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Workshop:Lessons Learned from Medical Systems Development

Workshop Moderators: Dr. Dorin Panescu and Dr. NicolasChbat

Keywords: Physiological monitoring devices; RF and microwave ablation; Robotic-assisted medicine

Dr. Catherine Mohr Senior Director, Medical Research Intuitive Surgical, Inc. Sunnyvale, California, USA

Lessons Learned using the daVinci 3-D Robotic Vision: Augmenting the Surgeon's Senses

The success of surgical robots depends heavily on the high quality three-dimensional capture of clinical images and the subsequent display of this clinical information to the surgeon. Until recently, these images were limited to reflected white light images, replicating what the surgeon could see. Currently, new imaging technologies that augment the surgeon's senses are being explored for use with less invasive robotic surgery. Dr. Mohr will explain how improved imaging has the potential to radically change the way surgery is performed. In particular, she will describe the technologies used at Intuitive Surgical that allow surgeons to operate through the small ports used in minimally invasive surgery. But unlike traditional laparoscopic surgery, the highly intuitive user interface provides an experience very much like that of performing open surgery.

Reese S. Terry, Jr. IEEE Life Fellow Founder of Cyberonics, Inc. BK Consulting Houston, Texas, USA

<u>Lessons Learned from the Development Therapies and Technologies based on Parasympathetic Nervous System Stimulation</u>

The study of the brain and parasympathetic nervous system (PNS) has improved our knowledge of the projections of the PNS into the brain and stimulated the formation of several companies that are investigating new therapies in clinical studies. The first PNS therapy approved was vagus nerve stimulation (VNS) to treat partial epilepsy seizures that failed other treatments. Over 100,000 devices have been implanted by Cyberonics. VNS Therapy for the treatment resistant depression was also approved by the US FDA.

Building on lessons learned from VNS technology development, Mr. Terry will review potential therapies that have emerged from Cunningham brain mapping. The presentation will also cover VNS treatment of congestive heart failure based on results from a 32 patient pilot study. Interest has been building on the possibility of PNS to promote brain re-wiring. In other significant applications, patient recruitment is underway for VNS treatment of traumatic brain injury (TBI) and for a study of VNS

treatment to improve stroke recovery. The talk will conclude with the presentation of positive results from pilot clinical studies achieved using devices that externally stimulate the vagus nerve.

Dr. Andrea Schenk Head of Liver Research Fraunhofer Institute for Medical Image Computing MEVIS Bremen, Germany

Lessons Learned from the Development of Liver Surgery Planning Systems

There are two major challenges facing liver surgery: The complex anatomy of the organ, with four interwoven vascular systems, and the requirement of leaving sufficient tissue after intervention. Especially in cases with multiple tumors, diseased organs, or in extended liver surgeries such as adult live liver transplantations, the decision about the optimal resection strategy is demanding.

In this talk, Dr. Schenk will provide a brief overview of the procedural steps in liver surgery planning and discuss lessons learned during system development and related research project. Aspects presented will include clinical requirements related to anatomical and functional image analysis, risk factors in tumor resections and their computation, as well as accuracy demands and limitations. Challenges and recent experience in the transfer of planning results into the operation room using navigation systems and mobile devices will conclude this section.

Dr. NicolasChbat Principal Member Research Staff Philips Research North America New York, New York, USA

Lessons Learned from Cardiopulmonary Decision Support Development

Dr. Chbat will review some challenging points in infusing advanced engineering methodologies to clinical medicine. Specifically, this section of the workshop will visit lessons that were learned from clinical decision support, algorithm development, metrics, and mathematical modeling targeted for clinical applications. Particular emphasis will be placed on system development for clinical applications targeted for the intensive-care-unit (ICU) environment.

Dr. Dorin Panescu, IEEE Fellow Senior Director, Product Development Intuitive Surgical, Inc. Sunnyvale, California, USA

Lessons Learned from the Development of Wearable Cardiac Remote Monitors

This section of the workshop focuses on engineering knowledge learned from developing cardiac remote monitoring devices. The discussion will provide a brief overview of cardiac signals, with an emphasis on detection of conditions such as atrial fibrillation and acute myocardial infarction. Engineering aspects related to the design of wearable remote monitors, patient interfaces and datalogging centers will be discussing. Developmental aspects of algorithms for detection of cardiac events will also be covered. Lastly, Dr. Panescu will review a summary of some engineering standards required for proving regulatory compliance for wearable remote patient monitors.

Workshop Panelists

Dr. Catherine Mohr Senior Director, Medical Research Intuitive Surgical, Inc. Sunnyvale, California, USA

Dr. Catherine Mohr is the Senior Director of Medical Research at Intuitive Surgical, a high technology surgical robotics company that makes the da Vinci Surgical System. In this role she evaluates new technologies for incorporation into the next generation of computer aided surgical platforms. In addition, she is a Consulting Assistant Professor in the department of Surgery at Stanford School of Medicine, and Faculty at Singularity University based at NASA Ames which studies the impact of exponentially changing technologies on our society.Dr. Mohr received her BS and MS in Mechanical Engineering from the Massachusetts Institute of Technology, and her MD from Stanford University School of Medicine. She has been involved with numerous startup companies in the areas of alternative energy transportation, and worked for many years developing high altitude aircraft and high efficiency fuel cell power systems, computer aided design software, and medical devices.Dr. Mohr has served as a scientific advisor for several startup companies in Silicon Valley, the NCI SBIR program, and government technology development programs in her native New Zealand. She is the author of numerous scientific publications, and the recipient of multiple design awards.

Reese S. Terry, Jr., IEEE Life Fellow Founder of Cyberonics, Inc. BK Consulting Houston, Texas, USA

Mr. Terry earned Bachelor and Master of Science degrees in Electrical Engineering from the University of Kentucky. In 1987, after holding key engineering positions with Cordis Corporation, now a division of Johnson and Johnson, and with Intermedics, Inc., Freeport, Texas, Mr. Terry co-founded Cyberonics, Inc. in Webster, Texas. Cyberonics was founded to develop, manufacture and market neuromodulation therapies for patients with epilepsy and other inadequately treated neurological disorders. There are over 4.7 million people living with epilepsy in the United States, Western Europe and Japan. For some of these individuals the Vagus Nerve Stimulation (VNS) Therapy using the CyberonicsNeuroCybernetic Prosthesis ("NCP") System has been proven to provide efficacious treatment. Mr. Terry served as board member of the South East Texas Chapter of the Epilepsy Foundation of America and the National Epilepsy Foundation of America. In 1993, Mr. Terry was awarded the Industrial Research, Inc. 100 Award for the CordisOmnicor Programmable Pacemaker; was nominated for the 1992 Smithsonian Institute and Computer World Advancement of the Year Award; the 1990 Houston Entrepreneur of the Year, and the 2009 Houston Health Care Innovation Hero. Mr. Terry holds numerous issued US patents, is an IEEE Life Fellow and the recipient of the 2012 IEEE EMBS Professional Career Award.

Dr. Andrea Schenk Head of Liver Research Fraunhofer Institute for Medical Image Computing MEVIS Bremen, Germany

Dr. Andrea Schenk is Head of Liver Research at the Fraunhofer Institute for Medical Image Computing MEVIS, Bremen, Germany. She studied Mathematics and Computer Science in Dublin and Dortmund and

graduated at the Technical University Dortmund in 1998. Dr. Schenk received a Ph.D. in Medical Engineering with Summa Cum Laude from the University of Bremen. Her research interests include image processing on all scales with different image modalities, morphological and functional liver analysis, and the transfer of research results into clinical applications and routine. She has coordinated several projects with clinical and industrial partners in Asia, US, and Europe.

Dr. NicolasChbat Principal Member Research Staff Philips Research North America New York, New York, USA

Dr. NicolasChbat is Principal Member Research Staff at Philips Research North America. He leads efforts in clinical decision support for cardiopulmonary medicine. Dr. Chbat received his PhD from Columbia University. Later, he joined General Electric Global Research Center (GE GRC) for 7 years. In 2000, Dr. Chbat won the Dushman Award, GE GRC's Highest Technical Team Achievement Award. Dr. Chbat then spent four years at the Mayo Clinic, Division of Engineering. In 2005, he won the Best Teacher of the Year Award from the Mayo Graduate School. Dr. Chbat holds 12 issued US patents, 5 filed patents, and 6 invention disclosures. He coauthored the book Discrete-Time Control Problems Using MATLAB, a chapter in a Healthcare Technology book, and has more than 20 publications. Dr. Chbat was awarded, as co-PI, three governmental grants (NIH and CMS) totaling more than \$17M in the past two years 2010-2012. In addition, Dr. Chbat is Adjunct Professor in the departments of Biomedical Engineering and Mechanical Engineering at Columbia University, where he is also chair of the External Advisory Board. Dr. Chbat is an IEEE-EMBS officer, where he is Theme Chair at the yearly IEEE EMBC conference. He was Conference Chair of the 2nd Annual AMA-IEEE conference 2011 in Boston. Dr. Chbat is the recipient of the 2013 EMBS Technical Achievement Award.

Dr. Dorin Panescu, IEEE Fellow Senior Director, Product Development Intuitive Surgical, Inc. Sunnyvale, California, USA

Dr. Dorin Panescu, is Senior Director for New Product Development with Intuitive Surgical, Inc., the world leader in the development of medical robotic technology and minimally invasive surgery. Previously, he held Research and Development leadership positions with other medical device companies, such as Boston Scientific Corporation and St. Jude Medical, Inc. Most recently, he was Chief Technical Officer with NewCardio, Inc., of Santa Clara, CA, USA, a start-up involved with software and equipment for cardiac diagnosis and remote patient monitoring. Dr. Panescu has over 145 issued US patents and over 130 publications to his credit. His patents and publications have topics mostly related to devices for cardiac diagnosis and therapy delivery. Dr. Panescu earned his Ph.D. and M.S. degrees in Electrical and Computer Engineering from the University of Wisconsin at Madison. He has a Bachelor of Science degree in Electronics and Telecommunications from the Polytechnic Institute, Timisoara, Romania. He held various offices with the IEEE Engineering in Medicine and Biology Society (EMBS), such as Chair of the Industry Relations Committee and past Chair of Therapeutic Systems and Technologies of the EMBS Technical Committee. Dr. Panescu is a Fellow of the IEEE, 2012 – 2013 EMBS Distinguished Lecturer, and Fellow of American Institute for Medical and Biological Engineering (AIMBE).