

The Artificial Heart:

Towards The Attainment Of Heart Replacement

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The Tutorial Address To The Artificial Organs Section. A discussion of recent progress in a specific area of artificial organs - artificial hearts. An attempt will be made to review the field currently, give comment on some systems being used, and to discuss the overall philosophy of artificial heart development. In summarizing, a report of the author's current work in the field will be reviewed, in terms of the guidelines previously discussed.

Ten years ago the development of an artificial heart was not even considered a possibility. Approximately six years ago at the meeting of the American Society of Artificial Internal Organs, it was suggested that efforts be made toward the development of an artificial heart. In subsequent years, several research groups throughout the country actively undertook the development of a mechanical blood pump. Until recently, however, the level of activity remained at a relatively low level. However, in 1962 and '63, numerous papers describing artificial hearts were presented at the A.S.A.I.O. Meetings. Actual devices were described, and attempts of implantations with varying degrees of success were presented.

Up until this time, most of the work had been carried on by medical groups. It was becoming more evident that engineering support was vital to any successful program. In fact, the development of an artificial heart was the epitome of a combined medical and engineering problem.

In late 1964 and '65, the government thought it to be advantageous to establish a coordinated program for the development of artificial hearts. The Artificial Heart Pro-

gram was established by the PHS at the National Heart Institute. A program was designed to establish a purposeful methodology of developing a refined artificial heart. The "crash" program instituted, patterned after the nation's space effort, has generated much interest in the engineering profession and industry.

The importance of developing an artificial heart has been made relatively obvious by the six study contracts awarded by the PHS in the initial phase of the Artificial Heart Program. Over six-hundred-thousand people per year die of heart disease. Of these, many are relatively young productive members of society. Many victims are in the prime years of life, have families, and are community leaders. The merit of saving these individuals certainly is a worthwhile consideration.

An important secondary consideration of the development of such a prosthetic device is its impact on cardiovascular research, physiology, and medicine. Certainly many unknowns in the field of cardiac physiology will be answered with the aid of an implantable prosthetic.

The significant advances which will be provided by the artificial heart system must be weighed against its eventual cost and the socio-logical changes, which are sure to accompany the successful use of such a device on a large scale. The socio-logical impact of an artificial heart will approach, it not exceed, that currently being created by the oral contraceptive agents. If implantation of such a device ever approaches the predicted one-hundred-thousand unit per year level, socio-economic considerations will become of prime importance. The impact of such a device on the philosophy of medicine, current medical-legal criteria, and moral and ethical considerations will be comprehensible. Not only is a physician confronted with new decision involved in surrounding the implantation of such a device, but a manufacturer has to build such a device which has real life-time guarantee. Quality

control, manufacture reliability, and the many decisions surrounding who is to live and who is not to live must be confronted. Certainly the development of such a device takes us much closer to **The Brave New World**. The successful implantation of the artificial heart in itself constitutes the acception to euthanasia.

The need for a more clear understanding of the terminology surrounding artificial hearts was made obvious at a recent meeting sponsored by the Artificial Heart Program, and it was more fully exemplified by the recent publicity surrounding one of the circulatory assist devices. In discussing the field of cardiac prosthetics, the following nomenclature is offered:

A. Restorative Prosthetics - this includes prosthetics used to correct existing heart defects, but which do not supplement heart functions. Included here would be intracardiac patches, prosthetic valves, and pacemakers.

B. Cardiopulmonary Bypass Units - including short-term emergency blood pumps and oxygenators which permit temporary heart bypass to permit restorative operative procedures.

C. Circulatory Assist Devices -

1. External units without vascular connections.
2. External units with vascular connections.
 - a. Diastolic augmentation-arterial pumps, counter pulsation.
 - b. Systemic shunt devices, venous to arterial shunt pumps.
 - c. Partial left heart bypass units.

D. Implantable Circulatory Assist Devices -

1. Implanted partial left heart bypass - pump internally situated within the closed chest.
2. Internal heart massage units - devices which encapsulate one or both ventricles to augment ventricular work.

- E. Artificial Hearts - included in this class are total cardiac replacements; hearts designed to take over complete cardiac functions.

Another classification system has been suggested by Dr. Hastings, of the PHS Artificial Heart Program. It is as follows:

1. Emergency Device - for example, mechanical external massage unit or cardiopulmonary bypass unit.
2. Convalescent Device - the would include circulatory assist devices of the counter pulsation-diastolic augmentation, and the circulatory assist devices planned for short-term use.
3. Permanent Assist Devices - this would include any implantable artificial circulatory assist device, whether it be partial left ventricular bypass or cardiac massage unit.

4. Total Cardiac Replacment.

He has pointed out the importance of developing the system around the total cardiac replacement. These supportive devices are essential to permit the maximum number of patients which are salvageable with total cardiac replacement. Furthermore, a total cardiac replacement is essential as a backup if any of the first three steps fail. This is an important concept, because once artificial hearts are successful, total cardiac replacement will become an elective procedure. Certainly assist devices will be essential and should be used before a total cardiac replacement is used.

In recent weeks several circulatory assist devices have received much publicity in the lay press. One of these assist devices, an externally placed partial left heart bypass, received much coverage as an artificial heart. For those who were able to read the articles in detail, the problems and progress in assist devices was evident. In the face of coma, diminished renal function, and pulmonary congestion, it appears that the circulatory assist was unable to help maintain adequate circulation. In cases where standard medical treatment, emergency card-

iac resuscitatory procedures, and circulatory assists fail, the remaining alternative is total cardiac replacement.

The remainder of the presentation will be devoted to the discussion of total cardiac replacement. An implantable heart represents the ultimate in refinement of the cardiac prosthetics. The complexity of controls, the need for high efficiency and phenomenal reliability, and the requirements of minimal patient handicap at a low cost all exemplify the bioengineering problem presented.

Presently the problems involved in the development of an artificial heart are predominately engineering problems; however, eventually it is felt that the major problems and limitations will become medically related. There is a big unknown area involving the physiological changes that will accompany prolonged blood pumping. Even more awesome are the effects of blood clotting and metabolic changes which might accompany a mechanical system. Changes in the pulmonary circuit, possible carcinogenic effects of materials used, and exogenous heat production, all point to eventual medical complications involved in any system selected.

It appears that currently the two major problems involved are those of preventing clot formation and the selection or development of proper materials for the blood pumping chambers. Although the government has placed much emphasis on power supply and development, it appears that this and other engineering techniques required in the development of the totally implantable artificial heart are currently within the limits of the present state of the art development. It also appears somewhat irrational to be developing fuel cells and nuclear power supply before the problems surrounding the blood pumping system are understood. Certainly one can predict to an order of magnitude what degree of power might be required. However, many of the physiological questions of prolonged blood pumping are unanswered and until successful artifi-

cial heart are used, one must question the merits of developing a power source for an undefined system. Problems concerning heat and metabolic changes involved in nuclear power systems and fuel cells are of sufficient magnitude in their own right, that exploration of these is somewhat premature.

Much has been written concerning GBH coating, negative zeta potential endothelial lining prosthetic materials, wettability, and effects of turbulence and stagnation upon clotting. The voluminous amount of literature recently being published in the area only reflects the current lack of concrete knowledge. It is reasonably safe to say that embolic and thrombotic phenomena currently pose the greatest threat to the overall success of the artificial heart development, especially any total replacement.

The second major problem is the proper material selection. The human heart has the infinite advantage of having self repair characteristics. Biological systems are able, to a large degree, to repair defects created by fatigue and to respond by strengthening stress points. Unfortunately these capabilities are not possessed by man-made materials currently available. The importance of material selection in an artificial heart system which requires atraumatic blood handling without clotting or noticeable wear in a system not readily inspected cannot be minimized. Thin, flexible plastics which face repeated stressing of up to 700 million times at a ten year period are required. During this time, over 20 million gallons of blood will be pumped. Materials must be selected with the thought that any material failure will have catastrophic results—the death of the host. This is combined with the severe limitations in a number of materials presented by the patient. Toxic materials or materials which excite the immune response must be eliminated. The biological degrading potentials of the host further impose design restriction on materials. Further complications are the restrictions which are designed into the system, including cross compatibility of materials, manufacturing

techniques, and changes created by time. These limitations, along with the phenomenal reliability which is required, illustrate the importance of material problems.

Now we would like to take liberty to describe one approach taken for a totally implantable artificial heart. It is our feeling that this probably represents the state of the art of refinement in terms of the total cardiac replacements.

In 1963 the development of an artificial heart was undertaken at Indiana University with optimism because of the following background considerations:

1. Successful permanent union of host to vascular grafts.
2. Successful cardiopulmonary bypass.
3. Recent engineering advances, including miniaturization and high reliability.
4. Reasonably suitable materials.
5. Initial experiences of Hastings, Kolff, and Shudder.
6. Reliable efficient power sources - electrical energy.

The following obstacles which have been discussed above were anticipated:

1. Thrombosis and embolic phenomena.
2. Hemolysis.
3. Material fatigue.
4. Limitation of prosthetic valves.
5. The need for responsive controls.
6. Space limitations.
7. Efficiency.
8. Difficulties in animal testing.

Initially a study period was undertaken, and the following goals and guidelines were established, which for the most part have been followed:

1. Duplicate the human heart as nearly as possible.
2. The need for pulsatile blood flow.
3. A four chambered heart, with two pumping chambers and two passive reservoirs.
4. A heart controlled by venous filling.
5. An electrically oriented system.

6. The need for an active and relatively unencumbered life of the patient.

The latter point is most worthy of discussion. Certainly efficiency and reliability must be a major consideration so as to produce a patient who is able to return to society as a useful and contributing member. If this ultimate goal is not kept constantly in mind, the artificial heart can serve only as a research tool. It is medicine's obligation to prolong useful life, not vegetative existence.

The importance of engineering collaboration was appreciated at the onset. The project has been characterized by the close ties between engineering and medical colleagues.

The use of a closed-loop electrohydraulic system was selected for reasons of size, efficiency, reliability, and atraumaticity of blood handling. Such an approach makes it possible to utilize the major advantages of a fluid hydraulic or a pneumohydraulic system in combination with the overwhelming advantages of electricity and electronics energy storage, reliable miniaturized electronic control, efficient electro mechanical energy conversion and the great ease of energy transmission available. The use of fluid permits the optimum power transmission to the blood without localized higher pressures, or excessive turbulence. Thus, atraumatic blood handling is possible. Fluid permits uniform energy transfer without the need for complicated power trains, gear systems, or mechanical linkages—all of which tend to diminish reliability and efficiency. Transient high pressures, large pressure differentials between the pumping system, and the intraventricular and arterial blood are alleviated. Such a system makes it possible to pump blood in a non-positive displacement manner by a ventricular pump in which fluid pressures need not exceed the intraventricular pressure which are normally seen by the blood. Thus, it is possible to hold blood trauma to a minimum. The use of noncompressible fluid permits more accurate regulation and monitoring of the total system than is possible with

compressible fluids, such as gas. Direct volumetric measurement is possible due to compressibility of gases being eliminated. The use of a closed-loop system with a non-compressible fluid makes it possible to create a totally implantable unit in a package arrangement only slightly larger than normal ventricular volume. External vents or atmospheric equalization techniques are not needed. The only variable in package volume is directly related to changes in venous return. The problem of increased fluid losses inherent in the use of a non-compressible fluid is overcome by placing the hydraulic pumping unit in close proximity to the ventricles, rather than using long tubing to transmit the energy from a distant source.

With electricity, transthoracic transmission is the next step—a step which will make the system implantable without breaks in the skin barrier. Certainly the use of atomic batteries with thermoelectric power conversion is possible to ultimately make such a system totally implantable with a life of several years.

The use of electromotors to drive the hydraulic pump permits the use of reliable highly efficient electrical power. Motors can be driven at or near maximum efficiency, because near constant hydraulic output is required. Out of phase ventricular pumping makes this possible. Efficiency levels can be obtained which do not create excessive heat production. Actually, it is quite possible to approach and even exceed the efficiency of the normal human heart. The submersion of the electromotors in oil permit highly reliable long-term operation of high span motors. Lubrication is increased. Bearing life is markedly prolonged and effective cooling is provided.

Phase I - Feasibility Phase:

Varied aspects of the problem surrounding total cardiac replacement were investigated simultaneously. These included a study of the feasibility of a closed-loop hydraulic principle, the examination and testing of a variety of motors and pumps, hydraulic fluid and material

systems, and the construction of prosthetic cardiac valves.

The initial electrohydraulic model was designed primarily for the testing of concept feasibility. Emphasis was not placed on system reliability or longevity. A blood flow of 5-6 liters was obtained. This system was comprised of three separate units: a ventricular package, an electrohydraulic package, and an electronic power supply. The first of the two packages were implanted and connected by means of hydraulic lines. The third package was external and required trans-thoracic chest leads. The ventricular package was about 4/5 the size of the normal human heart and contained the actual blood which consisted of two collapsible ventricles in semirigid housings. Two leaflet inflow and two outflow valves were provided. Anastomosis between atrial remnants, pulmonary artery, and aorta were utilized to permit total cardiac replacement following excision of the heart. The abdominally situated hydraulic package included electromotor, hydraulic reservoir, mixed flow pumps, and fluid control valves. A power requirement of approximately 25 watts was required.

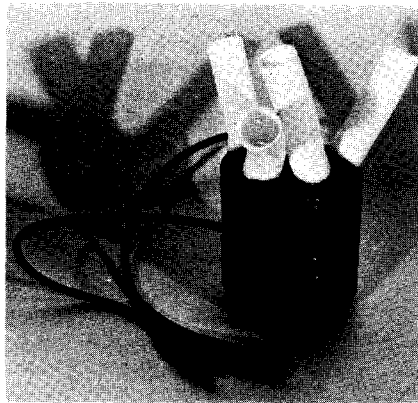
Phase I - Evaluation:

The feasibility model developed in Phase I was successfully tested in calves and dogs. Preliminary studies indicate the closed-loop electrohydraulic concept is sound. In short-term experiments, normal physiological responses were encountered. Pulmonary edema, hepatic congestion, splanchnic pooling, or other signs of circulatory failure were not encountered. Normal systemic and pulmonary pressures were present. The system responded to various circulatory stresses, including hypovolemia, vasopressors, vasodilators, and septic shock in the anticipated manner. The heart produced no significant hemolysis. Thrombosis or embolic phenomena were not observed. Postmortem examination of the liver, kidney, spleen, and lung revealed no unexplainable abnormalities.

Phase II - Design:

In Phase II the hydraulic and ventricular packages were combined into a single IPM (Intrapericardial Pumping Module). Redundancy of many components could be used to achieve the reliability needed for clinical trials.

IPM Packaging: It was apparent that in the first model, size and



weight would have to be compromised in the interest of reliability. An ellipsoidal solid proved to be an ideal package form. The cross-section of the IPM approximates an ellipse with a 9 cm. minor axis, and a 12 cm. major axis.

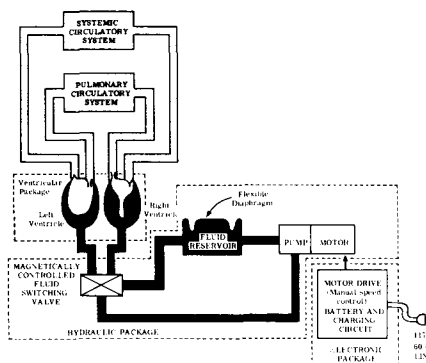


FIGURE 2 - FIRST ARTIFICIAL HEART PROTOTYPE SYSTEM

Its' height approaches 15 cm. The weight of this unit is 2000 grams, and it displaces approximately 1200 cc. This will be reduced by nearly 40% in future models. This additional engineering effort will be undertaken in Phase III.

The Phase II IMP and EPM (Extracorporeal Power Module) are interconnected with an umbilical cable. The EPM is approximately

the size of an attache case and weighs 22 lbs. This module contains the redundant motor drive-control electronics, silverzinc battery with capacity for 8 hours of complete mobility, automatic battery charging facility while operating from conventional 110 AC Power. This module was assembled from off-the-shelf components and does not reflect any effort to minimize size or weight. In comparison, the Phase III EPM will be approximately one-half the size and weight.

Operational Data: This system has a cardiac output capability of from 5-12 liters/minute/side at 180 MM HG. The energy demand rates vary proportionately with cardiac output. Maximum demand rate is 22 watts. The parallel redundancy utilized in the critical components enhances overall reliability and negates the possibility of a catastrophic failure because of breakdown in single component. Should a malfunction occur, the system will continue to function normally at a reduced cardiac output of 6 liters/minute.

A discussion of artificial hearts has been presented. Several major problems were elucidated and some philosophy was provided. In addition, a total cardiac replacement which probably represents the state of the art of refinement in terms of current hardware was presented. The paper is presented as being representative of the type of progress that can be made by close cooperation of medical personnel and commercial engineering organization. In a small way, the program discussed represents a pilot program similar to the Artificial Heart Program currently being undertaken by the PHS.

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