



Exponent[®]
Engineering & Scientific Consulting

Ryan L. Siskey, M.S.

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Professional Profile

Mr. Siskey 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 during the product development cycle.

Mr. Siskey 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 have 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 21 CFR part 58 U.S. FDA Good Laboratory Practices (GLP). Specifically, he is responsible for maintenance of 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 quality related capabilities include gap assessment, root cause analysis, supply chain management, decision rule use in conformity assessment, 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 wear simulators. 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

ASTM Manny Horowitz Award, May 2018

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

Professional Affiliations

ISO TC 150:

- Chair of ISO TC150 SC5 - Osteosynthesis and Spinal Devices
- Convener of ISO TC150 SC1/WG5 - Medical Plastics

American Society for Testing and Materials:

- Member of ASTM Committee F04 on Medical and Surgical Materials and Devices
- Member of ASTM Committee D13 on Textiles
- Member of ASTM Committee F15 on Consumer Products
- Member of ASTM Committee F42 on Additive Manufacturing Technologies

Patents

System for Testing Valves. Patent Number: 10,105,227 (U.S.), October 23, 2018.

Publications

Higgs GB, MacDonald DW, Lowell J, Padayatil A, Mihalko WM, Siskey RL, Gilbert JL, Rimnac CM, Kurtz SM. Technical Note: Is Corrosion a Threat to the Strength of the Taper Connection in Femoral Components of Total Hip Replacements? *Corrosion* 73(12): 1538, 2017.

Ansari F, Lyons C, MacLean S, Siskey R, Donthu, S. Mechanical characterization and fractography of PC, ABS and PMMA - a comparison of tensile, impact and ESC fracture surfaces. *Proceedings, ANTEC*, 2017

Rau A, Siskey R, Ochoa J, Good T. Factors affecting lethal isotherms during cryoablation procedures. *The Open Biomedical Engineering Journal* 2016; 10: 62-71.

Baykal D, Siskey R, Underwood RJ, Briscoe A, Kurtz SM. The biotribology of PEEK-on-HXLPE bearings Is comparable to traditional bearings on a multidirectional pin-on-disk tester. *Clin Orthop Relat Res.* 2016;474:2384-2393.

Siskey R, Ciccarelli L, Lui MK, Kurtz SM. Are PEEK-on-Ceramic bearings an option for total disc arthroplasty? An In Vitro Tribology Study. *Clin Orthop Relat Res.* 2016;474:2428-2440.

Siskey R, Peck J, Mehta H, Kosydar A, Kurtz S, Hill G. Development of a clinically relevant impingement test method for a mobile bearing lumbar total disc replacement. *Spine J.* 2016;16:1133-1142.

Siefert, AW, Siskey, RL (2015). Bench models for assessing the mechanics of mitral valve repair and percutaneous surgery. *Cardiovascular engineering and technology* 2015; 6(2): 193-207.

Baykal D, Siskey R, Haider H, Saikko V, Ahlroos T, Kurtz SM. Advances in tribological testing of artificial joint biomaterials using multidirectional pin-on-disk testers. *J Mech Behav Biomed Mater* 2014; 31C:117-34.

Kurtz SM, Toth JM, Siskey R, Ciccarelli L, MacDonald D, Isaza J, Lanman L, Punt I, Steinbeck M, Goffin J, van Ooij A. The latest lessons learned from retrieval analyses of ultra-high molecular weight polyethylene, metal-on-metal, and alternative bearing total disc replacements. *Semin Spin Surg* 2012; 24:57-70.

Siskey R, Auerbach J, Geisert C, Ellfeldt K. Using the Screw Sock as a simple method to salvage stripped lateral mass screws in the subaxial cervical spine. *The Spine Journal* 2011; 11(10):S168-S169.

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. *International orthopaedics* 2011; 35:1131-1137.

Kurtz SM, Siskey R, Reitman M. Accelerated aging, natural aging, and small punch testing of gamma-air sterilized polycarbonate urethane acetabular components. *J Biomed Mater Res B Appl Biomater* 2010; 93:442-447.

Ianuzzi A, Kurtz SM, Kane W, Shah P, Siskey R, van Ooij A, et al. In vivo deformation, surface damage, and biostability of retrieved dynesys systems. *Spine* 2010; 35:E1310-1316.

Kurtz SM, Dumbleton J, Siskey R, Wang A, Manley M. Trace concentrations of vitamin E protect radiation crosslinked UHMWPE from oxidative degradation. *J Biomed Mater Res A* 2009 Aug; 90(2):549-563.

Choma TJ, Miranda J, Siskey R, Baxter R, Steinbeck MJ, Kurtz SM. Retrieval analysis of a ProDisc-L total disc replacement. *Journal of spinal disorders & techniques* 2009 Jun; 22(4):290-296.

Kurtz SM, Siskey RL, Dumbleton J. Accelerated aqueous aging simulation of in vivo oxidation for gamma-sterilized UHMWPE. *J Biomed Mater Res B Appl Biomater* 2009 Jul; 90(1):368-372.

Kurtz SM, Siskey R, Ciccarelli L, van Ooij A, Pelozo 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, Pelozo J, Siskey R, Villarraga ML. Analysis of a retrieved polyethylene total disc replacement component. *Spine J* 2005; 5(3):344-350.

Book Chapters

Ochoa, JA, Siskey, RL, Kuehn, CM, and Ciccarelli, L, Medical device regulation and retrieval analysis. In: Mihalko WM, Lemons J, Greenwald AS, Kurtz S, eds. *Beyond the Implant Retrieval Analysis Methods for Implant Surveillance*. STP 1606. ASTM International, West Conshohocken, PA, 2018:23-38.

Siskey R, Smelt H, Boon-Ceelen K, Persson M. UHMWPE Homocomposites and Fibers. In: Kurtz S, editor. *Biomaterials Handbook, Ultra-High Molecular Weight Polyethylene in Total Joint Replacement and Medical Devices*. Third Edition, 2016.

Underwood RJ, Kocagoz SB, Smith R, Sayles R, Siskey R, Kurtz SM, Cann P. A protocol to assess the wear of head/neck taper junctions in large head metal-on-metal (LHMoM) hips. In: Kurtz SM, Greenwald AS, Mihalko WM, Lemons J, editors. *Metal-on-Metal Total Hip Replacement Devices*, STP 1560. Conshohocken, PA: ASTM; 2013.

Reitman M, Jaekel D, Siskey R, Kurtz SM. Morphology and crystalline architecture of polyaryletherketones. In: Kurtz SM, editor. *PEEK Biomaterials Handbook*. 2012.

Siskey R, Kurtz SM. Tribology of total disc arthroplasty. In: *Tribology and Bearing Surfaces in Total Joint Replacements*. Streicher R (ed), Transworld Research Network, India 2011: 267-286.

Scientific Exhibits

Siskey R, Hill GA, Peck J, Rundell SA, Kurtz SM. Impingement characterization of total disc replacements, Scientific Exhibit No. 69, 79th Annual Meeting of the American Academy of Orthopaedic Surgeons, San Francisco, CA, February 7-11, 2012.

Conference Papers and Abstracts

Higgs G, Siskey R, Rimnac C, Mihalko W, Gilbert J, Kurtz S. Electrochemical impedance spectroscopy as a method to distinguish corrosion severity and damage modes in retrieved femoral heads, ISTA 31st Annual Congress, London, United Kingdom, October 10-13, 2018.

Riva F, Meneghello S, Celo C, Siskey R, Buttazzoni E, Kurtz S, Pressaco M. What's behind acetabular impingement: An in vitro study, ISTA 31st Annual Congress, London, United Kingdom, October 10-13, 2018.

Siskey R, Ciccarelli L, Kurtz S, Singh V, Toth J. Retrieval analysis of a titanium ceramic composite cervical total disc replacement, 18th Annual Conference of the International Society for the Advancement of Spine Surgery, Toronto, Ontario, Canada, April 11-13, 2018.

Basgul C, Yu T, Dobson B, MacDonald DW, Siskey R, Marcolongo M, Kurtz SM, Characterization of 3D printed PEEK lumbar interbody fusion devices via fused filament fabrication. Annual Meeting of the

Society for Biomaterials. Atlanta, GA, April 11-14, 2018.

Basgul C, Yu T, MacDonald DW, Dobson B, Baxter JN, Siskey R, Marcolongo M, Kurtz SM. Is it possible to ensure enough strength via 3D printing for PEEK lumbar interbody fusion devices? Poster 1262, Transactions of the Orthopaedic Research Society, New Orleans, LA, March 10-13, 2018.

Higgs GB, MacDonald DW, Lowell J, Padayatil A, Mihalko WM, Siskey RL, Gilbert JL, Rimnac CM, Kurtz SM. Does Corrosion Loosen the Taper Connection of Femoral Components in Total Hip Replacements? Paper 0276, Transactions of the Orthopaedic Research Society, New Orleans, LA, March 10-13, 2018.

Basgul C, Yu T, Dobson B, MacDonald DW, Siskey R, Marcolongo M, Kurtz SM. Is it possible to ensure enough strength via 3D printing for PEEK lumbar interbody fusion devices? Annual Meeting of the American Academy of Orthopaedic Surgeons, New Orleans, LA, March 6-10, 2018.

Lyons C, Ansari F, Siskey R, Donthu S, MacLean S. Environmental stress cracking (ESC) failure of amorphous polymer materials. Materials Science & Technology (MS&T) Conference, Pittsburgh, Pennsylvania, October 8-12, 2017.

Ansari F, Lyons C, Siskey R, Donthu S, MacLean S. Mechanical characterization and fractography of PC, ABS & PMMA: A Comparison of tensile, impact & ESC fracture surfaces. Society of Plastic Engineers, ANTEC 2017 Conference, Society of Plastics Engineers, Anaheim, CA, May 8-10, 2017.

Bertone T, Toner G, Siskey RL, Kurtz SM. How does the coefficient of friction of all cartilage bearings compare to cartilage-on-biomaterial bearings? Poster No. 1364, 63rd Annual Meeting of the Orthopaedic Research Society, San Diego, CA, March 19-22, 2017.

Weisenburger J, Kyomoto M, Siskey R, Kurtz S, Garvin K, Haider H. Friction and wear in phospholipid polymer surface treated ceramic on polyethylene total hip replacements. Podium Presentation, ISTA 2016: Annual Congress of the International Society for Technology in Arthroplasty, Boston, Massachusetts, October 5-8, 2016.

Siskey R. Tribological studies of PEEK on PEEK facet resurfacing devices. 2nd International PEEK Meeting. Washington, DC, April 23-24, 2015.

Higgs GB, MacDonald DW, Mihalko WM, Siskey RL, Gilbert JL, Rimnac CM, Kurtz SM. A pilot study characterizing taper interface integrity and its relationship with taper damage in retrieved femoral components of total hip replacement devices. Symposium on Modularity and Tapers in Total Joint Replacement Devices. ASTM International, New Orleans, LA, November 10th, 2014.

Gong XY, Siskey R, Rau A, Anderson S. Effect of prestrain on the fatigue life of nitinol wire. Presented at the International Conference on Shape Memory and Superelastic Technologies (SMST), Pacific Grove, CA, May 12-16, 2014.

Kurtz SM, Walkenhorst R, Hufen J, Siskey RL. Baseline properties and wear resistance of Vitamin E containing ultra-high molecular weight polyethylene grades. Poster No. 1235A, 59th Annual Meeting of the Orthopaedic Research Society, San Antonio, TX, January 26-29, 2013.

Underwood RJ, MacDonald D, Higgs G, Siskey RL, Day J, Kurtz SM. Tribocorrosion in Taper Junctions: Measurements and Observations from Explanted MoM Hips. Poster No. 1763, 59th Annual Meeting of the Orthopaedic Research Society, San Antonio, TX, January 26-29, 2013.

Siskey RL, Kurtz SM, Kyomoto M, Masaru U, Weisenburger J, Haider H. In vitro Wear Performance of MPC-grafted UHMWPE for Total Hip Replacement. Poster No. 1785, 59th Annual Meeting of the Orthopaedic Research Society, San Antonio, TX, January 26-29, 2013.

Underwood RJ, MacDonald D, Higgs G, Day J, Siskey RL, Kurtz SM. Does visual inspection of the taper head / stem junctions in metal-on-metal hips accurately characterize the corrosion and wear? Poster No. 1797, 59th Annual Meeting of the Orthopaedic Research Society, San Antonio, TX, January 26-29, 2013.

Briant P, Siskey R, Rau AC, Easley S, James B. Effect of strain rate on nitinol constitutive modeling in the clinically relevant strain range. Proceedings, 2011 ASM Materials and Processes for Medical Devices, Minneapolis, MN, August 8-10, 2011.

Siskey R, Day J, Kurtz S. Validation of a test method for evaluating the fatigue performance of PEEK spinal fusion rod systems. Paper 0274, Transactions of the Orthopaedic Research Society, Vol. 35, New Orleans, LA, March 6-9, 2010.

Baykal D, Siskey R, Kurtz S. Tribological studies of highly crosslinked and Vitamin-E blended UHMWPE. Poster 2297, Transactions of the Orthopaedic Research Society, Vol. 35, New Orleans, LA, March 6-9, 2010.

Kurtz S, Siskey R. Small punch testing of artificially aged gamma-sterilized polycarbonate urethane acetabular components. Vol. 34, No. 0471. Transactions of the 55th Annual Meeting of the Orthopaedic Research Society, Las Vegas, NV, February 22-25, 2009.

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 R, 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

Ansari F, Sullivan M, Siskey R. Mechanical properties and fractography of Polyetheretherketone (PEEK) composites as a function of filler content. Materials Science & Technology, Columbus, OH, October 14 - 18, 2018.

Siskey R. Preclinical and clinical evaluation of an all PEEK total facet arthroplasty. 3rd International PEEK Meeting, Washington, DC, April 27-28, 2017.

Baykal D, Rau AC, Underwood RJ, Siskey R, Kurtz SM. Frictional heating of PEEK-UHMWPE bearing couple on pin-on-disk tester. Presented at the First International PEEK Meeting, Philadelphia, PA, April 25-26, 2013.

Duggan A, Siskey R, Kurtz S. Risk assessment of the biocompatibility of Vitamin E blended UHMWPE. 5th UHMWPE International Meetings, Philadelphia, PA, 2011.

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.