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Kaitlin Alexander, Ph.D.

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Professional Profile

Dr. Kaitlin Alexander has expertise in evaluating and providing technical support for regulatory submissions, product development, risk management, and post-market surveillance of medical devices. As a licensed regulatory affairs (RAC-Devices) professional, she uses her knowledge of global regulatory strategy, U.S. FDA regulations, and E.U. directives and regulations to aid in the development of optimal strategies for medical devices, including preparation of submissions and activities throughout the total product lifecycle for Class I, II, and III medical devices. Dr. Alexander is knowledgeable with respect to numerous industry standards and regulations impacting the medical device industry, including ISO 10993, ISO 13485, ISO 14971, and 21 CFR 820. She additionally has experience in protocol development for institutional review board (IRB) and institutional animal care and use committee (IACUC) protocols, evaluation of regulatory submissions and regulatory strategies of biologic/pharmaceutical products, as well as assessment of the use of digital health technology in the medical device and pharmaceutical industries.

Dr. Alexander's background is in biomedical engineering with a focus on human biomechanics, wearable sensors, as well as prosthetic and assistive device technology. She has extensive experience in experimental design, clinical research protocol development, image processing, and machine learning. Additionally, she has experience with ultrasound imaging, computed tomography, image segmentation, computational modeling, and is proficient in MATLAB, Python, and OpenSim. Dr. Alexander's specific research interests involve bridging the disciplines of wearable sensing, biomedical imaging, and human biomechanics to develop robust technologies for prediction and assessment of human movement to improve rehabilitation strategies and devices for individuals with mobility impairments.

Dr. Alexander received a PhD in Biomedical Engineering from the University of Texas at Austin in 2022. While investigating wearable sensing technology for lower-limb assistive device control and assessment, Dr. Alexander developed a novel framework that combined sonomyography, or the evaluation of dynamic ultrasound imaging of skeletal muscle, and machine learning for accurate continuous prediction of human motion. Prior to graduate school, she worked as a clinical research assistant in Physical Medicine and Rehabilitation where she was the clinical coordinator for various industry-sponsored and investigator-initiated clinical trials and observational studies and assisted in the development of image segmentation algorithms to evaluate novel imaging biomarkers to detect the onset and progression of knee osteoarthritis.

Academic Credentials & Professional Honors

Ph.D., Biomedical Engineering, University of Texas, Austin, 2022

M.S., Biomedical Engineering, University of Texas, Dallas, 2020

B.S., Chemical Engineering, The University of Kansas, 2015

Cockrell School of Engineering Graduate Fellowship, The University of Texas at Austin, 2021-2022

Jonsson School Excellence in Education Doctoral Fellowship, The University of Texas at Dallas, 2019-2020

Outstanding Lecture Teaching Assistant, Biomaterials and Medical Devices, Jonsson School Department of Bioengineering, The University of Texas at Dallas, 2019

Licenses and Certifications

Certified ISO 13485 Medical Device Management Systems Lead Auditor

Regulatory Affairs Certification (RAC: Devices)

Prior Experience

Graduate Research Assistant, Systems for Augmenting Human Mechanics Laboratory, The University of Texas at Austin, 2020 – 2022

Graduate Teaching Assistant, Biomechanics of Human Motion, The University of Texas at Austin, 2021

Graduate Research Assistant, Systems for Augmenting Human Mechanics Laboratory, The University of Texas at Dallas, 2018 – 2020

Graduate Teaching Assistant, Introductory Biomechanics, Biomaterials and Medical Devices, The University of Texas at Dallas,2018 – 2019

Clinical Research Assistant, Clinical Osteoarthritis Research Program, University of Kansas Medical Center 2016 – 2018

Research Technician, Baylor College of Medicine, 2015 – 2016

Professional Affiliations

Institute of Electrical and Electronics Engineers (IEEE)

Biomedical Engineering Society (BMES)

Regulatory Affairs Professional Society (RAPS)

Publications

Matsuse H, Segal NA, Rabe KG, Shiba N. Effect of Neuromuscular Electrical Stimulation During Walking on Pain Sensitivity in Women With Obesity With Knee Pain: A Randomized Controlled Trial. Archives of PM&R. Sep (2022).

Rabe KG, Fey NP. Evaluating Electromyography and Sonomyography Sensor Fusion to Estimate Lower-Limb Kinematics Using Gaussian Process Regression. Frontiers in Robotics and AI. Mar (2022).

Rabe KG, Lenzi T Fey NP. Performance of Sonomyographic and Electromyographic Sensing for Continuous Estimation of Joint Torque During Ambulation on Multiple Terrains. IEEE Transactions on Neural Sciences and Rehabilitation. Dec (2021).

Rabe KG, Stockman TJ, Kern AM, Wirth W, Eckstein F, Sharma L, Lynch JA, Felson DT, Lewis C, Nevitt M, Anderson DD, Segal NA. The longitudinal relationship between tibiofemoral contact stress at baseline

and worsening of knee pain over 84-months in The Multicenter Osteoarthritis Study. American Journal of PM&R. Oct (2021).

Rabe KG, Jahanandish MH, Boehm JR, Majewicz A, Hoyt K, Fey NP. Ultrasound-Based Sensing Improves Continuous Classification of Multiple Ambulation Modes Compared to Surface Electromyography. IEEE Transactions on Biomedical Engineering. Apr (2021).

Jahanandish MH, Rabe KG, Fey NP, Hoyt K. Ultrasound Features of Skeletal Muscle Can Predict Kinematics of Upcoming Lower-Limb Motion. Ann Biomed Eng. Sept (2020).

Matsuse H, Segal NA, Rabe KG, Shiba N. The Effect of Neuromuscular Electrical Stimulation during Walking in Comparison with Sensory TENS on Muscle Strength and Knee Pain in Obese Women: A Randomized Controlled Trial. American Journal of PM&R. Jan (2020).

Kothari M, Segal NA, Rabe KG, Anderson DD, Lynch J, Nevitt MC. The Relationship of Three-Dimensional Joint Space Width Measured on Standing Computed Tomography with Pain and Physical Function. Journal of Orthopaedic Research. Dec (2019).

Steidle-Kloc E, Rabe KG, Eckstein F, Wirth W, Glass NA, Segal NA. Is Muscle Strength in a Painful Knee Affected by Pain Status of the Contralateral Knee – Data from the Osteoarthritis Initiative (OAI). Annals of Anatomy. Jan (2019).

Rabe KG, Matsuse H, Jackson A, Segal NA. Evaluation of the Combined Application of Neuromuscular Electrical Stimulation and Volitional Contractions on Thigh Muscle Strength, Knee Pain and Physical Performance in Women at Risk for Knee Osteoarthritis: A Randomized Controlled Trial. PM&R. Dec (2018).

Rabe KG, Segal NA, Waheed S, Anderson DD. The Effect of Arch Drop on Tibial Rotation and Tibiofemoral Articular Contact Stress in Postpartum Women. PM&R. Nov (2018).

Presentations

Rabe KG, Fey NP. Forward Models That Integrate High-Dimensional and Localized Sensing of Peripheral Muscle Behavior Enable Task Independent Prediction of Lower-Extremity Torque and Position Future States. 2022 IEEE International Conference on Robotics and Automation (ICRA), May 2022.

Rabe KG, Fey NP. Continuous Prediction of Leg Kinematics During Ambulation using Peripheral Sensing of Muscle Activity and Morphology. 2021 International Symposium on Medical Robotics (ISMR), Nov 2021.

Rabe KG, Jahanandish MH, Fey NP. Ultrasound-Derived Features of Muscle Architecture Provide Unique Temporal Characterization of Volitional Knee Motion. 43rd Annual IEEE EMBS International Conference on Engineering in Medicine and Biology (EMB), Nov 2021.

Rabe KG, Lenzi T, Fey NP. Comparing Sonomyography and Electromyography Using Bayesian Regression to Continuously Estimate Joint Torques During Ambulation on Varying Terrains. 2021 International Conference on Rehabilitation Robotics (ICORR) at RehabWeek, Sept 2021.

Rabe KG, Fey NP. Benchmark Comparisons of Ultrasound to Electromyography for Estimation of Joint Torques During Ambulation. 2021 Military Health System Research Symposium (MHSRS). Aug 2021. (poster)

Jahanandish MH, Rabe KG, Srinivas A, Hoyt K. Task-Invariant Learning of Continuous Joint Kinematics during Steady-State and Transient Ambulation Using Ultrasound Sensing. 2021 IEEE International Conference on Robotics and Automation (ICRA). Jun 2021.

Rabe KG, Jahanandish MH, Hoyt K, Fey NP. Use of Sonomyography for Continuous Estimation of Hip, Knee and Ankle Moments During Multiple Ambulation Tasks. 8th IEEE RAS/EMBS International Conference on Biomedical Robotics and Biomechatronics (BioRob). Nov/Dec 2020.

Rabe KG, Lenzi T, Fey NP. Sonomyography: An Input for Control of Powered Lower Limb Assistive Devices. 2020 IEEE/RSJ International Conference of Intelligent Robots and Systems (IROS) – Powered Leg Prostheses Workshop. Oct 2020. (invited workshop presentation)

Rabe KG, Hoyt K, Fey NP. Benchmark Comparisons of Ultrasound to Electromyography for Classifying Human Ambulation. 2020 Military Health System Research Symposium. Aug 2020. (poster)

Rabe KG, Jahanandish MH, Hoyt K, Fey NP. Use of Sonomyographic Sensing to Estimate Knee Angular Velocity During Varying Modes of Ambulation. 42nd Annual IEEE EMBS International Conference on Engineering in Medicine and Biology (EMB), Jul 2020.

Rabe KG, Jahanandish MH, Boehm JR, Majewicz A, Hoyt K, Fey NP. Comparison of Ultrasound to Electromyographic Sensing for Ambulation Mode Classification. 2019 BMES Annual Meeting. Oct 2019. (poster)

Srinivas A, Jahanandish MH, Rabe KG, Fey NP, K Hoyt. Task-Sensitive Mapping of Skeletal Muscle Activity during Ambulation Using Ultrasound Imaging. 2019 BMES Annual Meeting. Oct 2019. (podium)

Segal NA, Ho M, Rabe KG, Nevitt MC, Anderson DD. 24-Month Responsiveness of Tibiofemoral 3D Joint Space Narrowing Measured With Standing CT in The MOST Study. 2019 International Workshop on Osteoarthritis Imaging. Jun 2019.

Jahanandish MH, Rabe KG, NP Fey NP, Hoyt K. Gait Phase Identification During Level, Incline and Decline Ambulation Tasks Using Portable Sonomyographic Sensing. 2019 IEEE International Conference on Rehabilitatoin Robotics. Jun 2019.

Kothari M, Segal NA, Rabe KG, Anderson DD, Nevitt MC. The Relationship of Three-Dimensional Joint Space Width Measured on Standing Computed Tomography with Concurrent Pain and Physical Function in The MOST Study. 2019 World Congress on Osteoarthritis. May 2019. (poster)

Srinivas A, Jahanandish MH, Rabe KG, Fey NP, Hoyt K. Representing Muscle Activity Patterns During Different Locomotion Modes Using Ultrasound Imaging. 2019 South Central American Society of Biomechanics Regional Meeting. Apr 2019.

Rabe KG, Jahanandish MH, Hoyt K, Fey NP. Ultrasound Derived Timing of Kinetics and Kinematics of Rectus Femoris Contraction During Volitional Knee Motion. GCMAS Annual Meeting. Mar 2019. (poster)

Matsuse H, Segal NA, Rabe KG, Hu B, Shiba N. The Effect of Electrical Stimulation of Antagonist Contraction During Walking in Comparison with Those of Sensory TENS on Muscle Strength and Knee Pain in Obese Women with Knee Pain: A randomized controlled trial. AAPM&R Annual Assembly. Oct 2018.

Rabe KG, Segal NA, Anderson DD, Dibbern KN, Nevitt MC. Responsiveness of Standing CT for Measurement of Joint Space Narrowing Over 60 Months. 2018 International Workshop on Osteoarthritis Imaging, Jul 2018.

Rabe KG, Segal NA, Hausdorff JM, Gazit E, Tolstykh I, Felson DT, Lewis CE, Nevitt ME. Relationship Between Gait Complexity, Physical Function and Knee Pain – Data from the MOST Study. 2018 World Congress on Osteoarthritis. Apr 2018. (poster)

Segal NA, Rabe KG, Lynch JA, Everist BM, Roemer F, Guermazi A. Detection of Meniscal Extrusion: Comparison of Standing Computed Tomography to Non-Loaded Magnetic Resonance Imaging. 2018

World Congress on Osteoarthritis. Apr 2018. (poster)

Rabe KG, Matsuse H, Jackson A, Segal NA. The Combined Application of Neuromuscular Electrical Stimulation and Volitional Contraction Improves Knee Pain and Physical Function in Women At Risk for Knee OA: A Randomized-Controlled Trial. 2018 AAP Annual Meeting. Feb 2018. (poster)

Rabe KG, Segal NA, Waheed S, Anderson DD. The Effect of Arch Drop on Tibial Rotation and Tibiofemoral Articular Contact Stress. 2017 World Congress on Osteoarthritis. Apr 2017. (poster)

Editorships & Editorial Review Boards

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