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RESEARCH ARTICLE

Wireless Power Transmission for Left Ventricular Assist Devices: In-Vivo Trials, Challenges, and Future Directions

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ABSTRACT This paper aims to provide an overview of research achievements in the application of wireless power transfer (WPT) technology to power left ventricular assist devices (LVADs). These devices are implanted cardiac pumps designed to support patients with severe heart failure. LVAD implants are currently powered through a percutaneous cable that is often the cause of critical infections known as driveline infections (DLI) that require device explantation. The innovative WPT technology to power LVAD systems is a particularly attractive solution to overcome the criticality related to DLI and to improve patient comfort. A central focus is placed on the in vivo evaluation of a transcutaneous wireless LVAD power system, with comprehensive details provided regarding its architecture, technical specifications, and the data gathered during experimental trials. The successful in vivo testing underscores the practical feasibility and clinical relevance of this approach.

INDEX TERMS Active implantable medical device (AIMD), cable driveline, left ventricular assist device (LVAD), magnetic resonant coupling (MRC), wireless power transfer (WPT).

I. INTRODUCTION

Patients with severe heart failure may benefit significantly from a left ventricular assist device (LVAD), an advanced, electrically powered mechanical pump designed to support the function of a failing heart. The current generation of LVADs is surgically implanted into the left ventricle, offering a lifeline to patients awaiting heart transplants. Initially, LVADs were considered temporary solutions for bridging patients to transplantation. However, due to the chronic shortage of donor hearts, these devices are now being considered for long-term use, known as destination therapy, which can sustain patients indefinitely [1], [2], [3]. The efficacy of an LVAD hinges on its uninterrupted operation, as any downtime can be life-threatening. This continuous operation requires a substantial and consistent supply of electrical energy and, for this reason, complete power supply via an internal battery is impractical.

Therefore, the traditional approach involves using a driveline (DL) cable, which connects the implanted LVAD to an external power source. This DL is percutaneous, meaning it passes through the skin, which unfortunately introduces a significant risk of infection at the exit site, typically located in the abdomen. This type of infection, known as driveline infection (DLI), is a major complication and is statistically the leading cause of death among LVAD patients within the first-year post-implantation. To improve the long-term viability of LVADs, it is crucial to address and mitigate the risk of DLI.

A promising approach to eliminate this risk is to completely remove the percutaneous section of the DL, thus eliminating the potential entry point for bacteria but opening a new challenge on how to provide the necessary electrical

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power to the LVAD without using a percutaneous DL. For this purpose, wireless power transfer (WPT) technology offers an innovative and extremely interesting solution to the problem [4], [5], [6], [7], [8], [9], [10], [11], [12], [13], [14], [15], [16], [17], [18], [19], [20], [21], [22], [23], [24], [25], [26], [27], [28], [29], [30], [31], [32], [33], [34], [35], [36], [37]. WPT involves transmitting electrical energy without the need for physical wires, relying instead on electromagnetic coupling between a transmitter (TX) and a receiver (RX). Various coupling mechanisms can be used in wireless power technologies, ranging from near-field coupling (capacitive or inductive) to far-field coupling (radiative). The selection of the appropriate WPT technology depends on several factors, including the separation distance between the TX and RX, the required power level, and the specific application constraints.

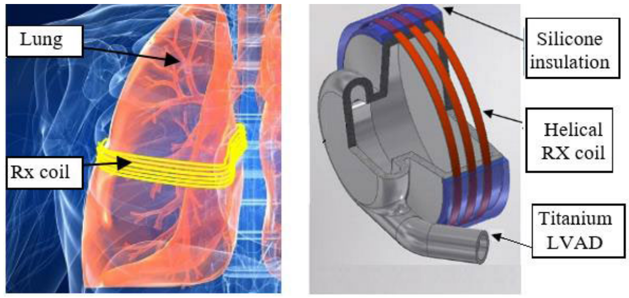
Among the different WPT technologies, resonant inductive coupling, also known as magnetic resonance coupling (MRC), has garnered significant attention for powering LVADs. MRC involves inductive coupling under resonant conditions, achieved by incorporating additional capacitors into the TX and RX circuits. This method enhances the efficiency and range of power transfer. Despite the focus on MRC, there is considerable variability in the specific strategies employed by researchers. These variations include differences in the design of the mechanical pump powering system, the shape and positioning of the coils, and the overall system architecture.

This paper aims to provide an overview of the current state of WPT systems for LVADs, outlining recent advancements, ongoing challenges, and future perspectives. We analyze the technical aspects of various WPT approaches, their advantages and limitations, and their potential to make LVADs a safer and more effective long-term therapy. A key focus of the work is the in vivo validation of the wireless power system, successfully tested on a porcine model, demonstrating its feasibility and clinical relevance in overcoming DLI-related issues and improving patient outcomes.

This paper is organized as follows: Section II presents the historical background of the LVAD from its introduction onward, with particular attention to the different proposed architectures; Section III discusses the limits in terms of electromagnetic safety, interference and thermal safety; Section IV analyzes the set-up and results of the in-vivo trial procedure; and Section V explores the future scenarios and challenges for these applications.

II. HISTORICAL BACKGROUND

The development of LVADs dates back to the 1960s with early contributions from DeBakey and Kantrowitz [1]. Significant milestones include the Jarvik-7 in 1982 [2] and the HeartMate series in the 1990s and 2010s, incorporating continuous-flow designs and magnetically levitated rotors [3]. These innovations led to FDA approval for both bridge-to-transplantation and destination therapy. Current research focuses on miniaturization, energy efficiency, and expanding applications for severe heart failure patients.



(a) (b)

FIGURE 1. **RX coil separated from the pump wound around lung [20] (a) and wound around the pump [33] (b).**

Integrating WPT into LVADs [4], [5] offers benefits such as reducing driveline infections, enhancing mobility, and improving patient comfort [6], [7], [8], [9], [10], [11], [12], [13], [14], [15], [16], [17], [18], [19], [20], [21], [22], [23], [24], [25], [26], [27], [28], [29], [30], [31], [32], [33], [34], [35], [36]. However, two major engineering challenges persist: high power consumption (average 5 W, peak 20-25 W) and implant depth. Wireless powering must address heat generation, energy efficiency, and safe transmission to be viable.

Early applications of WPT in LVADs, mainly through transcutaneous energy transfer (TET) systems, emerged in the late 1990s and early 2000s [12], [13], [14], [15], [16], [17], [18]. TET relies on aligned TX and RX coils to wirelessly transmit power, but earlier technologies lacked the efficiency, cost-effectiveness, and compactness needed for commercial adoption.

Waters et al. introduced the FREE-D system, which utilized a two-coil TX and RX to improve alignment flexibility [19]. Despite overcoming some TET limitations, it was not widely adopted. More recent designs operate at frequencies below 300 kHz, focusing on optimizing coil design for better range and efficiency. Pya proposed a system with a large RX coil implanted around a lung and a TX coil surrounding the torso as shown in Fig.1a [20], but the method remains clinically intrusive.

Other approaches explored higher frequencies, such as 6.78 MHz [23], which improved inductive coupling but introduced power losses and electromagnetic field (EMF) safety concerns [39], [40], [41], [42]. Campi et al. suggested an RX helical coil mounted on the LVAD surface as shown in Fig. 1b [33], though only numerical simulations were presented. These designs require a TX coil generating a field aligned with the RX coil, often achieved through a planar belt-like TX coil, though patient anatomical variations can impact effectiveness.

Several prototypes have been tested for TET [21], [22], but none specifically for LVADs. Studies [24], [25], [26] have analyzed coil misalignment effects but lacked in-vivo validation. Other research [27], [28], [29] proposed hybrid or miniaturized LVAD systems to enhance mobility and reduce infection risks, but long-term reliability remains unverified.

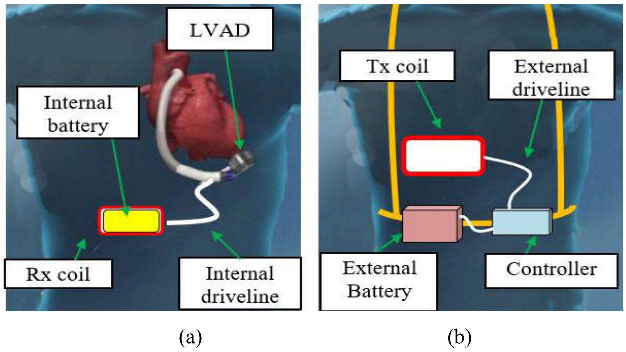


FIGURE 2. System architecture: (a) internal; b) external.

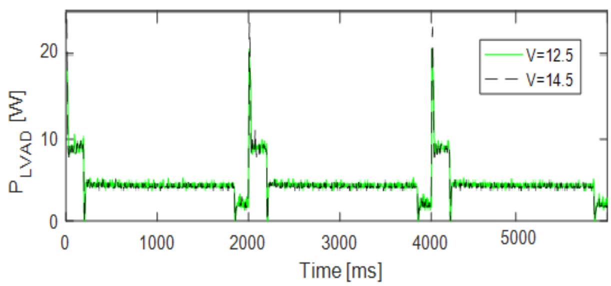


FIGURE 3. Instantaneous power absorbed by an LVAD in pulsatile mode.

With advancing technology, TET is regaining interest due to its ability to transfer substantial power over short distances using two planar coils. A TX coil placed on the skin and an RX coil implanted subcutaneously (1-2 cm apart) optimizes power transmission for LVAD applications.

In recent years, Campi et al. proposed a simple yet highly efficient WPT architecture for a fully implanted RX [34], [35], based on MRC. In this system, the RX coil is implanted subcutaneously, while the TX coil is placed externally. The RX, which includes the coil, the impedance matching network (IMN), and the rectification unit, is connected to the LVAD via a fully internal DL. Additionally, a backup battery is implanted near the RX coil within the human body, as shown in Fig. 2. The inclusion of the internal battery is particularly crucial as it provides electrical energy during the peak power demands of the LVAD when operating in pulsatile mode, as shown in Fig. 3. This design allows the WPT system to be sized for average power consumption (around 5 W), while the battery handles the energy peaks (20-25 W) and ensures an uninterrupted power system. The internal battery also permits the patient's implant not to be powered by the external battery for limited periods (1-2 hours), enhancing mobility and quality of life. The ability to operate without permanent connection to the external battery is a very important benefit, offering greater freedom and flexibility to patients who rely on LVADs for their heart function. Detailed specifications of the last generation of this system is reported in Section V.

An apparently similar TET system is proposed in [30], with the goal of developing a fully-implanted LVAD. Although details on the system are not provided, the preliminary presented results are encouraging. A similar architecture was also announced by Abbot and Resonant Link for future commercial LVADs [43].

III. SAFETY AND INTERFERENCE

In developing a WPT system for an LVAD, besides the high electrical performance, there are three critical aspects that must be carefully considered:

1. Electromagnetic field (EMF) safety
2. Thermal effects
3. Electromagnetic interference (EMI)

The first two aspects concern the impact of the generated magnetic field and heat on the human body, while the third pertains to the potential interference caused by the magnetic field on other devices, such as cardiac implanted electronic devices (CIEDs). These three aspects will be explored in depth in the following sub-sections.

A. EMF AND THERMAL EFFECTS

WPT systems must comply with EMF safety standards to ensure patient safety [38], [39]. The primary limits of internal physical quantities, known as basic restrictions (BRs), include the induced (or internal) electric field (E) for frequencies up to 10 MHz and the Specific Absorption Rate (SAR) for frequencies above 100 kHz. SAR is obtained as SAR = $\sigma E^2 / \rho$, where σ is the electrical conductivity, ρ the mass density and E the rms electric field.

Given the high power consumption required for LVADs, ensuring compliance with BRs presents a significant challenge. As operating frequency increases, SAR tends to rise substantially, making it preferable to use, when possible, a relatively low frequency, typically in the 100-300 kHz range. In this frequency range, the primary concern shifts to maintaining compliance with the internal electric field E.

The reference level (RL), i.e. the strength of the permissible external field, was introduced into the guidelines for practical reasons, as RLs can be easily measured in air without taking the human body into account while BRs are not easily measurable physical quantities without invasive measures that might be dangerous for humans. However, the RLs were derived by considering the worst-case exposure scenario, i.e. assuming that a human is standing in free space and exposed to a spatially uniform field.

It should be noted that for exposures at low frequency (LF) and intermediate frequency (IF) fields, i.e., $f \leq 10$ MHz, the averaging time of the internal electric field is zero due to instantaneous response of the nervous systems to LF / IF field excitation, while in radio frequency exposures the SAR is time averaged for time intervals ≥ 6 min.

The procedure for the EMF safety assessment according to ICNIRP Guidelines [38], [39] can be summarized by the following steps:

1. Measure the spatial peak rms value of the maximum external field strength in air and compare it to the RL, i.e., the magnetic field for the considered application.

2. If the measured field strength exceeds the RL, evaluate the physical quantities within the human body and compare them to the BR. For $f \leq 10$ MHz the spatial peak value of the induced electric field, averaged over a $2 \times 2 \times 2$ mm^3 cube must be assessed. For 100 kHz $\leq f \leq 6$ GHz the SAR must also be evaluated. The local SAR in the head/torso is the most stringent limit and must be averaged over a 10 g cubic mass.
3. If the physical quantities within the human body exceed the BRs, reconsider the overall design.

Step 1 requires measurements of the magnetic field distribution surrounding the system under test. If the measured field exceeds the RL, assessing the BR becomes necessary (Step 2). Since direct measurement of BRs within the human body is not feasible, numerical dosimetric analysis must be conducted. The analysis simulates the interaction of electromagnetic fields at both low and high frequencies with the human body to ensure exposure levels remain below the BRs. This analysis involves simulating how electromagnetic fields interact with the human body to ensure that exposure levels remain within safety limits. A numerical dosimetric analysis involves the following phases:

- Human body modelling by creating detailed anatomical models with specific electromagnetic properties.
- Simulation of EMF exposure by solving electromagnetic field equations in the human body model. At LF / IF the magnetic field is predominant and is not significantly perturbed by the presence of the human body, so the magneto-quasi-static (MQS) field equations can be applied to predict the internal physical quantities.
- Comparison of the calculated physical quantities, averaged according to ICNIRP standards [38], [39], with the BRs.

Some specialized software tools such as Sim4Life [40] includes detailed models of the human body, characterized by various factors such as age, sex, and body composition (e.g., fat or slim) [41]. These models consist of over 80 different biological tissues, each defined by its unique electromagnetic and thermal properties.

Safety considerations also extend to the thermal effects of WPT systems. A temperature increase of 1 or 2 °C in the trunk area is generally considered the maximum allowable limit [44]. Heating in biological tissues can occur due to SAR, as described by the bio-heat equation, or through heat propagation resulting from Joule losses in conductive materials, as well as heat dissipated in electrical and electronic circuits [34], [35].

To ensure compliance with these safety standards, extensive modelling and simulation are required. By simulating various scenarios, researchers can identify potential hotspots and areas of concern, enabling the design of safer and more efficient WPT systems. An example of an E-field distribution obtained is shown in Fig. 4a, while an example of a calculated temperature increase is shown in Fig. 4b [35]. The simulations were performed assuming the worst-case scenario with an output fixed power of 25 W for the LVAD, while the frequency of the WPT system was set at $f = 300$ kHz with subcutaneous configuration [35]. The maximum calculated rms electric field E_{max} and the maximum SAR were found to be 26 V/m and 0.043 W/kg, respectively, which are much lower than the ICNIRP BRs in terms of E and 10g average SAR are 40.5 V/m and 0.2 W/kg in trunk for general people, respectively. The comparison shows that the limits are not exceeded. In addition to compliance with regulatory standards, patient-specific considerations must be taken into account. Factors such as individual anatomy, health conditions, and activity levels can influence how EMF and thermal effects manifest in a particular patient. Personalized simulations and adjustments to WPT systems can help tailor solutions to individual needs, further enhancing safety and efficacy.

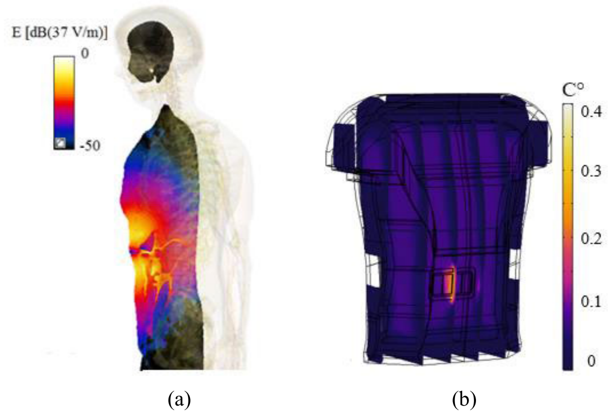


FIGURE 4. Distribution of the electric field E inside the HBMs (a) and map of the temperature rise inside the simplified torso (b).

B. EMI EFFECTS

The utilization of WPT technology introduces the possibility of EMI issues with nearby electronic devices. One of the most significant concerns involves potential EMI effects on other critical implants, such as CIEDs. This is especially critical for implantable cardioverter defibrillators (ICDs), which typically have at least one long lead. These leads can easily act as a loop, collecting electromagnetic energy by Faraday's law of induction, which could lead to malfunctions or unintended operations that can be very dangerous for the patient. Given that ICDs are always implanted in patients undergoing LVAD therapy, the interaction between these devices warrants thorough investigation. To address EMI in CIEDs, the reference standard is ISO 14417 [44], which outlines test procedures to verify the immunity of these devices. The most stringent criterion is the peak-to-peak amplitude of the open-circuit voltage, V_{pp}, driving the pacemaker at the outputs of the tissue-equivalent interface. In CIEDs with leads, V_{pp} is the voltage induced on the effective lead loop area S by the external field according to Faraday's law of induction. In the case under study, this external field is generated by

TABLE 1. Peak-to-peak induced voltage limits vs. frequency.

Frequency range	V_{pp} limit
3 kHz $\leq f \leq$ 150 kHz	6 mV × (f / 1 kHz)
150 kHz $\leq f \leq$ 167 kHz	6 mV × (f / 1 kHz)
167 kHz $\leq f \leq$ 1 MHz	1 V
1 MHz $\leq f \leq$ 10 MHz	1 V × (f /1 MHz)

the WPT system used for wirelessly powering the LVAD. The amplitude of V_{pp} for the unipolar test and the bipolar common mode test is a function of the carrier frequency f, as show in Table 1 [43].

The voltage V induced on the lead loop area S can be obtained by Faraday' law that in the frequency domain is:

$$V = -j\omega\Phi \tag{1}$$

where

$$\Phi = \int_S \boldsymbol{B} \cdot \boldsymbol{dS} \tag{2}$$

being $\boldsymbol{B}$ the magnetic flux density.

When the incident magnetic field is assumed to be spatially constant, the magnetic flux is given by $\Phi = BS$ and the rms value of the magnetic flux induction B is obtained as

$$B = \frac{V}{\omega S} \tag{3}$$

where the rms voltage V, assuming a sinusoidal waveform, is given by:

$$V = \frac{V_{pp}}{2\sqrt{2}} \tag{4}$$

At $f = 300$ kHz, for example, the ISO limit is equal to $V_{pp} = 1$ V, which corresponds to a rms voltage $V = 0.3536$ V. For a semi-circular loop lead with an effective area of 225 cm^2, defined in ISO 14117 as standardized effective lead loop area, the admissible magnetic flux density for a spatially uniform incident field is calculated as $B = 0.3536/(2\pi\ 300000 \cdot 0.0225) = 8.33\ \mu$T. It should be remarked that this value is significantly lower than the RL of 27 μT specified by the ICNIRP 2010 guidelines for human exposure to electromagnetic fields in the frequency range 3 kHz – 10 MHz. However, the magnetic field produced by a WPT system is far from having spatial uniformity, so the evaluation of the open circuit voltage V_{pp} must be carried out by experimental or numerical analyses.

Ensuring the compliance with this limit is very important for a WPT system for LVAD due to the very close position of the WPT coils (magnetic source) and the CIED lead (victim). A sketch of the configuration is reported in Fig. 5. An in-depth investigation was conducted to assess the EMI produced on an ICD by a WPT system operating at $f = 300$ kHz to power an LVAD [34]. This investigation involved both numerical simulations and experimental measurements to ensure the accuracy and reliability of the results. In the experimental study, the voltage induced at the input port of an ICD was measured, considering a semicircular lead loop with an effective area $S = 225$ cm^2 according to ISO 14117 [44]. A WPT system was used to power the LVAD delivering an average power of 20 W, which is significantly higher than that typically required for normal LVAD operation. This conservative approach ensured that the results accounted for worst-case scenarios, providing a robust safety margin. In the experimental setup, a realistic scenario was chosen where the ICD lead was positioned in various orientations relative to the WPT system. The obtained results demonstrated that, regardless of the loop's orientation, the voltage induced in the lead loop area remained well below the safety limits defined by the ISO 14117 standard, i.e., $V_{pp} < 1$ V. It was also verified that the induced voltage measured in air or in saline solution was almost identical. This means that at $f = 300$ kHz the absorption of the electromagnetic field in biological tissues is negligible, so the human body is almost transparent to magnetic fields. The induced voltage was largely within safe limits of EMI for cardiac devices to ensure their safe operation, suggesting that the WPT system does not pose a significant EMI risk to ICDs, at least for the solution proposed in [34]. As the assumption of a spatially uniformity of the incident field is highly conservative, a numerical procedure was developed to evaluate the induced voltage on the lead loop area [45].

The key assumption of this method was that the magnetic field can be calculated in air, without accounting for the presence of the human body, as the field attenuation due to the presence of biological tissues was considered negligible at the considered frequency, as experimentally demonstrated. The procedure permits to calculate the magnetic flux linked with a semicircular area of 225 cm^2 and subsequently determining the induced voltage by (1). Obviously, the induced voltage depends on the position and orientation of the semicircle loop area. Therefore, the procedure calculates the induced voltage in a discrete 3D grid of points separated by 1 cm and with many orientations along the three orthogonal directions. The discrete rotation steps along each coordinate

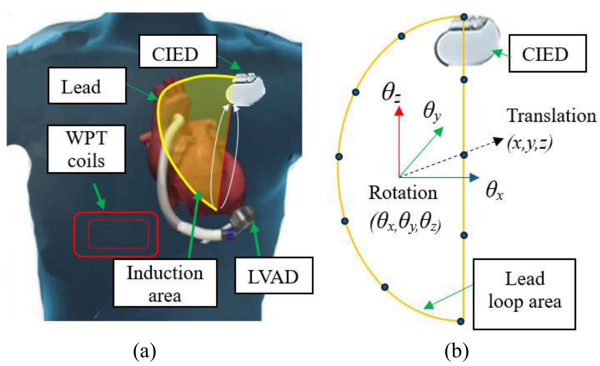


FIGURE 5. Configuration of the CIED with wirelessly powered LVAD (a), Lead loop with discretized boundary (b).

axis was fixed in 10 degrees. As the number of simulations required to find the maximum voltage is very high, the magnetic flux within the semicircle area is calculated by postprocessing the obtained numerical solution in terms of the distribution of the magnetic vector potential **A** in air. As illustrated in Fig. 5b, the boundary of the semicircle area is first discretized into line segments and then the magnetic flux is obtained from the discrete contour integral of the magnetic vector potential along the closed boundary. Adopting a roto-translation algorithm, the magnetic flux and induced voltage is quickly calculated at any grid point of the computational domain for any orientation of the semicircle area [45].

Furthermore, the study's methodology involved considering various factors that could influence EMI, such as the distance between the WPT system and the ICD, the specific configuration of the coils, and the operational frequencies used. By systematically analyzing these parameters, the research provided comprehensive insights into the EMI behavior of the LVAD-WPT system.

Although the potential for EMI with WPT systems is a valid concern, rigorous testing and validation, as demonstrated in [44] and [45], can help mitigate these risks. By following established safety standards and using conservative design principles, WPT technology can be safely and effectively integrated with other critical medical implants.

IV. IN VIVO TRIALS

A. SYSTEM SPECIFICATIONS

The fully implanted LVAD architecture proposed in [34], [35], and [36] has demonstrated to be effective in terms of simplicity, cost, size, EMF safety, temperature rise, etc... It has therefore been adopted for a 2-year clinical trial on animals by a team of cardiac surgeons in Italy starting in spring 2022. Please note that in Italy in vivo experiments on animals are subject to particularly stringent regulations aimed at protecting and safeguarding animals and must be authorized by the Ministry of Health.

The TX architecture of the WPT prototype is rather traditional and composed of a driving stage operating at 300 kHz and powered by an external battery, connected to the TX wearable planar coil. The RX architecture is based on the architecture described that demonstrated high efficiency and good safety margins. [35], and is mainly made up of a subcutaneous planar coil facing that of the transmitter, a backup battery, power converters and a fully internal DL that connects the receiver to a traditional heart pump.

In this study, several enhancements were incorporated into the WPT prototype for *in vivo* experimentation, specifically to minimize the size of the implanted coil-battery unit. Specifically, the volume of the new implanted device is reduced by 43%, while the weight is reduced by 36%. The WPT coils were designed to optimize the number of turns for the TX and RX coils, and the Litz wire configuration, as described in details in [32] and [33]. As a result, the implanted coil has external dimensions $l_{rx} \times w_{rx} = 95 \times 70$ mm^2 with a

(a) (b)

FIGURE 6. WPT coils for in-vivo experiment. TX coil (a), RX coils (updated version and the previous one presented in [33], [34], and [35]).

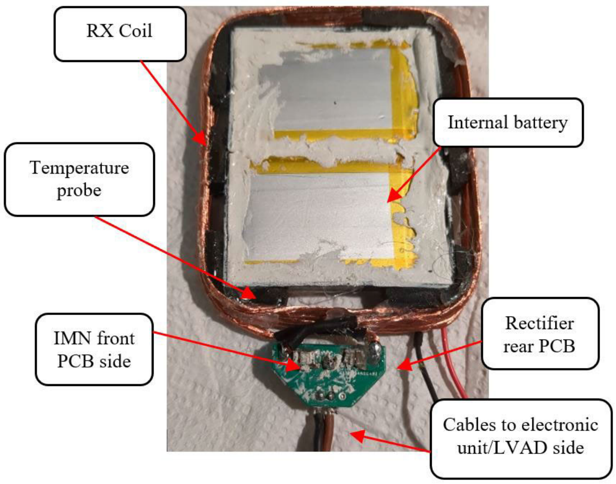


FIGURE 7. RX coil, battery pack and electronics.

thickness of 9 mm. The RX coil has 4 turns and incorporates a 800 mAh battery pack with a nominal voltage of 14.4 V. The total weight of the coil and battery pack is approximately 130g. The proposed implant is not significantly larger than other widely used implants, for example an implantable cardioverter-defibrillator (ICD) has external dimensions of 70×60 mm^2, with a thickness of 15 mm and a weight of more than 100 g. The TX coil has dimensions $l_{tx} \times w_{tx} = 150 \times 60$ mm^2. Both the external TX and implanted RX coils were embedded in neutral silicon for protection, as shown in Fig. 6.

Moreover, the coil and modular battery pack provide good flexibility for the device. In the improved version of the system, part of the electronic units—comprising the high-frequency rectifier, and the IMN—have been positioned in the coil area. An image of the new implanted coil is reported in Fig. 7.

B. ELECTRONIC ARCHITECTURE

The electronic architecture aims to maximize system reliability while minimizing the number of components in the

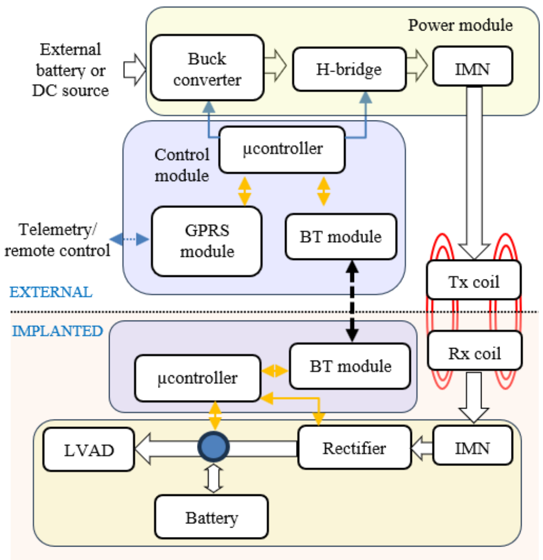


FIGURE 8. System architecture used in in vivo testing.

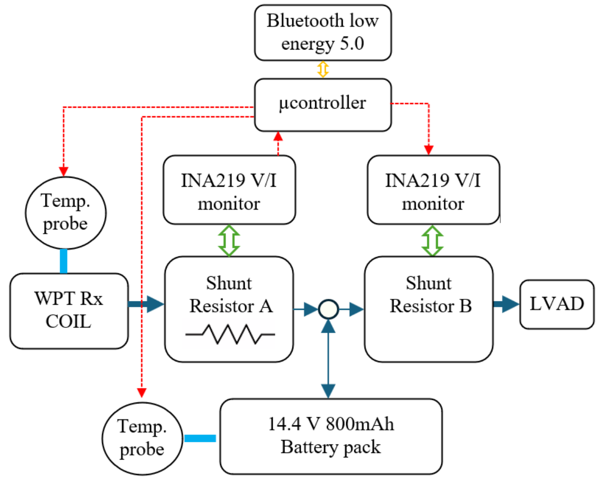


FIGURE 9. RX architecture.

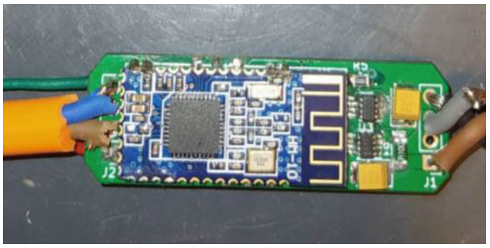


FIGURE 10. RX electronic unit.

FIGURE 11. Operating room for the in-vivo experiment.

implanted unit. The adopted scheme is illustrated in Fig. 8. In this design, all power regulation and charging control are handled by the external transmitting units.

The power module in the transmitting unit includes a DC/DC voltage regulator based on a buck converter and a high-frequency inverter, along with a series compensation capacitor. The control module is built around an ATmega328 microcontroller, interfaced with an HM-10 Bluetooth module.

On the receiving side, the coil is connected to a parallel compensation capacitor and then to a full bridge rectifier. The output of the WPT system is connected in parallel with the battery pack and the LVAD to ensure maximum reliability, as there are no electronic units between the power source and the load. Two current sensors measure coil current, battery current, and derived LVAD current, complemented by a single voltage sensor on the shared bus. Additionally, a microcontroller in the implanted unit is used for data acquisition and wireless communication with external units. The implanted coil is also equipped with a precision temperature probe (see again Fig. 7). The diagram of the receiving unit is reported in Fig. 9 and an image of the implanted electronic board, placed along the cable that connect the coil to the LVAD, is shown in Fig. 10.

C. IN-VIVO TRIAL

The proposed WPT system was tested on an LVAD implanted on a pig, as shown in Fig, 11. The purpose of the experiment was to verify the correct operation of the wireless powered pump in a real operating environment. Approved by the Italian Ministry of Health, the experiment was conducted at the A. Cardarelli animal facility in Naples, Italy. The experiment was divided into four main phases:

1. LVAD implantation on the pig.
2. Verification and acquisition of clinical and electrical data with a traditionally powered pump.
3. Connection and installation of the wireless system.
4. Verification and acquisition of clinical and electrical data with wireless powered pump.

The first step involved the cardiac surgery team implanting the LVAD using extracorporeal circulation techniques. This is a critical phase due to the anatomical differences with the human subjects. Establishing a proper procedure in this stage is crucial for moving to the following stage. As the details mainly regard the medical domain, they are not here included for the sake of brevity and also because they are outside the

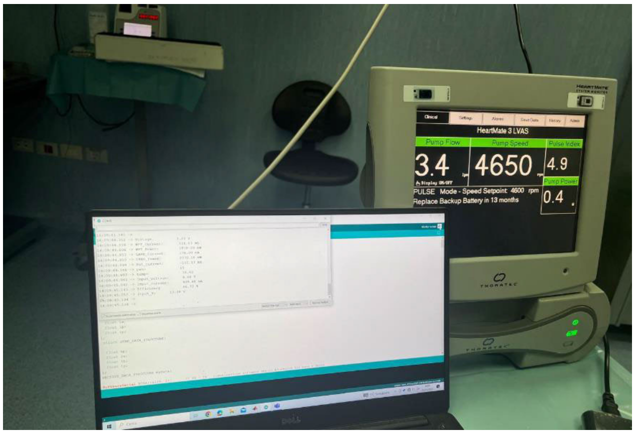


FIGURE 12. Data acquisition during the experiment.

scope of this article. During this step, the pump was connected to the controller using the standard percutaneous DL.

In the second phase of the experiment, the electrical parameters of the pump (i.e., absorbed power, voltage and current of the pump) were recorded. Clinical parameters in terms of pulsatile index and pressure were also saved.

In the third phase the receiver unit was implanted in a subcutaneous position. The percutaneous cable was removed and connected directly to the implanted receiver units. The external transmitter was positioned on the outer surface of the skin, and the alignment of the coils was verified by monitoring the coupling factor value provided by the electronic unit of the receiving system.

The final part of the experiment focused on data acquisition and verifying the normal operation of the pump, as illustrated in Fig. 12. The pump speed was set to 4650 rpm. For the first 50 minutes of operation, the TX coil was not in place, so the pump was powered by the internal battery. Wireless telemetry recorded the pump's electrical parameters and monitored the thermal conditions of the implanted units. When the battery reached a low voltage level, the TX coil was placed over the skin, aligned with the implanted RX coil. This phase is the most critical for the WPT system, as it must simultaneously power the LVAD and recharge the internal battery. During this phase, electrical and thermal data were recorded and are shown in Fig. 13.

It can be noted that during the entire cycle the power supplied to the pump remained almost constant and the system allowed the battery to be completely recharged in approximately 100 minutes. Furthermore, the temperature increase during the charging procedure (between 50 and 100 minutes) was less than 1 degree Celsius, well below the 2 degree Celsius limit for implanted medical devices. Note that adopting a lower charging current would result in an even smaller temperature increase. At the end of the final phase, once the constant voltage battery charging phase was completed, the WPT system delivered only the power required by the LVAD.

During the testing procedure, the clinical parameters were monitored, and an identical operation of the pump was observed in the wireless power mode. The test lasted approximately four hours, simulating all possible operating conditions of the system. Furthermore, the collected data enabled the validation of the results previously obtained through numerical simulations.

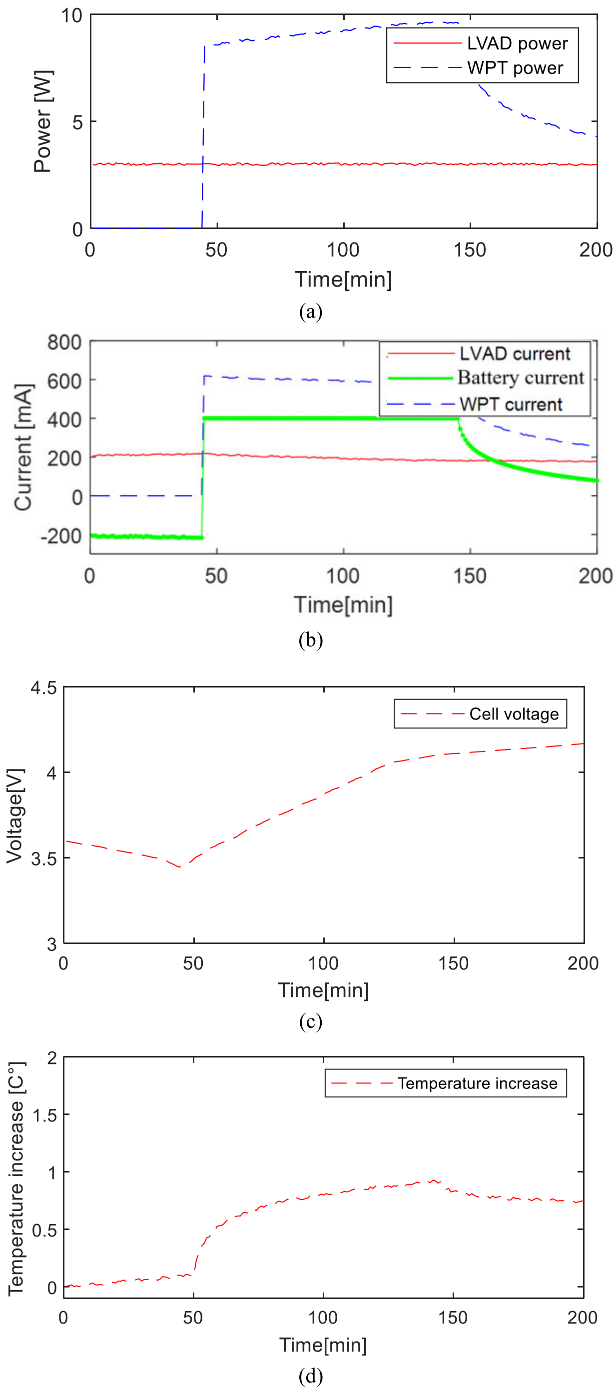


FIGURE 13. Data Experimentally recorded data: power (a), current (b),voltage (c) and temperature (d).

V. CHALLENGES AND FUTURE DIRECTIONS

Despite the conducted in vivo experimentation represents an important step forward, some aspects need to be further investigated to make wireless technology for powering LVAD systems available on the market.

A. MINIATURIZATION AND BIOCOMPATIBILITY

For WPT systems to be applicable to LVADs, the implanted coils and associated electronics must be sufficiently miniaturized to fit into the limited space available within the body. Additionally, implanted components of the WPT system must remain biocompatible over the long term. This includes avoiding immune responses and ensuring that the materials used do not degrade or cause adverse effects within the body. Long-term studies and biocompatibility testing are essential to validate the safety and reliability of these implants.

B. ADVANCED MATERIALS AND COIL DESIGNS

The development of new materials with superior electromagnetic and thermal properties is a key area of research. These materials can improve the efficiency of power transfer and reduce heat generation. Additionally, innovative coil designs, such as metamaterials and flexible coils, offer the potential to enhance alignment tolerance and overall system performance.

C. CLINICAL TRIALS AND REGULATORY APPROVALS

Extensive clinical studies are needed to validate the safety, efficiency and reliability of WPT systems for LVADs. Collaboration with regulatory bodies to establish clear guidelines and standards for these systems will facilitate their approval and adoption in clinical settings. Ensuring patient safety and meeting regulatory requirements is critical to the successful implementation of WPT technology in healthcare.

D. FUTURE DIRECTIONS

Currently, individual powering of any implanted medical device is the research trend in WPT applications to biomedical devices. This vision states that each implanted device in a patient, if multiple devices are present, will be individually powered by an ad-hoc WPT system. However, a new visionary way to power implanted devices was proposed in [36]. The basic idea is to create a wired power network inside the human body by connecting different implants to each other via wired connections, as shown in Fig. 14. All systems will then be connected to an electrical control unit positioned under the skin and energized by an external electrical source via a transcutaneous WPT system. To guarantee continuous powering of the implants, a backup battery is placed in the electrical control unit. This visionary architecture can bring much more electrical energy into the human body than is currently possible using separate WPT systems. All this considerable amount of energy can power various implanted devices, not only for medical purpose but also for other types of applications.

E. CLINICAL AND REGULATORY HURDLES

For WPT to be adopted in LVADs, it must pass rigorous clinical trials demonstrating safety and reliability under real-world

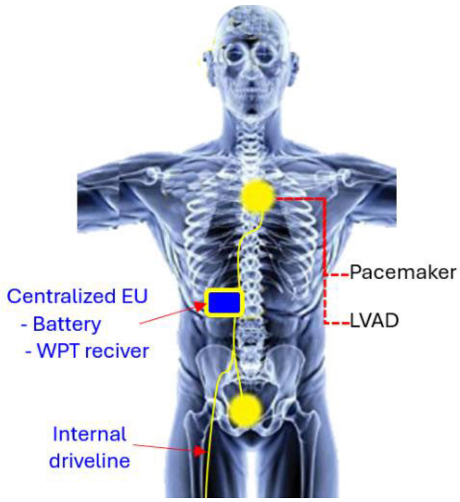


FIGURE 14. Power supply wired network in the human body fed by a WPT system.

conditions. Biocompatibility testing is critical to ensuring that materials and emitted electromagnetic fields do not cause adverse tissue reactions or long-term health risks. Regulatory approval involves navigating frameworks such as the Food and Drug Administration (in U.S.) and European Medicines Agency (in Europe), which require extensive preclinical and clinical validation, including electromagnetic safety, thermal performance, and failure recovery mechanisms. Successfully integrating WPT into LVAD systems requires collaboration between engineers, clinicians, and regulatory bodies to meet stringent medical device standards.

VI. CONCLUSION

The recent research aims to make LVADs more patient-friendly by reducing invasiveness and infection risks. The consistent focus on wireless power solutions highlights a trend toward enhancing patient mobility and quality of life. The studies are methodically sound and present innovative approaches to a critical medical device. However, practical implementation and long-term success of these devices require more extensive clinical trials and real-world testing.

While challenges remain in terms of complexity, cost, and long-term reliability, the direction these studies are taking is promising. Continued research and development, coupled with rigorous clinical testing, will be crucial to realize the full potential of these innovative LVAD designs.

Addressing technical and biological challenges, such as advanced materials, coil designs, smart power management, and biocompatibility, is essential. Rigorous clinical testing and regulatory compliance will help bring wireless power transfer-powered LVADs closer to reality, ultimately improving outcomes for patients with severe heart failure.

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