HealSuture: A Suture That Deposits a Tissue Regenerative Medicine to Prevent Scarring During Surgical Wound Healing

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Unmet Need

Scars are an inescapable consequence of surgical wound healing, because of normal processes of healing in mammals. For functional and cosmetic reasons, there is great interest in developing tools for non-scarring regeneration of normal tissue after a surgical procedure. While considerable effort has been dedicated to improving suturing and wound healing strategies that reduce scarring, more effective approaches are still needed.

Basic research into the regenerative capabilities of amphibians and the MRL mouse strain that can regenerate lost appendages, where scars do not develop at the injury site as a result of epimorphic healing, have now led to the development of a novel suture formulation that limits scarring. This clinical device – referred to as *HealSuture* due to its deposition of a compound LIMR scientists have determined can promote epimorphic regenerative healing – offers an off-the-shelf modality to reprogram the capabilities of a tissue microenvironment, limiting the formation of scar tissue during the healing of surgical wounds.

Opportunity

HealSuture is conceptualized in two forms for different surgical uses. The first is a dissolvable polylactic acid (PLA)-based suture infused with the active compound. The second is a compound-coated silk suture with similar properties. In essence, these sutures locally re-activate a latent fetal program of stem cell-based regenerative healing that avoids fibrotic deposition (scar tissue).

Using the suture as a depot for release, the active compound is released continuously into the local tissue over a ~2 week period as the PLA suture dissolves or the silk suture is removed. Varying doses released by different PLA suture preparations are envisioned to tailor treatments to maximize non-scarring healing of various types or locations of surgical wounds. This technology does not interfere with other methodologies that may be applied by surgeons to improve wound healing, including to limit scar formation, infection risk or other factors that influence optimal wound healing in a patient.

In summary, *HealSuture* offers an off-the-shelf clinical device to capture a latent capability for epimorphic healing, a non-scarring process of tissue regeneration suppressed in mammals after fetal development that can locally re-activated by this technology.

Unique Attributes

To our knowledge, there is no dissolving suture technology that re-activates the natural latent process of epimorphic regenerative healing that is characteristic of fetal tissue at a surgical wound site. Unlike other technologies, the active compound deposited by suture does not directly prevent scarring, but instead relieves suppression of a latent fetal pathway that reprograms local inflammatory and stem cell functions in the wound. The active compound in this technology was characterized extensively for its ability to promote regeneration in a variety of tissue types damaged by trauma, surgical resection, infection and age-related degeneration. Accordingly, *HealSuture* may have special utility to promote optimal healing of many types of surgical wounds.

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Clinical Applications

HealSuture applications are based on preclinical studies suggesting that deposition of the active compound can promote regeneration of cartilage, nerve, bone, vasculature, muscle, and organ tissues while limiting the formation of fibrotic tissue, the major constituent of wound scars. Thus, the suture technology is expected to be suitable for repairing surgical wounds, but also wounds caused by trauma, infection, normal or pathogenic tissue degeneration and other types of wounds that require suturing. Accordingly, we envision broad general applications in diverse tissues where clinical proof of concept is testable.

Stage of Development

Preclinical genetic and therapeutic proof of concept in mice has been published for a first-generation drug-hydrogel formulation. Current work focuses on second-generation drug-hydrogel or other drug-conjugates thought to offer potential clinical lead agents. Investigations on deposition efficiency, time-course and drug clearance after wound suturing with *HealSuture* are ongoing.

Intellectual Property

1. Novel drug-hydrogel conjugates and their uses for epimorphic tissue regeneration. Pending patent application filed with University of California at Berkeley.
2. Epimorphic tissue regeneration and related hydrogel delivery systems. U.S. Patent No. 10,307,415 (issued 4 June 2019) and U.S. Patent No. 9,675,607 (issued 13 June 2017) are each co-assigned to The Wistar Institute and Northwestern University where Dr. Heber-Katz and her co-inventor (now at University of California at Berkeley) had worked previously.

Collaboration Opportunity

LIMR seeks partners to advance IND-enabling studies of the *HealSuture* as a unique clinical device for non-scarring regenerative healing of surgical wounds.

References and Publications

- Zhang Y, Strehin I, Bedelbaeva K, Gourevitch D, Clark L, Leferovich J, Messersmith PB and Heber-Katz E. (2015). Drug-induced regeneration in adult mice. Sci Transl Med. 7: 290ra92.
- Cheng J, Amin D, Latona J, Heber-Katz E and Messerschmidt PB. (2019). Supramolecular polymer hydrogels for drug-induced tissue regeneration. ACS Nano. 13: 5493-5501.

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