

BIOGRAPHICAL SKETCH

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NAME Badylak, Stephen F.	POSITION TITLE		
eRA COMMONS USER NAME (credential, e.g., agency login) Sbadylak	Professor		
EDUCATION/TRAINING <i>(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)</i>			
INSTITUTION AND LOCATION	DEGREE <i>(if applicable)</i>	YEAR(s)	FIELD OF STUDY
Purdue University, West Lafayette, Indiana	DVM	05/76	Veterinary
Purdue University, West Lafayette, Indiana	MS	05/78	Clinical Pathology
Purdue University, West Lafayette, Indiana	PhD	05/81	Anatomic Pathology
Indiana University, Indianapolis, Indiana	MD	07/85	Medicine

A. Personal Statement

The Badylak laboratory is focused upon the development and clinical translation of biologic scaffolds for functional tissue reconstruction. There is a heavy emphasis upon the interdisciplinary and translational aspects of regenerative medicine. All body systems are the subject of research projects, with special emphasis upon head and neck structures, liver, cardiovascular system, the esophagus, musculoskeletal system (soft tissue), and central nervous system. There is a heavy emphasis upon the interdisciplinary and translational aspects of regenerative medicine including bioengineering, cell biology, molecular biology, biochemistry, and immunology. All studies, including those studying the most fundamental mechanisms such as the host innate immune response, gene transcription, metabolic pathways, and effectors of cell phenotype are conducted with the effect of the findings upon patient care in mind. Our studies involve several forms of biologic scaffolds which typically are composed of xenogenic (animal origin) mammalian extracellular matrix; including whole organ 3-dimensional scaffolds derived by organ decellularization. Genetic profiling, cell signaling, cell matrix interactions, in-vitro cell culture, biomechanical testing, preclinical animal studies, and human clinical studies are actively pursued in the Badylak laboratory (Dr. Badylak is currently the PI on one active clinical trial focused upon musculotendinous tissue reconstruction). The laboratory is highly interdisciplinary by design and therefore close communication among all members of the research team is vital to success. All members of the laboratory are keenly aware of meeting milestones and all members of the laboratory are exposed to a productive mixture of industry sponsored research and federally funded basic science research. My interest in the utilization of biologic scaffolds, including the preparation and characterization of such scaffolds, spans more than 25 years. More than 4 million human patients have now been successfully treated with scaffold materials developed by our laboratory. The laboratory consists of approximately 6 staff scientists, 4 – 5 postdoctoral fellows, 6 predoctoral students (including about 50% MD/PhD students), 3 – 5 undergraduate students, a technical support staff, and an administrative support staff. For more information, please see <http://www.mirm.pitt.edu/badylak/>.

B. Position and Honors

Professional Experience

1985 – 2002 Senior Research Scientist, Department of Biomedical Engineering, Purdue University
1987 – 2002 Practicing Physician for Purdue University
1993 – 1996 Associate Professor, Dept. of Vet. Physiology & Pharmacology, Purdue University
1995 – 2002 Adjunct Associate Professor of Pathology & Laboratory Medicine, Indiana University School of Medicine
1995 – 1998 Director, Biomedical Engineering Center, Purdue University
2003 – 2007 Professor-Research, Department of Surgery, University of Pittsburgh
2007 – Professor, Department of Surgery, University of Pittsburgh
2003 – Deputy Director, McGowan Institute for Regenerative Medicine

2010 – 2012 Tissue Engineering and Regenerative Medicine International Society (TERMIS),
President

Honors

2005 Clemson Award for Applied Science – Society for Biomaterials
2005 and 2008 Carnegie Science Center Award for Excellence-Life Sciences Category
2008 Carnegie Science Center Award for Advanced Materials Category
2008 Chancellor's Distinguished Research Award
2012 Founding Fellow of the International Fellows of Tissue Engineering &
Regenerative Medicine (FTERM)
2012 TERMIS (America's Chapter) Senior Scientist Award – 2012

Advisory Board Memberships

2005 – Member – Scientific Advisory Board for Humacyte, Inc. (North Carolina)
2007 – Member – Scientific Advisory Board for Ratner BioMedical Group (Washington)
2009 – Member – Scientific Advisory Board for Carmell Therapeutics Corporation

Federal Government Public Advisory Committee Service

1995 – 2002 NIH SBIR Study Section – Chair, National Institutes of Health
1997 – Cardiovascular Study Section and BTSS – Ad Hoc Member, National Institutes of Health
2000 DARPA Study Section, Ad Hoc Member
2002 – 2006 Surgery and Bioengineering Study Section – Chair, National Institutes of Health
2006 – Special Emphasis Study Section – National Institutes of Health
2009 – College of Scientific Reviewers – National Institutes of Health

C. Selected Peer-Reviewed Publications (Partial list from more than 280)

Most relevant publications to current application

1. Crapo PM, Medberry CJ, Reing JE, Tottey S, van der Merwe Y, Jones KE, **Badylak SF**. Biologic scaffolds composed of central nervous system extracellular matrix. *Biomaterials*, 2012. 33 (13): 3539-3547. PMID: 22341938. PMCID: 3516286.
2. Medberry CJ, Crapo PM, Siu BF, Carruthers CA, Wolf MT, Nagarkar SP, Agrawal V, Jones KE, Kelly J, Johnson SA, Velankar SS, Watkins SC, Modo M, **Badylak SF**. Hydrogels derived from central nervous system extracellular matrix. *Biomaterials*. 2013 Jan;34(4):1033-40. PMID: 23158935. PMCID: 3512573.
3. Bible E, Dell'Acqua F, Solanky B, Balducci A, Crapo PM, **Badylak SF**, Ahrens ET, Modo M. Non-invasive imaging of transplanted human neural stem cells and ECM scaffold remodeling in the stroke-damaged rat brain by (19)F- and diffusion-MRI. *Biomaterials*, 2012. 33 (10): 2858-2871. PMID: 22244696. PMCID: 3268910.
4. Crapo PM, Tottey S, Slivka PF, **Badylak SF**. Effects of biologic scaffolds on human stem cells and implications for CNS tissue engineering. *Tissue Eng Part A*. 2014 Jan;20(1-2):313-23. doi: 10.1089/ten.TEA.2013.0186. Epub 2013 Oct 10. PubMed PMID: 24004192; PubMed Central PMCID: PMC3875189.
5. Modo M, Ambrosio F, Friedlander RM, **Badylak SF**, Wechsler LR. Bioengineering solutions for neural repair and recovery in stroke. *Curr Opin Neurol*. 2013 Dec;26(6):626-31. PubMed PMID: 24136127.

Additional recent publications of importance to the field

1. Wolf MT, Daly KA, Brennan-Pierce EP, Johnson SA, Carruthers C, D'Amore A, Nagarkar SP, Velankar SS, **Badylak SF**. A hydrogel derived from decellularized dermal extracellular matrix. *Biomaterials*. 2012;33(29):7028-38.
2. Agrawal V, Brown BN, Beattie AJ, Gilbert TW, **Badylak SF**. Evidence of innervation following extracellular matrix scaffold-mediated remodelling of muscular tissues. *J Tissue Eng Regen Med*, 2009. 3 (8): 590-600. PMID: 19701935.

3. Reing, J.E., Zhang, L., Myers-Irvin, J., Cordero, K.E., Freytes, D.O., Heber-Katz, E., Bedelbaeva, K., McIntosh, D., Abiche, D., Braunhut, S.J., **Badylak, S.F.** Degradation Products of Extracellular Matrix Affect Cell Migration and Proliferation. *Tissue Engineering*. 2009 Mar;15(3):605-14. PMID: 18652541.
4. Brown BN, Ratner BD, Goodman SB, Amar S, **Badylak SF.** Macrophage polarization: an opportunity for improved outcomes in biomaterials and regenerative medicine. *Biomaterials*, 2012. 33 (15): 3792-3802. PMID: 22386919.
5. Brown BN, Valentin JE., Stewart-Akers AM, McCabe GP, **Badylak SF.** Macrophage Phenotype and Remodeling Outcomes in Response to Biologic Scaffolds With and Without a Cellular Component. *Biomaterials*. 2009. Mar;30(8):1482-1491. PMID: 19121538. PMC: 2805023
6. **Badylak, S. F.**, Valentin, J., Ravindra, A., McCabe, G., Stewart-Akers, A. Macrophage Phenotype as a Determinant of Biologic Scaffold Remodeling. *Tissue Engineering* 2008 Nov;14(11):1835-1842. PMID 18950271.
7. Brown BN, Londono R, Tottey S, Zhang L, Kukla KA, Wolf MT, Daly KA, Reing JE, **Badylak SF.** Macrophage phenotype as a predictor of constructive remodeling following the implantation of biologically derived surgical mesh materials. *Acta Biomater*. 2012 Mar;8(3):978-87.PubMed PMID: 22166681.
8. Valentin JE, Stewart-Akins, A., Gilbert TW, **Badylak SF.** Macrophage Participation in the Degradation and Remodeling of ECM Scaffolds. *Tissue Engineering*. 2009. Vol 15(7):1687-1694. PMID: 19125644. PMC: 2792102
9. Tottey S, Johnson SA, Crapo PM, Reing JE, Zhang L, Jiang H, Medberry CJ, Reines B, **Badylak SF.** The effect of source animal age upon extracellular matrix scaffold properties. *Biomaterials*. 2011 Jan;32(1):128-36PubMed PMID: 20870285.
10. Crapo PM, Gilbert TW, **Badylak SF.** An overview of tissue and whole organ decellularization processes. *Biomaterials*, 2011. 32 (12): 3233-3243. PMID: 21296410. PMCID: 3084613.

D. Research Support

N10OT0001 (Badylak, PI)

03/05/10 – 05/04/14

Dept. of the Interior

Conduct Efficacy Studies for Muscle Tissue Regeneration via Biological Scaffolding Composed of Xenogeneic Extracellular Matrix (ECM) (OTT tasks 1a and 1b)

For patients suffering massive muscle loss, conduct efficacy studies for muscle tissue regeneration using biological scaffolding composed of xenogeneic extracellular matrices and transfer the technology and expertise gained to DoD medical personnel and facilities.

1 R01 HD061811 (Moalli, PI)

08/15/09 – 06/30/14

NIH (R01)

Comprehensive Evaluation of Prolapse Meshes by an Interdisciplinary Research Team

To evaluate the effect of modifying surgical meshes for use in pelvic floor reconstruction to achieve a more biocompatible and bio-friendly remodeling response. Biohybrid scaffolds consisting of extracellular matrix (ECM) plus synthetic scaffold material will be manufactured by the Badylak lab and provided to Dr. Moalli for surgical implantation in her animal models. Dr. Badylak will provide advice on study design as well as assist with histologic evaluation of the harvested samples.

(Badylak, PI)

04/01/11 – 08/31/14 (NCE)

University of New South Wales

SurgiLux ECM Materials and their Potential for Wound Healing

A dog model study to evaluate the efficacy of a hybrid extracellular matrix (ECM) chitosan scaffold for dura mater repair.

(Badylak, PI)

01/01/13 – 09/30/14

ACell, Inc.

Studies to Evaluate the Effect of Processing Methods upon UBM-ECM

The purpose of this study is to determine the effect(s) of various processing methods upon in vitro and in vivo properties of urinary bladder matrix – extracellular matrix (UBM-ECM). It has been well established that

virtually every step in the manufacturing process of biologic scaffolds has an effect upon structure and/or composition and/or function of an ECM bioscaffold. ACell, Inc. wishes to determine the effect of selected processing steps upon in vitro and in vivo properties of their MatriStem® product in an animal model.

(Badylak, PI)

12/15/11 – 12/14/14

Vertex Pharmaceuticals, Inc.

Injectible ECM Gel for Targeted CNS (Spinal Cord) Therapy

This project involves investigation of the use of ECM derived from either spinal cord or brain as a therapeutic intervention for spinal cord (contusion) injury. We will explore both pepsin digests of the ECMs as well as peptides isolated from the digested ECMs

(Badylak, PI)

01/01/14 – 12/30/14

C. R. Bard

Optimization of Surgical Mesh Materials

New Individual Project Agreements project have been instated to carry on research of well described benchtop assays and animal models which evaluate in vivo biocompatibility for novel surgical mesh materials. The project(s) involve a combination of in vitro and preclinical in vivo methods to further develop and evaluate biologic surgical mesh materials.

R03AG043606-01A1 (Brown PI)

07/01/13 – 06/30/15

NIH (R03)

Macrophage Polarization and Aging in the Context of Regenerative Medicine

The completion of these studies will not only further the understanding of the mechanisms by which ECM scaffolds modulate the host response, but will also lead to a better understanding of the impact that the changes in macrophage physiology which occur with aging will have upon the potential to utilize regenerative medicine strategies in an aging population.

1 R01 DE022055 (Badylak PI)

07/01/12 – 06/30/16

NIH (R01)

A Regenerative Medicine Approach for TMJ Meniscus Restoration

This proposal describes work in which a biologic scaffold composed of mammalian extracellular matrix will be used as an inductive scaffold for the in vivo generation of the temporo-mandibular joint meniscus. Pilot studies suggest that this inductive template can stimulate the endogenous formation of a fibrocartilaginous disc that closely mimics the structure, composition and function of native disc material. A pig model will be used in the proposed studies.