Exponent®
Engineering & Scientific Consulting

Howard Loree, II, Ph.D.

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Professional Profile

Dr. Howard Loree joined Exponent in 2020 with over 25 years of diverse R&D experience in the medical device industry and a hands-on aptitude across the complete product development life cycle in both startup and growth stage companies. He has developed highly innovative surgical and interventional products for mechanical circulatory support, vascular access, peripheral vascular, neurovascular, spine, and ophthalmology applications.

Dr. Loree provides scientific consulting services in many aspects of medical devices including, but not limited to, technology assessment, product design optimization, blood damage analysis, design verification & validation (V&V) testing, human factors, health risk assessment (HRA), and post-market regulatory affairs. He has also supported both law firms and medical device manufacturers with post-market regulatory/compliance inquiries, recalls, and product liability litigation.

Dr. Loree is a recognized expert in the development of rotary blood pump systems for implantable and wearable cardiovascular applications. This includes his role as Senior Scientist / Manager of Research at Thermo Cardiosystems / Thoratec (now part of Abbott) in starting and leading the HeartMate III program which commercialized a highly successful ventricular assist device (VAD) product for long term use. As Principal Staff Scientist at ABIOMED, he contributed to the regulatory approval and ongoing innovation of the Impella VAD product line for short term use. Most recently, as Vice President of R&D at Flow Forward Medical (now part of Artio Medical), Dr. Loree led the development of the Amplifi System, a novel wearable device that rapidly dilates peripheral veins for use in creating reliable and durable arteriovenous fistula (AVF) vascular access sites for hemodialysis.

Dr. Loree's background also includes senior leadership roles in research focused on minimally invasive treatments and combination products. At Orthopeutics, he developed injectable, nontoxic crosslinking agents and associated delivery systems for treatment of degenerative disc disease, scoliosis, and other orthopedic disorders. At Avedro, Dr. Loree oversaw preclinical research on the KXL system to deliver a riboflavin/UVA collagen crosslinking treatment to treat keratoconus. Most recently, he engineered catheter-based devices for embolic occlusion of aneurysms (Endura) and arteries (Solus) at Metactive Medical (now Artio Medical).

Dr. Loree has direct experience in leading projects from initial concept through *in vivo* feasibility, intellectual property (IP) development, design requirements, human factors analysis, failure mode and effects analysis (FMEA), design freeze, technology transfer from product development contractors, design V&V testing, and preparation for first-in-human trials. His personal technical accomplishments include raising over $4.5M in NIH funding for medical device development; planning, executing, and reporting preclinical studies to rapidly establish *in vitro* and *in vivo* feasibility; and supporting successful FDA submissions including IND, IDE, HDE, 510(k), and PMA.

Dr. Loree's education includes B.S. and M.S. degrees in Mechanical Engineering from MIT as well as a

Ph.D. in Medical Engineering from the Harvard-MIT Division of Health Sciences and Technology. At MIT, his coursework and research focused on design, biomaterials, fluid mechanics, and medical sciences. He also completed a postdoctoral research fellowship in cardiovascular biomechanics at the Brigham and Women's Hospital, Harvard Medical School.

Academic Credentials & Professional Honors

Ph.D., Medical Engineering, Massachusetts Institute of Technology (MIT), 1992

M.S., Mechanical Engineering, Massachusetts Institute of Technology (MIT), 1988

B.S., Mechanical Engineering, Massachusetts Institute of Technology (MIT), 1986

Sezai Award for most innovative paper (International Society for Rotary Blood Pumps, 2000)

Wunsch Foundation Award for outstanding design (MIT, 1986)

Pi Tau Sigma (MIT, 1985)

Prior Experience

Vice President of Research and Development, Flow Forward Medical, Inc., 2011-2020

Vice President of Research and Development, Metactive Medical, Inc., 2013-2018

Vice President of Research and Chief Scientist, Avedro, Inc., 2009-2010

Principal Staff Scientist, ABIOMED, Inc., 2006-2009

Vice President, Orthopeutics, L.P., 2005-2006

Manager of Research, Thoratec Corp., 2002-2005

Senior Scientist, Thermo Cardiosystems Inc. / Thoratec Corp., 1995-2002

Postdoctoral Research Fellow, Brigham and Women's Hospital, Harvard Medical School, 1992-1995

Professional Affiliations

American Society of Mechanical Engineers (ASME)

American Society for Artificial Internal Organs (ASAIO)

International Society for Mechanical Circulatory Support (ISMCS)

Patents

U.S. Patent 10,258,730: Blood Pump Systems and Methods, 2019 (Franano NF, Loree HM 2nd, Tansley G, Woodard S, Hutto B).

U.S. Patent 9,662,431: Blood Pump Systems and Methods, 2017 (Franano NF, Loree HM 2nd, Tansley G, Woodard S, Hutto B).

U.S. Patent 9,555,174: Blood Pump Systems and Methods, 2017 (Franano NF, Loree HM 2nd, Tansley G, Woodard S, Hutto B).

U.S. Patent 5,887,985: Wear-Resistant Bearings, 1999 (Loree HM, Gernes DB, Armini AJ, Gadarowski DA).

U.S. Patent 4,955,893: Prosthesis for Promotion of Nerve Regeneration, 1990 (Yannas IV, Orgill DP, Loree HM, Kirk JF, Chang AS, Mikic BB, Krarup C, Norregaard TV).

Publications

Loree HM, Agyapong G, Bailey EG, Ngai GA, Tansley GD, Dixon BS, Franano NF. In vitro study of a medical device to enhance AVF eligibility and maturation. ASAIO J. 2015; 61(4):480-6.

Kavarana MN, Loree HM 2nd, Stewart RB, Milbocker MT, Hannan RL, Pantalos GM, Kung RT. Pediatric mechanical support with an external cardiac compression device. J Cardiovasc Dis Diagn. 2013;1(2). pii: 1000105.

Burgreen GW, Loree HM, Bourque K, Dague C, Poirier VL, Farrar D, Hampton E, Wu ZJ, Gempp TG, Schöb R. Computational fluid dynamics analysis of a maglev centrifugal left ventricular assist device. Artificial Organs 2004;28:874-880.

Smith WA, Allaire P, Antaki J, Butler KC, Kerkhoffs W, Kink T, Loree H, Reul H. Collected nondimensional performance of rotary dynamic blood pumps. ASAIO J. 2004;50(1):25-32.

Bourque K, Gernes DB, Loree HM, Richardson JS, Poirier VL, Barletta N, Fleischli A, Foiera G, Gempp TM, Schoeb R. Incorporation of electronics within a compact, fully implanted left ventricular assist device. Artificial Organs. 2002;26:939-942.

Bourque K, Gernes DB, Loree HM, Richardson JS, Poirier VL, Barletta N, Fleischli A, Foiera G, Gempp TM, Schoeb R, Litwak KN, Akimoto T, Watach MJ, Litwak P. HeartMate III: pump design for a centrifugal LVAD with a magnetically-levitated rotor. ASAIO J 2001;47:401-405.

Loree HM, Bourque K, Gernes DB, Richardson JS, Poirier VL, Barletta N, Fleischli A, Foiera G, Gempp TM, Schoeb R, Litwak KN, Akimoto T, Kameneva M, Watach MJ, Litwak P. HeartMate III: design and in vivo studies of a maglev centrifugal LVAD. Artificial Organs 2001;25:386-391.

Lee RT, Schoen FJ, Loree HM, Lark MW, Libby P. Circumferential stress and matrix metalloproteinase in human coronary atherosclerosis: implications for plaque rupture. Arteriosclerosis, Thrombosis, and Vascular Biology 1996;16:1070-1073.

Lee RT, Loree HM, Fishbein MC. High tensile stress regions in saphenous vein bypass graft atherosclerosis lesions. J Am Coll Cardiology 1994;24:1639-1644.

Loree HM, Grodzinsky AJ, Park SY, Gibson LJ, Lee RT. Static circumferential tangential modulus of human atherosclerotic tissue. J Biomechanics 1994;27:195-204.

Loree HM, Tobias BJ, Gibson LJ, Kamm RD, Small DM, Lee RT. Mechanical properties of model atherosclerotic lesion lipid pools. Arteriosclerosis and Thrombosis 1994;14:230-234.

Cheng GC, Loree HM, Kamm RD, Fishbein MC, Lee RT. The distribution of circumferential stress in ruptured and stable atherosclerotic lesions: a structural analysis with histopathologic correlations. Circulation 1993;87:1179-1187.

Lee RT, Loree HM, Cheng GC, Lieberman EH, Jaramillo N, Schoen FJ. Computational structural analysis based on intravascular ultrasound imaging before in vitro angioplasty: prediction of plaque fracture locations. J Am Coll Cardiology 1993;21:777-782.

Lee RT, Richardson SG, Loree HM, Grodzinsky AJ, Gharib SA, Schoen FJ, Pandian N. Prediction of mechanical properties of human atherosclerotic tissue by high-frequency intravascular ultrasound imaging: an in vitro study. Arteriosclerosis and Thrombosis 1992; 12:1-5

Loree HM, Kamm RD, Stringfellow RG, Lee RT. Effects of fibrous cap thickness on peak circumferential stress in model atherosclerotic vessels. Circulation Research 1992;71:850-858.

Loree HM, Kamm RD, Atkinson CM, Lee RT. Turbulent pressure fluctuations on the surface of model vascular stenoses. Am J Physiology 1991;261:H644-650.

Research Grants

1R43NS092184-01A1 (Franano) 09/15/18-8/31/20

Source: NIH NINDS SBIR Ph1 $196,273

Title: Device for Rapid, Complete & Durable Occlusion of Wide-Neck Cerebral Aneurysms
Description: Compare in vivo effectiveness of Ballstent Microcatheter™, an innovative catheter-based embolic device designed to rapidly and permanently occlude wide-neck cerebral aneurysms, with that of currently available devices. Demonstrate that treatment of wide-neck bifurcation and sidewall aneurysms with Ballstent and coils is superior to coils only, flow diverting stents, and intrasaccular flow diverters in acute and chronic aneurysm occlusion.

2R44HL124832-02A1 (Franano) 10/01/18-09/30/20

Source: NIH NHLBI SBIR Ph2 $1,295,528

Title: Over-the-Wire Device for Immediate and Complete Peripheral Artery Occlusion
Description: Commercialize Blockstent Microcatheter™, an over-the-wire embolic device which is easy to use, can be placed with a high degree of precision, and delivers immediate, complete and sustained vascular occlusion. Includes implementation of a quality management system, verification & validation testing, and submission of 510(k) and CE Mark regulatory filings.

1R43DK117739-01 (Loree) 09/15/18-08/31/20

Source: NIH NIDDK SBIR Ph1 $195,621

Title: Ovine Study of Medical Device to Improve Arteriovenous Fistula Maturation
Description: Evaluate in vivo effectiveness of Arteriovenous Fistula Eligibility (AFE) System™, a small temporary wearable rotary blood pump system that rapidly and persistently dilates peripheral veins prior to arteriovenous fistula (AVF) surgery. Evaluate cephalic vein diameter before and after AFE System treatment and compare the maturation of AVFs made using AFE System-treated veins and untreated veins in ovine model.