Thoracic and Cardiovascular Surgery

Total Artificial Heart—Concepts and Clinical Use

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End-stage congestive heart failure remains the leading cause of death in the United States. Despite advances in medical treatment, it also remains the most common reason for admission to the hospital. The gold standard of treatment for the failing heart, orthotopic heart transplantation, is limited by a shortage of donor hearts. There are also a significant number of patients who are not transplant candidates due to comorbid conditions and/or inability to tolerate immunosuppressive therapy. To meet the need for this latter group, the medical field has embraced ventricular assist device (VAD) therapy to extend survival and improve quality-of-life for the end-stage cardiac patient. This therapy, however, has been currently limited to the failing left ventricle and is still fraught with complications that limit long-term and widespread use. The total artificial heart, as currently available with two devices, is rapidly becoming the treatment of choice for biventricular failure.
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Total replacement of the failing heart with a mechanical pump has been the Holy Grail for cardiac surgeons for decades. The U.S. Artificial Heart Program was begun in 1964 under President Johnson. This was at the behest of surgeons such as William DeBakey and Willem Kolff who, with others, visualized and pioneered early work to create a total artificial heart (TAH).[1] A number of iterations of complete replacement of the failing heart have been developed and tested clinically. These include the Liotta heart,[2] the Akutsu TAH,[3] and the trailblazing Jarvik-7.[4]

In the 21st century, this goal is on the horizon, as the total artificial heart (TAH), in two differing conceptualizations, has been tested in feasibility trials. The two devices that are now commercially available are the CardioWest TAH (Syncardia Systems, Inc., Tucson, AZ), and the AbioCor TAH (Abiomed, Inc., Danvers, MA). The CardioWest TAH (hereinafter referred to as the TAH-t) has reached significant clinical use and, thus, full FDA approval in 2004 as a bridge to transplant. The AbioCor implantable replacement heart (referred to as the TAH-irh) received FDA approval in 2006, under the Humanitarian Use Device (HUD) provision of the Food, Drug, and Cosmetic Act, for destination therapy. Their concepts of design, indications for their use, methods of implantation, patient management regimens, and clinical experiences are presented below.

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Devices—Concept of Design

CardioWest TAH

The CardioWest TAH is an iteration of the original Jarvik-7. A pair of prosthetic ventricles, made of polyurethane, is pneumatically driven and provides pulsatile flow (Fig. 1).

The prosthetic ventricles, made of biocompatible polyurethane, have a capacity of 70 mL. The ventricles are pneumatically driven and there are four flexible polyurethane diaphragms between the blood surface and the air sac. When compressed air is forced into the air sacs simultaneously, compression is effected onto the blood sac and ejection occurs in simulation of cardiac systole. Cardiac ejection in the TAH-t thus occurs in parallel from the left and right side. As the air sac is deflated, the blood sac is filled passively from the atrial connection. This can be altered slightly by adding a small amount of vacuum to the prosthetic ventricle. Two mechanical valves are situated along the prosthetic ventricle to provide unidirectional inflow and outflow. These are single-leaflet Medtronic-Hall valves, respectively sized 27 mm (for inflow to the ventricle) and 25 mm (for outflow from the ventricle). The large valves and short outflow blood path are advantageous in decreasing stasis and thrombosis (Fig. 2).

The ventricles are also configured slightly differently. The left-sided ventricle has inflow and outflow valves slightly closer together to match the proximity of the mi-

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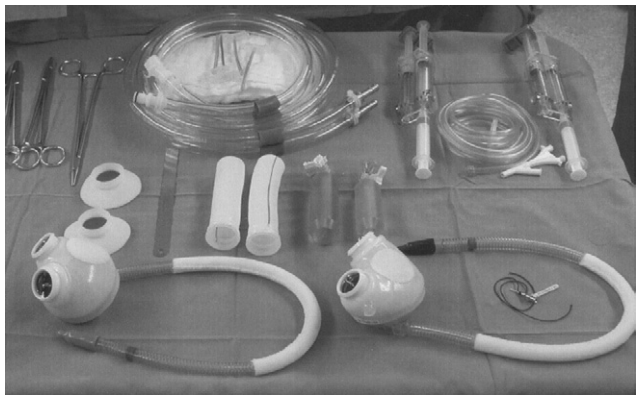

Figure 1 TAH-t components. (Courtesy of Syncardia Systems, Inc.)

tral annulus to the aorta. The right-sided ventricle is farther apart to not only reflect the slightly greater distance between the tricuspid annulus and the pulmonary artery but also to allow the pulmonary outflow graft to override the aortic outflow graft.

The prosthetic ventricles are connected via quick-connect silicone cuffs to two atrial connectors on the cuffs and two connectors on the end of the grafts sewn to the aorta and pulmonary artery. Of high importance, in the process of cardiectomy, great care must be maintained to preserve the atrial annuli. This not only gives needed strength to the connection but is a hemostatic boon to suturing to atrial tissue. The device atrial cuffs are trimmed to approximately 3 to 5 mm to minimize thrombotic surface area.

The compressed air is delivered via an external console through two separate air tubes connected to the right and left prosthetic ventricles. The console has two independent controllers that allow redundancy for emergency backup. Compressed air cylinders inside the console can be used to mobilize the patient. Maximum stroke volume is 70 mL but, ideally, partial fill and full ejection is the goal. Generally this is about 50 to 55 mL. Partial fill allows for stroke volume alteration as the patient's volume status changes. Full ejection

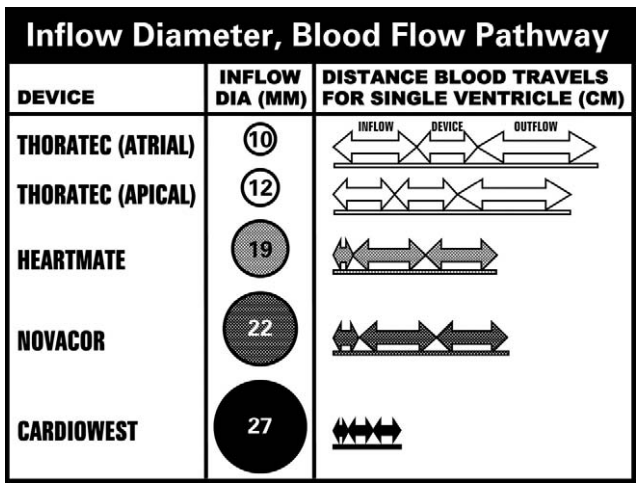

Figure 2 Inflow comparison of VAD/TAH. (Courtesy of Richard Smith, MSEE, CCE.)

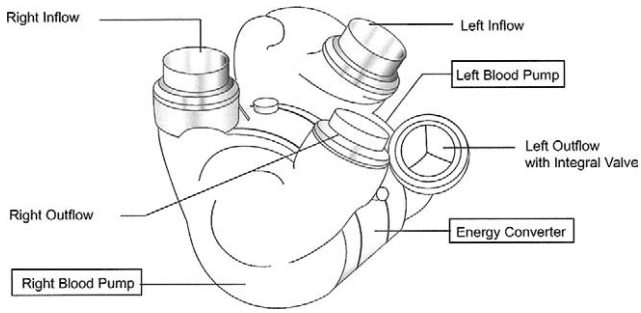

Figure 3 TAH-t design. (Courtesy of Abiomed, Inc.)

maximizes cardiac output and ventricular washing with minimal changes to the controller settings. A diagnostic unit (laptop on the console) from the console presents parameters of the TAH-t, stores data, and configures the system. Pressure waveforms are displayed beat-to-beat for each cardiac cycle, as well as for the continuum of support. Of note, if the laptop unit malfunctions or loses power, the TAH-t will continue to function. The pressure waveforms displayed confirm full ejection of the ventricles. The drive flow waveforms, also displayed concurrently, mark the beginning and end of diastole and calculate fill volumes. These drive flow waveforms help determine the partial fill and volume status.

The large console, although mobile, does not allow for discharge from the hospital. Newer portable drivers, which have been tested in Europe, are undergoing trial currently in the United States.

AbioCor TAH

The AbioCor TAH (Fig. 3) consists mainly of a thoracic unit, which houses two blood pumps in one housing, separated by an energy converter. Each blood pump is a hard-shelled chamber containing a blood sac, which has inflow and outflow valves. The inner lining of this chamber, including the trileaflet valves, are made and lined seamlessly from a proprietary membrane termed Angioflex. Hydraulic fluid fills the space between the blood sacs and the energy converter. When the hydraulic fluid is moved from one side to the other, the blood is squeezed in one chamber, thus effecting systole. During this part of the cycle, blood is actively drawn into the other pump, filling it for the next cycle, thus effecting systole. The left and right blood pumps alternately eject blood. A true innovation, this engenders that the left and right "hearts" are ejecting in series, and not in parallel (Fig. 4). Furthermore, the thoracic unit is an actively filled device, rather than allowing passive filling. Low atrial, or filling, pressures can therefore limit inflow and decreased pump output.

The energy converter consists of a unidirectional hydraulic pump that spins at 3,000 to 10,000 rpm to pressurize the hydraulic fluid. A bidirectional switching flow control valve directs flow of the hydraulic fluid toward either side of the energy converter, or simply toward each of the ventricles. These components, including pressure transducers that measure the hydraulic fluid pressure on each side, are mounted in a metal artificial septum.

The pumping chambers contain one-way inflow and out-