

REVIEW

**Present and Future of the Artificial Heart\***

CLARENCE DENNIS,<sup>†</sup>M.D., Ph.D.

National Heart and Lung Institute  
Bethesda, Maryland 20014

In 1963 the Advisory Council of the National Heart Institute expressed an interest in circulatory assistance devices and artificial hearts. The Director of NIH, Dr. James Shannon, asked Dr. Ralph Knutti, D/NHI, to appoint an Advisory Group on Mechanical Heart. This group met on February 21, 1964, and consisted of the following: E. Cowles Andrus, M.D.; M. E. DeBakey, M.D.; Ben Eiseman, M.D.; Willem J. Kolff, M.D.; John R. Beem, M.D., Associate Director for Program Planning and Scientific Information, NHI; Robert L. Bowman, M.D., Laboratory of Technical Development, NHI, Intramural; Eugene Braunwald, M.D., Chief, Cardiology Branch, NHI, Intramural; Joseph W. Gilbert, M.D., Deputy Chief, Surgery Branch, NHI, Intramural; C. Wm. Hall, M.D., NHI; Philip Janus, Program Planning Officer, NHI; Ralph E. Knutti, M.D., Director, NHI; and James M. Stengle, M.D., Office of Program Planning and Evaluation, NHI, Extramural. The group recommended encouragement of work in this area, including the making of contracts with industrial groups and the assignment of staff and consultants as necessary.

Initially Dr. Beem was in charge of this staff. When he departed in 1965, Dr. Frank Hastings, who had joined the staff the preceding year, was placed in charge of the Artificial Heart Program.

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†Present address: State University of New York at Stony Brook, Stony Brook, New York 11794.

In 1965 contracts were let to six contractors to explore the feasibility of an artificial heart from an engineering point of view, and in 1966 an additional contractor was chosen, Hittman Associates, to integrate the reports of the initial six contractors. The AEC and NHI collaborated on selection of contractors and review of reports. The result was a study which became available late in 1966, indicating that an implantable artificial heart was feasible and predicting that totally implantable hearts could be ready for trial in animals in 1968 and in man in 1970, provided sufficient funds and efforts were to be applied.

This report was made the basis of the Artificial Heart Program, later broadened to become the Medical Devices Applications Branch, and in 1972 renamed the Division of Technological Applications (DTA). DTA dealt with research and development in devices and instrumentation in the cardiovascular and pulmonary fields, including circulatory assistance devices and artificial heart.

In the fall of 1972, the new law on Heart, Blood, Lung, and Blood Vessel Diseases added to the activities and responsibilities of NHLI. The stipulated addition of personnel for mandated new programs, mandated enlargement of specified programs, and the preparation of a National Plan added to the cost of running the institute. These factors plus a mandated pay raise added about 4 million to that annual cost. In addition, a mandated redistribution of funds within the institute reduced the funding available for DTA. Although there were two vetoes of money bills for HEW in fiscal year 1973, there was some relief from the continuing resolution, utilized to fulfill earlier commitments.

In fiscal year 1974 there is some amelioration of our difficulty, albeit already overcommitted in restoration, for instance, of some training funds, but the support for the artificial heart and associated instrumentation was cut painfully. The addition of ceilings on personnel to all this cancelled the plans for expansion of the staff and scope of DTA, of which my coming had been a part. DTA thus was deemed to be too poorly funded and too small in manpower to be viable, and the decision was made to disband DTA and to distribute the projects and personnel among the categoric divisions, i.e., most of the artificial heart program to the Division of Heart and Vascular Diseases, most of the biomaterials work to the Division of Blood Diseases and Blood Resources, and the work on oxygenators to the Division of Lung Diseases. I was brought into Dr. Cooper's office as Special Assistant for Technology, Office of the Director, i.e., to serve as coordinator for all technological development in the NHLI. This represents a means of endeavoring to strengthen the program on the artificial heart in the face of unanticipated strictures in personnel and support.

One of the problems addressed in the early 1960s by the Advisory Group on the Artificial Heart had been that of the most effective method of administration in a coordinated, target-oriented program designed to engage the expertise of industry as well as that of academia. Straightforward grant support for profit-making institutions was contrary to NIH policy, and in addition uneasiness was expressed about freedom of exchange of information concerning work performed on this basis in such institutions. The contractual pattern was therefore chosen.

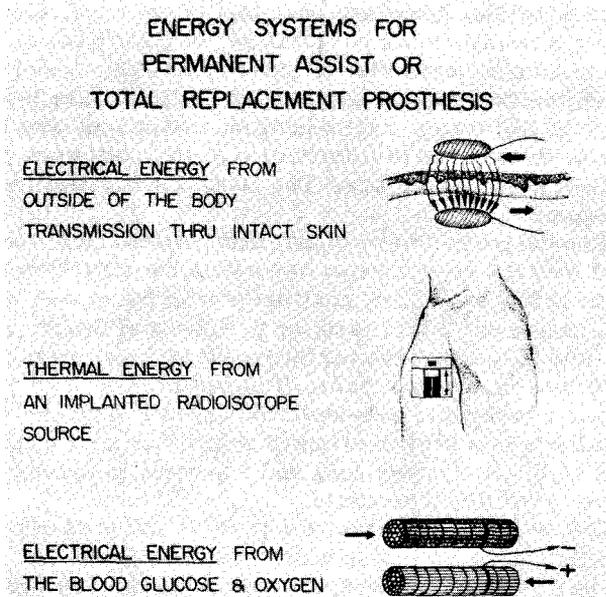
Yet another choice had to be made, that between an attempt to recruit staff with the proper expertise within the structure of NHI or whether to select a primary contractor with personnel of proper expertise to devise and coordinate the protocols of the remaining contractors and to monitor the performance of their work. As you know, the former choice was made. Today, in the light of our reduction in force, thoughtful consideration is being given to the possibility of dealing with a proper primary contractor as a means of provision of recognized experience and expertise in the planning and direction of the whole program.

I would like to speak now about the present status of development and some of the major problems which are to be faced.

Power sources can be of several types (Fig. 1). The program has explored in detail biological fuel cells and regretfully come to the conclusion that the feasibility of this source of power is not such as to warrant continuance in that area.

A second source of power lies in the utilization of electrical conduits passing through the skin, supplemented by rechargeable implantable batteries. Although the freedom from connection to a power supply outside the body would not be longer in all probability than 1 or 2 hours with present battery capabilities, nevertheless the patient would have such periods of freedom from outside connections as to permit him to take a shower bath or go swimming. The disadvantages of this pattern lie in the necessity for an available outside power supply almost continuously and the risks of ascent of infection along the power supply lines. The Artificial Kidney Program of the National Institute of Arthritis, Metabolism, and Digestive Diseases has in the last few years had a rather intensive program of study on this matter. It appears that it is feasible to develop a transcutaneous conduit without ascent of infection. Some work is supported by NHLI and appears to be approaching success in this area also.

Another source of power lies in thermal energy. The likely origin appears to be plutonium-238. The Artificial Heart Program has reached a point at which calves have survived more than 4 days with a left ventricular support device powered in this fashion. The



**FIG. 1.** Power sources without percutaneous conduits can be fuel cells, nuclear fueled thermal engines, or transcutaneous transformers.

problems which are primary are related to the amount of radiation, proper shielding against heat loss to the surrounding tissues, dissipation of the excess heat resulting from inherent inefficiencies in the system, and enhancement of those efficiencies. The bulk of the work on the effects of irradiation and the approach to the problems of shielding against heat loss to the tissues will be presented by Dr. Mott in view of the extent of the work on these two subjects which has been performed in the AEC.

It has been demonstrated in the program that animals can dissipate the waste heat of a thermal engine via the blood stream. Thus far, however, it has not been possible to dissipate this waste heat through flocked surfaces in pumping chambers without disappearance of living cells from the pseudointima. It is very difficult to believe there would not be serious problems with embolization and protein denaturation under these circumstances. This is a problem which has not yet been resolved.

An additional pattern by which power can be provided is through



FIG. 2. The secondary coil and core of the transcutaneous transformer are completely buried beneath the skin. A portion of the core, however, is enclosed by skin in the form of a suitcase handle. The core of the primary, entirely outside the body, can be snapped into an interlocking position.

a skin transformer, the primary coil being outside the body and the secondary coil being buried beneath the skin (Fig. 2). It is essential that the positioning of the primary and secondary cores be precise in order that sufficient energy can be transferred. As indicated in Fig. 2, the plastic surgical creation of a suitcase handle containing the core of the secondary coil permits the snapping of the core of the primary coil through the suitcase handle in such a fashion as to assure precise positioning. This has proven necessary when cattle are the subjects. Presumably, it would be most effective in clinical applications as well. Tests are currently in progress to determine whether such a device can remain implanted over many months in calves without erosion of skin and contamination of the tissues around the secondary coil.

This skin transformer serves as a satisfactory solution experimentally, and assist pumps have been powered with such devices over extended periods of time by several different contractors. This device imposes the same limitations on the freedom of the patient (to move away from outside power sources) as does the utilization of conduits through the skin.

The conversion of thermal or electrical energy to pumping power

has been studied by several different mechanisms. Rotary electric motors are in process of study by two different contractors. Each has worked satisfactorily in bovine implantations over periods of time. A piezoelectric converter has also functioned upon implantation. Both of these patterns raise questions with regard to mechanical wear and resulting limitations on durability. A solenoid drive which has been developed by one of our contractors appears to be the most efficient power converter in the program. This also has been utilized in bovine implantations.

Of the thermal sources, there are two Stirling engines in addition to that being developed by the AEC. All of these appear to offer promise of reaching efficiencies above 20%. There is one modified Rankine engine which had a low efficiency until a binary system was developed. The efficiency appears capable of considerable enhancement by this means, but it is much less than that of the Stirling engine.

The remaining problems are related to configuration of the pumps, durability of the materials employed, especially in the presence of tissue fluids, and development of appropriate surfaces for contact with tissues, but especially with blood. These problems of materials are immense and probably constitute the major challenge in the whole program. I know that Dr. Bruck has already addressed this group on this subject and therefore I will say no more about it.

Many other problems also persist, perhaps chief among them that of the most effective types of physiological controls, but it appears to us in NHLI that those which I have touched upon are probably the major ones.

One may make a speculation as to the length of time until success shall have been achieved, but such speculations are very dangerous. It is likely that support for left ventricular function for periods up to 3 months may become operative within a year, but it would take a luminescent crystal ball to give a meaningful answer with regard to the total artificial heart. Suffice it to say that it is the conviction in the NHLI that it is possible and that it will be accomplished.

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