

## Ken Gall

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### Summary

Professor Gall is currently the Associate Dean of Entrepreneurship and Professor of Mechanical Engineering and Materials Science at Duke University. His expertise is in the mechanical behavior of materials with emphasis on the creation, modification, understanding, and commercialization of synthetic biomaterials. His publications have been cited over 21,000 times with an H-index of 77. He is a founder and director of six active medical device start-ups (Restor3d, Lacuna, Pressio, Huxley, DeepBlue, and Penderia). He is also a Director in four other early stage medical device companies (InnAVasc, Sparta, Kinoss, and Orthobond). He was a founder and board member of two medical device startups, MedShape and Vertera, that have been acquired by public strategies for a total of \$215M on \$18M in combined annual run rate sales. MedShape was acquired through two different exits, the sports medicine division was acquired by Conmed (NASDAQ:CNMD) and the foot and ankle division was acquired by Colfax-DJO (NASDAQ:CFX). Vertera was acquired by Nuvasive (NASDAQ:NUVA).

### Education

|     |      |                        |                                            |
|-----|------|------------------------|--------------------------------------------|
| PhD | 1998 | Mechanical Engineering | University of Illinois at Urbana Champaign |
| MS  | 1996 | Mechanical Engineering | University of Illinois at Urbana Champaign |
| BS  | 1995 | Mechanical Engineering | University of Illinois at Urbana Champaign |

### Academic Appointments

|              |                     |                                            |
|--------------|---------------------|--------------------------------------------|
| 2019-Current | Associate Dean      | Entrepreneurship, Duke University          |
| 2016-Current | Professor           | Orthopaedic Surgery, Duke University       |
| 2015-Current | Associate Director  | MEDx, Duke University                      |
| 2015-Current | Professor           | MEMS Department, Duke University           |
| 2015-2019    | Chair               | MEMS Department, Duke University           |
| 2007-2015    | Professor           | Georgia Institute of Technology            |
| 2005-2007    | Associate Professor | Georgia Institute of Technology            |
| 2003-2005    | Associate Professor | University of Colorado at Boulder          |
| 1999-2003    | Assistant Professor | University of Colorado at Boulder          |
| 1998-1999    | Post-Doc            | Sandia National Laboratories               |
| 1995-1998    | Research Assistant  | University of Illinois at Urbana-Champaign |

### Academic Leadership

#### *MEMS, Department Chair*

As department chair Professor Gall grew the MEMS department from 27 to 40 faculty in a four-year period. This includes key senior hires of Professor Cate Brinson, Professor Michael Rubinstein, Professor Shyni Varghese, Professor Christine Payne, and Professor Tony Huang. Professor Gall also built the MEMS department from a near neutral budget to one generating approximately \$1M a year due to substantial growth in student and research programs. Professor Gall works closely with faculty to encourage and reward startup companies, with four new companies coming out of MEMS during his time as chair. During his tenure as chair, the number of PhD student applicants has doubled from 144 students in 2014 to over 300 students in 2017, a number that was held at about 150 for a decade. Finally, he is working with the

provost's office on a new science and technology initiative that will bring further growth in the areas of computing, robotics, and materials to the department.

*MEDx, Associate Director*

In collaboration with the Duke School of Medicine (SOM) Professor Gall co-directs the MEDx program with a professor in the SOM. MEDx is a campus wide initiative aimed at uniting the medical school and engineering school. We have built multiple programs within the MEDx framework including a seed grant program that has funded a dozen new collaborations between engineering and SOM, a vibrant competition to link surgeons and physicians to senior design teams in engineering, and a new program in engineering pulmonology funded by a Duke alumni donor. MEDx also serves an important role as a match maker between the over 1,000 faculty in the SOM and 120 faculty in the Pratt School of Engineering.

**Start-Up Companies**

*MedShape Founder, BOD Member*

Founded in 2005, Professor Gall has maintained an active leadership role in the company for over a decade across both business and technology fronts. He co-led a multi-year capital raise of approximately \$45M in private, non-institutional equity investment. This investment allowed MedShape to successfully clear seven orthopedic implant systems containing advanced materials through the FDA, including multiple "firsts": a new polymer chemistry, a shape memory PEEK, and an implant comprised of both Ti and NiTi. MedShape's products are based on shape memory polymers for soft tissue reconstruction (Eclipse, ExoShape, Morphix), 3D printed Titanium for bunion repair (FastForward), and shape memory alloys for foot and ankle joint fusion (DynaNail, DynaClip, DynaNail mini). MedShape is a self-sustaining, growing company with annual revenue run rate of approximately \$15M and two of its product lines have won industry-level (MDEA) device design excellence awards.

*MedShape's Sports Medicine Business was acquired by ConMed in 2017*

*MedShape's FastForward system was acquired by a private company in 2018.*

*Vertera Founder, BOD Member*

Founded in 2013, Professor Gall led a \$6.0M private non-institutional capital raise and used this money to develop, clear, and launch a the first ever porous PEEK spinal fusion cage cleared through the FDA for both Cervical Fusion (Cohere) and Lumbar Fusion (Coalesce). The porous PEEK technology was supported in-part financially by the Duke Angel Network (DAN).

*Vertera was acquired by NuVasive in 2017.*

*DeepBlue Founder, BOD member*

Founded in 2015, and funded by angel investors, DeepBlue is commercializing a novel hernia mesh that distributes stresses evenly across hernia repair sites for improved clinical outcomes.

*restor3d Founder, BOD Member*

Founded in 2017, and funded by angel investors at approximately \$8M restor3d is commercializing 3D printed implants across a broad range of markets. Professor Gall led fundraising efforts and is currently leading the broad technology vision of the company as they prepare for market release. Restor3d currently has 2 FDA clearances and with an annual revenue run rate of approximately \$2M.

*Lacuna Founder, BOD Member*

Founded in 2017, and funded by angel investors, Lacuna is developing a shape memory catheter that deploys itself into restricted spaces and prevents mechanical occlusion of the drainage ports. The launch product was submitted to the FDA for 510(k) clearance in late 2019.

*Kinos                      BOD Member*

Kinos is developing a new anatomic total ankle replacement. The launch product was submitted to the FDA for 510(k) clearance in late 2019.

*InnAVasc                BOD member*

InnAVasc is commercializing a soft arteriovenous graft (AVG) modification that incorporates two multilayer cannulation chambers, with low bleed technology, that are resistant to posterior and sidewall needle penetration and injury. The launch product is currently in a overseas clinical study.

**Federal and Industry Grants**

Professor Gall has extensive fundraising experience through government agencies, in particular the National Science Foundation (NSF) and the National Institute of Health (NIH), and the commercial sector including numerous industrial grants. His grants include both basic research awards aimed at new fundamental science and Small Business Innovation in Research awards (SBIR) aimed at hastening technology commercialization. He has been a PI, Co-PI or consultant on 60 grants over the past fifteen years that have totaled \$17M.

**Awards**

Professor Gall has received several dozen national and international research and teaching awards including the Presidential Early Career Award for Scientists and Engineers (PECASE), the TMS Robert Lansing Hardy Award, and the ASME Gold Medal, all given to top young scientists in their field. He also recently received the Curtis McGraw Award from ASEE given for excellence in publication for a scientist under 40 years of age. His teaching awards include the ASM Bradley Stoughton Award and numerous campus wide awards at both Georgia Tech (Senior Faculty Outstanding Undergraduate Research Mentor Award) and the University of Colorado (Sullivan-Carlson Innovation in Teaching Award) .

**Graduate Students Advised**

|                         |                    |                                                                                                  |
|-------------------------|--------------------|--------------------------------------------------------------------------------------------------|
| Katie Nelson            | PhD, Current, Duke | 3D printed CoCr and Titanium Materials                                                           |
| Emilio Bachtiar         | PhD, Current, Duke | 3D printed soft biodegradable and composite polymers                                             |
| Will Koshut             | PhD, 2021, Duke    | Reinforcement and Durability of tough PVA hydrogels                                              |
| Natalia<br>Von Windheim | PhD, 2021, Duke    | 3D printed PEEK tissue scaffolds                                                                 |
| Brian Allen             | PhD, 2020, Duke    | Antibiotic release from 3D printed scaffolds                                                     |
| Cambre Kelly            | PhD, 2020, Duke    | 3D printed metal tissue scaffolds                                                                |
| Dalton Sycks            | PhD, 2017, Duke    | Development of Mechanically Robust 3D-Printable Photopolymers                                    |
| Andy Miller             | PhD, 2017, GaTech  | Fatigue and cyclic loading of 3D printed soft polymers for orthopedic applications               |
| Brennan Torstrick       | PhD, 2017, GaTech  | Effects of Surface Chemistry and Surface Topography on Poly-Ether-Ether-Keytone Osseointegration |

|                 |                   |                                                                                                                                                          |
|-----------------|-------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------|
| Nathan Evans    | PhD, 2016, GaTech | Processing-structure-property relationships of surface porous polymers for orthopedic applications                                                       |
| Reza Mirzaeifar | PhD, 2013, GaTech | A multiscale study of NiTi Shape Memory Alloys                                                                                                           |
| Yuan Zhong      | PhD, 2012, Gatech | Nanomechanics of plasticity in ultra-strength metals and shape memory alloys                                                                             |
| Mary Pitz       | MS, 2011, Gatech  | Compression-Aided stability of Orthopedic Devices                                                                                                        |
| David Safranski | PhD, 2010, Gatech | Poly(beta-amino esters) for cardiovascular applications                                                                                                  |
| Kathryn Smith   | PhD, 2010, Gatech | Tailoring the toughness and Biological Response of Photopolymerizable Networks for Orthopedic Applications                                               |
| Bhaskar Pant    | MS, 2010, Gatech  | Experimental nanomechanics of 1D nanostructures                                                                                                          |
| Alicia Ortega   | PhD, 2010, Gatech | Structure-property relationships in photopolymerizable polymer networks.                                                                                 |
| Walter Voit     | PhD, 2009, Gatech | Optimization of Mechanical Properties and Manufacturing Techniques to Enable Shape Memory Polymer Processing                                             |
| Scott Kasprzak  | PhD, 2009, Gatech | Small-Scale Polymer Structures Enabled by Thiol-Ene Copolymer Systems.                                                                                   |
| Matthew DiPrima | PhD, 2009, Gatech | Thermo-Mechanical and Micro-Structural Characterization of Shape memory Polymer Foams.                                                                   |
| Heidi F. Khalil | MS, 2009, Gatech  | Changes in the mechanical behavior of Nitinol following variations of heat treatment duration and temperature                                            |
| Greg Vialle     | MS, 2009, Gatech  | Inductive Activation of Magnetite Filled Shape Memory Polymers                                                                                           |
| Brian Lin       | MS, 2009, Gatech  | Structure and Thermomechanical Behavior of NiTiPt Shape Memory Alloy Wires.                                                                              |
| Edem Wornyo     | PhD, 2008, Gatech | Nanomechanics of Shape Memory Polymers.                                                                                                                  |
| David Safranski | MS, 2008, Gatech  | Effect of Chemical Structure and Crosslinking Density on the Thermo-Mechanical Properties and Toughness of (Meth)Acrylate Shape Memory Polymer Networks. |
| Terra Keim      | MS, 2007, Gatech  | Synthesis, Characterization, and Cyclic Stress-Influenced Degradation of a Poly(ethylene)glycol based Poly(beta-amino ester)                             |

|                |                     |                                                                                                                                            |
|----------------|---------------------|--------------------------------------------------------------------------------------------------------------------------------------------|
| Austin Leach   | PhD, 2007, Gatech   | Atomistic Modeling of the Mechanical Behavior of Nanometer Scale Metals.                                                                   |
| Chris Yakacki  | PhD, 2007, Colorado | Shape-Memory Polymers for Biomedical Applications: An Investigation into Thermomechanics, Recovery Characteristics, and Cytocompatibility. |
| David Miller   | PhD, 2007, Colorado | Galvanic Corrosion-Induced Damage of Miniaturized Silicon Structures.                                                                      |
| Jeff Tyber     | MS, 2005, Colorado  | Mechanical Behavior of Materials for Reconstructive Bioengineering Applications.                                                           |
| Carl Frick     | PhD, 2005, Colorado | Processing, Structure, and Property Relationships in NiTi Shape Memory Alloys at Multiple Length Scales.                                   |
| Yiping Liu     | PhD, 2004, Colorado | Thermomechanics of Shape Memory Polymers.                                                                                                  |
| Jiankuai Diao  | PhD, 2004, Colorado | Atomistic and Continuum Modeling of the Structure and Mechanical Properties of Metal Nanowires.                                            |
| Alicia Ortega  | MS, 2004, Colorado  | Cast NiTi Shape Memory Alloys.                                                                                                             |
| Neil West      | MS, 2003, Colorado  | Factors Affecting Creep in Gold on Polysilicon Bi-layer Cantilevered MEMS Beams.                                                           |
| Kevin Juntunen | MS, 2001, Colorado  | Effects of Precipitate Size and Surface Normal Orientation on Micro-Indentation and Compressive Fatigue of NiTi Shape Memory Alloys.       |
| Brian Corff    | MS, 2000, Colorado  | High Strain Rate Damage in Ductile Metals.                                                                                                 |

### University Course Instruction

#### *Duke University, 2015-Current*

Students provide individual course evaluations online at the end of a course. The maximum score on a question is 5.0 (Strongly Agree) and the minimum is 1.0 (Strongly Disagree), and interpolated medial values are presented. The overall measure for teaching effectiveness is captured in the “Instructor Effectiveness” score.

| <i>Year</i> | <i>Term</i> | <i>Course Title</i>                | <i>Enrollment</i> | <i>Quality of Instructor</i> |
|-------------|-------------|------------------------------------|-------------------|------------------------------|
| 2016        | Spring      | Structure and Properties of Solids | 33                | 4.83                         |
| 2018        | Fall        | Freshman Design Projects           | 45                |                              |
| 2019        | Fall        | Startup Fundamentals and Strategy  | 9                 | Current                      |

#### *Georgia Institute of Technology, 2005-2015*

Students provide individual Course Instructor Opinion Surveys (CIOS) online at the end of a course. The maximum score on a question is 5.0 (Strongly Agree) and the minimum is 1.0 (Strongly Disagree), and interpolated medial values are presented. The overall measure for teaching effectiveness is captured in the “Instructor Effectiveness” score. The symbols U and G designate Undergraduate and Graduate courses, respectively.

| <i>Year</i> | <i>Term</i> | <i>Course Title</i> | <i>Enrollment</i> | <i>Instructor Effectiveness</i> |
|-------------|-------------|---------------------|-------------------|---------------------------------|
|-------------|-------------|---------------------|-------------------|---------------------------------|

|      |        |                                  |     |                   |
|------|--------|----------------------------------|-----|-------------------|
| 2015 | Spring | Mech Behavior of Materials (U/G) | 59  | 5.0               |
| 2015 | Spring | Materials Entrepreneurship (U/G) | 17  | 4.8               |
| 2014 | Fall   | Engineering Materials (U)        | 99  | 4.8               |
| 2014 | Spring | Materials Entrepreneurship (U/G) | 42  | 4.8               |
| 2014 | Spring | Engineering Materials (U)        | 106 | 4.9               |
| 2013 | Fall   | Engineering Materials (U)        | 106 | 4.8               |
| 2013 | Spring | Engineering Materials (U)        | 100 | 4.8               |
| 2012 | Fall   | Engineering Materials (U)        | 97  | 4.8               |
| 2012 | Spring | Engineering Materials (U)        | 97  | 4.9               |
| 2011 | Fall   | Engineering Materials (U)        | 95  | 4.9               |
| 2011 | Spring | Engineering Materials (U)        | 85  | 4.9               |
| 2010 | Fall   | Engineering Materials (U)        | 96  | 4.9               |
| 2010 | Spring | Mech Behavior of Materials (U/G) | 57  | 4.9               |
| 2009 | Fall   | Engineering Materials (U)        | 99  | 5.0               |
| 2008 | Spring | Engineering Materials (U)        | 100 | 4.8               |
| 2008 | Spring | Engineering Materials (U)        | 101 | 4.9               |
| 2007 | Spring | Engineering Materials (U)        | 112 | 4.8               |
| 2007 | Spring | Engineering Materials (U)        | 117 | 4.9               |
| 2006 | Spring | Engineering Materials (U)        | 88  | 4.9               |
| 2006 | Spring | Nanomaterials (U)                | 14  | 4.5 (team taught) |
| 2006 | Spring | Nanomaterials (G)                | 12  | 4.3 (team taught) |

#### *University of Colorado, 1999-2005*

Students provide individual course and instructor Faculty Course Questionnaire (FCQ) ratings anonymously. The cited “Course” and “Instructor” *overall* ratings are computed from the average of individual student rankings from a range of 0.0 (very poor) to 4.0 (very good). The symbols U and G designates Undergraduate and Graduate courses, respectively, and # is the number of students enrolled in the course.

| <i>Year</i> | <i>Term</i> | <i>Course Title</i>        | <i>#</i> | <i>Instructor</i> | <i>Course</i> |
|-------------|-------------|----------------------------|----------|-------------------|---------------|
| 2004        | Fall        | Failure of Materials (U/G) | 120      | 3.96 (A+)         | 3.85 (A)      |
| 2004        | Spring      | Material Science (U)       | 174      | 3.96(A+)          | 3.89 (A+)     |
| 2003        | Fall        | Failure of Materials (U/G) | 93       | 3.95 (A+)         | 3.84 (A)      |
| 2003        | Spring      | Freshman Projects (U)      | 32       | 3.85 (A)          | 3.85 (A)      |
| 2002        | Fall        | Failure of Materials (U/G) | 77       | 3.97 (A+)         | 3.87 (A)      |
| 2002        | Spring      | Freshman Projects (U)      | 33       | 3.88 (A+)         | 3.85 (A)      |
| 2001        | Fall        | Failure of Materials (U/G) | 60       | 3.90 (A+)         | 3.83 (A)      |
| 2001        | Fall        | Materials Science I (G)    | 19       | 3.78 (A)          | 3.67 (A)      |
| 2001        | Spring      | Freshman Projects (U)      | 19       | 3.93 (A+)         | 4.00 (A+)     |
| 2000        | Fall        | Failure of Materials (U/G) | 33       | 4.00 (A+)         | 3.96 (A+)     |
| 2000        | Spring      | Freshman Projects (U)      | 30       | 3.96 (A+)         | 3.75 (A)      |
| 1999        | Fall        | Materials Science I (G)    | 19       | 3.89 (A+)         | 3.67 (A)      |

#### **Publications and Patents Via Google Scholar** Attached