

PANEL CONFERENCE

PORTABLE ARTIFICIAL HEART SYSTEMS

W. S. Pierce¹, Chairman

Panelists:

R. Jarvik², H. P. Heimes³, G. Rosenberg¹, and J. Watson⁴

Research during the decade of the '70s in the area of artificial heart development was characterized by the development of thrombus-free blood pumps and by a progressive increase in the duration of use of pneumatic artificial hearts in experimental animals. The clinical use of an artificial heart for permanent substitution of a diseased heart has resulted in increased attention to the bulky pneumatic power units required to energize the artificial heart. This panel conference was convened to document the state of the art regarding portable artificial heart systems and to discuss the potential use of these systems for long-term cardiac replacement.

PROGRESS AND PERSPECTIVES

R. Jarvik

The University of Utah and Kolff Medical, Inc., in cooperation with the Helmholtz Institute of Aachen, Germany, are pursuing development of portable artificial heart systems for human use. Our developments emphasize utilization of the JARVIK-7[®] heart as the blood pump and actuation of its free diaphragm pumping system by a fluid medium of either compressed air or hydraulic fluid¹. Our approach anticipates a progressive development from more cumbersome to more compact devices and a program of development and experimentation which permits application of information learned from human implantations to the systems development. We believe that we will learn a great deal about the quality of life that patients experience with portable systems from their early use. We also hope to have an opportunity in the reasonably near future to begin testing of the portable electro-pneumatic system (HEIMES PORTABLE DRIVER[®]) in humans².

Our efforts are to maintain the maximum simplicity of the implanted elements (principally the blood pump) and maintain the portable drive systems external to the body where they are accessible for maintenance and replacement and can incorporate redundant elements. A most obvious crucial element in this approach is the practicality of use of percutaneous leads. Our recent total artificial heart experience in Dr. Barney Clark has been encouraging. Dr. Clark's percutaneous leads were maintained for 112 days with no infection despite 3 thoracotomies and the use of steroids during the first month. Dr. Clark's leads utilized the stress-relief design tested for the past several years in animals. Leads of this same design have remained free of infection for up to 297 days (in a sheep). However, other leads in calves and sheep have become infected in a matter of weeks and months. We believe that better hygiene in humans will result in a lower infection rate than in animals. Dr. Clark's leads were swabbed every 8 hrs with hydrogen peroxide and Betadine, treated with Betadine ointment, and dressed with sterile gauze 4 x 4 pads. Although we anticipate some percutaneous lead infections in humans as the use of the artificial heart becomes more common, with good protection of the skin junction from mechanical stress, we believe the incidence is likely to be quite low and the infection manageable.

Successful percutaneous leads have extremely important implications for portable artificial heart systems. Dr. Clark was specifically questioned about pain or discomfort at the percutaneous leads on many occasions and repeatedly said that he had no pain and no discomfort. He was either bedridden or confined to a chair or wheelchair most of his life with the artificial heart and therefore his air lines were not moved about a great deal or subjected to repeated mechanical stress. Percutaneous lead designs for portable systems should give careful consideration to patient comfort, position of exit of the leads, the method of protecting the skin junction from stress, the positioning related to the patient's clothing, and the carrying method of the portable heart device. Other considerations crucial to the patient's lifestyle when using portable heart systems include: 1) a high level of patient confidence which we believe will be best achieved with a highly reliable redundant and rugged external drive system; 2) good cosmetics with silent operation and attractive appearance; 3) patient comfort, requiring a lightweight device and convenience including sufficient battery life; and 4) a practical service and a maintenance regime.

The experience in Dr. Barney Clark indicated that the JARVIK-7 heart fit very well and was adequately fixed in place at the suture lines, the connection via the air lines, and the pseudopericardium which formed around the heart. The necessity of reoperation in Dr. Clark to replace one ventricle after failure of a BJORK-SHILEY[®] valve emphasizes the need for the simplicity of the internal elements and the possibility of difficult reoperative

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surgery if the implanted elements are complex, widely separated, and susceptible to becoming scarred down. This, in our opinion, supports the desirability of utilizing a system which does not require a compliance chamber or an abdominally implaced component, in addition to a thoracic component.

Dr. Peter Heimes will be presenting the electropneumatic drive system at this panel conference, so I will only briefly mention that it has the advantages of very high reliability, full redundancy, and an advanced control system which has been shown to work well in experimental animals. The HEIMES PORTABLE DRIVER is now ready for intermittent tests with the UTAH HEART DRIVER available as an emergency backup. Dr. Clark and his family were aware of many details of the HEIMES PORTABLE SYSTEM and were enthusiastic about the possibility of using it.

The electrohydraulic total artificial heart continues under development with an NIH grant³. The system has potential advantages of the HEIMES SYSTEM in that the mechanism is much smaller and more compact and would permit the patient to carry the necessary electronics and batteries worn on a belt or vest. Also, the electric cable coming through the skin could be smaller diameter and more flexible than the 2 air tubes required for the portable pneumatic system. The principal emphasis of research with the electrohydraulic system concerns the control aspects. We are now developing automatic control systems to regulate cardiac output while maintaining acceptable right/left balance.

While we expect the HEIMES SYSTEM can be ready for permanent human use within the next 2 yrs, the electrohydraulic heart is in a much earlier phase of development and will probably require at least 5 to 6 yrs of further development before human trials may begin.

PARACORPOREAL PORTABLE PNEUMATIC ADAPTIVE HEART DRIVER VERSUS IMPLANTABLE TAH SYSTEM

H. P. Heimes

A realistic state of the art total artificial heart has to be engineered with the following basic components:

1. The blood pump (e.g., both ventricles and the valves).
2. The secondary blood pump energy converter (the simplest form is the air/blood diaphragm).
3. The drive system or primary energy converter.
4. The physiological control system.
5. The energy source.

There has been and there still is a race between proponents of the philosophy of the total implantable heart system and the mainly 2-component system, extracorporeal driver with the intracorporeal ventricles.

This discussion is not to justify the way we have worked on the problem; it is merely to discuss the problems and to find a suitable way to get to the clinically feasible TAH. Figure 1 shows the state of our involvement in the paracorporeal pneumatic heart driver. On one hand, we find it very impressive, how small and efficient our latest development became. On the other hand, the picture of "Magic and the Heimes Driver" shows the severe disadvantage of this kind of system: the pneumatic drive lines coming from the skin buttons to the portable driver.

After intensive work^{4,5} on a totally implantable electrohydraulic energy converter with the pusher plate "doughnut" and other ventricles, we finally came back to the pneumatic system. Some of the key decision points which brought us back to this concept will now be considered. The overall design difficulties involved in the successful development of a portable complete heart prosthesis are:

1. The blood pump itself must fit into the thoracic cavity without any restrictions, especially on the connecting geometry.
2. The available space (if in/outflow conditions are considered) is nearly that of the maximum stroke volume, and there is very little room for any kind of energy converter inside the blood pump.
3. The heart must be physiologically controllable and should have some Starling characteristic (inherent or externally controlled).
4. The thoracic cavity is a closed low pressure chamber and venting is not possible.
5. Today, no electrical rechargeable battery of sufficient output capability is available which could be implanted for a longer period of time.
6. Because of point number 5, energy has to be transmitted through the skin, either by a tube, a wire or wireless.
7. Automatic control feedback systems, which are mandatory on a portable patient system, need to have some input informations; therefore, the transducer problem with long-term stability in reference and calibration is still present.

If one compares the advantages of a pneumatic blood pump system and a mechanical heart system (Table I), it is obvious that the pneumatic heart has some advantages over the mechanical heart, but lacks the disadvantage of

TABLE I

TOTAL IMPLANTABLE TAH-SYSTEM (Mechanical Heart)		PARTIAL IMPLANTED TAH-SYSTEM (Pneumatic Heart)
HEART:	High mech. complexity Higher weight (2-4) Larger size (1.5-2) Fitting more difficult No or less inherent Starling resp.	+ Ventricles only + Low weight (1) + Small size (1) + Good fitting possible + Fairly good Starling resp.
SAFETY:	No redundancy in heart Driver-redundancy difficult Driver maintenance very difficult	No redundancy in heart + Driver-redund. possible + Driver maintenance very easy
CONTROL:	With less Starling more difficult Long-term stability mandatory	+ Proven to work even with simplest or no control + No long-term stability problems (simple control)
POWER:	* Easy distribution through transcut. leads or wireless	Transcutan. tubing with skin-buttons only
ENERGY:	Electrical batteries, problematic, if implanted High efficiency possible Add. losses if transcut. energy-transmission	External electric batteries High efficiency possible Addit. pneumatic losses
EXPERIENCE:	Little animal experience	+ High animal experience
ETHICS:	* Invisible or nearly invisible total system	Tubing-disadvantage Driver can be very small

* = Advantage implantable mechanical system (2)
+ = Advantage extracorporeal pneumatic system (10)

the transcutaneous drive lines. Because of its advantages, we have pursued the idea of an extracorporeal pneumatic heart driver since 1978 and have done 49 animal experiments on calves and sheep, the longest lasting 16 days continuously. During this latter experiment, the driver was running in the automatic, adaptive mode. The results show a decrease in cardiac output without any noticeable effect on the hemodynamics, blood gases or pH.

Presently the Helmholtz Institute; the Division of Artificial Organs, University of Utah, Salt Lake City; and Kolff Medical, Inc., Salt Lake City, Utah are developing a failsafe portable human driver. It is quite possible that the first human portable driver will be a pneumatic "Rucksack Driver". It will use the pneumatic transcutaneous drive lines, which everyone would like to avoid, but in our opinion this is the first feasible step toward the implantable total artificial heart prosthesis.

THE PENNSYLVANIA STATE UNIVERSITY
IMPLANTABLE ELECTRIC MOTOR-DRIVEN ARTIFICIAL HEART

G. Rosenberg

Over the past year in vivo testing of an electric motor-driven total artificial heart has been conducted. The implanted system consists of an electric motor drive located between 2 pusher plate activated sac-type pumps (Figure 2). Each prosthetic ventricle is constructed of a rigid outer polysulfone case. Within the case is a smooth, seam-free, polyurethane sac that employs size 29 inlet and 25 outlet convexo-concave Bjork-Shiley valves. The prosthetic ventricles have a maximum stroke volume of 97 cm³.

The motor drive that has been implanted is based on a DC brushless motor-driven triple track drum cam mechanism. In this system, the motor stator rotates the cam. As the cam is rotated in one direction, the cam follower and pusher plate actuator move in a rectilinear fashion. The actuator is restrained from rotating by a set of bearings running in tracks on the actuator. When the stroke is completed, the motor stops, reverses direction, and moves the pusher plates in the opposite direction. Thus, alternate actuation of the pumps is achieved.

An electronic control system is utilized to minimize inertial effects, to control cardiac output, and to balance the output of the 2 pumps⁶.

The cardiac output control is based upon the same philosophy as used in the Penn State pneumatic system⁷. The pump rate is an inverse function of the animal's peripheral resistance. As the animal's blood pressure decreases, pump output increases. The blood pressure is determined by sampling motor current; thus, no implanted transducers are required.

Balancing the output of the 2 ventricles is more complicated. At present, a fill switch is employed in the left pump. The fill time is inversely related to the atrial pressure. If fill time is short, the left atrial pressure is high and the right pump output must be decreased. This is accomplished by varying the stroke time division between the left and right pumps. A complete explanation of this method is given in reference 8.

Three acute in vivo experiments have been conducted. In the first experiment, an unrecognized cut in the percutaneous tube allowed blood from the thorax to enter the system and cause experiment termination. In the second experiment, the animal lived for 9 days but had excessive chest tube drainage and suspected caval obstruction. Both of these animals demonstrated satisfactory system control. In the third experiment, a slightly modified atrial connector was employed. This animal is surviving at 114 days and is in excellent health. He is shown in Figure 3 being exercised outside. The automatic control system allows the animal to exercise or rest. There have been no electronic system adjustments made since the first postoperative week. The resting cardiac output is 8.5 L/min for this animal and cardiac outputs in excess of 12 L/min have been obtained. Typical system power into a mean aortic pressure of 100 mm Hg and a flow of 9 L/min is 20 watts, 8 of which are required by the electronics; thus, only 12 watts are delivered to the motor. In future systems, CMOS electronics will reduce the required 8 watts to less than one watt. Under the described conditions, the tissue temperature at the surface of the motor is less than 2°C above the calf's rectal temperature. Thus, thermal management does not appear to be a problem with the system.

Work is continuing to employ an implanted compliance chamber in future experiments. The chambers will be of the same design as that employed in our motor-driven left heart assist experiments but smaller in size. A transcutaneous energy transmission system is under development. This system will follow the general approach of Sherman⁹ and Schuder¹⁰ and their associates.

Figure 4 depicts the project goal where the motor and compliance chamber are implanted in the thorax while the electronics, a small battery pack, and secondary coil are implanted in the abdomen. An external battery pack and primary coil for radio frequency transcutaneous energy transmission will be carried externally.

NHLBI ENERGY CONVERSION PROGRAM

J. Watson

We are now in the 20th year of the effort supported by the National Heart, Lung and Blood Institute to develop mechanical circulatory support devices capable of assuming the total volume and pressure work of the natural heart. Since the program's inception, the major goals for developing devices of appropriate size, physiologic effectiveness, biological capability, and required reliability have remained unchanged.

To achieve these goals, it was imperative to develop a miniature energy converter to power and control implanted blood pumping ventricles used in either a ventricular assist or artificial heart device. The first generation energy converters were to be designed to operate without catastrophic failure or maintenance for a minimum of 2 yrs or 100 million cycles. Second and third generation converters were projected to have a demonstrated reliability of 5 and 10 yrs, respectively.

During the years 1967 through 1973, studies were undertaken to establish component feasibility. It was during this period that work on an organized energy conversion program was initiated and objective criteria developed for what was both desirable and required for adequate power and control of mechanical circulatory support devices.

The majority of component development work was completed between 1974 and 1980. The electrical and thermal energy converter program received particular emphasis and the design of several converters had progressed to an implantable size with increased engineering efficiencies and durability. Converters now weigh 300-600 gm and occupy a volume of 150-300 cc. The efficiency of electrical engines has increased from 18% to well over 40%, with bench life tests of over 3 yrs and limited testing in animals. Thermal engine efficiencies have increased to over 15% with bench testing lifetimes of over 4 yrs.

Over the past 20 yrs, approximately \$40 millions in grants and \$170 millions in contracts have been spent on mechanical circulatory support devices and biomaterials. Their funding levels compare favorably with the original cost project of between \$150 and \$250 millions. Considering inflation, the program has done well to remain within the original cost projections of 1964.

Of the total research and development support, about 20% has gone for biomaterials, 20% for special programs (such as the test and evaluation centers), 25% for blood pumps, and over 30% for energy conversion technology. Therefore, the largest portion of contracted dollars, over 50 millions, have gone into pneumatic, electrical and thermal energy conversion research and development.

While excellent progress has been made, many real and interesting questions remain unanswered. Feasible solutions have evolved for technical problems such as the variable volume behind the pusher plate, often referred to as the compliance chamber. The remaining problems are probably due more to lack of study than to scientific difficulty.

In the future, we hope for improved, implantable, sealed rechargeable electrochemical batteries. Current nickel-cadmium batteries are only marginally suitable for implanted operation because of several factors including performance degradation at body temperature. Modest improvements are expected but no alternative is in prospect. Energy transmission devices may work but limits of mechanical strength and the hazards of extrusion and infection remain as problems to be resolved with further study.

The work on implantably electrically powered ventricular assist systems is nearing completion and will begin systematic laboratory and animal testing of reliability. Limited clinical evaluation is expected by 1986. The success of the implantable devices will relate directly to the progress in developing safe and reliable energy conversion systems.

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Figure 1. "Magic" with the Jarvik-7 artificial heart and Heimes portable driver.

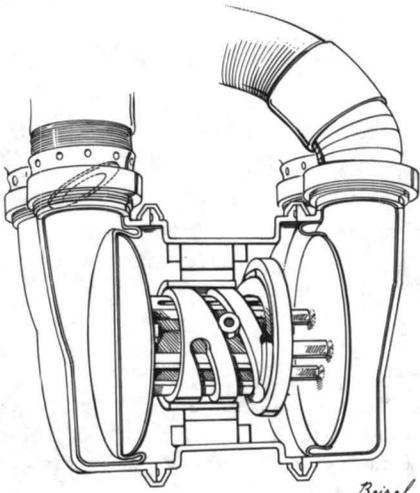


Figure 2. The cam drive electric motor-driven artificial heart.



Figure 3. "E.T." A calf with the implanted electric motor-driven total artificial heart. The technician is holding the electronics and a small NiCd battery pack. This animal has survived 114 days (May 1983) and is in excellent health.

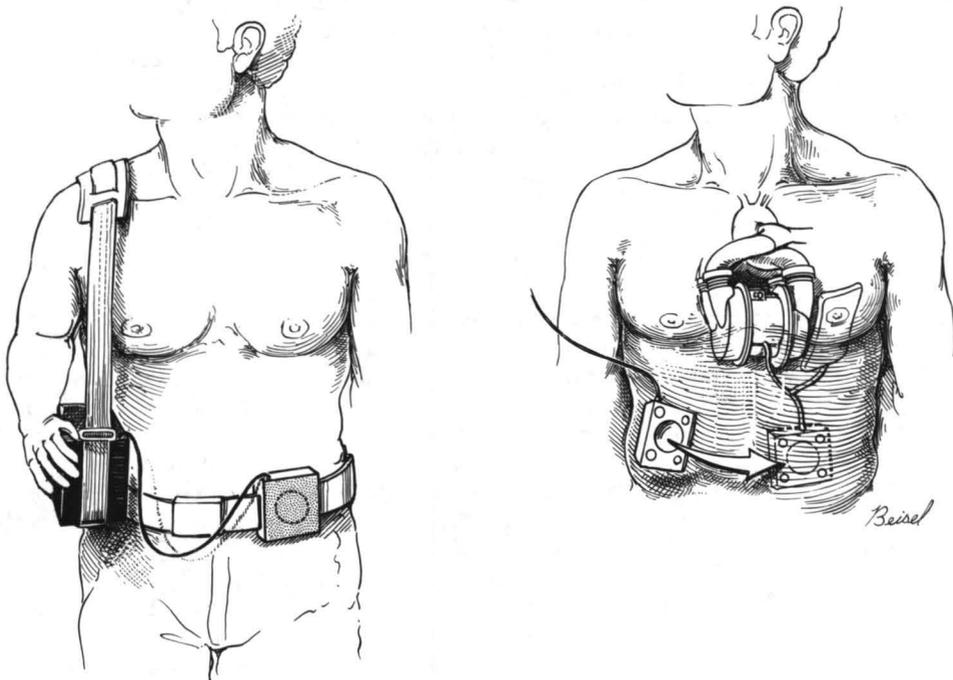


Figure 4. This figure shows the artist's conception of the clinical artificial heart. The motor and compliance chamber are implanted in the thorax while the electronics, a small battery pack, and a secondary coil are implanted in the abdomen. Carried externally will be a main battery pack and a belt holding the primary coil for inductive coupling.