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INTERIM PROGRESS REPORT
AEC CONTRACT NO. AT (11-1)-2208

"STUDY TO DETERMINE THE SIZE AND SHAPE OF
THE AVAILABLE SPACE IN THE INTRATHORACIC
AND INTRAABDOMINAL CAVITY FOR A TOTALLY
IMPLANTABLE CARDIAC PROSTHESIS"

2/15/72 - 5/1/72

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AEC INTERIM PROGRESS REPORT

The goal of the present program has been the determination of the spacial constraints of the human and calf body for a totally implantable AEC artificial heart system. Quantitative data generated from our studies will cover an area which was not completely explored in the past.

The basic idea has been to find a space mutually compatible for both human patients and calves so that systems designed for the ultimate human use would also fit in the experimental animal, therefore saving time and effort since only one basic design will be required.

The mold studies are for the purpose of defining a shape model which, when combined with a statistical analysis using a relatively large number of radiographs, will enable a prediction of the dimensions of the space as a function of the percentage of the population of adult human males. In addition from a radiograph of a specific patient candidate for the artificial heart system, the shape and size of the space can be determined from the model allowing fitting and attaching hardware to be sized prior to the implanting procedure.

This report will give an account of the work performed from February 15, 1972, (date of effective initiation of the work was March 1, 1972) until May 1, 1972. The entire program will be completed on June 15, 1972 and the final report will be submitted within two weeks after that date.

According to the proposed schedule the following tasks have already been completed:

- Establishment of precise experimental protocols for both calves and human cadavers;
- Five calves have been subjected to measuring and molding protocols.

The following tasks are currently in progress:

- Two cadavers have been subjected to measuring and molding protocols, and it is hoped to complete three additional cases.
- Evaluation of the molds is in progress, as well as their comparison with external measurements.
- Review of the published data and their comparison with our experimental findings is currently in progress.

A short preliminary account of the experimental findings will be reported as well as samples of the preliminary results and a short description of the methods used.

Evaluation Of Molding Materials:

Two materials have been selected for our experiments:

- Silastic RTV A + Catalyst 4^{*}
- Polyurethane foam Froth-Pak Insta-Foam[†]

Silastic: Base material and catalyst ratio was changed in order to determine the curing time as a function of this ratio since different curing times are desirable for different situations.

Both materials produce different alterations on the soft structures as shown in Figure 1, due to the high specific gravity of Silastic and to the pressure generated by spraying the urethane foam. The position of the animal is irrelevant using foam as the molding material, but the load distribution of Silastic on the soft tissue will produce different shapes according to the position of the animal. This artifact is minimal for osseous structures such as the chest cavity but can become quite important

^{*}Dow Corning Corporation, Midland, Michigan.

[†]Insta-Foam Products Inc., Addison, Illinois 60101.

FIGURE 1

Schematic drawing of sections of calf thorax showing the different deformation produced on the pericardial sac by the different molding materials, according to their specific gravity and expansive tendency.

for structures such as the pericardial sac (Fig. 2). Therefore, Silastic was selected for the thoracic and abdominal cavities and urethane foam for the pericardial sac.

Molds Evaluation Strategy:

- Molds obtained are measured externally, the position of organs and critical structures assessed.
- Molds are sectioned in slices 2.5 cm thick, following the transversal section plane.
- The profile of each section is separately marked on drawing paper. On each section the position of critical structures is marked. The heart contour is imprinted in the mold itself.
- The area of the cross-section is measured planimetrically; areas with and without the heart and midline structures are considered.
- The best fitting geometrical shape is found and its area calculated.
- Correlation between the actual and calculated areas is found with its standard error; this will make it possible to predict from radiological measurements the spaces and volumes involved.
- Volumes are calculated for each section or group of sections according to the cone frustrum method.
- Correlation with external measurements is looked for.

Calf Experiments:

The protocol is shown in Appendix I. Five calves about 16 weeks old and weighing 180-200 lbs. were anesthetized with our standard technic and mechanically ventilated throughout the experiments with a Bennett volume controlled respirator. After induction external measurements were made, including heights, widths, lengths and perimeters at different levels of the trunk. The chest was then opened and molding material inserted in the

PRONE

SUPINE

URETHANE FOAM

SILASTIC

FIGURE 2

In contrast to urethane foam, Silastic produces deformation on the soft structures (pericardial sac) depending on position due to its high specific gravity.

cavity. After curing time was over the mold was carefully withdrawn. A second mold was done after left or right pneumonectomy. The pericardium was then opened, the heart excised, and tubes positioned in the main vascular structures; the pericardial sac was carefully sutured and molding material inserted. The abdomen was open, and molding material introduced before and after total gastrectomy. The calves expired at the time of excision of the heart. To determine the influence of position, long curing time Silastic was inserted into the thorax and abdomen of one of the calves and the animal was suspended after closing the surgical incisions; the molds were withdrawn after 24 hours of suspension. No marked changes were observed in the molds compared to those obtained in the supine position.

Human Molds:

Molds have been obtained from two human cadavers, following the protocol enclosed (Appendix II) as well as a complete set of external measurements. Evaluation of these molds has already been initiated according to the program schedule. A large amount of literature has been reviewed and no study like the present one has been found so far, however, many details from the literature will be included in the evaluation of the molds and in the final report. The possibility of predicting from simple radiological measurements the dimensions and volumes involved is presently under consideration.

Preliminary Results Of Available Space In Calves:

Chest Cavity.

a. Pericardial Sac. Three molds of urethane foam were produced. The dimensions and configurations of one mold is depicted in Figure 3.

FIGURE 3 - HALF-SCALE PROJECTIONS OF THE PERICARDIAL SAC MOLD

They represent the distended pericardial sac, that is the maximal space available for an intrapericardial prosthetic pump. Closing the pericardial sac for a long-term implantation could be advisable since it isolates the foreign materials from the surrounding structures and gives positional stability to the prosthesis.

In calves, the chest cavity follows roughly the elliptical curve for transversal sections. The ellipse has a higher ratio in higher sections (narrower) approximating gradually a circle at the abdominal level. The dimensions and configuration of one section at the level of the heart are given in Figure 4.

Accordingly, the maximal dimensions for the cardiac prosthesis at this section is shown as shadowed area in Figure 5. The prototype model of the blood pump received from AEC fits a 180 lb. calf but no space has been provided for atrial and arterial connections.

Since the chest is elliptical, any excess of width will cause the prosthesis to be pushed down, therefore, compressing the soft vascular structures of the midline (Fig. 6). Therefore, a safety limit should be considered in the width as well as in the depth of the prosthesis.

Some space could be used cephalic and caudal to the pericardial sac limits, but is very limited, cephalic by many vascular structures and the thymus and caudal by the diaphragm. Also, going up the space is progressively narrower. Any extra space occupied by the pump, connections, or lines will correspondingly decrease the space normally occupied by the lungs.

Abdomen. There exists a very large capacity, mostly in the ventral aspect, which is normally occupied by the stomach. The pelvic cavity is

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FIGURE 4 - Transverse Section of Calf Thorax Mold at the Heart Level

FIGURE 5 - Maximal Area Potentially Usable for the Artificial Blood Pump

FIGURE 6 - A blood pump design wider than the ventral thoracic cavity will be pushed down following closure of the wall, compressing the soft midline structures.

small and narrow and probably cannot be used.

Human Molds:

Thorax. The human thorax is wider, less deep, and shorter than the calf chest. The pump prototype fits in the pericardial sac. Actually, more space could be used sacrificing a portion of the lungs. Also, a larger portion of the pericardial sac volume could be used for an even larger pump by proper shape design. The driving unit fits in the lung space but it requires the sacrifice of one whole lung (pneumonectomy) which may be excessive. Figure 7 shows a comparison between human and calf thoracic anatomy, illustrating the marked differences existing.

In the abdomen the situation is essentially the same as in the calf, but the pelvic space appears to be larger. The prototype sent for the power unit, however, probably will disturb the function and anatomy of the pelvic structures.

The relationships of sizes and volumes of the proposed unit with both calf (Figs. 8, 9) and human chest (Figs. 10, 11). The potential usefulness of the same proposed unit for both calf and human patients becomes apparent.

Prepared by
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TRANSVERSE SECTION

CALF THORAX

HUMAN THORAX

LATERAL VIEW

FRONT VIEW

FIGURE 7 - Schematic Drawings Showing Anatomical Differences Between the Human and Calf Chest.

FIGURE
*8

FIGURE
9

FIGURE 10

FIGURE
11

LIST OF APPENDICES

- APPENDIX I Calf Molding Protocol
- APPENDIX II Human Molding Protocol
- APPENDIX III A Series of Cross-Sections Obtained from One Calf's
Thoracic Cavity Mold

CALF PROTOCOL:

Molds are produced using polyurethane foam. Calves ca 180 lbs. have been used so far. The following steps have been followed:

- Thorax.
- a) Anesthesia, IPPV, sternotomy, hemostasis
 - b) Molding of the thorax, without touching the organs
 - c) Inferior left lobectomy
 - d) Molding of the left hemithorax; diaphragm up, lung inflated
 - e) Left pneumonectomy (leaving ligatures in place to signal the point of emergency of the pulmonary vessels)
 - f) Molding of left hemithorax. Withdrawing the mold, the ligatures are cut to enable seeing in the mold the position of the pulmonary hilus. In this mold, as well as the preceding ones, the chest wall is approximated during the molding process and curing, to obtain a real picture of the actual volumes and shapes involved.
 - g) Pericardiotomy, excision of the heart (the animal usually dies at this point of the operation) cutting in the same way as in the heart transplant operation; the arteries near the outflow valvular plane, the atria near the atrioventricular valvular plane.
 - h) Insertion of tubes (plastic) in the arteries and atria. It is advisable to aspirate all the animal's blood at this point.
 - i) Careful suture of the pericardial sac.
 - j) Molding of the pericardium; the plastic tubes will mark, in the mold, the position and orientation of the atria and arteries.

HUMAN PROTOCOL:

Probably should follow the calf protocol. Further discussion needed.

Points to clear up:

- Position
- Ventilation or lung inflation
- Pattern of resections
- Diaphragm positions
- External measurements
- Internal measurements
- Radiological measurements
- Literature survey

Molds evaluation:

- Volume (total)
- Volume (usable)
- Sectioning and measuring
- "Critical distances"
- Points of anatomical danger (veins)
- Photography of intact molds
- Spatial relationship between molds
- Relationship molds-external measurements
- Relationship molds-radiological measurements
- Possibility of prediction of available space according to external measurements and/or radiology

Additional considerations:

The safety, stability, rigidity, protection against external trauma, extent of surgery necessary to utilize it, for any given space under consideration, should be appreciated. At this stage only a subjective appraisal appears feasible, because of the time and budget limitations,

based upon the clinical and pathological experience of the investigators.

This protocol has been prepared by Jorge Urzua, M.D. following the discussions in which the following people participated: Dr. Urzua, Dr. Sudilovsky, Dr. Panke, Mr. Kiraly, and Dr. Nose.

March 3, 1972

cc: Dr. Sudilovsky
Dr. Panke
Mr. Kiraly
Dr. Nose

AEC MOLD EXPERIMENT

BASIC CONSIDERATIONS REGARDING THE HUMAN MOLDING PROTOCOL

According to the distribution of size, age, weight, and pathology of the autopsies performed in the Autopsy Service of CWRU Department of Pathology, the following criteria were selected regarding the population that will be studied:

Age: 40-65 years

Sex: Male or female; no race limitations

Height: Males - 161 to 180 cm; Females - 156 - 175 cm

Weight: Males - 60 to 75 kg; Females - 50 to 75 kg

Pathology: The following lesions will be excluded: Any lesion distorting diaphragmatic or mediastinal anatomy, or deforming the thoracic wall;
Any space occupying or fibrotic lesion in the abdomen;
Cardiac hypertrophy over 550 gm; preferably normal heart size;

The usefulness of the cadaver will be determined in situ, according to the common sense of the investigator, and to the pathological changes observed.

Since the artificial heart will eventually be implanted in patients with cardiac insufficiency, patients with no excessive cardiac enlargement can be considered for this study.

A detailed protocol of the measurements that will be considered was prepared. The external measurements will be made using a caliper. The internal ones can be directly made from the molds. The correlation between them will be studied. The molds will be done using Silastic A RTV and

Catalyst 4 (200:1), to obtain a useful molding time of 5 minutes and a total cure time of 30 minutes. The position of the cadaver will be lying on his back; if necessary to study the anterior wall, the body can be turned down while the Silastic is curing. Probably this will not be required.

A set of measurements from radiological measurements and their correlation with the intrathoracic volumes will be available. Our data will be correlated with them.

The cadaver will be opened in a routine way; the external measurements done. The thorax and abdomen will be filled with Silastic, at the same time, and the walls closed until the Silastic is cured. The molds will then be removed. A left inferior lobectomy will be performed and this lobe molded. Under air inflation to 30 cm H₂O the lobe will be sprayed in a rigid container with urethane foam; a second cast will be made with Silastic from the impression of the lobe in the urethane foam, being a positive replica of the volume and configuration of the space available by taking out the left inferior lobe.

The heart will be removed, and tubes inserted in the atria and arteries to mark their position -- Silastic for the right side, tygon for the left. Then the molding material will be inserted, if Silastic, and the pericardium closed. If urethane is used, a pericardial suture should be done first. Careful removal of the cast will allow visualization of the volume and anatomy of the heart and major vessels. The heart will be separated at the atria, as for a homotransplant, and at the cava veins, in different patients, the reason being the different types of cardiac prosthesis in use.

It was agreed that CCF Department of Artificial Organs would supply endotracheal tube, manometer, and tubing to inflate the left inferior lobe

while being molded. Also tygon and Silastic tubing for the heart molds. More molding materials, Silastic and urethane foam, have been ordered and we are waiting for them.

The abdominal molds are rather difficult to interpret. Depending upon the observed results the intestines and other hollow viscera can be taken out or displaced while the Silastic is poured in, in order to see the conformation of the posterior abdominal wall and pelvic space. The liver, spleen, and kidneys probably should be in their normal position.

The simultaneous molding in the thoracic and abdominal cavities will allow the appraisal of the diaphragm position and the anatomical relationships involved.

This protocol was prepared by J. Urzua from the meeting held at CWRU on March 17, 1972 with Drs. O. Sudilovsky and T. Panke.

cc: O. Sudilovsky
T. Panke
Y. Nosé
R. Kiraly
J. Urzua

Ellipse

LOOK POSTERIORLY

Vertebral

Body

Midline

STRUCTURE

LUNG

vertebral
BODY

M. S.

LUNG

THORACIC
WALL

LUNG

M.S.

V. Body

V.B.

MIDLINE
STRUCTURES

PERICARDIAL
SACK

TRUERA

DIAPHRAGM
ABDOMEN

LUNG

LUNG

VERTEBRAL
BODY

V.B.

LUNG

LUNG

↑
LINE
OF
DIAPHRAGM

ABDOMEN

ABDOMEN

LUNG

LUNG

BODY

VERTICAL