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MAIN TEXT ARTICLE

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Apical aortic blood pump preclinical assessment for long-term use: Durability test and stator topology to reduce wear in the bearing system

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Abstract

This study presents an assessment for long-term use of the apical aortic blood pump (AABP), focusing on wear reduction in the bearing system. AABP is a centrifugal left ventricle assist device initially developed for bridge to transplant application. To analyze AABP performance in long-term applications, a durability test was performed. This test indicated that wear in the lower bearing pivot causes device failure in long-term. A wear test in the bearing system was conducted to demonstrate the correlation of the load in the bearing system with wear. Results from the wear test showed a direct correlation between load and wear at the lower bearing pivot. In order to reduce load, thus reducing wear, a new stator topology has been proposed. In this topology, a radial stator would replace the axial stator previously used. Another durability test with the new stator has accounted twice the time without failure when compared with the original model.

KEYWORDS

apical aortic blood pump, long-term assessment, mechanical circulatory support, ventricular assist device

1 | INTRODUCTION

Apical aortic blood pump (AABP) (Figure 1) is a centrifugal left ventricle assist device (LVAD) with its inlet cannula remaining fixed at the left apex and the outlet cannula connecting to a polytetrafluorethylene (PTFE) graft anastomosed to the ascendant portion of the aorta. AAPB concept is an idea of renowned Brazilian surgeon, Dr. Adib Domingos Jatene (*1929-†2014), based on other similar devices. The initial concept of AABP development has been included several studies. In 2012, Silva et al[1,2] presented AABP's concept validation through in vitro tests including impeller geometry and hydrodynamic performance optimization, hemolysis assessment, anatomical positioning, and analysis in a cardiovascular simulator. Those studies indicated a satisfactory device performance for its use as a LVAD. In 2015, Leão[3] presented a control algorithm for AABP and similar devices consisting of an automated rotational speed control based on a natural heart rate estimator.

Original AABP concept was exclusively for Bridge to Transplantation; however, in order to further study AABP performance in long-term, a durability test was conducted. Results from the durability test indicated a main point for device improvement due to bearing system wear. AABP's bearing system consists of a mechanical bearing, a bearing axis holds the impeller in its working position. The bearing axis

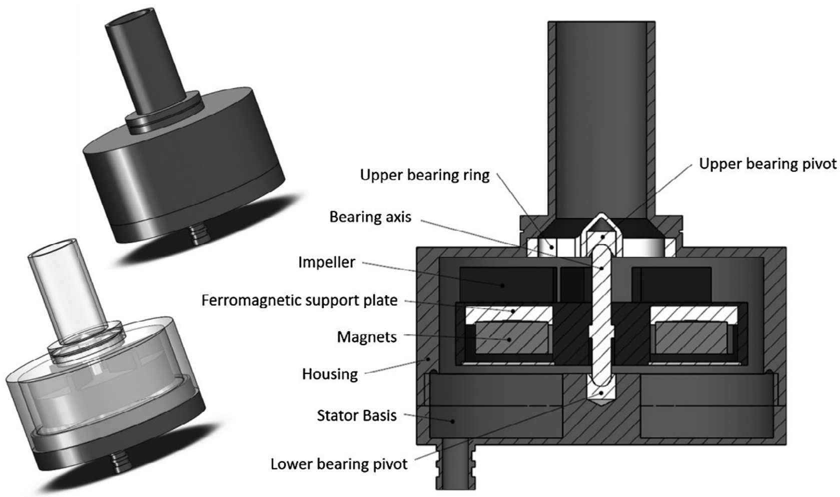

FIGURE 1 Apico Aortic Blood Pump (AABP): External views and internal components

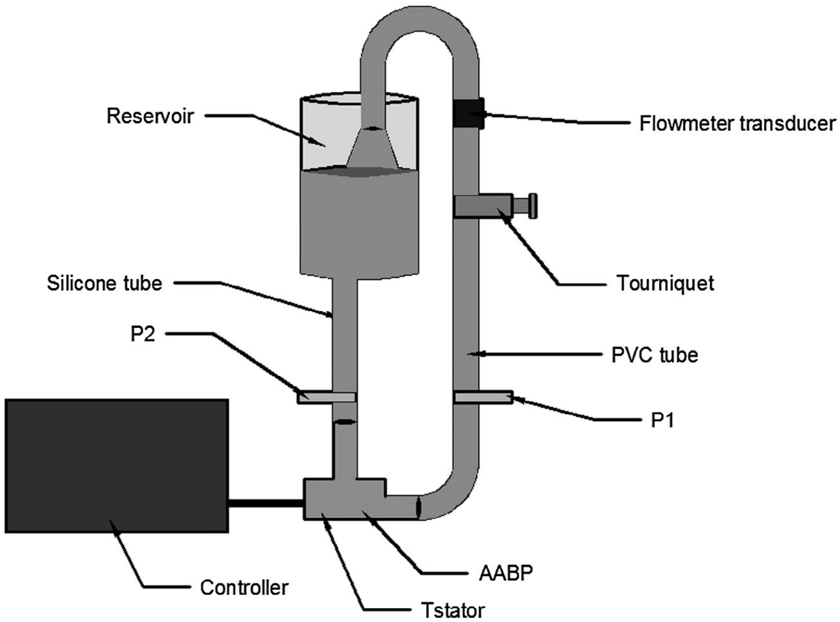

FIGURE 2 Mock Loop Circulation System for durability test. Tstator: portion where temperature was measured

can only rotate on its own axis due to a pair of pivots in each extremity of the bearing axis.

AABP's increased durability is important for device validation for long-term therapy strategies such as destination therapy.

This article presents results from this durability test, improvement development, and implementation, which were performed in order to evaluate AAPB's long-term performance.

2 | MATERIALS AND METHODS

2.1 | Durability test

A durability test was the starting point for AAPB long-term assessment. This test consists of maintaining the device under similar (head pressure and flow) conditions when implanted until device failure. An AAPB prototype was connected to a mock loop circulation system[4–6] for specific parameters register, and those registered parameters include: current consumption [A], stator (Tstator) and environment temperatures [ºC], and head pressure [mm Hg)]. Figure 2 presents a scheme for the mock circulation loop system.

Head pressure in this system was maintained at 100 mm Hg, flow was 5 L/min. Those values represent the mean operation values for a LVAD during mechanical assistance and were considered as reference for the durability tests.[2,6] Those parameters were adjusted by AABP rotation speed and by a tourniquet. A physiological solution (0.9% NaCl) described in Ref.[7] was used. The mass of the bearing system components (upper bearing pivot, lower bearing pivot, and bearing axis) was measured before and after the test.

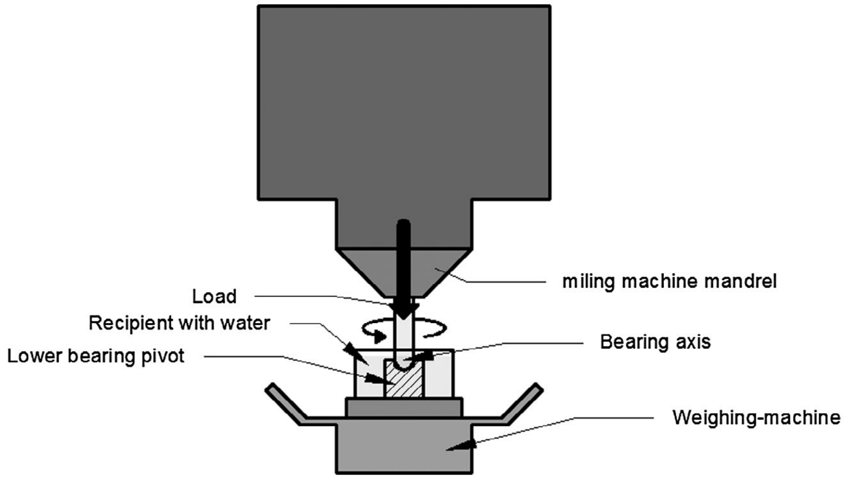

FIGURE 3 Wear assessment system scheme

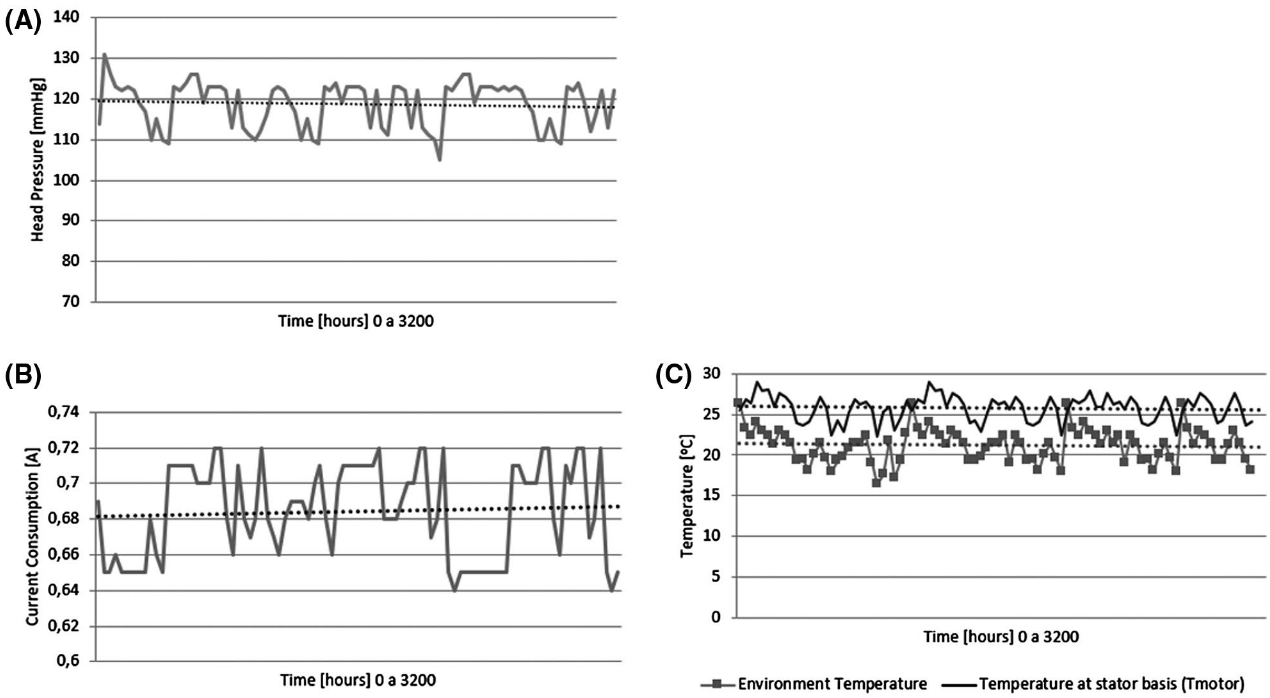

FIGURE 4 Monitored parameters during durability test. A, Head pressure; B, Current consumption; C, Temperature

2.2 | Bearing system wear assessment

Following the durability test, a wear assessment in the bearing system was conducted to evaluate effect of load in the bearing axis and lower bearing pivot wear. In this wear assessment, components' mass loss was used as a wear indicator. Three sets, each containing a bearing axis and a lower bearing pivot, were subjected to different loads in order to evaluate wear as a function of the load applied in the bearing system; different loads used were 0.5, 2.5, and 5 kgf. Test methodology used the system proposed by Refs.[8,9]. Figure 3 shows a schematic of the system used for the wear assessment.

Components' mass was measured in 1-hour intervals for the first 8 h of test and in 2-hour intervals until each set reached a total of 26 hours of test. The measurement interval was increased due to a minimum change in the mass. For statistical analysis of mass loss correlation between each set, a hypothesis test with a significance level of 5% was applied.

3 | RESULTS AND DISCUSSION

Durability test duration was 4 months and 15 days or 3200 hours, with a mean rotational speed of 2500 rpm, which equates to about 480×10^6 cycles. Flow was maintained at

5 L/min. Figure 4 shows the monitored parameters during the test.

After 3200 hours, the testing device presented a failure and its components analysis indicated that the bearing axis decoupled from the upper bearing pivot causing the impeller to not be able to rotate, thus the device was not able to maintain flow and pressure levels. The lower bearing pivot showed signs of intense wear which possibly lead to the decoupling in the system. There were no visible signs of corrosion at the components. Table 1 shows components mass before and after testing.

TABLE 1 Components mass before and after the durability test

Component	Initial mass [g]	Mass after testing [g]
Lower bearing pivot	1.1775	0.5375
Upper bearing pivot	1.1176	1.0536
Bearing axis	1.6548	1.5474

Table 1 indicates a high-intensity wear at the lower bearing pivot, which explains how the decoupling might happen. In order to confirm the load at the lower bearing pivot effect on its wear, a specific test was performed in order to investigate systems force effects. Figure 5 shows a graph of wear at the lower bearing pivot during this test.

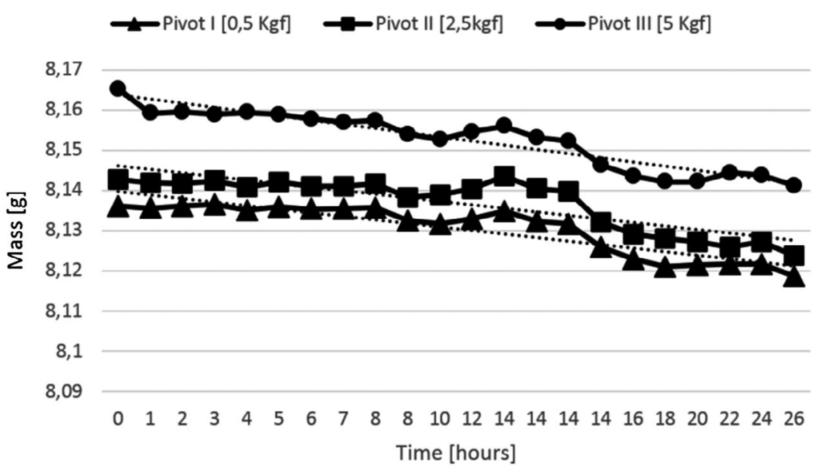

FIGURE 5 Wear at the lower bearing pivot with different loads

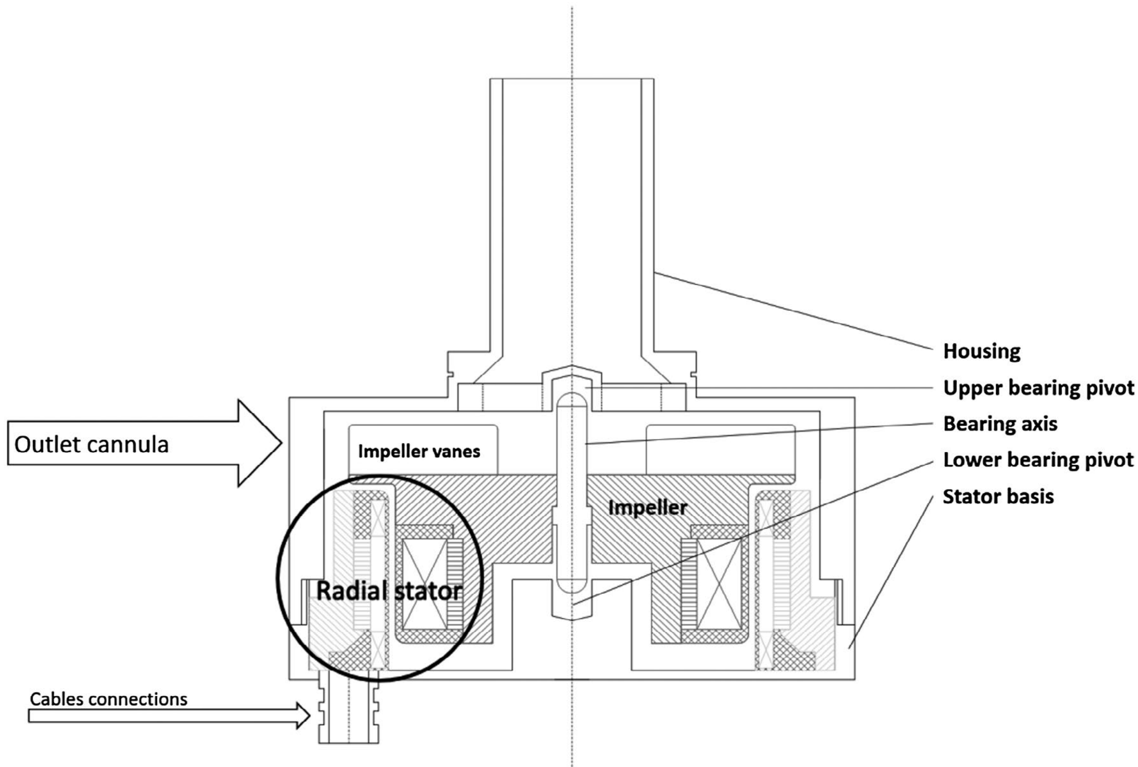

FIGURE 6 Drawing of AABP with radial stator topology

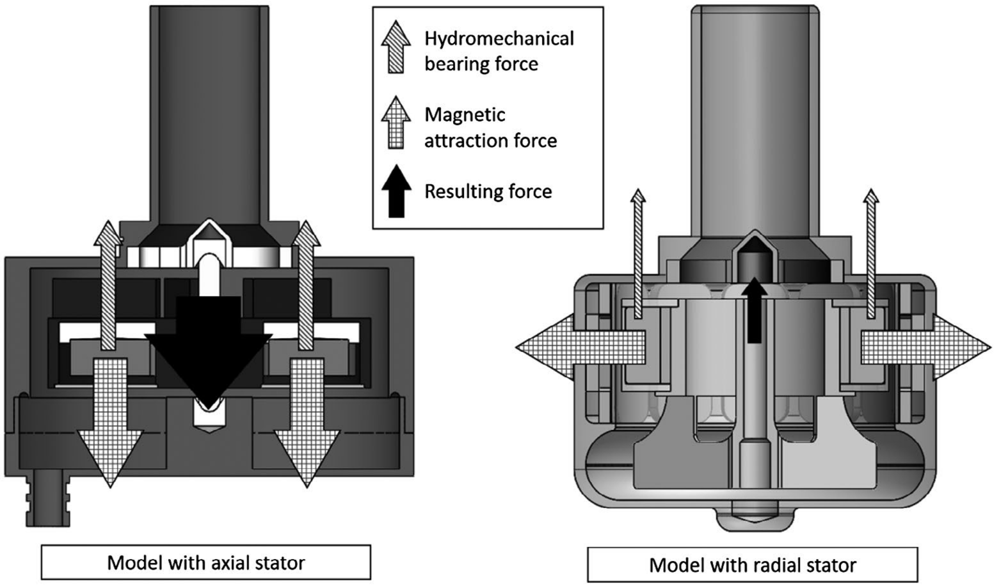

FIGURE 7 Scheme of force distribution on both models

There was no significant wear at the bearing axis. Results from Figure 5 indicates that load has a direct effect on the lower bearing pivot wear; thus, reducing the load that could improve system durability. Our group adopted a new stator topology in order to reduce the load in the bearing system. This new topology consists of a radial stator (Figure 6), which reduces load in the bearing system. A scheme from the distribution of forces comparing both models (axial and radial) is presented in Figure 7.

A prototype of the model with a radial stator was constructed for a new durability test; so far in an ongoing test, this prototype has completed approximately 7200 hours of testing with the same conditions as the model with a axial stator. However, the model with a radial stator is under ongoing vane optimization studies for improvement of the hydrodynamic performance and hemolysis index.

4 | CONCLUSION

Durability testing demonstrated a failure of the AABP bearing system due to excessive wear. In order to certify that the cause of the excessive wear was the load from the magnetic coupling force between the stator and the impeller, the bearing system was subjected to a test that indicated a direct relation between load and wear. A different stator topology was proposed to reduce the load in the bearing system by using a radial stator topology. A prototype with this radial stator topology, subjected to an ongoing durability test, has accrued more than twice the time compared with the first prototype.

Prospective further studies with the AABP with the radial stator include stator optimization and rotor geometry optimization.

CONFLICT OF INTEREST

The authors declare that they have no conflicts of interest with the contents of this article.

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