

Optimization of a Novel Organic-Mineral Bone Adhesive



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“The ITP program has been an innovative partnership between NIDCR, academia and a corporate entity. This partnership is ideally suited for a product such as Tetranite. With multiple resources available to all parties, the development process has been streamlined and made more efficient.”

www.launchpadmedical.com

CLINICAL NEED

Although over 50% of adults over the age of 45 in the US have one or more missing teeth, only 2% of the eligible population receives a prosthetic tooth due to factors including time involved in multi-stage bone grafting procedures and associated costs. While most bone grafting materials demonstrate osteoconductivity to regenerate bone, many suffer from poor mechanical properties, necessitating the use of ancillary fixation or containment devices to prevent graft migration and ingrowth of fibrous tissue that impedes bone regeneration and remodeling.

SOLUTION

Researchers at LaunchPad Medical are exploring a novel technology, Tetranite[®], for bone grafting applications. Tetranite is an injectable, synthetic, wet-field bioresorbable biomaterial which can create a strong load-bearing bond between wet bone tissue and metals. The material is chemically and structurally stable in a neutral pH aqueous environment and is degraded and resorbed in vivo without the loss of bond to bone, resulting in continuous bone deposition to exposed surfaces.

COMPETITIVE ADVANTAGE

The unique hard-setting and adhesive properties of Tetranite enable it to conform and fixate to complex, open-walled, horizontal, and vertical defect sites. Given these unique properties, the material is predicted to eliminate the need for ancillary or graft containment devices currently required to support the existing bone graft. In addition, Tetranite enables immediate placement of implants simultaneous to the bone augmentation procedure, simplifying the bone grafting procedure. The reduction in surgical intervention and costs are expected to enable prosthetics to more widely benefit patients.

ITP SUPPORT

The work supported by the ITP program will prepare for the pivotal animal studies to assess the optimal Tetranite formulation for bone regeneration. The data from this investigation will better characterize the temporal formation of bone and resorption of the Tetranite graft material.

CLINICAL TRANSLATION PATHWAY

Publications:

Optimization of a Novel Organic-mineral Bone Adhesive for Dental Bone Grafting. Presented at IADR General Session 2019, Academy of Osseointegration Annual Meeting 2019

Intellectual Property:

US 8,232,327, US 8,273,803
Tetra calcium phosphate based organophosphorus compositions and methods
US 8,765,189 Organophosphorous and multivalent metal compound compositions and methods

Regulatory Pathway:

Anticipated: Device, 510(k)/de novo (clinical trial underway for dental implant stabilization)

Commercialization Strategy:

In development with the MPWRM Commercialization/Market Needs Core

Product Launch Strategy:

In development with the MPWRM Commercialization/Market Needs Core

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