ISSN 2176-5480

22nd International Congress of Mechanical Engineering (COBEM 2013)
November 3-7, 2013, Ribeirão Preto, SP, Brazil

ACCELERATED LIFE TESTS WITH AN APICO AORTIC BLOOD PUMP FOR LEFT VENTRICLE ASSIST IN A CLOSED MOCK LOOP CIRCULATION CIRCUIT OF THE CARDIOVASCULAR SYSTEM

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Abstract. *Past decade, blood pumps for mechanical circulatory support have contributed to decrease of mortality in patients with severe heart failure. Apico Aortic Blood Pump (AABP) it's a centrifugal continuous flow blood pump for left ventricle assistance. This work reports the results from AABP's life tests, which are the first approach for its reliability studies.*
Life tests were performed in a closed mock circulation loop circuit of the cardiovascular system. In this circuit physiological parameters were simulated: arterial pressures (systolic, diastolic, preload and afterload), blood corrosion proprieties, vessel compliance, and peripheral vascular resistance. Differential of pressure between inlet and out let cannulas, current consume, flow, systolic and diastolic pressures, AABP and ambient temperatures were registered.
In this test methodology, AABP failure was defined as device inability to maintain flow at 4 l/min or mean pressure at 90mmHg or if the device reaches a temperature higher than 50ºC.
After 1.104 hours of test which corresponds to approximate 132,48x10^6 cycles, none failure event were registered, the device was opened for macro analysis which showed no wear in the internal moving components.

Keywords: *Mechanical Circulatory Support, Life tests, Blood pumps*

1. INTRODUCTION

Cardiovascular diseases (CD) are the leading cause of death in the world. In 2008, were registered 56 million deaths (30, 5% of the total) due to CD (WHO, 2008).

Even with advances in biochemistry and medical intervention in some CD the best treatment available is heart transplantation (SILVA, 2012a). However, because several factors the number of heart transplants performed is not enough to attend the demand of patients (SILVA, 2011a; HRSA/OPTN/SRTS, 2011). An option for these patients, which have an advanced CD and are waiting for heart transplantation, to support their falling heart and also to increase the quality of life, is the implant a ventricular assist device (VAD).

A VAD is a device implanted together with the diseased heart, supporting the cardiovascular system and maintaining arterial pressure and cardiac output into normal values.

ISSN 2176-5480

Johnson (2010) in a study about death rate of patients awaiting for heart transplantation showed that the use of VADs in the United States of America make the mortality decrease considerably.

Apico Aortic Blood Pump (AABP) Fig. 1 (A and B) is a miniaturized VAD. AABP uses a single impeller with a mechanical suspension system Fig. 1B. Impeller rotation in its on axis promotes ejection of blood through the outlet cannula by centrifugal force. AABP improved design allows it to be implanted directly in the ventricle and remain fixed at the ventricle when implanted. Inlet cannula it's inserted in the ventricle by using a guide ring Fig. 2, which is previously sutured in the ventricle. Outlet cannula Fig. 1A it's connected to a vascular graft, attached to the aorta by an anastomosis (SILVA, 2012b; SILVA, 2010).

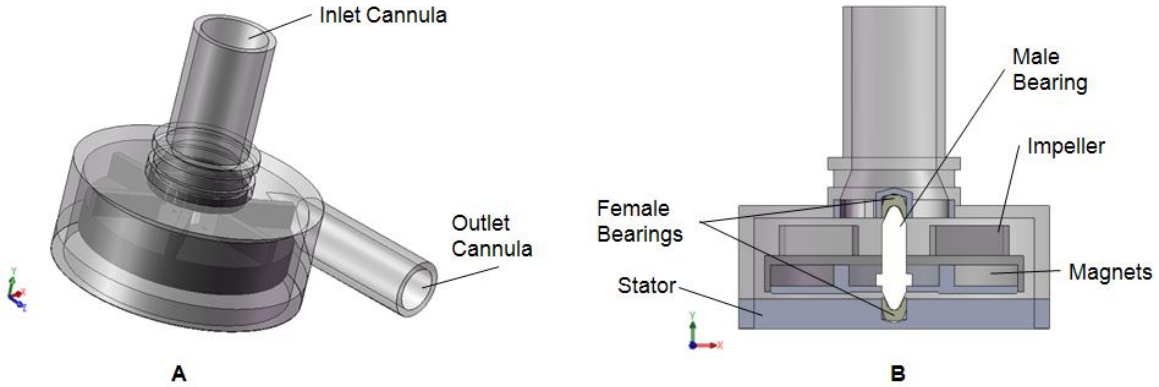

Figure 1 – Drawings showing AABP design and its parts.

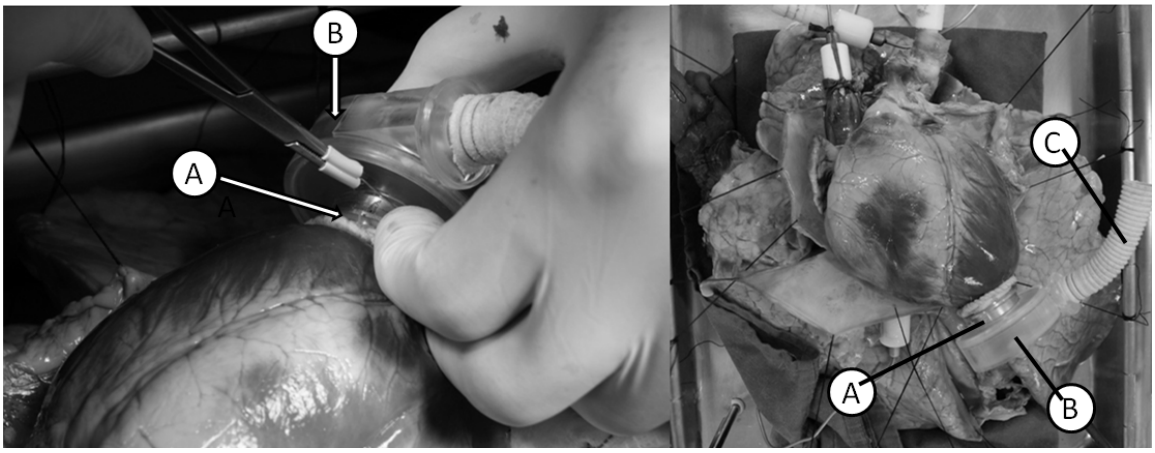

Figure 2 - A. Left: Inlet cannula been fixed in the guide ring. Right: Picture from AABP already implanted in the left ventricle apex. A- Guide ring. B – AABP. C – Outlet cannula and vascular graft.

AABP previous studies indicated an adequate haemolisys index and hydrodynamic performance, for its use on bridge for transplantation (SILVA, 2012a).

To evaluate AABP performance during the intended period for its application a life test was realized.

2. METHODOLOGY

Besides obtaining data about AABP's performance over the time, life test also registered failures for further reliability studies.

AABP failure was defined as: an inability of the device to maintain an interval of pressure (ΔP) between outlet (P1) and inlet (P1) cannulas in at least 90mmHg or an inability to maintain the output flow (in this case it was also considered as our cardiac output) in at least 4 l/min or if the device stator basis reaches a temperature of 50ºC.

The mean time for bridge for transplantation, when VAD supports the patient until an organ be found, it's about one month (720 hours). The duration of this life test was determined based on this information.

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AABP operational parameters were determined base on the studies of Nosé (1998) and Silva (2012). During the test the ΔP was maintained in about 120 mmHg, output flow at 5 l/min, peripheral vascular resistance was determined using Eq. (1): Mean Arterial Pressure (MAP) and Eq.(2) Peripheral Vascular Resistance (PVR) (MCGEE, 2009).

$$MAP = SP + (2x\ DP)/\ 3 \quad (1)$$

$$PVR = 80\ x\ (MAP - SP)/\ CO \quad (2)$$

Where:

MAP: Mean Arterial Pressure [mmHg]
SP: Arterial Systolic Pressure [mmHg]
DP: Arterial Diastolic Pressure [mmHg]
PVR: Peripheral Vascular Resistance [dines-seg/cm^{-5}]
CO: Cardiac Output / Output Flow (for AABP) [l/min]

Closed Mock Circulation Loop Circuit was assembled to simulate some parameters of the cardiovascular system which would be necessary to generate an operation condition for AABP evaluation. Simulated parameters included: Arterial Pressure in the circuit (systolic, diastolic, preload and afterload); Peripheral Vascular Resistance, Corrosive Proprieties of Blood and Vessel Compliance. During the test were registered: Pressures (systolic and diastolic), Current consume (A) by AABP, AABP output, Ambient temperature and AABP's stator basis temperature.

To simulate corrosive proprieties of blood a working fluid composed of a solution with NaCl 0,9% was used. Dynamic viscosity of fluid was not considered in this test.

3. RESULTS AND DISCUSSION

This life test reports the first 1104 hours of test, which corresponds to 132,48x10^6 cycles of the AABp impeller through its own axis. At this moment the device was opened to allow observation of the internal moving parts.

The following graphs represent the values of simulated parameters obtained during the test. Figure 3 shows the differential of pressure from the outlet cannula to the inlet cannula. Figure 4 shows MAP, calculated from Eq. 1 and Fig. 5 shows the data from the PVR calculated from Eq. 2.

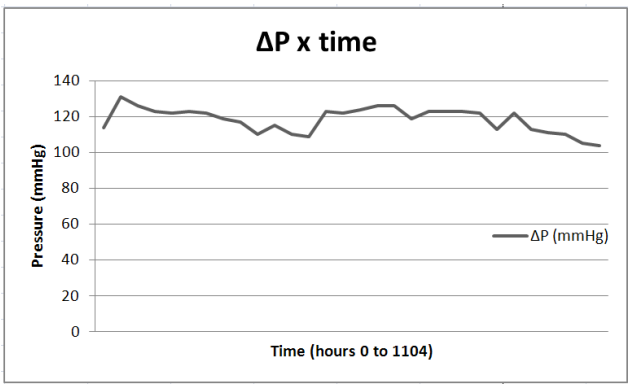

Figure 3 - Differential of pressure from the outlet cannula (systolic) to the inlet cannula (diastolic).

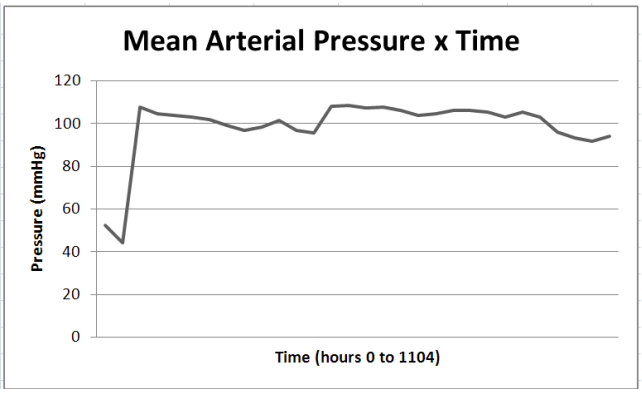

Figure 4 – Mean Arterial Pressure (MAP).

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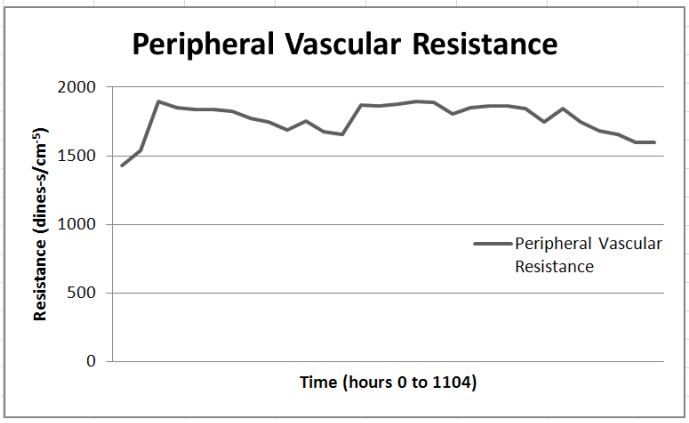

Figure 5 – Peripheral Vascular Resistance (PVR).

Figure 6 shows values obtained in the life test for consume current by AABP over time. Current consume peak reaches 720 mA and mean current consume was about 680 mA, this values where considered not to be in an ideal interval, do solve this problem several alterations in the device electronic controller and in the stator dimensioning are been implemented.

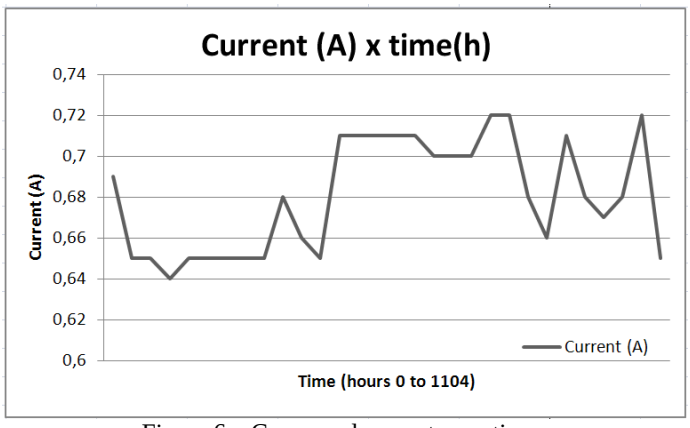

Figure 6 – Consumed current over time.

Figure 7 shows ambient and stator basis temperature. As that in a temperature of 50ºC begin the degradation of proteins, an effect not desirable, it was used to establish the peak temperature for the stator. A temperature higher than 50ºC would be considered a failure event.

Through this analysis was observed that the device temperature was directly correlated to the ambient temperature and not so closely correlated to the current consume.

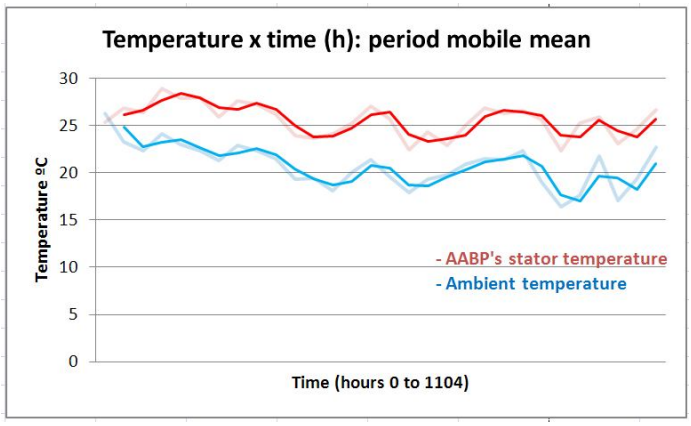

Figure 7 – Temperatures in the life test.

ISSN 2176-5480

Figure 8 shows a picture from the device after the test showing the aspect of the internal parts. Through an observational analysis all parts were considered to be functional and without signs of wear.

Figure 8 – Pictures from AABP after the life test.

4. CONCLUSION

So far none failure event was registered and none other complications happened so far, the monitored parameters indicated that the consume of current by the device must be improved, even that it has not caused any malfunction on the device, in the future the duration of batteries may a differential for AABP for the clinicians and the patients. We will proceed with this test, using the same device and in the next tests it will be exposed to an external ambient with a controlled temperature similar to the human body, this will allow us to get more close to the operational working conditions of AABP when implanted.

5. ACKNOWLEDGEMENTS

The authors would like to thanks Adib Jatene Foundation for the support in this research.

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7. RESPONSIBILITY NOTICE

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