

APPENDIX A: THE ARTIFICIAL CARDIAC PACEMAKER

by Thomas Preston

The first totally implantable cardiac pacemaker was implanted in Sweden in 1959. This was followed by the development of implantable pacers by three companies in the United States in 1960 (17,37,78). Although animal investigations predicted a problem with electrodes (rising excitation threshold), this problem was considered manageable, and there were widespread forecasts for a 5-year pacemaker longevity. The 5-year longevity prediction was based on battery capacity and calculated discharge rate. The first commercially available pacemakers were designed with the pulse generator and leads as one inseparable unit, i.e., there was no design allowance for replacement of the pulse generator alone, without disturbing the electrical connections (leads) to the heart. Although some investigators voiced caution about heightened expectations (78), in general there was optimism that a 5-year pacemaker was at hand (17,37).

Risks

The major risk of permanent pacing—operation mortality—initially was about 7.5 to 10 percent due to the requirement for thoracotomy and epicardial electrode placement. That risk was deemed acceptable because of the poor prognosis of untreated patients and the dramatic relief of successfully paced patients (see the section below on benefits). Other risks that also usually meant pacemaker system failure included infection at any part of the operative area (from epicardium with myocardial abscess to infection around the pulse generator) and dehiscence (bursting) of the pulse generator. In its worst manifestation, the patient had an acquired abscess with draining fistula. These complications were relatively common initially (5 to 10 percent), but not unexpected. Improved surgical technique solved most of these problems.

Complications peculiar to pacemakers that were relatively or totally unanticipated are discussed below.

- **Wire (lead) break.** Fatigue of the metal leads resulted in premature system failure at a high rate, such that this was the primary limiting factor for the first few years of permanent pacing. The solution of this problem required engineering analysis of fracture points and modes, followed by multiple design changes. Although lead breaks still occur, this complication was con-

trolled to an acceptable incidence over a period of 6 to 7 years.

- **High threshold of cardiac excitation.** As noted above, animal testing revealed this complication, which was medically unique to this technology. The biotechnical factors involved were not well worked out until about 1967, and electrode evolution pertaining to this feature still continues. In the first 5 years of permanent pacemakers, at least 10 percent of system failures were from this cause.
- **Battery failure.** The predicted battery longevity did not materialize until about 1975 because of defects with the batteries and current shunting due to structural defects within the pulse generator. Excluding all other failure modes, pulse generator longevity as limited by battery exhaustion is listed in table A-1. The dramatic increase in pacemaker longevity from 1975 to 1979 reflects the development of a new technology battery (lithium).
- **"Runaway" pacemakers.** Rarely, but dramatically, pulse generators can fail with an accelerated rate (up to 800 impulses per minute). In some cases, this complication was fatal. Although design changes have made this complication quite rare, it still occurs (e.g., recall of American Pacemaker Co., June 1979).
- **Electromagnetic interference.** Interference caused by extrinsic noncardiac signals can alter pacemaker output signals. This problem was greatly magnified by creation of the sensing ("on demand") pacemaker, which must sense cardiac signals but reject all other electrical signals. This complication (incorrect sensing) still occurs with approximately 5 percent of implanted units.
- **Competition with natural heart beats.** Although this complication was anticipated, it was not

Table A. 1.—Pacemaker Longevity Excluding Causes of Failure Other Than Battery Exhaustion

Year pacemaker implanted	Longevity (50%)
1961.....	6 to 12 months
1965.....	12 months
1970.....	24 months
1975.....	42 months
1979.....	10 years (est.)

SOURCES: S. Furman and D. Escher, *Principles and Techniques of Cardiac Pacing* (New York: Harper and Row, 1970); and M. Bilitch, "Performance of Cardiac Pacemaker Pulse Generators," *PACE* 2:259, 1979.

considered serious (78). Although it is an infrequent occurrence, pacemaker stimulation during the vulnerable period of a preceding natural beat can precipitate ventricular fibrillation and death (59). proper sensing of natural depolarizations (demand function) precludes this complication, but inadequate sensing still occurs with about 5 percent of implanted units.

- **Surgical *inexperience*.** The use of a prosthetic device posed new problems for surgeons. Many complications—e. g., incorrect connection of pulse generator to leads, improper positioning of electrodes or pulse generator—are related to expertise in this particular operation. Furthermore, normally functioning pacemaker systems have been removed, because the surgeon and/or cardiologist did not understand the proper functioning of the system. Trauma to the device through mishandling still occurs in the hands of the inexperienced.
- **Manufacturing errors.**
- **Sudden failure.** From specifications and performance of the batteries (for the first 15 years, virtually all batteries were the same type), the expected failure mode was a slow but detectable change in pacer rate. Unexpected, sudden failure without prior detected rate change has occurred and still does occur for a number of reasons (lead break, component failure, short circuit, etc.). For a patient who is pacemaker dependent, this mode of failure produces syncope (temporary suspension of circulation) or death. Sudden unexpected failure is now uncommon (approximately 1 in 50 to 100 pulse generators), but occurred with 5 percent or more of pulse generators for the first 10 years of permanent pacing.

Benefits

- **Survival.** There never has been a well-controlled study comparing survival of patients with and without pacemakers, presumably because of the apparent immediate and dramatic success of pacemakers. Analysis of survival benefit has always been made by comparison of prepacing and post-pacing groups. Patients with complete (or intermittent) heart block and syncopal episodes have a 1-year mortality of 50 percent (29,36), whereas similar patients who are paced have a 2-year survival of 70 to 80 percent (68). Survival analysis of patients paced for reasons other than complete heart block is virtually impossible, as no “natural history” data exist for other conditions. The diagnoses of partial blocks and sick sinus syn-

drome appear to be a consequence of pacing, as these disorders were relatively unknown prior to permanent pacing, and investigations into these disorders probably resulted from the innovation of a treatment for them. Thus, the availability of pacemakers led to investigation into nonheart block causes of syncope. Pacemaker therapy was applied to other presumed causes of syncope as soon as a cause and effect relationship seemed to exist, as in sick sinus syndrome. The universally acknowledged success of pacing for heart block led to an uncritical extension of the therapy to patients with “preheart block” EKG patterns, and sinus node dysfunction. Consequently, there are no data (even uncontrolled) by which to judge the effect of pacing on survival in these groups of patients. Some believe that the widespread use of pacing for preheart block syndromes does not increase survival (46). Of all patients receiving pacemakers, about 55 to 60 percent now survive 5 years (31).

- **Treatment of symptomatic complete heart block.** The advent of pacing led to legendary tales of how the moribund rose to walk. For those who remember the plight of patients with symptomatic complete heart block, the benefit in terms of decreased syncopal episodes and increased activity level is beyond question. For patients with other maladies, however, the benefits are more questionable. Most patients with light-headedness spells, or true syncope, and without evidence of heart block or sinus arrest associated with syncope, end up with pacemakers. Many are not improved.
- **Treatment of symptomatic bradycardia.** Availability of pacing has created the option of adjunct therapy (e. g., large doses of propranolol) with pacing to avoid symptomatic bradycardia.
- **Treatment of tachyarrhythmias.** An unanticipated new use of pacemakers is in treatment of tachyarrhythmias, using overdrive or interruption techniques. This accounts for less than 1 percent of all permanent pacing.

Capital Investment

- **Initial cost.** The cost of hospitalization and hardware was estimated easily and adequately at the time of initiation of this technology.
- **Followup care.** The unanticipated complications of systems failures meant greater than estimated followup costs. I know of no studies in 1960-61 estimating followup costs. Although the anticipation was for 3 to 5 years of fault-free system performance, during the first 3 years of pacing, the average system longevity was about 6 months. Some pa-

tients had in excess of 15 operations (some more than 20) in 3 to 5 years, most of them thoracotomy (surgical incision of the chest wall). During the next 5 years, the average system failure (any failure requiring surgical correction, e.g., wire break, displacement of catheter, generator failure) was about 1 in 12 months of pacing (or greater).

Exclusive of complications requiring hospitalization/operative repair, modern followup methods now cost from \$100 to \$1,600 per year, depending on the mode of followup. Office visits (minimum, EKG; maximum, detailed pacemaker analysis at a "pacemaker clinic") vary from 2 to 6 years in routine followup. Electronic monitoring (even interrogation of implanted units) has become widespread in this country during the last 10 years. It can be done directly (with the patient present at a clinic) or indirectly by telephone, with or without automatic computer analysis. The availability of such monitoring has made it mandatory in the minds of most physicians, as this represents the "best" means of followup. Indeed, there is now a whole ancillary industry in this area. The artificial heart, for which monitoring would be even more

necessary, will undoubtedly have more advanced forms of electronic monitoring. Third-party payers (Blue Cross/Blue Shield, medicare) now pay \$30 per telephone call for pacemaker monitoring. Many patients are monitored weekly (there is a scale of allowable calls, as a function of the age of the pacemaker), meaning a monitoring cost of \$1,560 per year. I anticipate a minimum of one call per week for artificial heart patients.

- **Indirect cost (or gains)**, There are no data on return to employment of paced patients, but for those who were incapacitated from symptomatic complete heart block, there is a return to normal existence (excluding other limitations). Thus, for the group heavily dependent on pacemakers, there would appear to be a large net gain in return to gainful employment. For others, the result is less evident. To the degree that a patient is restored to normal function, there should be an economic gain. The countereffect, as seen with coronary artery surgery, of legitimization of illness and retirement may also be present. I know of no data on this subject.