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Peripheral Nerve Regeneration: Translation of a Medical Device from Small Animals to Large Animals to Humans

Abstract: Severe injuries to peripheral nerves are challenging to repair. For nerve gaps >2-3 cm, the standard of care is autografting; however, autografting can result in neuroma formation, loss of sensory function at the donor site, and increased operative time. To address the need for an off-the-shelf synthetic nerve conduit to treat large nerve gaps, we developed a biodegradable conduit comprised of poly(caprolactone), (PCL). The inner portion of the PCL nerve conduit was embedded with double-walled poly(lactic-co-glycolic acid)/poly(L-lactic acid), (PLGA)/(PLLA) microspheres encapsulating glial cell line-derived neurotrophic factor (GDNF). Functional, electrophysiological and histological assessments demonstrated the efficacious bridging of a long gap in a non-human primate 5-cm median nerve defect model. The next steps (e.g. clinical translation) for those in academia can be particularly challenging. This talk describes the 20-year journey from biomaterials fabrication and characterization, to in vitro cell studies, to small animal studies, to large animal studies, and finally to clinical trials.