Development, Characterization, and In Vitro Assessment of Additive Manufactured Biomimetic Implant Surfaces

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Disclosures

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• MPI Research
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Introduction

• Chronic low back pain – tremendous public health burden
  – When conservative treatments fail, surgical fusion may be an option

• Successful fusion dependent on implant osseointegration
  – Host bone currently incorporates only 15-40% of implant surface area

• Additive manufacturing (3D printing) may offer a solution
  – Consistently fabricate implants with complex geometries and “bone-like” porous surfaces

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1 Cher, et al., 2014, Medical Devices: Evidence and Research
Objective

• Develop additive manufactured trabecular-like implant surfaces

• Assess how human bone cells respond to them in comparison to titanium plasma spray (TPS) coating
Methods

- Machined vs. Additive Manufactured 15 mm diameter discs

<table>
<thead>
<tr>
<th>Manufacturing Method</th>
<th>Base Material (1.25 mm thick)</th>
<th>Surface (0.75 mm thick)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Machined</td>
<td>Wrought Ti6Al4V ELI</td>
<td>60% porosity (CP Ti TPS)</td>
</tr>
<tr>
<td>Additive Manufactured (AM)</td>
<td>Ti6Al4V ELI powder</td>
<td>60% target porosity</td>
</tr>
<tr>
<td></td>
<td></td>
<td>65% target porosity</td>
</tr>
<tr>
<td></td>
<td></td>
<td>70% target porosity</td>
</tr>
</tbody>
</table>

- Human osteoblasts seeded at 50,000 cells/disc
  - Metrics: Initial cell attachment, proliferation, intracellular alkaline phosphatase (ALP) levels, and calcium production
  - Statistics: ANOVA followed by post hoc test; n = 5/group
Results (Surface Characterization)

<table>
<thead>
<tr>
<th>Metric</th>
<th>TPS</th>
<th>AM60%</th>
<th>AM65%</th>
<th>AM70%</th>
<th>Goals</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean Porosity (%)</td>
<td>58.8 ± 6.2</td>
<td>60.0 ± 3.7</td>
<td>62.9 ± 7.0</td>
<td>70.9 ± 6.7</td>
<td>60 - 70&lt;sup&gt;3&lt;/sup&gt;</td>
</tr>
<tr>
<td>Mean Pore Size (µm)</td>
<td>141.7</td>
<td>290.6</td>
<td>281.2</td>
<td>357.1</td>
<td>≥ 300&lt;sup&gt;4&lt;/sup&gt;</td>
</tr>
</tbody>
</table>

<sup>3</sup> Heinl, et al., 2008, Acta Biomaterialia  
<sup>4</sup> Karageorgiou, et al., 2005, Biomaterials
Results (Cellular Response)

Initial Cell Attachment
(t = 4 hrs)

Cell Proliferation

Intracellular ALP Levels

Calcium Production
(t = 21 days)

* = \( p < 0.05 \)
Discussion and Conclusions:

• Additive Manufactured vs. TPS surfaces
  – Controlled trabecular-like surfaces
  – Earlier proliferation
  – Potentially higher early ALP activity
  – Significantly increased calcium-containing mineralization

• Additive Manufactured surfaces may induce a more osteogenic environment
  – Possibly promote accelerated bone formation and greater fixation
The iFuse Implant System® is CE marked and is intended for sacroiliac joint fusion.

There are potential risks associated with the iFuse Implant System. It may not be appropriate for all patients and all patients may not benefit. For information about the risks, visit: www.si-bone.com/risks

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