Reversible Hydrogel Adhesive for Temporary Stabilization of Full-Thickness Corneoscleral Injuries

USC Ginsburg Institute for Biomedical Therapeutics

Triton Systems

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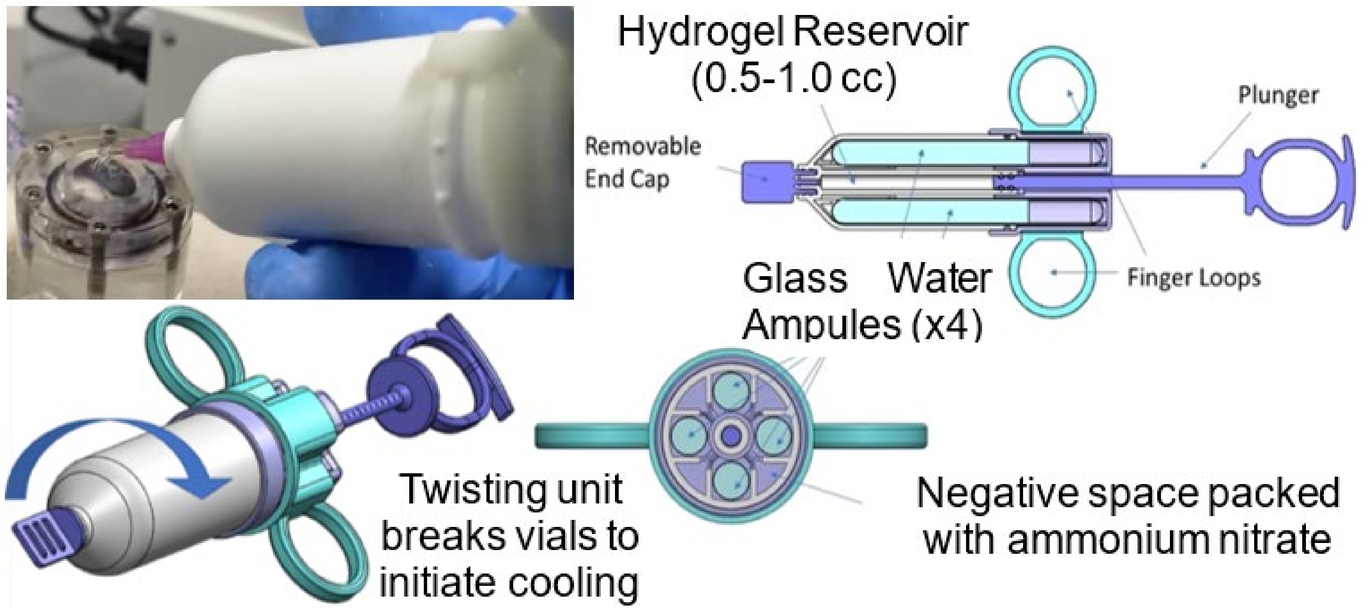

Technology

DoD Capability Gap

The current standard of care for temporary stabilization of corneal and corneoscleral open globe injuries in austere conditions is to implement a Fox Shield over the orbit. While this provides some mechanical protection against additional disturbance of the trauma, it does not provide a direct closure of an open globe which would help to preserve anatomical structures, to maintain neurosensory viability, and to reduce potential exposure to pathogens. This technology addresses that gap.

Technical advantages

- A thermo-responsive hydrogel (Bayat et al., 2017 & Whalen et.al, 2017)
- When cooled below 15C, absorbs water becoming a viscous-fluid behavior for easy deployment onto the eye
- When raised to body temperature (30C), the hydrogel expels water to become a semi-solid patch for occTo blusion of large open globe injuries
- A self-cooling syringe-like instrument requiring minimal skills for use in austere environments
- Softened hydrogel patch can be readily removed after application of cool water, causing minimal trauma to surrounding tissues

Work to Date

- ✓ We have advanced the development of this project in four key areas:
  1. Transition to GMP manufacturing
  2. Preclinical safety and performance testing
  3. Development of a regulatory strategy
  4. Design of a pilot clinical testing plan
- ✓ Different variants of the hydrogel have been produced, yielding a range of physical properties and related hydrogel performance
- ✓ Preliminary cytotoxicity testing has been performed demonstrating safety
- ✓ Successful hydrogel cooling by the applicator has been characterized
- ✓ Assessment of hydrogel-tissue adhesion and IOP sustainment for lacerated/unlacerated porcine cornea bench tests have been performed
- ✓ Ophthalmologists, other physicians, and medics evaluated the system (usability, ergonomics, and function) at USU's Ocular Trauma Workshop

Triton Systems, Inc.

- Established in 1992, Triton transitions R&D concepts manufactured products
- Combines private equity investments with public non-dilutive funds
- Large in-house team of engineers, applications developers and process experts develop products, in house and through partnerships
- Created > $4B in shareholder value over the past 15 years by leveraging > $370M in non-dilutive development funds.
- Market based focus areas:
  - ✓ Structures & AM
  - ✓ Specialty Materials
  - ✓ Sustainment
  - ✓ Artificial Intelligence
  - ✓ Living Systems
  - ✓ Ocean Systems
  - ✓ Robotics
  - ✓ Acoustics
  - ✓ Human Systems
  - ✓ Sensors

Work Yet to be Done

Remaining Effort	~ Cost Estimate	Time Estimate
Pre-clinical Biocompatibility and Safety Testing	$260k	2-3 months
Clinical Trial Planning and Proposal Development	$60k	2-3 months
FDA IDE	$75-150k	2-3 month
GMP Finalization	$90k+	5-6 months

Acknowledgements/Disclaimer

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