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Spiral blood pump: conception, development and clinical application of the original project

Bomba sangüínea espiral: concepção, desenvolvimento e aplicação clínica de projeto original

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Abstract

Introduction: **This paper addresses an original project that encompasses the concept, development, and clinical application of a helical bypass pump using the association of the centrifuge and axial propulsion forces based on the Archimedes principle, referred to as Spiral Pump. This project has obtained Brazilian Patent and a Preliminary International Report defining it as an invention.**

Methods: **We seek to evaluate the homodynamic capacity and the impact of its application to the blood cells by means of experimental *"in vitro"* tests, such as Hydrodynamic Efficiency, Normalized Hemolytic, and Flow Visualization. The *"in vivo"* experimental tests were carried-out in lambs submitted to bypass for 6 hours and in 43 patients undergoing bypass heart surgery using the Spiral Pump.**

Results: **When the rotor – plastic carcass gap was 1.5 mm, the generated flow was nearly 9 L/min; pressure above 400 mmHg at 1500 rpm, normalized hemolytic indexes not superior to 0.0375 g/1001 under high-flow and pressure conditions, and by the flow visualization at the entrance and exit of the pump, as well as the extremity of the spindles. At the *"in vivo"* tests in the lambs, the pump was capable of maintaining adequate pressure and the Free Hemoglobin ranged between 16.36 mg% and 44.90 mg%. Evaluating the results of the 43 patients using this pump in bypass heart operations we observed that the Free Hemoglobin ranged from 9.34 mg% to 44.16 mg% before and after surgery, respectively; the Serum Fibrinogen from 236.65 mg% to 547.26 mg%; Platelet Blood Count from 152.465 to 98.139; and the Lactic Dehydrogenase from 238.12 mg% to 547.26**

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mg%. The Activated Coagulation Time was near 800 seconds during the bypass.

Conclusion: **The Spiral Pump was very effective in generating adequate flow and pressure, causing no excessive harm to the blood cells.**

Descriptors: **Heart-assist devices, classification. Flow mechanics. Hydrodynamics. Hemolysis.**

Resumo

Introdução: **O trabalho aborda projeto original relativo à concepção, ao desenvolvimento e à aplicação clínica de bomba sangüínea que associa forças centrífuga e axial de propulsão hidráulica, baseada no princípio de Arquimedes, denominada Bomba Espiral (BE), tendo recebido Patente Nacional e Relatório Preliminar Internacional categorizando-a como invento.**

Método: **Visa avaliar sua capacidade hidrodinâmica e seu impacto aos elementos figurados do sangue por meio de testes *"in vitro"*, como Eficiência Hidrodinâmica, Hemólise Normalizada e Visibilização de Escoamento, e, nos testes *"in vivo"* experimentais, feitos em carneiros submetidos a Circulação Extracorpórea (CEC), e clínico, em 43 pacientes submetidos a operações cardíacas com CEC, nas quais o elemento propulsor foi a BE.**

Resultados: **Na dependência da distância entre o rotor e a carcaça (fenda) da bomba pôde-se observar que com 1,5 mm gerou escoamento ao redor de 9 L/min, pressão acima de 400mmHg com 1500 rotações por minuto (rpm), índices de Hemólise Normalizada não superiores a 0,0375 g/100l em condições de alto fluxo e pressão, e pelo estudo de Visibilização do Escoamento no interior da bomba não se detectou áreas de estagnação ou turbulência na entrada, saída e junto à extremidade dos fusos. Nas pesquisas *"in vivo"* experimentais em ovinos em CEC por 6 horas a BE foi capaz de manter parâmetros pressóricos adequados e Hemoglobina Livre entre 16,36 mg% e 44,90 mg%. Durante sua aplicação em cirurgias cardíacas com CEC, num grupo de 43 pacientes, pôde-se constatar variações pré e pós-CEC, na Hemoglobina Livre de 9,34 a 44,16 mg%, no Fibrinogênio, de 236,65 a 547,26 mg%, na contagem do número de Plaquetas de 152,465 a 98,139, Desidrogenase Láctica, de 238,12 a 547,26 mg%, com tempo de coagulação ativada ao redor de 800 seg. quando em CEC.**

Conclusões: **A BE mostrou resolutividade por gerar escoamento e pressão adequados, sem causar danos excessivos aos elementos figurados do sangue.**

Descritores: **Coração auxiliar, classificação. Mecânica de fluídos. Hidrodinâmica. Hemólise.**

INTRODUCTION

At the beginning of the 80s, the Brazilian cardiovascular surgeons felt the lack of a Mechanical Circulatory Assist device with a greater comprehensiveness and effectiveness than the Aortic Counterpulsation Balloon (intra-aortic balloon counterpulsation), or even the Roller Pump of the extracorporeal circulation machine, that besides their own limitations presented complications and discouraged outcomes in patients with a clinical picture of severe low deficits after cardiotomy. A lot had been claimed about the clinical applications of Centrifugal Pumps with outcomes consistent enough in developed countries [1]. At that time arouse the need to have a device of easy access and low-priced specially manufactured in Brazil taking into account the very principles of a blood propulsion pump considered as ideal:

1) It should propeller up to 5 to 6 liters of blood per minute against pressures up to 180 mmHg, depending on the resistance circuit;

2) The deficit yielded should be proportional to number of rotations per minute;

3) It should be capable to propel the blood for the purpose of reducing the blood crasis wound and injuries;

4) The internal parts should have smooth surfaces without bounces tat could cause turbulence, stagnation (cavitation);

5) It should be easy to assemble and disposable;

6) and should have a mechanism to be hand-activated in case of electrical power failure;

The main idea came from the application of Archimedes' Principles of an endless screw so that as the axis spins by means of its spindle stress shear it moves its content forward. The first prototype was developed in the Experimental Workshop of the Instituto Dante Pazzanese de Cardiologia, São Paulo, Brazil (IDPC/SP). It was composed of cylindrical rotor with endless spindles and a fixed magnet at its base inside the cylindrical plastic carcass. It has a superior entrance and a lateral exist. This device was fixed in a rotary electrical motor and had also a magnet in its axis, that in spindling, by means of the magnetic power span the rotor inside the plastic carcass propelling the fluid spread in the interior of its spindles.

As the flow and pressure yielded were not appropriated the "*in* vitro" hydraulic tests were not satisfactory. For this reason some modifications were being introduced in the following models (Figure 1) concerning the angle of both the pump entrance and exit path (A 1); the increment of an additional entrance chamber to improve the pump filling (A 2); the significant increase of the diameter of the rotor with more deepened spindles augmenting its dimensions and filling volume (b), and farther on, by the introduction of conic-shaped axis of the cylindrical rotor

(c). Again, despite the advances observed, the tests with these models and the modifications done, the outcomes were not the expected ones.

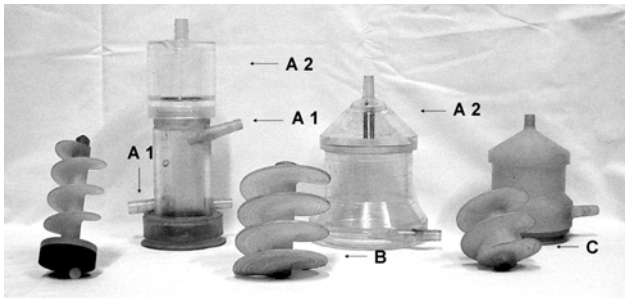


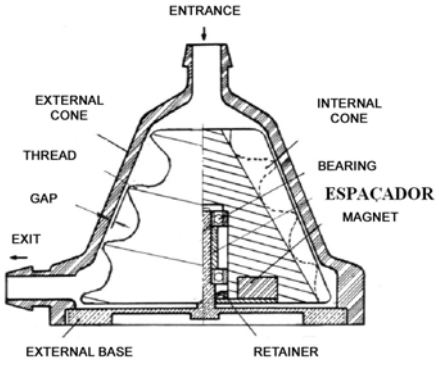
Fig. 1 – Prototypes of the blood pump and the modifications introduced (A1, A2, B,C)

The next step was the introduction of a conical shape both in the carcass and in the rotor seeking to add a centrifugal effect to the stress shear. With these alterations the hydraulic capacity of flow and pressure generation became satisfactory. Through a more advanced evaluation processes the final prototype was achieved, which was the model of the present study (Figure 2).

In the last years, the use of centrifugal blood pumps have considerably increased and this was evident when its advantages were studied and compared to others, such as the pulsating and roller pumps. In heart surgery, both centrifugal and roller pumps are the most one used to perform extracorporeal circulation in heart surgeries. The safety, the impossibility of pumping volumes of air, or generate in the fluid column low pressures in both the pump entrance and exit is an important characteristic of the centrifugal pump, and it influences the surgeon's choice [1].

The fact that the mechanical action of its components causes destruction of the blood cells is controversial when the performance of these pumps is compared among themselves [2]. Therefore, the uniformity of the comparative tests is important and the literature outcomes are difficult to compare due to the great variability of these conditions. Some studies have shown that for applications in the extracorporeal circulation when high pressures and low flows are required, the roller pumps show better hemolyses indexes than the centrifugal pumps [3]. Thus, a number of modifications in the "*design*" have been researched extending its application and augmenting its efficiency in high pressures and low flow conditions [4-6].

The hydraulic principles that propel the fluid column of these devices are either centrifugal or axial and both have been applied isolated and are based on the movement of a rotor that can be composed of superposed cones or small blades which yield kinetic power or stress shear, which with its spinning action around an axis generate flow and pressure.



(A)

(B)

(C)

Fig. 2 – (A) Scheme of Transversal section of the spiral pump, (B) conical shape propeller, (C) Spiral Pump ready to use

METHOD

The researches that assessed the Spiral Pump hydrodynamic capacity and its impacts on the blood-formed elements involved several steps and have been subdivided into ("*in* vitro") experiments in which the *Hydrodynamic Efficiency, Normalized Hemolytic, and Flow Visualization of the Spiral Pump* were investigated [7, 8].

The "*in vivo*" studies that sought the same answers as those of the "*in vitro*" researches did, were performed in laboratory animals (experimental animals) and in a group of patients with heart diseases submitted to a surgical treatment with the aid of Extracorporeal Circulation in which the Spiral Pump was the propeller element.

The Spiral Pump *Hydrodynamic Efficiency* was studied in models with different s taking into account that the bigger ones settle the lower hydrodynamic effect and the smaller ones major cellular trauma. To quantify this phenomenon, the pumps with gaps of 0.5, 1.0, 1.5, and 2.0 mm were studied. The hydraulic circuit employed used a flexible deposit (a plastic bag to collect the blood) having inside a 40% glycerin and water solution in a temperature of 25 ºC simulating the blood viscosity; and having in the base two connections with ½" plastic tubes (Tygon, Norton Performance Plastics, Akron, Ohio, USA) allowing an easy displacement of the solution at both the entrance and the exit of the bag. (Figure 3)

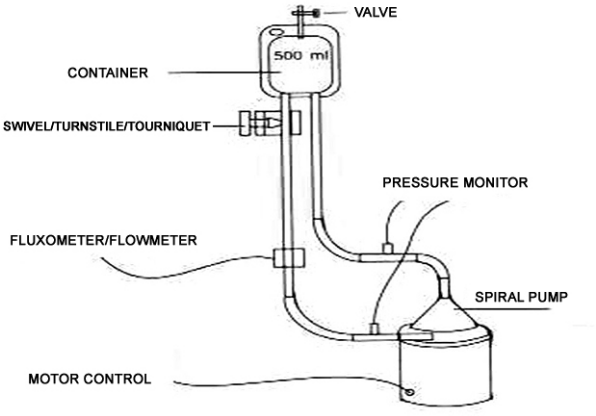


Fig. 3 – Experimental Model for Hydrodynamic Efficiency assessment

It was used 500 mL of bovine blood at 25 ºC in the same circuit used to perform the hydrodynamic assessment to quantify the hemolysis (*Normalized Hemolysis Test*) and to verify how much the gap affects this parameter. Fresh blood was withdrawn in a 450 mL-plastic bag with 65 mL anticoagulant citrate phosphate dextrose adenine (CPDA-1) solution (Baxter Health care Corporation, Dernfield, Illinois, USA).

There are different methods to investigate the velocity and flow behavior in the blob pumps. A computer simulation is frequently used, and it can predict characteristics of flow in particular regions and can influence the "*design*". Other researchers have proposed mathematical simulations with these purposes [9-11]. The visualization is an effective method to study the velocity and flow of the blood pumping in its interior because it is not invasive.

The *Flow Visualization Study* was performed with a helium-neon planar laser (7 mW) highlighting polymer non-ionic particles of Amberlite (80 mesh) in a glycerin-water suspension at 25 °C as described previously. During the tests, the solution was pumped in flow ranging between 1 to 5 L/min, and at a total pressure between 100 e 350 mmHg. The circuit was composed of ½ inch tubes, connectors, and a deposit (a modified blood bag) with 500 mL-capacity. The laser was projected in the area to be study. The entrance and exit paths and the top of the thread fillet had been analyzed. Pumps with the same shape, but with different gaps (0.5, 1.0, 1.5, and 2.0) were tested with microcameras (CCD, Elmo, Tokyo, Japan) and an image recorder (Betacam-SP, Sony, Tokyo, Japan) (Figure 4).

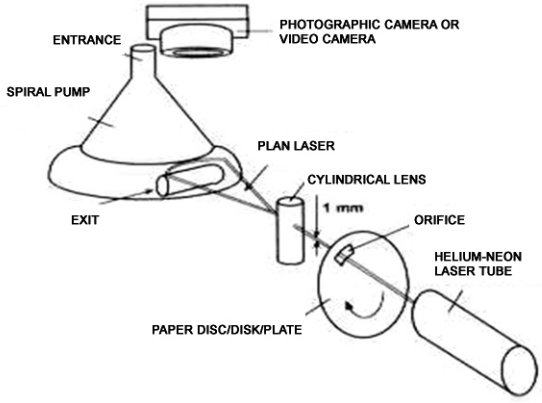


Fig. 4 – Visualization Flow Method with helium-neon planar laser

The "*in vivo*" experiment was performed in three adult lambs in which were installed an Extracorporeal Circulation Circuit with a venoarterial conventional membrane oxygenator interposing the Spiral Pump as a propeller element. It is worth saying that in the experiment model in which the animal is not presupposed to have a severe picture of circulation failure, the installation of a circuit seeking to assist the heart found out a summation of effects between the pump and the normal heart making it hard to carry out an accurate analysis of the hemodynamic effects established by the pump. Therefore, it was necessary to provoke a myocardial injury to the extent of jeopardizing the myocardial contractility and to determine the circulatory

collapse. In the light of this, the circuit is the adequate model to assess the Spiral Pump by its stability and by providing filling volume, which is one of the functioning basic requirements of this type of device. Evidently, it should be taken into account that despite of the little traumatic and already known action on the blood that the membrane oxygenator may provoke, the laboratorial analyses should appreciate this aspect.

The clinical assessment of the Spiral Pump was carried out in a group of adult patients submitted to Heart Surgeries with conventional ECC in which the roller pump was replaced by the Spiral Pump, like in the researches using animals. The clinical assessment was carried out in a group of 43 patients, age ranged from 47 to 83 years (mean plus or minus standard deviation 58.1 ± 19). Body weight ranged from 51 to 80 kg (mean plus or minus standard deviation 66.5 ± 8.7). The majority of the patients were male (34 – 79%). All the patients signed the Informed Consent of the IDPC. At the time of the research was carried out the Institutional Review Board of the IDPC had not been yet created.

The study was prospective and the exclusion criteria was Acute Myocardial Infarctation, Coagulopathy, emergence Surgery, Renal Failure with Creatinin over 2.0 mg%, insulin-dependent *Diabetes Mellitus,* and anemia. It were performed 43 surgical procedures that included 31 cases (72%) of Myocardium Surgical Revascularization (MR), 10 cases (23%) of Orovalvar Surgeries, and 2 cases (5%) of Myocardium Surgical Revascularization associated to Valvar Surgery. In all of the cases, the oxygenator used was the membrane oxygenator MACCHI – Edwards LifeScience Oxim II 34 Ultra, Edward Lifescience-SP, the perfusate of crystalloid solution. The myocardium protection was performed with an intermittent clamping technique of the aorta in 33 (79%) of the cases, except in the cases of Aortic Valve Replacement in which was administered a cardioplegia crystalloid solution at 4 ºC in 9 cases (21%) and the esophageal temperature was kept around 32 ºC.

According to the cardiovascular surgery routine with ECC in our facility, after monitoring the cardiac rhythm; the peripheral center line catheterization to continued control of Median Arterial Pressure (MAP) and the withdraws of samples for arterial gasometries; the introduction of the catheter in central vein to assess Central Venous Pressure (CVP); the drug administration path and vesical probing (sounding) to assess the urinary output, the patient was anesthetized and an endotracheal intubation was carried out to assist the pulmonary ventilation during the procedure following the positioning of the esophageal thermometer to control the body temperature. Through median thoracotomy, the heart was exposed and after systemic heparinization (5 mg/kg/weight), the ECC circuit was installed through the cannulation of ascending aorta or femoral artery to inject oxygenated blood from the oxygenator pumped by the Spiral Pump, and from the right atrium (RA) with a unique cannula or selective of superior vena cava and inferior vena cava to drain the venous blood towards the membrane oxygenator to perform the CO_2/O_2 exchange. Completed these operative times, the ECC was started and after the metabolic and perfusion parameters were stabilized with the esophageal temperature around 32 ºC, the pulmonary ventilation is interrupted and the procedure main time started.

The perfusionist, at each 5 minutes, recorded in the balance chart the following: MAP, VCP, diuresis, temperature, arterial flow, and occasional events in that period of time. The routine laboratory examinations were withdrawn at the beginning, middle and end of procedure (gasometry, A/V, K^+, Na^+, hematocrit (Hct), and glycemia) which were the base for any therapeutic correction during the procedure. The anticoagulation control during the ECC was carried out through checking the activated clotting time (ACT) in a monitor of activated clotting (MCA 2000 – Fundação Adib Jatene-SP, Brazil) where the tubes containing 0.013 mg of Purified Silica Earth and a magnet that homogenizes the blood inside the tube were inserted during the examination. The quantification of ACT indicated the minimum seconds necessary to coagulate the blood retained inside the tube trying to keep it over 500 seconds after the heparinization and in ECC. The heparin reversion was obtained with protamine sulfate using 80% of th overall dose (1 mg/100 UI of heparin). At the end of the surgical procedure, the patient was referred to the Postoperative Recovery Unit still under mechanic ventilation, continued monitoring of ECG, MAP, diurese, and temperature.

Considering the unknown interactions between the Spiral Pump and the human blood crasis, and taking into consideration the possible occurrence of excessive occasionally traumas, it was established during the ECC the determination of each 15 minutes of Free Hb by the urinalysis tape, which when dampened into the patient's urine provided levels that could sway between 0 and ++++. When the positivity in the urinalysis occurred during the ECC presupposing the presence of an important blood trauma, the Spiral Pump would immediately replaced by the Roller Pump.

With the purpose of evaluating the trauma the Spiral Pump might cause on the blood-formed elements, the specific parameters investigated were as follows: the dose of Frre Hemoglobin (mg%), Fibrinogen (mg%), Platelets (nº), Lactate Dehydrogenase (mg%), Activated clotting time (ACT) (sec), and urinalysis tape (0/++++) before and after ECC in all the patients. To evaluate the levels of Lactate Dehydrogenase, Fibrinogen, and Pleatelets, the samples of whole blood were withdrawn in tubes with

ethylenediaminetetraacetic acid (EDTA) and homogenized, and after the application of reagents, they were analyzed through Cell-Dyn 3000 and 1400 (Abbott™ Laboratories, CA, USA). The Lactate Dehydrogenase was checked through LDH (Liquiform Labtest Diagnostica) using kinetic method through pyruvate lactate reaction. The amount of platelets was verified through the impedance method with volumetric measure; through the funnel the cells pass to the transducer of the device occurring change on the electric current generating impulse. The amount of pulses obtained during the counting cycle corresponded respectively to the number of cells counted. The pulse amplitude was directly proportional to the volume of cell counted. The Fibrinogen was checked through the Organon Teknika Fribiquik™, which uses the principle by means of which thrombin is added to the plasma sample, transforming the fibrinogen into fibrin. The fibrin, in your turn, by polymerization forms a network. The factor XIII activated by the thrombin catalyzed the formation of stabilizers cross-links to produce a visible clot. The elapsed time since the thrombin addition until the formation of the clot was inversely proportional to the level of fibrinogen.

These parameters were checked in the period before ECC and after its conclusion with the patient still in the operating room before being referred to the Recovery Unit. To sequential evaluation, Free Hemoglobin and the Activated Clotting Time (ACT) were determined in the period prior to ECC in all the patients (43/100%), during ECC after 30 minutes (3/6.9%), after 60 minutes (9/20.9%), after 90 minutes (13/30.2%), after 120 minutes (18/41.8%), and after the end of ECC in all the patients 43/100%.

Statistical Analysis

The comparison of Free Hb, Fibrinogen, Platelets, Lactate Dehydrogenase, and Activated Clotting Time values before and after ECC was performed by paired Student's *t* test [9].

The analysis of variance (ANOVA) [10] was used to verify if there was any difference between the values of free Hb and ACT in different periods. This analysis was carried out for each one of the 3 sub-samples; the first sample with 9 patients, the second with 13 patients, and the last one with 18 patients. In the first case it was evaluated if there was any difference before and after ECC, at 30 minutes, at 60 minutes, and after ECC; in the second case, it was included the 90 minute-time and finally the 120 minutes-time. Whenever the ANOVA have indicated any difference, it was done multiple comparisons by the BONFERRONI test [11]. The level of significance was established when $p < 0.005$. The software program used to do the calculations was the SPSS for Windows – Version 8.0.

RESULTS

The *Hydrodynamic Efficiency* "*in vitro*" tests proved generation with a 1.5 mm-gap, flows around 9 L/min, and pressure over 400 mmHg at 5000 rpm. (Figure 5)

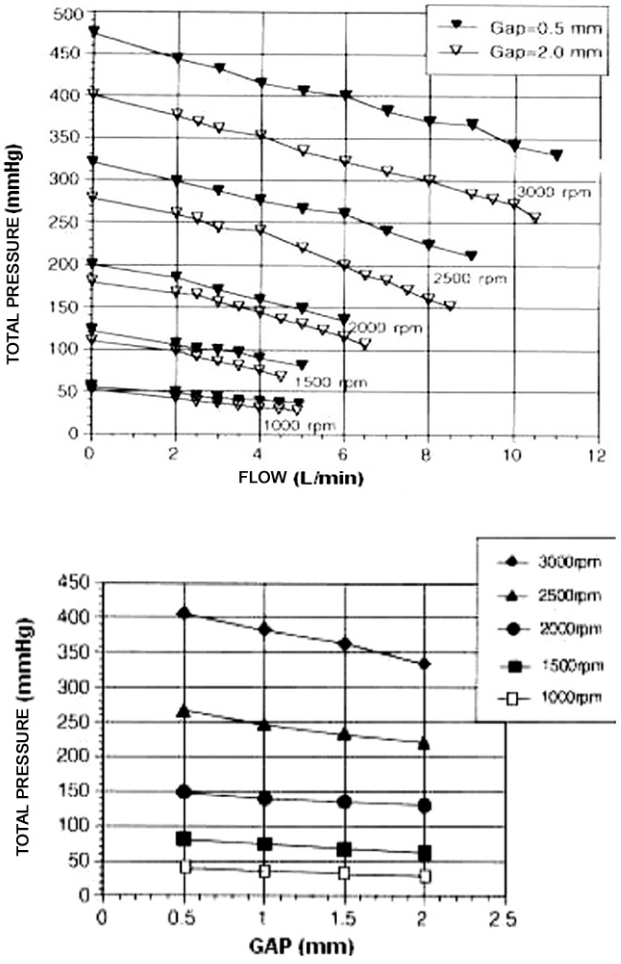


Fig. 5 – Results of the Hydrodynamic Efficiency ("gap")

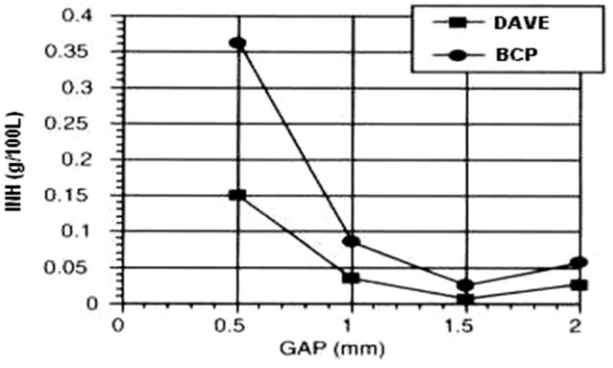


Fig. 6 – Normalized Hemolysis (DAVE – Circulatory Assistance, BCP – Extracorporeal Circulation)

At the *Normalized Hemolysis* using the same circuit, it was observed indexes not superior to 0.375 g/1001 in conditions of flow and high pressure with 1.5 mm-gap. (Figure 6).

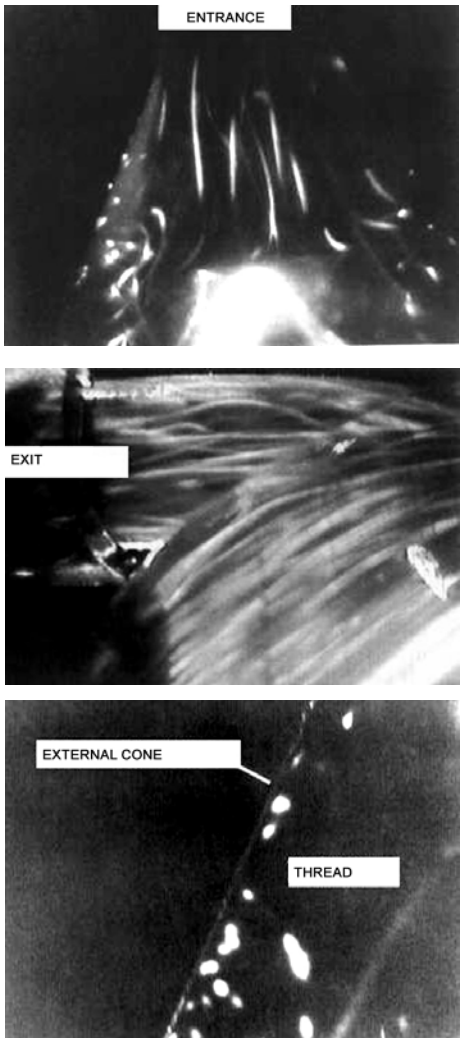


Fig. 7 – Visualization Flow ("gap")

Regarding to the *Flow Visualization*, it was detected stagnation or turbulence areas in the entrance, exit, and along the extremities of the spindles also with 1.5 mm-gap. (Figure 7).

The "*in vivo*" outcomes in lambs showed that the spiral Pump kept the Mean Arterial Pressure between 55 to 65 mmHg and the flow between 4 to 5 L/min. All the other data were kept within the acceptable limits for the test conditions. The Free Hemoglobin before the beginning of the tests was 8.73 ± 5.45 mg/dL; after 2 hours ECC was 16.36 ± 12.10 mg/dL. At the end of the tests, after 6 hours, ECC was 44.9 mg/dL for the worst case and 24.4 mg/dL for the best case (36.63 ± 10.81 mg/dL). (Figure 8).

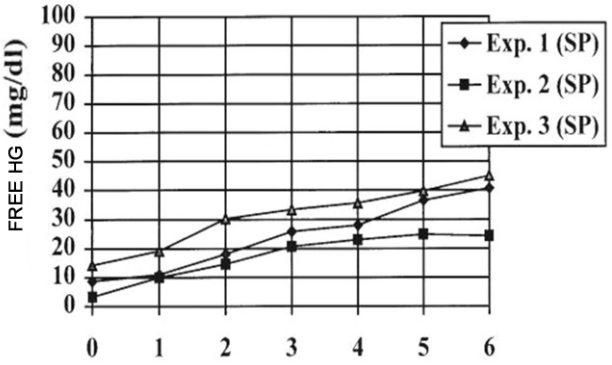


Fig. 8 - "In vivo*" outcomes in lambs*

At the clinical research, it was observed that all the procedures took place within the normal routine with patients keeping the adequate metabolic, perfusion and hemodynamic parameters. It was not observed cases of low output after perfusion or from other nature. The clinical evolution in the postoperative immediate period occurred within the normal expectations to theses types of surgical interventions. It was not reported immediate mortality.

The simultaneous control of the hemolysis was carried out by the urinalysis tape aiming at identifying the possible harmful effects during the application of Spiral Pump. Positivity was not revealed in any case until 90 minutes of ECC, and at 120 minutes 6 patients (14%) presented + positivity. In the period after ECC occurred a +++ positivity in 2 patients (4.6%), and ++++ positivity in 1 patient (2.3%). The patients that presented a relevant positivity in the urinalysis tape in the period after ECC, at the end of 6 to 8 hours of postoperative procedure no longer presented any positivity.

The average doses and mean standard deviation before ECC of Free Hb, Fibrinogen, Platelets, Lactate Dehydrogenase, and Activated Clotting Time (ACT) were within the normal limits and the impact caused by ECC together with the Spiral Pump (period after ECC) showed that some trauma did occur translated by the increase of

Free Hb, Lactate Dehydrogenase, and a fall in the number of Platelets and Fibrinogen, all of them with statistic significance ($p < 0.001$). The ACT did not have differences in this phase due to the neutralization of the circulating heparin through the administration of protamine after ECC (p 0.81). (Table 1) (Figure 9)

Table 1. Laboratorial outcomes comparing periods before and after ECC with P-value.

	Pre-	Post	p-value
Free Hb(m)	9.34±3.31	44.16±10.65	<0.001
Fibrinogen(m)	236.65±75.76	119.07±59.42	<0.001
Platelets(m)	152.465±36.942	99.139±16.504	<0.001
Lactic Dehydrogenase(m)	238.12±57.87	547.26±151.28	<0.001
ACT(m)	106.74±7.64	109±5.80	0.81

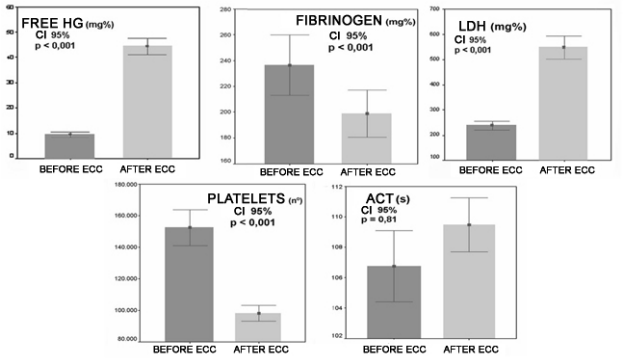


Fig. 9 – Shows confidence intervals [IC]; Free Hb; Fribrinogen; Platelets; Lactic Dehydrogenase; and ACT, at moments before and after ECC

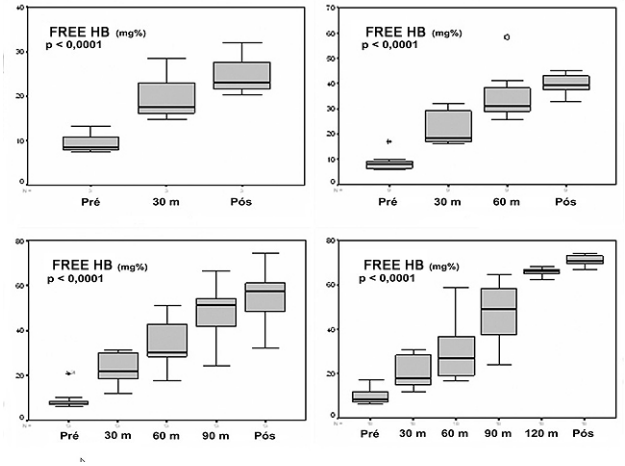


Fig. 10 – Free Hemoglobin "Box Plot"

Regarding the sequential Free Hemoglobin before and after ECC, Figure 10 with *"Box Plot"* show the differences detected in the samples before ECC, at 30 minutes, 60 minutes, 90 minutes, 120 minutes, and after ECC (Figure 10)

Comparing the findings of Free Hb achieved by ANOVA, the *P*-value was inferior to 0.001 and the BONFERRONI multiple comparisons detected differences before ECC and 30 minutes (p??0.0002); between 30 minutes and 60 minutes (*p*???0.0003); between 60 minutes and 90 minutes ($p < 0.0001$); between 90 minutes and 120 minutes (*p*???0.0001); and finally between 120 minutes and after ECC. ($p < 0.0001$).

Regarding the sequential Activated Clotting Time before and after ECC, Figure 11 with "Box Plot" show the differences of ACT detected in the samples before ECC, at 30 minutes, at 60 minutes, at 90 minutes, at 120 minutes, and after ECC. (Figure 11)

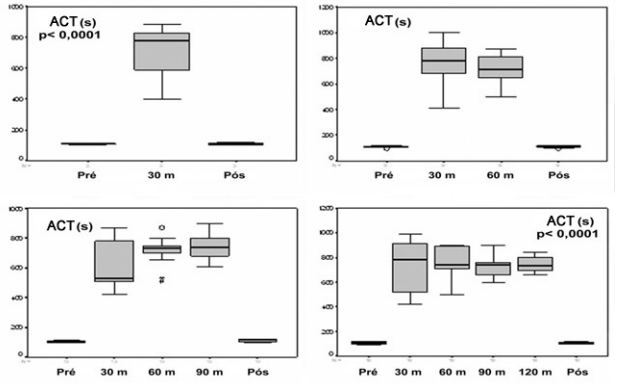


Fig. 11 – ACT "Box Plot"

Comparing the values of ACT done by ANOVA, the *P*-value was inferior to 0.0001 and the BONFERRONI multiple comparisons detected differences before ECC and at 30 minutes ($p < 0.0001$), at 120 minutes, and after ECC ($p < 0.0001$). There were no significant differences at 30 minutes and 60 minutes; at 60 minutes and 90 minutes; at 90 minutes and 120 minutes

DISCUSSION

The devices of blood thrust can be categorized according to the mechanism of the mobile components that generate flow, pressure, and based on this criterion they are classified into 2 types: positive dislocation devices that progressively push its content from a suction orifice (entrance) to the discharge orifice (exit); and the kinetic pump, which propeller action is developed by the transmission of power generated by the rotation of a rotor. With specific characteristics, the first one due to its simplicity, use facility, and the safety provided, the flow has linear characteristics with some degree of pulsatility, and one of the advantages is the increased negative

pressure exerted on the entrance orifice to aspirate the blood to be pushed not filling passively, but by suction, thus leading to a possibility of aspirating or pumping air in the arterial line causing complications to the patient.

Another model is the Centrifuge Pump [1], that is, the pushing of the blood is carried out through the kinetic energy yielded at each rotation of the rotor element. There is no pre-charge and the flow depends on the number of engine rotation and the peripheral vascular resistance against which the pump pushes the blood.

When the velocity of the rotor is reduced or when the peripheral resistance increases, the flow is reduced. If the velocity is kept constant (rpm) and the peripheral vascular resistance is reduced, the flow substantially increases, thus, it is essential the coupling of the fluxometer in the arterial line. This type of pump pushes the blood through different types of rotors, so the lower pressures stay at the entrance while the high ones stay at the exit compartment. The blood-formed elements are not compressed by the occlusive direct mechanic force, so that if there are obstacles occluding the exit flow, the blood circulates in its interior and pressure gradient are not yielded. Hence it is possible to speculate that not only contribute to better outcomes as well as to avoid complications in patients with multiple comorbidities, especially in a prolonged ECC and in the Mechanical Circulatory Assistance for longer periods of time.

The centrifuge principle can be generated by the passage of fluid towards the apex to the base of the rotary superposed cones, or by high rotation around the axis speeding up the fluid column and generating flow and pressure. Despite acting under the same hydraulic principle these models have different performances [12].

The characteristics of a mechanic device of blood propulsion are important to verify its hydrodynamic effectiveness and the intensity of trauma imposed to the blood-formed elements [13]. Therefore, the same pump model can present different degrees of cellular trauma many times related to small changes in the "*design*", what have demonstrated through studies and evaluation of the pump flow with the same diameter, but with varied positions of the wings in relation to the axis, observing a difference as to the movement of the particles in its interior [14].

The axial principle of flow and pressure is generated through a cylindrical blade arranged spirally around a rotary axis [15, 16]. It is admittedly more traumatic due to the high rates of shear stresses imposed to the blood-formed elements established by the spirals and the negative pressure caused when there are blade intervals along the axis [17]. On the other hand, the conditions of high flow and lower pressure did not cause significant differences resulting in different types of blob pumps [7].

The conic shape of the rotor with coiled spindles of the Spiral Pump associate at the same time both the axial hydraulic and centrifuge principles, besides its hydrodynamic performance depend, among other factors, on the internal space between the plastic cone and the spindles of the rotor gap. That is, the smaller the internal space is, the larger will be the device hydrodynamic performance, reaching its better performance when the number of rotations gets to 2000 rpm due to the greater centrifuge effect produced [7]. The Flow visualization test of the fluid column inside the Spiral Pump where were analyzed the movement characteristics of the particles in the cone entrance and exit regions, as well as the top of the lines of the spiral under different gaps, flow and resistances influenced decisively in the changes of the Spiral Pump design [8, 18]. In the analysis of the images obtained with a video camera and with the studies of the photographs of the Spiral Pump entrance and exit path, it were observed no turbulence or stagnation insinuating that the different outcomes of the hemolysis tests were not caused by different path of flow in these regions.

The behavior observations of both the flow and the velocity of the particles at the top of the thread provide important information about the results of the hemolysis tests obtained with different gaps showing changes in the velocity of the particles and explaining the different outcomes in these tests. The velocity has a direct relation with the turbulence causing damages to the blood crasis, as well as the differences in the levels of velocity modify the exposition time of the blood cells to the turbulence [7]. In the flow visualization tests it was sought to verify the causes of the augment of INH when the gap was different from 1.5 mm, especially in conditions of pumping with velocity over 2000 rpm. In those conditions the effect of axial pumping was bigger than the centrifuge effect and the recirculation started at the top of the threads [8].

In view of the findings, it was necessary to build the rotor with two-face lines seeking to balance the pressure in its interior and the augment of both the cone and rotor angle from 60 to 70 degrees [7] to enhance the centrifuge effect counterbalancing it with the axial effect.

In the evaluation of the "*in vitro*" hemolysis, the Spiral Pump showed a lower index when submitted to lower resistance and to a constant number of rotations as to balance both the centrifuge and axial effects. These are the ideal functioning conditions to this device. It was observed that the use of different gaps in situation of constant flow by alternating resistances, the gap with lower Index of Normalized Hemolysis was that with 1.5 mm [7, 15].

The hemolysis analysis in a comparative clinical trial of patients submitted to heart surgeries with EC, where were used the superposed cones pump (BIOPUMP) and the Spiral Pump came to a conclusion that the values found in both groups are the normal ones for procedures of such nature, while the comparison between both groups shows lower

INHs pro superposed pump [19]. According to Andrade *et al*. [8], the factors that have contributed to this outcome were the presence of higher pressure areas and flow of Spiral Pump with increase of the pressure gradient and the decrease of the perfusion needs.

The hemolysis appearance does not depend only on the interaction of the Spiral Pump with the blood-formed elements. Factors such as age, clinical conditions, type of heart disease, and the presence of comorbidities, different surgical and myocardial protection techniques, oxygenator, tubes, cannulas, and different perfusates can influence the hemolytic indexes [3, 20, 21]. The amount of Free Hemoglobin in the plasma depends on both the velocity and the capacity of removal of the pigment by the body of each individual. Normally, the reticuloendothelial system is capable of removing it about 0.1 mg/Kg/minute. When the Free Hemoglobin surpasses 100% in the plasma, it is filtered by the kidneys and the urine acquires the reddish color, characteristic of the hemoglobinuria. Depending on the amount of hemoglobin, the color of the urine can vary from slight to richly winy or dark red.

The normal plasma contains a small amount of free hemoglobin which corresponds to the released by the destruction of the "*old*" packed cells and the amount is almost 6 mg%. The extracorporeal circulation properly conducted with the devices and materials currently available uses to enhance it to 20 to 40 mg% on account of the hemolysis produced by trauma and when the incident can surpass the 100 mg%, by producing hemoglobinuria.

The hemolysis is the motive of extensive researches in the development of devices of blood propulsion [20-25] by starting from the presupposed that it is impossible to avoid the mechanical hemolysis caused by a propulsion device and, besides that it has been checked through different indexes making comparisons often difficult [21]. The definition of the "*in vitro*" Hemolysis index was established by the amount of Free Hemoglobin per 100 liters of pumped blood with fresh blood and hemoglobin e" 14 g/dL and if its deposit was located 140 cm above the pump [26, 27].

The Normalized Hemolysis index was defined by the insertion of hematocrit (Hct) in the traditional formula, because the lower the amount of packed cells is, the lower the cells should be mechanically destroyed. So it is defined as the amount of free hemoglobin released at each 100 liters of pumped blood normalized by the hematocrit (Hct) [28].

The use of the Hemolysis Index is important because the simple check of the supposedly free Hb would cause linear outcomes. Thus, the introduction of a correction factor such as the hematocrit (Hct) would afford more accuracy [28]. However, despite the clinical evaluation in the present research is performed in patients with several diseases, the group presented homogeneity and due to the fact of being prospective and with exclusion criteria added by the fact that in all the cases the perfusate of EC was crystalloid solution.

CONCLUSIONS

By the aforementioned it is possible to conclude that:

1) The Spiral Pump is an invent characterized by original the blood propulsion device designed and developed in Brazil, whose hydrodynamic conception associates the axial and centrifuge power;

2) The Spiral Pump "*in* vitro" evaluations suggested that the modifications implemented in its design made it efficient and less traumatic to blood crasis;

3) The animal "*in vivo*" evaluations reproduced the experimental findings proving its safety and effectiveness;

4) It was proved the hydraulic efficiency and the low traumatic impact to the blood-formed elements observed in a group of patient submitted to heart surgery with ECC in which the propeller element was the Spiral Pump;

5) In view of these evidences the National Institute of Industrial Property (Instituto Nacional de Propriedade Industrial [INPI]) granted the patent considering the Spiral Pump as an invent (05/30/2000). Thus, as it was classified as "*novelty inventive step*" by the International Preliminary Examination Report (03/15/1993) .

REFERENCES

1. Lynch MF, Peterson D, Baker V. Centrifugal blood pumping for open heart surgery. Minn Med. 1978;61(9):536-8.

2. Pêgo-Fernandes PM, Miura F, Higa SS, Moreira LFP, Dallan LA, Chamone DAF, et al. Hemólise em circulação extracorpórea: estudo comparativo entre bomba de rolete e bomba centrífuga. Rev Bras Cir Cardiovasc. 1989;4(3):220-4.

3. Tamari Y, Lee-Sensiba K, Leonard Ef, Parnell V, Tortolani AJ. The effects of pressure and flow on hemolysis caused by Bio-Medicus centrifugal pumps and roller pumps. Guidelines for choosing a blood pump. J Thorac Cardiovasc Surg. 1993;106(6):997-1007.

4. Kijima T, Oshiyama H, Horiuchi K, Nogawa A, Hamasaki H, Amano N, et al. A straight path centrifugal blood pump concept in the Capiox centrifugal pump. Artif Organs. 1993;17(7):593-8.

5. Nishida H, Yamaki F, Nakatani H, Endo M, Koyanagi H, Oshiyama H, et al. Development of the Terumo Capiox centrifugal pump and its clinical application to open heart surgery: a comparative study with the roller pump. Artif Organs. 1993;17(5):323-7.

6. Orime Y, Takatani S, Sasaki T, Aizawa T, Ohara Y, Naito K, et al. Cardiopulmonary bypass with Nikkiso and BioMedicus centrifugal pumps. Artif Organs. 1994;18(1):11-6.

7. Andrade A, Biscegli J, Dinkhuysen J, Sousa JE, Ohashi Y, Hemmings S, et al. Characteristics of a blood pump combining the centrifugal and axial pumping principles: the spiral pump. Artif Organs. 1996;20(6):605-12.

8. Andrade A, Biscegli J, Souza JE, Ohashi Y, Nosé Y. Flow visualization studies to improve the spiral pump design. Artif Organs. 1997;21(7):680-5.

9. Johnson RA, Winchern DW. Applied multivariate statistical analysis. 4th ed. New Jersey:Prentice Hall;1998. p.290.

10. Mongomery DC. Design and analysis of experiments. 4th ed. New York:John Wiley & Sons.

11. Neter J, Kutner MH, Nachtsheim CJ, Wasserman W. Applied linear statistical Models. 4th ed. USA: Timer Mirror Higher Education Group;1996. 1408p.

12. Schima H, Trubel W, Muller MR, Papantomis D, Salat A, Schluche C et al. Development of a centrifugal blood pump with minimal hemolysis. In: Schima H, Thoma H, Wieselthaler G, Wolner E, eds. Proccedings of international workshop on rotary blood pumps. Vienna, Austria, 1991; 141-7.

13. Naito K, Mizuguchi K, Nosé Y. The need for standardizing the index of hemolysis. Artif Organs. 1994;18(1):7-10.

14. Ohara Y, Makinouchi K, Glueck J, Byron S, Shimono T, Naito K et al. Development and evaluation of antihrombogenic centrifugal pump: The Baylor C-Gyro pump eccentric inlet port model. Artif Organs 1994; 18:673-9.

15. DeBakey ME. Left ventricular bypass pump for cardiac assistance: clinical experience. Am J Cardiol. 1971;27(1):3-11.

16. Kubrusly LF, Martins AF, Madeira J, Savytzky S, Wollman D, Melhem A, et al. Dispositivo de assistência circulatória mecânica intraventricular de fluxo axial: estudo in vitro. Rev Bras Cir Cardiovasc. 2000;15(2):169-72.

17. DeBakey ME. A miniature implantable axial flow ventricular assist device. Ann Thorac Surg. 1999;68(2):637-40.

18. Ahmed S, Funakubo A, Sakuma L, Fukui Y, Dohi T. Experimental study on hemolysis in centrifugal blood pumps: improvement of flow visualization method. Artif Organs. 1999;23(6):542-6.

19. Neves MT Jr. Estudo comparativo das bombas centrífuga e espiral através da avaliação de performance hidrodinâmica e análise hematológica in vitro e in vivo [Dissertação de Mestrado]. São Paulo:Faculdade de Medicina da Universidade de São Paulo;2002.

20. Kawahito K, Nosé Y. Hemolysis in different centrifugal pumps. Artif Organs. 1997;21(4):323-6.

21. Naito K, Mizuguchi K, Nosé Y. The need for standardizing the index of hemolysis. Artif Organs. 1994;18(1):7-10.

22. Schima H, Muller MR, Papantonis D, Schlusche C, Huber L, Schmidt C, et al. Minimization of hemolysis in centrifugal blood pumps: influence of different geometries. Int J Artif Organs 1993;16(7):521-9.

23. Mizuguchi K., Damm GA, Bozeman RJ, Akkerman JW, Abber GS, Svejkovsky PA et al. Development of the Baylor/NASA axial flow ventricular assist device: in vitro performance and systematic hemolysis test results. Artif Organs 1994;8:32-43.

24. Masuzawa T, Tsukiya T, Endo S, Tatsumi E, Tenaka Y, Takano H et al. Development of design methods for a centrifugal blood pump with a fluid dynamic approach : results in hemolysis tests. Artif Organs. 1999;23(8) 757-61.

25. Ohuchi K, Kikugawa D, Takahashi K, Uemura M, Nakamura M, Murakami T, et al. Control strategy for rotary blood pumps. Artif Organs, 2001;25(5):366-70.

26. Yada Y, Yausa U, Suzuki H, Hatanaka K, Kondo C, Wada K, et al. Clinical experience using the Biopump for extracorporeal circulation during open heart surgery. Artif Organs. 1993;7(7):619-24.

27. Allen JG ed. Extracorporeal Circulation. Springfield, IL, Charles C Thomas; 1960. p.514.

28. Koller T, Hawrylenko A. Contribution to the in vitro testing of pumps for extracorporeal circulation. J Thorac Cardiovasc Surg. 1967;54(1):22-9.