

Conversion of Cardiac Contractions into Electrical Energy Using an Epicardial Wireless Pacemaker

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The operating principles of an epicardial pacemaker (EPM) with microelectromechanical system (MEMS) converter in patients with cardiovascular pathology are described. Biological tests of this device in a patient with a rhythm abnormality after heart surgery are described in detail. Correlation analysis of all the input parameters of the device was run to obtain high power for MEMS output parameters to ensure effective operation of the pacemaker.

Introduction

Contemporary cardiac surgery uses implanted devices for stimulation or substitution of the function of various organs, such as pacemakers, which drive the heart rhythm, or cardioverter defibrillators, for electrotherapy of life-threatening cardiac arrhythmias. The service life of such devices or the planned intersurgery period is limited mainly by the capacity of the power source used and is usually 5-7 years, after which reoperation is performed with device reimplantation. At first sight it seems clear that the solution to this problem is to increase the electrical capacity of the power source, which understandably leads to increases in the weight and size of the device and can produce discomfort or side effects.

In 2013, studies at the Bakoulev Scientific Center for Cardiovascular Surgery developed, made, and tested a single-chamber pacemaker for epicardial autonomous wireless electrocardiostimulation [1], which has a minimal risk of producing electrode complications. Positioning of the pacemaker epicardially required development of a construct with the smallest possible weight and size, which included employment of a smaller power

source — which limited the lifetime of the pacemaker to three years. Achievement of an adequate service life and potentially increasing it requires consideration of the possibility of periodic or constant production of electrical energy to supply the pacemaker directly within the body.

The body is the source of the following types of non-electrical energy which might be converted to electrical: mechanical, thermal and chemical reaction energy. From the point of view of physics, the body is a mechanical system whose separate elements change their spatial positions relative to each other as time passes, and these changes can be used to convert mechanical energy into electrical energy. Contractions of the muscles and internal organs can be converted into electrical energy. Thus, patent [2] describes a device and means of generating electrical energy using cyclical changes in the diameter of a large artery as blood pulses through it by placing a cuff with a piezoelectric converter on the artery surface. Changes in artery diameter induce deformation of the converter and polarize the piezoelectric device, leading to formation of a difference between the potentials on its electrodes, i.e., generation of an electromotive force (EMF).

Heat energy is produced as a result of oxidation (degradation) of organic substances and can be converted into electrical energy by a thermoelectric converter using the temperature difference between organs with increased heat production and the surrounding tissues.

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Chemical Reaction Energy

The possibility of making biofuel elements (BFE) for conversion of biochemical reaction energy into electrical energy was first demonstrated in 1967 [3]. Theoretically, implanted BFEs using various biocatalysts (oxidoreductases, organelles, live cells) can produce electrical energy throughout life. However, the main characteristics of biofuel elements — specific power and stability [4, 5] — have relatively low values such that they are unsuitable for practical application.

The question of the technological features and reliability of these devices also needs brief consideration. In fact, we can refer to a distributed system consisting of the implant itself carrying out its function of providing electrical stimulation, the converter (electric generator), and the conducting part providing electrical connection between the implant and the converter and transmission of electrical pulse stimuli. This type of construct requires detailed preparation of the device both before surgery (complete or partial connection of all parts, testing reliability and hermetic sealing of the electrical contacts, etc.) and during surgery (positioning of conductors, their fixation, and rechecking). These actions take considerable periods of time.

Placement of the converter in the casing of the implanted device excludes a conductor component and increases the overall reliability by eliminating the connection between units. A reduction in the duration of surgery and its possible replacement by a laparoscopic procedure decreases the risk of complications and shortens recovery time. It is understandable that integration of the converter into the hermetically sealed casing of the EPM excludes the conversion of heat and chemical reaction energy into electrical energy. There remains only one source — conversion of the mechanical energy of the displacement of the epicardium into electrical energy [6].

Potential sources of mechanical energy are not only contraction or displacement of the internal organs, but also the body itself as an object with mass and speed. Displacement can be converted into electrical energy using the forced oscillation of a physical pendulum, which has already been in use in the self-winding mechanisms of watches for several decades.

Overall, the operating principles of such mechanisms are understood, and construction is simple and reliable. The self-winding mechanism model can therefore be used as the basis of designing a device converting the mechanical oscillations of the wall of the epicardium into electrical energy, taking account of a number of conditions:

1) the amplitude of displacement of the wall of the epicardium is many times smaller than the amplitude of displacement of the wrist, being no more than 20 mm;

2) in contrast to the self-winding mechanism, which makes oscillations mainly in a segment of a circle, displacement of the epicardium has a complex trajectory;

3) individual parts of the epicardium can move with accelerations of up to 2 g when the heart contracts.

Figure 1 shows the main elements of the mechanical construction of the converter.

In terms of its principle of operation, the converter is an electrical generator of alternating current. The disequilibrated mass in the form of sector 1 is rigidly fixed to rotating shaft 2; driving cogwheel 3 is also rigidly attached to the shaft and engages with driven wheel 4, forming a multiplier. Cogwheel 4 and rotor 5 are rigidly attached to driven shaft 6 and rotate synchronously. Rotor 5 is located in the gap of magnetic stator 7. Displacement of the sector through some angle relative to the starting position induces rotation of driving wheel 3 and driven wheel 4 with rotor 5. The rotating magnetic rotor induces changes in the magnetic flux through coil 8 of the stator and induces an EMF in its coils by magnetic induction.

Laboratory tests were performed by making a stand simulating displacement of the epicardium. The stand consists of a drive unit and displacement control system.

Figure 2 shows the mechanism of the converter on the mobile platform of the stand. The platform has six degrees of freedom, allowing it to simulate not only plane-parallel displacement in three axes, but also tilts. Displacement trajectories were specified on the basis of data obtained during an experiment studying the mechanical activity of the left ventricular myocardium [7].

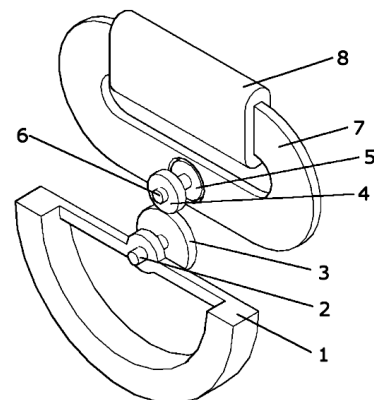


Fig. 1. Diagram of the mechanical unit of the converter: 1 — sector; 2 — shaft; 3, 4 — gear cogwheels; 5 — rotor with permanent magnet; 6 — driven shaft; 7 — stator; 8 — induction coil.



Fig. 2. MEMS converter on mobile test stand platform.

Figure 3 shows an oscillogram of the EMF at the coil output during simulation of systole lasting 40 ms with a displacement amplitude of 8 mm. The maximum recorded EMF amplitude at the coil output was 2.4 V when connected to an equivalent load with resistance 300 k Ω .

The tension on the induction coil output of the electromagnetic converter depends not only on construction factors, but also on the displacement of the epicardium and the heart rate, and can have an amplitude in the range 1.5–4 V at a pulse frequency of 200–400 Hz and volley duration 100–150 ms in a single heart cycle. Voltage with these characteristics cannot be used directly for supplying the EPM. After electromagnetic transformation, the AC pulsed voltage is therefore converted to direct current and stabilized at a level of 2.5–3 V.

Testing of the converter on the stand in the assembled state was run with the following parameters: voltage 2.5 V and current 8 μ A, which corresponds to 20 μ W of developed electrical power.

Biological Tests

The study aims were:

- to test the methodology of implantation of the EPM with a MEMS converter;
- to assess the efficiency of conversion of displacement of the epicardial surface of laboratory animals into electrical energy;
- to determine the recipient body's response to implantation in *in vivo* conditions;
- to identify the period of stability of the electrotechnical characteristics of the converter.

The timing stability was determined by adding measurement and information transmission functions to the programmer software and EPM to report the tension at the output of the converter.

In vivo tests were carried out in 10 domestic pigs.

Implantation was carried out epicardially on the free wall of the left ventricle of the heart and was followed by observations. The maximum duration of observation was six months. Post-operative observations after implantation of the mock-up stimulator with the MEMS device converting kinematic heart energy into electrical energy were made on the day of surgery, on post-operative days 2, 5, and 10, and then monthly for six months.

On the day of surgery, the median voltage on the output of the MEMS converter was 2.32 (2.22; 2.52) V, the current at the MEMS output was 7.52 (7.32; 8.12) μ A, and the electrical power developed by the converter was 17.42 (16.22; 19.32) μ W.

At six months after surgery, the median voltage on the output of the MEMS converter was 2.71 (2.54; 2.88) V, the current at the MEMS output was 7.88 (7.64; 8.44) μ A, and the electrical power development developed by the converter was 17.14 (16.68; 20.71) μ W.

Considering differences in epicardial activity (at different HR) and observation times, a descriptive and correlational analysis of the data was performed using non-parametric statistical methods (determination of median values and interquartile ranges, along with Spearman rank correlation coefficients, *R*).

The statistical analysis of the study results demonstrated stability in the voltage and current at the MEMS output and power at the MEMS input at the early time points after surgery (up to 10 days), after which statistically significant changes in voltage were seen (an increase five and six months after surgery), with decreases in current at the output and power at the input of the

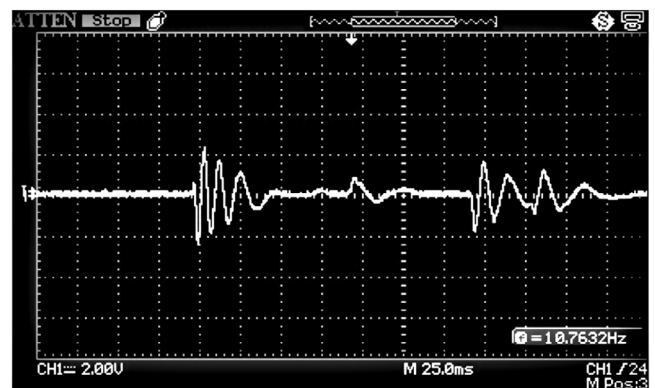


Fig. 3. EMF oscillogram.

MEMS, with a tendency to increase in these parameters.

Correlation analysis showed a strong direct relationship between power at the output of the MEMS converter and current strength at the output of the MEMS converter ($R = 0.894$), voltage at the output of the MEMS converter and current at the output of the MEMS converter ($R = 0.826$), and voltage at the output of the MEMS converter and power at the output of the MEMS converter ($R = 0.752$).

Direct correlational relationships between mean voltage on the output of the MEMS converter, the current at the output of the MEMS converter, and the power at the input to the MEMS on the one hand and heart rate on the other were found ($R = 0.476$, 0.466 , and 0.470 , respectively); the current at the output of the MEMS and the power at the input to the MEMS correlated with the gear ratio ($R = 0.289$ and 0.287 , respectively).

Conclusions

The experiments reported here identify stability in the voltage and current at the output of the MEMS and the power at the input of the MEMS, indicating that it can be used as the supply for the electronics (including the stimulating part) of an epicardial pacemaker. The implantable device has no general toxic actions on the patient's body.

Decreases in the output current and input power of the MEMS at the later post-operative period can be explained in terms of potential adhesion processes at the implantation site, which are complete by six months after surgery and do not progress further. This tendency to increased output current and input power in the MEMS at the late post-implantation period (five and six months) may indirectly reflect the adhesion process and normalization of the electrotechnical parameters of the mock-up MEMS converter.

The electrotechnical parameters of 10 implanted mock-up MEMS devices converting the kinematic activity of the heart into electrical energy (eight versions of the

kinematic converters with different inertial component masses and gear ratios) were studied.

The use of kinematic converter constructions with high gear ratios has potential for increased epicardial kinematic activity (increased HR) in terms of producing high power at the MEMS output.

In conditions of low kinematic epicardial activity, stable operation of implanted devices requires use of sensitive kinematic converters with lower gear ratios.

This study was supported by the Russian Ministry of Education and Science grant No. 14.607.21.0192 "Creation of a Lineup of Miniature Wireless Epicardial Pacemakers with MEMS Converters for the Treatment of Bradycardia and Cardiac Failure" (unique contract identifier RFMEFI60717X0192).

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