

# Stem cell-based therapies for bone regeneration around ailing dental implants



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## Clinical Need

Peri-implantitis is a destructive inflammatory process around osseointegrated implants in function, leading to pocket formation and loss of supporting bone. Disease prevalence is reported from 5–56%, with up to 80% of patients demonstrating peri-implant mucositis which can become peri-implantitis if untreated. Peri-implantitis is characterized clinically as soft tissue inflammation or infection (bleeding upon probing, loss of gingival attachment, and suppuration), and progressive loss of supporting bone beyond biological remodeling. Unfortunately, no therapy exists to regenerate bone around implants, leaving a major unmet need, where treatment will have a large market and immediate clinical adoption.

## Solution

We have developed and optimized a cell-based therapy where gingival mesenchymal stem cells (GMSCs) that possess immunomodulatory and anti-bacterial properties are delivered to the inflamed peri-implant bone defect site by a light curable, adhesive hydrogel that can be easily applied in the moist oral environment. These GMSCs are reproducible and consistent in their ability to differentiate into osteoblasts in vitro and regenerate bone defects in vivo. The product is effective, biocompatible, and safe, and utilizes a readily available MSC source from discarded oral surgical procedures.

## Competitive Advantage

We are a group of clinicians and scientists who understand the field of implant dentistry and the complications for our patients, especially the “time-bomb” of peri-implantitis. We have the necessary expertise in stem cell biology, biomaterials, basic science, translational models, and clinical research. This product is easy to use, effective, safe, and will fit right into the private dental office.

## Target Market

According to the American Dental Association, 5 million implants are placed per year, and a conservative estimate of 10% peri-implantitis would mean 500,000 new cases annually. This is in addition to the existing cases that develop bone loss over time, targeting specific patients at risk for disease progression and increased severity (smokers, history of or current periodontal disease, diabetics, and lack of regular dental maintenance). They will first target patients with smaller defects that do not have additional risk factors.

## Regulatory Pathway

Combination product (biologic–device) with the Primary Mode of Action (PMOA) being the stem cells so the regulatory path will be an IND with CBER as the lead agency. PMOA is well defined so no Request for Designation should be required.

## Intellectual Property

Permanent patent application (Patent No. PCT/US19/21660) on March 11, 2019 by Pearl, Cohen, Zedek, Latzer, Baratz LLP in New York City, NY.

## Related Publications

Hasani-Sadrabadi M, Sarrion P, Nakatsuka N, et al. (2019) Hierarchically patterned polydopamine-containing membranes for periodontal tissue engineering. ACS Nano, epub ahead of print.