TIM BROWN

Mr. Brown can be reached through Clinical Device Group. Please click here.

Curriculum Vitae

EDUCATION

THE UNIVERSITY OF ILLINOIS AT CHICAGO - Chicago, Illinois
Master of Science in Bioengineering, 2004

Bachelor of Science in Bioengineering, 2001
Minor in Computer Science

PROFESSIONAL EXPERIENCE

CLINICAL AND SCIENTIFIC RESEARCH ASSOCIATES, LLC. (CASRA), Negaunee, Michigan

Founder and President, 8/2013 to Present

Providing clinical and scientific research for the medical device community, CASRA offers clinical evaluations for the EU, clinical and / or scientific assessments to support new product development or existing product pipelines, white paper, scientific and clinical manuscript preparation, and peer review of client written communications.

RTI SURGICAL (FORMERLY PIONEER SURGICAL), Marquette, Michigan

Senior Research Engineer, 11/2003 to Present

Advanced into senior-level engineering role within spinal / orthopedic medical device producer, providing leadership to fusion and non-fusion product development across the entire life cycle of design, development, pre-clinical validation / verification testing, and clinical data collection / research. Collaborate internally and externally in clinical / non-clinical strategies. Design non-clinical / clinical studies, including protocols and clinical data collection methodologies. Provide clinical input for new product development, post-market surveillance and support of due diligence assessments. Manage multiple concurrent projects in phased product development, providing autonomous leadership and decision-making for diverse projects and sub-projects. Serve in consulting / advising role for cross-functional projects and teams. Perform extensive research into current and emerging medical device technology to inform product feasibility assessments and development / commercialization strategies.

Key Contributions:

- Lead engineer for device development efforts for motion preservation product lines: lumbar nucleus replacement (NuBac) and cervical disc replacement (NuNec) and novel PEEK spacers.
- Authored testing protocols, rationales, results, technical / test reports, clinical reports and required documentation for FDA submission, including Investigational Device Exemption (IDE) and 510(k) Pre-Market Notification (PMN), as well as European Union (EU) Clinical Evaluation (CE) reports for Medical Device Directive (MDD) requirements.
- Provided leadership to product development teams in the evaluation of product risk and design control processes. Ensured non-clinical / clinical accuracy of risks in support of various product FMEA's.
- Served as non-clinical / clinical research subject-matter expert (SME) and present product specific non-clinical / clinical data analyses to key opinion leaders (KOL) for motion preservation platform.
- Authored clinical evaluation reports for identification / monitoring of product risks, risk / benefit analysis and overall support of safety and performance for product approval and lifecycle for all CE marked products.
- Authored manuscripts for publication in peer-reviewed journals and presented at international

scientific conferences.

- Routinely presented domestic and internationally, product development statuses, clinical results, and issue resolutions to senior leaders, clinicians, Clinical Advisory Board (CAB) / Medical Advisory Board (MAB) members, and FDA.
- Leveraged expertise in spinal biomechanics / pathophysiology to orchestrate studies to support product development, including biomechanical assessments, surgical techniques, and animal studies.

RUSH UNIVERSITY MEDICAL CENTER, Chicago, Illinois

Student Engineering Assistant II – Department of Orthopedic Surgery, 06/1999 to 08/2001

Supported orthopedic and spinal research, developing CAD-based and Finite Element modeling techniques and models using commercial imaging software (MIMICS) and finite element software (ADINA).

Key Contributions:

- Created 2D and 3D finite element models of the spine, knee and hip for biomechanical analyses.
- Reduced creation time of finite element models by 50%.

PUBLICATIONS

Peer-Reviewed Journals

1. Hallab NJ, **Brown T**, Bao QB, Songer M. Assessment of Epidural vs. Intra-discal Biocompatibility of PEEK Implant Debris: An In-vivo Rabbit Model. Accepted to *Eur Spine J*.
2. **Brown T**, Bao QB, Yuan HA, Songer M. Design rationale and preclinical testing of a self-mating PEEK cervical disc arthroplasty device. Submitted to *Eur Spine J.*
3. Ordway N, **Brown T**, Bao QB, Yuan HA. Biomechanical assessment and fatigue characteristics of an articulating nucleus replacement implant. Submitted to *Int J of Spine Surg*.
4. **Brown T**, Bao QB. The use of self-mating PEEK as an alternative bearing material for cervical disc arthroplasty: a comparison of different simulator inputs and tribological environments. *Eur Spine J*. 2012 Jun;21 Suppl 5:S717-26.
5. **Brown T**, Bao QB, Agrawal CM, Hallab NJ. An in vitro assessment of wear particulate generated from NUBAC, a peek on peek articulating nucleus replacement device. Methodology and results from a series of wear tests using different motion profiles, test frequencies, and environmental conditions. *Spine*. 2011 Dec 15;36(26):E1675-85.
6. **Brown T**, Bao Q, Kilpela T, Songer M. An in vitro biotribological assessment of NuBac, a polyetheretherketone-on-polyetheretherketone articulating nucleus replacement device: methodology and results from a series of wear tests using different motion profiles, test frequencies, and environmental conditions. *Spine*. 2010 Jul 15;35(16):E774-81.

Books

1. **T. Brown**, Qi-Bin Bao and Hansen A. Yuan (2012). The use of PEEK in spine arthroplasty, Recent Advances in Arthroplasty, Samo K. Fokter (Ed.), ISBN: 978-953-307-990-5, InTech. Available from: http://www.intechopen.com/articles/show/title/the-use-of-peek-in-spine-arthroplasty.
2. **T. Brown,** William Levelle, Qi-Bin Bao, Domagoj Coric, and Hansen A Yuan (2013). Classification of lumbar nucleus replacement systems, mechanism of action and surgical technique, Dynamic Reconstruction of the Spine 2nd Edition, Daniel H. Kim, Frank Cammisa, Richard G. Fessler, Dilip K. Sengupta, and Do Heum Yoon (Eds.). Thieme Medical Publishers Inc., New York, NY.

PRESENTATIONS

Podium

1. **Brown T**. PEEK on PEEK articulations in spinal arthroplasty. 1st PEEK International Meeting. Philadelphia, Pennsylvania 2013.
2. **Brown T**, Bao QB. The use of self-mating PEEK as an alternative bearing material for cervical disc arthroplasty. International Society for the Advancement of Spine Surgery. Barcelona, Spain 2012.
3. **Brown T**, Pernsteiner W, Bao QB. Design rationale and pre-clinical studies of NuNec, a PEEK on PEEK cervical disc arthroplasty device with unique cam fixation and hydroxyapatite coating. Polish Spine Society. Zakopane, Poland 2010.
4. **Brown T**, Bao QB, Kilpela T, Schwenke T, Wimmer MA. A wear assessment of NuBac, an articulating nucleus replacement device using several different testing methodologies. Asia Pacific Spine Arthroplasty Society. Sanya, China 2010.
5. **Brown T**, Bao QB, Hallab N. Biotribology assessment of NuNec, a PEEK on PEEK cervical disc replacement according to ISO and ASTM recommendations. Spine Arthroplasty Society. London, England 2009.
6. **Brown T**, Bao QB, Kilpela T, Schwenke T, Wimmer MA. A comprehensive wear assessment of NuBac. Spine Arthroplasty Society. Miami, Florida 2008.
7. **Brown T**, Bao QB, Kilpela T. Wear and mechanical durability of the Pioneer Surgical Technology Disc Arthroplasty Device. Spine Arthroplasty Society. Montreal, Canada 2006.

Posters

1. **Brown T**, Bao QB. PEEK as an alternate bearing material for cervical arthroplasty. SpineWeek 2012. Amsterdam, The Netherlands, 2012.
2. **Brown T**, Bao QB. Design rationale and pre-clinical studies of NuNec, a PEEK on PEEK cervical disc arthroplasty device with unique CAM fixation and hydroxyapatite coating. Global Spine Congress. Barcelona, Spain, 2011.
3. **Brown T**, Bao QB. Biotribological assessment of NuNec, a PEEK on PEEK cervical disc replacement according to ASTM and ISO recommendations. European Cervical Spine Research Society. Uppsala, Sweden, 2009.
4. **Brown T**, Bao QB. Compressive load sensitivity on the biotribological properties of NuBac. Spine Arthroplasty Society. London, England, 2009.
5. Bao QB, **Brown T**, Pernsteiner W. An HA-coated PEEK-on-PEEK cervical disc arthroplasty device: Design rationale and preclinical testing of NuNec. European Cervical Spine Research Society. Warsaw, Poland, 2009.
6. **Brown T**, Bao QB. Wear evaluation of a PEEK on PEEK disc arthroplasty device. Eurospine. Geneva, Switzerland, 2008.
7. **Brown T**, Bao QB, Kilpela T, Schwenke T, Wimmer MA. A comprehensive wear assessment of PEEK-OPTIMA for disc arthroplasty applications. World Congress of Biomaterials. Amsterdam, Netherlands, 2008.
8. Wimmer MA, Schwenke T, **Brown T**, Kilpela T, Bao Q. Effect of accelerated aging on the wear of PEEK in disc arthroplasty. Orthopedic Research Society. San Francisco, California, USA, 2008.
9. Schwenke T, **Brown T**, Bao Q, Kilpela T, Wimmer M. Wear assessment of a self-mating polymer for nucleus replacement devices. Orthopedic Research Society. San Diego, California, USA, 2007.
10. **Brown T**, Bao QB, Kilpela T. A wear assessment of NuBac under a cross shear motion profile. Spine

Arthroplasty Society. Berlin, Germany, 2007.

11. Bao, QB, **Brown T**, Kilpela T. Design rationale and preclinical summary of the NuBac Disc Arthroplasty System. Spine Arthroplasty Society. Montreal, Canada, 2006.