Chapter 3: Numerical Simulation of the PUCA pump: a Left Ventricular Assist Device

Abstract

The Pulsatile CAtheter (PUCA) pump, a left ventricular assist device, consists of a hydraulically or pneumatically driven membrane pump, extracorporeally placed and mounted to a valved catheter. The catheter is introduced into an easily accessible artery and positioned with its distal tip in the left ventricle. Blood is aspirated from the left ventricle during systole and ejected into the ascending aorta during diastole.

A numerical model of the PUCA pump has been developed to determine the internal diameter of the PUCA pump catheter that allows a certain blood flow. The model considers a limitation of mechanical blood damage and determines the accompanying pressure and flow profile for driving the pump.

For a flow of 5 L/min a catheter with an internal diameter of at least 6.95 mm is required. For 3 L/min the minimal diameter is 5.50 mm. The latter catheter can be introduced in the axillary artery, the former via the aorta during an open thorax surgical procedure. To validate the numerical model two different PUCA pump configurations were tested in-vitro. Results showed a good resemblance between model and in-vitro behavior of the PUCA pump.

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Introduction

The use of mechanical circulatory support systems can be a life-saving procedure\(^1\). Short-term (up to three weeks) mechanical support of the heart can be necessary when patients need to be 'bridged' to heart surgery, aimed at alleviating severe ventricular failure, e.g. mitral valve surgery after ischemic rupture of a papillary muscle or closure of a ruptured ventricular septum. It also can be used as an adjunct to pharmacological treatment of severe heart failure.

The situations in which short-term left ventricular assist devices (LVAD) have to be applied often constitute cardiac emergencies. Hence, they need to be applied expeditiously, without a difficult and time-consuming operation. Transarterial assist devices like the Hemopump\(^5\) answer these requirements.

A new concept of a transarterial assist device, the Pulsating Catheter (PUCA) pump (Fig. 1) was developed with special emphasis on a fast and easy application with minimal surgery\(^3,4\). The PUCA pump consists of an extracorporeally placed membrane pump connected to a valved catheter. The catheter will be introduced into an easily accessible artery and the tip will be positioned in the left ventricle via the aorta\(^5\). The membrane pump, driven pneumatically or electrohydraulically, aspirates blood from the left ventricle thus unloading it and ejects it into the ascending aorta, thus ensuring an adequate blood supply to the coronary arteries. To keep a patient alive during several days, a pump output of 3 L/min at least is required\(^6\). To provide all organs with an adequate pulsatile blood flow, a pump output of 5 L/min is sufficient.
The PUCA pump is ECG-triggered. In case of severe cardiac arrhythmia or signal disorders, the pump driver switches automatically to an untriggered mode. To avoid blood coagulation caused by interaction with the internal surface of the assist device, a special heparin coating, developed at the University of Twente (Enschede, the Netherlands) is applied.

To determine the optimal dimensions and driving parameters of the PUCA pump, a numerical simulation model was developed. The model makes it possible to calculate:

1. Which internal diameter for a certain catheter and pump configuration is necessary to get an output of 3 or 5 L/min while limiting pump and blood damage, caused by mechanical forces.
2. The optimal pressure and flow profile for driving the pump with a pneumatic respectively hydrodynamic driving system.
3. The influence of patient hemodynamics on the functioning of the pump.
4. The most effective way to improve PUCA pump performance.

This study describes the numerical simulation model, and the results obtained with the model for 2 PUCA pump configurations in 4 situations. The validity of the model was determined by comparing the simulation results with in-vitro test results of 2 other PUCA pump configurations in 4 situations.

**Materials and Methods**

**Simulation model**

A lumped parameter model has been designed to describe the hydrodynamic behavior of the PUCA pump. PSI software (BOZA, Nuenen, The Netherlands), especially developed to build lumped parameter models, has been used. Basic assumptions are a sufficient description of the flow behavior by the modified Bernoulli equation and blood viscosity to be Newtonian. The functioning of the PUCA pump depends on many factors. The simulation model takes the following (input) parameters into account:

- Required flow ($Q$), in L/min.
- Blood density ($\rho$), put at 1,060 kg/m³.
- Dynamic blood viscosity ($\eta$); because blood flow is presumed to be Newtonian, $\eta$ is a constant (0.0036 Pa.s).
- Internal diameter ($d$, in millimeters), flow resistance factor ($\lambda$) and effective length ($L$, in meters) of the catheter. During aspiration, the effective catheter length is equal to the real catheter length; during ejection effective length is less, because the outlet valves are positioned 5 cm from the tip. The flow
resistance factor $\lambda$ is a dimensionless coefficient of friction that relates pressure gradient and mean blood velocity and depends on the Reynolds number ($Re$, dimensionless):

$$Re = \frac{\nu d}{\eta}$$

in which $\nu$ is the mean blood velocity in the cross section area of the catheter. We assume the flow in the catheter to be turbulent with $Re$ in the range of 4,000-100,000 and the inner wall of the catheter to be smooth. In that case, $\lambda$ can be calculated by:

$$\lambda = 0.096 - [0.0157 \times \log_{10}(Re)]$$

Flow resistances caused by the valves ($K_v$)

These values have been determined experimentally. In a valved catheter pressure difference $\Delta P_v$ over the valve system was measured at a flow of 3.0 L/min. $K_v$ was calculated by:

$$K_v = \frac{\Delta P}{0.5 \nu^2}$$

Mean flow resistance during aspiration appeared to be 3.0, during ejection 3.2.

Flow resistances caused by diameter changes ($K_c$) from membrane pump to catheter

Applying the examples, given in Prandtl et al. $^8$, we found that during aspiration $K_c = 1.0$ and during ejection $K_c = 0.5$.

Pump stroke volume

The stroke volume ($s$) is derived from the pump frequency ($f$) and the required flow ($Q$):

$$s = \frac{Q}{f}$$

The stroke volume must be larger than the volume of the catheter:

$$s > \frac{\pi d^2 L}{4}$$
otherwise most of the blood will be pumped from catheter to membrane pump without ever leaving the pump system.

**Pressure in the left ventricle and aorta**

The pulsatile nature of pressure was not considered. Only mean left ventricular and aortic pressures (during systole and diastole) from a patient in cardiogenic shock were implemented: mean aortic pressure was put at 62.5 mm Hg, and mean left ventricular pressure was put at 37.5 mm Hg.

An optimal driving mode was developed to realize a maximal blood flow by the PUCA pump with minimal driving pressures. Time for changing blood flow from aspiration to ejection should be kept to a minimum. The time loss is determined by the acceleration (change of velocity in time), meaning the higher the acceleration, the lower the loss of time. However, acceleration has been limited to 150 m/s² to make it possible to design a driver with reasonable dimensions. Having this restriction, time loss has been kept to a minimum by always applying the maximum acceleration (positive or negative), resulting in a block form acceleration curve (alternately a constant maximum positive and negative acceleration).

The model calculates the following output parameters:

- How long should the acceleration (\(a\)) be at its maximum to obtain a complete stroke of the membrane pump (full fill, full eject)?
- The velocity profile (\(v\)) was obtained by integrating the acceleration profile.
- The volume of the membrane pump, filled with blood, was calculated by integrating the mean blood velocity, multiplied by the cross section area of the catheter.
- The pressure on the membrane pump, necessary to pump the blood with the calculated velocity profile, was calculated using the modified Bernoulli equation:

\[
\Delta P = P_1 + \rho a L + \frac{1}{2} \rho v^2 \left( \frac{L}{d} + K_v + K_s \right)
\]

with: \(\Delta P\) = pressure difference between pump and catheter inlet or outlet
\(P_1\) = mean aortic or (negative) left ventricular pressure.

- The maximum shear stress (\(\tau\)) in the catheter was calculated by:

\[
\tau = \frac{\Delta P_c d}{4L}
\]

with: \(\Delta P_c\) = pressure drop over the catheter (\(\frac{\sqrt{2} \rho v^2 \lambda L}{d}\)).
**PUCA pump configurations**

Two kinds of configurations have been analyzed:

- **Configuration A** will be inserted directly into the aorta; catheter length is 0.4 m, aimed flow is 5 L/min, and the stroke volume of the membrane pump is 100 cc.
- **Configuration B** will be inserted in the axillary artery; catheter length is 0.4 m, aimed flow is 3 L/min, stroke volume of the membrane pump is 60 cc.

Because the PUCA-pump functioning will be controlled by the ECG signal, there will be a large variation in pump frequencies (50-240 bpm). However, pump frequencies should be limited to prevent high driving pressures. To avoid clotting, pump frequency must be higher than 50 bpm. To keep pump frequencies within reasonable limits (50-100 bpm), it was decided to use different synchronisation ratio’s (Table 1). The two most extreme frequencies (100 and 50 bpm) were applied in the analysis.

<table>
<thead>
<tr>
<th>Heart rate (bpm)</th>
<th>Synchronisation ratio (pump : heart)</th>
<th>Pump frequency (bpm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>50-100</td>
<td>1:1</td>
<td>50-100</td>
</tr>
<tr>
<td>100-150</td>
<td>2:1</td>
<td>50-75</td>
</tr>
<tr>
<td>150-240</td>
<td>3:1</td>
<td>50-80</td>
</tr>
</tbody>
</table>

Table 1. Synchronisation ratio and pump frequency as function of heart rate.

**Analysis method**

To determine the minimal internal diameter of the catheter for a PUCA-pump configuration, defined by stroke volume, pump frequency, required flow, and catheter length, several internal catheter diameters were tried in steps of 0.05 mm. The minimal catheter diameter is the smallest diameter that fulfills the following requirements:

- shear stress for long residence times (>2 msec) remains below 150 Pa\(^9\) to limit mechanical blood damage.
- negative driving pressure does not exceed -460 mm Hg to limit mechanical blood damage\(^10\)
- high positive pressure will hardly cause blood damage\(^11\)
- positive driving pressure remains below 760 mm Hg to prevent pump damage, caused by mechanical forces.

For the minimal catheter diameter, the numerical model calculates driving pressure and shear stress.
Validation of the numerical model

Two PUCA-pump configurations were tested in a container filled with water. Both arterial and left ventricular pressure were kept at 0 mm Hg. Both configurations consisted of a 60 cc membrane pump, driven by an electrohydraulic driver. Pressure was measured with Uniflow pressure transducer (Baxter, Deerfield, USA) at the connection between catheter and membrane pump. Flow in the catheter was measured by an Scalar electromagnetic flowmeter (Scalar Medical, Delft, The Netherlands).

- **Configuration C** had a valveless catheter with a length of 0.4 m and an internal diameter of 8.0 mm. Frequency was set at 75 and 50 bpm, stroke volume was set at 45.0 and 55.0 ml, respectively, resulting in flows of 3.4 and 2.75 L/min.
- **Configuration D** had a valveless catheter with a length of 1.0 m and an internal diameter of 6.0 mm. The frequency was set at 75 and 50 bpm, stroke volume was set at 26.7 and 60.0 ml, respectively, resulting in flows of 2.0 and 3.0 L/min.

So in total 4 situations were tested. All situations were simulated as well. Instead of the velocity profile, derived from the block-type acceleration profile of the simulation model, the measured velocity profile from the electrohydraulic driver was used as starting point for the simulation. To what extent similarity exists between stroke volume and pressure profiles calculated by numerical simulation and stroke volume and pressure profiles measured in-vitro, determines the validity of the simulation model.

Patient hemodynamics

The influence of patient hemodynamics on the driving pressures of configuration A was investigated by varying the mean aortic and left ventricular pressure between 75 and 125% of the basic values.

Optimization

Optimizing the performance of the PUCA pump is possible by changing the dimensions of the catheter. However, this will have consequences for the ways of introducing the catheter into the body. The wider the catheter, the less chance for introduction into the axillary access exists. Normal access is assumed to be limited to 6 mm, but in case of a congenital disease or arteriosclerosis access is more restricted. A better way of optimizing the PUCA pump performance could be a decrease of flow resistance of the catheter. To check the effectiveness of this measure, valve resistance was decreased by 25%, and the resulting driving pressures for configuration A were calculated by the simulation model.
Chapter 3

Results

By varying the internal diameter of configuration A and B, the optimal internal diameters have been found (Fig. 2). It appeared that catheter configuration A must have an internal diameter of at least 6.95 mm to be safe in use, and catheter configuration B must have an internal diameter of at least 5.50 mm.

The characteristics in time of configuration A, driven with 100 bpm, are presented in Fig. 3. All other simulations resulted in comparable graphs.

Table 2 summarizes maximum positive and negative driving pressure and maximum shear stress of all four simulated situations when ignoring the short-duration pressure peaks.

<table>
<thead>
<tr>
<th>Configuration</th>
<th>Frequency (bpm)</th>
<th>Shear stress (Pa)</th>
<th>Positive pressure (mm Hg)</th>
<th>Negative pressure (mm Hg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>50</td>
<td>114</td>
<td>620</td>
<td>-395</td>
</tr>
<tr>
<td>A</td>
<td>100</td>
<td>133</td>
<td>718</td>
<td>-444</td>
</tr>
<tr>
<td>B</td>
<td>50</td>
<td>110</td>
<td>624</td>
<td>-402</td>
</tr>
<tr>
<td>B</td>
<td>100</td>
<td>127</td>
<td>716</td>
<td>-448</td>
</tr>
</tbody>
</table>

Table 2. Maximum driving pressures and shear stress in configuration A and B, predicted by the simulation model for pump frequencies of 50 and 100 bpm.

Results of numerical simulation and in vitro validation measurements of configurations C and D are presented in Figs. 4-7 and Table 3.

The influence of patient hemodynamics on the functioning of the pump appeared to be minor. Varying the left ventricular and aortic pressure between 75 and 125% of the basic values resulted in a maximum change of the driving pressure of only 2.2%. Decreasing the flow resistance of the inlet and outlet valves by 25% resulted in a decrease of the positive driving pressure by 13.1% and a decrease in magnitude of the negative driving pressure by 13.7%.
Fig. 2. The influence of the internal catheter diameter on driving pressure and shear stress, calculated for configuration A and B. The dotted horizontal lines represent the limits.
Fig. 3. The performance of catheter configuration A, predicted by the simulation model, is shown. Specifications: internal catheter diameter 6.95 mm; length 0.4 m; pump frequency 100 bpm; stroke volume 50 ml; systole 46%; resulting flow 5.0 L/min. In the upper graph, mean blood velocity and volume of the membrane pump filled with blood are shown as a function of time. In the lower graph, the necessary pump pressure (p_membrane) and blood shear stress are shown in time.
Fig. 4. The results of the validation study with configuration C are presented. Specifications: internal catheter diameter 8 mm; length 0.4 m; pump frequency 50 bpm; systole 50%; resulting flow 2.75 L/min. In the upper graph, mean blood velocity and volume of the membrane pump filled with blood are shown as a function of time. In the lower graph, calculated necessary blood pressure ($p_{\text{predicted}}$) and measured blood pressure ($p_{\text{measured}}$) are shown in time.
Fig. 5. The results of the validation study with configuration C are presented. Specifications: internal catheter diameter 8 mm; length 0.4 m; pump frequency 75 bpm; systole 50%; resulting flow 3.4 L/min. In the upper graph, mean blood velocity and volume of the membrane pump filled with blood are shown as a function of time. In the lower graph, calculated necessary blood pressure (p_predicted) and measured blood pressure (p_measured) are shown in time.
Fig. 6. The results of the validation study with configuration D are presented. Specifications: internal catheter diameter 6 mm; length 1.0 m; pump frequency 50 bpm; systole 50%; resulting flow 3.0 L/min. In the upper graph, mean blood velocity and volume of the membrane pump filled with blood are shown as a function of time. In the lower graph, calculated necessary blood pressure ($p_{predicted}$) and measured blood pressure ($p_{measured}$) are shown in time.
Fig. 7. The results of the validation study with configuration D are presented. Specifications: internal catheter diameter 6 mm; length 1.0 m; pump frequency 75 bpm; systole 50%; resulting flow 2.0 L/min. In the upper graph, mean blood velocity and volume of the membrane pump filled with blood are shown as a function of time. In the lower graph, calculated necessary blood pressure ($p_{predicted}$) and measured blood pressure ($p_{measured}$) are shown in time.
Numerical simulation

<table>
<thead>
<tr>
<th>Configuration</th>
<th>Frequency (bpm)</th>
<th>Stroke volume (ml)</th>
<th>Error (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>C</td>
<td>50</td>
<td>55.0</td>
<td>0.0</td>
</tr>
<tr>
<td>C</td>
<td>75</td>
<td>45.0</td>
<td>0.7</td>
</tr>
<tr>
<td>D</td>
<td>50</td>
<td>60.0</td>
<td>1.2</td>
</tr>
<tr>
<td>D</td>
<td>75</td>
<td>26.7</td>
<td>0.4</td>
</tr>
</tbody>
</table>

Table 3. Stroke volumes of two PUCA pump configurations, C and D, predicted by the simulation model and realized during the in-vitro tests.

Discussion

Potential advantages of the PUCA pump are its fast application and minimal vascular surgery, leaving the left ventricle intact. In case of an infarct, fast intervention will limit ventricular damage. The need for stand-by surgical support during high-risk cardiologic interventions will be reduced. The period of hospitalizing a patient might be reduced also due to the simple surgical procedure. Another potential advantage is the pulsatile nature of the flow, which appears to be advantageous over non-pulsatile flow\(^\text{12-14}\).

In the design process, numerical models will be used to find the optimal parameter values. The numerical tool, described in this study, simulates the hydraulic behavior of the PUCA-pump. With this model, it should be possible to find for each application the minimal internal diameter of the catheter that prevents red blood cell damage and membrane pump damage. The numerical model avoids a further development by trial and error that necessitates building several prototypes with different internal diameters and testing them.

Each numerical model, however, is a simplification of reality. In this model, flow was considered to be Newtonian and turbulent. The considered catheter diameters and velocities justify blood to be treated as a Newtonian fluid\(^\text{15}\). The flow profiles in the considered catheters show a turbulent behavior, because most of the time the Reynolds number is (far) above 2,300.

Another simplification concerns the elasticity of catheter and membrane pump. Both components are considered to be completely rigid whereas in reality they show elastic behavior. As a consequence, pressure profiles will not have high peaks in reality. Another consequence of this phenomenon is that strongly negative \(dP/dt\)-values, which could cause cavitation\(^\text{16,17}\), will not occur. These negative \(dP/dt\)-values could occur especially at valve closure, but the flexibility and (limited) leakage of the valves will prevent this.
Patient hemodynamics have not been implemented in great detail in this numerical simulation model. Only mean aortic and left ventricular pressure have been taken into account. Because these pressures are small when compared to the driving pressures, influence of patient hemodynamics on the calculated driving pressure profile appears to be minor, so a more detailed description can be refrained. The interaction with the circulatory system will be studied in detail later: a numerical model of the circulation will be coupled with the numerical model of the PUCA-pump, described in this article.

In spite of these simplifications, the simulation model is able to predict the PUCA-pump behavior. The results from the validation study show a good prediction of the stroke volume (Table 3).

Pressure profiles in general show a good resemblance. Some discrepancies have been found:

When the membrane pump is almost emptied and the blood is accelerated, predicted pressure falls sooner than the measured pressure. Also, the simulated pressure reaches more negative values than the measured one. These phenomena appear in all Figs. 4-7. Air in the hydraulic part of the electrohydraulic driver is most probably the reason for these phenomena. In Fig. 7 these phenomena appear also during pressure rise.

When the blood acceleration phase during aspiration is finished and blood velocity becomes constant, pressure becomes constant too. Measured pressure shows more oscillations around the constant level than simulated pressure, which again could be caused by air in the electrohydraulic driver. In Fig. 4 this phenomenon appears most prominent. In Figs. 6 and 7 in which blood velocity does not have a constant phase, measured and simulated pressure are more equal. During ejection this difference has not been found because of absence of a constant phase at higher pump frequencies.

In Fig. 4 there appears to be a difference in level of the constant pressure phase between simulated and measured pressure. We do not have a solid explanation for it.

The minimum catheter diameters that have been calculated show that the anticipated applications can be realized. Having in mind that production of catheters with a 0.25 mm wall thickness is presently possible, a catheter with internal diameter of 5.5 mm has an external diameter of 6 mm and thus can for most patients be introduced in the anticipated introduction place, the axillary artery.
A further improvement of the PUCA-pump performance appeared to be possible by decreasing the flow resistance of the valves and by smoothing diameter changes. When considering the pressure losses in the numerical simulation of catheter configuration A, the pressure losses of the valves appeared to be twice as high as from the catheter itself. New valve designs are under construction to decrease pressure losses. As a result, smaller catheters can be applied. The other anticipated introduction place, directly into the aorta, can be realized as well; the calculated minimal internal catheter diameter (6.95 mm) will result in an external diameter of 7.5 mm. This moderate dimension will allow easy access to the aorta.

Fig. 3 shows that apart from short-duration pressure peaks, maximum positive- and negative-driving pressure do not exceed the limits. These pressure peaks can easily be avoided by adapting the block wave acceleration curve: a less abrupt change between maximum positive or negative acceleration and zero acceleration will suffice. In practice, less abrupt changes will occur automatically because a block form acceleration curve is difficult to realize because of inertia effects. Shear stress values also remain within the limit. The maximum time exposure of blood to the wall shear stress in both configurations A and B is 0.09 sec. Because blood residence time for the described applications is > 60 msec, the described limit was valid. So hemolysis is not likely to occur. However, it remains uncertain, to what extent hemolysis will originate from the valves and catheter inlet. In vitro experiments will be performed to clarify this.

It is not possible to use only one pressure profile to drive the membrane pump. For each catheter configuration and for each pump frequency, a different pressure profile (in case of a pneumatic driver) or velocity profile (in case of a hydraulic driver) must be applied.

Conclusions

With the numerical simulation model, described in this study, the hydraulic functioning of the PUCA-pump can be predicted for each type of configuration. The validation study showed, that the numerical model is able to predict the behavior of the PUCA-pump accurately.

When the PUCA pump is introduced into the axillary artery, a catheter with an internal diameter of at least 5.5 mm must be used to realize a flow of 3 L/min without pump or blood damage. If the PUCA-pump is introduced directly into the aorta, a catheter with an internal diameter of at least 7.0 mm must be used to realize a flow of 5 L/min without pump or blood damage. The amount of blood damage caused by mechanical forces will be reduced because the driving pressure and shear stress are limited.
Several pressure or velocity profiles, depending on catheter configuration and heart frequency, are necessary to obtain an efficient driving system. The influence of patient hemodynamics on the necessary driving pressures is only minor, so mean values can be used. The influence of the flow resistance of the valves is more distinct. Decreasing the flow resistance is an effective way to improve PUCA-pump performance.

A numerical simulation model is a very useful instrument to get an impression about the functioning of a left ventricular assist device. With a simulation model, building several prototypes and testing them on their flow behavior can be avoided, saving money, time, and animals.

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References


