STATUS OF BRAZILIAN DEVELOPMENT ON BLOOD PUMPING DEVICES

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Abstract. *The blood pump development started with Dr. Michael DeBakey developing the first continuous blood pump for transfusion in 1934. Dr. Denton Cooley performed the first TAH clinical implantation for 112 days, in 1969. This success motivated many research groups to develop their own project. One of the most difficult problems encountered by those groups is the device dimension. Some of the commercially available pulsatile VADs are not readily implantable into the thoracic cavity due to size limitation. The TAH research groups experienced many other difficulties. One such problem is the device control system. According to their pumping principles and clinical application the devices are classified in three categories: centrifugal, axial (continuous flow) and pulsatile. Some of the most important centrifugal, axial and pulsatile, from other countries, are presented. Also, some of the devices developed or under development in Brazil are presented. More details and status from three devices of Institute Dante Pazzanese of Cardiology are presented, such as: Centrifugal Pump (Spiral Pump) for cardiopulmonary bypass, Implantable Auxiliary Total Artificial Heart (ATAH) a pulsatile pump and Implantable Centrifugal Pump.*

Keywords*: Centrifugal Pump, Ventricular Assist Device, Axial Pump, Artificial Heart and Blood Pump.*

1. Introduction

The blood pump development started with Dr. Michael DeBakey developing the first continuous blood pump for transfusion in 1934 (DeBakey, 1934). After surgical technique improvements, studies about pulsatile Left Ventricular Assist Devices (VAD) were initiated and the first clinical implantation was performed by Dr. Domingo Liotta in 1961 (Liotta, 1963), followed by Dr. DeBakey in 1963 (DeBakey, 1971). In 1965, Dr. Yukihiko Nosé demonstrated that it was possible to implant a Total Artificial Heart (TAH) inside the pericardial sac of calves (Nosé, 1965). Dr. Denton Cooley performed the first TAH clinical implantation, in 1969 (Cooley, 1969). In 1983 at Utah University, Dr. Devries performed the first successful TAH implantation. The patient, even in an unstable condition, survived for 112 days (Devries, 1984). This success motivated many research groups to develop their own project. Presently, various VAD and TAH designs are being studied. One of the most difficult problems encountered by those groups is the device dimension (Jarvik, 1986; Shiono, 1991). Some of the commercially available pulsatile VADs are not readily implantable into the thoracic cavity due to size limitation. Most of the TAHs, which are under development, have dimensions requiring the removal of the patients' native heart.

The TAH research groups experienced many other difficulties. One such problem is the TAH control system; this fact is aggravated by the removal of the native heart. Thus, eliminating the natural cardiac output control performed through the mechanoreceptors and chemoreceptors, and also, the right-left flow balance which is helped by the natural heart (Michelini, 1986; Chalmers, 1991; Fukamachi, 1993).

Various types of blood pumps have been developed to attend different clinical applications. The blood pumps can be divided in three categories according to their pumping principles: Centrifugal pumps; Axial Pumps (Continuous Flow) and Pulsatile Pumps.

2. Centrifugal Blood Pumps

The uses of centrifugal blood pumps in various applications are rapidly increasing. This fact became obvious when the advantages of centrifugal pumps were studied and compared to other devices, such as pulsatile pumps or roller pumps.

The centrifugal pumps and roller pumps are commonly used for extracorporeal circulation during open heart surgery. The safety in centrifugal pump usage is an important characteristic that influences the surgeons' choice of pumps. This safety is an inherent characteristic of centrifugal pumps. The fact is that they are unable to pump large amounts of air or create a considerable amount of low pressure in the inlet section or high pressure in the outlet (Lynch, 1978).

However, blood cell destruction is still controversial when comparing these devices. To determine blood cell destruction, the test conditions are very important and results found in the literature are difficult to compare. Some studies indicate that for specific applications in extracorporeal circulation, when elevated pressures and low flows are required, the roller pumps have a better Index of Hemolysis than the centrifugal pumps (Tamar, 1993). Many research

groups improved the design of centrifugal pumps, focusing on solving application limitations, also increasing the pumping efficiency (Kijima, 1993; Nishida, 1993, Orime, 1994).

For a short term ventricular assist device (VAD) the ideal factors are simplicity of operation, cost-effectiveness, and a low Index of Hemolysis. These factors make the centrifugal pump device of choice over the pulsatile or the roller pump. Since many years, reports also have showed advantages of centrifugal pumps in patients that develop postoperative cardiogenic shock (Joyce, 1990; Killen 1991).

Short durability of the centrifugal pump limits the utilization period. The recommended time of currently available pumps is less than 2 days, due to the possibility of seal disruption and blood leakage. In order to improve this durability, new pump designs were developed, the so-called seal-less centrifugal pumps (Ohara, 1994).

At that time, for a long-term VAD or bridge to cardiac transplantation some basic rules were established for a successful and approved device, concerning safety and efficiency (Hill, 1993). For this application the pump needs to be efficient, atraumatic, durable and moreover needs to be anti-thrombogenic (Schima, 1993).

In the literature, different types of blood pumps and studies performed with these pumps show the advantages for specific applications and disadvantages for other applications. Therefore, it is difficult to define which pump is the best. To select the appropriate device for a specific application, the most important characteristic of each device has to be known. One must consider several variables involved in each application, such as: flow, pressure, utilization time and the ambient, cost of device and the general patient condition.

Modifications in details of the pump design can induce great modifications in the device performance. For example, in centrifugal pumps the results obtained with hemolysis tests can vary when modifications of the impeller shape or angle are made (Schima, 1993). Studies of the vortex formation on the outlet side of the centrifugal pump can reveal turbulence that is strongly dependent of the outlet angle (Andrade, 1997).

2.1. The New Blood Pump Concept for CPB in Brazil

Both, centrifugal and axial pumping principles have been applied to several different blood pumps. However, a new type of blood pump uses both centrifugal and axial pumping principles, simultaneously, improving pump efficiency without increasing hemolysis. To generate both pumping principles, inside the pump there is a spiral impeller, it is a conical shape with threads on the surface. The worm gears provide axial motion of the blood column through the threads of the central cone, and the rotation of the conical shape generates the centrifugal pumping effect. Actually, this pump could be denominated a mixed pump because it uses the two pumping principles. Also, it is possible and useful to denominate as a Spiral Pump™ (SP).

The SP is disposable, composing of several plastic parts that is molded by injection. The external conical shaped housing has a maximum diameter of 92 mm and a height of 90 mm, and the included angle of the cone is 60 degrees. The total priming volume is 75 ml. Inside the housing is a spiral impeller and inside this impeller is two bearings separated by one plastic spacer. The internal bearing diameter is 8 mm and external diameter is 19 mm. Inside the impeller, there are also, one seal, made of silicone rubber, and one cylindrical magnet, with an internal diameter of 24 mm and external diameter of 51 mm. The impeller base is attached to the bottom of the spiral impeller in order to avoid blood contact with the magnet. All internal parts are assembled in the shaft that exists in the housing base (Figure 2.1-1).

Figure 2.1-1. Spiral Pump™ and driver.

At the top of the housing there is an input area and at the bottom an output area, both with 3/8 inch connections. The base is attached under the housing, consisting of a disc with a stainless steel shaft that holds all the internal components of the pump. The housing base provides total isolation between the inside and outside of the pump. This is an important factor to avoid blood contact and contamination during pumping.

The torque is transmitted from the motor to the spiral impeller by magnetic coupling using two magnets; one inside the impeller and other fixed in the motor. In order to avoid contact between blood and the ball bearing a seal made of silicone rubber is in the shaft of the housing base.

Clinical study was performed with a group of 43 patients with age between 47 and 83 years old, weight between 51 and 80 Kg, 34 patients are male (table 1).

The used exclusion criteria were: myocardial acute infarct, emergency surgery, renal disease with creatinine above of 2,0 mg%, diabetes mellitus insulin-dependant and anemia.

Table 1. Demographic Appearance of group patient.

Number of studied cases	43 (100%)
Age	47 to 83 years old
Weight	51 to 80 Kg
Number of Male patients	34 (79%)
Number of Female patients	09 (21%)

It was made a total of 43 surgeries where: 31 (72% of cases) was made with MR (Myocardial Revascularization); 10 (23% of cases) with orovalvares surgeries and 2 (5% of cases) with MR associated to valves surgery. In that cases, was used a membrain oxigenator. The esophagic temperature was kept about 32 Celsius degrees (table 2).

Table 2. Clinic suggestions and surgery data. Number of surgeries with Cardiopulmonary Bypass - 43 (100%).

Miocardius Revascularization	31 (72 %) of cases
Orovalvar Surgery	10 (23 %) of cases
MR with valve surgery	2 (05 %) of cases

The surgery duration time was between 1h and 3h30. During this period, the Spiral Pump™ do not shown any malfunction.

The results were satisfactory, and the Spiral Pump shown a secure and stable behavior with sufficient hydraulic capacity in order to keep the demanded blood flow and debit for long periods.

3. Implantable Centrifugal Pumps

Gyro™ C1E3

The implantable centrifugal pump Baylor-Kyocera Gyro™ has been developed since 1995, with successful results on patients over 284 days as left ventricular assist device (Figure 3-1) (Nonaka, 2001; Nosé, 2004).

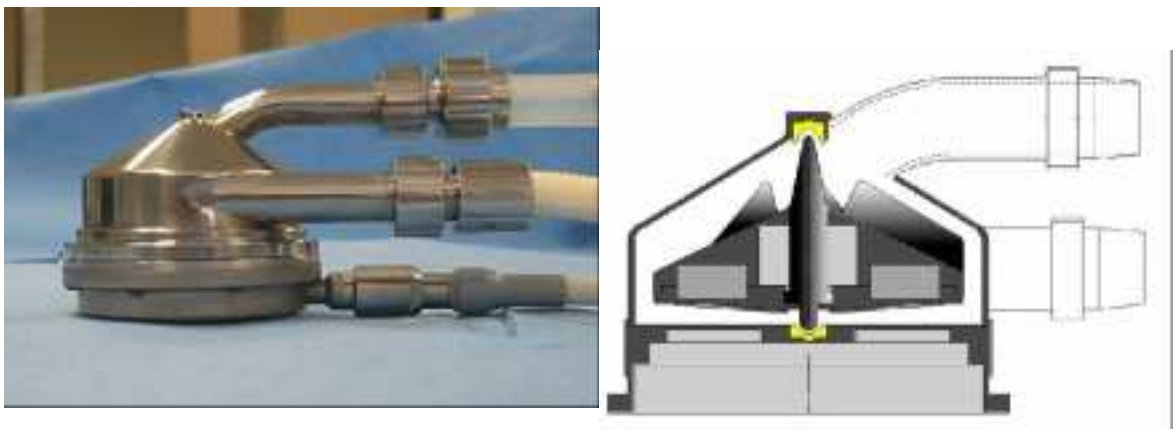

Figure 3-1. Picture and schematic drawing of Gyro™ centrifugal pump (Nosé, 2004).

This pump is made of Titaniun alloy, has a internal volume of 25 ml, a weight of 204 g and produce a flow of 5 l/min at 2000 rpm under a presure of 100 mm Hg (Nosé, 1998). The life time for Gyro™ is 10 years as RVAD ("right ventricular assist device"), 8 years as LVAD ("left ventricular assist device") and 5 years as CPB ("cardiopulmonary bypass") (Makinouchi, 1996).

Heartmate III™

The Heartmate III™ is the last generation of centrifugal pump as left ventricle assist device because its impeller is the rotor of the motor (Figure 3-2).

Figure 3-2. Picture and assembly of HeartMate III™

CorAide™

The CorAide™ from Cleveland Clinic Foundation is a device with low cost with large clinical application (Figure 3 -3) (Golding, 1998). This device has been evaluated in patients since 2003 in Europe, with successful results (Arrow, 2004).

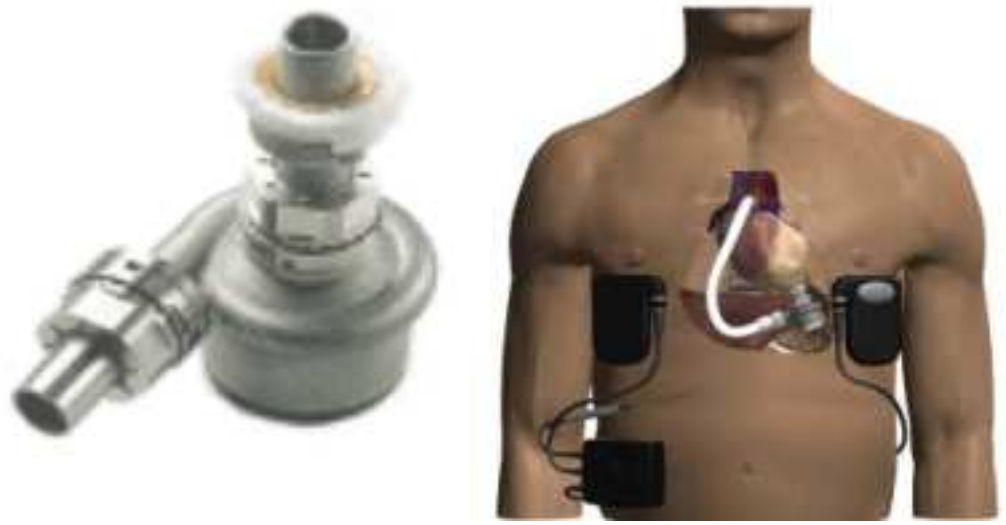

Figure 3-3. Picture and positioning of CorAide™

Duraheart™

The implantable centrifugal pump Duraheart™ (Figure 3-4), from Terumo Heart Inc. (USA), is an option for chronic cardiac patients in Europe. It uses the magnetic suspension technology the minimize friction between mechanical parts, and blood cell damage. The first implantation in human was performed on 2004 (Terumo, 2004).

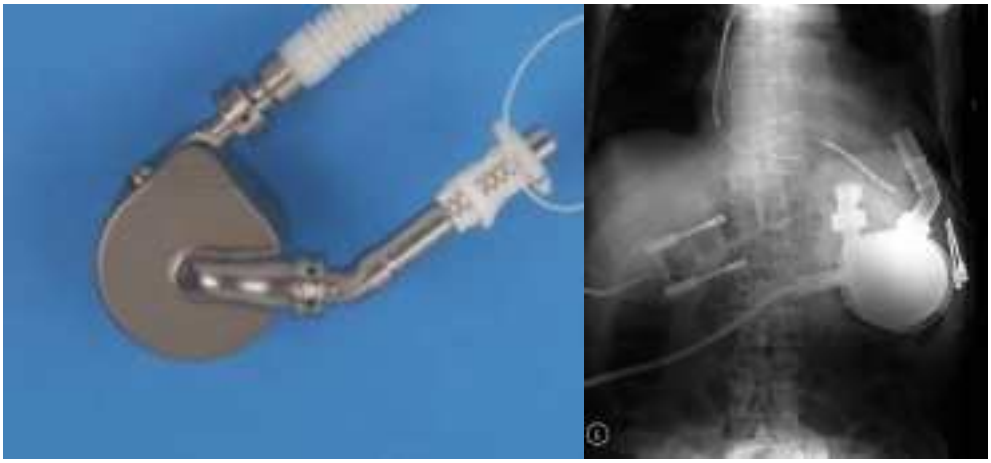

Figure 3-4. Picture and x-ray from DuraHeart™.

3.1. Implantable Centrifugal Pump in Brazil

A new implantable centrifugal pump has been developed in our laboratories. It is a implantable long-term Left Ventricle Assist Device (LVAD). Dr. Nosé (1998) proposed a step-by-step development strategy to the conversion of a two days antitraumatic pump (Phase 1) to a 2 week antithrombogenic pump (Phase 2) and, after this step, the conversion of this device to a durable, implantable, and long-term blood pump (Phase 3). We are working to convert the Spiral Pump™ (SP) to this new durable LVAD. Nowadays, the SP is in the last clinical test for cardiopulmonary bypass and has proven to be a safe and reliable option (Andrade, 1996). As proposed by Takami *et al*. (1997), a completely sealless pivot bearing system is under evaluation in our laboratories, as seen on the Figure 3.1-1.

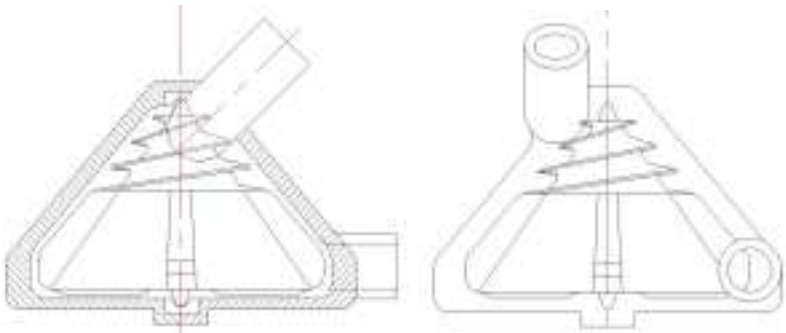

Figure 3.1-1. A schematic drawing from implantable, long-term, centrifugal blood pump.

4. Axial Pump

Hemopump™

The first device known as an axial pump was the Hemopump™ created by Wampler. The pump actuator, placed outside the patient's body, drive the pump's impeller trough a catheter-mounted steel cable, as seen on the figure 4-1, with rotations between 17000 to 25000 rpm. It's clinical short-term use began at the Texas Heart Institute on April 1988. Today, the Hemopump™ is no longer used (Wampler, 1988).

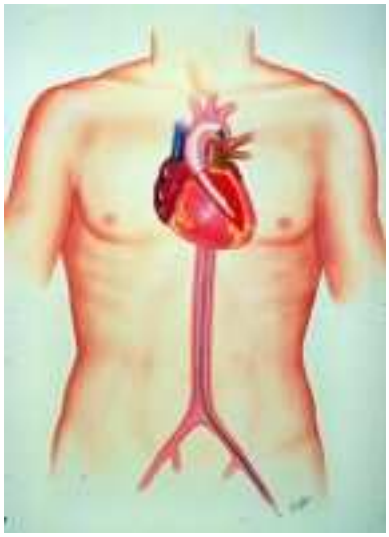

Figure 4-1. Schematics of the position and driving of Hemopump™ (Texas Heart Institute).

Jarvik 2000™

The Jarvik 2000™ is an axial pump developed by the Texas Heart Institute and St. Luke's Episcopal Hospital using a Brushless Direct Current Motor, see figure 4-2. It's magnetic impeller is built in neodymium, steel and boron with ceramic bearings. It works about 8000 and 12000 rpm to provide 5 l/min (Jarvik, 2001).

Figure 4-2. Picture from Jarvik 2000™ (Texas Heart Institute)

DeBakey/NASA™

The DeBakey™ axial flow device was built with NASA Johnson Space Center founds in the Baylor College of Medicine on June 1996. Nowadays, it's commercialized by MicroMed Technology Inc. All the external surfaces are made in titanium, see the figure 4-3. It could provide more than 10 l/min in 12500 rpm (Nosé, 2000; DeBakey, 2000).

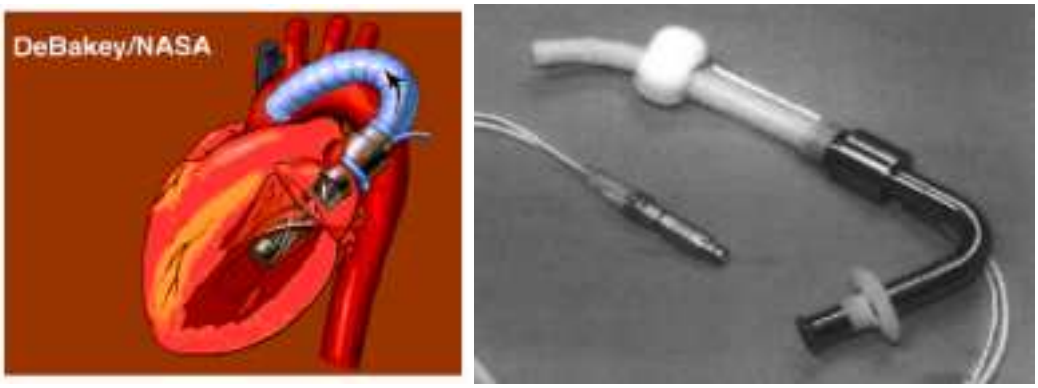

Figure 4-3. DeBakey™ Implantable Axial Blood Pump (BCM and NASA Johnson Space Center)

HeartMate II™

The Thermo Cardio Systems, Inc developed the HeartMate II™, see the figure 4-7. The main efforts of this group is the pump design of sealing (Burke, 2001).

Figure 4-4. Heart Mate second generation device (Thermo Cardio Systems, Inc)

4.1. Implantable Axial Pumps in Brazil

K-Pump

In Brazil, Kubrusly developed an implantable axial flow blood pump, the K-pump, as seen on the figure 4.1-1, that works between 8000 and 12000 rpm. It's 70 mm length and 194 g weight. The first prototype was built with stainless steel (Kubrusly, 2000).

Figure 4.1-1. The Brazilian first axial pump, K-pump (Kubrusly, 2000)

Braile

Also in Brazil, the "Braile Biomédica" industry developed in its laboratories another axial pump, as seen on the figure 4.1-2. It works with a Brushless Direct Motor stator and ceramic bearings.

Figure 4.1-2. The Brazilian Braile's axial pump

5. Pulsatile Pump

Thoratec™

The Thoratec™ from Nimbus, Inc (USA) (Figure 5-1) was implanted as artificial ventricle on 1997. A flexible polyurethane diaphragm pumps the blood using pneumatic compressor and tubes through the skin. The maximum flow is 12 l/min and more than 3600 patients received this device (Fuchs, 2002).

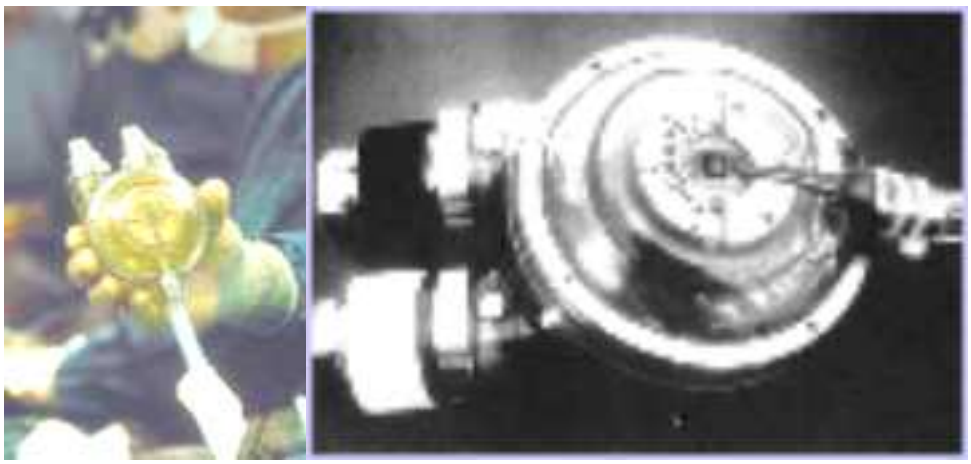

Figure 5-1. Pictures from Thoratec™ (Texas Heart Institute)

Novacor™

The Novacor™ pulsatile partially implantable devices (Figure 5-2), from Baxter Laboratories (USA), use biological artificial valves in a polyurethane sac compressed by two metallic plates attracted by electromagnetic fields. It is the most implanted left ventricle assist device (Rose, 2001).

Figure 5-2. Picture from Novacor™ (Baxter Laboratories).

HeartMate™

The pulsatile device HeartMate™, from Thoratec Corporation (USA) with Thermo Cardio Systems, Inc (USA), consist of a electromechanical device with a polyurethane diaphragm and two porcine valves. Its weight is 1150 g and is able to pump 10 l/min of blood (Figure 5-3) (Frazier, 2001).

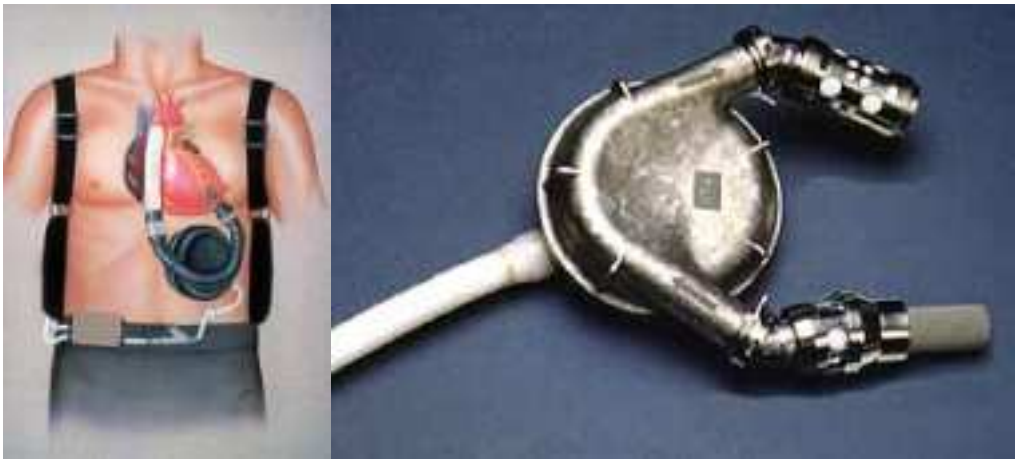

Figure 5-3. Pictures from HeartMate VE ™ (Texas Heart Institute)

DAV-INCOR

The Ventricle assist device InCor, from Heart Institute (Brazil), is a paracorporeal pneumatic device. It has been evaluated in patients with successful results (Figure 5-4).

Figure 5-4. Picture from pulsatile paracorporeal pneumatic device DAV- INCOR.

Jarvik-7™ TAH

The Jarvik-7™ total artificial heart (TAH), also called Utah-TAH and Symbion-TAH, started to be tested on meadows of 1982 by Utah University's surgeons. It has two spherical chambers and disc shaped polyurethane diaphragms. It works with four disc valves (Medtronic-Hall Ind.), see figure 5-5. The Jarvik-7™ was designed to total heart replacement but is not a totally implantable device cause its pneumatic driven have a large console. It can provide between 6 and 10 l/min (Arabia, 1999).

Figure 5-5. Cardiowest / Jarvik-7™ TAH

AbioCor™

The AbioCor™ is produced by the ABIOMED industry and was developed by the Penn State and Texas Heart Institute with founds of National Heart, Lung and Blood Institute. It was designed to total replacement as a totally implantable TAH. The AbioCor™ is an electro hydraulic driven device and the energy supply is given by a Transcutaneous Energy Transmission System (TETS).

Figure 5-6. Pictures of AbioCor™ TAH electro hydraulic driven device (ABIOMED)

6. Implantable Auxiliary Total Artificial Heart™

A Total Artificial Heart (TAH) is being tested "In Vivo", in our laboratories. This totally implantable artificial heart has two pumping chambers and four biologic prosthetic valves (LABCOR, Belo Horizonte, Brazil). This electromechanically driven artificial heart is called Auxiliary Total Artificial Heart™ (ATAH) due to its reduced dimensions (outer diameter is 85 mm and the thickness is 65 mm), being able to be implanted in the right thoracic cavity (in parallel) or in the abdominal cavity (in series) of an average human patient without removing the natural heart or the heart neuro-humoral inherent control mechanism for the arterial pressure. When in the abdominal cavity (in series), the device can be implanted with two artificial ventricles (as Auxiliary Total Artificial Heart™ - ATAH) or with only one pumping chamber (Left Ventricle Assist Device – LVAD). Figure 6-1 shows a schematic drawing of the implantation options.

Figure 6-1. Schematic Drawing showing the implantation options for the Auxiliary Total Artificial Heart (ATAH) in parallel (left) or in series (center) and with only one pumping chamber as Left Ventricle Assist Device (LVAD) (right).

The ATAH's beating frequency is regulated through the change of the left preload, based on Frank-Starling's law, assisting the native heart in obtaining adequate blood flow. The ATAH left and right stroke volumes are 38 ml and 34 ml, respectively, giving approximately, 5 L/min of cardiac output at 160 bpm (Andrade, 1999).

This device is an electromechanical pulsatile blood pump with left and right chambers. A brushless direct current (DC) motor which is fixed in a metallic centerpiece provides the actuation. A mechanical actuator, the planetary roller screw, converts the motor rotation into a rectilinear motion that advances the left and right diaphragms. A support plate with three stabilizer rods is welded to one edge of the roller screw to avoid rotation. The diaphragms are adhered to conical pusher plates. The left and right housings are made of an epoxy resin and covered by polyurethane.

His device operates in left master alternate mode (LMA), with the left auxiliary ventricle, as the master, setting the ATAH pumping rate and the right beating alternatively with a fill-limited flow (Ohashi, 1997). The ATAH frequency can be constant, operating in a fixed rate mode (FR) or variable when in a variable rate mode (VR) (Andrade, 1999). In

FR, the waiting time is pre-fixed by the ATAH electronic controller. In VR, the left ejection phase commences when the Hall sensor detects a complete filling of the auxiliary left ventricle. Therefore, the ATAH pulse rate depends on the left chamber filling time and is dictated by the left preload.

Sixteen In Vivo tests were performed in calves with 80 ± 5 Kg of weight. The device was implanted as LVAD in their abdominal cavities in series with their native hearts to verify the device performance and operating functions. The implantation was performed connecting a flexible polymeric graft from the left ventricle apex to the artificial ventricle inlet port. From the LVAD outlet port, the blood was pumped to the descending aorta through another polymeric graft. Inside the LVAD inlet port was a biological prosthetic valve with 25 mm of diameter and inside the outlet port was a 23 mm artificial valve. The LVAD internal blood-contacting surfaces are also made of polymeric materials (polyurethane). The pumping diaphragm is made of polyurethane rubber and the housing is made of acrylic resin covered by polyurethane rubber. During all the tests, heparin was administrated. To control the anticoagulation effect we used the blood Activated Coagulation Time (ACT). The ACT was maintained in 350 ± 50 s by adjusting the heparin (anticoagulant) infusion flow. The calves were kept in an appropriate cage with LVAD controller in their right side and the heparin infusion pump fixed to the cage.

In addiction, with these experiments it was possible to observe the LVAD behavior. With the LVAD helping the natural heart to obtain the appropriate blood flow, the native heartbeats decreased. It was observed that the LVAD and the native heart worked synchronously, with the left artificial ventricle and the natural heart contracting alternatively. Thereby, it is possible to predict that the ATAH will help a sick heart to recover its pumping function. With the ATAH and the natural heart working simultaneously, the control system is simplified and the surgical risks are reduced.

7. Acknowledgement

We would like to acknowledge CNPq and FAPESP for partially support this project.

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