Historical Perspectives

A Brief History of Cardiac Pacing

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The electrical stimulation of diseased and damaged hearts is such a widely accepted and prescribed therapy today that it may be difficult to believe that the implantable cardiac pacemaker has been in clinical use only slightly more than 30 years. It is also interesting to note that industry forecasts of the early 1960s predicted all-time, worldwide sales of some 10,000 pacemakers,* but in the 1990s an estimated 350,000 pacemakers, manufactured by about 20 different companies, are implanted worldwide each year.[1]

However, the advanced electronics, small size, exceptional reliability, and extended life span of modern pacemakers could scarcely have been imagined 3 decades ago. Today, cardiologists, cardiovascular surgeons, and electrophysiologists can provide their bradycardia patients with fully integrated systems comprising multisensor pulse generators that provide physiologic response, yet weigh as little as 25 grams. Low-threshold, steroid-eluting leads, used in conjunction with lithium-iodine power sources, can extend the practical life of the device to upwards of 10 years. These features, combined with a wide range of computer-based programming options, make modern pacing a cost-effective technology capable of yielding demonstrable benefits to patients. Hundreds of thousands of patients around the world are living proof of the diminutive device's restorative powers.

The success of the implantable pacemaker as a therapy for patients with slow or irregular heartbeats caused by electrical conduction disorders can be attributed to a series of discoveries and advances dating back much farther, however, than the early 1960s. Today's implantable pacemaker owes its existence to the invention and refinement of external pacing devices that began in the 1920s, as well as to several coincidental developments in such diverse fields as cardiovascular surgery, electrical engineering, polymer chemistry, and public policy.

External Beginnings

The concept at the core of pacing therapy—applying an outside source of electrostimulation to human tissue—goes back at least as far as ancient Rome, where physicians used the natural electrical discharges of the electric ray (sometimes known as a crampfish or torpedo) to treat patients with gout and other painful ailments.[2]

At least as early as the middle of the 18th century, there were rudimentary attempts to accelerate the heart with electricity. Dr. Charles Kite of England, during the latter part of that century, wrote about an electrical device—perhaps the world's 1st direct-current defibrillator—that he used to revive a patient who appeared to be dead.[3,4] It was not, however, until the late 19th century, when the British physician John Alexander MacWilliam pulled together the diverse components of existing electrostimulation knowledge, that medicine had its 1st integrated theory of cardiac pacing.[2]

In the 1920s and 1930s, pacing theory was for the 1st time translated into effective, albeit limited, therapy. Working independently of one another, Drs. Mark Lidwill of Australia and Albert Hyman of the United States developed external cardiac pacemakers for clinical application. Lidwill described his portable, alternating-current device at a medical conference in Sydney in 1929.[5,6] He told the gathering that he had used an earlier model of the pacemaker to resuscitate a stillborn infant and that the infant had "recovered completely," apparently becoming (according to historian Kirk Jeffrey) "the first human being to be paced suc-

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cessfully."[7] Hyman, in New York City, reported on his own pacing device in 1932.[8] Unlike Lidwill's machine, which plugged into a wall socket and required "plunging" a needle into the patient's ventricle, Hyman's device was driven by a hand-cranked spring-wound motor and provided electrical pulses to the right atrium via a needle electrode (Fig. 1). Jeffrey suggests that while Hyman was aware of and "likely . . . found encouragement" in Lidwill's breakthrough, the New Yorker "designed his pacemaker entirely on his own."[7]

Relatively little is known about Lidwill's device or what became of his efforts in the cause of electrostimulation. Hyman's pioneering work, for its part, came to a decidedly unfortunate end because the inventor, despite a solid personal reputation in cardiology, was beset by professional skepticism, litigation, negative publicity, and even accusations that his pacemaker was an infernal machine that interfered with the will of God. He never found a manufacturer for the device.[7]

An external pacemaker developed in the early 1950s by Dr. Paul Zoll for acute heart block brought happier results. In November 1952, Zoll, an experienced cardiologist and researcher working at Beth Israel Hospital in Boston, announced the resuscitation of a 65-year-old cardiac patient suffering from angina, congestive heart failure, and Adams-Stokes disease. Zoll's external pacemaker maintained the patient's heartbeat for more than 50 hours at a time, and the man recovered sufficiently to eventually go home.[7-9] The advances reported by Zoll and others during the 1950s, historian Jeffrey suggests, marked the real "takeoff stage of cardiac pacing, a stage dominated by radically new devices invented by physician-led research teams working in teaching hospitals. . . ."[7]

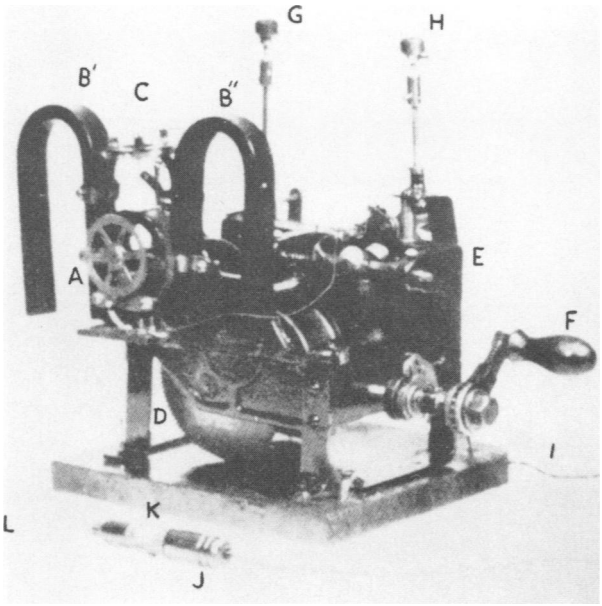

Fig. 1 *A.S. Hyman's pacemaker, from a 1932 photograph.*

A = magnetogenerator; B' and B" = companion magnet pieces; C = neon lamps; D = spring motor; E = ballistic governor; F = handle; G = impulse control; H = speed control; I = flexible electric cord; J = insulated handle; K = handle switch; L = electrode needle.

(From: Hyman AS[8])

By the mid-1950s, pacemaker developers were not only beginning to reap the benefits of improved electrical technology and materials, but of new ways of understanding and treating diseased hearts. Physicians were learning more about cardiac arrhythmias, and were becoming increasingly involved in invasive procedures in and around the heart. They were also paying more attention to diseases of the heart and doing so in a hospital setting. The public, excited by accounts of surgical heroics during World War II and of brave new technologies that presumably would lead to longer, better lives, generally applauded the new work in pacing. As Jeffrey says, ". . . Zoll's pacemaker of 1952 appeared not as an isolated foray into largely unknown territory, but as part of a broadly developing technological front. Pacing emerged in an era of intense investigation and high expectations for interventionist approaches to the heart."[7]

The external pacemakers of the 1950s had, however, several serious drawbacks. They were uncomfortable and traumatic for the patient, often burning the skin where the electrodes were attached to the chest. They were large and cumbersome—the size in most instances of the proverbial bread box—and had to be transported on carts, if they and the patient were to be transported at all (Fig. 2). Moreover, they were AC-powered devices that plugged into the wall and therefore necessitated the additional encumbrance of extension cords. The AC requirement severely limited the patient's mobility and, more significantly, made the occasional power outage a potentially life-threatening event.

It was indeed after a power outage in 1957 that Dr. C. Walton Lillehei, a pioneer in the nascent practice of open-heart surgery at the University of Minnesota in Minneapolis, asked a local electrical engineer named Earl Bakken to come up with a compact, lightweight, battery-operated pacing device. Bakken went back to the Minneapolis garage (Fig. 3) that served as headquarters and laboratory for his fledgling Medtronic, Inc., and a few weeks later brought Lillehei the world's 1st transistorized, battery-powered, wearable pacemaker.[4] About the size of a large bar of soap (Fig. 4), the device was powered by transistors instead of bulky vacuum tubes, and was equipped with myocardial leads that eliminated the old discomfort of electrodes attached

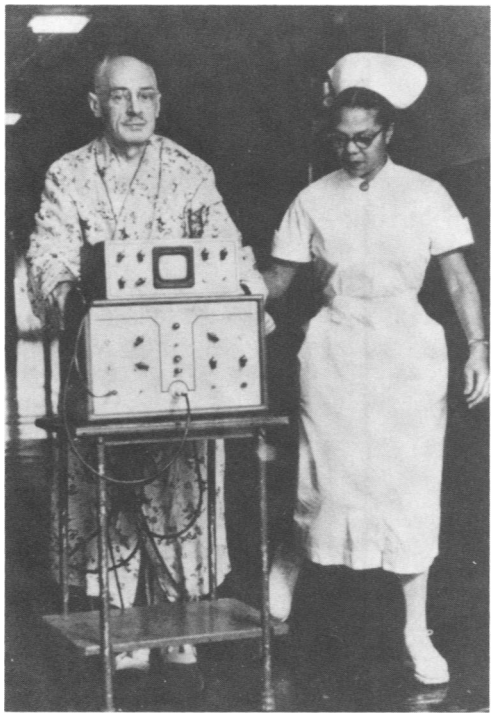

Fig. 2 *The 1st patient paced with a long-term transvenous lead, which was developed by Dr. Seymour Furman. Pacing was maintained for 96 days in 1958, at Montefiore Hospital in New York City. A 50-ft extension cord enabled ambulation.*

(From: Furman S, Escher DJW. Principles and techniques of cardiac pacing. New York: Harper & Row, 1970:283.)

to the skin.[1] The device was soon in wide use for postoperative heart block following cardiac surgery (Fig. 5).[4]

Pacing technology had taken a giant step forward during the early and mid-1950s. Moreover, the availability of the semiconductor transistor (invented in 1948), the development of biocompatible materials, and the refinement of open-heart surgery techniques made the next step—the fully implantable cardiac pacemaker—not only possible, but probably inevitable.

The Development of Implantable Pacemakers

In 1958, a Swedish team led by Åke Senning, a physician, and Rune Elmqvist, an engineer, implanted (in a heart-block patient) the 1st internal pacemaker.[10,11] That device, incorporating a transistor and powered by a nickel-cadmium battery, functioned for 3 hours before failing; a 2nd unit stimulated the patient for 8 days.[12] That same year, Dr. William Chardack and electrical engineer Wilson Greatbatch built, in Buffalo, New York, the 1st American implantable pacemaker, and began animal studies with it. (When Greatbatch approached Chardack with the concept, the physician thought about it for a moment and then exclaimed that the device could save 10,000 or more lives per year.[1] As noted earlier, industry forecasts of the early 1960s predicted all-time, worldwide

Fig. 3 *Earl Bakken at work in the 1950s, in the garage that served as Medtronic's 1st laboratory.*

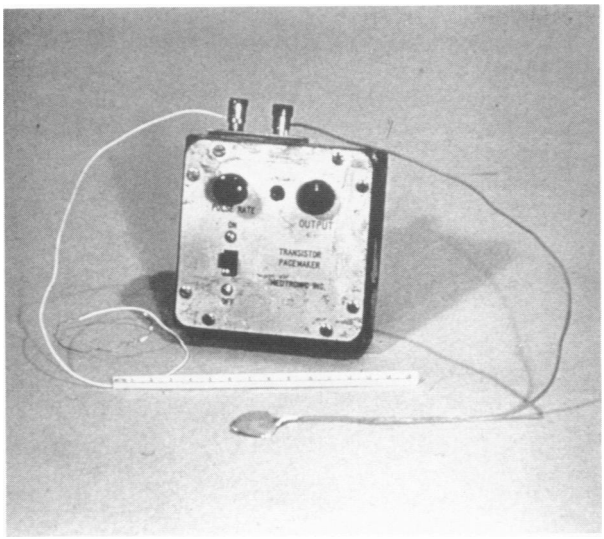

Fig. 4 *Medtronic's 1st pacemaker, built in 1957 by Earl E. Bakken for use by Dr. C. Walton Lillehei of the University of Minnesota Hospitals. About the size of a large bar of soap, it was the world's 1st transistorized, battery-powered, wearable pacemaker.*

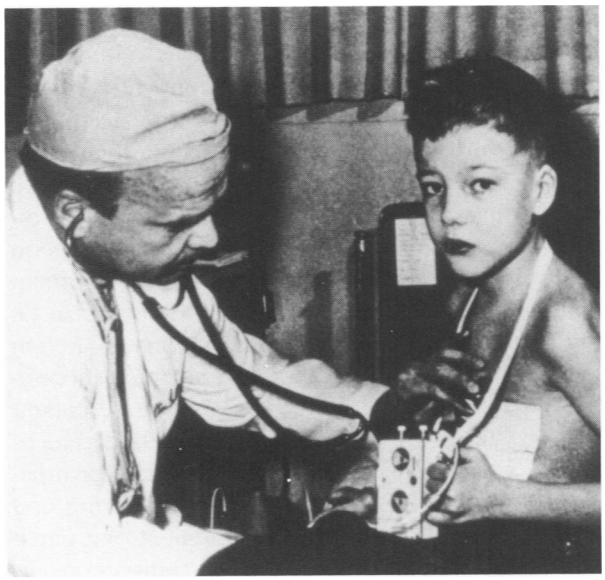

Fig. 5 *Dr. Lillehei examines a young patient who is wearing an external pacemaker of the type invented by Earl Bakken.*

(From: The Saturday Evening Post, *4 March 1961.)*

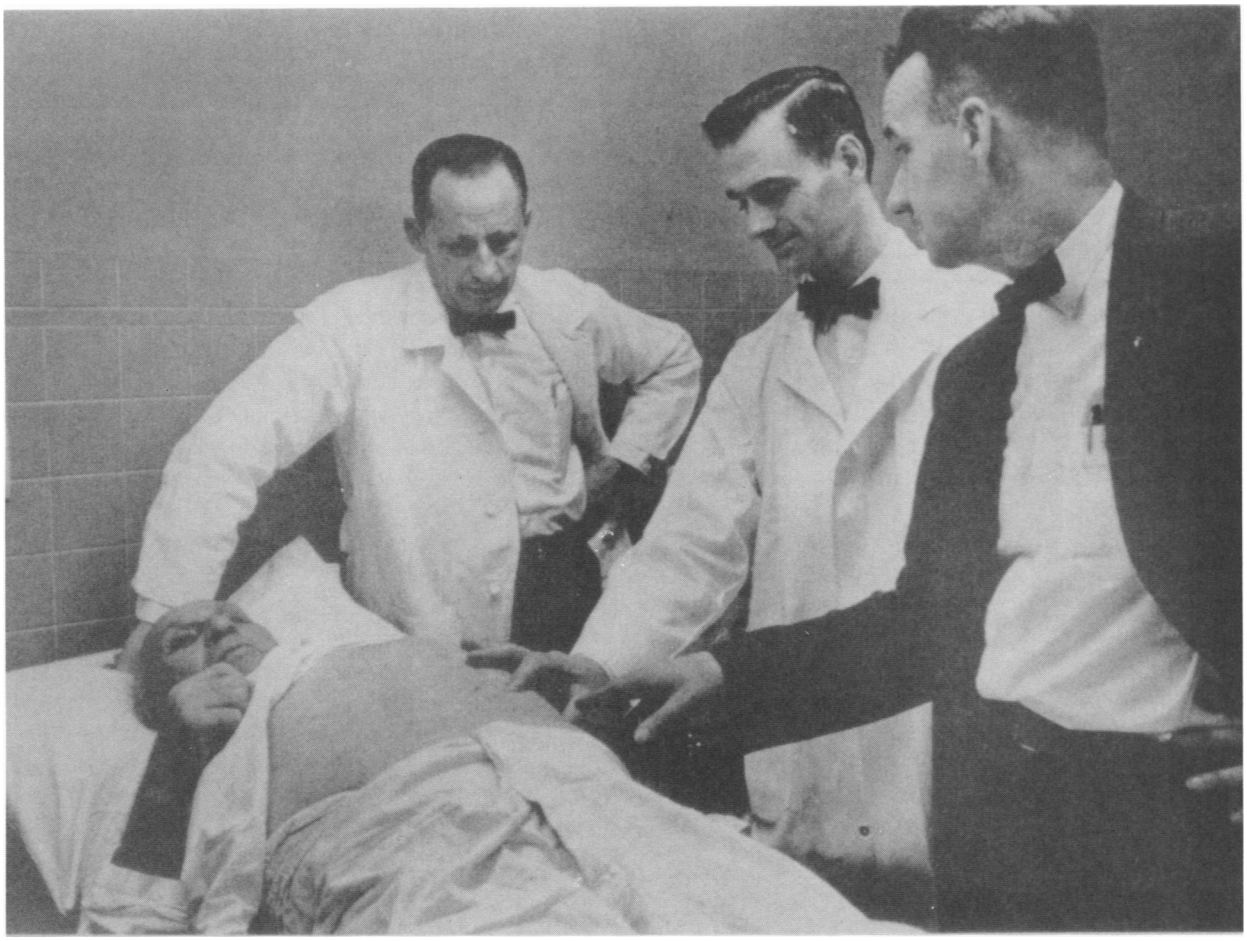

Fig. 6 *The 1st American implantation of a cardiac pacemaker was performed on 18 April 1960 by Drs. William Chardack (left) and Andrew Gage (middle). Wilson Greatbatch (right), an electronics engineer, designed and built the unit. The patient was Frank Henefelt, age 77.*

sales of about 10,000 pacemakers.* (In both instances, of course, the number proved to be far too low.) The Chardack-Greatbatch group reported its 1st human implantation in 1960 (Fig. 6).[13]

The Chardack-Greatbatch device incorporated yet another important component generated during the accelerating advance of pacing technology: the bipolar lead developed by St. Paul, Minnesota, surgeon Dr. Samuel Hunter and Medtronic engineer Norman Roth (Fig. 7). The Medtronic Hunter-Roth electrode —comprising a pair of stainless steel pins secured in a silicone rubber base—had been implanted successfully in a 72-year-old Adams-Stokes disease patient in 1958 (Fig. 8).[1] Other breakthroughs in lead technology were Chardack's invention of a myocardial electrode featuring a platinum/iridium spring coil and Dr. Seymour Furman's development of a transvenous insertion technique (Fig. 2). Transvenous insertion enabled pacemaker implantation without a thoracotomy, and with use of a local anesthetic.[14]

Fig. 8 *Warren Mauston, 1st recipient of the Hunter-Roth electrode, holds the battery-operated pulse generator developed by Earl Bakken in 1958.*

Subsequent Improvements

During the ensuing 3 decades, a series of improvements and additions made implantable cardiac pacemakers more dependable and effective. For example, the integrated circuit replaced the transistor, and was in turn replaced by the microprocessor—each permitting a smaller pulse generator while adding features and enhancing flexibility of function. Improvements in internal power sources—from the zinc/mercury oxide batteries that drove early implantable devices through experiments with plutonium power packs and rechargeable nickel/cadmium systems, to the lithium-based batteries of most of today's pacemakers—have dramatically increased both the safety and the longevity of the units, while enabling further miniaturization. More durable, biocompatible materials for both the pulse generator and the leads have allowed manufacturers to overcome problems of moisture damage, component fracture, and tissue reaction.[15-17]

Moreover, the asynchronous pacemaker that had been the standard through the early 1960s was succeeded by a more physiologic atrial-synchronous device pioneered by Drs. David Nathan and Sol Center and engineer Walter Keller.[4] Dr. Victor Parsonnet began clinical use of an implantable "standby" pacemaker in 1965,[4] and the following year Drs. Robert Goetz, Luigi Donato, and Dwight Harken, working with electrical engineer Barouh Berkovits, reported the use of an implantable "demand" (or standby) pacemaker. The demand device—which sensed whether the heart had beat or not and (if it hadn't) provided electrical stimulation in place of the natural impulse—helped establish ventricular demand pacing as a mainstream therapy within the subsequent few years.[4] Tined leads, introduced commercially during the mid-1970s, made pacing safer, more reliable, and more effective.[1]

Beginning early in the 1980s, several additional important advances were reported in the United States and around the world, including dual-chamber pacemakers that enable pacing in both the ventricle and atrium and rate-responsive devices that continuously and automatically adjust the heart rate to the patient's changing physiological requirements (Fig. 9). With the advent of rate-responsive pacing, bradycardia patients were given not only a steady "normal" heart beat, but the physiologic rate response necessary to resume everyday functions, to return to their jobs, and to enjoy vigorous exercise. Now pacemakers could not only sustain life, but significantly improve its quality.

*Bakken E. Personal communication, November 1992.

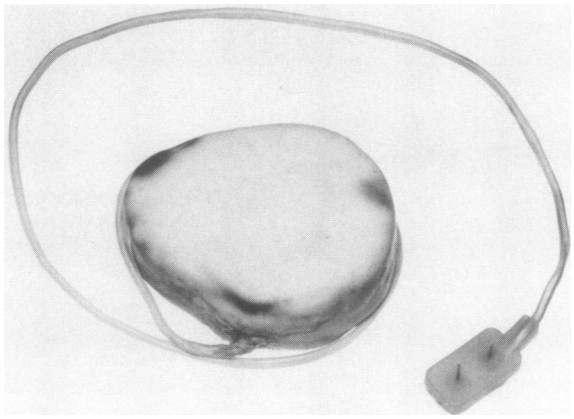

Fig. 7 *The Hunter-Roth bipolar lead, shown here on a Medtronic implantable pacemaker of 1960.*

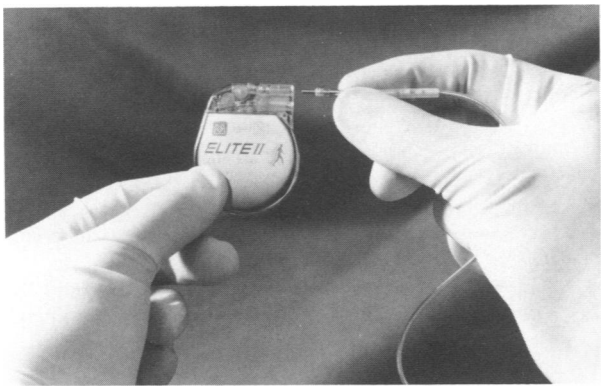

Fig. 9 *The Medtronic Elite II™, one of the world's smallest dual-chamber pacemakers, is rate responsive and offers diagnostic capabilities to the physician.*

Professional and social developments have also contributed significantly to the success of cardiac pacing. Among these are the growth in numbers and influence of cardiologists as hospital-centered medical specialists, and, more recently, the development within cardiology of the subspecialty of electrophysiology. Other important factors have been: increased support for research in cardiac disease and its treatment; the formation of productive working relationships among medical professionals, research institutions, and biomedical-device manufacturers; and the 1965 enactment of Medicare legislation, which substantially increased the elderly population's access to pacing technology in the United States.

Future Applications

Although the global growth-rate of pacemaker use has slowed somewhat in recent years, pacing therapy continues to aid more patients each year. In addition to their established use in treating bradycardia, pacemakers may prove eventually to be cost-effective and reliable therapy for such under-treated disease states as cardiomyopathy and congestive heart failure. Several methods and materials used in bradycardia pacing—e.g., microelectronics, implantable power sources, electrical stimulation and sensing, algorithms and software, and biomaterials—are being applied, successfully, to a growing list of current and forthcoming therapeutic devices, such as implantable antitachyarrhythmia pacemaker/cardioverter/defibrillators, implantable drug-administration systems, and pain-control mechanisms.

In the formative years of implantable pacemakers, most physicians had little experience with these new devices and relied on technical education and support from developers and manufacturers. In the past several years physicians have become accustomed to implantable therapeutic devices. While these devices have become easier to implant, they have become increasingly complex in both their capabilities and their maintenance. Consequently, the close collaboration between the pacing industry and the medical profession that has resulted in so many of pacing's advances is now more important than ever. The growing awareness of health-care costs will require continued collaboration to assure that future pacing systems can provide demonstrable benefits in a cost-effective manner.

Conclusion

The implantable cardiac pacemaker, now at the age of "30-something," has accomplished more as a treatment for bradycardia and as the vanguard of a host of new therapies than even the most enthusiastic of its early developers might have imagined. Each year, about a third of a million bradycardia patients worldwide receive the device, for pacing has become a standard treatment for slow or irregular heartbeats.

While the concept of electrostimulation as therapy has been recognized by scientists and physicians for centuries, the actual development of a practical, effective cardiac pacemaker required the confluence of several streams of technology, clinical experience, and social approval; this confluence began in the 1950s. A few of the essential technologic and social advances have been open-heart surgery, the semiconductor transistor, the transvenous lead, lithium-based power sources, physiologic sensors (such as the activity sensor), and, in the United States, the Medicare payment system.

Moreover, the eventual birth of the implantable pacemaker marked the practical beginning of an entire industry devoted to the development and manufacture of implantable medical devices. This industry now offers doctors and their patients an armamentarium of therapeutic devices for a range of cardiovascular, neurological, and orthopedic applications. Cardiac pacing itself may someday be applied to cardiomyopathy and congestive heart failure.

New cardiac pacing systems will incorporate further advances in sensor technology, miniaturization, and computerized instrumentation. Continued collaboration among physicians, scientists, and manufacturers will be required to provide these advances in pacing technology, together with evidence of improved and cost-effective outcomes.

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