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Thoughts and Progress

Recharging the Battery of Implantable Biomedical Devices by Light

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Abstract: This article describes a new powering system for implantable medical devices that could significantly increase their lifetime. The idea is based on the substitution of the usual implantable device battery for an electric accumulator (rechargeable battery), which is fed by the electric power generated by a photovoltaic converter inside the implantable device. Light impinges on the photovoltaic device through an optical fiber going from the photovoltaic device to just beneath the patient's epidermis. Light can enter the optical fiber by passing through the skin. A complete power-by-light system has been developed and tested with a real implantable pulse generator for spinal cord stimulation. The feasibility of the proposed system has been evaluated theoretically. For example, after 13 h/week of laser exposure, the lifetime of the implantable device would increase by 50%. Other combinations resulting in lifetime increases of more than 100% are also possible. So, the proposed system is now ready to take a further step forward: in vivo animal testing. **Key Words:** Implantable devices—Power supply—Photovoltaic converter—Optical fiber—Skin.

As time goes by, implantable medical devices have begun to carry out other functions in addition to that of replacing a lost physiological function of the human body. Among these are digital data telemetry through the telephone (or Internet) networks, chronic data monitoring, etc. (1). Therefore, an increasing demand for electrical energy is becoming evident. Batteries are responsible for supplying electrical energy to implantable medical devices. Batteries are currently required to power implantable devices for 3–8 years. Therefore, chronic patients will undergo several surgical operations throughout their lives because of battery exhaustion. On the other hand, the battery occupies about half (or even more) of the internal space of an implantable device. This fact goes against the tendency of both surgeons and patients to demand that implantable devices and consequently, their integrated batteries be as small as possible.

Accordingly, this article describes a powering system for implantable medical devices that could significantly reduce the aforementioned problems. The idea is based on the substitution of the battery for an electric accumulator (rechargeable battery), which is fed by the electric power generated by a photovoltaic (PV) converter inside the implantable device. Light impinges on the PV device through an optical fiber going from just beneath the patient's epidermis to the PV device. Light can enter the optical fiber by passing through the skin. Although there is another approach to recharging the batteries consisting of the wireless power transmission through the skin by means of inductive coupling (2,3), optical power transmission has a significant advantage: The significant immunity from electromagnetic noise and interference, which is an inherent feature of optical systems. So, the substitution of the antenna coils by other devices (such as the PV converters described here) can eliminate the interference between external RF emitters and the powered devices.

METHOD

When light impinges on the human body, a part of it is transmitted through the skin and could reach a subcutaneous PV converter. A PV device would transform the light into electricity, which could then feed an implantable device. Following this principle, preliminary experiments were carried out in the mid-1990s (4). A more complete work was carried out in 2001 by using a commercial silicon photodiode array embedded under the skin of a rat to charge a lithium battery that directly powered a pacemaker (5). In both cases, the implantable device should be located at about 1–3 mm under the skin. With the exception of implantable sensors, the usual implantable devices cannot be placed so close to the surface of the skin. In order to solve this problem, we proposed the use of an optical fiber for transporting light from a region just under the skin to any part of the human body

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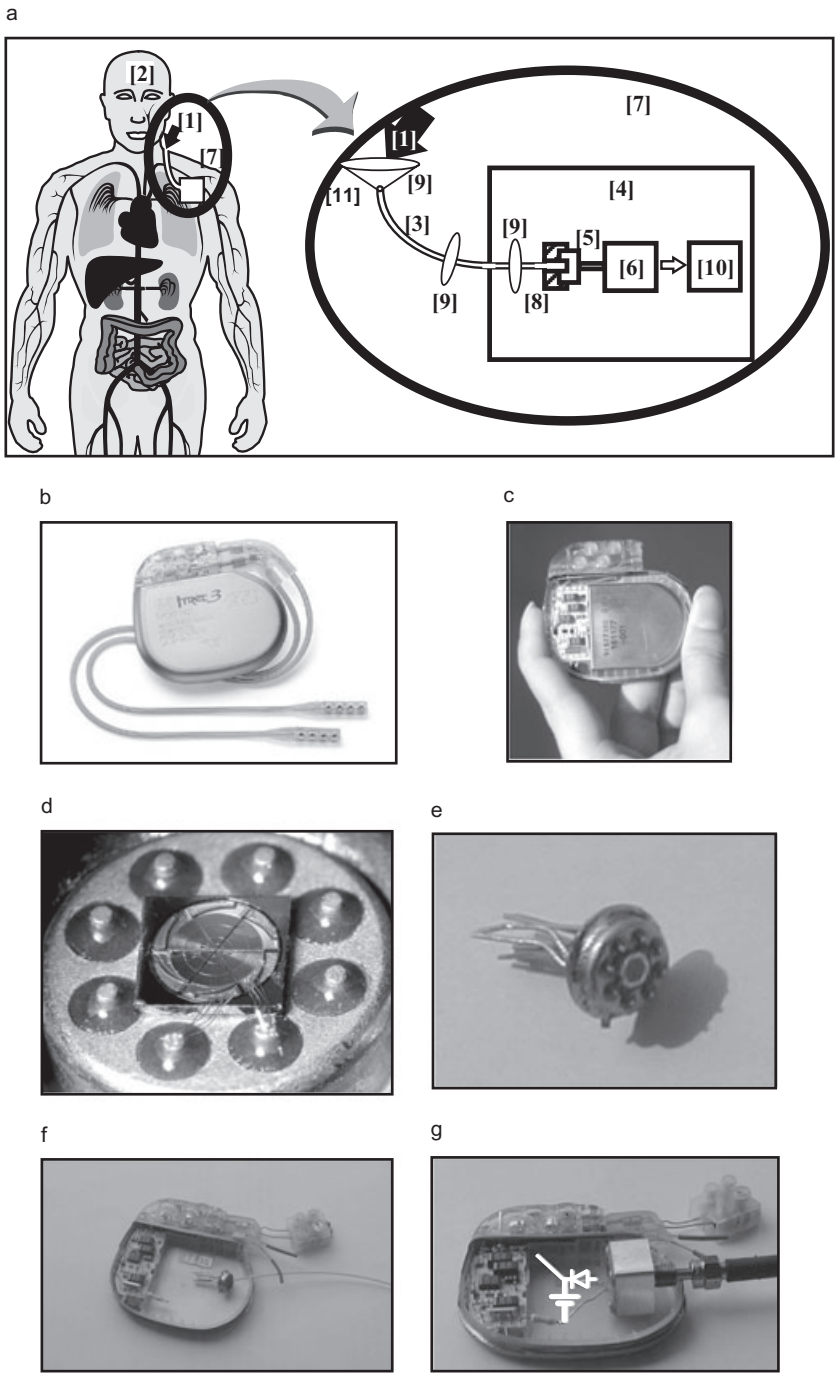

FIG. 1. (a) Proposed system setup. (b) External view of an implantable (ITREL® 3) pulse generator of the next generation although very similar to that used in our work (ITREL® II). (c) Inside view of the ITREL® II after opening the hermetically sealed case. (d) Photograph of a six-sector GaAs PV converter packaged in a TO-5 housing. (e) Complete aspect of the PV device. (f) Conceptual connection of an optical fiber to the PV device. (g) The PV converter is now encapsulated (although oversized), and the optical fiber has a commercial connector. The electric connections from the PV converter to the rechargeable battery through a blocking diode and from the battery to the ITREL® II circuit are superimposed.

with no significant losses (6). Thus, surgeons would have the freedom to place the implantable device in any part of the body without the limitations of absorption of light.

Figure 1a shows our proposed system in more detail. The PV converter (Fig. 1a [5]) is placed inside the implantable device (Fig. 1a [4]). Its electric terminals are connected to a power conditioner (Fig. 1a [6]) adapting the voltage and current levels to the requirements of the other conventional elements (Fig. 1a [10]). Conventional elements are understood as those already used in nonphotovoltaically powered implantable devices. The PV converter would have a connector (Fig. 1a [8]) in order to make an efficient link with the optical fiber plus additional optical elements (Fig. 1a [9]). From the connector, the optical fiber (Fig. 1a [3]) will run a short distance inside the implantable device before

coming out of the device, thus making it the only element inside the human body (Fig. 1a [2]) until it reaches the epidermis at a specific point where the light can enter the fiber (Fig. 1a [1]) by passing through the skin. This end of the optical fiber could have some kind of "optical funnel" or lens (Fig. 1a [11]) in order to concentrate the light energy to send to the PV device. If ambient light is to be used in this way, the energy supply would be weak but almost permanent, and the site of the end of the fiber under the skin should be chosen to provide maximum light exposure, such as the hands, neck, ears. Other light sources such as lasers and lamps could also be used, with which much more energy could be supplied per unit of time but with less frequency. In these cases, any part of the human body could be used for locating the end of the subcutaneous optical fiber.

EXPERIMENTAL RESULTS

In order to assess the viability of our proposed system, we have used an implantable pulse generator, model ITREL II (Medtronic, Inc., Minneapolis, MN, USA) (see Fig. 1b), for spinal cord stimulation. Figure 1c shows that the conventional battery occupies about 75% of the device volume. Then, we removed the battery, which produces a voltage ranging from 2.5 to 3.7 V and has a capacity of 2.7 Ah. In our proposed system, a smaller rechargeable battery has to be installed in this empty space so that the final size of the implantable device would be considerably reduced. For this first demonstration, we have used a 3.6 V Ni-MH rechargeable battery with 150 mAh capacity (VARTA), which is commonly used in conventional electronics. It would be desirable for the PV device to be able to charge the rechargeable battery directly to that voltage. Silicon PV converters can supply about 0.6 V at open circuit conditions, while gallium arsenide (GaAs) PV converters are able to supply about 1.0 V. Therefore, we have manufactured ad hoc GaAs PV converters following the process described in (7). A photograph of one of these GaAs PV converters can be seen in Fig. 1d, where there are six series-connected subcell parts (circular sectors), so this PV converter could supply about 6 V (about 1 V supplied by each sector) under open-circuit conditions. The diameter inside the bus bar (external golden circular frame) of the PV converter is 2 mm; thus, it has an active size of 3.1 mm^2. The semiconductor die is packaged into a TO-5 housing. A photograph of the complete device is shown in Fig. 1e. The PV device was characterized under the illumination of an 808 nm laser diode. The performance of the GaAs PV converter at laser intensities ranging from 13 to 7600 mW/cm^2 was measured with efficiencies between 29 and 44%, respectively. The open-circuit voltage ranges from 5.75 to 6.80 V. The short-circuit current increases linearly with optical power density and ranges from 0.036 to 21.4 mA.

The GaAs PV converter was placed inside the implantable device, and an optical fiber was connected (Fig. 1f). The 50-micron fiber core diameter has a 200-micron external diameter. The fiber diameter can be thicker, with its main limitation being the degree of invasion allowed by the patient. Silica and plastic are the preferred materials for the core housed in a plastic cladding. In order to provide a more robust setup, we have encapsulated the PV converter inside a small box (see Fig. 1g) and attached a commercial connector to the optical fiber.

First, we discharged the Ni-MH battery through the ITREL II (without connection to the PV converter) for 71 days. The discharge was made up of large periods with 6 μA consumption plus occasional periods with 15 μA consumption. The first current corresponds to that required by the ITREL II on stand-by (OFF), while the average current of the ITREL II in operation (ON) is 15 μA. This average experimental current is the result of adding the required current for periods with standard duty cycles for actuation pulses of up to 5000 μA (8) to the stand-by current. This way, we try to simulate the use of an implantable pulse generator, which is turned ON only when the patient needs stimulation. In the experiment, we set 15% of the time, ON and 85% of the time, OFF. Therefore, the experimental average consumption current is 7.5 μA. The starting voltage of the battery was 3.77 V, and, after 71 days of continuous operation, the voltage decreased to 3.73 V. After this discharge period, we proceeded with the charge of the battery by connecting the GaAs PV converter by means of a blocking diode (as Fig. 1g shows), which requires 0.4 V. The PV converter was illuminated by sending the laser light (808 nm) down to the fiber. Two different laser intensities were selected, which produced short-circuit currents in the PV converter of 0.15 and 0.39 mA when the PV converter receives 53 and 138 mW/cm^2, respectively. However, the aforementioned short-circuit currents (0.15 and 0.39 mA) decreased to 0.13 and 0.35 mA, respectively, as a consequence of the load exhibited by the battery and the blocking diode. When a current charge of 0.13 mA is used, about 95 h (4 days) is required in order to recover the 0.04 V lost by the battery in 71 days of ITREL II operation. When the charge current is 0.35 mA, this time decreases to 50 h (about 2 days). In real conditions, the patient should

charge the battery more often, decreasing the charging time dramatically.

DISCUSSION

In this section, we calculate the increase in the implantable device lifetime theoretically. We take into account the following aspects: (i) skin is considered as a single layer with refractive index, $n_{skin} = 1.5$ (9) and with the rest of its optical properties homogenous across the whole layer; (ii) wavelength-dependent absorption, reflection, transmission, and scattering are considered; (iii) radiative transfer equation (10) is considered for the light propagation within the skin that, with the assumptions of Haskell et al. (11), can be reduced to the so-called steady-state diffusion-type equation:

$$-D\nabla^2\phi(\mathbf{r}) + \mu_a\phi(\mathbf{r}) = q_0(\mathbf{r}) \quad (1)$$

where D is the diffusion coefficient, $\phi(\mathbf{r})$ is the fluence rate (light power per unit area), μ_a is the absorption coefficient, and $q_0(\mathbf{r})$ is the source term expressed as volumetric power density. This equation has an analytical solution for both the cases of laser beam incident on the surface of the skin (12) and sunlight (or ambient light) incident on the surface of the skin (12).

By assuming the continuous average current consumption of the ITREL II resulting from the previous section, $I_{ITREL} = 7.5\ \mu A$, we can calculate the increase in the implantable device lifetime, as a first approach, by means of the percentage of the ITREL II rechargeable battery charge:

$$C(\%) = \frac{I_P}{I_{ITREL}} 100 \quad (2)$$

where I_P is the average current supplied by the PV converter. This definition is also valid in energy terms by assuming that the voltage supplied by the PV converter is the same as that required by the rechargeable battery, as in our case. I_P can be expressed as

$$I_P = I_{pnor} \frac{p_L}{p_{nor}} \frac{\tau_W}{\tau_T} \quad (3)$$

where I_{pnor} is the current supplied to the ITREL II by the PV converter at a normalized light power density p_{nor}, p_L is the light power density impinging on the PV converter, and τ_W/τ_T is the time ratio that the PV converter is illuminated. For this ratio, we have chosen h/week (h/w) as the preferred units for τ_W, so τ_T is the total time in the units in which τ_W expresses, that is, 168 h/week. In order to evaluate the system feasibility, we briefly consider two representative cases.

Case 1: Laser beam incident on the surface of the skin

Fluence rate as a function of the depth of the skin can be calculated (12). Just under the surface of the skin, light is still rather forward directed, and, farther away from the source, the light is more diffuse. Radial diffusion creates edge effects, making it necessary to have a laser beam diameter of about 3 mm. Thus, laser light distribution under the skin would have a central cylinder of about 1 mm that would be unaffected by the edge effects (13). Therefore, we have considered a diode laser with the following easy-to-find characteristics: wavelength 808 nm, output power: 4 mW; class: 3R; and beam diameter: 3 mm. The latter characteristics produce a power density on the skin, $p_{skin} = 57\ mW/cm^2$ ($4\ mW/\pi \cdot 0.15^2\ cm^2$). Fluence rate under the skin may be several times that of the incident beam (14). Therefore, our recommendation is to place the end of the fiber under the skin as close as possible to the surface of the skin because (i) the light fluence rate will be higher; and (ii) the light anisotropy (collimation) will be higher, too. We will consider here the case in which the end of the fiber is located at a depth of 1 mm, making the fluence rate 207 mW/cm^2. Considering the optical coupling efficiency, $\eta_{coupling}$ (ratio of the optical fiber cross section divided by the light beam area under the skin), the light power received by the PV converter is

$$P_L = \phi \cdot \pi \cdot r_{light-skin}^2 \cdot \eta_{coupling} = 207\ mW \cdot cm^{-2} \times 0.0078\ cm^2 \times 0.36 = 0.58\ mW \quad (4)$$

where, as an example, we have assumed a fiber diameter of 0.6 mm and the aforementioned 1 mm light beam diameter under the skin, which results in $\eta_{coupling} = 0.36$. Therefore, we obtain $p_L = P_L/0.031 = 19\ mW/cm^2$ ($0.031\ cm^2$ being the area of the previously presented PV converter).

For C to be calculated, the following two variables, r_{fiber} (with $\eta_{coupling}$ varying accordingly) and τ_W, have been given multiple values in our calculations, while $I_{Pnor} = 0.26$ mA for our GaAs PV converter under a 808 nm light at $p_{nor} = 100\ mW/cm^2$ has been taken from our measurements. As Fig. 2a shows, multiple combinations are possible, showing that the proposed system will be of interest. Two examples are as follows: (i) An increase to 50% of the implantable

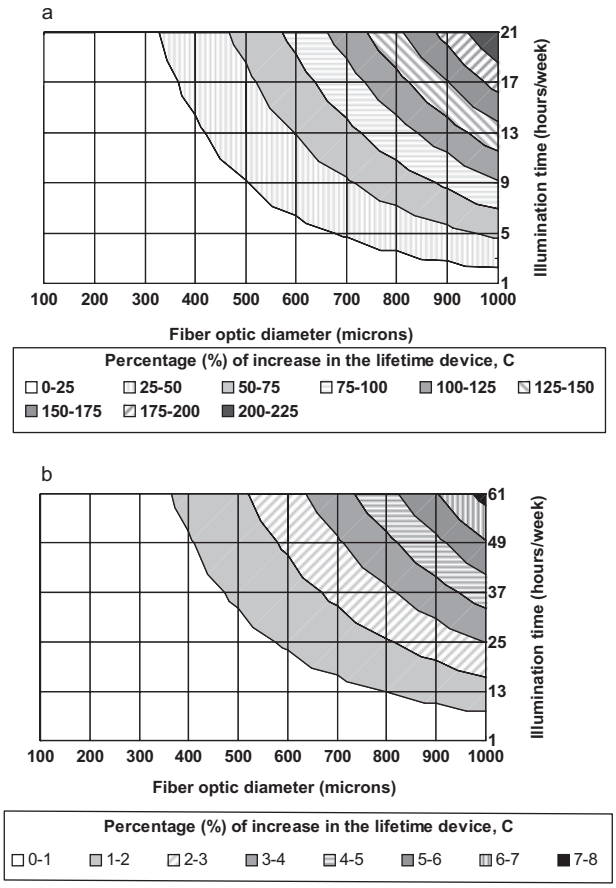

FIG. 2. Curves (in gray color) with same increase in implantable device lifetime *C* (%) for two different illumination cases. Laser light of 808 nm, power density of 57 mW/cm^2, and light beam diameter of 3 mm on the skin corresponding to Case 1 in the text (a). Solar illumination with a power density of 10 mW/cm^2 corresponding to Case 2 in the text (b).

device lifetime can be achieved for a fiber optic diameter of 600 microns together with an illumination time of 13 h/week; and (ii) an increase to 145% of the implantable device lifetime can be achieved for a fiber optic diameter of 800 microns together with an illumination time of 21 h/week.

Several options could be taken into account for the proposed system to become reality. An example is to include the laser diode in a kind of clamp which could be adapted to any given part of the body. Another possibility could be the use of thicker fibers (close to 1 mm) so the exposure will be reduced to about half an hour per day. An additional way of increasing *C* would be using a higher power laser with a larger spot diameter by keeping p_{skin} constant. A concentrator lens should also be secured to the fiber. Considering the étendue invariant (15), a concentration factor of about 18.3 is calculated, which means a linear increase in P_L and consequently, an increase in *C*. The huge influence of the concentrator lens can be seen by applying this 18.3 factor to Fig. 2a. So, fibers of 300 microns are able to achieve an increase of 90% in *C* for a light exposure of only 5 h/week. Consequently, our proposed system would be completely suitable in this case.

A key aspect to consider is the patient's tolerance to a given laser power density. Class 3R lasers, such as those assumed in this case, emit between 1 and 5 mW of output power within the 302.5–10^6 nm wavelength range. The risk of injury from directly viewing a Class 3R laser beam remains relatively low, but users should take greater care to avoid direct eye exposure, especially when handling invisible output, as in our case. However, scattered light is typically safe to the eye (16). In any event, a secure exposure to laser light suggests the use of protective goggles. However, the skin Maximum Power Exposure (MPE) set by ANSI Z136.1-2000 is well below the damage threshold (17). For CW lasers, as in our case, the MPE is 317 mW/cm^2 and 399 mW/cm^2 for wavelengths of 800 and 850 nm, respectively (http://www.ensc.sfu.ca/people/faculty/chapman/e894/lasersafety.html). Therefore, the laser density power on the skin assumed in Case 1 (57 mW/cm^2) is well below the MPE of the skin, and no risk to long-term exposure is envisaged.

Case 2: Sunlight incident on the surface skin

Our proposed system is also able to operate with sunlight. The standard sunlight power density is 100 mW/cm^2 for direct exposure. In order to be conservative, we have adopted $p_{skin} = 10$ mW/cm^2 for the simulation of the expected system performance under sunlight presented in Fig. 2b. Again, a depth of 1 mm is chosen in correspondence with that analyzed in Case 1. Besides, Case 2 is different from Case 1 in the following: (i) sunlight is assumed to be isotropic; and (ii) the sunlight is polychromatic so we have recalculated the skin optical properties. Figure 2b shows much lower values of *C* than in Case 1. For example, an increase to 5% of the implantable device lifetime can be achieved for a fiber optic diameter of 900 microns together with an illumination time of 49 h/week. Consequently, sunlight and ambient illumination can be used as a complement to the laser illumination but not as the unique illumination exposure.

SUMMARY AND CONCLUSIONS

A new powering system based on the use of a rechargeable battery that is fed by electric power generated by a PV converter inside the implantable device is presented. A complete power-by-light

system has been developed and tested with a real implantable pulse generator for spinal cord stimulation. By using a specifically manufactured 6 V GaAs PV converter, a successful charge of the rechargeable battery of the pulse generator is achieved. The feasibility of the proposed system has been theoretically evaluated showing that the proposed system is ready to proceed to a further experimental step.

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