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$10,000 "Cure it!" Lemelson-MIT Student Prize
Undergraduate Team Winner

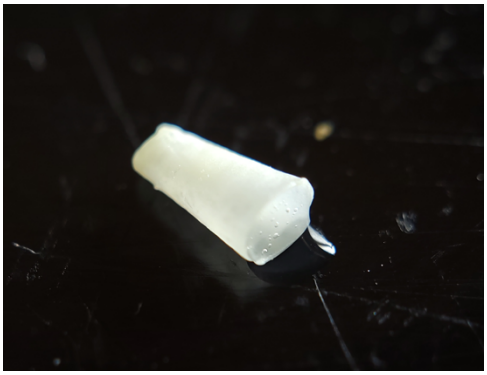
Innerva: A biodegradable nerve conduit device that connects severed, mismatched-sized nerves during surgery to treat peripheral nerve injuries and prevent neuromas

The Challenge: There are 20 million people in the U.S. with peripheral nerve injuries,[1] the most severe of which are caused by amputations. Following amputation, nerve cells at the amputation site often grow in a disorganized way, creating clusters of cells that form tumors known as neuromas. Neuromas are present in up to 80% of amputees,[2] and while they are not cancerous, they cause debilitating pain and seriously impede a patient's wellbeing. Patients may need medications or even repeat surgeries to address neuromas. The lost productivity, repeat hospital visits, and prescriptions are estimated to cost an average of $27,000 per patient annually.[3]

No existing technology can both promote functional peripheral nerve regeneration and inhibit neuroma formation, though some surgical procedures have tried. Targeted muscle reinnervation (TMR) is a promising amputation approach in which surgeons stitch the severed nerve to a smaller motor nerve. TMR facilitates nerve regeneration and is compatible with advanced prosthetics. There is a considerable size mismatch, however, between the small motor nerve and the larger severed nerve from which axons may continue to grow and form neuromas at the repair site. This results in a high failure rate, with 30% of patients still experiencing neuromas and subsequent pain.[4]

[1] Grinsell, D. & Keating, C.P. Peripheral nerve reconstruction after injury: a review of clinical and experimental therapies. BioMed Research Int. 2014: 698256 (2014).
[2] Hsu, E. & Cohen, S.P. Postamputation pain: epidemiology, mechanisms, and treatment. J. Pain Res. 6, 121–136 (2013).
[3] Schaefer, C. et al. Pain severity and the economic burden of neuropathic pain in the United States: BEAT neuropathic pain observational study. Clinicoecon. Outcomes Res. 6, 483–496 (2014).
[4] Dumanian, G. A. et al. Targeted muscle reinnervation treats neuroma and phantom pain in major limb amputees: a randomized clinical trial. Ann. Surg. 270, 238–246 (2019).

The Solution: The Innerva team invented a cone-shaped, biodegradable device that creates a bridge between nerves of different sizes, to be implanted during TMR. The device, inspired by a simple funnel, is made of an outer synthetic polymer cylinder and an inner biologically-based gel. The outer cylinder is made by electrospinning — a process that uses electric force to strip down and thin out a polymer solution into nanofibers that can be molded into a structure, in this case the cone shape. The cone structure creates a physical conduit that is flexible and tapered so that it can bridge different sized nerves together during TMR. The inner gel includes synthetic, biological components like natural sugars and nerve growth inhibitors to reduce inflammation and prevent neuromas. The combination of the gel and the cylinder allows for controlled nerve regeneration that promotes nerve recovery and inhibits formation of neuromas. The entire device also biodegrades in one to two years, leaving behind healthy, connected nerves.



Innerva's conduit device with gel filling. Photo Credit: Innerva

Early animal studies show that the device enhances normal nerve growth, prevents neuroma, and enhances muscle function in the area fed by the motor nerve. The device also integrates easily into TMR surgery since the conduit creates a larger surface area to work with, resulting in less need for surgical specialization and training.

Commercialization: Within the larger $2.7 billion nerve injury market, is a $500 million market comprising the 2 million current and 185,000 new amputees annually in the U.S.[5] Use of the TMR surgical procedure is gaining popularity, and has increased ten-fold since 2015.[6] Using this new invention within TMR could replace all other surgical procedures to address neuroma formation and pain.

The inventors founded Innerva to commercialize their device, and anticipate that it may be ready for market in as soon as five years. They have filed a provisional patent and plan to file for a utility patent later this year.

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[5] Axogen advances its platform for nerve repair at annual analyst and investor day. 2018 Report. https://ir.axogeninc.com/press-releases/detail/852/axogen-advances-its-platform-for-nerve-repair-at-annual, accessed on January 30, 2021.

[6] Part B National Summary Data File (Previously known as BESS) | CMS. https://www.cms.gov/Research-Statistics-Data-and-Systems/Downloadable-Public-Use-Files/Part-B-National-Summary-Data-File/Overview.