Aggressive Aging of Cyclically Loaded Lipid-Doped UHMWPE

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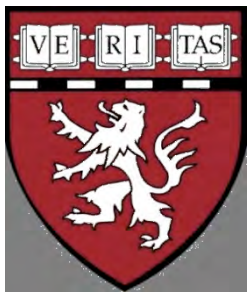

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Disclosure

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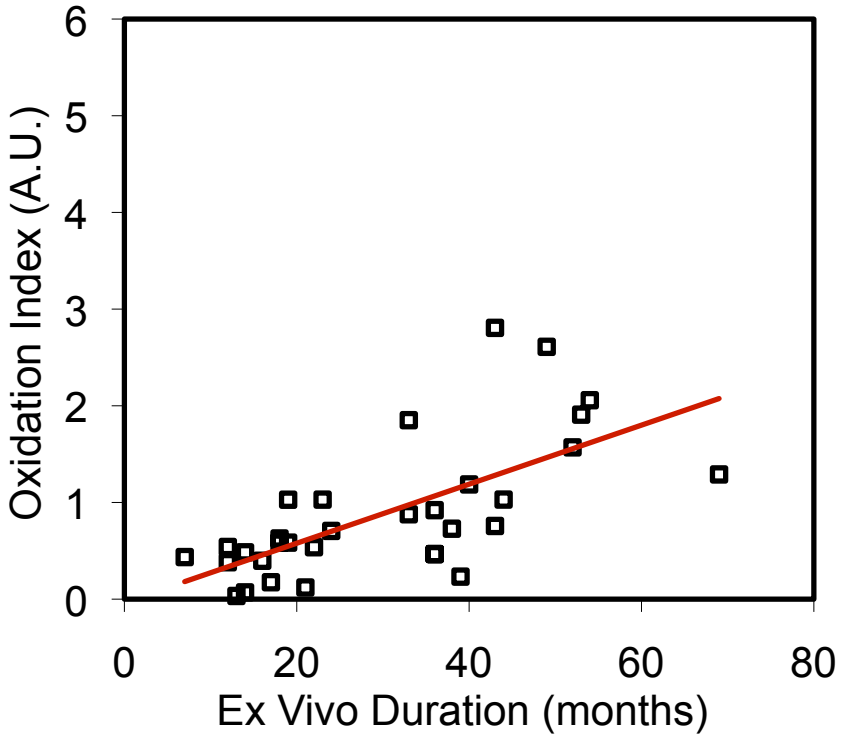
Background

Explant Study



Irradiated and melted explants oxidized *ex vivo*

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Oxidative stability reduced *in vivo*

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Potential causes

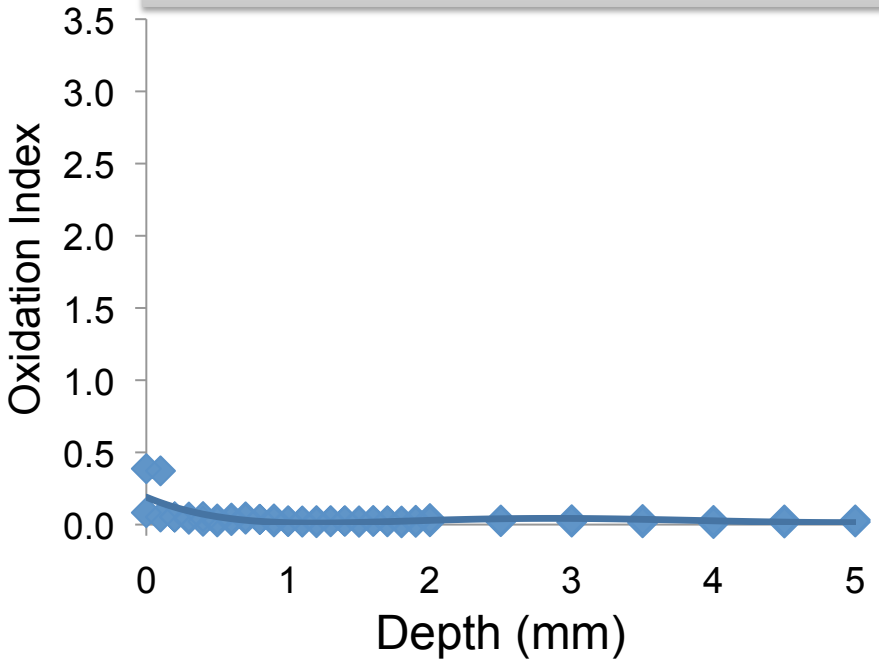
- **Lipid induced**
- **Cyclic loading**

Source: Muratoglu, et al. JBJS 2010; 92:2809-2816

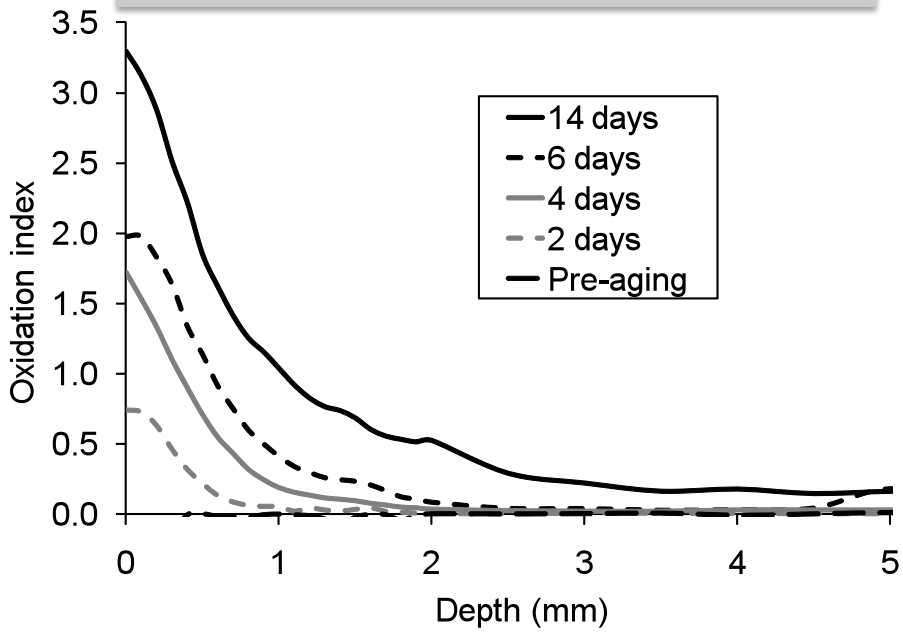
Background

Aging Induced by Squalene

CISM-100, 2 week Aged



Squalene-Doped CISM-100

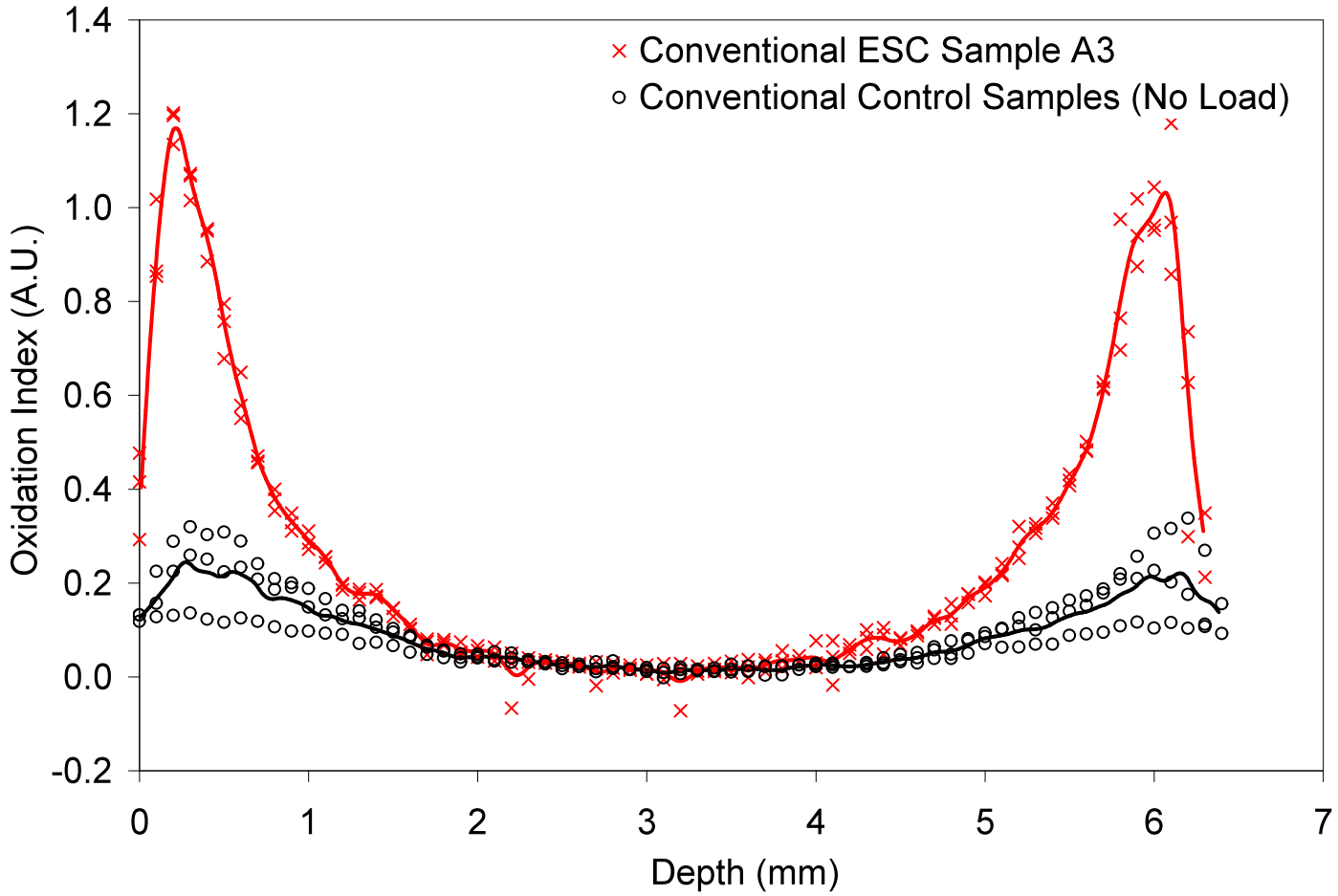


Source: Neils A, et al. ORS 2011 Poster #1180.

Source: Oral E, et al. ORS 2010 Poster # 2283

Background

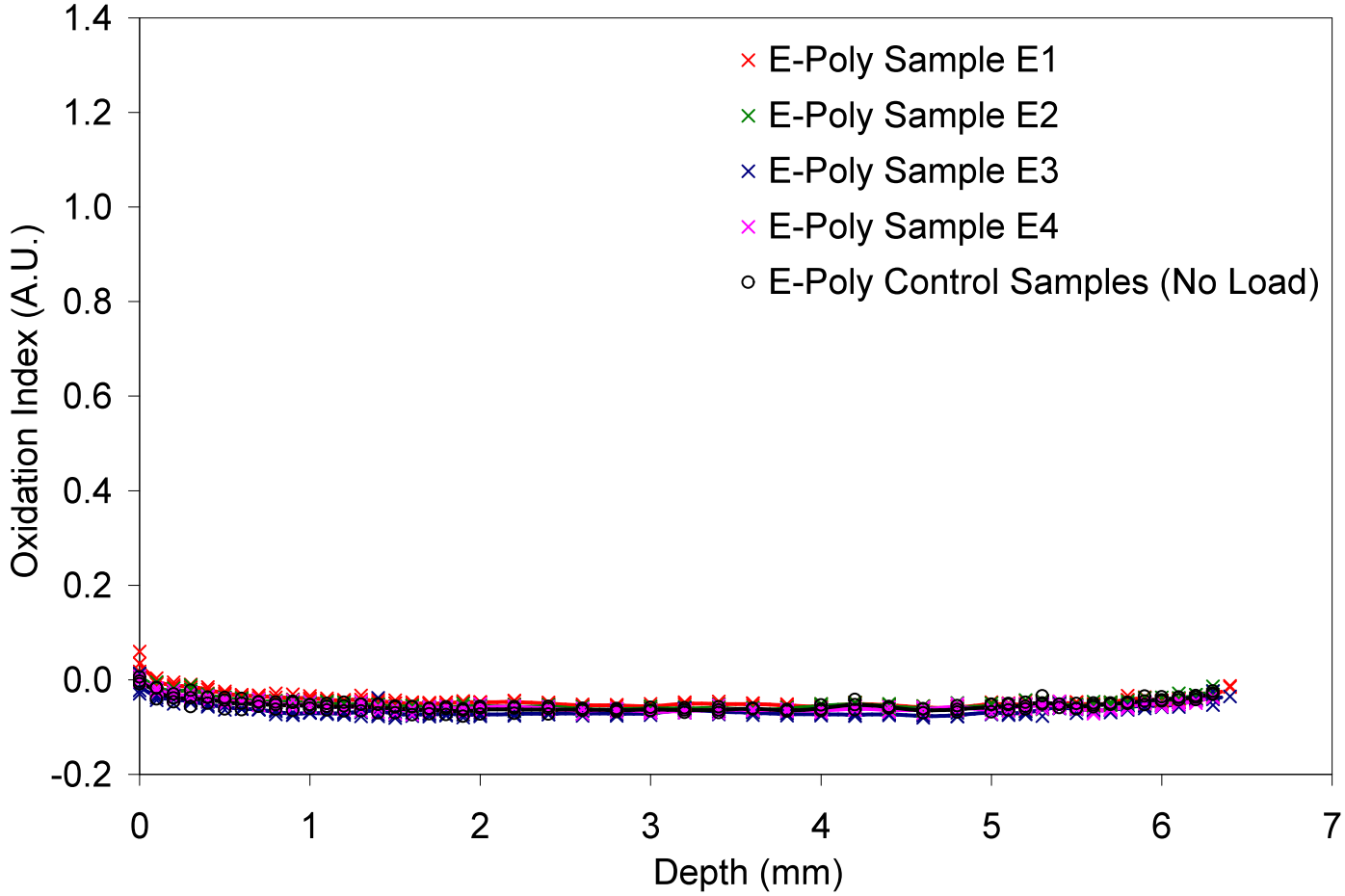
Aging Induced by Cyclic Loading – Conventional PE



Wannomae KK, et al. EFORT 2008: F265

Background

Aging Induced by Cyclic Loading – Vit E Diffused, Irradiated PE

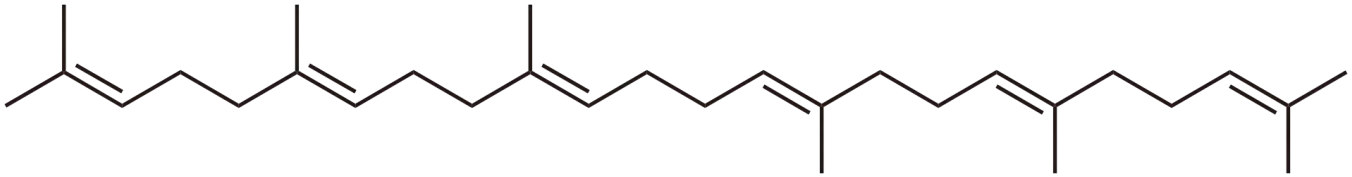


Wannomae KK, et al. EFORT 2008: F265

Purpose

Investigate the oxidative stability of squalene-doped UHMWPE subjected to cyclic loading

- Vitamin E Diffused, Irradiated
- Irradiated and Melted



Squalene

Materials and Methods

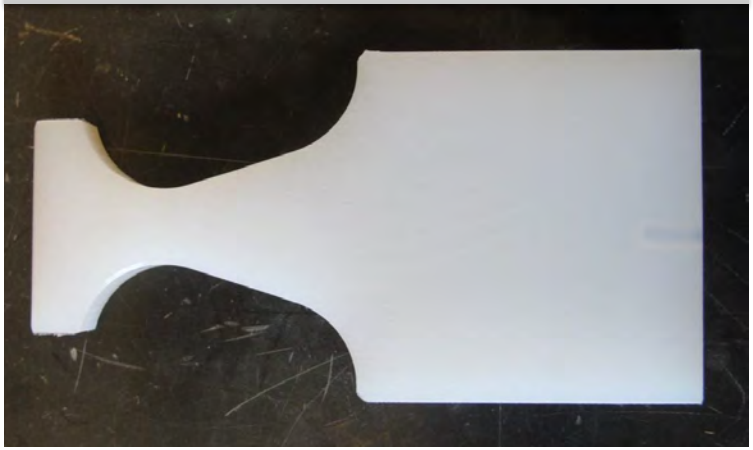
E-PE: 100 kGy irradiated GUR1050, vitamin E diffused and homogenized, terminally gamma sterilized

CISM-100: 100 kGy irradiated GUR1050, subsequently melted

Groups:

1) Lipid-Doped E-PE
2) Lipid-Doped CISM-100
3) Non-Doped CISM-100

ASTM D671 – Type A



Materials and Methods
Squalene Doping

Goal: match the squalene absorption of E-PE to that of CISM-100 doped for 4 hrs

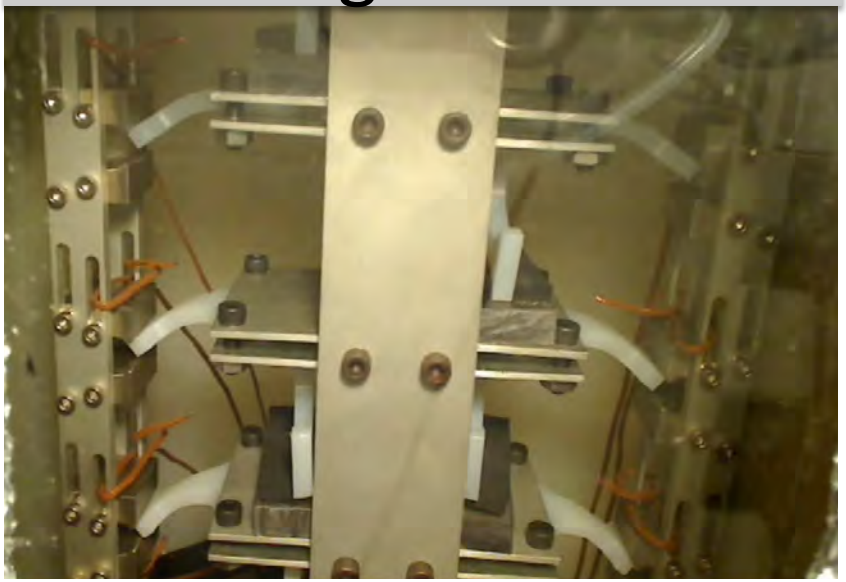
- Doping Temperature: 55°C
- Initial experiments determined E-PE doping time
- Gravimetric Doping Results

CISM-100:	16 ± 0.5 mg	(4.0 hrs)
E-PE:	19 ± 1 mg	(7.1 hrs)

Materials and Methods
Parameters

- Environment: **80°C in Air**
- Cyclic Load:
  - Alternating Stress: **10 Mpa**
  - Frequency: **0.5 Hz**
  - **5 weeks** ($1.5x10^6$ cycles)

Testing Chamber



Materials and Methods
Alternating Stress

Assuming a case of pure bending, the load required to produce the tensile/compressive stresses are given by:

$$P = \frac{Sbd^2}{6L}$$

Where:

P = load to be applied to the specimen

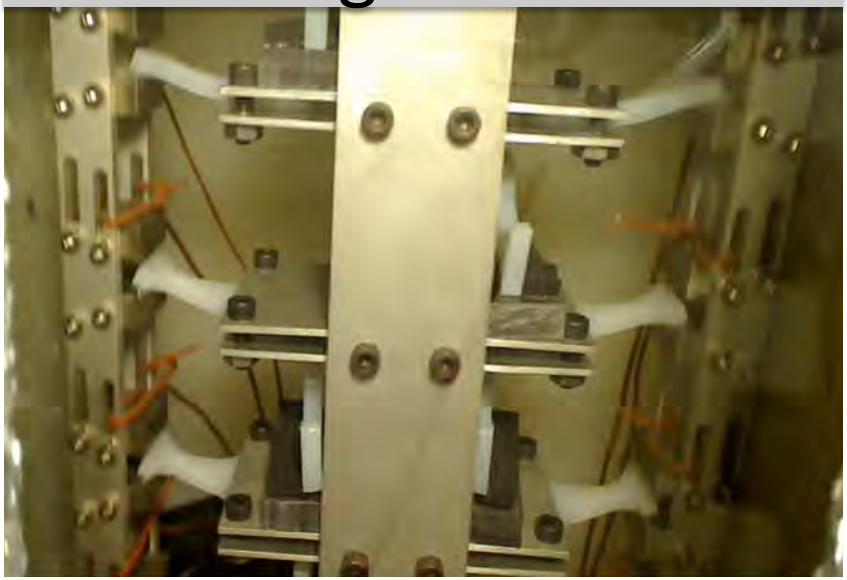
S = desired alternating stress

b = specimen test width (20.6 mm)

d = specimen thickness (6.5 mm)

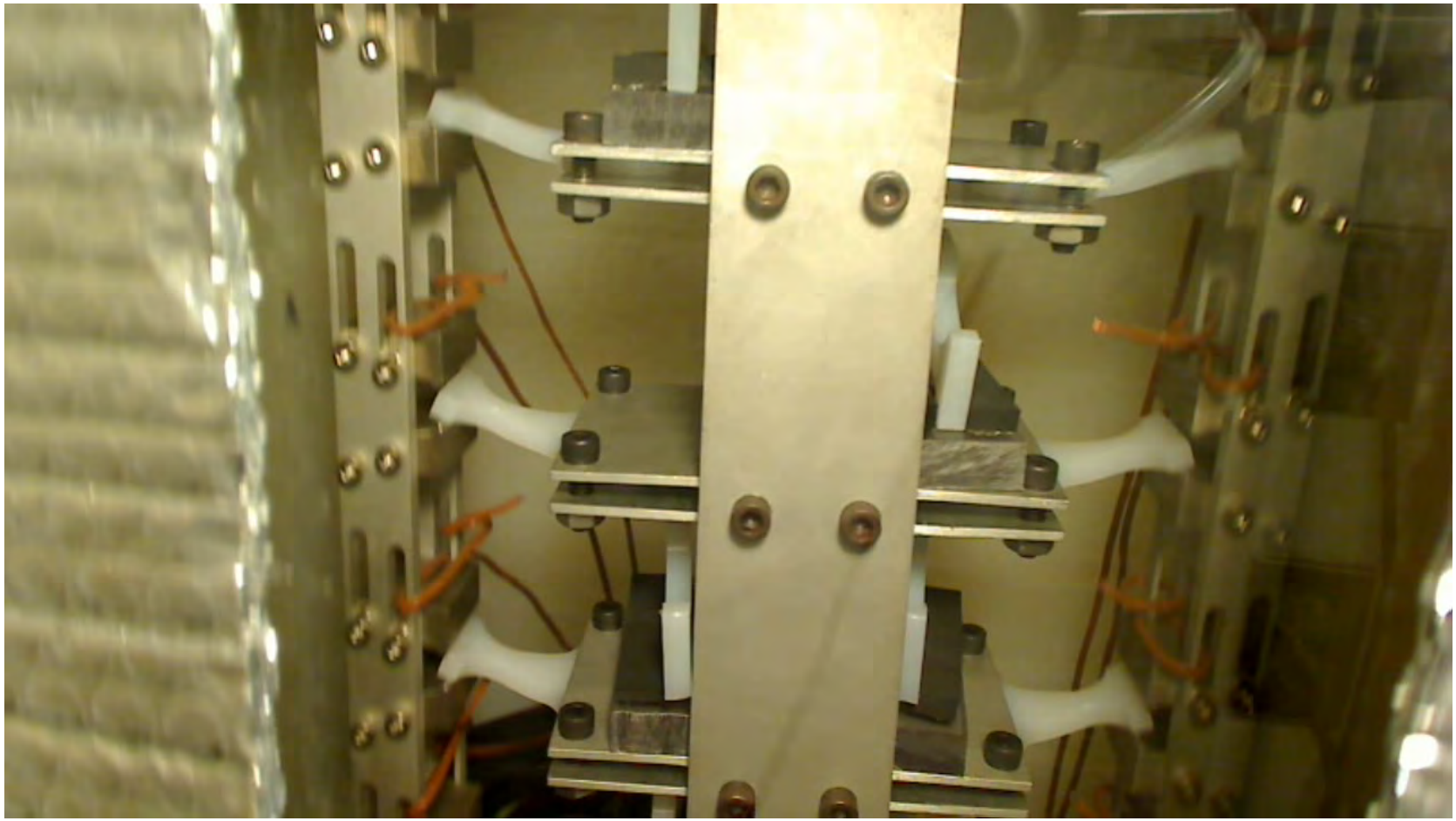
L = test span (31.8 mm).

Testing Chamber



ASTM D671

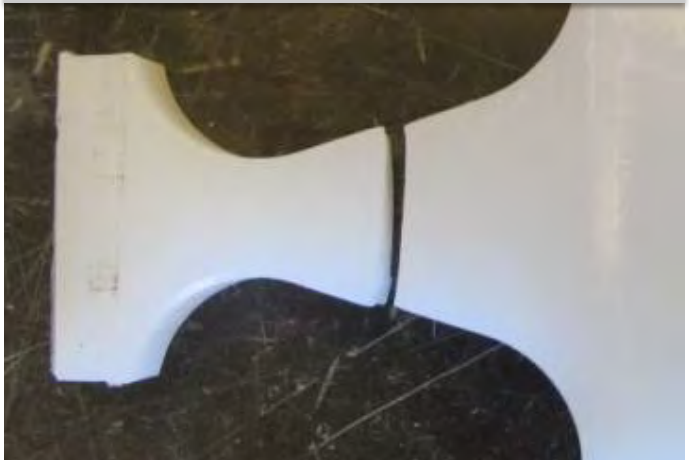
Demonstration Video



Materials and Methods

Analysis

FAILURE



OR

5 Weeks
(1.5×10^6 Cycles)

FTIR for Oxidation (ASTM F2102)

Results
Survivorship

Survival: completion of 1.5x10^{6}cycles of testing

	Samples	Failed	Survivorship	N*f* (10^{6}cycles)
Lipid-Doped E-PE	4	0	100%	N/A
Lipid-Doped CISM-100	4	4	0%	0.76 ± .09
Non-Doped CISM-100	4	2	50%	1.39

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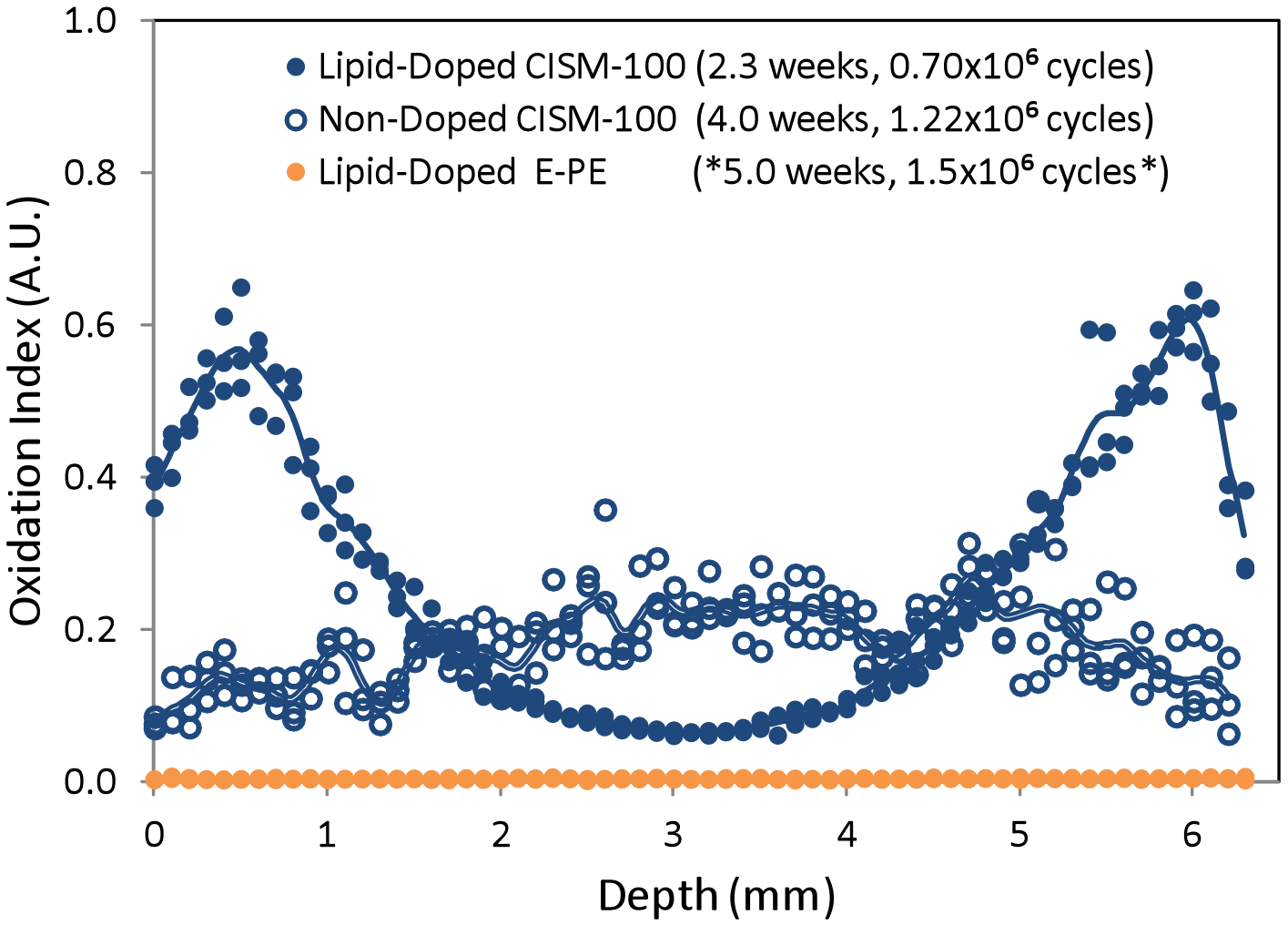
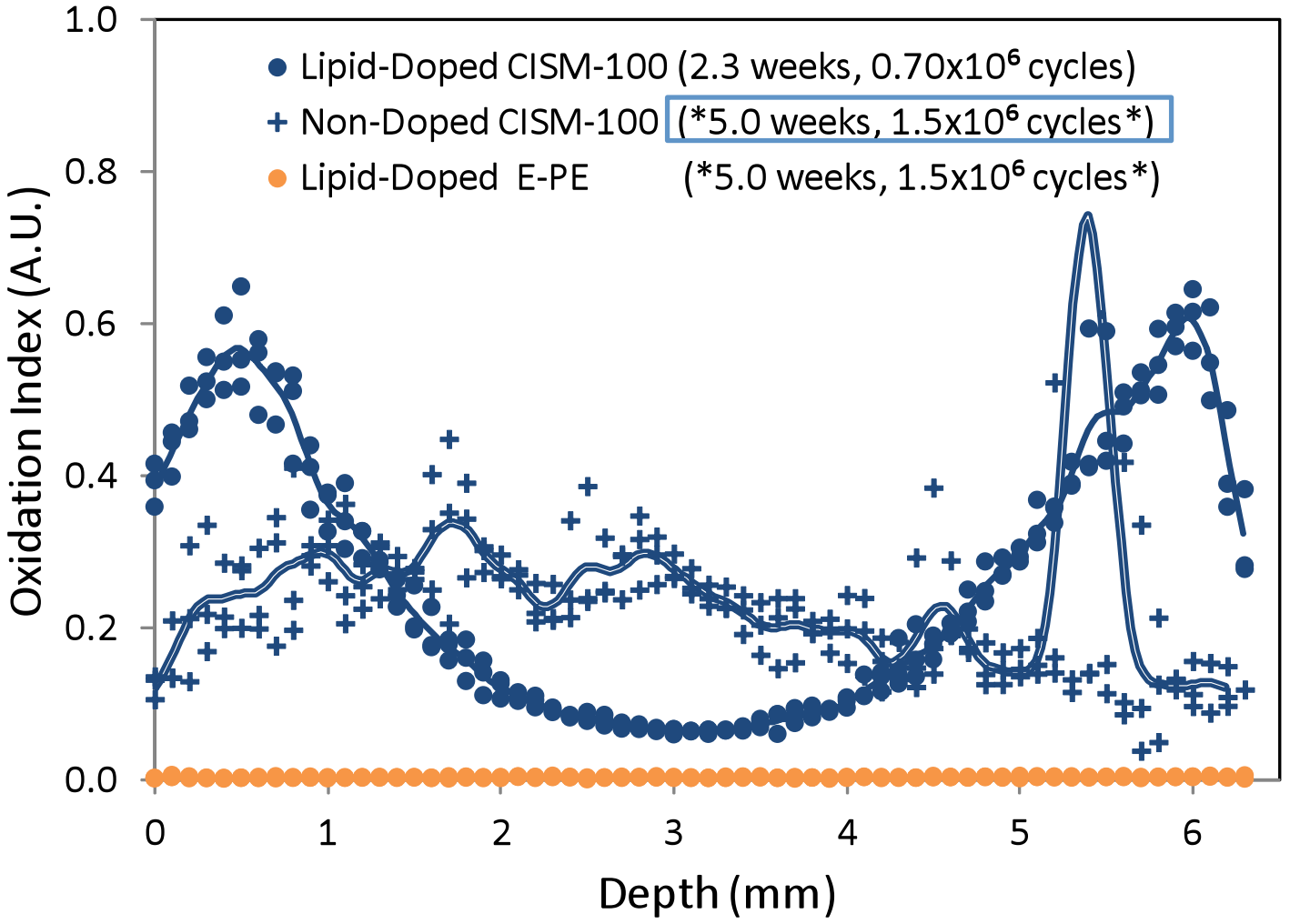
Results

Oxidation Profiles – Loaded Samples



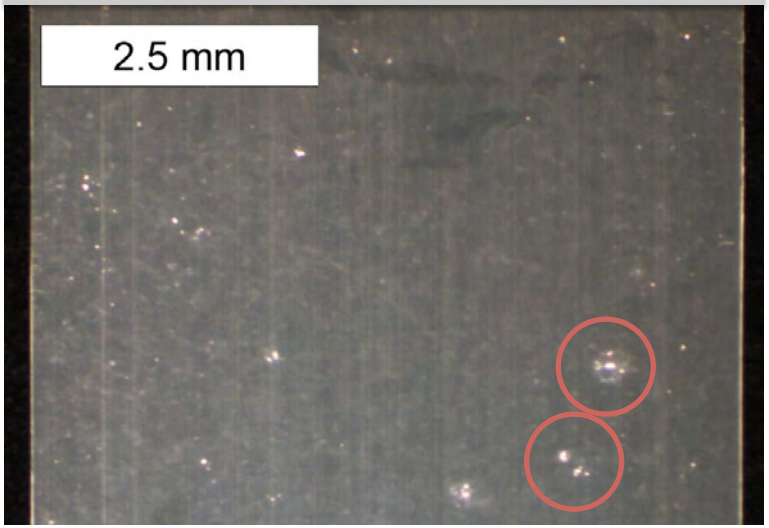
Results
Oxidation Profiles – Loaded Samples

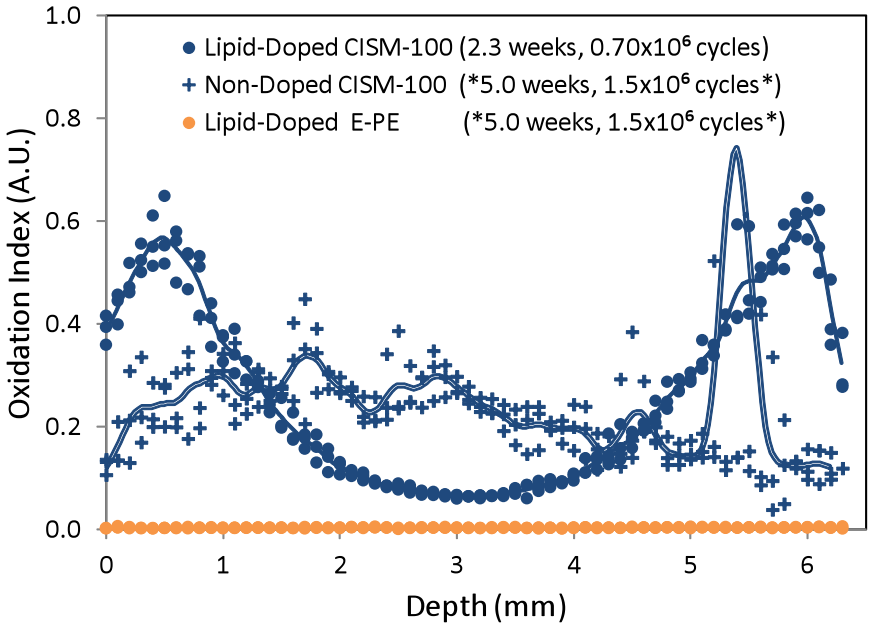


Results

Oxidation Pockets in Non-Doped CISM-100

Non-Doped CISM-100 Thin-Film





Average Testing Duration: 4.6 weeks

Slight inhomogeneities

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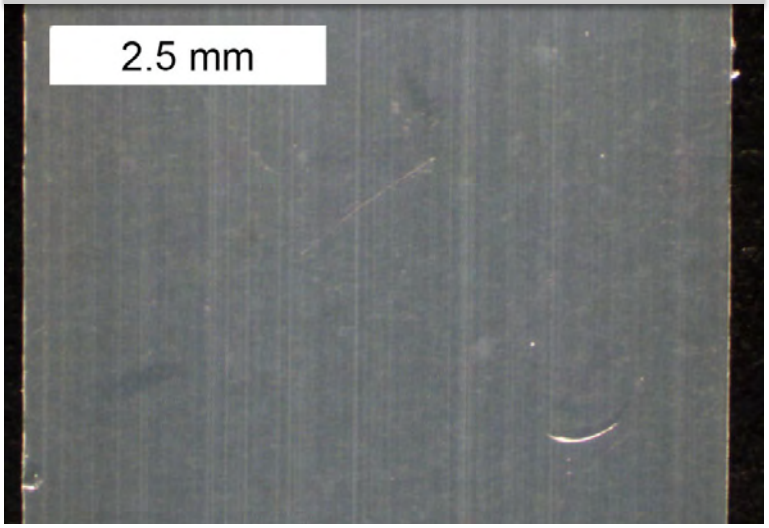
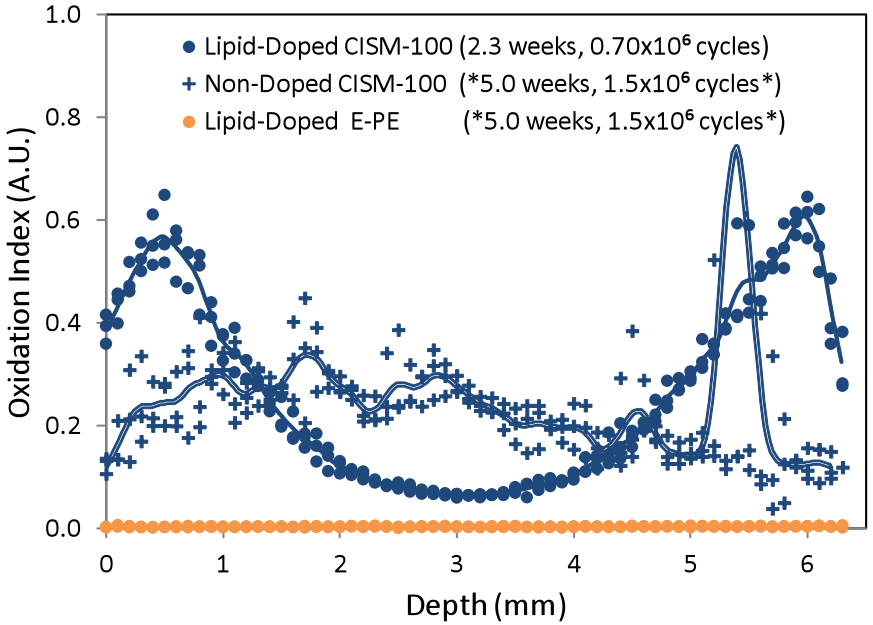
Concentrated oxidation pockets

Results
Lipid-Doped CISM-100 Comparison

Lipid-Doped CISM-100 Thin Film



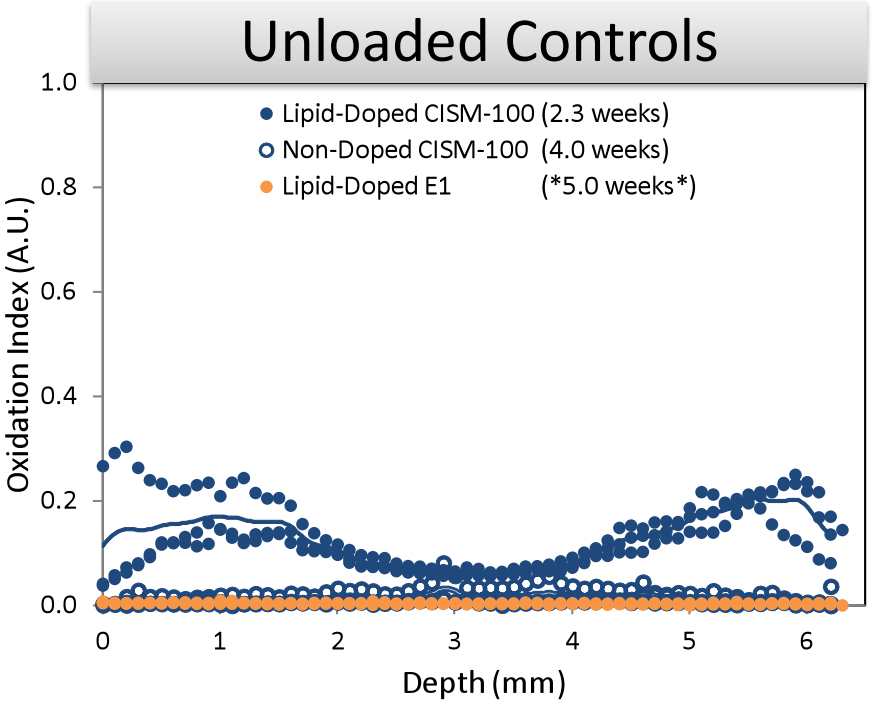


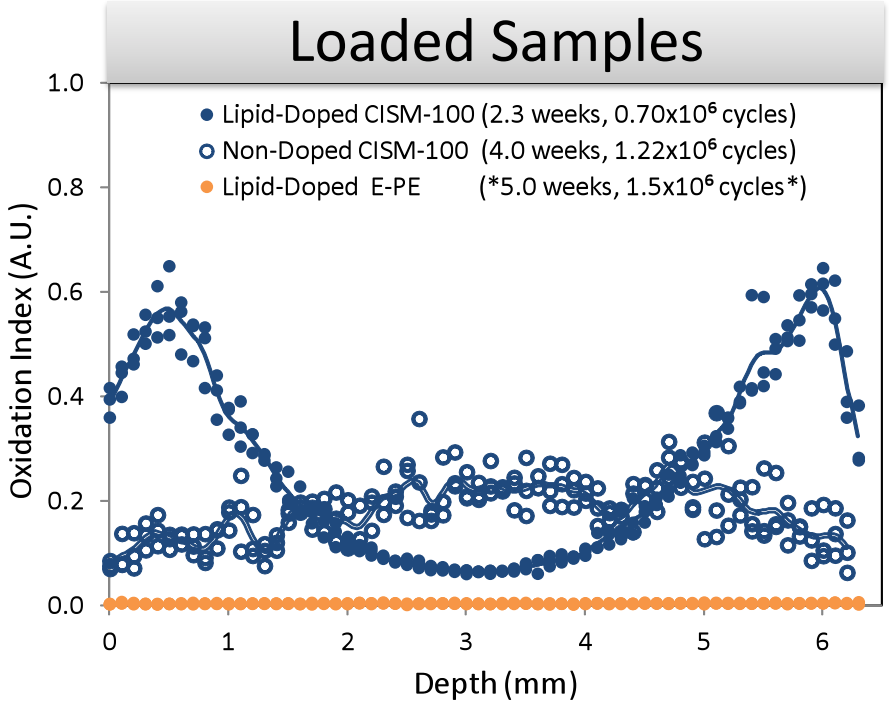
Average Testing Duration: 2.5 weeks

Pro-oxidant Squalene affected a more wide-spread sub-surface oxidation

Samples failed before concentrated oxidation pockets could form

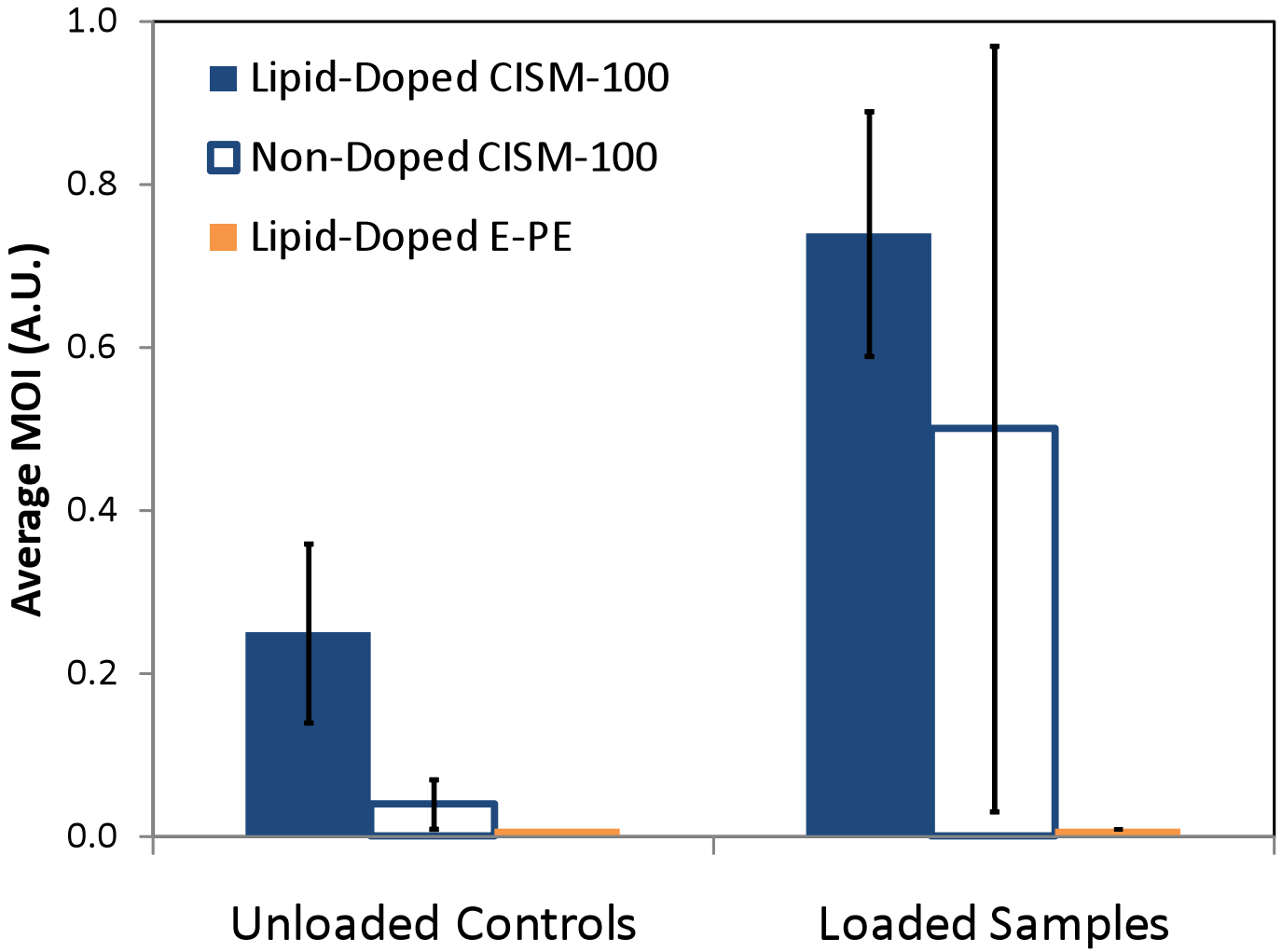
Results
Oxidation Profiles – Unloaded Controls





***Unloaded Controls exposed to 80°C as long as Loaded Samples**

Results
Average Maximum Oxidation Index



Discussion

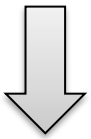
- Aggressive aging of Cyclically Loaded, Lipid-Doped UHMWPE lacks clinical relevance
- More comprehensive than standard accelerated aging tests
  - Lipids
  - Cyclic-Load
- Long term clinical studies needed for validation

Future Work

- Match the lipid profile to explants
- Dope components with a clinically relevant blend of lipids found *in vivo*
- Currently conducting a parametric study to determine the effect of:
  - Stress
  - Frequency
  - Temperature

Conclusion

- CISM-100 oxidized and failed
  - Squalene → Oxidation
  - Cyclic Load → Oxidation
  - Squalene + Cyclic Load → Enhanced Oxidation
- E-PE survived and did not oxidize



Vitamin E actively protects against oxidation induced by squalene and cyclic loading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VE RI TAS
Thank you