

## **IN VIVO TESTS WITH THE AUXILIARY TOTAL ARTIFICIAL HEART AS A LEFT VENTRICULAR ASSIST DEVICE IN CALVES**

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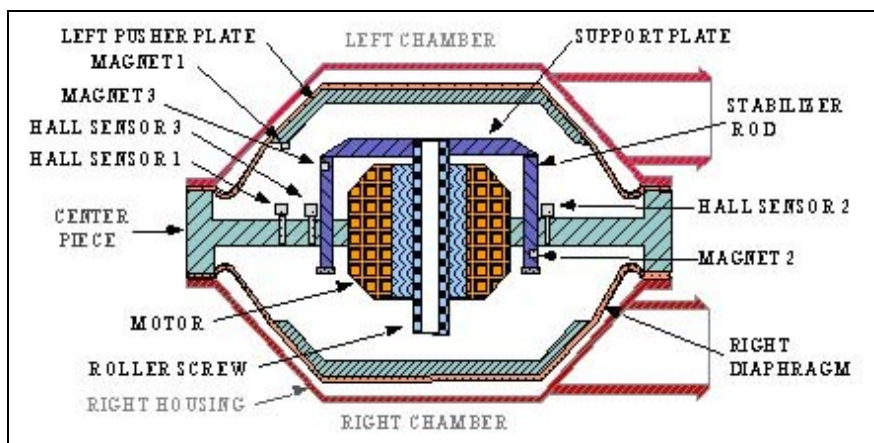
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**Abstract.** *A totally implantable electromechanical Auxiliary Total Artificial Heart (ATAH) has been developed at Institute Dante Pazzanese of Cardiology (IDPC). Because of its assembly characteristics, the ATAH can be configured as a Left Ventricular Assist Device (LVAD). The developed system consists of three modules: the device; the electronic controller and driver; and the batteries. Nowadays, the LVAD has been tested in female calves with weight of 85±5 Kg. The device implantation is made through cannulation from the left ventricle apex to the descending aorta. The experiment occurs in three phases: preoperative, when animal preparation occurs and it is submitted to especial care with foods and drugs administration; surgery, when the intervention occurs; and postoperative when animal care is performed by diagnostic exams and by monitoring the device operation through data acquisition. The results demonstrated the ATAH biocompatibility and showed a relation between the Activated Coagulation Time (ACT) and the anti-coagulant infusion (sodic heparin, 20.000 UI/500ml of physiologic solution). To keep the animal's condition stable, it is necessary to maintain heparin solution infusion in a rate of 80 ml/h, which correspond to 450±50 seconds of ACT.*

**Keywords:** *Auxiliary Total Artificial Heart, Artificial Circulation, In Vivo experiments, Left Ventricle Assist Device.*

## 1. Introduction

The Auxiliary Total Artificial Heart (ATAH) is an electromechanical device (Fig. 1) controlled by an electronic unit as shown in Fig. 2. (Andrade, 1999a). The ATAH is a pulsatile blood pump that operates in *Left Master Alternate* (LMA) mode, so that the left ejection depends on the complete fill of the left chamber. The sequence of operation happens in 4 steps: 1<sup>st</sup> step - the device starts with complete right ejection; 2<sup>nd</sup> step - when a sensor detects the end of right ejection, the electronic controller keeps the device in a steady state while the blood fills the left chamber. 3<sup>rd</sup> step – after the left chamber is completely filled with blood, condition noticed by another sensor, the electronic controller drives the device so that a left ejection occurs; 4<sup>th</sup> step – when another sensor detects the end of left ejection, the electronic controller changes the operation direction and the system returns to step one.



**Figure 1.** ATAH schematic drawing shows the electrical position sensors. The Hall sensor 1 with magnet 1 work together to detect the down position of the left pusher plate. The Hall sensor 2 with magnet 2 detects the up position of the support plate, and the Hall sensor 3 with magnet 3 detects the down position of the support plate.



**Figure 2.** ATAH electronic controller unit (right side) and batteries (left side)

Nowadays, the ATAH has been studied as a Left Ventricular Assist Device (LVAD). It is possible because of ATAH assembly proprieties. As shown in Fig. 1, in order to convert the ATAH to a LVAD, all that is necessary is to remove the left right chamber. The electronic controller is the same, so it does not need changes.

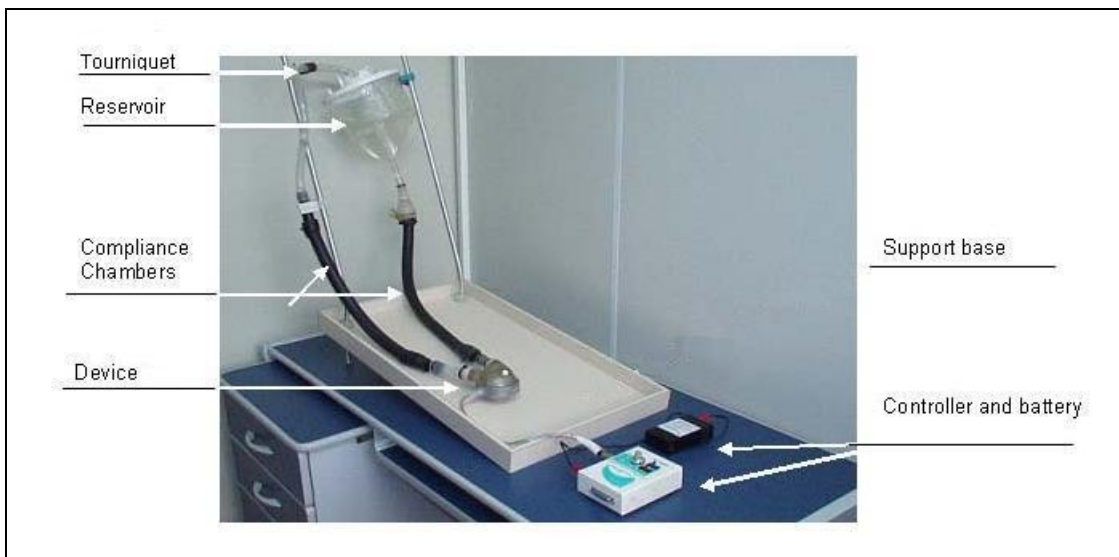
## 2. Materials and Methods

In order to study the LVAD operation, before the *in vivo* tests, some *in vitro* tests have been performed.

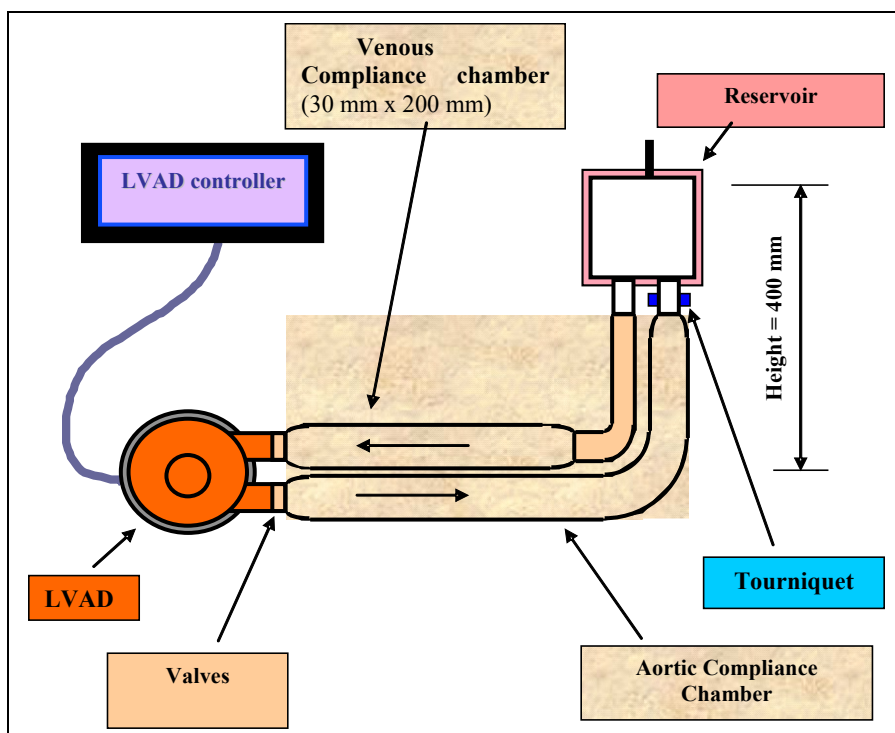
*In vitro* tests are performed with the device operating in variable rate and fixed rate of 100, 120, 130 and 140 beats per minute (bpm). In fixed rate mode the electronic controller does not wait for the signal of left chamber filling sensor, so the device pulsates at a fixed frequency depending on the motor speed. In the variable rate mode, the system operation occurs in 4<sup>th</sup> steps, and the electronic controller waits for the signal of complete left chamber filling sensor (Andrade, 1998).

*In vitro* tests are performed in a mock loop circuitry assembled with two compliances chambers made of 1.5” diameter silicone rubber tube with a tourniquet in order to constrict the outflow, a fluid reservoir and pressure gauges.

Figure 3 presents the *in vitro* assembly where the rubber tubes are connected in order to simulate the compliances. At the end of the outlet tube is a tourniquet in order to regulate the outflow pressure. The schematic drawing of this assembly is shown in Fig. 4.



**Figure 3.** Assembly used in *in vitro* tests

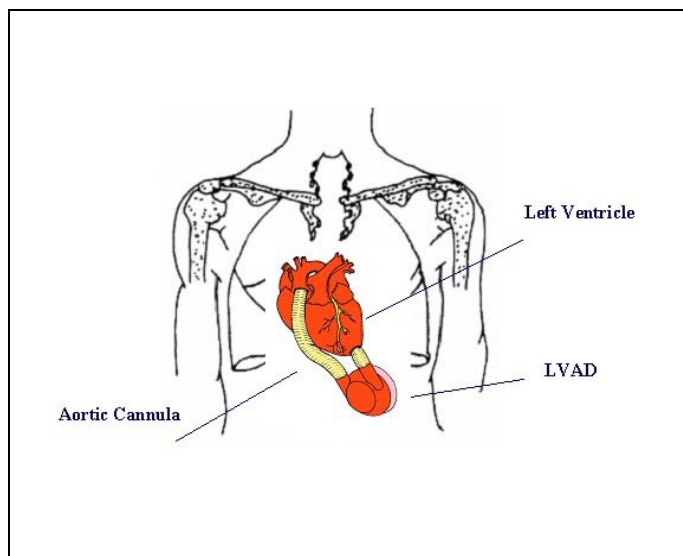


**Figure 4.** Schematic draw of the *in vitro* test circuit

*In Vivo* tests are performed in female calves with weight of 85±5 Kgf. The LVAD implantation occurs in three phases: in the preoperative phase the animal is prepared and food and drugs administration is controlled; in the surgery

phase when the intervention occurs, the device implantation is made through cannulation from the left ventricle apex to the descending aorta, Fig. 5; in the postoperative phase, animal's care is performed by diagnostic examination and by monitoring the device operation through data acquisition (Andrade, 1999b).

In the postoperative phase some studies are realized such as: - Biochemistry study, which intends to evaluate the effect of pump biomaterials and possible disturbances in the animal physiology; - LVAD performance when some pathologic effects are observed since the first days of postoperative phase; - Anatomic exam, which has the objective to evaluate the LVAD system and its *in vivo* performance in the morphologic point of view; - Configuration, weight and size compatibilities are realized in order to verify anatomic acomodation and injury in some surfaces like atrium, vena cava, lungs and diaphragm; - Effects of hemodynamic performance, where the stroke volume produced by the pump is evaluated through the increase of animal weight and size alterations of organs.

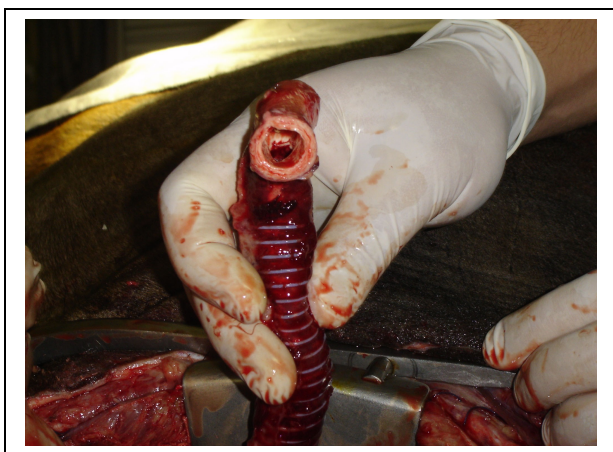


**Figure 5.** Schematic drawing of LVAD implantation in human.

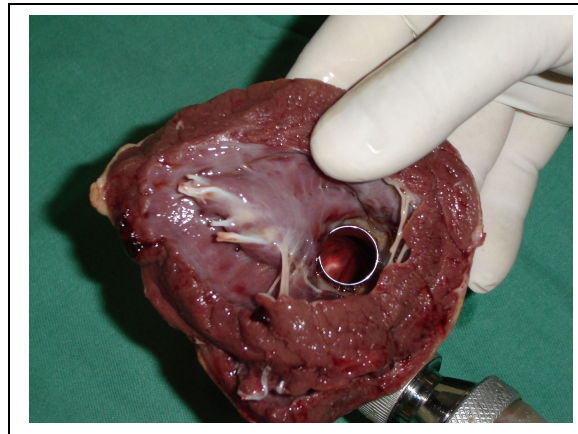
The anti-coagulant infusion (sodic heparin, 20.000 UI/500ml of physiologic solution) was released at a rate of 80 ml/h, and the Activated Coagulation Time (ACT) is measured in periods of 4 hours in the first day after surgery and in intervals of 12 hours in other days.

### 3. Results

In one of the *in vivo* tests, the animal survived for seven days. In the necropsy no thrombus was verified in the animal, tubes and in the device, Figure 6.



(a)



(b)

**Figure 6.** Aorta without internal thrombus (a); left ventricle cannula without internal thrombus.

#### 4. Conclusions

The results obtained demonstrates that there is no thrombus formation when the anti-coagulant infusion (sodic heparin, 20.000 UI/500ml of physiologic solution) is realized in a rate of 80 ml/h which correspond to  $450\pm 50$  seconds of ACT.

#### 4. References

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#### 5. Responsibility notice

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