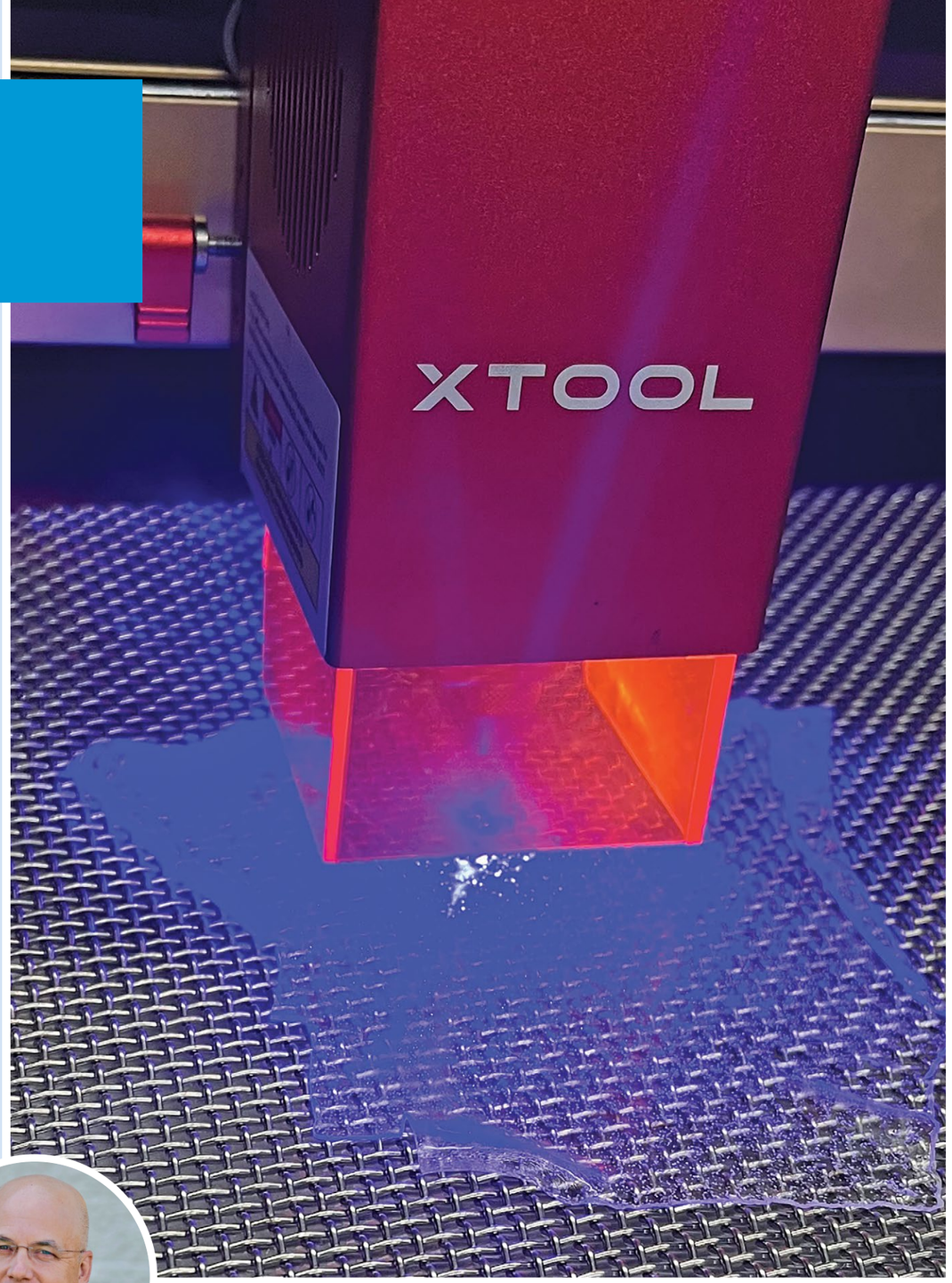
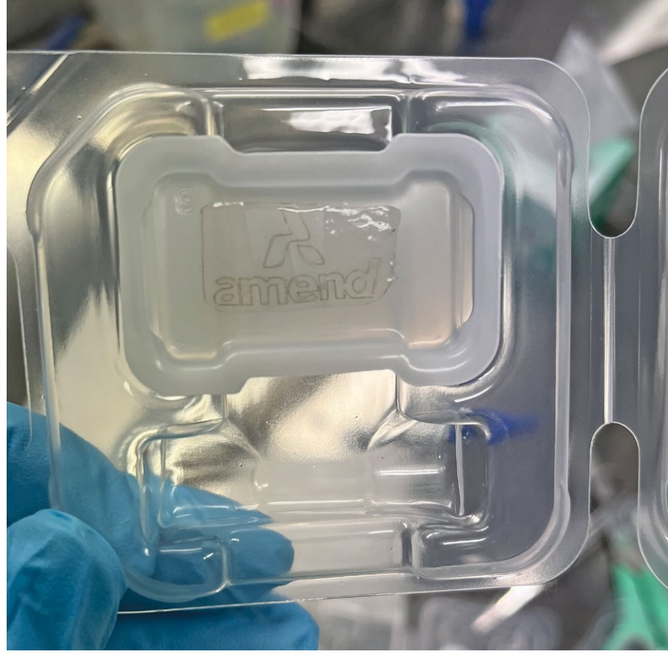
Suture-less Trigeminal Repair Device





Clinical Need

Micro-suturing is the current standard of care for the repair of trigeminal nerve injuries. Micro-sutured repairs are technically challenging and often inconsistent, with flaws in both fascicular alignment and spacing between severed nerve ends. Scar tissue associated with suture placement can impede axonal regeneration. Clinical need for oral surgeons: a suture-less repair solution.

Solution

Tissure™ is a degradable, hydrogel and chitosan-based nerve connector that has the adhesion and mechanical strength required to eliminate the need for suture to reconnect peripheral nerves. The product adheres to wet nerve tissue and provides over five times the adhesion energy of cyanoacrylate while also providing flexibility to stretch through range of motion without damaging nerve healing.

Competitive Advantage

Current competitors in peripheral nerve repair offer largely undifferentiated collagen and polymer materials for connectors, conduits, and wraps. None of the competitors offer a suture-less alternative for a direct (non-connector) nerve repair and all of their product lines require suture to prevent migration of their product.

Foundational Publications & Patents

- Wu DT et al. Tough adhesive hydrogel for intraoral adhesion and drug delivery. J Dent Res 2023
- Freedman, B et al. Degradable and removable tough adhesive hydrogels. Adv Mater 2021
- US9,387,276, US10,383,980 Interpenetrating networks with covalent and ionic crosslinks

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ITP Support

At the time of entry into the ITP program in 2023, the project already had a prototype and initial benchtop testing completed. At the end of the project period, design freeze and a non-GLP animal study are anticipated.

Key Inflection Points/ Regulatory Pathway

- 510(k) anticipated; pre-submission meeting will be held in Q2 2024
- Research and planning: market assessment, regulatory opinion and potential corporate partnerships
- Determine degradation rate, tune adhesion strength and perform benchtop comparative testing
- Perform animal nerve conduction study

Opportunities for Partnerships

- Company will initiate a Series A financing in Q4 2023 to support final year of development of Tissure™
- Company is in due diligence with a strategic product development and distribution partner

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