Michigan • Pittsburgh • Wyss
Regenerative Medicine Resource Center

Gel-Factor Delivery for Reinnervation

David Mooney, PhD
Harvard University

Clinical Need

Craniofacial skeletal muscle plays a number of crucial roles, including control over facial expression, mastication, and respiration. There is a significant need for functional skeletal muscle tissue in reconstructive craniofacial surgery, where the current standard treatment for facial paralysis is the microvascular transfer of an innervated gracilis muscle to the affected side. However, this approach is limited by the unpredictable recovery and reinnervation of the muscle after transfer, leaving some patients with less than desirable functionality post-treatment.

Solution

A team of researchers at the Wyss Institute led by Dr. David Mooney has developed a degradable hydrogel that provides sustained release of growth factors when injected into transferred muscle. These hydrogels provide a direct neuroprotective role to the transplanted tissue, enhance reestablishment of neuromuscular junctions, and promote muscle engraftment. With these added functionalities, this approach is expected to enhance the success of the current clinical standard for skeletal muscle replacement in the craniofacial complex.

Competitive Advantage

There is currently no approach utilized in the clinic to enhance the function of these grafts. This new strategy is envisioned to be used with the current standard of care and is anticipated to provide a practical and clinically relevant approach that could be readily translated to the clinic. Furthermore, this product is expected to find utility in other clinical applications once it is established in the craniofacial complex.

"With minimally invasive injections we can deliver a combination of these active molecules while controlling degradation rates, and our tests in different ischemia animal models are very promising."

mooneylab.seas.harvard.edu

How the ITP Program Supports this Project

The goal of the work under the ITP program is to develop and validate a process to terminally sterilize the final hydrogel/ growth factor product. Demonstrating an effective terminal sterilization process that can provide sterility assurance without compromising the effectiveness of factor delivery, biocompatibility, and mechanical properties would be a major advancement towards clinical trials and potential commercial launch.

Clinical Translation Pathway

Publications:

VEGF and IGF Delivered from Alginate Hydrogels Promote Stable Perfusion Recovery in Ischemic Hind Limbs of Aged Mice and Young Rabbits. J. Vasc. Res. 2017. *(https://www.ncbi.nlm.nih.gov/pubmed/28930755)*

Intellectual Property:

US 9,610,328 Enhancement of skeletal muscle stem cell engraftment by dual delivery of VEGF and IGF-1. *(https://patents.google.com/patent/US9610328B2/)*

PCT/US2016/058866 Reduce and Oxidized Polysaccharides and Methods of Use Thereof. *(https://patents.google.com/patent/WO2017075055A1)*

Commercialization Strategy:

In development with the MPWRM Commercialization/ Market Needs Core

Regulatory Pathway:

In development with the MPWRM Regulatory Core

Product Launch Strategy:

In development with the MPWRM Commercialization/ Market Needs Core

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