

Dr. Jay M. Vincelli, PhD, PE

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EDUCATION AND LICENSING

Professional Engineer License (PE), Mechanical Engineering, Rhode Island: December 2015, New Hampshire: April 2025
PhD, Electrical, Computer & Biomedical Engineering, University of Rhode Island, Kingston, RI, August 2024
MSc, Engineering Sciences, Dartmouth College, Hanover, New Hampshire, June 2013
BSc, Materials Science & Engineering, University of Florida, Gainesville, Florida, May 2007

Dr. Jay Vincelli, PhD, PE, is a licensed Professional Engineer (PE) in mechanical engineering and PhD-level biomedical engineer specializing in the failure analysis of medical devices. His work is built on a strong educational foundation, including a BSc in Materials Engineering, and an MSc and PhD focused on Biomedical Engineering. This unique, cross-disciplinary background allows him to provide clear, credible, and defensible insights into complex device failures.

Dr. Vincelli's expertise is highlighted by his deep experience in litigation support, where he has provided engineering analysis for approximately 100 cases involving failed medical devices. His case experience is extensive, covering orthopedic implants, transvaginal mesh, cardiac devices, forced-air warming systems, and more. His work at Dartmouth College involved the detailed failure analysis of over 500 metal-on-metal hip implants, including wear measurements and pore size measurements on the bone ingrowth surface. In addition to his litigation work, he has direct industry experience supporting FDA regulatory submissions, including performing degradation experiments for the OrthoSpace rotator cuff balloon's FDA submission and providing guidance to CREmedical for the FDA clearance of their advanced EEG amplifier and electrode devices. He holds a patent for a miniaturized cardiopulmonary bypass circuit which includes a fluid pump and oxygenation system. His practical experience also includes the design and manufacturing of a hip explant surgical tool.

His qualifications are further strengthened by comprehensive training and experience in industry-standard quality systems. This includes developing an ISO 17025-compliant quality manual, and receiving training in ISO 10993 for the Biological Evaluation of Medical Devices and as an ISO 9001 lead auditor.

While his primary focus is biomedical engineering, Dr. Vincelli also has significant experience in other industries. His background includes automotive failure analysis and product launches, as well as numerous forensic investigations of aviation components for the U.S. Naval Air Warfare Center in Cherry Point, NC, where he also performed welding analysis and certification of the Navy's welders. Additionally, he is a published author on the use of photogrammetry for underwater analysis and forensic science.

EXPERIENCE

Principal Forensic Engineer & Founder, May 2025 to present, Quantify Engineering, LLC.

Scope of practice:

- **Medical Device Failure Analysis:** Engineering investigation of Class II and III devices involved in adverse events, utilizing root cause analysis methodologies (Fishbone, FTA), Human Factors Engineering, and standard testing protocols (ASTM, ISO).
- **Design & Regulatory Consultation:** Technical review of Design History Files (DHF), verification/validation testing (V&V), and risk management documentation (ISO 14971) for compliance with FDA 21 CFR Part 820.
- **Litigation Support:** Provision of expert engineering reports and honest testimony regarding product liability, patent infringement, and mechanical failures.
- **Pre-Suit Technical Evaluation:** Rapid assessment of potential claims to determine engineering merit and technical validity prior to filing.

Postdoctoral Researcher, October 2024 to present, Dartmouth College, Psychophysics & Cognitive Neuroscience Laboratory and Mutual Understanding Laboratory.

Cognitive Neuroscience Laboratory:

- Developed the world's first non-invasive EEG recording system for octopuses using tri-polar concentric ring electrodes adapted to a flexible PCB for underwater use.
- Designed and conducted visual psychophysics experiments using Arduino-controlled LED stimuli to assess visual perception, attention, and cognition in *Octopus bimaculoides*.
- Restored and maintained IACUC compliance and approval for live animal research.

- Developed analysis methods for detecting steady-state visually evoked potentials; results presented at Vision Sciences Society 2024.

Mutual Understanding Laboratory:

- Designed and built a complete iEEG analysis pipeline in MATLAB for a Tacit Communication Game (TCG) paradigm, studying the neural mechanisms of social context switching (child vs. adult addressee) and communication under uncertainty in epilepsy patients with implanted electrodes.
- Pipeline includes a GLM with detailed communication strategy regressors, AIC/BIC model comparison across strategy models, multicollinearity diagnostics (VIF), and parallel processing across 16 workers for multi-subject, multi-frequency-band analysis (high gamma, alpha, beta, theta); atlas-based brain parcellation (AAL and DK atlases) and network centrality analysis identify involved regions, rendered as 3D brain visualizations via FreeSurfer meshes; orbitofrontal and anterior cingulate cortex centrality identified during social context switching.
- Mentoring a postbaccalaureate researcher in coding and iEEG data analysis; she independently produced statistically novel OFC centrality findings, which are being integrated into a generalized region-selection analysis tool currently under development.

PhD Candidate, September 2016 to August 2024, University of Rhode Island, Electrical, Computer, and Biomedical Engineering, Neural Rehabilitation Engineering Laboratory.

- Converted a 3D printer into a high-precision EEG phantom testbed by replacing the printhead with a custom-designed dipole antenna, building a layered human head phantom with tissue-mimicking electrical properties and an integrated PCB electrode array, and writing a MATLAB GUI to control dipole position via G-code for both manual positioning and automated 3D rasterization while recording synchronized EEG data.
- Designed a GUI-based analysis pipeline with extensive functionality for rapid analysis of large EEG datasets in the time and frequency domains
- Designed rigid PCBs for EEG electrode impedance testing and tripolar concentric ring electrode arrays; prototype-manufactured boards in-house, then sent validated designs to professional fabricators and verified the final boards.
- Adapted rigid PCB electrode designs to a flexible PCB format for underwater use on an octopus, working around the constraints of a soft-bodied marine animal in a saltwater tank.
- Developed and evaluated novel EEG electrode designs, conductive gels, and amplifier systems for brain recording and stimulation.
- Mentored undergraduate senior design teams (BME 484/485) in biomedical device development; guided student groups building brain-computer robotic interfaces and hydrogels for long-lasting tEEG use.
- Finalist, URI Three Minute Thesis competition; first-place winner, Graduate Research Showcase.

Senior Forensic Engineer, Laboratory Director, June 2013 to August 2018, Materials Science Associates, LLC, North Kingstown, RI.

- Performed biomedical engineering, metallurgical, materials science & mechanical engineering consulting services and testing for government, hospital, legal, insurance, medical, and manufacturing needs.
- Performed failure analysis, materials and process evaluations, biomaterial and medical implant design and testing, professional reports, oral presentations & expert opinions, including patent infringement consulting.
- Led 110+ forensic investigations for medical device lawsuits (orthopedic implants, surgical mesh, IVC filters), delivering expert testimony in 5 depositions, including the Christiansen v. Wright bellwether case.
- Developed ASTM-compliant wear quantification algorithms for metal-on-metal hip implants
- Authored a 62-page ISO 17025 quality manual and 21 ASTM test protocols (e.g., F2979 for implant wear analysis) and managed several technical staff.
- Prototyped a 3D-printed diabetic neuropathy insole using multi-material rubber printing; developed wearable biosensor prototypes for sports applications.

MSc Candidate, Sept. 2011 to June 2013, Dartmouth Biomedical Engineering Center, Dartmouth College, Hanover, NH.

- Performed failure analyses on 100+ hip and knee implants.
- Developed numerical methods for quantifying wear in metal-on-metal hip retrievals and for quantifying pore spacing in plasma-sprayed titanium coatings.
- Evaluated enzymatic degradation of the OrthoSpace rotator cuff balloon (PCL/PLA polymer) using FTIR, DSC, visco-elastic analysis and tensile testing to aid FDA regulatory clearance.
- Invented a patented miniaturized cardiopulmonary bypass circuit machine with a novel oxygenator design for transgenic mouse testing

Product Engineer and Project Manager, Nov. 2009 to Sept. 2011, Freudenberg-NOK, Northfield, NH.

- Managed multiple product launches from initial design to production launch, including design, validation and production verification testing, following APQP procedures and leading a multidisciplinary team.
- Designed rotary shaft seals, molds and components for injection/compression molding, finishing & inspection.
- Designed the pinion seal for the Chevrolet C7 Corvette and including the prototype and production seal design and compression molds, and managed the entire production launch.
- Developed new test methods in collaboration with axle manufacturers for testing of rotary shaft seals and set up and performed testing in-house.
- Obtained training in lean systems and Six Sigma methodology while participating in major and minor kaizens and Six Sigma investigations.

Failure Analysis Engineer, June 2008 to Nov. 2009, U.S. Naval Air Systems Command (NAVAIR), Cherry Point, NC.

- Performed metallurgical analysis for failure analyses involving engine blades/vanes, foreign object damage, corrosion, aircraft structures, wire bundles, bolts & fasteners, gearboxes, circuit boards, and hydraulic/pneumatic tubing.
- Updated the welder certification and inspection program; created process improvement updates to industry-wide, military-wide, Navy-wide, and local manuals/instructions and performed welding analysis and certification for Navy welders.

Application Engineer, June 2007 to June 2008, Elan Technology, Midway, GA.

- Supported 25 customers worth ~\$1 million annually through feasibility analysis, quoting, purchase orders, production, shipping, and technical support of glass and ceramic components in the electronics industry.
- Received training in the ISO/TS16949:2002 and AS9000 quality systems to perform as an internal quality auditor.

PATENTS

Jay Vincelli, David McClatchy, Stephanie Wolf, Ryan Halter (PhD), and James Yun (MD). U.S. Patent #9,561,315.

"Miniaturized cardiopulmonary bypass circuit for a mouse model." This invention was created to allow researchers to study the serious side effects of cardiopulmonary bypass surgery in humans by using a transgenic mouse model.

RESEARCH PUBLICATIONS

J. M. Vincelli, W. G. Besio, G. Caplovitz, M. R. Maechler, and P. U. Tse, "Octopus electroencephalography permits detection of light-induced steady state visually evoked potentials in *Octopus bimaculoides*," *Current Biology* (manuscript prepared for submission).

J. Vincelli, *Development and evaluation of novel electrode designs and gels for use in electroencephalography*, PhD dissertation, University of Rhode Island, August 2024

J. Vincelli, F. Calakli, M. Stone, G. Forrester, T. Mellon, and J. Jarrell, "Identification of a putative man-made object from an underwater crash site using CAD model superimposition," *Forensic Sci. Int.*, vol. 285, pp. 129–134, Apr. 2018.

Vincelli JM, *Development of Contact Metrology and Numerical Methods for Quantifying and Locating Wear in Metal on Metal Hip Retrievals*, Master's Thesis, Dartmouth, Hanover, NH, May 2013.

A. Kumar, M. Sapp, **J. Vincelli**, and M. C. Gupta, "A study on laser cleaning and pulsed gas tungsten arc welding of Ti–3Al–2.5V alloy tubes," *J. Mater. Process. Technol.*, vol. 210, no. 1, pp. 64–71, Jan. 2010.

J. M. Vincelli, F. Calakli, M. A. Stone, G. E. Forrester, T. Mellon, and J. D. Jarrell, "Characterizing a Debris Field Using Digital Mosaicking and CAD Model Superimposition from Underwater Video," *Photogrammetric Engineering & Remote Sensing*, vol. 82, no. 3, pp. 223–232, 2016.

CONFERENCE ABSTRACTS AND POSTERS

Holm Roeser, Kyle Forgetta, **Jay Vincelli**. *System for Evaluation of EEG Electrodes via Inverted Phantom*, 47th Northeast Biomedical Engineering Conference, March 2021.

Vincelli JM, Carlson EM, Currier JH, McHugh DJ, Van Citters DW, Collier JP. *Methodology and validation of taper wear measurements in hip arthroplasty retrievals*. 59th Annual Meeting of the Orthopaedic Research Society. San Antonio, TX. January 2013.

Vincelli JM, Tomek IM, Berton C, Carlson EM, Van Citters DW. *Optical profilometry comparison of the US and International ongrowth surface of a monoblock acetabular design*. 59th Annual Meeting of the Orthopaedic Research Society. San Antonio, TX. January 2013.

Carlson EM, Currier JH, Currier BH, McHugh DJ, Mayor MB, **Vincelli JM**, Collier JP. *Retrieved MoM implants provide evidence for hip distraction during swing phase*. Annual Meeting of the American Academy of Orthopaedic Surgeons. Chicago, IL. March 2013.

SEMINAR PRESENTATIONS

Tse PU, **Vincelli JM**, Caplovitz G, Besio WG. *Octopus electroencephalography permits detection of light-induced Steady State Visually Evoked Potentials*. Vision Sciences Society 2024. St. Pete Beach, FL. May 2024.

Invited Speaker: **Vincelli JM**. McHugh DJ, Carlson EM, Collier JP. *Numerical Methods for Quantifying Wear in Metal-on-Metal hip retrievals*. 2nd Seminar on Surface Metrology for the Americas 2012. Worcester Polytechnic Institute. October 2012.

Vincelli JM, McHugh DJ, Carlson EM, Van Citters DW, Collier JP. *Metal-on-Metal Hip Wear Measurement of Retrievals, Methodology and Validation*. Society for Biomaterials Annual Conference. Denver, CO. April 2014.

Vincelli JM, Jarrell JD, McHugh DJ, Carlson EM, Van Citters DW, Collier JP. *Metal-on-Metal Hip Wear Patterns of Explanted Components Do Not Match Simulator Results*. Society for Biomaterials Annual Conference. Denver, CO. April 2014.

Vincelli JM, McHugh DJ, Carlson EM, Van Citters DW, Collier JP. *Methodology and validation for accurate measurements of material loss in retrieved metal-on-metal hip components*. 2nd International Conference on Biotribology. Toronto, CAN. May 2014.

Vincelli JM, Jarrell JD, McHugh DJ, Carlson EM, Van Citters DW, Collier JP. *Non-polar loading in metal-on-metal hip retrievals*. 2nd International Conference on Biotribology. Toronto, CAN. May 2014.

MAGAZINE PUBLICATIONS

Mong, D., **Vincelli, J.**, Jarrell, J., Magnan, T. “*Small Unmanned Aerial System Photogrammetry*”. *Law and Order*. May 2016, Vol. 64, No. 5.

TEACHING

BME 484 – Biomedical Engineering Capstone Design I – Team Mentor, University of Rhode Island. Fall 2020.

BME 485 – Biomedical Engineering Capstone Design II – Team Mentor, University of Rhode Island. Spring 2021.

Photogrammetry in Defective Products and Personal Injury. University of Rhode Island Forensic Science Partnership Seminar Series. October 17, 2014.

Structure from Motion in Accident Reconstructions. University of Rhode Island Fall 2014 Traffic Accident Reconstruction Course. September 19, 2014.

Photogrammetry Applications for Insurance Fraud. National Insurance Crime Bureau Seminar. Lincoln, RI. November 2014.

CERTIFICATIONS

NAMSA Training ISO 10993 Biological Evaluation of Medical Devices, ISO 9001 Lead Auditor Training, Six Sigma Green Belt, Hazardous Waste, Laboratory Safety, Blood Borne Pathogens, PADI Advanced Open Water Diver

AWARDS & HONORS

- 2024 URI Three Minute Thesis (3MT) competition finalist - Minding Ethics - Non-Invasive Octopus EEG Recording
- 2020 URI Electrical Computer and Biomedical Engineering Graduate Student Research Showcase - first place winner - Language Mapping using Tripolar Concentric Ring Electrode Electroencephalography

3. Recipient of the 2017 American Society of Photogrammetry and Remote Sensing John I. Davidson President's Award for Practical Papers for "Characterizing a Debris Field Using Digital Mosaicking and CAD Model Superimposition from Underwater Video," PE&RS, 82 (3), 223
4. 2012 John C. Woodhouse Engineering Design prize for innovation and ingenuity in developing the most inexpensive but effective experimental research equipment
5. 2012 Thayer Visionaries in Technology Artistic Image Contest Winner
6. 2006 Particle Engineering Research Center Undergraduate Research Scholarship

SOCIETY AFFILIATIONS – National Society of Professional Engineers (NSPE), American Society for Testing and Materials International (ASTM), Society for Biomaterials (SFB), Sigma Xi Scientific Research Society (invitation only).

EXPERT WITNESS DEPOSITIONS

12/29/2014	Christiansen v. Wright Medical Technology (metal-on-metal hip system, wear measurements)	US District Court, N. Dist. Georgia Firm: Pope, McGlamry, Kilpatrick, Morrison & Norwood, P.C.
10/16/2015	Tucker v. Wright Medical Technology (metal-on-metal hip system, wear measurements)	California Superior Court, LA County Firm: Pope, McGlamry, Kilpatrick, Morrison & Norwood, P.C.
10/11/2016	Zimmer Biomet Holdings v. Four Mile Bay (IPR patent validity for bone ingrowth system)	U.S. Patent & Trademark Office Firm: Four Mile Bay, LLC
06/29/2017	Estate of Marsha Jane Snider v. Wright Medical (metal-on-metal hip system, wear measurements)	Circuit Court of Harrison County, WV Firm: Saunders & Walker, PA
05/07/2018	Edward McAnneny v. Smith & Nephew (metal-on-metal hip system, taper fretting corrosion)	US District Court, District of Connecticut Firm: Law Office of Andrew J. Pianka, LLC

MEDICAL DEVICE EXPERIENCE

Participated in forensic investigations of the following device classes, performing physical inspections, document review (design history files, manufacturing records, testing records, failure reports), and contributing to expert reports under the direction of a principal engineer.

Orthopedic Implants

- Hip replacement systems (metal-on-metal, metal-on-polymer, ceramic-on-metal, ceramic-on-ceramic)
 - Modular neck and acetabular components
 - Surgical implantation and removal tools
 - Trunnions, femoral stems, and bone ingrowth surfaces
 - Knee replacement systems
- Spinal implant systems, including:
 - Spinal rods
 - Interspinous fixation devices
 - Spinal fusion systems
 - Cervical fixation systems (anterior plating and fusion devices)
- Bone plates and fixation devices:
 - Mandible locking plate
 - Clavicle rod
- Bone graft materials and biologic combination systems

Urological & Gynecological Implants

- Surgical mesh systems (POP and SUI mesh)
- Abdominal and hernia mesh (polypropylene and resorbable materials)
- Intrauterine devices (IUDs)

Neurological Devices

- EEG recording systems and stimulation equipment
- EEG gels and pastes
 - Laser and radiofrequency ablation systems
 - Neurovascular microcatheters and embolic delivery systems
 - Neurovascular embolization coils
 - Aneurysm treatment systems

Postoperative Recovery & Rehabilitation Devices

- Cold therapy systems
- Compression therapy equipment

Surgical Instruments & Assistive Devices

- Suture-assist systems
- Surgical staplers

Cardiovascular Implants & Devices

- Inferior Vena Cava (IVC) filters
- Intra-aortic balloon pumps
- Mitral valve repair devices
- Implantable cardioverter-defibrillator (ICD) leads
- Cardiac pacing components

Perioperative & Surgical Environment Devices

- Forced-air warming systems
- Heater-cooler units and temperature control devices
- Surgical waste and fluid management systems
- Ultrasonic cleaning and reprocessing systems

NAVAIR PARTIAL INVESTIGATION LIST

The following is a partial list of failure analyses Dr. Vincelli investigated during his engagement with NAVAIR. The range of services provided included chemical analysis to identify the composition of the metal used, metallurgical analysis including hardness testing and electrical conductivity testing, and analysis of the fracture surface to identify if the component slowly failed due to fatigue, or if a sudden failure due to overload occurred. A brief description of the services provided is included below.

NAVAIR, Cherry Point, NC

- Boeing AV-8B Harrier II Jet, Aluminum Panel - metallurgical analysis
- Titanium Tube Welding Dross – Visual characterization
- Bell Boeing V-22 Osprey Aircraft, Shaft Driven Compressor (SDC) Inlet - aluminum metallurgical and mechanical analysis
- Lockheed C-130 Hercules Aircraft, Hydraulic Motor - chemical, metallurgical, and fracture analysis
- McDonnell Douglas F/A-18 Hornet, Tie Rod, Air Bearing Shaft, and Nut – chemical and metallurgical analysis
- Boeing AV-8B Harrier II Jet, Port Hot Nozzle from Universal Yoke Assembly – visual analysis of nut and bolt system
- Rolls-Royce Pegasus Aircraft Turbofan (F-402), Compressor Blade - foreign object damage analysis
- Sikorsky CH-53E Super Stallion Helicopter, Main Gearbox Housing – chemical and fracture analysis
- Sikorsky CH-53E Super Stallion Helicopter, Rescue Hoist – chemical, metallurgical, and fracture analysis
- Bell Boeing V-22 Osprey Aircraft, Circuit Board Diode – visual analysis
- Bell Boeing V-22 Osprey Aircraft, Hydraulic Tube Assembly, Swage Fitting – dimensional, chemical, and visual analysis
- Sikorsky MH-60S Knighthawk Helicopter, Main Gearbox Dipstick Rivets – dimensional analysis
- Boeing AV-8B Harrier II Jet, F-402-RR-408B Engine, Low Pressure Compression Rotor Blades – foreign object damage, chemical and dimensional analysis
- Boeing AV-8B Harrier II Jet, Landing Gear Nitrogen Line – tube thread dimensional and visual analysis
- Boeing AV-8B Harrier II Jet, Web, Cascade Assembly – dimensional, chemical, metallurgical, and fracture analysis
- Sikorsky CH-53E Super Stallion Helicopter, Cargo Ring – chemical, metallurgical, and fracture analysis
- Boeing AV-8B Harrier II Jet, Hydromechanical Unit Wiring – dimensional and fracture analysis
- General Electric T-64 Turboshift Helicopter Engine, Stage 1 Vane, Blade, and Inlet Guide Vane – dimensional, chemical, and visual analysis
- C-130 Trailing Edge Strip – chemical, corrosion, metallurgical, analysis
- McDonnell Douglas F/A-18 Hornet, Cooling Turbine Wheel and Housing – dimensional, chemical, metallurgical, fracture analysis
- Sikorsky MH-60S Knighthawk Helicopter, Air Cycle Machine (Turbine Shaft Bearing, Compressor and Turbine Wheels, Compressor Housing, Cooling Fan, and Fractured Blade) – chemical, metallurgical, and fracture analysis
- Rolls-Royce Pegasus Aircraft Turbofan (F-402), Nut Plate/Anchor Nut – chemical and metallurgical analysis
- General Electric T-64 Turboshift Helicopter Engine, Stage 1, 2, 3, 4, and 6 compressor blades, Stage 1 retaining ring – foreign object damage, chemical, metallurgical, and fracture analysis
- Sikorsky SH-60B Seahawk, Engine Coupling Retainer Bolt, Shaft Screw, Uitorque Nut – Chemical, metallurgical, and fracture analysis
- Boeing AV-8B Harrier II Jet, RCS Duct Fastener Bolt – Chemical analysis