INVITED PAPER

Mechanical Circulatory Assist Device Development at the Texas Heart Institute: A Personal Perspective

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In December 2013, we performed our 1000th ventricular assist device implantation at the Texas Heart Institute. In my professional career, I have been fortunate to see the development of numerous mechanical circulatory support devices for the treatment of patients with advanced heart failure. In fact, most of the cardiac pumps in wide use today were developed in the Texas Heart Institute research laboratories in cooperation with the National Heart, Lung and Blood Institute or device innovators and manufacturers and implanted clinically at our partner St. Luke's Episcopal Hospital. My early involvement in this field was guided by my mentors, Dr Michael E. DeBakey and, especially, Dr Denton A. Cooley. Also, many of the advances are directly attributable to my ongoing clinical experience. What I learned daily in my surgical practice allowed me to bring insights to the development of this technology that a laboratory researcher alone might not have had. Young academic surgeons interested in this field might be well served to be active not only in laboratory research but also in clinical practice.

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I first became involved in the field of mechanical circulatory support in 1965 as a student at Baylor University Medical School. The previous year, Dr Michael DeBakey had been awarded the first federal grant for establishing a program at Baylor to develop a total artificial heart (TAH). For my second-year research project, I worked with Dr Domingo Liotta, under DeBakey's supervision, to develop and test the TAH. At that time, Dr Denton Cooley was on the faculty at Baylor, and he was also interested in artificial devices.

As a senior medical student at Baylor, I had an experience that further focused my interest on artificial hearts. I scrubbed in for an aortic valve replacement in a young Italian boy whose case I had worked up earlier. He seemed to be doing well after the operation. But the night of the surgery, his heart fibrillated. We opened his chest in the recovery room, and I began massaging his heart. As long as I massaged his heart, he was alive… awake… looking at me. But despite our efforts, he died. It occurred to me then that if my hand could keep this young boy alive, why couldn't we make a pump that would keep him alive?

The next year, in 1969, Dr Denton Cooley implanted a TAH in a human for the first time, with the assistance of Dr Liotta.[1] Because that operation resulted in considerable controversy, Cooley and Liotta resigned from Baylor, and the device program there was discontinued. Dr DeBakey did not to speak to Cooley for the next 38 years. Dr Cooley started his own device program at the Texas Heart Institute (THI), which he had founded in 1962. Although Cooley had the world's largest heart transplant program, his outcomes and those of others were poor, so by 1971, he and most other surgeons had stopped doing transplants. As a result, the Devices and Technology Branch of the National Heart and Lung Institute under the direction of John Watson—now the National Heart, Lung and Blood Institute (NHLBI)—changed its focus to support

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development of a long-term (destination) left ventricular assist device (LVAD). This became the main goal of THI's Surgical Research Laboratory, which Cooley established at THI in 1972. The laboratory was initially directed by Dr John Norman, who had come from Boston.

I began my cardiac training at THI under Dr Cooley in 1974, after completing my general surgery residency under Dr DeBakey. I made the decision to go to THI so that I could continue device research. Although I thought my decision to leave Baylor for THI would go unnoticed, Dr DeBakey did not speak to me for another 10 years.

In 1981, when Dr Norman left THI, I was appointed director of the research laboratory. I have now been involved in the research and clinical development of mechanical circulatory support for nearly half a century.

ABDOMINAL LVAD

With NHLBI support, our THI laboratory worked on developing an abdominally positioned, pulsatile-flow LVAD. Between 1975 and 1980, 22 patients were supported with this device, and the series included the first bridge-to-transplant with an LVAD in 1978.[2] The device was indicated mainly for postcardiotomy shock, to provide support until the heart could recover. Although the LVAD functioned well, the delay before implantation was so long that the patients were already too sick to recover, and there were no long-term survivors.

In our laboratory, research was also underway to develop a destination-therapy LVAD. Our primary engineering partner was Boston-based Thermo Cardiosystems. The request for proposal called for a device with primary goals of reliable 2-year durability, transcutaneous power, and up to 12 L/min of flow. In pursuing these goals, we encountered 2 important barriers: compliance-chamber performance and inflow-graft occlusion. The compliance chamber was necessary to compensate for volume displacement behind the pump diaphragm. Despite extensive research, we could not achieve 2-year compliance-chamber durability. To solve this problem, I suggested simple percutaneous venting to the atmosphere, an idea that was based on my experience with chronic venting of bronchopleural fistulas in tuberculosis patients. With percutaneous venting, transcutaneous power became unnecessary.

The other problem that nearly led to failure of our LVAD program was inflow-graft occlusion. Possibly, Dr DeBakey should be credited for solving this problem. When I was an intern, he reprimanded me for asking him why a patient's femoral-popliteal graft kept occluding. After "frogging" me in the chest (a common occurrence in those days), he said and made me repeat, "When blood stops moving, it clots. Got that? When blood stops moving, it clots." I never forgot that incident. Because the early LVAD design included a long inflow graft, blood stoppage occurred during systole, a condition that led to accelerated pannus formation and graft occlusion. I solved this problem by simply shortening the inflow graft so that the pump was juxtaposed to the heart, minimizing stasis and controlling pannus.[3]

In 1994, this pump (the pneumatic HeartMate) became the first implantable device to be approved by the Food and Drug Administration (FDA) as a bridge to transplantation.[4,5] Without the solution of these 2 problems, which represented finite barriers to further pump development, this milestone would not have been achieved.

BRIDGE TO TRANSPLANTATION

The world's first 3 clinical bridge-to-transplant experiences (2 TAHs and 1 LVAD) occurred at THI.[6,7] All 3 patients died of septic complications. After cyclosporine was introduced (a more forgiving immunosuppressant), we and others had renewed interest in cardiac transplantation. Our early transplant experience was favorable, even in patients with active sepsis.[8] This also encouraged us to begin a new bridge-to-transplant program.

In 1986, I implanted the first HeartMate as a bridge to transplantation. Although developed for destination therapy, it was clearly satisfactory as a bridging device. Our favorable initial experience with this device as a bridge to transplantation is what led to its widespread use and ultimate FDA approval.[4]

In 1991, I implanted the first electrically powered HeartMate LVAD. After more than 500 days of support, that patient became the first to be discharged from the hospital with an LVAD (Fig. 1).[9] In 1999, the untethered HeartMate XVE was selected for the REMATCH trial (Randomized Evaluation of Mechanical Assistance for the Treatment of Congestive Heart Failure).[10,11] That trial, led by Dr Eric Rose, resulted in the first FDA approval of an LVAD for destination therapy, thus achieving the original goal of the NHLBI request for proposal issued more than 20 years earlier.

BIOMEDICUS CENTRIFUGAL-FORCE LVAD

I became interested in a continuous-flow assist device for ventricular support early in my professional career. I had used the extracorporeal BioMedicus centrifugal-force pump for both a short-term LVAD and an extracorporeal membrane oxygenator, and this experience convinced me that continuous flow might also work for long-term support. I also remembered being fascinated by an embryology