The AbioCor implantable replacement heart
Robert D. Dowling, Laman A. Gray, Jr, Steven W. Etoch, Hillel Laks, Daniel Marelli, Louis Samuels, John Entwistle, Greg Couper, Gus J. Vlahakes and O. H. Frazier

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The incidence of congestive heart failure is high in all developed countries and continues to increase particularly with aging of the population. Despite advances in medical therapy, the prognosis with heart failure remains poor [1]. A recent population-based study demonstrated survival from the initial diagnosis of heart failure was worse than survival associated with common malignancies, with the exception of lung cancer [2]. Conservative estimates indicate that a considerable number of patients would benefit from some form of cardiac replacement therapy. Currently the only form of cardiac replacement therapy is heart transplantation, which is limited to slightly more than 2,000 heart transplants being performed each year in the United States. Furthermore, in 3 of the last 4 years that number of heart transplants performed has decreased [3]. Clearly alternative therapies are needed to address the increasing numbers of patients with end-stage heart failure.

The AbioCor implantable replacement heart (IRH) is the first available totally implantable artificial heart. We recently initiated a multicenter trial of this device in patients with severe, irreversible biventricular failure. Patients who were not candidates for other therapies, including transplantation, were evaluated. All candidates were adults with inotrope-dependent biventricular failure, whose 30-day predicted mortality was higher than 70%. A three-dimensional computerized fit study predicted fit of the AbioCor thoracic unit in all recipients. At operation, the internal battery controller and transcutaneous energy transfer unit were placed. The AbioCor thoracic unit was placed in an orthotopic position after incision of the ventricles. There were 2 intraoperative deaths (due to intraoperative bleeding or aprotinin reactions). Four late deaths were recorded, 1 from multisystem organ failure and 3 cerebrovascular accidents. Autopsy revealed thrombus on the atrial struts of the 3 patients with cerebrovascular accident. Blood pumps and valves were clean on all patients. Significant morbidity was observed, primarily related to preexisting severity of illness. However, 3 patients recovered to the point of being able to take multiple trips outside of the hospital. Two patients were discharged from the hospital, with 1 patient being discharged home for more than 7 months. No significant device malfunctions or multi-system organ failure device-related infections were noted. The AbioCor IRH may be effective therapy for patients with end-stage heart failure. Many milestones have been achieved in the initial trial in humans, including the successful discharge of a patient to home and no significant device malfunctions. The occurrence of stroke is likely related to the presence of thrombus on the atrial struts and may be decreased as these atrial struts have been removed for future clinical implants.

Device Description

The AbioCor IRH system is the first artificial heart system that does not require percutaneous lines or the need for percutaneous access [4]. This system consists of both external and internal components. The four internal components are the AbioCor thoracic unit, battery, controller and transcutaneous energy transfer (TET) coil (Fig 1). The AbioCor thoracic unit (Fig 2) is placed in the chest in an orthotopic position after excision of the native ventricles. The thoracic unit consists of an energy converter and two pumping chambers that function as the

Material and Methods

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left and right ventricles. The energy converter is situated between the ventricles and contains a high-efficiency miniature centrifugal pump that operates unidirectionally to pressurize a low-viscosity hydraulic fluid. A two-position switching valve is used to alternate the direction of hydraulic flow between the left and right pumping chambers that result in alternate left and right systole. The rate of the switching valve determines the beat rate of the device and can be varied between 75 and 150 BPM, resulting in a range of flows from 4 to 8 L/min. An atrial balance chamber is present and allows for decreased right-sided stroke volume to maintain right and left balance [5, 6]. A portion of hydraulic fluid is shunted into the balance chamber rather than to the right hydraulic pumping chamber. The pump motor impeller and the switching valve are the major moving parts of the energy converter. All blood contacting surfaces of the AbioCor thoracic unit including the trileaflet valves (24 mm internal diameter) is polyether urethane (Angioflex [ABIOMED, Inc, Danvers, MA]) resulting in a smooth, continuous blood-contacting surface from the inflow cuffs to the outflow grafts.

The internal battery is lithium-ion based and is able to power the thoracic unit for brief (up to 20 minutes) periods of time. The internal controller drives the energy converter in the thoracic unit, monitors the implanted components, and transmits device performance data to a bedside console through radiofrequency (RF) telemetry. These RF transmissions from the internal controller to the external console convey information including continuous real time telemetry of hydraulic pressure waveforms, system operating parameters, battery status, component temperature, and alarm information. The internal TET coil receives high frequency power that is transmitted across the skin from the external TET coil. The internal TET system electronics convert this oscillating current to a direct current that is used to power the thoracic unit and to recharge the internal battery.

The four external components consist of an external TET coil, batteries, a TET module, and a bedside console (Fig 3). The external TET coil transfers energy across the skin to the internal TET coil and is secured over the internal TET coil with an adhesive dressing [7]. The external TET coil can be connected to either the bedside console or a portable TET module. When the patient is ambulatory, the external TET coil is connected to the portable TET module. The TET module delivers energy to the TET coil from external batteries and contains basic alarm systems that are activated in the event of TET coil misalignment, low external battery voltage, or a general alarm indicating a potential problem with the system that is determined by reestablishing RF communication with the bedside console. The bedside console is used during implantation, recovery, and when the patient is in his or her primary residence. The bedside console provides clinicians with a graphic user interface for control and monitoring of the implanted system through RF communication. The console can be remotely monitored when connected to a telephone jack by a laptop computer. The external batteries are lithium-ion based and are able to
provide up to 1 hour of support per pound of battery. The external batteries can either be carried in a vest or a handbag, or attached to a Velcro belt.

**Clinical Trial Design**

Food and Drug Administration approval for initiation of a multicenter clinical trial was granted in January 2001. The institutional review board at each of the institutions approved the clinical protocol. The centers involved in this clinical trial are Hahnemann University, Massachusetts General Hospital/Brigham and Women’s Hospital, Texas Heart Institute, University of California at Los Angeles, and University of Louisville.

The AbioCor IRH is intended for use as destination therapy. The design of the clinical trial has been described previously [4]. Patients who were candidates for other types of therapy including heart transplantation were not considered for this trial. Potential candidates must be adult patients with biventricular failure who are on maximal medical therapy and dependent on inotropic agents or unable to tolerate inotropic agents due to severe arrhythmias. All patients who are candidates have a 30-day predicted mortality of more than 70% based on the AbioScore prognostic model or acute myocardial infarction shock scores [8]. The AbioScore mortality prediction model was developed based on previous prognostic models with selection of measurements that had the highest prognostic value for mortality in patients with end-stage heart failure. Prognostic variables include laboratory and clinical measurements such as age, serum sodium, renal function, need for inotropic agents or intraaortic balloon pump, body mass index, left ventricular end-diastolic diameter, peak exercise oxygen consumption, and New York Heart Association functional class. Exclusion criteria include active infection, severe peripheral vascular disease, blood dyscrasia, and recent stroke or transient ischemic attack (TIA) due to atherosclerotic disease. All potential recipients undergo a complete psychosocial evaluation. If the initial screening indicates the patient is a potential candidate, a computerized tomography scan of the chest is performed.

A sophisticated software program allows for a virtual surgery implant of the AbioCor thoracic unit. The native ventricles are removed and the AbioCor thoracic unit is implanted as would be performed at operation. This virtual model allows the surgeon to determine if the AbioCor thoracic unit can be positioned in the chest without impairing on vital structures such as the left pulmonary veins and the left lower lobe bronchus. The surgical implant team must have a high degree of certainty that the AbioCor thoracic unit will fit in the chest before proceeding with operative implantation.

The primary end point of this trial is to determine the effect of the AbioCor on all-cause mortality in patients with severe heart failure and a predicted life expectancy of less than 30 days despite optimized medical management. Secondary end points include determination of adverse events, device malfunctions, or complications related to the presence of the device and quality of life.

**Operative Approach**

The operative approach has been described previously [4]. At operation, an infraclavicular incision is made and the internal TET coil is placed anterior to the pectoral muscle fascia. A median sternotomy incision is then made and the cable from the internal TET coil is passed to the lower part of the sternotomy incision. The incision over the TET coil is then closed in layers.

The internal TET coil is placed before heparinization to decrease the likelihood of a pocket wound hematoma. A sternal retractor is placed and a pericardial cradle is created. Dissection for placement of the internal battery and controller is performed in either the preperitoneal space or deep to the rectus abdominus muscle. Caval tapes are placed and heparin is given. Cannulation of the aorta or femoral artery is performed depending on the length of aorta available, as many of these patients will have had previous cardiac surgery. A superior vena cava cannula is placed and a femoral venous cannula is placed and guided up into an appropriate position. Cardiopulmonary bypass is initiated, the caval tapes are snared down, and the aorta is cross-clamped. The right and left ventricles are excised just below the atrioventricular groove to allow for anastomosis at the level of the annuli. The mitral and tricuspid valve leaflets are excised. The left atrial appendage is ligated, then the coronary sinus and patent foramen ovale (if present) are oversewn. The left atrial cuff of the device is trimmed to an appropriate dimension and sewn to the native left atrium at the level of the annulus using two layers of running 4-0 Prolene (Ethicon, Somerville, NJ) reinforced with felt strips.

Leak testing is performed after the creation of each anastomosis to decrease the likelihood of suture line bleeding or air entrainment after placement of the de-
vice. Anastomosis of the right atrial cuff to the native right atrium is then performed in similar fashion followed by leak testing. A cast model of the AbioCor thoracic unit is positioned in the chest to determine the appropriate length and orientation of the outflow grafts to the aorta and pulmonary artery. These outflow grafts are then sewn end-to-end to the great vessels with running 4-0 Prolene suture. The aortic outflow graft is positioned anterior to the pulmonary artery graft.

The AbioCor thoracic unit is then brought up to the operative field and appropriate electrical connections are made. The thoracic unit is placed in the pericardial space and attached to the left atrial cuff and outflow grafts by snap-lock connectors. The right ventricle of the thoracic unit is filled with saline and the right atrial cuff is connected to the device. The caval tapes are released and air is completely removed from the device by allowing blood and air to be ejected through the side ports arising from the outflow grafts. Once air has been removed from the right side of the heart, the side port of the pulmonary artery (PA) outflow graft is occluded. Air is then removed from the left side of the heart through the side port on the aortic outflow graft. The device flow is increased up to 4 to 5 L/min with the cross-clamp on and all the blood ejected through the side port of the left outflow graft and returned to the cardiopulmonary bypass circuit.

Once enough air has been removed from the device, the cross-clamp is removed, the left side port is occluded, and the patient is weaned from cardiopulmonary bypass onto full device support. The left and right filling pressures are monitored and used to determine the beat rate and to adjust the balance chamber. Protamine is administered after demonstrating adequate hemodynamics. The sternal edges are approximated and transesophageal echocardiography is performed to determine if there is impaired flow in the left pulmonary veins. Increased pulmonary vein flow velocity dictates the need to reposition the thoracic unit caudally or anteriorly. Repositioning is readily accomplished by placing sutures through the eyelets on the thoracic unit and around the left lower ribs. Irrigation with topical antibiotics is performed following by standard wound closure. Prophylactic intravenous antibiotics are given per each center’s protocol. The anesthetic management for these patients has been described previously [9].

Anticoagulation Management

Anticoagulation has been with antiplatelet therapy and heparin followed by warfarin. Routine monitoring has been with assessment of platelet aggregation, partial thromboplastin time, and international normalized ratio. The goal of therapy is to maintain an international normalized ratio between 2.5 and 3.5. Some centers have also used daily thromboelastograms to guide the anticoagulation therapy. With this approach the goal is to maintain a normal coagulation index [4], which has been achieved with warfarin and aggressive antiplatelet therapy. Platelet aggregation is usually maintained at 50% of normal. Initial antiplatelet therapy is with low-dose aspirin unless significant gastritis is present, in which case clopidogrel sulfate is used. Often, a combination of aspirin, clopidogrel sulfate, and dipyridamole are used to achieve a normal coagulation index and a therapeutic platelet aggregation.

Results

The early results of the clinical trial have been summarized previously [4]. Seven male patients have been implanted with the AbioCor IRH system. The age range was 51 to 79 years. Six of the 7 patients had ischemic and 1 had idiopathic cardiomyopathy. Four patients had previous bypass surgery. All patients were dependent on inotropic agents. Three patients had not been considered transplant candidates because of their age (≥70 years), 4 were excluded due to elevated pulmonary vascular resistance, and 2 patients had significant renal dysfunction. Pulmonary vascular resistance was considered elevated if the transpulmonary gradient was greater than 15 mm Hg despite all therapeutic interventions including inhaled pulmonary vasodilators. The AbioScore predicted a 30-day mortality of more than 89% in 6 patients and 75% in 1 patient. Body surface area [2] ranged from 1.83 to 2.17 mol/L. Cardiopulmonary bypass times ranged from 125 to 240 minutes.

The first recipient was a 59-year-old man with ischemic cardiomyopathy who had previous bypass surgery. The operative procedure was uneventful. This patient was not able to tolerate anticoagulation with heparin or warfarin due to recurrent gastric bleeding. He did tolerate antiplatelet therapy and therefore his initial anticoagulation was antiplatelet therapy alone. During the first 60 days after surgery the patient was on antiplatelet therapy 80% of the time. By the third postoperative month the patient was able to tolerate warfarin without further gastric bleeding. He had progressive improvement in his nutritional status and level of activity. He was eventually able to take more than 20 trips out of the hospital. He had a TIA on postoperative day (POD) 61 and a large cerebrovascular accident (CVA) on POD 130. His anticoagulation was increased after his stroke, resulting in a large retroperitoneal hemorrhage. This resulted in multisystem organ failure and death on POD 151.

The second recipient was a 70-year-old man with ischemic cardiomyopathy. The operative procedure was uneventful and he had an uncomplicated initial postoperative course. He was extubated early after surgery. However, due to recurrent aspiration the patient underwent tracheostomy on POD 40. This patient developed two episodes of drug fever with temperatures as high as 107.1°F. The second febrile episode resulted in transient liver and hepatic dysfunction that prolonged his convalescence. The patient continued to show progressive improvement and was eventually discharged from the hospital on POD 182 and discharged home on POD 209. He has been living at home for more than 7 months. Approximately 10 months after implant of the AbioCor he underwent elective replacement of the internal battery.

The third recipient was a 68-year-old man with isch-
emic cardiomyopathy. The implant of the AbioCor IRH was uneventful. In the early postoperative course acute developed in the patient cholecystitis for which he required a cholecystectomy. At the time of laparotomy, the patient also had a tracheostomy. After his laparotomy, significant renal and hepatic dysfunction developed. The patient did have complete resolution of his end-organ dysfunction and marked improvement in his functional status. The recipient had a small CVA on POD 97 followed by a large CVA on POD 129. Due to the lack of neurologic recovery, support was withdrawn and the patient expired on POD 142.

The fourth recipient was a 74-year-old man with ischemic cardiomyopathy. He was not a transplant candidate because of advanced age and multiple previous cardiac operations. The patient did require an early reoperation for bleeding around the internal battery and from a femoral arterial line. The operation was remarkable for the presence of severe adhesions and early coagulopathy. The patient’s postoperative course was remarkable for the development of progressive renal dysfunction, which required dialysis and progressive hepatic dysfunction with marked hyperbilirubinemia. Due to the lack of end-organ recovery, support was withdrawn on POD 56. The patient had no thromboembolic events.

The fifth recipient was a 51-year-old man with idiopathic cardiomyopathy and pulmonary hypertension with a high transpulmonary gradient. Respiratory failure developed early after surgery that did not respond to conventional measures and necessitated the initiation of temporary venovenous extracorporeal membrane oxygenation support. Echocardiography at the time of surgery and in the postoperative period demonstrated normal flows in the pulmonary veins. There was rapid clearing of the chest radiograph and improvement in lung function that allowed for the removal of extracorporeal membrane oxygenation on the third postoperative day. The etiology of the respiratory failure was unknown. Renal dysfunction also developed that required hemodialysis during the early postoperative period. This patient improved to the point that he was discharged from the hospital on POD 70. He was readmitted with pneumonia and respiratory failure, which resolved with aggressive therapy, and the patient improved to the point that he was able to take frequent trips out of the hospital. He had a large CVA on POD 291 and died 3 days later.

The sixth recipient was a 79-year-old man with ischemic cardiomyopathy who was not a transplant candidate because of advanced age. He underwent an uncomplicated implant with restoration of normal hemodynamics. Profound coagulopathy developed that could not be corrected despite aggressive measures. Due to excessive bleeding, the patient became hypovolemic and entrained air into the right side of the device. Cardiopulmonary bypass was re instituted, air was removed from the device, and the patient was again weaned from cardiopulmonary bypass. The coagulopathy could not be corrected and the patient died shortly after surgery.

The seventh recipient was a 61-year-old man with ischemic cardiomyopathy who was not a transplant candidate because of pulmonary hypertension and renal dysfunction. He underwent an uncomplicated implant of the device with restoration of normal hemodynamics. He had profound coagulopathy and underwent aggressive treatment with cryoprecipitate, fresh frozen plasma, and platelets. He had also received full-dose aprotinin therapy. Approximately 3 hours after surgery was completed, an acute decrease in the device output was noted. Echocardiography demonstrated thrombus in the native right atrium. The patient was reopened and explored with the findings of thrombus in the native right atrium and pulmonary artery. Despite all attempts at resuscitation, the patient died in the operating room. Autopsy confirmed extensive thrombosis of the pulmonary vasculature and no evidence of deep venous thrombosis. The device was found to be free of thrombus. The autopsy findings were thought to be consistent with an aprotinin reaction [10–12].

All the AbioCor systems operated or continue to operate satisfactorily. The system implanted in the fifth recipient experienced three and two skipped beats on two separate occasions on PODs 42 and 43, respectively. This malfunction was due to delayed motion of the switching valve of unknown etiology. All implanted components have been well tolerated. The balance chamber has allowed for left to right balance in all patients. No patients had significant hemolysis or device-related infections.

Four patients improved to the point that they were ambulatory after surgery. Three patients took multiple out-of-hospital excursions. Two patients were discharged from the hospital to a transitional care setting with one of those patients discharged to home on POD 215. Total days on support with the AbioCor system have been 1,087.

Autopsies were performed on 4 patients. All 4 had thrombus adjacent to the lateral atrial cuff struts that were in contact with atrial tissue. The medial atrial struts, which were adjacent to the atrial septum, were clean of thrombus. The blood pumps did not contain thrombus. There was no evidence of infection or significant tissue injury related to the internal components. The patient who died from multisystem organ failure had preexisting lung fibrosis related to chronic passive congestion. This patient had no evidence of kidney or brain infarcts at autopsy.

Comment

Despite advances in medical therapy the prognosis for end-stage heart failure remains poor. Heart transplantation remains the mainstay of surgical therapy for such patients. Despite all efforts to increase organ donations, donor hearts are rare. The need for an alternative form of cardiac replacement therapy is substantial and will only increase with time. The expanded use of left ventricular assist devices (LVADs) as destination therapy is likely to have a significant clinical impact. However, data are limited on the long-term clinical reliability of current...
generation LVADs. Little information is available about native heart complications after LVAD placement. The role of LVADs versus total artificial hearts as destination therapy remains to be defined [13].

The AbioCor IRH has been designed from inception as a destination device. Successful preclinical implants and in vitro studies resulted in initiation of clinical trials in June 2001. To date 7 patients have received the AbioCor IRH system. As noted above, the system has been designed to be totally implantable without the need of percutaneous lines or the need for percutaneous access. Energy transfer across the skin has been achieved with inductive coupling and has resulted in excellent patient comfort. Placement of the internal TET coil in the infraclavicular fossa coupled with design modifications of the external coil has resulted in minimal misalignment of the internal and external TET coils. The atrial balance chamber that allows for decreased right-sided stroke volume to maintain left right balance has performed flawlessly in all recipients. The balance chamber can be controlled by using either an automatic or manual mode. Both modes have worked well clinically without any malfunctions. Manual control of the balance chamber has been used for rapid manipulation of left atrial filling pressures in the instances when pulmonary vascular congestion has developed.

The internal battery has allowed for brief periods of untethered mobility, primarily allowing patients to shower and make brief trips to the bathroom or around their living quarters. The ability to provide untethered ambulation even for a brief period of time is a major advantage of this device and has significantly improved quality of life for these patients. However, the support time on the internal battery is limited and remains a weakness of the system. Additionally, the lifetime of current generation batteries is approximately 1 year. At the time of initial device implant, the internal battery is positioned to allow for easy replacement. One patient has had elective replacement of the internal battery. The operation was similar in duration and extent to replacing an implantable cardiac defibrillator generator. In the near future, advances in battery technology are likely to allow for increasing periods on internal battery support [9, 14].

Similar to current generation LVADs, the AbioCor IRH has allowed patients to be discharged from the hospital. Indeed, the second recipient of the AbioCor has been living at home for more than 7 months. Another highlight of the clinical trial is that all of the AbioCor systems have continued to operate satisfactorily. No significant device malfunctions have been noted and all internal components have been well tolerated. The use of the AbioFit virtual fit evaluation to help determine if a potential candidate is of adequate size for the thoracic unit has been of substantial benefit. We have found that we quickly gained confidence in this computer model and have relied on it for determining selection of patients with the appropriate chest dimensions. We have also found that transeosophageal echocardiography to be invaluable at the time of chest closure to ensure that the left pulmonary veins are not compressed.

Multiple morbidities were noted in this patient population as described above. These patients have all been ill, with a 30-day mortality of more than 75%. A significant number of postoperative complications have been related to the preoperative comorbidities, including the presence of end-organ dysfunction and severe malnutrition. Four of the 5 patients who survived the early operative period have died, with 3 of these deaths related to stroke. Autopsies in the patients who had a stroke revealed thrombus on the left atrial struts that were in contact with the lateral wall of the left atrium. The blood pumps and valves were clean of thrombus. The atrial struts were placed on the atrial cuffs during the early animal implants to avoid collapse of the small bovine atrium by this active fill device. There was no thrombus related to the presence of struts in the animal model. These findings have resulted in the removal of the atrial struts for the next series of recipients of the device. It is hoped that the absence of the atrial struts will result in an acceptably low level of thromboembolic events without leading to problems with inflow to the device. There was no evidence of infection, significant tissue injury, or hemolysis related to the device components.

In summary, the AbioCor system is the first totally implantable artificial heart. Early results from this multicenter trial have demonstrated excellent function of all device components. Successful implants at four of the centers have been accomplished, suggesting this operative approach may eventually have widespread applicability. Many notable milestones have been achieved including successful discharge of a patient to home. Patient and family acceptance has been high, primarily related to the quiet nature of the device and the absence of percutaneous lines. The major adverse finding has been the development of thromboembolic events that appear to be related to the development of thrombus on struts that are attached to the left atrial cuffs. These struts have been removed and the next series of implantations will determine if removal of the atrial struts results in an acceptably low level of thromboembolic events.

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