In Vivo Performance of Highly Cross-linked UHMWPE

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Harris Orthopaedic Laboratory
Massachusetts General Hospital
Harvard Medical School, Boston, MA
### Retrievals

<table>
<thead>
<tr>
<th>Type</th>
<th>Number of Retrievals</th>
<th>In Vivo Durations (months)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Marathon™</td>
<td>12 hips</td>
<td>0.9-84</td>
</tr>
<tr>
<td>Longevity™</td>
<td>28 hips</td>
<td>2.5-120</td>
</tr>
<tr>
<td>Prolong™</td>
<td>5 knees</td>
<td>4-47</td>
</tr>
<tr>
<td>Crossfire™</td>
<td>1 hips</td>
<td>120</td>
</tr>
<tr>
<td>X3™</td>
<td>27 (16 hips, 11 knees)</td>
<td>0.5-48</td>
</tr>
<tr>
<td>E1™</td>
<td>10 (9 hips, 1 knee)</td>
<td>0.1-19.5</td>
</tr>
</tbody>
</table>

**Patient Ages:** 67 ± 12.5 years  
**Patient Gender:** 28 males, 42 females (13 unknown gender)  
**Reasons for Revision:** Infection (33), dislocation (14), loosening (13), instability (12), femoral fracture (1), rim fracture (2), poly wear (1), osteolysis (1) unknown (5)
Cleaning and Storage of Retrievals

1. **Arrive at lab from OR or off-site institution**
2. **Ethanol Soak**
3. **Rinse with H₂O and soft brush to clean**
4. **Air dry in hood**
5. **Vacuum package and store at -20°C until analysis or -80°C for long-term storage**
Retrieval Analysis Methods

- FTIR: Lipid absorption, **oxidation**
- Nitric Oxide Staining: Oxidation potential
- **Crosslink Density**
- DSC: **Crystallinity**, melt temperature
- ESR: **Free radical content** (only E1 retrievals)
Marathon Retrievals

<table>
<thead>
<tr>
<th></th>
<th>Retrievals</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maximum Oxidation</td>
<td>0.004 - 0.160</td>
</tr>
<tr>
<td>Cross-link Density (mol/dm³)</td>
<td>0.237 ± 0.017</td>
</tr>
<tr>
<td>Crystallinity (%)</td>
<td>53.0 ± 1.4</td>
</tr>
</tbody>
</table>

In Vivo Duration (Months)

Maximum Oxidation Index (A.U.)
Longevity Retrievals

<table>
<thead>
<tr>
<th></th>
<th>Retrievals</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maximum Oxidation</td>
<td>0.012 - 0.366</td>
</tr>
<tr>
<td>Average Cross-link Density (mol/dm³)</td>
<td>0.293 ± 0.020</td>
</tr>
<tr>
<td>Average Crystallinity (%)</td>
<td>52.7 ± 1.7</td>
</tr>
</tbody>
</table>

![Graph showing oxidation index over depth for different retrieval times](image-url)
Maximum Oxidation

In Vivo Duration (Months)

Maximum Oxidation Index (A.U.)

- Prolong
- Longevity
- Marathon
4 Year Prolong Tibial Insert

<table>
<thead>
<tr>
<th></th>
<th>Articular Surface</th>
<th>Unloaded Eminence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maximum Oxidation</td>
<td>0.863</td>
<td>0.049</td>
</tr>
<tr>
<td>Cross-link Density (mol/dm³)</td>
<td>0.215 ± 0.020</td>
<td>0.213 ± 0.006</td>
</tr>
<tr>
<td>Crystallinity (%)</td>
<td>51.2 ± 1.1</td>
<td>50.9 ± 0.9</td>
</tr>
</tbody>
</table>

Max = 0.863

Cross section of articular surface:
After xylene etching
Maximum Oxidation

In Vivo Duration (Months)

Maximum Oxidation Index (A.U.)

- X3
- Prolong
- Longevity
- Marathon
Acetabular Liners vs. Tibial Bearings

Maximum Oxidation Index (A.U.) vs. In Vivo Duration (Months)

- Red diamonds: Acetabular Liners
- Green squares: Tibial Bearings
Loaded vs. Unloaded Regions of Oxidation

![Graph showing Maximum Oxidation Index (A.U.) vs. In Vivo Duration (Months)]

- **Articular Surface Knee**
- **Unloaded Knee**
- **Articular Surface Hip**
- **Unloaded Hip**
Two 4 Year X3™ Acetabular Liners

<table>
<thead>
<tr>
<th></th>
<th>All Retrievals</th>
<th>45 Month Retrieval</th>
<th>48 Month Retrieval</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maximum Oxidation</td>
<td>0.023 – 1.601</td>
<td>1.601</td>
<td>1.587</td>
</tr>
<tr>
<td>Cross-link Density (mol/dm$^3$)</td>
<td>0.213 ± 0.036 (0.120 - 0.331)</td>
<td>0.192 ± 0.041</td>
<td>0.167 ± 0.039</td>
</tr>
<tr>
<td>Crystallinity (%)</td>
<td>62.2 ± 2.3 (58.3 – 69.3)</td>
<td>60.6 ± 1.3</td>
<td>65.1 ± 2.9</td>
</tr>
</tbody>
</table>

45 Month Retrieval: After Xylene Etching
(a) Articular surface and (b) Rim

Max = 1.601

Max = 1.587

Max = 0.634
# Case Study: 10 Year Crossfire

<table>
<thead>
<tr>
<th></th>
<th>Never Implanted Control*</th>
<th>&lt;3 Year Retrievals*</th>
<th>10 Year Retrieval</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Maximum Oxidation</strong></td>
<td>0.16 ± 0.02</td>
<td>0.22 - 5.81</td>
<td>7.35</td>
</tr>
<tr>
<td><strong>Cross-link Density (mol/dm³)</strong></td>
<td>N/A</td>
<td>N/A</td>
<td>0.079 ± 0.29</td>
</tr>
<tr>
<td><strong>Crystallinity (%)</strong></td>
<td>64.9 ± 0.51</td>
<td>64.4 - 79.2</td>
<td>78.2 ± 1.7</td>
</tr>
</tbody>
</table>

* Wannomae, et al.
### E1 Retirevals

<table>
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<tr>
<th></th>
<th>Never Implanted Control</th>
<th>Retrievals</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maximum Oxidation</td>
<td>0.029 - 0.060</td>
<td>0.041 - 0.187</td>
</tr>
<tr>
<td>Average Cross-link Density (mol/dm³)</td>
<td>0.275 ± 0.015</td>
<td>0.289 ± 0.023</td>
</tr>
<tr>
<td>Average Crystallinity (%)</td>
<td>58.8 ± 2.2</td>
<td>58.6 ± 1.9</td>
</tr>
</tbody>
</table>

\[
y = -4E+15 \ln(x) + 2E+16
\]

\[R^2 = 0.74419\]
Observations

- Both first and second generation highly cross-linked retrievals show signs of oxidation otherwise not predict by the current standard of in vitro testing
  - Lipid absorption
  - Cyclic loading

- In vivo oxidation is consistently in the form of subsurface peaks regardless of loaded or unloaded regions
  - Ex vivo studies (Muratoglu, JBJS, 2010)
Limitations and Questions

Larger sample sizes and/or comparable retrievals
  ▪ Matched physical variables
    ▪ Hips vs. Knees
    ▪ Liner design
    ▪ In vivo durations
  ▪ Patient variables
    ▪ Matched lipid profiles
    ▪ Activity levels and weight

Establish baseline controls for all materials
  ▪ Pre-implantation material variations
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Collaborators

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- CA Engh Sr., M.D., Anderson Orthopaedic Research Institute, VA
- CA Engh Jr., M.D., Anderson Orthopaedic Research Institute, VA