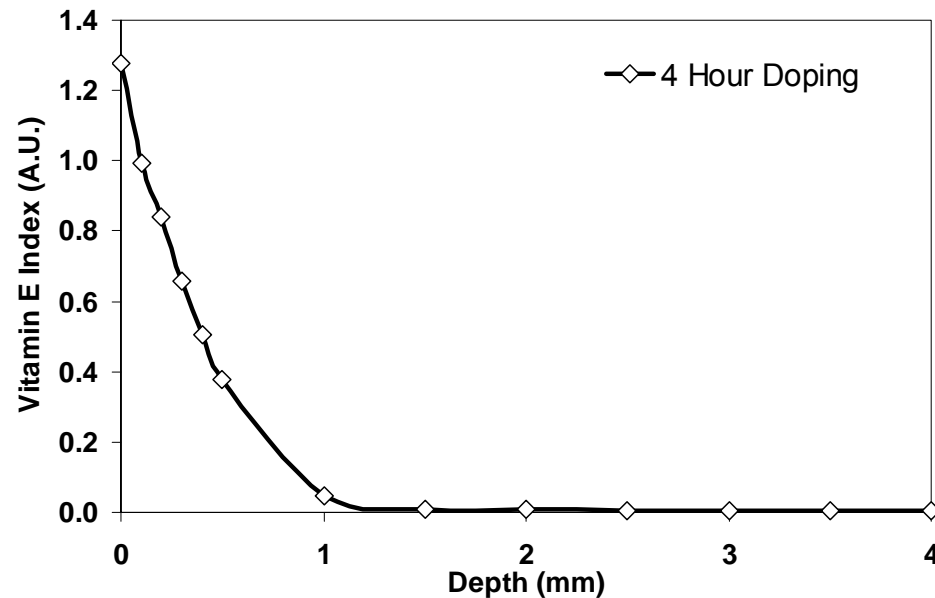


Diffusion Model

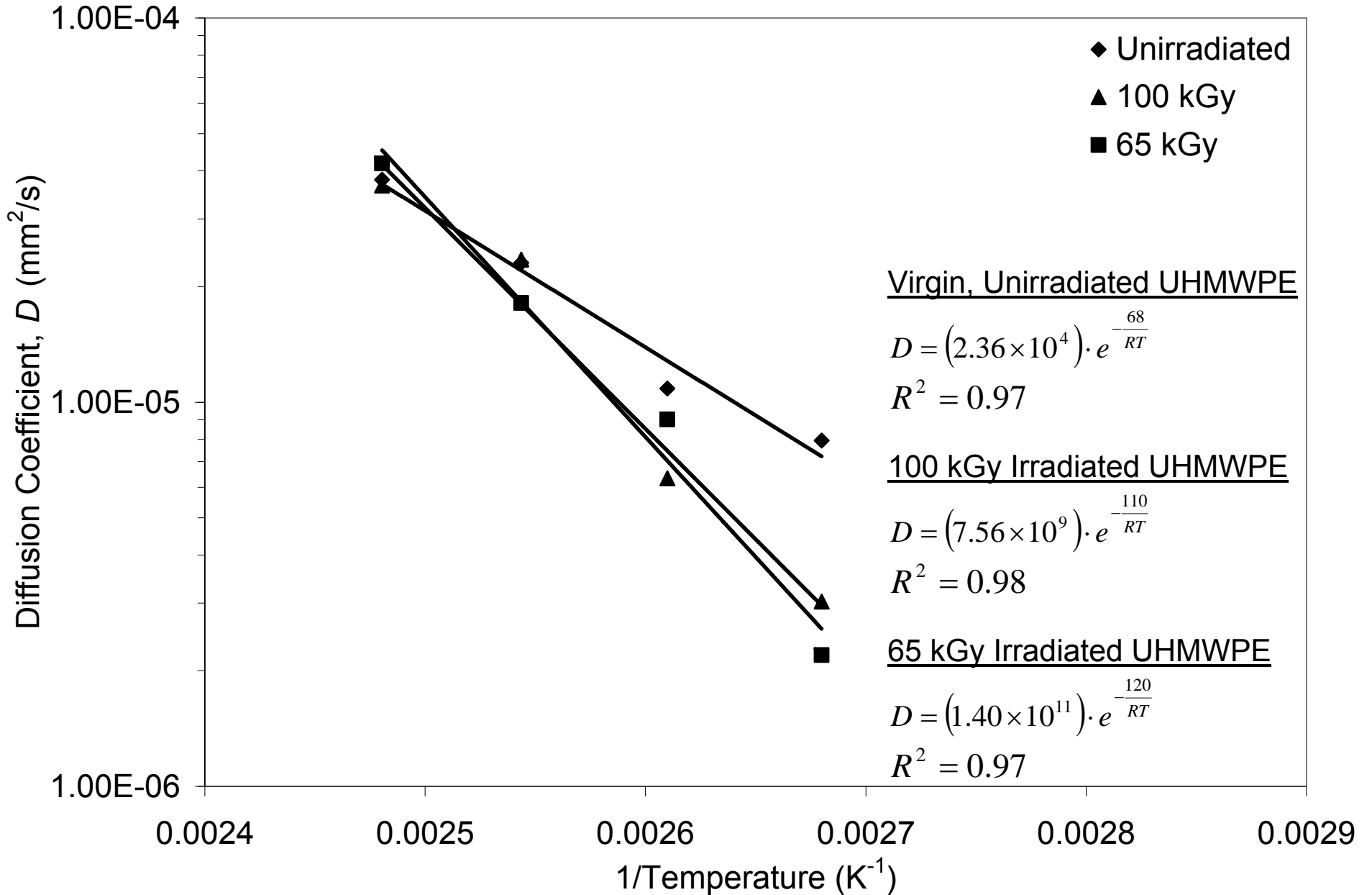
assume Fick's 2nd Law for diffusion

$$C(x, t) = C_0 \cdot \operatorname{erfc}\left(\frac{x}{2\sqrt{Dt}}\right)$$

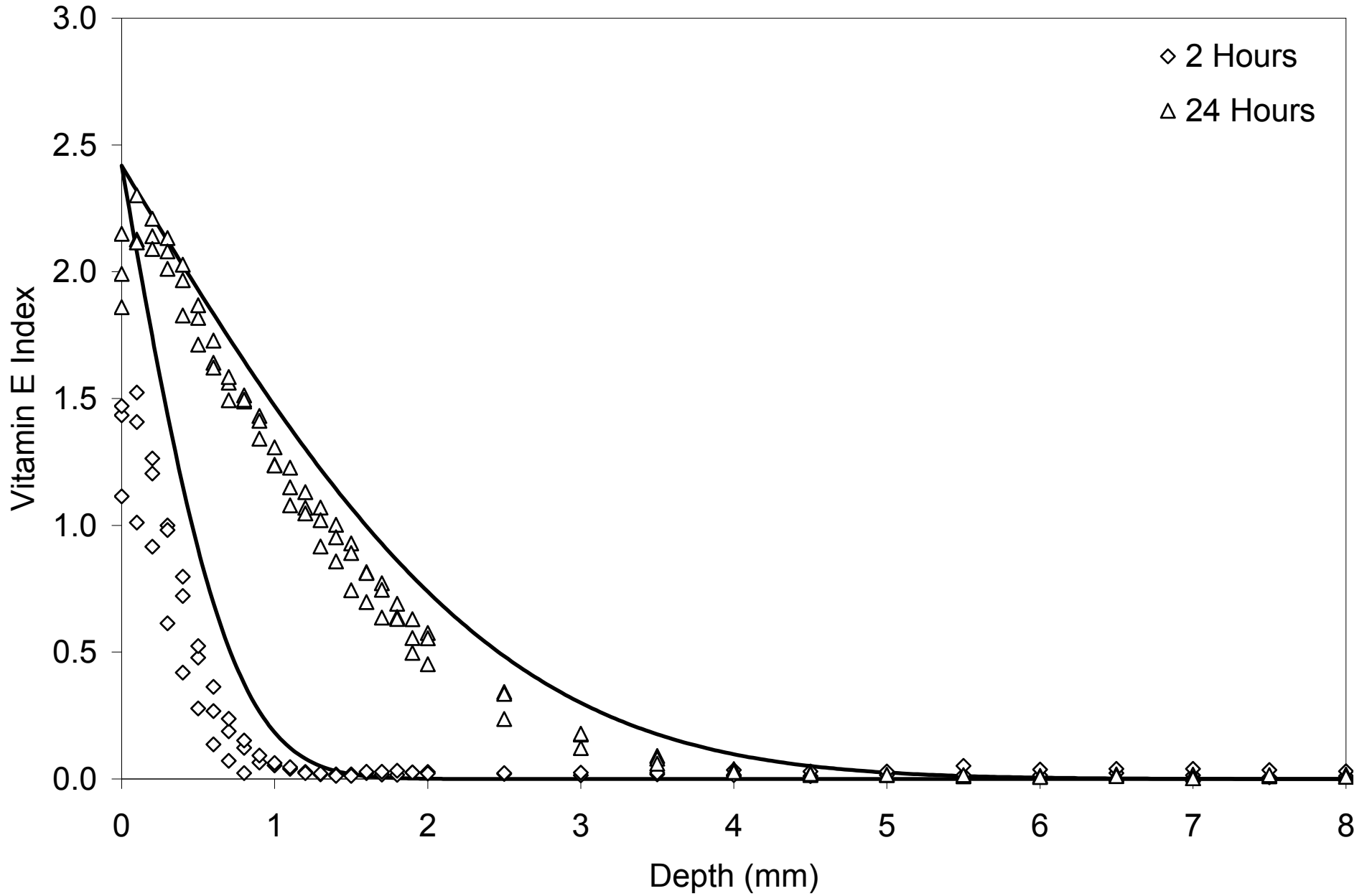
$$D = D_0 \cdot e^{-\frac{Q}{RT}}$$



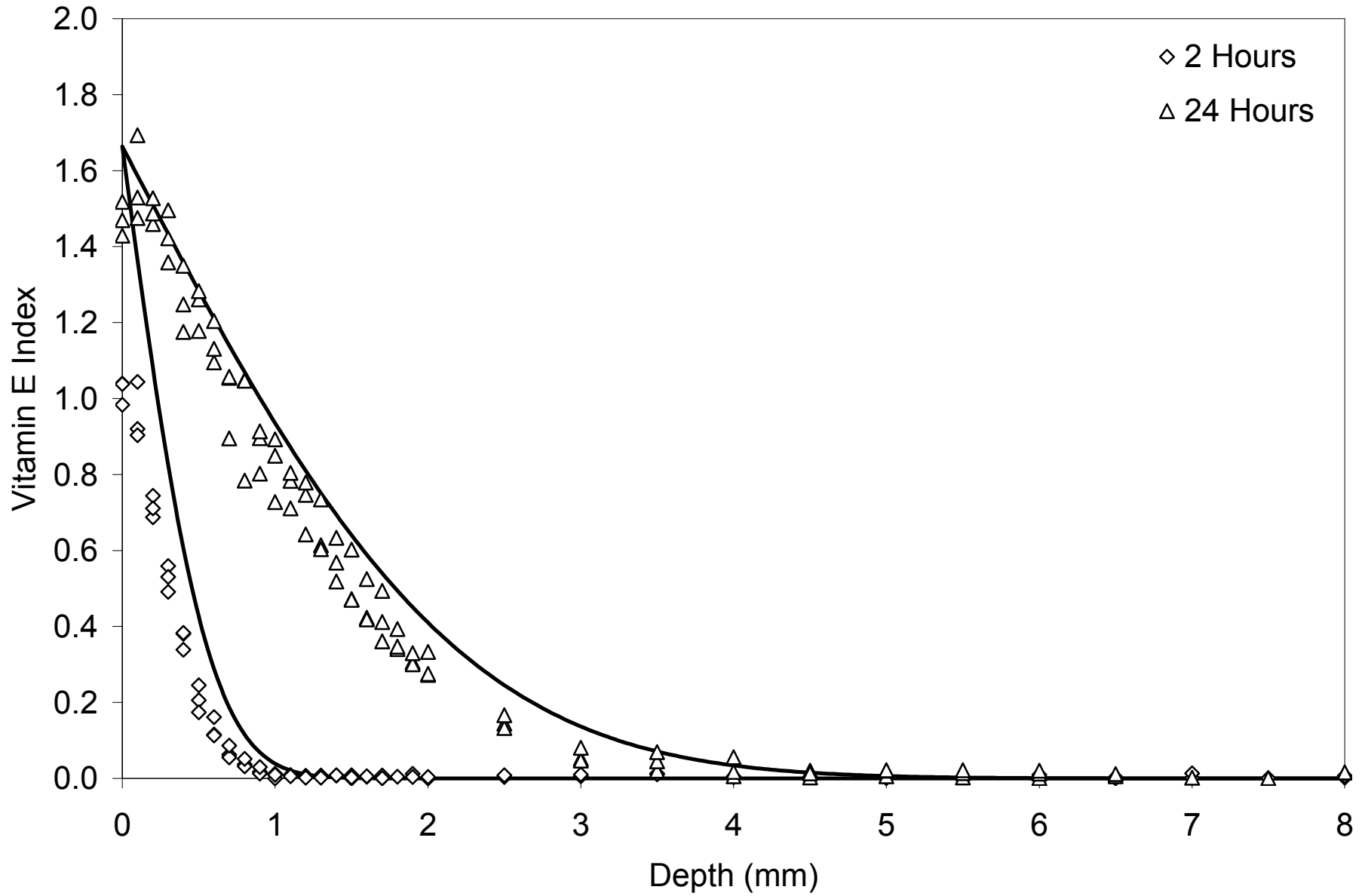
D vs. 1/T



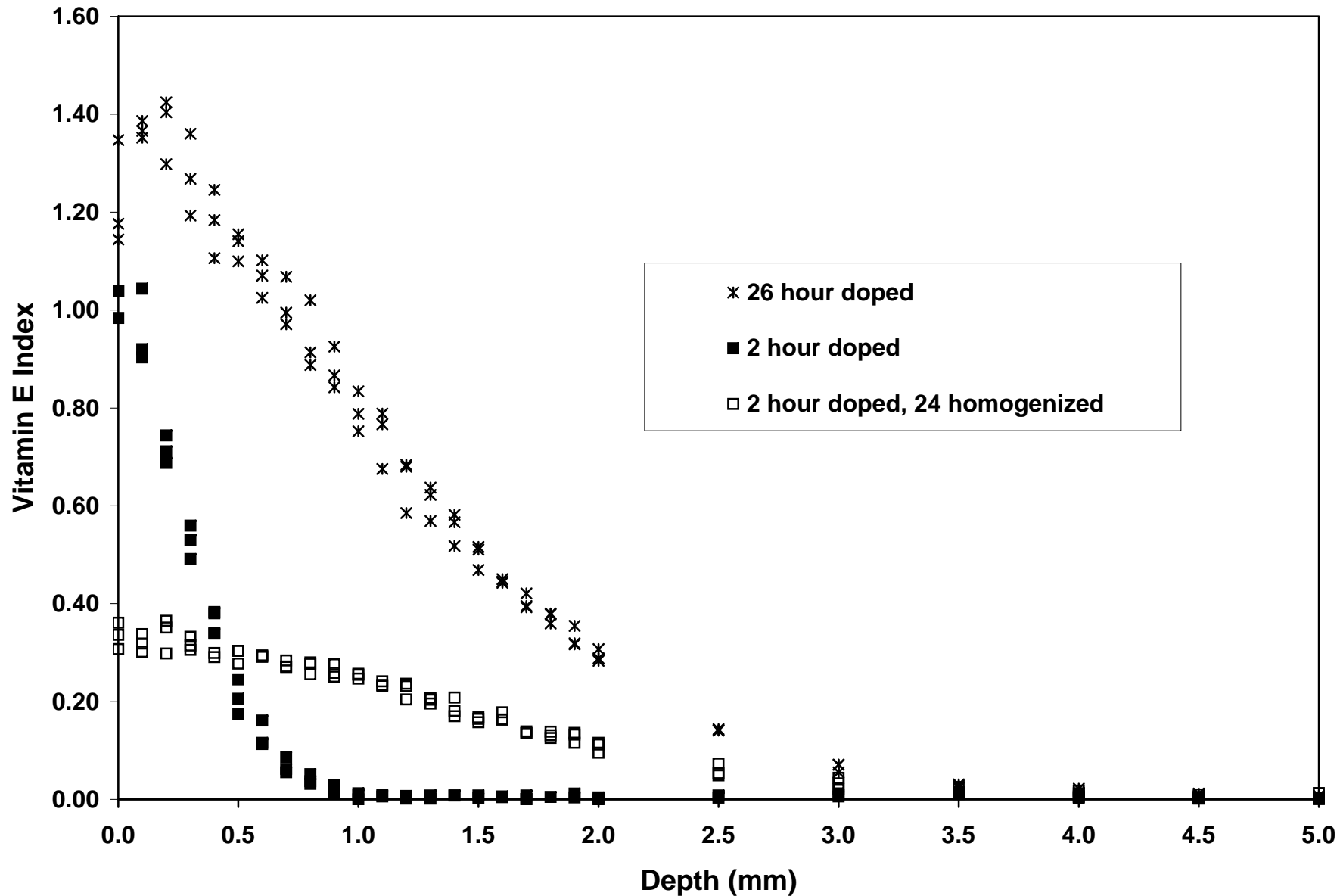
Virgin UHMWPE at 120°C



100kGy UHMWPE 100°C

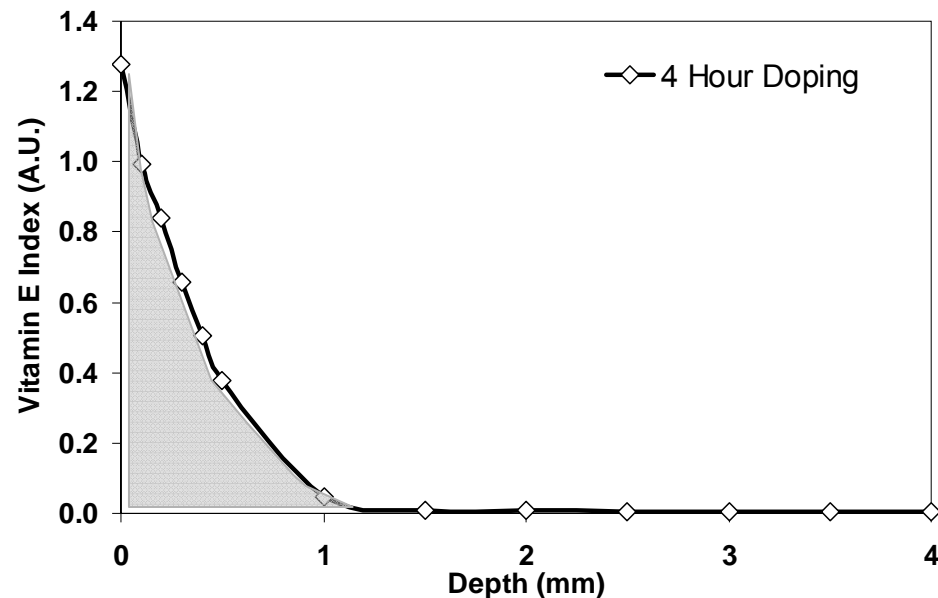
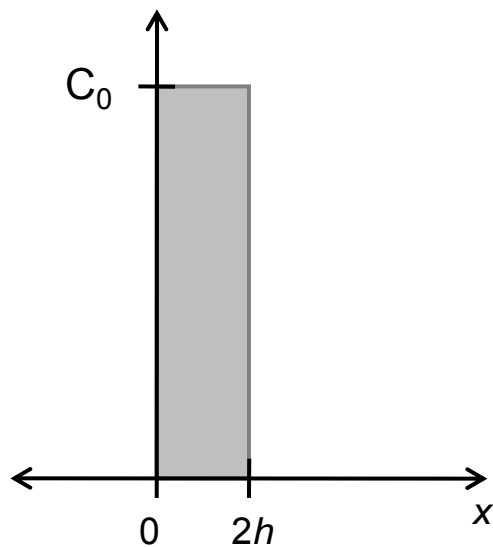


Effect of Homogenization on 100kGy UHMWPE at 120°C



modeled homogenization as thin film of α -tocopherol diffusing into a semi-infinite UHMWPE medium

$$C(x,t) = \left(\frac{C_0}{2}\right) \cdot \left[\operatorname{erf}\left(\frac{h-x}{2\sqrt{Dt}}\right) + \operatorname{erf}\left(\frac{h+x}{2\sqrt{Dt}}\right) \right]$$

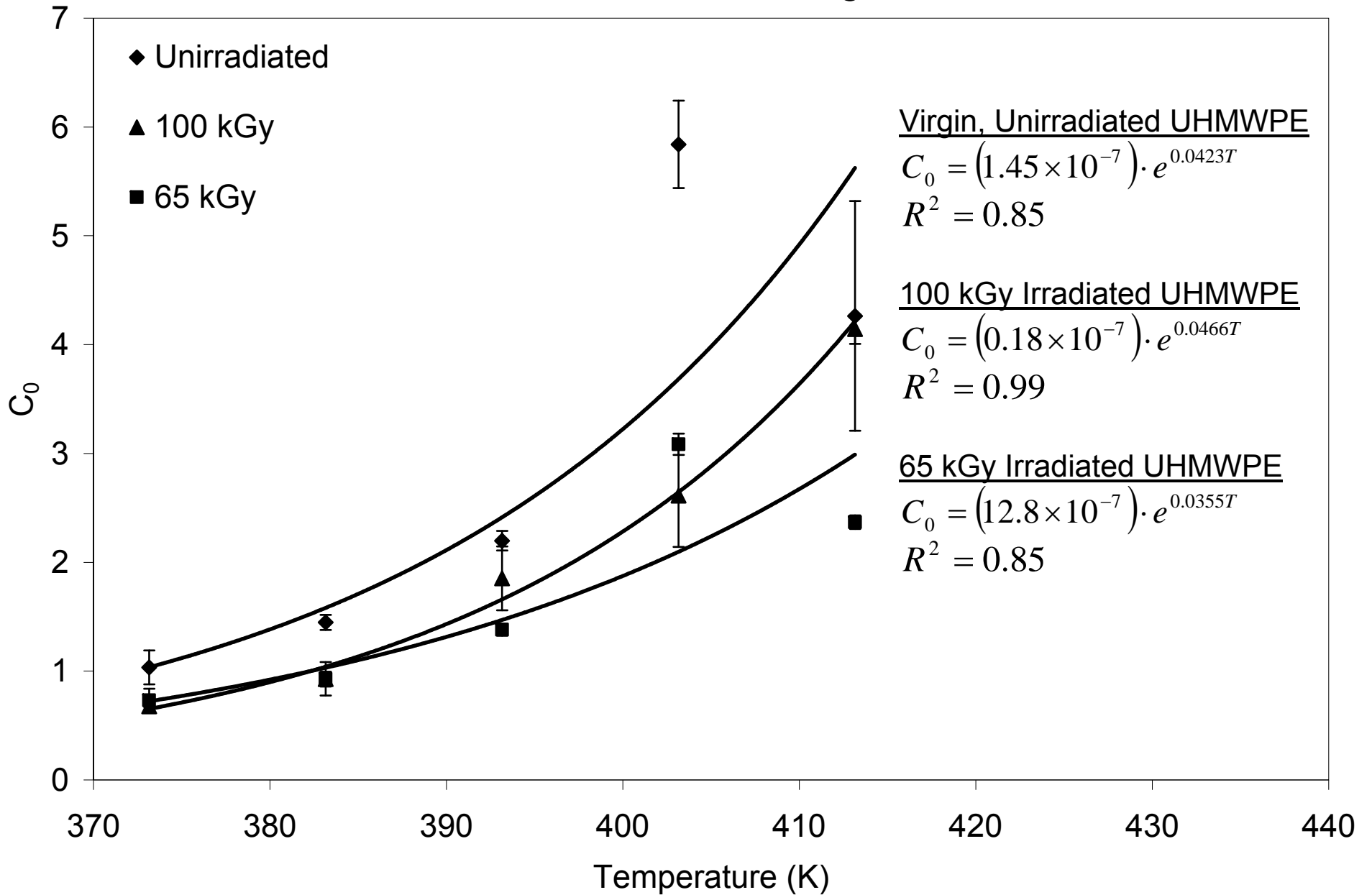


vitE did not elute out during homogenization, assumed that there was an impermeable barrier at depth $x = 0$

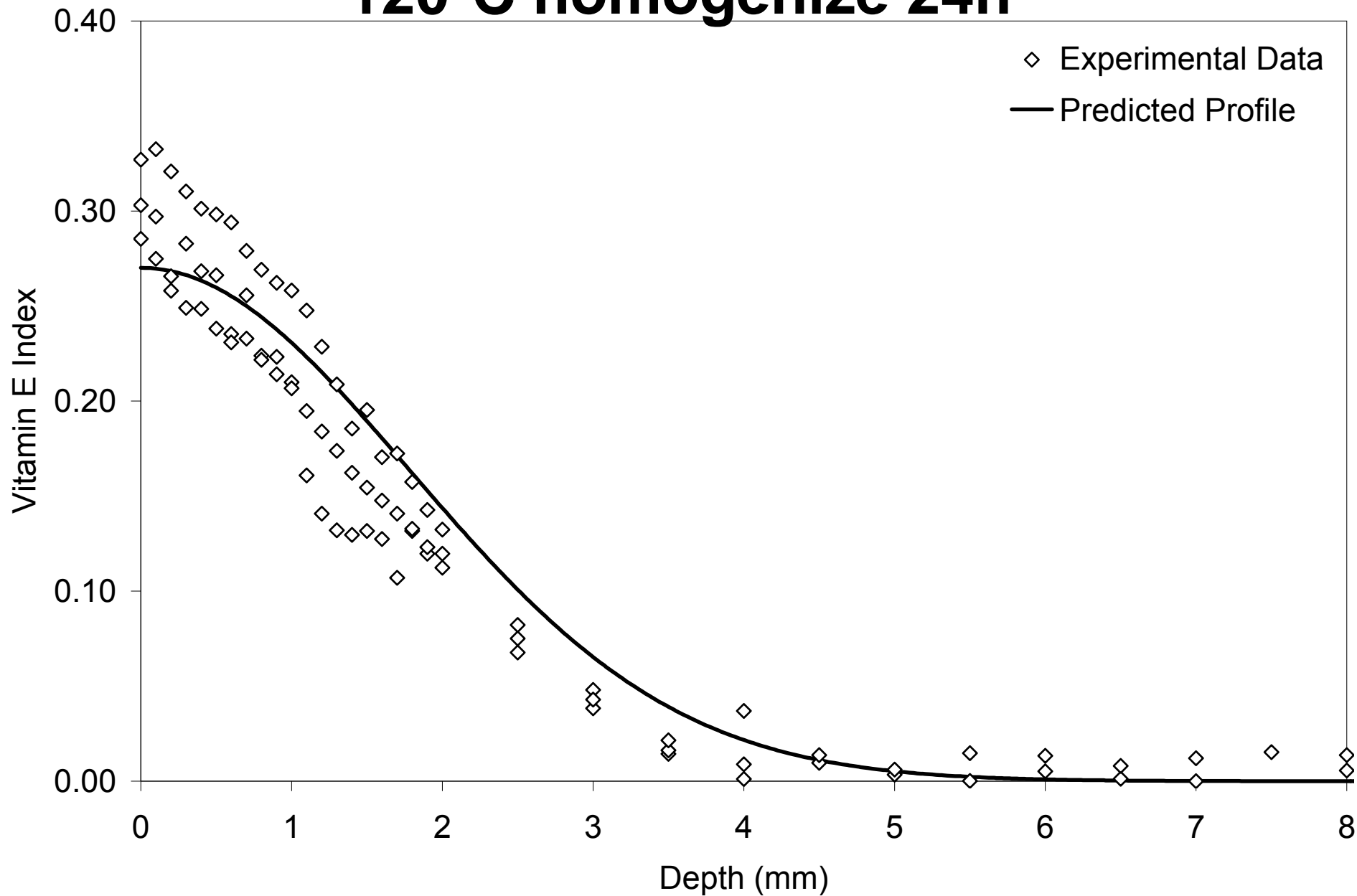
$$C(x,t) = C_0 \cdot \left[\operatorname{erf}\left(\frac{h-x}{2\sqrt{Dt}}\right) + \operatorname{erf}\left(\frac{h+x}{2\sqrt{Dt}}\right) \right]$$

$$2h = \left(\frac{1}{C_0}\right) \cdot \int_0^{\infty} C(x,0) dx$$

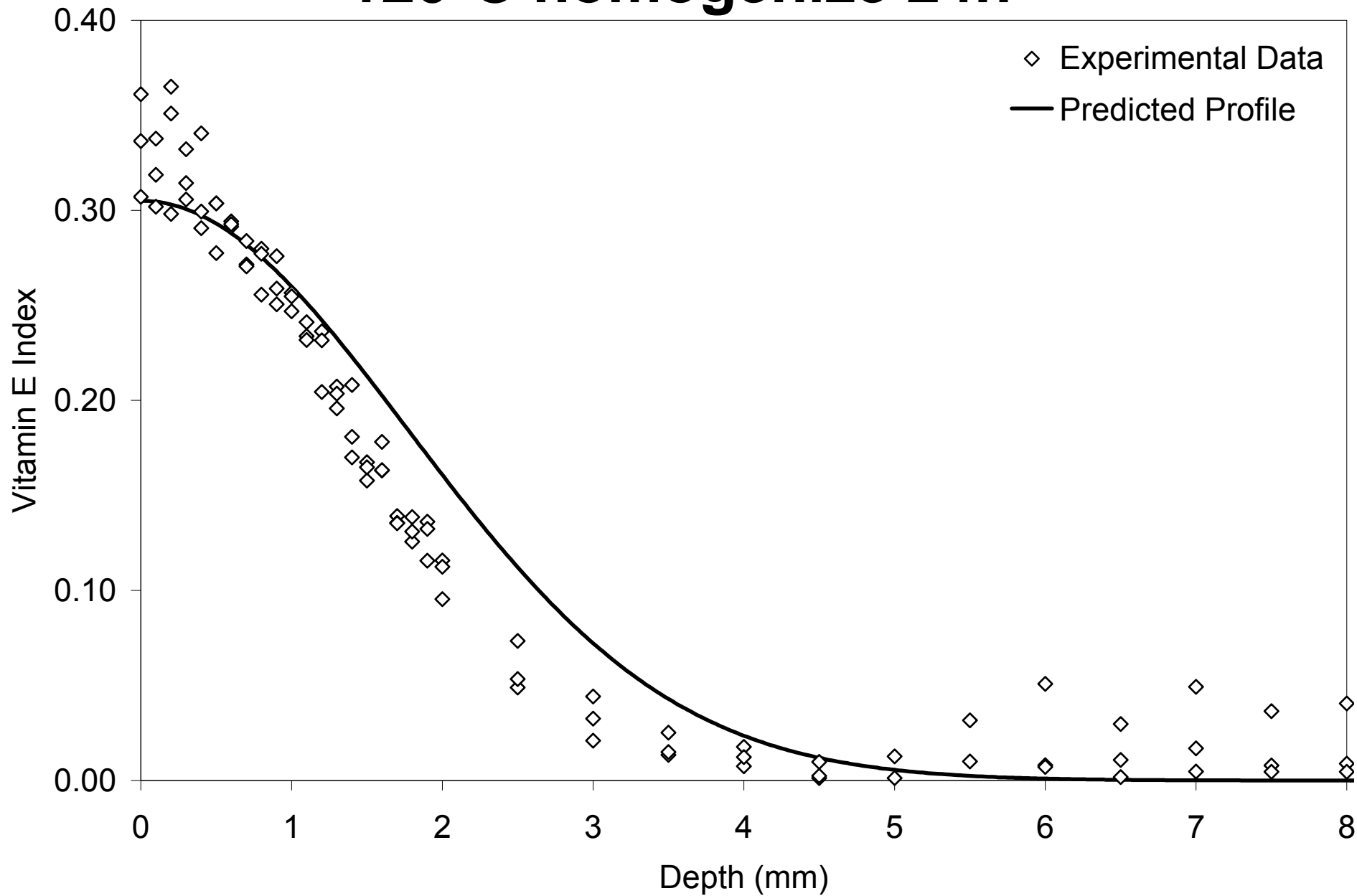
VitE Saturation (C_0) vs. T



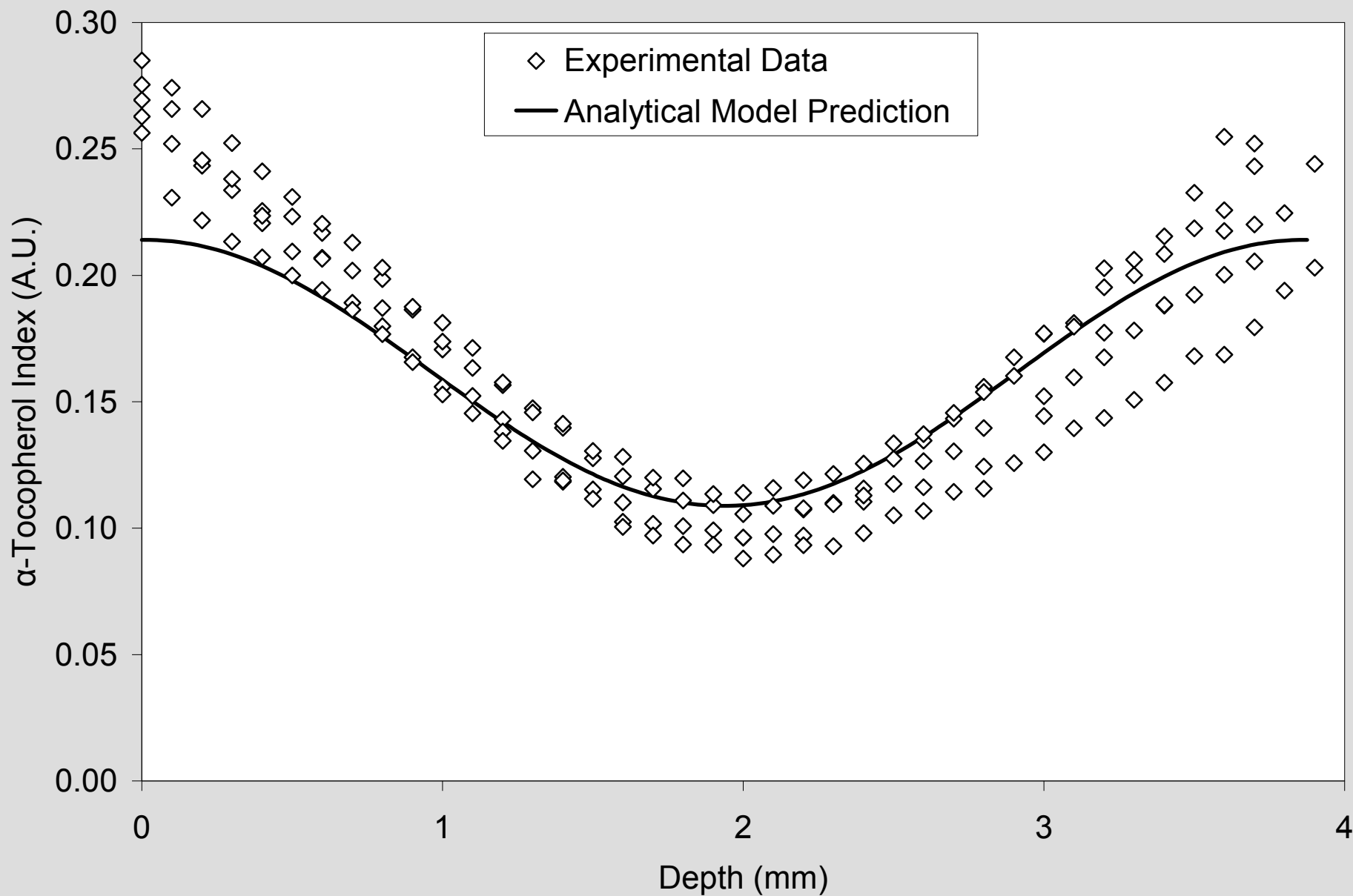
65kGy UHMWPE 120°C dope 2h + 120°C homogenize 24h



65kGy UHMWPE 120°C dope 2h + 120°C homogenize 24h



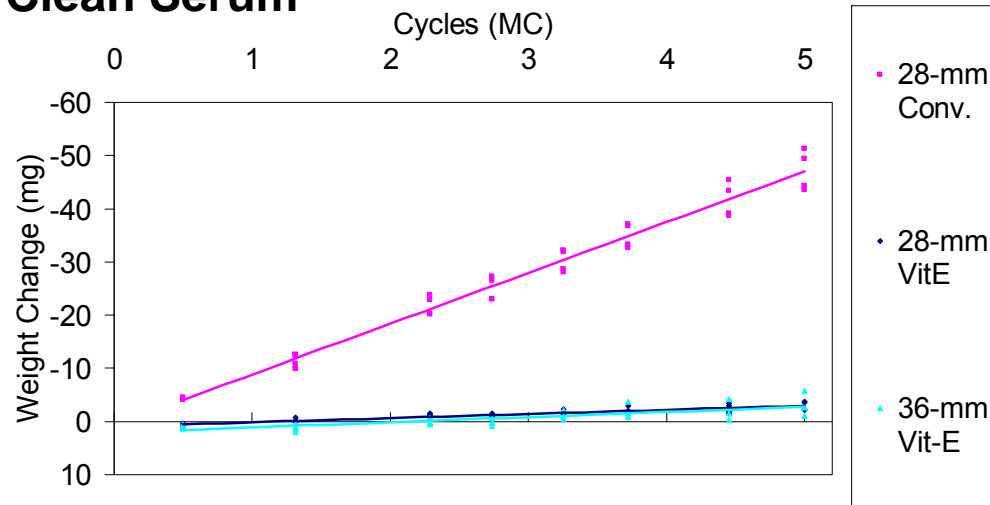
100kGy UHMWPE Dope 120°C 1.5h + homogenize 120°C 16h



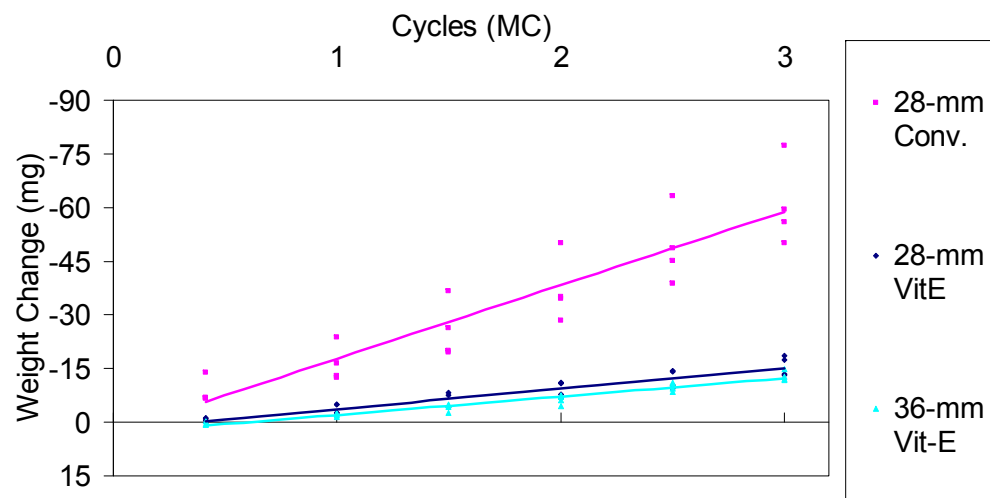
100kGy VitE-UHMWPE (diffused)



Clean Serum



3rd Body Testing



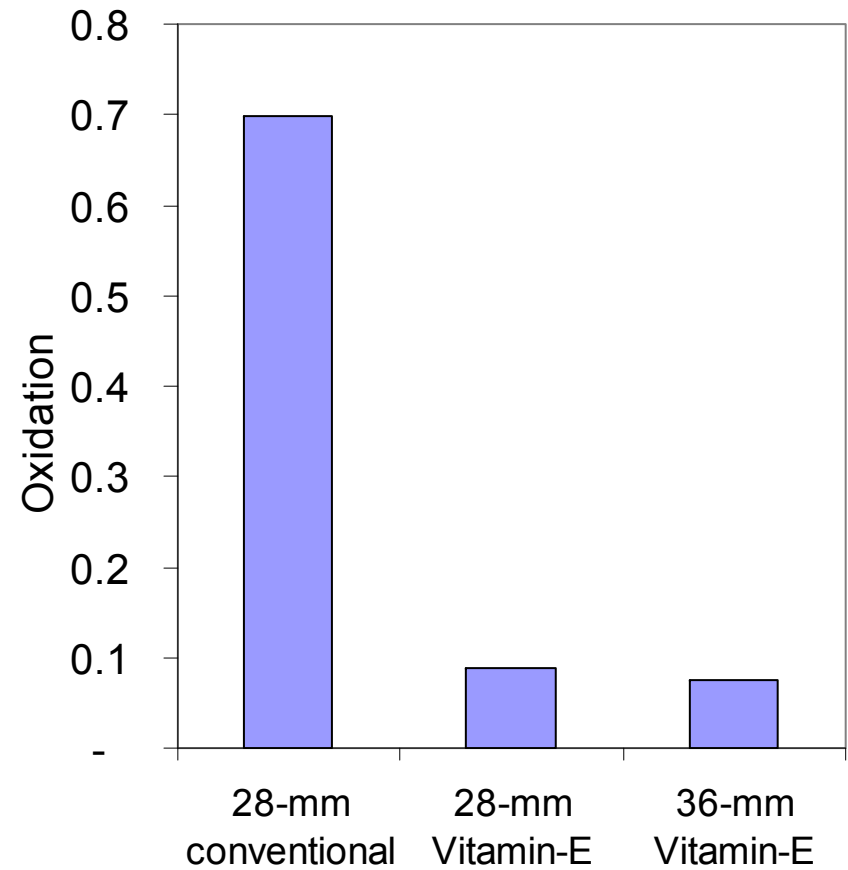
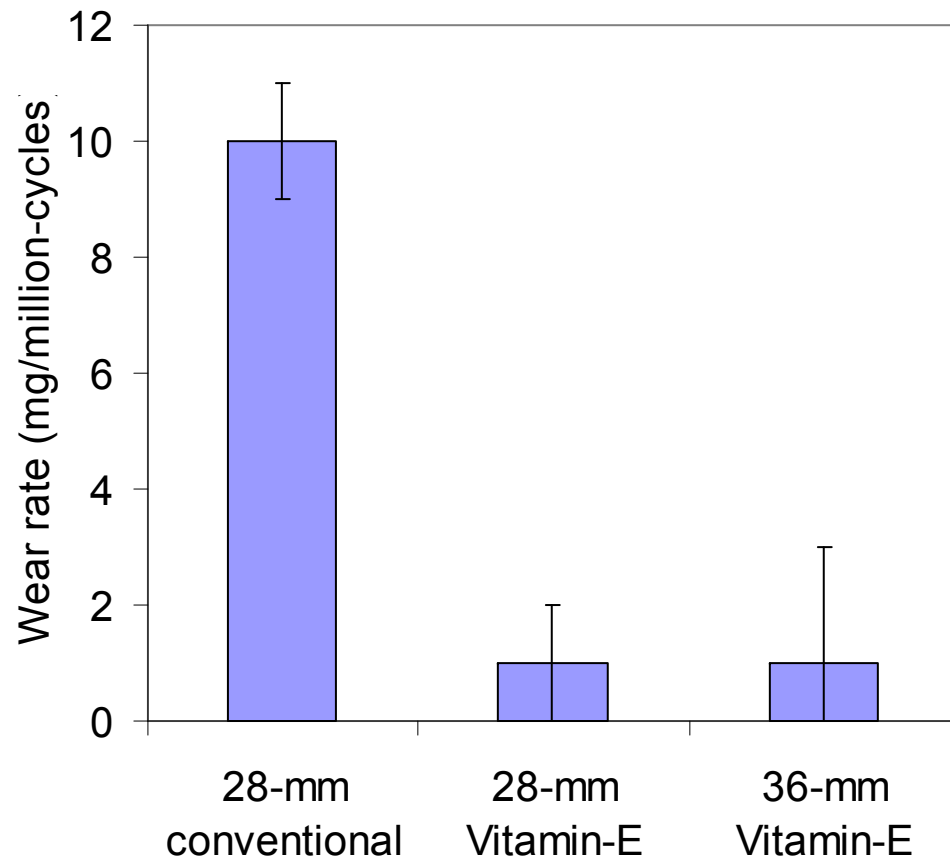
	Clean Wear (mg/MC)	3 rd Body Wear (mg/MC)
28-mm Conventional	10±1	21±3
28-mm Vit-E	1±1	6±2
36-mm Vit-E	1±2	5±3

Elution of Vitamin-E

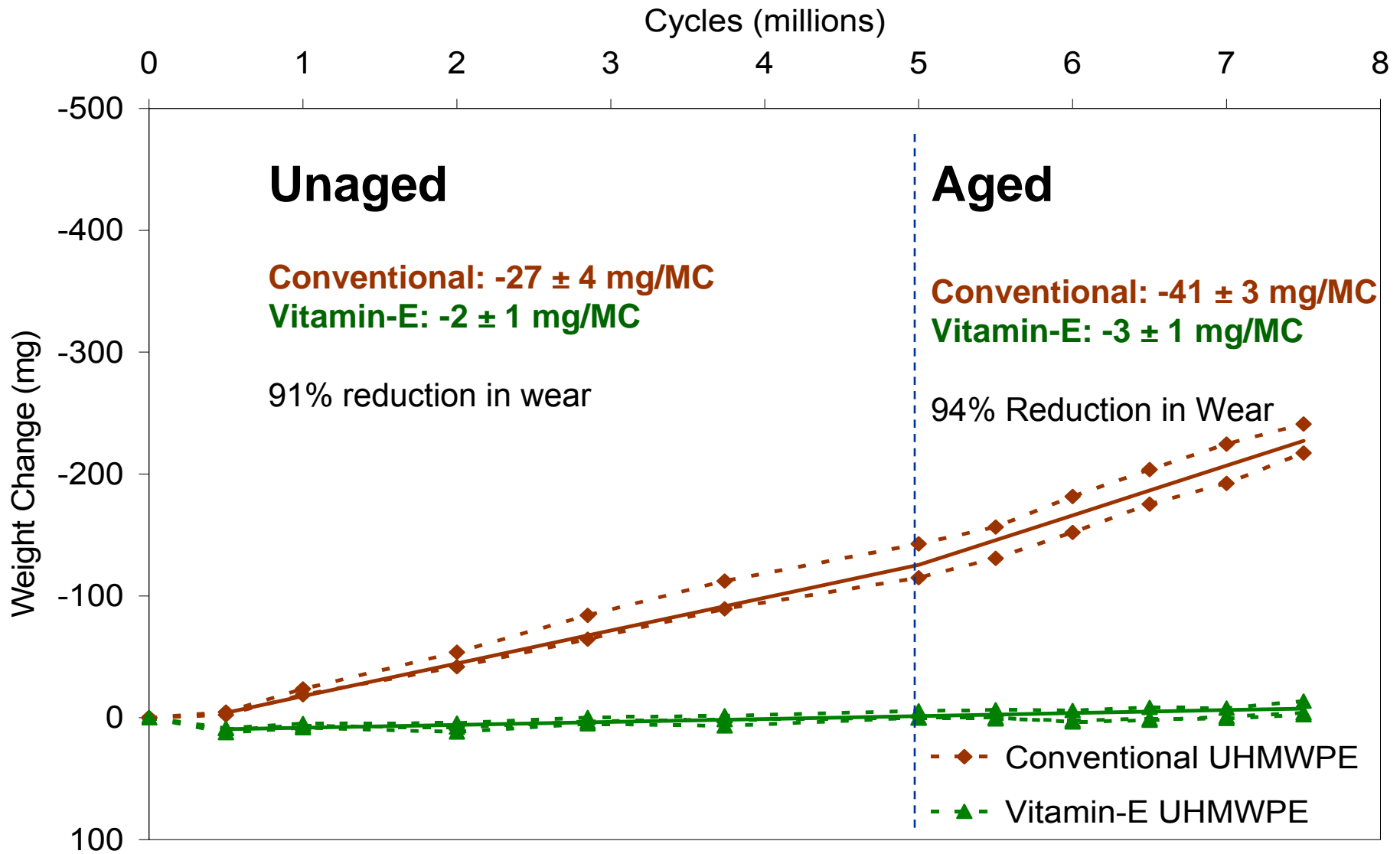
- **Effect on long-term oxidative stability**
 - In vitro forced elution study
 - Joint simulator elution study
- **Local soft tissue response**
 - Rabbit and K9 studies
- **Effect on bony in-growth**
 - K9 total hip study

Elution – Effect of articulation

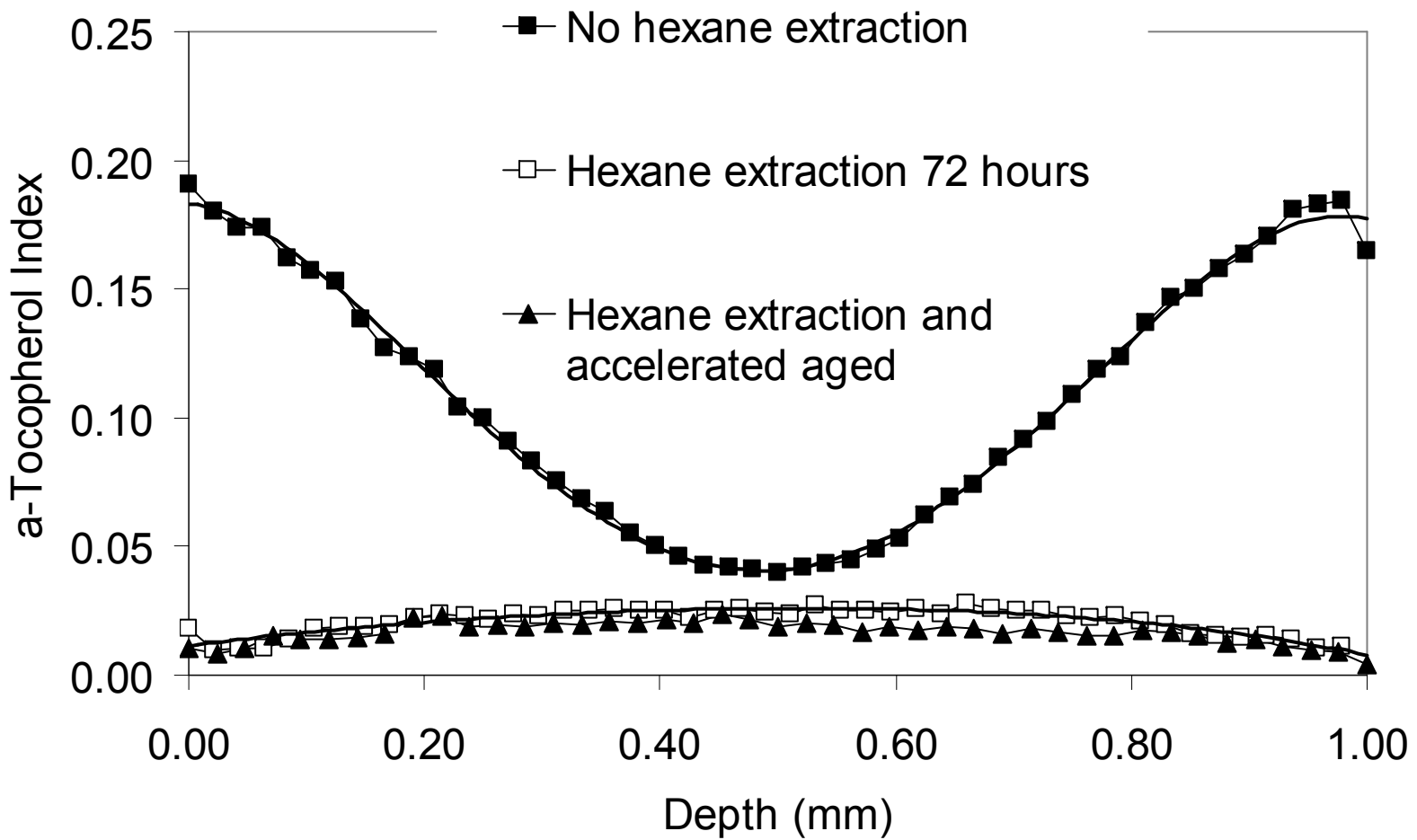
Simulated Hip Wear + Accelerated Aging



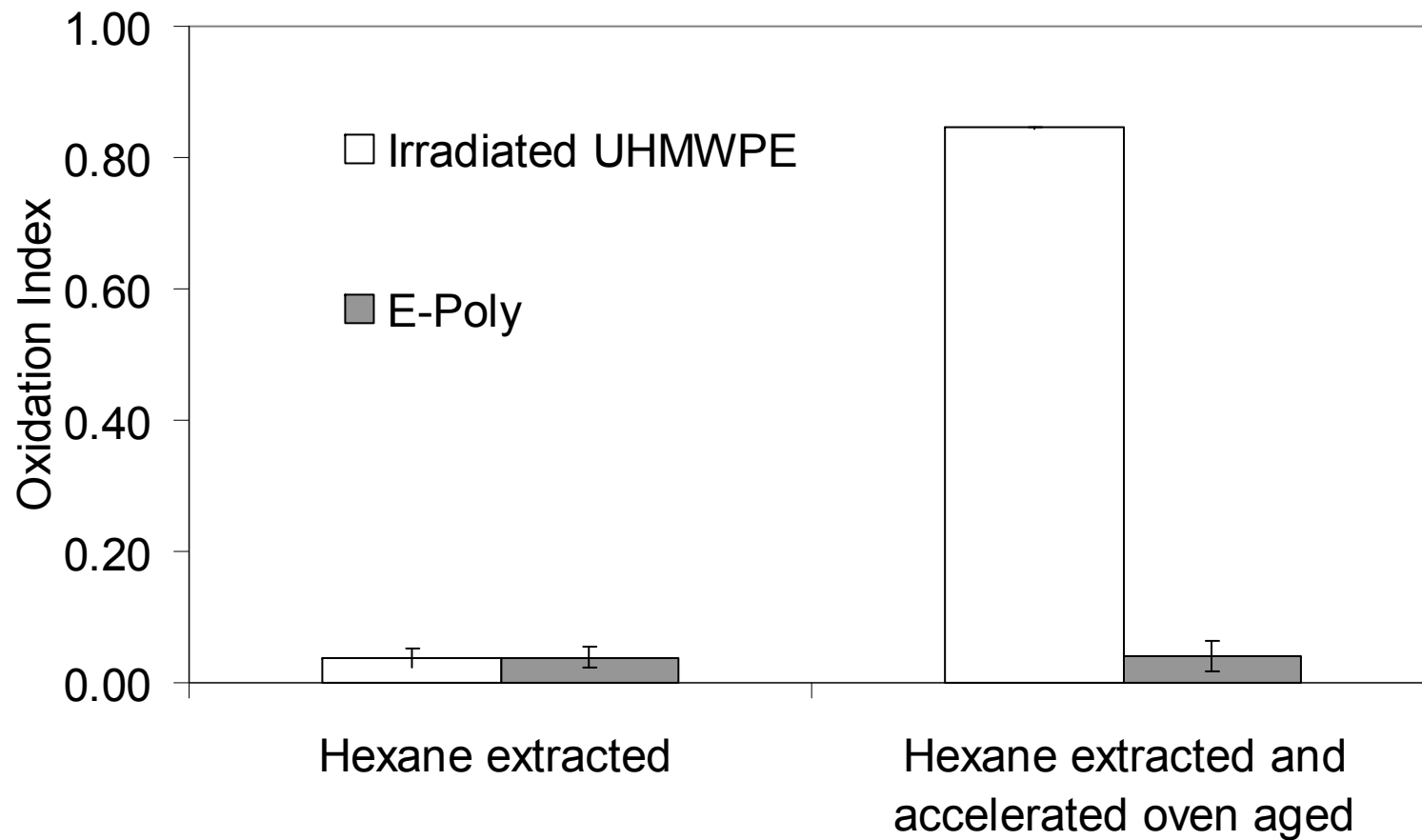
CR Knee 100kGy Vit-E/UHMWPE (diffused)



Forced elution in boiling hexane (72hrs)



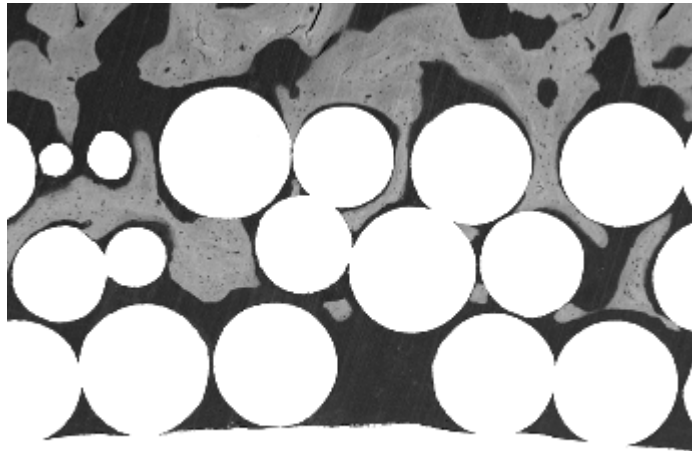
Forced elution: Hexane Extraction + Aging



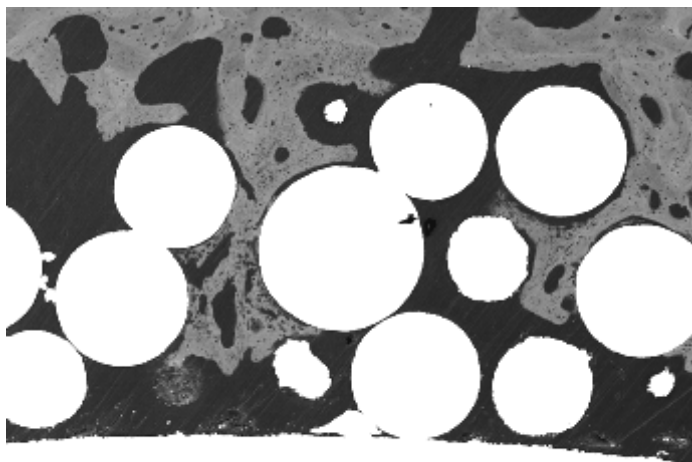
Animal Studies with Vitamin-E

- **Rabbit knee injections**
 - 2 week (n=3) and 12 week (n=6) 10mg of vitE in emulsion or solution; carrier control: no inflammation in soft tissue in either groups
- **Sub-Q plugs in rabbits**
 - 3 and 12 week (n=6) implantation with vitE doped and control plugs of PE
 - both groups showed acute inflammation at 3 weeks and no inflammation at 12 weeks

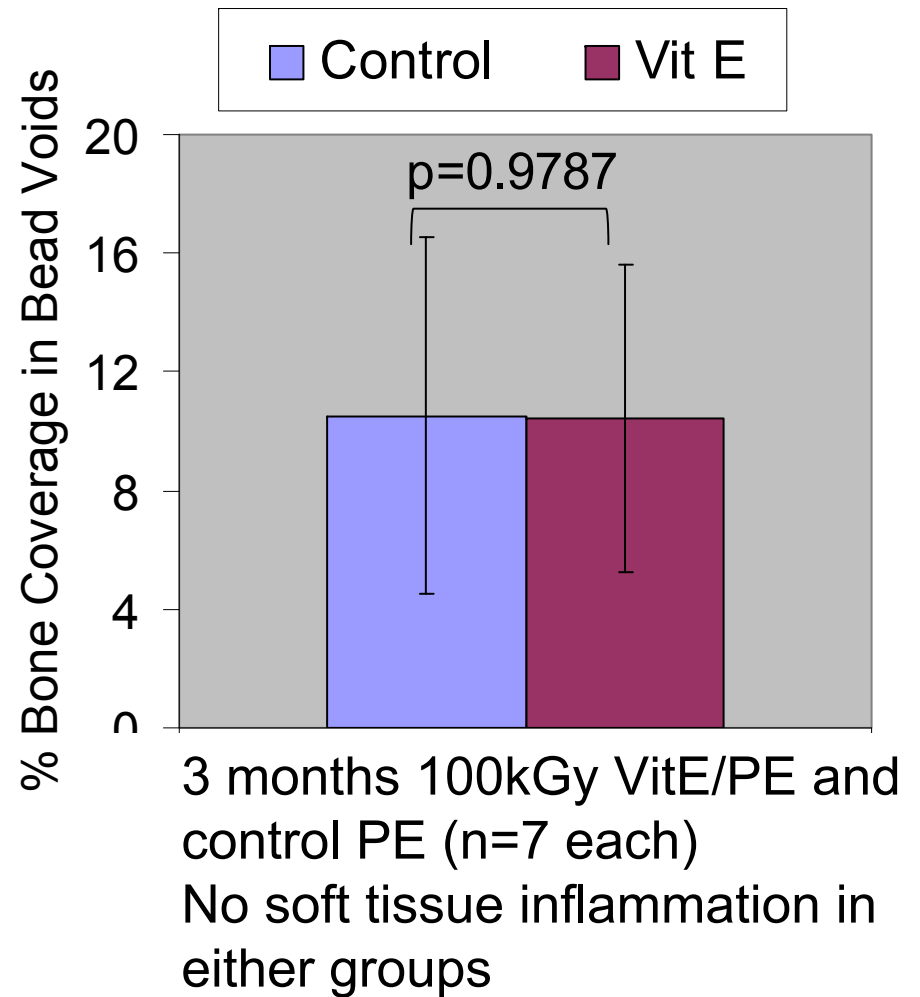
K9 Total Hip Model Bone In-Growth



A7_08



H6_09



2nd Generation: Vitamin-E

- **In comparison to 1st generation, goals with 2nd generation were to achieve:**
 - Wear resistance equivalent to 1st generation
 - High oxidative stability
 - Better mechanical properties
 - Better fatigue strength



U.S. Department of Health
and Human Services

NIH R01 – AR051142

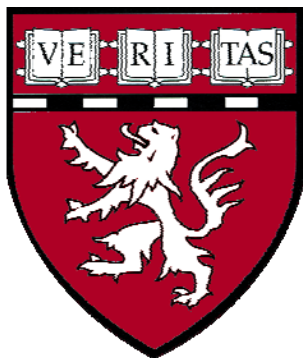
Supported by the

**National
Institutes
of Health**



Additional Funding:

- William H. Harris Foundation
- Biomet, Inc
- Zimmer, Inc

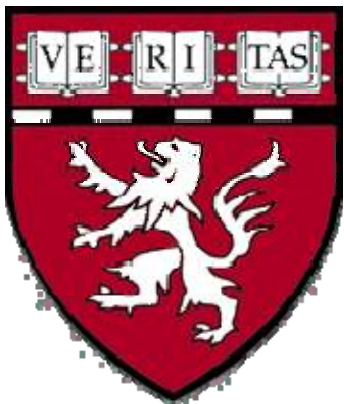


1st and 2nd Generation Highly Crosslinked UHMWPEs for Total Joints

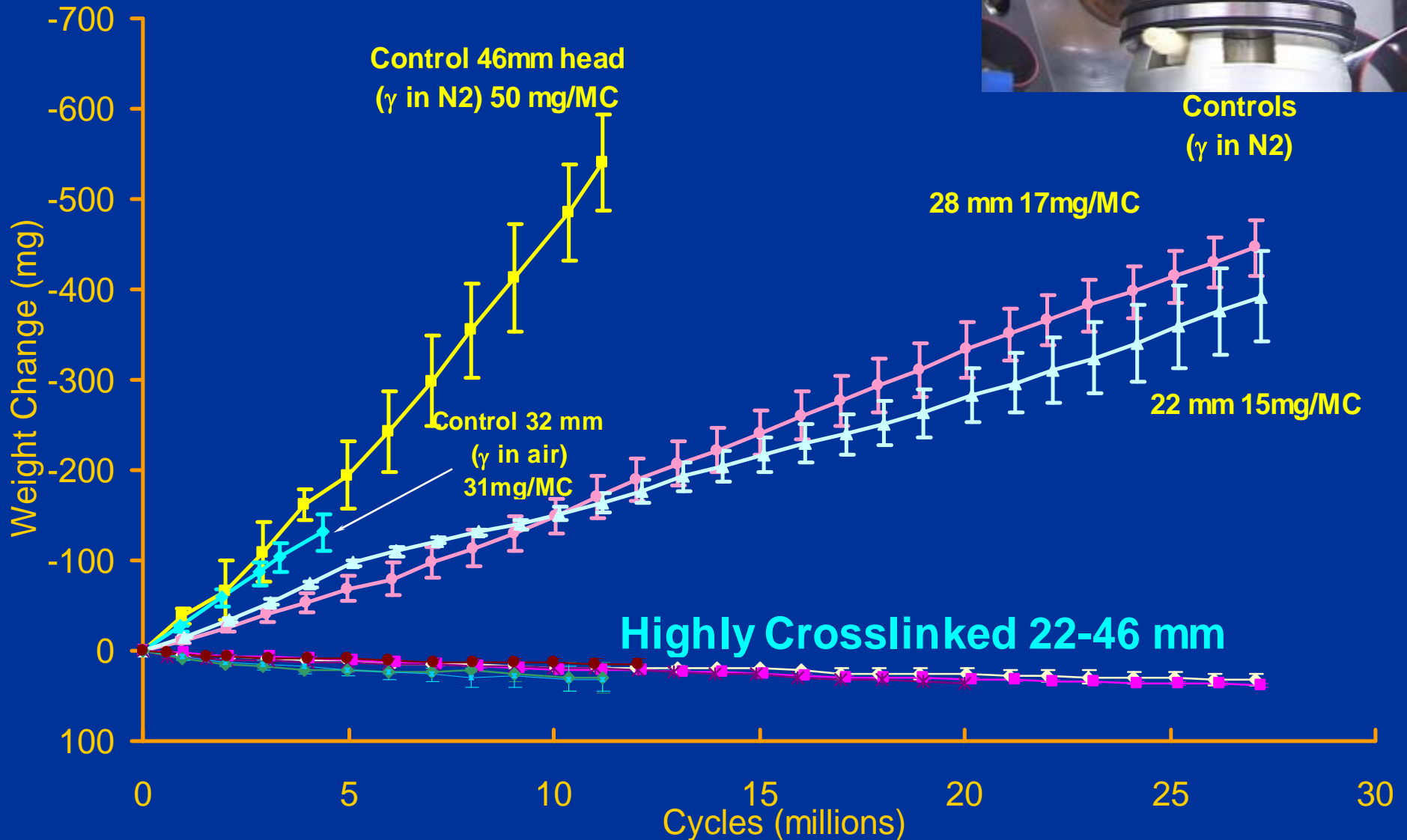
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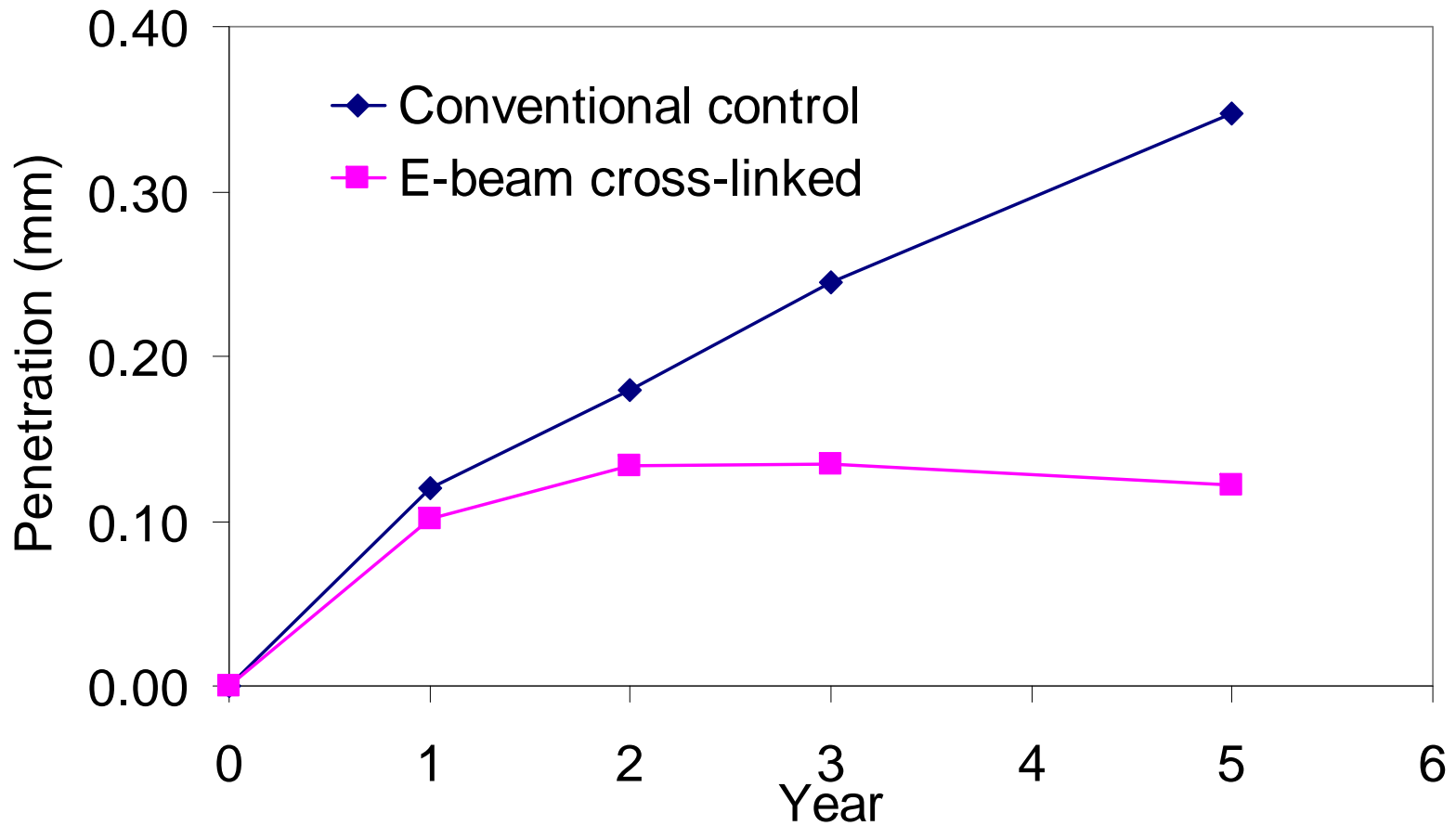
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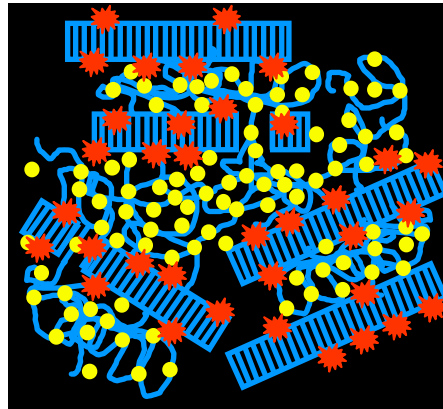
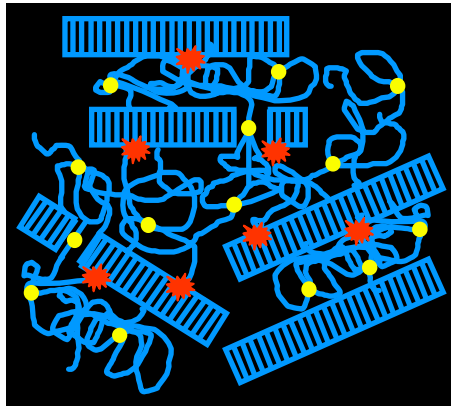
1st Generation Highly Crosslinked Polyethylene - Simulated Hip Gait



RSA 28mm Cemented all-poly; Durasul vs. Conventional – Malchau 2006 AAOS-Hip Society

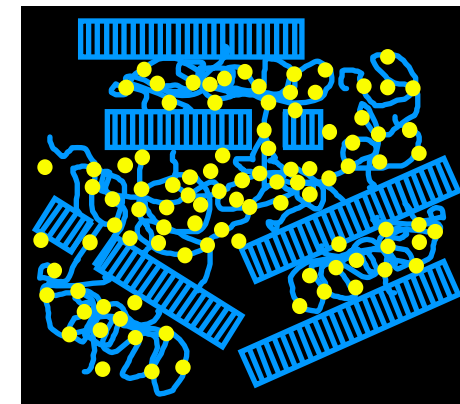


Crosslinking And Free Radicals

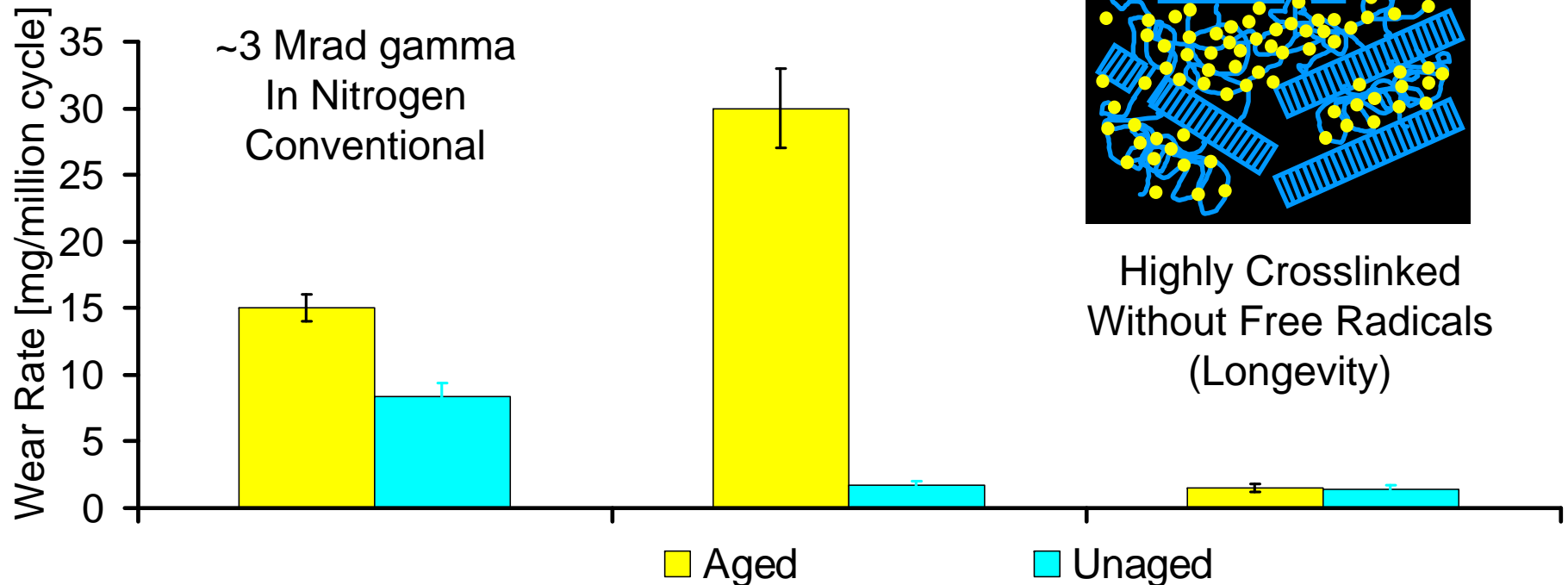


Highly Crosslinked
With Free Radicals
(Crossfire)

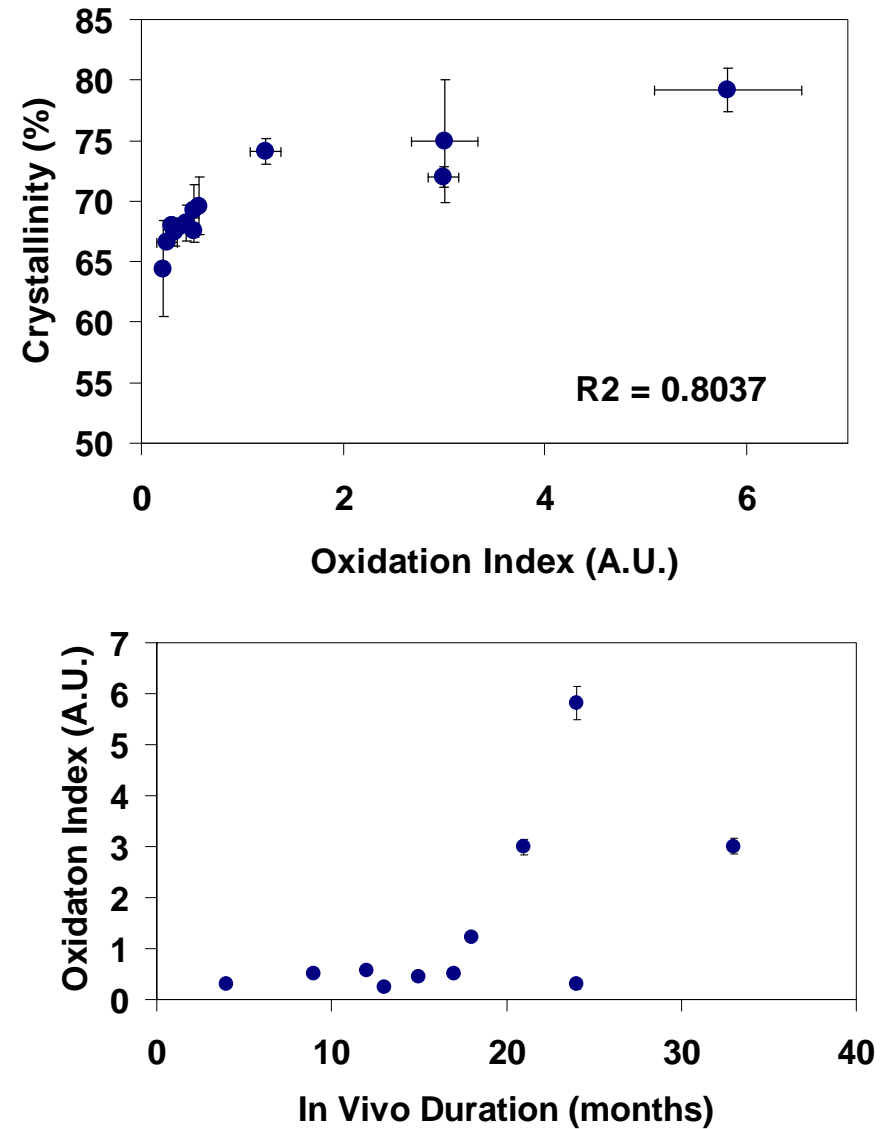
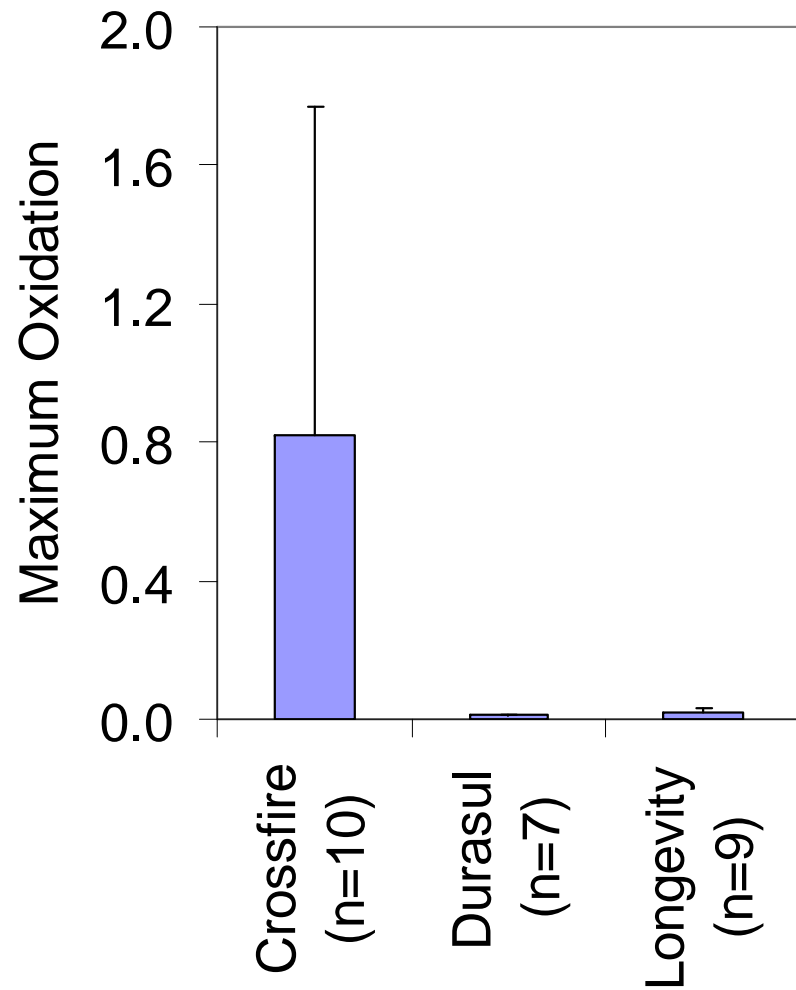
Muratoglu et al.,
CORR, 2003



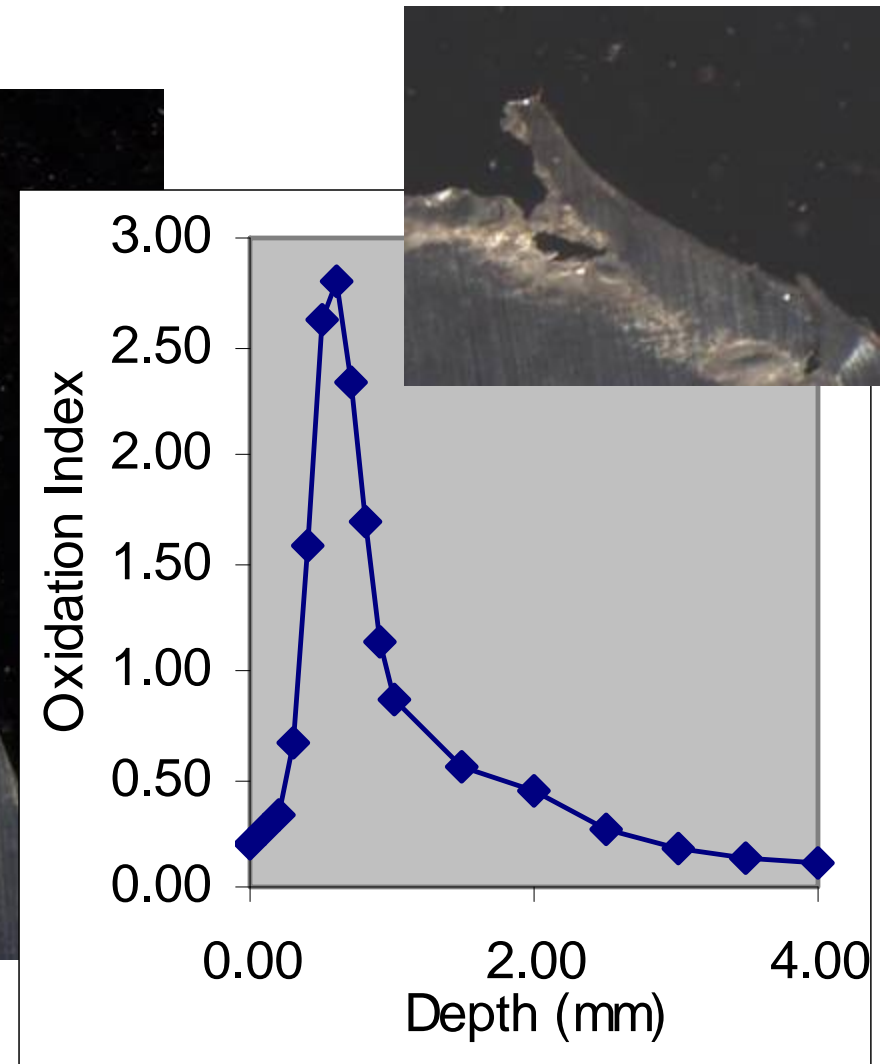
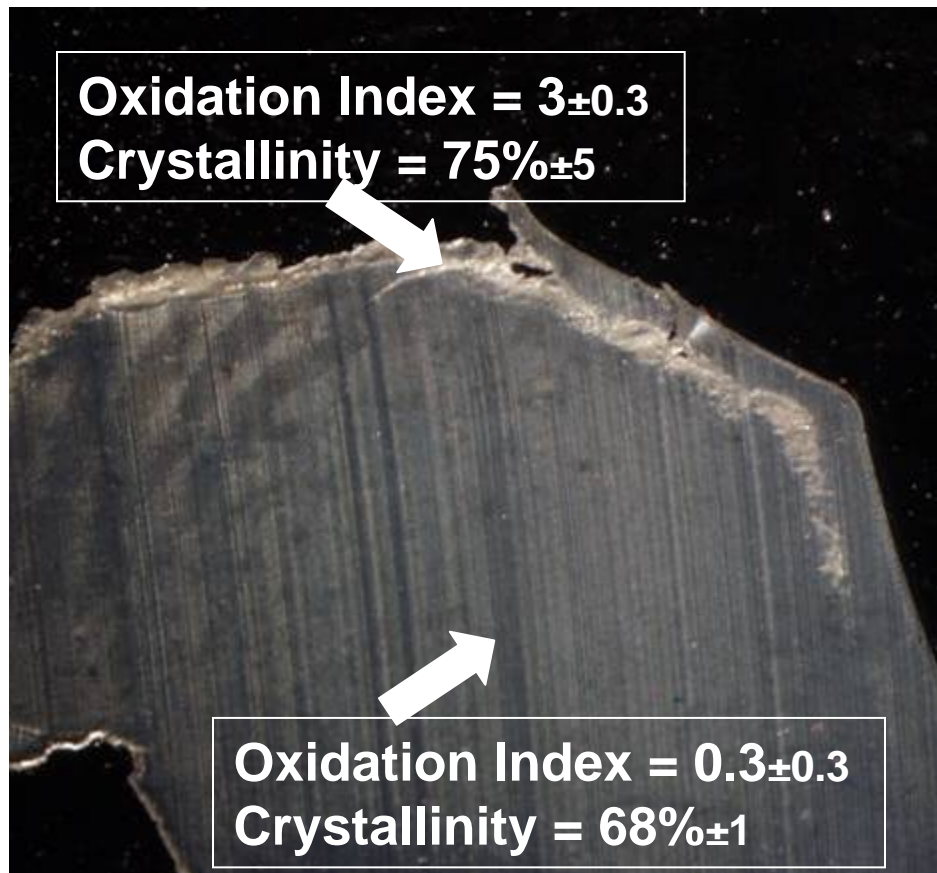
Highly Crosslinked
Without Free Radicals
(Longevity)



Explants – Oxidation Study: Wannomae, JOA 2006

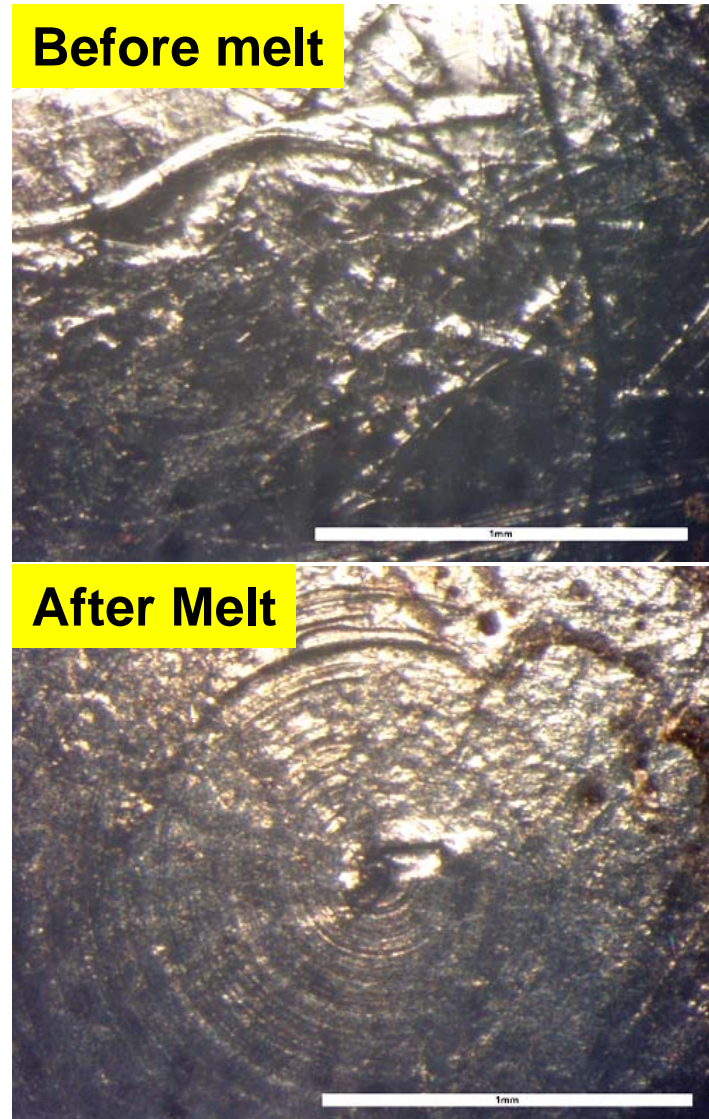


Case Study: Crossfire™ explant (33 months in vivo)



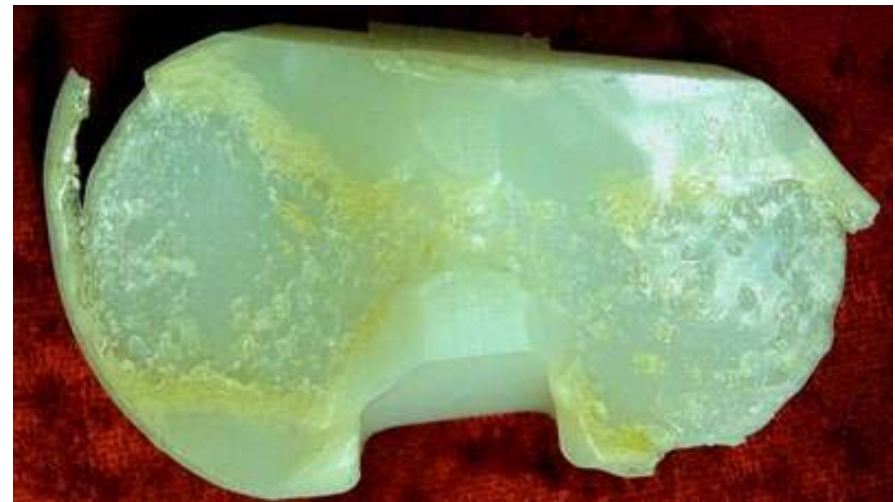
Case Study: Longevity explant (54 months in vivo)

- Removed because of dislocation
- No oxidation
- No changes in crystallinity



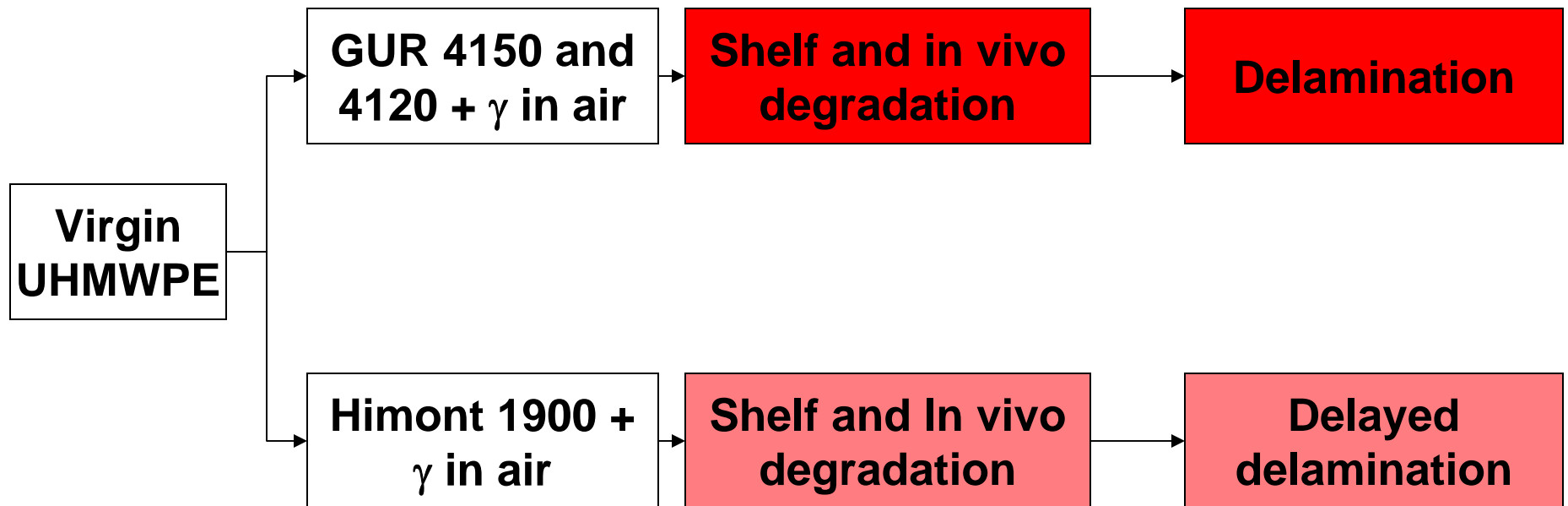
TKA performance can be compromised due to...

- Osteolysis secondary to adhesive wear



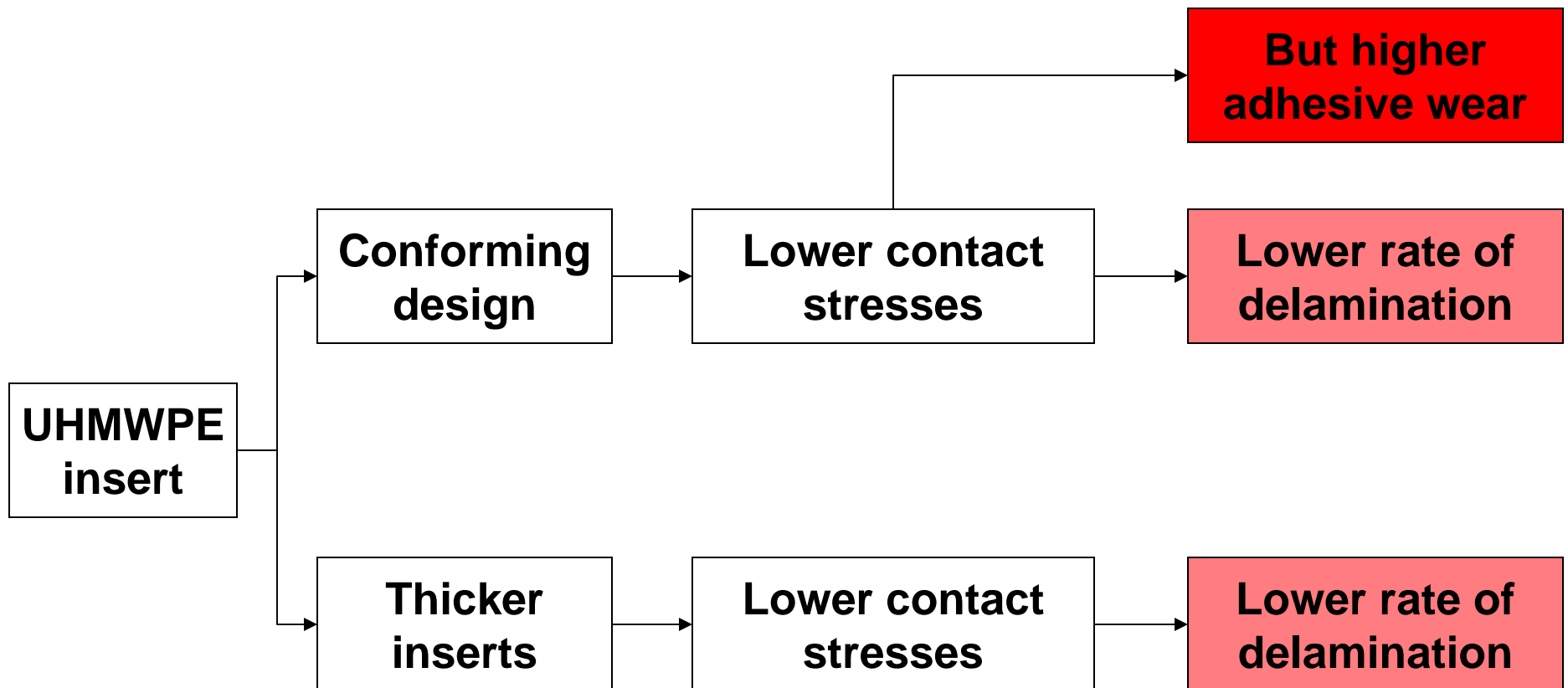
- Delamination

UHMWPEs for TKR: Effect of Resin

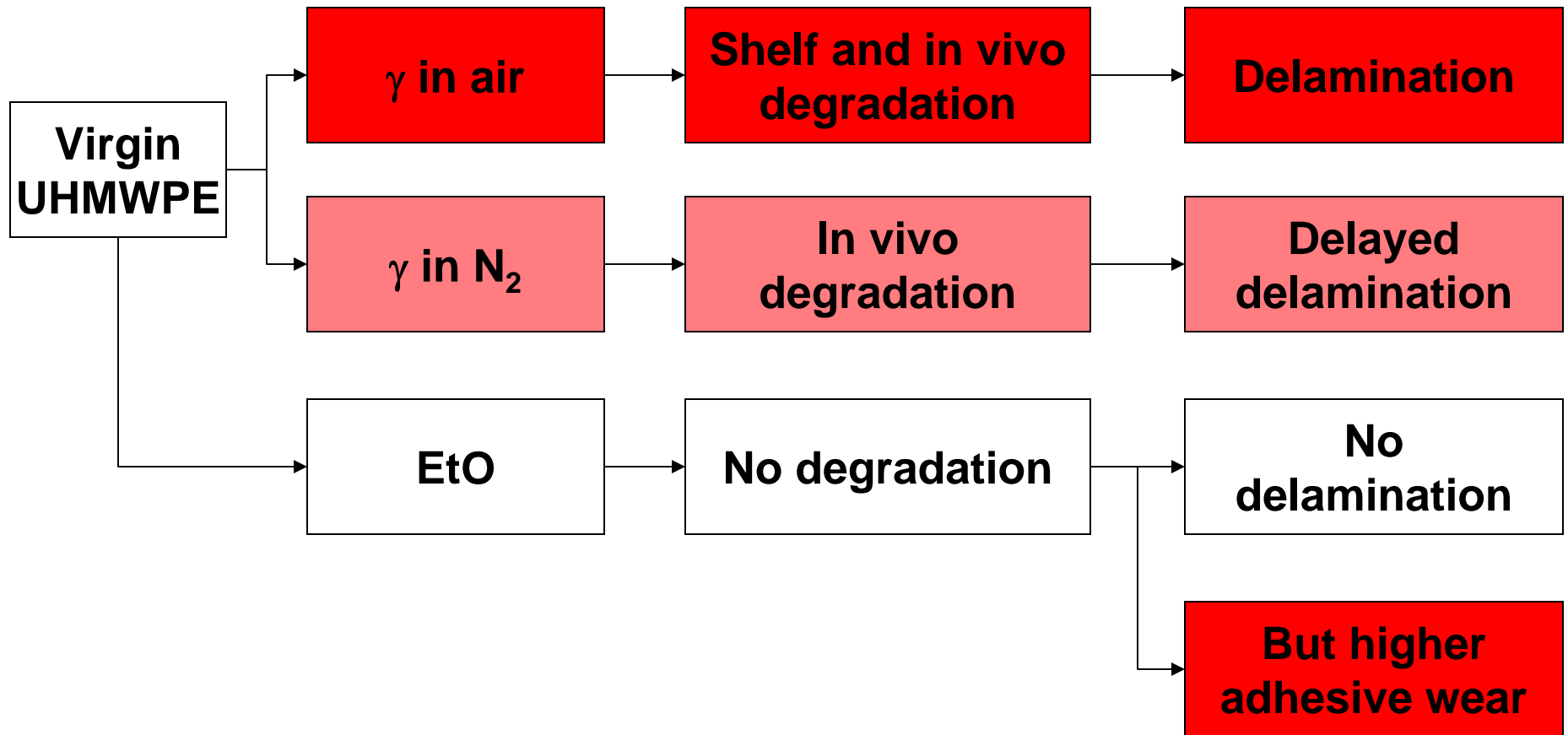


Himont 1900 is no longer available. Production discontinued.

UHMWPEs for TKR: Contact Stresses



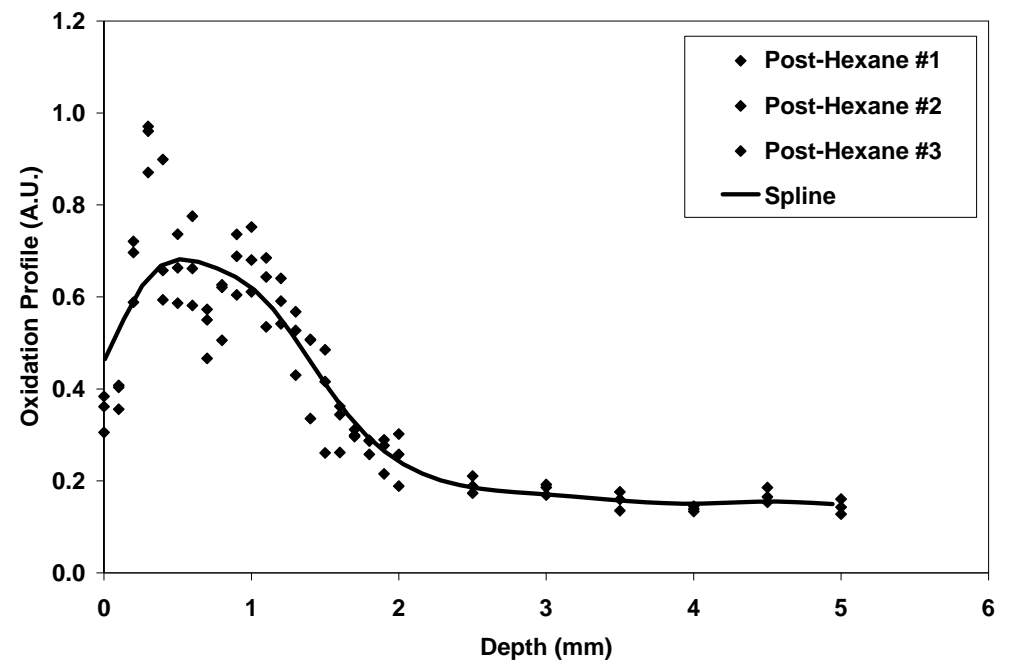
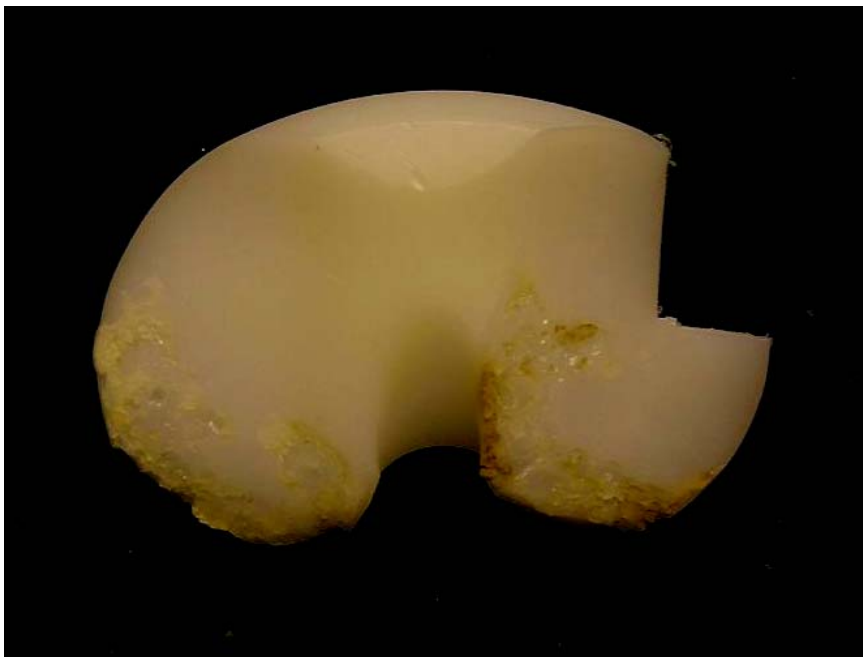
UHMWPEs for TKR: Effect of Sterilization



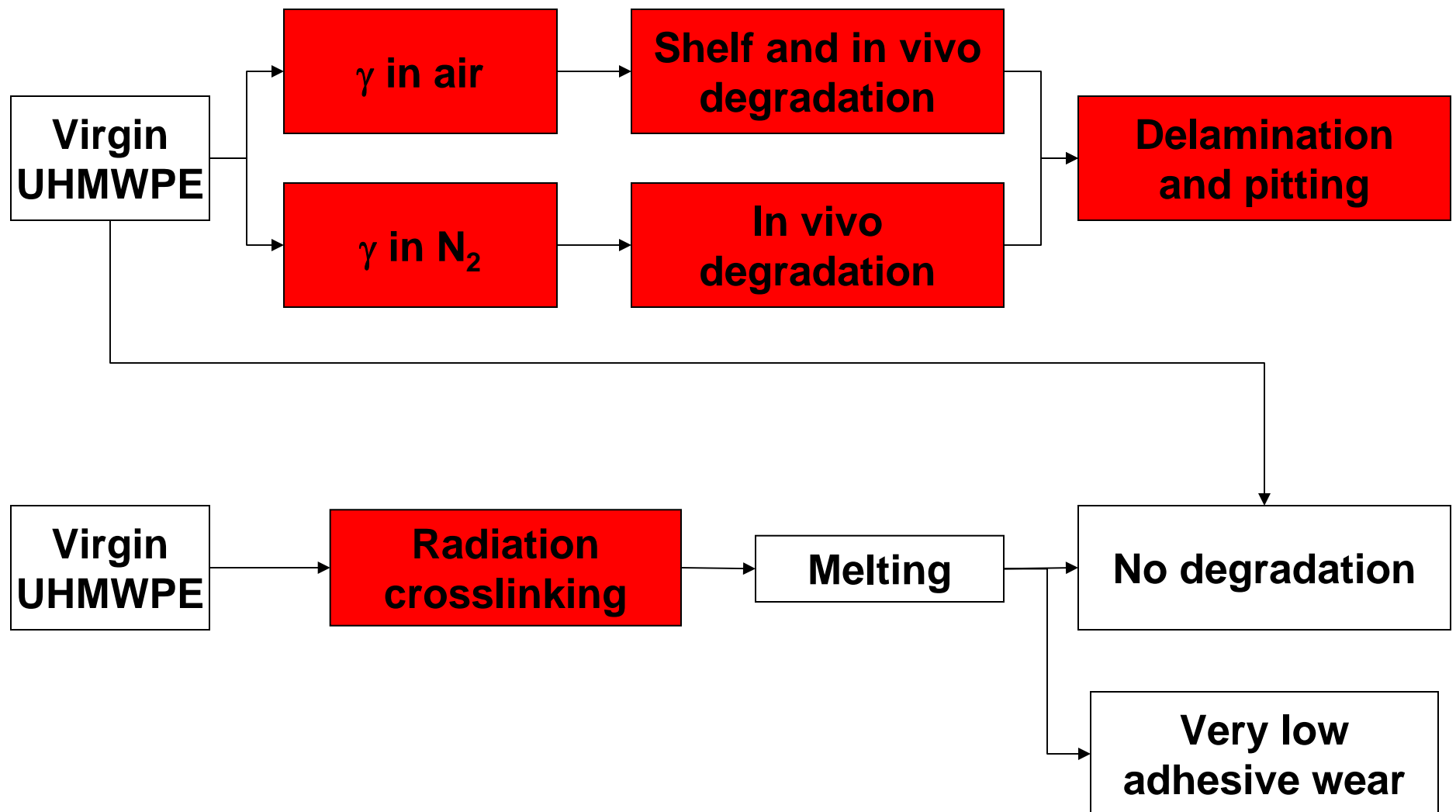
Case: γ in N2 sterilized tibial insert

Gamma sterilized in nitrogen

48 months in vivo; revised due to pain



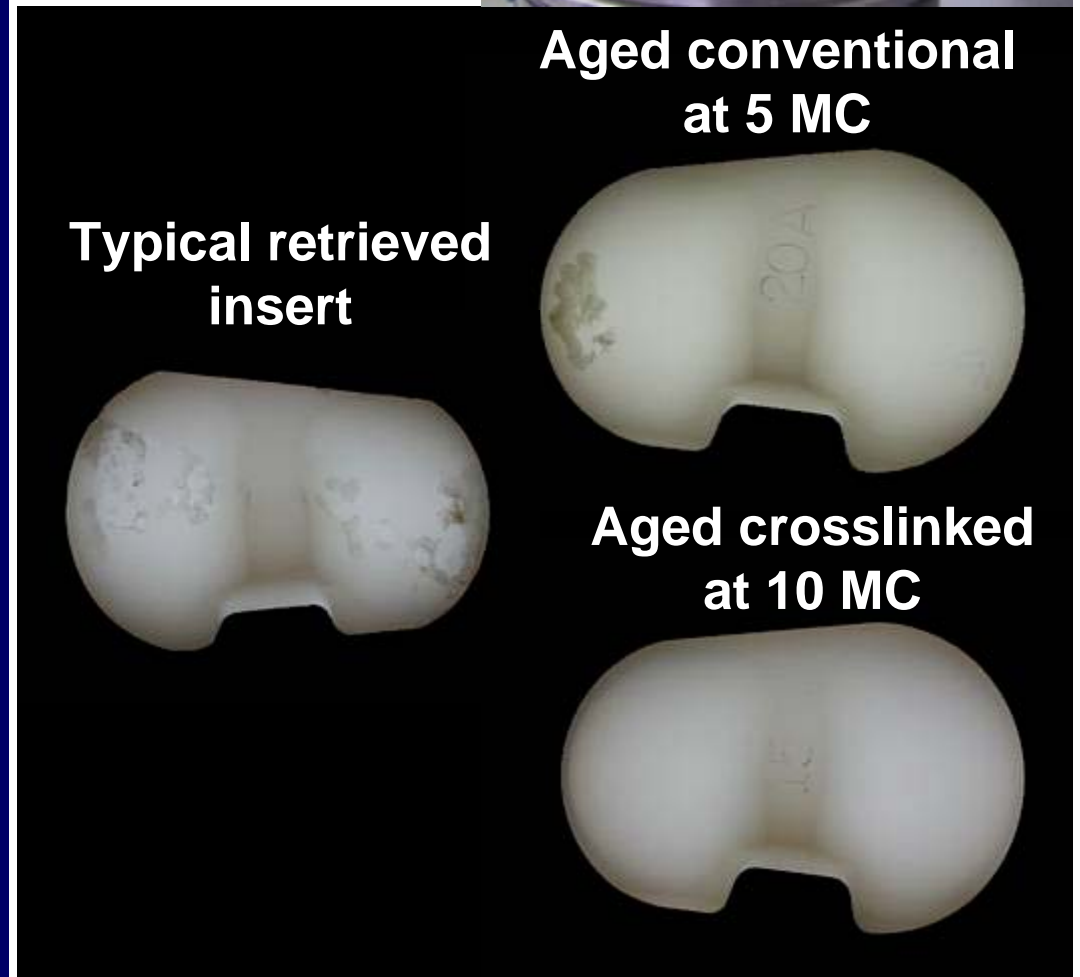
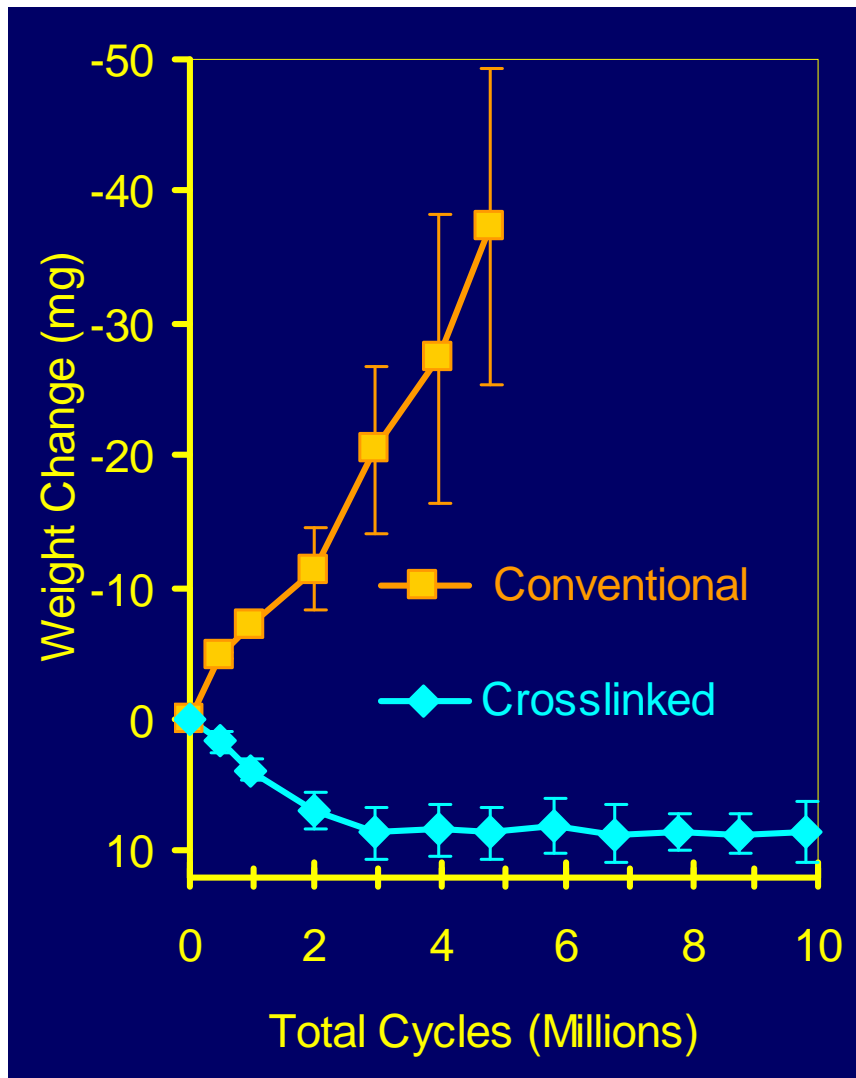
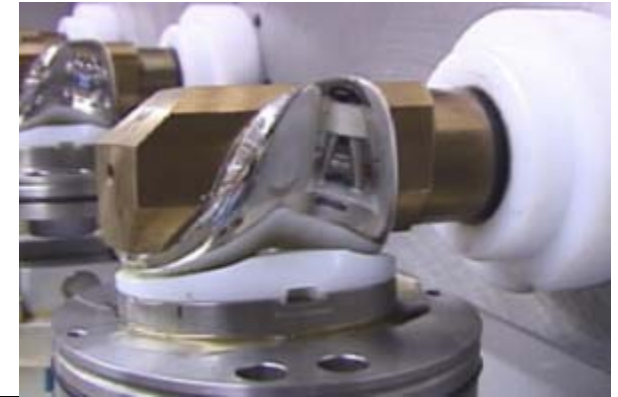
Highly Crosslinked UHMWPE for TKR



NKII Cruciate Retaining – Simulated Gait

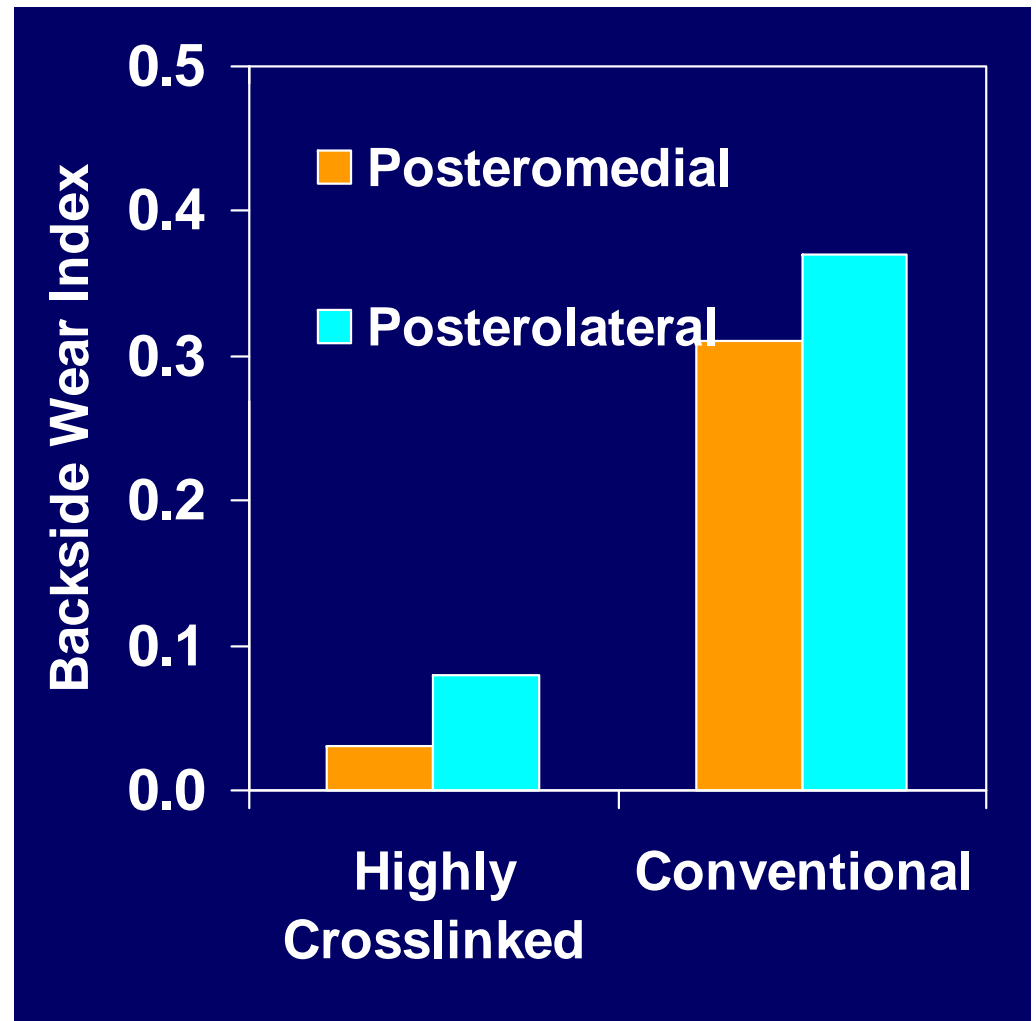
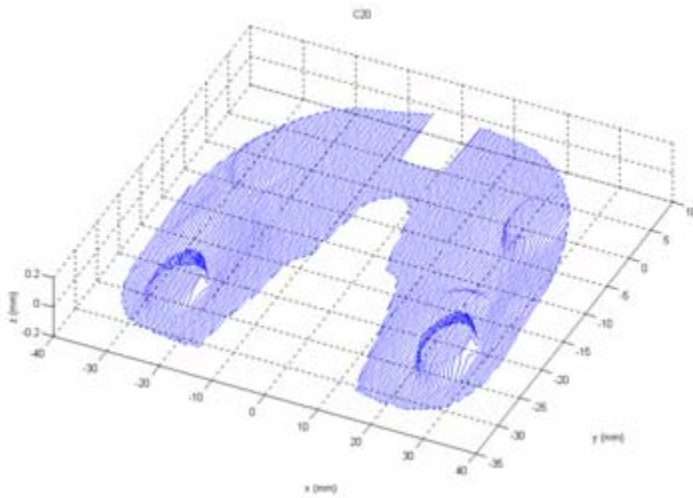
Articular Wear

Delamination

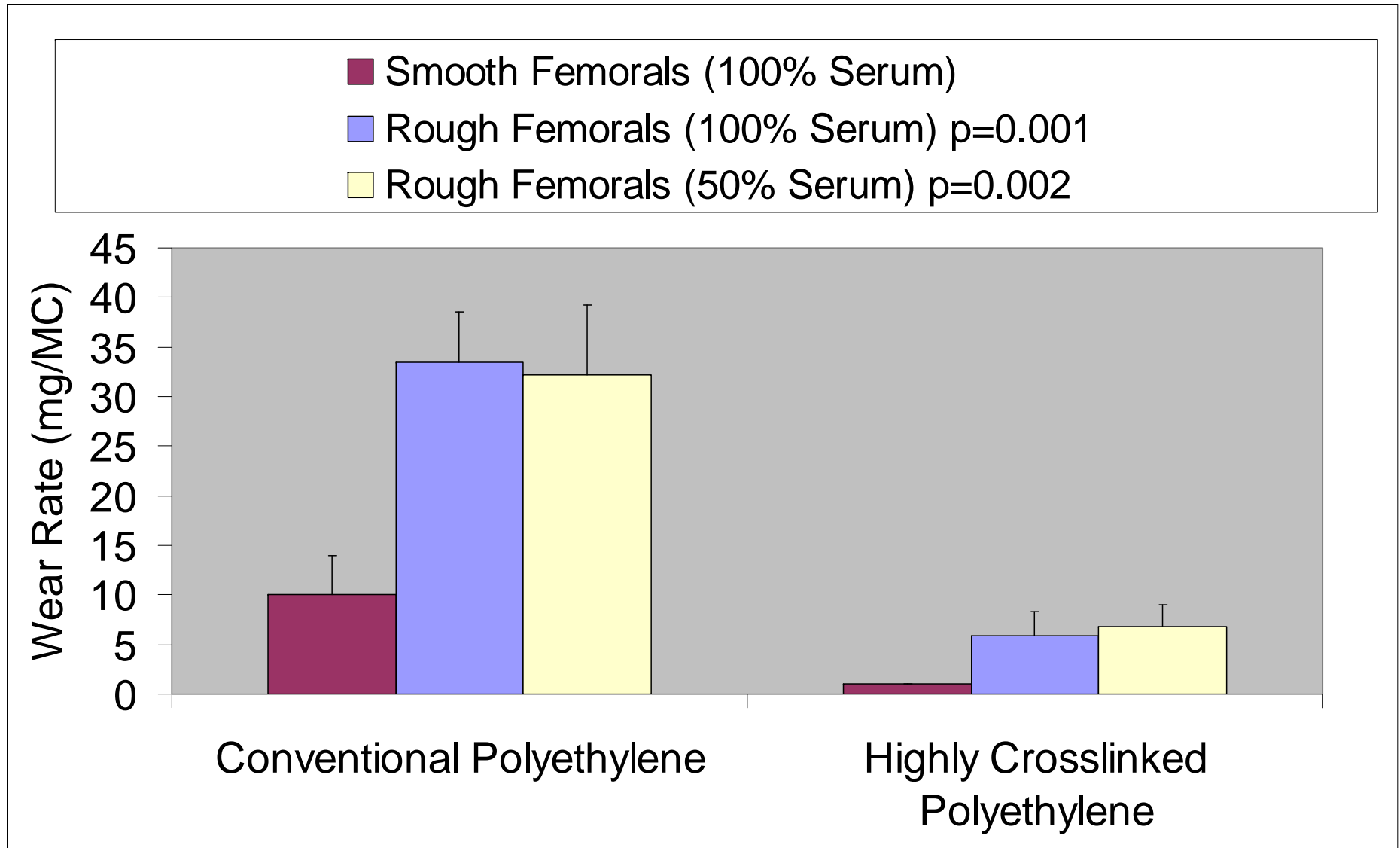


Backside Changes

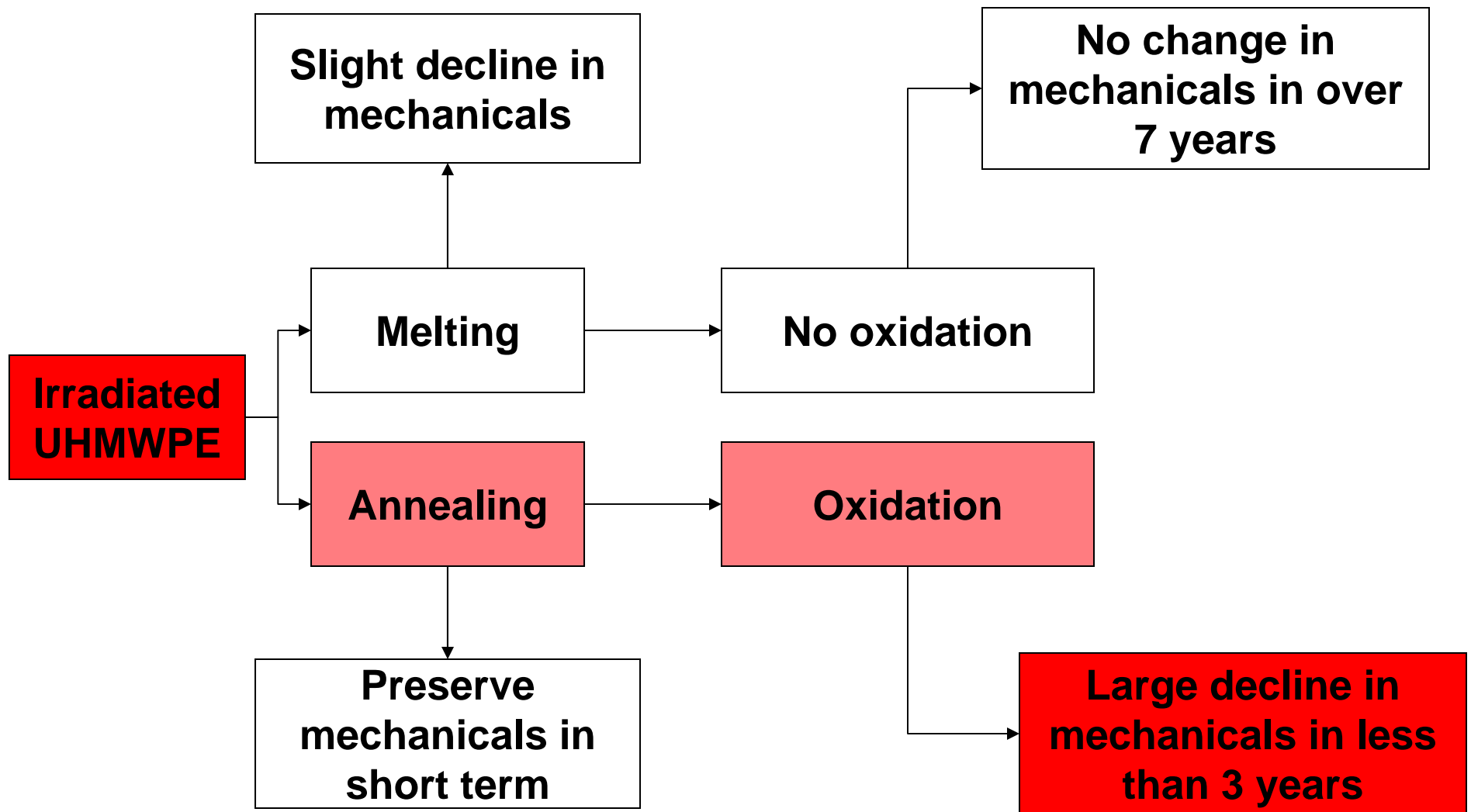
Backside Wear

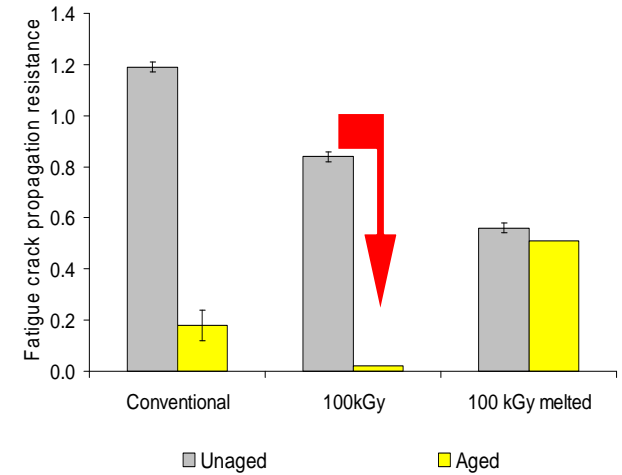
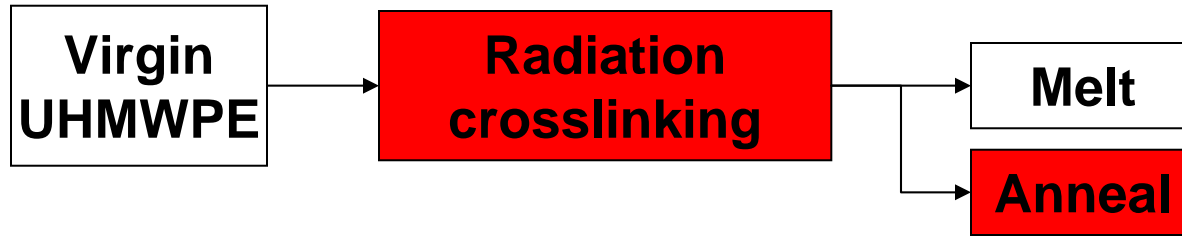


Effect of counterface roughness on wear

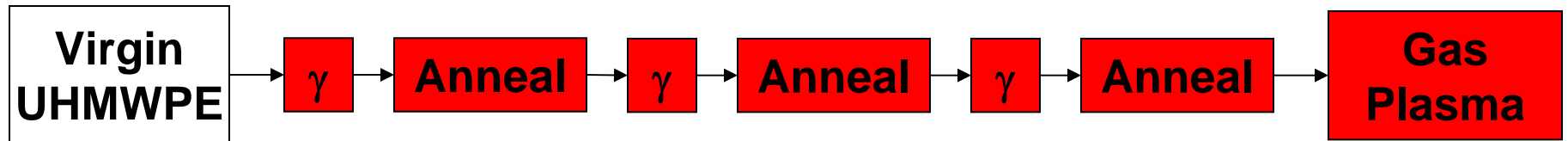


1st generation Xlinked UHMWPEs

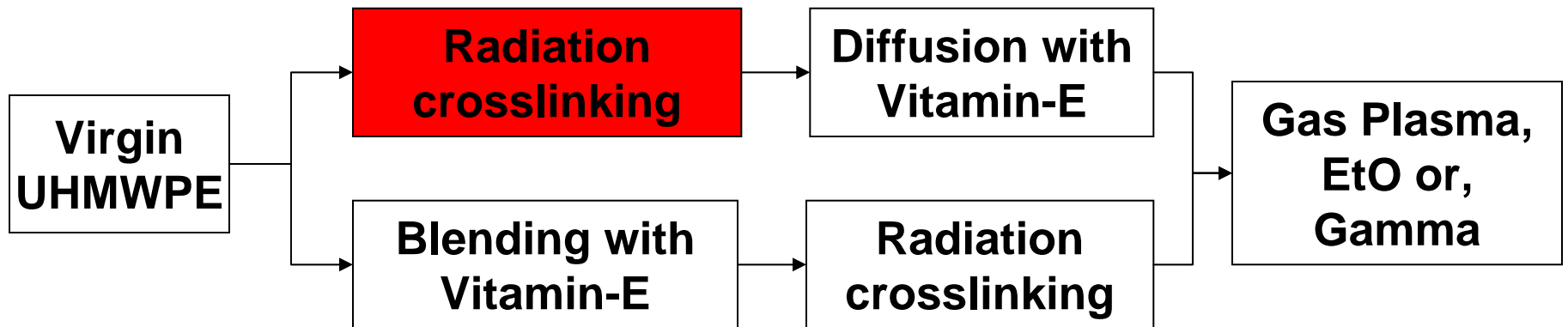




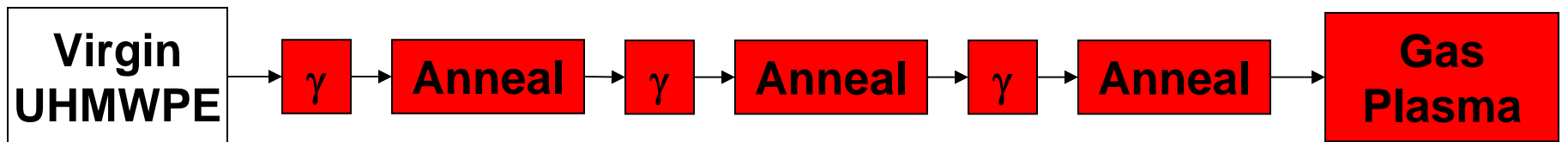
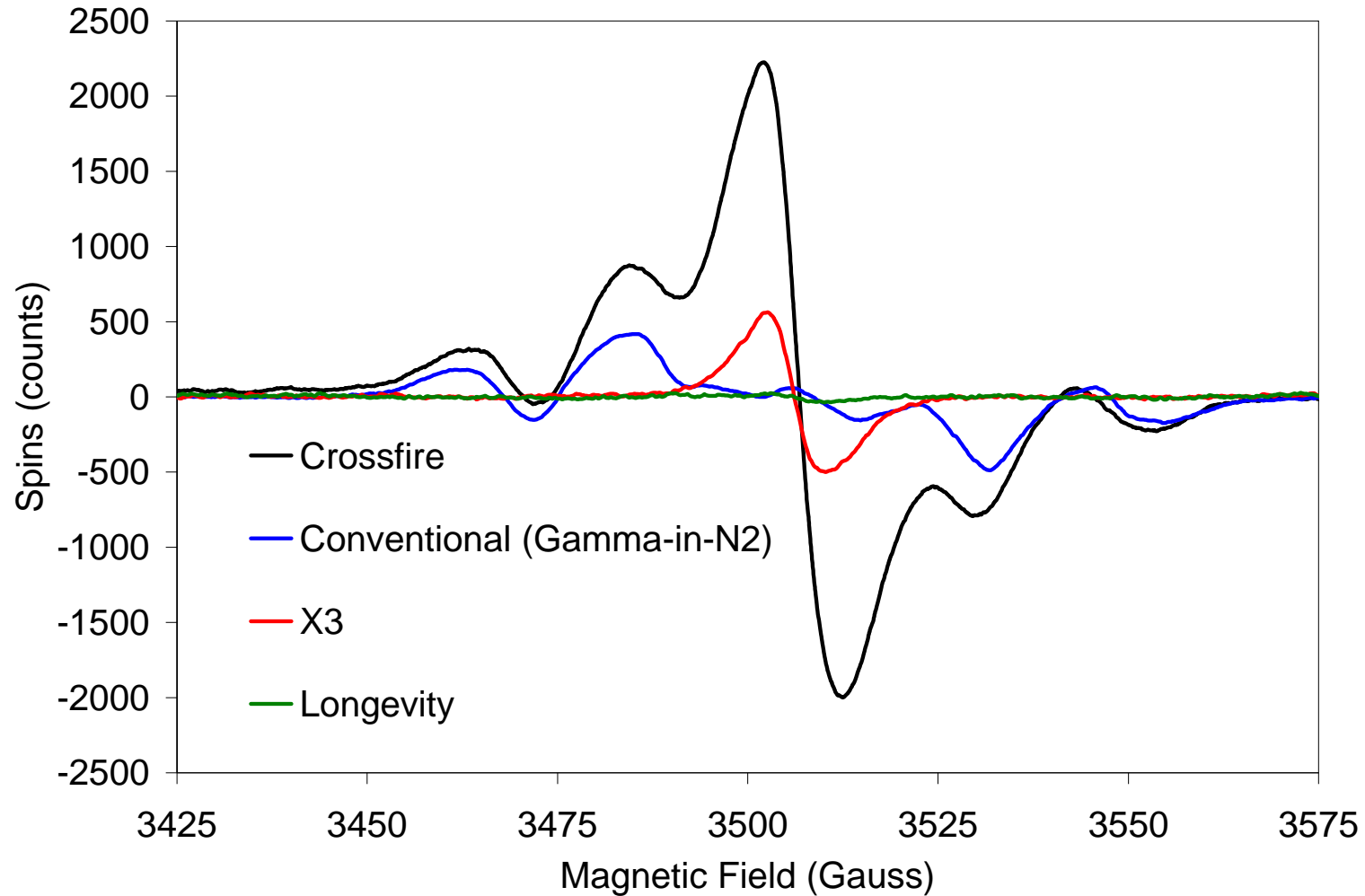
X3

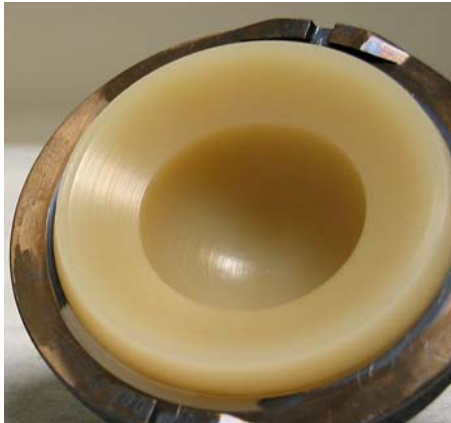


Vitamin-E

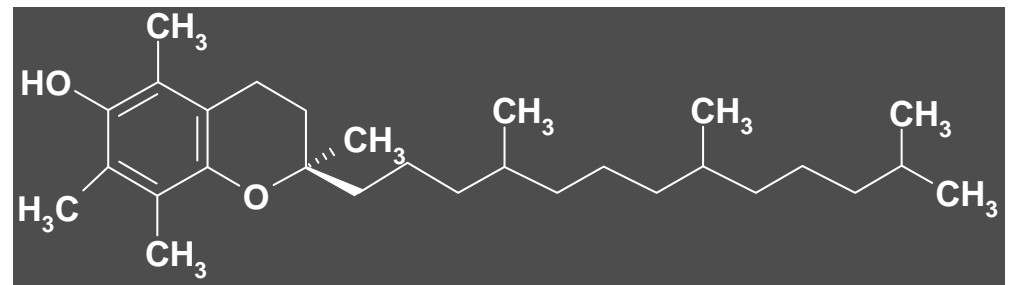
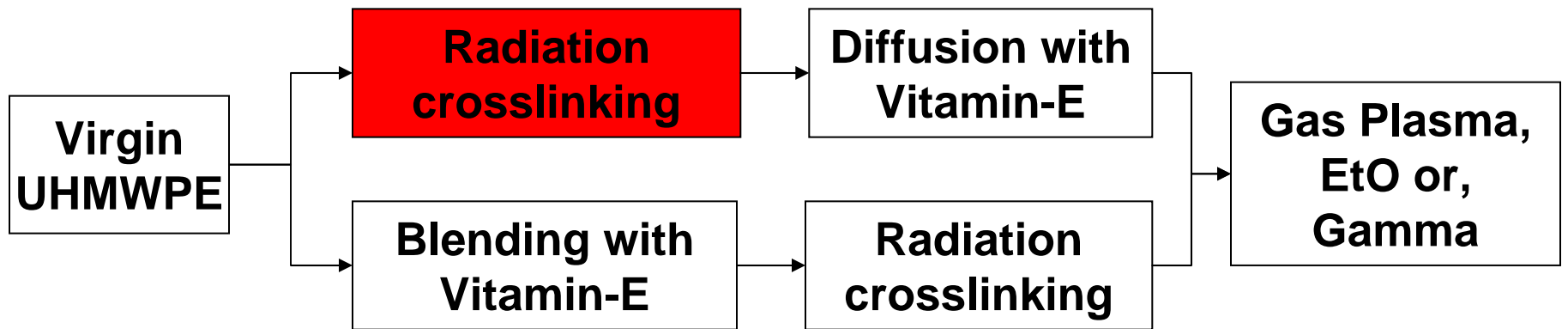


Residual Free Radicals in X3

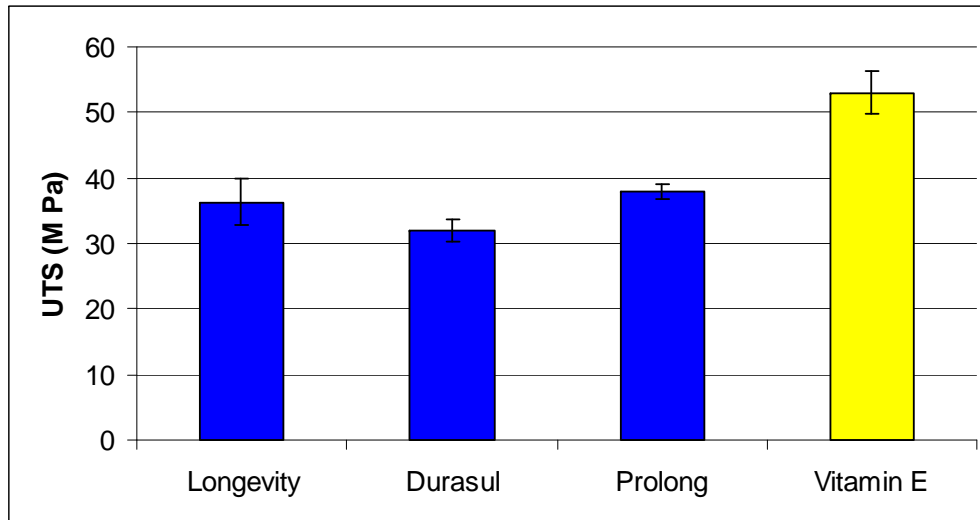




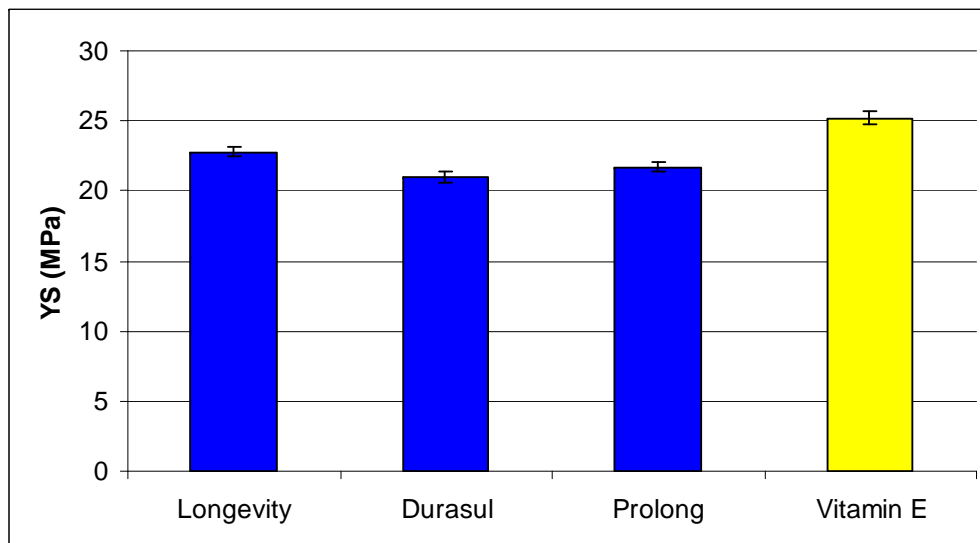
Vitamin-E



Mechanicals – VitE/UHMWPE Blend

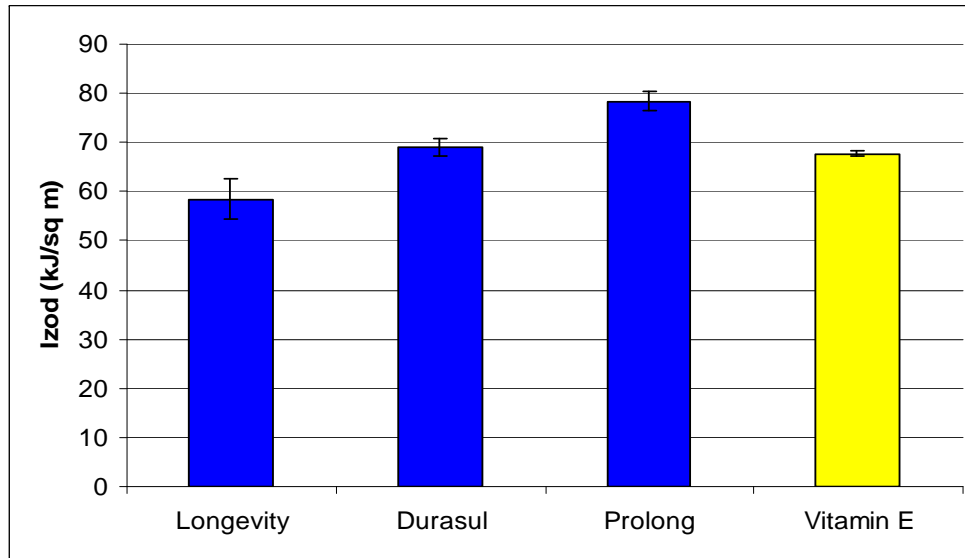


Improved toughness
Ultimate Tensile Strength



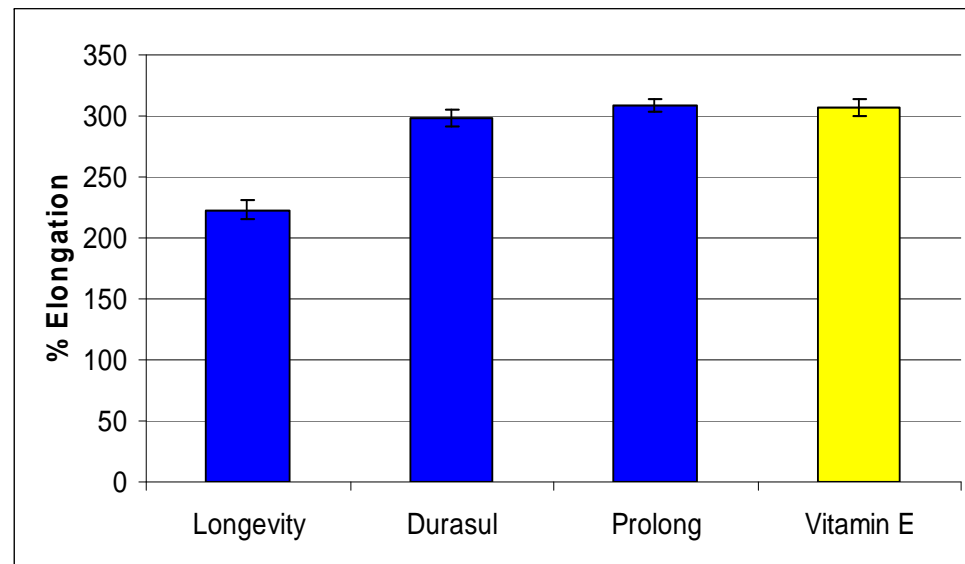
Improved deformation resistance
Yield Strength

Mechanicals – VitE/UHMWPE Blend



Equivalent impact strength

Izod Impact

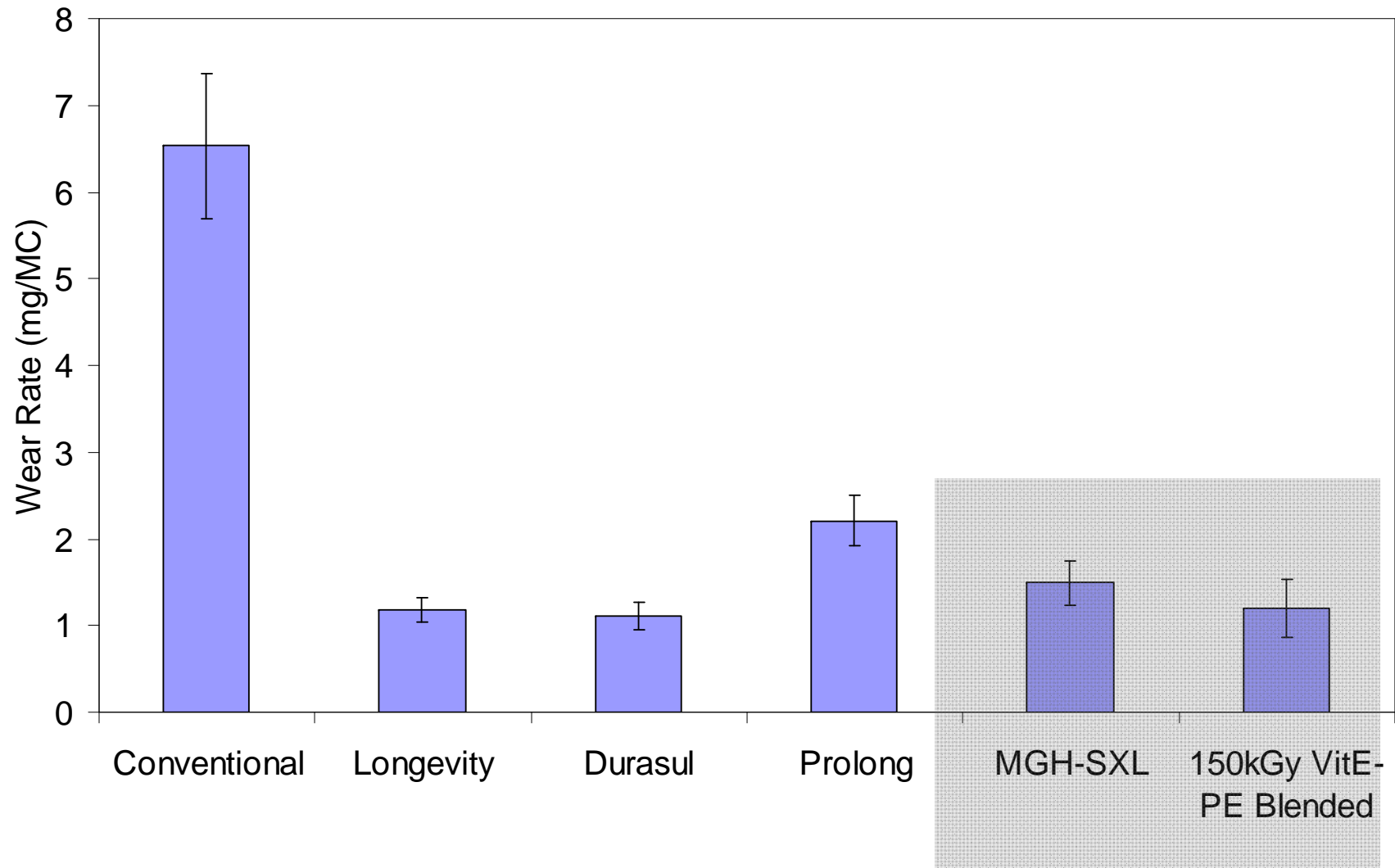


Equivalent elongation

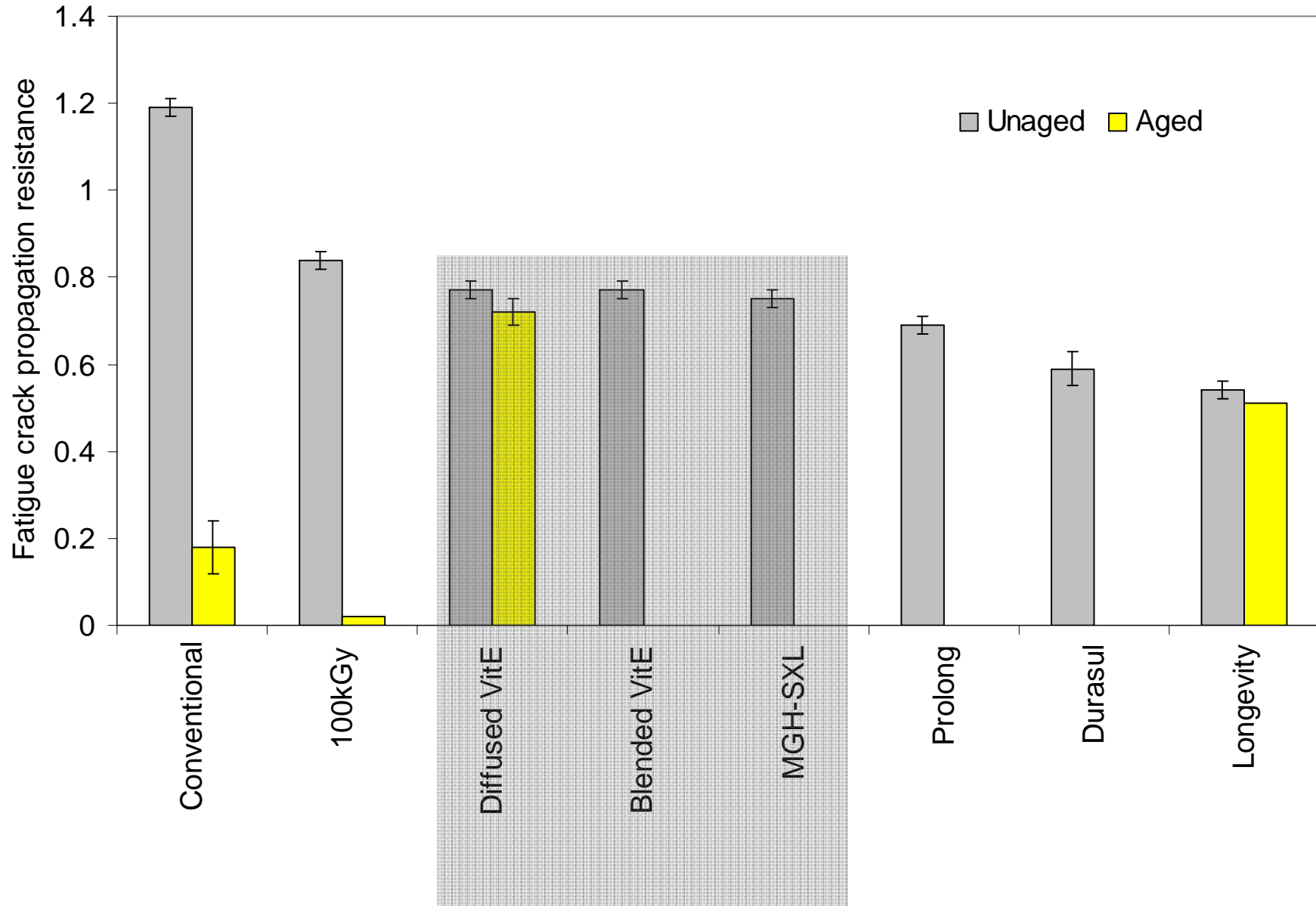
Property Comparison

	2 nd Generation Highly Crosslinked UHMWPE				
	GUR 1050	MGH-SXL	VitE/PE diffused	VitE/PE Blended	100 kGy Melted
UTS (MPa)	53 ± 1	51 ± 1	49 ± 2	53 ± 3	36 ± 4
e _b (%)	311 ± 9	237 ± 4	239 ± 7	301 ± 7	223 ± 8
Cryst (%)	50 ± 4	54 ± 1	51 ± 3	59	49 ± 1

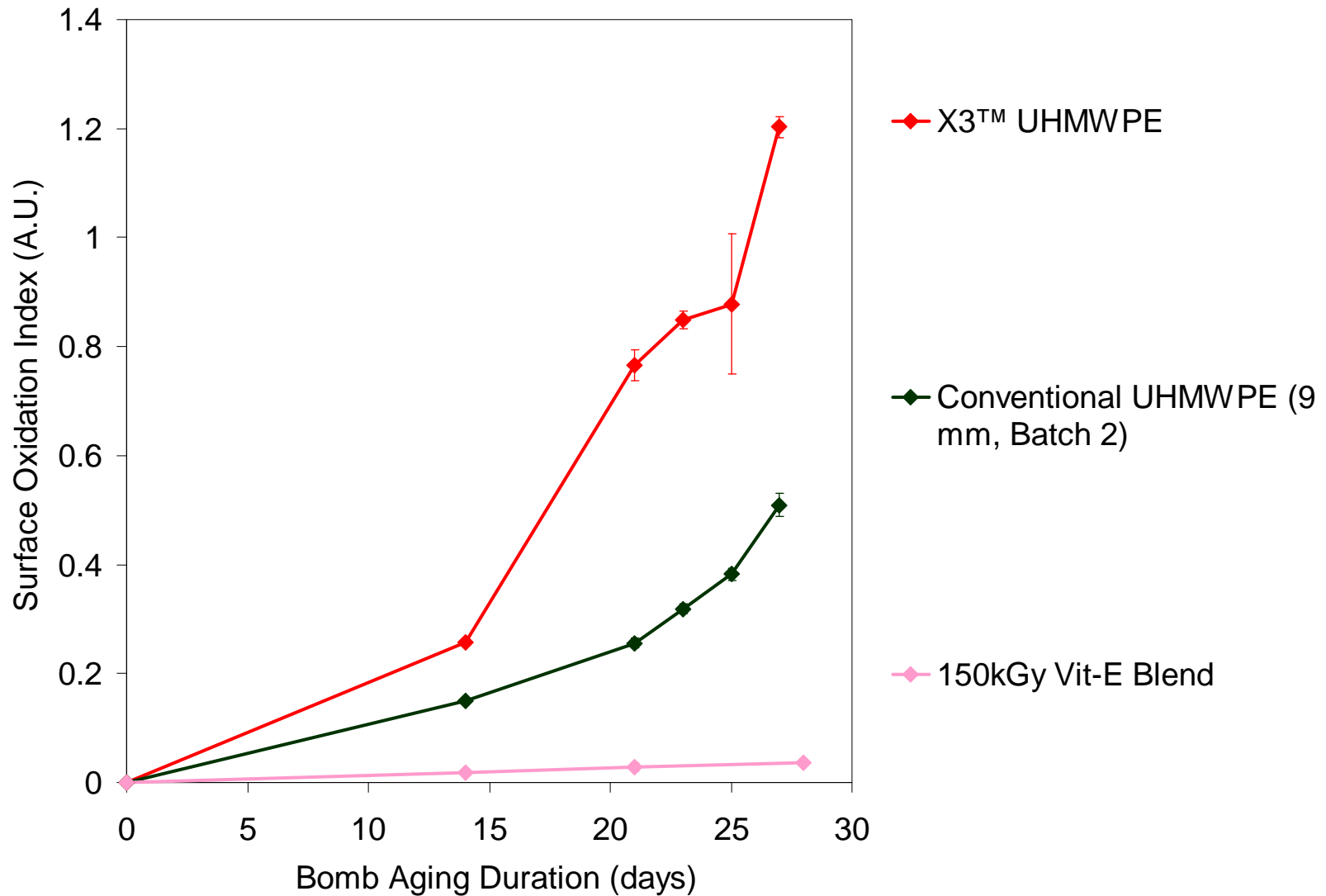
POD Wear Comparison



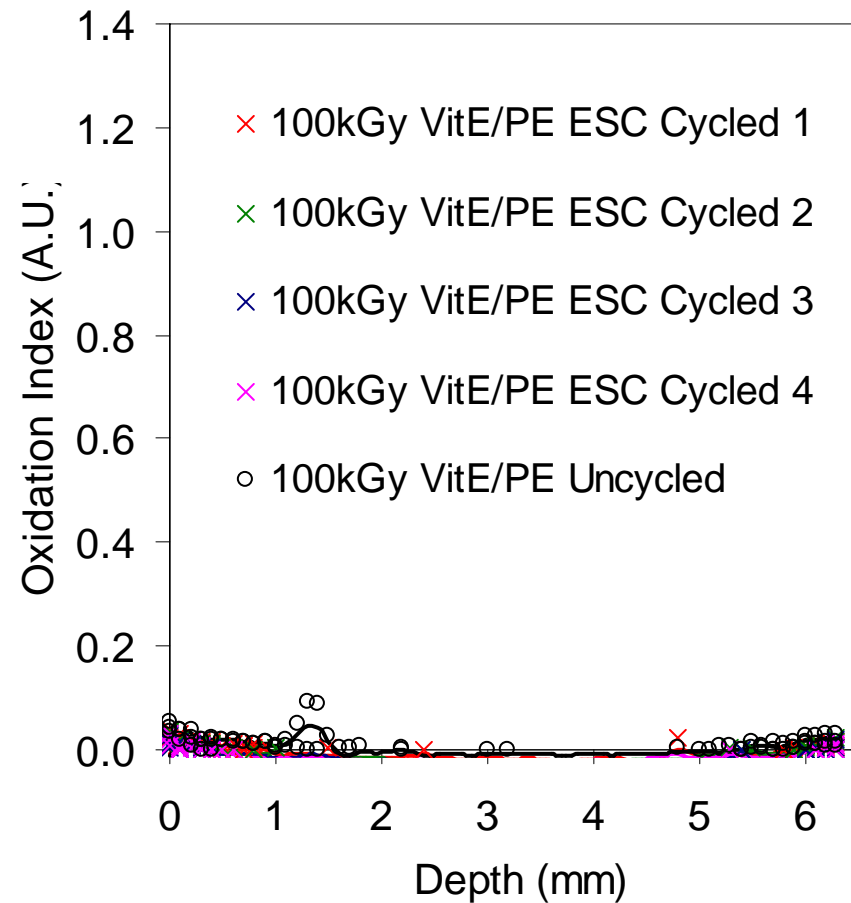
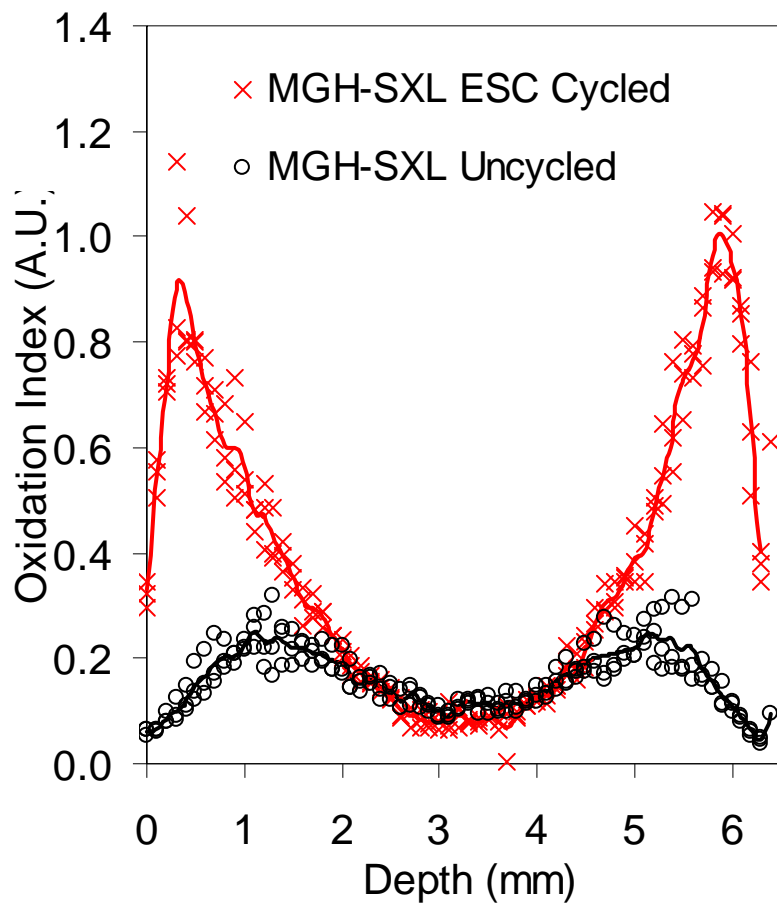
Fatigue Crack Propagation



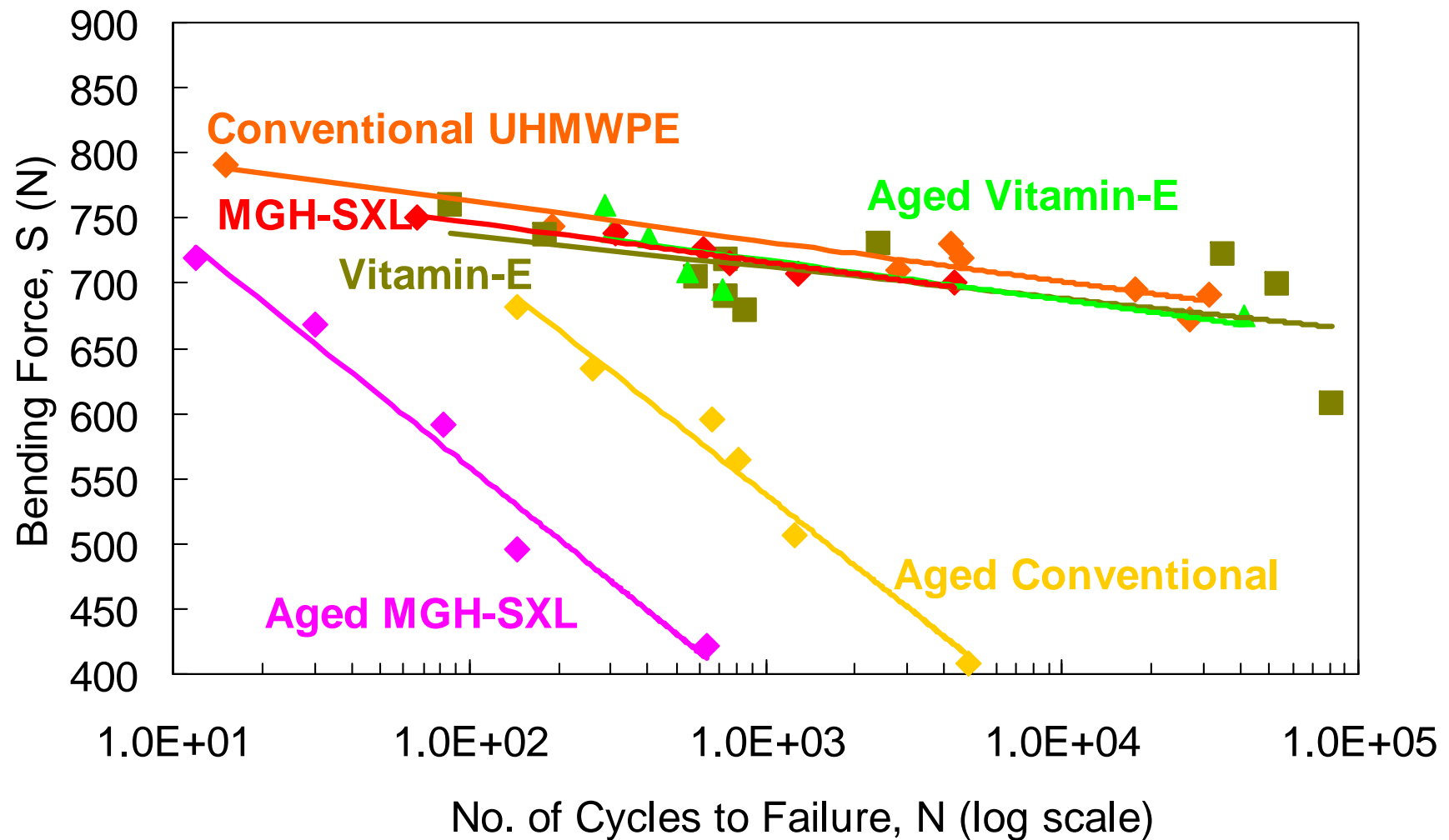
Oxidative Stability: Long Term Aging



Environmental Stress Cracking



Bending Fatigue Comparison



Summary

- **X3**
 - Low wear
 - Contains free radicals
 - Prone to oxidation
 - Long-term performance is questionable due to compromised oxidative stability
- **VitE Stabilized Radiation Crosslinked UHMWPE**
 - Low wear
 - No compromise on oxidation resistance of virgin UHMWPE
 - Higher strength and higher fatigue
 - Suitable for high activity patients and also for more demanding joint implant designs



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