

RegendoGEL: A Bioinspired Hydrogel System for Endodontic Therapy

Clinical Need

Dental caries is the most common non-transmissible infectious disease in the world. If untreated, caries lesions will progress to the dental pulp, exposing it to infection. Standard of care techniques involve removing infected pulp and capping the defect with inert material, or root canal therapy. Currently, there are no clinically available materials that regenerate the pulp-dentin complex.

Solution

A team led by Luiz Bertassoni, DDS, PhD and Pamela Yelick, PhD has developed a novel material, RegendoGEL, intended to be the first-of-its-kind clinical product to promote vital pulp and dentin regeneration. RegendoGEL contains key bioactive molecules present in healthy teeth that naturally promote dental pulp and dentin regeneration and may be used for pulpotomies.

Competitive Advantage

Compared to non-degradable silicate/calcium hydroxide-based products currently used for endodontic treatments, RegendoGEL is a soft, biodegradable hydrogel material. RegendoGEL stimulates cells to migrate into the defect site and regenerate living dental pulp tissue and dentin in 5 days. RegendoGEL is designed as a ready-to-use product that can easily be applied using routine dental procedures.

Foundational Publications & Patents

- Cunha et al. 3D-printed microgels supplemented with dentin matrix molecules as a novel biomaterial for direct pulp capping. [Clin Oral Investig 2023](#)
- [PCT/US2018/035200](#) Dental pulp constructs
- [US11,278,474](#) Pulp regeneration compositions and methods of forming and using the same



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ITP Support

The project entered the ITP program in 2018, and since then has leveraged support from the Resource Center Cores including Regulatory, Preclinical Studies, microCT, Histology, Statistics, Market Assessment, and Commercialization. The ITP program has supported two in vivo experiments that have provided key results that catalyzed the formation of a new company, RegendoDent, Inc. Further, the program provided networking opportunities that led to third-party funding enabling the hire of a CEO for the company and preparing the company to attract potential business partners.

Key Inflection Points/ Regulatory Pathway

- Submit STTR grant & seed raising in Q3 2023
- Complete GLP Validation in Q4 2024
- 510(k) submission in Q1 2025
- First in human study anticipated to start upon FDA clearance

Opportunities for Partnerships

- Series A Funding for RegendoDent, Inc. to launch RegendoGEL and conduct a clinical trial

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