

The role of lithium batteries in modern health care

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Received 6 June 2000; accepted 11 December 2000

Abstract

Since the implantation of the first lithium-powered pacemaker in 1972, biomedical devices powered by lithium batteries have played a significant role in saving lives and providing health-improving therapy. Today a wide variety of devices performing functions from managing cardiac rhythm to relieving pain and administering drugs is available to clinicians. Newer devices such as ventricular assist devices and implantable hearing devices are powered by lithium ion secondary batteries. © 2001 Elsevier Science B.V. All rights reserved.

Keywords: Medical; Applications; Lithium; Review

1. Introduction

It has been 28 years since the first implantable device powered by a lithium battery was implanted. The implantation of the first lithium-powered pacemaker took place in Italy in 1972 [1], and it ushered in an era of development of many different battery-powered devices that have contributed greatly to human health. The use of lithium batteries in implantable devices was arguably one of the first successful commercial applications of lithium battery technology, and today virtually all implantable devices requiring battery power use lithium primary or lithium-ion secondary batteries. This technology has enabled the development of a wide variety of devices used in the treatment of a remarkable number of human ailments. Lithium batteries have proven to be reliable, safe, and long lasting in this important application. This paper will review the battery-powered devices in use or in development today.

2. Cardiac rhythm management

The first successful cardiac pacemaker was implanted in 1960 [2]. That unit used zinc/mercuric oxide batteries. Although nuclear batteries and rechargeable batteries were evaluated and used in some pacemakers, the use of zinc/mercuric oxide batteries became the standard power source for most pacemakers in the 1960s [3]. Although they enabled

the first pacemakers, this technology had several drawbacks, including the generation of hydrogen gas, high self-discharge, and an abrupt end-of-service indication. Pacemakers typically lasted between 24 and 36 months. With the advent of lithium batteries, longevity in excess of 10 years was possible, the pacemakers could be hermetically sealed, and a more gradual approach to end-of-service voltage was seen. Several lithium-anode systems were used in the late 1970s, including lithium/silver chromate, lithium/cupric sulfide, and lithium/thionyl chloride. The most commonly used system, however, was the lithium/iodine-polyvinylpyridine (PVP) system, invented by Schneider and Moser [4,5] and improved by Greatbatch, Mead, and Rudolph [6]. By the late 1980s almost all cardiac pacemakers were powered by this system, and that remains the case today. This system can provide the microampere-level pulses required by the device and has a gradual and easily detectable approach to end-of-service voltage. It is expected, however, that some pacemakers of the future may be powered by medium-rate lithium batteries such as lithium/manganese dioxide or lithium/carbon monofluoride [7].

Cardiac pacemakers treat a variety of illnesses known collectively as bradycardia, in which the heart beats too slowly. A more malevolent disease is tachycardia, in which the heart rate is too fast. Left untreated, this condition can lead to ventricular fibrillation. The heart stops beating and, absent intervention, the patient dies. The use of external defibrillators to stop ventricular fibrillation and restore the heart to normal rhythm had been used for several decades, and a physician named Michel Mirowski believed that an implantable defibrillator that detected and stopped ventri-

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cular fibrillation was possible. In 1980, the first such device was implanted into a human patient [8]. This development set off intense developments by several companies to improve the device. The first implantable defibrillators simply detected ventricular fibrillation and provide an electrical shock of about 20–40 J directly to the heart via an electrode that was sutured onto the heart. Most ICDs use lithium/silver vanadium oxide batteries today, although lithium/manganese dioxide batteries are also used. The lithium/silver vanadium oxide system, originally developed for commercial applications by Liang and coworkers [9], has been adopted for implantable medical use in both multiplate prismatic designs [10] and rectangular “jellyroll” designs [11]. Implantable cardioverter/defibrillators (ICDs) today have many sophisticated capabilities compared to first units that simply stopped ventricular fibrillation. These units sense tachycardia and attempt to pace the heart back to normal sinus rhythm before ventricular fibrillation occurs. Today’s units can perform bradycardia pacing as well. The patch electrodes, which required a thoracotomy to install, have been replaced with a transvenous lead that can be implanted into the heart without such invasive surgery. The devices are programmable and can transmit clinical data through telemetry. Some such devices can also treat atrial fibrillation.

Studies are currently underway to test the effectiveness of biventricular pacing devices in the treatment of congestive heart failure [12]. More will be known about the effectiveness of this treatment when these trials are completed. Devices to treat this condition typically have both bradycardia and tachycardia capabilities.

3. Neurostimulators

Neurostimulators were developed in the 1980s to provide relief for intractable pain [13]. The devices provide electrical stimulation in the form of pulse trains to various nerves in the human body. In the intervening years since their initial application, many other medical conditions have been treated with neurostimulators. Today these devices are used in the treatment of urinary incontinence, intractable spasticity, and tremor control [14]. One such device has been determined to be effective in controlling epileptic seizures and is under evaluation for the treatment of clinical depression [15]. Neurostimulators are essentially pacemakers that operate at higher currents, typically 1–5 mA pulses. They are powered by lithium/thionyl chloride or lithium/carbon monofluoride medium rate batteries.

4. Implantable drug delivery devices

Implantable drug delivery systems are sealed devices which contain a refillable reservoir, a pumping mechanism, electronic control circuitry which can be programmed exter-

nally, and a catheter to deliver the drug to the appropriate location. They are used to provide chronic administration of drugs to treat such conditions as cancer, multiple sclerosis, cerebral palsy, and traumatic injury [16]. A device to provide controlled administration of insulin is under clinical investigation at this time, and well over one thousand devices have been implanted in insulin dependent diabetics [17]. These devices are typically powered by lithium/thionyl chloride or lithium/carbon monofluoride primary batteries.

5. Devices using lithium ion rechargeable batteries

There are implantable devices whose current demands preclude the use of primary batteries because of size limitations. The left ventricular assist device (LVAD), an implantable pumping mechanism, provides long-term support to patients afflicted with heart disease. It is attached to the heart by a valving mechanism and is powered by external batteries worn by the patient. Some such devices also include an implantable secondary battery that provides for about 1 h of operation per day [18]. LVADs were originally thought of as devices for patients who were waiting for a human heart for transplantation. However, with the acute shortage of such hearts, the devices are serving as more permanent treatment for many patients. Lithium ion rechargeable batteries are seeing service as both the external and implantable power source for some such devices.

Implantable hearing devices treat hearing loss in patients whose hearing loss is not adequately treated by external hearing aids. Implantable cochlear devices treat profound deafness by stimulation of multiple locations in the cochlea. Other devices convert acoustic signals into mechanical energy that stimulates the bones of the ossicular chain [19]. The devices must be small, and the high current requirements are well met by rechargeable lithium ion batteries [20].

6. Summary

Since 1972 well over five million patients have received implantable medical devices powered by lithium batteries. The first devices, implantable pacemakers, treated bradycardia. Later cardiac rhythm control devices treated tachycardia and ventricular fibrillation. Implantable neurostimulators treat a remarkable variety of medical conditions, from intractable pain to incontinence, epilepsy, and tremors. Drug delivery systems treat a variety of illnesses. Left ventricular assist devices save lives that otherwise might be lost, while waiting for a heart transplant. More recent biomedical devices treat hearing loss. The contribution of lithium batteries to medical science and practice has been great, and the more recent development of lithium ion rechargeable batteries for newer implantable device offers even more available therapies for patients in need.

References

- [1] G. Antonioli, F. Baggioni, F. Consiglio, G. Grassi, R. LeBrun, F. Zanardi, Stimulatore cardiaco impiantabile con nuova batteria a stato solido al litio, *Minerva Med.* 64 (1973) 2298.
- [2] W. Greatbatch, W. Chardack, A transistorized implantable pacemaker for the long-term correction of complete atrioventricular block, *Proc. New England Res. Eng. Meeting (NEREM)* 1 (1959) 8.
- [3] A. Salkind, S. Ruben, in: B.B. Owens (Ed.), *Batteries for Biomedical Implantable Devices*, Plenum Press, New York, 1986, p. 261.
- [4] J.R. Moser, Solid state lithium iodine primary battery, US Patent 3,660,163 (1972).
- [5] A.A. Schneider, J.R. Moser, Primary cells and iodine-containing cathodes therefor, US Patent 3,674,562 (1972).
- [6] C.F. Holmes, Electrochemical power sources — an important contributor to modern health care, *J. Power Sources* 65 (1997) XV.
- [7] W. Greatbatch, C.F. Holmes, E.S. Takeuchi, S.J. Ebel, Lithium carbon monofluoride: a new pacemaker battery, *Pacing Clin. Electrophysiol.* 19 (1996) 1836.
- [8] M. Mirowski, M.M. Mower, P.R. Reid, The automatic implantable defibrillator, *Am. Heart J.* 100 (1980) 1089.
- [9] C.C. Liang, M.E. Bolster, R.M. Murphy, Metal oxide composite cathode material for high energy density battery, US Patent 4,310,609 (1982).
- [10] P. Keister, R.T. Mead, B.C. Muffoletto, E.S. Takeuchi, S.J. Ebel, et al., Non-aqueous lithium battery, US Patent 4,830,940 (1989).
- [11] A.M. Crespi, F.J. Berkowitz, R.C. Buchman, M.B. Ebner, W.G. Howard, R.E. Kraska, P.M. Skarstad, The design of batteries for implantable cardioverter defibrillators, in: A. Attewell, T. Keily (Eds.), *Power Sources 15: Research and Development in Non-Mechanical Electrical Power Sources*, Alan Sutton Publishing Ltd., Stroud, UK, 1995, p. 349.
- [12] R.W. Moore, Congestive heart failure — causes and treatments, in: *Rhythm and News*, 1999, URL: <<http://www.guidant.com/patient/rhythmnews/1999/chf.htm>>, accessed 9 May 2000.
- [13] A.J. Salkind, A.J. Spotnitz, B.V. Berkovits, B.B. Owens, K.B. Stokes, M. Bilitch, Electrically driven implantable prostheses, in: B.B. Owens, (Ed.), *Batteries for Biomedical Implantable Devices*, Plenum Press, New York, 1986, p. 26.
- [14] Neurological and Spinal Overview, URL: <<http://www.medtronic.com/neuro/>>, accessed 11 May 2000.
- [15] R. Terry, W.B. Tarver, J. Zabara, An implantable neurocybernetic prosthesis system, *Epilepsia* 31 (Suppl. 2) (1990) S33.
- [16] C.F. Holmes, Electrochemical power sources — an important contributor to modern health care, *J. Power Sources* 65 (1997) XVII.
- [17] C.D. Saudek, J.L. Selam, H.A. Pitt, K. Waxman, M. Rubio, et al., A preliminary trial of the programmable implantable medication system for insulin delivery, *NEJM* 321 (1989) 574.
- [18] C.F. Holmes, R.A. Leising, D.M. Spillman, E. Takeuchi, Batteries for biomedical implantable devices, *ITE Battery Lett.* 1 (1999) 132.
- [19] G.R. Ball, J.M. Culp, C. Marr, R. Dietz, J.D. Salisbury, Implantable and external hearing systems having a floating mass transducer, US Patent 5,624,376 (1997).
- [20] C.F. Holmes, R.A. Leising, D.M. Spillman, E. Takeuchi, Batteries for biomedical implantable devices, *ITE Battery Lett.* 1 (1999) 134.