

The Role of Electrochemical Power Sources in Modern Health Care

by Curtis F. Holmes

It has been more than forty years since the first implantable pacemaker was implanted into an animal. Two years later, in 1960, the first successful pacemaker was implanted into a human. This event ushered in an era of battery-powered biomedical devices that have played an increasingly important role in health care.¹

Today a variety of battery powered implantable devices are routinely implanted into patients to treat ailments ranging from irregular heartbeat to pain and epilepsy. Moreover, a wide variety of battery powered external devices are used to administer drugs, treat ailments, and monitor bodily functions. Battery powered devices thus play a very important role in the treatment of disease. This paper will discuss some of the more common applications of batteries in medical devices.

The Cardiac Pacemaker

In the 1950s it became common to treat a patient suffering from bradycardia with an external pacemaker which applied electrical shocks through the skin. The first units were powered by normal line power. The treatment was painful and patient mobility was severely restricted. Later a battery-powered hand-held device was developed by Earl Bakken and was used with myocardial leads, which eliminated much of the discomfort caused by the earlier line-powered units.

The invention of the transistor in the 1950s provided the possibility of creating an implantable battery-powered pacemaker. Greatbatch and Chardack in the U.S. and Sennig in Sweden were both pursuing this goal.² The Greatbatch/Chardack team succeeded in producing a device powered by zinc/mercuric oxide cells. The first of the Sennig units was powered by nickel-cadmium rechargeable cells. The first implants of this unit were not successful, but the Greatbatch/Chardack unit was successfully implanted into a patient in 1960. Figure 1 is a picture of a very early pacemaker. This unit contained ten zinc/mercuric oxide cells and two transistors.

For the next ten years, pacemakers became increasingly common. The zinc/mercuric oxide battery system remained the system of choice, although a rechargeable pacemaker, using nickel cadmium cells, and a nuclear-powered pacemaker were also developed. There were drawbacks associated with the zinc/mercuric oxide cells, notably the evolution of hydrogen, the significant self-

discharge, and the abrupt end of service characteristic.

The development of lithium batteries in the late 1960s provided an attractive alternative to the zinc/mercuric oxide cells. The first lithium battery to be used in a pacemaker was the lithium/iodine-polyvinylpyridine (PVP) battery, first implanted in Italy in 1972. Other lithium systems were also used, notably silver chromate, cupric sulfide, and thionyl chloride. However, these systems have lost favor, and today almost all pacemakers use the lithium/iodine-PVP system. This system has a volumetric energy density of nearly 1.0 Wh cm^{-3} , and has shown outstanding reli-



Fig. 1. A very early cardiac pacemaker (ca. 1961), containing two transistors and ten zinc/mercuric oxide primary batteries.

bility. One significant advantage of the lithium/iodine-PVP system is the design flexibility of the system. The batteries can be designed in a wide variety of shapes and sizes, offering design options to device developers. Figure 2 shows an example of different lithium/iodine-PVP battery shapes. Over five million lithium/iodine-PVP cells have been implanted since 1972.

The lithium/iodine-PVP system has one significant drawback, which may lead to the use of solid cathode, liquid electrolyte batteries in some advanced pacemakers. This drawback is the high internal impedance of the system, which causes the system to be significantly limited in its current-delivery capacity, particularly late in battery service. However, this system will still see significant service for the foreseeable future.

Devices to Treat Tachycardia and Fibrillation

Tachycardia is a condition in which the heart beats very fast. Untreated, it can degenerate into ventricular fibrillation, where the heart stops beating and shakes uncontrollably. Without emergency intervention such as the application of external defibrillation, the outcome of this is always fatal.

Dr. Michel Morowski believed that an implantable device could be developed which could sense ventricular fibrillation and supply a shock directly to the heart, saving the life of the patient. In 1980, the first such device was implanted and proved effective. The first units were powered by lithium/vanadium pentoxide solid cathode, liquid electrolyte batteries. These were soon replaced by batteries using a cathode material known as silver vanadium oxide. This system can power the background monitoring functions and can provide a 30 joule pulse when ventricular fibrillation is sensed.

The first implantable cardioverter/defibrillators simply detected ventricular fibrillation and provided a high-energy shock to stop the fibrillation and restore normal sinus rhythm. Today's units provide a much wider variety of functions. They sense tachycardia and attempt to pace the patient back to normal sinus rhythm before ventricular fibrillation results. They also can provide normal bradycardia pacing. More sophisticated units can store clinical data which can be retrieved by the physician via telemetry. Such units can also sense and pace in both the ventricles and the atria, providing a treatment for atrial fibrillation, a less serious but still health-damaging condition.

There also exists a device designed to treat only atrial fibrillation. This device provides lower energy shocks (1-4 joules) to stop atrial fibrillation. The device uses a lower-rate lithium/silver vanadium oxide battery.

Neurological Stimulators

A variety of medical problems can be treated by neurostimulators. These devices stimulate various nerves to provide relief of chronic pain and address other neurological disorders. It has been found that electrical stimulation of nerves in the spinal chord area can provide dramatic relief of chronic pain. Neurostimulators have been used for several years for this purpose. Other uses of these devices include stimulation of the brain to treat the symptoms of Parkinson's disease and stimulation of the vagus nerve to prevent epileptic seizures.

Neurostimulators operate electrically much like cardiac pacemakers. However, the current required to produce the desired result is usually much higher than the currents required to treat bradycardia. The pulse currents are typically in the milliampere range rather than the microampere range used for cardiac pacing. Accordingly, the batteries powering these devices must provide higher current drains than do those used in cardiac pacemakers, and the lithium/iodine system is not suitable for this application.

Both lithium/thionyl chloride batteries and lithium/carbon monofluoride batteries are used in neurostimulators. These systems provide the current-delivery capability necessary for this application. Another result of the higher current requirements of neurostimulators is that the batteries must be rather large to pro-

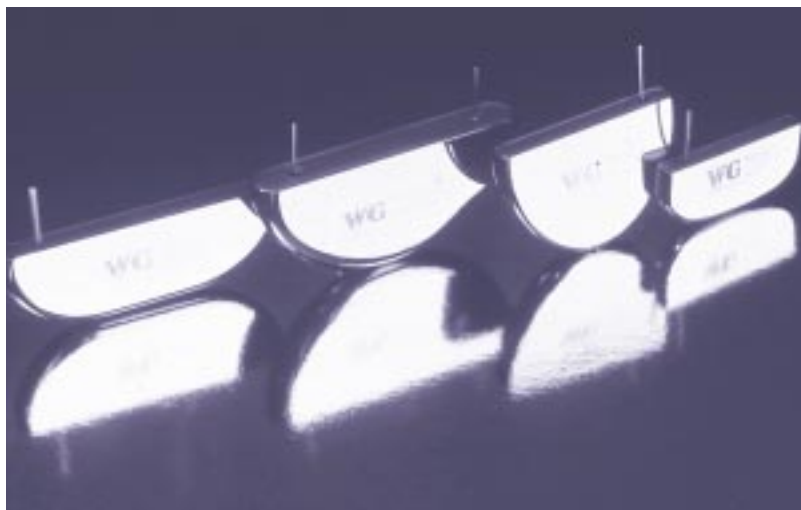


Fig. 2. Typical lithium/iodine pacemaker batteries in use today.

vided adequate longevity. Neurostimulators of the future may be powered with secondary batteries, as will be discussed later in this paper.

Implantable Drug Delivery Systems

Implantable drug delivery systems have been used for over ten years to provide chronic drug treatment. The devices consist of a reservoir to contain the drug, a pumping mechanism to deliver the drug through a catheter to the destination site, electronics to control the system, and a primary battery. The device is refilled through the skin with a hypodermic needle, which enters a septum on the device.

Among the diseases treated with these devices are cancer, multiple sclerosis, cerebral palsy, and chronic pain. The largest potential application of this technology, however, is the administration of insulin to diabetics. This application is under clinical investigation now, and developers and physicians are optimistic about the prospect of treating diabetes with this device.

The drug delivery system is a medium-rate application, requiring milliamperic level current pulses over a constant microampere level background drain. Both lithium/thionyl chloride and lithium/carbon monofluoride batteries are used in these devices.

Devices Requiring Secondary Batteries

There exist several implantable medical devices, which, because of the high current drains required, need secondary batteries for their successful use. Among these are left ventricular assist devices (LVAD), implantable hearing assist devices, and some neurostimulators.³

As was stated above, the use of rechargeable batteries in implantable devices is not new. The first pacemakers developed in Sweden in 1958 used such batteries, and later, in the late 1960s, a more sophisticated pacemaker was designed using a nickel cadmium secondary battery optimized for use at 37°C. Accompanying this technology was the development of the techniques of recharging the battery by transcutaneous transmission of energy by telemetry.

Because primary lithium batteries could power pacemakers for many years, the rechargeable pacemaker was supplanted in the marketplace by devices using lithium primaries. However, the devices mentioned above will require secondary batteries to provide adequate longevity.

The LVAD is a pumping mechanism attached to the heart. It was originally designed as a "bridge" to transplant, i.e. as a device that would allow a candidate for heart transplant to survive until a donor heart was available. Today the devices have been recognized as having therapeutic benefit even if a heart transplant is not forthcoming.

The power requirements for this device are so high that even a rechargeable implantable battery is inadequate to provide the power. Accordingly, the patient wears an external battery pack on a vest-like device, and power is transmitted to the device by telemetry. A small implantable battery pack is used in some such devices to provide the patient with a backup implantable device in case of failure of the external pack, and to provide the patient with about one hour per day of independent power support.

Lithium-ion rechargeable batteries are in development for use in both the implantable and the external battery systems for these devices. Preliminary test results are encouraging.

Several implantable hearing assist devices are in use or are under development. Implantable cochlear stimulation devices convert acoustic signals to stimulation of the cochlear nerves in order to treat profound deafness. They have been in use for several years. Less invasive implantable hearing devices are now in clinical evaluation. These devices may offer effective treatment for patients who are not adequately served by conventional hearing aids. Lithium-ion rechargeable batteries are in development for these devices. The batteries are small coin-type cells, which can be implanted with the device and recharged through the skin.

Finally, some neurostimulators may require secondary batteries to achieve adequate longevity in a device that is of acceptable size for implantation. The higher power requirement of such devices make lithium-ion rechargeable cells an attractive technology for the power source.

External Medical Devices

Many external medical devices rely on electrochemical power sources for their energy. Indeed, one can think of examples ranging from battery operated wheelchairs to Holter monitors. External defibrillators typically use sealed lead acid or nickel cadmium rechargeable batteries as power sources. However, the newer, smaller devices

use primary cells such as the lithium/manganese dioxide cell. Ambulatory drug delivery systems and Holter monitors use either rechargeable cells or commercial alkaline AA cells for power.

Many surgical tools are battery-powered, allowing the surgeon to use the device unencumbered by chords or air-driven power sources. Some such tools, designed to be used in the magnetic resonance environment, are powered by specialty lithium/oxyhalide cells designed to have a very low magnetic signature.

Summary

Medical devices powered by electrochemical power sources play a vital role in the treatment of disease and the well-being of patients. Since the first pacemaker was developed in the 1950s, advances in battery technology, electronics, and medical knowledge have produced a remarkable variety of sophisticated implantable and external medical devices. The development of lithium-ion rechargeable battery technology is beginning to make its contribution to medical devices capabilities, offering higher energy density and good reliability.

It is expected that newer generations of battery-powered devices will treat even more diseases, such as congestive heart failure and neurological disorders. The continued progress in development of batteries and devices will continue to make an important contribution to health care. ■

References

1. C. F. Holmes, *Journal of Power Sources*, **65**, xv (1997).
2. W. Greatbatch and C. F. Holmes, *IEEE Engineering in Medicine and Biology*, p. 38 (September 1991).
3. C. F. Holmes, R. A. Leising, D. M. Spillman, and E. S. Takeuchi, *ITT Battery Letters*, **1**, 133 (1999).

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