CARDIAC PACEMAKERS

FUTURE POWER SOURCES FOR CARDIAC PACEMAKERS

By J. Edward Cheatham

When the implantable cardiac pacemaker was first introduced in 1962, the pacemaker manufacturers were projecting a service life of approximately five years. This was based on extrapolation of data provided by the battery manufacturers as to the battery's capacity and the predictable current drain on these batteries by the asynchronous pulse generators of that period. It all too soon became evident however, that these predictions were highly optimistic. In fact, today pacemakers which are ending their service life are averaging 21 to 24 months service life to the 10% failure point.

Perhaps even more frustrating than the overall shorter than predicted service life is the wide distribution of failures. Pacemakers have suffered premature battery depletion in a matter of a few months and others have served for longer than four years. It is this combination of short overall life and relatively wide distribution of failure times that has prompted the establishment of pacemaker clinics, telephone monitoring, oscillographic analysis, and various other methods of attempted follow up of patients with implanted cardiac pacemakers. It has also led many groups to the investigation of alternative power sources to the one in common usage in implanted cardiac pacemakers, the certified version of the zinc/mercury cell developed by Samuel Ruben, the Mallory RM1 cell. It is the purpose of this presentation to present an over view of alternative power sources, and also to discuss what has been done and what can be done to the present power source to make it more appropriate for future use.

Power sources considered appropriate for cardiac pacemaker application fall into four general categories:

- non-rechargeable chemical systems
- rechargeable chemical systems
- fuel cell and biogalvanic cells
- nuclear or isotopic systems

All four of these systems have been developed into cardiac pacemakers which have been implanted in humans with varying degrees of success. Of these, probably the least successful to date have been the biogalvanic and the fuel cell sources. It is an intriguing thought to tap the energy of the body itself to power a cardiac pacemaker, but all attempts to tap this source of energy have been fraught with tissue reaction problems and degredation of the electrode materials. The author considers this category of power sources as unlikely candidates for a future pacemaker power source in light of their history of problems and the great promise that lies ahead both in the chemical battery systems and in the nuclear power sources available today.

Rechargeable chemical systems have been tried by various groups for long term cardiac stimulation with a limited degree of success. The problems hinge primarily around the fact that rechargeable chemical cells tend to be bulkier, that is have inferior volumetric efficiency, than the non-rechargeable cell. This means that for a reasonably sized cardiac pacemaker frequent recharges are required. Also, rechargeable cells do not react favorably to repeat deep discharge and complete recharge cycles. Thus, it is necessary to recharge the pacemaker at the 10 to 20% depletion point and keep the cell toward full charge; this further shortens the interval between recharge cycles. Also, there are difficult problems in recharging these cells as one must have a charging apparatus which insures full charge to bring the system back to full capacity without overcharging. Overcharging of chemical cells results in gassing and possible rupture of the cell. Again, this system has not received wide-spread use because it does not appear to offer any advantage over the non-rechargeable chemical systems in terms of total implant longevity and offers the above mentioned problems.

Nuclear powered or isotopic pacemakers have reached the clinical investigation stage. There are three energy conversion techniques under evaluation:

1. Thermoelectric
2. Thermoionic
3. Betavoltaic

Thermoelectric conversion utilizes a series of thermocouples heated at one end by a radioisotope. The difference in temperature across this thermopile results in the generation of an electrical potential. Bismuth-telluride thermocouples are being used in the French battery manufactured by Society Alcatel in Paris. It is fuelled by 142 mg of a plutonium^{238}-scandium metal alloy. This battery has been incorporated in the ventricular program demand pulse generators manufactured by Medtronic, Inc. of Minneapolis, Minnesota USA. In excess of fifty of these units have been implanted in patients with good success to date.

The thermoionic energy conversion technique operates on the principle that a heated metal surface readily emits electrons into a vacuum and these electrons can be collected to provide electrical energy. A tiny thermoionic device called an isomite has been built by the D. W. Douglas Laboratory of Richland, Washington USA. These power sources again use plutonium^{238} to provide the energy. More work is required to determine whether these microwatt power sources are practical for pacemaker applications.

The betavoltaic technique differs because it is a non-thermal process; beta particles from a beta-emitting isotope penetrate NP junctions in semiconducting materials producing free electrons which diffuse into the junction, this generates a voltage capable of providing current to an electronic circuitry. Betavoltaic devices fuelled by promethium^{147} encapsulated in stainless steel are being investigated for cardiac pacemaker application.

Of these three types of isotopic power sources, the bismuth-telluride thermocouple system fuelled with Plutonium^{238} has had the most success. It is believed that this unit may be capable of operating in the body for periods of at least ten and possibly fifteen years. Its major limitation to success is governmental regulations regarding the use and recovery of the Plutonium^{238} material and in the high cost of the unit (approximately $5,000 US).

The remaining category of sources to be discussed are the non-rechargeable chemical systems. Of the several possible systems, the ones most commonly regarded as useful for cardiac pacemakers are the mercury-zinc system, which is the system in present use, the mercury-cadmium system and the lithium-iodine solid state system. Of these three, the conventional mercury-zinc system and the lithium-iodine system appear to have the greatest advantages in terms of volumetric efficiency and reliability.

The mercury-zinc system, in the form of the RM-1 cell, has proven to be a reasonably reliable source for

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a two-year cardiac pacemaker. However, based on the battery's initial capacity, four to five year lifetimes are theoretically possible. The problem with this battery as it exists today is that it is not optimized for very low current drain, long shelf life characteristics. The materials used for the separators between the cathode and anode are such that mechanical and chemical degredation takes place allowing electrical leakage paths to exist between the cathode and anode causing approximately 15% per year internal loss rate. It is the variability of loss rates due to mechanical and chemical degredation which causes the wide variability between individual cells. Work is well under way on a new separator system for the mercury-zinc battery which should cause significantly greater life and much reduced variability between battery lifetimes. An internal loss rate of 4% per year should be achievable. Thus, the mercury-zinc system should not be dismissed as a possible future power source for cardiac pacemakers.

Of the new chemical sources which appear promising, the most promising is the lithium-iodine solid state cell. These have the unique property that there is no liquid phase between the operating electrodes. Elimination of the liquid phase allows the use of such highly reactive electrodes like lithium, thereby achieving a high energy per unit weight and volume. While the high reactivity of the lithium electrode with water vapor and air requires hermetic sealing of the battery, the source can easily be formed into a variety of shapes to obtain a better packaging efficiency in a pacemaker than the cylindrical mercury-zinc cell.

The final determination of the optimum power source for a cardiac pacemaker lies in a trade-off of cost versus longevity and reliability. Obviously, if one is faced with only a choice between a two year pacemaker with a high variability of service life and a fifteen year nuclear powered unit, then the nuclear powered unit offers significant advantages in terms of final cost to the patient. However, it appears that the most likely alternatives facing the physician in the future will be a four to five year chemically-powered system, at approximately the same costs as today's unit, versus a five to seven year Promethium^{147} fuelled betavoltaic system, at approximately double the costs of today's pacemakers, or a ten to fifteen year thermoelectric conversion unit using Plutonium^{238}, at a cost approximately five to six times that of standard chemical pacemakers. Faced with these choices, it appears to the writer that for the vast majority of patients a four or five year chemical system would be the unit of choice as certainly the original pacemaker plus one replacement would serve better than 90% of the patient population. It appears that if this system, using either lithium-iodine or mercury-zinc, proves feasible, then the five to seven year betavoltaic system, at approximately twice the cost of a conventional chemical system, would have little utility. For the young patient who would otherwise have a six year or longer expected lifetime, the Plutonium^{238} thermoelectric would appear to be the unit of choice.