Optimization of a Novel Organic-Mineral Bone Adhesive for Dental Bone Grafting

Clinical Need

Based on market research conducted by RevBio, almost half the patients that seek a dental implant supported crown suffer from chronic edentulism and require extensive bone grafting to rebuild their alveolar ridge. Over 30% of the time, these grafting procedures achieve less than desired results and require some form of re-grafting adding to the overall cost, treatment time, and morbidity for these patients.

Solution

Tetranite® (TN) is a synthetic, injectable, cohesive organic-mineral bone scaffold with adhesive properties that resorbs and is replaced by bone on a timescale commensurate with existing graft materials but does not require ancillary fixation (screws, tacks) or containment devices (membranes, mesh). The Tetranite Dental Adhesive Bone Scaffold (TN-ADBS) product comprises of a kit consisting of (a) the formulation powders and granules sealed in a mixing bowl, (b) aqueous medium pre-filled syringe, (c) a spatula and (d) delivery system that is sourced as an off-the-shelf syringe.

Competitive Advantage

Currently available particulate bone grafting products require significant surgical skill to apply. In contrast, TN-ADBS is a flowable biomaterial that is both cohesive and adhesive which enables the placement of the product without the ancillary containment and fixation aids. The product will reduce the overall time necessary to conduct ridge augmentation procedures, better maintain graft volume over time, and minimize the need for re-grafting, which adds time, cost, and risk to successful patient care.

ITP Support

ITP support has enabled RevBio to accomplish key product development and marketing milestones, including market survey to validate the clinical need and a lack of any known competitive products with comparable clinical value proposition, refinement of preclinical animal model and product formulation, GLP preclinical studies and supplier audits, provision of advice on user handling trials, and regulatory guidance in developing and refining a cohesive strategy for the commercial approval of the product.

Clinical Translation Pathway

Publications: Brown et al. From bench-to-bedside: Licensing and development of a mineral-organic bone adhesive for bone repair. Transactions of the Annual Meeting of the Society for Biomaterials and the Annual International Biomaterials Symposium 2019

Taylor et al. Translating Dental, Oral, and Craniofacial Regenerative Medicine Innovations to the Clinic through Interdisciplinary Commercial Translation Architecture. J Dent Res 2021

IP: US8,232,327, US8,273,803 Tetracalcium Phosphate Based Organophosphorus Compositions and Methods

US8,765,189 Organophosphorous & Multivalent Metal Compound Compositions and Methods

Anticipated regulatory pathway: Device-led combination product

Anticipated commercialization strategy: In development

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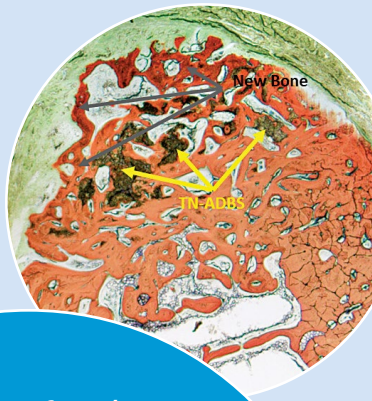

"The Resource Center has been an excellent collaboration between NIDCR, academia and industry. Not only does the collaboration foster the development of a clinical product but also accelerates the process. From histology core services to regulatory advice, the Center has worked hand in hand with us to ensure not only first-class science but development of the program for other investigators. All in all, this has been one of the most enriching processes in my time in translational research."

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