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NIKITA PAK, PH.D., P.E.
SENIOR CONSULTANT

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Dr. Nikita Pak has over a decade of experience in mechanical engineering design, primarily focusing on medical device design and testing. This includes evaluating the safety and efficacy of various types of medical devices with cadaveric and surrogate tissue experiments, custom test rigs, and by testing to standards such as ASTM and ISO. He has experience in developing machines and instruments from the design phase through final testing and documentation, including designing devices such as PCR thermocyclers, microfluidic devices, surgical robots, microscopes, cell culture bioreactors, and implantable devices. Dr. Pak was trained as a mechanical engineer with a focus on machine design, manufacturing, mechatronics, and optics, and he applies these skills to the world of medical devices.

Dr. Pak is experienced with all aspects of the medical device lifecycle, including design, risk management, verification and validation testing, failure analysis and device examination, manufacturing, post-market surveillance, and the regulatory process. He has experience working on all classes (I-III) of medical devices including surgical tools, bone fixation devices, orthopedic devices, implantable filters, pacemakers, and biopsy markers.

Prior to joining ESi, Dr. Pak was a senior mechanical design engineer at a commercial air conditioning startup where he designed and tested novel liquid desiccant dehumidification systems. Before this, he was a managing engineer in Exponent, Inc's Biomedical Engineering and Sciences practice. He has assisted clients through all stages of the medical device life cycle including the initial concept stage of novel products, design improvements to established products, testing and failure analysis, litigation support, due diligence, and intellectual property analysis. He has also performed risk analysis and testing on consumer products and industrial machines that interact with the human body.

Areas of Specialization

Design Analysis
Inspection Services
Intellectual Property
Manufacturing
Medical Devices
Risk Analysis

January 2025

Education

Ph.D., Mechanical Engineering, Management minor, 2018, Massachusetts Institute of Technology, Cambridge, Massachusetts

MS Mechanical Engineering (Graduate), 2012, Georgia Institute of Technology, Atlanta, Georgia

BS Mechanical Engineering - graduated with highest honors (Undergraduate), 2010, Georgia Institute of Technology, Atlanta, Georgia

Licensed Professional Engineer (P.E.)

State of California .... License No. 40647

Activities and Organizations

Engineering for Us All (E4USA)
Industry Liaison

ENROOT, Cambridge, MA
Tutor

GHOST (Georgia High School Outreach for Science and Technology)
Member of high school outreach

Atlanta chapter of Habitat for Humanity
Member

Atlanta Community Food Bank
Participant

American Society of Mechanical Engineers
Member

Inter-Religious Fellowship for the Homeless
Volunteer

Fellowships

NSF Graduate Research Fellowship

Positions Held

Mojave Energy Systems, Sunnyvale, California
Senior Mechanical Engineer, 2023-2024

Exponent, Menlo Park, California
Managing Engineer, 2018-2023

Synthetic Neurobiology Laboratory, Cambridge, Massachusetts
Thesis: Automation and Scalability of *in vivo* Neuroscience, 2012-2018

Precision Biosystems Laboratory, Atlanta, Georgia
Thesis: Simultaneous Amplification of Multiple DNA Targets with Optimized Annealing Temperatures, 2010-2012

ME 2110, Georgia Institute of Technology, Atlanta, Georgia
Graduate Teaching Assistant, 2010-2012

Radiant Energy Systems, Hawthorne, New Jersey
Intern, 2005-2009 (summers)

Patents

Apparatus for Automated Opening of Craniotomies for Mammalian Brain Access, US 11564701B2

Method for Automated Opening of Craniotomies for Mammalian Brain Access, US 10820914B2

Publications

Lovald, S. L., Gorji, M. B., Chen, M., **Pak, N**., (2023). Developing failure criteria for laceration injury of dermal tissue, Journal of the Mechanical Behavior of Biomedical Materials.

Alon, S., Goodwin, D. R., Sinha, A., Wassie, A. T., Chen, F., Daugharthy, E. R., Bando, Y., Kajita, A., Xue, A. G., Marrett, K., Prior, R., Cui, Y., Payne, A. C., Yao, C-C., Suk, H-J., Wang, R., Yu, C-C. J., Tillberg, P., Reginato, P., **Pak, N**., Liu, S., Punthambaker, S., Iyer, E. P. R., Kohman, R. E., Miller, J. A., Lein, E. S., Lako, A., Cullen, N., Rodig, S., Helvie, K., Abravanel, D. L., Wagle, N., Johnson, B. E., Klughammer, J., Slyper, M., Waldman, J., Jané-Valbuena, J., Rozenblatt-Rosen, O., Regev, A., IMAXT Consortium, Church, G. M., Marblestone, A. H., Boyden, E. S., (2021). Expansion sequencing: Spatially precise in situ transcriptomics in intact biological systems, Science.

Yoon, Y-G., Wang, Z., **Pak, N**., Park, D., Dai, P., Kang, J. S., Suk, H-J., Symvoulidis, P., Guner-Ataman, B., Wang, K., Boyden, E. S., (2020). Sparse decomposition light-field microscopy for high speed imaging of neuronal activity, Optica.

Shemesh, O. A., Linghu, C., Piatkevich, K. D., Goodwin, D., Celiker, O. T., Gritton, H. J., Romano, M. F., Gao, R., Yu, C-C. J., Tseng, H-A., Bensussen, S., Narayan, S., Yang, C-T., Freifeld, L., Siciliano, C. A., Gupta, I., Wang, J., **Pak, N**., Yoon, Y-G., Ullmann, J. F. P., Guner-Ataman, B., Noamany, H., Sheinkopf, Z., R., Park, W. M., Asano, S., Keating, A. E., Trimmer, J. S., Reimer, J., Tolias, A. S., Bear, M. F., Tye, K. M., Han, X., Ahrens, M. B., Boyden, E. S., (2020). Precision calcium imaging of dense neural populations via a cell-body-targeted calcium indicator, Neuron.

Piatkevich, K. D., Jung, E. E., Straub, C., Linghu, C., Park, D., Suk, H-J., Hochbaum, D. R., Goodwin, D., Pnevmatikakis, E., **Pak, N**., Kawashima, T., Yang, C-T., Rhoades, J. L., Shemesh, O., Asano, S., Yoon, Y-G., Freifeld, L., Saulnier, J. L., Riegler, C., Engert, F., Hughes, T., Drobizhev, M., Szabo, B., Ahrens, M. B., Flavell, S. W., Sabatini, B. L., Boyden, E. S., (2018). A robotic multidimensional directed evolution approach applied to fluorescent voltage reporters, Nature Chemical Biology.

Chang, J.-B., Chen, F., Yoon, Y.-G., Jung, E. E., Babcock, H., Kang, J. S., Asano, S., Suk, H-J., **Pak, N**., Tilberg, P. W., Wassie, A. T., Cai, D., Boyden, E. S. (2017). Iterative expansion microscopy. Nature Methods, 14(6), 593–599.

Phaneuf, C. R., **Pak, N**., Saunders, D. C., Holst, G. L., Birjiniuk, J., Nagpal, N., Culpepper, S., Popler, E., Shane, A. L., Jerris, R., Forest, C. R. (2015). Thermally multiplexed polymerase chain reaction. Biomicrofluidics, 9(4), 044117.

Pak, N., Siegle, J. H., Kinney, J. P., Denman, D. J., Blanche, T. J., & Boyden, E. S. (2015). Closed-loop, ultraprecise, automated craniotomies. Journal of Neurophysiology, 113(10).

Prevedel, R., Yoon, Y.-G., Hoffmann, M., **Pak, N**., Wetzstein, G., Kato, S., Schrödel, T., Raskar, R., Zimmer, M., Boyden, E. S., Vaziri, A. (2014). Simultaneous whole-animal 3D-imaging of neuronal activity using light-field microscopy. Nature Methods, 11(7), 727–730.

D.C. Saunders, G.L. Holst, C.R. Phaneuf, **N. Pak**, M. Marchese, N. Sondej, M. McKinnon, C.R. Forest, Rapid, quantitative, reverse transcription PCR in a polymer microfluidic chip, Biosensors and Bioelectronics, Vol. 44, p. 222-228, June 2013.

C.R. Phaneuf, K. Oh, **N. Pak**, D.C. Saunders, C. Conrardy, J. Landers, S. Tong, C.R. Forest, Sensitive, microliter PCR with consensus degenerate primers for Epstein Barr virus amplification, Biomedical Microdevices, doi:10.1007/s10544-012-9720-1.

N. Pak, C. Saunders, C.R. Phaneuf, C.R. Forest, Plug-and-play infrared laser-mediated PCR in a microfluidic chip, Biomedical Microdevices, Vol. 14(2), p. 427-433, April 2012.

N. Pak, M. Dergance, M. Emerick, E. Gagnon, C.R. Forest, An Instrument For Controlled, Automated, Continuous Production of Micrometer Scale Fused Silica Pipettes, ASME Journal of Mechanical Design, Vol. 133(6), 061006, June 2011.

C.R. Phaneuf, **N. Pak**, C.R. Forest, Modeling radiative heating of liquids in microchip reaction chambers, Sensors and Actuators: A. Physical, Vol. 167(2), p. 531-536, February 2011.

Presentations

N. Pak, J.P. Kinney, E.S. Boyden, Automation of brain surgery: Towards automation of In vivo neuroscience, Neuroscience 2013, San Diego, CA, Nov. 13, 2013. (poster)

N. Pak, C.R. Phaneuf, D.C. Saunders, C.R. Forest, Simultaneous Amplification of Multiple DNA Targets with Optimized Annealing Temperatures, Proceedings of the Biomedical Engineering Society (BMES) 2012 Annual Meeting, Atlanta, GA, October 24-27, 2012. (poster)

G.L. Holst, D.C. Saunders, C.R. Phaneuf, **N. Pak**, C.R. Forest, Sensitive, Open-loop, rapid, laser PCR system using transient thermal analysis, optimization, and environmental control, Proceedings of the Biomedical Engineering Society (BMES) 2012 Annual Meeting, Atlanta, GA, October 24-27, 2012. (poster)

C.R. Phaneuf, K. Oh, **N. Pak**, D.C. Saunders, C. Conrardy, J. Landers, S. Tong, and C.R. Forest, Sensitive, Microliter PCR with Degenerate Primers for Respiratory Virus Detection and Discovery, Proceedings of the Biomedical Engineering Society (BMES) 2012 Annual Meeting, Atlanta, GA, October 24-27, 2012. (poster)

N. Pak, G.L. Holst, C.R. Phaneuf, C. Saunders, C.R. Forest, Control Schemes for Microfludic Viral DNA/RNA Amplification, Proceedings of the 27th Annual Meeting of the American Society for Precision Engineering, San Diego, CA, October 21-26, 2012. (talk)

C.R. Phaneuf, **N. Pak**, C. Saunders, C.R. Forest, Rapid, independently controlled polymerase chain reaction via multiplexed laser radiation, Proceedings of the 15th International Conference on Miniaturized Systems for Chemistry and Life Sciences (μTAS), p.1689-1692, Seattle, WA, October 2-6, 2011. (poster)

C.R. Phaneuf, **N. Pak**, C.R. Forest, Modeling and design of a microscale multiplexed temperature control system, Proceedings of the 26th Annual Meeting of the American Society for Precision Engineering, V. 52, p. 181-184, Denver, CO, November 13-18, 2011. (poster)

Pak, N., Phaneuf, C.R., Kodandaramaiah, S.B., Forest, C.R. Modulation of electromagnetic radiation using a dot matrix printer. Proceedings of the 25th Annual Meeting of the American Society for Precision Engineering. 2010. Atlanta, GA. (poster)

Pak, N., Dergance, M.J., Emerick, M.T., Gagnon, E.B., Forest, C. R., An instrument for controlled, automated, continuous pulling of sub-micrometer fused silica pipettes, Proceedings of the 25th Annual Meeting of the American Society for Precision Engineering. 2010. Atlanta, GA. (talk)

Phaneuf, C.R., **N. Pak**, C.R. Forest, Rapid, Low-Cost, Microfluidic Thermocycler For High-Throughput Genetic Diagnostics, Oral Presentation, Proceedings of the ASME 2010 Summer Bioengineering Conference (SBC 2010), Paper #19714, p. 57, Naples, FL, June 15-19, 2010. (talk)

Symposia

N. Pak, G.L. Holst, C.R. Phaneuf, D.C. Saunders, C.R. Forest, Control schemes for microfluidic viral DNA/RNA amplification, Southern Section of Association of Official Agricultural Chemists (AOAC) International Meeting, Atlanta, GA, April 29-May 1, 2012.

N. Pak, C.R. Phaneuf, D. Curtis Saunders, and C.R. Forest, Dual independent temperature control of infrared PCR . Georgia Tech Research and Innovation Conference (gtRIC), Atlanta, GA, February 7th, 2012.

C.R. Phaneuf, **N. Pak**, C.R. Forest, An instrument for multi-temperature, multi-chamber, and micro- liter amplification of RNA/DNA, Proceedings of the Workshop on Novel Sampling and Sensing for Improving Food Safety, Atlanta, GA, June 16-17, 2011, p. 79-80.

N. Pak, M.J. Dergance, M.T. Emerick, E.B. Gagnon, and C.R. Forest, An Instrument For Controlled, Automated, Continuous Production of Micrometer Scale Fused Silica Pipettes, Georgia Tech Research and Innovation Conference (gtRIC), Atlanta, GA, February 8th, 2011.

C.R. Phaneuf, **N. Pak**, C.R. Forest, Arrayed, independently-controlled PCR thermocycling in a polymeric microchip, Poster Presentation, Georgia Tech Research and Innovation Conference (gtRIC), Atlanta, GA, February 8, 2010.

Selected Project Experience

Medical Device Design, Development, and Manufacturing Support

Dr. Pak utilizes his foundation in mechanical engineering to assist clients with the design and development of novel medical devices as well as design improvements for existing devices. He has also designed and overseen the manufacturing of tools and fixtures used on medical device manufacturing lines. Selected project examples include:

- Design support for a novel implantable sensor. A startup was interested in outsourcing design work including determining manufacturing best practices, testing to ensure performance was met under typical use scenarios, and guidance on design improvements for manufacturing, miniaturization, and robustness. This was a long-term engagement where Dr. Pak essentially acted as an engineer on call for any problem or inquiry.
- Design and construction of prototype medical devices spanning the industry. Prototypes include micropipette pulling machines, cell culture bioreactor, diagnostic equipment, and mechanical hand tools. He has worked with clients that had specific functional requirements from the start as well as those that had a general idea of what they wanted and worked together to come up with a prototype that met their needs.
- Design and manufacturing of medical device surrogates to calibrate and verify machines that are used to test medical devices on a production line. A large medical device manufacturer needed a way of testing and calibrating the machines used to test disposable medical devices on their manufacturing lines. Since the devices being tested were disposable, a surrogate needed to be developed that behaved the same way as the devices, but that could be reused so that any degradation in performance of the testers over time could be captured. Dr. Pak designed a prototype, tested the prototype to ensure performance, presented the results to the client to ensure they were satisfied, designed five different variants to capture the range in performance of the entire product line, and worked with outside vendors to manufacture multiple copies of each variant to be used on multiple manufacturing lines.
- Due diligence investigation on behalf of a potential investor looking into the viability of a startup medical device company in the in vitro diagnostics space. Dr. Pak read through documentation and conducted interviews with engineers at a startup medical device company that an investor was interested in acquiring to determine the viability of the technology, any potential issues or concerns with the device design, and the ability of the company to meet deadlines with respect to device performance.

Verification and Validation of Medical Devices

Dr. Pak has assisted clients with all aspects of verification and validation of medical devices. This includes reviewing testing documents, offering advice on testing required for regulatory submissions, designing tests for novel medical devices that have no testing standards, executing the testing, and writing reports that can be submitted to regulatory agencies. Selected project examples include:

- Verification of a biopsy marker migration. Dr. Pak performed testing to verify that a redesigned biopsy marker did not migrate to a greater extent than the previous generation marker. He built a test rig to simulate the forces caused by activities of daily living and measured the displacement and rotation of the markers within a surrogate tissue designed to mimic the properties of human tissue. He performed all activities of the testing including finding the correct surrogate tissue, designing and building the test rig, executing the testing, and documenting the results in a test report.
- Wound closure device utilized in a new application. Dr. Pak assisted a client that was interested in expanding the indications for use of an established wound closure patch. He worked with the client to understand the new indication, researched relevant standardized testing for similar products, determined the most relevant methods, executed the testing, and documented the results in a test report.
- Testing of a guidewire for FDA submission. Dr. Pak assisted an inventor with determining and executing the testing necessary for regulatory submission for a novel guidewire. He determined the relevant tests, executed the testing, and submitted a final test report.

Post-market Surveillance and Failure Analysis of Medical Devices

Dr. Pak has conducted failure analysis investigations of a wide variety of medical devices, including conducting retrieval analysis per ISO 17025 accredited methods. He has utilized techniques such as digital microscopy, X-ray computed tomography (CT) scanning and 2D X-ray imaging, electron microscopy and energy-dispersive X-ray spectroscopy (SEM/EDS), Fourier-transform infrared spectroscopy (FT-IR), and profilometry. Selected project examples include:

- Investigating the use of surgical hand tools. Dr. Pak has utilized his expertise to understand how the tools were used and what caused them to fail. Examples include mechanical wound closure devices as well as electromechanical tools such as surgical drills.
- Investigating the use of a cryotherapy sauna. Dr. Pak analyzed internal company documents and participated in an inspection of the subject device to understand how it operated and what series of events was necessary to cause an accident.
- Investigation of an injury caused by an incubation bed. Dr. Pak investigated company documents such as the instructions for use (IFU), design failure mode and effects analysis (DFMEA), and regulatory submissions as well as hospital records to determine the cause of injury.

Experience Outside of the Medical Device Industry

Dr. Pak was trained as a mechanical engineer with a focus on machine design, manufacturing, mechatronics, and optics. His primary interest is in the field of medical devices, but he has used his skills and expertise in other industries. Selected project examples include:

- Dr. Pak previously held a role as a senior mechanical design engineer at an HVAC startup where he designed novel liquid desiccant systems. He came up with concepts, conducted testing to verify the performance of his designs, and worked with the manufacturing team to build, test, and modify the components he designed. The main manufacturing techniques used were plastic welding and sheet metal bending, and he also designed concepts to be manufactured with large scale manufacturing techniques such as thermoforming.
- Failure analysis investigations outside of the medical device field including devices such as injection molding machines and consumer electronics.
- Safety and risk assessments of consumer goods that interact with the human body and have the potential for injury through means such as tissue laceration/penetration, bruising, or thermal injury.
- Laceration and penetration testing of human cadaveric skin and surrogate tissues. Testing was conducted both to assess the risk of injury from the misuse of a consumer electronic good as well as to find a suitable alternative to human tissue that had the same mechanical properties.