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Fifteen years of the first Brazilian Centrifugal Ventricular Assist Device for long term Mechanically Assisted Circulatory Support

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Abstract. More than simply being a review paper and telling the story of the development of a ventricular assist device, this paper aims to critically review changes in technical nomenclature and scientific positioning, taxonomy and its applications, therapeutic indications and the results of its application in patients. After 15 years of the first Brazilian Centrifugal Ventricular Assist Device, many things have changed for the better. Mechanically Assisted Circulatory Support is a therapy consolidated as a safe and effective alternative for the treatment of congestive heart failure, as well as heart transplantation and other drug therapies. It is still seen as science fiction in several countries or media, but that is a cruel reality in our post-truth and fake news times. In reality, it should receive more funding resources especially in developing countries and emerging economies with strong hospital industry of the cardiovascular field that may have surprising results with all the technology already established.

Keywords. *Centrifugal Ventricular Assist Devices, critical review, Mechanically Assisted Circulatory Support, Continuous Flow Ventricular Assist Device CFVAD.*

Introduction. In order to start describing this first-person review, something not very common in the field of engineering or medicine, I need to go back a little over 15 years. More precisely, I will need to go back 20 years in this review to give an overview of Ventricular Assist Devices (VADs) research at the beginning of the 20th century. At that time, ending Engineering graduation, I decided to study with Prof. Jeison Fonseca at USJT joining the group of Institute "Dante Pazzanese" of Cardiology (IDPC), lead by Prof. Aron Andrade in Sao Paulo, Brazil. IDPC is a teaching, research and public health care institute that has always been at the forefront technological development of medical equipment, prostheses and surgical techniques related to cardiology. Prof. Aron Andrade studied with Prof. Yukihiko Nosé, a pioneer of artificial organs together with Prof. Adrian Kantrowitz. Nosé *et al.* (1963) were always ahead of their time (1) as one of the main paradigm breakers, developing the centrifugal Gyro Pump as VAD while the market was dominated by pulsatile pumps Novacor, Thoratec and HeartMate (2). Centrifugal blood pumps are just for Extracorporeal Circulation. To better understand the extension of his research, at that time, he was already comparing the design philosophy and strategy behind the three generations of VAD, since the pulsatile of the 60s that he followed the birth (1) until the

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appearance of Continuous Flow Ventricular Assist Devices (CFVAD), from the first DeBakey-VAD axial pump, to the first Gyro-Pump Implantable Centrifugal pump (3).

As can be seen in Table 1, the first barrier to be broken was the implantability. While the pulsatile devices were large and heavy, often with actuators impossible to be implanted, the CFVADs brought the miniaturization of the devices and said goodbye to the pulsatility. Even today, after thousands of patients benefited from the assistance of CFVADs, as we will show, we still find supporters of pulsatile devices.

Table 1. Blood pumps general characteristics at 00's and the revolution of continuous flow ventricular assist devices (Nosé, 1998).

	Priming volume [ml]	**Rotation or Speed**	**Actuators**
Pulsatile VAD	>60	150	Electromechanical
Centrifugal	<25	2,000	Electromagnetic
Axial	<5	10,000	Electromagnetic

Novacor considered long-term support the use of 1,000 days by a 54-year-old man patient (4). Researchers studying the HeartMate device, on the other hand, were proposing its use as bridge to heart transplantation (5)(6). Thoratec was already publishing results for 213 patients divided into: group 1 (n = 74) LVAD; group 2 (n = 37) patients initially receiving an LVAD and later requiring an RVAD; and group 3 (n = 102) BiVentricular assistance (BiVAD) from the beginning (7). The main application was precisely the bridge for transplantation and a major scientific and technological challenge was to control infections (8). Table 2 shows the differences in size and implantability of two pulsatile devices and one CFVAD, Gyro-Pump (2).

Table 1. Comparison between Novacor, HeartMate VE (Pulsatile VADs) and Gyro PI 700 (CFVAD) sizes and weights (2).

	Novacor	**HeartMate**	**Gyro**
Height [mm]	65	40	53
Width [mm]	130	112	65
Length [mm]	160	112	65
Weight [g]	860	1,193	465

(Adapted from Yoshikawa, M. *et al.*, 2000).

This was the reality when I started at IDPC in 2002 to work with the Auxiliary Total Artificial Heart (ATAH) project. Due to its constructive characteristics, with an electromechanical actuator

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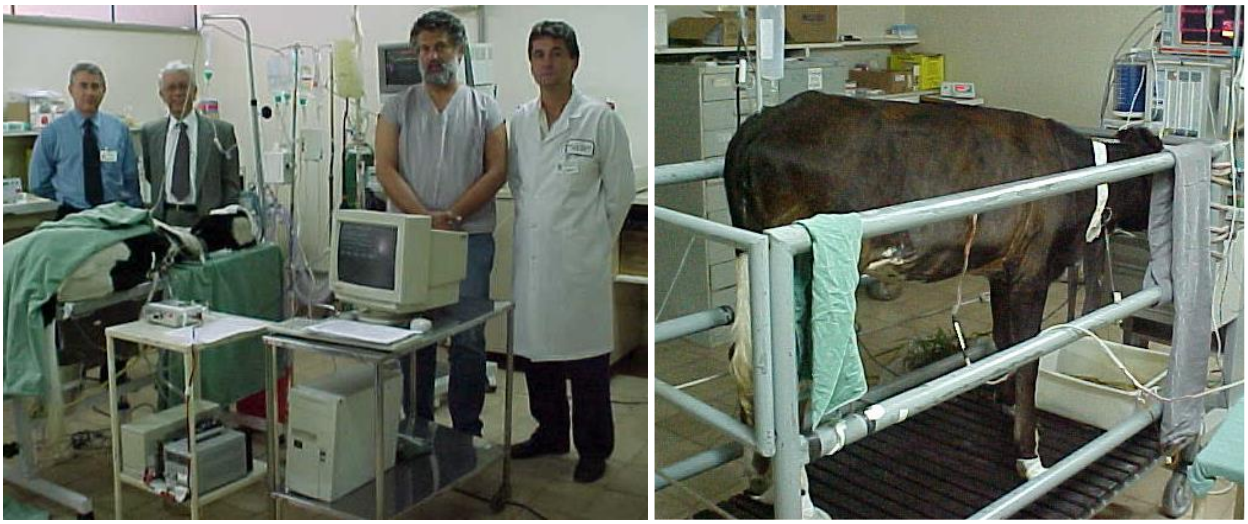
in the center, alternating the rotation of screws that push diaphragm propelling plates, the ATAH can be used as Total Artificial Heart (TAH) or VAD (9). Research team and animal experiments can be seen in Figure 1.



(a) (b)

Figure 1. (a) IDPC researchers group (b) ATAH "in vivo" experiments in calves as LVAD.

The group was struggling to keep up with the development of pulsatile devices and was losing the fight. In certain way, Brazil had been following several technologies with a few years' delay, manufacturing roller pumps, blood oxygenators, various types of valves, pacemakers and cardioverters. But, in the case of VADs, even today, although with economy and a competitive market, Brazil does not have a national manufacturer even though it had developed several technologies like Brushless Direct Current (BLDC) motors, high performance batteries, Transcutaneous Energy Transmission System (TETS), hydraulic or magnetic suspension, electronic controllers, cardiovascular simulators, biofunctional biomaterials and supervisory control logic. So, we decided that my master's topic would be a Centrifugal Flow Ventricular Assist Device (CFVAD), something new at that time in Brazil, and I would try a scholarship as visiting researcher in Prof. Nosé Lab at Baylor College of Medicine (BCM) in Houston. The year was 2005, everything was just an idea, but I knew that my life was going to change a lot. I just didn't know that I was going to meet the most incredible scientist I've ever met.

But this review paper is not about Prof. Nosé but the first Brazilian centrifugal ventricular assist device for long term mechanically assisted circulatory support. The first study and first publication to inaugurate this VAD idea was to make a conversion of a two days' antitraumatic pump (Phase 1) Spiral Pump (SP) to a 2 weeks' antithrombogenic pump (Phase 2) (3) and, after this step, the conversion of this device to a durable, implantable, and long-term blood pump (Phase 3)(10) Figure 2 shows the SP performance curves with different inlet ports.

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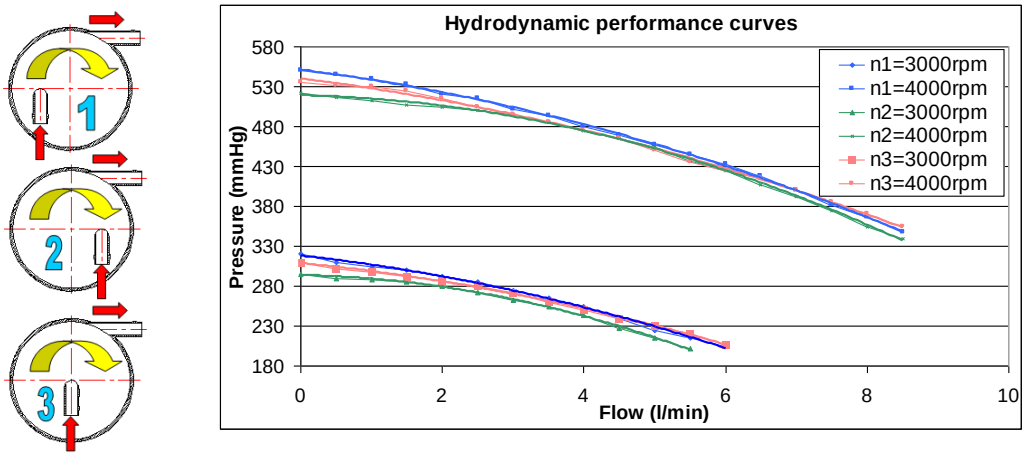

Figure 2. Comparison between three inlet ports. In red, the blood flow, in yellow, the impeller rotation of Spiral Pump.

Although obvious, this publication is actually a milestone for our group. The published study is a conversion of the concentric inlet of IDPC Spiral Pump (SP) Cardiopulmonary Bypass (CPB) pump to an eccentric inlet (10) required for the future ceramic bearings of our VAD that would only appear effectively in the following year. We count the first Brazilian centrifugal ventricular assist device conceiving in 2006, thus, turning 15 years now in 2021. At BCM, I started studying VADs and biotribology involved in ceramic pivot bearings that led me to visit Prof. Ryo Kosaka's group (11,12), three different stages seen in Figure 3.

(a) (b) (c)

Figure 3. (a) In 2003 at IDPC, with the Auxiliary Total Artificial Heart project; (b) In 2006 at BCM, with Prof. Aron Andrade and Prof. Denys Nicolosi; and (c) In 2017, at AIST Tsukuba Japan.

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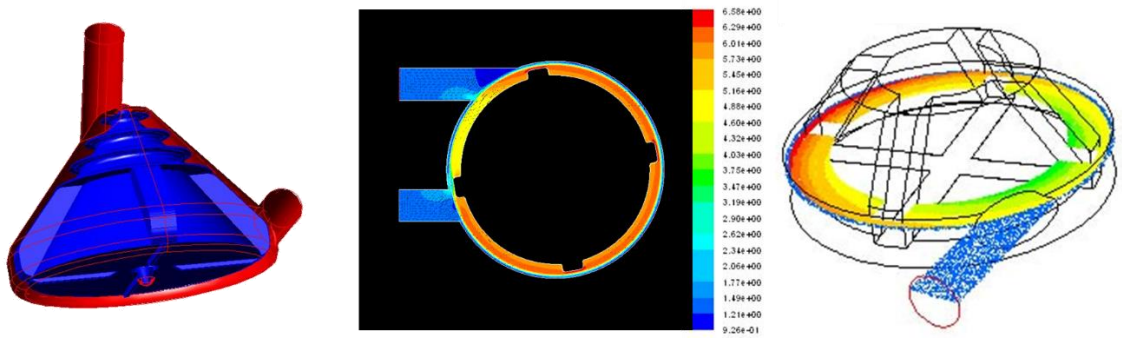
Implantable Centrifugal Blood Pump (ICBP). Still in Brazil, talking to old machinists from the IDPC machine shop, many had already worked on centrifugal pump designs in the 1970s and 1980s. They described cable driven pumps and the famous Blackshear-Medtronics centrifugal pump (1969) that had a shaft and seal. It was nothing like what we wanted to do, or what was being done in Houston. We would be the first in Brazil and the second in the world.

Our inventiveness and boldness started by proposing a mixed flow rotor, a spiral cone and straight centrifugal vanes. Thus, the inlet stream would take advantage of an axial component and gradually convert the mixed flow to the centrifugal outlet at the end of the pump base. We hadn't even done the first mechanical design, nor the computer numerical simulations, and we were already defining the geometry. Or rather, we wanted to define initial parameters such as speed, volume, pressure and flow, so our range started with 2,000 RPM, 50 cc ($5.10^{-5}m^3$), 100 mmHg, 5.0 L/min, Figure 4 (13).



(a) (b) (c)

Figure (4). (a) Primitive three-dimensional conceptual design, (b) first two-dimensional numerical simulation and (c) three-dimensional flow with velocity distribution inside the pump.

It was defined that it would be a mixed flow pump (centrifugal + axial flow) with magnetic coupling and ceramic pivot bearings. The tribology pairs would need to be studied, the axis in Al_2O_3 (ceramic alumina with processes possibilities to be determined) and pivot in Ultra High Molecular Weight Polyethylene (UHMWPE) (in order to attenuate the vibration). The NIH Hemolysis tests according to ASTM F1840 would be performed with blood. Anatomical position tests in cadavers and animal experiments (6 pigs).

All set, we machined first pieces and assembled a first prototype just to get an idea of the proportions. The small pieces were glued in rotor and they eventually came loose as they were made of different materials like acrylic resin and Delrin, Figure 5.

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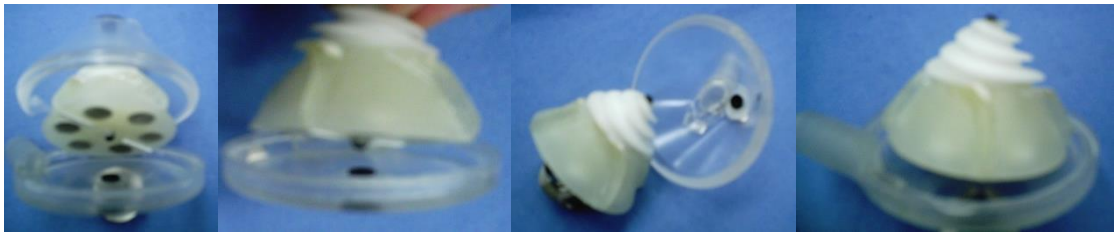

Figure 5. First prototype with rotor composed of two separate parts and vanes glued in different materials.

Since this approach presented results much lower than expected, the entire rotor was covered with white polyurethane resin, Figure 6. Not only this first prototype shown (Figure 5 and 6) with the rotor composed of glued parts without resin coating, as well as the model with improvements, proved to be amateur devices. They could serve as model for a casting mold, or even lost wax casting, but it was decided that the best strategy would be Computer Numerical Control (CNC) machining in a high speed 3-axis machining center.

Figure 6. Second prototype: rotor covered with a white polyurethane resin.

Since this technology was not available in our laboratory in Brazil at that time, this was the last part of development before the BCM phase. With the approval of the CNPq research grant, I received a visiting researcher scholarship to begin studies in Houston in February 2006.

Biomaterials, Hemocompatibility and Computational Fluid Dynamics. Even with all the progress achieved, it is difficult to talk briefly about the three topics, which is why it is even more difficult to correlate the three, create a logical causal link and propose a wide VADs' development strategy. Much has already been achieved in this field of knowledge, as mentioned at the beginning of this paper, both in the prediction of hemolysis by Computational Fluid Dynamics (CFD), which was much more direct, but less exploratory (14–17). As for the knowledge of the blood interaction in turbulent flows, the mechanical trauma that is imposed to the wall of the red blood cells and how this can be quantified. Although there are still several methodologies and much to discover, the computational power and ease of validation of

mathematical models and numerical simulations gives modern VAD scientists a broad toolbox (18–25).

After this first phase of conception and three-dimensional design, the BCM group helped us with decades of knowledge in biomaterials research, *in vitro* tests and animal experimentation. But, especially, it helped us with personal financial support from Prof. Yukihiko Nosé (I will be eternally grateful for that), since the Brazilian grant did not cover costs with equipment and expenses with materials.

But this feature facilitated access to BCM's mechanical workshops and brought me closer to professionals who also had decades of experience in manufacturing processes such as Mr. Juan Fernandez, that helped me to obtain the best parameters for ceramic materials, the possibilities of machining green bodies, its characterization techniques, sintering and finishing, as well as the first tribological tests and evaluation of biomaterials in pivot bearings (26–32).

The issue of pivot bearings has always raised doubts about hemocompatibility and its feasibility, since its appearance in Gyro pump (2). But it became a consensus a long time ago when it made possible to support axial pumps impellers that, in the vast majority, appeared working with similar pivot bearings (33,34). In the Brazilian CFVAD, we decided to call "support bearings" and the dual impeller Implantable Centrifugal Blood Pump (ICBP) device (35). The assay methodology following ASTM F1830 and ASTM F1841 for Normalized Index of Hemolysis (NIH) was done with the measurement of Plasma-Free Hemoglobin (PFH) by the Tetramethylbenzidine (TMB) method, but it was replicated in the future with Harboe method when we developed a new pump, recently (36).

Conclusions. After the prolific period as invited researcher at BCM, the IDPC group had a productive leap. The contact with researchers from the University of São Paulo (USP) generated FAPESP's first thematic project and each of the colleagues there had the opportunity to develop their own specific theme within the large project of this CFVAD. The project title even focused on the pump's propulsion system (37).

But the fact is that several parallel projects, within the IDPC, USP, and even in the Instituto Federal de São Paulo (IFSP) were born from that interaction, such as the electromagnetic suspension for a fourth generation of CFVADs (38–51).

Another important factor, which we can characterize as a paradigm shift in mechanical circulatory assistance is its size reduction due to the mechanical demand of pumps, which were previously designed to work in a range of 7-10 L/min with 120 mmHg and nowadays are much smaller and provide only 3-5 L/min (52).

But a promising bet that could be made is that the future belongs to the peripheral countries in this technological race, such as Brazil, Russia, India, China and South Africa, which are large emerging economies of the BRICS bloc. These countries are the future for those who want to invest in VADs (23,25,53–57).

Another important step for monitoring and evaluating the technologies involved in VADs is the Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) (58). The fact of accumulating data between agencies makes it possible to analyze previously unknown parameters and search for correlations between therapies and clinical results on statistical basis, which, in the case of VADs, is often not significant. Future data mining and Internet of Things (IoT) tools will enable not only analysis but also the adjustment of control in real time through secure artificial intelligence.

I like to say that's when the **Artificial Heart** will meet the **Artificial Intelligence**…

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