Vital-Dent, A Revitalizing Root Canal Implant

Clinical Need

Approximately 5 million procedures are performed in the USA each year to treat pulpitis of permanent teeth in the pediatric population. Children are often subject to multiple procedures because the standard of care is to stabilize the tooth until more definitive treatment can be performed when the child's growth stops. The outcomes are unideal, because the whole tooth is not revitalized after pulp removal, resulting in tooth discoloration, loss of tooth structure, and limited (if any) tooth growth.

Solution

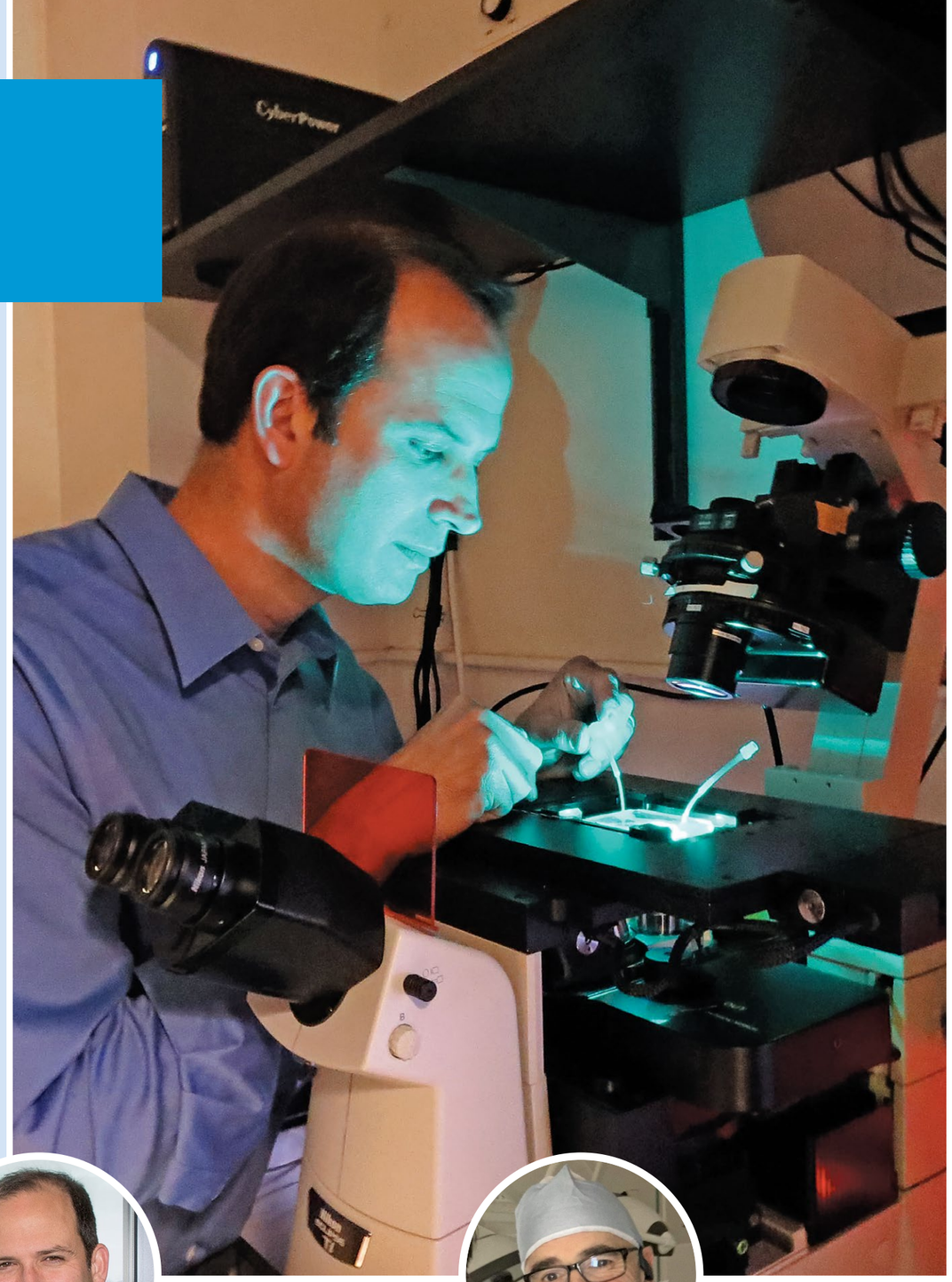
Vital-Dent is an acellular, resorbable hydrogel scaffold intended for revitalization of tooth pulp and maintenance of tooth vitality in immature permanent teeth treated with endodontic therapies. It is supplied as a powder in a single-use kit with sterile saline. The powder is rehydrated at the chairside using kit tools to make a clear liquid. The liquid is inserted into the instrumented canal space as would conventional sealers and sets in three minutes with a dental curing lamp to form the colorless Vital-Dent hydrogel. The tooth is then sealed with a bioceramic and restored with conventional techniques.

Competitive Advantage

Unlike current obturating materials, Vital-Dent is resorbable and promotes continued development of immature teeth, pulp revitalization and regenerative dentin, root strengthening, and long-term survival of the tooth. Vital-Dent eliminates difficulties of the only available revitalization procedure, revascularization therapy, with more consistent outcomes including root development, and a better fit with conventional clinic workflows including no phlebotomy and faster delivery.

Foundational Publications & Patents

- Zaky et al. Effect of the periapical "inflammatory plug" on dental pulp regeneration: A histologic in vivo study. J Endod 2020
- PCT/US2019/023132 Regeneration of Vital Tooth Pulp



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ITP Support

Through the ITP program, biocompatibility and in vivo proof-of-concept of Vital-Dent were demonstrated. In collaboration with the Regulatory Core, design control process has been implemented, and regulatory strategy established. With the Market Assessment and Commercialization Cores, user needs and the indication for market entry were defined and a commercialization strategy, including business and funding plans, was developed.

Key Inflection Points/ Regulatory Pathway

- 510(k) anticipated
- Submission of SBIR Phase II in Q3 2023
- Verification and validation of GMP product, GLP preclinical testing: estimated completion Q4 2025
- Regulatory approval and initiation of first-in-human study in Q3 2026

Opportunities for Partnerships

- Seeking corporate partner to back fundraising efforts for first-in-human studies and facilitate market adoption
- Academic partnership in studies that promote adoption and advance therapy development

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