

Development and Implementation of a Project Using IoMT Technology for Monitoring, Remote Control, and Tracking of a Left Ventricular Assist Device: Reduction of Adverse Events Caused by Malfunction Leading to Critical and Catastrophic Failures

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ABSTRACT

Ventricular Assist Devices (VADs) have emerged as an effective alternative in destination therapy, offering increased longevity to implanted patients. However, survival rates remain a concern, with only 49% of patients surviving after four years of use, mainly due to adverse events, including critical or catastrophic failures caused by device malfunction. This study presents partial results from a project aimed at developing and implementing IoMT technologies for the monitoring, remote control, and georeferenced tracking of VADs, targeting the early detection of critical and catastrophic failures. Tests will be conducted using an automated bench setup with blood pump or VAD prototypes, enabling the construction of performance curves and the execution of reliability and risk analyses to improve prototype designs. The initial prototypes will be manufactured using PETG, with potential future upgrades to metal versions, and will be equipped with magnetic motors, Arduino-controlled drives, and cloud connectivity to assess the efficacy of cloud integration and the use of an application for monitoring data and controlling parameters—initially focusing on speed regulation. The embedded system is expected to remotely adjust operational parameters and detect failures in real time, within the projected efficacy range, by comparing performance data against standard curves and indicating corrective parameter adjustments. Partial results achieved so far include the identification of key technologies used in medical device monitoring and control, as well as the design of the

electrical schematic for the main components involved in the monitoring, control, and georeferenced tracking of VADs. These findings contribute to the technological development addressing the proposed research problem.

1. INTRODUCTION

Ventricular Assist Devices (VADs) are used as circulatory support in patients with advanced heart failure [1]. However, these patients are subject to adverse events such as mechanical dysfunction, thrombosis, or obstruction, which may pose life-threatening risks [2, 3]. Currently, monitoring of patients with implanted VADs is performed periodically, but there is no system capable of effectively providing information on impending adverse events, which limits the medical team's ability to make proactive decisions for patients with VADs [4].

The use of VADs as destination therapy for heart failure has been successfully implemented in recent years [1, 2, 5]. Nonetheless, even with significant advances in this field, the five-year survival rate for implanted patients remains around 50%, while the one-year survival rate reaches 82.7% [3, 6]. This survival rate is affected by adverse events that occur soon after cardiac surgeries, including mechanical complications and thromboembolism [3, 6-8]. Among these, failures related to VAD malfunction have been identified as a major factor [3, 9, 10]. According to the 2024 J-MACS (Japanese Registry for Mechanically Assisted Circulatory Support) report, the most common causes of rehospitalization in implanted patients in Japan are infections, arrhythmias, neurological dysfunctions, hemorrhages, and VAD malfunction. Statistically, the survival rates for patients implanted in the first, second, third, and fourth years were 93%, 91%, 87%, and 83%, respectively [11].

Patients implanted with VADs experience changes in the systemic circulatory system due to the parallel function of a pulsatile or continuous blood pump inserted into the left ventricle, providing additional pumping into the aorta [12, 13]. In the cardiac physiology of patients with VADs, certain pathologies may emerge related to the synchrony between the native heart flow and the supplementary continuous-flow VAD. These include those associated with inadequate ventricular reserve combined with fluid shifts that increase wall stress (right ventricle) and cause tricuspid regurgitation, potentially leading to early/perioperative right ventricular failure [14].

For the follow-up and monitoring of VAD patients, continuous monitoring can facilitate the identification of pathophysiological states and allow for early intervention in adverse events, thus improving the patient's therapy outcomes [15]. Remote monitoring may be a tailored tool for VAD patients, providing updated feedback on VAD functional parameters and monitoring the patient's health status [16]. While VAD technology has extended life expectancy, adverse events remain a concern. Early detection—through continuous and remote monitoring before the onset of major event symptoms—would be a significant contribution to improving patient survival [16]. Therefore, research into the development of new technologies is justified.

The study by [17] emphasizes the urgency of early integration in patient care, with particular focus on identifying and managing poorly controlled symptoms that significantly affect quality of life. It underscores the need for further research and educational efforts to empower healthcare professionals and align clinical practice with existing guidelines, thus reducing the gap between theoretical recommendations and actual care delivery. These findings highlight the necessity of an in-depth study of technologies applied to the monitoring, control, and localization of patients implanted with medical devices in emergency situations, which could help reduce fatalities caused by critical or catastrophic failures. It is worth noting that the existing projects analyzed do not present integrated technologies for monitoring, control, and georeferenced tracking within a single VAD system.

Thus, the objective of this study is to develop an integrated IoMT system for monitoring, parameter control, and tracking of patients implanted with VADs in situations of critical adverse events, using embedded systems with Wi-Fi connectivity that can not only generate monitoring data but also support decision-

making. This justifies the application of associated technologies that can adapt VADs for their intended use, ensuring both efficacy and safety.

2. MATERIALS AND METHODS

2.1. Materials

As an initial approach for the development of the proposed electronic circuit in this research, it was established that the acquisition and availability of real-time data would be the main criteria for selecting the components. For vital sign acquisition, the MAX30100 sensor was chosen due to its compact size, low thermal variation, reduced power consumption, and compatibility with the ARDUINO platform, facilitated by the availability of native libraries. According to [18], this sensor is an integrated solution for measuring pulse oximetry and heart rate—essential features for the purpose of this study.

To enable IoMT (Internet of Medical Things) application, the project required the use of versatile and low-cost microcontrollers. The ESP32 was selected for its wide range of functionalities, Wi-Fi and Bluetooth connectivity, and ease of integration with sensors and embedded systems. The system's power supply was planned based on an analysis of the components' energy consumption, resulting in the selection of a 3.7 V, 1000 mAh rechargeable lithium battery. For charge management, the TP4056 board was adopted due to its simplicity, efficiency, and compatibility with USB-C chargers, ensuring portability and autonomy of the device.

2.2. Description of the Test Bench and Control Architecture

The test bench, **Figure 1**, was designed to evaluate the performance of hydraulic systems, featuring two main tanks (T1 and T2) responsible for storing and circulating the fluid through the system. The transfer of fluid between the tanks is carried out by pump B1, which provides energy to the system and ensures continuous flow. During operation, various sensors monitor critical variables: pressure at the outlet of tank T1, speed of motor M1, vibration of pump B1, electric current of motor M1, fluid pressure and temperature at the pump outlet, flow at the outlet of the ventricular assist device (VAD), as well as the parameters of motor M2 and valve V1, including electric current and pressure at the inlet of tank T2.

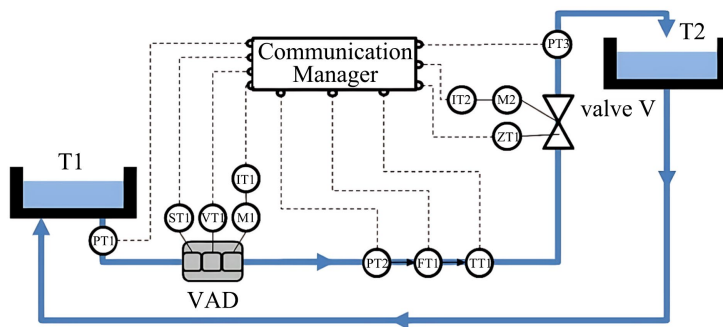


Figure 1. VADs test bench. Source: Author.

Data collection and management are performed by a dedicated communication system that distributes information between sensors and actuators. The test bench is not equipped with an embedded command and monitoring unit; instead, it is operated through a remote control system connected to a supervisory platform accessible via mobile and desktop devices. Within this architecture, operators interact through the user interface to adjust set points, such as the rotation speed of motor M1 and the position of motor M2 controlling valve V1, thereby enabling precise management of test events. User requests are centrally processed by an information system that translates commands and directs the local communication manager to replicate the data to the control system. Test monitoring is supported by the communication manager, which collects sensor signals and publishes this information for storage in a dedicated database. Users can

retrieve this data on demand through request/response queries on the mobile or desktop interface, enabling real-time consultation and decision-making. The entire cycle of data acquisition, storage, monitoring, and control is coordinated by the use case manager, ensuring seamless integration between sensors, actuators, and operators.

2.3. Maintaining the Integrity of the Specifications

The methodology adopted in this study follows a theoretical-methodological framework of an applied nature, employing a descriptive, quantitative, and prospective design through experiments using *in vitro* models [19]. The approach is grounded in concepts of reliability, risk management, and product life cycle analysis, applied specifically to the failure assessment of Ventricular Assist Devices (VADs). A deductive method guides the research, with hypotheses derived from existing theory to support the development of a monitoring and control model aimed at detecting critical and catastrophic failures, thereby enhancing decision-making processes and improving device reliability [20]. The quantitative dimension is reinforced by computational analyses of data obtained from controlled experimental testing.

A systematic literature review was conducted, initiating searches across Google Scholar, Mendeley, and Scopus databases using the descriptors “monitoring and control of medical devices.” Subsequent filtering steps refined the selection to include publications addressing “patients implanted with VADs,” “monitoring and control,” “georeferenced location,” and “IoMT.” The final corpus consisted of studies focused on VAD monitoring and control systems employing GPS-based geolocation, with an emphasis on reducing adverse events arising from critical device malfunctions. The initial synthesis of these findings is presented in Figure 2 [21].

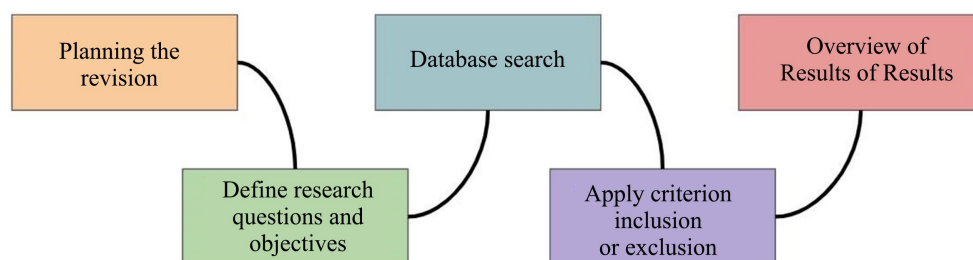


Figure 2. General steps for the bibliographic research methodology. Source: Author.

To support the design and construction of a model for monitoring and controlling critical and catastrophic failures—aimed at facilitating decision-making and enhancing device reliability—a block diagram was developed to guide the creation of both the electrical schematic and the logic diagram for subsequent stages. Each block is intended to define the key components of the proposed VAD monitoring, control, and geolocation system, while arrows indicate the primary flows of energy, data, and communication. In the electrical schematic, each block component is represented by its corresponding electrical or electronic element, providing the foundation for the development of the printed circuit board (PCB) layout and enabling *in silico* testing of the projected energy and data flows.

3. RESULTS AND DISCUSSION

3.1. Literature Review of the Main Technologies Used in the Monitoring, Control, and Localization of Medical Devices (VADs)

The main technologies used for the monitoring, control, and localization of medical devices (VADs) were identified according to the proposed research methodology, using the databases “Google Scholar” and “Scopus.” The descriptors used were: “remote” AND “monitoring” AND “control” AND “of” AND “VAD.” In the “Scopus” database, four articles were found. In “Google Scholar,” nine articles were identified. Table

1 below summarizes the findings, indicating the authors and the focus of the research. The identified authors are listed with their last name in uppercase, followed by the first name, the indication “et al.,” and the year of publication.

Table 1. List of authors and research proposals published in selected articles.

Article Number	Research proposal
1	Facilitate remote patient monitoring systems within the context of a 5G environment.
2	To evaluate the benefit of daily implant-based multiparametric telemonitoring in patients with high-risk heart failure (HF) on ventricular assist device (VAD) therapy, carriers of an implantable cardiac defibrillator (ICD) or a cardiac resynchronization cardiac defibrillator (CRT-D), both with telemonitoring function.
3	Wireless monitoring system for outpatients equipped with a pulsatile bi-ventricular assist device of the mobile actuator type.
4	Wireless hemodynamic monitoring system of cardiac output (CO) and pulmonary artery pressures (PAP), which can theoretically improve the management of patients with left ventricular assist devices (LVADs) by optimizing medication, pump parameters, and timing of transplantation.
5	Development of the principles and methods for the implementation of the remote monitoring (RM) system of the operation of the Russian ABK-N implantable axial pump.
6	Integrated, end-to-end architecture for patients with Ventricular Assist Devices (VAD), consisting of a web-based, HL7-compatible Expert Monitoring App, an Android-based Patient Monitoring App, and a built-in Portable Self-Regulation Unit.
7	Telehealth platform developed specifically for patients with Left Ventricular Assist Device (LVAD).
8	Self-Regulatory Unit (ARU)—developed to expand the applicability of Ventricular Assist Devices (VADs) as a long-term solution to heart failure (HF).
9	Customized virtual care telemedicine platform for patients with Ventricular Assist Device (VAD).
10	Useful monitoring system for the remote monitoring of patients with an implanted artificial heart.
11	Monitoring of patient and AVV status, as well as enabling remote control, configuration, and self-regulation of any DAV.
12	Design of a fully implantable pulsatile DAV (i.e., one that works without the need for percutaneous connections and ventilation), which also offers remote patient monitoring and control capabilities.

Of the twelve articles initially analyzed on monitoring, control, and localization technologies, articles 1, 2, 4, 5, 7, and 9 used technology for parameter monitoring.

On the other hand, articles 3, 6, 8, 11, and 12 employed monitoring and control technologies specifically for VADs in their research. Only article 10 used technologies for both monitoring and localization of VADs.

The literature review can still be further expanded to explore additional requirements and gain a better understanding of other complementary technologies important to the objectives of this study.

3.2. Block Diagram of the Monitoring, Control, and Localization System for VADs

Figure 3 illustrates and defines the main components of the proposed system for monitoring, control, and localization of the Ventricular Assist Device (VAD) developed in this research project, along with the corresponding energy and data flows. The core components, highlighted in green, include the blood pump, parameter controller, cloud platform, and smartphone interface. Additionally, Battery 1, Battery 2, the GPS locator, and the display unit are also identified as integral elements of the system.

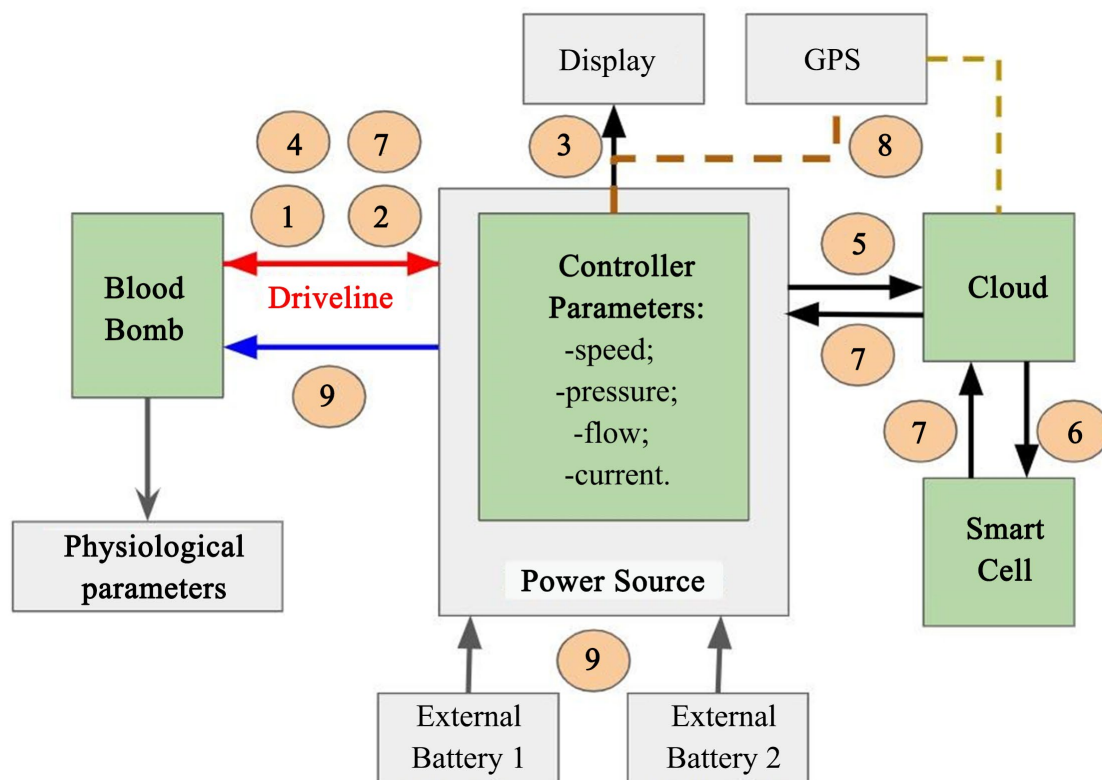


Figure 3. Block diagram of the DAV monitoring, control and location system. Source: Author.

The energy and data flows are enumerated from 1 to 9. In Flow 1, the monitored parameters transmitted from the blood pump to the driveline comprise pump speed (rpm), electrical current consumption (mA), internal pressure (mmHg), and blood flow rate (L/min). Flow 2, connecting the driveline to the controller, enables bidirectional data transmission of these parameters. Flow 9 represents the power supply circuit, delivering energy from the batteries to the blood pump.

In Flow 3, the controller transmits data to the display, providing a local visual interface showing key parameters such as speed, current, pressure, flow rate, alarm conditions, and system errors. Flow 4 enables dynamic speed adjustments (rpm) from the controller to the pump, based on real-time monitoring of speed, pressure, and flow, while Flow 7 encompasses remote control commands.

Flow 5 involves data transmission from the controller to the cloud, including the parameters displayed in Flow 3, as well as event logs, fault reports, alarm records, and the device's operational history. Flow 6 delivers this data from the cloud to the smartphone application, allowing users to monitor variables such as pump speed, pressure, current, flow, pump and battery status, and receive notifications related to alarms or failures.

Flow 7 represents the remote control pathway, allowing users to send commands from the smartphone application to the cloud, then to the controller, and ultimately to the pump, enabling remote management of operational variables such as pump speed (rpm), start/stop commands, alarm thresholds, and re-enablement actions.

Flow 8 addresses the transmission of location data, sending GPS signals to the cloud for geolocation tracking. Finally, Flow 9 consolidates the electrical power flows throughout the system.

3.3. Electrical Circuit of Monitoring, Control and Location of DAV

As an outcome of the project and the development of the monitoring, control, and localization system for the Ventricular Assist Device (VAD), an integrated electrical circuit was designed, as depicted in **Figure 4**. This circuit employs the ESP microcontroller, which replaces the conventional Arduino platform to enhance connectivity and integration with Internet of Medical Things (IoMT) systems.

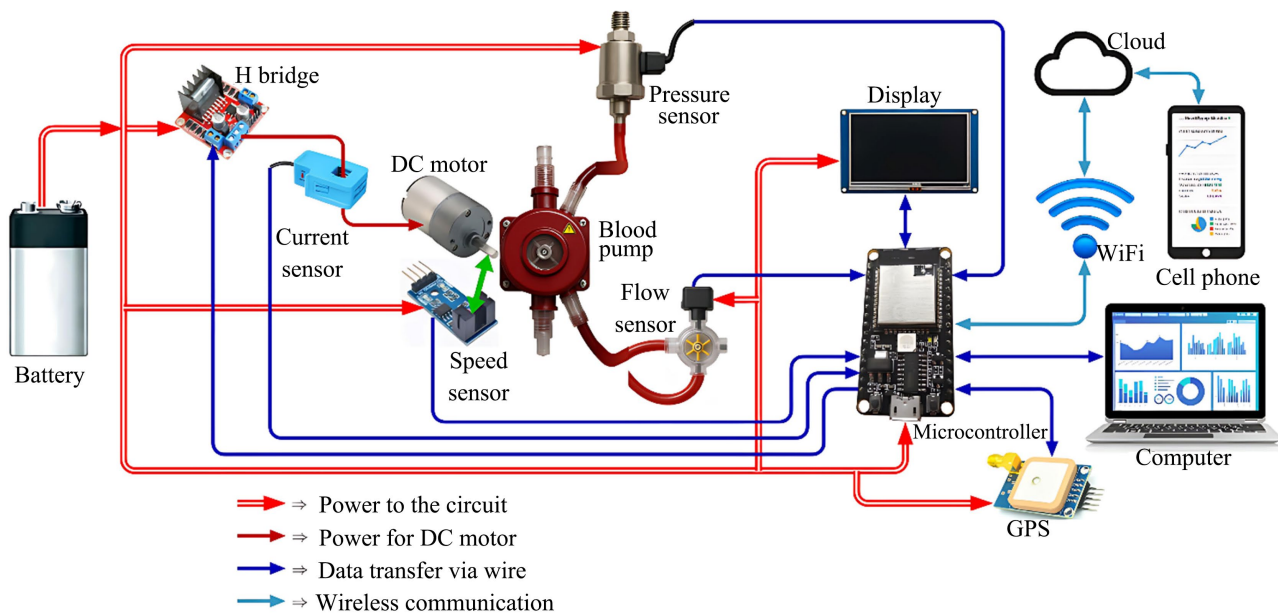


Figure 4. Electrical circuit of the components of the DAV monitoring, control and location system. Source. Author.

The ESP microcontroller is interfaced with both a computer and a Wi-Fi network, enabling seamless communication with the cloud infrastructure and, subsequently, with mobile devices such as smartphones. A direct connection from the ESP to a display allows real-time visualization of system parameters.

The controller processes input from the pressure and flow sensors—both coupled to the pump—as well as from the speed sensor connected to the pump's DC motor. This motor is monitored by a current sensor, which is also linked to the controller. The circuit is completed by an H-bridge, which receives control signals from the ESP and interacts with the current sensor to regulate motor activation.

All components, including the pressure sensor, flow sensor, speed sensor, controller, display, H-bridge, and GPS module, are powered by a 3.7 V battery, providing system portability and operational autonomy.

This configuration enables remote monitoring, control, and adjustment of critical parameters, contributing to the prevention of failures in implantable medical devices.

3.4. Quantitative Validation and Comparative Performance Analysis of the BSI-PETG.01 and BSI-PETG.02 VAD Prototypes

The alternative project progressed to the prototype construction phase using PETG material. Following fabrication, the samples underwent a series of empirical tests on the Test Bench, enabling the collection of quantitative data. The pump performance curves, presented in Figure 5, allowed for a comparative analysis of the efficacy and efficiency between the BSI-PETG.01 and BSI-PETG.02 VAD models.

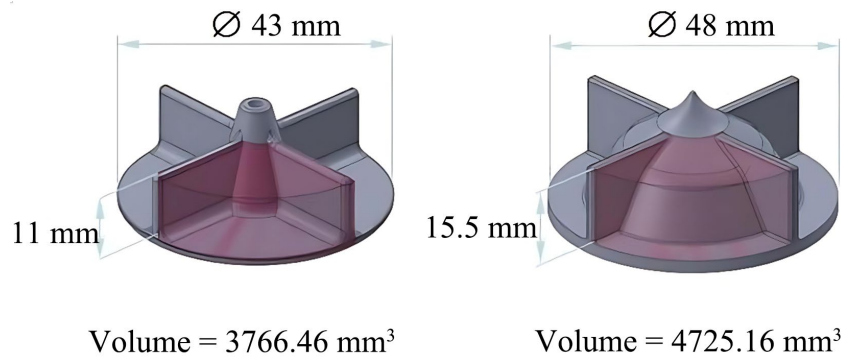


Figure 5. Evolution of blood pumps: performance graph of BSI-PETG.01 and BSI-PETG.02 models. Source. Author.

As shown in Figure 6, the BSI-PETG.01 model features a blade-to-blade volume of 3766.46 mm², while the BSI-PETG.02 exhibits a larger volume of 4725.15 mm².

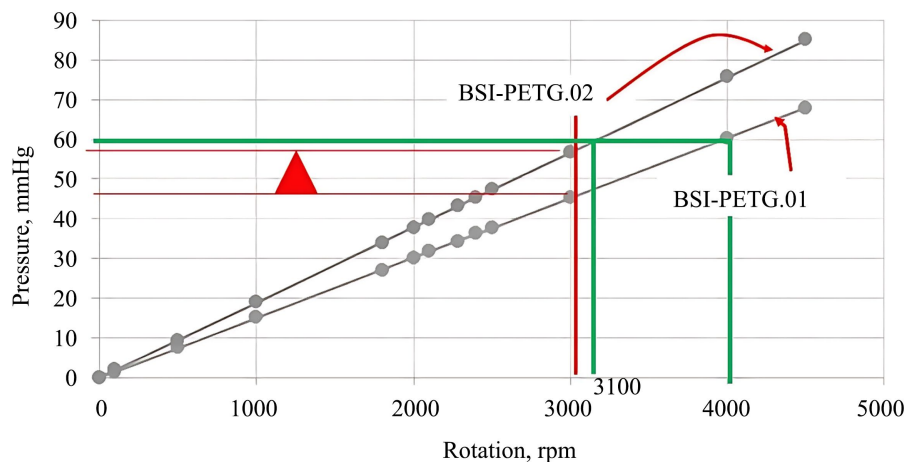


Figure 6. Evolution of blood pumps: Improvement in blade-to-blade volume of BSI-PETG.01 and BSI-PETG.02 models. Source. Author.

In the analysis of the pressure versus rotation curve, the BSI-PETG.01 reached a pressure of 60 mmHg at 4000 rpm, whereas the BSI-PETG.02 achieved the same 60 mmHg pressure at a lower rotation speed of 3100 rpm. Additionally, at the common rotation speed of 3000 rpm, the BSI-PETG.01 recorded a pressure of 47 mmHg, while the BSI-PETG.02 obtained 58 mmHg. These quantitative results reinforce the superiority

of the BSI-PETG.02 model in terms of efficiency and accuracy in fault detection, validating its claims of greater reliability and reduced operational risks associated with the use of the new prototypes.

3.5. Improvement in the Design of the Bearing Cradle: From Fixed Configuration to Threaded System in VAD Prototypes

After a detailed risk analysis conducted on the ventricular assist device (VAD) prototypes—or implantable blood pumps—it was identified that one of the main potential causes of critical failures was related to the design of the bearing cradle in the BSI-PETG.01 model. In this initial model, the bearing cradle was fixed, and after implantation, this configuration could lead to bearing misalignment, resulting in rotor misalignment and potential system seizure. This risk was associated with a possible clearance between the bearing and its cradle, which could worsen under prolonged operating conditions. As a corrective measure, a design change was proposed, transforming the bearing cradle from a fixed to a threadable system. This design improvement, presented in the BSI-PETG.02 model and illustrated in [Figure 7](#), aims to eliminate unwanted clearance, allow more precise adjustment during assembly, and thus significantly reduce the risk of rotor misalignment and seizure, increasing the reliability and safety of the implantable device. Consequently, the BSI-PETG.02 model became safer and compliant with the risk control requirements established by ISO 14971:2019—Risk Management for Medical Devices—and the product control improvement requirements outlined in ISO 13485:2016.

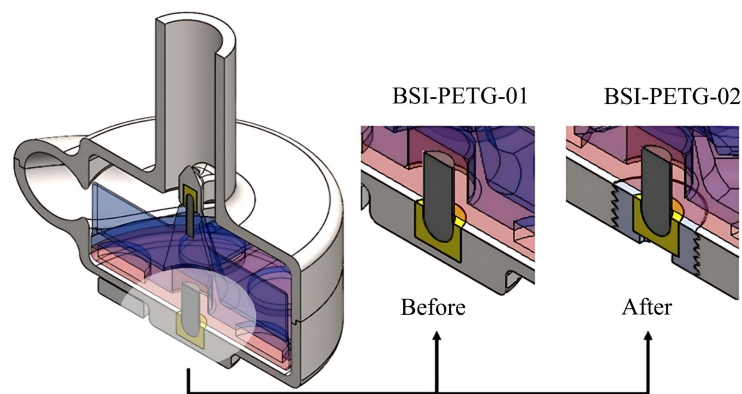


Figure 7. Improved housing cradle design from fixed to threadable. Source. Author.

4. DISCUSSION AND CONCLUSION

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A systematic review was conducted to map the state-of-the-art technologies employed in the monitoring, control, and geolocation of Ventricular Assist Devices (VADs), following the established research protocol. Database searches in Scopus and Google Scholar using the descriptors “remote,” “monitoring,” “control,” “of,” and “VAD” yielded a total of twelve relevant publications—four from Scopus and nine from Google Scholar.

The technical analysis of these studies revealed that a substantial portion (articles 1, 2, 4, 5, 7, and 9) focused solely on parameter monitoring, employing sensor-based solutions to measure pump speed (rpm), electrical current consumption (mA), internal pressure (mmHg), and blood flow rate (L/min). These contributions, while valuable, are limited to passive data acquisition without enabling direct intervention on device operation.

Conversely, a smaller subset (articles 3, 6, 8, 11, and 12) addressed both monitoring and control functionalities, incorporating feedback mechanisms capable of adjusting operational parameters to optimize hemodynamic performance and device reliability. These solutions represent an advancement but remain fragmented and often lack scalability for broader clinical deployment.

Critically, only one publication (article 10) reported the simultaneous use of monitoring and geolocation technologies, leveraging GPS-based tracking to localize patients implanted with VADs. However, no existing study was found to integrate the trifecta of monitoring, dynamic control, and real-time georeferenced localization into a single cohesive system. This gap underscores the current technological limitations and highlights an unmet need in the comprehensive management of VAD-supported patients, particularly in the context of preventing catastrophic device failures and adverse clinical events.

The findings from this review thus delineate the fragmented landscape of current VAD technologies and emphasize the absence of integrated platforms capable of supporting closed-loop control, remote supervision, and geospatial tracking in real-time. Furthermore, the literature lacks discussion on essential adjunctive technologies, including cybersecurity frameworks for implantable devices, IoMT connectivity standards, and AI-driven predictive analytics for early fault detection and risk mitigation.

Within the proposed research, which is still ongoing, partial objectives were defined for the methodology, including a literature review, the development of a block diagram, an electrical diagram, the performance improvement between the BSI-PETG.01 and BSI-PETG.02 models and the improvement of the bearing cradle design from fixed to threaded system. The results achieved for this stage of the project are considered satisfactory, given the limited time available. As for the overall objective of the project, which remains in progress, further development of the research—particularly in the literature review and refinement of the component proposals for the monitoring, control, and localization system—will be explored in greater depth.

However, the results obtained so far underscore the relevance of the research and its potential contribution to the advancement of medical devices, especially implantable ones.

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CONFLICTS OF INTEREST

The authors declare no conflicts of interest regarding the publication of this paper.

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