DRUG-LOADED, BIOPRINTED FIBRIN SCAFFOLDS FOR USE DURING CRANIAL NERVE REPAIR SURGERY

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CLINICAL NEED

Surgeons currently use collagen wraps or fibrin-thrombin tissue adhesives to reinforce nerve repairs and prevent axonal escape. Existing nerve wraps are xenografts made from non-human collagen (i.e., porcine), may induce inflammation, and do not deliver drug to the site of nerve repair. The ideal nerve wrap would allow therapeutic drug delivery, be easy to use intraoperatively, and would deliver therapeutic drugs to the site of repair.

SOLUTION

We will use 3D bioprinting with fibrinogen substrates to create nerve conduits that effectively seal sites of surgical nerve repair and release the small molecule SAG21k onto the repair site. Fibrin is an effective carrier protein for small molecule delivery.

COMPETITIVE ADVANTAGE

Despite the clinical need, there are no existing topical drug treatments for direct application to sites of nerve grafting or repair. Furthermore, existing devices for surgical nerve repair fail to incorporate modern 3D printing methodologies that promote migration of cells and elongation of cellular processes.

TARGET MARKET

Peripheral nerve injury (inclusive of facial and other cranial nerve injury) that requires surgical repair, with estimates of 200,000 cases per year in the United States. The global nerve repair and regeneration market size was estimated at USD 9.8 billion in 2021.

REGULATORY PATHWAY

Clinical application of a nerve wrap would also be subject to 510k approval from the FDA. As a small molecule therapy, SAG21k would require approval as an Investigational New Drug application.

INTELLECTUAL PROPERTY

US patent No. 63/445,963.

RELATED PUBLICATIONS

(1) Bobarnac Dogaru GL, Juneja SC, Shokrani A, Hui RY, Chai Y, Pepper JP. The role of Hedgehog-responsive fibroblasts in facial nerve regeneration. Exp Neurol. 2018;303:72-79. **(2)** Faniku C, Kong W, He L, Zhang M, Lilly G, Pepper JP. Hedgehog signaling promotes endoneurial fibroblast migration and Vegf-A expression following facial nerve injury. Brain Res. 2021;1751:147204.

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