Nationally recognized cardiothoracic surgeon, scientist Dr. Todd Rosengart to lead BCM surgery

By Lori Williams

Dr. Todd Rosengart, nationally recognized cardiothoracic surgeon and a pioneer in gene therapy, has been named Chair of the Michael E. DeBakey Department of Surgery at Baylor College of Medicine.

“Dr. Rosengart has an impressive background as a cardiothoracic surgeon, scientist and educator, as well as the track record of a dynamic leader,” said Dr. Paul E. Klotman, BCM president and CEO. “He will provide innovative direction to this important area, while continuing the department’s legacy of excellence in patient care, scientific research and physician training.”

His appointment is effective Nov. 1.

Rosengart is coming to BCM from Stony Brook University, where he serves as professor and chair of the Department of Surgery, chief of the Division of Cardiothoracic Surgery and co-director of the Stony Brook University Heart Center. He also serves as president of Stony Brook Surgery Associates and board officer of the Stony Brook Clinical Practice Management Plan.

“It is truly an honor and a privilege to join the esteemed faculty of Baylor College of Medicine,” said Rosengart. “The history of the DeBakey Department of Surgery is one of the great traditions of modern medicine, and I look forward to joining these physicians and scientists as part of a new era of accomplishment.”

Rosengart is an NIH-supported scientist with nearly uninterrupted NIH funding since 1998, and has published extensively, most recently being named editor of *Seminars in Thoracic and Cardiovascular Surgery*. He was one of the early leaders in the field of gene therapy, with work beginning in the 1990s on gene transfer therapy and delivery and minimally invasive gene therapy delivery.

On November 5, he will present work at the national American Heart Association meetings in Los Angeles on a novel gene transfer strategy that appears capable of converting cardiac scar tissue directly into functional myocardium - representing a potential paradigm shift in the treatment of heart failure. As a physician-entrepreneur, he is co-founder of Vitals.com, a leading health provider search and physician-patient interface website with over 11 million monthly visits. He also holds nearly a dozen patents, including those for a method of inducing angiogenesis, a remote sensing gene therapy delivery device, and an apparatus for creating anastomoses.

He has mentored many trainees, both in scientific research and clinical work, receiving a number of teaching and research awards for this work.

Rosengart received both bachelors and medical degrees from the Honors Program at Northwestern University. He completed residency training at New York University Medical Center and was a medical fellow at the National Institutes of Health.

Prior to joining the faculty at Stony Brook University, he held positions on the faculty of Northwestern University where he was the inaugural Owen L. Coon Chair of Cardiothoracic Surgery at Evanston Northwestern Healthcare and at Weill Medical College of Cornell University. He has held positions with a number of national associations, including the American Association for Thoracic Surgery, Society of Thoracic Surgeons, American Heart Association, American College of Cardiology, and the 21st Century Cardiac Surgical Society.

He has served on the editorial board or as guest editor of several publications, including the *Journal of Thoracic and Cardiovascular Surgery*, *Seminars in Thoracic and Cardiovascular Surgery*, *CT Digest*, *Council of Cardiovascular Surgery and Anesthesia Newsletter*, and the *Journal of Clinical Laser Medicine and Surgery*. 
Unprecedented Study shows Berlin Heart device provides life-saving “bridge” for young children and babies
HOUSTON – (Aug. 8, 2012) – More than seven years ago Dr. Charles Fraser Jr., Surgeon In-Chief at Texas Children’s Hospital and the Susan V. Clayton Chair in the Michael E. DeBakey Department of Surgery at Baylor College of Medicine, first used a new heart pump device to keep an infant alive as he waited on a heart transplant. Today the child is well into his first year of grade school.

The success of that device, the Berlin Heart® EXCOR Pediatric Ventricular Assist Device (VAD), encouraged Fraser, who is also the Chief of the Division of Congenital Heart Surgery at BCM, to direct a study to determine its safety and effectiveness.

In a study coordinated by Fraser’s team at Texas Children’s Hospital, the tiny heart pump has been demonstrated to be effective and life-saving by maintaining blood flow in babies and small children with serious heart failure as they wait for a new heart. The results of the study, published in the New England Journal of Medicine, were compiled from 17 institutions led by Texas Children’s Hospital and Baylor College of Medicine.

The study found that patients who received the device, the only VAD available for babies and children, lived longer and were more likely to receive a transplant or recover heart function than children who were maintained on more traditional support using extracorporeal membrane oxygenation (ECMO).

“This study is unprecedented and represents broad collaboration among the top pediatric cardiac transplantation centers in North America, really the who’s who in the field,” Dr. Fraser was the primary author of the report and was national principal investigator of the study. “This study now becomes the gold standard for VAD therapies in children. Everything going forward will be compared to this.”

Before the Berlin Heart
Before the Berlin Heart, physicians used complicated medical therapies to treat children with heart failure, hoping to keep them alive until a suitable donor heart became available. Newborns and small children often died as they waited since no more than 70 or 80 small donor hearts become available each year. ECMO provided only short term support when the child’s heart failed completely. The Berlin Heart offers families a new ray of hope.

“With the Berlin Heart, we have a more effective therapy to offer patients earlier in the management of...
Congenital Heart Surgery (cont.)

their heart failure,” said Fraser. “When we sit with parents, we have real data to offer so they can make an informed decision. This is a giant step forward.”

Children on the device can leave the intensive care unit and go to a regular hospital room where they receive rehabilitation and better nutrition while they wait for a transplant. While there are many such devices available for adults, development and approval of devices for children and especially for babies has lagged.

Prospective study

“This prospective trial is unprecedented because it was not a look back at how children on the device had fared, but instead followed their clinical course from the device’s implantation. The results were compared to those of children who received ECMO, the only other method of treatment,” said Fraser, also chief of congenital heart surgery at Texas Children’s.

“We thought we knew a lot about this device and how it worked, but the FDA was insistent that we conduct a trial and they were right. We did not know as much as we should about how the device performs in practice.”

Higher survival rate

For example, he said the survival rate with the device was higher than anticipated and so was the stroke rate. While the stroke rate was of concern, residual effects from the stroke did not prevent most patients from receiving a transplant, the researchers note.

The Berlin Heart is not totally implanted inside the body. Physicians insert cannulas, or flexible tubes, in the heart and they extend through the skin and connect to a small pump located outside the body. That pump, along with its computerized drive unit, maintains blood flow.

Fraser and his colleagues in the United States and Canada compared the outcomes for 48 children (infants to 16 years) who received the device between 2007 and 2010 to matched patients in a national registry for those patients supported by ECMO. They divided the patients who received the German-manufactured heart assist device into two groups based on their body size.

Those in the cohort of smaller patients (average age 1 year) survived on the heart for a median time of 28 days compared to five days for the children on the ECMO device. The longest time a child in this cohort was on the Berlin Heart was 174 days compared to 21 days for the ECMO group. At 174 days, 88 percent of the children in the cohort had been successfully transplanted and 12 percent had died or failed weaning. In the comparison group, 25 percent of the children had died at 21 days and none were still on the ECMO device.

For children in the second cohort with a larger body size (average age 9), the median survival on the Berlin Heart was 43 days compared to five days for the ECMO group. The longest a child stayed on the assist device was 192 days; the longest a member of the matched group was on ECMO was 28 days. In the device group, 92 percent of the children who had received the VAD had been successfully transplanted or weaned off the device at 192 days and 8.3 percent had died. In contrast, 33 percent of the children in the ECMO group had died at 30 days and none were still on that device.

Some children did suffer serious side effects, including major bleeding, infection, stroke and high blood pressure. These findings are as important as the survival statistics because they set the stage for future development and refinement of these devices, said Fraser.

Humanitarian Device Exemption approval

The Berlin Heart EXCOR Pediatric Ventricular Assist Device was approved by the U.S. Food and Drug Administration (FDA) for use in children in 2011. That allows the device to be used as a bridge to transplantation. The Berlin Heart has been used in approximately 1,000 children worldwide.

The heart pump assists the ventricles – the pumping chambers of the heart – in circulating blood throughout the body. In most children with heart failure, the left ventricle fails and the device is used to assist its activities. In some patients, two devices are needed to support both ventricles. One of the big advantages of the Berlin Heart is that the pump is available in a variety of sizes and is thusly useful for children of all sizes.

Without the assistance of the device, children awaiting a transplant would become increasingly ill as their heart failed. The device improves their circulation and keeps them alive until they receive a heart transplant. In some rare instances, patients recover enough to come off the device and maintain blood flow on their own.

Designing the study

Fraser said a major limitation of the study was that it was not truly randomized – a method by which patients are assigned an experimental treatment or currently accepted treatment by chance, as in the flip of the coin.

“There was no way we were going to randomize patients. Even using ECMO as a comparison was difficult,” Fraser said. They drew their comparison patients from the Extracorporeal Life Support
HEALTH CARE POLICY AND MANAGEMENT CURRICULUM

The Health Care Policy and Management Curriculum was added to the surgery resident education program at the beginning of the 2012-2013 academic year. The curriculum was developed by the Health Care Policy and Management Workgroup led by Carla Braxton, MD, MBA (General Surgery), Alan Milewicz, MD, MBA (Pediatric Surgery); Stephen Whitney, MD, MBA (Pediatrics) and Nicole Tapia, MD (Surgery Resident). Each member of the workgroup brings unique talent, experience and area of interest to the curriculum planning process.

The goal of the new curriculum is to introduce pertinent topics in health care policy, management and in leadership and to ensure that by the time the surgery resident completes clinical training he or she has a general understanding of the language of the ‘business side’ of surgical practice. The three broad categories (modules) are divided into smaller subjects to facilitate coverage of most of the areas of study over a two-year period. Management and Clinical Practice, for example, includes the introduction of basic management principles as well as discussions on contracts, Relative Value Units (RVUs), quality/performance improvement, clinical practice models and litigation/risk management. The Health Care Policy module introduces the structure and policies of the US health care system, the history and consequences of major health care legislation, medical economics and financing, comparative effectiveness, health information technology and innovation, as well as other subjects. The Leadership module introduces the residents to organizational psychology, power and influence, personal leadership styles, ethics, communication, and negotiation/conflict resolution.

The curriculum will use a combination of Grand Rounds ‘broad scope’ presentations and resident small group case-based and interactive learning methods to achieve its prescribed learning outcomes. The group has taken advantage of the rich resources of the Medical Center area to draw nationally and internationally recognized experts in health care policy and legislation, advocacy, ethics, medical liability, organizational psychology and technology/innovation to share their knowledge and experience. All of the guests are enthusiastic about the opportunity to be a part of the BCM program. We are also tapping individuals within the Department of Surgery family with interest and expertise in surgical practice specifics, management, surgical quality, compliance, clinical practice models and patient safety to educate the residents in these specialized areas.

The curriculum facilitates compliance with the ACGME Core Curriculum under the broad categories of Professionalism, Systems-Based Practice, Interpersonal and Communication Skills and Practice-Based Learning and Improvement. Pre- and post-tests will be used to determine the effectiveness of the program, and to help us to tailor the material to the needs of the residents.

It is a privilege to be able to offer this course content to the BCM surgery residents. The current curriculum offering is not the first educational effort in management principles for the department. We hope that the design of the current program and its integration into the existing resident didactic schedule will become the standard for policy and management instruction within surgical education.

CARDIOTHORACIC SURGERY

Division of Cardiothoracic Surgery Hosts Joint Session of the Michael E. DeBakey and Denton A. Cooley Societies

In June 2012, the Division of Cardiothoracic Surgery hosted a milestone Joint Session of the 19th Congress of the Michael E. DeBakey International Surgical Society and the 18th Symposium of the Denton A. Cooley Cardiovascular Surgical Society at Barton Creek in Austin. Dr. Joseph Coselli, of Baylor College of Medicine, President of the Cooley Society and Dr. Robert Salem, of Lubbock, President of the DeBakey Society served as activity co-hosts for the landmark session. For only the second time in history, this Joint Session brought together these two societies which separately have recognized and celebrated the mentorship of their namesakes for many years. These educational and scientific programs, part of a unique forum geared toward providing important updates on the latest advances in cardiovascular and general surgery, honored these two great legends.

In addition to the acclaimed program (previously featured in the Department of Surgery Newsletter), memorable highlights of the session included the recognition of Dr. Jimmy Howell for a lifetime commitment to the profession, the premier of the Michael E. DeBakey documentary film, DeBakey, and a very special and unforgettable presentation by Dr. Denton Cooley, who delivered an informal
Cardiothoracic Surgery (cont.)

For eight weeks, I had the exceptional opportunity to be part of the Michael E. DeBakey Summer Surgery Program through the Department of Surgery at BCM. This year, ten students were chosen and assigned different mentors in various disciplines spanning six affiliated teaching hospitals within the Texas Medical Center. It began with an orientation to the operating room and sterile technique. Afterwards, we each left for our respective hospitals, spending our weeks participating and building rapport with our mentors and surgical teams. Eleven exclusive brown bag lectures from physicians such as Melvyn Harrington, MD, and Mimi Leong, MD, helped join us together every week to share our experiences and also learn about various subjects from surgery specialties to skills needed to succeed in medical school.

Shadowing William E. Fisher, MD, closely, I saw him kindly attending patients, clearly explaining difficult matters, comforting them throughout their stay, and closely following their journey from admittance to successful recovery. Throughout many cases, I watched him share lovely humor with the whole staff and distinctly remember standing beside him during that long day as he performed the Whipple procedure, speaking little, intensely focused, and working with remarkable speed and dexterity.

In this program, I learned technical procedures, built a strong operating room discipline and skilled teamwork with the staff. This experience reinforced my conviction that this is the career that I want to build. I applied to Baylor College of Medicine for fall 2013 and hope to get accepted. Thank you to all who planned the program and gave us this excellent opportunity.

The Summer Surgery Program is directed by Bradford G. Scott, MD, who opened his house to the whole student program and was very hospitable. The author, Jean Ghosn, is a senior at Houston Baptist University majoring in Biochemistry/Molecular Biology.

SUMMER SURGERY PROGRAM

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EXPERIMENTAL SURGERY AND SURGICAL TRAINING LABORATORIES

The Experimental Lab has yielded life-saving medical devices including the artificial heart, ventricular assist devices, autologous blood salvage, and innovative surgical approaches such as stem cell and gene therapies.
Research Services
Our research support services include dedicated surgical facilities, instrumentation, support equipment, trained surgical support staff and assistance with protocol development. The laboratories include two surgical rooms, one imaging room, and sterilization, storage and preparations areas.

Education Services
The experimental lab is a comprehensive resource for surgical learning with activities that support continuing medical education (CME) organizations and the biomedical industry.

The two operating rooms are configurable to handle up to 7 training stations. The lab includes four video stations for hands-on, basic and laparoscopic skills training, while the imaging room is equipped with a portable fluoroscopy unit.

ELKINS PANCREAS CENTER
Please join us in welcoming George Van Buren II, MD. Dr. Van Buren is an assistant professor of surgery in the Division of Surgical Oncology of the Michael E. DeBakey Department of Surgery at Baylor College of Medicine. He is a board-certified surgeon specializing in surgical oncology and pancreatic disorders.

Dr. Van Buren earned his undergraduate degree at The University of Texas at Austin and his medical degree at The University of Texas Medical School at Houston. He completed his general surgery residency at The University of Texas Medical School at Houston. During that time period, he spent two years at MD Anderson Cancer Center as an NIH T32 research fellow studying pancreatic cancer, colorectal cancer, and neuroendocrine tumors. He completed his surgical oncology fellowship at the University of Pittsburgh Medical Center in the Translational Pancreas Research Track.

During Dr. Van Buren’s research and clinical fellowships, he was able to expand upon his interest in gastrointestinal surgical oncology. Specifically, his training had a heavy emphasis on upper gastrointestinal and hepatobiliary malignancies with exposure to a wide breadth of cases, including specialized procedures such as robotic pancreatic surgery and minimally invasive lower gastrointestinal surgery.

Dr. Van Buren is active in both patient care and research. He has been involved in both basic science and clinical research and believes heavily in the surgeon’s role as a leader of the translational research team. His goals are to provide high quality clinical care while offering his patients access to innovative clinical and therapeutic trials.

VASULAR SURGERY AND ENDOVASCULAR THERAPY
Carlos F. Bechara, MD, assistant professor of surgery in the Division of Vascular Surgery and Endovascular Therapy recently developed and published an endovascular technique to treat a complex vascular problem. The technique will be featured during the VITH 39th Annual Symposium on Vascular and Endovascular Issues in New York this year. The VEITH Symposium is one of the world’s largest gatherings of Vascular Surgeons and vascular specialists to discuss groundbreaking research, updates on clinical trials and more on vascular disease. The technique was published in the Journal of Vascular Surgery.

Flush Iliac artery occlusion is a difficult problem to treat with minimally invasive surgery using a stent and is most often treated by open bypass surgery. Dr.

Continued next page >> >>
Organization registry based in Ann Arbor, Michigan. They matched each patient who received the Berlin Heart to two closely comparable individuals in the registry. While using these historical control patients was difficult, it was the only ethical method of obtaining comparison, Fraser said he believes the study will provide important information for the future.

“I don’t think we are far from a small, implantable VAD in children,” he said. “The implantable devices will be less cumbersome. There are approved, fully implantable devices already available for adults. This gives us the drive to push even further for more devices like this that may be life-saving options for these children who have no other treatment options.”

Under Fraser’s leadership, more Berlin Heart devices were implanted at Texas Children’s Hospital by BCM surgeons during the course of the study than any other center. The Texas Children’s Hospital pediatric heart failure team includes one of the most comprehensive pediatric ventricular assist device programs in the world.

Others who took part in the study include Drs. Robert D.B. Jaquiss of Duke Children’s Hospital and Duke University School of Medicine in Durham, North Carolina; David N. Rosenthal of Lucile Packard Children’s Hospital and Stanford University School of Medicine in California; Tilman Humph of the Hospital for Sick Children and the University of Toronto in Canada; Charles E. Canter of St. Louis Children’s Hospital and the University of Washington in St. Louis, Mo.; Eugene H. Blackstone of the Cleveland Clinic and Lerner College of Medicine Of Case Western Reserve University in Cleveland, Ohio; David C. Nafte1 and F. Bennett Pearce, of the University of Alabama School of Medicine; Rebecca N. Ichord of Children’s Hospital of Philadelphia and Perelman School of Medicine of the University of Pennsylvania in Philadelphia; Lisa Bomgaars and Kathleen E. Carberry, RN, MPH, of Texas Children’s; James S. Tweddell of Children’s Hospital of Wisconsin and Medical College of Wisconsin in Milwaukee; Patricia Massicotte of Stollery Children’s Hospital and University of Alberta School of Medicine in Edmonton, Alberta; Mark W. Turrentine of Riley Hospital for Children and Indiana University School of Medicine in Indianapolis; Gordon A. Cohen of Seattle Children’s Hospital and University of Washington School of Medicine in Seattle; Eric J. Devaney of C.S. Mott Children’s Hospital and University of Michigan Health System in Ann Arbor; Robert Kroslovitz of Berlin Heart Inc., of The Woodlands Texas and Christopher S. Almond of Children’s Hospital Boston and Harvard Medical School.

Funding for this study came from the U.S. FDA’s Office of Orphan Product Development and Berlin Heart Inc.

Dr. Fraser holds the Clayton Chair in Surgery and the Donovan Chair in Congenital Heart Surgery at TCH.