

## Assessment of the Biodegradation Rate of Novel Peptide Amphiphile-Based Implants

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**INTRODUCTION:** AMFX-100 is a bone graft substitute designed to promote bone formation in spinal fusion procedures. It consists of peptide amphiphile (PA) molecules, polyethylene glycol (PEG), and tri-calcium phosphate (TCP) granules. The PA molecules include a non-bioactive filler PA (PA1) and a PA containing a BMP-2-binding motif (PA2), co-assembled at a ratio of 1:1 by weight. The device is implanted into the intervertebral space, where it facilitates new bone growth to achieve vertebral fusion. Ideally, the graft should gradually resorb as natural bone forms and remodels. This study aims to assess the degradation rate of the PA-based graft using fluorescently-tagged implants (Cy5.5 and Cy7 dye) via *in vivo* imaging (IVIS).

**METHODS:** Six female Sprague Dawley rats underwent bilateral posterolateral spinal fusion (PLF) with one of two tagged implants. As this is a pilot study, only female rats were used for uniformity in preliminarily estimating the degradation rate of the graft. This study was approved by IACUC. Group 1 received PA1-Cy5.5 implants (N=3), and Group 2 received PA2-Cy7 (3 mol%) implants (N=3). Beginning on postoperative day (POD) 1, rats were imaged using IVIS, and the average radiant efficiency was recorded through POD 84 for each animal using the Cy 5.5 channel for PA1-Cy 5.5 group and the Cy 7 channel for PA2-Cy 7 group. Untagged implants were placed in an additional 3 rats and imaged on POD1 to use as negative controls. After POD 84, rats were euthanized, and the lungs, heart, liver, spleen, kidneys, and spine were harvested. These organs were subsequently imaged under identical IVIS settings to assess individual organ radiant efficiency.

**RESULTS SECTION:** Average radiant efficiencies were plotted alongside those of an untagged implant control. Based on preliminary data up to POD 57, the radiant efficiencies of both tagged implants had decreased to levels comparable to the untagged control (Figure 1). To better illustrate the rate of degradation, average radiant efficiency values were normalized to their respective POD 1 values (Figure 2), and the percent change from baseline was calculated for each implant type (Figure 3).

**DISCUSSION:** This study helped both visually and quantitatively demonstrate the *in vivo* degradation rate of a PA-based graft following posterolateral spinal fusion surgery. This study is limited methodologically by small sample size and its reliance on dye-based signal decay as a surrogate for material breakdown.

**SIGNIFICANCE/CLINICAL RELEVANCE:** This study seeks to characterize the biodegradation profile of our novel PA-based implant in an established animal model for spinal fusion. This data will aid the understanding of how the implant behaves in human subjects and is a crucial component of its safety profile.

### IMAGES AND TABLES:

