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A biomedically engineered myocardial prosthetic system

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A BIOMEDICALLY ENGINEERED MYOCARDIAL PROSTHETIC SYSTEM

by

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I. INTRODUCTION

Biomedical engineering is, among other things, concerned with artificial organs for either chronic implantation or temporary substitution to replace or augment the functions of organs which are impared. Particularly in the cardiovascular area, should a successful artificial heart be developed, many deaths resulting from heart disease may be avoided.

As cited by Saxton (26), only as recently as 1956 research was started by McCabe, Salisbury, and Kolf on the development of a replaceable intracorporeal pumping system. Their first model was a diaphragm-type pump consisting of a fluid-filled space around two plastic squeeze bottles in a sealed rigid glass container. Connections to the four vessel groups of the heart were made with plastic elements containing flap valves to control the direction of blood flow. In their second model, the chambers were made of semi-rigid plastic outer housing encasing two separate pliable mixer chambers. This model was excessively bulky to enclose in the chest of an anesthetized dog. Three hours was the longest that they were able to keep a dog alive with their system. Death resulted from embolism caused by air sucking into the atria or breakdown of the plastic components.

Seidel, et al. (29) developed a rolling diaphragm-type artificial heart which uses a hydraulic system of two cylinders, one for each ventricle. Air pressure is used to activate the pistons in each cylinder to simulate ventricular contraction. During the period corresponding to ventricular relaxation or diastole a small spring returns the plungers. Filling of the cylinders during diastole depends on the atrial pressure. The air pressure mechanisms and the electronic actuating devices were external.

The same group of researchers developed a sac-type artificial implantable heart which consists of a flexible plastic ventricle made from polyurethane-estane fitted into a slightly larger rigid housing made from aluminum or fiberglass. The flexible sections are activated by increasing the air pressure between the rigid wall and the plastic sac. Compression of the sac simulates ventricular contraction. These hearts were tried on 11 mongrel dogs. The maximum survival time was 21 hours.

Kolff, et al. (13) developed an implantable electrically driven artificial heart. Electric power was transmitted to the device through two wires entering the thoracic cavity. The unit consisted of five coordinated electromagnets arranged in a rosette. Two collapsible plastic ventricles made from polyurethane VC are situated on either side of the rosette in one housing. The pressure stroke or systole is effected by the magnets. The pressure depends on the force of the magnets and the time during which they are energized. No information is available on the actual use of the heart in animals.

Roller and pendulum types of artificial hearts were developed by Houston et al. (10). In the roller type, a small roller rotates within a larger housing in which are two simulated ventricles made of polyurethane. These ventricles are 2 mm deep, 25 mm wide and lie against the housings with ports to permit entries from the vena cava and pulmonary veins, and exits to the aorta and the pulmonary arteries. This implantable unit replacing the biological heart, maintained the circulation of a 24.8 kilogram dog for two hours. The unit was too large to permit closing of the thorax of the dog after implantation. Their pendulum type heart consisted of a motor,

suspended by pivots, which swings back and forth within a rigid housing. The swing is caused by an eccentric and a ball-bearing lever arm fixed to one side of the housing. Two flexible bags are suspended on opposite sides of the housing with the swinging motor on one side and the rigid housing on the other side of the bag. These two bags simulate the left and right ventricles, as the motor swings from one side to the other, one bag is compressed and emptied while the other bag is released and filled. This pump was placed in the thoracic cavity of a 30 kilogram dog. Circulation was maintained for a little over five hours.

Kusserow (14, 15) developed an implantable diaphragm pump consisting of a cam-yoke and worm gear mechanism which develops to and fro oscillations of the pump diaphragm. Originally the device contained a small electric motor directly coupled to the mechanism. The entire unit with motor was implanted intracorporeally. To obviate the need for bringing wires through the thorax wall and the possibility of motor failure, in a later model the unit was driven magnetically by an external device. An Alnico bar magnet one inch in diameter and three inches long was attached to a worm gear drive mechanism. The 60-watt drive motor with a similar magnet on its shaft oriented parallel to the implanted magnet provided the torque and drive for the internal device.

An attempt was made by Kantrowitz (12) to artificially pump blood by assisting the pumping action of the left ventricle without removing the biological heart. Their method consisted of mobilizing the left leaf of the diaphragm, preserving its blood and nerve supply. A section of flat muscle from the diaphragm with its phrenic innervation intact

is then wrapped around the distal portion of the thoracic aorta and stimulated during each diastolic period. Stimulation was effected by either stainless steel of silver wire electrodes attached to the phrenic nerve. The connecting wires to the electrodes were brought through the skin to a terminal strip. This "auxiliary heart" added pressure and energy for propelling the arterial blood through the systemic system. This method caused the mean blood pressure to rise.

The basic theme underlying the methods described above is based on the complete removal of the natural biological heart and its replacement by an electrical-pneumatic-mechanical device to effect a blood pumping system. This procedure involves first severing four major vessel junctions of the heart: (1) the aorta, (2) vena cava, (3) right pulmonary vessels and (4) left pulmonary vessels. After the heart is removed, the replaceable unit is inserted into the thoracic cavity. The four vessel arrays are then connected to the pumping system. During this operation, a heart-lung by-pass apparatus (8) for extracorporeal blood perfusion is needed to effect circulation until the artificial unit is operating. Electrical power for operating the unit is supplied by wires brought through a hole in the thoracic wall.

With the completely replaceable unit there are several basic inherent problems which researchers have had difficulty in overcoming (25): (1) thrombus formation caused by blood coming in contact with a foreign surface of large area, (2) leakage and embolism formation at the four vessel junctions, (3) electrical or mechanical failure of the system during chronic operation. A method for artificially providing the pumping of blood

without removing the biological heart and severing the natural vessel connections would eliminate these problems.

Although substantial progress has been made, researchers have not yet solved the basic problem of using the surgical approach of completely replacing the biological heart with an electro-pneumatic-mechanical device to effect an artificial heart. Other approaches might prove fruitful upon further exploration. Since 1959, Bolie* has given consideration to the possibility of developing an artificial heart system, operating on the principle of a "reverse plethysmograph" and making use of the intact, but inactive, biological heart. Adams** has developed a mechano-cardiac pulsator, which on a short-term emergency basis can maintain arterial circulation in a dog with cardiac standstill for a period of two hours by compressing the left ventricle of the heart with an inflatable cuff.

The purpose of this dissertation is to report the results of an investigation of a biomedically engineered myocardial prosthetic system which is capable of artificially causing the contraction of the myocardium, and thus enable the ventricles to eject blood into the systemic and pulmonary circuits of the cardiovascular system.

The myocardial prosthetic system basically consists of a pneumatic system to support a prosthetic device which is designed to tailor-fit around and completely encapsulate the intact biological heart. The

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*Bolie, V. W., Chairman of Biomedical Electronics, Iowa State University of Science and Technology, Ames, Iowa. Information concerning reverse plethysmograph. Private Communication. 1962.

**Adams, W. E., Department of Surgery, University of Chicago, Chicago 37, Illinois. Information concerning the mechano-cardiac compressor. Private communication, 1962.

prosthesis contains an inner elastic liner bonded to an inelastic, yet flexible outer shell having a stem as an integral part. Electronically timed pulses of air-pressure and vacuum that correspond to the duration of ventricular contraction and relaxation are programmed into the stem. Air-pressure causes the inner liner to inflate with respect to the inelastic outer shell producing a force against the myocardium, and in this manner artificially contracts the ventricular musculature. During the vacuum period, air is removed from the space between the inner liner and outer shell, allowing the myocardium to relax. During this period the ventricular cavities expand and fill with blood as they ordinarily would when functioning normally.

The system possibly may be adaptable eventually for chronic implantation in cases of imminent irreversible heart failure. The system may also be useful in situations of reversible cardiac lesions where the cardiac output is diminished, due to acute myocardial infarction or intractable congestive heart failure which may be ultimately corrected by surgery. The myocardial prosthetic system might also find extensive use in physiological and pharmacological studies and research on the cardiovascular system. By providing a known fixed pumping rate and stroke volume, and thus cardiac output, the neural and other pharmacological effects of specific autonomic drugs on the heart, arterioles, and peripheral circulation, may be isolated in the cardiovascular system.

The presentation is organized in the following manner. This introductory section reviews the state of the art of artificial heart development and introduces the specific problems concerned here. Section II

outlines the anatomical problems involved in fitting a prosthesis to the heart which will encapsulate it and yet not interfere with its afferent and efferent vessels, or the organs and tissues adjacent to the heart. The operative techniques required for insertion of the device into the thoracic cavity and fitting it to the heart are also described in this section. The physiodynamics pertinent to system operation are described in Section III. The method of forming the prosthesis, pictorially illustrated, is given in Section IV. Section V, describing the electronic-pneumatic part, follows. In Section VI is an account of the experimental tests performed with the system, and graphs of the results are shown. The final section offers a summary and conclusion.

II. ANATOMICAL STUDIES AND OPERATIVE TECHNIQUES

Developing the prosthetic device and fitting it to the heart required an anatomical exploration and study of the heart and its adjacent structures in the thoracic cavity. It was also necessary to investigate a location for a thoracotomy incision and a method most suitable for placement into the thoracic cavity and attachment of the device to the heart. Explorations, measurements, fittings and experimental operations were performed on four embalmed and eight live anesthetized dogs, each weighing approximately 10 kilograms.

This section will describe and present photographic records of the findings of the anatomical studies in relation to the solution of the above problems. Only those anatomical features unique to the location, insertion, fitting and operation of the prosthetic device not readily or directly available in the literature or text books with this orientation, will be identified and discussed. The general detailed anatomy of the heart and surrounding organs, although important to the investigation, will not be treated or emphasized. For the anatomy of the thoracic area in greater detail, Miller (20) for the dog or Hamilton (9) for the human may be consulted. The operative techniques which were developed to permit entrance into the thoracic cavity and attachment of the prosthesis to the heart in vivo will also be presented in this section.

Heart size and shape will vary from animal to animal. According to Joseph (11) and Marthaler (18), the influencing factors are body weight, age, species, health and sex. In the anatomical studies, physiological tests, and design criteria for the prosthetic device, an attempt was made

to standardize the body weight to 10 kilograms, thus eliminating at least one of the factors which cause heart size and shape to vary. No attempt was made to standardize the other factors. In practice where the myocardial prosthetic system is to be adapted, the variations in heart size among animals should not pose a serious problem. Either, a prosthesis may be fitted to a specific heart after thoracotomy by making available a group of devices of assorted sizes, or the size and shape of the heart may be determined prior to thoracotomy. A method is available, developed by Rushmer et. al. (24) for measuring the size of the left ventricle in an intact conscious animal using a variable inductance guage. Information concerning heart size and shape in an intact animal may be derived from cinefluorographic, angiocardiographic, or roentgenographic techniques (21). From the results of these tests a device may be custom-fabricated to fit a particular heart.

Heart size may differ in embalmed animals when compared to its size when the animal was alive and functioning normally. Method and quality of embalming, health of the animal at the time of expiration, euthanizing procedure, vessel injection, and storage all influence the size and shape of the embalmed animal's heart. For these reasons, after having made the explorations and dissections in the embalmed dogs for determining the principle anatomical factors and dimensions involved in the development of the prosthesis, all dimensional studies for fitting and attachment of the device were then concentrated on anesthetized thoracotomized animals. In one situation, however, the size and shape of the heart of an embalmed animal closely corresponded to that of an anesthetized thoracotomized one of

approximately the same weight. The prosthesis tailored to a live anesthetized animal is shown in place on this embalmed dog in Figure 25.

Rushmer (23) has found that the size of the heart, area of the cardiac silhouette and diameter of the left ventricle all diminish in an anesthetized thoracotomized dog. After recovery the heart returns to its preoperative dimensions. This investigation was not concerned with recovery situations, but was limited to the anatomical and dimensional study of the thoracotomized animal. In later work concerning chronic implantations and recovery situations, the size of the heart under intact conditions will have to be taken into account and the prosthesis fitted accordingly.

In the embalmed dogs a careful study was made of the thoracic walls, tissues, nerves and organs surrounding the heart. Photographic records of the results on two of the dogs studied were made for presentation here. In order to locate the position of the heart in relation to the rib structure, with the object of determining the most suitable location for a thoracotomy incision to permit access into the thoracic cavity for the prosthetic device, the left and right sides of the thorax of an embalmed specimen weighing approximately 10 kilograms were dissected and studied.

After removing the skin and the thoracic appendages, the cutaneous trunci, latissimus dorsi, pectorals, external abdominal oblique and scalenus muscles were dissected away. The ribs and intercostal muscles were exposed. Figure 1 shows a photograph of this exposure on the left side. In Figure 2 the intercostal musculature was removed showing the lungs and part of the left side of the heart. It was found that the intercostal veins, arteries and nerves were located adjacent to their respective ribs. Severing of

Figure 1. Thorax, lateral view, with superficial musculature removed

A - first rib

B - intercostal muscles

C - costochondral junction

Figure 2. Thorax, left side, lateral view with intercostal musculature removed

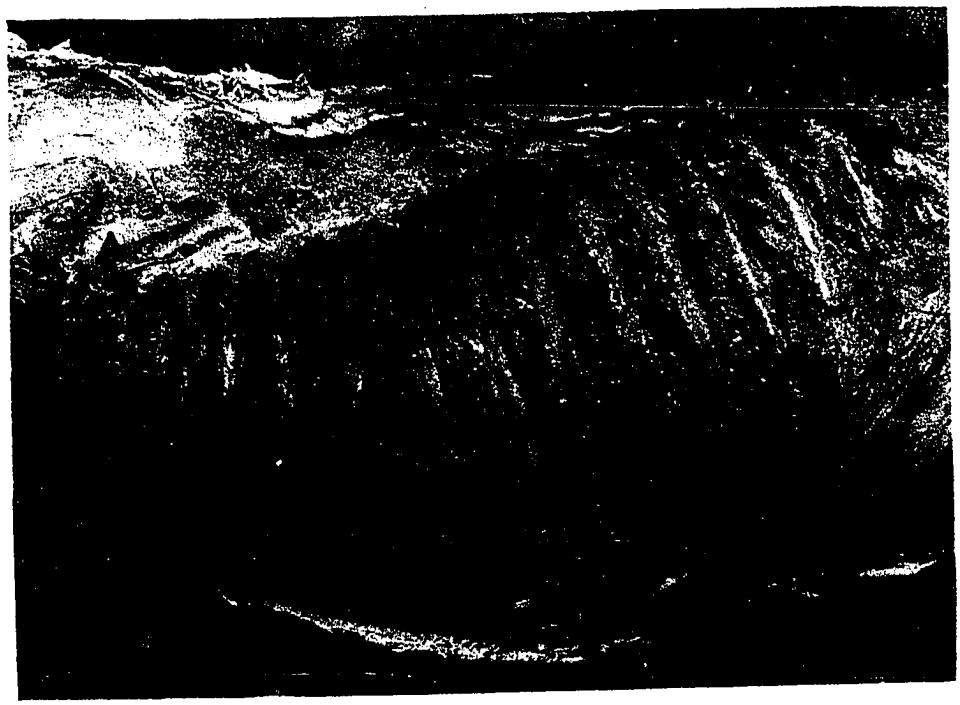
A - first fib

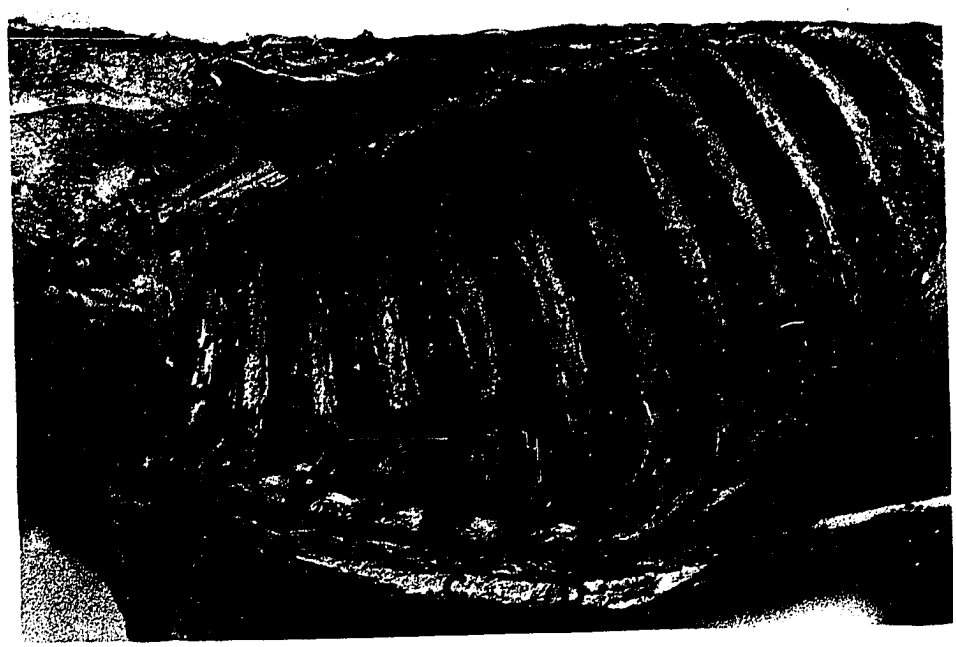
B - lungs

C - costochondral junction

D - heart

E - intercostal space





the vessels will be avoided if the thoracotomy incision is made along the mid line of an intercostal space. In Figure 2 it is seen that the apex of the heart lies approximately at the location of the seventh rib slightly ventral to the costochondral junction. The first rib is identified by A in this group of photographs and it should serve as a useful reference. All the ribs, except for the first and twelfth, are removed in Figure 3. The position of the three lobes of the lungs in the left side are shown. The position of the diaphragm E in relation to the lungs is also shown. In Figure 4 the lungs are reflected and the diaphragm's position B in relation to the heart C is placed in evidence. D shows the location of the left phrenic nerve. It is attached to the pericardial mediastium which in turn is connected to the pericardium with connective tissue. This nerve was easily separated from the pericardium by blunt dissection.

The same study was made on the right side. Figures 5, 6, and 7 show, respectively, the ribs with the musculature removed, the ribs removed and the lungs reflected. In Figure 6 it is seen that the lungs on the right side completely cover the heart, whereas on the left side a section of the heart called the cardiac notch was exposed, see Figure 3. The right phrenic nerve is shown by C in Figure 7 and is attached and separated from the heart in the same manner as is the left phrenic nerve.

Figure 8 shows the dorsal view of the sternal plate cut away from the thorax. The dark line E corresponds to the edge of a section of the transversus thoracis muscle dissected away from the ribs. The corresponding black line is identified on Figure 7. Underneath this muscle, approximately three-quarters of an inch laterally from the mid-line of the sternum, lies

Figure 3. Thorax, left side, lateral view with ribs 2 through 11 removed

A - first rib

B - apical lobe of lungs

C - cardiac lobe of lungs

D - diaphragmatic lobe of lungs

E - diaphragm

F - heart

Figure 4. Thorax lateral view, left side with lungs reflected

A - first rib

B - diaphragm

C - heart

D - left phrenic nerve

E - left internal thoracic artery and vein

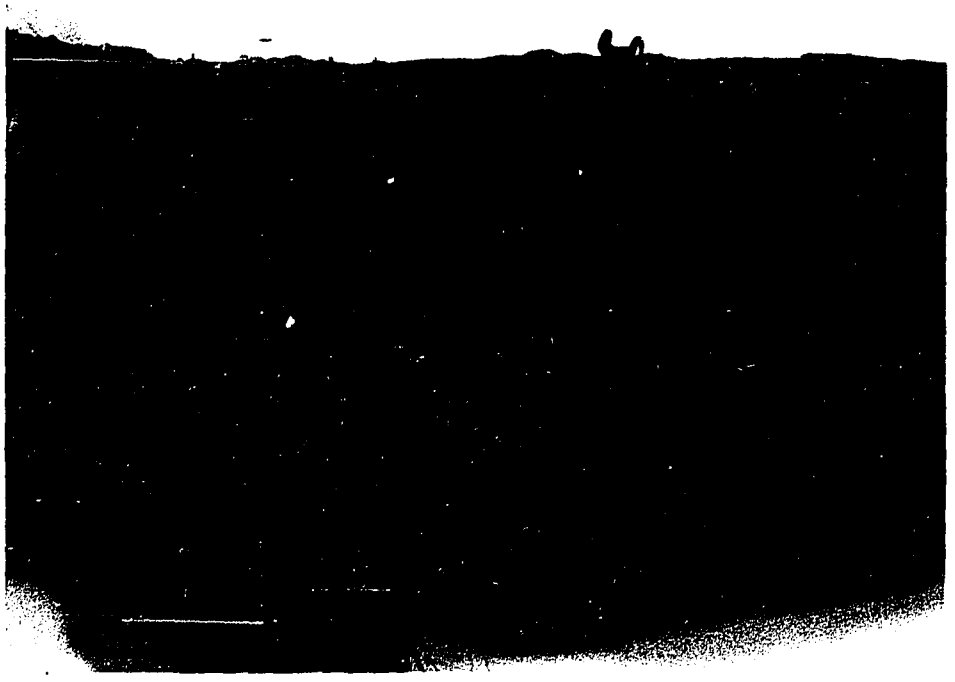


Figure 5. Thorax, right side, lateral view, intercostal musculature removed

A - first rib

B - lungs

C - costochondral junction

D - intercostal space

E - diaphragm

Figure 6. Thorax, right side, lateral view, ribs 2 through 11 removed

A - first rib

B - apical lobe of lungs

C - cardiac lobes of lungs

D - diaphragmatic lobe of lungs

E - diaphragm

Figure 7. Thorax, right side, lateral view with lungs reflected

A - first rib

B - heart

C - right phrenic nerve

D - diaphragm

E - cut edge of transversus thoracis muscle (black line)

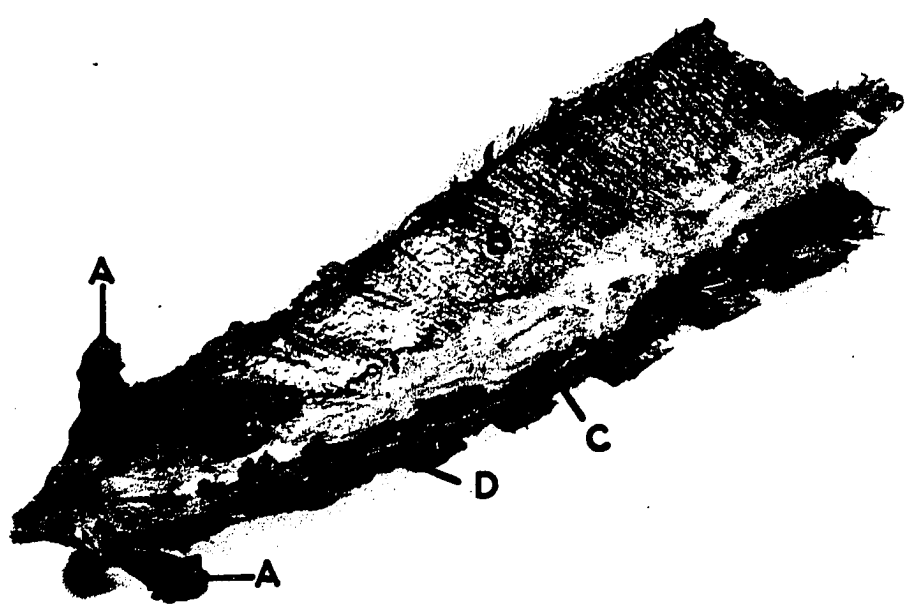
Figure 8. Dorsal view of sternal plate cut away from thorax

A - first rib

B - transversus thoracis muscle

C - internal thoracic artery

D - internal thoracic vein


A
B
C
D
A

the internal thoracic artery and vein shown as C and D in Figure 8. Their locations are important for trephining the sternum to provide an opening for the stem of the prosthetic device. The position of these vessels influenced the location and design of the stem on the device. Mediastinal arteries and veins were found to connect to the intercostal arteries and veins along the dorsal section of the sternum. This prevented shifting the location of feed-through on the sternum either cranial or caudal relative to the position of the stem on the device. By trephining a three-eights inch diameter feed-through opening on the sternum directly in line with the stem as is shown in the dorsal and ventral views of the sternum of a second dog in Figures 17 and 18, no interference is offered by either the internal thoracic, mediastinal, or intercostal vessels.

Figure 10 shows a ventral view of the heart and diaphragm with the lungs reflected. It is clearly seen how the heart B is connected to the diaphragm K by the diaphragmatico-pericardial ligament J. This ligament connects the mediastinal diaphragmatic pleura to the pericardial mediastium. In Figure 9 the right side of the heart is shown with the lungs reflected. The posterior vena cava B is clearly seen in this photograph. Its location is important to the fitting of the prosthetic device to the heart, particularly where it joins the anterior vena cava to enter the right atrium on the diaphragmatic surface near the lower border of the heart. It was found that this location served as a limit point for the periphery of the prosthesis at this section of the lower border.

An entirely different approach was taken in the anatomical study of the thorax and thoracic cavity of a second embalmed dog. The sternum was first

Figure 9. Right side of heart and diaphragm with lungs reflected

A - first rib

B - vena cava (posterior)

C - right phrenic nerve

D - heart

E - diaphragmatico-pericardial ligament

F - diaphragm

Figure 10. Ventral view of heart and diaphragm with lungs reflected

A - first rib (cut)

B - heart

C - apical lobe, right side

D - cardiac lobe, right side

E - diaphragmatic lobe, right side

F - intermediate lobe, right side

G - apical lobe, left side

H - cardiac lobe, left side

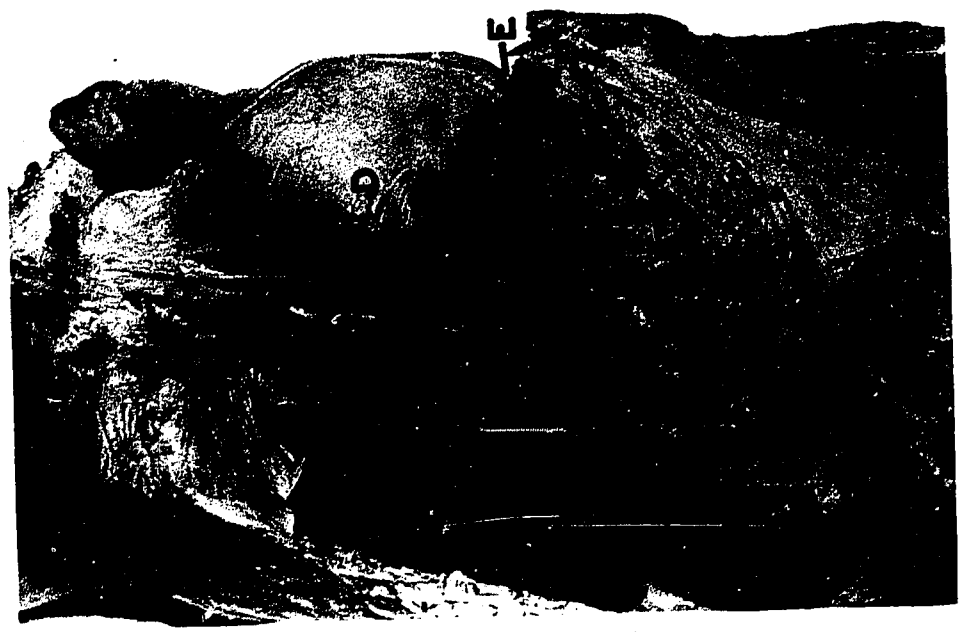
I - diaphragmatic lobe, left side

J - diaphragmatico-pericardial ligament

K - diaphragm

L - apex of heart


B
A


E
D

removed using a Stryker autopsy saw. Figure 12 shows a ventral view of the resulting exposure. The various lobes of the lungs are clearly seen in relation to the position of the heart F. This photograph clearly shows the diaphragmatico-pericardial ligament G. In this photograph it is seen that the apex of the heart I lies and is oriented to the left of the sternum. By referencing a line J-K through the *manubrium* and xyphoid cartilage in the mid-saggital plane and ranging a line through the apex in the direction of the longest linear dimension of the heart I-L, it may be said that the heart is oriented 28 degrees to the left of the mid-saggital plane. In this dog the apex is located at the level just caudal to the seventh rib.

In Figure 11 the ribs, except for the first, and the lungs were reflected, clearly showing the heart H and the vessels and nerves connected to the cranial aspect of the heart along its upper border. The internal thoracic veins B and arteries C where they connect to the sternum, the anterior vena cava D, the brachiocephalic artery E, left subclavian artery F, and the ligamentum arteriosem G beneath the pericardium are all shown in this photograph. The area cranial to the heart was studied with the object of finding a suitable location should it have become necessary to anchor the prosthetic device to the cardiac structure. The ligamentum arteriosum appeared to provide a suitable tissue on which to tie the device. Anchoring the device to the ribs or sternum offered another possible method. Forming a flexible plate to the contour of the base surface of the heart near its upper border and providing suspenders to connect to the plate from the device itself offered a third possibility. The myocardial prosthetic device discussed in Section III was designed with the aim of requiring no external

Figure 11. Ventral view showing diaphragmatico-pericardial ligament and vessels along upper border of heart

A - first rib

B - internal thoracic veins (right and left)

C - internal thoracic arteries (right and left)

D - anterior vena cava

E - brachiocephalic artery

F - left brachiocephalic artery

G - ligamentum arteriosem (beneath pericardium)

H - heart

I - diaphragmatico-pericardial ligament

J - diaphragm

K - left phrenic nerve

L - right phrenic nerve

V - coronary sulcus

Figure 12. Ventral view of thorax of second dog with sternal plate removed

A - apical lobe, right side

B - apical lobe, left side

C - cardiac lobe, left side

D - diaphragmatic lobe, left side

E - diaphragmatic lobe, right side

F - heart

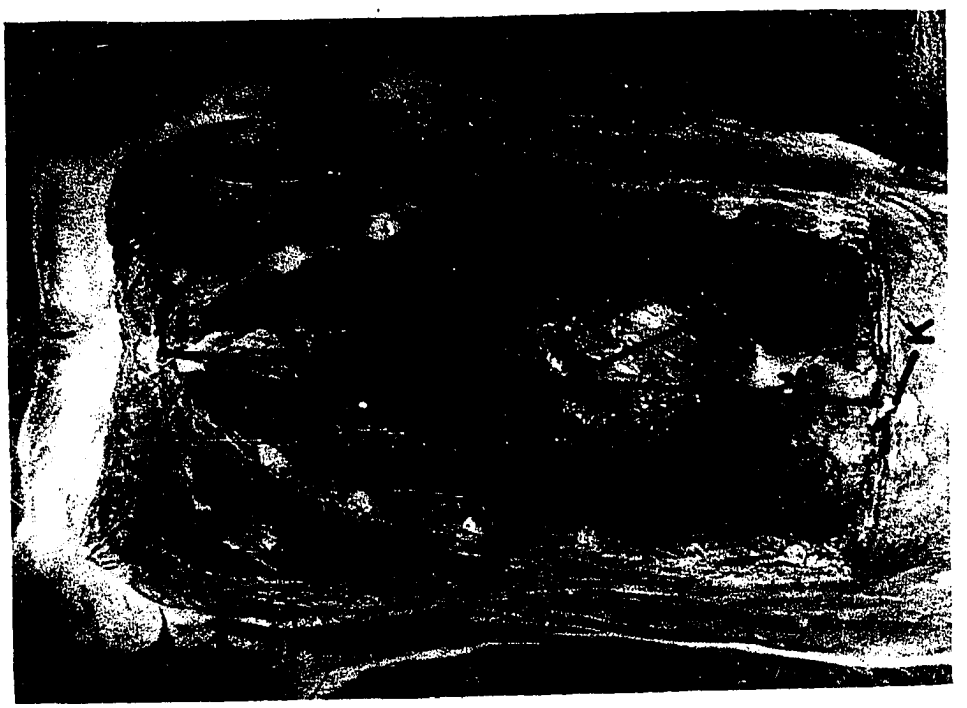
G - diaphragmatico-pericardial ligament

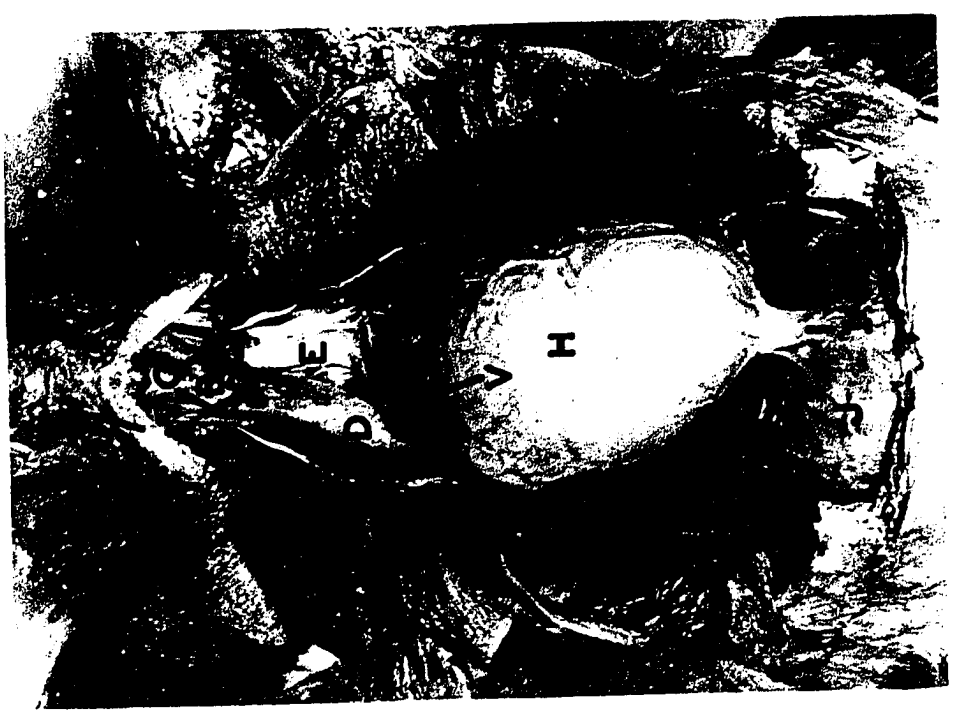
H - diaphragm

I - apex of heart

J - manubrium

K - xyphoid





measures to hold it in place on the heart.

The mediastinal diaphragmatic ligament B is cut and the left C and right D phrenic nerves are dissected away from the heart M in Figure 14. Except for the vessels connecting the heart to the pulmonary and systemic circuits, the heart is now free.

A study was next made to determine the locations of the connecting vessels of the heart, for these will serve as limits for the form of any foreign object that is placed around the heart. Figure 13 shows a ventral view with the heart pulled over to the left side. The anterior B and posterior C vena cavae are seen to be oriented slightly to the right of the midline of the base-diaphragmatic surfaces of the heart. In Figures 13 and 14 it is seen how the surface of the heart curves inward on its ventral and lateral aspects over the sterno-costal surfaces as a range is taken in the cranial direction from the ventricles to the atria. The right atrium G in Figure 13 and left atrium N in Figure 14 are located along the inwardly curved surface. An outline of the left I and right H coronary arteries are seen in Figure 13. The coronary sulcus which is the boundary between the ventricles and atria V are shown in both photographs.

The location of the exit of the pulmonary arteries from the right side of the heart into the lungs is indicated by E in Figure 13. Contour X just ventral to this junction must serve as a limit to any foreign object that is to be placed around the right side of the heart. Otherwise, the possibility of occlusion of these pulmonary vessels will exist. The contour Y, just above the posterior vena cava, serves as a contour-limit for the device on its dorsal-cranial periphery where it covers the dextro-caudal

Figure 13. Ventral view with heart reflected to left

A - first rib

B - anterior vena cavae

C - posterior vena cavae

D - right phrenic nerve

E - pulmonary vessels (right side)

F - diaphragm

G - right atrium

H - right coronary artery

I - left coronary artery

X - line (dotted), limiting boundary on right side above pulmonary vessel junction

Y - line (dotted), limiting boundary on right side at lower border above posterior vena cava junction

V - coronary sulcus

Figure 14. Ventral view showing phrenic nerves dissected and cut diaphragmatico-pericardial ligament

A - first rib

B - cut diaphragmatico-pericardial ligament

C - left phrenic nerve

D - right phrenic nerve

E - right apical lobe

F - right cardiac lobe

G - right diaphragmatic lobe

H - left apical lobe

I - left cardiac lobe

K - intermediate lobe

K' - left diaphragmatic lobe

L - diaphragm

M - heart

N - left atria

V - coronary sulcus

surface of the heart.

In Figure 15 the heart is shown pulled over to the right side. In this ventral view the left phrenic nerve D is shown dissected away from the heart. Once removed from the heart the nerve is completely separated from any other tissues. The locations of the entrance of the pulmonary vessels B are shown in this photograph. Contour Z just ventral to this junction determines the limit of the periphery of the prosthetic device on the left side, and contour O clearing the array of vessels in this location determines the periphery of the section of the device near the upper border of the heart.

By piecing together the contours E and C in Figure 14, and O and Z in Figure 15, the resulting composite will set and establish the shape of the throat or opening of the prosthetic device. This contour also serves as a boundary for the placement of the device on the heart and the device may now be designed so that the heart may be completely encapsulated and at the same time the critical pulmonary and systemic vessels will be avoided.

With the device completely encapsulating the heart, all of the heart's vasculature is enveloped by it. Figures 16 and 17 show photographs* of vinyl acetate casts of the vasculature of a canine heart. During the artificial contraction of the ventricles effected by the prosthesis the coronary arteries and all of the heart's vasculature will also be somewhat contracted and occluded. This poses no problem because in the normal operation of the heart, during ventricular contraction the vasculature of the heart also is contracted and occluded (9).

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*Through courtesy and permission of Dr. George C. Christianson, Head, Department of Veterinary Anatomy, Purdue University, Lafayette, Indiana.

Figure 15. Ventral view with heart reflected to the left

A - first rib

B - left pulmonary vessels

Z - line (dotted), limiting boundary on left side abobe junction of pulmonary vessels

O - limiting boundary on sterno-costal surface at upper border

D - left phrenic nerve

After the initial anatomical studies on embalmed dogs, similar explorations were performed on anesthetized dogs. The dogs were anesthetized by injecting one cubic centimeter per five pounds of body weight of sodium pentobarbital, at a strength of 60 milligrams per cubic centimeter into the right cephalic vein. One-half of the calculated dose was given rapidly; the remainder was injected in one-half cubic centimeter dosages until the pedal and palpebral reflexes disappeared. As the explorations progressed additional anesthetic was injected as needed. At the conclusion of a study the dog was euthanized by injecting a massive dose of potassium permanganate into the heart.

A Murphy endoctracheal catheter with a built-in cuff was inserted into the trachea and the cuff was inflated. A tank of oxygen with a Prothoracic respirator attachment was placed in the ready position. In the initial live exploration, the thoracic cavity was opened by making a mid-line incision along the sternum and then cutting through the sternum with a Stryker autopsy saw. The respirator was connected to the endotracheal tube as soon as the chest was punctured.

The thoracic walls were slightly separated by hand. A study was made of the orientation of the heart, lungs and diaphragm. Movements of the heart were observed during the various phases of the heart cycle. The heart was seen surrounded by the pericardial mediastium. A definite space exists between the surfaces of the heart and the lungs and the diaphragm which is adjacent to it. As the heart moved rhythmically during its periodic beating, neither the diaphragm nor the lungs congested the space between them and the heart. This observation was highly encouraging, for it

Figure 16. Vinyl acetate cast of vasculature of canine heart, diaphragmatic view

A - left coronary artery

G - right coronary artery

H - dorsal right atrial artery

Figure 17. Vinyl acetate cast of vasculature of canine heart, left side

A - aorta

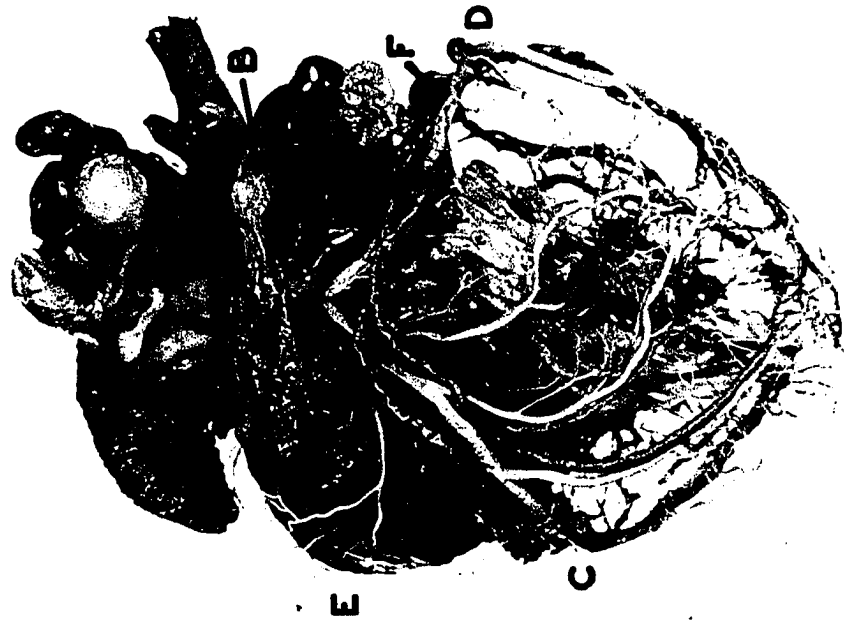
B - pulmonary artery

C - descending branch of left coronary artery

D - circumflex branch of left coronary artery

E - ventral right atrial artery

F - great cardiac vein


B
F
D
E
C


G
H
A

placed in evidence the possibility of surrounding the heart with a foreign object and yet not have it interfere with the movements of the heart, lungs and diaphragm.

The diaphragmatico-pericardial ligament was incised with a pair of scissors, and the diaphragmatic pleura separated from the pericardial pleura. As no arteries or veins are involved in the ligament, no bleeding resulted from this operation. With the ligament cut no change in the action of the heart was observed and the quality of the beat as sensed by palpation did not differ from that prior to cutting the ligament. The left and right phrenic nerves were separated from the pericardium by blunt dissection. At this point a wax negative form, developed from a positive plaster cast whose shape resembled the heart, was fitted around the heart. Figure 18 shows this form being slipped on to the heart. The green liner shown in the photograph is a latex liner within the form. From fittings such as these, the wax model was reshaped and resized in the manner described in Section IV to tailor-fit the heart and have its periphery conform to the limiting contours previously discussed, which were established by the position of the pulmonary and systemic vessels leaving and entering the heart.

No marked interference with normal cardiac function was offered by the wax model. With the wax model in place, the thorax opening was held closed with hemostats. After fifteen minutes it was opened and no apparent damage or irritation to the heart, lungs, vessels or diaphragm was noticed.

In the next studies of anesthetized dogs, entrance was made into the thoracic cavity by a thoracotomy incision through the centerline of the sixth intercostal space between the sixth and seventh ribs on the left side.

Figure 18. Ventral view, sternum incised for fitting of first wax negative model over heart of anesthetized dog

A - negative wax model over heart

B - piece of lung

C - latex liner

Bleeding was arrested with hemostats and sponging. The ribs were separated with rib-retractors. The cardiac notch, heart and lungs are well exposed with this type of entry as is seen in the photograph in Figure 19. Through this opening the mediastinal diaphragmatic ligament is easily accessible. In Figure 20, the cut ligament E held by forceps is shown. The heart is slightly raised and a hemostat is pointed to the right phrenic nerve. By blunt dissection, the left phrenic nerve is separated from the pericardium. Figure 21 shows the nerve D after the dissection. Figure 22 shows the right phrenic nerve D after dissection from the pericardium. Now the heart is free and further fittings of a wax model shown in Figure 23 are permitted.

After making fittings on several live anesthetized dogs, a final well-tailored wax model was developed, and is shown in place over a beating heart in Figure 24. The shape and size of this model corresponds to the shape and size of the heart. Its periphery or throat corresponds to the limiting contour of E on the right border, C on the lower border (see Figure 13) and D on the upper border and Z on the left border (see Figure 15). The curvature of the surface of the model which covers the atria corresponds to the curvature of the atria's surface. Therefore, a considerable reduction in the diameter of the model is realized when compared to its largest diameter which occurs caudally at a section over the surface of the ventricles. For this reason, in placing the model over the heart, it was required that the ventricles be squeezed in order to make possible the heart's insertion into the device. Because of the flexibility of the heart this requirement posed no problem. Once the model encapsulated the heart,

Figure 19. Thoracotomy incision in anesthetized dog, sixth intercostal space

A - piece of lung

B - heart

Figure 20. View with diaphragmatico-pericardial ligament incised, anesthetized dog

B - heart

C - right phrenic nerve in normal position

E - incised diaphragmatico-pericardial ligament

Figure 21. View with left phrenic nerve dissected away from heart, anesthetized dog

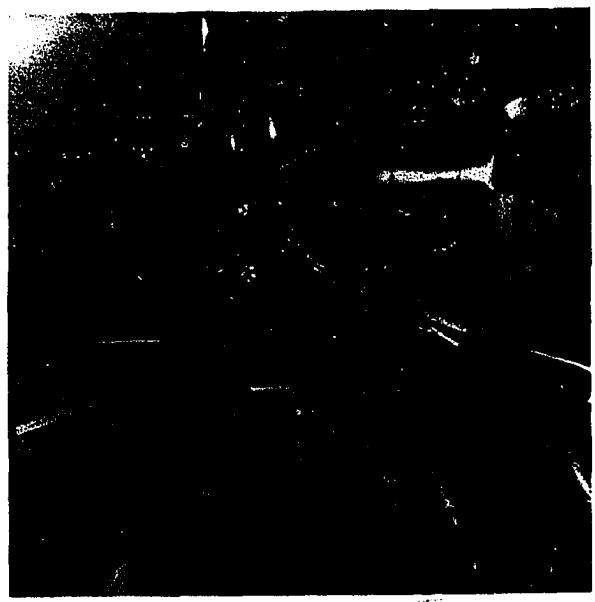
B - heart

D - left phrenic nerve dissected away

Figure 22. View with right phrenic nerve dissected away from heart

D - right phrenic nerve dissected away

B - heart



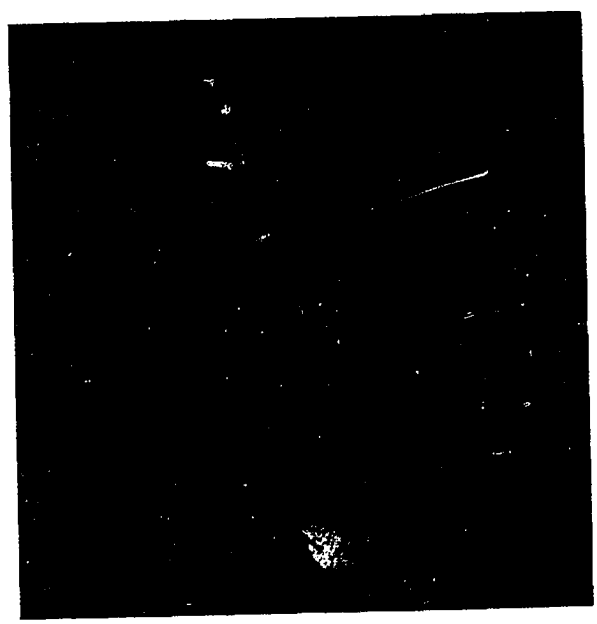


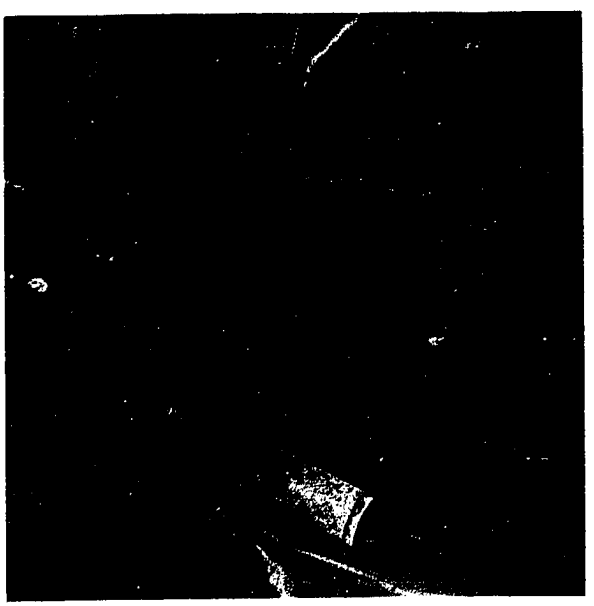
Figure 23. View of wax negative model fitting in initial phase of development, on thoracotomized anesthetized dog

A - negative wax model over heart

B - latex liner

Figure 24. View of wax model fitted to heart in final stage of development, on thoracotomized anesthetized dog

F - wax model in place over heart



it could not be easily slipped out of place. A considerable pull on the model was necessary in order to remove it from the heart. From these observations, it was concluded that a prosthetic device could be designed and fitted in such a manner as to make the best possible use of this feature to hold the device in place on the heart.

Figure 25 shows a photograph of a final model of a functional myocardial prosthetic device fitted to the heart of an embalmed dog. It is seen how the device follows the curvature of the heart over the cranio-sterno-costal and cranio-left surfaces of the heart. The throat of the device at its extremity along the upper border O follows the same contour established in Figure 15. The vessels along the upper border are completely avoided. The contours along the right, lower and left borders of the device also correspond to their respective limiting contours X, Y, and Z in Figures 13 and 15. The apex B of the device sits in place over the diaphragm.

On the sterno-costal surface of the device the stem D is located so that it is in the position of the mid-line of the sternum at the location of the fourth sternebrae. By trephining a hole in the sternum at this location a provision is made for projecting the stem through the sternum. Figures 26 and 27 show ventral and dorsal views of a hole in the sternum made at that location. In Figure 28 this sternal section is in place on the ventral side with the stem C of the prosthesis protruding through the trephined hole.

For chronic implantation of the prosthesis a stainless steel plate such as that sketched in Figure 29c may be attached to the sternum with

Figure 25. Functional prosthetic device fitted to heart of embalmed dog

A - first rib

B - apex

C - diaphragm

D - stem of device

O - periphery of device along upper border

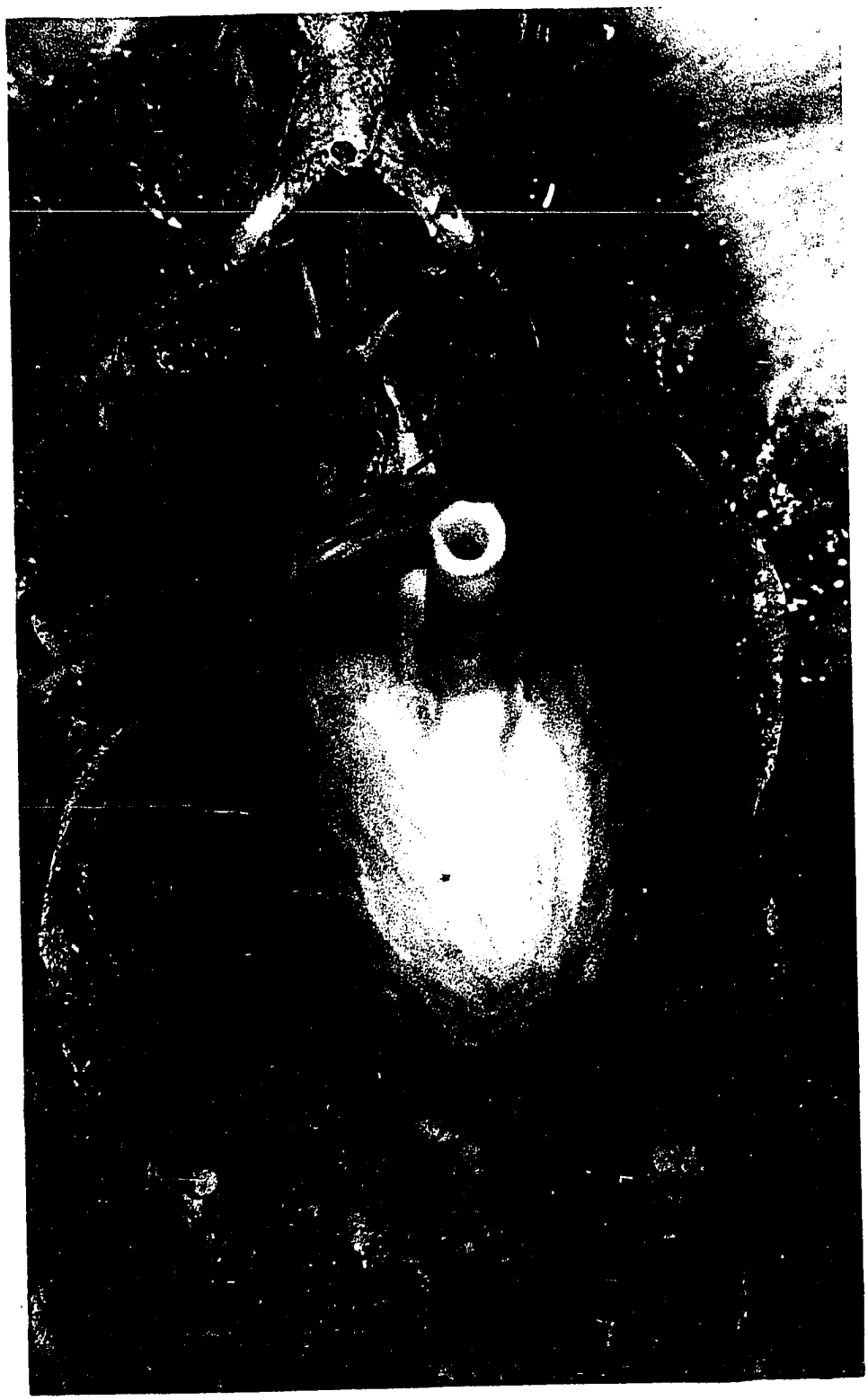


Figure 26. Dorsal view of sternal plate showing trephined hole

A - sternum

B - manubrium sterni

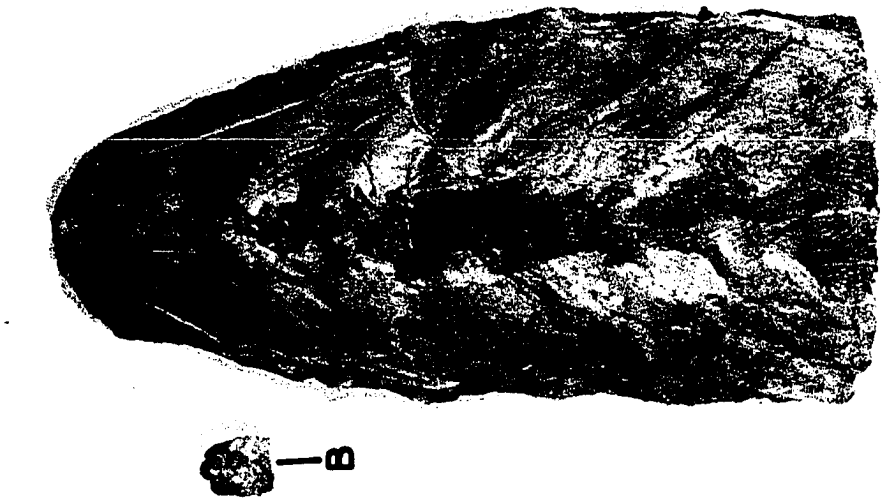
C - transversus thoracis muscle

D - removed section of sternum

Figure 27. Ventral view of sternal plate showing trephined hole

A - sternum

B - removed section from sternum


a

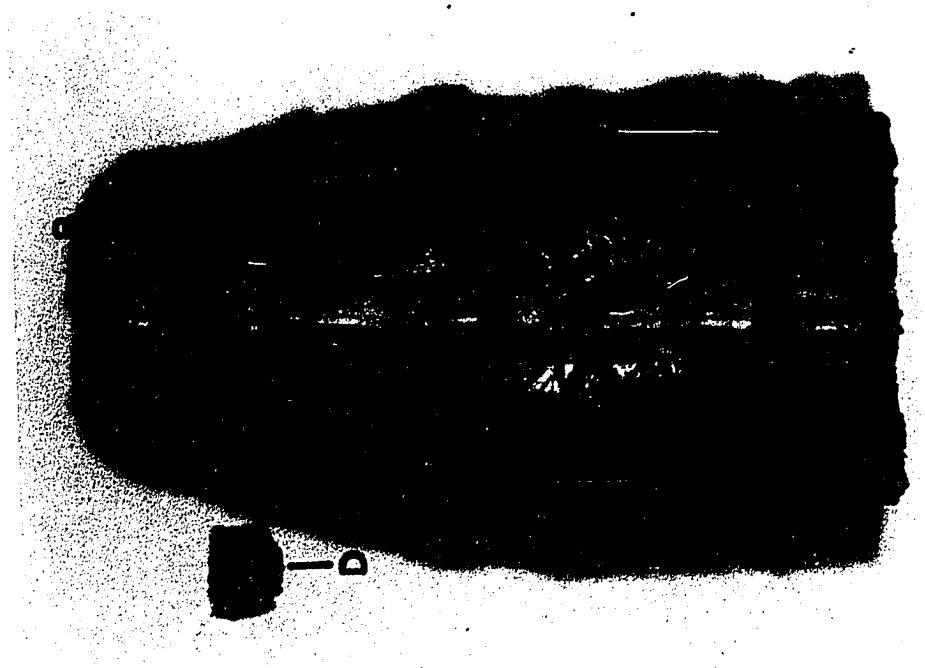

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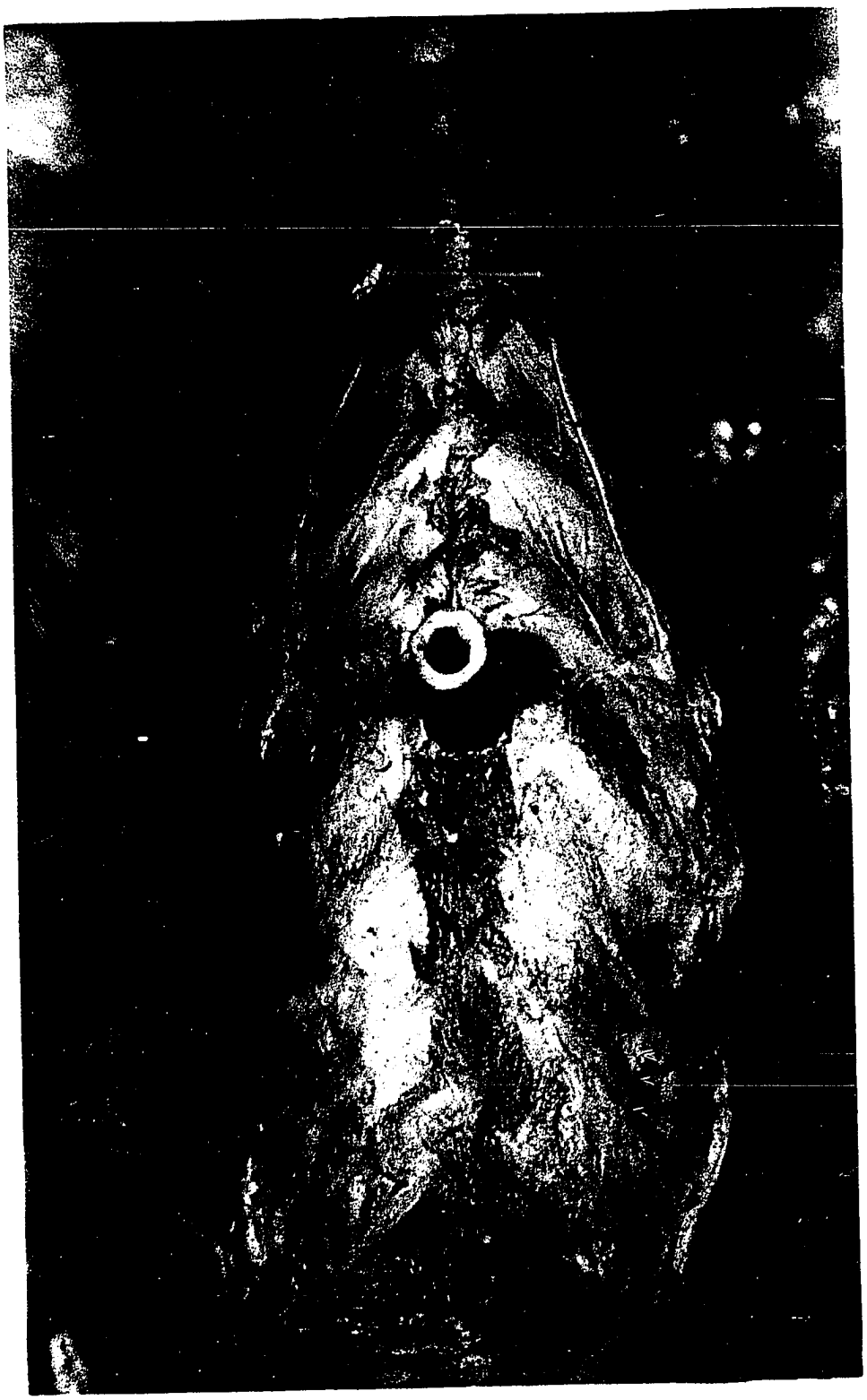
Figure 28. Ventral view showing sternal plate in place with prosthetic device fitted to heart underneath

A - first rib

B - manubrium sterni (cut)

C - stem of the device projected through sternum



two stainless steel screws and nuts as shown in Figure 29b. The stem of the device would attach to the internal protrusion and the air supply hose would be attached to Y externally. This method would also offer a more effective manner of providing an air passage from the prosthetic system to the device, than the method of projecting the stem through the sternum.

As a result of the anatomical studies, explorations and fittings described in this section on both embalmed and live anesthetized thoracotomized dogs, the following operative procedures were believed necessary and adequate to permit insertion of the myocardial prosthetic device into the thorax and fitting it to the heart:

1. Make a thoracotomy incision on the left side through the midline of the sixth intercostal space.
2. Separate the sixth and seventh ribs with rib retractors.
3. Cut with a pair of surgical scissors the diaphragmatico-pericardial ligament, separating the mediastinal pleura from the pericardial mediastium.
4. By blunt dissection separate the left and right phrenic nerves from the pericardium. The heart should now be free for fitting the myocardial prosthetic device.
5. Trephine a three-eights inch diameter hole through the center of the fourth sternebrae.
6. One experimenter should place himself on the dorsal lateral side and another on the ventral lateral side of the dog. The man on the dorsal side should, with his left hand over the dog, place it under the heart and tip it in an upward direction as is shown

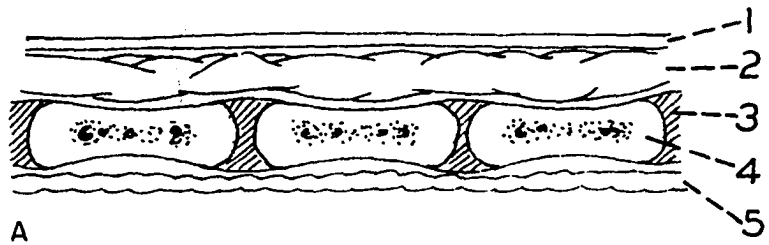
Figure 29. Stainless steel adaptor plate assembly for sternum

A - Cross-sectional sketch of sternum

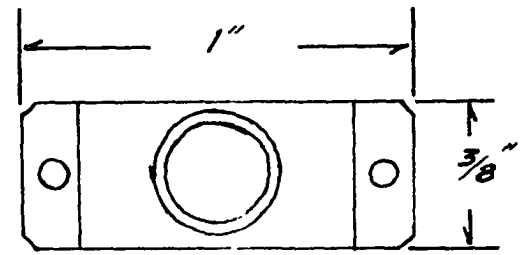
1. skin
2. fascia
3. cartilage
4. sternebrea
5. transversus-thoracic muscle

B - Sketch of stainless steel adaptor plate shown attached to sternum

C - Top and front views of stainless steel adaptor plate (scale: 1/2" = 1")



A



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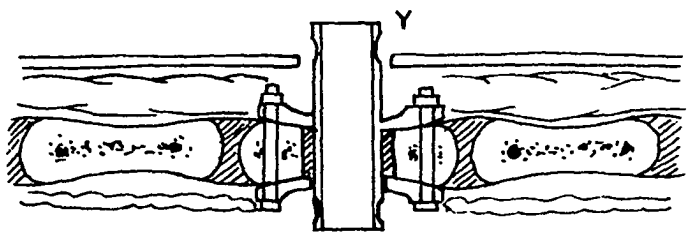
INLET



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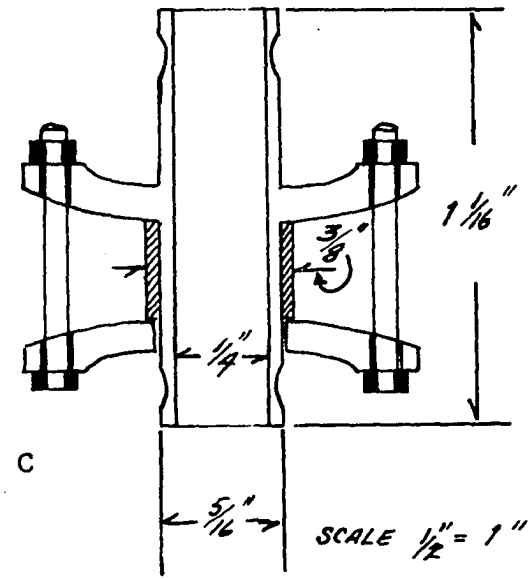


C

in Figure 30.

7. The experimenter on the ventral side should now orient the device, readying it for insertion through the thorax opening. Figure 31 shows this procedure.
8. The experimenter holding the device now eases it onto the heart while the other man with his fingers helps to manipulate the heart into the device, as is shown in Figure 32.
9. Pull the stem through the trephined hole in the sternum.
10. Figure 33 shows the prosthetic myocardial device in position on the heart in vivo.

The problems of fitting and tailoring the device to the heart and designing its shape and size so as to conform to the heart were resolved. The study also provided the necessary information for designing the device so that it would not interfere physically with the vessels entering and leaving the heart, nor with the lungs and diaphragm adjacent to the heart. The location for the stem so that the pneumatic system could be connected to the device was determined. After these affirmative results, the anatomical studies were continued with the purpose of assisting in the design of the prosthetic device.

Figure 30. First stage for fitting functional prosthesis to thoracotomized anesthetized dog

A - heart

B - left hand of man on dorsal lateral side of dog elevating the heart

C - dorsal side

Figure 31. Second stage for fitting functional prosthesis to thoracotomized anesthetized dog

A - heart

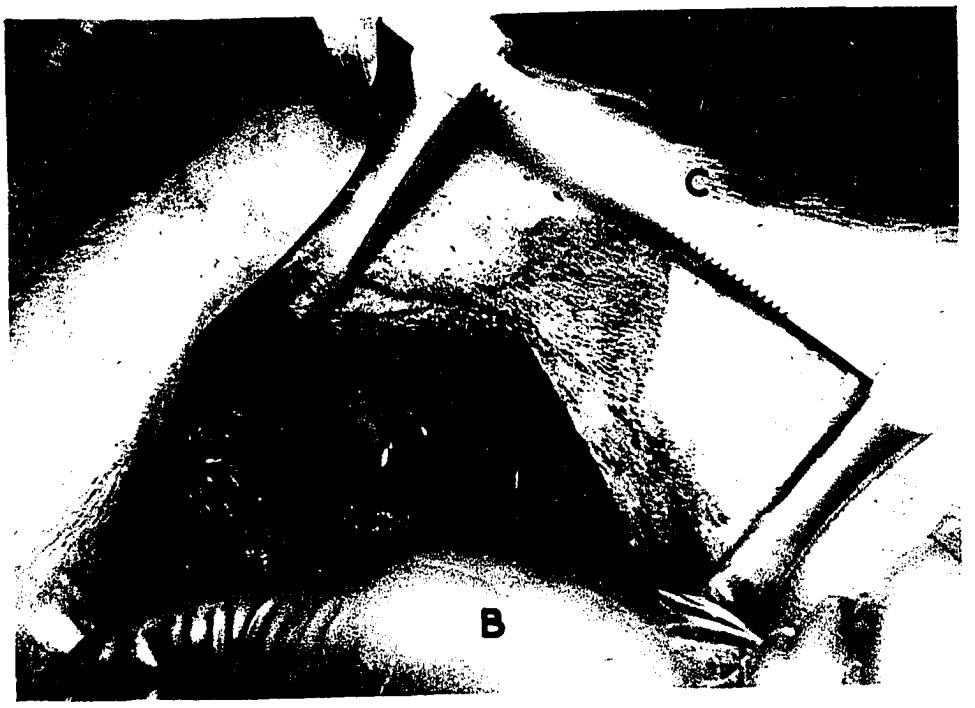
B - left hand from dorsal lateral side

C - dorsal side

D - right hand of man on ventral side

E - left hand of man on ventral side

F - myocardial prosthetic device


C
B

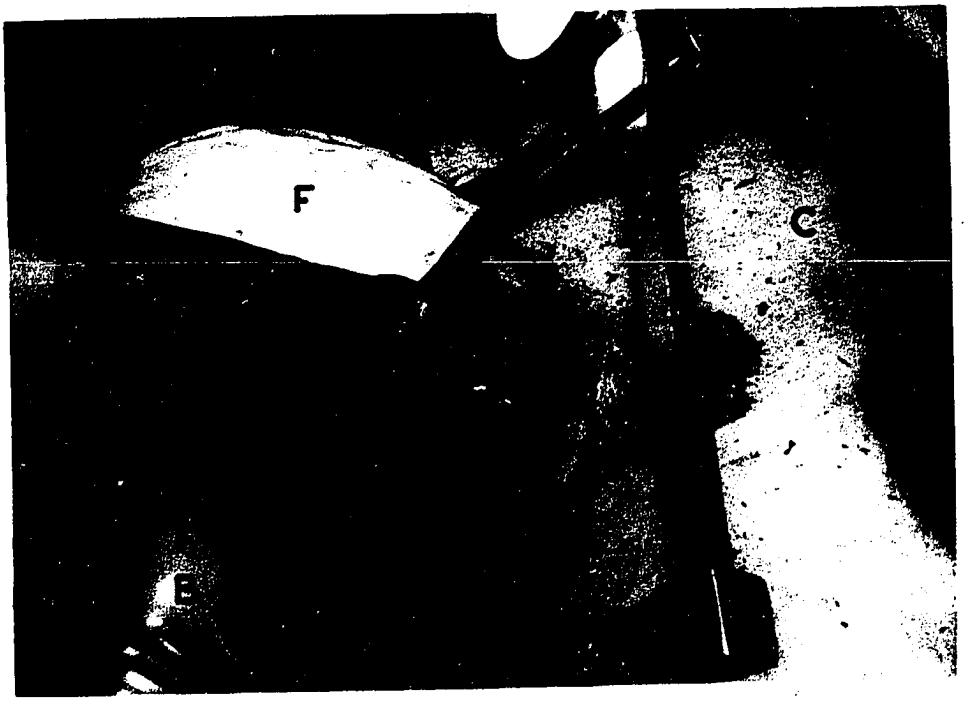

F
C
B

Figure 32. Third stage for fitting functional prosthesis to thoracotomized anesthetized dog

B - left hand from dorsal side

C - dorsal side

D - right hand of man on ventral side

E - left hand of man on ventral side

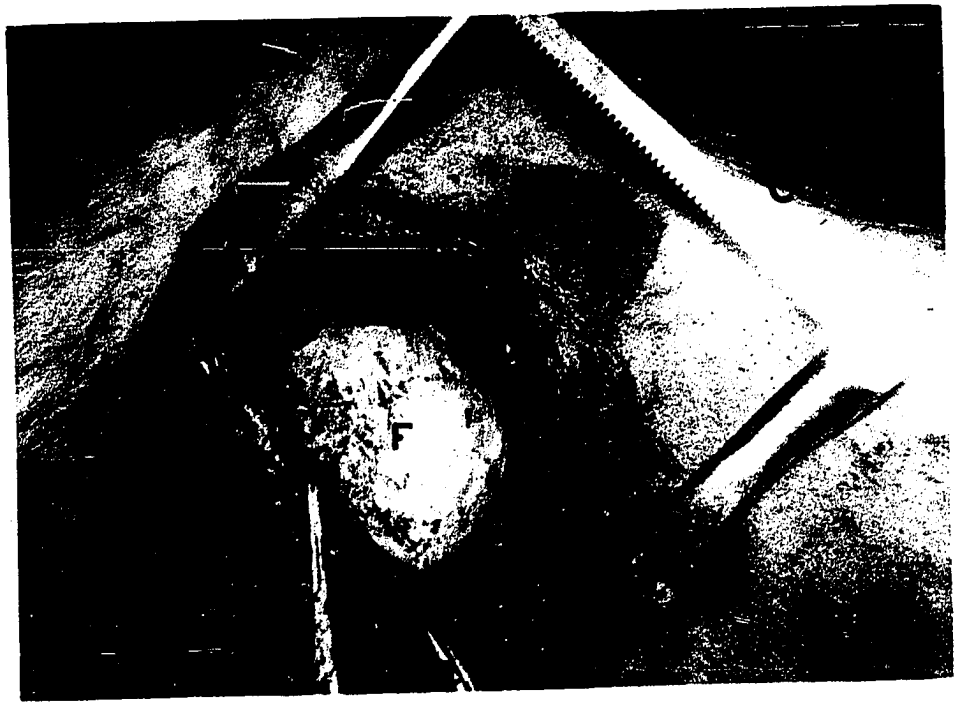
F - myocardial prosthetic device in position

Figure 33. Functional prosthetic device in position in thoracotomized anesthetized dog, fitted through sixth intercostal space

C - dorsal side

F - myocardial prosthetic device in position over heart in vivo


E
F


F

III. CARDIOVASCULAR DYNAMICS

The heart serves as a central pump in the cardiovascular system which performs the function of circulating the blood. Figure 34 shows a schematic diagram of the major components of the cardiovascular system: the right and left hearts, each consisting of an atrium and ventricle, the systemic and the pulmonary circuit. Blood is returned from the systemic circuit in the vena cavae to the right atrium and then flows into the right ventricle through the atrioventricular (A-V) valves, also known as the tricuspid. Upon contraction, the right ventricle forces blood into the capillary bed of the lungs where it is oxygenated. Pulmonary blood is returned to the left atrium. Through a second set of A-V valves, known as the bicuspid or mitral, the blood is drained into the left ventricle. Upon contraction of the ventricular musculature during systole (systole refers to the period of ventricular contraction), the blood is forced through the aortic valve and then through the vascular system of the body.

The function of the myocardial prosthetic system is to provide a substitute for the normal activity of the myocardium which effects contraction during systole. By its action, the prosthetic device compresses the heart and thus effects artificial contraction of the intact musculature during the period which normally would correspond to systole. The support system supplies the necessary energy and programming to the prosthesis to simulate the normal periods of contraction and relaxation of the heart. In this manner the blood is pumped through the arteries of the systemic and pulmonary circuits.

Those aspects of cardiovascular biophysics and physiology which are

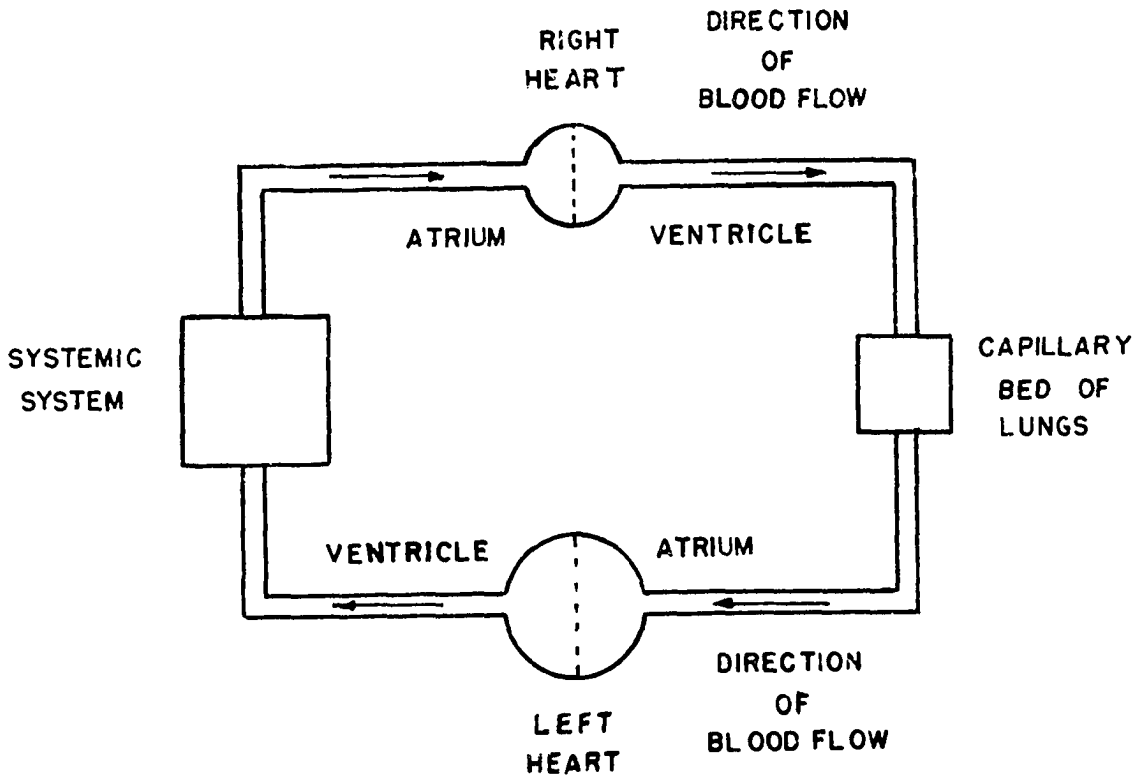


Figure 34. Schematic diagram of the cardiovascular system

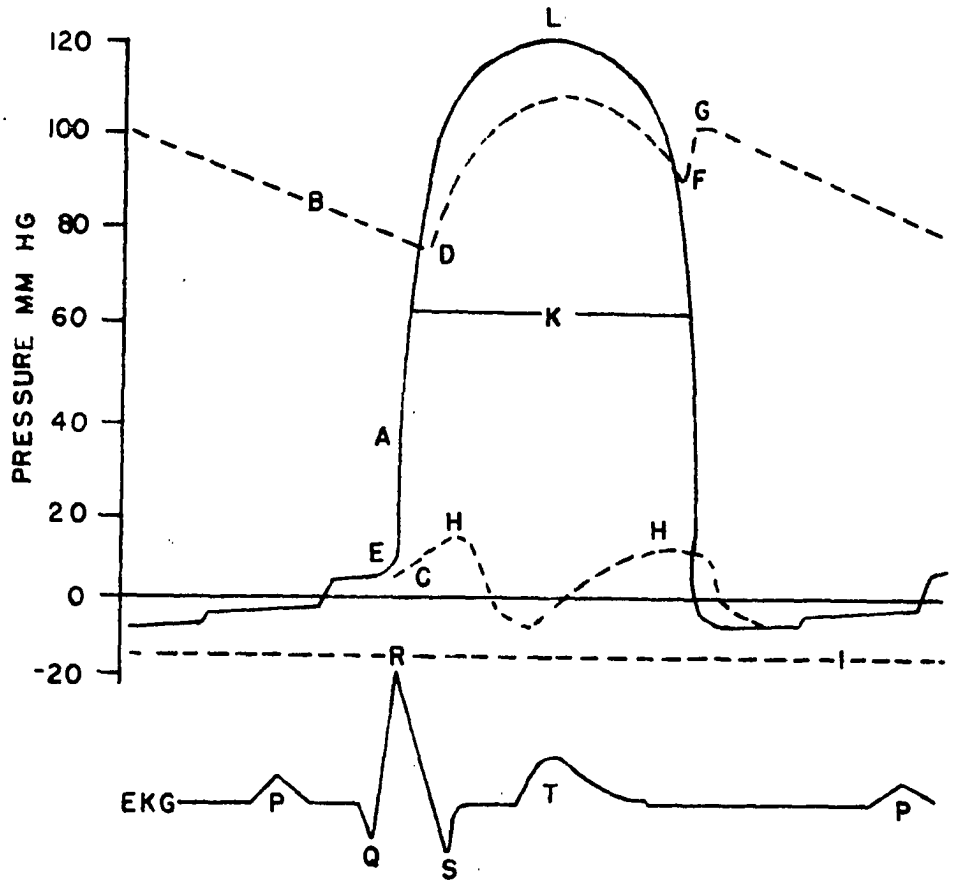
related to the energy, power, blood flow, blood pressures, and the pumping activity of the heart that are significant to the design of the myocardial prosthetic or artificial heart system will be considered here. A more detailed account of the hemodynamics and biophysics of the cardiovascular system for man is found in Ruch and Fulton (21) and dog in Dukes (6).

As is seen in Figure 34, the systemic and pulmonary circuits are connected in series. Therefore, the output of both the left and right ventricles averaged over a given period of time must be the same for the systemic and pulmonary circuits. Stroke volume, the volume ejected into the aorta during each ventricular contraction may be determined from Equation 1

$$\text{Stroke Volume} = \frac{\text{Cardiac Output}}{\text{Heart Rate}} \qquad (1)$$

where the stroke volume is in milliliters per beat, the mean cardiac output (total blood pumped by the heart averaged over many cycles) is in milliliters per minute and heart rate is in beats per minute. In normal man the stroke volume averages between 70 milliliters per beat under resting conditions and 80 under severe exercise (21). The cardiac output may be determined experimentally by either a dye-dilution method, utilizing the Fick principle, or other standard physiological experimental techniques (21).

Figure 35 shows a graph of the pressures at the various location of the heart during the cardiac cycle (33). The corresponding electrocardiagram is also shown. For dog or man the form and variation of the blood pressure wave and EKG (electrocardiagram) over the cycle are similar. However, the time base will differ. For the dog the normal resting heart



A - ventricular pressure

B - aortic pressure

C - atrial pressure

D - aortic valves open

E - A-V valves close

F - aortic valves close

G - dicrotic wave (conversion of potential energy to kinetic energy)

H - produced by ventricular contraction

I - base line of energy (thoracic pressure)

J - isometric relaxation

K - period when energy is imparted to blood

L - end of systole

Figure 35. Instantaneous pressure curves during the cardiac cycle, with corresponding electrocardiogram (EKG)

rate ranges from 70 to 120 while in man it ranges from 60 to 90 beats per minute. The peripheral resistance of the arterial system is related to the blood pressure and cardiac output as follows:

$$\text{Total Peripheral Resistance} = \frac{\text{Average Arterial Pressure}}{\text{Cardiac Output}} . \quad (2)$$

It is seen in Figure 35 from the ventricular pressure Graph A that the pressure in the ventricles rises from practically zero when the A-V valves close at E to 70 mm at D when the aortic valves open. Then during systole, the pressure rises to a maximum of approximately 120 mm which occurs at the end of systole L.

The work done and power required to overcome the arterial pressure during systole may now be determined. Under resting conditions the maximum systolic pressure in the left ventricle is about 120 mm of Hg or 160×10^3 dynes per sq. cm.* The stroke work done by the left ventricle is calculated from Equation 3

$$W = PV \quad (3)$$

where V is the stroke volume and P the maximum pressure during one stroke. At rest, for man it is found to be $(160 \times 10^3)(70) = 112 \times 10^5$ ergs or 1.20 joules.** Considering the resting heart rate to be 72, the corresponding maximum power delivered by the left ventricle to overcome arterial pressure is 1.4 watts. The pressure in the right ventricle is approximately one sixth (6) of that of the left. Inasmuch as the average volume ejected by

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*760 mm of Hg = 1 atmosphere; 1 atmosphere = 1.013×10^6 dynes/sq. cm.

**10^7 ergs = 1 joule.

the right ventricle may be considered the same as the left, the power required by it to overcome pulmonary-artery pressure is $\frac{1.4}{6} = 0.232$, making a total of 1.632 watts.

In standard resting dogs with an average maximum systolic pressure of 120 cm of Hg and a stroke volume of 14 milliliters, the work done by the left ventricle in overcoming arterial pressure during systole is 0.224 joules. Based upon 100 beats per minute, the corresponding power becomes 0.373 watts. The power for the right ventricle is $\frac{0.373}{6} = 0.062$ watts. The total power becomes 0.435 watts.

Under resting conditions the theoretical static work done by the heart to overcome arterial pressure, calculated on the basis of blood pressure and stroke volume, accounts for only approximately 95% of the actual work done by the heart. Additional work must be done to accelerate the blood through the system. For one ventricle the kinetic energy KE, in ergs, required to accelerate the blood is given by Equation 4.

$$KE = \frac{mV^2}{2} \tag{4}$$

where m is the weight in grams of blood ejected during systole, V is the average velocity, in centimeters per second, of the blood at which it is ejected. For both ventricles the energy is approximately twice this amount. During marked exercise this kinetic energy factor may add approximately 20 percent to the total theoretical static work calculated above (6).

In the human under severe conditions or marked exercise the maximum systolic pressure may rise to 300 mm of Hg and the heart rate may increase to 150 beats per minute. Considering the stroke volume to be nearly the same as at rest, the power required for the contraction of the left

ventricle to overcome arterial pressure then becomes about 6.0 watts. Adding the power for the right ventricle results in a total of 7.0 watts. Taking into account the kinetic energy power of 20% results in a total of about 8.2 watts. For the dog, considering the same maximum pressure and 180 beats per minute, under marked exercise the power required to overcome arterial pressure for the left ventricle is 1.68 watts, for the right ventricle 0.28 and the total power including that for blood acceleration is about 3.00 watts.

Energy is also required by the heart for the metabolic and mechanical requirements of the myocardial musculature during the contraction process which may amount to 5 percent of the mechanical energy required for blood ejection. Therefore, the prosthetic system must be capable of supplying at least 9.00 watts for man and 3.00 watts for the dog to the musculature of the heart under the most severe conditions.

These power levels are certainly in the order of magnitude which make possible and feasible the use of a prosthetic myocardial substitution device or artificial heart system to effect blood flow in the cardiovascular systemic, and pulmonary circuits. Assuming that the electropneumomechanical artificial heart system could be designed with a maximum efficiency of only 25 percent, then for the human the order of 35 watts and the dog 11 watts would be needed to power the entire system. With the energy-developing and control elements external to the body, supplying and developing the necessary power for the prosthesis pose no problem. When considering the equipment for complete chronic implantation into the body and bringing the energy into the system by electrical induction through the

body walls, the power levels to be transferred still appear feasible. Schuder, et al. (27, 28) show that it is entirely feasible to transmit inductively through the body walls powers in the order of 50 watts.

In the design of the artificial heart system employing a myocardial prosthesis the pressure and force distribution over the contraction period in the cardiac cycle must be considered. Although the ventricles of the mammalian heart are irregular in shape, the intraventricular cavities may be considered spherical (3) to a good approximation for the purposes of analysis. By basing surface and volume changes on the spherical configuration, the presence of the trabeculae carnae and papillary muscles in the ventricular cavities do not greatly affect the calculations.

The force exerted on the blood in the left ventricular cavity is given by Equation 5.

$$F = PA \tag{5}$$

where P, the pressure within the ventricular cavity, is in dynes per square centimeter, and A, the area of the inside surface is in square centimeters and F is in dynes. Considering the left ventricle to be spherical, its internal surface area may be expressed by:

$$A = 4\pi r^2 \tag{6}$$

and the volume contained by the ventricle by

$$V = 4/3\ \pi r^3 \tag{7}$$

where r is the radius of the sphere which resembles the inside size of the ventricle. As a sphere of changing radius contracts, the ratio of change of the internal volume to surface area is 1/3 r. Thus, as the heart

contracts the inside surface area changes proportionately less than the volume of the ventricles. In the normal beating heart for the human, the ventricular volume varies from an average maximum of 85 cubic centimeters at the beginning of systole to an average minimum of 25 cubic centimeters at the end of systole. The internal surface area changes from 94 to 42 square centimeters upon contraction.

During the ventricular contraction, as is seen from Graph A in Figure 35, at the beginning of systole the pressure is 70 mm and end systole it reaches a maximum of 120 mm. The pressure within the ventricles and the internal surface area are both changing during systole and as a consequence the force load on the walls of the ventricle is also changing. At the beginning of systole, the force exerted by the heart is (70 x 1332.2) (94) = 8.7×10^6 dynes at the end of systole when the pressure is greatest is (120 x 1332.2)(42.0) = 6.6×10^6 dynes. Therefore, as the left ventricle pumps blood against an aortic pressure which is increasing during the systolic phase of the cardiac cycle from 70 to 120 mm, the force averaged over the active ventricular area, exerted by the ventricles does not rise but slightly decreases. Thus an impulse of pressure into the prosthesis at the beginning of contraction, corresponding to the required conditions at the end of contraction, and maintained during the contraction period should be fully effective to artificially compress the ventricles during systole. On this basis, one of the aims established for the support system design was a pressure pulse maintained at constant amplitude during the simulated contraction period. The pressure pulse was abruptly terminated at the end of the period.

IV. THE PROSTHETIC DEVICE

With the anatomical and dynamic requirements thus established for the myocardial prosthetic system to effect ventricular contraction artificially, the design and fabrication of the prosthesis and the support system followed. The anatomical studies and explorations of the thoracic cavity of the embalmed and anesthetized dogs formed the foundation for the solution of the following problems encountered in the engineering of the prosthesis: 1) size and shape of the device, 2) materials used in its fabrication, 3) fitting and attaching it to the heart, as well as inserting it into the thoracic cavity, 4) and physical interaction with adjacent tissues, nerves, vessels, and organs. Among other objectives, it was desired to permit insertion of the prosthesis through a thoracotomy incision without requiring the removal or reflection of a rib. A flexible, yet firm, outer shell sufficiently rigid to withstand the maximum dynamic pressure of five pounds per square inch developed by the support system without appreciable stretching, made this possible. An intentional moderate flexibility of the outer shell further provided for some freedom of movement should some heart distention and rotation occur. Also, less irritation to the mediastium, phrenic nerves, lungs and vessels leaving and entering the heart is likely to result when these structures come in contact with the device when the device is made of a moderately flexible substance rather than if the outer shell were fabricated from a hard rigid material.

In order to minimize the problem of keeping the prosthesis in position on the heart during chronic use, the prosthesis was especially shaped to fit the contour of the heart, particularly on the sternocostal surface near

the upper border, where a marked curvature is found. The cross-sectional area at the collar or opening of the device is made smaller than the maximum diameter of the heart in order to help prevent the heart from slipping out of the prosthesis. Additional insurance against slippage of the device from the heart is provided by the air-stem attached to a sternum-plate, or having it project through the sternum. As a possible long-term measure, Cholvin (4a) considered the feasibility of using special non-toxic synthetic materials to develop a strong adhesive bond between the myocardial surface and surgically desirable attachments to the heart. The flexible feature of the prosthetic device made it possible to squeeze the heart through the collar into the device in a manner described in Section II and shown pictorially in Figures 30, 31, 32, and 33.

In addition to a description and detailed account of the fabrication of the myocardial prosthetic device, this section will introduce, as a documentation of an interesting by-product of the principles of fabrication and operation of the myocardial device. This by-product, or "MOD-VESOCCLUDER" is a special device which may be applied where either a constant or periodically modulated occlusion of an artery or a vein in an intact conscious or anesthetized animal is desired.

Figures 36 and 37 show photographs of a functional model of the prosthetic myocardial device. It consists of a thin elastic inner liner of moulded Dermoid* and Guardex** composition and a thicker non-elastic, yet

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*Latex Foam, manufactured by Williams Gold Refining Co., Inc., 2978 Main Street, Buffalo 14, New York.

**Latex Compound, manufactured by The Hygienic Dental Manufacturing Co., Akron 10, Ohio.

Figure 36. Functional model of myocardial prosthetic device, right view

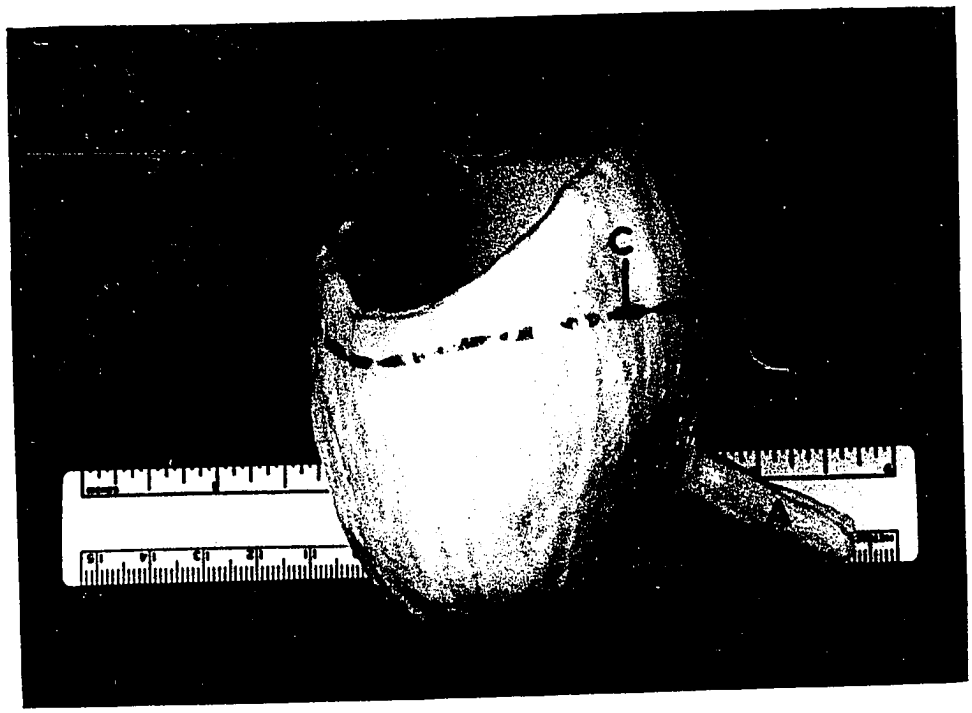
A - stem

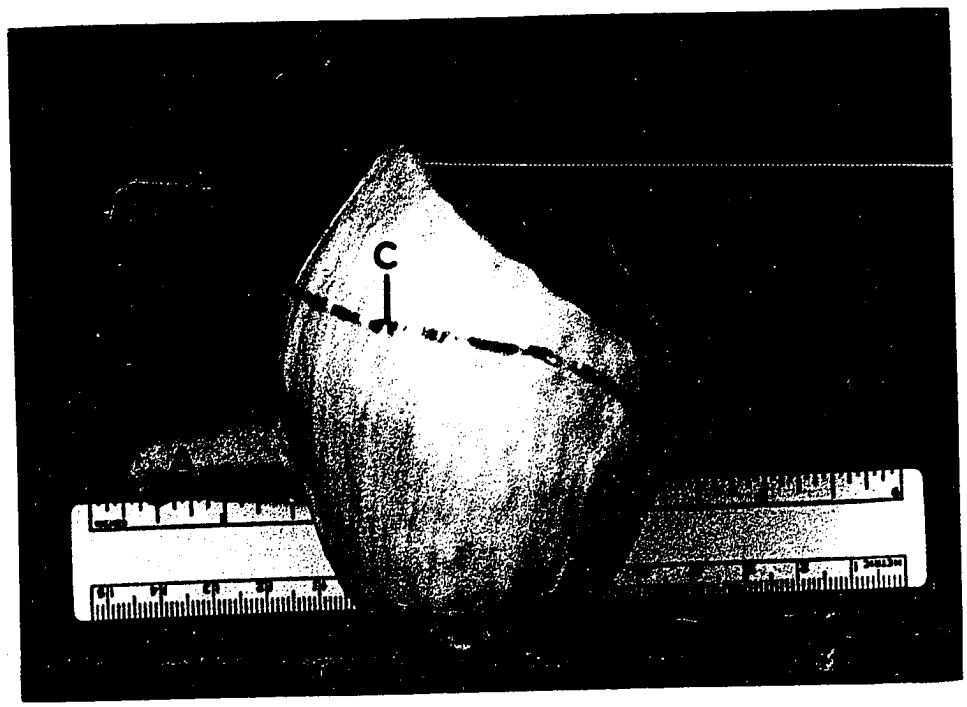
C - contour of separation between bonded and unbonded sections of inner liner and outer shell, corresponds to coronary sulcus on heart

Figure 37. Functional model of myocardial prosthetic device, left view

A - stem

C - contour of separation between bonded and unbonded sections of inner liner and outer shell, corresponds to coronary sulcus on heart


C


C

moderately flexible outer shell of the same composition. Stem A which serves as an inlet for air pressure, is moulded as an integral part of the outer shell. The inner liner and outer shell are bonded together in the fabrication process in the area which corresponds to the surface of the atria. At the surfaces covering the ventricles there is no connection between the inner liner and outer shell, except at the ventricular apex as noted later. Contour C shows the line of separation between the bonded and separable sections of the two parts of the device. This contour corresponds to the coronary sulcus along the boundary of the atria and ventricles. Because the two sections are not separable above the contour no direct pressure is exerted over the atria during the operation of the prosthetic device.

The position and location of the stem is designed for chronic losed-chest use to fit an adaptor plate attached to the sternum shown in Figure 29. For experimental short-term, open-chest operation, the stem may be directly projected through a hole in the sternum made with a trephine drill through the center of the fourth sternebrae.

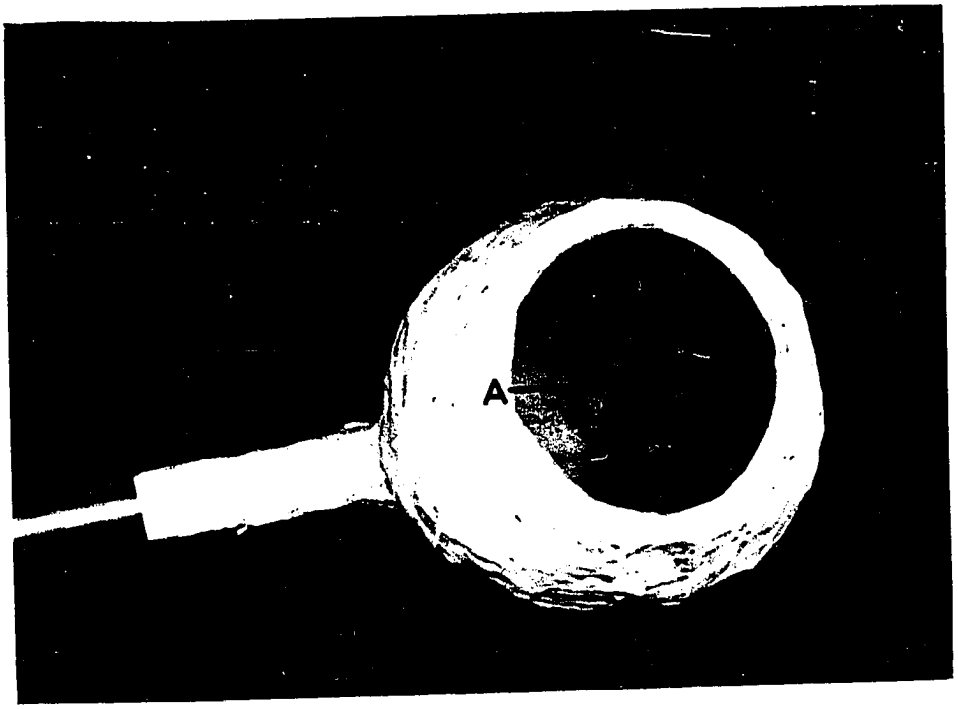
By pumping controlled periodic pulses of air and vacuum into the stem, a periodic force is created between the thin flexible inner liner and thicker outer shell over the surfaces where no bond exists. The inner liner, shown separated from the outer shell in Figure 39 by a pulse of air, consequently compresses and relaxes as a function of the air pressure and vacuum pulses. Figure 38 shows the inner liner deflated after the air is removed. The inner liner inflating and deflating with respect to the outer shell causes periodic contractions of the left and right ventricles. No

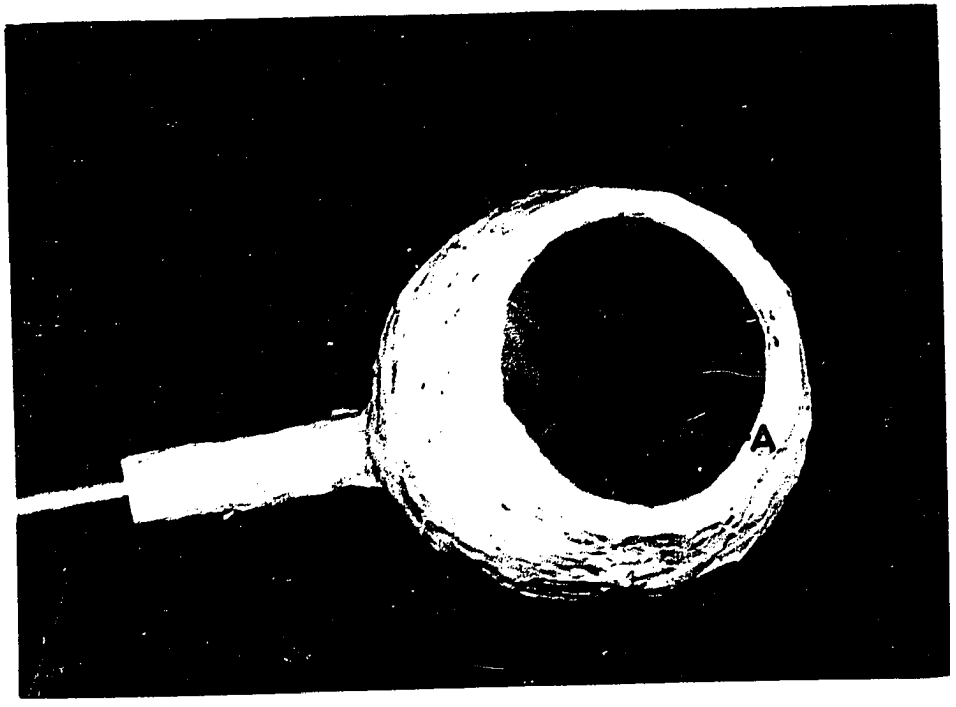
Figure 38. Internal view of myocardial prosthetic device, inner liner deflated

A - inner liner shown DEFLATED

Figure 39. Internal view of myocardial prosthetic device, inner liner inflated with pulse of air pressure

A - inner liner shown INFLATED


A


A

direct pressure is developed on the atria, due to the bond that exists between the inner liner and outer shell in this area.

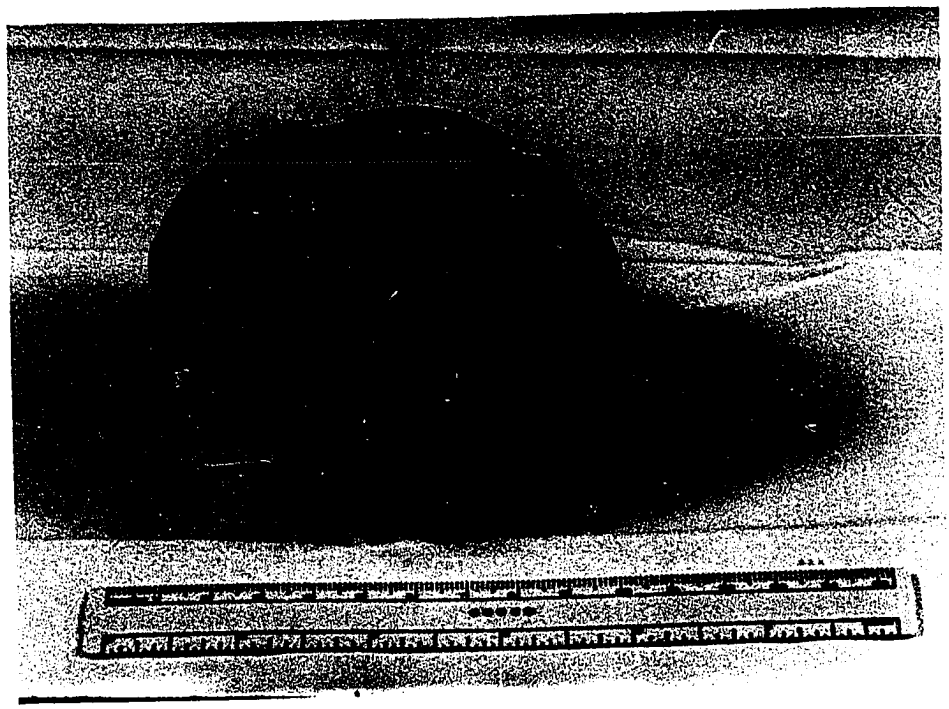
Special attention was given to the functioning of the inner liner in the vicinity of the apex of the heart. Over a small elliptical area surrounding the apex the inner liner is intentionally bonded to the outer shell, so that separation of the inner and outer shell are prevented in the neighborhood of the apex, thus minimizing the upward force components on the lower portions of the diaphragmatic and sternocostal surfaces of the heart and further reducing the tendency for the device to slip out from the heart.

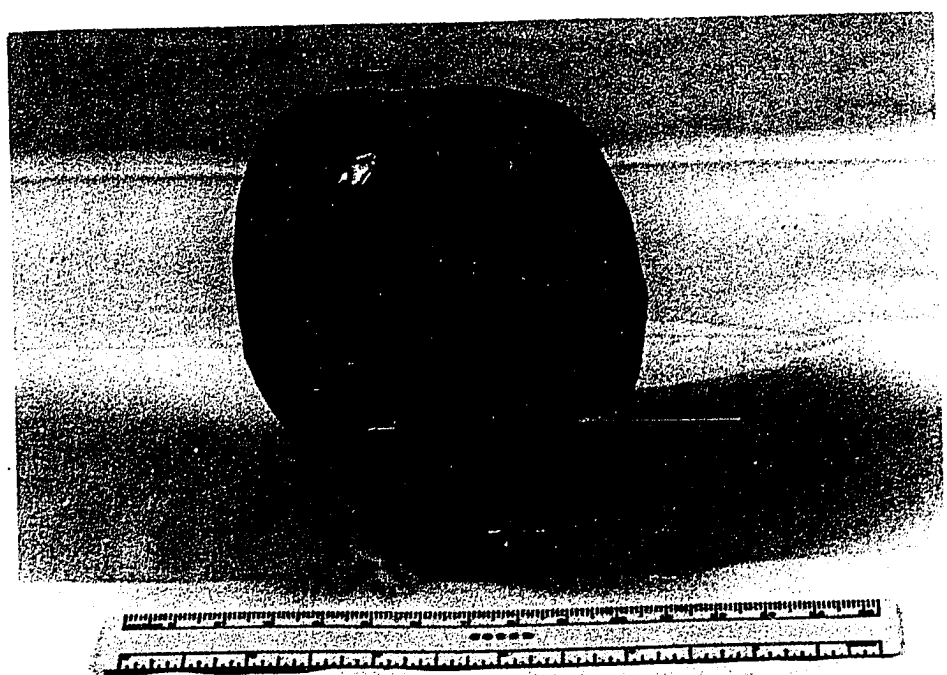
The muscle fibers of the myocardium are arranged spirally. Upon ventricular contraction the blood is wrung out of the cavity. As a result, the heart rotates slightly to the right, pressing the apex more firmly against the chest wall. The flexible nature of the stem where it meets the body of the prosthesis permits slight turning of the encapsulated heart during artificially induced ventricular contraction.

The first step in fabricating the device consists in developing a negative wax model, shown in Figures 40 and 41, of the heart. The model was made by first studying the shape and size of the heart of several embalmed dogs each weighing approximately 10 kilograms. From the results of the study a positive plaster model of the heart was sculptured. By successively dipping the plaster model into a bath of molten wax, the first wax model was evolved. The wax model was removed from the plaster cast. It then was shaped and tailored by hand with sculpturing tools and a flame to conform to the shape and size of the heart of anesthetized dogs weighing approximately

Figure 40. Negative wax model of heart, top view looking inside

Figure 41. Negative wax model of heart, front view; corresponds to sternocostal surface of heart





10 kilograms. Fittings on three anesthetized dogs were required before a tailored model was evolved. Figure 24 in Section II shows the tailored wax model in place over the beating heart of a anesthetized dog in the final experimental fitting.

Using the negative model as a form, two plaster positive heart models were cast with plaster of paris. The dimensions of one of the casts were uniformly reduced one-thirtysecond inches with sandpaper. The smaller plaster model serves as a mannequin on which the inner liner of the prosthesis is developed, the larger for the outer shell. Figures 42, 43, 44, and 45 show four views of the smaller mannequin. In these photographs the contour establishing the periphery of not only the inner liner but the completed prosthesis is seen near the base and sectionally designated by O, X, Y, and Z. These sections correspond to the contours around the heart that serve as a limit beyond which a foreign object around the heart may occlude some of the vessels entering and leaving the heart. These contours were established from the anatomical explorations and here they correspond to those similarly designated in Figures 13 and 15 in Section II.

The contour is marked on the mannequin with an indelible pencil. As a result, the moisture in the material used in forming the inner liner reacts with the penciled line and causes an impression of the line to be formed on the inner surface of the liner. Thus, when the completed device is removed from the mannequin after fabrication, the periphery of the device is outlined and a guide line for trimming is provided.

Figures 46 and 47 show two views of the larger casts. The polystyrene rod serves as a form for the fabrication of the stem. The copper wires C

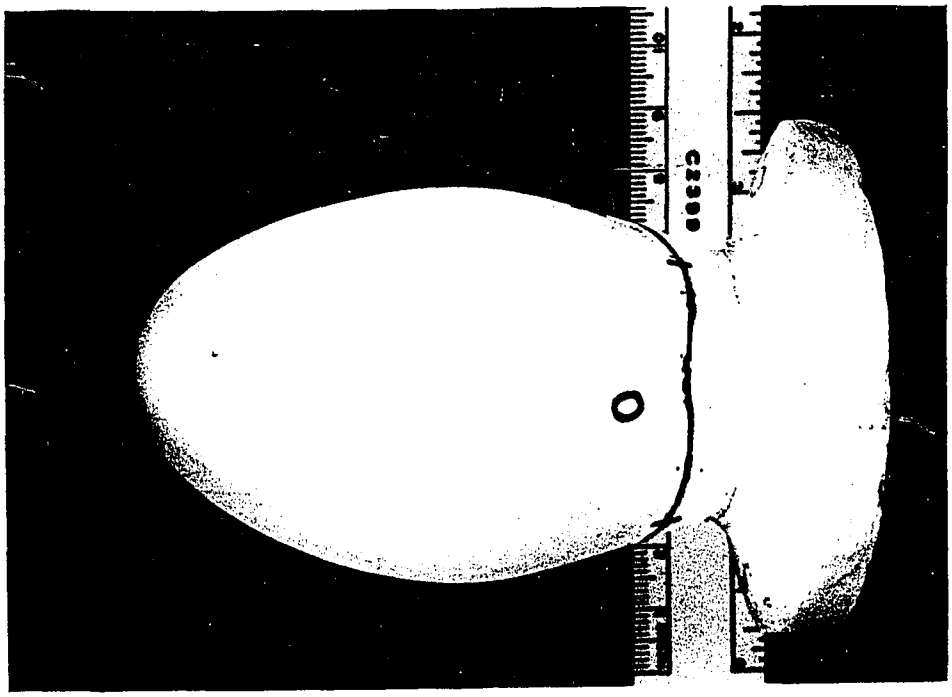
Figure 42. Right side view of mannequin for inner liner

X - section of contour that corresponds to periphery of prosthesis along right pulmonary junction at right border of heart

Y - section of contour that corresponds to periphery of prosthesis along posterior vena cava at lower border of heart

Figure 43. Ventral view of mannequin for inner liner

0 - section of contour that corresponds to periphery of prosthesis along upper border of heart


O

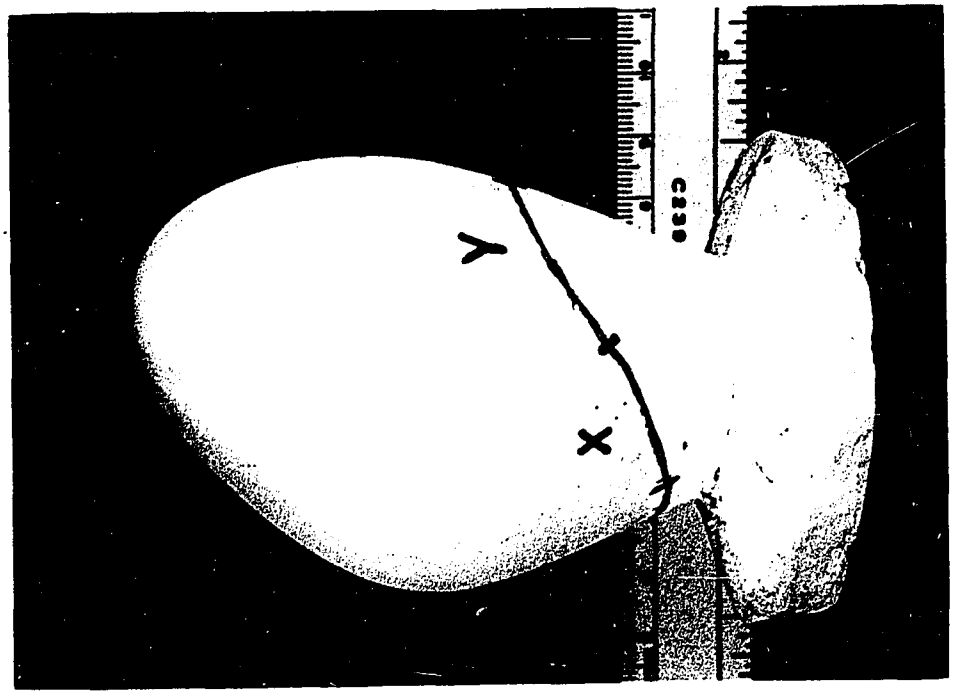
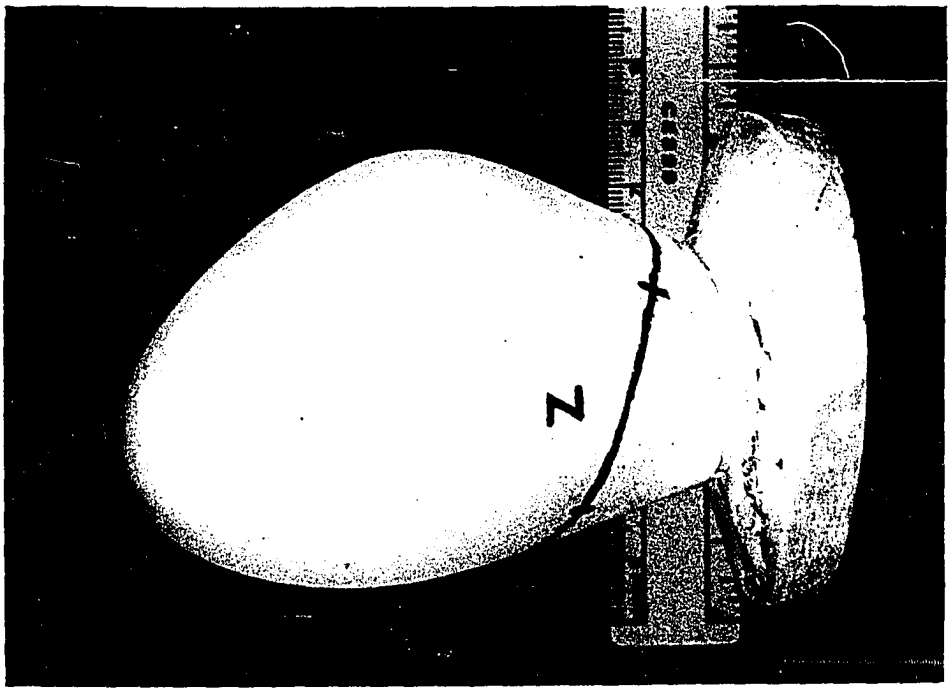

Y
X

Figure 44. Dorsal view of mannequin for for inner liner

Y - section of contour that corresponds to periphery of prosthesis along posterior vena cava at lower border of heart

Figure 45. Left side view of mannequin for inner liner

Z - section of contour that corresponds to periphery of prosthesis along left pulmonary junction at left border of heart


Z

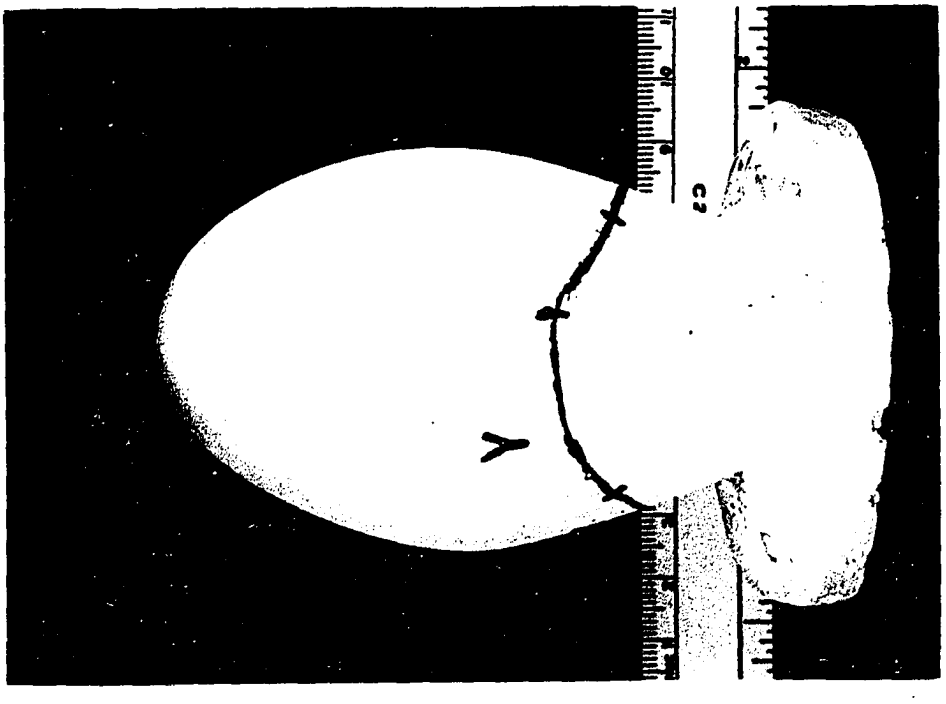

Y

Figure 46. Dorsal view of mannequin for outer shell

C - copper wires which serve as a form for air-passage grooves on inside of shell

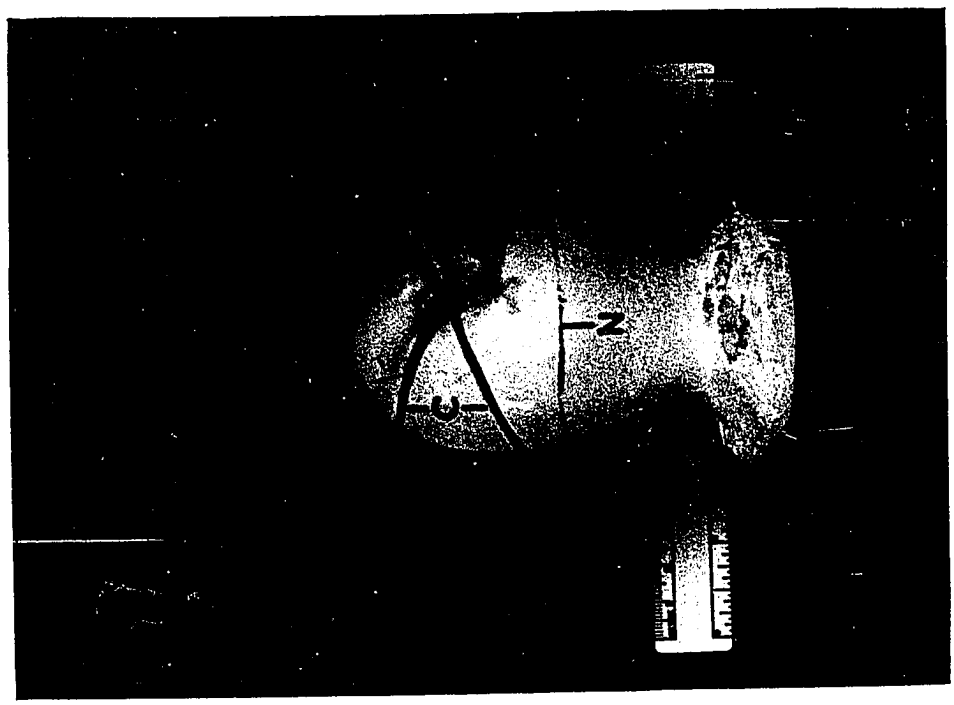
N - contour corresponds to periphery of first stage of outer shell

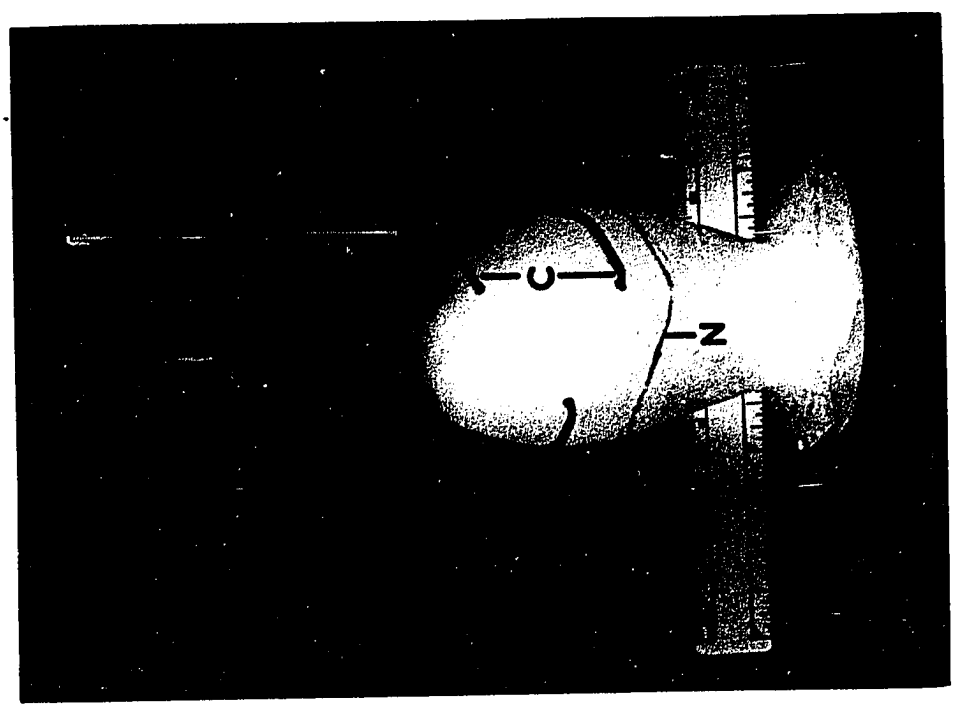
Figure 47. Ventral view of mannequin for outer shell

A - polystyrene rod for forming stem as integral part of outer shell

C - copper wires which serve as a form for air-passage grooves on inside of shell

N - contour corresponds to periphery of first stage of outer shell


C
Z

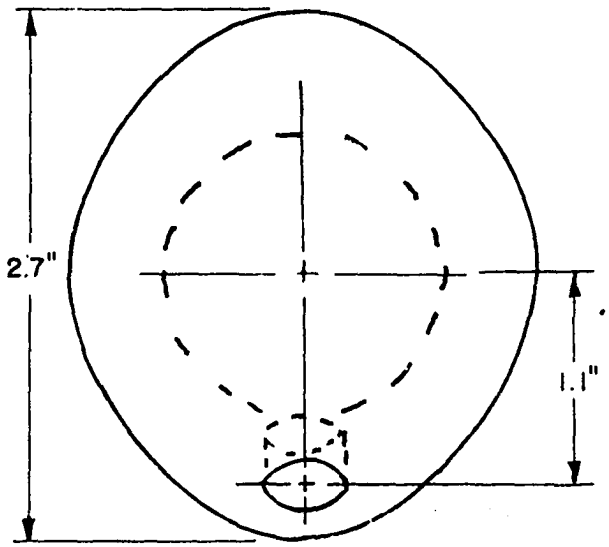

C
Z

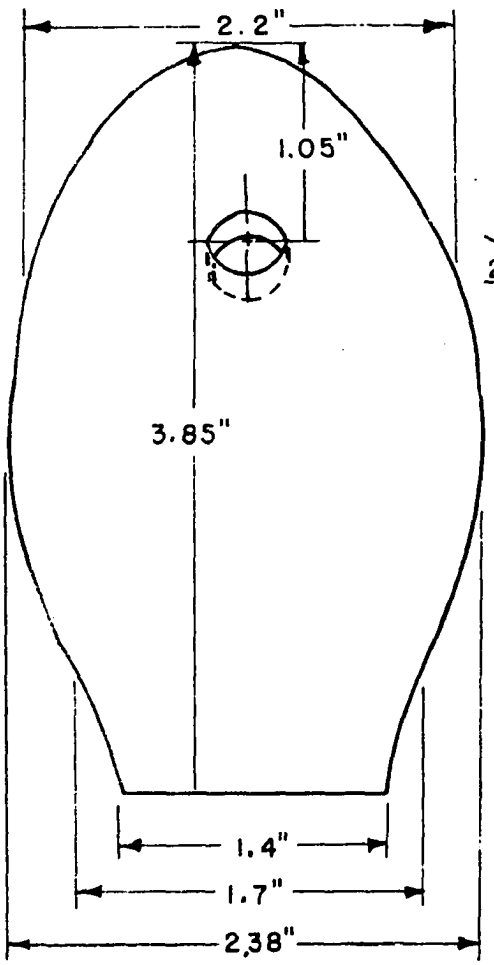
provide for a series of grooves, to be described later, on the inside surface of the outer shell. Contour N is also outlined with an indelible pencil and it corresponds to the edge of that part of the outer shell which is separable from the inner liner. This contour is the same which is shown as C in Figures 36 and 37, and as previously indicated outlines the right and left ventricles of the heart where they meet the atria along the coronary sulcus.

A hole three-sixteenth inches in diameter and one-half inch deep is drilled on the ventral surface of the mannequin at the location and angle shown in the mechanical drawing for the outer cast in Figure 48. The function of the hole is to support the three-sixteenth inch diameter polystyrene rod, three inches long which serves as a form for the moulding of the stem as an integral part of the outer shell. In order to provide channels on the inside of the outer shell for air-passage ways to permit complete escape of air from the volume between the inner liner and outer shell during the vacuum periods, sections of number fourteen American Wire Guage (AWG) wire are fitted around the cast as is seen in Figures 46 and 47. The pieces of wire are held in place by a hole drilled with a number 42 drill at the location for one end of the wire, a shallow groove formed with a knife along the path for the wire, and a depression cut with a knife in the side of the opening for the polystyrene stem for the placement of the other end of the piece. The development of the outer shell is started on this mannequin. The contour N is registered on the inside by the indelible ink and provides a guide for trimming.

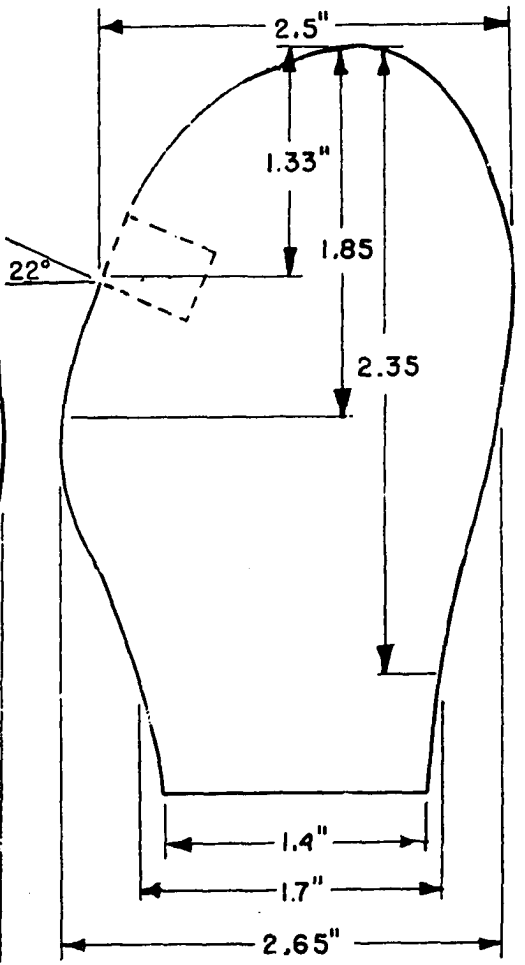
Figure 48. Full scale mechanical drawing for outer cast, fully dimensioned; location of hole for polystyrene rod given

TOP VIEW





FRONT VIEW



SIDE VIEW

The problem of toxicity of the Dermoid and Guardex materials out of which the prosthesis was formed was considered but not undertaken in this investigation. However, the manufacturers* of Dermoid claim that by placing the cured material in a bath of hot water at 160 degrees for one hour, the material becomes non-toxic. The manufacturers of Guardex reported that the toxicity of Guardex has not been investigated, although it is commonly used in the fabrication of mouthpieces worn by athletes for teeth protection. Silastic Silicone (46), a proven non-toxic material used extensively in other internal implantable devices may be adapted, at least as a coating, for use in fabricating a myocardial prosthesis.

Using Dermoid and Guardex, the following procedure was developed to form the inner liner for the prosthesis on the smaller mannequin:

1) With a small brush paint a thin layer of Dermoid on the mannequin covering beyond the limit contour, O, X, Y, Z.
2) Allow to vulcanize for at least 15 minutes at room temperature.
3) Paint on a second thin layer of Dermoid.
4) Allow to vulcanize for at least 15 minutes.
5) Spread with a spatula or brush a thin layer of Guardex
6) To facilitate vulcanization, place the unit in an oven** at 150 degrees Fahrenheit for at least an hour.
7) Apply a final thin coat of Dermoid and allow to vulcanize.

---

*Slayton, W. S. William Gold Refining Co., 2978 Main Street, Buffalo 14, New York. Information concerning toxicity of Dermoid. Private Communication. 1962.

**A simple oven may be constructed from 1/4" thick wood, 14" L x 10" W x 9" D, lined with heavy duty tin foil, with a socket for a 50-watt electric lamp mounted on the inside surface of the cover hinged to the structure.

Figure 49 shows the completed inner liner on the smaller plaster cast and Figure 50 shows the actual liner removed from the cast and trimmed along the contour. The thickness of this liner is in the order of one thirtysecond inches.

The outer shell is fabricated in a similar manner to the inner liner. Use is made of the larger plaster cast with the dowel and copper wires in place. The following procedure was developed in forming the outer shell:

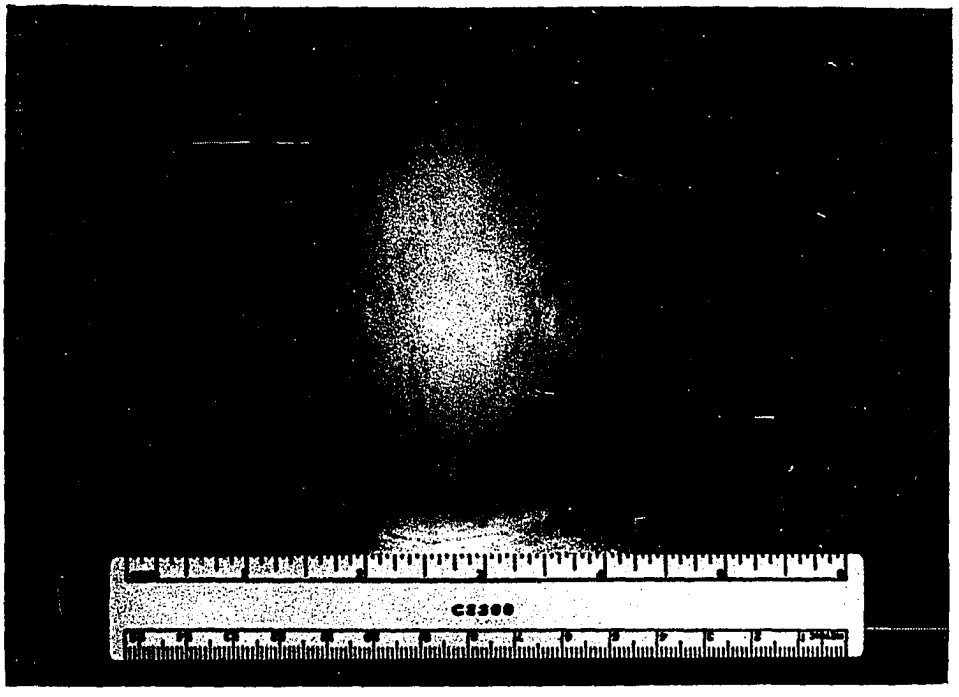
1) Paint on a thin layer of Dermoid covering the dowel and beyond the contour N.
2) Allow to vulcanize for at least 15 minutes at room temperature.
3) Paint on a second coat of Dermoid and allow to vulcanize.
4) With a spatula spread on a thin layer of Guardex with flock*. The flock thickens the consistency of the Guardex and also provides for the inelastic yet moderately flexible characteristic of the outer shell.
5) Vulcanize in an oven for approximately two hours at 150 degrees Fahrenheit.
6) Apply a slightly heavier layer of Guardex with flock.
7) Vulcanize at 150 degrees Fahrenheit for approximately two and one-half hours.
8) Apply a medium layer of Guardex without flock.
9) Vulcanize at 150 degrees Fahrenheit for approximately two hours.
10) Apply a medium layer of Guardex without flock.
11) Vulcanize for one hour at 150 degrees Fahrenheit.

---

*Flock is pulverized pieces of nylon which is furnished separately with Guardex by the manufacturer of Guardex. Three cubic centimeters of flock is mixed with 20 cubic centimeters of Guardex.

Figure 49. Completed inner liner on mannequin

Figure 50. Inner liner removed from mannequin and trimmed



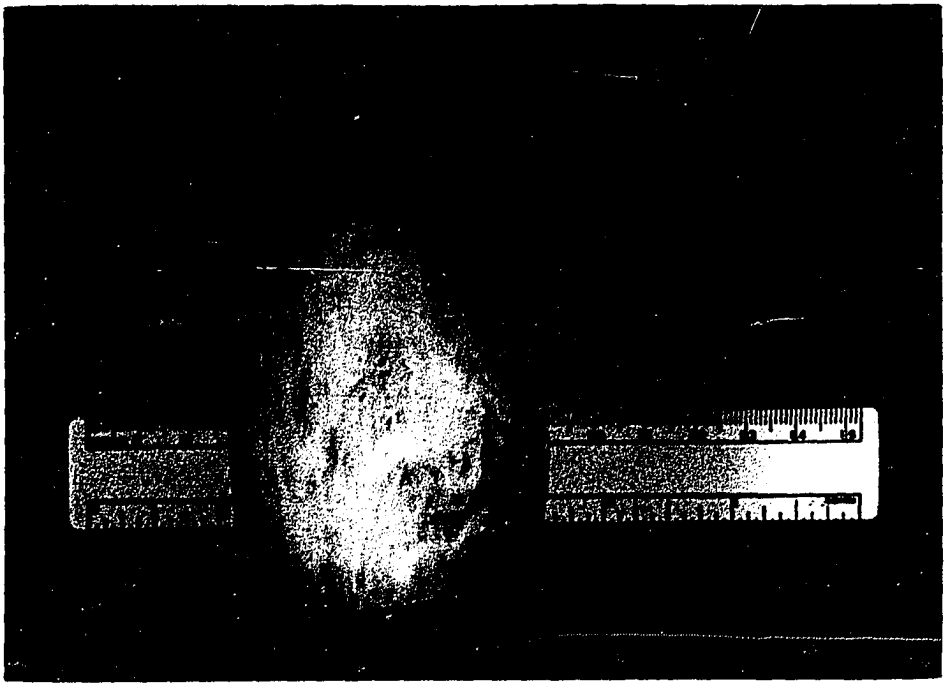


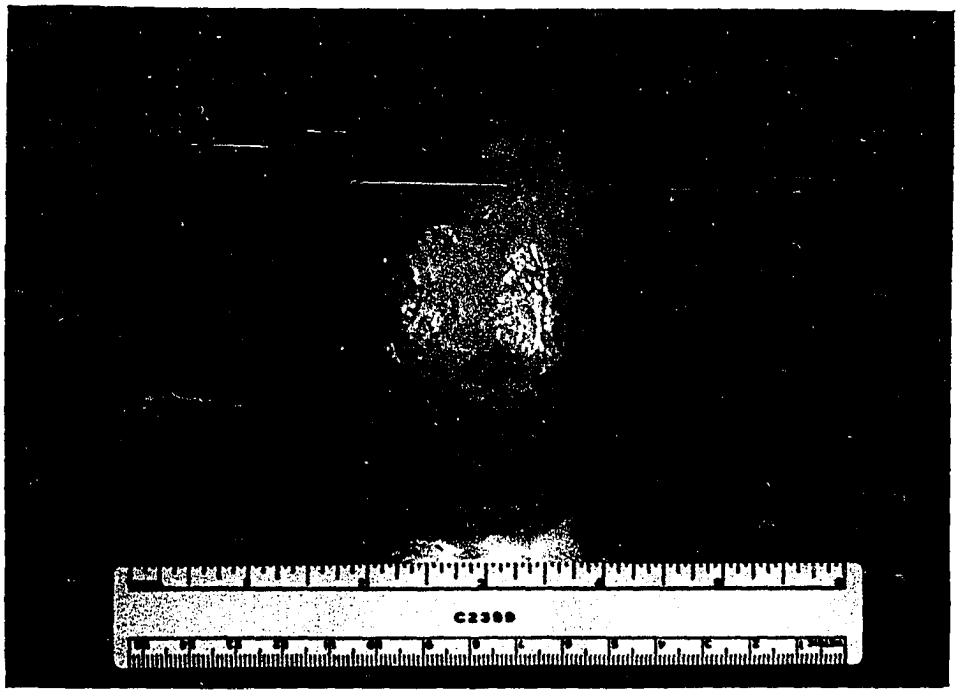
Figure 51 shows the formation of the outer shell at this stage on the plaster cast. The partially completed shell is now removed from the mannequin and is trimmed around the line printed on the inside by the indelible ink of the contour N on the cast. Two views of the trimmed shell are shown in Figures 52 and 53. Figures 55 and 56 where the shell is turned inside-out show the grooves on the inside of the shell that will provide for air-passage during the vacuum period.

An elliptical hole three quarter inches along its major axis and three-eights inches along its minor axis with the apex as its center is cut at the bottom of the outer shell. This hole is shown in Figure 54. The shell is now placed over the inner liner which is still in place on the smaller cast. The resulting configuration is shown in a full-scale photograph in Figure 57. The inner liner is ordinarily not at all removed from its mannequin during the fabrication process. In this case it was done to take a photograph of the trimmed inner liner. The following process completes the fabricating procedure for the device:

1) Apply a thin coat of Dermoid over the entire assembly.
2) Allow to vulcanize for at least 15 minutes at room temperature.
3) Apply a second thin coat of Dermoid over the entire assembly and allow 15 minutes to vulcanize.
4) With a spatula apply a thin layer of Guardex without flock to the section of the inner liner which extends beyond the outer shell and the hole at the apex.
5) Vulcanize in an oven at 150 degrees Fahrenheit for at least one hour.

Figure 51. First stage of outer shell formed on mannequin

Figure 52. Outer shell, first stage completed with trimmed periphery to correspond to contour N in Figures 46 and 47



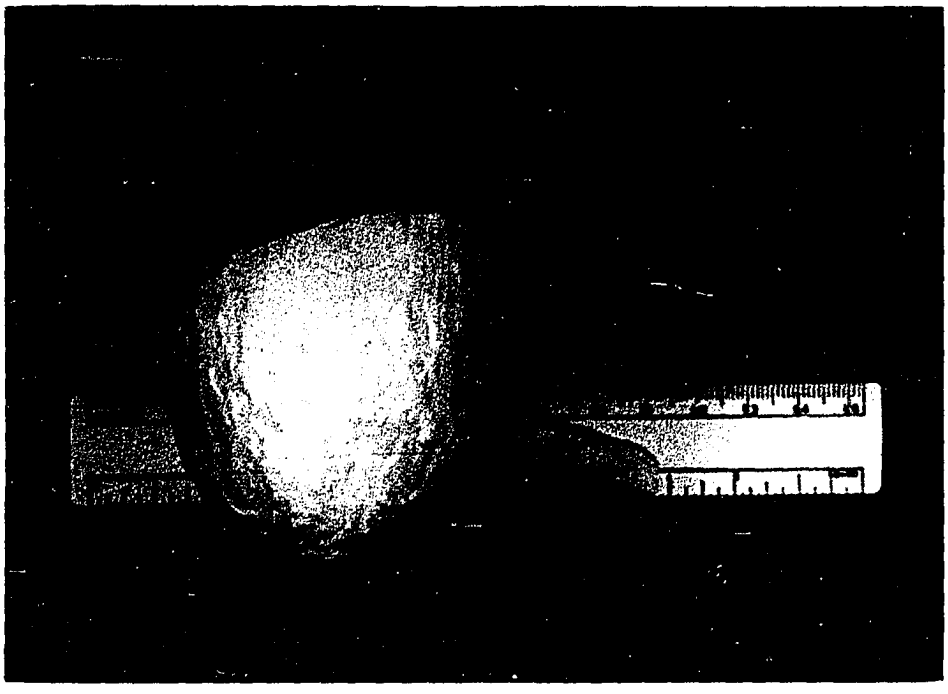
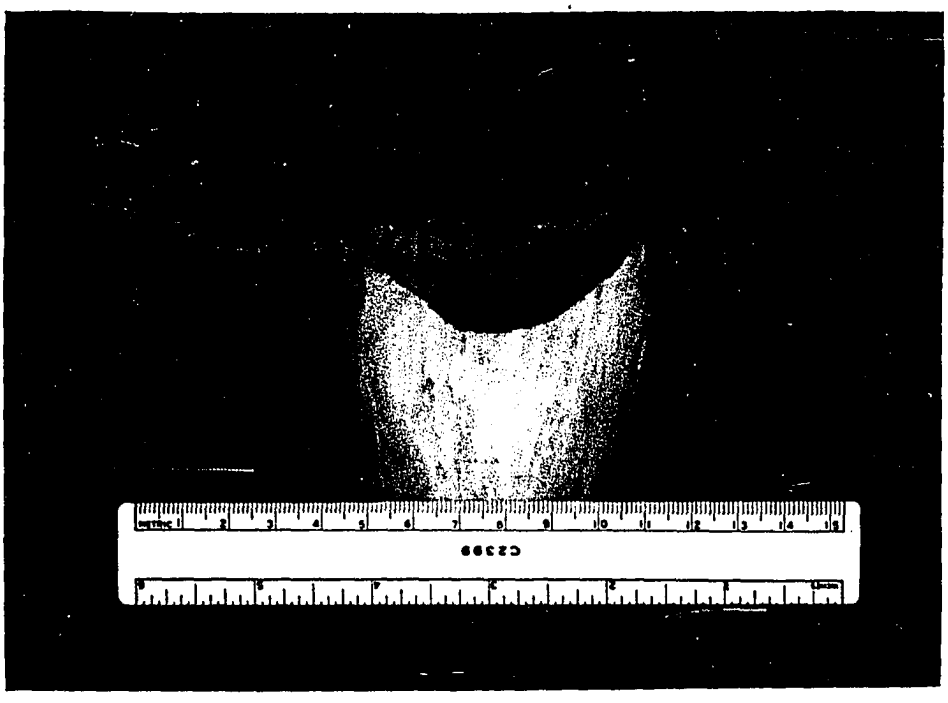


Figure 53. Dorsal view of completed first stage of outer shell, trimmed to correspond to contour N in Figures 46 and 47

Figure 54. View of first stage of outer shell showing elliptical cutaway at apex



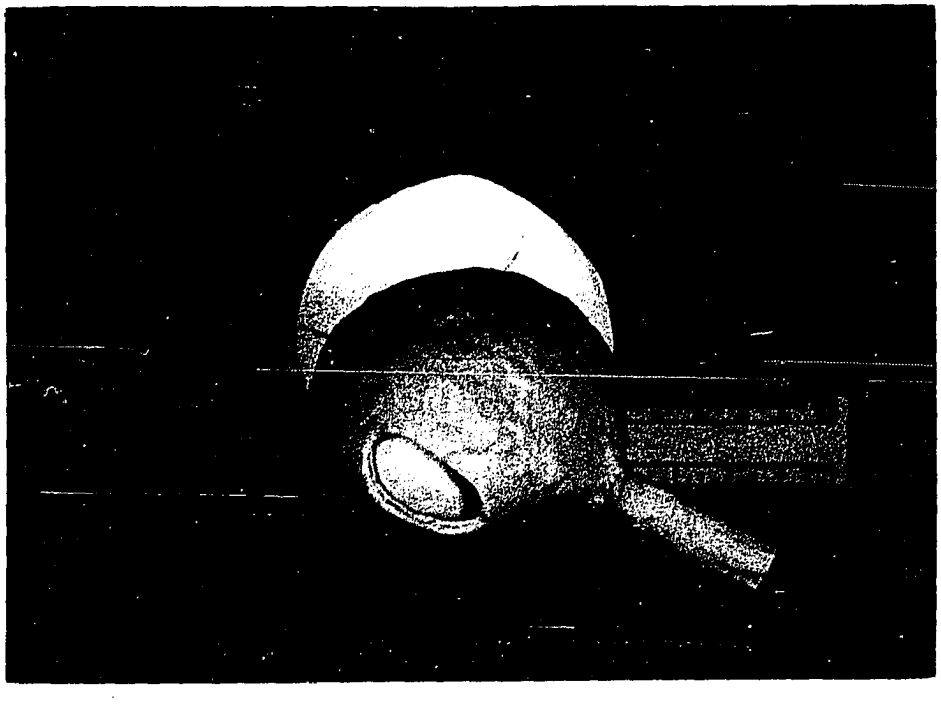
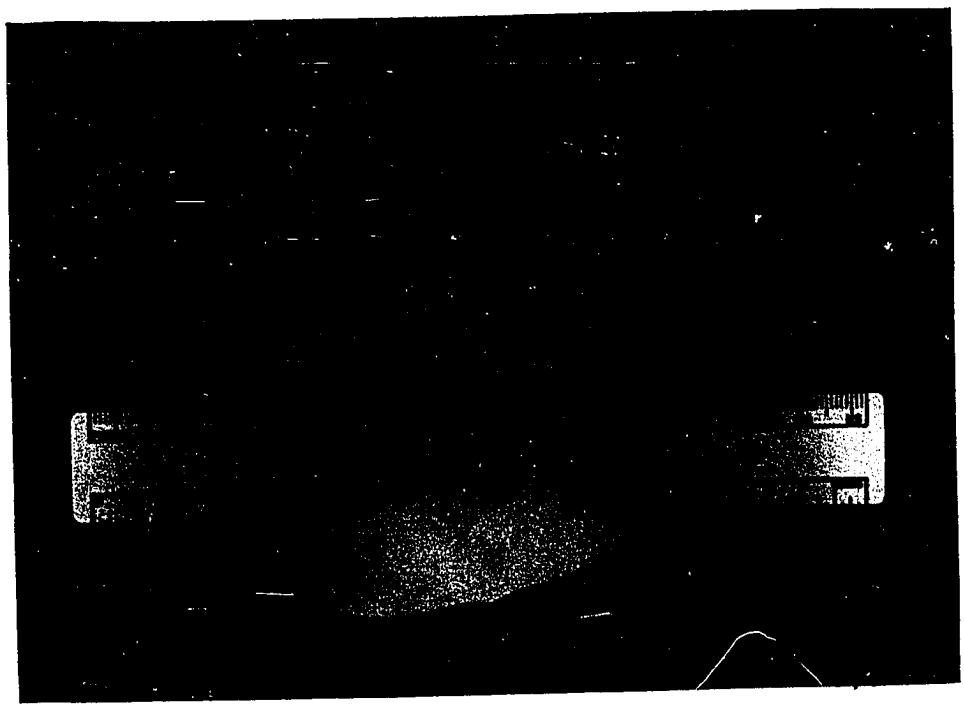


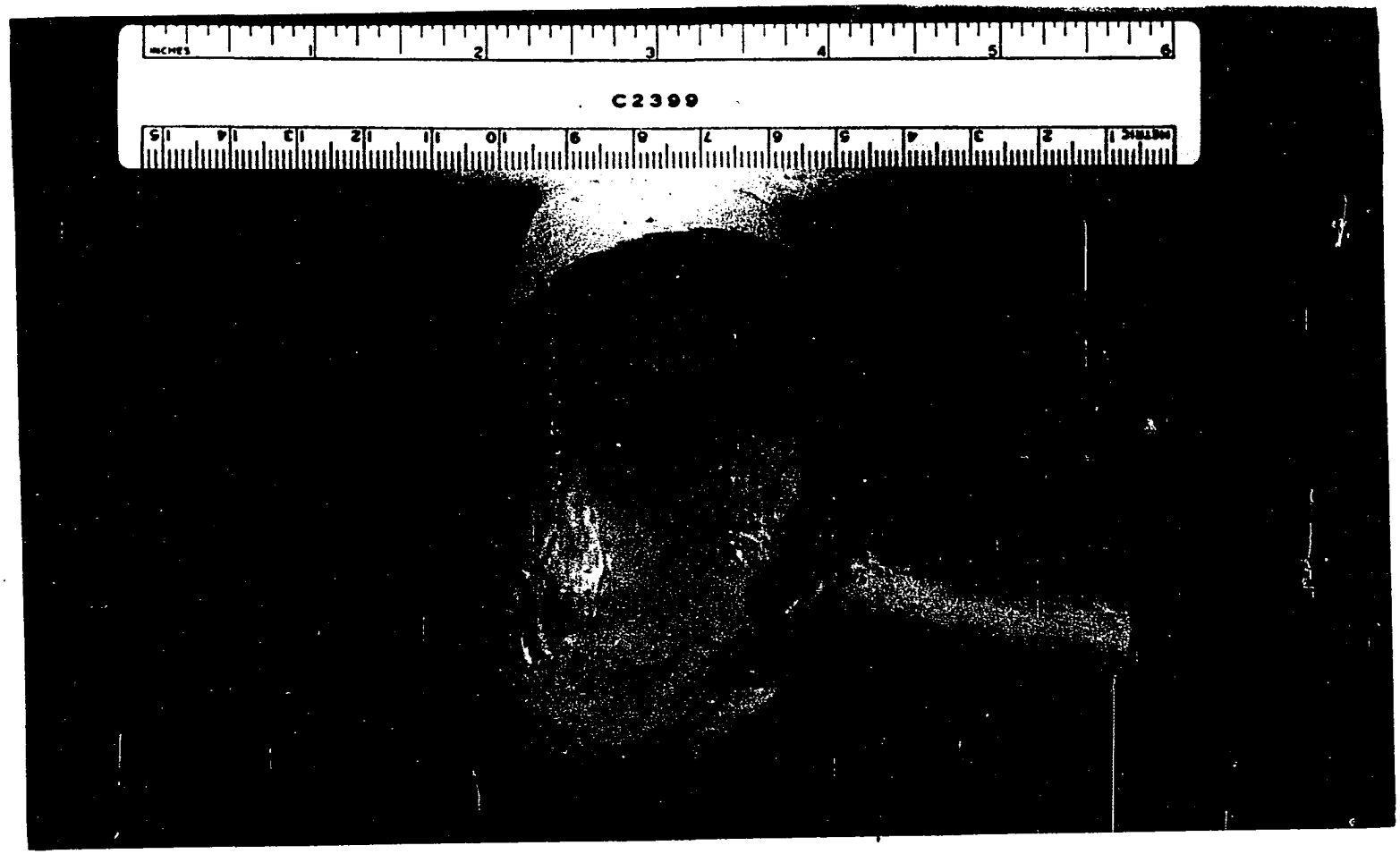
Figure 55. Inside-out view of outer shell, first stage, ventral view

C - grooves for providing air-passage pathways

Figure 56. Inside-out view of outer shell, first stage, dorsal view

C - grooves for providing air-passage pathways




C2399

6) To the same sections as in step 4, apply a medium layer of Guardex with flock.

7) Vulcanize in an oven at 150 degrees for at least one and one-half hours.

8) To the same sections as in step 4 and step 6, apply a thick layer of Guardex with flock. Do not extend this layer beyond the boundary.

9) Vulcanize in an oven at 150 degrees Fahrenheit for at least two hours.

10) Apply a final layer of Guardex with flock to the same sections as in steps 4, 6, and 8, sufficiently thick to make the thickness of the assembly uniform with the outer shell.

11) Vulcanize in an oven at 150 degrees Fahrenheit.

12) Cover the entire assembly including stem with a layer of Dermoid and allow to vulcanize at room temperature.

13) Apply a second layer of Dermoid and allow to vulcanize.

14) Apply a medium layer of Guardex with flock.

15) Vulcanize in an oven at 150 degrees Fahrenheit for at least two hours.

16) Apply a thick layer of Guardex with flock and vulcanize in an oven at 150 degrees Fahrenheit.

17) Apply a layer of Guardex being careful to make the cover smooth and even, and vulcanize in an oven at 150 degrees Fahrenheit.

18) Apply two successive layers of Dermoid and allow to vulcanize between layers.

Remove the assembly from the cast. Trim with a pair of scissors along the line imprinted by the indelible ink. The prosthetic myocardial device as shown in Figures 36 and 37 is now finished.

A. MODVESOCCLUDER

Utilizing the same principles of operation and fabrication for the myocardial prosthesis, a device may be developed which permits either the constant or periodic occlusion of a vein or artery in a live intact or anesthetized dog. The device consists of an elastic inner liner and flexible outer shell to which a stem is attached as an integral part. The completed device is shown in Figures 60 and 61. The body of the device is slipped over the vessel to be occluded after surgical exposure. The stem is brought through a small incision. After suturing the incision, a section of the stem remains external to the body. Pulses of air pressure and suction delivered to the stem will correspondingly expand and contract the inner liner of the MODVESOCCLUDER, thus effecting modulated occlusion of the vessel.

Figures 58, 59, and 60 show the stages of fabrication of the device. In Figure 58 is shown the inner liner and the started outer shell with stem. The stem consists of a section of rubber tubing. A hole in the dowel for the outer shell supports the stem. The Dermoid and Guardex is applied in the same manner as is described in the fabrication procedure for the myocardial prosthesis. The thickness of the inner liner and outer shell, their diameters, and the size of the stem will be governed by the size of the vessel to be occluded. Figure 59 shows the trimmed outer shells in places on their inner liners. Figure 60 shows the completed devices with

the slit which facilitates placing the device over a vessel. The inner and outer liner are bonded together around the edges of the slit S and the ends C in Figure 60.

The MODVESOCCLUDER should prove useful in cardiovascular and pharmacological research, as well as in clinical applications where a method of occluding an arterial supply of blood to a pathological or surgically repaired area on an intermittent emergency basis is needed.

Figure 58. Outer shell on inner liner of MODVESOCCLUDER

A - number 1

B - number 2

Figure 59. Inner liners and outer shells of two MODVESOCCLUDERS of different sizes shown formed on dowels

A - start of outer shell for number 1

B - inner liner for number 1

C - start of outer shell for number 2

D - inner liner for number 2

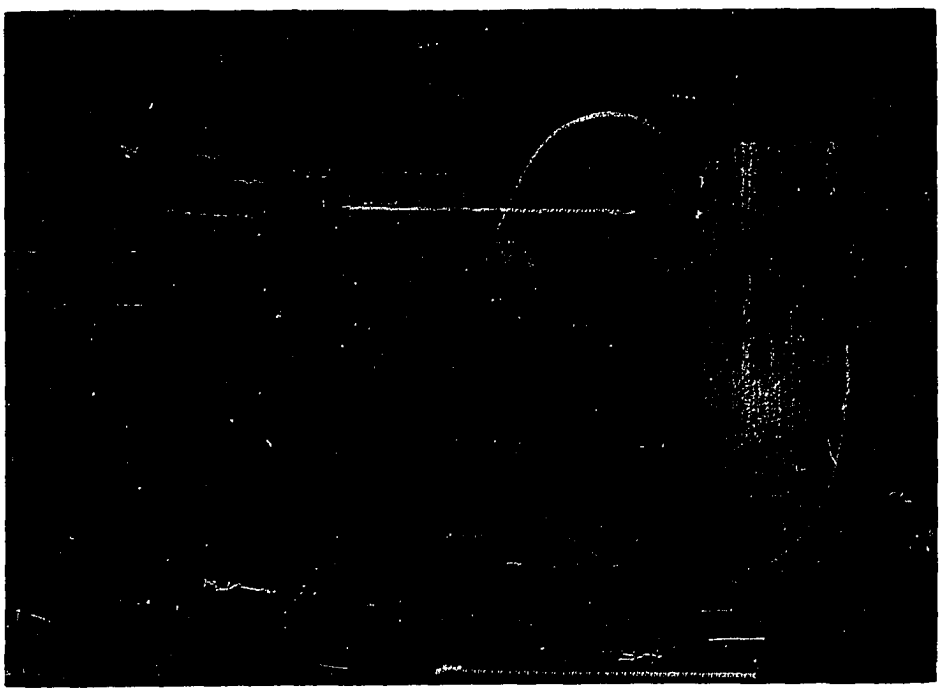


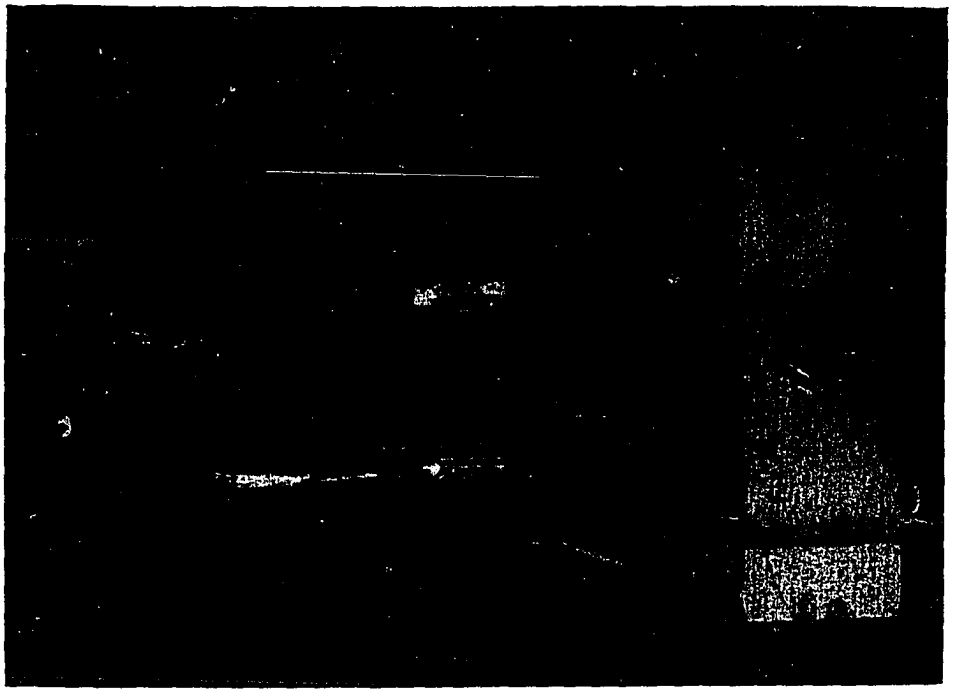
Figure 60. Completed MODVESOCCLUDERS

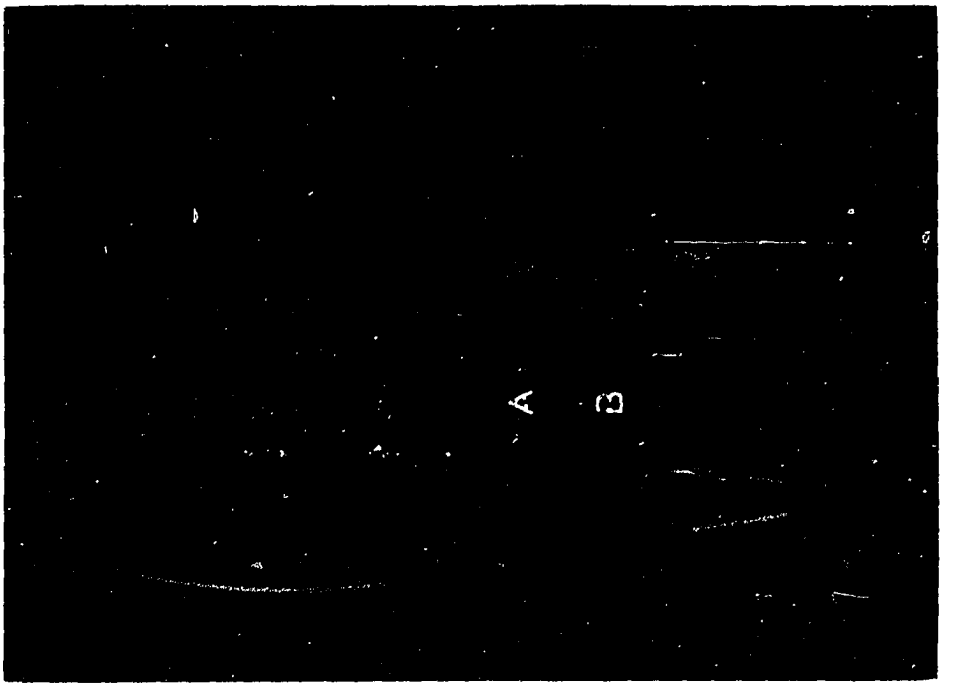
A - number 1

B - number 2

Figure 61. Trimmed completed MODVESOCCLUDERS on dowels

Bond exists along cut section and circular periphery at upper and lower edges. Pulses of air pressure and vacuum applied to the stem will inflate the inner liner and produce alternate occlusion and relaxation of a vessel around which the device is placed. Same principle of operation as myocardial prosthesis.




A B

V. THE SUPPORT SYSTEM

The prosthesis required an electronic-pneumatic support system for supplying to the device the necessary alternate pulses of air pressure and suction. This support system consists of a pneumatic pump with pressure and suction outlets, auxiliary external regulators or controls and gauges, a 3-way solenoid valve and an electronic transistorized controller. The support system with the prosthesis shown in block diagram form in Figure 62 and photographically in Figure 63 constitutes the myocardial prosthetic system which provides for the artificial contraction of the ventricles of the natural biological heart.

The timing of the 3-way solenoid valve is controlled by the electronic controller. Pulses of air pressure are programmed to the prosthesis during the period corresponding to systole or ventricular contraction. Suction pulses are programmed to the prosthesis during the period corresponding to diastole or ventricular filling in the cardiac cycle.

This system was basically designed to be adapted to a dog weighing 10 kilograms whose average maximum systolic pressure is 120 mm of Hg or 2.29 pounds per square inch. With a resting stroke volume of the order of one cubic inch, considering 100 beats per minute and the duration of ventricular contraction or systole as being 0.2 seconds, a pump having an airflow capacity of at least 300 cubic inches per minute at a pressure of the order of 5 pounds per square inch is required to supply the necessary pressure-energy to the device. On the vacuum side of the pump, sufficient suction is required to remove the air from between the inner liner and outer shell during that part of the cardiac cycle when the ventricles are relaxed

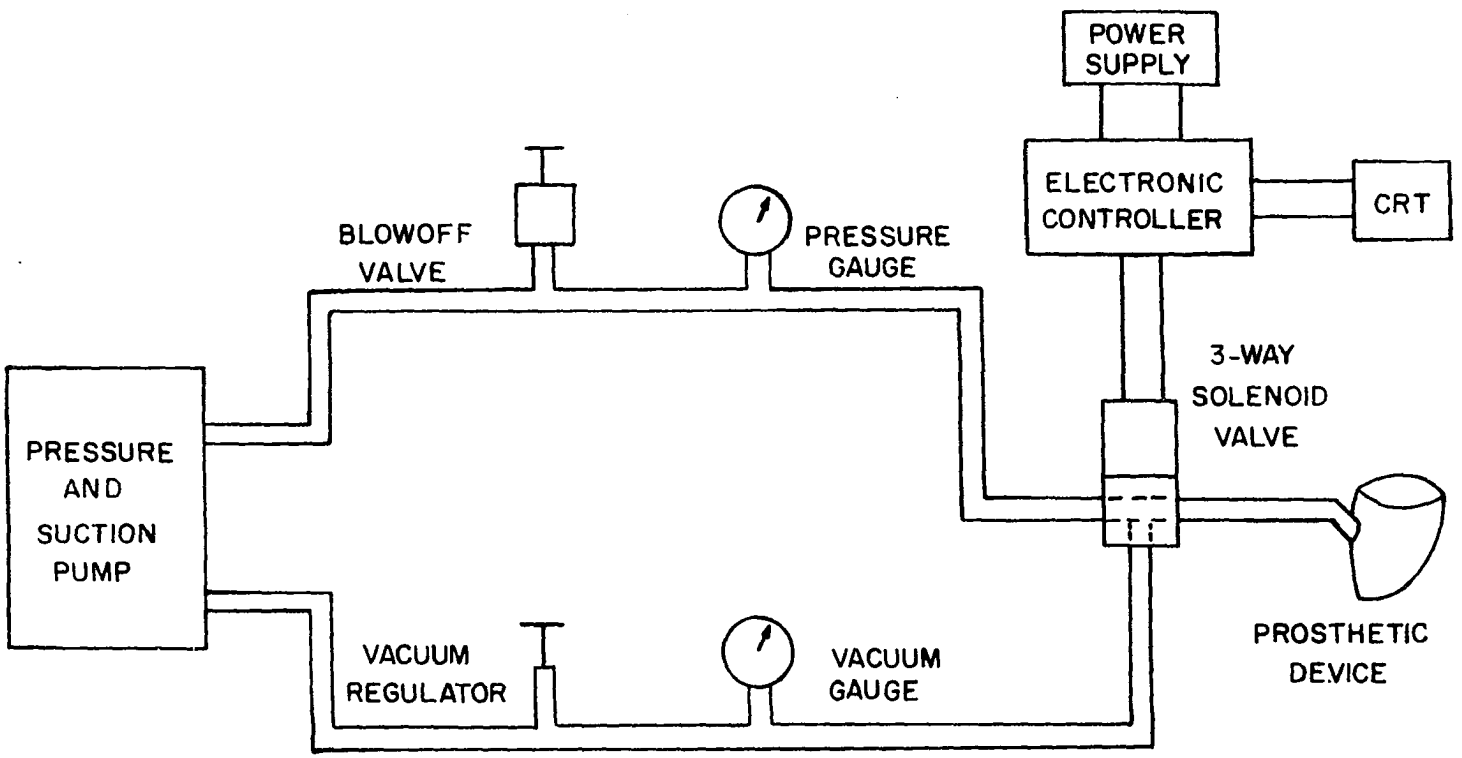


Figure 62. Block diagram of support system

Figure 63. The myocardial prosthetic system

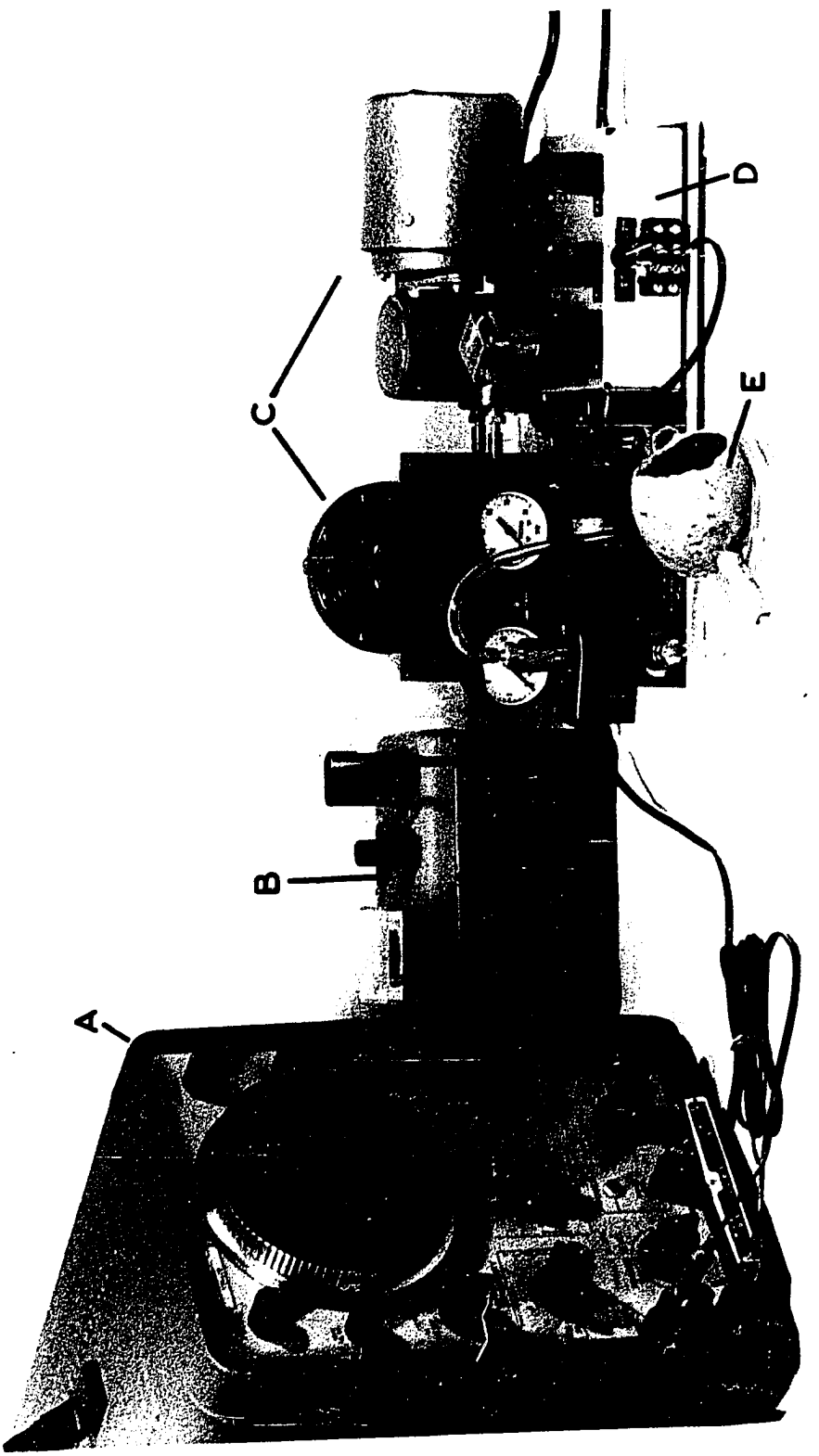
A - cathode ray oscilloscope, used as an aid in adjusting period and duty cycle of pneumatic pulses

B - commercial power supply, supplying 27 volts, 24 milliamperes to electronic controller

C - dyna-pump

D - electronic controller

E - prosthesis


A
B
C
D
E

and filling. A vacuum of three inches of mercury delivered to the stem of the device provided the necessary suction. A larger pump would be required to provide higher flow rates necessary for heavier dogs or for providing the necessary air-flow where considerably greater cardiac stroke volumes are required.

Figure 64 shows a photograph of the pneumatic equipment. All components of the pneumatics are identified by name plates. The Neptune Co. model 4-K Dyna-pump* with the following characteristics and specifications provided the pneumatic power for the system:

Dimensions - 8" x 3-5/8" x 4-3/4"

Power - A.C., 115 volts, 60 cps

Motor - 1/50 horsepower

Displacement Capacity - 600 cubic inches per minute

Maximum Pressure - 18 pounds per square inch

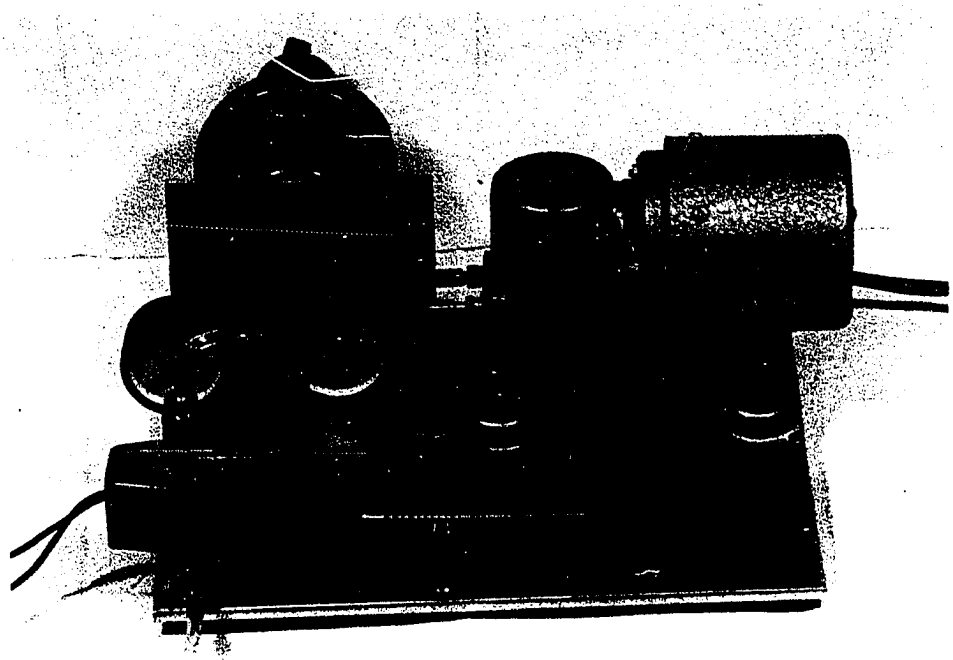
Maximum Suction - 18 inches of mercury

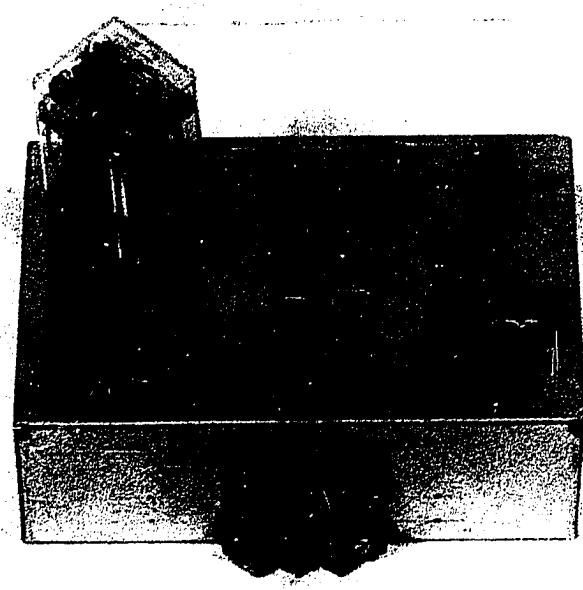
Regulation of the pressure and vacuum delivered to the prosthesis was provided by a variable pressure relief valve, Fisher Governor Co. model 289H and vacuum adjustor consisting of a simple needle valve. This arrangement permitted the simultaneous use of the pressure and vacuum outlets of the pump, for the pneumatic requirements of the system were smaller than the pump's capacity. The pressure (0-15 pounds per square inch) and

*A somewhat larger pump (General Electric Model SKH35KG-122E), having separately driven pressure and suction sections was later substituted in order to achieve better operation.

Figure 64. Pneumatic section of support system

Figure 65. Electronic controller



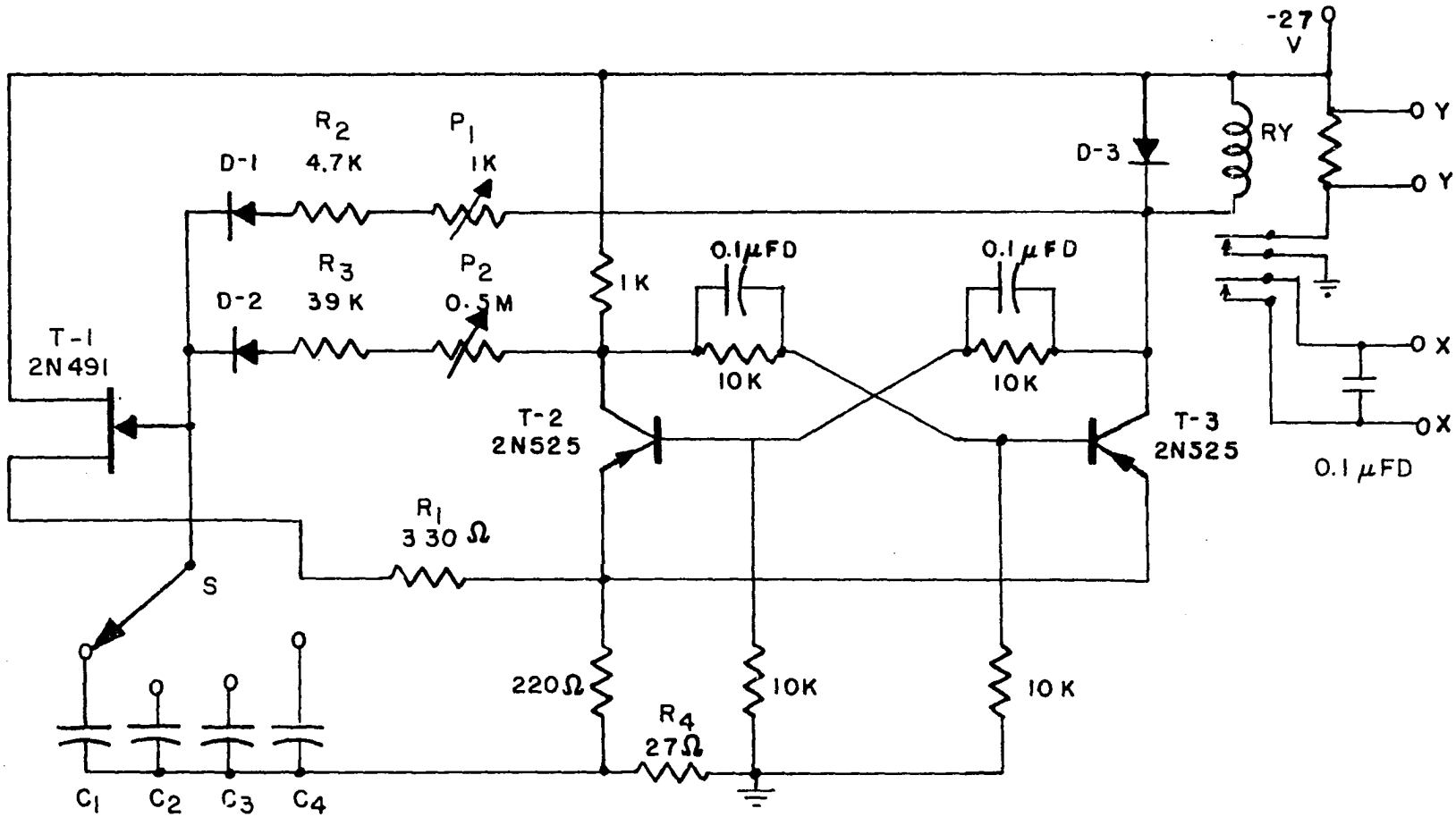


vacuum guages (0-30 inches of Hg) are Marshalltown Guage Co. type J500. The solenoid valve, (Automatic Switch Co., midget-size general purpose valve number 83148) is designed for 100 volt A.C. 60 cps continuous operation. With the coil of the valve energized, the passage for air pressure to the prosthesis is opened and when unenergized, the vacuum path is opened and suction is applied to the prosthesis.

Smaller and more sophisticated pumps, valves, guages, and solenoids to perform the necessary system functions may be utilized to effect a miniaturized package. The units used here were employed because of either their short-term or immediate availability.

Figure 65 shows a photograph of the electronic controller for the 3-way solenoid valve. The schematic diagram for the unit is shown in Figure 66. A 110 volt, A.C. source, is connected to the coil of the solenoid valve in series with the normally open relay contacts X-X. Energizing the relay closes the circuit and causes the pressure path in the solenoid valve to open, allowing a pulse of air-pressure to pass from the pressure regulator to the prosthetic device, thus compressing the inner liner. With the relay unenergized the pressure circuit is closed, and the vacuum circuit to the prosthesis is opened, thus the air from the space between the inner liner and outer shell is removed by suction. The periodic action of the relay simulates the basic durations of systole and diastole in the cardiac cycle.

The relay RY is connected in the output collector circuit of a transistor hybrid unsymmetrical multivibrator (16, 31). In Figure 66, T-2 and T-3 (PNP transistors) are in a circuit designed to function as a saturated



D-1, D-2, D-3 - 1N457 RY - Sigma Relay, type 42RO-1000G-Sil

C_1 - 2μfd, C_2 - 4μfd, C_3 - 5μfd, C_4 - 10μfd

Figure 66. Schematic diagram for electronic controller

flip-flop. T-1, a unijunction transistor (7), triggers the flip-flop from one state to another by developing negative trigger pulses across the resistance R-4.

Timing of the circuit is controlled by S, a selector switch for capacitors C_1, C_2, C_3, and C_4, and the linear potentiometers P_1 and P_2. The circuit is designed so that S has gross control of the repetition rate at 50, 100, 120, and 200 cycles per minute when P_1 and P_2 are set approximately in their middle range. P_1 and P_2 not only offers independent controls of the pressure and vacuum periods, but also serves as a vernier control of the repetition rate.

The behavior of the circuit in relation to the design of the timing may be seen by first considering transistor T-2 conducting and transistor T-3 cut-off. During this time the voltage of the collector at T-3 is -27 volts and the relay is unenergized. Silicone diode D-2 is forward biased, for the collector of T-2 is less negative than the emitter of the unijunction transistor. The capacitor in the selector circuit now charges through the series combination of R_3 and P_2. Diode D-1 is cut-off and isolated from the circuit. When the voltage across the charging capacitor reaches the emitter peak point voltage of the unijunction transistor, a negative resistance is developed across its emitter terminals and the capacitor rapidly discharges. A trigger pulse is realized across R_4 causing the flip-flop to be triggered to the other state. For the 2N491 unijunction transistor in this circuit configuration V_p is about 18 volts (7), which is 65% of the supply voltage. The charging equation for the capacitor is

$$V_{C_s} = 27(1 - e^{-t/(R_3 + P_2)C_s}) \quad .$$

The emitter peak-point voltage V_p, to a good approximation, will be reached in one time constant. Therefore, the time interval corresponding to diastole is determined by the following relationship:

$$T_{diastole} = (R_3 + P_2)C_s$$

With the capacitor discharged, the voltage across the emitter is decreased and unijunction transistor returns to its positive mode of operation where the emitter resistance is high. Now with transistor T-2 cut-off, T-3 is conducting, the relay is energized, and air pressure is delivered to the prosthesis. Diode D-1 now conducts and the capacitor is charged through the series combination of R_2 and P_1 until its voltage reaches the emitter peak point voltage V_p of the unijunction transistor when it again fires causing a voltage pulse across R_4 and the states of the flip-flop to again change.

The timing of the duration corresponding to systole considering the above analysis for the diastole period, is determined by the following relationship:

$$T_{systole} = (R_2 + P_1)C_s$$

The advantages of using a hybrid transistor timing circuit over the more conventional types are:

1) The flip-flop is controlled by a device which has a highly stable firing voltage V_p with variations in temperature, life, and firing-current amplitude.

2) The negative resistance characteristics of the unijunction transistor which also influences the firing are highly stable with temperature and life.

3) The circuit offered a convenient method of controlling the repetition rate and duty cycle.

Resistor R_5 connected in series with the D.C. supply and a second set of normally open relay contacts develops a small voltage across terminals Y-Y when the relay is closed. By connecting a CRT oscilloscope to the terminals Y-Y, adjustment of the period and duty cycle may be facilitated by visually observing the corresponding periodic pulses.

VI. EXPERIMENTAL TESTS AND RESULTS

In the development of the myocardial prosthetic system several trials and tests on anesthetized dogs were performed with the purpose of making adjustments and modifications in the design. However, only those experimental tests made after the prosthesis and the support system reached the feasible and workable stage from which defined results were obtained will be described here. The results of the after effects of some of the operative techniques previously described, performed under aseptic survival conditions by veterinarians at the Small Animal Clinic of the Iowa State University of Science and Technology will be reported.

Prior to physiological recordings, an anatomical test* of the myocardial prosthetic system was performed on a 27-pound female dog. The dog was anesthetized by injecting 6 cc of sodium pentobarbitol (strength of 60 mg/cc) into the left cephalic vein in the standard manner. An endotracheal catheter was inserted into the trachea. A Prothoracic respirator attached to a tank of oxygen with regulator was connected to the catheter. The techniques and procedures described in Section II were followed for performing the thoracotomy incision through the sixth intercostal space, trephining a hole in the sternum, sectioning the diaphragmatico-pericardial ligament, freeing the phrenic nerves from the pericardium and fitting the prosthesis to the heart.

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*Assisted by Mr. Kenneth A. Bell and Mr. George C. Slott, advanced students, Dept. of Veterinary Medicine, and Mr. David Hench, senior, Dept. of Electrical Engineering, Iowa State University of Science and Technology.

The tube from the output of the 3-way solenoid from the support system was connected to the stem protruding through the trephined hole in the sternum. The supporting system was operated at 100 cycles per minute with a duty cycle corresponding to a 0.18-second duration for the air pressure pulse and a 0.42-second duration for the vacuum pulse. Air pressure supplied to the device during the pulse was at a nearly constant magnitude of 3 pounds per square inch, vacuum at 3.5 inches of mercury.

For a period of 48 minutes the system was operated with the prosthesis remaining in place on the heart. After this period the prosthesis was removed and the heart was examined. No visible damage or irritation to the pericardium and the tissues and vessels adjacent to the heart was observed grossly. The heart resumed its normal cycling.

By means of an American Electronics Laboratory (Model 761) stimulator, the atria was stimulated with 60-volt pulses of 5 milliseconds duration at a repetition rate of 60 cycles per second causing fibrillation of the heart. The prosthesis was again fitted to the heart and the system was operated for twelve minutes with the same rate, duty cycle and pneumatic levels as in the previous test. During this period the prosthesis remained in place on the heart, periodically contracting and relaxing the musculature of the ventricles. No physiological tests were performed during this experiment.

Physiological tests* were later performed to test the operation of

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*Assisted by Dr. V. W. Bolie, Chairman of Biomedical Electronics, Mr. Kenneth A. Bell and Mr. George C. Slott, advanced students, Dept. of Veterinary Medicine, and Mr. David Hench, senior, Dept. of Electrical Engineering, Iowa State University of Science and Technology.

the myocardial prosthetic system on an anesthetized dog. Figure 67 shows a photograph of the experimental arragement. The 28-pound male dog was anesthetized in the usual manner. The femoral vein I was exposed by making a 3-inch incision on the medial right pelvic appendage near the line of separation of the semimembranosis and sartorius muscles, which were separated by blunt dissection. One end of a catheter was inserted into the vein and the other end was connected to a Harvard infusion apparatus J. The left carotid artery L was exposed by making a 5-inch incision on the mid-line of the neck and then separating the sternohyoidus and sternothyroidus muscles by blunt dissection. A standard cannulation was performed on this artery. Instantaneous blood pressures were recorded on one channel of an E. and M. Instrument Co. 3-channel physiograph A by means of a transducer connected to this artery through a tube of isotonic saline containing an anticoagulant. On the second channel of the physiograph an EKG recording was taken, with leads connected to the thoracic appendages and a ground lead on the chest. Artificial respiration was applied to the dog through an endotracheal catheter in the usual manner.

The sternum H was split by first making a mid-line incision with a scalpel through the skin, connective tissues and fascia and then with a Stryker autopsy saw cutting the cartilage and bone of the sternum through the mid-saggital plane. Rib-retractors were used to separate the thorax walls. The diaphragmatico-pericardial ligament was incised and the mediastium freed from the pericardium. Figure 68 shows the opened chest with rib-retractors in place.

At this point blood pressure recordings showed a systolic pressure of

Figure 67. Apparatus and dog during test of myocardial prosthetic system with physiological measurements

A - E. and M. physiograph

B - CRT oscilloscope

C - pre-amplifier for EKG channel

D - blood pressure transducer

E - pressure bottle

F - prothoracic respirator

G - pneumatic equipment of support system

H - incision made along mid-line with scalpel

I - catheterized right femoral vein

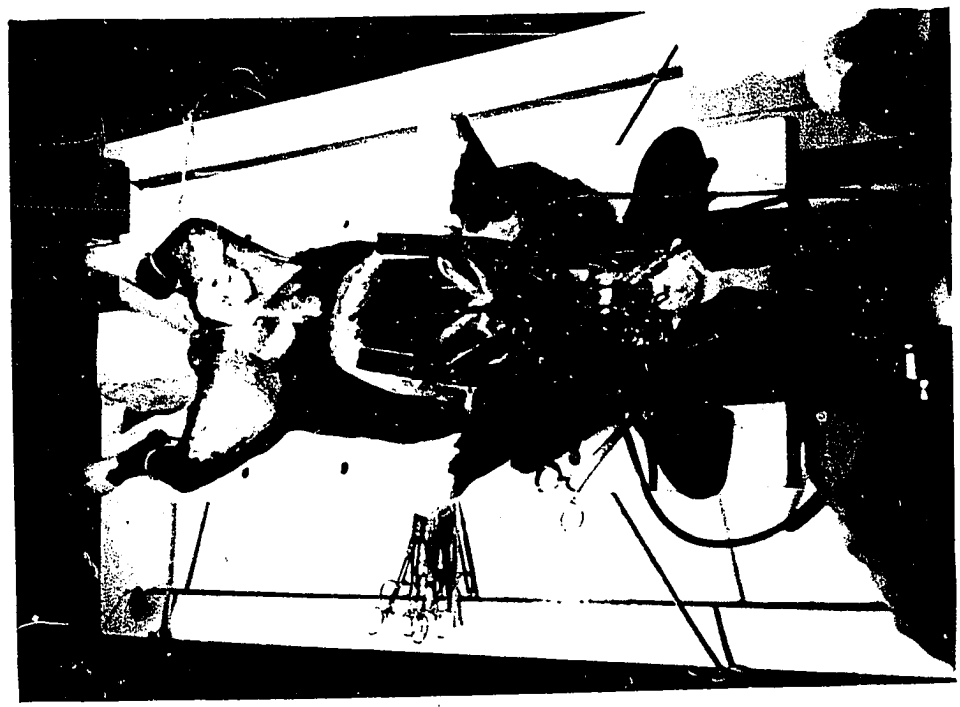
J - Harvard Infusion Apparatus with auxiliary syringe for alternate manual injections of saline or other drugs

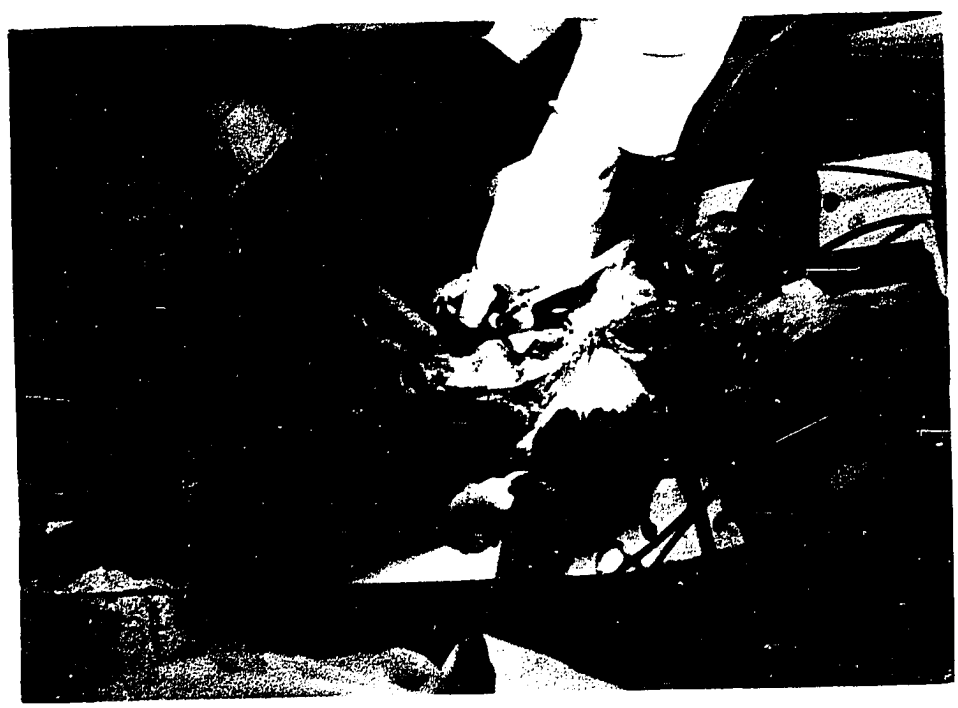
K - electronic equipment of support system

L - cannulated left carotid artery

Figure 68. View of anesthetized dog with sternum split and thoracic walls separated with rib-retractors

Figure 69. Prosthesis fitted to the heart during physiological tests





160 with an average of approximately 125, as shown in the blood pressure recording prior to A in Figure 70. The electrocardiogram recording, graph 0 in Figure 70 was normal. With a stimulator the heart was placed into fibrillation in exactly the same manner as described in the previous experiment. Arrow A corresponds to the time when fibrillation started. It is seen that the blood pressure starts to drop to zero at this time and the EKG becomes erratic and disappears. Immediately after the occurance of fibrillation, the prosthesis was inserted into place over the heart. Figure 69 shows the prosthesis being fitted to the heart. Twenty-six seconds later corresponding to arrow B in Figure 70, the system was turned on and adjusted to a repetition rate of 100 cycles per minute and duty cycle giving an air pressure of 0.18 seconds duration and a suction of 0.48 seconds duration. At this time the systolic blood pressure rose to approximately 95 mm of mercury and the normal periodic blood pressure as shown by the wave form was again established as a result of artificially contracting the myocardium with the prosthetic system. The presence of the dichrotic notch E during each blood pressure cycle shows that the intact valve systems of the heart are functioning normally.

The above blood pressure record during fibrillation resulted while the device was being held in place manually. Figure 71 shows a record of the blood pressure when the hands were removed and the prosthesis was held in place on the heart without manual assistance. During this time the systolic pressure dropped to 70 mm Hg. Several experiments were tried with epinephrine infusion into the femoral vein. However, only erratic results were obtained due to artifacts and clotting in the blood pressure measuring

Figure 70. Recordings from E. and M. Physiograph

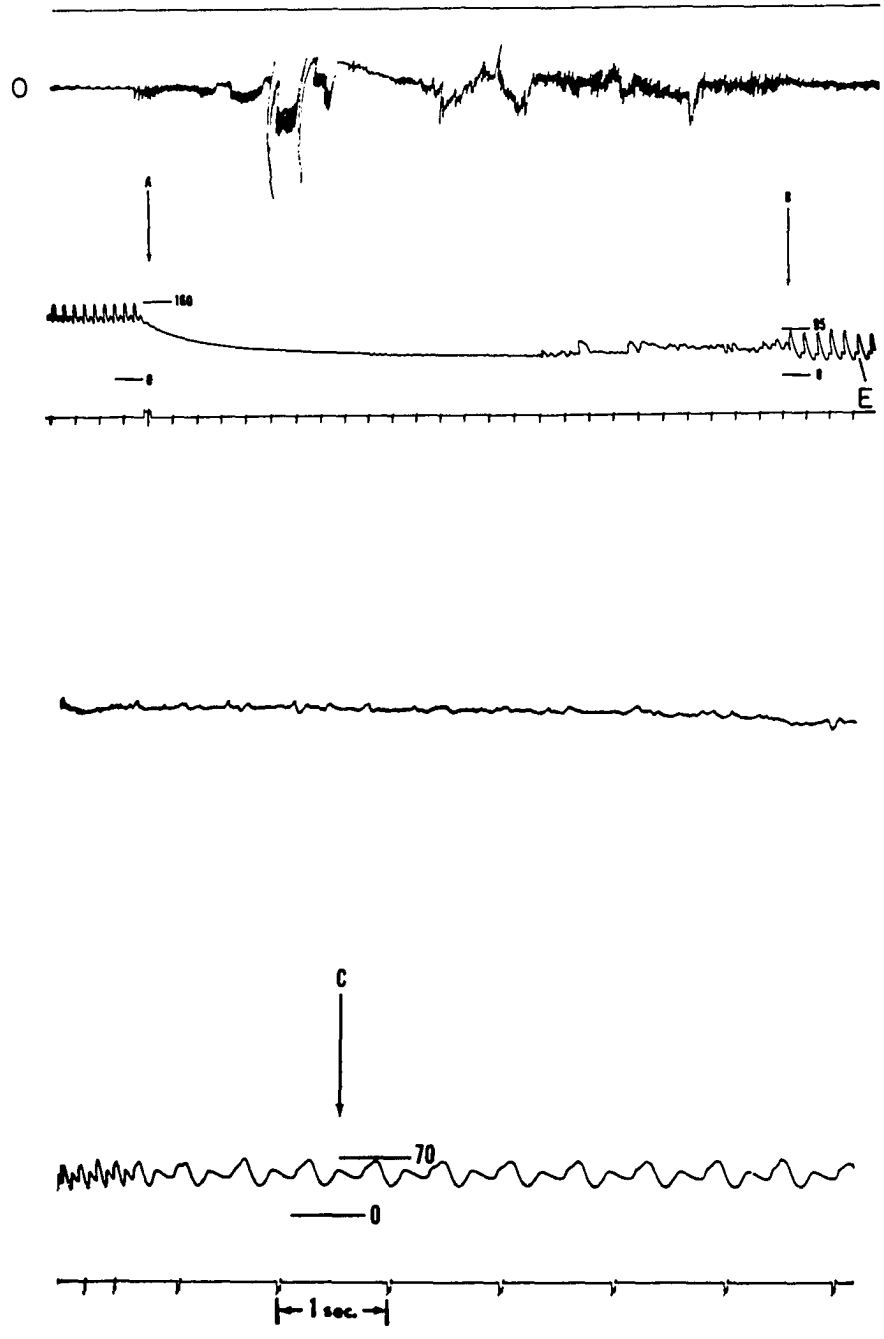
A - time when heart was placed into fibrillation

B - time when prosthetic system was in operation

Top graph O-EKG. Center graph - instantaneous blood pressure recording from left carotid artery. Bottom graph - timing pulses are one second apart.

Figure 71. Recordings from E. and M. Physiograph

Center graph - instantaneous blood pressure from left carotid artery while prosthesis was in operation without manual assistance. Lower graph - timing pulses one second apart.


O
A
B
160
95
E
C
70
0
1 sec.

apparatus.

Fifty-four minutes after fibrillation the system was stopped and the prosthesis was removed from the heart. Five cc samples of blood were removed with a syringe from the left and right ventricles of the heart, and were noted to be bright red and purplish-red, respectively. Hence (assuming that the pressure pulses observed in the carotid artery during the period of artificial massage were indicative of actual circulation) the peripheral tissues of the dog had been continuously extracting oxygen from the arterial blood, and the lungs correspondingly had been re-oxygenating the venous blood.

In this experiment, the prosthesis was inserted into the thoracic cavity by a thoracotomy incision through the sternum instead of the sixth intercostal space for the reason that a better view for the purposes of studying the fit and operation of the prosthesis could be realized.

A study of the after-effects on a live dog of the operative techniques and procedures described in Section II was made. Under aseptic conditions on a survival basis at the Stange Memorial Clinic of the Iowa State University of Science and Technology, the described surgery was performed by a veterinarian*. A 38 pound male dog was operated upon on June 16, 1962. After anesthetizing the dog and providing for artificial respiration in the usual manner, a thoracotomy incision was made through the sixth intercostal space, the diaphragmatico-pericardial ligament was cut and the phrenic nerves were separated from the pericardium by blunt dissection. Except for

*Surgery performed by Dr. P. Pierson, Asst. Professor of Veterinary Medicine and Surgery, assisted by the author.

trephining a hole in the sternum for the stem, these surgical procedures are the same as those required for the insertion of the prosthesis into the thoracic cavity and fitting it to the heart.

For the purpose of obtaining information concerning the reaction of a foreign sleeve around the phrenic nerve in the vicinity of the heart, a piece of thin-walled polyethylene tubing, three-sixteenth inches in diameter, one and one-half inches long was slit along its longitudinal direction and placed around the left phrenic nerve in the vicinity of the heart. The slit was sutured together; the thoracotomy incision was then closed and sutured.

Two days after surgery, it was observed that the dog had regained its normal activity of eating, exercise, sleeping and bowel movements. The dog remained normal until the chest was again opened.

On July 26, 1962, approximately five and one-half weeks after the initial surgery, the chest was again opened by surgery* performed under aseptic survival conditions at the Stange Memorial Clinic. The dog was anesthetized and artificially respirated in the usual manner. After making the thoracotomy incision through the sixth intercostal space, the thoracic cavity was examined.

There appeared to be no visible damage to the pericardium, the diaphragm, lungs or the other tissues surrounding the heart that resulted from the cutting of the diaphragmatico-pericardial ligament or from the separation of the phrenic nerves from the heart. The right phrenic nerve

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*Surgery performed by Dr. E. C. Jensen, Asst. Professor of Veterinary Medicine and Surgery, assisted by the author.

which had been separated from the pericardium by blunt dissection became reattached to the heart by connective tissue. A layer of fibrous connective tissue was found to completely encapsulate and adhere to the polyethylene sleeve that was placed around the right phrenic nerve. The fibrous connective tissue around the sleeve containing the phrenic nerve had adhered to the pericardium rather tenaciously. It appeared to be impossible to separate by blunt dissection the tissue-coated sleeve from the pericardium without rupturing the pericardium. Two days after the second operation the dog again appeared to behave normally.

It may be concluded from this study that the surgery required to fit the prosthesis to the heart should not prove damaging to the otherwise normal operation of the heart or the functioning of the body.

VII. SUMMARY AND CONCLUSIONS

The myocardial prosthetic system consisting of the prosthesis to fit and encapsulate the heart and the electronic-pneumatic support system has been found to be capable of periodically contracting the myocardium. By programming pulses of air pressure and suction into the prosthesis, periods corresponding to systole and diastole may be artificially established in the intact natural heart of an animal and thus causing blood to be pumped through the cardiovascular system. The prosthesis may be inserted through a thoracotomy incision in the sixth intercostal space, and fitted to the heart. The stem of the prosthesis can be projected through a trephined hole in the sternum. The support system is connected to the stem.

Full use is made of the chambers, valves and vessel connections of the natural intact biological heart in the operation of the prosthetic system to effect artificial pumping of the blood through the cardiovascular system. Further development may make the system adaptable for clinical use particularly in cases in which only temporary support of a healing myocardial infarction is needed. From a biomedical engineering point of view, artificial intracorporeal blood-pumping through the cardiovascular system, making use of the natural, but inactive, heart, appears to provide a possibly safer, more reliable and effective artificial heart system than the methods based on the surgical approach of complete replacement of the biological heart as cited in the literature. Not only are the problems of embolism and thrombus formation likely to be reduced, but with a failure occurring in the prosthetic system, particularly in cases where the functioning natural heart is only partially supported by the prosthetic system, the patient

may survive long enough to permit adequate corrective measures. In contrast, in an artificial heart system which completely replaces the natural heart, certain death would result if a failure in the system should occur since the time required for the extensive surgery involved for its complete replacement would endanger the brain and other tissues by stoppage of circulation.

Developmental alterations of the shape and fit, as well as the bonding areas between the inner liner and outer shell of the prosthesis, may make it possible for the system to produce larger stroke volumes at higher pneumatic pressures. As a result, higher arterial blood pressures than those realized in the physiological tests presented here could be developed. These alterations may further aid the device to remain in place over the heart.

The pericardium showed no irritation or damage when observed grossly by the eye after the myocardium was artificially operated by the prosthesis for approximately one hour, both with and without previous induced fibrillation. For the chronic use of the myocardial prosthetic system, it is possible that the inner liner may be coated with a non-toxic adhesive material which in time will adhere to the pericardium through the formation of fibrous connective tissue that will effect a bond between the inner liner of the device and the pericardium. The bond should not interfere with the operation of the device or the artificial contraction of the myocardium. The bond may further prevent the prosthesis from slipping off the heart when in operation.

According to Montgomery* it is possible to entirely remove the pericardium from the heart without disturbing its normal operation and without causing any ill-effects to the patient. Thus, if it is found that the pericardium is punctured or damaged in the chronic use of the prosthetic system, the pericardium may be completely removed and the prosthesis fitted directly to the epicardium.

With further development of the myocardial prosthetic system, it may possibly be used to keep alive patients who otherwise might die from imminent cardiac arrest or insufficiency resulting from heart disease, in a manner similar to the use of the "Iron Lung" in keeping patients alive with respiratory insufficiencies. The cardiac patient, like the pulmonary patient, would be immobile, with the support system resting by his side and with the prosthesis implanted in the thoracic cavity, encapsulating the heart.

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*Montgomery, G. T., M.D., McFarland Clinic, Ames, Iowa. Described to the author his surgical experiences in removing the pericardium from three patients suffering from calcified pericarditis without any ill after effects. Private communication. 1962.

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