Michigan • Pittsburgh • Wyss
Regenerative Medicine Resource Center

Bioabsorbable Magnesium/ PLGA Barrier Membranes

Clinical Need

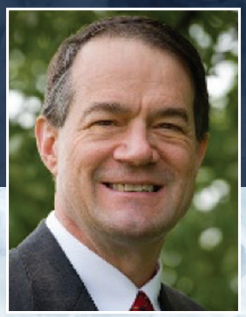
Over one million dental bone grafting procedures are performed annually in the U.S., most frequently in the preparation of dental implant placement. While alveolar ridge preservation and augmentation procedures are mostly associated with positive outcomes, results for defects with a significant vertical component are unpredictable and unreliable. Maximization of the alveolar ridge augmentation is frequently attempted through guided bone regeneration using a form-stable barrier membrane that can protect the healing site from mechanical insults. Unfortunately, existing membranes require an invasive removal procedure, which decreases the likelihood of achieving optimal grafting outcomes, and currently available resorbable membranes lack the form-stability needed to maximize alveolar ridge augmentation.

Solution

An interdisciplinary team at nanoMAG and the University of Pittsburgh is developing a barrier membrane with handling characteristics that enable customization to the defect site while providing mechanical strength and controlled degradation to enable unimpaired implant placement post-bone grafting. Proof-of-concept studies in a canine model of vertical ridge preservation showed safety and effectiveness of the membrane in regenerating bone.

Competitive Advantage

The barrier membrane in development is designed to meet critical clinical design requirements of mechanical properties to provide form stability and resorbability. Taken together, these characteristics enable maximization of alveolar ridge augmentation while obviating the need for device removal.



Stephen LeBeau, PhD
nanoMAG, LLC

"nanoMAG is an advanced materials and medical device manufacturing company that has developed a patented magnesium-based alloy that provides the strength of metal but is biocompatible and bioabsorbable. We are very excited about our collaboration with the University of Pittsburgh under the ITP program to provide us access to pre-clinical expertise and market knowledge in dental reconstruction as well as FDA regulatory assistance via the ITP core services team that will assist us in our commercialization efforts."

www.nanomag.us

How the ITP Program Supports this Project

The objective of the work to be completed under the ITP program is to establish design freeze and manufacturing methods in support of an FDA submission. Towards this end, longer term studies will also be conducted in a canine vertical ridge augmentation model.

Clinical Translation Pathway

Publications:

A Brown et.al. "Porous magnesium/PLGA composite scaffolds for enhanced bone regeneration following tooth extraction" Acta Biomaterialia, Vol 11, Jan 2015, p 543-553. *(https://www.ncbi.nlm.nih.gov/pubmed/25234156)*

S LeBeau, et.al. "Controlling the Degradation Profile of Mg Biomedical Devices by Alloy Design and Thermomechanical Processing" National Association of Corrosion Engineers, 2017. *(https://www.onepetro.org/conference-paper/NACE-2017-9395)*

Intellectual Property:

US 9,017,602 Method and Apparatus of Forming a Wrought Material Having a Refined Structure. *(https://patents.google.com/patent/US9017602B2/en)*

W002014145672 High Strength and Bio-absorbable magnesium alloys. *(https://patents.google.com/patent/W02014145672A1)*

W020188076003 Degradable bulk metallic magnesium/ polymer composite barrier membranes for dental, craniomaxillofacial and orthopedic application s and manufacturing methods. *(https://patents.google.com/patent/W02018076003A1/)*

Commercialization Strategy:

Via collaboration between NanoMAG, University of Pittsburgh, and strategic dental device OEM manufacturers

Regulatory Pathway:

In development with the MPWRM Regulatory Core

Product Launch Strategy:

In development with the MPWRM Commercialization/Market Needs Core

Michigan-Pittsburgh-Wyss Regenerative Medicine Resource Center is supported in part by the National Institute of Dental & Craniofacial Research of the National Institutes of Health under Award Number U24DE026915. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

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