



Exponent[®]
Engineering & Scientific Consulting

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Professional Profile

Mr. Siskey's specializes in applying experimental methods to assist in the product development process. While his focus has been on medical device development projects, he also consults on material selection, consumer products and consumer electronics. As the supervisor of the ISO 17025 accredited ISO (A2LA Certificate 2561.01) medical device testing laboratory in Exponent's Philadelphia office, he has a strong foundation in the quality system requirements for medical device development. Additionally, as a certified lead ISO 13485 auditor, he is able to bridge his experimental background and the regulatory and compliance issues that manufacturer's routinely face.

Mr. Siskey's has extensive experience in performing wear and material testing in accordance with ASTM and ISO standards, conducting cadaveric testing, and developing customized protocols. This includes analyzing and testing devices from feasibility through post market surveillance and helping to obtain regulatory approval for their devices. His experience includes materials characterization, complete device evaluation, and a firm understanding of the device tissue interface including coatings characterization. Mr. Siskey also has experience in failure analysis of devices that has been used to help client's conduct root cause investigations of their devices and respond to FDA deficiency letters. While standardized testing plays a key role in characterizing most devices, new devices and new questions about existing products makes custom protocols a necessity in the lab. Mr. Siskey has experience with developing these protocols for devices and products, from Class I to Class III.

In his role as a laboratory manager, Mr. Siskey is responsible for maintaining the Philadelphia Laboratory's ISO 17025 accreditation with A2LA and conformance to CFR 21 part 58 U.S. FDA Good Laboratory Practices (GLP). Specifically, he is responsible for maintenance of all accredited procedures, overseeing the development of new accredited procedures, overseeing the maintenance of existing equipment, developing strategic equipment acquisition strategies, conducting internal conformance audits and ensuring the proficiency of the lab personnel. His internal auditing experience and understanding of quality management standards has enabled him to assist manufacturers by conducting third party quality and safety audits. Additional audit related capabilities include vendor qualification, gap assessment, root cause analysis and corrective action review.

Mr. Siskey has assisted medical device manufacturers by reviewing their laboratory facility design for engineering controls, equipment needs, and procedural flow. Specifically, the laboratory requirements included ensuring these elements would accommodate procedures related to handling and inspecting contaminated field returns and accepting, handling and disposing of human cadaveric tissues. Working with the manufacturer's contractors and architects, Exponent's expertise was used to ensure proposed solutions met the manufacturer's needs and budget constraints. Exponent specifically was able to review proposed solutions and provide an assessment of the benefits and risks at decision points along the design and construction pathway. Exponent also assisted in developing the process flow and procedures related to the new facility to expedite the training of staff and commissioning of the laboratory through

process validation.

Mr. Siskey received his MTS certification, which enables him to develop customized testing procedures on the laboratory servo-hydraulic load frames and spine wear simulator. He also maintains an understanding of mechanical testing using a wide variety of testing equipment. Additional methods include surface characterization using a Zygo white light interferometer, and chemical characterization using FTIR. Previous experience in tribology has included re-design of a Matco hip wear tester, re-design of a biaxial knee wear tester, and design of a spine disc wear tester. Mr. Siskey has also developed procedures for devices including syringes, luer fittings, needles, and catheters.

Additionally, Mr. Siskey has conducted environmental monitoring with Exponent's Environmental Sciences group. Specifically he has set up, maintained, and calibrated air particulate monitoring equipment and weather monitoring equipment. He has also conducted analysis of the data collected with these systems.

Academic Credentials & Professional Honors

M.S., Biomedical Engineering, Drexel University, 2008

B.S., Biomedical Engineering, Drexel University, 2005

ASTM Robert E. Fairer Award, May 2010

A.J. Drexel Scholarship, 2000-2005; Alpha Chi Rho Richard V. Olson Scholarship, 2004

Senior Design Honorable Mention: "Developing a Cost-Effective Mechanical Spine Simulator" (Jared Grochowsky and Ryan Siskey; Advisor: Dr. Steven Kurtz)

Licenses and Certifications

Certified ISO 13485 Lead Auditor

Convener of ISO TC150 SC5 - Osteosynthesis and Spinal Devices

Convener of ISO TC150 SC1/WG5 - Medical Plastics

Professional Affiliations

American Society for Testing and Materials

Member of ASTM Committee F04 on Medical and Surgical Materials and Devices

Publications

Kurtz SM, Siskey R, Ciccarelli L, van Ooij A, Peloza J, Villarraga ML. Retrieval analysis of total disc replacements: Implications for standardized wear testing. J ASTM International 2006; 3(6):1-12.

Grochowsky JC, Alaways WL, et al. Digital photogrammetry for quantitative wear analysis of retrieved TKA components. J Biomed Mater Res B Appl Biomater 2006; 79(2):263-267.

Kurtz SM, Peloza J, Siskey RS, Villarraga ML. Analysis of a retrieved polyethylene total disc replacement component. Spine J 2005; 5(3):344-350.

Conference Papers and Abstracts

Kurtz S, Siskey R, Whipperman B, Siebert W, Mai S. Wear mechanisms of human retrieved polycarbonate urethane acetabular components. World Congress of Biomaterials, 2008.

Kurtz S, Siskey R. Accelerated aging of gamma-sterilized polycarbonate urethane acetabular components. World Congress of Biomaterials, 2008.

Kurtz S, Siskey R, Shah P. Validation of MicroCT measurement of in vivo volumetric wear for retrieved PCU acetabular components. World Congress of Biomaterials, 2008.

Siskey R, Kurtz S, Shah P, Ciccarelli L, Harper M, Chan F. A validation of ISO-standard wear testing using retrieved metal-on-metal cervical disc replacements. Spine Arthroplasty Society, 2008.

Kurtz SM, Ebert M, Siskey R, Ciccarelli L, Reitman M, Harper ML, Chan FW. Natural and accelerated post-sterilization aging of polyurethanes in the BRYAN® Cervical Disc. Spine Arthroplasty Society, 2008.

Siskey RL, Villarraga M, Guerin H, Shah P, Kurtz SM. Developing a surrogate annulus fibrosus model for nucleus pulposus replacement wear and fatigue characterization. Spine Arthroplasty Society, 2008.

Siskey RL, Kurtz SM, Shah P, Ciccarelli L, Harper M, Chan F, White S. Validation of ISO-standard wear testing with retrieved metal-on-metal cervical disc replacements. Transactions of the Orthopaedic Research Society Vol. 33, p. 1927, San Francisco, CA, 2008.

Siskey RL, Villarraga M, Guerin H, Shah P, Kurtz SM. Design and validation of a surrogate annulus fibrosus model for nucleus pulposus replacement wear and fatigue characterization. Transactions of the Orthopaedic Research Society Vol. 33, p. 1924 San Francisco, CA, 2008.

Guerin HL, Heinly JN, Auerbach JD, Siskey RL, Lonner BS, Villarraga ML, Kurtz SM. Human intervertebral disc cartilaginous endplate tensile mechanical properties are anisotropic and degeneration dependent. Transactions of the Orthopaedic Research Society Vol. 33, p. 1444, San Francisco, CA, 2008.

Ianuzzi A, Kurtz SM, van Ooij A, Bindal RK, Ross R, Bohinski RJ, Kane W, Siskey R, Shah P, Villarraga ML. In vivo deformation, surface damage, and biostability of retrieved Dynesys components for posterior dynamic stabilization. Transactions of the Orthopaedic Research Society Vol. 33, p. 1325, San Francisco, CA, 2008.

Markel D, Day J, Siskey R, Liepins I, Kurtz S, Ong K. Deformation of metal-backed acetabular components and the impact of liner thickness in a cadaveric model. Transactions of the Orthopaedic Research Society, Vol. 33, p. 1769, San Francisco, CA, 2008.

Kurtz SM, Powell M, Ciccarelli L, Siskey R, White S, Chan F. Correlation of in-vivo and simulator-retrieved metal-on-metal cervical disc replacements. Proceedings, Eurospine 2007, Paper No. 10, Brussels, Belgium, October 2-6, 2007.

Markel D, Day J, Siskey R, Kurtz S, Ong K, Liepins I. Deformation of metal-backed acetabular components and the impact of liner thickness in a cadaveric model. 20th Annual Symposium of the International Society for Technology in Arthroplasty, Paper A3-2, Paris, France, October 4-6, 2007.

Kurtz SM, Powell M, Ciccarelli L, Siskey R, White S, Chan F. Correlation of in-vivo and simulator-retrieved metal-on-metal cervical disc replacements. 7th Annual Meeting of the Spine Arthroplasty Society, Paper No. PA-WE08, Berlin, Germany, May 1-4, 2007.

Kurtz S, Mazzucco D, Siskey R, Dumbleton J, Manley M, Wang A. Trace concentrations of vitamin e protect radiation crosslinked uhmwpe from oxidative degradation. Transactions of the Orthopaedic

Research Society 2007; 32.

Kurtz SM, Grochowsky J, Siskey RS, Most E, Alaways L. Digital photogrammetry for quantitative wear analysis of retrieved TKA components. Transactions of the Orthopaedic Research Society 2005; 30:153.

Kurtz SM, Grochowsky J, Siskey R, Sharkey P, Purtill J, Hozack W. Relationship between post damage and condylar damage in posterior-stabilized TKA. Transactions of the Orthopaedic Research Society 2004; 29:1394.

Kurtz SM, Siskey RL, Cooper C, Allen M, Hubbard N. Effects of dose rate and thermal treatment on the physical and mechanical properties of highly crosslinked UHMWPE used in total joint replacement. Transactions of the Orthopaedic Research Society 2003; 28:1411.

Conference Presentations

Siskey R, Kurtz S, Shah P, Ciccarelli L, Harper M, Chan F. Validation of ISO total disc wear testing using retrieved metal-on-metal cervical disc replacements. Spine Arthroplasty Society, 2008.