

CURRICULUM VITAE FOR CARL R. McMILLIN, Ph.D.

EDUCATIONAL BACKGROUND

MS & Ph.D. Case Western Reserve University (CWRU) - Macromolecular Science
Bachelors General Motors Institute of Technology - Mechanical Engineering/Material Science

PROFESSIONAL AFFILIATIONS AND HONORS

Recipient of 2015 C. William Hall Award from the Society for Biomaterials, 2015
Delegate on first People-to-People program on Biomaterials, Peoples Republic of China, 2010 & attended World Biomaterials Congress, Changdu, China 2012
University Hospitals of Cleveland, Cleveland, OH - Scientific/Community Member of the Human Institutional Review Board (IRB), 2005 to present – gratis. Certified in Human Research Protection.
Edison Biotechnology Center and Omeris (State of Ohio) 1992–2002. Commercialization Cabinet 1997-2002; Scientific Advisory Council 1992-1994, Executive Advisory Committee 1992-1996
External Advisory Board, Center for Cardiovascular Biomaterials, CWRU, Cleveland, OH, 1994-1998
Executive Editor (USA) of the international journal, *Bio-Medical Materials and Engineering*, 1990-1996
Editorial Advisory Board of *Medical Plastics and Biomaterials*, Canon Communications, 1994-1998
Society for Biomaterials offices: Member Council 1999, 2000, 2001, Chair of the Biomaterials and Medical Device Commercialization Special Interest Group 1998, 1999 & 2005–2012 (former Biomaterials Availability and Policy SIG), and Vice Chair, 2000 – 2004 & 2012 - present.
Reviewer for J. Biomedical Materials Res., J. Artificial Organs, Macromolecules, J. of Applied Biomaterials, Biomaterials Society annual meetings/Transactions, and Nanomedicine and Nanobiotechnology
Member: Society for Biomaterials, American Society for Testing and Materials, and others when they existed - Cleveland Area Research Directors, NeoBio (Northeast Ohio interactive group on biomedical topics), One of thirty University of Akron faculty honored for "Significant Accomplishments in Teaching, Research, and Public Service," in 1984-1985
One of ten USA scientists, 2nd Joint USA/USSR Symposium on Circulation and the Artificial Heart, Houston, 1981
One of seven USA scientists, 3rd Joint USA/USSR Symposium on Artificial Heart R&D, Moscow, USSR, 1985
Chair, Research (Faculty Grants) Committee of Univ. Akron (1987- 1989); Committee member 1984-87
Adjunct Faculty, Cleveland State University, Applied Biomedical Engineering doctoral program, 2001-present
Adjunct Staff, The Cleveland Clinic Foundation, Cleveland, OH, 1984-1993, 1995, 1996
Member of several NIH Contract and Grant Peer Review Panels.
Reviewed grants for Edison Biotechnology Center and for Summa Health System Foundation
Member, Akron Campus Clinical Deans, 1984-88
Topic Coordinator: Novel Biomaterials, 6th World Biomaterials Congress, 2000
Invited speaker at Gordon Conference on Biomaterials, 1980
Grantsmanship Director, State of Ohio Jaycees, 1978 & 1979
NIH (Heart, Lung & Blood Institute) Post-Doctoral Research Fellowships, 1974 & 1975
Macromolecular Science Graduate Fellowships, 1969-1974
Girnell Scholarship, 1964
DoD Secret Clearance, 1980-1983

SELECT RECENT MEETINGS ATTENDED

2019 – Society for Biomaterials annual meeting, Seattle, WA
2018 – Society for Biomaterials annual meeting, Atlanta, GA
2017 – Society for Biomaterials annual meeting, Minneapolis, MN
2016 – World Congress for Biomaterials, Montreal, Canada
2012 – World Congress for Biomaterials, Chengdu, China
2011 – North American Spine Society (NASS), Chicago, IL
2010 – People to People Biomaterials Delegation to China (First “Biomaterials” delegation, organized by the President of the Society for Biomaterials)
2008 – World Congress for Biomaterials, Amsterdam, Netherlands

WORK EXPERIENCE DETAIL

- 1997 – present: **Independent Consultant**, Brecksville, Ohio, President **Synthetic Body Parts, Inc.**
Biomedical product development and biomaterials consulting conducted for start-up to multi-national companies. Occasional expert witness in patent and product liability lawsuits. Member of Univ. Hospitals of Cleveland Institutional Review Board (IRB) for human research protection (June 2005– present).
Adjunct faculty at Cleveland State University (1999–~2009) teaching occasional courses.
- 1989 - 1997: AcroMed Corporation, Cleveland, Ohio
Director of R&D, Director Polymer Laboratory, Senior Scientist. Conducted and directed research, development, evaluation, and commercialization of many metal, polymer, polymer/carbon fiber composite and elastomer-based orthopedics products, primarily for the spine.
- 1983 - 1989: The University of Akron, **Associate Professor**, Dept. Biomedical Engineering, **Director of the Cardiovascular Laboratory.** Conducted research on accelerated rubber fatigue testing of rubber, blood-materials interactions, permeability of elastomers, and hemodynamics of artificial hearts, Taught graduate engineering courses in Biomaterials (& laboratory), Biocompatibility, and Artificial Organs.
- 1975 - 1983: Monsanto Research Corporation, Dayton Laboratory, Dayton, Ohio
1978 - 1983: **Contract Manager, Senior Research Chemist.**
- 1974 - 1975: Case Western Reserve University, Cleveland, Ohio, **NIH Postdoctoral Research Fellow.** Studied blood platelet/surface interactions.
- 1974 - 1975: Cleveland Clinic Foundation, Cleveland, Ohio, **Visiting Scientist**, Artificial Internal Organs Dept.
- 1972 - 1974: Case Western Reserve University, Cleveland, Ohio, **Doctoral Research.** Elucidated the conformation of blood clotting proteins and changes in structure with surface interaction.
- 1971 - 1972: Queen Mary College, University of London, England, **Research Associate.** Studied solvent effects on craze and crack growth in amorphous and semicrystalline polymers (with the world renowned fracture mechanics expert, Professor Andrews).
- 1969 - 1971: Case Western Reserve University, **Masters Research.** Evaluated vacuum ultraviolet spectroscopy for characterizing the conformation of biopolymers.
- 1964 - 1969: Packard Electric Division, General Motors Corporation, Warren, Ohio, **Jr. Engineer, Engineer.**
Bachelor's Thesis on flammability of polymers for use in electrical wiring systems.
- Over 100 journal, symposia & contract research publications, book chapters, patents, and theses
 - Over 75 national or international meeting presentations as author or co-author

Worked with surgeons to develop implants for custom implantation & some for wider commercialization

- Designed and oversaw over \$1M in research to achieve successful FDA approval for the use of PEEK, PEKEKK and carbon fiber reinforced versions of these polymers for orthopedic use (esp. PLIF & ALIFs) including biocompatibility, long-term rat carcinogenicity, & Spanish goat implants.
- Materials and design optimization of the worlds first carbon fiber composite posterior lumbar interbody fusion (PLIF) cages (Brantigan Cage, now sold by J&J), including material selection, cadaver spine measurements, strength vs size optimization, and production quality control issues.
- Developed with Dr. Brantigan, the world's first carbon fiber composite anterior lumbar interbody fusion (ALIF) cages (e.g. measured about 100 cadaver spines to determine size and shape of system of cages to optimize strength vs footprint, material specification, oversight of cage production and quality control, in charge of instrument development and acquisition and engineering changes of instrument and cage drawings
- Extended this technology to thoracic and cervical ALIFs and PLIFs including many additional cadaver vertebral body measurements
- Developed and patented a novel process and fiber orientation to achieve 3D structure for the first carbon fiber composite spine fusion cages (solo patent)

- Developed first functional artificial spinal discs implanted in patients in the USA with Dr. Steffee. Was listed as lead inventor on one disc patent using polyolefin rubber with Ti end plates and listed as an inventor on other artificial disc patents.
- Developed first functional artificial spinal discs with Dr. Steffee constructed using silicone rubber and titanium and implanted in patients
- Developed first functional cervical artificial spinal discs with Dr. Steffee. These were clinically implanted in both polyhexene and silicone rubber-based versions
- Developed world's first custom carbon fiber composite artificial vertebral bodies as well as UHMWPE/Titanium artificial vertebral bodies designing and have manufactured devices based on individual patient x-ray, CT and MRI information
- Developed the Brantigan stackable system for variable heights of artificial vertebral bodies, determined cage sizes, spline composition, had CAD drawings & prototypes made, evaluated dimensions and fit of prototypes.
- Developed world's first carbon fiber composite skull plate (presented at the Sidney World Congress of Biomaterials with clinical x-ray)
- Invented a new fiber structure to make a composite structure that would not split when used for long bone fixation plates. The PEEK carbon fiber composite long bone plate was clinically implanted and I was granted a solo patent on the fiber structure making it possible
- Developed first PEEK carbon fiber composite ankle stabilization spool implant with Dr. Steffee for a custom implant
- Developed first PEEK carbon fiber composite wrist stabilization wedge implants for Dr. Steffee and scrubbed in for implantation
- Developed world's first PEEK carbon fiber composite spine stabilization plates using custom TiN coated titanium washers and screws to interface with composite plates. About a dozen were clinically implanted and explanted after a year after fusion was achieved.
- Worked with Dr. Steffee to develop and implant the world's first (custom) artificial sacrum
- Worked with Dr. Keppler to develop and implant world's first (custom) carbon fiber composite intramedullary nail
- Developed world's first PEEK and also PEEK/Carbon fiber injection molded screws (with custom screw thread design to match material properties) - used clinically for spine implant stabilizations
- Developed world's first PEEK cable ties for orthopedic stabilization (after a surgeon had used a common nylon cable tie in a spine surgery)
- Helped develop and had manufactured linear polyethylene "Graf loops" and associated Ti screws for spine stabilization
- Translated stainless steel screw design to first AcroMed titanium posterior cervical screws
- Evaluated commercial potential of new materials and designs for AcroMed spine products
- As consultant, worked with over 50 small to multi-national companies helping to solve biocompatibility and commercialization problems. Also, expert on patent and device failure litigation issues. Expert & testified on Bianco v Globus theft of trade secrets re expandable spine fusion cage. Expert & testified on Gore v Bard patent case on basic patents relating to the structure of PTFE vascular grafts.

9/27/2019