

PART IX. CLINICAL RESULTS OF VARIOUS PACING TECHNIQUES

MYOCARDIAL ELECTRODE IMPLANTATIONS: INDICATIONS AND ADVANTAGES*

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The enthusiasm of the cardiology community for permanent cardiac pacing by the transvenous endocardial electrode threatened the transthoracic myocardial electrode system of pacing with obsolescence. Increased ease of installation and a negligible surgical morbidity have continued to be the outstanding virtues of endocardial pacing. Experience with 263 patients† receiving implantable pace-makers since 1961 suggests that both systems have basic advantages and that neither should be replaced entirely by the other.

INDICATIONS FOR PERMANENT TRANSVENOUS PACING

The remarkable ease of installation and minimal surgical trauma attendant upon insertion of the permanent transvenous pacemaker make it admirably suited to elderly, frail, and otherwise poor-risk candidates for cardiac pacing. The system eliminates the intermediate step of temporary pacing by an external pulse generator, and one surgical procedure provides definitive permanent pacing.

Disadvantages

Problems inherent in the endocardial electrode, namely, dislocation, perforation, and threshold elevation, have been cited in earlier reports.^{1,2} In our experience, 28 patients receiving permanent endocardial electrodes in the past 18 months have experienced seven complications, for a rate of 25%. In order of frequency, the complications were electrode displacement (three cases), ventricular perforation (three cases, two producing diaphragmatic tic), and threshold elevation (one case). In the same period of time, 33 myocardial electrodes of patch design (to be described) were inserted transthoracically, and no complications attended their performance. A comparison of threshold measurements made in both groups of patients indicated that the average threshold value for the endocardial electrode was 300% higher than for the myocardial electrode (TABLE 1).

INDICATIONS FOR PERMANENT TRANSTHORACIC PACING

Preference for the transthoracic myocardial electrode is maintained in relatively young and active patients, in whom the prognosis is more favorable for long-term survival. In this group, comprising 50% of patients receiving pace-makers for the first time, the endocardial electrode is held in reserve for later use if necessary. Advantages of the myocardial electrode include absolute stability and increased reliability. Displacement and perforation problems are eliminated.

The single disadvantage of the transthoracic myocardial electrode is that

* This work has been supported in part by the Michigan Heart Association.

† Patients were cared for at the University of Michigan Medical Center and at St. Joseph Mercy Hospital, Ann Arbor, Mich. Pacemaker equipment was manufactured by the General Electric Co., Milwaukee, Wisc.

implantation requires a major thoracotomy to expose the myocardium. Surgical technology and anesthesiology have reduced such risk to an acceptable minimum of less than 1%. Out of 205 patients with transthoracic pacemakers, two deaths occurred following second operations to replace myocardial electrodes. There were no deaths related to initial transthoracic implantation.

TECHNICAL FACTORS OF IMPORTANCE IN MYOCARDIAL ELECTRODE IMPLANTATION

Handling and Sterilization

Optimal performance of myocardial electrodes demands that they be meticulously handled during sterilization and operation. Lint-free and talc-free gloves should be worn. The static electrical charge on the silicone surface of the electrode increases its affinity for dust, lint, talc, starch, and other foreign particles that may be carried into the myocardium with the electrode. Foreign body material between the electrode and myocardial interface may provoke a chronic inflammatory response that will adversely affect threshold values.³

Braley⁴ has pointed out that "many, if not most, of the cold sterilizing solutions and gases will be absorbed into the silicones, and unless extreme care is taken to get rid of them, will subsequently cause tissue reaction when the piece is implanted. For this reason, cold sterilizing methods are not recommended. Autoclaving under standard conditions or dry heat sterilizing for several hours at 300° F is preferred." The detachable design of myocardial electrodes permits sterilization of the electrodes separately from the pulse generator by means of autoclaving. Gas or cold sterilization is reserved for the pulse generator, which

TABLE 1
THRESHOLD MEASUREMENTS ON PACEMAKERS FUNCTIONING FOR SIX MONTHS OR LONGER

Transvenous Electrode (18 Patients)		Myocardial Electrode (18 Patients)		Improved Patch Electrode (5 Patients)	
Patient No.	Threshold (%)	Patient No.	Threshold (%)	Patient No.	Threshold (%)
1	10	1	7	1	8
2	15	2	10	2	8
3	15	3	10	3	10
4	16	4	11	4	10
5	18	5	11	5	12
6	20	6	12		
7	25	7	13		
8	25	8	15		
9	27	9	15		
10	30	10	15		
11	30	11	15		
12	30	12	17		
13	50	13	17		
14	50	14	25		
15	55	15	30		
16	65	16	35		
17	75	17	53		
18	90	18	70		
Threshold range	10-90		7-70		8-12
Average threshold	35		20		9.6
Mean threshold	28.5		15		12

must not be subjected to the high temperatures of autoclaving. After gas sterilization (ethylene oxide), ventilation is recommended for 16 hours at room temperature, or for eight hours at 120° F with forced ventilation. Seven days of ventilation are required to dissipate the ethylene oxide when sterilization has been carried out in sealed plastic bags containing the electrode or pacemaker.

After cold sterilization by immersion, all surfaces should be generously rinsed with sterile water, and the electrode should be permitted to soak in sterile water until ready for use. Sterilizing agents noxious to body tissue which might be soluble in silicone rubber would thereby have the opportunity to diffuse out of the silicone insulation.

Anatomical Considerations

The evolution of superior lead materials and designs has all but eliminated problems of lead breakage. When lead breakage was a serious problem, however, distribution of the leads during implantation appeared to be an important factor

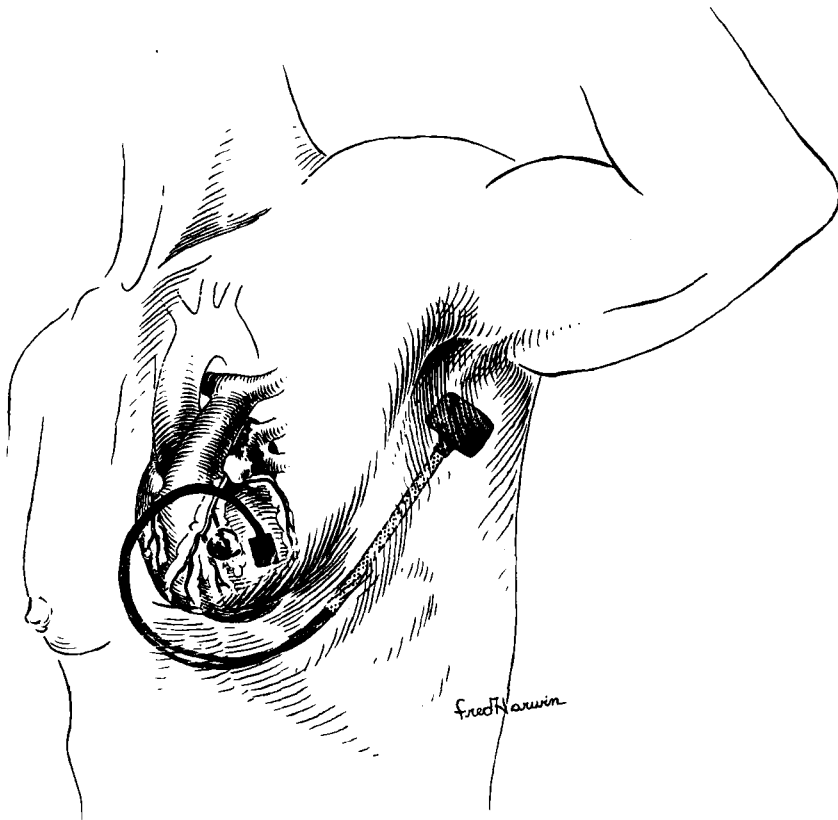


FIGURE 1. The myocardial electrode, leads, and pulse generator are subjected to less strain when the unit is positioned in the thoracic segment with the pulse generator in the left axilla. The leads describe a C-shaped loop from the electrode attached to the left ventricle near the atrioventricular groove.

in the incidence of lead breakage. Breakage occurred most commonly near the attachment of the leads to the pulse generator and near the attachment of the electrode to the myocardium. Both of these areas are junctions between a point of relative fixation and a point of movement of leads. In the case of abdominal implantation of the pulse generator, a third common area of lead breakage was where the lead passed over the costal margin to the anterior thorax. Lead stress in this area corresponds to dorsal lumbar flexing of the trunk. These three sites share the common feature of repetitive motion and deformity. Implantation that minimizes lead stress, movement, and deformity reduces the incidence of lead breakage. The implantation arrangement of pulse generator and leads that minimizes stress on leads and electrodes is the left axillary position.⁵ The leads are passed through the fourth or fifth intercostal space to the anterior mediastinum, where they are carried mesially, superiorly, and down to the left ventricle near the atrioventricular groove (FIGURE 1).

Evidence exists that stimulation of the left ventricle near the apex provides ventricular contraction of greatest efficiency.⁶ It is also true that the apical area of the myocardium is furthest from the origin of the coronary artery network and more likely to experience ischemia in coronary artery disease. The metabolic consequences of myocardial ischemia are increased threshold to stimulation and, ultimately, refractoriness of the ventricles to stimulation applied in the zone of ischemia. It is therefore suggested that electrodes be placed high on the left

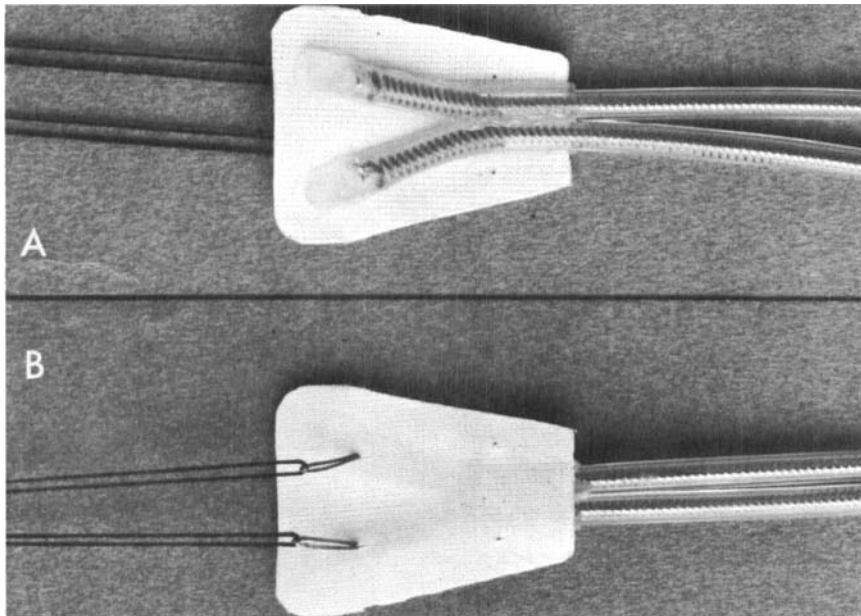


FIGURE 2. Photograph of the patch, or single-pass, electrode. (A) The outer side of the Dacron patch is coated with a thin veneer of silicone rubber to prevent fixation of the patch to the pericardium or surrounding tissues, which would provide a shearing force on the electrode with cardiac motion. (B) Under side of the Dacron patch, featuring the open mesh that provides fixation of the patch to the epicardium and gives stability to the electrode. The loop electrode and attached silk suture are shown.

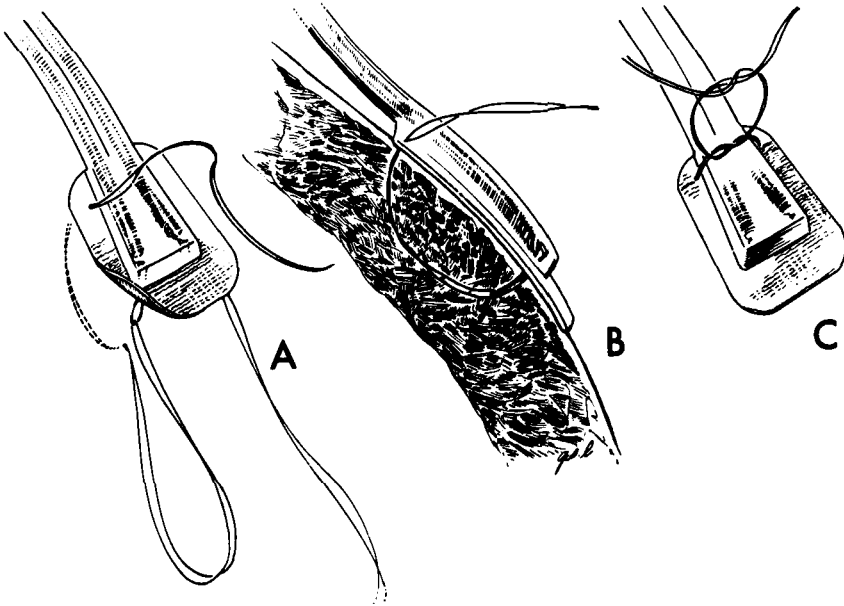


FIGURE 3. Steps in implantation of the single-pass electrode. (A) Suture pass in the left ventricle in a direction from the apex toward the atrioventricular groove. (B) Sectional view, showing the loop electrode drawn vertically into the myocardium and the silk suture passed up through the proximal end of the patch. (C) The silk lead-in sutures, which are positioned parallel and 1 cm apart, are tied together to approximate the Dacron patch snugly to the epicardium, and the silk ends are trimmed away.

ventricle near the atrioventricular groove, where myocardial vascularization is more constant and myocardial infarction is rare.

THE MYOCARDIAL PATCH ELECTRODE

The ideal myocardial electrode should meet the following requirements: stability, endurance, and low-threshold performance. The design should provide maximal simplicity of implantation while assuring that trauma and risk of injury to the heart will be minimal. One electrode meeting the above requirements is the patch, or single-pass, electrode (General Electric). The patch, fabricated of woven Dacron®, is porous on the inner surface to allow for fixation to the epicardial surface of the heart. Silicone rubber on the outer surface of the patch prevents adherence to extracardial structures. The helical cable leads of stainless steel pass over the outer surface of the patch to the distal edge, where they pass through and emerge 1 cm apart on the inner face as the myocardial electrodes.

In the earlier design, atraumatic cardiovascular needles were swaged directly on the electrodes. After making parallel suture passes 1 cm apart through the myocardium in a direction from the apex toward the atrioventricular groove, traction on the electrodes drew the patch firmly against the epicardium. The stainless-steel, silver-coated electrode was then drawn through the proximal margin of the patch and secured by ferrules crimped to the electrode. The redundant length of electrode wire was then trimmed off.

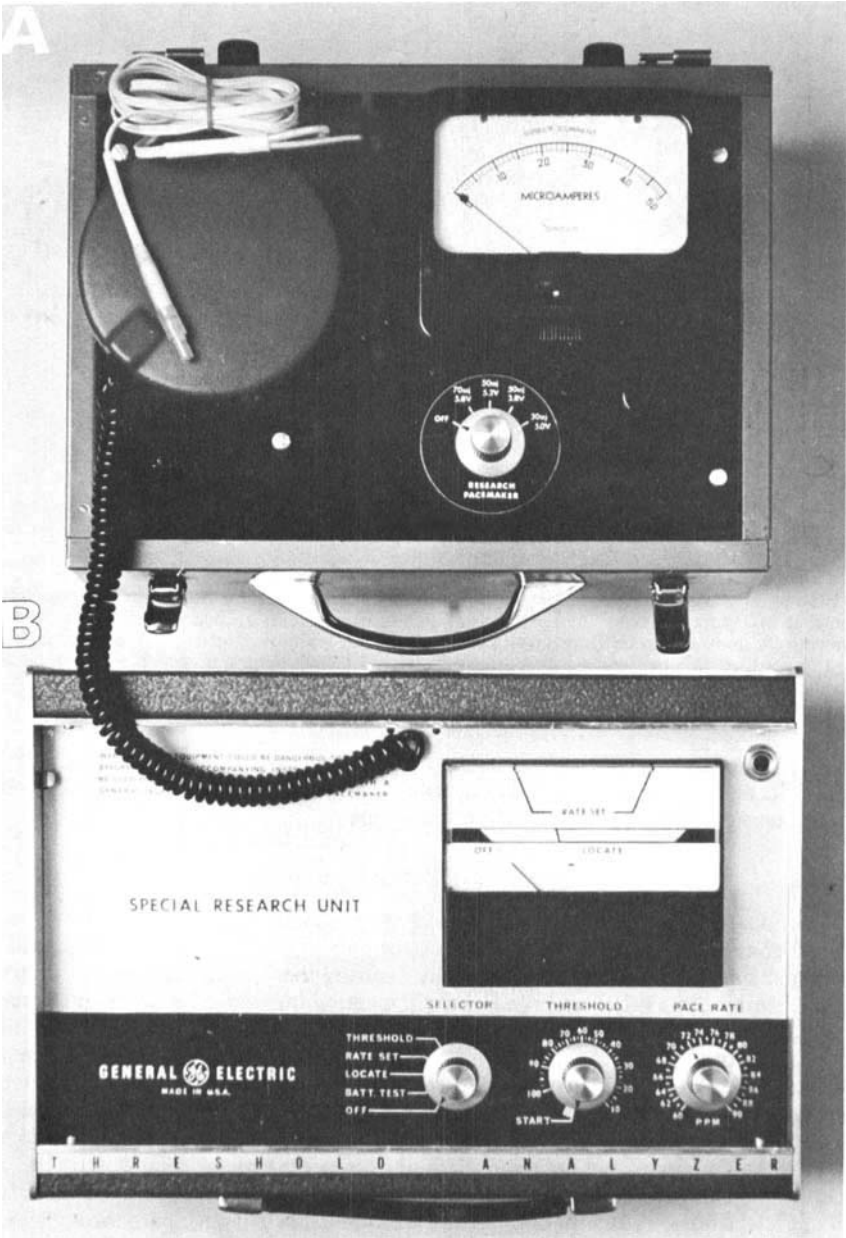


FIGURE 4. (A) Battery-powered external pacemaker, which permits selection of pulse signals of varying energy and waveforms. The unit is connected to patient's myocardial electrode when the pulse generator is removed for replacement, and it simulates a low-energy pulse generator. (B) Threshold analyzer for measuring threshold with the simulated low-energy pulse generator above.

Eighteen patients who had been pacing with such a patch electrode for over six months were subjected to threshold analysis.⁷ Threshold determinations ranged from 7% to 70%, and the average value was 20%. A comparable group of 18 patients who had been paced by an endocardial electrode for over six months exhibited threshold values ranging from 10% to 90%, with an average value of 35% (TABLE 1).

While threshold performance of the myocardial electrode was superior to the endocardial electrode, it was thought that more stable and consistent threshold values could be achieved. The long length of electrode in contact with the myocardium diminished current density. The terminal of the electrodes ended on the exterior surface of the patch, where the ferrules were crimped on, and pulse generator energy could be dissipated at this level rather than at the electrode-myocardial interface.⁸

A modification of the patch electrode has been achieved whereby the electrodes are formed as 1-cm loops of the stainless-steel, silver-coated leads (FIGURE 2). The loops are attached to silk atraumatic sutures, and the electrodes are implanted as previously described. The silk sutures are brought up through the proximal end of the patch and tied snugly over the back of the patch (FIGURE 3). The resulting reduction in surface area of the myocardial electrode provides higher current density to the electrode-myocardial interface. The loop electrode theoretically resists electrolytic deterioration better than the more efficient, open-end electrode. Electrolytic alteration in the stainless-steel, silver-coated electrode has not been observed in our experience, despite long-term pacing.

This optimal design reduces the technique of myocardial implantation to passing two sutures into the anterior left ventricle and then tying the two lead-in silk sutures together to secure the patch to the heart. Any bleeding from the suture site is tamponed by the patch. The sutures may parallel or straddle coronary artery branches, if necessary. Five patients who have been paced with this electrode for over six months have had an average threshold value of less than 10% (TABLE 1).

A stable, low threshold permits the selection of a low-energy pulse generator at the time of replacement for battery depletion, thereby providing the advantage of increased life expectancy of the pulse generator unit. Two low-energy replacements have been made on the basis of thresholds of 10% and 13% with standard pulse generator units. The low-energy generators, with a pulse energy output of 30 microjoules, have continued to pace at threshold levels of 10% and 30%, respectively.

The decision to use a low-energy unit is determined by the threshold analyzer, which is used in conjunction with a specially designed external pacemaker (FIGURE 4). When a pulse generator change is made, the *in situ* electrode is connected to the external unit, which permits a selection of various pulse signals, varying in character in regard to waveform and energy. An accurate prediction of low-energy pulse generator performance can thereby be made for any specific patient. If such a unit offers a reasonable safety factor of energy output relative to threshold (i.e., threshold measured at less than 35% with a low-energy pulse generator circuit), then implantation of a low-energy pulse generator is desirable.

CONCLUSION

The endocardial electrode and the transthoracic electrode possess unique and special advantages that assure the rightful place of each in cardiac pacing. The

endocardial transvenous electrode, due to its low order of trauma associated with installation, appears best suited for the poor-risk patient whose prognosis is for short-term survival because of associated disease or older age. Specific shortcomings of the endocardial electrode are dislocation, perforation, and threshold problems.

The transthoracic myocardial electrode is preferred for active and younger patients whose prognosis is for long-term survival. The advantages of the myocardial electrode are stability, reliability, and the preservation of lower cardiac thresholds. Positioning the myocardial electrode high on the left ventricle may avoid threshold problems due to myocardial ischemia, which is more likely to occur near the left ventricular apex.

An improved myocardial electrode maintains consistent and stable thresholds in the range of 10% over the long term. This level of electrode efficiency permits use of a low-energy pulse generator when replacement is necessary.

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