Amend Tissue Tape™ for Oral Wound Care

Clinical Need

An intraoral wound overlay for soft tissue that is easy to apply, remains in place for the duration of wound healing, and can be removed without causing damage to underlying tissue. Current options for oral wound care are limited to difficult to use, uncomfortable, and largely ineffective glues and resins.

Solution

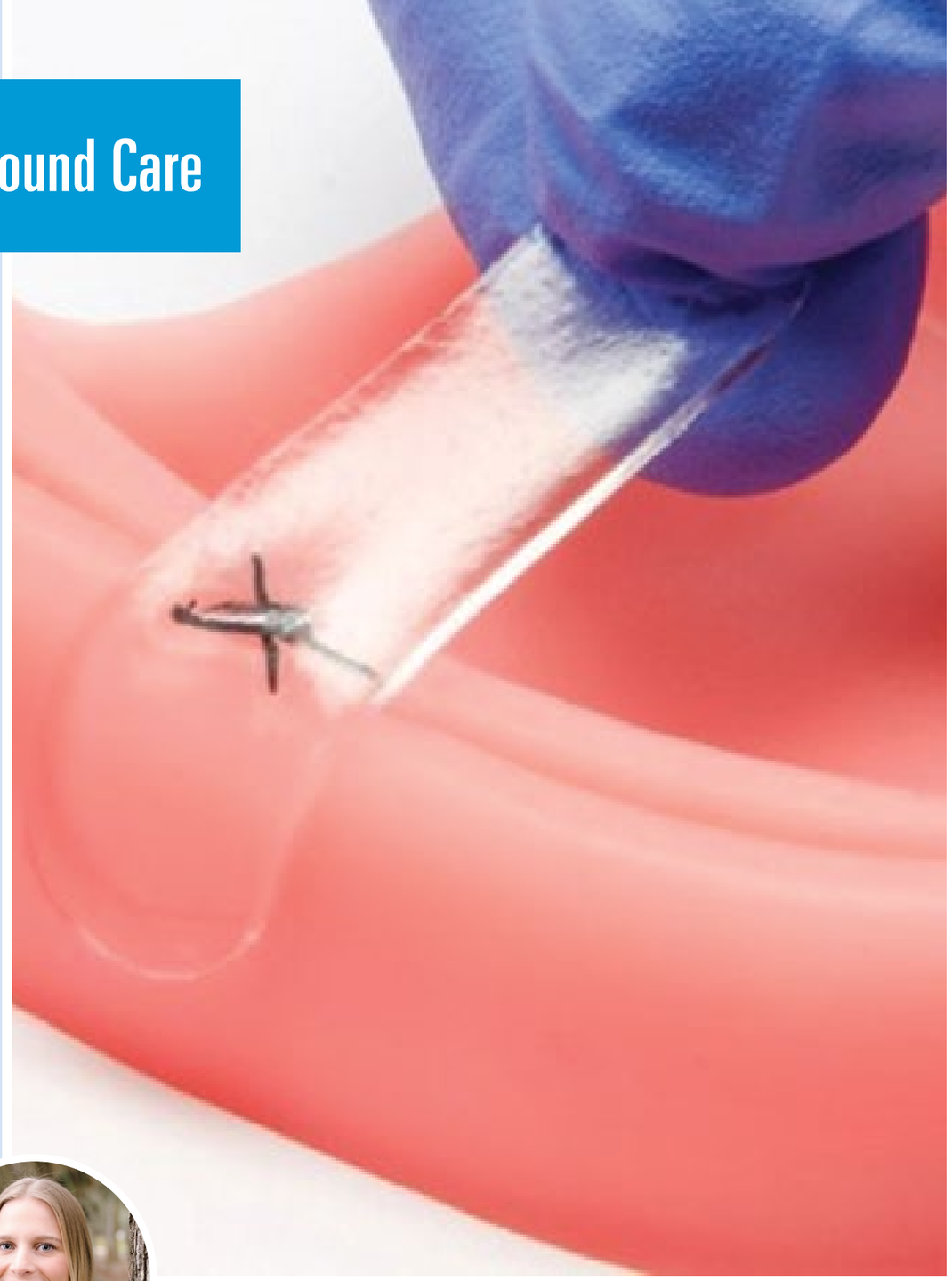
Amend Tissue Tape™ is a hydrogel-based adhesive comprised of two primary elements. The hydrogel consists of an interpenetrating network of alginate and polyacrylamide. The adhesive is composed of chitosan, which forms covalent bonds across the interface. When used together, the hydrogel and adhesive adhere to wet tissue and provide over five times the adhesion energy of cyanoacrylate while also providing a long duration mechanical barrier for the wound and flexibility to stretch with the wound without damaging the underlying tissue.

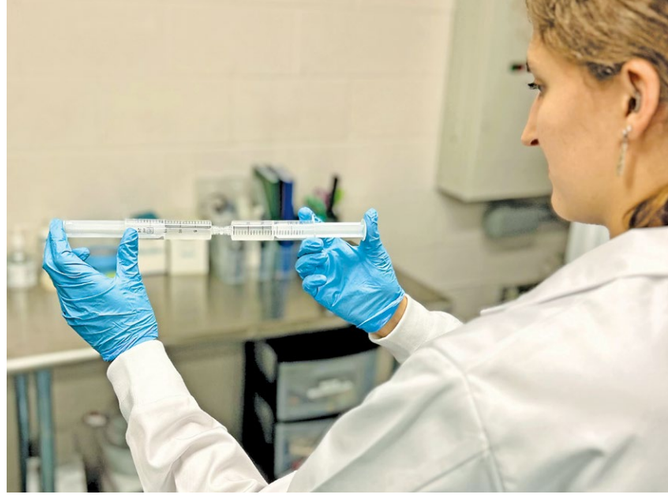
Competitive Advantage

There are limited products available that will safely adhere to sutured or non-sutured oral wounds. Periacryl, a cyanoacrylate-based product indicated as a dental cement, is often used off-label for wound closure. It requires a dry environment to fully set and is rigid, not stretching to accommodate movement or swelling. Amend Tissue Tape™ adheres to tissue in a wet environment, stretches with the wound, and stays in place for weeks, allowing wound healing to occur.

Foundational Publications & Patents

- Li et al. Tough adhesives for diverse wet surfaces. Science 2017
- PCT/US2019/055779 Bio-Inspired Degradable Tough Adhesives for Diverse Wet Environments





ITP Support

- Upon entry to the ITP program in 2021, optimization and initial demonstration of safety and efficacy of Amend Tissue Tape was performed.
- In the current ITP project stage in 2023, advanced characterization, initiation of manufacturing, and regulatory submission will be completed by the end of the grant period.

Key Inflection Points/ Regulatory Pathway

- 510(k) to be filed Q1/2024
- Upon FDA clearance, a post-market multisite clinical study will be initiated
- Initiate GMP production
- Perform non-GLP animal studies to assess adhesion performance on different tissue types
- Compile documents for 510(k) submission, submit 510(k), and obtain FDA clearance

Opportunities for Partnerships

- Pursue OEM partner
- Engage with commercial partner
- Initiate Series A equity financing round

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