The Total Artificial Heart - A Bridge to Transplantation

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Abstract
Many heart centers are utilizing the total artificial heart for a bridging technique to transplantation, particularly in patients with bi-ventricular failure or irreversible left ventricular failure, where a donor heart is not readily available. This discussion includes the training procedure, operation and management of Canada's first total artificial heart performed on May 1, 1986.

Introduction
Although significant advances have been made in therapeutic and diagnostic techniques, heart disease remains the leading cause of death in North America, claiming the lives of 50,000 Canadians each year.

Pharmacological and surgical intervention may not reverse the course of cardiac failure. It is this type of patient with terminal heart disease in whom the use of an artificial heart as a bridge to transplantation is contemplated.

The modern era of the total artificial heart (TAH) development began with Kolff's report in 1958 on a polyvinyl chloride prothesis which sustained an animal for 90 minutes. Over the past 28 years, obstacles have been encountered resulting in modification to the device which has culminated in the Jarvik-7.

Many heart centers are utilizing the total artificial heart for a bridging technique to transplantation, particularly in patients with bi-ventricular failure, where a donor heart is not readily available (Figure 1). This discussion includes the training procedure that lead to Canada's first total artificial heart transplantation.

The Jarvik-7 Total Artificial Heart
The Jarvik-7 is composed of two hemispherical diaphragm pumps held together by Velcro, and designed to fit into the human mediastinum. This state of the art heart is made of seamless segmented polyurethane, which incorporates Dacron mesh for added support and strength. The ultra smooth polyurethane lining results in improved thromboreistance and decreases trauma to the blood (Figure 2). The base of the ventricles is moulded of plastic, incorporating pneumatic drive lines and a diaphragm. This diaphragm consists of four layers of segmented polyurethane, each layer being 0.006 inches thick and separated by dry granite for lubrication. This arrangement minimizes resistance to movement, thereby increasing durability and decreasing the chances of rupture and thrombus formation. The inflow and outflow tracts incorporate Hall-Medtronic tilting disk valves and are designed with quick connect ports. Snaps are molded of polyurethane and plastic cuffs, which are sewn to the remnant atria. They are pressure tested for competency and then snapped into the inflow port. The outflow port snaps onto Dacron woven grafts, which are first anastomosed to the pulmonary artery and aorta. This quick connect principle enables the Jarvik-7 to be snapped into and out of the chest with great ease should a ventricle need to be changed.

The drive lines originating from the base of the ventricles exit percutaneously to the heart driver. To avoid infection and tissue stress, skin buttons are attached to the drive lines to eliminate pressure transmission to the surrounding tissue caused by movement, and to decrease the chances of infections.

Utahdrive System III ™
The Utahdrive III ™ (c) allows independent regulation of the artificial right and left ventricles. The console consists of two heart drivers (one as a backup unit), a computer to monitor heart function and storage of information, a vacuum control and an alarm panel to monitor loss of gas, computer malfunction and/or low cardiac output. The heart drivers consist of a pressure regulator for the right and left ventricles (mmHg), a rate controller, a percent systolic duration representing the percent of cardiac cycle spent in systole and a rate delay feature used with the Jarvik acute ventricular assist device (AVAD) (Figure 3). Regulated pulses of air from the heart controller exert pressure on the diaphragms of the artificial ventricles. As the diaphragm

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Figure 5

(c) SV = 57
CO = 6

Figure 6

Figure 7

Figure 8

SEQUENCE

<table>
<thead>
<tr>
<th>Initial CPB</th>
<th>CPB</th>
<th>CPB</th>
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<tr>
<td>&gt;4.0 lpm</td>
<td>3.0 lpm</td>
<td>&lt;1.0 lpm</td>
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RATE: 40 -- 60 -- 80
override

LDP: 50 -- 70 -- 90 -- >120 CPB

RDP: 0 -- 30 -- >40

increase to

MSYST: 40 -- 40 - 45 -- 45

VAC: 0 -- 0 -- 0

off CPB

LECLAIR N May 5/86 8:32:05 PM

--- left: FU=44, CO= 4.5
--- right: FU=38, CO= 4.0

104 bpm

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inflates, blood on the opposite side is displaced and thus ejected through the outflow valves. Drive pressures must exceed the afterload pressures in order to eject blood from the ventricle. The compliance of the diaphragm allows passive filling of the ventricles during diastole as the air on the drive side is expelled to the atmosphere. Vacuum is generally not required during normal heart operation, however it is used for rapid heart rate and in conjunction with acute ventricular assist device (AVAD).

The Jarvik-7 response is directly proportional to the diastolic filling volume in much the same way cardiac muscle stretches to accommodate larger filling volumes. This representation of the Frank-Starling law is limited to 100 ml (6). Incomplete filling and complete ejection allows the heart to accommodate larger filling volumes and thus stroke volumes at a fixed rate, which is associated with increased venous return during exercise. The drive unit and heart function are continuously monitored by the cardiac output monitoring diagnostic unit (COMDU). This computer sits on top of the console and is helpful in providing data and diagnosis of certain physiologic processes affecting the performance of the Jarvik-7 artificial heart.

Two pressure waveforms are generated on the computer screen by the artificial heart and by the driver. The driver generates a drive pressure waveform. Once displayed on the computer screen, one can determine the filling point, isovolumic contraction and the empty point to make the necessary adjustments to achieve complete ejection without overdriving or underdriving the ventricle (Figure 4). The other waveform generated is the filling volume, and enables diagnosis of functional problems associated with the use of the Jarvik-7.

A pneumotachometer measures the amount of air that is passively exhausted from the ventricles, which corresponds to the amount of blood that will be ejected on the next systole. Multiplication of the filling volume and the heart rate will yield a cardiac output for each respective ventricle (Figure 5). Rapid displacement of measured air may indicate high filling volumes. This could be the result of hypervolemia, high systemic vascular resistance (SVR), valvular disfunction or high left atrial pressures. Low filling rates result in low filling volumes which could be the result of hypovolemia, a low systemic vascular resistance, or valvular inflow obstruction.

The training period in Salt Lake City consists of a two week course, involving six surgical implantations in calves and classroom lectures. Emphasis is placed on surgical techniques, diagnosis of waveforms, termination from cardiopulmonary bypass and post-operative management. On-going inservice continues at our institution on a regular basis. One must be aware, however that implantations were performed on healthy animals. Clinical implantations in the presence of cardiogenic shock present a more difficult course of management.

Indications for the use of the TAH are: patients with endstage heart disease and for whom no donor heart is available, patients with irreversible cardiogenic shock and transplant candidates who cannot be weaned from cardiopulmonary bypass.

On May 1, 1986, our institution implanted a Jarvik-7-70 total artificial heart into a 41-year-old female. The patient was well prior to her myocardial infarction. She subsequently extended her infarct, developing cardiogenic shock. Emergency percutaneous transluminal coronary angioplasty, streptokinase injection and counterpulsation balloon (IABP) failed to improved her condition. She underwent emergency coronary bypass surgery to the left anterior descending and second marginal coronary vessels. Multiple attempts at weaning from cardiopulmonary bypass with inotropic and IABP support were unsuccessful. A decision to implant the TAH was made only after all attempts of more conventional means had been exhausted (Figure 6).

Cardiopulmonary bypass was relatively uneventful, except for the length of bypass. Total bypass time was 380 minutes (6.3 hours). 164 minutes being the time for aorto-coronary bypass surgery and several attempts at weaning; 216 minutes being the time to implant the total artificial heart. Implantation of the TAH is similar to orthotropic transplantation.

Due to expected long bypass time, large fluid intake and post-operative anti-coagulation, the perfusionist should always utilize a membrane oxygenator, ultrafiltration device and a autotransfusion apparatus.

Termination of cardiopulmonary bypass is accomplished in the usual fashion, except for the greater duration at weaning in increments of 1.5-2.0 l/min. The TAH does not respond to large changes in preload as the natural heart does. Adjustment are made on the Utah drive console accordingly by observing the waveform and patient status, as cardiopulmonary bypass flow is reduced. Initially during full CPB flow, there is little ejection and filling. CPB pressure is overridden by increasing the drive pressure and preload volume (Figure 7). As preload volume is increased, one can maximize stroke volume by changing the left/right drive pressures, heart rate and systolic duration time to achieve an ideal waveform (Figure 8). CPB can then be discontinued. Termination usually will take 20-30 minutes. By modification and experience, the termination of cardiopulmonary bypass will take 5-10 minutes.

Device failure has not been a problem to date; however, there are a number of concerns with the use of the TAH. A major complication is thrombus formation possibly resulting in stroke, thus precluding the patient for subsequent transplantation. Another serious complication is hemorrhage secondary to anticoagulation. Intravenous heparin was used on our patient and partial thromboplastin times (PTT) were kept at twice the normal control levels (ACT 170-270 secs) (Figure 9). The patient was returned to the operating room due to chest wall bleeding secondary to anticoagulation. Heparin was then reduced for 24 hours (Figure 10). Infection can also be a concern, however in our implantation this did not present a problem. Our patient's post-operative course with the TAH was uneventful. She was subsequently transplanted on the eighth day post implant with a donor heart from a 44-year-old man. Our patient made a slow but uneventful recovery and was discharged from the hospital on the 50th day post implant. To date, she continues to do very well.

To summarize, in our experience, there are a number of
important considerations with the use of the TAH. Hemodynamically, one should keep parameters such as blood pressure and central venous pressure within the normal range. The ventricular filling should be 80% of the maximum (95±5 cc) and the ventricles should completely eject with incomplete filling so that variations between the left and right ventricles can compensate in accordance with Starling's law. Movement should be avoided in the first 24 hours since compression of the atria can result in reduced cardiac outputs and undesirable filling volumes. The patient should be treated rather than the console (unless necessary to do so). For example most patients with a TAH become hypertensive, therefore treatment should be with nitroprusside rather than increasing the drive pressures. Also the lowest possible drive pressures should be used to reduce blood damage, and a standard procedure of autotransfusion employed post-operatively to reduce massive blood transfusion.

While there are many forms of cardiac support such as long term membrane oxygenation and left/right ventricular assist devices utilizing a centrifugal pump, most would preclude use over a period of days or months. The use of the TAH or single artificial ventricle implanted internally or extracorporeally would ideally lend these devices to stabilizing the patient's condition prior to transplantation. What, then, is the future of the TAH? Certainly an increased use as a device to bridge patients for transplantation. Although the TAH at the present time is not meant to be a substitute for the natural heart, it remains a dream that may become a reality in the future. Increased knowledge from the use of the device and research will result in improved designs. Advancement of the TAH as a permanent replacement are already being done, such as the electrohydraulic heart, utilizing a battery belt operated by a microcomputer.

Possibly, nuclear energy power packs will be used in the future (Figure 11). The TAH at present is state of the art technology and has become the reasonable alternative for a bridge to transplantation.

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