The Swiss approach for a heartbeat-driven lead- and batteryless pacemaker

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Introduction

Active medical implants play a crucial role in cardiovascular medicine. Their task is to monitor and treat patients with minimal side effects. Furthermore, they are expected to operate autonomously over a long period of time. However, the most common electrical implants, cardiac pacemakers—as all other electrical implants—run on an internal battery that needs to be replaced before its end of life. Typical pacemaker battery life cycles are in the range of 8–10 years[1]; however, they strongly depend on the device type and usage. Therefore, many patients are confronted with repeated surgical interventions[2] that increase the risk of complications such as infections or bleedings[3–5] and are costly. Furthermore, the battery accounts for a majority of a pacemaker's volume and weight. Its large footprint demands locating conventional pacemakers at a remote pectoral implantation site. Moreover, the large battery is responsible for another major limitation: To deliver the electrical stimulus at the pacing site, conventional pacemakers require long leads. They are exposed to continuous mechanical stress and are prone to fracture. Especially for younger patients this is a critical factor.[6,7]

In brief, batteries are the Achilles heel in the design of cardiac pacemakers. Therefore, an inexhaustible power supply and a leadless design are highly desirable. Different approaches have been investigated to extract energy from various sites and sources of the body[8,9] as, for example, the knee,[10] the chemical reaction of glucose and oxygen in dedicated fuel cells,[11] the skin-penetrating sunlight by solar cells,[12] the body movements using nanowires,[13] or the body heat.[14]

The human heart is another convenient energy source for medical implants, in particular for cardiac pacemakers: Regardless of a person's activity, the myocardium contracts in a repetitive manner and thereby reaches high accelerations of ≈2 m/s^2,[15] an excellent endurance (>2.5 billion cycles in a 70-year lifetime), and a large hydraulic power (≈1.4 W, with mean aortic pressure ≈ 100 mm Hg and cardiac output ≈ 6.3 L/min[16]). Researchers have been exploring ways to take advantage of this energy source, for instance, by harvesting energy from blood pressure differences using a micro barrel[17] or a dual-chamber system.[18] Furthermore, piezoelectric materials[19–22] as well as electromagnetic systems[23,24] have been used to harvest energy from the ventricular wall motion.

The automatic clockwork of a wristwatch is an example of a well-established and successful approach to convert human motion into electrical energy. The automatic clockwork captures the motion of a person's wrist during daily activities by an oscillation weight. A mechanical transmission gear and an electromagnetic generator finally convert the oscillations into electrical energy, which powers the wristwatch. Such energy harvesting mechanisms typically generate a power of 5–10 μW on average but can get as high as 1 mW, depending on the person's activity.[25–27] As a comparison, contemporary leadless pacemakers require <10 μW mean power to operate (according to device manufacturers' reference manuals).

The aim of this study was to demonstrate the feasibility of battery- and leadless cardiac pacing using a custom-made pacemaker supplied by an energy harvesting mechanism derived from

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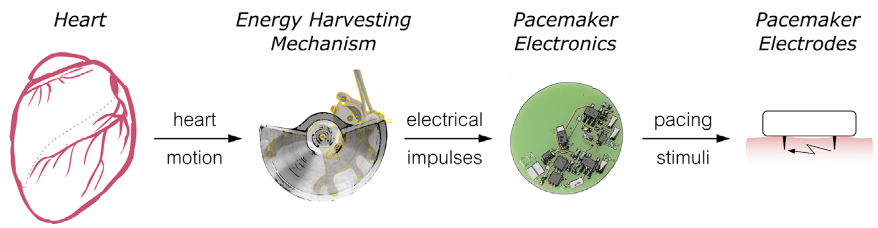

Figure 1 Working principle: The mechanical heart motion is converted into electrical impulses by an energy harvesting mechanism. The pacemaker electronics processes the electrical impulses, temporarily stores the energy, and generates electrical stimuli to pace the myocardium with 2 pacemaker electrodes.

a reliable Swiss wristwatch. The device's ability to harvest energy from heart motions was tested during experiments with a robot that mimics human heart motions. Finally, the pacemaker prototype was tested during an acute animal trial to show the feasibility of pacing a heart with its own energy.

Methods

Myocardial contractions provide continuous energy in the form of mechanical motion. An energy harvesting mechanism was introduced to convert the heart's mechanical energy into electrical energy. A dedicated electronics was developed to process and store the converted energy and to treat the heart with minute pacing stimuli (cf Figure 1). As the results will show, during this process, only a small portion (~80 μW) of the heart's total energy (~1.4 W) is converted and can be used to power the device electronics. The following subsections describe the energy harvesting mechanism and the pacemaker electronics, as well as the setup for testing the device on the bench and in vivo.

Energy harvesting mechanism

The energy harvesting mechanism is based on an automatic clockwork (ETA 204, ETA SA, Grenchen, Switzerland). The system was adapted to harvest energy from heart motion: time and date indicating parts were removed and a new oscillation weight was developed.[28] The total weight of 9.2 g was achieved by skeletonizing the clockwork's framework. This reduced the energy harvesting system to 4 main components (cf Figure 2) with the following functions:

1. The *oscillation weight* translates externally applied accelerations into an oscillating rotational motion. To increase its sensitivity to heart motions the oscillation weight was optimized and redesigned using a mathematical model reported previously.[24,28] The new oscillation weight features a mass of 7.7 g and is made of a platinum alloy (Pt 950/CO).
2. The *mechanical rectifier* translates the previously described oscillation into a unidirectional rotation. This allows harvesting energy from rotations in both directions.
3. The unidirectional rotation spans a *spiral spring* that temporarily stores the energy in mechanical form.
4. At last, an *electrical micro generator* (MG205, Kinetron bv, Tilburg, The Netherlands) converts a rotational motion into an electrical signal. When the torque of the spiral spring equals the holding torque of the generator, the spring unwinds and drives the electrical micro generator. The resulting impulse comprises ∼80 μJ at a load resistance of 1 kΩ.

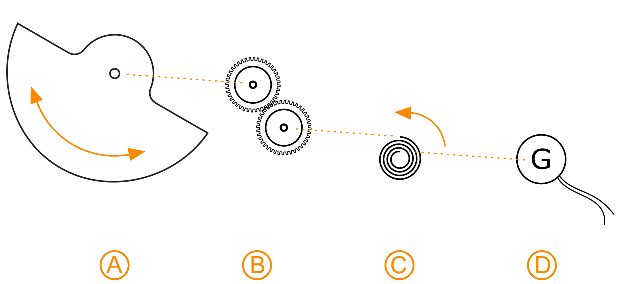

Figure 2 Energy harvesting mechanism: The schematics of the energy harvesting mechanism illustrating (A) an oscillation weight, (B) a mechanical rectifier, (C) a spiral spring, and (D) an electromagnetic micro generator.

Pacemaker electronics

The electronics of pacemakers typically includes different features such as sensing, pacing, or automatic rate adaptation. Each individual feature consumes energy from the battery and determines the lifetime of the device. Therefore, in the development of the modern pacemaker electronics, it is important to reduce the power consumption of the electronics to a minimum. But their lifetime is also determined by external factors: a small tissue impedance, a high pacing threshold voltage, a wide pacing pulse, or a high pacing frequency will increase the overall power consumption of a pacemaker electronics.

The here presented pacemaker electronics inherits 2 main functions that serve the purpose of demonstrating the feasibility of battery- and leadless pacing (cf Figure 3):

1. An energy management circuit receives an alternating current impulse from the micro generator that needs to be rectified. Each such impulse is temporarily stored in a buffer capacity (47 μF capacitor TM8T476K010UBA, Vishay, Shelton, CT). The voltage level in the buffer capacity can reach levels between 0.8 and 6 V, which mainly depends on the actual energy conversion rate of the energy harvesting mechanism for the present myocardial motion.
2. A simple pacemaker circuit uses the buffered energy to generate pacing stimuli. Solely relying on the previously harvested energy, the stimulus' voltage amplitude adopts the present voltage level of the buffer capacity (ranging