COO-2208-2

FINAL TECHNICAL REPORT

"Study To Determine The Size And Shape Of The
Available Space In The Intrathoracic And
Intraabdominal Cavity For A Totally
Implantable Cardiac Prosthesis"

THE CLEVELAND CLINIC FOUNDATION
DEPARTMENT OF ARTIFICIAL ORGANS
9500 EUCLID AVENUE
CLEVELAND, OHIO 44106

This report covers the period comprised from 2/15/72 to 6/30/72

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PUBLICATIONS UNDER THIS CONTRACT

A Totally Implantable Artificial Heart: Anatomical Space Availability:
Urzua, J., Kiraly, R.J., Lint, F., Nose, Y., Sudilovsky, O., and Panke,
T. Submitted to 25th ACEMB Meeting, Bal Harbor, Florida, Oct. 1-5,
1972 (abstract).

ACKNOWLEDGEMENT

The following individuals contributed to the efforts reported in this document:

Carse, C.
Jacobs, G.
Kiraly, R.
Lint, F.
Nose, Y.
Panke, T.
Sudilovsky, O.
Urzua, J.

SUMMARY

Totally implantable artificial heart development appears technologically feasible. AEC-Westinghouse have designed a totally implantable artificial heart. In order to establish the anatomical adequacy of this AEC-W unit, studies were performed in both 80 kg calves and human cadavers. Anatomy of body cavities available for the implantation of this device was examined not only by conventional methods but also by plastic molding technic (Silastic A RTV and polyurethane foam were selected as molding materials.) Special emphasis was placed on anatomy of vascular structures.

Space within the pericardial sac proved to be enough for implantation of AEC-W blood pump; design of vascular connections must be carefully made. These vascular connections will differ for humans and experimental animals, but the same basic design can be utilized.

Maximal usable spaces for human's and calf's blood pump are defined; they exceed the size of the normal heart. To utilize the maximal space, however, extreme care should be used in designing the blood pump anatomy, since small differences from specifications will result in vascular compression.

Power pack implantation appeared anatomically feasible within the thoracic cavity in both humans and calves. However, it would require the sacrifice of part of pulmonary function and diaphragm displacement.

Power pack implantation appeared anatomically feasible within the abdominal area in both humans and calves. Physiological tolerance, fixation techniques, acceleration-deceleration effects will be investigated under follow-on contract.

Available areas, dimensions, and volumes, are described in detail for thoracic cavity. Abdominal cavity is constructed partially by a

SUMMARY (Cont'd.)

movable wall, which makes it rather difficult to establish a rigid numerical description. However, the space available in the abdominal region is well beyond the size and space of the AEC power pack.

These results apply to anatomical space availability and do not predict physiological tolerance, which will be experimentally determined.

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The present level of technological development has made permanent artificial organs implantation a real possibility. Technics of miniaturization, coupled with improved knowledge of isotope powered engines, made feasible the design of a totally implantable artificial heart.

Several groups have worked on artificial heart implantation; a totally implantable heart, however, requires additional components within the body, compared to externally driven pumps used in the past. Therefore, the space availability within the body for such implantation should be known. Westinghouse Astro Nuclear Research Laboratory, under a contract from the Atomic Energy Commission, has generated a design that could be used in experimental animals as well as in human patients, saving therefore the time and efforts involved in separate designs. This report discusses the efforts conducted under AEC Contract AT(11-1)-2208 "Study To Determine The Size And Shape Of The Available Space In The Intrathoracic And Intra-abdominal Cavity For A Totally Implantable Cardiac Prosthesis".

This study involved the making of molds of the thoracic and abdominal cavities of calves and human cadavers. These molds are then used to determine the size and shape of the space available for implanting the total artificial heart system. The efforts reported here are the first phase of a continuing effort to determine the anatomical space, tolerance to the implants, and functional constraints of the body.

Calves weighing 80 kg were selected for our study, since those animals approximate the hemodynamic requirements of a human adult, and since experimental implantations are likely to be performed in those animals. Even if larger animals are used for experimental implantation,

the reported results are still useful to establish safe design limitations.

Normally, all body cavities are almost completely occupied by organs and tissues. Some tissues, however, could tolerate displacement or excision much better than others. This study established some spaces where implantation of cardiac prosthesis appeared to be feasible from the anatomic point of view, and probably safe from functional and physiological standpoints. Physiological tolerance is being experimentally determined at the present time under the follow-on contract.

2.0 MATERIAL & METHODS

The position, sizes, and relative positions of anatomic structures were determined both by conventional direct measurement and by the use of plastic molds to obtain a tridimensional replica of the body cavities. Molds represent approximately the space of the cavity, yielding all necessary information regarding the shape of said cavity for further analysis.

2.1 MOLDING MATERIALS

Any liquid could be used as a molding material, since upon solidifying it will preserve the shape of its container. For anatomical studies, however, several prerequisites are to be fulfilled. Solidification must take place in a useful period of time from 1-30 minutes, at room temperature. Strong exo or endothermic reactions are to be avoided. A minimum of toxic or chemically irritating substances should be released during curing process. The solid mold must be stable at room temperature, and no shrinkage or deformation should take place. Flexibility is desirable in the mold, coupled with adequate reproduction and preservation of anatomical

details. Deformation of anatomical structures is unavoidable, but it must be within reasonable limits.

Accordingly, the following molding materials were chosen: 1) Silastic RTV A + Catalyst 4* (Varying the amount of catalyst resulted in different curing times.) and 2) Polyurethane foam Froth-Pak Insta-Foam†.

Both materials produced different effects on the soft structures 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. This effect is minimal for osseous structures such as the chest cavity but can become quite important for soft structures such as the pericardial sac. Therefore, Silastic was selected for the thoracic and abdominal cavities and urethane foam for the pericardial sac.

2.2 EXPERIMENTAL ANIMAL STUDIES

Seven calves were studied. Six of them weighed 80 kg; one heavier animal, 95 kg body weight, was included for the sake of comparison (Table 1).

Following induction of fluothane - N_2O-O_2 anesthesia, tracheal intubation and controlled ventilation were maintained throughout the studies.

For molding studies, sternum was longitudinally split and a median laparotomy performed; molding material was introduced within thoracic and abdominal cavities, and surgical incisions were temporarily closed

*Dow Corning Corporation, Midland, Michigan.

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

until curing of molds was completed. Some animals were subjected to pneumonectomy and/or gastrectomy for better detail of the surrounding walls (Table 1). One animal was suspended during curing process, for establishing the influence of position on molds configuration. Slow curing Silastic was used in this experiment.

Once these molds were removed, the pericardial sac was longitudinally opened and the heart excised as usual for total heart replacement, leaving "in situ" the atria, aorta, and pulmonary artery. The relative positions, dimensions and orientation of vascular structures were determined.

After inserting plastic tubes into the vascular structures for marking their position, pericardium was closed and urethane foam sprayed into it. After the few minutes required for curing, the mold was withdrawn; the plastic tubes were surrounded by the molding material, becoming an integral part of the mold, and marking the position and orientation of vascular structures in relation to the heart.

One animal (Table 1) was anesthetized and suspended by means of orthopedic bone pins inserted in spinal bones. The right foreleg and right rib cage section were removed, for establishing the normal thoracic anatomy. Right pneumonectomy was performed. Distances from osseous walls to vascular structures were measured and recorded. Position of pulmonary hilus was determined. The heart was excised, in order to determine anatomy of the large vessels with special interest on position and direction of connections to an artificial heart.

2.3 HUMAN CADAVER STUDIES

Four adult cadavers were selected for this study, according to criteria shown in Table 2.

TABLE 1 - ANIMAL EXPERIMENTS

Calf	Weight	Thoracic Mold	Position	Abdominal Mold	Pericardial Mold	Pneumonectomy	Gastrectomy	Anatomical Study Only
1	80	+	Supine		+	+		
2	80	+	Supine		+	+		
3	80	+	Suspended	+				
4	80		Supine	+	+		+	
5	95	+	Supine	+	+	+		
6	80		Suspended					+
7	80		Supine	+			+	

TABLE 2

SELECTION CRITERIA FOR HUMAN CADAVER CANDIDATES FOR MOLD STUDIES

1. * Males -- Age: 40-54 years
Weight: 60-85 kg
Height: 160-190 cm

Females -- Age: 40-70 years
Weight: 50-75 kg
Height: 150-175 cm

2. Pathology:

Absence of any pathology deforming the thoracic and abdominal walls, or generating major changes in organs anatomy. Absence of marked cardiac enlargement. Absence of pulmonary pathology.

*Determined following distribution of age, weight, and height of autopsies performed throughout 1971 at CMRU Autopsy Service, Dept. of Pathology.

Table 3 shows their ages, weights, heights and major pathological findings.

After removing the anterior thoracic wall and widely opening the abdomen, Silastic A RTV mixed with Catalyst 4 was poured within the cavities and the walls were closed temporarily until molding material solidified.

In three cadavers, pericardial sac molds were obtained using the technic previously described. The relative positions and orientation of vascular structures were ascertained, and compared to those found on calves.

2.4 MOLDS EVALUATION METHODOLOGY

All molds obtained were externally measured, and organs and vascular structures positions assessed.

Thoracic molds were transversally sectioned forming slices 2.5 cm thick, starting from the apex. The human thoracic molds required filling with urethane foam in order to make them rigid enough for slicing.

Each section was traced on drawing paper. On each section, the position of anatomical structures was marked (Fig. 1). Dimensions and distances from walls to critical points such as vena cava were measured, and areas potentially usable for total cardiac prosthesis implantation were defined accordingly.

The pericardial sac contour was evident in the molds, however, due to the technic utilized, it did not reflect the real anatomy; data for assessing heart volume, dimensions and position were obtained from pericardial sac molds and from direct measurements. The external profile of each section was approximated to the best fitting geometric figure.

TABLE 3
HUMAN CADAVERS STUDIES

Hosp. No.	Weight (kg)	Height (cm)	Age	Sex	Pathological Diagnosis
A72-243	109 (obese)	189	51	♂	Adenocarcinoma obstruction of hepatic ducts
A72-164	80.1	173	54	♂	Atherosclerosis
A72-185	62.5	171	65	♀	Atherosclerosis
A72-221	52.5	144	69	♀	Diabetes mellitus Generalized atherosclerosis

FIGURE 1 - TRANSVERSAL SECTIONS OF CALF AND HUMAN THORAX SHOWING SCHEMATICALLY THE POSITION OF VARIOUS STRUCTURES

Each section's area was planimetrically measured, and compared to the area calculated from the geometric approximation. These geometric figures will be used for prediction of thoracic cavity anatomy starting from radiological measurements.

Thoracic cavity volume was calculated from measured areas using the cone frustrum method. Using areas defined as "safe", volumes in the thorax available for the artificial heart pump and power unit were calculated.

2.5 COMPARISON OF ANATOMICAL FINDINGS WITH AEC-W UNIT

The AEC totally implantable artificial heart is composed of: a) a blood pump with a built-in driving mechanism (Fig. 2), and b) a thermal source actuating a Stirling type engine (Fig. 3), which in turn actuates the blood pump driving mechanism by means of a flexible shaft.

Shapes, dimensions and physical characteristics of these components are described in Figures 2 and 3, and in Table 4.

In order to ascertain the anatomical adequacy of this described unit, an actual size replica was positioned within pericardial, thoracic, and abdominal cavities of calves and human cadavers. It was also compared to molds shapes and dimensions.

3.0 RESULTS

3.1 CALF ANATOMY

The calf thorax can be roughly estimated as a truncated elliptical cone with its axis in a cranio-caudal orientation. The larger circular base is caudal and the ellipse forming the cranial base is elongated in the dorso-ventral direction.

Symmetry, with respect to the longitudinal axis was found in both saggital and transverse planes. The symmetric figures formed in saggital sections are parabolic and in transverse sections are elliptical (Fig. 4,

FIGURE 2 - AEC-WESTINGHOUSE BLOOD PUMP COMPONENT DIMENSIONS

FIGURE 3 - AEC-WESTINGHOUSE POWER PACK COMPONENT DIMENSIONS
 DRIVING SHAFT ORIGIN IS NOT SHOWN

TABLE 4

PHYSICAL CHARACTERISTICS OF AEC-WESTINGHOUSE UNIT

	Dimensions (cm)			Volume (cm ³)	Weight (gm)	Density
	Length	Width	Depth			
Power Unit	19.7	8.5	8.2	820	1200	1.463
Blood Pump	12.5	8.0	9.5	560	590	1.054

SIDE VIEW

FRONT VIEW

FIGURE 4a - CALF THORACIC CAVITY MOLDS

FIGURE 4b - CALF THORACIC CAVITY MOLD; SCALED DRAWING

and 5).

The cranial or upper thorax bifurcates the two small dome-like thoracic apices, both lateral to the base of the neck.

The caudal base or lower thorax is defined by the diaphragm. It has a double-dome shape; its ventral insertion is cranial to the dorsal one (Fig. 5). Its shape and relative position are variable, mostly dependent on animal position, pressure from the various organs, and muscular tonus of the diaphragm itself. It separates thoracic from abdominal cavities (Fig. 6).

The inner aspect of the thoracic wall limits laterally the cavity. The pericardial sac and other midline structures divide the thorax in two pleural cavities that are independent under normal conditions.

The heart is medial, occupying almost symmetrically the thorax, resting on the sternum and against the diaphragm (Fig. 5). Virtually no space exists lateral or ventral to the heart. Dorsally, we find the great vessels, and other midline structures (trachea, esophagus, vagi nerves, ductus thoracicus, sympathetic ganglia, lymphatic ganglia, thymus).

The cava veins follow the longitudinal axis. They practically mark the center line of the thoracic cavity (Fig. 5). With the calf in the supine position, the cava veins were dorsally displaced, dropping ventrally when the calf was returned to the prone position. Most of this movement was attributed to diaphragmatic position change.

Pulmonary hiluses were found dorsal and caudal to the heart base, at the level of the xyphoid process. The right lung usually had an accessory hilus approximately 7 cm cephalic to the main hilus. The bulk of the lungs occupied the dorso-caudal thorax. Comparatively small

FIGURE 5

SCALED DRAWING SHOWING SCHEMATICALLY POSITION OF HEART
AND MAIN VASCULAR STRUCTURES WITHIN CALF'S THORACIC CAVITY

FIGURE 6

Thoracic and abdominal cavities of calf. Diaphragm separates both cavities, and its position change will change cavities anatomy accordingly.

percentage of pulmonary tissue existed in the cranial part of the chest which was mostly occupied by vascular structures. The space lying between the pericardial sac and the diaphragm was negligible at the xyphoid process level, but dorsally a small cavity was noted, normally filled by lung (Fig. 5).

Dimensions obtained from thoracic cavity molds are shown in Table 5. They are not affected by changes in animal position, except for the diaphragm shape. Table 6 shows the dimensions, depth-width ratios, actual areas, areas from ellipse best fitting the sections, and error percentage between these two areas, for transversal sections of one thoracic cavity mold obtained from an 80 kg calf. These sections were 2.5 cm apart, from first rib to sternal insertion of diaphragm.

All sections obtained from this mold are shown in Figure 7; shaded areas represent spaces anatomically available for implantation of the blood pump and power unit. Diaphragm can be further displaced, as marked with arrows; thus, more volume for the power unit implantation becomes available by using abdominal cavity space. Dimension for each section are listed in Table 7. The abdomen appeared as a roughly ovoidal cavity (Fig. 6) filled with viscerae; most of the volume was occupied by the stomachs. Abdominal molds morphology do not allow extensive analysis; furthermore, the extreme variability of abdominal wall position would make such analysis inconclusive. Dimensions of the abdominal molds are listed in Table 8; the volume of molding material was included, since it shows the space that could be occupied by the power unit without interfering with wall closure.

Pericardial sac molds morphology is illustrated in Figure 8. The dimensions are listed in Table 9. These molds show the heart anatomy in

TABLE 5
CALF THORACIC MOLDS
(see Fig. 4b)

Mold No.	Calf Weight (kg)	Maximum Length (C-C) (l)	Sternum Length (s)	Maximum Width (w)	Width at Pulmonary Hilus (pw)	Width at 1st Rib (rw)	Maximum Total Depth (D-V) (d)	Depth at Pulmonary Hilus (pd)	Depth at 1st Rib (rd)
M172	80	39	20	30	19	9	22	22	13
M272	80	39	20	24	21	10	22	22	13
M472	80	35	18	29	15	9	21	21	13
M672	95	41	21	27	16	12	26	26	15
M772*	95	46	21	30	18	8	26	26	15
M972*	80	41	20	23	15	9	23	23	13

*Silastic.

TABLE 6 - CALF THORACIC MOLD M972

Section No.	Depth	Width	Ratio	Actual Area	Ellipse Area	% Error	Heart
1	15.5	7.0	2.21/1	86.8	92.5	6.5	
2	18.4	9.0	2.04/1	122.7	118.8	3.0	
3	21.0	10.5	2.0/1	165.7	114.8	12.0	
4	23.0	12.0	1.91/1	199.4	193.3	3.0	X
5	23.0	14.0	1.64/1	240.5	239.0	1.0	X
6	24.0	15.0	1.6/1	275.0	275.0	.33	X
7	24.0	15.5	1.55/1	294.9	294.4	.17	X
8	23.5	17.5	1.34/1	321.5	308.7	3.78	

Comments: Average 1.78 W/D ratio.
Standard deviation - 3.72
Computed Volume - 3.75 liters.

TABLE 7 - SECTIONS OF CALVES THORACIC MOLDS

Section	Total Area (cm ²)	Area For Blood Pump (cm ²)	Area For Driving Unit (cm ²) Left Side	Area For Driving Unit (cm ²) Right Side	Volume For Driving Unit (cm ³)		Total Volume 1-8 (cm ³)	Total Vol. Blood Pump (cm ³)	Total Vol. Left Side Driving Unit (cm ³)	Total Vol. Right Side Driving Unit (cm ³)
					Left Side	Right Side				
1	86.8	23	5.4	4.5			375	1435	1651	1325
2	122.7	39.4	6.0	10.3						
3	165.7	56.5	10.1	3.2						
4	199.4	76.4	12.6	12						
5	240.5	94.2	9	2						
6	275.0	116.0	7	6						
7	294.9	107.4	3	5						
8	321.5	121.1	41.4	43.1						
9			85.5	81.2	161	157.8				
10			82.8	81	213	206				
11			101	105	331.8	236				
12			98.7	112	523.4	275.6				
13			87.6	91.2	236.4	257.8				
14			58	60.5	184.4	192.6				

TABLE 8
ABDOMINAL MOLDS

	Molds	Length (cm)	Width (cm)	Depth (cm)	Vol. (cm ³)
CALF	M 872	43.1	45.7	15.2	6218
	M 1072	45.7	34.3	13.9	2990
	M 1172	50.8	33.0	21.6	7472
	M 1272	48.2	35.5	20.3	7577
HUMAN	HM 272	25.4	27.9	7.62	1409
	HM 572	33	30.5	15.2	3254
	HM 872	30.5	27.9	17.8	2695
	HM 1172	25.4	20.3	12.7	1745

TABLE 9
CALF PERICARDIAL MOLDS
(see Fig. 8)

Mold No.	Total Length (l)	Sternal Length (ls)	Cava Vein Length (lc)	Width (w)	Anterior Depth (da)	Posterior Depth (dp)	Distance of Cava Vein to Lateral Wall (vw)	M (l-lc)	N (l-ls)	Volume in cm ³ (Vol)
M 372	15	12	10	12.3	10	11.2	3.5	2	4	1000
M 572	14.2	14	9.5	10.0	7.5	10.6	2	2.7	.2	700
M1272	11	8.4	9.5	10	12	10	23	1.5	2.6	600

FIGURE 7 (14 SECTIONS)

Transversal sections obtained from calf thoracic cavity mold M172. The external contour represents the inner aspect of thoracic walls. Shaded areas represent space probably available for total heart implantation.

Blood pump component implantation

Power pack component implantation

Diaphragm outline is marked with arrows, representing the possibility of displacing it should more space be required.

FIGURE 7 (Cont'd.)

-8k-

FIGURE 7 (Cont'd.)

-8m-

M 972 SECTION 13

M 972 SECTION 14

FIGURE 8

CALF'S PERICARDIAL SAC MOLD; SCALED DRAWING

a filled condition, and they include atria and segments of large vessels; therefore, the space available within the pericardium for blood pump implantation is actually less.

3.2 HUMAN ANATOMY

Many detailed studies of the human anatomy have been reported since Aristotle. However, the application to artificial heart implantation was not previously studied.

Morphology of thoracic cavity molds is shown in Figure 9, and their dimensions are listed in Table 10. Sections obtained from one mold are shown in Figure 10; shaded areas represent space anatomically available for blood pump and power unit implantation. Extra volume can be used by pushing down the diaphragm. Dimensions for each section are listed in Table 11. Comparison with calves' chest showed that the human thorax was shorter, wider, and less deep. The bulk of the lungs is lateral to the heart, not caudal, and pulmonary hiluses were cranial to the heart base rather than caudal.

Abdominal molds were smaller than those from calves, mostly due to the smaller stomach. Dimensions are listed in Table 8.

Figure 11 shows the configuration of the pericardial sac molds, and their dimensions are listed in Table 12. Like in calves, they represent the filled heart's size with atria and large vessels included; the space available for blood pump implantation is accordingly smaller. The larger mold was obtained in a patient showing a clinically moderate cardiac enlargement.

3.3 COMPARATIVE ANATOMY OF THE ARTIFICIAL HEART PUMP

As shown in Tables 9 and 12, dimensions and volumes of pericardial

TABLE 10
HUMAN THORACIC MOLDS
(see Fig. 9b)

Mold No.	Maximum Length (l)	Maximum Depth (d)	Maximum Width (w)	Sternum Length (s)	Depth at 1st Rib (rd)	Width at 1st Rib (rw)	Volume cm ³ (vol)	Maximum Depth Maximum Width Ratio (D/W Ratio)
HM 172	25	19	26	22	7	19	5107.5	.730
HM 472	30	21	39	14.2	7.2	15	5789.0	.538
HM 772*	25	16	21	15	9	15	3573.6	.762

*Female.

TABLE 11a - SECTIONS OF HUMAN THORACIC MOLDS

Section	Mold	Left Depth	Right Depth	Sternal- Vertebral Depth	Width	Left Side		Right Side	
						Usable Width	Usable Depth	Usable Width	Usable Depth
1	HM 172	5	6.5	4	15	3	5	4	6.5
	HM 472	12.2	11.8	7	22.5	6	12.2	5	11.8
	HM 772	8	9	4	14.5	4	8	4	9
2	HM 172	11	1.3	8.5	20.5	7.3	11	6.5	11.5
	HM 472	14.8	14.5	8.5	24	7.5	14.8	6.5	11.8
	HM 772	10	12	6.5	17.5	4.5	10	5	12
3	HM 172	12.5	14	11	23.5	6	12.5	9	14
	HM 472	17	17.2	10.4	26	7.5	17	7.5	17.2
	HM 772	13	14	9	19.8	3	13	5	10
4	HM 172	16.5	17	13	26	9	14.5	7	15
	HM 472	18.2	18	12	27.5	5	17.5	8	18
	HM 772	16	16	11	21.3	2	11	6	16
5	HM 172	15.5	16	12	24.5	7	14.5	7	14
	HM 472	17.5	18	11.5	29.5	5	17	8	18
	HM 772	16	17	11.5	22	3	7	6	17
6	HM 172	17.5	18.5	15	26.5	5	14	8	17
	HM 472	18	19	11.5	32	5	14	8.5	19
	HM 772	16	16	11.5	23	3	10	7	16
7	HM 172	19	19	15.5	26.5	6	19	9	19
	HM 472	18	19.5	12.5	34	5	17	9	19.5
	HM 772								
8	HM 172	19	19	14	28	6	19	8	18.5
	HM 472								
	HM 772								

TABLE 11b
SECTIONS OF HUMAN THORACIC MOLDS

MOLD HM 172

Section	Total Area cm ²	Area Left Side For Driving Unit cm ²	Area Right Side For Driving Unit cm ²	Vol. Left Side For Driving Unit cm ³	Vol. Right Side For Driving Unit cm ³
1	32.9 16.7	31	16	123	114
2	184.6	66	74	162.6	186.7
3	272.8	62	94	222.3	225
4	324.2	113	97	293.4	283.2
5	355.0	118	101	288.3	308.6
6	398.6	109	124	264.2	326.4
7	420.6	99	133	303.5	353
8	433.4	140	145	283.5	Diaphragm
	Total Vol. in Thorax 5107 cm ³			Total Vol. Left Side for Driv- ing Unit cm ³ 1940.8	Total Vol. Right Side for Driving Unit cm ³ 1796.9

TABLE 12
HUMAN PERICARDIAL MOLDS
(see Fig. 11)

Mold No.	Total Length (l)	Sternal Length (ls)	Total Width (w)	Posterior Depth (dp)	N (l-ls)	Volume - cm ³ (Vol)
HM 672	17	15	13	10	2	1200
HM 972	14	10	12	7.5	4	700
HM 1272	15	13	11.3	9.5	2	800

FRONT VIEW

BACK VIEW

FIGURE 9a - HUMAN THORACIC CAVITY MOLD

FIGURE 9b - HUMAN THORACIC CAVITY MOLD; SCALED DRAWING

FIGURE 10a - HUMAN THORACIC CAVITY MOLD SECTIONS

FIGURE 10b

Transversal sections obtained from human thoracic cavity mold HM 172. External contour represents the inner aspect of thoracic walls. Shaded areas represent space probably available for total heart implantation.

Blood pump component implantation

Power pack component implantation

Additional space which could be used if pneumonectomy is performed

Diaphragm outline is marked with arrows, representing the possibility of displacing it should more space be required.

FIGURE 10b (Cont'd.)

HM172 SECTION 2

HM 172 SECTION 3

FIGURE 11 - HUMAN PERICARDIAL SAC MOLD; SCALED DRAWING

sac molds obtained from human cadavers and calves are similar. Their shapes are also comparable (Fig. 8 and 11). However, a number of differences, essential for artificial heart design, appeared to exist: a) Position - The calf heart is symmetrically placed in the thorax (Fig. 5); the human heart is assymetric, the ventricles being mostly toward the left hemithorax; b) Relative Position of the Lungs - The calf thorax is elongated and most of the lungs occupy the caudal thorax. The pulmonary hiluses are displaced in this direction, being found at the level of the xyphoid process. In humans, most of the lungs are lateral to the heart, the pulmonary hiluses being at a mid-sternal level; c) Vascular Connections for the Artificial Heart - Due to the two facts mentioned, the vascular connections should differ for human patients and calves.

In calves, the four major vascular connections lie in a horizontal plane, 10 cm dorsal to the inner surface of the sternum. The atria are facing the sternal surface. The aorta originates cephalic to the left atrium, and is directed dorsally. Shortly distal to the valvular plane it bifurcates in brachiocephalic and descending major branches (Figs. 5 and 12). The pulmonary artery originates anteriorly to the aorta, since the right ventricle occupies a cranial position. After excision of the heart, due to arterial elasticity and to the caudal position of pulmonary hiluses, the pulmonary artery is found to the left of the aorta, and caudally directed (Fig. 12) in a $\sim 45^\circ$ angle to the cava veins axis. Cava veins are essentially horizontal in a standing animal and hemiazygos veins relatively large (Fig. 5, 6). Pulmonary veins are caudally oriented and the left atrium slightly caudal to the right atrium (Fig. 12).

The human heart is displaced to the left, therefore, the atrial

connections lie in a vertical plane which is oblique to the sternal plane, facing the left hemithorax. Therefore, the right atrial connection will be somewhat anterior relative to the left (Fig. 13).

The aorta originates as a vertically ascending trunk, which afterward arches dorsally and gives origin to brachial and carotid arteries. The pulmonary artery originates anteriorly to the aorta, since the right ventricle is anterior relative to the left, and its direction is dorsal and cephalic in a $\sim 60^\circ$ angle to the cava veins axis (Fig. 13). The pulmonary arterial connection to the artificial heart, like in the calf, should be made to the left side of the aorta. Cava veins are essentially vertical, in a standing human, and dorso-lateral in the right side of the heart. Hemiazygos veins are less prominent than in the calf.

Pulmonary veins are laterally and slightly cephalically oriented; the left atrium is slightly cranial to the right atrium (Fig. 13). d) Relationship to the Thoracic Walls - Calf anatomy is more restrictive than human's for artificial heart design, since calf's heart practically contacts the ventral and lateral thoracic walls, which are inextensible. Considering 10 cm the maximal safe dorsoventral distance from the sternal plane, the space usable for a prosthetic blood pump is shown in Figure 14. It has a volume of $1,435 \text{ cm}^3$ which represents the maximal possible space to be utilized for the blood pump component. The elliptical shape shown must be rigidly observed; an improper design, as shown in Figure 15, will result in dorsal displacement of the pump and compression of vascular structures.

FIGURE 12 - SIDE VIEW OF CALF'S HEART
SHOWING ORIENTATION OF VASCULAR STRUCTURES

After heart excision, all four vascular connections lie in an horizontal plane. Left atrium is slightly caudal to right one.

FIGURE 13 - SIDE VIEW OF HUMAN HEART SHOWING POSITION AND
ORIENTATION OF VASCULAR STRUCTURES

After heart excision, right atrium is slightly caudal and anterior to left one; arterial connections form an angle with atrial connections.

FIGURE 14

GRAPHICAL REPRESENTATION OF SPACE AVAILABLE IN AN 80 KG CALF
FOR BLOOD PUMP COMPONENT IMPLANTATION

Lines represent outline of sections 2.5 cm apart. This is the
maximal space safely available, and it exceeds the pericardial
sac capacity.

FIGURE 15

AEC-W blood pump positioned transversally into calf's chest will be pushed up upon wall closure, generating compression of vascular structures. Longitudinal orientation will be well tolerated.

The human heart is mostly surrounded by pulmonary tissue in the left side, which makes it possible to utilize more space than is normally used by the heart. The dorso-ventral distance, and the right side of the heart, should be respected (Fig. 10).

3.4 COMPARISON OF AEC-W UNIT TO ANATOMICAL FINDINGS

Blood Pump. Comparison with pericardial sac molds showed that the proposed unit could be implanted within the pericardium in both calves (Fig. 16; Table 9) and humans (Fig. 17; Table 12). Proposed unit does not include, however, vascular connections, which must be carefully designed following these reported results.

Power Unit. Comparison with calves thoracic molds showed that the only intrathoracic space able to receive this unit implantation was dorso-caudal space (Fig. 7, 18), probably requiring the diaphragm to be pushed down.

Intrathoracic implantation appeared possible in humans, requiring, however, pulmonary resection and possibly diaphragm displacement (Fig. 10, 19).

Intraabdominal implantation appeared feasible in both calves and human cadavers (Fig. 20, 21). The minor pelvic space is very small in the calves; it is larger in humans, but hardly enough for this unit implantation. The abdominal space can be used by implanting the unit retroperitoneally.

4.0

DISCUSSION

The totally implantable artificial heart appears to be technologically feasible. Adequacy of the proposed AEC-Westinghouse model to anatomical

FIGURE 16 - COMPARISON OF AEC-W BLOOD PUMP
WITH CALVES' PERICARDIAL SAC MOLDS

FIGURE 17 - COMPARISON OF AEC-W BLOOD PUMP
WITH HUMANS' PERICARDIAL SAC MOLDS

FIGURE 18 - COMPARISON OF CALF CHEST MOLD WITH AEC-W POWER UNIT

FIGURE 19 - COMPARISON OF HUMAN CHEST MOLD WITH AEC-W UNIT

FIGURE 19 (Cont'd.)
COMPARISON OF HUMAN CHEST MOLD WITH AEC-W UNIT

FIGURE 20 - COMPARISON OF CALF'S ABDOMINAL MOLD WITH AEC-W UNIT

constraints was shown, both for human patients and calves. Actual tolerance to implantation, however, cannot be ascertained a priori without extensive implantation studies in both experimental animals and human subjects. Furthermore, hemodynamic performance will depend on many factors other than anatomical. Research efforts are required in order to ascertain this point.

Solving the problem of spatial adequacy is a prime requisite, however, for any future development. Many failures of artificial heart implantations were due to defective anatomical design which resulted in compression of vascular and soft tissue structures.

Calf Application. According to our anatomical studies, the power unit could be implanted in the dorso-caudal thoracic cavity, or in any place within the abdominal cavity. If fixation of power unit is a prime requirement, probably the extrapleural and/or extraperitoneal space will be selected. If it is not, the abdominal cavity provides more than enough space for the proposed unit. The effect of visceral compression or displacement, sudden accelerations and decelerations, changes in body position, and so forth, should be ascertained by further investigation.

The selection of dorso-caudal thorax implies the sacrifice of part of pulmonary function, and probably partial loss and displacement of diaphragmatic movement. Extrapolating the human clinical experience, this sacrifice could be tolerated.

Human Application. Space wise, the power unit does fit in one hemithorax. It is known from respiratory disease and lobectomy patients that the body can survive a 40-50% loss in respiratory volume or efficiency. Our measurements showed that enough volume exists in one hemithorax to

accommodate the driving unit displacing to some extent the diaphragm. The location in the human thorax for a driving unit should be lateral and dorsal to the heart, and it probably requires lung resection. In order to closely fit the thoracic wall and bring the shaft closer to the heart, the larger base could be caudal, facing toward the diaphragm. The narrow end containing the power source would point in a cranial direction.

Extensive studies for accurate prediction of the available space to be found in 90% of the human adult population are currently underway.

The abdominal cavity also provides space enough for the proposed power unit; actual physiological tolerance cannot be predicted at this stage since complications could result from mechanical compression on organs and tissues.

Blood Pump. The anatomy for a blood pump is extremely restrictive in the calf. Small changes in anatomical design will easily end up in vascular compression and occlusion, as it has been demonstrated by many experimental failures during the last 15 years.

The available space for an 80 kg calf is shown in Figure 14. Volume wise, there is more than enough space for a unit with a reasonable stroke volume. The shape of this volume, however, is quite restrictive; the blood pump design must rigidly adapt to these constraints. The vascular structures as shown in Figure 12 are quite different to the human and this difference precludes the use of the same vascular connections in both species. Minor changes in position of vascular connections will make possible the use of the same blood pump, since the hemodynamic requirements are similar, and the volumes shown for the pericardial

FIGURE 21

COMPARISON OF HUMAN'S ABDOMINAL MOLD WITH AEC-W BLOOD PUMP COMPONENT

cavities are quite comparable. Considering that candidates for artificial heart implantation usually show an enlarged heart, even larger blood pumps could be eventually fabricated.