Aggressive Aging of Cyclically Loaded Lipid-Doped UHMWPE

Zachary B. Konsin, B.S.
Harris Orthopaedic Laboratory, Mass General Hospital

Orhun K. Muratoglu, Ph.D.
Co- Director Harris Orthopaedic Laboratory, Mass General Hospital

Keith K. Wannomae, B.S.
Harris Orthopaedic Laboratory, Mass General Hospital
Disclosure

These studies were funded through laboratory funds as well as through institutional support from Biomet Inc.

One of the co-authors has received royalties from Biomet, Inc., Zimmer, Inc., Aston Medical, Iconacy, Corin, Renovis, ConforMIS; and is an unpaid consultant for Biomet, Inc.
Background

Explant Study

Irradiated and melted explants oxidized *ex vivo*

Oxidative stability reduced *in vivo*

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: 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
**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)

[Image: 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

5 Weeks
(1.5x10⁶ Cycles)

OR

FTIR for Oxidation (ASTM F2102)
## Results

### Survivorship

**Survival:** completion of $1.5 \times 10^6$ cycles of testing

<table>
<thead>
<tr>
<th>Samples</th>
<th>Failed</th>
<th>Survivorship</th>
<th>$N_f$ ($10^6$ cycles)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lipid-Doped E-PE</td>
<td>4</td>
<td>0</td>
<td>100%</td>
</tr>
<tr>
<td>Lipid-Doped CISM-100</td>
<td>4</td>
<td>4</td>
<td>0%</td>
</tr>
<tr>
<td>Non-Doped CISM-100</td>
<td>4</td>
<td>2</td>
<td>50%</td>
</tr>
</tbody>
</table>
## Results

### Survivorship

Survival: completion of $1.5 \times 10^6$ cycles of testing

<table>
<thead>
<tr>
<th>Samples</th>
<th>Failed</th>
<th>Survivorship</th>
<th>Nf ($10^6$ cycles)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lipid-Doped E-PE</td>
<td>4</td>
<td>0</td>
<td>100%</td>
</tr>
<tr>
<td>Lipid-Doped CISM-100</td>
<td>4</td>
<td>4</td>
<td>0%</td>
</tr>
<tr>
<td>Non-Doped CISM-100</td>
<td>4</td>
<td>2</td>
<td>50%</td>
</tr>
</tbody>
</table>
Aggressive Aging of Cyclically Loaded Lipid-Doped UHMWPE

Results

Oxidation Profiles – Loaded Samples

- **Lipid-Doped CISM-100** (2.3 weeks, 0.70x10^6 cycles)
- **Non-Doped CISM-100** (4.0 weeks, 1.22x10^6 cycles)
- **Lipid-Doped E-PE** (*5.0 weeks, 1.5x10^6 cycles*)

Oxidation Index (A.U.) vs Depth (mm)
Results

Oxidation Profiles – Loaded Samples

Oxidation Index (A.U.)

Depth (mm)

- Lipid-Doped CISM-100 (2.3 weeks, 0.70x10^6 cycles)
- Non-Doped CISM-100 (*5.0 weeks, 1.5x10^6 cycles*)
- Lipid-Doped E-PE (*5.0 weeks, 1.5x10^6 cycles*)
Results

Oxidation Pockets in Non-Doped CISM-100

Average Testing Duration: 4.6 weeks

Slight inhomogeneities

Concentrated oxidation pockets

Non-Doped CISM-100 Thin-Film

2.5 mm
Results

Lipid-Doped CISM-100 Comparison

Lipid-Doped CISM-100 Thin Film

2.5 mm

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

![Bar chart showing average maximum oxidation index for different conditions.]

- Lipid-Doped CISM-100
- Non-Doped CISM-100
- Lipid-Doped E-PE
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
Thank you