CLINICAL NEED

Injuries resulting in facial paralysis significantly affect a patient both physiologically and psychosocially. The standard of care for nerve injury requiring surgical repair is nerve autograft, which is suboptimal for various reasons. While several nerve guides are commercially available for regeneration of nerve gaps <3cm, those for use in large nerve gaps (>3cm) are not. Furthermore, despite the available interventions, current cases of nerve autografting or allografting result in insufficient functional recovery, where ~50% of patients are unable to return to pre-injury employment 1 year post-operation.

SOLUTION

Kacey Marra, PhD, and her team at the University of Pittsburgh have developed a novel conduit for long-gap nerve repair, named AxoMax®. AxoMax® consists of a degradable poly(caprolactone) nerve guide capable of controlled local delivery of drugs for nerve regeneration. Evaluation of the AxoMax® in a 5cm median nerve defect model showed ~80% return to function after one year.

COMPETITIVE ADVANTAGE

Unlike decellularized technologies, AxoMax® elutes factors essential to nerve growth for several months, rendering it biologically similar to an autograft, the standard of care, without the need for a surgery to harvest the graft, thereby avoiding comorbidities associated with such procedures. The elimination of the harvesting procedure spares the patient from lifelong loss of sensation, as well as operating room time, saving an excess of 60 minutes per case.

ITP SUPPORT

With the ultimate goal of commercialization of AxoMax® for bridging craniofacial nerve defects, the work supported by the ITP program includes continued market validation and biocompatibility testing in support of a Q-submission to the FDA.

AxoMax®: A Novel Conduit for Enhanced Nerve Repair

KACEY MARRA, PHD
University of Pittsburgh

“This technology has the potential to revolutionize treatment of long gap nerve repair.”

https://www.mirm.pitt.edu/our-people/faculty-staff-bios/kacey-g-marra-phd

KACEY MARRA, PHD
University of Pittsburgh

AxoMax®: A Novel Conduit for Enhanced Nerve Repair

CLINICAL TRANSLATION PATHWAY

Publications:
Incorporation of double-walled microspheres into polymer nerve guides for the sustained delivery of glial cell line-derived neurotrophic factor. Biomaterials, 2010.

Intellectual Property:
US 9,498,221 Implantable medical devices having double walled microspheres.

Regulatory Pathway:
Anticipated: Device, 510(k), then IDE to enable PMA

Commercialization Strategy:
Technology licensed by AxoMax Technologies, Inc., a start-up company founded to advance AxoMax®

Product Launch Strategy:
In development with the MPWRM Commercialization/Market Needs Core

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A Novel Conduit that Enhances Nerve Repair
Benjamin Schilling, Baris Bengur, Chiaki Komatsu, Caroline Fedor, Amy Wylie, Patsy Simon, Mario Solari, and Kacey Marra
University of Pittsburgh, Pittsburgh, PA

UNMET CLINICAL NEED
Injuries resulting in facial paralysis significantly affect a patient both physiologically and psychologically. The standard of care for nerve injury requiring surgical repair is nerve autograft, which is suboptimal for various reasons. While several nerve guides are commercially available for regeneration of nerve gaps >1" are not. Furthermore, despite the available interventions (Figure 1), current cases of nerve autografting or allografting result in insufficient functional recovery, where ~50% of patients are unable to return to pre-injury employment 1 year post-operation.

MARKET ANALYSIS
Global nerve repair market: $2.7B
• Over 20M people worldwide suffer from nerve damage
• Over 800,000 surgical nerve repairs annually in the US
• Small gap nerve repair: $283M
• Large gap nerve repair: $668M

RESEARCH & DEVELOPMENT
We have initiated the rat facial nerve repair study as well as mechanical testing with Dr. Alex Almarza’s Laboratory. Figure 4a is a schematic of the rat facial nerve anatomy while Figure 4b is the actual rat dissection.

RESULTS
We will measure functional recovery by recording whisker movement. Figure 5a is a photo of a rat with one whisker marked in black, while Figure 5b is a restraint we will use while recording whisker movements.

Figure 6 depicts the testing of the nerve guides in Dr. Almarza’s laboratory. Suture retention strength, per ISO 7198:1998, will determine the ability of the device to hold a suture under increasing tensile load normal to the longest axis. We will include the mechanical testing results in our regulatory application to the FDA for the first clinical trial.

MANUFACTURING
We are working with Surgical Technologies, Inc. (STI) to produce our nerve guides under GMP manufacturing for the first clinical trial. Figure 7 depicts the packaging system that our lab as well as STI has developed.

REGULATORY PATHWAY
Our regulatory timeline for the next year is depicted above. We have had multiple phone conferences with both the Center for Devices and Radiologic Health (CDRH) and the Office of Combination Products (OCP) over the past 5 months, and we are on a pathway to an Investigational Device Exemption (IDE). However, if the OCP determines that our nerve guide is to be regulated as a drug, we will pivot and submit an Investigational New Drug (IND) application.

REFERENCES

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