

Integration of Breast Reconstruction with Cancer Diagnosis and Treatment by Nanomedicine

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and

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Breast Cancer is Diagnosed in over 200,000 American Women Each Year

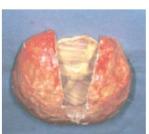
- Breast cancer claims >40,000 American lives each year
- Mastectomy with postoperative chemotherapy offers the best rate of survival
- Current tissue expanders and implants for reconstruction are silicone rubber-based that contains potentially harmful chemicals and cause inflammatory reactions
- 19% of post-mastectomy patients are currently subjected to recurrent cancer (2-3 years average)

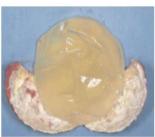


Reconstruction

Silicone Rubber is Permeable, Prone to Rupture and often Elicits an Inflammatory Response

 With current breast implants: 35-50% of breast reconstruction patients require revisional surgery within 6 years







Capsular Contracture: A thick fibrous capsule forms around some implants leading to pain and disfigurement

Chemotherapy

IV or oral – attacks all cells, causing side effects (hair loss, nausea, etc.)

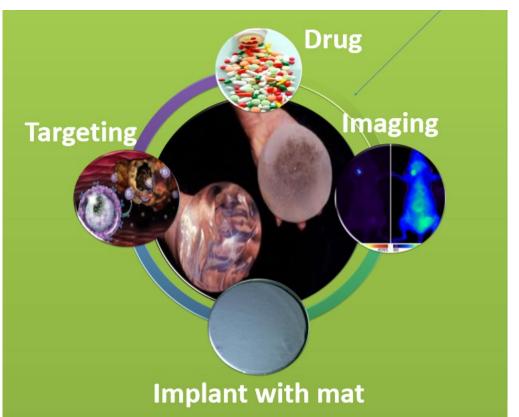
Targeted Chemotherapy
Only cancer cells

Still experimental, did not live up to promise





Polymer-based Integration of Breast Cancer Imaging/Treatment with Reconstruction





Winners of the GE Healthymagination Challenge

- Launched by GE in September 2011 to identify and accelerate ideas to advance breast cancer early detection and diagnostics to help save lives
- GE healthymagination Challenge promised a \$100 million open innovation challenge help to identify and bring to market ideas that advance breast cancer diagnostics and treatment.
- More than 500 proposals from 40 countries were submitted in response to the "GE Healthymagination Cancer Challenge"
- GE awarded \$100,000 to each of five, breakthrough research ideas, including ours then disappeared













Allomatrix[™]: A Novel, High Performance Biomaterial



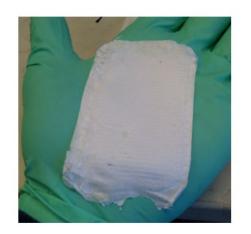
- Chemically and biologically stable
- Biocompatible
- Softer with better fatigue properties
- Impermeable to gases and liquids
- Self-sealing
- Reduced inflammatory response
- Thermoplastic rubber; no chemical additive

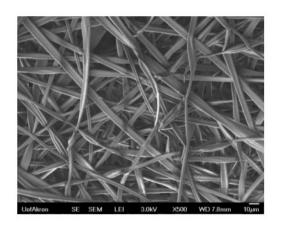
The first polymer Puskas coinvented serves as the drug-eluting coating on the Taxus coronary stent that has been implanted into > 6 million patients



Allomatrix™ Self-Supported Fiber Mats Provide Textured Vehicle for Local Drug Delivery

Electrospun Allomatrix™ fiber mat





Implant covered with mat



Encapsulation of traditional and nanomedicine for a slow, sustained local release:

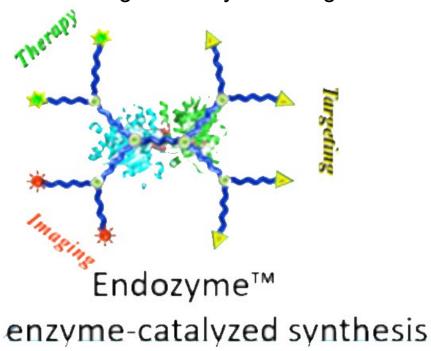
Cancer diagnosis and treatment

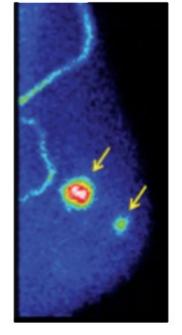


Multifunctional Nanodevices

- Lower doses in chemotherapy
- Less/no side effects (hair loss, nausea)
- Imaging stray cancer cells

Folate-targeted Polymer-Drug

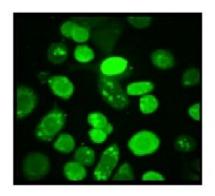




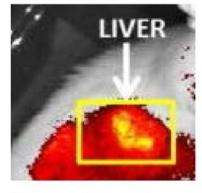


Recent Results

Fluorescein imaging

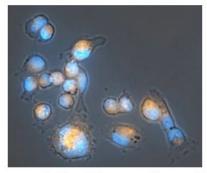


Delivery inside breast cancer cells



Rat liver tumor diagnosis

Drug delivery inside breast cancer cells



Blue: nuclei Orange: Doxorubicin



The Allomatrix/EndozymeDrug Delivery Platform Can be Expanded for a Range of Application

- Needs: establish GMP manufacturing of Allomatrix[™] and Endozyme[™] and to move to pilot scale production
- Technology can be expanded to allow for implantable devices with Antimicrobials, Anti-inflammatory agents, Steroids, Analgesics
- Aim to improve the efficacy of current biomedical devices by providing an improved biomaterial with pharmaceutical capabilities and to allow for the development of novel device technologies
- Medical Device Development: Ongoing collaboration with the Cleveland Clinic and the Semmelweis Medical University (Hungary)







