Learning from (heart) failure

The implantable cardiac pacemaker is now beginning to reach the useful lifetime it was supposed to have had 15 years ago

Thousands of people throughout the world are alive today and leading normal, or nearly normal, lives because of the implantable cardiac pacemaker. This remarkably successful electronic device paved the way for implants of other electronic devices such as those used to relieve pain or stimulate body functions. But in spite of this success, the implantable cardiac pacemaker during its evolution has been plagued with problems that caused premature failures. Batteries didn't last as long as anticipated. Electrode leads carrying pulses from the pacemaker to the heart broke, developed open circuits, corroded and conducted poorly, moved out of position, got lodged in the wrong places, perforated the walls of the heart, and got disconnected from the pacemaker. But the pacemaker's number one enemy was moisture, which, indiscriminately, knocked out batteries, transistors, diodes, resistors, and capacitors.

Many of these early failures of pacemakers now occur only rarely. But why they occurred at all, what was learned from them, and what has been done to try to prevent them from recurring, is the essence of the story that follows.

Early stimulation techniques

Prior to the advent of the totally implantable cardiac pacemaker, various clinical techniques had been used to stimulate the human heart electrically, but none of them proved satisfactory for day-to-day use by patients threatened by certain heart malfunctions—particularly that known as heart block.

For example, external stimulation systems applied high voltages to the patient's chest. Such techniques had the advantage of being easily adjustable for frequency, pulse shape, and pulse amplitude; defects in the stimulation system could be readily found and corrected; and an unlimited energy supply was available since the system was connected to a wall outlet or a relatively large, easily replaceable battery. But such external units also had many disadvantages—such as the restriction of patient mobility; the psychological burden on the patient of the constant reminder of his dependence on the equipment; and the occurrence of painful, noncardiac muscular contractions because of the high voltages involved. Worst of all, the intense pain and burning of the skin limited such treatment to two or three days, after which some patients literally committed suicide by ripping off the electrodes.

Ronald K. Jurgen   Managing Editor

Cross section of the heart as viewed from in front of the body, looking directly at the chest. A typical pacemaker (upper right) and lead into the right ventricle of the heart are also shown. This artist's rendering is based on illustrative material that was supplied by Medtronic, Inc.

External stimulators were also used with needle electrodes passing through the chest and onto the heart. This technique carried significant risk of infection and damage to important structures and could be used only for brief periods.

Secondary coils and electrodes implanted in the patient with external pulse-generating equipment were used in clinical tests. In one approach inductive coupling from an external primary coil and pulse generator was utilized to induce stimulation of the heart. Technical disadvantages included the need for accurate positioning of the primary coil and the loss of energy because of the inductive coupling. The signal was rectified by means of a diode and, in some cases, a buffer–capacitor was also employed and the resultant pulses were used to stimulate the heart. The implanted coil technique had the clinical disadvantage of burdening the patient with a transmitter constantly attached to his chest, thereby providing only limited rehabilitation. And skin irritation was a major problem.

Another early pacemaker, fully implantable, used rechargeable batteries—but battery life proved to be short after the necessary periodic inductive rechargings.

By 1960, the time was right for the clinical use of totally implantable, self-powered cardiac pacemakers. The disadvantages of alternate techniques such as chemotherapy, surgery, and use of external or partially implanted pacemakers had already been demonstrated. And the availability of high-efficiency transistors, which could be powered by small-sized, low-voltage mercury batteries, made the totally implantable approach technologically feasible. The first total implants proved successful, and others followed in rapid succession amid confident predictions by physicians and device manufacturers that average pacemaker lifetimes of five years could be expected. However, the implanted pacemakers began failing much sooner, after an average of about 18 months of life. What went wrong?

The human body's harsh environment

The early predictions of five-year lifetimes for implanted cardiac pacemakers were based largely on a lack of appreciation of the fact, now well understood, that reliability requirements for components to be used in pacemakers are more severe than all but the most stringent military and space requirements. The batteries and other components, such as transistors, resistors, etc., in early pacemakers were off-the-shelf items. Even though they were encapsulated in epoxy, they were easy prey for the harsh environment of the human body.

The first commercially available totally implantable pacemakers used mercury batteries. Mercury battery life, estimated by taking into account only total initial battery energy available and the rate at which that energy could be depleted by the pacemaker, proved *in vivo* to be far less than predicted. One of the most common causes of

How an implantable cardiac pacemaker works

The normal human heart regulates itself by means of a conduction system, a group of structures within the heart that governs heart rate and conducts stimulating pulses to all parts of the heart muscle. The result is a coordinated heart beat. Cells in the sino-atrial (S-A) node of the heart normally initiate the heartbeat. When something goes wrong with the conduction system, heart block and other arrhythmias result.

Heart block is the condition in which electric signals from the S-A node do not pass in the normal fashion from the atria down to the ventricles. As a result, the heart rate may be too slow, and the heart muscle may not get the flow of oxygenated blood it needs. The body's supply of oxygen is often inadequate because the heart is not pumping sufficient oxygen-carrying blood to the body. Exercise becomes progressively less tolerable. In the extreme case, Stokes–Adams seizures may develop; these are manifested by a loss of consciousness and convulsions because of lack of oxygen in the brain. Heart block does not usually cause the heart to stop beating completely. The ventricles often beat for varying intervals but at a greatly slowed rate.

An arrhythmia is any disturbance in the rhythm of the heart with respect to its rate or its regularity. Arrhythmias are of two kinds: disturbances of conduction and disturbances of the origin of the impulse.

Those failings of the conduction system of the human heart can often be corrected with a cardiac pacemaker.

The pacemaker supplies properly timed stimulating pulses to the heart muscle, to maintain an effective heartbeat when the heart itself fails to do so. The function of the pacemaker is analogous to simply touching an electric wire to a muscle to cause a contraction. The basic function of the implantable pacemaker is to send pulses of current from the battery to the heart.

Any pacemaker is made up of a power source or battery, a pulse generator, and an electrode lead. Different circuits provide different pacemaker functions, each of which is designed to assist the heart in a specific way. Fixed-rate pacemakers provide the simple automatic switching of pulses of current to the heart and run undeviatingly at a preselected rate, usually 70 beats per minute. Demand pacemakers sense any spontaneous ventricular contractions and avoid competing with naturally occurring rhythms. When the heart does not beat for a predetermined time, the demand pacemaker takes over, feeding pacing pulses to the heart. If the natural heartbeat appears and begins to pace itself, the pulse generator in the pacemaker is suppressed and no pacing pulses are released. Other specialty pacemaker types include atrial synchronous, which sense and are controlled by atrial activity; and R-triggered, an early design aimed at avoiding competition with natural rhythms.

(This description was adapted, with permission, from *An Overview of Pacing*, by William Jakobi, published by Medtronic, Inc., Minneapolis, Minn., 1973.)

---

battery failure at that time was moisture penetrating the pacemaker package. The moisture caused metallic dendrites to grow, with the result that one or more of the battery cells would eventually short-circuit.

Once these various failures started being documented, and certain failure patterns emerged, steps were taken to find solutions to the problems. Power sources were improved, new power sources were developed, pacemaker current drain was reduced, electrodes were designed to prevent the problems described earlier, and stricter manufacturing specifications were instituted for electric and other components. Encapsulation of the entire pacemaker package received a lot of attention. All of these approaches were aimed at extending pacemaker lifetimes.

Improved power sources

Mercury–zinc oxide cells are still widely used in cardiac pacemakers. Although they do not approach the five-year lifetimes predicted in the early 1960s, they now last considerably longer than they used to, perhaps 33 months on the average as compared with 18 months in the early days. Numerous improvements have been made in their design, including better electrode separators within cells, improved sealing, and much more stringent quality control. But longevity for pacemakers is apparently keyed to other types of power sources.

One of the new power sources is the solid-state lithium battery. A radically new approach to primary electric cells, a spontaneously forming salt crystal—lithium oxide—is used instead of a liquid for the electrolyte. The anode is lithium and the cathode is an iodide, and the cell generates electricity by means of migrating lithium ions through the salt. Pacemaker circuits must be designed to match the high internal resistance of the lithium-iodide battery. In addition to its higher energy density as compared with that of a mercury battery, the lithium battery

has the added advantage of not generating gas, and thus can be hermetically sealed. This combination of high energy density and hermetic sealing is expected to lead to longer battery life than that of mercury types—but the lithium units have not been in use long enough to demonstrate whether, in reality, this life expectancy will be realized. (In more than 35 000 clinical implants to date, some more than 4½ years old, no lithium-powered pacemaker is known to have been explanted because of a failed battery.) There are also many liquid-electrolyte lithium batteries. Each type has its advantages and possible disadvantages.

Another approach to improved power sources is the use of radioactive materials such as plutonium 238. In the thermoelectric type of nuclear power source, heat is produced by absorption of the radiation emitted from the radioactive element plutonium 238. This heat is then converted into electric energy by thermoelectric elements. In the beta-voltaic type of nuclear power source, beta radiation from the radioactive element prometheum 147 produces electron-hole pairs in a pn junction of a semiconductor crystal. Predicted service life for plutonium-powered pacemakers is more than ten years but, as with lithium battery units, it is too early to know whether this prediction will hold true. The fact that more than 2000 plutonium-powered units have already been implanted, some as long as five years ago, with no known failure of a nuclear power supply, suggests that the ten-year objective may easily be achieved.

Nuclear-powered pacemakers are about four times as expensive as mercury battery pacemakers and about two to three times as expensive as lithium battery pacemakers. The cost/benefit ratio is more favorable for younger patients with longer anticipated lifetimes than it is for older patients whose life expectancies fall far short of the nuclear pacemaker's projected life. Nuclear pacemakers are expensive to manufacture because of the extensive

amount of record keeping required by the Nuclear Regulatory Commission (NRC). Manufacturers are licensed by the NRC and, at present, are not allowed to distribute more than 20 nuclear-powered pacemakers per month. This restriction by the NRC is based on a concern for the possible risk to the environment. A recently issued environmental impact statement, however, reports that benefits to be derived from use of plutonium-powered cardiac pacemakers are greater than the risk to the environment. As a result, NRC is working on new rules and regulations under which unlimited distribution by licensed manufacturers will be possible.

As mentioned previously, in the early days of implantable pacemakers, those with rechargeable batteries were found to be unsatisfactory. One of the reasons was that battery technology was not sufficiently advanced to give long battery life through multiple rechargings. Now, however, rechargeable pacemakers are once again being implanted. They take advantage of experience with space satellite power cells and use modified versions of these cells specially designed for implantation in the body.

Present-day rechargeable pacemakers use hermetically sealed nickel-cadmium power sources believed to be unaffected by repeated charging or total discharging so that a 30-year design life is expected. The charging procedure is performed by the patient using a portable charging console that accompanies the pacemaker. By placing a small charging head over the pacemaker (held in position by a small vest), the charge energy is transmitted safely without sensation through the intact skin. Charge time required is one hour per week or four hours per month.

Rechargeable pacemakers, now account for only about 10 percent of all pacemakers being implanted. One disadvantage is the psychological effect on the patient of going through the periodic recharging routines. Also, many doctors prefer to control the recharging process in the hospital or at their offices, rather than having it done by the patient at home. A new pacer, which has been developed at The Johns Hopkins University, requires recharging for only 1½ hours every four to six months, when the patient has his or her regularly scheduled physical checkup. Implanting of this type of rechargeable pacemaker was started early this year.

Other power sources under investigation include electrochemical sources of energy within the human body. In Germany, biogalvanic pacemakers have been implanted in humans for up to 18 months. And if selective electrodes are implanted in the body, body-integrated fuel cells can be created. Their life would be limited only by the natural aging of the catalyzers and by the growth of impermeable membranes within the body.

Improved electrodes and leads

Because of the history of troublesome leads and electrodes, much developmental effort has been expended to find more reliable designs. These designs have been aimed at eliminating the problems mentioned earlier, such as shifts in position. Many of the problems arose because pacemaker leads flex each time the heart beats. With an average heart beat of 70 times per minute, the leads flex 36 million times in just one year. And corrosion effects caused poor signal conduction to the heart.

Some of the design approaches taken to offset these problems are: bipolar electrodes (two electrode contacts

on the heart itself) instead of unipolar electrodes (only one electrode contact on the heart); coil spring leads less subject to breaking; screw-in electrode heads and hook electrodes to eliminate shifts in position; and use of new electrode materials to offset corrosion—such as platinum, platinum-iridium alloy, and titanium.

Have the problems been solved?

Despite the improvements described, problems still remain. In recent months, for example, two leading cardiac pacemaker manufacturers have had to notify physicians of potential problems with certain models of their pacemakers. In one case, the manufacturer warned that failure might occur because of corrosion when body fluid penetrates the pacer's epoxy seal. In the other, the manufacturer warned that water vapor might penetrate a solder seam on the circuitry case, causing a short circuit due to "metal migration." Both of these problems have a familiar ring.

Since early 1972, according to the U.S. Food and Drug Administration, there have been 35 000 to 40 000 "recalls" of pacemakers identifying specific problems. Most of these problems did not require surgical removal of the pacemaker but did necessitate careful monitoring of the patient by a physician.

In spite of problems that remain, few would dispute that the cardiac pacemaker is a "successful" medical electronic development. New developments may make it even more versatile. For example, Dr. Funke at the University Clinics of West Germany is testing, in animals, a pacemaker he has developed that is controlled by the rate at which the user breathes. Most pacemakers in use today are units that cannot compensate for the increased respiratory rate that accompanies increased physical activity. Dr. Funke's pacemaker operates between 60 and 146 pulses per minute, depending upon changes in the patient's breathing rate.   ◆

Aeronautics

Apollo

Skylab

Viking—Mars

High-Energy Astronomy Observatory

Mariner—Jupiter/Saturn

Pioneer—Venus

Space Shuttle

Ground instrument and data analysis

Nimbus

Tiros

Landsat (ERTS)

Seasat

70

60

50

40

30

20

ATS—IV and V

10

ATS—VI

0

1968