Implantable Centrifugal Blood Pump designed for Long Term Left Ventricular Assistance

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ABSTRACT

Implantable Centrifugal Blood Pump (ICBP) is a Left Ventricular Assist Device (LVAD) multicenter project designed for long term support of patients with severe cardiovascular diseases. LVADs are indicated as bridge to heart transplantation, bridge to myocardial recovery, bridge to therapy (including regenerative therapy and tissue engineering) or destination therapy. ICBP system includes centrifugal blood pump with double ceramic pivot bearings, hydraulically-levitated impeller, magnetic passive coupling and rpm-controlled miniaturized actuator. Computational Fluid Dynamics (CFD) numerical simulations were applied to define impeller characteristics. Rapid Prototyping (RP) techniques and Computer Numerical Control (CNC) machining promoted construction of physical models. In vitro tests were performed in order to evaluate wear in pivot bearings, hydraulic performance of different impeller geometries and index of hemolysis with human blood. Anatomical studies in calves show good implantability. General results were considered satisfactory and next step is to evaluate device’s performance “In Vivo”.

Keywords: Left Ventricular Assist Devices, Implantable Centrifugal Blood Pump, Artificial Heart.

INTRODUCTION

The Implantable Centrifugal Blood Pump has been developed for long term circulatory assistance with a unique impeller design concept [1]. This feature was called dual impeller because it allies a spiral-shaped cone with vanes to improve blood flow characteristics around the top inflow area to avoid blood clot due to stagnant flow, see figure 1 [2].

\textbf{Figure 1:} Picture of Implantable Centrifugal Blood Pump showing pump’s case, rotor and actuator.
A series of previous studies demonstrated significant advantages from spiral shaped impeller design, providing axial characteristics to the flow in Left Ventricle Assist Devices [1]. The axial force component can avoid stagnant flow formation. Therefore, this principle can help to avoid thrombus related with blood stagnation [3].

This work presents results from Design, Manufacturing and Tests of an Implantable Centrifugal Blood Pump. The double pivot bearing system has been used and studied in the last decade showing simplicity and reliability [4]. Recent studies evaluated the particle release from a centrifugal blood pump with double pivot bearing system composed of alumina ceramic (Al2O3) and ultrahigh molecular weight polyethylene (UHMWPE). This pivot bearing system was tested under severe conditions showing very small risk of releasing debris particles to blood [1, 5].

MATERIALS AND METHODS

Performance tests were conducted with several different prototypes, some of them machined in regular Mill and Lathe, or machined in High Speed Cutting (HSC), in polycarbonate (PC) and titanium (Ti). Other prototypes were obtained by Rapid Prototyping (RP) processes of Selective Laser Sintering (SLS) in Nylon, Fused Deposition Modelling (FDM) in acrylonitrile butadiene styrene (ABS) polymer, and Tridimensional Printing (3DP) in VeroGray (VG), see Table 1.

Table 1: Prototypes machined and obtained by different processes and materials.

<table>
<thead>
<tr>
<th>Material</th>
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<td>Ny</td>
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Figure 2 shows pictures of ICBP prototypes assembled before “In Vitro” pump’s performance tests in workbench.

Figure 2: Different types of prototypes obtained by SLS or Machined in different types of materials from translucent polymers to titanium.
In vitro performance tests were made in order to characterize hydraulic performance curves for the pump. These tests can provide important information about the pump’s capability and function ability. The generated curves can be used as a tool to predict which rotation is necessary to provide specific pressure and flow [6].

During performance tests, two different types of pump’s inlet port were compared, with 45° and 30° of inlet angle. Finally, two isolated normalized tests of hemolysis with human blood were performed producing four values of normalized index of hemolysis (NIH), obtained from variation of plasma free hemoglobin (PFH), measured by a tetramethylbenzidine (TMB) assay method (Catachem, Bridgeport, CT, USA).

Prior to evaluate pump’s performance during animal studies, anatomical studies were necessary to achieve best configuration and cannulation for Left Ventricular Assistance [1]. The chosen animal model for this experiment was male calves with weight between 90 to 100 kgf.

RESULTS AND DISCUSSION

The bearing composed of alumina with UHMWPE showed the best results in wear evaluation trials with ceramic–polymeric pairs [8]. Four pairs had the minimum mass loss (0.1 mg): alumina with UHMWPE, silicon nitride with silicon nitride, carbon with UHMWPE, and carbon with nylon.

Pivot bearing systems composed only of ceramic are known to have higher vibration during pumping applications instead of shock absorption experienced in ceramic–polymeric pivot bearing systems [4, 7].

As described by several authors, NIH for LVAD should be between 0.004 to 0.02 mg/100 L to be considered satisfactory and antitraumatic blood pump [1, 6, 9, 10]. After calculations, the preliminary hemolysis tests showed an NIH value of 0.0054 ±2.46x10-3 mg/100 L.

Two flexible polytetrafluoroethylene (PTFE grafts) cannulas were used to connect left ventricle to the pump. The first surgical technique option consisted to place ICBP in the animal thoracic cavity, Figure 3a.

One cannula was inserted into left ventricle apex and connected to the pump’s inlet port while the other was sutured to descending aorta and connected to pump’s outlet port. The second option was to place pump in abdominal cavity inserting cannulas through the diaphragm, Figure 3b. Third option was to place pump in abdominal cavity, but outlet cannula was connected to abdominal aorta, instead of descending aorta, Figure 3c.

**Figure 3:** Anatomical Studies: (a) Thoracic implant technique. (b) Abdominal implant technique with outlet cannula connected to descending aorta. (c) Abdominal with outlet cannula connected to abdominal aorta.
CONCLUSIONS

The pair composed of alumina and UHMWPE was chosen to be the materials of the double pivot bearing system in order to avoid vibration problems. The dual impeller centrifugal blood pump had proven to be a promising LVAD. The hydraulic characteristics are similar to other reported curves from established, durable, and reliable devices. As conclusion of anatomical studies, the three surgical techniques options were considered anatomically feasible. The first option was chosen to be the preferable configuration since it causes no incision at diaphragm, fact that can prejudice animal’s normal behavior and respiration. Results were considered satisfactory and next step is to test device’s performance “In Vivo”.

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REFERENCES