Executive Summary (modified from awarded Partners for Innovation NSF grant)

Lower urinary tract reconstruction requires luminal anastomoses that are complex and require significant skill and experience to minimize the current high-risk of post-operative complications. Additionally, tissue in many cases is suboptimal resulting from poor vascularity and quality due to radiation or fibrosis secondary to traumatic injury. There is a need to consistently and reliably support and secure suture lines to promote wound healing in the absence of urine leak, regardless of tissue quality and/or surgeon experience.

Based on >100 qualitative interviews performed during the NSF I-Corps program, the Bio-Zipper development team found that the key value proposition across stakeholders was a need to reduce complications and readmissions. Specifically, a solution was needed to reinforce tissue and remove localized tension from suture lines in flexible, expandible organs.

Areas of proposed testing for future application: Initial use is proposed in lower urinary tract reconstruction, ensuring secure anastomosis (urethrovesical, ureteroenteric, bowel-to-bladder, bladder-to-bladder, bowel-to-bowel) to ensure rapid closure and expedited healing. However, additional uses anticipated are to support suture lines in cardiovascular, pulmonary, gastrointestinal, and gynecologic procedures.

The Value Proposition.

The **Bio-Zipper** is a surgical device that is designed to **reinforce** suture lines in the urinary tract for urologists to decrease total complications and readmissions by ~**20%**, resulting in an average savings of at least **$5.6k to the hospital per procedure**.

The Innovation:

The Bio-Zipper is a rapidly deployable, bioabsorbable internal surgical closure device used to reinforce suture lines in flexible, distensible organs. The proposed value of this device is to decrease post-operative complications through improved alignment of adjoining tissue, alleviation of tension across the suture line, and promotion of faster healing and revascularization of the conjoined tissues. The Bio-Zipper is composed of multiple bioabsorbable patches that adhere to tissue and then connect across the suture line using a drawstring suture or latching system. The device has a flexible backbone tuned to the mechanical characteristics of the tissue to which it is applied, a bio-adhesive, and a mechanism for pulling the two aspects (across the closure line) together. The Bio-Zipper provides support that eliminates regions of localized tension and facilitates rapid return to physiologic function in these cycling organs. IP protection is in place for both the device design as well as the novel biomaterials used in the surgical adhesive.

The Partnership

The research team at UCLA collaborates closely with the Terasaki Institute for Biomedical Innovation (TIBI) and its CEO Dr. Ali Khademhosseini, PhD as the project was initiated at UCLA prior to his relocation. TIBI will play a significant role in ongoing materials testing and optimziation of the bioabsorbable flexible backbone, as well as the bio-adhesive mechanism. In addition to scientific advising, Dr. Khademhosseini will act as the Co-Founder of the new small business entity, along with his collaborative partner Dr. Renea Sturm. Dr. Reihaneh Haghniaz at TIBI, plays a major role coordinating material and adhesive research efforts at TIBI.Dr. Sturm is a pediatric urologist and scientist with strong background in tissue engineering and device evaluation. She has been PI for the prior grants supporting this work, and is Co-Founder of the small business entity. Dr. George Aninwene II, a project scientist in her lab, supported the initial needs mapping and early prototyping phases of this work. We are in need of a CEO to join our expanding team as we initiate a small business, and seek SBIR and outside investments to support commercialization of this award winning innovation.