Development of a non-pulsatile permanent rotary blood pump

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Abstract

For many years, a common belief was that non-pulsatile perfusion produced physiological and circulatory abnormalities. Since 1977 our group has reported, if a 20% higher blood flow was used more than required for a pulsatile blood pump, there would be no circulatory or physiological abnormalities. These experimental findings confirmed that there was no difference in clinical outcome when using a pulsatile or non-pulsatile blood pump. Furthermore, the non-pulsatile rotary blood pump has demonstrated efficient and reliable performance in various clinical situations. The non-pulsatile blood pump is a simple and reliable design, that can be easily manufactured, and has the following desirable features. There is no need to incorporate heart valves, a large orifice inflow conduit, or a compliance volume-shifting chamber. Since an electrical motor operates continuously, the on-and-off motion required for a pulsatile pump is not necessary; therefore, it becomes a more efficient and durable system. Further, the control algorithm is simpler and more reliable than a pulsatile pump. Considering these factors, the non-pulsatile blood pump can be selected for a permanently implantable assist device. To develop an implantable non-pulsatile cardiac device, it is necessary to incorporate seven features in the system such as: small size, atraumatic features, anti-thrombogenic features, anti-infection features, durable and simple design, and low energy requirement with easy controllability. © 1997 Elsevier Science B.V.

1. Justification of non-pulsatile perfusion

The clinical results show that the centrifugal pumps which provide non-pulsatile circulation as ventricular assist devices for post-cardiotomy cardiogenic shock is the same as that of the pneumatic pulsatile flow devices even though the pumps were developed for cardiopulmonary bypass [1-4]. In experimental data, Griffith et al. reported that pulseless flow and relief from the demands of external work provided by left ventricular bypass with a centrifugal pump system permitted adequate myocardial perfusion at normal coronary flow rates without myocardial ischemia or acidosis [5]. Moreover, Kanamori et al. noted that the non-pulsatile left ventricular assist was more effective on reducing left ventricular work and myocardial oxygen consumption than pulsatile ventricular assist if a higher left heart bypass flow was maintained (more than 75% bypass rate) [6]. Therefore, it is clear that the effectiveness of non-pulsatile circulatory support is at least the same as that of pulsatile circulatory support in terms of ventricular assistance or saving of the diseased heart.

The main concern is whether non-pulsatile circulation will maintain the normal physiology of all body organs, or whether non-pulsatile circulation will apply to a long term life support system. Since 1977, these authors have been involved in the investigation of the physiological responses to non-pulsatile total body perfusion [7].

Traditionally, it was considered that non-pulsatile perfusion was not good for the physiology. During 1976, Johnston, Bernstein and colleagues conducted studies on the pulseless LVAD for 2 weeks in calves [8]. They demonstrated that various physiological abnormalities occurred in the pulseless animals. Higher venous pressure, higher cardiac output, and varied peripheral resistance were among the abnormalities.
We have been implanting cardiac prostheses in calves for many years while maintaining normal circulatory parameters in a pulsatile mode of perfusion. However, during the initial 2 weeks after implantation of a pulsatile cardiac prosthesis, we have seen non-physiological circulatory parameters in this group of animals [9]. At that time many research groups had shown high peripheral resistance (initially within a few days), high venous pressure, and increased circulating blood volume during this period. After pumping for more than 2 weeks, this abnormal physiology often has a tendency to disappear. The results that Johnston et al. observed with a non-pulsatile mode of perfusion in 2 weeks were identical to what we have seen with the pulsatile mode of total body perfusion.

These authors studied pulseless total body perfusion for both the right and left circulation utilizing centrifugal pumps. The total bypass was made for the right and left heart, and blood flow was maintained as high as possible. During this bypass procedure, the natural heart was sustained in a ventricular fibrillation state [10]. Five animals were kept for 1- and 3-month periods [11,12]. Implanted pumps were exchanged every 2 weeks to avoid thromboembolic complications. Comparative studies were conducted in hemodynamics and other physiological parameters with the pulsatile TAH animals [13,14].

As was predicted in the non-pulsatile group, it was initially very difficult to maintain sufficient blood flow together with high peripheral resistance for 2 days [14]. Despite the initial difficulty in maintaining the higher flow, all the long-term survival animals had maintained a blood flow of 110 ml/kg or higher for at least the initial 6 weeks. The blood flow used for the pulsatile TAH was usually below 100 ml/kg. Under these conditions, the near normal physiology of the calves with both non- and pulsatile artificial hearts were observed. We recognized that it is extremely important to keep a 20% higher blood flow if the non-pulsatile mode of perfusion is applied [15].

The high left atrial pressure, which was very difficult to reduce in the non-pulsatile group of animals, almost reached the same level as that of the pulsatile animals after 2 weeks of perfusion. The same range of circulatory blood volume was maintained in both the pulsatile and non-pulsatile modes of perfusion. The right atrial pressure in both groups had a tendency to increase during the initial 2 weeks; however, after 2 weeks it had a tendency to decrease in the same fashion.

In both groups, the catecholamine level was initially increased. Particularly in the non-pulsatile mode of perfusion, the level measured during the initial few days of perfusion was approximately two times higher. However, after 2 weeks of perfusion, the level became the same in both groups [14].

Higher SGOT levels in the pulsatile and non-pulsatile modes of perfusion in the first week were seen; however, again after 2 weeks of perfusion, the SGOT levels in both groups became the same as the control levels. Colloid osmotic pressure, serum osmotic pressure, and red cell mass volume did not show any differences in these two groups of animals during these initial 2 weeks [16].

Treadmill exercise tests demonstrated that both non- and pulsatile groups showed moderate to good tolerance at 1.5 mph tests without hemodynamic or metabolic deterioration [17–19]. The increased O₂ demand during exercise was met by augmented O₂ extraction for non-pulsatile bi-ventricular bypass while increased cardiac output and O₂ extraction for pulsatile TAH recipients. The non-pulsatile group has a higher norepinephrine response to exercise than the pulsatile TAH group. Although patients can tolerate moderate exercise with the constant flow of non-pulsatile circulation, a regulation system which can increase pump flow during exercise is necessary for a higher quality of life.

Thus, our experiences demonstrate that if a 20% higher blood flow was used more than that required for a pulsatile blood pump, there would be no circulatory or physiological abnormalities. These experimental findings confirm that there is no difference in the clinical outcome if we use a pulsatile or a non-pulsatile blood pump as a permanent blood pump. Based on this information, a non-pulsatile blood pump can be chosen as a long-term implantable blood pump.

### 2. Desirable features of the non-pulsatile blood pump

Non-pulsatile rotary blood pump demonstrates an efficient and reliable performance in various clinical situations. The non-pulsatile rotary blood pump is a simple and reliable design, that is easily manufactured, and has the following desirable features:

1. There is no need to incorporate heart valves, the most thrombogenic and blood trauma inducing components of a pump design.
2. A continuous flow pump does not require a large orifice inflow conduit and is proven to be easier to implant in patients, with minimal damage to the myocardium.

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<td>Anti-thrombogenic features</td>
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<td>Durable and simpler design</td>
<td>Lower energy requirement</td>
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<tr>
<td>Easy controllability</td>
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3. There is no need to incorporate a compliance volume-shifting device, which is essential for a pulsatile blood pump. The implantation of additional intrathoracic hardware is eliminated in a continuous flow pump.

4. In the continuous blood pump, the control algorithm is simpler and more reliable than a pulsatile pump.

5. Due to a rotary blood pump's structure, only one moving part is necessary for the blood pumping motion. By using durable components for this moving part, an overall durable system becomes possible.

6. Since an electrical motor operates continuously, the on-and-off motion required for a pulsatile pump is unnecessary; therefore, it becomes a more efficient and durable system.

3. Seven features to develop a permanent implantable non-pulsatile pump

In order to achieve a permanently implantable non-pulsatile rotary blood pump, it is necessary to incorporate at least seven features in the system as listed below and in Table 1. In addition, the pump should be noiseless, operating independently, and stable. It is also necessary to eliminate electric and electromagnetic influence inside or outside of the system.

3.1. Smaller size

As for the pulsatile pump, due to the inflow limitation, the maximum pulse rate is in the range of 150 bpm. Therefore, it is necessary to have an effective stroke volume of over 50 cc, and have a pumping chamber of 60–65 cc. However, for the rotary blood pump, the RPM is typically in the range of 2000 for a centrifugal pump and 10000 for an axial pump. The rotary blood pump is very small as evidenced by the axial flow pump (Fig. 1). So the size required for these pumps that have been developed is in the range of 1/10th and 1/50th. Table 2 shows the size of our pulsatile LVAD [20], centrifugal pump [21] and axial flow blood pump [22].

3.2. Atraumatic feature

The normalized index of hemolysis (NIH) in most pulsatile pumps is in the range of 0.04. This is due to the high dp/dt required to generate a pulsatile flow and the need for two blood trauma inducing heart valves. The roller pumps generate an IH level of 0.06. We have achieved an NIH level of 0.002–0.004 in both centrifugal pumps and in the axial flow blood pump [22,23] by optimizing the design of pumps and their operational
parameters (Table 3). The system optimization was derived not only from an atraumatic feature point of view, but also from the system efficiency and system endurance point of view. The higher system efficiency produces a longer life expectancy in the electrical system. The lower RPM in the system produces the longer life of the mechanical system, particularly for the bearings.

3.3. Anti-thrombogenic feature

In the past, a long-term anti-thrombogenic feature of a rotary blood pump was considered one of the most difficult tasks to achieve. However, many groups are attempting to achieve this objective by a seal-less design, elimination of blood stagnant areas inside the pump, and a smooth blood-contacting surface. Considering this, a short term centrifugal blood pump called the CIE3 pump has been developed in our laboratory [21]. Currently, the process of converting this pump into a permanent device is underway. This pump’s excellent anti-thrombogenic feature was achieved by eliminating an impeller shaft and replacing it with two pivot bearings incorporated both at the top and bottom of the pump’s impeller. Based on the design of the pump, effective flow dynamics inside the pump produce continuous blood washout at both pivot bearing areas, thus eliminating any thrombogenic areas inside the pump. Fig. 2 and 3 show the CIE3 pump, there is a high blood flow at the top bearing area and an effective secondary flow at the bottom bearing area. All clinically available mechanical heart valves employ the same basic concept of eliminating any blood stagnant areas. Since the CIE3 pump eliminates the blood stagnant regions, particularly at both pivot bearing areas, we are confident this device will be long term anti-thrombogenic.

3.4. Anti-infection feature

An intrathoracic cardiac prosthesis, such as the Jarvik-7 TAH, has a tendency to develop device-centered infection [24,25]. This infection occurs after implantation of a man-made prosthesis and material is very often fatal or requires the removal of the implanted material. Based on this experience, it is proposed that if the intrathoracic cardiac prosthesis is volumetrically stable and made of a rigid structure, we can avoid the device-centered infection successfully [26]. The Novacor LVAD and the Therm0 Cardiosystem LVAD are of this construction.

It is further advantageous if the surface of the device is texturized because a healthy layer of the tissue capsule will adhere to the surface of the device. This healthy tissue capsule integrated with the device will eliminate the possible device-centered infection, not only inside the chest but also elsewhere in the body [27]. Thus, if the biomaterial is covered with healthy cells, infection is prevented. In order to avoid device-centered infection, all the tissue-contacting surfaces are texturized allowing the growth of healthy tissue. We know the healthy tissue capsule integrated with the device will eliminate possible device-centered infection [27]. In addition, the device is a volumetrically stable structure that avoids mechanical damage of the tissue capsules that forms on the surface [28]. This surface texturized design is proven to be infection free in longer than 2-year implantations [29]. During the past 10 years, we intensively investigated the phenomena of tissue capsule formation on the cardiac prosthesis and its relationship

Table 2
Size requirement of ventricular assist device

<table>
<thead>
<tr>
<th></th>
<th>Smallest pulsatile LVAD (electro-mechanical LVAD)</th>
<th>CIE3 centrifugal pump</th>
<th>DeBakey/NASA axial flow LVAD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Height (cm)</td>
<td>70.7</td>
<td>40.0</td>
<td>7.0</td>
</tr>
<tr>
<td>Width (cm)</td>
<td>98.9</td>
<td>86.0</td>
<td>2.7</td>
</tr>
<tr>
<td>Volume (cc)</td>
<td>310</td>
<td>130</td>
<td>15</td>
</tr>
<tr>
<td>Weight (g)</td>
<td>570</td>
<td>125</td>
<td>54</td>
</tr>
</tbody>
</table>

Abbreviations: LVAD; Left ventricular assist device.

Table 3
Blood trauma induced by a blood pump

<table>
<thead>
<tr>
<th></th>
<th>Pulsatile LVAD</th>
<th>Non-pulsatile CIE3 centrifugal pump</th>
<th>DeBakey/NASA axial flow pump</th>
</tr>
</thead>
<tbody>
<tr>
<td>N.I.H. (g/100 l)</td>
<td>0.04 ±</td>
<td>&lt; 0.002</td>
<td>&lt; 0.003</td>
</tr>
</tbody>
</table>

Abbreviations: NIH, normalized index of hemolysis; LVAD, Left ventricular assist device.
to infection around these devices including compliance chambers. Even in a volumetrically variable device such as compliance chamber, the texturized surface structure proves to avoid device-centered infection [28].

3.5. Durable and simpler design

The life of the currently available centrifugal pump is limited to a few days due to blood leakage and thrombus formation around the shaft-seal. In order to extend the pump life, we propose a seal-less centrifugal pump by replacing the shaft seal with pivot bearings supporting the top and bottom of the impeller in the ClE3 pump (Fig. 3). Due to the durable and simple design of this pump, the key factor for determining the pump life is the endurance characteristics of the pivot bearing system, both at the top and the bottom. That is to say, life limitation of bearing systems dictates the mechanical life of the LVAD. Recent endurance studies reveal that a ceramic–polyethylene pivot bearing system has an 8-year life as an LVAD [30].

On the other hand, a lower-power-requiring pump dictates the electrical life of the LVAD. With excessive rise in temperature, the motor life will shorten. The lifetime of the electronic devices and related components can be calculated using Arrhenius equation:

\[
L_f = e^{-\frac{E_a}{k} \left( \frac{1}{T_f + 273} - \frac{1}{298} \right)}
\]

where \(L_f\) is the lifetime factor, \(E_a\) is the activation energy of the electronic device in electron-volt, \(k\) is the Boltzman’s constant, and \(T_f\) is the temperature of the electronic device in centigrade [31]. To calculate the effect of an increased temperature on the device life, \(L_f\) is calculated for two temperatures of interest. The ratios of the two \(L_f\)s define the ratio of the resulting change in the device lifetime. Considering the Arrhenius equation, there is a 40% increase in the electronic failure rate when operating at 42°C as opposed to 37°C. In the planned permanent pump system, the motor and pump casing will be fabricated with titanium, a good heat transfer is anticipated from the motor to the blood. Also, some heat can be dissipated into the surrounding tissue. Since the energy converter and electronics will use 6 or 7 W under a normal condition, the temperature rise in the motor will be small with most of its heat transmitted into the blood and subcutaneous tissue [32].

3.6. Lower energy requirement

Since our ClE3 pump requires only less than 8 W, the wasted heat is considered to be less than in a pulsatile
pump which is typically in the range of 10 W or higher. As mentioned, the endurance life of the electronic components is heavily dependent upon their exposure to higher temperatures. Since this lower-power-requiring pump generates less wasted heat, we anticipate less electrical and mechanical failure from the system. Therefore, the life of the system is expected to be longer. In addition, we expect less heat dissipation problems and less thermal damage to the tissue. Thus, the rotary blood pump is expected to have a longer life than that of the pulsatile pump.

3.7. Easy controllability

Intrinsic control of a rotary blood pump without any physiological parameters was once considered to be difficult. Since a pulsatile pump employs a passive fill mode, position sensor on the pusher plate will provide a satisfactory and simple control. On the contrary, rotary blood pump changes its output due to changes in afterloads even though the RPM is constantly maintained. It was mistakenly thought that it was necessary to monitor its operation by an extrinsic parameter, such as arterial blood pressure or pump output. However, a recently developed feedback servo utilizing the input current wave form to regulate the pumps’ RPM proves to provide an effective, reliable and automatic control of the rotary blood pump. The pump’s intrinsic parameters, such as voltage and current, demonstrates sufficient RPM control for the rotary blood pump.

4. Conclusion

Ten years ago, to develop a permanent rotary blood pump was considered to be an impossible dream. But now, almost all the technical problems associated in developing a permanent non-pulsatile rotary blood pump have been solved. Although achieving this goal is not an easy task, advance of the technology has made this idea a reality.

References


