In Vivo Evaluation of Novel Implant Topologies Designed for Bone Fixation under Multi-Directional Loading

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Introduction

While contemporary prosthetic devices provide some restoration of function to individuals who have lost a limb, there are ongoing efforts to develop bio-integrated prostheses that would enhance functionality by providing motor control and sensory feedback. A critical step in the development of a bio-integrated prosthesis will be establishing long-term, secure fixation to the remnant bone. This would allow the transfer of multi-axial and multi-directional loads generated during normal daily activity, and establish a secure interface for the acquisition and transmission of neural or muscular data.

As part of a large program to study technologies for bio-integrated prosthetic limb development, we investigated mechanisms for establishing long-term, robust fixation in bone under complex loading environments. Specifically, the purpose of this study was to test the potential of using a topologic optimization strategy to design implant interface conditions that would promote secure fixation under multi-directional loading in a unique in vivo model.

Methods

Topology optimization coupled with a finite element (FE) model was used to find optimal implant structures under a specified loading condition by distributing limited implant material in a specified domain [1]. For initial evaluation, our loading condition consisted of uni-axial forces with equivalent tension and compression. The 3-D FE model had a cylindrical implant design domain surrounded by trabecular bone. The optimization objective was to minimize the total compliance of the bone-implant system (analogous to minimizing interface motion) subject to the implant filling no more than 50% of the design domain. The resulting implant designs were axisymmetric due to model symmetries.

Two optimized implants made of Ti-alloy were selected for in vivo analysis. Both were based upon the same optimized design; one was derived directly from the output of the topology optimization and had a solid structure, while the other had the additional step of converting the design domain into a hierarchical scaffold resulting in a porous structure [2] (Fig 1A). The addition of the scaffold served to facilitate bone infiltration and improve implant fixation. A third design, a solid cylinder with a porous Ti-bead coating [3], was fabricated for comparative analysis of a non-optimized control.

Results

All 18 pairs of implants were harvested and analyzed after the 12 week experiment. In vivo loading significantly increased the stiffness of the bone-implant constructs (p=0.04) (Table 1, values from loaded specimens highlighted in gray). Trabecular thickness (Th.Th.) also significantly increased due to loading (p=0.05), and bone volume fraction (BVF) suggested a similar anabolic effect (p=0.131). While no significant differences were detected between the three designs, the strongest effects of loading were consistently associated with the porous optimized design (p-values < 0.10) and the weakest effects were generally associated with the solid optimized design.

Osseointegration patterns were distinct for each of the three designs (Fig 2). For the solid optimized design, most of the bone apposition was along the outer implant surfaces with little bone contact on the inner, concave surfaces. In contrast, the porous optimized and porous cylinder designs had a more uniform distribution of bone apposition; these two designs also trended toward increased bone apposition associated with implant loading. Bone ingrowth was primarily found within <1mm of outer implant surfaces. Therefore, only a limited amount of bone penetrated into the deep pore structures of the porous optimized design.

Discussion

Using a topology optimization scheme, implant structures were developed to have a favorable fixation response under multi-directional (tension/compression) loading. These implants were then evaluated using an in vivo loading system, which enhanced implant fixation and had an anabolic effect on the adjacent trabecular bone. The porous optimized design trended towards the strongest effect associated with loading. It appears that the addition of the multi-scale scaffold may have improved fixation and enhanced formation of the adjacent bone.

Functional bone-implant systems, such as an anchored frame for a bio-integrated prosthetic limb, will undergo mechanical loading during daily use. This experimental model can be used to better understand how multi-scale variations in implant topology can enhance mechanically-mediated bone formation along bone-implant interfaces to improve structural integrity for robust, long-term use.

Acknowledgements

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Table 1: Mechanical Testing and Bone Morphology Measurements

<table>
<thead>
<tr>
<th></th>
<th>Solid Optimized</th>
<th>Porous Optimized</th>
<th>Porous Cylinder</th>
<th>Pooled</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stiffness (kN/mm)</td>
<td>8.8±2.39</td>
<td>9.42±1.37</td>
<td>8.90±1.78</td>
<td>9.05±1.80</td>
</tr>
<tr>
<td>Th.Th. (µm)</td>
<td>9.53±1.97</td>
<td>11.36±2.74*</td>
<td>10.90±3.94</td>
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<td></td>
<td>131±39</td>
<td>122±30</td>
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<td>129±34</td>
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<td></td>
<td>144±47</td>
<td>160±25†</td>
<td>148±37</td>
<td>151±36†</td>
</tr>
<tr>
<td>BVF</td>
<td>0.31±0.132</td>
<td>0.28±0.128</td>
<td>0.29±0.118</td>
<td>0.30±0.119</td>
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<tr>
<td></td>
<td>0.31±0.127</td>
<td>0.379±0.103†</td>
<td>0.34±0.106</td>
<td>0.347±0.109</td>
</tr>
</tbody>
</table>

Values from loaded specimens are highlighted in gray. Data are expressed in mean±SD. An asterisk (*) indicates a p-value <0.05 and a dagger (†) indicates a p-value <0.10.

Fig 2: Examples of loaded implant cross-sections imaged with a backscatter SEM show patterns of osseointegration for each design.

References