ANATOMY STUDIES FOR AN ARTIFICIAL HEART

C00-2208-10

Final Summary Report

December 1977

NOTICE
This report was prepared as an account of work sponsored by the United States Government. Neither the United States nor the United States Department of Energy, nor any of their employees, nor any of their contractors, subcontractors, or their employees, makes any warranty, express or implied, or assumes any legal liability or responsibility for the accuracy, completeness, or usefulness of any information, apparatus, product or process disclosed, or represents that its use would not infringe privately owned rights.

Prepared by

Raymond J. Kiraly and Yukihiro Nosé
Department of Artificial Organs
The Cleveland Clinic Foundation
Cleveland, Ohio 44106

NOTICE

This report was prepared as an account of work sponsored by the United States Government. Neither the United States nor the United States Energy Research and Development Administration, nor any of their employees, nor any of their contractors, subcontractors, or their employees, makes any warranty, express or implied, or assumes any legal liability or responsibility for the accuracy, completeness, or usefulness of any information, apparatus, product or process disclosed or represents that its use would not infringe privately owned rights.

Prepared for

THE U.S. ENERGY RESEARCH AND DEVELOPMENT ADMINISTRATION
UNDER CONTRACT NO. EY-76-S-02-2208

DISTRIBUTION OF THIS DOCUMENT IS UNLIMITED *ef*

DISCLAIMER

This report was prepared as an account of work sponsored by an agency of the United States Government. Neither the United States Government nor any agency Thereof, nor any of their employees, makes any warranty, express or implied, or assumes any legal liability or responsibility for the accuracy, completeness, or usefulness of any information, apparatus, product, or process disclosed, or represents that its use would not infringe privately owned rights. Reference herein to any specific commercial product, process, or service by trade name, trademark, manufacturer, or otherwise does not necessarily constitute or imply its endorsement, recommendation, or favoring by the United States Government or any agency thereof. The views and opinions of authors expressed herein do not necessarily state or reflect those of the United States Government or any agency thereof.

DISCLAIMER

Portions of this document may be illegible in electronic image products. Images are produced from the best available original document.

CONTENTS

	page
1.0 ABSTRACT	1
2.0 STATEMENT OF EFFORTS	2
3.0 PROGRESS REPORT	3
3.1 Calf Thoracic Anatomy	3
3.2 Calf Tolerance to Implanted Mockups of the Thermal Converter	4
3.3 Acceleration Experienced by the Thermal Converter Implanted in Calves	4
3.4 Human Thoracic Anatomy Relevant to Implantable Artificial Hearts	5
3.5 Intrathoracic Compliance	5
4.0 CONCLUSION	12
5.0 REFERENCES	13

1.0 ABSTRACT

In the interval from February of 1972 through December of 1977, studies were conducted relating to the anatomical feasibility of implanting a total artificial heart system. These studies included both the calf as an experimental animal as well as the ultimate human recipient of the artificial heart system. Studies with the calf included definition of the thoracic anatomy relative to the size, shape, and vascular connections for implanting the blood pump. To test the animal's tolerance to an implanted engine system, mockups of the thermal converter were implanted chronically in various locations within the calf. No problems developed in retro-peritoneal or intraperitoneal implants ranging from 8 to 15 months. A study to determine accelerations experienced by an abdominally implanted thermal converter was performed in calves. Under the most severe conditions, accelerations of a maximum of 34 Gs were experienced. The largest effort was devoted to defining the human anatomy relative to implanting an artificial heart in the thorax. From a number of data sources, including cadavers as well as living patients, a quantitative, statistical analysis of the size and shape of the male thorax was obtained. Finally, an in vivo study of a functional intrathoracic compliance bag in a calf demonstrated the feasibility of this method.

2.0 STATEMENT OF EFFORTS

Dr. Y. Nosé and Mr. R. Kiraly, the principal investigators under this contract, have devoted approximately 10% of their time over the duration of the contract. Mr. G. Jacobs was project leader and the principal contributor to the human anatomical studies, which was a major part of the total program. Dr. J. Urzua and Dr. T. Agishi were major contributors to the study of the calf anatomy and the anatomical tolerance to the implanted thermal converters. Dr. I. Koshino and Mr. R. Sukalac studied the accelerations of the thermal converter implanted in calves. Mr. J. Przybysz conducted the compliance studies. The authors wish to acknowledge the contributions of the following individuals to specific projects in the studies reported here: Dr. K. Hayashi, Mr. R. Louie, Dr. T. Meaney, Dr. T. Panek, Dr. G. Picha, Dr. R. Seale, Dr. O. Sudilovsky, Dr. N. Taslitz, Dr. H. Harasaki, and Dr. T. Washizu.

3.0 PROGRESS REPORT

This report provides a brief summary of the efforts conducted in the studies over the interval from February, 1972 through December, 1977. These studies all related to the implantation of a total artificial heart system in the calf as an experimental animal while developing the device, as well as the definition of the human anatomy for the ultimate recipient of such a system. The studies that were conducted are divided into five principal areas; three have to do with the calf anatomy, the fourth and major effort was devoted to the study of human anatomy, while the last study related to a functional intrathoracic compliance bag. The calf anatomical studies include the calf thoracic anatomy; the calf tolerance to an implanted mockup of the thermal converter; and accelerations likely to be experienced by the thermal converter implanted in the calf. By far the largest effort was devoted to the study of the human thoracic anatomy relevant to the implantation of an artificial heart. The final study examined the feasibility of an intrathoracic compliance bag. Since nine progress reports have been previously submitted covering most of these areas in detail, only a summary of the technical efforts is presented along with references to the previous documents containing details on each specific area. The compliance study, conducted recently and not previously reported on, is described in more detail.

3.1 CALF THORACIC ANATOMY

Anatomical features of the calf thorax, pericardium, and abdominal cavities were obtained utilizing molding techniques with either silicone rubber or polyurethane foam molding materials. The configuration dimensions, and volumes are described in detail for the thoracic cavity. Specific features also include the vascular connection points to the major vessels which would be necessary for implanting a total artificial heart. Details of these studies and the results obtained can be found in references 1, 2 and 10, while reference 2 summarizes the overall study. The conclusion of this study was that the prototype blood pump, having dimensions of 8 cm in diameter and 12.5 cm in length, could be accommodated in a 90 kg calf thorax, provided care was exercised in the method of implantation so that the soft vascular structures would not be compressed. In addition, the abdominal cavity of the calf

being massive would most likely accomodate the thermal converter in any of a number of locations. It was recommended that specific studies be conducted to determine the actual tolerance of the animal to the implanted thermal converter.

3.2 CALF TOLERANCE TO IMPLANTED MOCKUPS OF THE THERMAL CONVERTER

The purpose of this study was to examine the anatomical and physiological tolerance of the calf to implanted models of the thermal converter in various trial locations. Silicone rubber reproductions of the converter were fabricated to the proper weight of 1200 gm and volume of 820 cu cm. Calves weighing about 90 kg each were used for these experiments. The models were implanted in the extrapleural subcostal area in one case, in the retroperitoneal infrarenal area in three cases, and in the intraperitoneal location in one case. After implantation, the animals were maintained for durations between 8 and 15 months and then sacrificed for autopsy. During the interval, the animals were kept on a farm and found to be normal in physical, biochemical, and histological parameters, which were periodically examined during the course of the experiment. The conclusion of this study indicated that all the locations appeared somewhat tolerable; however, the retroperitoneal infrarenal space was preferable for implantation of the thermal converter not only from an anatomical space availability standpoint but also from the physiological view of minimal possible sacrifice of function of the neighboring tissues or organs. The details of this study are reported in references 3-6, while reference 6 summarizes the entire study.

3.3 ACCELERATION EXPERIENCED BY THE THERMAL CONVERTER IMPLANTED IN CALVES

In this study a full scale weighted mockup of the thermal converter was fabricated containing a triaxial accelerometer. The mockup was implanted in calf cadavers which were subjected to falls from an operating table. The highest acceleration recorded was 34 Gs. The mockup was then implanted in living animals and acceleration measurements made under various maneuvers, including walking, standing from a laying position, walking up and down stairs, jumping and falling from a standing position. The maximum acceleration recorded in a live animal was 8 Gs and occurred in the falling maneuver. The details of this study were reported in reference 8. It was concluded that the magnitude and duration of accelerations expected to be experienced by the

thermal converter for future animal experiments was relatively low, and with care in maintaining the experimental animal postimplantation, the accelerations may, in fact, be negligible.

3.4 HUMAN THORACIC ANATOMY RELEVANT TO IMPLANTABLE ARTIFICIAL HEARTS

This was the major effort of the program and was underway for the full duration of the contract. The objective of this study was to define the human thorax in a quantitative statistical manner such that the information will be useful to the designers of cardiac prostheses, both total replacement and assist devices. This pertains specifically to anatomical parameters relevant to the total cardiac prosthesis. This information will also be clinically useful in that the proposed recipient of a cardiac prosthesis can by simple radiography be assured of an adequate fit with the prosthesis prior to the implantation.

Methods were developed for generating an integrated, statistical model of the anatomical structures within the human thorax relevant to artificial heart implantation. These methods involve definition of anatomy in four areas: chest wall, pericardium, vascular connection locations, and great vessels.

A model for the prediction of thorax features from radiograms was finalized. The models have been combined with radiograms to arrive at a size distribution representing the adult male and female populations.

Results are presented in three scale views of the human thorax showing the main features relevant to cardiac prosthesis implantation. Data is available for size distribution as a function of the population having specific sizes. Data was obtained from a number of sources and represents both normal and diseased patients. The ERDA total artificial heart blood pump was shown to successfully fit the fifty percentile adult male human. Details of this study are included in references 1 through 7 and 9 and 10. Reference 9 contains all data and complete results of this study.

3.5 INTRATHORACIC COMPLIANCE

All pulsatile pumps achieve fluid motion by virtue of the changing volume within the pump. It is obvious that in any closed system, if the volume in any one component changes, an equal but opposite change of volume occurs somewhere else in the system. For example, if the pump is filled with

90 cc of blood, the space on the back of the diaphragm also is displaced through 90 cc. Similarly, on ejection of the blood pump, when the volume in the blood chamber is reduced by 90 cc, the volume behind the diaphragm must increase by this same amount. If the system were rigid, and the space behind the diaphragm were filled with a gas, then, depending on the total gas volume, this pressure might vary through a very large magnitude causing inefficiencies in the system and overloading of the components and energy source. There are two methods to accommodate this change of volume without causing an increase in pressure. The first would be to have a vent via a percutaneous connector to the outside of the body. This would allow air in and out from the backside of the diaphragm and always maintain this space at atmospheric pressure. The second approach is for a totally implantable system without a percutaneous connection. This involves placing a functional compliance within the body. The only location in the body allowing a high compliance (i.e., a low pressure change for the volume change required in the pump) would be within the thorax. Any other locations within the body could not reliably offer a very low pressure as the cyclical volume changes take place. The thorax is ideal, since the intrathoracic pressure is of necessity very near to atmospheric pressure. The compliance member would be a flat, flexible bag connected to the backside of the pump diaphragm. It may also be possible to build a compliance member integral with the pump housing.

To evaluate the feasibility of the intrathoracic compliance bag a series of in vivo experiments were performed. Two simplified pneumatic drive systems were constructed to actuate the implanted devices with air pressure. Figure 1 shows the schematic of the overall system implanted in a calf. A stroke volume limiter was constructed containing internal bias springs in order to overcome the negative pressure within the thorax of the animal. The system was designed for a stroke of 90 cc at atmospheric pressure. Pressure pulses from the drive system actuate the stroke volume limiter forcing 90 cc of air from the stroke volume limiter into the implanted compliance bag. During diastole of the drive system the bias springs return the diaphragm within the stroke volume limiter back to its original position deflating the implanted bag. The actual air volume within the bag cycles between 60 and 150 cc. The pressure tap located between the compliance bag and the stroke volume limiter allow periodic measurements to be made of the pressure-volume curve

Figure 1: Compliance test schematic

of the implanted bag. Four compliance bags were constructed of a flat pancake shape nominally 5 inches in diameter. The first two bags were fabricated from polyolefin rubber which required a compression molding procedure for fabrication. The resulting bags were somewhat thick and stiff and for this reason the third and fourth bags were fabricated using Biomer, a polyurethane. The bags were implanted in 90 kg calves through the 6th intercostal space into the left pleural cavity with the bag positioned against the rib cage. After implantation, the bag was pulsed at 100 BPM through a stroke of 90 cc for the duration of the experiment. The pressure-volume curve for the bag was measured several times a week. In all cases the animals recovered satisfactorily from the implantation surgery and were in good condition for the duration of the experiment.

In the first case, experiment 76122, the pneumatic drive tube became disconnected from the implanted compliance bag 10 days postimplantation, requiring termination of the experiment. Over the 10 days, however, no change in the pressure-volume curve for the implanted compliance bag was noted. In the second experiment, number 76127, a compliance reduction was observed starting at 3 weeks and by 7 weeks the resistance to bag inflation was very high, necessitating termination of the experiment. The data from this experiment is shown in Figure 2. Note that the pressure volume curve for the first 10 days was essentially the same, but by the third week the pressure required to inflate the bag began a continual rise. At autopsy a relatively thick tissue capsule was formed around the bag with caseous mass in the capsule. It is thought that the localized infection around the bag contributed significantly to the tissue capsule growth altering the compliance characteristics. In the final two experiments, both bags are presently functioning without marked changes in compliance at 7 and 4 weeks postimplantation respectively. The data from these experiments are shown in Figures 3 and 4. Note in Figure 3, the longer experiment, some change in compliance was noted at approximately 3 weeks, but this has subsequently remained stable. These experiments have demonstrated the feasibility, at least for the limited durations studied, of an intrathoracic compliance bag. It also indicates caution to those intending to use this method. Tissue capsule growth within the pleural cavity is very sensitive to infection, and therefore, the implant must remain sterile. This requires careful maintenance of any percutaneous connections.

Figure 2: Pressure volume curve obtained in Experiment 76127. Steadily decreasing compliance noted starting 3 weeks postimplantation.

Figure 3: Compliance experiment 77232. Some change noted at 3 weeks, but has been stable since. Experiment is continuing.

Figure 4: Compliance experiment 77238. Data has been stable for 3 weeks and experiment continues.

4.0 CONCLUSION

The studies conducted under this contract were unique in that they all have major significance to the ultimate implantation of an artificial heart in man and, to our knowledge, have never been undertaken previously. We believe the results of these studies already have had a major impact on the development of an artificial heart. Since the early 1970s when these studies were initiated, the anatomical features of the experimental animal, the calf, were quantitatively defined and were a major aid to extending the survival time of animals with implanted artificial hearts from a period of days to presently several months' duration. The major objective of the program, however, was to study the human anatomy and these studies are continuing under NIH support. ERDA's early initiation of this study has assured that devices that are now being developed for clinical application will have a very good chance of fitting the ultimate human recipients.

5.0 REFERENCES

The first nine documents have been previously submitted as reports under this contract. All originated in the Department of Artificial Organs at the Cleveland Clinic Foundation.

1. C00-2208-1 Progress Report. "Study to Determine the Size and Shape of the Available Space in the Intrathoracic and Intra-abdominal Cavity for a Totally Implantable Cardiac Prosthesis," February 15, 1972 - May 1, 1972.
2. C00-2208-2 Technical Report. "Study to Determine the Size and Shape of the Available Space in the Intrathoracic and Intra-abdominal Cavity for a Totally Implantable Cardiac Prosthesis," February 15, 1972 - June 30, 1972.
3. C00-2208-3 Annual Progress Report. "Available Space for a Totally Implantable Cardiac Prosthesis," July 1, 1972 - March 31, 1973.
4. C00-2208-4 Progress Report. "Available Space for a Totally Implantable Cardiac Prosthesis," April 1, 1973 - July 31, 1973.
5. C00-2208-5 Progress Report. "Available Space for a Totally Implantable Cardiac Prosthesis," August 1, 1973 - November 30, 1973.
6. C00-2208-6 Annual Progress Report. "Available Space for a Totally Implantable Cardiac Prosthesis," April 1, 1973 - March 31, 1974.
7. C00-2208-7 Progress Report. "Available Space for a Totally Implantable Cardiac Prosthesis," March 31, 1974 - September 15, 1975. (Draft Copy only)
8. C00-2208-8 Technical Report. "Acceleration Experienced by Thermal Converter Implanted in Calves," February, 1976.
9. C00-2208-9 Technical Report. "Human Thoracic Anatomy Relevant to Implantable Artificial Hearts," October, 1976.
10. Urzua, J., Sudilovsky, O., Panke, T., Kiraly, R., and Nose, Y. "Anatomical Constraints for the Implantation of an Artificial Heart," J Surg Res, 17:262, 1974.