Treatment of Ventricular Assist Device Test Bench Data for Prediction of Failures and Improved Intrinsic Reliability

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Abstract. This article regards over analytics of reliability of ventricular assist devices (VAD) used as therapy for advanced heart failure conditions in the face of malfunction related adverse events. This question directs research and the search for a solution proposal, even if prospective, but that promotes the longevity of these devices, increasing the intrinsic reliability. An "In Vitro" test bench is used to obtain variations of dynamic behavior over time; by means of a set of variables and the deviations (failures) compared between the standard and tested devices; since these devices are systems that vary in time. An intelligent systematics obtained through the automation of the test bench, using sensors and actuators to control the independent variables, and the data collection and analysis using the technologies present in the industry 4.0 completes the increase of the reliability of the VAD.

Keywords: Cardiovascular, Ventricular Assist Device (VAD), In Vitro, Big Data Analytics, Industry 4.0, Test Bench.

1 Introduction

Among cardiovascular diseases (CVDs), heart failure (HF) has a remarkable prevalence and a great impact on morbidity and mortality worldwide [1]. HF is considered to be a syndrome that renders the heart unable to supply oxygen at an adequate rate to the tissues, or at the expense of increasing the filling pressure (preload). Generally, HF results from structural or functional dysfunction of the heart, which compromises the ability to fill with blood or to eject it [2].

For refractory HF cases and when no further treatment is available, cardiac transplantation (CT) is considered the most effective therapeutic modality to significantly prolong the patient's life [1] [3] [4]. However, there is a fundamental problem in the practice of organ transplantation, according to the "Thirty-fourth Adult Heart Transplantation Report—2017" [5], the number of cardiac surgeries done for transplants in Europe, for example, does not grow significantly. For the rest of the world, just as in the US inclusive, there is a growing trend, but it is not enough to balance supply and demand. Drug therapy alone for refractory HF continues to have disappointing results. Because of this, VADs have emerged as a therapy for refractory

HF and are used, for example, as a long-term use strategy, to provide conditions so that the patient can receive the heart transplant at the expected time, a practice called by "bridge to the transplant", or if the patient is not able to perform the surgery because of a high probability of rejecting the transplant, VAD is recommended as a permanent practice known as "destination therapy" [1].

Although VADs have become an advantageous opportunity in refractory HF therapy, this alternative has opportunities for improvement in the face of adverse events caused by the use of these devices. For example, some of the main adverse events are: bleeding, infection, stroke and malfunction, the latter event being directly related to the failure of the device functionality, according to the *Interagency Registry for Mechanically Assisted Circulatory Support*[1] in its eighth annual INTERMACS report [6]. This leads us to reflect on the need to record reliability data and improve the reliability of these devices.

2 Relation with Industrial and Service Systems

The technological evolution observed in recent years; mainly related to: a) the digitalization that transforms the way in which we collect data to transform into useful information for decision making, b) the creation of increasingly smaller sensors from microelectronics with innovations in microchips and c) the technologies of communication networks wireless; has provided the development of products and processes in various market segments, from consumer goods to industrial automation systems [7].

This prospective article proposes the use of this technological evolution in the improvement of mechatronic devices, as is the case of VAD. The technological evolution based on multidisciplinary concepts that created the mechatronic devices, when applied in a project, and in this case for VADs, with resources that allow the communication through Internet (IoT), robotics, software and manufacturing accompanied by an integrated digital system, it was possible to provide the creation of smarter devices [8].

This paper highlights how this technological innovation can be used to improvement of VADs of continuous flow and with the mechanism of operation of the pump of the centrifugal type. The importance of technological application to improve these devices is justified by two reasons: a) To predict and avoid adverse events attributed to malfunction and b) The increasing use of VADs as destination therapy.

[1] INTERMACS - Interagency Registry for Mechanically Assisted Circulatory Support contemplates a database with a total of 22,866 patients who received a mechanical circulatory support device approved by the FDA. With registration from 06/23/2006 to 12/31/2016 of 185 participating hospitals.

3 Objective

To propose and test a method of improving the intrinsic reliability of ventricular assist devices (VADs) using: i) an automated test bench and ii) a knowledge base, allowing data-based decision making using the technologies present in the industry 4.0 such as: Cloud computing, Internet of Things (IoT) and technologies linked to Artificial Intelligence (AI) present in tools of Big Data Analytics and Data Mining.

The experimental performance, according to the proposed method, will result in: a) a knowledge base, coming from the data of failure of the behavior of a VAD throughout the tests, acquired knowledge, will allow intelligent control to predict future consequences and b) a knowledge analysis obtained will result in a set of improvements, which will be applied to the design of new devices, making these devices more durable.

4 Materials and Methods

Intrinsic reliability is not simple to achiev in time-varying devices, such as a VAD. For this reason, a five-stage cyclic process was developed, as proposed in Fig. 1. “4. VAD Test" is described in detail in the following sections. A VAD project, step 1, is drawn from demand requirements, in which it is evaluated in step "2. Risk Analysis” in such a way as to enable it to provide sufficient reliability for rapid prototyping production, provided in step "3.Production (3D-PETG)", of a bench test device in step "4. VAD Test on Bench ".

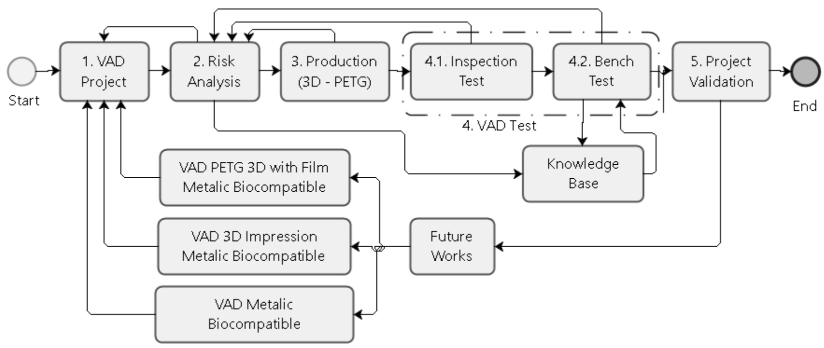

Fig. 1. VADs Validation Process. **Source**: Dias, J. C. 2019 (Author)

In these steps 1 through 4, the risk analysis evaluates how reliable the project, production, or testing is to then allow the project to be validated in step "5. Project Validation". This last stage guarantees the intrinsic reliability of the device, as well as its respective design, allowing a future verification to verify the reduction of adverse events due to the malfunction of these devices. A "Knowledge Base" in the cloud collects information for adjusting control parameters of the actuators in the test bench, so that the "Bench Test Procedure" described in the section below can be controlled [9].

4.1 VADs Test Bench

The test bench used in this work consists of the reservoirs 1 and 2 which store the liquid used is transported from tank T1 to tank T2, performed from a pump (VAD), which imposes energy on the system, according to Fig. 2.

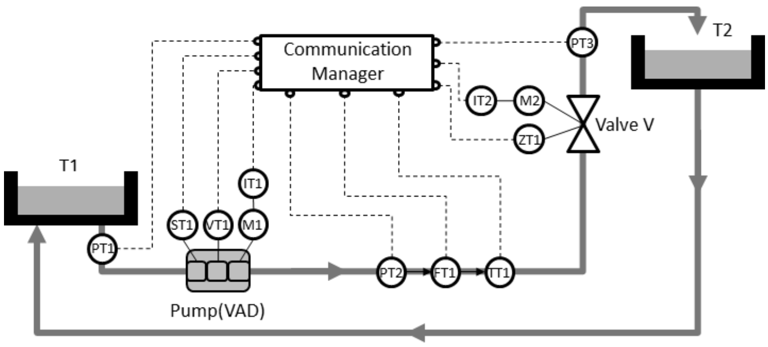

Fig. 2. Scheme of the "Test Bench" existing in the Department of Mechatronics of USP.
Source: Dias, J. C. 2019 (Author)

Sensors perform the collection of fluid pressure at the output of reservoirs 1, rotation, vibration and electrical current of the motor of the VAD, fluid pressure, flow and temperature at the output of the VAD, position and the electric current of the V-valve motor 2 and the pressure of the liquid at the inlet of the reservoir 2. The test bench has its own motor to ensure control of the rotation of the blood pump and the motor 2 that contours the valve V, so it is possible to control the flow of the liquid into the system.

4.2 Collection and Processing of Data

To collect information from the "context" [10] of the assisted device, emitted by the sensors in the "Test Bench", Fig. 2, and impose the new references to the actuators, a communication manager module is required for distribution and targeting of the collected data to the cloud knowledge base. These data from the sensors are processed for real-time error checking (failures), at which time the adjustment decisions are made. This knowledge base is handled by a standards analyzer for knowledge discovery using "Big Data Analytics". In this article "context" is any information that can be used to characterize the situation of an entity (object of interest), it is also known as sentient computing [10].

4.3 Knowledge Base Data Analysis

Big Data Analytics approaches to pattern discovery are based on: i) DESCRIPTIVE ANALYSIS: It is based on real-time understanding of events to make immediate decisions. Descriptive analysis works with historical data, cross-information to generate a clear and precise understanding of the relevant topics for the present moment, it is not necessary to relate past or future patterns [11]. ii) DIAGNOSTIC ANALYSIS: The objective is to understand the cause and effect relationship over time. The diagnostic analysis works based on the collection of data related to a certain subject and crosses information to understand which factors influenced the current outcome [11]. iii) PREDICTIVE ANALYSIS: It uses data mining as: statistical and historical data to know future trends [11]. iv) PRESCRIPTION ANALYSIS: Prescriptive analysis commonly confused with predictive analysis, because it works with the same logic. However, for different purposes, while the predictive analysis identifies future trends, the prescriptive delineates the possible consequences of each action [11].

4.4 Inspection Test Procedure

The inspection test, procedure 4.1 of Fig. 1, required for continuity in the following tests, is performed by means of roughness recognition through a top image. The method uses top images of calibrated roughness patterns. From these images computational information is obtained that allows the characterization of the surface and recognition of the roughness, according to technique of surface profilometry with and without contact.

4.5 Test Bench Procedure

The procedure "4.2 Test Bench", Fig. 1, occurs in three phases:

4.5.1. Standard Curve Survey

The VAD is fixed in the test bench to perform data collection of independent variables (velocity and rotor flow) that are manipulated with progressive values adjustment, impacting the behavior of the dependent variables (pressure, vibration, temperature and energy consumption). The data collection cycle (dependent variable values) begins with the fixed rotation speed for all flow variations. Thus, for each variation of the flow, the respective values of the dependent variables are collected.

After having performed all the variations of values referring to the flow variable; with the respective collection (reading) of the dependent variables (already mentioned); a new configuration is performed on the rotor speed variable and a new cycle is started. A pre-programming is established in the system that controls the execution of tests on the devices; for example: configuration speed ranges and flow variations. At the end of the test, the device is able to perform the next tests.

Gathering information during this step is useful for improving the default curve for this type of device.

Once the various standard curve tests have been performed considering the same type of device, the knowledge base for the behavior of dependent and independent variables will be used to observe deviations in the following test phases.

4.5.2. Short Term Testing

The short duration test consists of continuous repeatability of the standard curve test until the first failure is obtained, at which time the failure occurrence is recorded in the database. Thereafter, the pump is disassembled, so that each pump part goes through the surface inspection protocols. The defective part is replaced, just as the identified fault is recorded in the database. After identifying the causes of failure and risk analysis, the pump returns to the bench test until at least one failure is recorded for each pump part (VAD).

4.5.3. Long-Term Testing

Once the standard curve of the same type of device is defined, within its variables any observed deviations will be recorded and plotted on the graph. For the operating limits of the independent variables, only the speed limits are defined. Thus, tissue perfusion values simulated by speed limits will be appropriate for the human. Throughout the test deviations of the behavior of the variables can occur in relation to those registered in the standard curve.

Before the simulated tissue perfusion (independent variables) in the test bench, during the long-term tests become impracticable, through self-adjustments of the dependent variables, or a critical failure occurs, an AI manager module interrupts the device. The purpose of the long-term test is to obtain as much fault data as possible within the operating range of dependent and independent variables for a simulated human perfusion.

5 Results and Discussion

At the moment of the implantation of the method proposed in this work, according to Fig. 1, a VAD project was already underway, and a VAD made of aluminum with subtractive technology had already undergone a bench test; with the occurrence of failure. This is because the magnetic rotor had scraped on the upper casing, damaging the VAD. For this reason, the validation process of VADs was put into practice in the process "2. Risk Analysis" in which he submitted the damaged VAD parts to the "4.1 Inspection Test process".

The analytical procedure presents in the process "2. Risk Analysis", identified a fault in the bearing of the lower housing. A callosity at the center of the bearing was identified as the fault that caused the magnetic rotor to misalign, damaging the upper housing of the tested device.

An initial report was provided with improvement items, as Table 1, indicating the main points for increasing intrinsic reliability.

Table 1. Improvement items proposed during phase "2. Risk analysis"

PROBLEM	EFFECTS	CAUSE	SOLUTION
Bearing failure	Engine rotation error Change of pump flow Motor torque friction Rotor Locking	1. Bearing inclination	**R1.1** Ensure the production according to the project. **R1.2** Ensure compliance with the assembly procedure. **R1.3** Overall geometric and dimensional surface analysis with test protocols.
		2. Clearance between bearing and cradle	**R2.1** Make the cradle base mobile for adjusting the lower bearing clearance with wrench connection for clearance adjustment. **R2.2** Ensure compliance with the assembly procedure.
		3. Deformity in bearing cradle (manufacturing flha)	**R3.1** Ensure manufacturing according to design. **R3.2** Perform surface, geometric and dimensional analysis with test protocols.

Source: Dias, J. C. 2019 (Author)

The improvement items also caused a change in the design of the VAD, process "1. VAD design "resulting in the construction of the base of the mobile cradle for adjusting the lower bearing clearance, with tightening torque connection, as Fig. 3.

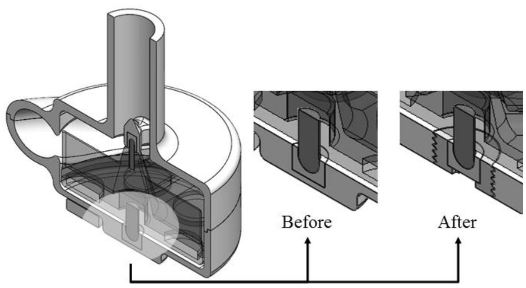

Fig. 3. Result of project improvements. **Source**: Dias, J. C. 2019 (Author)

6 Conclusions

This prospective project, still in progress of its finalization, has already been able to demonstrate its positive effects, according to results section. The next steps include the implementation of intelligent control of the test bench with the use of the knowledge base for the prescription and prediction of events for the decisions of adjustment of the variables of the bench to the device in test. Thus, during every test step, the collected data is stored for an evaluation of the failures. The data collected, when analyzed using Big Data Anlytics, allow the prediction of failures for analyzed sample. Thus, when performing the evaluation in the new devices tested for fault predictivity, based on the information acquired, it is possible to make a decision before the failures appear. This assists in the longevity of the device being tested, in a similar human perfusion condition.

With regard to the gap presented in the INTERMACS report on adverse events related to device malfunction, this work seeks to improve reliability by reducing failures that may cause malfunction of these devices. Thus, the tangible contributions are first divided into a test bench with an intelligent control system, improving from the collected data, and assisting in a geographical expansion in the treatment of failures of other distributed devices. And the second contribution is a verification and validation of devices, from the knowledge of stored reliability data.

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