



Esophagel™: Revolutionizing the way we treat esophageal disease ID: 3936

Featured Innovators: Stephen F. Badylak, DVM PhD MD, Juan Diego Naranjo, MD, and Lindsey Saldin






Patients diagnosed with esophageal adenocarcinoma (EAC) have a 5-year survival rate of only 20 percent. The main treatment for esophageal cancer is esophagectomy – a century-old procedure that requires significant surgical expertise – and the procedure alone carries a mortality rate as high as 18 percent. The most important risk factor for EAC is Barrett's Esophagus (BE). There are no known options for reversal of Barrett's disease in its early and more advanced stages. Currently, the standard of care for BE is endoscopic surveillance to detect early neoplasia. Although surgical removal of BE is possible, it is associated with a high risk of stricture, but applying a new material called Esophagel™ could mitigate this risk by providing favorable conditions for the esophagus to heal.

Technology Description

Esophagel™ is a hydrogel derived from the extracellular matrix (ECM) of tissues. The hydrogel is a liquid at room temperature and forms a gel at body temperature (37°C). It adheres to the esophageal mucosa. The components of the ECM can control inflammation and provide a normal favorable environment for cells. The hydrogel can be delivered to the esophagus by minimally invasive methods such as endoscopy or oral administration. Esophagel™ has beneficial effects such as the mitigation of scarring and stricture and the control of the immune response.

Advantages



-  Improves patient outcome and reduces costs by enabling earlier intervention
-  Modulates esophageal cell behavior and key signaling pathways
-  Can be administered orally or endoscopically to the mucosa or submucosal space
-  Forms stable gel within 5 minutes and is muco-adhesive
-  Strong intellectual property position (2 issued patents, 3 in prosecution)

Applications

- Treatment of Barrett's Esophagus
- Prevention of stricture after esophageal mucosal dissection
- Submucosal fluid cushion for endoscopic mucosal resection – endoscopic submucosal dissection

Stage of Development

Proof of concept experiments for submucosal fluid cushion application are complete. Clinically relevant pre-clinical studies for reversal/mitigation of Barrett's disease and for prevention of stricture after resection are currently in progress. FDA pre-submission is in preparation.

IP Status

- Granted patents for gelation method and production of ECM
- Patent for sterilization of material is pending
- Provisional patent filed for use of ECM in esophageal applications

Notable Mentions

Pitt Innovation Challenge (PInCh) 2016 winner - \$100,000

Innovators



Stephen F. Badylak, DVM PhD MD

Professor of Surgery
Director of the McGowan Institute for
Regenerative Medicine
University of Pittsburgh

Education

DVM Purdue
PhD Purdue
MD Indiana University Medical School
MS Purdue

Dr. Badylak has practiced both veterinary and human medicine, and is now fully engaged in research. He began his academic career at Purdue University in 1983, and subsequently held a variety of positions including service as the Director of the Hillenbrand Biomedical Engineering Center from 1995-1998.

Dr. Badylak holds over 60 U.S. patents and 300 patents worldwide. He has authored more than 350 scientific publications and 40 book chapters and has recently edited a textbook entitled "Host Response to Biomaterials". He has served as the Chair of several study sections at the National Institutes of Health (NIH), and is currently a member of the College of Scientific Reviewers for NIH. Dr. Badylak has either chaired or been a member of the Scientific Advisory Board to several major medical device companies. More than eight million patients have been treated with bioscaffolds developed in Dr. Badylak's laboratory.

Dr. Badylak is a Fellow of the American Institute for Medical and Biological Engineering, a member of the Society for Biomaterials, a charter member of the Tissue Engineering Society International, a past president of the Tissue Engineering Regenerative Medicine International Society (TERMIS) and a Founding International Fellow of TERMIS.

Publications

- Hussey GS, Keane TJ, Badylak SF. The extracellular matrix of the gastrointestinal tract: a regenerative medicine platform. *Nature Reviews Gastroenterology and Hepatology*. 2017 Sep 1;14(9):540-52.
- Keane TJ, DeWard A, Londono R, Saldin LT, Castleton AA, Carey L, Nieponice A, Lagasse E, Badylak SF. Tissue-specific effects of esophageal extracellular matrix. *Tissue Engineering Part A*. 2015 Aug 12;21(17-18):2293-300.



Juan Diego Naranjo, MD

Post-doctoral Fellow
McGowan Institute for Regenerative
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University of Pittsburgh

Education

MD Universidad de los Andes, Colombia
BS Asociación Colegio Granadino,
Columbia

Following his medical training, Dr. Naranjo interned in General Surgery in Fundacion Santa Fe de Bogota, Pediatric Surgery in Fundacion San Vicente in Medellin, Colombia and Plastic Surgery at Hospital Das Clinicas in Sao Paulo, Brazil.

Dr. Naranjo has worked with extracellular matrix for regenerative medicine since medical school, where he evaluated the use of extracellular matrix scaffolds as vascular grafts. Currently, he is a post-doctoral fellow in Dr. Stephen F Badylak's lab. His work focuses on investigating the use of extracellular matrix for esophageal repair. Dr. Naranjo is also a volunteer consultant for Fourth River Solutions, a student-led non-profit consulting organization, and he is part of the Due Diligence Team at BlueTree Allied Angels.



Lindsey Saldin

PhD Candidate
McGowan Institute for Regenerative
Medicine
University of Pittsburgh

Education

BS UC Berkeley

Lindsey Saldin is a Bioengineering PhD candidate and NIH National Cancer Institute F31 fellow at the University of Pittsburgh. Her thesis focuses on extracellular matrix changes in esophageal adenocarcinoma progression as well as the use of extracellular matrix hydrogels as a treatment for esophageal cancer and its cancer precursor stages. While pursuing her BS in bioengineering, Lindsey studied the effects of the microenvironment to suppress breast cancer in models of cancer cell dormancy in Dr. Mina Bissell's laboratory.

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