The first batteryless, solar-powered cardiac pacemaker

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BACKGROUND Contemporary pacemakers (PMs) are powered by primary batteries with a limited energy-storing capacity. PM replacements because of battery depletion are common and unpleasant and bear the risk of complications. Batteryless PMs that harvest energy inside the body may overcome these limitations.

OBJECTIVE The goal of this study was to develop a batteryless PM powered by a solar module that converts transcutaneous light into electrical energy.

METHODS Ex vivo measurements were performed with solar modules placed under pig skin flaps exposed to different irradiation scenarios (direct sunlight, shade outdoors, and indoors). Subsequently, 2 sunlight-powered PMs featuring a 4.6-cm^2 solar module were implanted in vivo in a pig. One prototype, equipped with an energy buffer, was run in darkness for several weeks to simulate a worst-case scenario.

RESULTS Ex vivo, median output power of the solar module was 1963 μW/cm^2 (interquartile range [IQR] 1940–2107 μW/cm^2) under direct sunlight exposure outdoors, 206 μW/cm^2 (IQR 194–233 μW/cm^2) in shade outdoors, and 4 μW/cm^2 (IQR 3.6–4.3 μW/cm^2) indoors (current PMs use approximately 10–20 μW). Median skin flap thickness was 4.8 mm. In vivo, prolonged S00 pacing was performed even with short irradiation periods. Our PM was able to pace continuously at a rate of 125 bpm (3.7 V at 0.6 ms) for 1½ months in darkness.

CONCLUSION Tomorrow's PMs might be batteryless and powered by sunlight. Because of the good skin penetrance of infrared light, a significant amount of energy can be harvested by a subcutaneous solar module even indoors. The use of an energy buffer allows periods of darkness to be overcome.

KEYWORDS Pacemaker; Batteryless pacemaker; Batteryless pacing; Solar pacemaker; Energy harvesting; Sunlight-powered pacemaker; Pacemaker technology; Sunlight

ABBREVIATIONS IQR = interquartile range; **PM** = pacemaker

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Introduction

Contemporary pacemakers (PMs), like other active medical implanted devices, are powered by primary batteries with limited energy-storing capacity. When the battery's lifetime ends, the device needs to be replaced. PM replacements are common, accounting for more than a quarter of all PM surgery procedures.[1] They are bothersome for patients, bear the risk of complications (eg, infections, bleedings), and are costly.

To overcome the limitations of today's systems, intracorporeal energy-harvesting techniques have been proposed.[2–6] Intracorporeal energy harvesting would allow PMs to be built without primary batteries, thus reducing the number of reinterventions. However, because of major drawbacks (eg, low energy output,[2,4,5] invasive implantation procedures[3,6]), none of these approaches has been implemented successfully in cardiac PMs to date.

On the basis of theoretical calculations and bench research measurements, we recently showed that direct sunlight may be used as an alternative energy source to power PMs.[7] Sunlight can be converted into electrical energy by solar cells. Because

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near-infrared light easily penetrates the human skin, this conversion is also possible if the solar cells are implanted subcutaneously.[7,8] Just a few minutes of direct sunlight may provide enough energy to power a PM by a subcutaneous solar module for an entire day.[7] However, a key limitation of this approach is that regular exposure of a person to direct sunlight cannot be guaranteed, for several reasons. Individual lifestyle (eg, indoor workplaces), location, and climate may heavily affect daily sunlight exposure. Thus, an appropriate energy storage and management system is a key element of a sunlight-powered (or solar-powered) PM. The goal of the present study was to investigate whether subcutaneous energy harvesting is possible not only under full sunlight (as reported previously[7]) but also under real-life low-light conditions, such as in shade or indoors. Moreover, we present the first functional prototype of an implantable sunlight-powered, batteryless PM. The design of this device is presented in detail, and its functionality was tested in bench research and in vivo. In particular, we demonstrate that it is feasible to overcome prolonged periods of darkness with this novel device.

Methods

The study was structured as 3 main experiments. First, ex vivo measurements under natural ambient sunlight were performed indoors and outdoors in bench research using pig skin flaps. Second, a dedicated batteryless, sunlight-powered cardiac PM was developed, implanted in a pig, and powered by a solar module to demonstrate the acute feasibility of the concept. This PM features dedicated energy management and storage elements. In a third step, the PM was explanted and run in complete darkness to assess the long-term performance of the device in a worst-case scenario.

The trial was approved by the ethics committee of the Veterinary Department of the Canton of Bern, Switzerland, and was performed in compliance with the *Guide for the Care and Use of Laboratory Animals*.[9]

Evaluation of different light irradiation intensities (experiment 1)

Solar module

To estimate the power output of subcutaneously implanted solar cells, we placed a solar module under pig skin flaps and exposed it to natural ambient light (ex vivo experiment). The solar module consisted of 3 monocrystalline solar cells (KXOB22-12X1, IXYS Corporation, Milpitas, California), which were soldered in series and contacted on the rear side. The module was encapsulated by transparent biocompatible silicone (Elastosil RT 601, Wacker, München, Germany). This silicone's light-absorption rate from 650 to 1100 nm, that is, in the relevant spectral band, is negligible.[10]

Skin model and light exposure

The solar module was placed ex vivo under 6 different nonvital pig skin flaps (6-month-old white domestic pigs). Although nonvital, these skin flaps are a reliable model for in vivo experiments[7] with similar optical properties as human skin.[8] The pigs were purchased directly from the slaughterhouse.

The skin flaps were exposed to 3 different lighting conditions:

(1) Outdoors under direct full sunlight (skin flaps aligned orthogonally to the direction of the sun, sun elevation 65°, on a sunny spring day with clear sky conditions). Median absolute light intensity was 842 W/m^2 (interquartile range [IQR] 835–859 W/m^2; measured by a calibrated reference cell).
(2) Outdoors, in shade on the same spring day. Only indirect diffuse light fell on the skin flaps. The measured absolute light intensity was 120 W/m^2.
(3) Indoors without direct sunlight exposure on the same spring day. The measurements were performed in a meeting room (2 m from the closed windows, with a northern exposure; no artificial lights were turned on). The measured absolute light intensity was 4 W/m^2.

Power measurement

The solar module was connected to a digital multimeter (Metrahit Energy, Gossen-Metrawatt, Nürnberg, Germany). To measure the maximum available output power of the solar module at the maximum power point,[11] we varied the load resistor using a resistor cascade board (SE40, Schärer Elektronik AG, Sarmenstorf, Switzerland). The maximum available output power was normalized to a standardized solar irradiation of 1 kW/m^2.

In vivo implantation of the sunlight-powered, batteryless PM (experiment 2)

PM description

We developed 2 custom-built batteryless, single-chamber PM prototypes. Both were powered by the solar module as described above and featured a 4.6-cm^2 solar module. An energy management system featuring an ultra-low-power boost converter (BQ25504, Texas Instruments, Dallas, Texas) and including a maximum power point tracker[11] allowed efficient energy harvesting for different irradiation scenarios (Figure 1). The measured housekeeping power of the electronic circuit was 7.15 μW. The energy was stored in a 100-μF ceramic capacitor (prototype 1; MC0402X104K100CT, Multicomp, Farnell element14, Leeds, United Kingdom) or a 9-mA · h lithium-ion polymer accumulator, respectively (prototype 2; GE020815, GE Battery, Shenzen, China). The entire electronics were embedded in a translucent biocompatible silicon housing (Elastosil RT 601, Wacker, München, Germany). The device's dimensions were 30 × 35 × 6 mm (volume 6.3 cm^3; weight of prototype 1, 11.5 g; weight of prototype 2, 11.1 g). It was equipped with a conventional IS-1 header (Figure 2) and operated in asynchronous SOO mode. A reed switch enabled inhibition of the device (magnet mode OOO) .

Device implantation

The acute animal study was performed on a 60-kg female domestic pig under inhalation anesthesia (isoflurane in oxygen [1.6 %] and fentanyl [5–10 μg/kg per hour]). Both