6. M. A. Acker, W. A. Anderson, R. L. Hammond, *et al.*, *Ibid.*, **94**, № 8, 163-170 (1987).
7. A. Carpentier, J.-C. Chachques, and P. Grandjean, in: *Cardiomyoplasty*, New York (1991).
8. R. C.-J. Chiu, in: *Biomechanical Cardiac Assist: Cardiomyoplasty and Muscle-Powered Devices*, New York (1986).
9. R. C.-J. Chiu, *Cardiac Chronicle*, **6**, № 9, 1-8 (1992).
10. K. B. James, *Cardio*, № 6, 68-73 (1992).
11. J. D. Manion and L. W. Stephenson, *Surg. Clinic. North Amer.*, **65**, № 3, 679-682 (1985).
12. J. D. Manion, M. A. Acker, R. L. Hammond, *et al.*, *Circulation*, **76**, 155-162 (1987).

Engineering Methods for Monitoring the Proper Localization of Muscle and Cardial Electrodes during Cardiomyoplasty Operation

I. A. Dubrovskii and A. N. Ryzhikh

UDC 616.127-089.844:615.84.03

Translated from *Byulleten' Eksperimental'noi Biologii i Meditsiny*, Vol. 117, № 3, pp. 325-328, March, 1994
Original article submitted June 9, 1993

Methods are elaborated for monitoring the localisation of muscle and cardiac electrodes during cardiomyoplasty operation. The necessary operation testing system is devised. The paper presents the results of the monitoring of 42 cardiomyoplasty operations with implantation of Stiminak-805 and EKS-445 electrostimulators.

Key Words: *cardiomyoplasty; localization of cardial and muscle electrodes; operation controlling system*

Cardiomyoplasty (CMP) is gaining growing acceptance both in Russia [2-4] and in the West [5]. To date more than 200 CMP operations have been performed [5], 40 of them in Russia. Specialists consider CMP potentially useful for 50,000 patients per year [8]. Lond-term reliable functioning of the muscle blood pump thus becomes of crucial importance.

This intricate problem is being solved by animal experiments, the creation of engineering devices for stimulation, patient selection, performance of the operation itself, and postoperative care of the patients. All these factors obviously affect the reliability of the muscle pump functioning. At the same time, the engineering accoutrements of CMP operations also play an essential albeit less evident role. This aspect of the reliability control is subject of the present study.

Engineering and Physical Institute, Moscow. (Presented by V. I. Burakovskii, Member of the Russian Academy of Medical Sciences)

From the technical point of view, a CMP operation is a process of creating a biotechnical system, consisting of a heart, a cardial (synchronizing) electrode, an implantable electrostimulator of the muscle blood pump (ESMBP), a muscle (stimulating) electrode, and muscle autograft (Fig. 1.) It is evident that failure of any element of this complex system renders its functioning impossible even in the case of irreproachable patient selection, operation, and postoperative treatment. Failure may evidently occure in both the technical (electrodes, ESMBP) and biological (heart, muscle) elements of the system.

It should be specified that neither clinical complication (suppurstions, necrosis, etc.) nor lethal outcomes which are not related to failure of the biotechnical system are considered here.

Analysis of the functioning of 52 biotechnical systems manufactured in Kaunas, Moscow, Tomsk, Kiev, and Delhi allow us to state that technical failures occur rather seldom. One electrode break-

0007-4888/94/0003-0330$12.50

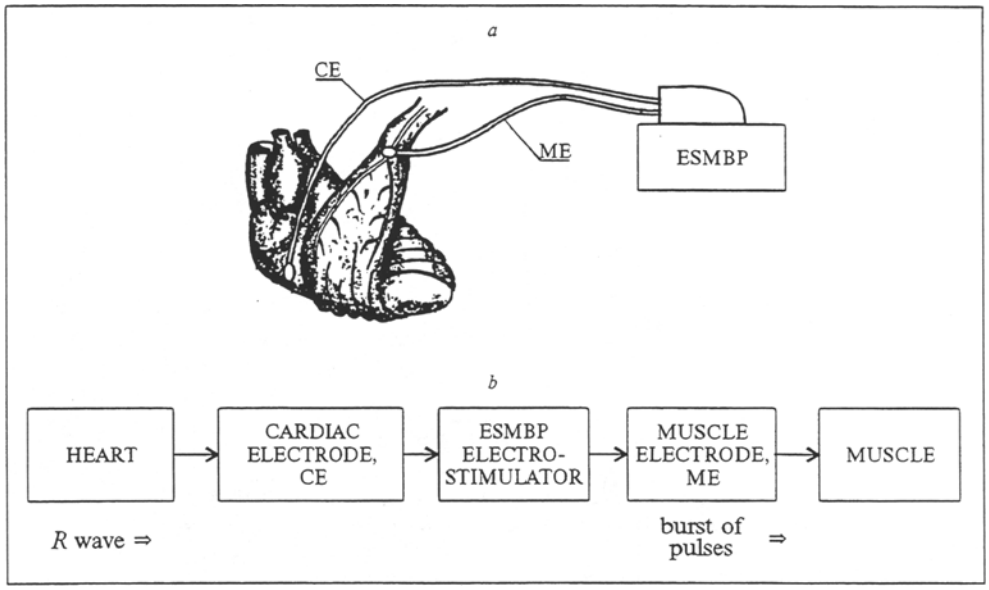

Fig. 1. Scheme of a muscle blood pump (*a*) and structure of the bioengineering system (*b*).

age occurred 8 days after implantation and resulted from incorrect incertion of the myocardial electrode into the thoracic cavity. Two cases of ESMBP failure were reported. The first occured 21 days postoperation and was caused by multiple discharges of the defibrillator through the implantation area. The second occurred 15 months postoperation and derived from improper control of the synchronization rate. It should be added that technical failure is usually easy to diagnose.

Much more often the technical components of the biotechnical system - electrodes and ESMBP - remain seviceable and the system still functional but ineffective. This is due to certain technical inoperation errors in localization of electrodes on heart and muscle, as a result of which the R wave may not provide for synchronization of ESMBP, while the burst of ESMBP pulses may not induce muscle contraction (Fig. 1, *b*). These disturbances are difficult to diagnose and even more difficult to repair in the postoperative period, and consequently, they should be prevented at all cost from arising during the operation. To this end we have developed test methods and quality criteria for the localization of the muscle and cardial electrodes during the course of the CMP operation and have devised special equipment. The testing protocols include the following measurements.

1. Quality control of the localization of the muscle electrode. For a burst of stimulating pulses to induce a proper muscle contraction it is necessary to determine quite precisely the electrode-muscle contact point near the muscle's nerve (Fig. 1, *a*) and then to fix precisely the electrode on the muscle.

However, first, the stimulation threshold has unambiguous significance for the heart, since its reaction obeys the well-known "all or nothing" law, whereas the muscle responds to the stimulus in a gradual manner (Fig. 2). Second, the heart is excitated with a single pulse, which is characterized by two parameters (amplitude and duration), whereas the muscle is excitated with a burst of pulses, which is characterized by four parameters (amplitude, duration, repetition rate, and number of pulses in a pack). Third, the reaction of the heart to a pulse may be easily and unambiguously assessed by ECG, while there is no simple instrumental, i.e., objective method for assessment of the muscle reaction to a pack of pulses during the course of a CMP operation.

For the above reasons the concept of a stimulation threshold of the muscle graft is in need of a definition agreed upon by leading surgeons and investigators studying diverse muscle blood pumps. Since no such agreed-upon definition exists, a special external device has been developed for estimating electrode position quality, which on a "start" command generates a burst of pulses. All param-

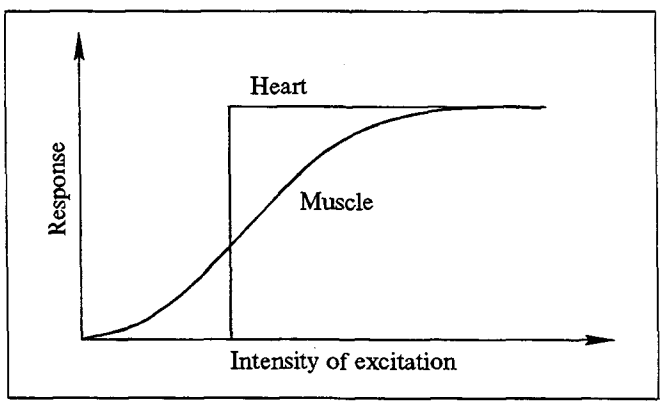

Fig. 2. Heart and muscle responses to electrical pulses.

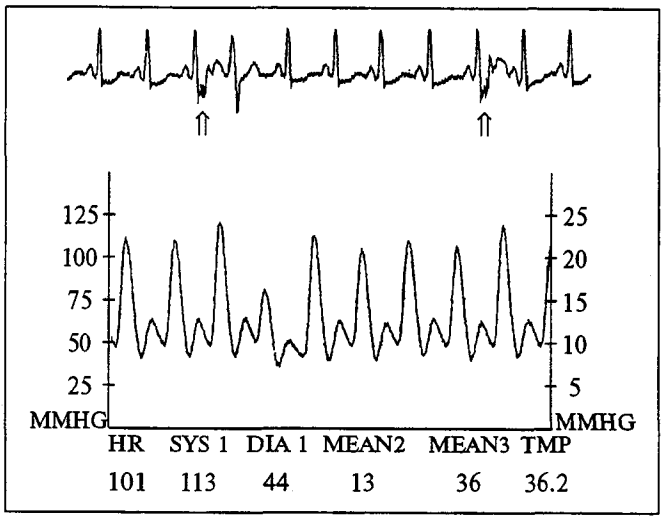

Fig. 3. Representative monitor lead of ECG, arterial pressure, and major physiological indexes. Conclusion of CMP operation performed at the A. N. Bakulev Institute of Cardiovascular Surgery. Testing of ESMBP (EKS–445 model) under a 1:6 synchronization rate. Arrows: bursts of pulses.

eters of the burst are set equal to those in a burst produced by the ESMBP to be implanted, exept for the amplitude, which may be set with a five-, twofold, or single margin vis-a-vis the amplitude of the given ESMBP.

During the control procedure the stimulating electrode is placed on the muscle near the thoracodorsal nerve, while the indifferent electrode (a round plate 24 mm in diameter) is placed in the middle of the distal part of the graft (the electrode together with the graft is held in the surgeon's hand), and a single burst of stimulating pulses is delivered.

If the muscle graft contracts powerfully enough in the case of a fivefold amplitude margin, the muscle electrode is to be considered properly positioned and ready to be fixed. In the case of a twofold margin a search for a better position is advisable. A single margin in installation of the electrode cannot be tolerated due to inevitable chronic alterations in exitability and contractility of the muscle.

Out of 52 cases of ESMBP implantation the proposed technique and criteria were applied in 42 cases and documented in 20 cases. According to documented protocols, the muscle electrodes were fixed properly in 12, satisfactorily in 4, and improperly in 4 cases. During the long-term postoperative period in these "documented" patients good contraction of the muscle was observed in 7, satisfactory contractions in 4, and no contraction in 2 patients. Of these two patients only one suffered a failure in engineering element of the system (Fig. 1, *b*), namely, the above-mentioned breaking of the myocardial electrode 8 days after implantation due to improper insertion.

Thus, quality control of the localization of the muscle electrode makes it possible to reduce the risk of such an annoying postoperative complications as an absence of muscle reactivity to a stimulating burst of pulses.

It should be noted that in the case of proper muscle contraction in response to a low amplitude of the pulse burst the implanted ESMBP works in a more economical regime, which extends its service period. For comparison: in CMP operations with the use of an SP1005 pacemakers the average amplitude was 4-6 V [6].

2. Quality control of the localization of the myocardial electrode. With respect to the cardiac pacemaker, the metrological characteristics of acute and chronic management signals have been well studied. Comprehensive statistics have been accumulated concerning the parameters of the *R*, *S*, and *T* waves, for both the myocardial and endocardial pacing [7]. However, this data cannot be directly applied to electrostimulators of the muscle blood pump.

The fact is that the state and electrical activity of the myocardium are markedly different in patients for whom permanent cardiac pacing and for whom CMP are indicated, and therefore the parameters of the *R* wave are also different. This may result in partial or absolute disturbance of the synchronization of the implanted ESMBP despite full compliance of its technical characteristics with the manufacturer's certificate. Hence, the parameters of the acute and chronic cardiac signals in these patients should be studied in order to adjust the input characteristics of the ESMBP to be implanted.

The procedure of gathering reliable data on the parameters of acute and chronic cardiac signals is involved and time-consuming. Hence, simultaneously with recording the shape of the cardiac signal we suggested determining the margins for the sensitivity threshold using a specially designed device. This device has input characteristics equal to those of ESMBP for implantation, except it allows an adjustment of the sensitivity threshold.

When positioning the electrodes of a pacemaker, a twofold margin above the minimal sensitivity threshold is required [7]. For lack of a better one, this quality criterion is also indicated for implantation of ESMBP. Namely, when the *R* wave measured with the myocardial electrode exceeds no less than twofold the minimal sensitivity threshold of the ESMBP (specified in its certificate and determined specifically for the endocardial *R* wave), the myocardial electrode may be

fixed without any additional measurements. If the margin for the sensitivity threshold is lower, the myocardial electrode should be repositioned.

Until this method was included into protocol of in-operation control, partial and complete asynchronism of the implanted ESMBP in the short- and long-term postoperative period was observed in 2 cases, even though all engineering elements of the system shown in Fig. 1, *b* were operable.

It is significant that, depending on the model of ESMBP used, such desynchronism resulted either in a shutdown of the muscle channel of the ESMBP (a STIMINAK-805 model [1]), or, much worse, in lack of synchronization between the myocardial and muscle channels of the ESMBP (SP1005 and EKS-445 [1]). The latter upset the synchronization between contractions of the heart and graft. Cases of such failures were also confirmed by follow-up examination of CMP-operated patients [6].

3. Monitoring of the stimulation threshold of the heart with single pulses. The technique and criteria are traditional [7]. A properly positioned myocardial electrode should ensure a double margin on the stimulation threshold relative to the minimal pulse amplitude of the myocardial channel of the ESMBP. This measurement prevents such postoperative complications as the appearance of muscle contractions asynchronous with the heart, if the heart rate drops below the value established by the VVI regime for the myocardial channel of ESMBP. The STIMINAK model requires no monitoring of the stimulation threshold of the heart.

4. Monitoring of the whole bioengineering system (Fig. 1). When the electrodes, first myocardial and then muscle, are attached to the ESMBP, the apparatus is set for a short time in the regime of higher synchronization rate. An example screen of the operation monitor is presented in Fig. 3. This test makes certain that the whole bioengineering system is functioning properly.

5. In some cases there is a need to ensure the working order of the apparatus under sterile conditions of the operation field. To this end a specialized tester was devised equipped with an indicator of the synchronization rate and number of pulses in a burst.

On the whole, following the above testing protocol considerably lessens the likelihood of failure in the key elements of the bioengineering system: in transition between the heart and the myocardial electrode and between the muscle electrode and the muscle (Fig. 1, *b*).

REFERENCES

1. I. A. Dubrovskii, A. V. Barkovskii, S. B. Shtolin, *et al., in: Mechanical and Biomechanical Support of the Heart* [in Russian], Tomsk (1991), pp. 47-68.
2. A. A. Krakovskii, V. S. Chekanov, and V. V. Pekarskii, *Experimental Cardiomyoplasty* [in Russian], Novosibirsk (1992).
3. V. V. Pekarskii, Sh. D. Akhmedov, V. V. Krivoshchekov, *et al., Abstracts of the First Slavonic Meeting on Electrical Stimulation and Electrophysiology of the Heart,* St.Petersburg (1993), pp. 156-157.
4. L. G. Ryabinina, *Principles of CHD Patient Selection for Cardiomyoplasty Operation. PhD Dissertation,* Moscow (1992).
5. R. C.-J. Chiu, *Cardiac Chron.,* **6**, № 9, 1-8 (1992).
6. P. Grandjean, L. Austin, S. Chan, and I. M. Bourgeois, *J. Cardiac. Surg.,* **6**, № 1, 80-88 (1991).
7. *A Practice of Cardiac Pacing.* Eds. S. Furman, D. L. Hayes, and D. R. Holmes, New York (1986).
8. R. Wilder, *Med. News Winter,* 51-62 (1992)