In vivo oxidation in Highly Cross-linked Tibial Bearings

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(1) Research funding DePuy/J&J
(2) Research funding ConforMIS
(3) Consultant DePuy/J&J

Highly Cross-linked (HXL) Polyethylene

- Produced using irradiation:
  - e-beam
  - gamma
- Post-irradiation thermal processing used to address free radicals from irradiation:
  - annealing below melt temperature
  - remelting above melt temperature

Highly Cross-linked Tibial Polyethylene

Material (Manufacturer)	Resin	Irradiation Source/Dose (KGray)	Thermal Treatment	Sterilization Method
Durasul (Sulzer/Zimmer)	1050	e-beam / 95	remelt	EtO
Prolong (Zimmer)	1050	e-beam / 64	remelt	Gas plasma
X3 (Stryker)	1020	gamma / 90	anneal	Gas plasma
XLK (DePuy)	1020	gamma / 50	remelt	Gas plasma

What can be learned from highly cross-linked tibial retrievals?

Effect of:

- post-retrieval (*ex vivo*) shelf time
- *in vivo* time
- post-irradiation thermal treatment
- irradiation dose
- irradiation source
- resin

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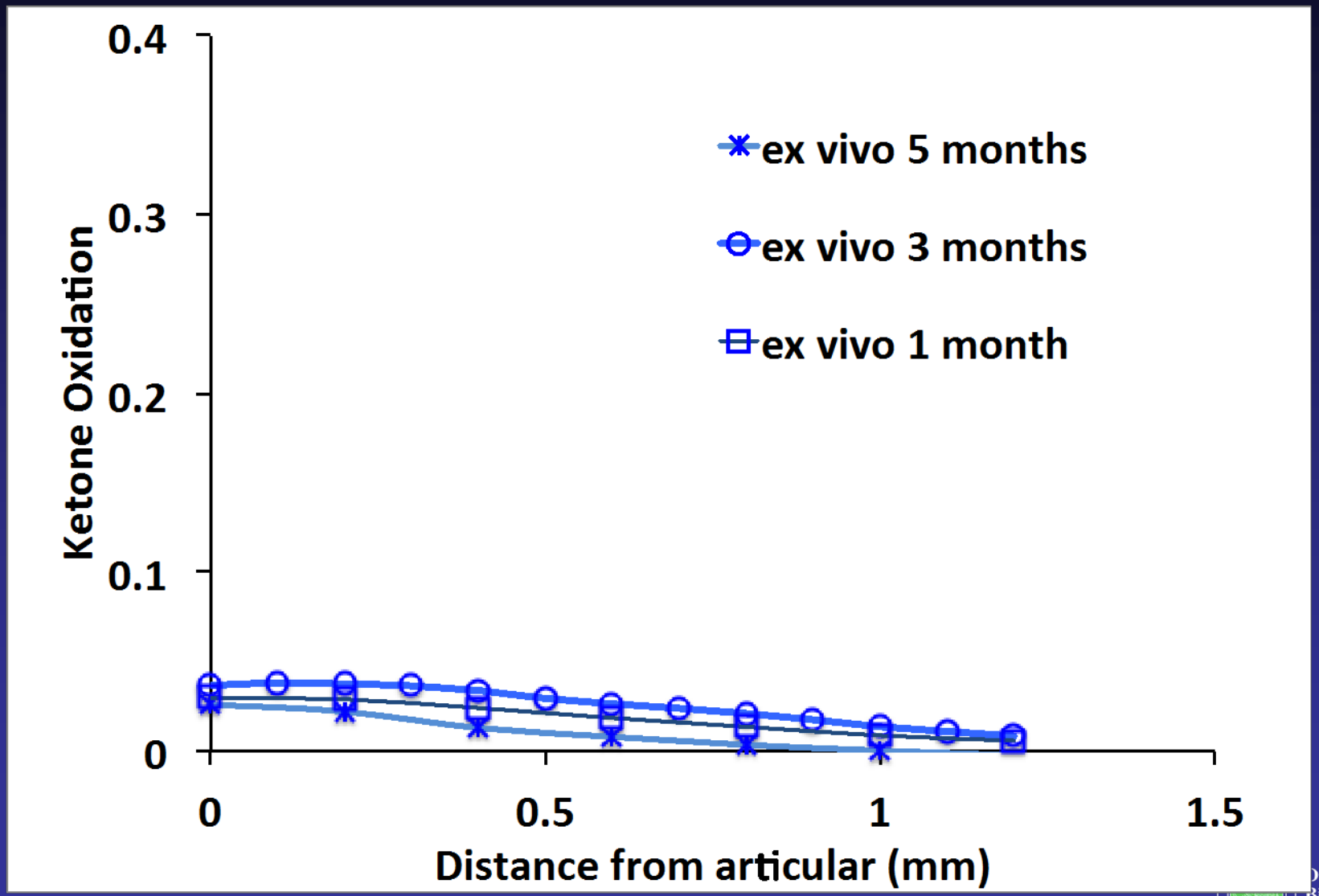
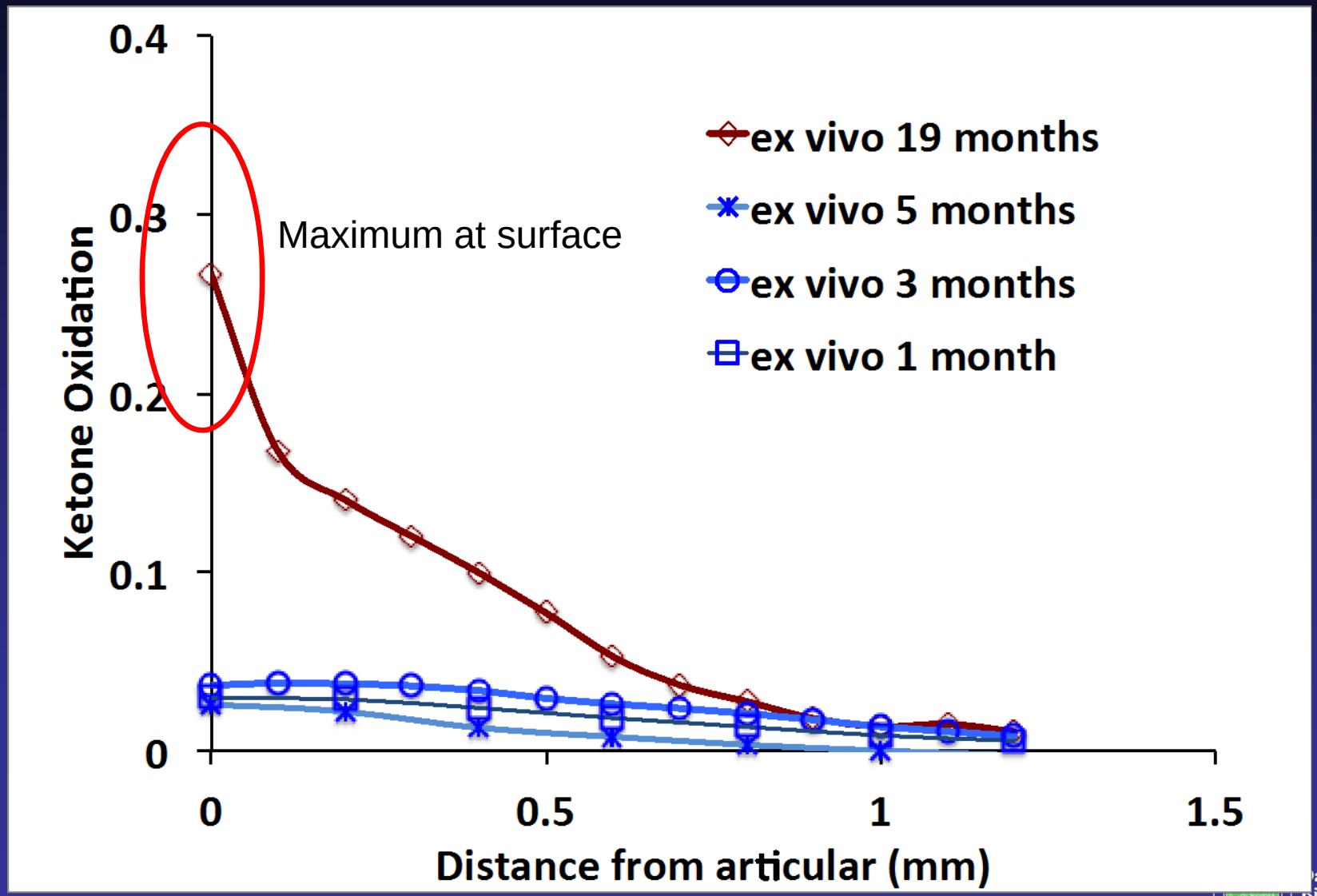
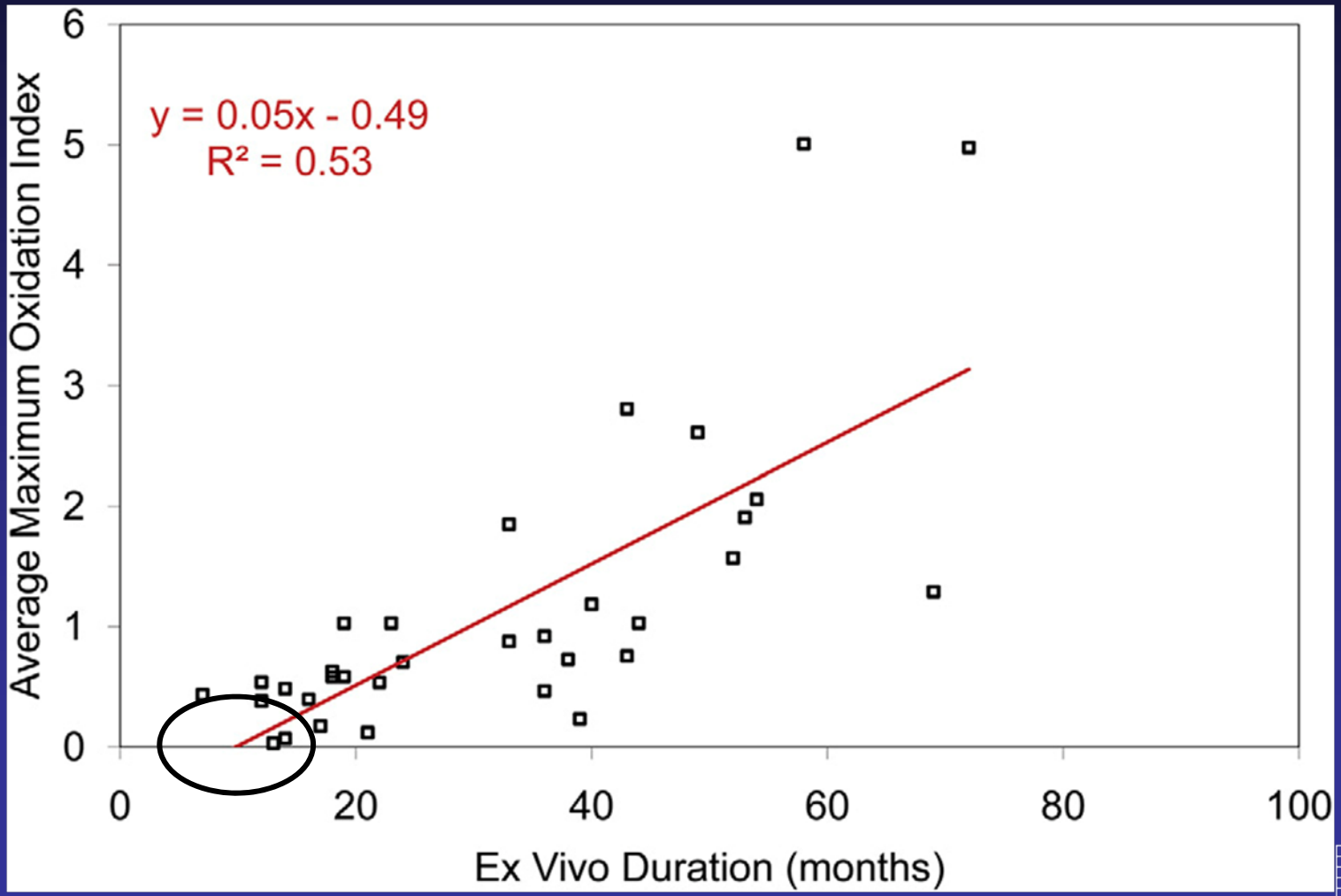
Effect of post-retrieval (*ex vivo*) shelf time



Effect of post-retrieval (*ex vivo*) shelf time



Muratoglu OK, et al: Ex vivo stability loss of irradiated and melted UHMWPE. J Bone Joint Surg Am. 2010;92:2809-16



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Materials

Retrieved HXL polyethylene tibial inserts

- < 6 months *ex vivo* before analysis
- 73 retrievals
- Durasul (5): mean *ex vivo* time 2.2 months
- Prolong (23): mean *ex vivo* time 1.9 months
- X3 (21): mean *ex vivo* time 2.0 months
- XLK (24): mean *ex vivo* time 2.9 months
- 0.1 – 6.9 years *in vivo*

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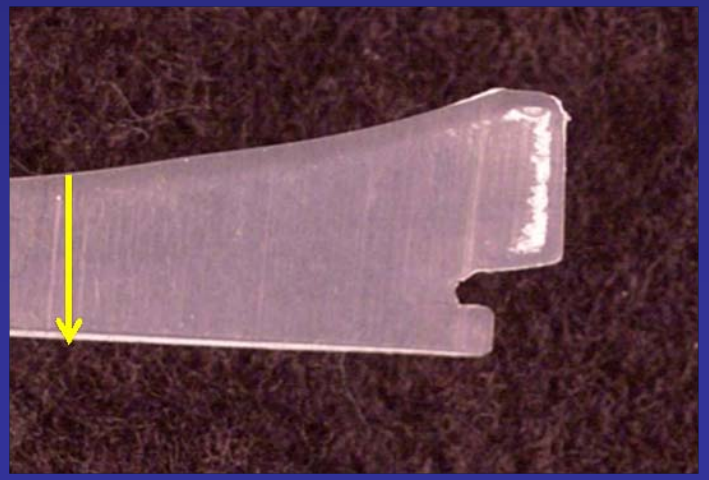
Methods

- Electron spin resonance
  - free radical concentration
- Fourier Transform infrared spectroscopy
  - oxidation, ketone peak height ratio (1715 cm^{-1}/1368 cm^{-1})

Denotes scan direction from articular to nonarticular surface



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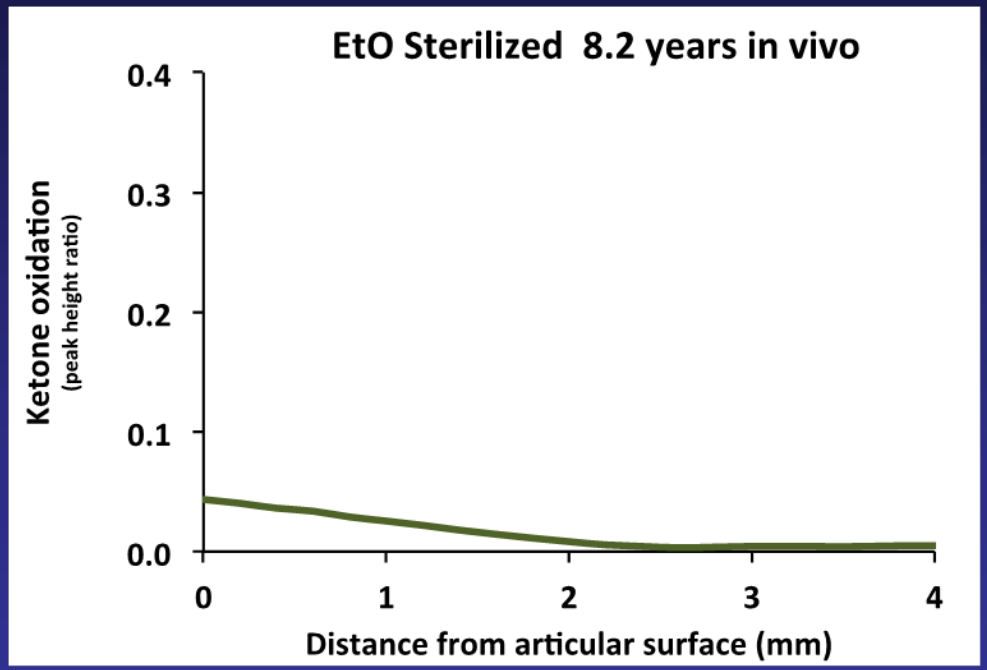
Retrievals

- Expectation: historical EtO sterilized UHMWPE best analogy for highly cross-linked, thermally stabilized UHMWPE *in vivo* oxidation



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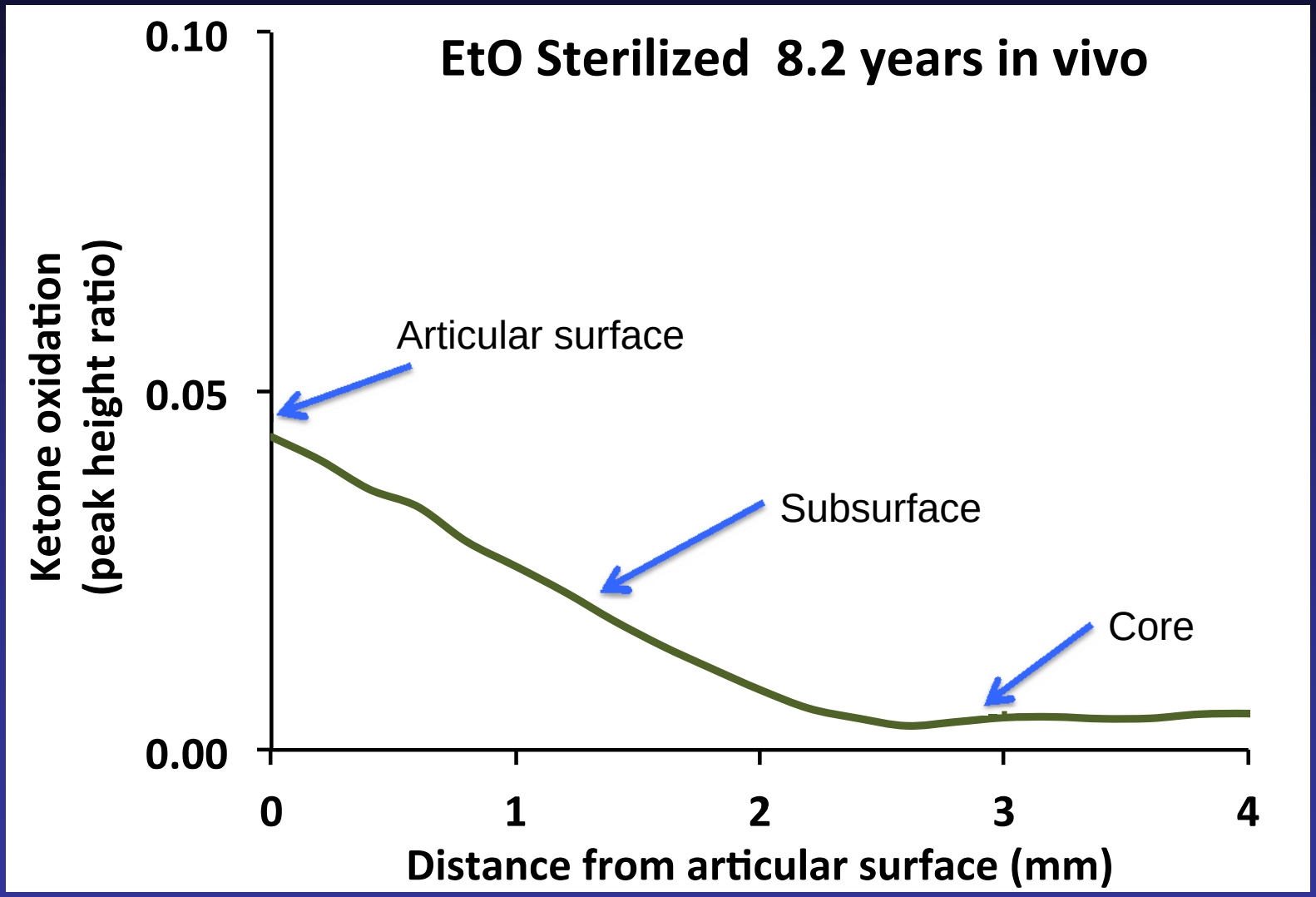
EtO Sterilized Standard UHMWPE



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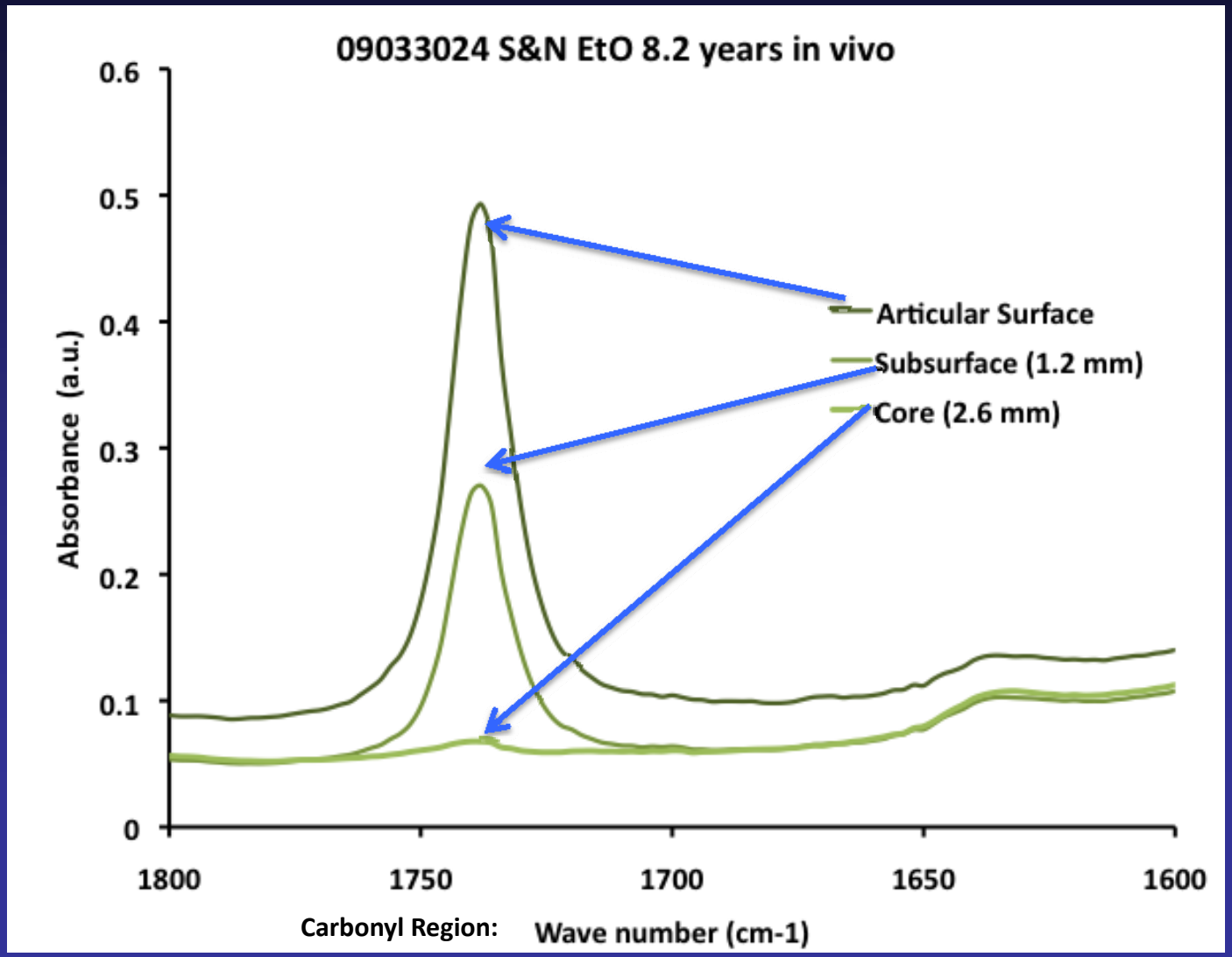
EtO Sterilized Standard UHMWPE



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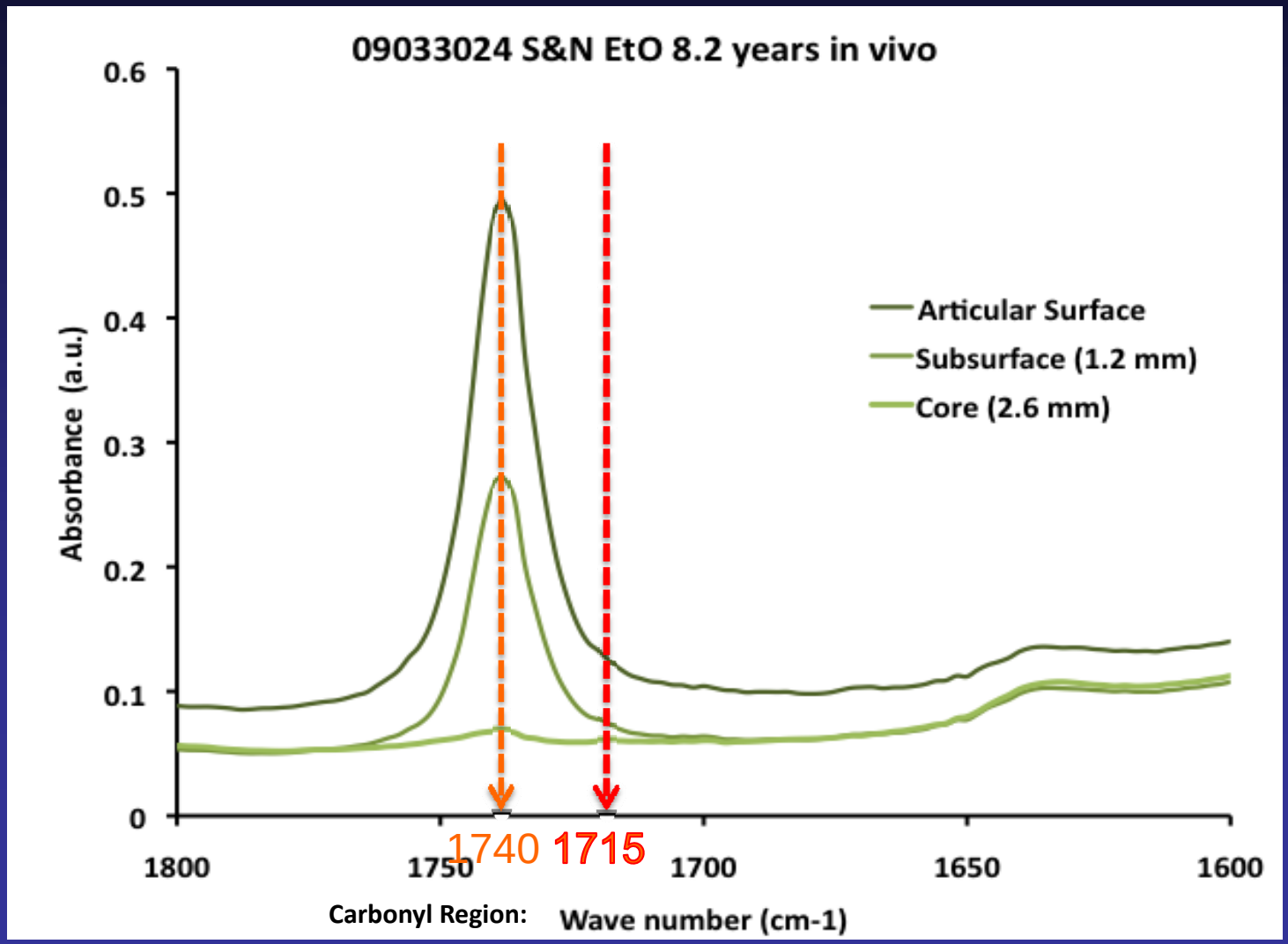
EtO Sterilized Standard UHMWPE



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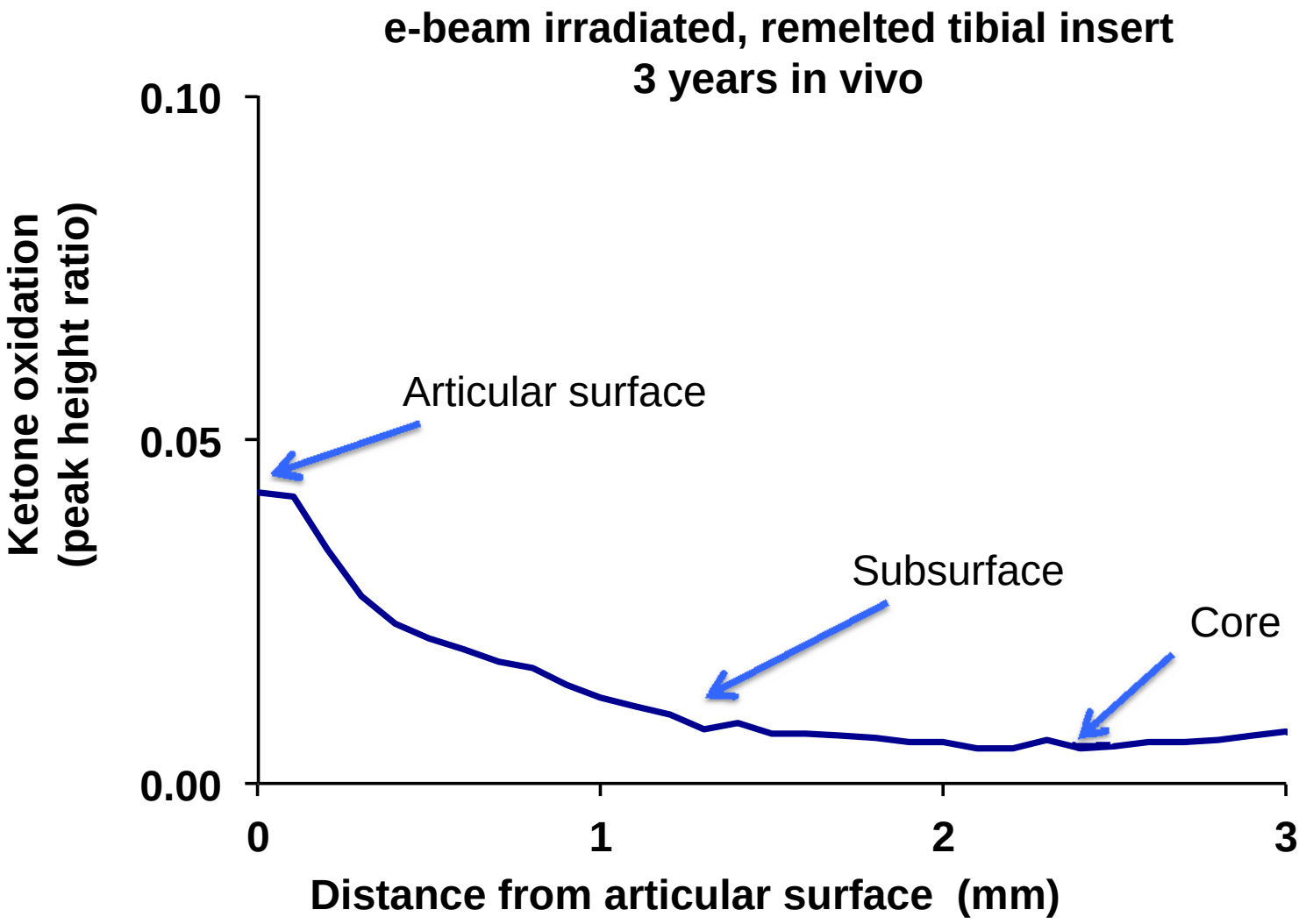
Highly Cross-linked Tibial Retrieval



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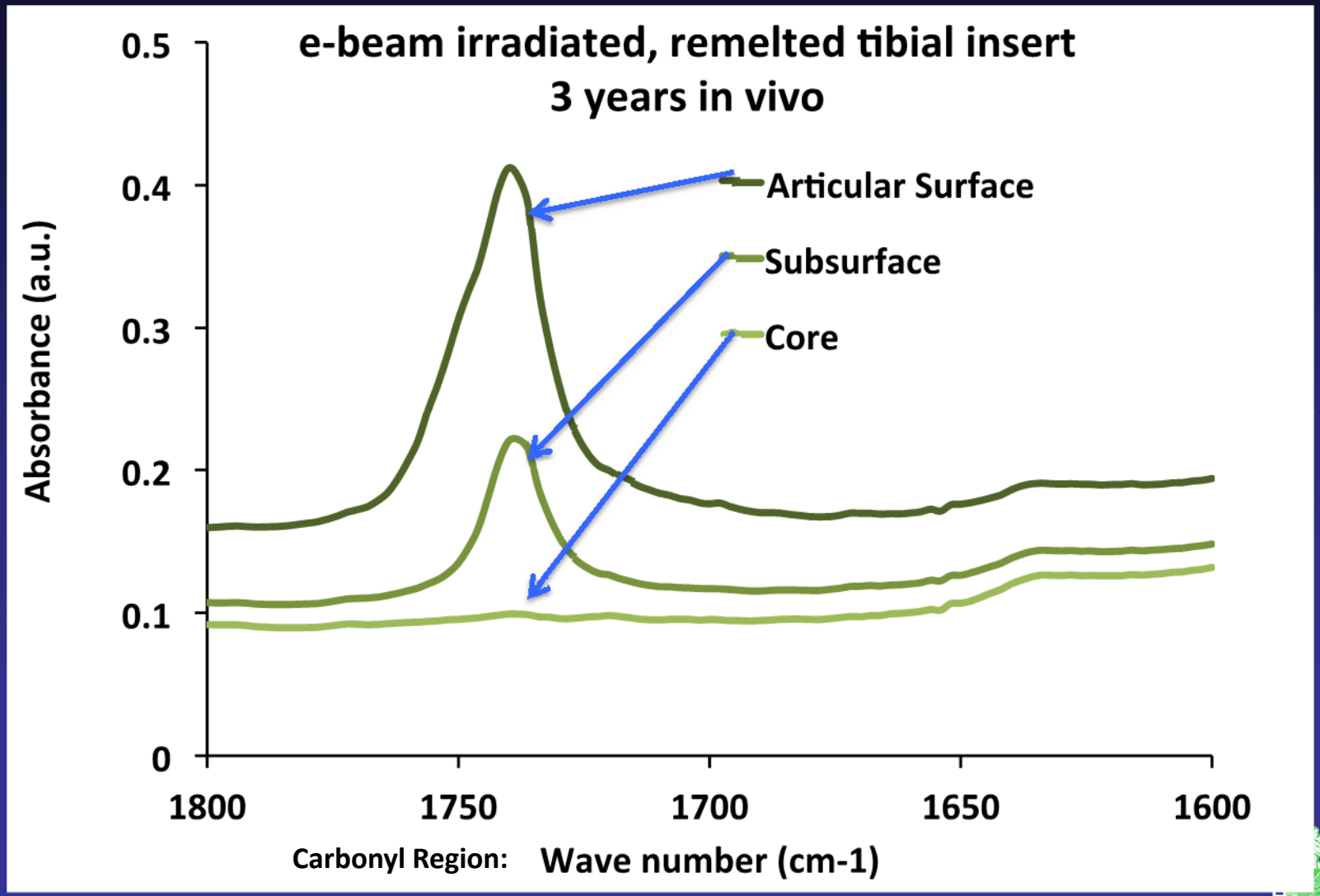
Highly Cross-linked Tibial Retrieval



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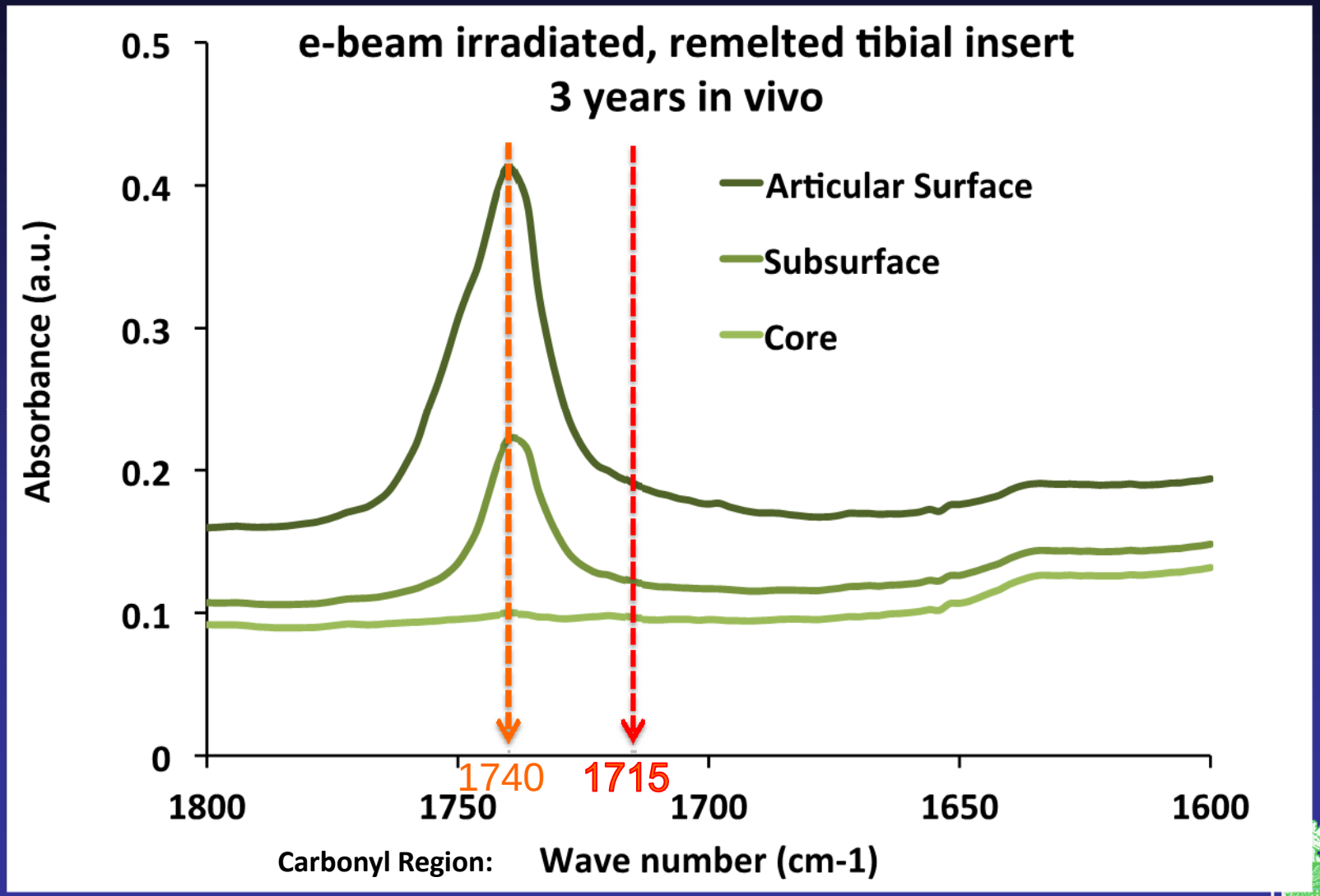
Highly Cross-linked Tibial Retrieval



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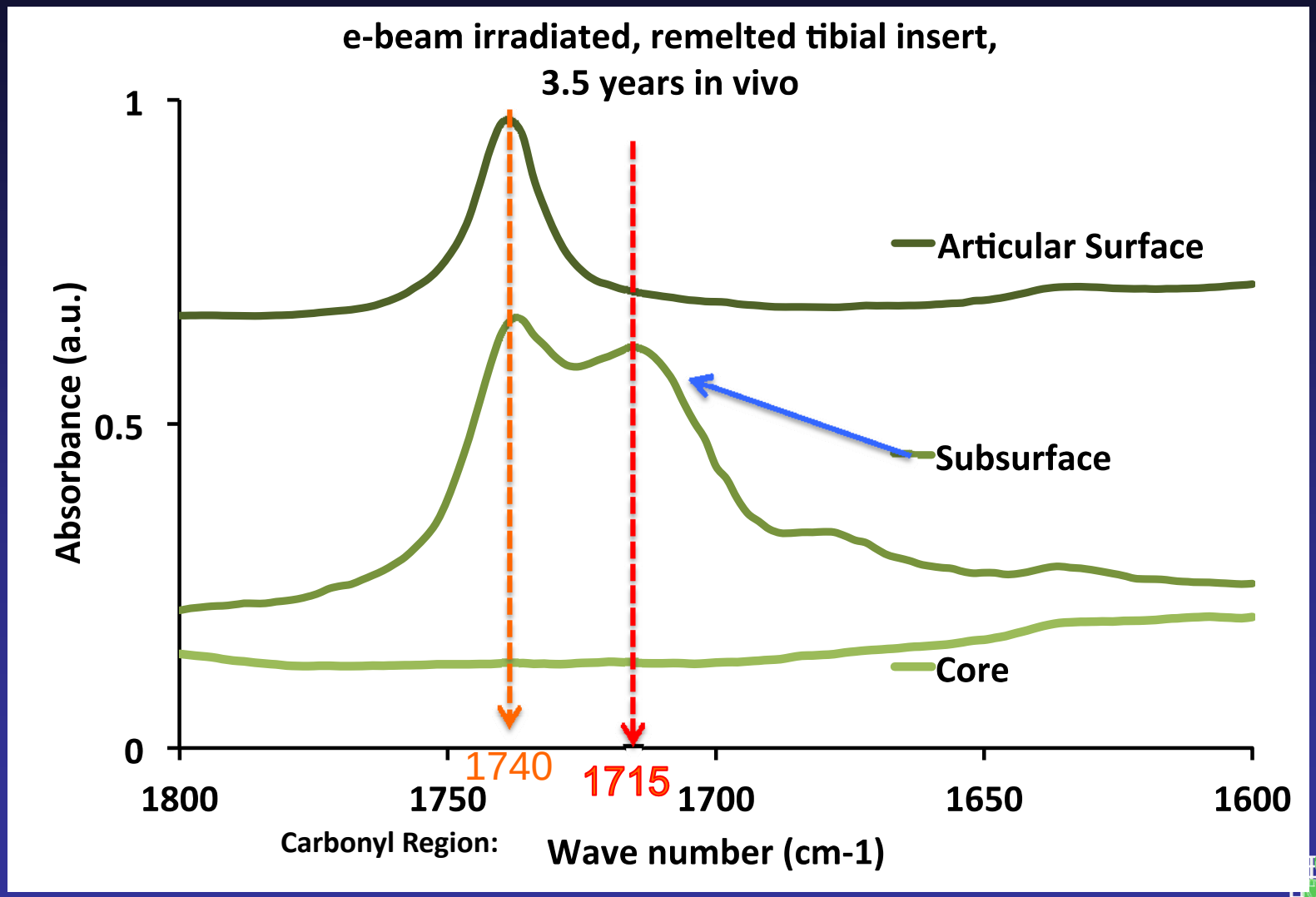
Highly Cross-linked Tibial Retrieval



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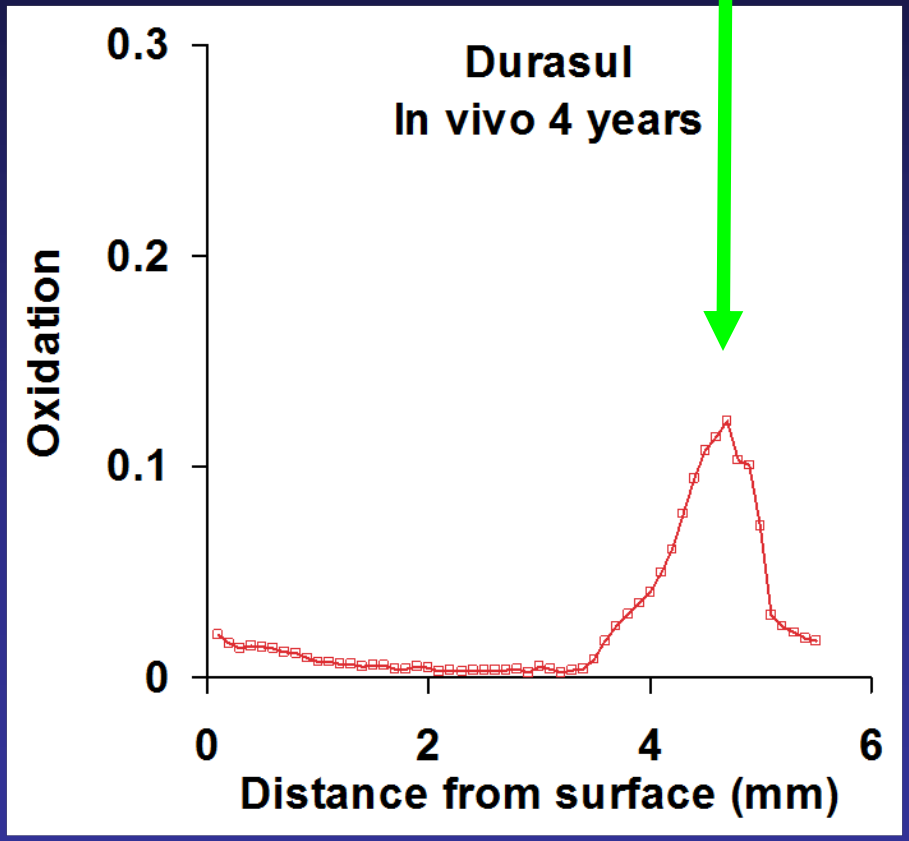
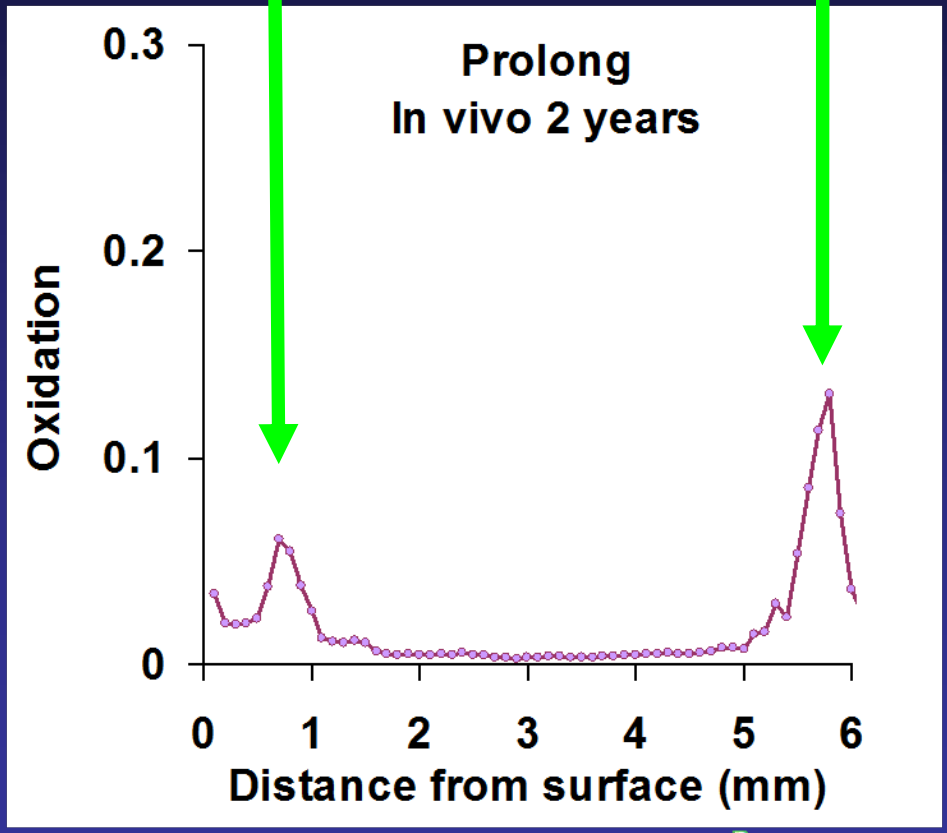
e beam-irradiated, remelted

Subsurface oxidation peak





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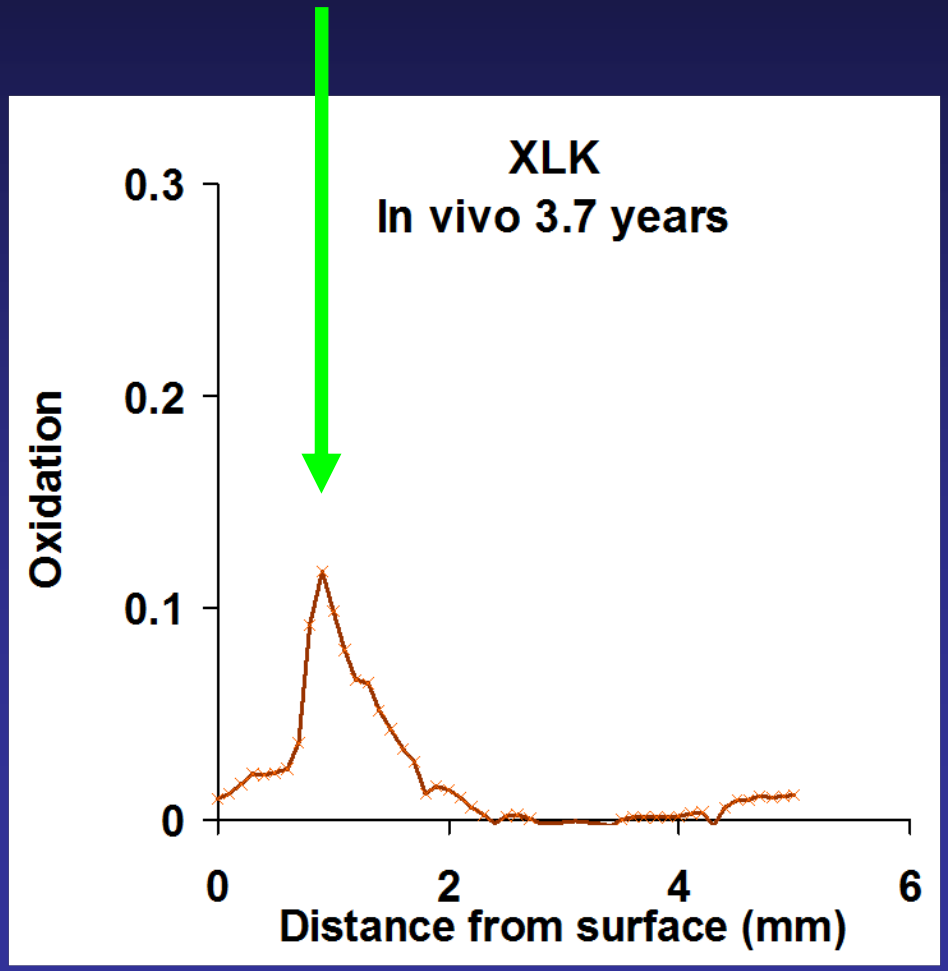
Gamma-irradiated, remelted

Subsurface oxidation peak



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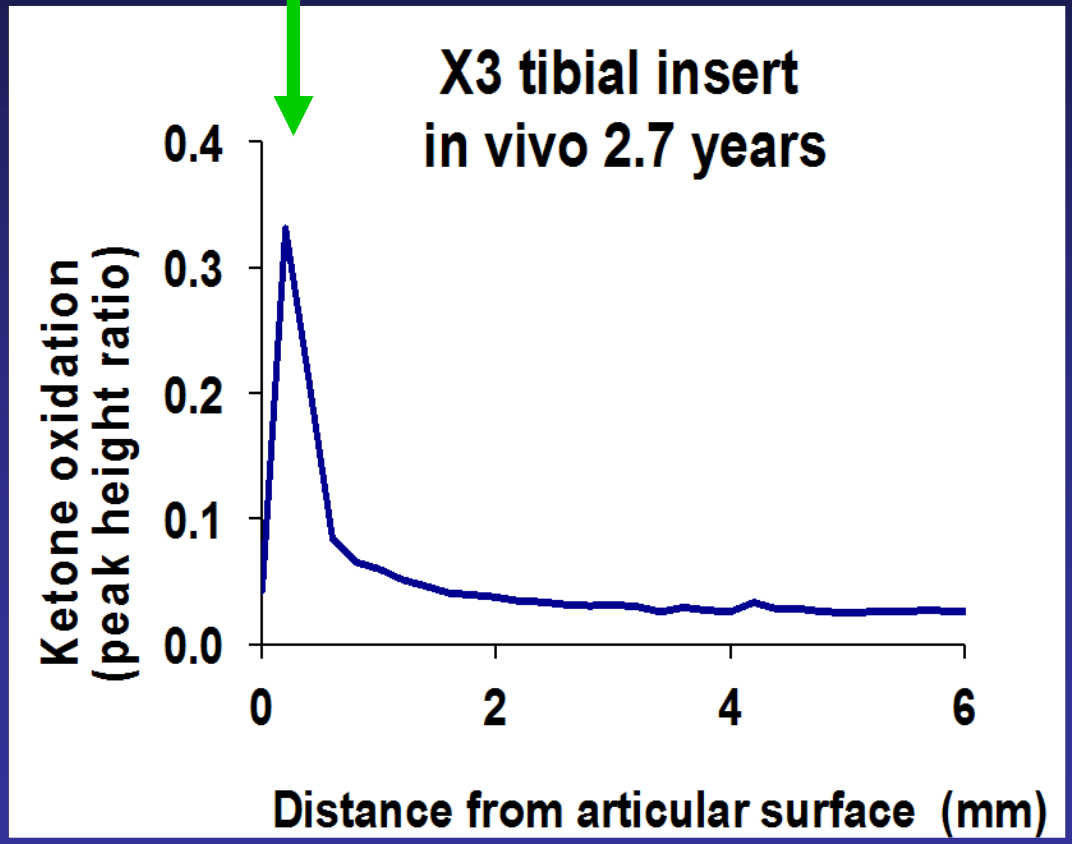
Gamma-irradiated, annealed

Subsurface oxidation peak



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What can be learned from highly cross-linked tibial retrievals?

Effect of:

- post-retrieval (*ex vivo*) shelf time
- *in vivo* time
- post-irradiation thermal treatment
- irradiation dose
- irradiation source
- resin

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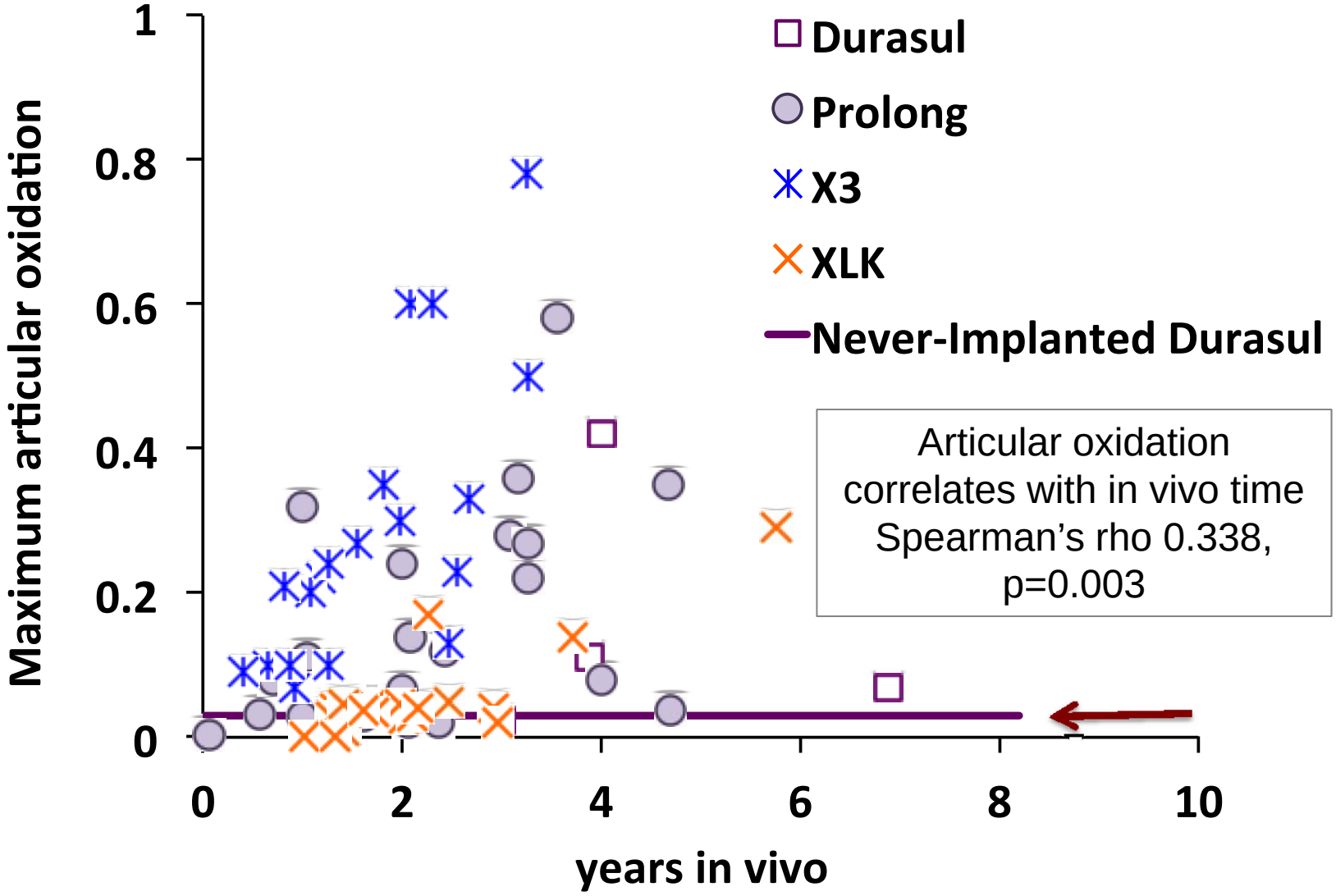
All HXL Tibial Retrievals



What can be learned from highly cross-linked tibial retrievals?

Effect of:

- post-retrieval (*ex vivo*) shelf time
- *in vivo* time
- post-irradiation thermal treatment: annealing
  remelting
- irradiation dose
- irradiation source
- resin

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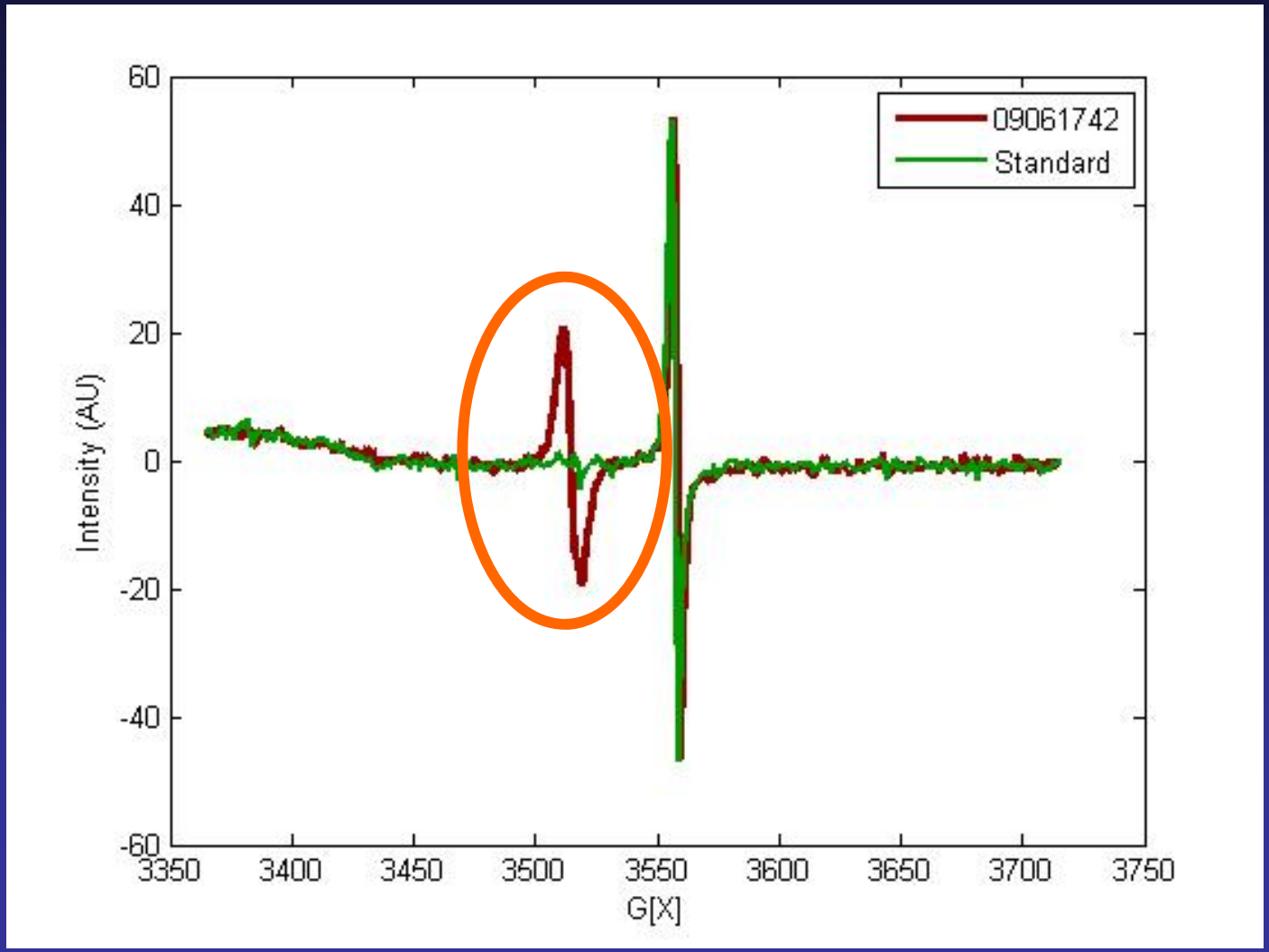
Free Radical Concentration annealed HXL: in vivo 1.3 years



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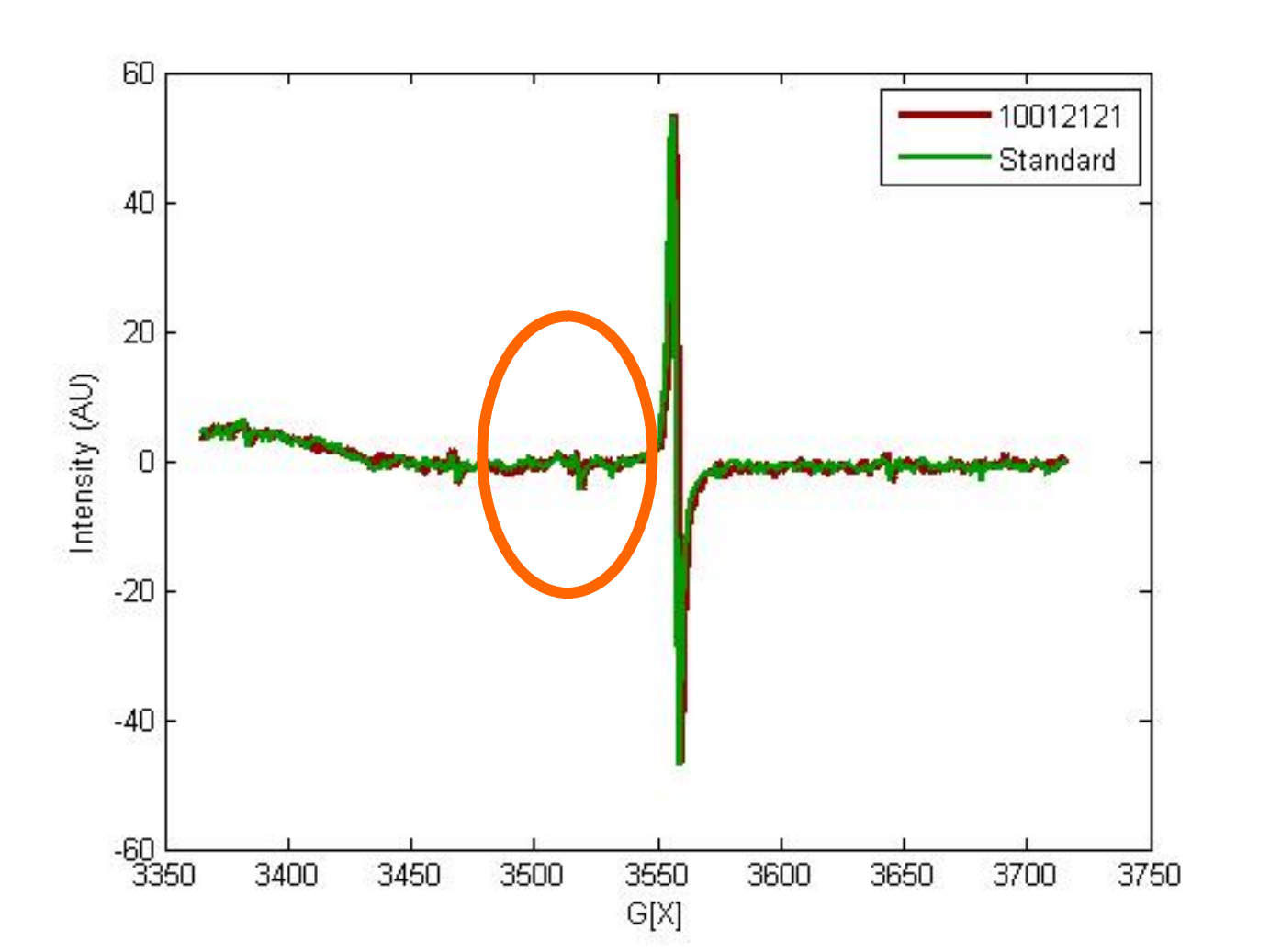
Free Radical Concentration: remelted HXL in vivo 9.8 years



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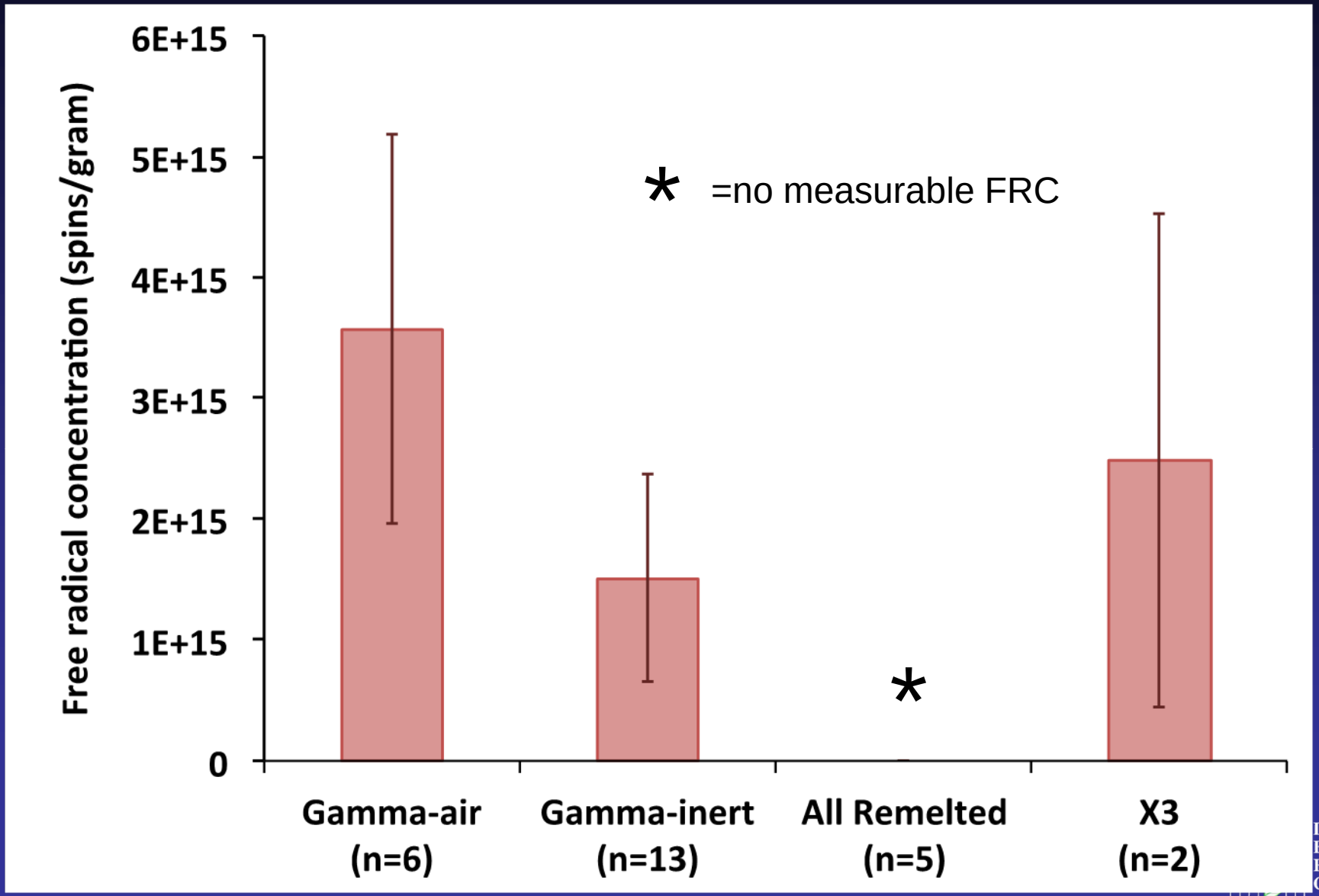
Free Radical Concentration: tibial retrievals



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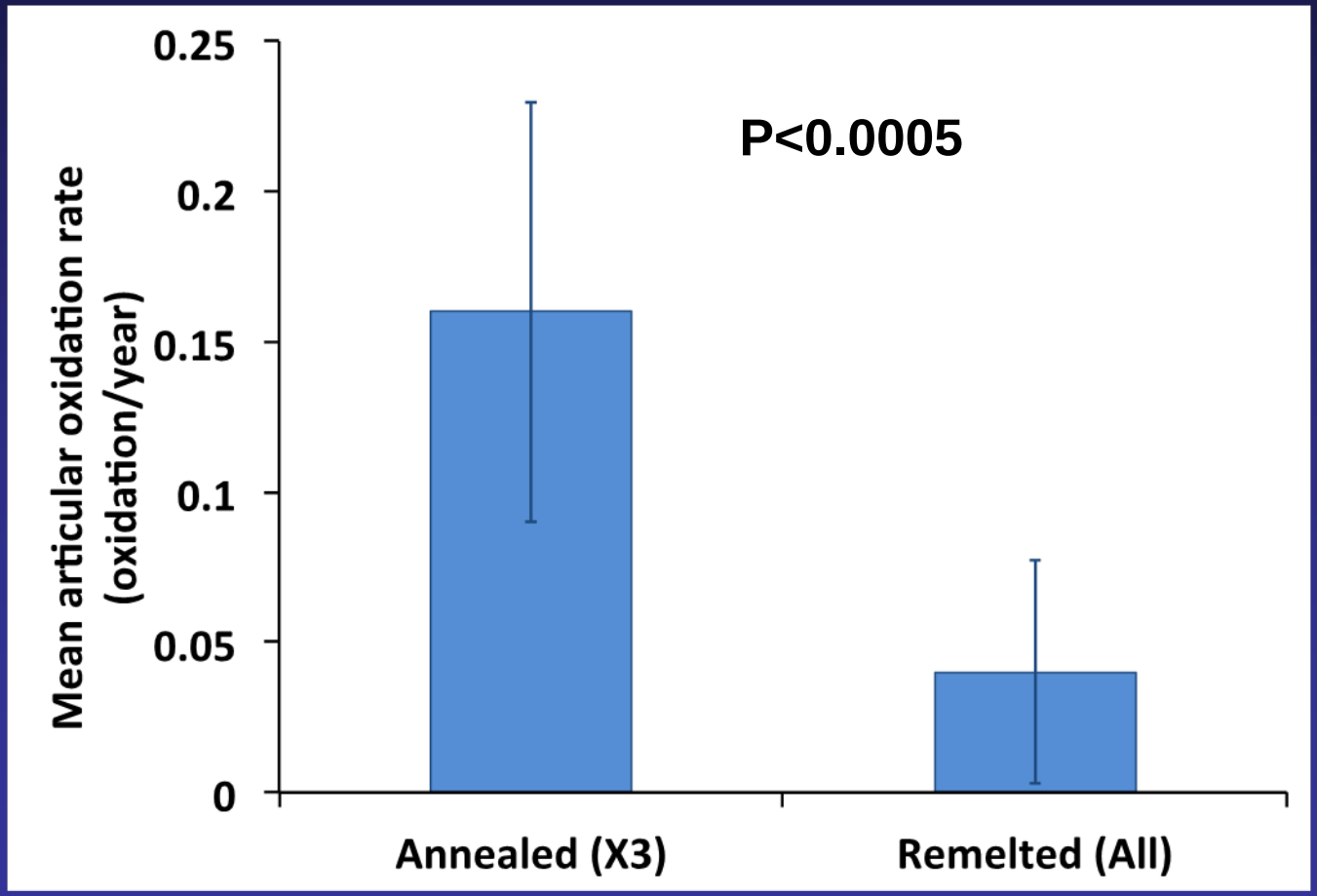
Articular oxidation rate

Articular oxidation rate correlates with post-irradiation thermal treatment, p<0.0005



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Highly Cross-linked Tibial Polyethylene

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X3 (Stryker)	1020	gamma / 90	anneal	Gas plasma
XLK (DePuy)	1020	gamma / 50	remelt	Gas plasma

All HXL Tibial Retrievals

- Articular oxidation rate no correlation with:
  - cross-linking source* (e-beam vs. gamma)

    Spearman's rho=0.080, p=0.503 or
  - resin type* (1050 versus 1020)

    Spearman's rho=0.080, p=0.503

*Cannot differentiate with current retrieval series

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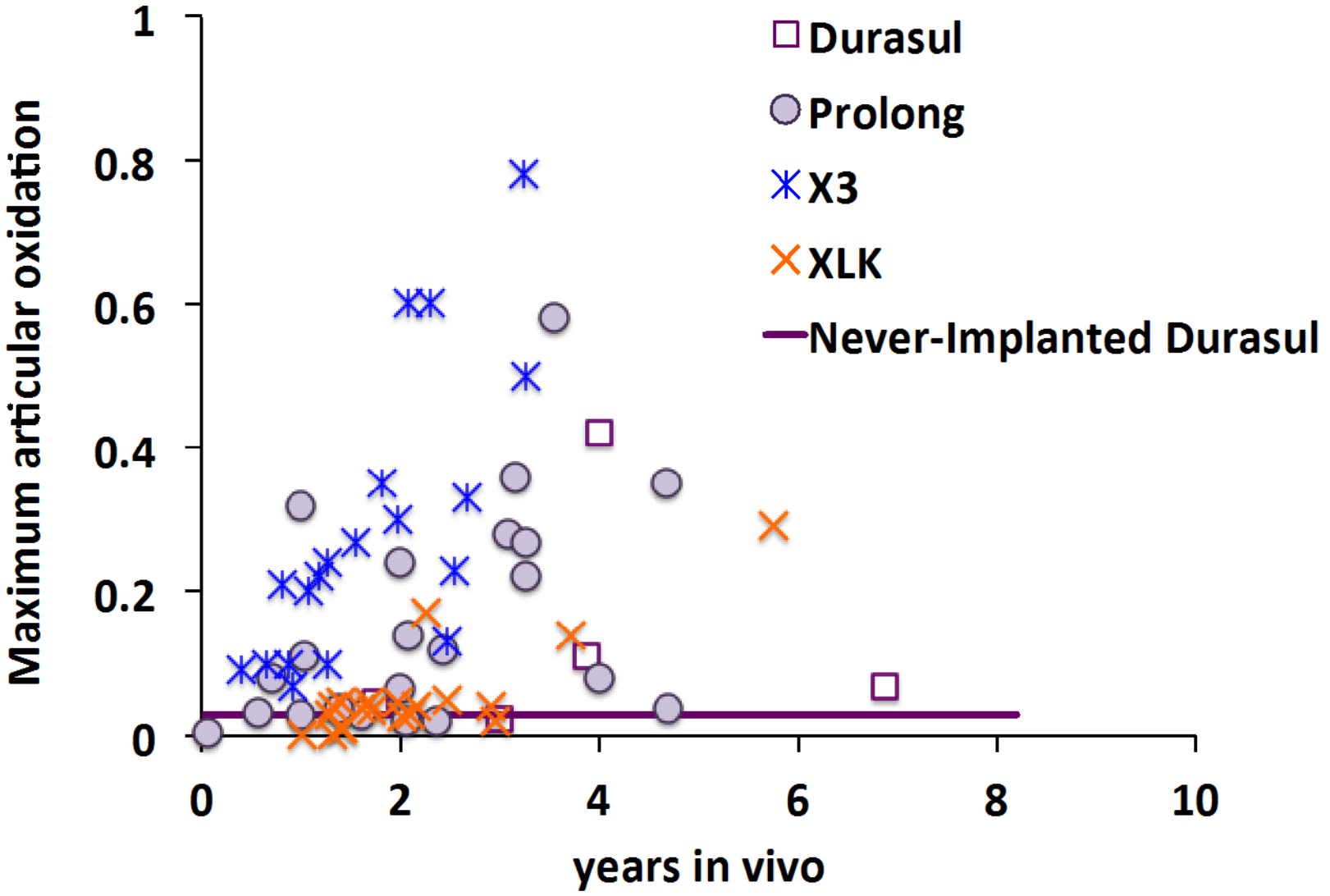
All HXL Tibial Retrievals



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All HXL Tibial Retrievals

- Articular oxidation rate correlates with:
  - cross-linking dose

  Spearman's rho=0.557, $p<0.0005$

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What can be learned from highly cross-linked tibial retrievals?

Effect of:

- post-retrieval (*ex vivo*) shelf time

Important to analyze retrievals as soon as possible after retrieval to prevent oxidation of absorbed lipids[1]

[1] Muratoglu OK, et al: Ex vivo stability loss of irradiated and melted UHMWPE. J Bone Joint Surg Am. 2010;92:2809-16

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What can be learned from highly cross-linked tibial retrievals?

Effect of:

- *in vivo* time

Subsurface oxidation similar to that seen in gamma sterilized UHMWPE results from time *in vivo.*[2] Oxidation correlates with *in vivo* time (p=0.003)

[2] Currier BH, et al: In vivo oxidation in remelted highly cross-linked retrievals. J Bone Joint Surg Am. 2010;92:2408-18

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What can be learned from highly cross-linked tibial retrievals?

Effect of:

- post-irradiation thermal treatment

  - Annealing and remelting are not equivalent post-irradiation thermal processes.
  - Annealing leaves measurable FRC.
  - Annealed inserts in this retrieval series have higher mean oxidation rate ($p<0.001$) than remelted inserts.

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What can be learned from highly cross-linked tibial retrievals?

Effect of:

- irradiation dose

Higher cross-linking irradiation dose correlates with higher oxidation rate in HXL tibial inserts ($p<0.001$)

What can be learned from highly cross-linked tibial retrievals?

Effect of:

- irradiation source
- resin

Indistinguishable in this retrieval series. No significant correlation with articular oxidation or oxidation rate. ($p>0.5$)

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THANK YOU!

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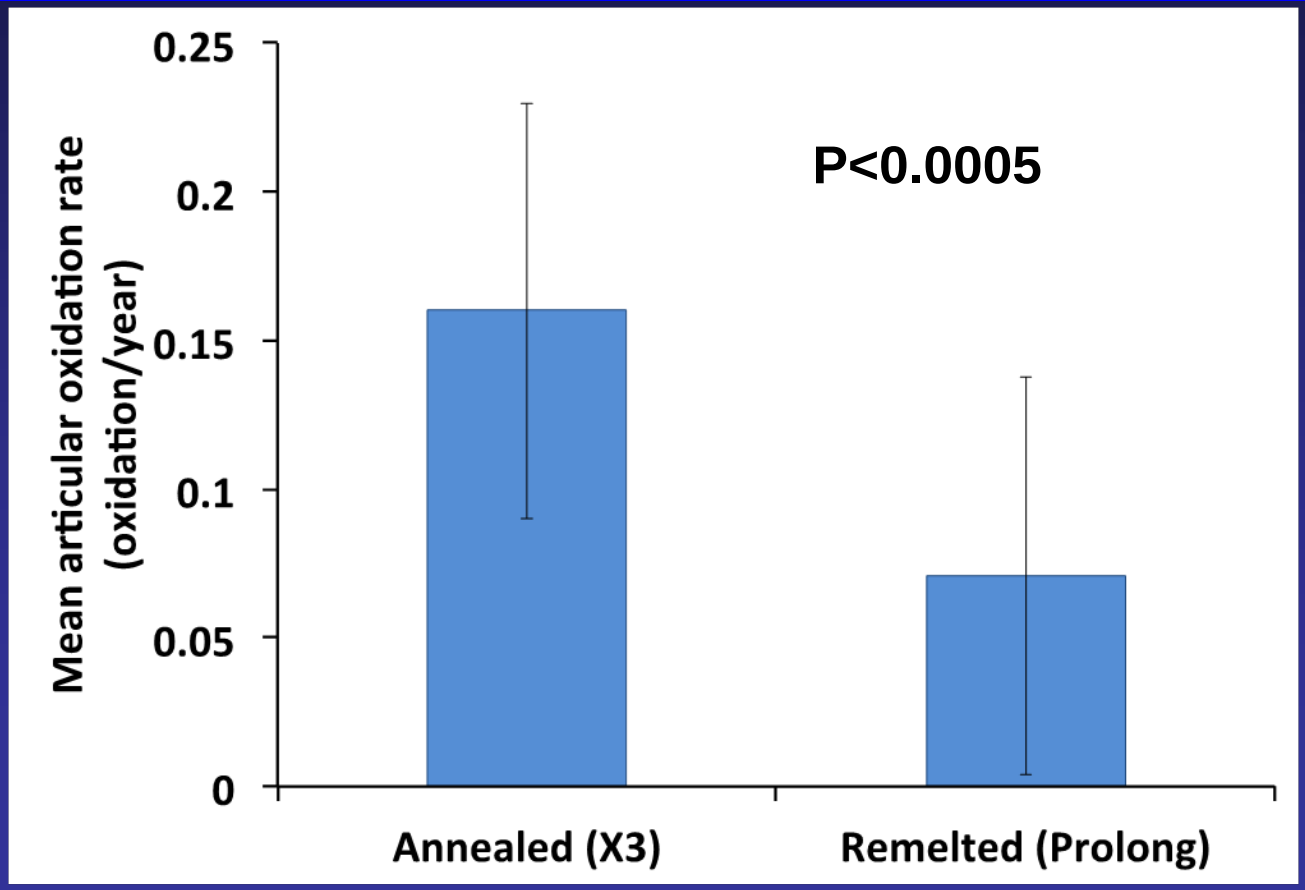
Articular oxidation rate

Articular oxidation rate correlates with post-irradiation thermal treatment, p<0.0005



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