

John C. Laughlin, M.Eng., P.E.

840 Threadneedle St. #185
Houston, Texas 77079
(281) 630-2281

Education

Master of Engineering Bioengineering, 1995 Texas A&M University, College Station, Texas
Emphasis in electrical engineering and biomechanics.

Bachelor of Science Bioengineering, 1993 Texas A&M University, College Station, Texas
Emphasis in electrical engineering and pre-medicine.

Licenses

Professional Engineer # 92944 Biomedical and Mechanical engineering, licensed in Texas

Patents

U.S. Provisional Patent Application Serial No. 60/941,118, Implantable Therapy System
International Patent Application No. pct/us 2008065386, Implantable Therapy System

Associations

National Academy of Forensic Engineers, Senior Member,
Society of Automotive Engineers, Member
National Society of Professional Engineers, Engineering Professional Membership
Texas Society of Professional Engineers, Engineering Professional Membership
Review committee member: Texas Gulf Coast Emerging Technology Fund – Gulf Coast Regional Center of Innovation and Commercialization.

Qualifications

As a licensed professional engineer with a background which encompasses biomedical, mechanical and electrical engineering, Mr. Laughlin brings a wealth of expertise to the Class III medical device community. Mr. Laughlin is experienced working in the highly regulated medical device industry and in the American legal system. He has supported clinical trials involving a varied array of indications, device designs and implant methods/locations. He makes a competent liaison between engineering and medical or regulatory professionals. As an individual that productively interacts with physicians, scientists, patients, attorneys and marketers, Mr. Laughlin prides himself on his ability work in a multidisciplinary environment and is a team oriented individual.

Mr. Laughlin has spent 17 years working in the field of biomechanical engineering. He has applied engineering principles in the areas of accident reconstruction, injury potential/causation analyses, human factors analyses, failure analysis and medical device engineering. As a forensic engineer, Mr. Laughlin has reconstructed accidents involving automobiles, motorcycles, pedestrians, amusement park rides, walking surfaces, public transportation, and railroad/industrial equipment. He has analyzed failures in products liability cases and determined the relationship of the defect with the injuries. Mr. Laughlin has performed analyses to determine damage consistency between vehicles, the order of impacts in multi-vehicle collisions and to determine the driver of vehicles involved in roll-over collisions, as well as other accident reconstruction related analyses. As a biomechanical engineer, he is qualified to use injury based evidence from medical records, photographs and autopsy reports to create a complete and quality analysis.

Mr. Laughlin is also an accomplished medical device engineer and has experience in the field of neuroelectrical engineering. As a clinical engineer, Mr. Laughlin worked in the field to advance the science of neuromodulation, or the application of electricity to a group of nerve fibers to reach a therapeutic result. Mr. Laughlin comprehends neuroscience principles and the generation/cessation of action potentials with the aid of an applied electrical signal. He has worked closely with research and development departments to

advance the design of tools and implantable devices used in the operating room and clinic. He has contributed to the content and design of study protocols used in clinical trials to evaluate the safety and efficacy of medical devices. He has trained surgeon investigators as well as clinical sales teams on the implantation of these devices. Mr. Laughlin is familiar with Investigational Device Exemption (IDE) and Pre-Market Approval (PMA) processes.

Mr. Laughlin is a proficient writer and has authored scientific publications, PMA submissions and study protocols as well as many reports which have been used as evidence in trials. In addition to his writing abilities, Mr. Laughlin has excellent public speaking talents. He has taught courses for continuing education credits and has been the key note speaker at several special investigator meetings. He has used these talents both domestically and abroad to train physicians and professionals on highly technical topics. Mr. Laughlin has the ability to take complex concepts and describe them in plain language so that patients and juries get the understanding they need.

Experience

10/09-present **President, Principal Engineer**
Laughlin Engineering Firm, LLC, Houston, Texas

- Determine injury causation/potential in legal cases
- Provide expert witness testimony
- Direct animations for use as device marketing aids or demonstrative evidence in the courtroom
- Provide forensic analyses in cases involving patent infringement and medical device litigation
- Create detailed scientific analysis and reports as evidence in legal trials
- Provide support services to for engineering, regulatory and clinical trials for Class III medical devices
- Provide risk assessment for implant techniques, device/human interaction, and clinical trial designs.
- Create detailed scientific analysis and reports for submission to the FDA
- Provide engineering support during implantation of Class III medical devices
- Facilitate feedback and communication between R&D and clinicians
- Conduct root cause analysis in medical device problems (MDRs) and for product liability purposes
- Create test plans and oversee vendors/engineers to complete lab tests on medical devices for IDE/PMA/510(k) submissions
- Teach continuing education seminars, in-service meetings, and train clinical trial investigators, site coordinators, CRAs, device sales teams and engineers

4/07-10/09 **Senior Field Clinical Engineer**
EnteroMedics, Inc., Minneapolis, Minnesota

- Provided engineering support in the operating room to surgeons in IDE study centers in the U.S.A., and OUS centers in Australia and Norway
- Invented a patient screening tool used to assess device compliance risk in potential patients. The tool was responsible for the second largest number of excluded patients in the study. There are patent applications in the U.S. and E.U. for this tool.
- Trained surgeons on the implantation of VBLOC neuromodulation system for obesity using animal models, original presentations and hands on system interaction.
- Contributed to the development of implant and explant techniques used in the VBLOC study.
- Studied the effects of various laparoscopic tools on the implant procedure for VBLOC.
- Conducted human factors analyses of equipment used by patient and of implant technique.
- Conducted Site Selection, investigator selection, gathering feedback on protocol design
- Conceptualized and implemented software routines which mined device data for statistical trends and troubleshooting analyses. These routines were compiled by R&D into an internal device monitoring/data analysis program.
- Contributed to protocol content and design
- Provided technical feedback to R&D concerning product function and design
- Provided troubleshoot services for implanted devices and related equipment
- Performed validation testing of hardware and software of an RF based medical device system.

9/05-4/07

Principal Field Clinical Engineer

Advanced Bionics Corporation, Valencia, California

- Provided field clinical engineering services to IDE study centers.
- Supported clinical trials investigating novel neurostimulation therapies for incontinence, migraine, and erectile dysfunction. Provided post-market operating room support for spinal cord stimulation therapy.
- Aided in the development of two different neurostimulation device modalities covering three different clinical indications, incontinence, migraine, and chronic pain, as well as human testing using early stage electrode prototypes for erectile dysfunction.
- Trained international sales team on the implantation of neurostimulation device for migraine in Budapest, Hungary. Responsible for both didactic and cadaver laboratory training. Created training materials for sales professionals.
- Trained surgeons on the implantation/explantation and programming procedures of various neuromodulation devices.
- Contributed to the development of second generation devices by analyzing field data and performing engineering and human factors analyses.
- Facilitated development of an implant tool for an incontinence neurostimulator to reduce the affect the implant procedure had on the device location.
- Provided technical feedback to R&D concerning product function and design
- Provided product and patient feedback to Marketing.
- Provided field testing of new products.
- Conducted statistical analysis of patient data and lab testing of device performance.

5/97-9/05

Senior Forensic Biomedical Engineer

Rimkus Consulting Group, Inc., Houston, Texas

- Determined injury causation/potential in legal/criminal/insurance cases
- Managed projects involving interdisciplinary teams of engineers/scientists
- Provided forensic analyses in cases involving trauma, accidental death, patent infringement and medical device litigation
- Reconstructed
- Provided expert witness testimony
- Created detailed analysis reports for submission as evidence in trials
- Directed animations of accident reconstructions for use as demonstrative evidence
- Presented continuing education seminars
- Analyzed scientific methods of other experts

1/96-5/97

Clinical Research Engineer

Cyberonics, Inc., Webster, Texas

- Provided engineering support in the operating room to surgeons in IDE study centers in the U.S.A., and Canada.
- Authored PMA submissions, FDA submissions and study protocols
- Managed clinical data acquisition and analysis team. Developed software routines which automated the verification of clinical data.
- Trained physicians on the implantation and programming of the NeuroCybernetic Prosthesis
- Provided engineering support and risk analysis for MDR investigations (21 CFR 803) and Complaint handling (21 CFR 820.198)
- Provided liaison service between clinicians and research personnel
- Recommended clinical considerations for implementation for future device models
- Assessed clinical efficiency of product software performance
- Site monitoring

1/97-5/98

Biomedical Engineer

Biomedical Device Consultants, League City, Texas

- Designed equipment and experiments for testing arterial implants

- Implemented a LabVIEW based porosity testing system for biological arterial and venous grafts
- Provided direction to LabVIEW development team

1/95-1/96

Orthopaedic Biomechanics Fellow

The University of Texas Medical Branch, Galveston, Texas

- Developed imaging and analysis system for the strain patterns on bone surfaces using the photoelastic technique and original software programs.
- Designed and constructed laboratory instrumentation
- Developed software tools to analyze two-dimensional (photographic) strain data
- Developed data acquisition programs using LabView
- Designed and implemented experiments for testing orthopedic surgery techniques using an MTS and LabView
- Assisted in three-dimensional kinematic testing of human joints using a Motion Analysis System
- Authored and reviewed research grants
- Supervised residents and medical students and their projects during research rotations

Publications

Laughlin, John, P.E. (NAFE 760S), "Forensic Engineering Investigation of a Police Shooting" Journal of the National Academy of Forensic Engineers, Vol. XXX No. 2 December 2013.

Grecula, M.J., Morris, R.P., Laughlin, J.C., Buford, W.L., Jr., and Patterson, R.M., "Femoral Surface Strain in Intact Composite Femurs: A Custom Computer Analysis of the Photoelastic Coating Technique", IEEE Transactions on Biomedical Engineering, July 2000.

Laughlin, J.C., "Analysis Methods for Determining Occupant Dynamics in High Speed Automobile Collisions." Sixteenth Annual Houston Conference on Biomedical Engineering Research, Houston Society for Engineering in Medicine and Biology, 1996.

Maschino, S, Laughlin, J, "Long Term Follow-Up Study for Protocols E01, E02, E03 and E04 Treatment of Refractory Epilepsy Using Vagus Nerve Stimulation - A Study Managed For Compliance With Good Clinical Practice", November, 1988 to December, 1986, Cyberonics, Inc., PMA Amendment for the FDA approval of the NeuroCybernetic Prosthesis.

Duffell, W., Laughlin, J, "Long Term (> 3 Months) Follow-Up Study for Protocol XE5 Open Label Treatment of Refractory Partial Onset Seizures Using Vagus Nerve Stimulation", September, 1985 to August, 1996, Cyberonics, Inc., PMA Amendment for the FDA approval of the NeuroCybernetic Prosthesis

Grecula, M.J., Laughlin, J.C., Morris, R.P., Buford, W.L., "Development of a Computer Analysis Technique For Strain Patterns On The Femoral Surface After Total Hip Arthroplasty Using the Photoelastic Method." American Academy of Orthopaedics Surgeons (AAOS), Orthopaedic Transactions, 1997.

Laughlin, J.C., Grecula, M.J., Buford, W.L., Stark, T., Morris, R.P., "A Photoelastic Study Of Femoral Strain Distributions After Implantation With Various Cementless Hip Stem Designs." Mid-America Orthopaedic Association, Orthopaedic Transactions, 1997.

Thesis: Laughlin, John: Development of a System for Photoelastic Analysis of Shear Strain Patterns on Bone Surfaces, Texas A&M University, 1996.

Laughlin, J.C., Grecula, M.J., Morris, R.P., "Development of a Computer Analysis Technique for Strain Patterns On The Femoral Surface After Total Hip Arthroplasty Using the Photoelastic Method." Fourteenth Annual Houston Conference on Biomedical Engineering Research, Houston Society for Engineering in Medicine and Biology, 1996.

Laughlin, John: A Wheelchair Triggered Door Opener for a Private Home, National Science Foundation 1993 Engineering Senior Design Projects to Aid the Disabled, North Dakota State University Press,