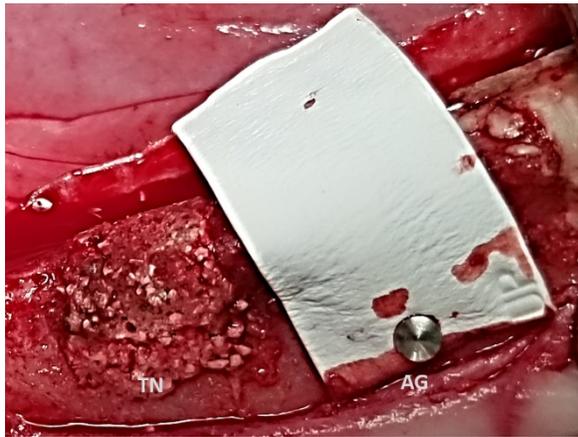


Launchpad Medical nabs \$1.8M grant for pivotal animal study of dental bone graft solution

By Meg Bryant



Jawbone from study with the optimized Tetranite (TN) bone graft formulation on the left, which is adhesive, vs. the standard-of-care treatment to the right, which is autograft (AG) particulate graft material contained into the bone defect using a membrane with tacks.

Credit: Launchpad Medical LLC

Lowell, Mass.-based startup Launchpad Medical LLC has picked up an additional \$1.8 million grant from the Michigan-Pittsburgh-Wyss Regenerative Medicine Resource Center to advance the development of its bone graft solution. The company plans to use the funds to conduct a pivotal animal study of the injectable biomaterial, which will pave the way for a U.S. FDA-approved clinical trial.

The grant follows two prior grants – totaling \$325,000 – from Michigan-Pittsburgh-Wyss, which received funding from the National Institute of Dental and Cranial Research to promote work on novel technologies for oral, dental and craniofacial conditions.

Founded in 2014, Launchpad licensed its bone adhesive technology from Stryker Corp. the following year, with the aim of commercializing it for use in repairing damaged teeth and bones. Previous animal studies have shown the self-setting synthetic biomaterial, called Tetranite, to be nontoxic and effective in repairing bone fractures and securing implanted devices. The osteoconductive bone adhesive is currently under development for several different applications.

Need for better dental bone grafts

According to the company, more than 4 in 10 patients already have a missing tooth at the time they get a dental implant, and with that varying degrees of bone loss. To repair the jawbone and receive the implant, these patients require a ridge augmentation using bone graft materials. However, current bone graft options fail in nearly a third of cases, necessitating another bone graft and extending the time and cost of treatment.

“Unlike most existing dental bone graft materials, this enhanced formulation of Tetranite resorbs and is replaced by bone on a timescale commensurate with existing graft materials but does not require ancillary containment devices like membranes or meshes or fixation aids like tacks and screws,” said Joseph Fiorellini, professor and director of the postdoctoral periodontics program and the University of Pennsylvania School of Dental Medicine and lead investigator for the grant. “The clinical use of this material will reduce the time and complexity of ridge augmentation procedures and likely to more consistent results with regard to maintaining the original volume of grafts.”

“The animal study will be a pivotal study to extend beyond [our] recent pilot study” of the Tetranite-based bone graft solution, Brian Hess, Launchpad Medical’s founder and CEO, told *BioWorld*. “The study is expected to start mid/late May and finish by late 2021, which is when the company plans to submit an IDE to FDA to initial a human pilot study.”

Dental implant trial underway

In 2019, the company got the go-ahead from the FDA to start a first-in-human clinical trial to evaluate the safety and efficacy of Tetranite for immediately stabilizing dental implants following tooth extractions. The two-site pilot study enrolled the first of 20 patients in December and is now fully enrolled, Hess said. “Longer-term assessments over a 12-month healing time frame are currently being conducted.”

The company expects to wrap up the study in early 2021 and use the data to seek FDA approval for a larger, pivotal clinical study. The results will form the basis for a regulatory submission to begin marketing a Tetranite-based dental stabilization product.

Launchpad Medical’s constellation of potential Tetranite-based applications goes beyond dental bone grafts and implants. In May, the National Institute of Neurological Disorders and Stroke awarded the company a \$2.5 million direct-to-phase II Small Business Innovation Research grant to advance the use of the biomaterial in cranial flap fixation procedures, which surgeons perform to gain access to the brain. The hope is that it will reduce infection rates and improve cosmetic results while freeing patients from the risks and constraints of metal fixation hardware.

Stemming bone loss

The company is also looking at Tetranite’s use in treating patients with osteoporosis, a major medical problem and health care expense given the aging of the global population. According to the International Osteoporosis Foundation, osteoporosis causes more than 8.9 million fractures a year – equivalent to one every three seconds.

In 2017, Launchpad Medical flew Tetranite on the International Space Station to study its behavior in microgravity and its ability to improve bone density in people with osteoporosis. Those experiments and other space-based research the company hopes to conduct could provide key insights on how Tetranite affects bone density, Hess said,

adding they “uniquely replicate conditions that stimulate an osteoporotic bone growth environment.”

“Many elderly patients who suffer from osteoporosis are denied hip replacement and other orthopedic surgeries due to the risk of additional bone fractures and further damage,” he said. “Tetranite might help in the treatment of these patients in the future.”

Source: <https://www.bioworld.com/articles/435528-launchpad-medical-nabs-18m-grant-for-pivotal-animal-study-of-dental-bone-graft-solution>