Experimental Experience With a Micromodule Pacemaker Receiver Sutured Directly to the Left Ventricle

By Harry Stoeckle, M.D., and John C. Schuder, Ph.D.

Since Weirich and associates introduced a method of artificial internal pacing for the treatment of complete heart block following injury to the conduction system during open-heart surgery, there has been a rapid growth of interest in the procedure for use with both medical and postoperative patients.1 Furman et al. have described an arrangement which employs an insulated conductor passed through a vein into the right heart.2 Greatbatch et al. advocate a method for long-term treatment which involves the subcutaneous implantation of a transistorized pacemaker-battery package in the abdominal region.3 Their unit is then connected by wires to electrodes on one of the ventricles. A similar arrangement with provision for pulse rate control, if desired, from outside of the patient by an inductive coupling scheme has been described by Kantrowitz et al.4 Eisenberg and his associates have recommended that the heart be paced by means of a pulsed radio-frequency source on the outside of the chest inductively coupled to a receiving coil buried subcutaneously in the region of the sternum.5 The output from this coil is then rectified and conducted by wires to the appropriate points on the heart.

As a result of a continuing study of the fundamental problems involved in high-level electromagnetic energy transport across tissue barriers, we became interested in the possibility of transporting the low levels required for cardiac pacing by direct inductive coupling between an external coil and a small receiver implanted on a ventricle.6,7 Figure 1 illustrates the arrangement considered in the present paper. The size and shape of the module are similar to the one introduced by Hunter et al.8 Because of the size of the module and the absence of connecting wires, it is hoped that the morbidity associated with the implantation procedure will be considerably less than that experienced with other systems.

Theoretical Considerations

The question of whether or not it is feasible to transport energy from a coil external to the chest to a very small receiving coil attached to the heart is intimately associated with the efficiency of transport that can be achieved. This aspect of the problem has been discussed in greater detail elsewhere,9 and the realizable efficiency of transport between the input to the external coil and the electrodes in the myocardium is found to be about 1 per cent. Under typical conditions, it has also been estimated that the power requirements can be met for one week with a battery package weighing 0.3 lbs.

Receiver and Transmitter Units

Receiver

The circuits used in the experimental receiver modules are shown in figure 2. In the circuit of figure 2a, the coil contains 65 turns of no. 40 wire wound on a 1.0- by 2.0-cm. hollow rectangular form of epoxy resin.* The shunt capacitors are ceramic units with a diameter of 0.23 cm. and a length of 0.81 cm.† The capacitors and the rectifying diode are positioned within the hollow coil form. The

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*Scotch resin no. 5, Minnesota Mining and Manufacturing Co., St. Paul, Minnesota.
†Type C80V102AM Cerafil, Aerovox Corp., New Bedford, Massachusetts.
pin separation is approximately 1.25 cm., and there are variations in pin length and diameter. A length of 1.0 cm. and a diameter of 0.08 cm. are representative values.

After the components are assembled, additional epoxy resin is added to make a solid module. The module is then covered with a thin coat of type-502 Silastic. While some of the earlier units were somewhat larger, recent models tend to be close to 2.3 by 1.3 by 0.3 cm. and weigh about 2 Gm. (less than a dime). The resonant frequency of the parallel inductance-capacitance combination is about 320 kilocycles per second. The circuit for a second type of receiver is shown in figure 2b. This circuit supplies a small reverse current during the period between pulses and, as a result, the net charge transfer is zero.

Transmitter

The circuit shown in figure 3 is a modified type of intermittent oscillator. It has a high efficiency, supplies a very rectangular radio-frequency pulse, and furnishes a power level to the external coil somewhat in excess of the anticipated requirements. The pulse rate is easily and conveniently adjusted by means of the variable resistor labeled “rate control.”

The external coil has an outside diameter of about 9 cm. and is flat-wound with 4-16-36 Litz wire. The number of turns on the coil are adjusted to yield an output frequency of about 320 kilocycles per second, and the taps are set for optimum performance. The approximate position of the taps is indicated in...
Module attached to heart.

Such a circuit has proved suitable for experimental work. However, a dependency of the pulse duration upon loading, and the critical nature of the coil tap location, suggest that a more sophisticated design would be indicated for clinical use.

Experimental Procedures

Heart block has been successfully created in mongrel dogs by following the technique described by Starzel and Gaertner. In addition, a natural heart block was found in one dog. The module was attached to the left ventricle 10 or more days after creation of the block. The attachment was accomplished by means of a left-sided thoracotomy in the fifth interspace. The module was positioned in such a way that there was little interference with the blood vessels visible on the surface of the heart. The position of the module was maintained during suturing by the pins in the myocardium and the pressure of an assistant's finger on top of the module. Single no. 3-0 braided silk sutures were passed through holes in each corner of the module and thence into the myocardium to complete the attachment. Figure 4 illustrates a pacemaker attached to the left ventricle. Functioning of the individual pacemaker was tested at this time. The pericardium was then loosely sutured over the module and the chest closed. The animals were maintained on an exercise regime, as permitted, or restricted by small individual cages.

In the early phase of this study, animals were paced only on an intermittent basis. Later, some animals were paced continuously with individual battery transmitters worn by each animal. More recently, techniques have been devised for inexpensive pacing of a group of eight dogs on a continuous basis. At present, there are animals in both the intermittently and continuously paced groups.

Figure 5 shows the method adopted for experimental group pacing. This method eliminates the expense of fabricating a number of transmitter packages and the periodic replacement of batteries. The rate is set for about 90 beats per minute. During the course of the study, there have been a total of 21 animals in the intermittently paced group and 11 in the continuously paced group. Periodic single-lead electrocardiograms have been used to evaluate the functioning of the modules.

Results

The heart of every animal responded well to external pacing at the time of operation. Except for the animals which died in the rather immediate postimplantation period, we have the impression that the threshold power required for pacing increases rather rapidly for the first few weeks and then tends to level off or increase at a comparatively slow rate. This impression is verified by a more detailed study reported by Albert et al.

Total experience with modules has not revealed any circuit failures. The circuit of each module removed at post mortem has been tested and found to be in operating condition. Only two modules have failed to remain implanted, after which greater efforts have been made to insert the sutures more deeply into the myocardium. The modules at post mortem have been found to be buried in reactive pericardial tissue except in those animals in which death occurred soon after implantation.

Tissue necrosis immediately around the pins has been observed in one animal in which...
brass pins were used. Reaction around the stainless steel and platinum (actually platinum-iridium alloy) pins appears to be sar tissue.

**Intermittent Pacing**

Table 1 refers to the 13 dogs which have died while in the intermittent-pacing program. These animals were paced for one to two minutes at intervals of approximately one week.

The deaths of the three animals, 26Q, 38Q, and 39Q, are believed to be associated with the longer-than-usual pin length (1.25 to 1.5 cm.). Penetration of myocardium was actually observed in two cases. In retrospect, it seems possible that penetration was also present in the third case, but was overlooked at autopsy. Acute pericarditis was found at the time of the implantation in animal 10Q. The same condition was noted at post mortem and is believed to be the cause of death. In 14Q and 15Q, the modules were out of position, but the exact cause of death was not evident. Dog 6Q died almost six months after the implantation, with signs of severe valvular disease which was presumably unrelated to the presence of the module. Either cardiac failure or no apparent cause of death was observed in the remaining six animals. No evidence of electrode erosion was observed.

Table 2 shows the experience with the eight dogs which have survived under the plan of intermittent pacing. All these remain in relatively good health as judged by healing of wounds, absence of respiratory distress, and no apparent edema or ascites.

**Continuous Pacing**

Two dogs of this group have died. The first had been paced 19 days and the second 5 days. The platinum pins were intact. No explanation for death was found at autopsy.

Table 3 refers to the nine animals which
survive. In two animals, 58Q and 61Q, there was nonfunctioning of the module. These two animals were reoperated and another module implanted in each. Both of the defective units utilized stainless steel and one of the pins from each module was found to be broken. Figure 6 is a microphotograph of the eroded pin from animal 58Q. On one module, the pin was broken at the point of attachment of the pin to the circuit. On the other module, the breaking point occurred just outside the plastic coating of the module. All of the surviving animals appear to be in relatively good health.

Discussion

Since the threshold power required for pacing has followed a similar trend in both intermittently paced and continuously paced animals, it seems likely that the observed increase is related to the presence of tissue changes in the neighborhood of the electrodes rather than to the pacing current. These tissue changes might be related to the development of scar formation around the pins as a reaction to the insertion of a foreign body into the myocardium. In all animals, the threshold has remained within the capability of the power source of the small portable unit. This finding is of considerable significance in relation to the possible adoption of the method to suitable human patients.

On the other hand, pin erosion appears to be related to the total duration of pacing. As yet, no pin breakage or pin failure has oc-

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**Table 2**

Intermittently Paced Group: Survivors

<table>
<thead>
<tr>
<th>Dog no.</th>
<th>Pin material and circuit</th>
<th>Block</th>
<th>Total days intermittently paced to 9/10/62</th>
</tr>
</thead>
<tbody>
<tr>
<td>9-Q</td>
<td>Brass (a)</td>
<td>2:1</td>
<td>350</td>
</tr>
<tr>
<td>23-Q</td>
<td>Stainless (a)</td>
<td>3:1</td>
<td>277</td>
</tr>
<tr>
<td>40-Q</td>
<td>Stainless (a)</td>
<td>3:1</td>
<td>215</td>
</tr>
<tr>
<td>45-Q</td>
<td>Stainless (a)</td>
<td>2:1</td>
<td>208</td>
</tr>
<tr>
<td>52-Q*</td>
<td>Platinum (a)</td>
<td>2:1</td>
<td>129</td>
</tr>
<tr>
<td>58-Q*</td>
<td>Stainless (a)</td>
<td>3:1</td>
<td>46</td>
</tr>
<tr>
<td>61-Q</td>
<td>Platinum (a)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>64-Q</td>
<td>Platinum (a)</td>
<td>2:1</td>
<td>130</td>
</tr>
</tbody>
</table>

*52-Q and 58-Q are no longer in this group, having been transferred to the continuously paced group at 129 and 46 days, respectively.

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**Table 3**

Continuously Paced Group: Survivors

<table>
<thead>
<tr>
<th>Dog no.</th>
<th>Pin material and circuit</th>
<th>Block</th>
<th>Total days continuously paced to 9/10/62</th>
</tr>
</thead>
<tbody>
<tr>
<td>52-Q</td>
<td>Platinum (a)</td>
<td>2:1</td>
<td>60</td>
</tr>
<tr>
<td>58-Q</td>
<td>Stainless (a)</td>
<td>3:1</td>
<td>24*</td>
</tr>
<tr>
<td>61-Q+</td>
<td>Stainless (a)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>71-Q</td>
<td>Stainless (b)</td>
<td>3:1</td>
<td>55</td>
</tr>
<tr>
<td>74-Q</td>
<td>Platinum (a)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>76-Q</td>
<td>Platinum (b)</td>
<td>4:1</td>
<td>53</td>
</tr>
<tr>
<td>80-Q</td>
<td>Stainless (b)</td>
<td>3:1</td>
<td>49</td>
</tr>
<tr>
<td>87-Q</td>
<td>Coiled platinum (a)</td>
<td>2:1</td>
<td>20</td>
</tr>
<tr>
<td>90-Q</td>
<td>Platinum (b)</td>
<td>3:1</td>
<td>18</td>
</tr>
</tbody>
</table>

*Module replaced after 24 days because of broken pin.

*61-Q is no longer in this group, having been transferred to the intermittently paced group at 52 days.

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**Figure 6**

Microphotograph of stainless pin stud from animal 58Q showing erosion after having pin in place for 46 days on intermittent pacing and 24 days of continuous pacing.
curved in the animals which have been paced intermittently, but only in those which have been paced continuously. Such findings suggest that an electrolytic process occurs each time the module is energized. Preliminary studies of the pins in saline solution simulating a life of 10 years of pacing indicate that platinum is much more resistant to electrolytic erosion than are different types of stainless steel. The early results from the continuously paced animals are compatible with this prediction in that there have been two failures of stainless steel pins but none of platinum. The experimental data are still too preliminary to differentiate between the circuits of figure 2a and b as to their influence on pin erosion.

The epoxy resin encasing the circuits has not been affected by the tissue juices. There has been some yellow staining of the Silastic covering.

Summary

It has been demonstrated that it is possible to transmit sufficient energy to pace a heart by means of inductive coupling between an external coil and a very small pacemaker receiver attached directly to the left ventricle. By the use of such a method in dogs, it has been found that the energy requirements for pacing are not dependent upon the total duration of pacing, but rather depend upon the tissue reaction occurring around the electrodes or pins. Electrode erosion, on the other hand, is related to the pacing process and dependent upon electrode material.

The operative implantation of this module is simpler than the other systems presently employed. However, the selection of suitable persons for wearing this unit has not been determined.

Acknowledgment

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References


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