

**JORGE A. OCHOA, Ph.D., P.E.****PRINCIPAL**[jaochoa@engsys.com](mailto:jaochoa@engsys.com)

Dr. Jorge A. Ochoa is a Principal at ESi. Dr. Ochoa has over 35 years of broad experience in all medical device R&D-related areas: design of medical devices, surgical instruments and techniques, biomaterials, combination devices, and preclinical regulatory testing. Dr. Ochoa is a classically trained mechanical engineer whose expertise bridges the domains of mechanical engineering and biology in therapeutic and diagnostic medical applications. Dr. Ochoa is an authority on the significant aspects of medical device total product lifecycle: design control, risk management, biocompatibility, verification/validation testing, device retrieval analysis, post-market surveillance, recalls, and failure analysis. Dr. Ochoa also consults with clients on intellectual property issues related to validity and infringement.

Dr. Ochoa's particular interests encompass solving complex interdisciplinary problems in the domains of cardiovascular, musculoskeletal, and ophthalmological tissue mechanics and associated medical devices. He applies fundamental mechanical engineering principles to the study of medical device performance, durability and wear, failure, and their interface with the human body. Dr. Ochoa routinely utilizes experimental and computational/analytical methods to execute *in vivo* and *in vitro* medical device performance evaluations and failure analyses, including computational methods (CFD & FEA). His strong background in mechanical metallurgy and biomaterials enables him to apply advanced techniques to study fracture and fatigue failures of components and determine the role of the mechanical behavior of metals, polymers, and coatings in the function and failure of medical devices.

Before joining ESi, Dr. Ochoa was a founding member of Exponent, Inc.'s Biomedical Engineering & Sciences practice, which he helped substantively grow. Before joining Exponent, Dr. Ochoa was Chief Technology Officer at Archus Orthopaedics, a privately held medical device start-up company. Before that, he spent 13 years at DePuy Orthopaedics, a division of Johnson & Johnson, in various roles of increasing responsibility within R&D, including Vice President of R&D. His responsibilities included new product development, customer needs analysis and support, M&A due diligence and integration, intellectual property analysis, and litigation support. Dr. Ochoa has directed or has had executive oversight of the commercialization of hundreds of Class I, Class II Pre-Market Notification (510(k))-cleared, and Class III Pre-Market Approval (PMA)- approved medical devices.

**Areas of Specialization**Biomechanics  
Design Analysis  
Intellectual PropertyMedical Devices  
Medical Investigations  
Risk Analysis

February 2024

## Education

- Ph.D. Mechanical Engineering, Purdue University, 1991
- M.S. Mechanical Engineering, Purdue University, 1987
- B.S. Mechanical Engineering, Missouri University of Science and Technology (cum laude), 1985

## Licensed Professional Engineer (P.E.)

- Licensed Professional Mechanical Engineer, California, #36186
- Licensed Professional Mechanical Engineer, Massachusetts, #40846
- Licensed Professional Mechanical Engineer, Michigan #6201309350
- Licensed Professional Mechanical Engineer, North Carolina #049456
- Licensed Professional Biomedical Engineer, Texas, #118411
- Licensed Professional Mechanical Engineer, Washington, #40751

## Professional Affiliations

### American Society of Mechanical Engineers (ASME)

Member

### ASM International

Member

### ASTM International

Member

### Association for the Advancement of Medical Instrumentation (AAMI)

Member

### Biomedical Engineering Society

Member

### National Society of Professional Engineers (NSPE)

Member

### North American Spine Society

Member

### Orthopaedic Research Society

Member

### Society of Hispanic Professional Engineers

Life Member

## Languages

Fluent in Spanish

## Positions Held

### Engineering Systems Inc., Dallas, TX

Principal, February 2024 – present

### Exponent, Austin, TX

Principal Engineer, July 2018 – October 2022

### Exponent, Menlo Park, CA

Principal Engineer, July 2013 – July 2018

### Exponent, Bellevue, WA

Principal Engineer, March 2011 – July 2013

Senior Managing Engineer, August 2008 – March 2011

### Archus Orthopedics Inc, Redmond, WA

Vice President, R&D and Chief Technology Officer, 2004 – 2008

### DePuy Orthopaedics, a Johnson & Johnson Co., Warsaw, In

Vice President, Hip R&D, DePuy, 2000 – 2004

Director, Hip R&D, DePuy, 1998 – 2000

### Johnson & Johnson Professional, Raynham, MA

Manager, Hip R&D, 1994 – 1998

Project/Senior Project Engineer, R&D, 1991 – 1994

### Chrysler Corp, Detroit, MI

Research Engineer, Manufacturing Technical Center, 1985 – 1987

## Teaching Experience

Dr. Ochoa was an Affiliate Associate Professor at the  
Department of Mechanical Engineering of the University  
of Washington from 2006 to 2018

## Publications/Presentations

Kreuzer SM, Briant PL, **Ochoa JA**. Establishing the biofidelity of a multiphysics finite element model of the human heart. *Cardiovasc Eng Technol*. Published online April 13, 2021. doi:10.1007/s13239-021-00538-7.

Rau A, Lovald ST, Nissman S, McNulty J, **Ochoa JA**, Baldwinson M. The mechanics of corneal deformation and rupture for penetrating injury in the human eye. *Injury*. 2018;49(2):230-235.

Lovald ST, Rau A, Nissman S, et al. Finite element analysis and experimental evaluation of penetrating injury through the cornea. *Journal of the Mechanical Behavior of Biomedical Materials*. 2017;66:104-110

- Rau AC, Siskey R, **Ochoa JA**, Good T. Factors affecting lethal isotherms during cryoablation procedures. *Open Biomed Eng J*. 2016;10(1):62-71.
- Farner S, Malkani A, Lau E, Day J, **Ochoa JA**, Ong K. Outcomes and cost of care for patients with distal radius fractures. *Orthopedics* Sep 1, 2014; 37(10):e866–878.
- Syamal MN, Lovald ST, **Ochoa JA**, Ghanem T. Comparative finite-element analysis for defect reconstruction with rhomboid flaps. *Otolaryngol Head Neck Surg*. 2014 Sept; 151(1) suppl:138-139.
- Ong KL, Auerbach JD, Lau E, Schmier J, **Ochoa JA**. Perioperative outcomes, complications, and costs associated with lumbar spinal fusion in older patients with spinal stenosis and spondylolisthesis. *Neurosurg Focus* Jun 2014; 36(6):E5.
- Sanders AP, Tibbitts IB, Kakarla D, et al. Contact-coupled impact of slender rods: Analysis and experimental validation. *Experimental Mechanics* 2013/08/10 2013:1–12.
- Prisco MR, **Ochoa JA**, Yardimci AM. Predictions of vacuum loss of evacuated vials from initial air leak rates. *J Pharm Sci* Aug 2013; 102(8):2730–2737.
- Lovald ST, Topp SG, **Ochoa JA**, Gaball CW. Biomechanics of the monopedicle skin flap. *Otolaryngol Head Neck Surg*. Dec 2013;149(6):858-864.
- Greenspon AJ, Patel J, Lau E, **Ochoa JA**, Frisch DE, Ho RT, Pavri BB, Kurtz SM. Trends in permanent pacemaker implantation in the United States 1993–2009: Increasing complexity of patients and procedures. *J Am Coll Cardiol* 2012; 59(13s1):E703–E703.
- Sjovold SG, Zhu Q, Bowden A, Larson CR, de Bakker PM, Villarraga ML, **Ochoa JA**, Rosler DM, Crompton PA. Biomechanical evaluation of the Total Facet Arthroplasty System® (TFAS®): Loading as compared to a rigid posterior instrumentation system. *Eur Spine J* 2012 Aug; 21(8):1660–1673.
- Sanders A, Tibbitts I, Kakarla D, Siskey S, **Ochoa JA**, Ong K, Brannon R. Contact mechanics of impacting slender rods: Measurement and analysis. 2011 SEM Annual Conference on Experimental and Applied Mechanics, Springer New York, pp. 229–236, Uncasville, CT, June 13–16, 2011.
- Greenspon AJ, Patel JD, Lau E, et al. 16-year trends in the infection burden for pacemakers and implantable cardioverter-defibrillators in the United States 1993 to 2008. *Journal of the American College of Cardiology* 2011 Aug; 58(10):1001–1006.
- Gornet MF, Chan FW, Coleman JC, Murrell B, Nockels RP, Taylor BA, Lanman TH, **Ochoa JA**. Biomechanical assessment of a PEEK rod system for semi-rigid fixation of lumbar fusion constructs. *Journal of Biomechanical Engineering* 2011 Aug; 133(8):081009:1:12.
- Greenspon AJ, Patel JD, Lau E, **Ochoa JA**, Frisch D, Ho RT, Pavri BB, Kurtz SM. Sixteen year trends in the infection burden for pacemakers and implantable cardioverter-defibrillators in the United States: 1993–2008. *Journal of the American College of Cardiology* 2011; 58(10):1001–1006.

- Kurtz SM, Lau E, **Ochoa JA**, Shkolnikov Y, Pavri BB, Ho RT, Frisch D, Greenspon AJ. Implantation trends and patient profiles for pacemakers and implantable cardioverter defibrillators in the United States: 1993–2006. *Pacing and Clinical Electrophysiology* 2010 Jan.
- Voronov LI, Havey RM, Rosler DM, Sjovold SG, Rogers SL, Carandang G, **Ochoa JA**, Yuan H, Webb S, Patwardhan AG. L5 – S1 segmental kinematics after facet arthroplasty. *SAS Journal* 2009; 3(2). <http://sasjournal.com/v2/content/l5-%E2%80%93s1-segmental-kinematics-after-facet-arthroplasty>.
- Phillips FM, Tzermiadianos MN, Voronov LI, Havey RM, Carandang G, Renner SM, Rosler DM, **Ochoa JA**, Patwardhan AG. Effect of the Total Facet Arthroplasty System after complete laminectomy-facetectomy on the biomechanics of implanted and adjacent segments. *Spine Journal* 2009 Jan; 9(1):96–102.
- Bowden AE, Guerin HL, Villarraga ML, Patwardhan A, **Ochoa JA**. Quality of motion considerations in numerical analysis of motion restoring implants. *Clinical Biomechanics* 2008 Jun; 23(5):536–544.
- Niu Q, Chi X, Leu MC, **Ochoa JA**. Image processing, geometric modeling and data management for development of a virtual bone surgery system. *Journal of Computer Aided Surgery* 2008 Jan; 13(1):30–40.
- Komistek RD, Kane T, Mahfouz M, **Ochoa JA**, Dennis DA. Knee mechanics: A review of past and present techniques to determine in vivo loads. *Journal of Biomechanics* 2005 Feb; 38(2):215–228.
- Dennis DA, Komistek RD, **Ochoa JA**, Haas BD, Hammill C. In vivo comparison of hip separation after metal-on-metal or metal-on-polyethylene THA. *Journal of Bone and Joint Surgery* 2002 Oct; 84(10):1836–1841.
- Kurtz SM, Srivastav S, Dwyer K, **Ochoa JA**, Brown S. Analysis of the stem-sleeve interface in a modular titanium alloy femoral component for total hip replacement, in functional biomaterials. Trans Tech Publications, Switzerland. Katsube N, Soboyejo WO, Sacks M (eds), pp. 41–68, 2001.
- Dennis DA, Komistek RD, Northcut EJ, **Ochoa JA**, Ritchie A. In vivo determination of hip joint separation and the forces generated due to impact loading conditions. *Journal of Biomechanics* 2001 Apr; 34(5):623–629.
- Kurtz SM, **Ochoa JA**, Hovey CB, White CV. Simulation of initial frontside and backside wear rates in a modular acetabular component with multiple screw holes. *Journal of Biomechanics* 1999 Aug; 32(9):967–976.
- Kurtz SM, **Ochoa JA**, White CV, Srivastav S, Cournoyer J. Backside nonconformity and locking restraints affect liner/shell load transfer mechanisms and relative motion in modular acetabular components for total hip replacement. *Journal of Biomechanics* 1998 May; 31:431–437.

- Ochoa JA**, Sanders AP, Kiesler TW, Heck DA, Toombs JP, Brandt KD, Hillberry BM. In vivo observations of hydraulic stiffening in the canine femoral head. *Journal of Biomechanics Engineering* 1997 Feb; 119:103–108.
- Wilson SF, **Ochoa JA**, Rogers LL, Lancaster RL, Ritchie A. Finite element analysis in the characterization of an absorbable cement restrictor. *Journal of Engineering in Medicine, IMechEng* 1995; 209:163–167.
- Ochoa JA**, Sanders AP, Heck DA, Hillberry BM. Stiffening of the proximal femur due to intertrabecular fluid and intraosseous pressure. *Journal of Biomechanical Engineering* 1991; 113(3):259–262.
- Ochoa JA**, Heck DA, Hillberry BM. The effect of intertrabecular fluid on femoral head mechanics. *Journal of Rheumatology* 1991; 18(4):580–584.
- Ochoa JA**. Wearable medical devices: intersection of technology, regulation, and hype. Bio2Device Group (B2DG) Member Meeting. Sunnyvale, CA, September 20, 2016.
- Ochoa JA**. Drug, device and biotechnology diary of an expert—An insider’s view on the proper care and feeding of experts. IADC 2014 Midyear Meeting, La Jolla, CA, February 12, 2014.
- Ochoa JA**. Medical device regulatory compliance & recalls. Life sciences legal summit. American Bar Association, San Francisco, CA, February 27, 2014.
- Ochoa JA**. Why did FDA refuse more than 58% of 510(k) submissions in 2013? The 10x Medical Device Conference, Minneapolis, MN, May 13, 2014.
- Ochoa JA**. Biomedical research—Helping others. Keynote Speaker. Emerging Ideas in Biomedical Research (EIBR) Conference, College of Engineering, Brigham Young University, San Provo, UT, October 17, 2013.
- Ochoa JA**. From start-up to market leader: Lessons learned in the orthopaedic R&D industry. Careers in Biomaterials Engineering-Professional Advancement Series, School of Medicine, Stanford University, San Antonio, TX, January 28, 2013.
- Ochoa JA**. How to use the design process to manage risk: Elements of design controls and why it matters. Stanford Industry Insights, School of Medicine, Stanford University, Stanford, CA, March 13, 2013.
- Ochoa JA**. Panelist on anatomy of medical device litigation in today's market. Hot Topics in Medical Device and Pharmaceutical Litigation – Bowman and Brooke, Minneapolis, MN, April 18, 2013.
- Ochoa JA**. From benchtop to bedside: The role of the (bio) engineer in new product realization. Distinguished Biomedical Engineering Lecture, School of Biomedical Engineering, Purdue University, West Lafayette, IN, February 10, 2012.

- Ochoa JA.** The role of analysis in medical device NPD. 2010 MD&D Annual Conference & Exhibition, Minneapolis, MN, October 13, 2010. Session Chair: Preclinical Testing of Implantable Medical Devices.
- Ochoa JA.** Technical fundamentals of R&D and portfolio management: New product realization in medical devices—The whole story. Invited Speaker, 2009 RAPS Annual Conference & Exhibition, Philadelphia, PA, September 14, 2009.
- Ochoa JA.** Career perspectives in the medical device industry. Penn Biotech Group Seminar, University of Pennsylvania, Philadelphia, PA, September 15, 2009.
- Ochoa JA.** Values and value—the role of the leader in work and life, 2008 NAE Engineer of 2020 Workshop, Purdue University, September 30, 2008.
- Ochoa JA.** Panelist on Consulting Agreements with Physicians: The Role of Bias and Compliance at the Philadelphia Medical Device Symposium, Philadelphia, PA, November 12, 2008.
- Ochoa JA.** Undergraduate research—(Why) does it matter? 4<sup>th</sup> Annual Undergraduate Research Conference, Keynote Speaker, Missouri University of Science & Technology, Rolla, MO, April 9, 2008.
- Ochoa JA.** The role of the biomedical engineer in new product realization. BME 390, Professional Seminar, Weldon School of Biomedical Engineering, Purdue University, W. Lafayette, IN, September 21, 2006.
- Ochoa JA.** Emerging field of biomedical engineering—A mechanical engineer's perspective. ASME District C Student Conference, Missouri University of Science and Technology, Rolla, MO, March 4, 2006.
- Ochoa JA.** Values based decision-making and its role in value creation. Technology MBA Graduate Seminar, University of Washington, Seattle, WA, October 16, 2004.
- Ochoa JA.** From bioengineering to interfacial and scale engineering—Evolution of new engineering disciplines. Graduate Seminar, School of Mechanical Engineering, Missouri University of Science and Technology, October 30, 2003.
- Ochoa JA.** Panelist on career and leadership development forum. Hispanic Organization for Leadership and Achievement (HOLA) at J&J, New Brunswick, NJ, October 23, 2003.
- Ochoa JA.** Values and value—The role of the leader in work and life. Society of Hispanic Professional Engineers Eastern Technical Career Conference (SHPE-ETCC '03), Keynote Speaker, Washington DC, November 14, 2003.
- Ochoa JA.** Orthopaedic research—The way forward. Oak Ridge National Laboratory, University of Tennessee Mechanical Engineering Combined seminar, Knoxville, TN, March 13, 2003.



- Ochoa JA.** Technology and IP management in new product commercialization. Guest Lecture, School of Engineering Management EMgt 320 Technical Entrepreneurship, Missouri University of Science and Technology, Rolla, MO, October 10, 2002.
- Ochoa JA.** The fruit of orthobiologic research. Faculty of Contemporary Techniques and Issues in Orthopaedics, Whistler, BC, Canada, March 6, 2002.
- Ochoa JA.** The pitfalls that remain in orthopaedic design in 2001. Contemporary Techniques and Issues in Orthopaedics, Vail, CO, February 12, 2001.
- Ochoa JA.** The role of design, materials, and testing in total joint replacement. Guest Lecture, SAE Fort Wayne Chapter, Fort Wayne, IN, April 2000.
- Ochoa JA.** Improved wear using gamma sterilization in a vacuum-foil package and calcium stearate-free material. Faculty of the 1<sup>st</sup> International Symposium on Total Knee Arthroplasty, Chiba University, Tokyo, Japan, May 1997.
- Ochoa JA.** Mechanisms of failure in THR. Faculty of the 6<sup>th</sup> Annual Symposium of Arthritis of the Hip and Knee, Vail, CO, March 9, 1996.
- Ochoa JA.** Proper femoral offset and its impact on THA biomechanics. Faculty at the Total Hip and Knee Replacement Symposium (Italy-US), Marco Island, FL, February 1995.
- Ochoa JA.** Experimental verification of hydraulic stiffening of cancellous bone. Invited lecture 2<sup>nd</sup> World Congress of Biomechanics Symposium on Bone Structure and Remodeling, Amsterdam, The Netherlands, July 1994.
- Ochoa JA.** The effect of intertrabecular fluid on the viscoelasticity of bone. 14<sup>th</sup> Annual Garceau-Wray Lectures, Indiana University School of Medicine, November 1989.
- Ochoa JA.** Orthopaedic biomechanics—An introduction. Seminar, School of Electrical Engineering, Purdue University, October 1987.
- Ochoa JA.** The effect of internal fluid on the viscoelasticity of bone. Design Seminar, School of Mechanical Engineering, Purdue University, November 1987.

## 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.
- Sanders, AP, Tibbitts, I, Kakarla, D, Siskey, S, **Ochoa JA,** Ong KL, Brannon R. Contact mechanics of impacting slender rods: Measurement and analysis. In: Dynamic Behavior of Materials, Vol. 1. Springer, New York, NY; 2011:229-236.



## Conference Papers and Abstracts

- Dillon A, Torres W, Bullard A, **Ochoa JA**, Siskey R. Variability in the analysis burden for evaluating radiofrequency induced heating of implanted medical devices. Presented at: 2022 Annual Meeting, Biomedical Engineering Society (BMES); October 12-15, 2022; San Antonio, TX.
- Shaw CB, Hamed E, Siskey RL, White J, **Ochoa JA**. Simulating MRI heating of surgical staples for wound closure in orthopaedic surgery. 65th Annual Meeting Orthopaedic Research Society, PS1-035:0920, Austin, TX, February 2-5, 2019.
- Siskey RL, Midha P, Okafor I, White J, Shaw CB, **Ochoa JA**. MRI heating of interbody fusion devices with radiographic markers. 65th Annual Meeting Orthopaedic Research Society, 44: PS1-034:0873, Austin, TX, February 2-5, 2019.
- Briant P, Kreuzer S, **Ochoa JA**. The ABAQUS living heart: comparison to static and dynamic in-vivo measurements, VVS2016-8001, ASME Verification and Validation Symposium, p. 49, Las Vegas, NV, May 19, 2016.
- Lovald ST, Rau A, Nissman S, Ames N, McNulty J, **Ochoa JA**, Baldwinson M. Finite element analysis of penetrating injury to the human eye. 2016 BMES/FDA Frontiers in Medical Device Conference, Innovations in Modeling and Simulation: Patient-Centered Healthcare, Washington, DC, May 23, 2016.
- Lovald ST, Rau A, Nissman S, Ames N, McNulty J, **Ochoa JA**, Baldwinson M. Finite element analysis of penetrating injury to the human eye. *Ann Biomed Eng* (2016). doi:10.1007/s10439-016-1710-7.
- Lovald ST, Rau A, Nissman S, Ames N, **Ochoa JA**, McNulty J, Baldwinson M. Finite element analysis of penetrating injury to the human eye. 2016 ARVO Annual Meeting, 2399-A0128, Seattle, WA, May 2, 2016
- Rau A, Lovald ST, Nissman S, Ames N, **Ochoa JA**, McNulty J, Baldwinson M. The Mechanics of Corneal Deformation and Rupture for Penetrating Injury in the Human Eye. 2016 ARVO Annual Meeting, 2384-A0013, Seattle, WA, May 2, 2016.
- Garcia M, Day J, Rau A, **Ochoa JA**, Lovald ST. Finite Element Analysis of Whole Globe Goldmann Applanation Tonometry: A Closer Look at Mechanics. 2016 ARVO Annual Meeting, 6458-D0178, Seattle, WA, May 5, 2016.
- Syamal MN, Lovald ST, **Ochoa JA**, Gaball CW, Ghanem T. Comparative finite-element analysis for defect reconstruction with local flaps. Triological Society Combined Sections Meeting, Miami Beach, FL, January 10–12, 2014.
- Syamal MN, Lovald SL, **Ochoa JA**, Ghanem TA. Comparative finite-element analysis for defect reconstruction with rhomboid flaps, SP108, AAO-HNSF Annual Meeting, Orlando, FL, September 21–24, 2014.

- Farner S, Malkani AL, Lau E, Day J, **Ochoa JA**, Ong K. Treatment patterns, outcomes, and cost of care for distal radius fracture patients in the Medicare population. Paper No. 606, 80<sup>th</sup> Annual Meeting of the American Academy of Orthopaedic Surgeons, Chicago, IL, March 19–23, 2013.
- Syamal MN, Lovald ST, **Ochoa JA**, Gaball CW. Comparative finite element analysis for defect reconstruction with local flaps. The Triological Society 2014 Combined Sections Meeting, Miami Beach, FL, January 10–12, 2014. Middle Section Joseph Ogura, MD – Research Award.
- Patel J, Ong K, Watson W, Kuehn C, **Ochoa JA**. Trends in revascularization and mortality for BMS and DES coronary stenting procedures: A Medicare study of 156,300 patients. Poster No. 659, Transcatheter Cardiovascular Therapeutics (TCT) Conference, Miami, FL, October 22–26, 2012.
- Patel J, Ong K, Watson W, Helmus M, Kuehn C, **Ochoa JA**. Historical trends in outcomes following aortic and mitral heart valve replacement procedures: A population-based study of 29,582 Medicare patients from 1997 to 2009. Poster No. 877 (Top 25 Poster), Transcatheter Cardiovascular Therapeutics (TCT) Conference, Miami, FL, October 22–26, 2012.
- Auerbach JD, Ong KL, Lau E, **Ochoa JA**, Schmier J, Zigler JD. Perioperative outcomes, complications, and costs associated with lumbar spinal fusion in older patients with spinal stenosis and spondylolisthesis: Analysis of the United States Medicare claims database. NASS 27th Annual Meeting, Dallas, TX, October 24–27, 2012.
- Auerbach JD, Ong KL, Lau E, **Ochoa JA**, Schmier J, Zigler JD. Cost-effectiveness of interlaminar stabilization compared with instrumented posterior spinal fusion for spinal stenosis and spondylolisthesis. NASS 27th Annual Meeting, Dallas, TX, October 24–27, 2012.
- Kuehn CM, Watson H, Ong KL, Mohamed M, **Ochoa JA**, Fryzek J. Descriptive epidemiology of medical device use among patients with breast, lung or prostate cancer in the national inpatient sample. ISPE's 28th ICPE: International Conference on Pharmacoepidemiology & Therapeutic Risk Management, Barcelona, Spain, August 22–26, 2012.
- Auerbach JD, Ong KL, Lau E, **Ochoa JA**, Schmier JK, Zigler JD. Perioperative outcomes, complications, and costs associated with lumbar spinal fusion in older patients with spinal stenosis and spondylolisthesis: analysis of the United States Medicare claims database. International Society of Pharmacoeconomics and Outcomes Research 17th Annual International Meeting, Washington, DC, June 2–6, 2012.
- Ong KL, Patel JP, Watson H, Helmus M, Kuehn CM, **Ochoa JA**. Historical trends in outcomes following aortic and mitral heart valve replacement procedures: A population-based study of 29,582 Medicare patients from 1997 to 2009. Presentation No. P20, Quality of Care and Outcomes Research in Cardiovascular Disease and Stroke (QCOR), Atlanta, GA, May 9–11, 2012.

- Auerbach JD, Ong KL, Lau E, **Ochoa JA**, Schmier J, Zigler JD. Perioperative outcomes, complications, and costs associated with lumbar spinal fusion in older patients with spinal stenosis and spondylolisthesis: Analysis of the United States Medicare claims database. Paper No. 516, International Society for the Advancement of Spine Surgery, Barcelona, Spain, March 20–23, 2012.
- Ong K, Patel J, Watson H, Helmus M, Kuehn CM, **Ochoa JA**. Historical trends in outcomes following aortic and mitral heart valve replacement procedures: A population-based study of 29,582 Medicare patients from 1997 to 2009. 4th Annual Joint Scientific Session of the Heart Valve Society of America and Society for Heart Valve Disease, Valves in the Heart of the Big Apple VII: Evaluation & Management of Valvular Heart Diseases, New York, NY, April 12–14, 2012.
- Ong K, Watson H, Patel JD, Kuehn CM, **Ochoa JA**. Population-based analysis of the epidemiology and reintervention rates of cardiovascular stenting procedures: A Medicare study. TCT 23rd Annual Scientific Symposium, San Francisco, CA, November 7–11, 2011.
- Hanzlik JA, Patel JD, Kurtz SM, Horn QC, Shkolnikov YP, **Ochoa JA**, Pavri BB, Greenspon AJ. Why are implantable cardioverter-defibrillators and pacemakers being revised today? MPMD 2011 – Fatigue Life and Durability of Medical Devices Session I, Minneapolis, MN, August 8–10, 2011.
- Kakarla D, Sanders AP, Siskey S, Ong K, Ames N, **Ochoa JA**, Brannon RM. Poster No. 2076. Modeling, testing, and analysis of impulse response of femoral head reduction in ceramic hip prostheses. 58<sup>th</sup> Annual Meeting Orthopaedic Research Society, P-2076, San Francisco, CA, February 4–7, 2012.
- Ong, KL, Auerbach, JD, Lau E, **Ochoa JA**, Schmier J, Zigler JD. Perioperative outcomes, complications, and costs associated with lumbar spinal fusion in older patients with spinal stenosis and spondylolisthesis: Analysis of the United States Medicare claims database. ISASS 12, No. A-425-0000-00516, Barcelona, Spain, March 20–23, 2012.
- Hanzlik J, Patel J, **Ochoa JA**, Pavri B, Greenspon A, Kurtz S. Retrieval analysis of implantable pacemakers and cardioverter-defibrillators. Biomedical Engineering Society, 2011 Annual Meeting, Hartford, CT, October 12–15, 2011.
- Ong KL, Watson H, Patel JD, Kuehn CM, **Ochoa JA**. Bare-metal and drug-eluting coronary and peripheral vascular stent procedures: Utilization in the U.S. 3rd North American Congress of Epidemiology, Montreal, Quebec, Canada, June 21–24, 2011.
- Sanders AP, Tibbitts IB, Kakarla D, Siskey SD, **Ochoa JA**, Ong KL, Brannon RM. Contact mechanics of impacting slender rods: Measurement and analysis. Paper No. 274, Society for Experimental Mechanics Annual Conference & Exposition on Experimental and Applied Mechanics, Uncasville, CT, June 13–16, 2011.
- Ong KL, Lau E, Patel JD, **Ochoa JA**. Epidemiology of heart valve repair and replacement procedures in the United States: A 15-year perspective. American Heart Association Quality of Care and Outcomes Research in Cardiovascular Disease and Stroke (QCOR), Washington, D.C., May 12–14, 2011.

- Ong KL, Watson H, Patel JD, Kuehn CM, **Ochoa JA**. Bare-metal and drug-eluting coronary and peripheral vascular stent procedures: Utilization in the United States. American Heart Association Quality of Care and Outcomes Research in Cardiovascular Disease and Stroke (QCOR), Washington, D.C., May 12–14, 2011.
- Hanzlik, J, Patel JD, Kurtz SM, Pavri BB, Greenspon AJ, **Ochoa JA**. Insights into cardiac pacemaker and defibrillator revision/upgrades. 37th Annual Northeast Bioengineering Conference, Rensselaer Polytechnic Institute, Troy, NY, April 1–3, 2011.
- Patel JD, Kurtz SM, Lau E, **Ochoa JA**, Pavri BB, Ho R, Frisch DA, Greenspon AJ. Comparison of pacemaker versus ICD infection burden in the United States from 1993–2008. Paper No. AB21-1, Transactions of the 32<sup>nd</sup> Annual Scientific Sessions of the Heart Rhythm Society, San Francisco, CA, May 4–7, 2011.
- Ong K, Ianuzzi A, Lau E, Kurtz S, **Ochoa JA**. Epidemiology and in-hospital complications associated with interspinous process decompression device procedures: The initial U.S. experience using national administrative data. 56<sup>th</sup> Annual Meeting Orthopaedic Research Society, P-428, San Francisco, CA, March 6–9, 2010.
- Kurtz SM, Lau E, **Ochoa JA**, Shkolnikov Y, Pavri BB, Ho RT, Frisch D, Greenspon AJ. Projections of pacemaker and ICD utilization in the US from 2010 to 2030. Paper No. AB06-5. Transactions of the 31st Annual Scientific Sessions of the Heart Rhythm Society, Denver, CO, May 12–15, 2010.
- Kurtz SM, Lau E, **Ochoa JA**, Pavri BB, Ho RT, Greenspon AJ. Complications and predictors of ICD outcomes. Paper No. AB28-1. Transactions of the 31st Annual Scientific Sessions of the Heart Rhythm Society, Denver, CO, May 12–15, 2010.
- Imsdahl SI, **Ochoa JA**, Ching RP. Kinematics of the lumbar facet joints and vertebral endplate. NW Biomechanics Symposium, ASB Northwest Regional Meeting, Pullman, WA, June 5–6, 2008.
- Voronov LI, Havey RM, Rosler DM, Sjovold SG, Rogers SL, Carandang G, **Ochoa JA**, Patwardhan AG. Kinematics of facet arthroplasty: A comparison of L5-S1 and L3-L4 levels. Annual Meeting of EuroSpine/SpineWeek, Geneva, Switzerland, p. 185, May 26–31, 2008.
- Voronov L, Havey R, Rosler D, Sjovold S, Rogers S, Carandang G, **Ochoa JA**, Patwardhan A. Kinematics of facet arthroplasty: A comparison of L5-S1 and L3-L4 levels. Spine Arthroplasty Summit 8, Miami, FL, May 6–9, 2008. **Best Scientific Paper Award**.
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## Scientific Exhibits

Mahfouz MR, Anderle M, Bajares G, Pérez Oliva A, Tokish LJ, **Ochoa JA**, Komistek RD, Zingde S. In vivo kinematics of the Total Facet Arthroplasty System (TFAS). 75<sup>th</sup> AAOS Scientific Exhibit SE61, Orlando, FL, San Francisco, CA, March 2008.

Dennis DA, Komistek RD, Northcut EJ, Kane TR, Rullkoetter PJ, **Ochoa JA**, Stiehl JB, Hammill CD, Walker SA. Determination of in vivo Total Hip Arthroplasty (THA) kinematics, kinetics and stresses using fluoroscopy and mathematical modeling. 67<sup>th</sup> AAOS Scientific Exhibit, Orlando, FL, March 2000.

Northcut EJ, Komistek RD, Dennis DA, **Ochoa JA**, Ritchie A. Impulse loading exhibited at the implanted hip during active joint separation. 66<sup>th</sup> AAOS Scientific Exhibit, Anaheim, CA, February 1999.

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## Patents

Patent 10,893,949. Crossbar Spinal Prosthesis Having a Modular Design and Systems for Treating Spinal Pathologies, issued January 19, 2021 (with M.K. Kuiper, D. Yager, L. Tokish Jr., D.M. Rosler, M.A. Reiley, M.J. Funk, S.L. Rogers, C.R. Ralph, M.T. Charbonneau).

Patent 10,010,426. Crossbar Spinal Prosthesis Having a Modular Design and Systems for Treating Spinal Pathologies, issued July 3, 2018 (with M.K. Kuiper, D. Yager, L. Tokish Jr., D.M. Rosler, M.A. Reiley, M.J. Funk, S.L. Rogers, C.R. Ralph, M.T. Charbonneau, R.J. Broman, and T.J. McLeer).

Patent 8,221,461: Crossbar Spinal Prosthesis Having a Modular Design and Systems for Treating Spinal Pathologies, issued July 17, 2012 (with M.K. Kuiper, D. Yager, L. Tokish Jr., D.M. Rosler, M.A. Reiley, M.J. Funk, S.L. Rogers, C.R. Ralph, M.T. Charbonneau, R.J. Broman, and T.J. McLeer).

Patents 6,866,685 and 6,660,040: Prosthetic Joints Having Reduced Area Bearing Surfaces and Application Thereof to a Range of Sizes of Prosthetic Joints, issued March 15, 2005 and December 9, 2003 (with F. Chan).

Patent 6,206,929: Bipolar Hip Prosthesis with Locking Head, issued March 27, 2001 (with F. Khalili).

Patent 6,139,584: Proximal Femoral Sleeve for a Revision Hip Prosthesis, issued October 31, 2000 (with F. Khalili).

Patent 6,019,765: Morsellized Bone Allograft Applicator Device, Issued February 1, 2000 (with T. Thornhill, W.H. Kennefick, and E. Larson).

Patent 5,935,172: Prosthesis With Variable Fit and Strain Distribution, issued August 10, 1999 (with M.J. O'Neil).

Patent 5,871,549: Femoral Stem with Reduced Coefficient of Friction with Respect to Bone Cement, issued February 16, 1999 (with C.M. Jayashankar and F.D. Matthews).

Patents 5,868,747 and 5,716,358: Directional Bone Fixation Device, issued February 9, 1999 and February 10, 1998 (with L.L. Rogers).

Patent 5,871,546: Femoral Component Condyle Design for Knee Prosthesis, issued February 16, 1999 (with D.P. Colleran, S.M. Gabriel, and R.E. Sommerich).

Patent 5,609,643: Knee Joint Prostheses, issued March 11, 1997 (with D.P. Colleran and R.E. Sommerich).

## **Advisory Appointments**

Board of Trustees, Missouri University of Science and Technology (2021-present)

Dean's Leadership Council, College of Arts, Sciences and Business, Missouri University of Science and Technology (2018–2022)

Missouri University of Science and Technology, External Advisory Board (EAB), Center for Bone and Tissue Repair and Regeneration (2012–present)

Missouri Center of Excellence of the Life Sciences Research Board—Screening Committee: Life Sciences Trust Fund (2008–2010)

Missouri University of Science and Technology, Industrial Advisory Board, School of Mechanical Engineering (1999–present)

Engineering Advisory Committee, Purdue University Schools of Engineering (2001– 2008)

Industrial Advisory Board, Purdue University School of Biomedical Engineering (2002–present)

Industrial Advisory Board, University of Tennessee School of Biomedical Engineering (2003–2008)

Academy of Mechanical and Aerospace Engineers, School of Mechanical Engineering, Missouri University of Science and Technology (President), (2005–present)

University of Illinois-Chicago, Industrial Advisory Board, School of Mechanical Engineering (2001–2004)

Board of Directors, International Society of Technology in Arthroplasty (ISTA) (2003–2006)

Intelligent Biomedical Devices and Musculoskeletal Systems, NSF-IUCRC- Industrial Advisory Board (Chairperson), Denver, CO (1996–2003)

## **Guest Lecturers**

Chiba University, Tokyo, Japan

Colorado School of Mines, Golden, CO

Indiana University, Bloomington, IN

Purdue University, W. Lafayette, IN

University of Illinois – Chicago, Chicago, IL

University of Pennsylvania, Philadelphia, PA

University of Tennessee, Knoxville, TN

University of Washington, Seattle, WA

California Polytechnic State University, San Luis Obispo, CA

University of Texas at Austin, Austin, TX

University of Texas at El Paso, El Paso, TX

## **Professional Honors**

Phi Eta Sigma

Pi Tau Sigma

Johnson & Johnson Professional Achievement Award, 1995

Clinical Biomechanics Best Paper Award, European Society of Biomechanics, 1998

Best Scientific Paper, Spine Arthroplasty Society, 2008

Outstanding Mechanical Engineer, Purdue University, 2002

Professional Degree, Mechanical Engineering, Missouri University of Science and Technology, 2005

Academy of Mechanical and Aerospace Engineers – Missouri University of Science and Technology, 2005

Distinguished Engineering Alumnus, Purdue University, 2009

Missouri University of Science and Technology Alumni Achievement Award, 2016

## **Selected Project Experience**

### **Medical Device Design and Development Support**

- Assist inventors, investors, and potential acquirers in validating the science and technology underlying novel medical devices and their market viability, performing thorough due diligence and technical evaluations. For example, evaluated a client's innovative tissue scaffold/regeneration technology and another's minimally invasive image-guided surgery platform for novelty, utility, and obviousness during the freedom to practice phase and patenting process. Evaluated the impact of potential prior art on the ultimate product designs, reduction to practice, manufacturability, safety, and effectiveness. The tissue engineering was used to stand up a start-up medical device company, while a market leader acquired the image-guided surgery platform.
- Guided individual inventor clients (practicing physicians) through the technical elements of IP strategy, regulatory strategy, and fundraising. Led a multidisciplinary team that collaborated with clients to establish product specifications and subsequent design inputs for an intelligent combination implantable drug-delivery medical device. The team created design outputs and associated battery of tests and evaluations to verify and validate product concepts. Risk management was considered and continuously applied to guide the project's risk profile. Guided the clients and team in selecting appropriate manufacturing vendors and compiling the Design History File. A leading medical device manufacturer acquired the technology product line.
- Led team that developed a comprehensive capability to evaluate MRI compatibility of medical devices using a combination of computational and experimental techniques in compliance with relevant ASTM and ISO standards. This included passive and active devices, fully and partially implanted devices, and devices residing within and outside the bore of an MRI scanner.

### **Verification and Validation of Medical Devices**

- Augmented a medical device manufacturer's existing internal new product development team's capability by advising during the establishment of the required verification and validation strategy for a novel spinal implant device being developed by a medical device company. Supervised the execution, troubleshooting, and reporting of the results and was an integral part of interaction with the FDA, from the presubmission (Q-sub) through response to FDA's questions about the regulatory submission.
- Assisted clients with evaluating novel biomaterials and coatings designed to be used with and on orthopaedics, spinal, neurosurgical, ophthalmic, and cardiovascular medical devices. The evaluation strategy satisfied FDA (Design Control) and EU (MDD/MDR) regulatory guidance and verification and validation requirements and was included in the corresponding regulatory submissions in support of the safety of the device, which were successfully cleared or approved via 510(k), IDE/PMA and De Novo pathways.

- Working in concert with research surgical veterinarians, medical toxicologists, and the client, designed a comprehensive, bespoke, preclinical testing strategy requiring regulatory compliance. This included biocompatibility and animal functional and safety studies. Suggested non-GLP feasibility evaluations were used to optimize the definitive GLP studies required for FDA approval of an implantable urological device. Evaluated, selected, and oversaw the work and reporting of certified preclinical research services laboratories.
- Directed or had executive oversight of the commercialization of hundreds of Class I, Class II Pre-Market Notification (510(k))-cleared, and Class III Pre-Market Approval (PMA)-approved medical devices.

### **Post-market Surveillance and Failure Analysis of Medical Devices**

- Routinely analyzes explanted medical devices and associated host tissues, surgical tools, and operating room and hospital durable medical equipment to provide insight into how a medical device performs in vivo and eventually fails clinically. This examination offers unique insights into the device/tissue interface's performance and the biomechanical, biochemical, bioelectrical, and biothermal conditions in which the devices operate. The complete medical device and host tissue, failure analyses, root cause analyses, and regulatory compliance elements of reports aid clients in device development, clinical trials, and post-market surveillance activities, including medical device recalls.
- Provide independent, impartial, critical support to device manufacturers for their Failure Analyses, Health Hazard Evaluations, Root Cause Analyses, and Complaint Handling and Recall processes based on real-world clinical evidence. Clients commonly utilize reports to communicate with regulatory bodies and support product liability litigation. Serve as an expert witness in product liability and intellectual property cases involving medical devices based on experience, investigations, and insights.