IMPLANTABLE CENTRIFUGAL BLOOD PUMP: ANALYSIS OF THREE DIFFERENT PROCESS OF RAPID PROTOTYPING

Beatriz Uebelhart, biauebelhart@hotmail.com
Eduardo Bock, eduardo_bock@yahoo.com.br
Aron Andrade, aron@dantepazzanese.org.br
Juliana Leme, juleme@dantepazzanese.org.br
Institute Dante Pazzanese of Cardiology
Av. Dr Dante Pazzanese, 500 , São Paulo-SP

Cibele Silva, Cibele.silva@dantepazzanese.org.br
Bruno Utiyama, jokuletal@hotmail.com
Universidade Estadual de Campinas, UNICAMP
Cidade Universitária, Campinas-SP

Pedro Antunes, antunes.pedro@yahoo.com.br
Luis Alexandre Silva, luisalexandreslv@gmail.com
Escola Politécnica of São Paulo University

Elvio Franco de Camargo Aranha, elvio@smaflex.com
Faculdade de Tecnologia de Sorocaba

Abstract*. About 300 000 people die annually from cardiovascular diseases in Brazil, according to a research of World Health Organization (WHO), Brazil is the 9th place among the countries that have these diseases as the leading cause of death. A heart transplant is often the only form of treatment for certain heart diseases, restoring normal conditions to the patient. Artificial Hearts or Circulatory Assist Devices may be used to maintain the patient's life on the waiting list for a transplant. A Centrifugal Blood Pump is normally used as Cardiopulmonary Bypass or Ventricular Assist Device due to its large discharge capacity and low cellular trauma. Generally, Circulatory Assist Devices have application as bridge to transplant (BTT), bridge to recovery (BTR), destination therapy (DT) and as temporary support in heart surgery (ECMO). It is important that the development of these devices is properly drafted to avoid failures in their operation, fact that can be fatal to the patient. The construction of circulatory assist device prototypes allows the analysis of its structure, identification and correction of mistakes. The technology of rapid construction and high quality one-dimensional model is called rapid prototyping (RP). This work analyzes three different types of RP processes in the development of Implantable Centrifugal Blood Pump (ICBP) and tests its prototypes. Physical models were constructed through the processes of selective laser sintering (SLS), fused deposition modeling (FDM) and 3D printing (PolyJet™ technology). A comparison of each prototype was performed analyzing conception, construction, assembling and pump's performance tests. The process which was considered more viable in this analysis is the 3D printing (PolyJet ™ Technology). The processes of SLS and FDM were considered feasible in performance tests but, due to require a post-processing of the prototype, including the use of the machining process for adjustments, the conception, construction and assembling was considered unsatisfactory. The hydrodynamic performance of the prototypes made of polyamide presented satisfactory results when compared to results of previously performed tests. In the future, new prototypes will be made through the process of FDM and 3D printing (PolyJet ™ technology) for the realization of new tests to reach statistically significant data.*

Keywords: *Rapid Prototyping, Centrifugal Pump, Circulatory Assist Devices*

1. INTRODUCTION

An Implantable Centrifugal Blood Pump (ICBP) is being developed at the Institute Dante Pazzanese of Cardiology since 2005. The system consists of a centrifugal pump, a motor, a controller and power supply. Battery or other electric source is responsible for providing power to the controller who operates a motor and causes the rotation of the pump through magnetic coupling. This coupling consists of the rotor magnets and magnets sealed inside the impeller. The ICBP is composed of an external cone, external cone base, impeller and impeller base. The rotor is supported by a pivot bearing system and its base is responsible for sheltering 6 permanent magnets (Uebelhart, 2010a).

Because of the fact that this pump is being developed for long term assistance, the pivot bearing system must have high durability. Takami, 1997 apud Bock 2008, using purely ceramic bearing obtained high normalized index of hemolysis, worse than those obtained using the ceramic male and polymeric female, and because of this, the system chosen was the ceramic-polymeric. Bock, 2008, by conducting tests for selecting the material of the bearing system, concluded that the male bearing should be made of alumina and the female of polyethylene.

The performance tests of the first prototypes were made in the Baylor College of Medicine, in Houston, EUA, in accordance with the internal procedures of the Michael E. DeBakey Department of Surgery for performance testing of blood pumps.

It is of great importance that the development of these devices are correctly elaborated to avoid flaws in its operation, because if its occurrences when implemented, they can be fatal to the patient. The construction of a prototype of a circulatory assist device allows the analysis of this operation, identification and correction of flaws. The high quality technology that allows the rapid construction of a tridimensional model is called rapid prototyping. Until now, many prototypes were made to realize the performance tests with the device, but this work shows the first prototypes made entirely through the rapid prototyping technology (Uebelhart, 2010b)

2. OBJECTIVE

This work aims for the construction of an Implantable Centrifugal Blood Pump through three different processes of rapid prototyping to conduct a comparative analysis between conception, construction, assembling and pump's performance tests. The processes used to construct the prototypes were the selective laser sintering (SLS), fused deposition modeling (FDM) and 3D printing through the Polyjet™ technology. Once built, was analyzed the feasibility of each process in the building of the 3D models to realize performance tests.

2. METHODOLOGY

To obtain the tridimensional model, the ICBP geometries were simulated (Figure 1) in the SolidWorks™ software (SolidWorks™ 2008, Dassault Systèmes, Concord, EUA).

Figure 1. Tridimensional CAD models of the ICBP components.

During the modeling of the rotor in SolidWorks™, was created a central support for the male bearing, a threading system to fix the rotor base increasing the assembly of the prototype and, in the rotor base, were created housing for the magnets (Figure 2).

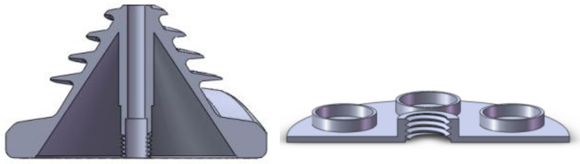

Figure 2. Male bearing support system and the housing of the magnets in the rotor base

Initially were constructed prototypes through the selective laser sintering process (Figure 4) in partnership with the Renato Archer Center of Technology of Information using the SinterStation 2000™ (3D Systems, Rock Hill, EUA). This process consists basically in the construction of tridimensional objects through repeated depositions of polymer powder layers, for example, polyamide and polystyrene (Heynick, 2006).

The powder polymers are housing in a construction recipient, which one is stored in a platform that moves vertically to supply the material as needed. The construction of the prototype begins when a powder layer is provided by the construction recipient and spread it by a cylinder in the construction chamber of the equipment (Ulbrich, 2010). Then a laser beam, guided by a movable mirror, moves to certain areas of the powder surface, providing energy to sinter the material particles, causing adhesion. Then, the platform of construction moves again, vertically, and the process begins again until the object is entirely constructed (Hotzda, 2009).

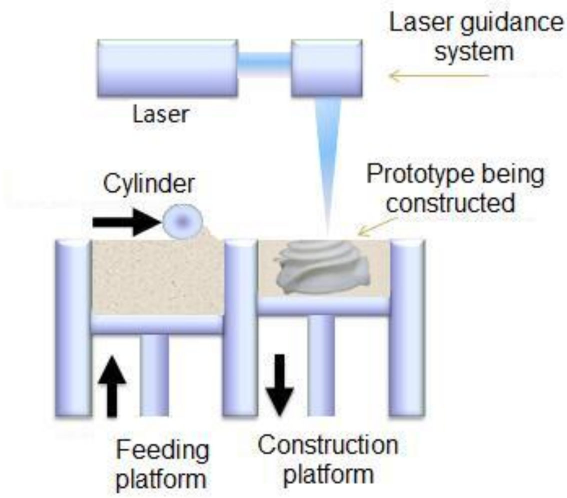

Figure 3. Process of Selective Laser Sintering

After made the prototype, the non-sintered powder by the laser is easily removed with a brush or compressed air, among others.

The prototypes made through the fused and deposition modeling process (Figure 4) were manufactured in partnership with the Faculdade de Tecnologia de Sorocaba using the Dimension SST 768™, (Dimension Inc., Eden Prairie, EUA). In this process, a filament of material is extruded from a heated matrix, and the prototype is constructed layer by layer. Two heads with nozzle extruders are responsible for providing the material. One is for the construction material of the prototype and the other, for the support material. After deposited the first layer, the support platform is lowered to the deposition of the second layer and successively, until the prototype is entirely constructed (Chua, 2004).

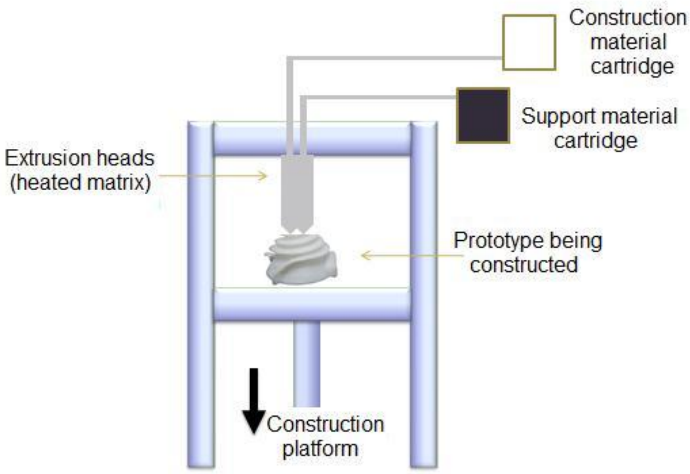

Figure 4. Fused and Deposition Modeling process

Two prototypes of the ICBP components (Figure 5) were printed in partnership with SYCAD (SYCAD Systems Ltda, Sao Paulo) using the Polyjet™ technology. This technology uses a deposition system of a resin in drops on a platform of construction. After the deposition of the material, an ultraviolet light is focused to cure the layer. This process uses the resin as construction material and a gel as support material, which one is easily removed with a water jet (Hotzda, 2009).

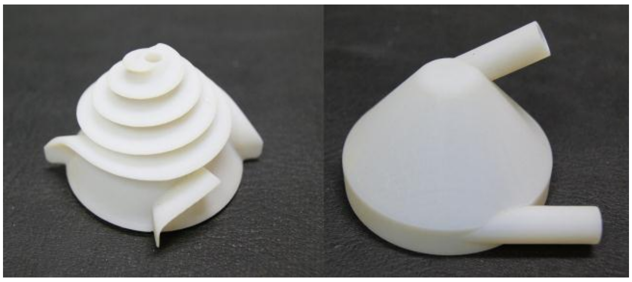

Figure 5. Prototypes of the rotor and of the rotor base, made through Polyjet™ technology.

The assembly of the ICBP prototypes consists to fix the magnets, positioning of the bearings, assembly of the rotor, positioning of the rotor and assembly of the external cone. During the assembly was verified if the processes were capable to keep the dimensions and features of the pieces simulated on the SolidWorks™ software.

Related to the prototypes made in ABS (FDM process), before starting the assembly, was necessary to remove the support material of the prototypes constructed. The components with simple geometry have their support material easily removed but the removal of this material in pieces like the rotor (Figure 6), which has a complex geometry, was really difficult and this couldn't be done as indicated by the manufacturer.

Figure 6. Prototype of the rotor still with the support material not removed.

After assembled, the prototypes were connected to a workbench of tests, a circulatory mock loop, which one consists of an acrylic water tank, an ultrasonic flowmeter (Transonic Systems, Ithaca, NY, USA), a drive module of the ICBP, a pressure monitor and an ICBP prototype (Figure 7). During the tests was observed the comportment of the prototype on the closed loop test and were established rotations from 1200 to 2200 to analyze pressure and flow in the ICBP.

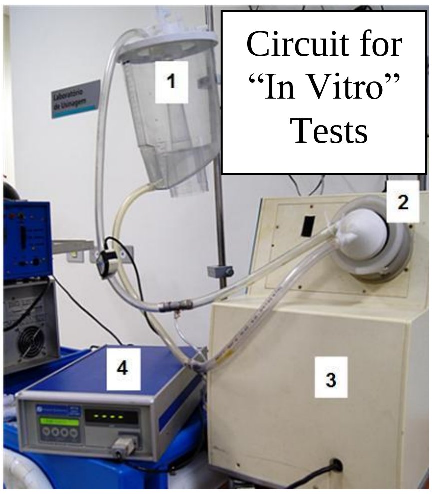

Figure 7. Circulatory Mock Loop: acrylic water reservoir (1), ICBP prototype (2), drive module of ICBP(3), ultrasonic flowmeter (4).

3. RESULTS

Among the ICBP components made through SLS process, the only one that presented fragility capable to compromise the assembly was the rotor base. The cylinders for housing the magnets easily released from the base, thus, these rings were removed to avoid interference in the setting of the magnets (Figure 8). Then the magnets were positioned and fixed with epoxy resin.

Figure 8. Housing of the magnets removed and the magnets fixed with epoxy resin

In addition to the fragility, it was observed that the cylinder designed to fix the rotor and the base had no functionality. During "in vitro" tests, the prototype presented leakage at rotation of 1200 rpm, fact that could affect the results of the flow test. Therefore, the prototype was covered with acrylic resin, because it was comparatively more efficient than the cyanoacrylate to contain the leakage, and the test could be performed. The results are showed in the graphic bellow (Figure 9):

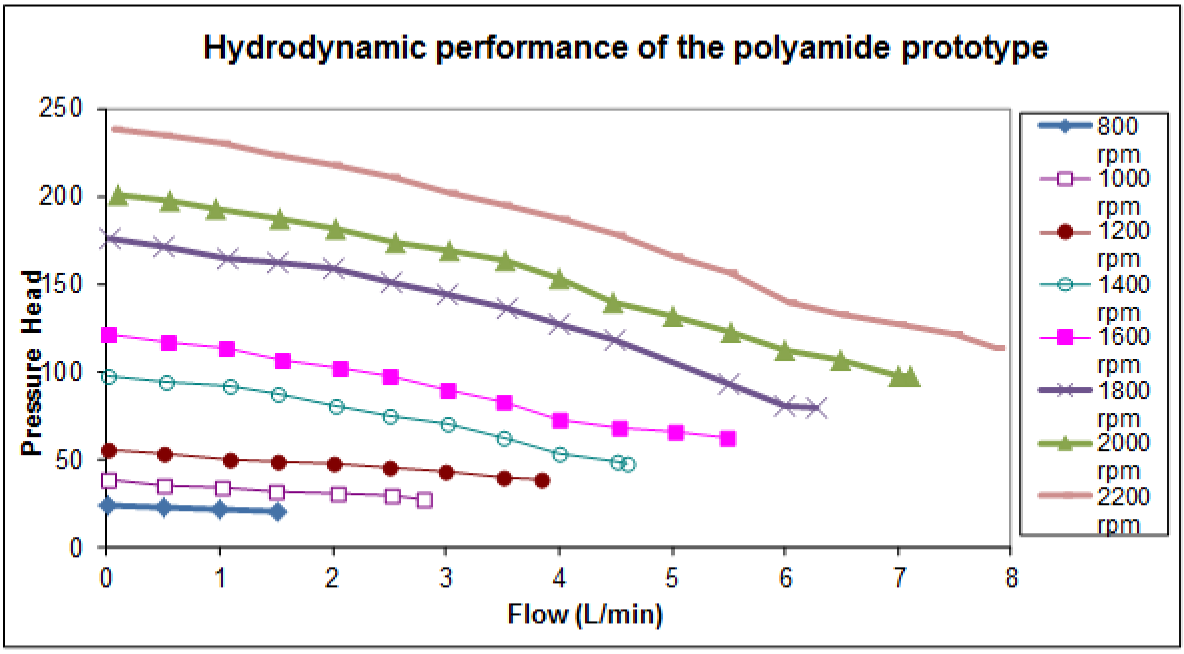

Figure 9. Curves of the hydrodynamic performance of the polyamide prototype.

The Figure 10 compares the hydrodynamic performance of the polyamide prototype, in legend, from top to bottom, range from 800 to 1200 rpm and then, the performance of the prototype in acrylic, in legend, the range of 1200-2300 rpm.

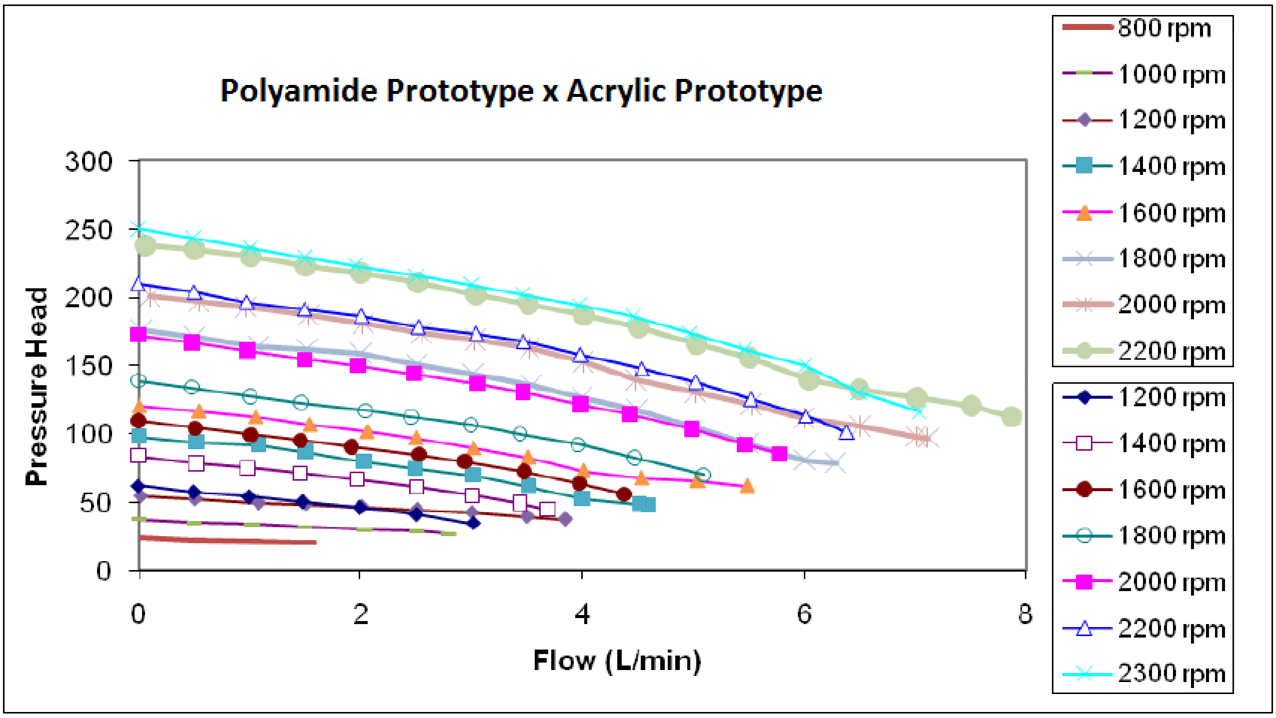

Figure 10. Hydrodynamyc performance compared of polyamide prototype and acrylic prototype.

The prototype of acrylic was used in previous tests and has some differences in geometry compared to the polyamide prototype (Figure 11).


Figure 11. Acrylic prototype and Polyamide prototype

The removal of the support material was hard and lots of tests were made, like the removal through scraping and twist, and the immersion in hot water. The ABS prototype presented basically the same imperfections of the prototype in polyamide, like the fragility of the rotor base and the lost of the threading system functionality.In addition, the outer cone and the rotor (Figure 12) presented build failures and high fragility.


Figure 12. Flaws from the construction process of the rotor

In the first performance test, a large water leakage was observed because the prototype was disconnected from the circuit to be covered. When disconnected, the prototype broken (Figure 13) due to its fragility, precluding their use. Later, through the SolidWorks™ software, changes in geometry of the ICBP were made aims to improve the resistance and a new prototype was made to realize the performance tests.

Figure 13. ABS prototype after disconnected from the circuit.

The two ICBP components made through the Polyjet™ technology showed no failures. The prototypes presented great surface quality, without flaws and the assembly was easily realized due to the preservation of the functionality of parts.

3. CONCLUSION

The prototypes made through the FDM and SLS processes can be used to realize the “In vitro” tests of the ICBP, but they need post processing to use, which implies in a longer time and work to prepare the prototype.

Despite possible, the assembly of the ABS prototype was difficult and the execution was slow due to all the necessary adjustments. When compared to the polyamide prototype, the ABS presented higher fragility and execution time. After tests, was decided that the best way to remove the support material of the ABS prototypes was the immersion in a water at 70°C during 4 hours. The performance test of the polyamide prototype, when compared with the results of the acrylic prototype was considered satisfactory.

The prototypes constructed through Polyjet™ technology preserved all the functionality of the piece simulated in the SolidWorks™ software allowing the fast construction of the prototype. Comparing the assembly of the prototypes, this process presented greater advantage than the others. This is due to the fact that the prototype didn’t needed post processing, improving a lot the time of assembly. In the future, the performance tests of the ABS and Polyjet™ prototypes will be made to do a comparative analysis between the results of the prototypes.

4. REFERENCES

Bock, E. et al., 2008 “New Centrifugal Blood Pump With Dual Impeller and Double Pivot Bearing System: Wear Evaluation in Bearing System, Performance Tests, and Preliminary Hemolysis Tests” − Artificial Organs,Vol.32, No.4, pp.329–333.

Chua, C.K.; Leong ,K.F.; Lim,C.S., 2003. Rapid Prototyping: Principles and Apllications. World Scientific Publishing Co.Pte.Ltd., USA, 25 p.

Heynick, M.; Stolz, I., 2006. “3D CAD, CAM and Rapid Prototyping” In: LAPA Digital Technology Seminar. École Polytechnique Féderale de Lausanne, Lausanne.

Hotzda, D.,2009. Prototipagem Rápida de Pilhas a Combustível de Óxido Sólido − Revista Matéria, Vol.14, No.4, pp.1101-1113.

Uebelhart, B.; Antunes, P.; Andrade, A.; Bock, E. 2010. “Coração Artificial e Dispositivos de Assistência Circulatória no Brasil e no mundo”− Revista Sinergia Vol.11, No.2, pp.151-155.

Uebelhart, B.; Bock, E.; Antunes, P.; Fonseca, J.; Leme, J.; Silva, B.; Silva, C.; Biscegli, J.; Cardoso, J.; Andrade, A. 2010, “Estudo de protótipos de bomba de sangue centrífuga implantável confeccionados por prototipagem rápida”. 6º Congresso Latino Americano de Órgãos Artificiais e Biomateriais, Gramado, Brazil, 17 a 20 de agosto de 2010b.

Ulbrich, C.B.L.; Oliveira, M.F.; Munhoz, A.L.J.; Zavaglia, C.A.C.; Silva, J.V.L. “Comparação entre três técnicas de prototipagem rápida para confecção de moldes para implantes personalizados”. 6º Congresso Latino Americano de Órgãos Artificiais e Biomateriais, Gramado, 17 a 20 de agosto de 2010.

5. RESPONSIBILITY NOTICE

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