## BIOGRAPHICAL SKETCH

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NAME: Balakrishna Haridas

eRA COMMONS USER NAME (credential, e.g., agency login): BHARIDAS

POSITION TITLE: Professor of Practice, Biomedical Engineering, Texas A&M University; Program Director of Entrepreneurship Programs, TEES Office of Commercialization & Entrepreneurship, Texas A&M Engineering Experiment Station (TEES).

EDUCATION/TRAINING

| INSTITUTION AND LOCATION | DEGREE *(if applicable)* | Completion Date MM/YYYY | FIELD OF STUDY |
|---|---|---|---|
| Bangalore University, Bangalore, India<br>BMS College of Engineering | BE<br>(w/Distinction) | 1990 | Civil Engineering |
| University of Alabama, Tuscaloosa, AL | MS | 1992 | Engineering Mechanics |
| University of Cincinnati, Cincinnati, OH | PhD | 2001 | Biomedical Engineering |

### A. Personal Statement

I am a Bioengineer, entrepreneur, and academician trained and experienced in medical device design & development, biomechanics, biologic/synthetic biomaterials, and technology commercialization. As a serial and parallel entrepreneur, I have 25+ years of experience in academia and industry based R&D, raised over $70 million in funding and led several R&D/commercialization projects towards FDA approvals in the field of medical devices & implants with a total market impact/revenues exceeding $2B.

I am currently a Professor of Practice in the Department of Biomedical Engineering, Director of the Bioinnovation Master's of Engineering Program, and Head of Entrepreneurship Programs for the TEES Division of Entrepreneurship & Commercialization at Texas A&M University. I am also closely involved with a medical technology startup company that spun out of Texas A&M technology, Shape Memory Therapeutics (www.shapemem.com) as its Senior Vice President of Engineering. SMT is commercializing a range of medical devices that have been engineered using a shape memory polymer platform technology that was developed at the Biomedical Devices Lab at Texas A&M.

Prior to joining Texas A&M, I was the Director of the National Award Winning *Medical Device Innovation & Entrepreneurship Program* (*mDIEP*), and Associate Professor of Biomedical engineering at the University of Cincinnati. My career prior to these appointments included the following: President and Founder of *Device & Implant Innovations LLC*; Chief Technology officer (CTO) of *Biomerix Corporation*; Founder and Director of the *National Science Foundation/Industry-University Cooperative Research Center on Minimally Invasive Medical Technologies (U of Cincinnati)*; Associate Professor in Biomedical Engineering (U of Cincinnati) and Principal and Managing Partner at *Stress Engineering Services Inc*.

My most recent successful translational research and product commercialization experience was as CTO at Biomerix, based in San Franscisco, where I was part of a management team that raised $45M in private investment capital. At Biomerix, I led several R&D teams in product R&D for various applications in soft tissue repair and vascular occlusion and successfully obtained 4 FDA 510k approvals for devices based on Biomerix' s polyurethane foam technology.

### B. Positions and Honors

**POSITIONS**

1989 – 1990 Engineer, Stress/Structural Technology Group, Aircraft Design Bureau, Hindustan Aeronautics Ltd., Bangalore, India.
1990 – 1992 Graduate Council Fellow, Department of Engineering Mechanics, University of Alabama.
1992 – 1993 Research Fellow, Noyes-Giannestras Biomechanics Laboratories, University of Cincinnati, Cincinnati,
1993 - 1994 Engineer, Thermoplastic Simulation Group, Structural Dynamics Research Corporation

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| | Cincinnati,Ohio. |
| 1995 – 1996 | Analysis Engineer, Stress Engineering Services, Inc., Cincinnati OH. |
| 1996 –1998 | Associate Mechanical Engineer, Stress Engineering Services, Inc., Cincinnati, Ohio. |
| 1999–2000 | Senior Associate & Technical Leader, Biomedical Simulation and Testing Group, Stress Engineering Services, Mason, OH |
| 2000–2001 | Principal and Partner, Biomedical Simulation & Testing, Stress Engineering Services, Inc. |
| 2001- 2004 | Director, Principal, and Managing Partner, Stress Engineering Services, Inc., Mason, OH |
| 2004–2008 | Associate Professor, Department of Biomedical Engineering, University of Cincinnati, Cincinnati, OH |
| 2005-2008 | Director, NSF Minimally Invasive Medical Technologies Center (MIMTeC), A National Science Foundation Industry/University Cooperative Research Center, University of Cincinnati. |
| 2003-2008 | Scientific Advisor/CTO (part-time), Biomerix Corporation, Fremont CA |
| 2008-2010 | Chief Technology Officer, Biomerix Corporation, Fremont, CA. |
| 2010-2015 | Associate Professor, Department of Biomedical Engineering, U of Cincinnati<br>Director, Medical Device Innovation & Entrepreneurship Program, Department of Biomedical Engineering Program, University of Cincinnati, Cincinnati, OH. |
| 2010-2015 | Director, Master of Engineering Program, Biomedical Engineering, U of Cincinnati, Cincinnati, OH |
| 2010-present | President, Device & Implant Innovations LLC, College Station, TX |
| 2015-present | Senior Vice President of Engineering (part-time), Shape Memory Therapeutics, College Station, TX. |
| 2015-present | Professor of Engineering Practice, Biomedical Device Laboratory, Department of Biomedical Engineering.<br>Director, BioInnovation Master's of Engineering Program, Department of Biomedical Engineering<br>Director & Head of Entrepreneurship Programs, TEES Division of Commercialization & Entrepreneurship, Texas A&M University, College Station TX |

**HONORS**

- *First Class with Distinction*, B.E Civil Engineering, Bangalore University 1990.
- Graduate Council Fellow, Department of Engineering Mechanics, Univ. of Alabama, (1990-91)
- Summer Graduate Fellow, Department of Engineering Mechanics, University of Alabama (1991)
- Graduate Research and Teaching Assistantship, Dept. of Engineering Mechanics, University of Alabama. (1991)
- Summer Graduate Fellowship, Department of Engineering Mechanics, Univ. of Alabama. (1992)
- Research Fellow, Noyes Tissue Engineering & Mechanics Labs, University of Cincinnati, (1992-1994).
- Society for Biomaterials (SFB); American Hernia Society (AHS); American Society of Mechanical Engineers (ASME);
- "Who's Who in Polymers & Plastics" – Society of Plastics Engineers
- Member, ASME Codes and Standards Committee for Biomechanical Devices (2001-2003).
- 8 Patents
- Member, External Advisory Board, Department of Biomedical Engineering, University of Cincinnati (2002-2004)
- Associate Editor, Journal of Biomechanical Engineering Special Issue on Medical Device Design, 2005.
- Reviewer, Journal of Ultrasound in Medicine and Biology, 2007.
- Reviewer, Journal of Biomechanical Engineering Special Issue on Medical Device Design, 2005.
- Reviewer, Journal of Biomechanics and Modeling in Mechanobiology, 2003
- National Juror, Medical Design Excellence Awards (MDEA), 2008-2010.
- Scientific Advisory Boards: *Ethicon-Johnson & Johnson- Anastomotic Leaks SAB (2010-11), Sentire Medical Systems (2012-present), Genetesis (2014-present).*
- Session Chair, Biomaterials & Regenerative Medicine, ASME Design of Medical Devices 2010, Minneapolis, MN. 2010.
- Chair, Medical Device Innovation Bootcamp, University of Cincinnati, Cincinnati, OH September 2010.
- National Juror, Medical Design Excellence Awards (MDEA), 2012-2014.
- Master Educator Award, University of Cincinnati 2014
- Professor of the Semester, University of Cincinnati, 2015
- Professor of the Year (Nominee – 1 of 3 total), University of Cincinnati, 2015
- Chair, Commercialization Bootcamp, TEES Division of Commercialization & Entrepreneurship, Texas A&M University, 2015

## C. Contribution to Science

a. ***Advancing technologies for medical device research & development:*** I started my career in the medical device industry and founded the medical device R&D and product development business for Stress Engineering Services, a $200 million corporation today with many

engineering R&D offices across the country and in Canada. During my tenure at Stress Engineering, I also pursued my PhD at the world renowned Noyes Giannestras Biomechanics Labs, U of Cincinnati on a part time basis. At Stress Engineering, I built a commercialization directed research portfolio, and assembled a team of MS/PhD scientists that worked on major advances in implantable medical devices in the cardiovascular, orthopedics, and general surgery area with a focus on minimally invasive interventions. We made significant strides and pioneered the application of computational and experimental methodologies to the design analysis, testing of medical device tissue interactions. I led a team of scientists and engineers working with corporate sponsors such as Johnson & Johnson, Medtronic, Depuy, Boston Scientific, Cook Medical, Eli Lilly and developed many of their medical devices that were launched between 1994-2001. Among these, the notable innovations included the following, *45mm, 60mm and 110 mm endoscopic staplers, and laparoscopic clip appliers, Zenith and Vanguard Aortic Aneurysm Graft devices, Humapen Insulin Delivery System, and the Mammotome Breast Biopsy System*

***b. Publications***

i. Haridas B, Hong H, Minoguchi R, Owens S, Osborn T; PelvicSim-A Computational experimental system for biomechanical evaluation of female pelvic floor organ disorders and associated minimally invasive interventions., in *Accelerating Changes in Healthcare: Next Medical Toolkit, Technology and Informatics Series*, Volume 119, pp182-187, 2006.

ii. SA Hunter, FR Noyes, B Haridas, MS Levy, DL Butler: Meniscal material properties are minimally affected by matrix stabilization using gluteraldehyde and glycation with ribose, *Journal of Orthopedic Research*, 23, 555-561, 2005.

iii. SA Hunter, DL Butler, FR Noyes, B Haridas, MS Levy: Effects of Matrix Stabilization When Using Glutaraldehyde on the Material Properties of Porcine Meniscus, *Journal of Biomedical Materials Research*. 67A, 1245-1254, 2003.

iv. Haridas B and Matice CJ: Performance Evaluation of Poly-Ethylene Terephthalate Angioplasty Balloons via Blow Molding Simulation and Structural Analysis, *Journal of Applied Medical Polymers*, 2001, Vol 5, No.2

2. ***Design Innovation Programs and NSF Industry Research Consortium at the U of Cincinnati****:* I joined the University of Cincinnati in 2004 and founded the National Award winning Medical Device Innovation & Entrepreneurship Program (MDIEP), Department of Biomedical Engineering. Concurrently I also founded an NSF Industry University Cooperative Research Center grant and established the *NSF Minimally Invasive Medical Technologies Center (MIMTeC)*. This was a research center that brought together a consortium of major medical device companies (8 total) to collaborate and fund enabling technology development projects for the advancement of minimally invasive surgical and endovascular interventions. I led many of these projects which were then transferred/licensed to industry following completion. Some publications from my work at U of Cincinnati.
    a. Nagle AS, Barker MB, Kleeman SD, Haridas B, Mast TD: Passive biomechanical properties of human cadaveric levator ani muscle at lowstrains, *J of Biomechanics*, Vol 47, 2014, p.583–586.
    b. Nagle, AS; Nageswaran, AR.; Haridas, B; Mast, T. Douglas. Validation of three-dimensional strain tracking by volumetric ultrasound image correlation in a pubovisceral muscle model, *Journal of Acoustical Society of America*, vol. 133 issue 5 May 2013. p. 3358-3363.
    c. Wilkes R, Kieswetter K, Zhao Y, Haridas B: Effect of dressing type on 3D microdeformations in dermal ulcers during negative pressure wound therapy – an experimental study, *ASME Journal of Biomechanical Engineering*, 131(2), 2009.
    d. Wilkes R, Kieswetter K, Zhao Y, Haridas B: 3D Strain Measurement in Soft Tissue: Demonstration of a Novel Inverse Finite Element Model Algorithm on MicroCT Images of a Tissue Phantom Exposed to Negative Pressure Wound Therapy, *J of Mechanical Behavior of Biomedical Materials*, Vol 2, p 272-287, 2009

3. ***Polycarbonate Urethane Matrices for Soft Tissue Repair and Vascular Occlusion – Biomerix Corporation****:* During my tenure at the U of Cincinnati 2004-2007, I was also involved on a part time basis with an exciting startup company in the field of biomaterial scaffolds (www.Biomerix.com). During this time, I advised and directed a Biomerix R&D team on the development of novel biostable and biodegradable 3D porous scaffolds based on polycarbonate-urethanes and polyester-urethanes for applications in soft tissue repair and reconstruction. Upon successful development of the biomaterials at the company, I was recruited by Board of Directors of Biomerix to join the company as their Chief Technology Officer on a full time basis in 2007-08. I left my position at the U of Cincinnati at that time

to join Biomerix and lead 5 R&D teams towards the development of various products for applications in rotator cuff repair, hernia repair, and vascular occlusion which were FDA approved and launched for commercialization in the US in 2009-2010.

a. US Patent 9050176B2 – *At Least Partially Resorbable Reticulated Elastomeric Matrix Elements and Methods of Making Same*. April 5, 2010.
b. Vascular Occlusion Device 510k – http://www.accessdata.fda.gov/cdrh_docs/pdf4/K043371.pdf
c. Rotator Cuff Device 510k - http://www.accessdata.fda.gov/cdrh_docs/pdf7/K070961.pdf
d. Hernia Mesh 510k - http://www.accessdata.fda.gov/cdrh_docs/pdf11/K112567.pdf

4. ***Web Content/Patents etc***
   a. Haridas B: Porous & Reticulated Polycarbonate-Polyurethane-Urea Scaffold for Soft Tissue Repair, *Biomaterial of the Month*, Society for Biomaterials, USA, July 1, 2009. http://www.biomerix.com/biomaterial-of-the-month/
   b. US20130096399, WO2012139092A2 – Methods and Devices for Detecting Bowel Perforation, Publication Date March 28, 2013.
   c. US Patent 9050176B2 – At Least Partially Resorbable Reticulated Elastomeric Matrix Elements and Methods of Making Same. April 5, 2010.
   d. USPTO 11/181,485 – In vivo measurement of Biomechanical Properties of Internal Tissues, July 14, 2005

5. ***Biomechanical Properties of Tracheal Cartilage Rings:*** This work is the foundation for the current proposal and serves as the source of the functional/biomechanical requirements that are the inputs to initiate the design, development and manufacturing of the exostent device for the tracheal reconstruction studies proposed in the lamb model.
   a. Karkhanis T, Rao M, Zafar F, Morales DL, **Haridas B**: Tracheal Cartilage Ring Biomechanical Properties for Pediatric Exostent Design, *ASME Journal of Medical Devices*, accepted to be published in June or September 2016 issue.)
   b. Karkhanis T*, Rao M, Zafar F, Morales DL, **Haridas B**: Tracheal Cartilage Ring Biomechanical Properties for Pediatric Exostent Design, *Design of Medical Device Conference*, Minneapolis MN, April 12-14, 2016.
   c. Karkhanis T*, Rao M, Zafar F, Morales DL, **Haridas B**: Intra- and Inter-animal Variations in the Biomechanical Properties of Tracheal Cartilage Rings, *Society of Engineering Sciences Conference*, College Station TX, October 26-28, 2015.

## D. Research Support (Total exceeding $70 million from 1992-present)

**Pending Support**

Design & Preclinical Testing of a hybrid bioprosthetic exostent graft for tracheal repair — 09/01/2016-08/31/2018
Sponsor: National Institutes of Health

Shape Memory Polymer Vascular Occlusion Device for Treatment of Venous Insufficiency Phase II SBIR — 06/06/2016 – 06/06/2018
Sponsor: National Institutes of Health — Role: Co-PI

Tracheal repair with hybrid bioprosthetic exostent graft — 1/1/2016-2/28/2017
Sponsor: DoD Congressionally Directed Medical Research program, Discovery Award — Role: PI

**Current Research Support**

Research Program Startup Funds — 6/1/2015-7/31/2017
Sponsor: Department of Biomedical Engineering, Texas A&M University — Role: PI

**Completed Research Support**

Biomechanical Testing of Human Stratum Corneum — 1/1/2015-6/30/2015
Sponsor: Procter & Gamble Company — Role: PI

Universal Targeting Set Design For Mammotome Breast Biopsy System — 8/25/2014-8/31/2015
Sponsor: Mammotome, Devicor Medical Company — Role: PI

Project Title: Design of Force Limiting Mechanism for LigaclipEr320; — 8/25/2014-8/31/2015
Sponsor: Ethicon Inc, A Johnson & Johnson Company; Budget — Role: PI

Project Title: Enseal End Effector 8/25/2014-8/31/2015
Sponsor: Ethicon Inc, A Johnson & Johnson Company Role: PI

Project Title: UC Forward – Enhancement of MDIEP Program 9/1/2012-8/31/2015
Sponsor: U of Cincinnati Provosts Office Role: PI

Device for Reducing Catheter Borne Blood Stream Infections 8/1/2012-7/31/2013
Sponsor: Davis Medical LLC Role: Principal Investigator

Design of Left Atrial Appendage Occlusion Device 9/1/2010-8/31/2011
Sponsor: Atricure Corporation Role: Principal Investigator;

Design of a Novel Probe for In-vivo Measurement of Viscoelastic Properties of Epidermal, Dermal and Subcutaneous Fat in Human Subjects 9/1/2010-8/31/2011
Sponsor: Procter & Gamble Company Role: Principal Investigator

NSF-IIP094487 SBIR Bioresorbable Polyurethane Scaffold Materials for Regenerative Applications in Advanced Wound Healing 9/1/2009-6/30/2010
Sponsor: National Science Foundation and VC funding Role: Principal Investigator

PolyCarbonate Polyurethane Scaffold and Device Development, Biomerix Corporation 2002-2010
Sponsor: Private Equity & Venture Capital. Role: PI

NIH #U54 EB007954 NIH Point-of-Care-Center for Emerging Neuro-Technologies (POC-CENT)
Agency: National Institutes of Health. Role: PI 2008-2013

MIMTeC – Minimally Invasive Medical Technologies Center –
NSF Industry University Cooperative Research Center 2/15/2007-2/14/2012
Sponsor: National Science Foundation Role: Principal Investigator

Ultrasound Image based deformation analysis of soft tissue: internal organs 6/1/2007-5/31/2010
Sponsor: NSF/MIMTeC Consortium Role: PI

In vitro model of arterial aneurysms with wall stress sensing capability 6/1/2007-5/31/2010
Sponsor: NSF/MIMTeC Consortium Role: PI

Generalized Cutting Work and Fracture Energy Characterization for Soft Tissue Resection in Minimally Invasive Surgery 2/15/2007-2/14/2009
Sponsor: National Science Foundation Role: Principal Investigator

Ex vivo testing of Mammotome System 3/1/2008-2/28/2009
Sponsor: Ethicon Endosurgery Role: Principal Investigator

Modeling modes of aneurysm recurrence after coil embolization:
mechanisms of coil compaction and aneurysm growth 7/1/2007-6/30/2008
Sponsor: American Society of Neuroradiology/NER Foundation Boston Scientific Role: Co-Principal Investigator

Research Startup Funds 9/1/2004-12/31/2007
Sponsor: University of Cincinnati. Role: Principal Investigator