



# Pulsatile Parathyroid Hormone Delivery for Local Bone Regeneration

## Clinical Need

Reconstruction of cranial and maxillofacial bone loss resulting from trauma, disease, or tumor remains a significant clinical challenge. While parathyroid hormone (PTH) is well known to stimulate bone remodeling, and its application in the treatment for osteoporosis has been widely-explored, its utility in bone regeneration via a localized delivery has not yet been established.

## Solution

A team of researchers at the University of Michigan led by Dr. Peter Ma and Dr. Laurie McCauley has developed a polymeric controlled release device to locally deliver PTH in a pre-programmed pulsatile manner. Using this approach, the local pulsatile delivery of PTH not only showed the regeneration of a critical-sized bone defect with negligible systemic side effects in a murine model, but also achieved higher quality regenerated bone than the standard systemic PTH injection.

## Competitive Advantage

Although intermittent administration of PTH is associated with net bone formation, continuous exposure to PTH has been associated with bone resorption. This controlled release system enables localized, pulsatile delivery of PTH to achieve bone formation, and is intended to avoid systemic side effects, enhance patient compliance, while preserving PTH bioactivity to promote bone regeneration via enhanced bone remodeling.



**Peter Ma, PhD**  
University of Michigan

*"This technology enables the regeneration of a critical sized bone defect without using transplanted cells, significantly simplifying the clinical translation"*

[www.media.dent.umich.edu/labs/ma/](http://www.media.dent.umich.edu/labs/ma/)

## How the ITP Program Supports this Project

The overall goal of this project is to develop a cell-free system to deliver PTH to regenerate bone. To build upon the proof-of-concept work completed in a murine model, the ITP program will support further studies to demonstrate efficacy in a larger animal model, while developing marketing and regulatory strategies.

## Clinical Translation Pathway

### Publications:

Local pulsatile PTH delivery regenerates bone defects via enhanced bone remodeling in a cell-free scaffold. *Biomaterials*, 2017, 114:1-9. (<https://www.ncbi.nlm.nih.gov/pubmed/27835763>)

### Intellectual Property:

PCT/US2017/052670 Delivery devices and methods for making the same. (<https://patents.google.com/patent/WO2018057709A1>)  
US 8,623,397 Delivery device and method for forming the same. (<https://patents.google.com/patent/US8623397B2>)

### Commercialization Strategy:

In development with the MPWRM Commercialization/Market Needs Core

### Regulatory Pathway:

In development with the MPWRM Regulatory Core

### Product Launch Strategy:

In development with the MPWRM Commercialization/Market Needs Core

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