FAILURE AND RELIABILITY ANALYSIS OF A LEFT VENTRICULAR ASSIST DEVICE (LVAD)

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Abstract. *This work presents a failure and reliability analysis of an electromechanic Left Ventricular Assist Device (LVAD) considering materials, assembling procedures and "in vivo" tests. It was achieved with the subsystems Failure Modes and Effects Analysis (FMEA). After that, the Fault Tree Analysis (FTA) was made from the critical events showed in the FMEA. The analysis of critical subsystems was performed by using the obtained results of "in vivo" tests. It was possible to verify that the critical points that might be observed are related to the LVAD inlet and outled cannulas set and to the motor-controller system driver. According to the results, it is possible to actuate in a specific way in the critical subsystems.*

Keywords*: Reliability analysis, Left Ventricular Assist Device, FMEA, FTA.*

1. INTRODUCTION

Ventricular Assist Devices (VAD´s), are blood pumps connected to the natural heart in order to provide support to the ventricular pumping function when the natural heart is weak and with low ventricular pumping capability (Andrade, 1998). Therefore, the VAD, usually connected between the left ventricle apex and the aorta, behaves with the left ventricle assistant (Andrade, 1998). Although there are many types of VAD´s around the world, it can be classified in function of the characteristic of operation. A kind of characteristic of operation that has been studied in the bioengineering laboratory at Institute Dante Pazzanese of Cardiology is an electromechanic VAD (Andrade *et al*, 1999). That device is composed by: a Brushless DC Motor (BLDC); a planetary roller screw responsible to change the rotor spin movement into linear pusher plate displacement; a polyurethane diaphragm and a pumping chamber. Figures 1 and 2 presents the device described.

The VAD operation, which is controlled by an electronic microcontroller, is detailed: Firstly, the controller drives the motor so that these perform a complete right ejection in order to let the total filling of fluid on the chamber. It occurs in a passive way.

Once time the chamber was completely full of fluid, which can be detected by a diaphragm positioning sensor, the controller drives the motor in order to banish the fluid from the chamber (systole). After the complete systole, the electronic controller drives the motor so that a complete right ejection is made, restarting the loop.

In order to make a reliability analysis of that electromechanical VAD, firstly was made a failure mode and effect analysis (FMEA) about the VAD assemble procedures. After that, a fault tree analysis (FTA) was made based in the critical events appointed by FMEA. In order to reach that objective, the system was divided in subsystems such as proposed in Patel (2006).

Figure 1. Electromechanical Ventricular Assist Device (VAD). (Andrade *et al*, 1999)

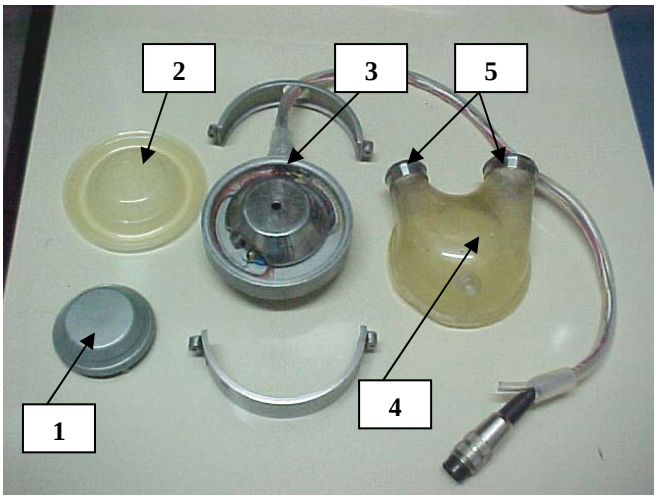

Figure 2. VAD and components. (1) Support Plate; (2) Diaphragm; (3) Brushless DC motor and pusher plate; (4) Pumping chamber; (5) Cannula connectors.

Besides that, in this paper is presented the reliability values to some VAD subsystems, which was evaluated from the results obtained by “in vivo” tests.

2. MATERIALS AND METHODS

In order to make the FMEA, firstly the stages of VAD assembly process and components were identified. In order to make numeric attribution for the severity and likelihood issues, some scales were created (Tab. 1 and 2). The detection value was considered equal a unit because all potential failures are detected during the manufacturing phase (Patel, 2006).

In function of those attributions, the next step was talk with VAD researchers and assemblers engaged professionals to know critical events in the assembly process and in the used materials. All VAD system was subdivided in subsystems such as Patel (2006), the FMEA’s were obtained and the critical events were observed. In the FMEA of inlet and outlet cannula, was possible to know that the critical events are the fluid leakages and breaks. It occurs because of failure on the assembly of cannula connector and to inefficient connector squeeze. In the FMEA of pumping

chamber assemble it was possible to observe that the critical events are: out of specifications because of bubbles or imperfections and thrombus occurrences. In the FMEA of motor-controller and driver system set, it was possible to verify that the critical event is related to failure on the power supplies because of break on the cables. In the FMEA of mechanical bearings, was observed that the critical events are bearings failure and inadequate lubrification. For each FMEA was constructed a corresponding FTA where the top event was chosen such as identified like critical event appointed by the Risk Priority Number (RPN) obtained by FMEA.

Table 1. Failure categories and Severity values.

Category	Effect	Project FMEA	Value
Catastrophic	Extremely critical	Complete loss of system function, without evidences.	5
	Critical	Irreversible failure, partial or complete loss of one or more functions.	4
	Grave	Significant failure but can be reversible.	3
Marginal	Significant	Intervention necessary but is not acute.	2
Minor	Not considered	Not serious enough to cause injury.	1

Table 2. Failure categories and Likelihood values.

Category	Frequency	Project FMEA	Likelihood Value
Critical	Frequent	Failure that always occurs.	5
	Probable	Failures with moderate frequency of occurrence.	4
	Occasional	Low occurrence frequency.	3
Marginal	Remote	Rare occurrence.	2
Minor	Improbable	Not common.	1

Besides that, another point studied was to extract the reliability information based on the results obtained from “in vivo” tests in calves performed in the Institute Dante Pazzanese of Cardiology.

A twenty calves sample was chose, and was observed that in three of them, problems related to the inlet and outlet cannulas of the device occurred. In another three ones was observed failures related to motor-controller and driver system set. Therefore, considering twenty samples, the reliability value for that mentioned subsystems was evaluated such as 85% (Colosimo, 1997). In that sample, others VAD subsystems did not show failures.

3. RESULTS AND DISCUSSION

The FMEA and FTA analysis appointed to suggestions of solutions to the critical events presented. The critical events appointed bellow in each subsystem was obtained by RPN evaluation, where it is calculated as severity x

likelihood x detection (showed in Tab. 1 and 2). The detection value was considered equal a unit in all cases because all potential failures are detected during the manufacturing phase (Patel, 2006).

3.1. Inlet and outlet cannulas

The greatest risk factor in this subsystem is the leakage in cannula, which was appointed in the FMEA by RPN = 12 (severity = 4 and likelihood = 3). It was observed that the leakage can occur because: inadequate material; incorrect assembly; and, in some times, the connector threads during surgery. Possible solutions to this failure are: the right material selection; to become the assembly process better; and the surgeons training.

3.2. Pump chamber

It was possible to observe two risk factors appointed in the pump chamber FMEA (RPN = 20, where severity = 4 and likelihood = 5): bubbles and thrombus formation. The bubbles formation depends on the chamber assembly process. It can be solved by improve on that process. The thrombus formation is related to: fluid stagnation points inside the chamber – in this case is necessary to make some modification on the shape of chamber; the chamber can eliminate some toxic material on the blood – it is related to kind of material that was chosen; defectiveness on the chamber – it can be caused by fail on the chamber manufacture process that must be verified; insufficient anti-coagulant amount administration – it can be verified with the medical team that takes care with the VAD implant.

3.3. Motor-Controller and Driver system subset

The critical events in the motor-controller and driver system subset that were appointed by FMEA are related to failure in the operation because of contact misses in wires and connectors or a broken wire (RPN = 20, where severity = 5 and likelihood = 4). The suggestion to eliminate this problem is to increase the mechanical resistance of the cables, also to exchange the connector by another one because of the kind of material used on the connector. Another possible verification is the right cables handling.

3.4. Power Supply

According to FMEA and FTA, the critical points are short or open circuit that can be caused by excessive mechanical stress on the cables (RPN = 16, where severity = 4 and likelihood = 4). Another presented problem is failure on the batteries recharge or AC/DC converter failure (RPN = 8, where severity = 4 and likelihood = 2). In order to eliminate those failures, the suggestions are: to verify the used material on the cables; batteries exchange or recharge system exchange; and preventive maintenance on the AC/DC converter.

3.5. Mechanical Bearings

In the FMEA mechanical bearings is possible to verify that the RPN is not high (RPN = 6, where severity = 3 and likelihood = 2), although failures occurs because of bearing break. It can happen because of excessive bearing wearing, insufficient lubrification or dirty and bearing overheating. The suggestion is preventive maintenance on the bearings. The overheating issue suggests that the bearing operates under insufficient lubrification, or the bearing can be in the ending of its life, that suggests its substitution.

In vivo tests with a twenty calf's sample, it was possible to verify that failures related to the VAD happened in six cases of that. In one of that, the delamination on the rotor permanent magnets was responsible by BLDC breaking. That problem could be happened because of blood or strange fluid infiltration in the BLDC motor. Another problem was the break of the cable and disconnection because of excessive mechanical stress on the cable. It can be improved by a better positioning of the elements on the physical space of the surgery room. The third problem presented was the incorrect material used on chamber manufactory.

4. CONCLUSION

With the FMEA analysis was possible to verify the critical points on the materials and VAD assembly procedure. That results were used to made the FTA, such as know what contributes to critical events appointed by FMEA. That analysis let to verify the assembly procedures to some subsystems which has been better results in the assembly procedures e in others cases the used material was exchanged. From the "in vivo" tests analysis, it was possible to verify potential points of risk, and it became possible the improvement on the used material, handling and assembly procedure.

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