

An Implanted, Controllable, Electronic Cardiac Pacemaker

Progress Report:

A cardiac pacemaker, developed jointly with the General Electric Company, has been implanted in 43 patients at our hospital and over 500 elsewhere. In the majority of them, heart block with intractable Stokes-Adams seizures was the indication for this treatment. The pacemaker's fixed rate is about 65 pulses/min. With use of an optional external control, the rate can be increased up to 120 pulses/min. The implantable unit consists of 5 batteries, 2 transistors, 3 resistors, and 1 capacitor--all chosen for high reliability, small size and weight, and low power drain. On the basis of rated capacity of presently available batteries, it should operate for about three years. Any decrease in voltage will be reflected in the patient's altered pulse rate. The pacemaker is functioning well in 30 patients, whose outlook has been improved with adequate cardiac output and relief of anxiety about impending Stokes-Adams seizures. Reliable regular sinus rhythm returned in another patient, obviating replacement of his malfunctioning pacemaker. None of the 12 deaths were related to failure of the pacemaker system. A total of 15 electro-mechanical failures occurred in nine patients. We have had no such complications with the latest pacemaker model.

Engineers at the General Electric Company are now attempting to modify the external control circuit so that, when placed over the implanted pacemaker, the rate will be synchronized with the atrial rate. To date they have developed a model for research purposes only. A sensing electrode is passed, via an esophageal catheter, to a point near the atrium to pick up the atrial signal in humans. (The signal can be sensed from the body surface in dogs.) The research model yields useful information for determining upper and lower limit ratings.

Publications:

1. Kantrowitz, A., Cohen, R., Raillard, H., and Schmidt, J.: Experimental and clinical experience with a new implantable cardiac pacemaker. Circulation, 24:967, 1961.
2. Kantrowitz, A.: Electronic physiologic aids. Proc. 3rd IBM Medical Symposium, October 1961, New York.
3. Kantrowitz, A: Life support by control of internal environment -- artificial hearts, lungs and pacemakers. NEREM Record, November 1961.

4. Kantrowitz, A.: The physiologic implication of implanted cardiac pacemakers in humans. Excerpta Med., Internat. Congress Series 48, International Congress of Physiological Sciences, No. 761, September 1962.
5. Kantrowitz, A., Cohen, R., Raillard, H., Schmidt, J. and Feldman, D.S.: The treatment of complete heart block with an implanted controllable pacemaker. Surg. Gynec. Obstet., 115:415, 1962.
6. Kantrowitz, A.: Clinical experience with an implanted controllable cardiac pacemaker. Digest 15th Ann. Conf. Engineering in Med. and Biol., p. 64, November 1962.
7. Kantrowitz, A.: Experimental and clinical experience with a new implantable cardiac pacemaker. Bull. Soc. Int. Chir., 6:691, 1962.
8. Feldman, D.S. and Kantrowitz, A.: Electrical characteristics of human ventricular myocardium stimulated in vivo. Clin. Res. 11:1:22, January 1963.
9. Kantrowitz, A.: Complete heart block treated with an implanted controllable cardiac pacemaker. In press (Ann. N.Y. Acad. Sci.).
10. Dressler, W., Jonas, S., and Kantrowitz, A.: Observation in patients with implanted cardiac pacemaker. I. Clinical experience. Amer. Heart J., 66:325, 1963.
11. Kantrowitz, A.: Implantable cardiac pacemakers. In press (Ann. N.Y. Acad. Sci.).
12. Kantrowitz, A.: The treatment of Stokes-Adams syndrome in heart block. In press (Prog. Cardio. Dis.).
13. Kantrowitz, A.: Problems in the clinical use of implantable cardiac pacemakers. In press (J. Cardio. Surg.).

Reports at Meetings by Dr. Kantrowitz:

1. Experimental and clinical experience with a new implantable cardiac pacemaker. V Congress of International Cardio-Vascular Society, Dublin, September 1961.
2. Stokes-Adams disease and its surgical control. Medical Surgical Conference, St. Thomas' Hospital, London, September 1961.
3. Heart block. Post-Graduate Conference, Coney Island Hospital (City of New York Department of Hospitals) October 1961.

4. Cardiovascular surgery. Medical Conference of General Electric Company, Utica, N.Y., October 1961.
5. Clinical use of an implantable cardiac pacemaker. Medical Society of Bay Ridge, Brooklyn, January 1962.
6. Clinical experience with a new implantable cardiac pacemaker. New York Society for Cardiovascular Surgery, New York, February 1962.
7. The treatment of complete heart block with an implanted, controllable electronic cardiac pacemaker. XI Congress of the European Society of Cardio-Vascular Surgery, Stockholm, July 1962.
8. Treatment of complete heart block with an implanted, controllable electronic pacemaker. XXII International Congress of Physiological Sciences. Leiden, September 1962.
9. Physiologic implication of implanted pacemakers in humans. IV World Congress of Cardiology, Mexico City, October 1962.
10. Implanted cardiac pacemakers. New York Academy of Sciences, New York, November 1962.
11. Clinical experience with an implanted, controllable cardiac pacemaker. New York Society for Thoracic Surgery, New York, November 1962.
12. Clinical experience with an implantable, externally controllable cardiac pacemaker. Conference on Engineering in Medicine and Biology, Chicago, November 1962.
13. Panel on cardiac pacemakers, American College of Cardiology, Fireside Conference, Los Angeles, February 1963.
14. The cardiac pacemaker. Veterans Administration Regional Office, New York, March 1963.
15. Conference on cardiac pacemakers, New York, September 1963.
16. Clinical use of implantable cardiac pacemakers. International Cardiovascular Society, Rome, September 1963.

Report at meeting by Dr. Martin Schamaun:

1. Experience with the implanted controllable cardiac pacemaker. New York Hospital, October 1962.

Exhibit:

Exhibit with film "An Implantable Cardiac Pacemaker" prepared with R. Cohen, M.D., was shown as follows: American Heart Association, Chicago 1962; American College of Cardiology, Denver 1962. Film only: International Congress of Physiological Sciences, Leiden 1962; European Society of Cardio-Vascular Surgery, Stockholm 1962.

Future Objectives:

1. Construction of a modified external control circuit capable of sensing the P-wave from the body surface and synchronizing the implanted pacemaker with the intrinsic auricular rate. It would have the following advantages over other synchronous pacemakers:
 - a. The implanted unit, our fixed-rate pacemaker, has been proved reliable.
 - b. This unit's minimal circuitry would require no changes.
 - c. A synchronous rate would not be obligatory.
2. Prolongation of the life expectancy of the leads, the major non-biologic problem remaining with all implanted pacemakers.
3. Comparative studies of our patients with pacemakers: cardiac catheterization, including measurement of cardiac output, and subjective as well as objective clinical evaluation of synchronous and asynchronous pacing in the same individual. If synchronous pacing should prove to be clearly superior, over 500 patients with our pacemaker could be changed over to this method by means of the modified external control circuit.
4. Studies aimed toward broadening of the range of indications for the pacemaker, especially in view of the relatively low operative risk. (Although complete heart block was the indication in 38 of our 43 patients, the other five--all in frank congestive failure of varying origin--were also benefited.)
5. Investigation into the possibility of developing a pacemaker with several rates that could be set externally with a magnet. A magnetically operated switch would be built into the implanted unit. By passing a strong magnetic field within 1/2 to 3/4 inch of the unit the rate could be changed, e.g., from 65 to 85. The circuitry changes would be relatively minimal.

Electrostimulation for Evacuation of the Neurogenic Bladder

Progress Report:

In early experiments the urinary bladder was directly stimulated, via two stainless-steel wire electrodes implanted in the detrusor muscle, in 10 normal dogs and in 17 dogs made paraplegic by transection of the lumbar spinal cord. Trains of biphasic square waves (4 msec., 20 cycles/sec., and 2.5-10 volts) provoked strong contractions of the detrusor and raised intravesical pressure considerably in both groups. In dogs with an upper motor neuron lesion, the bladder was easily emptied up to two or three weeks after transection. Cystography showed residual urine after later stimulations, despite higher voltage. Consistently high intravesical pressure suggested that the bladder's failure to empty was due to increased intraurethral resistance. In patients with an upper motor neuron lesion, this failure has been related to spasticity of the striated external sphincter. Three of the five long-surviving dogs were subjected to pudendal neurectomy, proposed by Bors to relieve the spasticity. The bladder was then periodically evacuated up to 9 months after cord transection. Correspondingly, complete evacuation was achieved in three animals with a lower motor neuron lesion produced by transection of the cauda equina. A radio-linked stimulator to control bladder evacuation has been developed jointly with the Avco Corporation. Its internal unit is a receiver, placed in a subcutaneous abdominal pocket, with two electrodes which are implanted in the bladder's detrusor muscle. The external unit, a small portable transmitter, is placed on the abdominal wall over the receiver. When the stimulator was tested in four paraplegic dogs, the chronic cord bladder invariably contracted and expelled its urine. Several problems have arisen in our two clinical cases, however, suggesting the need for further studies.

Publications:

Kantrowitz, A. and Schamaun, M.: Paraplegic dogs: urinary bladder evacuation with direct electric stimulation. Science, 139:115, 1963.

Schamaun, M. and Kantrowitz, A.: Management of the neurogenic urinary bladder in paraplegic dogs by direct electric stimulation of the detrusor. Surgery, 54:640, 1963.

Schamaun, M. and Kantrowitz, A.: Evacuation of the chronic cord bladder by a radio-linked stimulator. Surgical Forum, American College of Surgeons, Vol. XIV, 1963.

Reports at Meetings:

Kantrowitz, A. and Schamaun, M.: Bladder evacuation in paraplegic dogs by direct electric stimulation. Presented at AMA Discipline Research Forum, Atlantic City, June 1963.

Schamaun, M. and Kantrowitz, A.: Experimental studies in direct electric stimulation of the urinary bladder. Maimonides Hospital Research Society, June 1963. (Dr. Schamaun was awarded the Society's annual prize of \$500 for his meritorious work on this project.)

Kantrowitz, A. and Schamaun, M.: Neurogenic bladder stimulation. Albert Einstein College of Medicine, New York, March 1963.

Future Objectives:

1. Continuing animal experiments focused on problems emerging from our initial patient studies, chiefly the need for techniques to control external sphincter spasm associated with stimulation of the detrusor.
2. When these problems are solved, selected human paraplegics will be hospitalized for implantation of the radio-linked unit. Stimulation effects will be evaluated in collaboration with the Rehabilitation Service of Downstate Medical Center, in the hope of establishing sound criteria for selection of patients.
3. Long-term follow-up studies to determine whether regular evacuation of the neurogenic bladder by electrostimulation reduces genito-urinary damage.

Long-Term Continuous Stimulation of a Peripheral Nerve

Progress Report:

Continuous, day-and-night electrostimulation of the phrenic nerve has been effected in five dogs for periods up to five months. The phrenic nerve was chosen because of accessibility for placement of the electrodes and ease of checking diaphragmatic movement on the stimulated side. This project is the result of an objective mentioned in our first grant application -- development of an electrode that would stand up under constant stimulation and would be "accepted" by a peripheral nerve. Our encouraging progress toward this goal would appear to open many avenues of research.

During extensive preliminary studies, we encountered difficulties with all types of electrodes regardless of cuff material. The main problems were dislodgment of the electrode from the nerve, wire breakage or other mechanical failure, and current leakage to adjacent tissues. Working on these problems jointly with the Dow-Corning Center for Aid to Medical Research, we have developed a Teflon-coated, multi-strand, stainless-steel wire electrode with a short Silastic cuff reinforced with Dacron Tricot. The cuff can be placed around the nerve with a minimal dissection and without interruption of the blood supply. The lead wires are exteriorized between the scapulae and attached to a portable stimulator, mounted with a separate battery supply on a specially designed harness permitting the dog to move about freely.

The parameters of the stimuli used in this study were 0.3 or 0.5 msec. pulse duration, 60-90 cycles/sec. frequency, and 0.15-0.9 volt amplitude. The stimulus trains lasted 0.8-2.0 sec. and were repeated at the rate of 18-42/min.

Bipolar stimulation was effected in three dogs by placing two short cuff electrodes 1.0-1.5 cm. apart on the phrenic nerve. Unipolar stimulation was achieved in the other two animals by placing a single cuff electrode on the nerve and the indifferent electrode elsewhere in the body. The two forms of excitation proved to be equally effective. Hemi-diaphragmatic movements were palpated at least once daily

and the stimulus threshold was checked by oscilloscope. At the outset the stimulus was 0.2 volt but within 2-1/2 months it was usually about 0.4 volt. In several instances electrostimulation was interrupted briefly because of mechanical failure of the electrode.

Four of the five dogs were sacrificed when it became impossible to restore hemidiaphragmatic contractions after failure of stimulation on the 72nd, 98th, 120th, and 159th days, respectively. In all cases the dogs had pulled on the wires, partially dislodging the cuff and damaging the nerve. All failures were mechanical, and unrelated to the electrostimulation. Stimulation in the fifth animal was stopped on the 107th day. Histologic study of multiple sections from the phrenic nerve and ipsilateral diaphragm in all the dogs are now under way. Preliminary reports reveal no major changes in these structures beyond those attributable to mechanical failure.

Report in Preparation:

de Villiers, D.R., Nose, Y., Mauro, A. and Kantrowitz, A:
Continuous, long-term electrostimulation of the peripheral nerve.

Future Objectives:

1. Design and construction of appropriate implantable and portable hardware for continuous electrostimulation of the phrenic nerve.
2. Experiments involving the use of an implanted radio receiver and an external radio transmitter. Although this set-up would not permit measurement of the precise amount of energy required for constant nerve excitation, our early work suggests that a plateau is quickly reached and stimulation is maintained with 0.5-1.0 volt. We feel that the radio-linked stimulator would minimize the risk of electrode dislodgment and prevent trans-cutaneous infection.
3. Extension of studies to include other peripheral motor nerves such as those of:
 - a. Skeletal muscle
 - b. Smooth muscle of the bowel, bladder, and various sphincters
 - c. Glands such as the pancreas and adrenals.

4. Evaluation studies based on histologic examination of multiple tissue sections from animals sacrificed after a year of more of continuous electrostimulation.
5. Preliminary exploration of the feasibility of similar electrostimulation of sensory afferent nerves.
6. Electrostimulation of the phrenic nerve in human patients with various ventilatory problems such as bulbar polio, hypoventilation syndrome, and CO₂ narcosis.

An Electronically Controlled Mechanical Prosthesis as An Auxiliary Left Ventricle

Progress Report:

A pump for implantation in the aorta, consisting of a 15-ml. Silastic bulb encased in a rigid shell, has been developed jointly with the Avco Everett Research Laboratory. The pump is driven by applying and removing compressed air via a polyethylene tube. Contraction of the bulb is controlled by an electronically powered solenoid valve triggered by the ECG through a timing device. The prosthesis is designed to lighten the work load of the physiologic left ventricle by lowering its resistance toward emptying, i.e., by reducing aortic pressure during systole and increasing it during diastole.

We have performed 49 patency experiments and 49 system experiments to explore the feasibility of permanently implanting the prosthesis in the aorta. In patency studies, a Silastic bulb with woven Teflon cuffs was substituted for 6-7 cm. of the aorta at different sites. Three dogs with the prosthesis implanted in the abdominal aorta survived 9, 13, and 14 months, respectively. In 30 acute system experiments with the air-powered pump, end-to-side implantation in the ascending and descending aorta, paralleling the aortic arch, was found to yield the most satisfactory results--a 40-60% reduction in left ventricular pressure. We therefore implanted the device in that position in the next 19 animals. When the dogs became fully conscious they were placed in a harness from which two electrodes and an air tube were carried through the top of the cage by a sweep line. Polyethylene tubes were inserted into the carotid artery and the left ventricle, taped to the sweep line, and connected to a strain gauge for recording of pressure changes throughout the procedure. One dog lived 41 hours with a continuous functioning prosthesis. After this interval, its free serum hemoglobin was 85 mg.%. An inadvertently induced pneumothorax was the cause of death in this animal. Free serum hemoglobin was 240 mg.% in a dog surviving 25 hours. The other 17 animals lived 1-24 hours; death in most instances was due to clotting. We feel that this complication will be less of a problem now that we are implanting prostheses made of newer plastics.

Publication:

Nose, Y., Schamaun, M. and Kantrowitz, A.: Experimental use of an electronically controlled prosthesis as an auxiliary left ventricle. Trans. Amer. Soc. Artif. Intern. Organs, 9:269, 1963.

Reports at meetings:

Nose, Y. and Kantrowitz, A.: An electronically controlled prosthesis as an auxiliary left ventricle. Maimonides Hospital Research Society, January 1964.

Kantrowitz, A.: Experiences with electrostimulation in humans. Jewish General Hospital, Montreal, December 1963.

Future Objectives:

1. Design and development of a portable power supply, pressure system, and timing circuit, permitting use of the auxiliary ventricle in freely moving animals.
2. Cardiac catheterization studies to evaluate the effects of long-term continuous use of the auxiliary ventricle in animals.
3. Construction of similar equipment suitable for use in humans, if warranted by results of the studies outlined in Objective 2.

Electronic Control of the Postoperative Adynamic Ileus

Progress Report:

Investigators have long sought a reliable means of controlling postoperative adynamic ileus. Extensive experiments were conducted to determine whether electrostimulation could reactivate peristalsis in dogs with experimentally induced atony of the intestine. A bile peritonitis was induced, followed within 60-90 minutes by exposure of the bowel. The degree of atony, however, was too severe to permit diffuse peristaltic reactivation. Mere exteriorization of the bowel for two hours resulted in a condition closely resembling postoperative ileus in man. Separate long intestinal loops were prepared, with wire electrodes placed in the bowel wall. The mechanical effects of electrostimulation were evaluated by recording pressures from intraluminal balloons. We could initiate peristalsis by stimuli of moderate (50 msec.) to long (600-5000 msec.) duration, but repetitive short-pulse stimuli proved to be superior. Optimal parameters were 5-7 msec., 40-70 cycles/sec., and upward of 4-5 volts, which invariably evoked local intestinal activity lasting 3-4 minutes. The best response was obtained with a stimulus train lasting 5-7 sec. repeated every 3-4 min. over a 15-min. period each hour. Monophasic pulses were found to be superior to biphasic. Since all responses were in the form of local contractions, the above parameters could be determined mechanically and the pressure recorded by balloons placed at the electrode site. To find out whether the peristaltic wave was propagated throughout the intestine, we placed two intraluminal balloons at proximal and distal levels of the small intestine and implanted electrodes at the proximal level. Resumption of diffuse peristalsis was inconsistent, depending to some extent upon whether the bowel still had adequate tonicity. The same equivocal results in several clinical cases point to the need for considerable work before a reliable method is developed for controlling postoperative adynamic ileus electrically.

Publications:

deVilliers, D.R., Saltiel, I., Nonoyama, A. and Kantrowitz, A.: Control of postoperative adynamic bowel in dogs by electric stimulation. Trans. Amer. Soc. Artif. Intern. Organs, 9:351, 1963.

deVilliers, D.R., Saltiel, I., Nonoyama, A. and Kantrowitz, A.: Clinical experience in control of postoperative adynamic ileus by electrostimulation. Surgical Forum, American College of Surgeons, Vol. XIV, 1963.

Reports at Meetings:

Kantrowitz, A., Saltiel, I., Nonoyama, A. and deVilliers, D.R.:
Electronic control of postoperative adynamic ileus. Joint meeting
of New York and Philadelphia Surgical Societies, New York,
March 1963.

Kantrowitz, A.: Experiences with electrostimulation in humans.
Jewish General Hospital, Montreal, December 1963.

Future Objectives:

1. Better understanding of the adynamic bowel's response mechanism to electrostimulation, which we feel is related to the degree of tonicity it has retained.
2. Investigation of electromyographic patterns in the bowel in an attempt to reveal a point up to which stimulation will be effective, and beyond which even high voltage stimuli will be unavailing.
3. Setting up of criteria for selection of patients, including such factors as indications or contra indications after certain types of surgery.
4. A study to determine the relative value of bowel stimulation as a prophylactic and a therapeutic modality.
5. Establishment of optimal parameters of the stimulus and optimal pattern of the stimulus train.
6. A controlled study to compare electrostimulation with other methods of treatment for postoperative adynamic ileus.

Although other centers have reported peristaltic restoration by intraluminal electrostimulation, nasogastric suction was used concomitantly in the majority of cases--a fact militating against clear-cut conclusions. In our experience electrodes placed directly in the muscle evoked a much stronger and more consistent response than those merely left in vague contact with the bowel wall. The presence of a good medium such as gastric contents facilitates the spread of electric current, but this situation does not obtain with an electrode lying loosely in a gas-filled stomach.

Coordinated Limb Movements by Electronic Stimulation

Progress Report:

Exploratory studies begun under Grant HE-5977 suggest that electronic directions may at some far future time be substituted for nerve impulses destroyed in patients with an upper motor neuron injury. A four-track program was stored on a magnetic tape recorder. It was prepared by manipulating a specially built, jointed wooden model of a dog's hind leg. The model had two attenuators mechanically linked to each of two joints, the hip and knee, and electrically arranged so that when the signal intended for the agonist group of muscles was increased, the signal intended for the antagonist muscle group would be simultaneously decreased. When this program was played into the animal via electrodes implanted in the leg, it reproduced the same crude movements that had been prearranged on the model. The next step was preparation of a four-part stimulus with the aid of a tape recorder, which enabled a human paraplegic to rise from a sitting position, stand a few moments (using a bar for balance), and sit down in response to programmed directions. The stimulus was applied by placing electrodes on the skin over the motor points of the vastus and gluteus muscles of both legs.

Servomechanism #1. A servomechanism was then developed to explore the possibility of controlling one joint in the leg of a human paraplegic. A special brace was designed for his left knee, and a follow-up potentiometer was mounted on the brace to measure the angle of the knee. The voltage of this potentiometer was compared with that of a command potentiometer. A square-wave stimulator was built to generate 100-pulses-second stimuli with a pulse width of 1 msec. At peak amplitude a little over 40 volts was delivered into the rectus femoris muscle. Pulse amplitude was controlled by a modulator stage. The stimulus voltage was amplified and applied to the muscle, through a matching transformer, via surface electrodes. The subject was seated with his lower leg approximately perpendicular to the floor. The command potentiometer could be adjusted to increase the stimulator output, forcing the lower limb upward. The angle assumed by the knee brought the error signal (voltage of follow-up potentiometer minus voltage of position-command potentiometer) to a value near zero. The error signal changed the bias on the modulator stage, whose output voltage made the stimulator generate pulses of sufficient amplitude to force the knee into the desired angle, balancing the leg against gravity. Reducing the stimulus voltage allowed the leg to return to the floor by the force of gravity.

Servomechanism #2. Another servomechanism has been built to investigate the feasibility of stimulating both an agonist and an antagonist muscle controlling the knee joint. With this device we expect to lower the paraplegic's leg by electronic command rather than allowing it to return by the force of gravity. The adductor magnus, the semitendinosus, and the biceps femoris have thus far been stimulated.

Publications:

Kantrowitz, A.: Electronic physiologic aids. Proc. 3rd IBM Med. Symposium, October 1961.

Kantrowitz, A., Khafif, R., Kass, E. and Reiner, S.: Controlled movement of a paraplegic joint by a servomechanism. In preparation.

Reports at Meetings:

Kantrowitz, A. and Khafif, R.: Electronic production of coordinated limb movements. Forum on Fundamental Problems, 46th Clinical Congress of the American College of Surgeons, San Francisco, November 1960.

Kantrowitz, A.: Electronic production of coordinated limb movements. Veterans Administration Regional Office, New York, June 1961.

Future Objectives:

1. Mathematical analysis of the servomechanism system.
2. Evolving of a mathematical formula relating the physical and computer factors around a joint in a human paraplegic.
3. Construction of hardware for translating the theoretical factors into actual parameters in the experimental set-up.
4. Achievement of precisely controlled motion in a paraplegic joint (accurate to 1°).
5. Extension of the system to permit control of two joints.

Electrostimulation of the Esophagus

Progress Report:

In experimental studies now under way, we are exploring the feasibility of controlling peristaltic activity in the esophagus by electrostimulation. Either the thoracic or cervical esophagus was surgically exposed in 18 dogs. Two Teflon-coated, stainless-steel electrodes were implanted at various levels in the muscular layer. At the same time one or two small saline-filled rubber balloons with attached polyethylene tube were introduced, also at various levels. One or two days postoperatively, stimuli of 3-4 msec., 30-60 cycles/sec. and 3-6 volts were applied for 3-5 seconds via a physiologic stimulator, and the tubes from the balloons were connected to a strain gauge. This pressure-recording system made it possible to compare contractions caused by swallowing, drinking water and eating with those induced by electrostimulation.

Although the stimulus invariably caused local contractions, further studies are needed to determine the degree and extent of their propagation throughout the esophagus. It now appears that the presence of saliva, ingested fluids or food in the esophagus is necessary to propagate the contraction.

An attempt has been made to produce an achalasia syndrome in four dogs. The lowermost part of the esophagus was freed from surrounding tissues and packed in dry ice for 30 seconds. It is hoped that this will injure the more sensitive neural elements of the esophagus, resulting in an aganglionic segment simulating achalasia in man.

Future Objectives:

1. Development of an achalasia-like syndrome in a series of dogs.
2. Establishment of optimal electrical parameters for esophageal stimulation.
3. Electrostimulation studies involving intraluminal pressure recording and X-ray contrast media, to evaluate the effectiveness of the technique for propelling esophageal contents caudad.

Electrostimulation of the Esophagus--Page 2

4. If satisfactory results are achieved in animals, the method will be tried in human achalasia patients, using an electrode-carrying Levin tube.
5. Assessment of the method's potential in the treatment of human achalasia.

Repair of Ventricular Defects with a Functioning Diaphragmatic Patch

Progress Report:

There is good evidence that resection of ventricular aneurysms, particularly of the left side, tends to reduce paradoxical motion of the heart and thus increase cardiac output. We are exploring the possibility of substituting functioning muscle for the resected portion of the ventricle. Preliminary studies were undertaken in dogs to measure the pressure that could be generated by the diaphragm. The left diaphragm was mobilized, with the phrenic nerve and blood supply intact, and fashioned into a single- or double-thickness pouch. A rubber balloon was placed inside the pouch and connected by a polyethylene tube to a strain gauge. The pouch was distended by introducing 300 cc. of water, thus stretching the muscle fibers. When a stimulus of 2 msec., 40 cycles/sec., and 4-7 volts was applied to a single-thickness pouch, the pressure rose to about 50 mm. Hg under conditions of 20 mm. Hg basic resistance. Pressure of 150 mm. Hg, in a double-thickness pouch of 20-30 ml. capacity, under the same conditions, indicated satisfactory contractibility for the very short time involved.

In two acute experiments we resected up to 25% of the left ventricle, with the animal on a pump oxygenator, and repaired the defect with a double-thickness patch of diaphragm muscle. Upon electrostimulation, the patch contracted synchronously with the intact portion of the left ventricle at about 100 pulses/min. We could not achieve adequate arterial blood pressure levels for any length of time, however, because the patch became attenuated.

Future Objectives:

1. Continuing efforts to reduce clotting and achieve a sturdier repair by closing the ventricular defect with a Teflon patch before applying the double-thickness patch of innervated diaphragm muscle.
2. Upon achievement of a consistently satisfactory ventricular patch, we shall attempt to develop an implantable, transistorized amplifier and stimulator capable of triggering the patch to contract synchronously with the ECG.

Physiologic Access Plug

Progress Report:

We have been attempting to construct a mechanical access plug so that electrodes or tubes can be left in experimental animals without irritating or infecting the adjacent skin and subcutaneous tissue. Silastic, natural rubber, Teflon, and Dacron--alone and in various combinations--were tested on the upper dorsum in eight dogs. It was hoped that fibroblasts would invade the plug, fixing it permanently and sealing out infection. Subcutaneous infection developed in three dogs, however, and the plug became loosened. No infection occurred in the other five animals which were sacrificed between the first and the twelfth weeks. To date, a Silastic plug with a permanently bonded coating of Teflon felt has proved the most satisfactory.

The plug was installed in the large bowel in four dogs, preliminary to construction of an artificial anus. About two weeks later we resected the bowel below the plug in two animals and closed the natural anus. The plug cap was removed daily for several hours, and bowel lavage was carried out periodically through the artificial anus. One animal was sacrificed at three months because of chronic constipation; the plug was permanently fixed and there was no infection. The other dog, which also suffered from chronic constipation, was sacrificed at two months because of a subcutaneous infection. Autopsy revealed a somewhat stenosed bowel opening in both cases. Of the other two dogs, which acted as controls, one developed an infection and was sacrificed at two months. The other is alive one year after the plug was installed.

Future Objective:

1. Continuing studies involving various materials, designs, and implantation techniques, to develop an inert, permanent physiologic plug that will permit passage of wires and tubes through the skin.

A Monitoring System for Postoperative Patients

Progress Report:

A fully automated electronic system for postoperative monitoring, developed in our laboratory, has been used to obtain physiologic data on a number of patients. Eight parameters are monitored and displayed. Six of the parameters are available at 30-second intervals by means of appropriately placed transducers: systolic and diastolic blood pressure (percutaneous catheter in femoral artery connected to a strain gauge); heart rate (above-mentioned blood pressure transducer, or electrodes taped to the wrist and scapulae); respiratory rate (intranasal thermistor); temperature (rectal thermistor); and urine loss (Intraurethral catheter). The other two parameters--blood loss (via chest tube) and blood replacement--are obtained at one-minute intervals, alternating in 30-second cycles. The data are automatically transcribed in ink on an $8\frac{1}{2}$ x 11 inch chart.

The system has certain advantages over similar available equipments:

1. The patient's condition is constantly monitored and displayed.
2. The monitored data for a 12-hour period appear on one chart, enabling the physician to note trends at a glance and plan therapy accordingly. The chart becomes a valuable part of the patient's permanent record.

The method of monitoring the respiratory rate with an intranasal thermistor probe was developed in our laboratory. Changes in respiratory rate in the order of 17:1 can be detected. This thermistor may be used in the recovery room without interference with normal intensive care. Although especially designed for patients undergoing heart procedures, it may be equally helpful following other types of surgery.

Publications:

Hershberg, P., Kantrowitz, A. and Kass, E.: A method of monitoring ventricular contraction by intranasal thermometry. IEEE Trans. on Bio-Med. Electronics, Vol. BME-10, No. 2, April 1963.

Hershberg, P., Kantrowitz, A. and Kass, E.: A postoperative pneumographic monitoring unit. Amer. J. Med. Electronics, 2:3:207, 1963.

Future Objectives:

1. Evaluation of the monitor's usefulness in a clinical study involving about 100 patients, to assess:
 - a. Reliability of data
 - b. Speed of recording data
 - c. Ease of obtaining critical information and trends at a glance, from one sheet covering a 12-hour period.
2. Modifications in monitor design based on needs revealed with wide use.

Maintenance of Respiration by Direct Electric Stimulation of the Diaphragm

Progress Report:

In experiments aimed toward maintenance of respiration in apneic dogs, two stainless-steel electrodes were implanted in a hemidiaphragm, with the distal ends exteriorized between the scapulae. Several days later the dogs were lightly anesthetized and resting minute volume was checked by spirometry. Apnea was then induced by 10-25 minutes of hyperventilation and a stimulus of 2 msec., 60 cycles/sec., and 2.5-3.5 volts was applied at the rate of 30/min. A sawtooth-envelope stimulus caused smooth diaphragmatic contraction with a respiratory rate of 30/min. in animals with the phrenic nerve intact. To determine whether the diaphragm could be used for this purpose for long periods of time, we attached a portable stimulator to the dog's harness, permitting its free movement in the cage during electrostimulation lasting up to one week. Apnea was then induced, normal volume recorded, and the optimum stimulus given. When the phrenic nerve was intact the dog's resting minute volume reached normal or above-normal levels-- a rise directly proportional to amplitude of the stimulus up to about 4 volts. This project has been superseded by more recent experiments on long-term, continuous stimulation of the phrenic nerve.

Internal Mammary and Coronary Artery Suture-Anastomosis With Use of Patch Grafting

Progress Report:

Heretofore, small vessels have been anastomosed principally by shunting an extra-cardiac artery to the circumflex branch of the left coronary artery. Conventional suture methods have yielded only fair results because of a strong tendency toward thrombosis. Although successful nonsuture anastomosis has been reported with use of small rings of different materials, stapling instruments, and microsurgery, these methods are either somewhat complicated or require special instruments. Successful patch grafting of small arteries, especially of the circumflex coronary branch, has already been reported.

One of our Surgical Research Associates attempted to anastomose the internal mammary artery and the circumflex branch of the left coronary in 15 dogs, inserting a previously prepared patch from the animal's superficial femoral artery. Immediate results with the enlarged anastomosis were excellent. The anastomosis was open in four of the five dogs that died 3-69 days post-operatively. In five long-term survivors, however, aortographic studies 5-9 months after establishment of the shunt revealed an occluded anastomosis. This late occlusion is believed to be related to increasing compression of the lumen from the outside, rather than to thrombosis starting at the suture line itself. Dense fibrous scar tissue appeared to have gradually occluded the vessel, diminishing the flow. A report on this work has been submitted for publication.

Publication submitted:

Schamaun, M.: Internal mammary and coronary artery suture-anastomosis with use of patch grafting.

Future Objectives:

No further experiments are planned.