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Modeling And Control Of An Extracorporeal Heart Assist Device

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Abstract:
Heart assist devices provide mechanical circulatory support for patients with end-stage heart failure. Extracorporeal heart assist devices are applied to adult and pediatric patients in the case of uni- and biventricular assistance. Modern driving units provide more mobility what is an immense benefit to the quality of life of the patients. The treated heart assist device in this article is the EXCOR system (Berlin Heart GmbH, Germany). This device is pneumatically operated by a piston drive. Pump assistance for the native heart of the patient should be provided by an automatic control system. This could be achieved by the control of the piston movement and the enclosed air mass in the pneumatic system. The model based design of a control system for the extracorporeal assist device is described in this paper.

1. INTRODUCTION

Terminal heart failure deceases is one major cause of death in the industrialized countries. The pump output of the native heart is reduced. This could be caused for example by infects or genetic defects. In end-stage the only available treatment option is a heart transplantation or the mechanical circulatory support by an assist device. Heart assist devices can be divided into three main categories. Intracorporeal systems are characterized by an implanted artificial blood pump. Examples are the Heart Mate II® (Thoratec, Pleasanton, USA), the HeartWare Ventricular Assist System® (Heart Ware, Framingham, USA) or the INCOR System® (Berlin Heart GmbH, Berlin, Germany). Extracorporeal devices are nowadays used in special heart decease situations and especially for pediatrics. Here the artificial blood pump is placed outside of the body. Available systems are for example the Thoratec PVAD® (Thoratec, Pleasanton, USA) or the EXCOR® VAD (Berlin Heart GmbH, Berlin, Germany). The third category contains total artificial hearts. In that case the heart is replaced completely by an artificial heart. An example is the Aachen Total Artificial Heart ReinHeart (Helmholtz Institute of RWTH Aachen University & Hospital, Aachen, Germany). For intracorporeal and extracorporeal systems uni- and bi-ventricular heart support is possible, depending of the patient needs. This contribution deals with an extracorporeal heart assist device. The operating principle differs significantly between the varying kinds of heart assist devices. Also within the category of extracorporeal systems there are several types of devices. They differ by the available measurements and the driving concepts. Control approaches are not well known from published literature. The modeling process of the addressed system in this paper was presented in detail in [4]. A first presentation of the idea of a control system for the EXCOR heart assist system was published in [5, 6]. This paper should give a detailed overview of the developed control system for a extracorporeal heart assist device. Finally, results of the control of pump assistance are presented.

2. THE HEART ASSIST DEVICE

This contribution deals with the control of an extracorporeal ventricular assist system. A short description of the system is given in this section. Furthermore the control goal is defined.

System Description And Functionality Fig. 1 gives an overview over treated heart assist system. The EXCOR pump is operated by a battery powered, mobile driving unit. Mobility greatly improves the quality of life of the ventricular assist device (VAD) recipients [1]. An external pump is the main component of an extracorporeal heart assist system. It is connected to the natural heart of the patient via two cannulas. The inlet cannula is mostly coupled to the ventricle. Other options are a cannulization of the atrium or a direct connection to the pulmonary vein. The outlet cannula is connected to the aorta. Artificial valves at the accesses of the artificial blood pump constrain the possible flow direction. To separate the blood of the patient from the environment a flexible membrane is placed inside the blood pump. This membrane also couples the pressure in the blood chamber to the driving pressure in the pneumatic system. The pneumatic part of the VAD consists of the air chamber of the artificial blood pump, an air tube and a pneumatic piston drive chamber. A piston drive is used to generate the necessary pneumatic pressure to operate the system. The piston position can be controlled by a settable motor torque. Additionally a

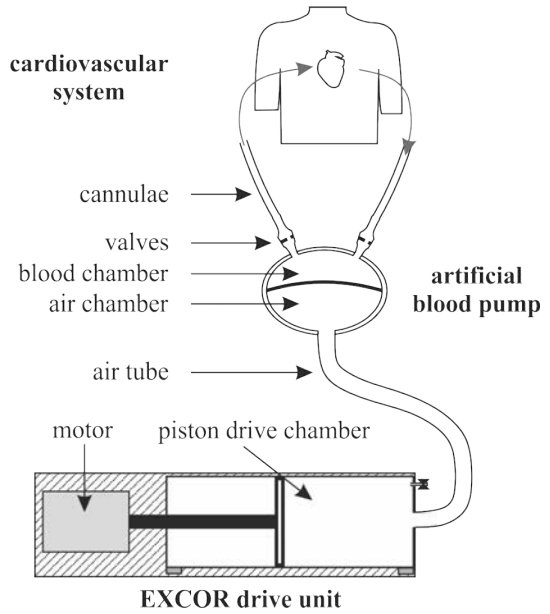

Fig. 1. Shematic representation of the treated VAD: EXCOR VAD (Berlin Heart GmbH, Berlin, Germany)

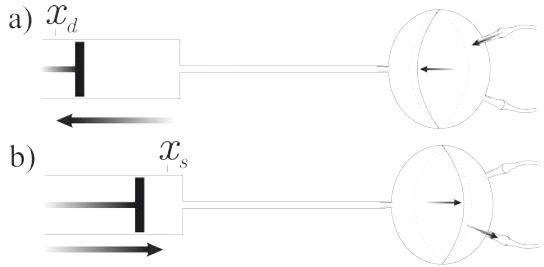

Fig. 2. Schematic of diastolic (a) and systolic (b) phase of the pump process of the EXCOR system

controllable balancing valve is present. This valve can be used to adjust the air mass in the pneumatic system.

The operation of the extracorporeal heart assist device can be divided into two phases. The diastole corresponds to the filling phase. Fig. 2 a) shows the piston movement towards the diastolic reversal point x_d. This movement expands the volume in the pneumatic system. As a result the pressure in the pneumatic system decreases. The pressure in the blood chamber is directly coupled to the pneumatic pressure by the flexible membrane. Due to the pressure gradient between the blood chamber and the cannulated heart (about 10 mmHg) a blood flow accrues into the artificial pump. The membrane has a specified hydraulic capacity according to the applied pump size. An overstretching of the membrane should be avoided after a complete filling is achieved. This would increase the power consumption of the system and decrease battery life time significantly. After the diastole the piston movement direction reverses and systole begins. Fig. 2 b) shows the piston movement to the systolic reversal point x_s. In this phase the volume decreases and the pressure increases. As a consequence the inlet valve closes. When the pressure in the blood chamber exceeds the pressure of the aorta (about 100 mmHg) the outlet valve opens. The obtained blood is pumped into the circulation system of the patient. The diastolic and systolic phase repeat cyclical with the given pump frequency.

Control Objective A heart assist system takes over the functionality of the human heart. All organs need a sufficient supply with nutrients and oxygen. For a sane patient the demand of cardiac output is not constant over the day. It depends on the physical load or stress conditions of the patient. A perfect control of a VAD should include these demands. The problem from the technical view is the availability of reliable measurements of physiological states which represent the actual load condition of the patient. Due to this reason the control goal for current heart assist devices is to keep up a desired cardiac output. This value is parameterized by a cardiologist and represents an estimated mean demand of cardiac output. The cardiac output for a pulsatile working extracorporeal heart assist system is the product of applied pump size and pump frequency. The pump size is fixed. The cardiologist parameterizes the pump frequency. The control goal is defined by the task to achieve a complete filling end depletion of the artificial blood pump. The control is performed once within a pump cycle.

3. MODELING

The developed model should be the basic for the controller synthesis. A model based controller design leads in most cases to a better control accuracy than empirical designs [2]. Therefore a lumped parameter model structure was chosen. The essential characteristic effects of the system should be reproduced to obtain comprehension of the system behavior. Models of different orders were analyzed. One of the developed models with a system order of nine offers sufficient model accuracy. This model should be described in the following.

$$\dot{v} = \frac{\mu}{2 \cdot \pi \cdot J}(M_m - M_f(v) - M_p(p_p)) \tag{1}$$

$$\dot{x} = v \tag{2}$$

$$\dot{p}_p = \frac{(\dot{m}_v(p_p) + \dot{m}(p_p, p_{ac})) \cdot R \cdot T - A \cdot v \cdot p_p}{V_{d_{p_p}} + A \cdot x} \tag{3}$$

$$\dot{p}_{ac} = \frac{-\dot{m}(p_p, p_{ac}) \cdot R \cdot T + (Q_a - Q_v) \cdot p_{ac}}{V_{d_{p_{ac}}} + V_{bc}} \tag{4}$$

$$\dot{V}_{bc} = Q_v - Q_a \tag{5}$$

$$\dot{Q}_a = \frac{f_m(p_{ac}, V_{bc}) - p_a - R_a(Q_a) \cdot Q_a}{L_a} \tag{6}$$

$$\dot{Q}_v = \frac{p_v - f_m(p_{ac}, V_{bc}) - R_v(Q_v) \cdot Q_v}{L_v} \tag{7}$$

$$\dot{p}_a = f_{artcirc}(Q_a, p_a, p_v) \tag{8}$$

$$\dot{p}_v = f_{vencirc}(Q_a, p_a, p_v) \tag{9}$$

Equations 1 and 2 describe the electro-mechanical component of the heart assist device. The dynamic relation between the controllable motor torque M_m and a resulting piston velocity v and piston position x is modeled. Drive specific constants are the spindle pitch μ and the moment of inertia J. The term $M_f(v)$ is a friction based counter moment. This moment includes the static and kinetic friction. Another moment component is the pressure moment $M_p(p_p)$. The pneumatic pressure p_p onto the piston surface

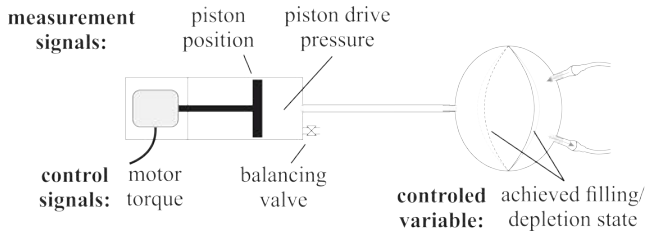

Fig. 3. Shematic of the system from a control point of view

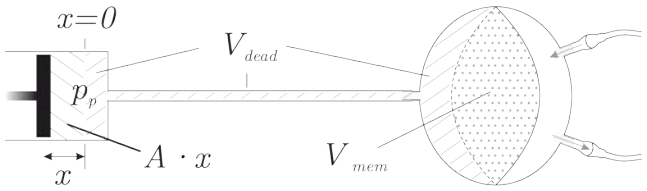

Fig. 4. Shematic of the relevant process values for the estimation equation of the blood flow

generates a force during the pump cycle.
Equations 3 and 4 model the pneumatic components of the system. This contains the piston drive chamber, the air tube and the air chamber of the artificial blood pump. The pressure in the piston drive p_p and in the air chamber p_{ac} is modeled under the assumption of the common gas equation for an isothermal process. The connecting air tube is described by its pneumatic resistance. The pneumatic resistance determines the air mass flow function $\dot{m}(p_p, p_{ac})$ between the piston drive and the pump. An additional term for the air mass flow against the environment $\dot{m}_v(p_p)$ is defined by the pneumatic resistance of the controllable balancing valve. The constants R and T in equations 3 and 4 represent the universal gas constant and the ambient temperature. Pneumatic dead volumes $V_{d_{p_p}}$ and $V_{d_{p_{ac}}}$ are given by the design of the piston drive and the artificial blood pump. A volume change in the piston drive is given by the product of piston movement v and the piston surface A. In the hydraulic blood chamber of the artificial pump a volume change $\dot{V}_{bc}$ is defined by the incoming, venous blood flow Q_v and the outgoing, arterial blood flow Q_a. The pressure drop across the flexible membrane is modeled by the function $f_m(p_{ac}, V_{bc})$. The flow through the cannulas is characterized by its hydraulic flow resistance $R_a(Q_a)$, $R_v(Q_v)$ and the hydraulic inductance L_a, L_v. A severe simplified circulatory replacement model $f_{artcirc}, f_{vencirc}$ was used to describe the arterial and venous pressure p_a, p_v of the human circulatory system. Several parameters of the introduced model are determined by physical properties of the EXCOR system. The remaining parameters were determined by experiments and suitable fitting procedures. More details about the modelling process are given in [4].

4. CONTROL SYSTEM

In this section the developed control system will be presented. At first an analysis from the control point of view is performed. After that an approach for a model based estimation of the control variable is given. Finally the basic control strategy is explained.

Fig. 3 shows an overview of the appreciable values of the control system. The available measurement variables of the treated heart assist device are the piston position x and the piston drive pressure p_p. Due to reliability there is no further sensor information in the artificial blood pump. There are two control signals in the EXCOR VAD. A motor torque can be applied to the electro-mechanical piston drive. Furthermore a balancing valve can be opened or closed to compensate the enclosed air mass in the pneumatic system. The controlled variable is the achieved pump filling and depletion state from one pump cycle to the next one.

4.1 Estimation For Control Feedback Application

No direct measurement for a control loop feedback is available. An estimation equation was developed to determine the achieved filling and depletion state of the last pump cycle. The benefit of the prediction of the blood flow against pure pressure-based algorithms [3] are better possibilities for the adaptation to the circulatory afterload of the patient. The estimation is based on the assumption of the ideal gas law. The pneumatic system of the VAD is supposed to be an isothermal process. This leads to the description for the pneumatic system consisting of the piston drive chamber, the air tube and the air chamber of the pump with

$$\dot{p}_p = \frac{\dot{m} \cdot R \cdot T - p_p \cdot \dot{V}_{pneumatic}}{V_{pneumatic}}. \tag{10}$$

Fig. 4 illustrates the composition of the pneumatic volume $V_{pneumatic}$ with the equation

$$V_{pneumatic} = V_{dead} + V_{membrane} + A \cdot x. \tag{11}$$

A constant pneumatic volume is defined as a dead volume of the piston drive chamber $V_{d_{pac}}$, the air tube V_{at} and a dead volume of the air chamber of the artificial blood pump $V_{d_{pac}}$

$$V_{dead} = V_{d_{pac}} + V_{at} + V_{d_{pac}}. \tag{12}$$

Two other parts of the pneumatic volume change over the time. The first one is the volume defined by the actual piston position x and the surface area of the piston A. The second volume is represented by the actual membrane volume $V_{membrane}$. Based on this assumptions the dynamic volume gradient $\dot{V}_{pneumatic}$ is defined as

$$\dot{V}_{pneumatic} = A \cdot \dot{x} + \dot{V}_{membrane}. \tag{13}$$

The air chamber and the blood chamber are directly coupled by the membrane. Blood is assumed to be an incompressible fluid for the relevant pressure range. So a movement of the membrane $\dot{V}_{membrane}$ is equal to a blood flow Q in or out of the blood chamber

$$\dot{V}_{membrane} = Q. \tag{14}$$

The application of the stated definitions to equation 10 leads to the estimation equation

$$Q = \frac{\dot{m} \cdot R \cdot T}{p_p} - \frac{\dot{p}_p \cdot \left(A \cdot x + V_{dead} + \int Q dt\right)}{p_p} - A \cdot \dot{x} \quad (15)$$

for the flow Q in and out of the artificial blood pump.

The term $\dot{m}$ is defined as an air mass flow through the controllable balancing valve. R is the universal gas constant and T is the ambient temperature. The resulting estimation equation 15 delivers a value which can be used for control feedback. This value can be calculated from the available measurements and from known constant parameters. For control application the reached filling state after the diastolic phase V_d and systolic phase V_s of each pump cycle is needed. So these values are calculated additionally from the estimation equation 15.

4.2 Control Principle

The basic idea of the developed control system should be presented at first. As a reminder that the goal is to achieve a cyclic filling and depletion of the artificial blood pump. This is realized by a cyclic, alternating pressure between over-pressure and below atmospheric pressure. The pressure is generated by a piston drive. Therefore also a cyclic piston movement is required.

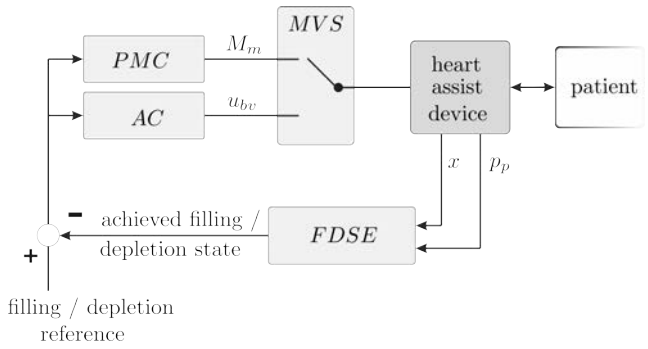

Fig. 5. Shematic of the control principle

The developed control approach is outlined in Fig. 5. So the control task is separated into two control circuits. The first loop contains the piston movement controller PMC. A control of the cyclic piston movement is implemented here. The second loop regulates the enclosed air mass in the pneumatic system by an airmass controller AC. As a result each available control signal is associated to one control loop. The motor torque M_m is used to control the piston movement. The balancing valve u_{bv} is used to control the air mass. A control action is performed once within a pump cycle. The introduced two control loops are used exclusively from each other. A manipulated variable selector MVS was developed to choose the suitable control loop. This decision is based on the estimated achieved pump filling and depletion state of the last pump cycle. This values are derived by the filling/ depletion state estimator $FDSE$ from the estimation of the flow Q introduced in section 4.1.

4.3 The Piston Movement Controller

The piston movement controller PMC has the task to control the piston in such a way that a cyclic filling and

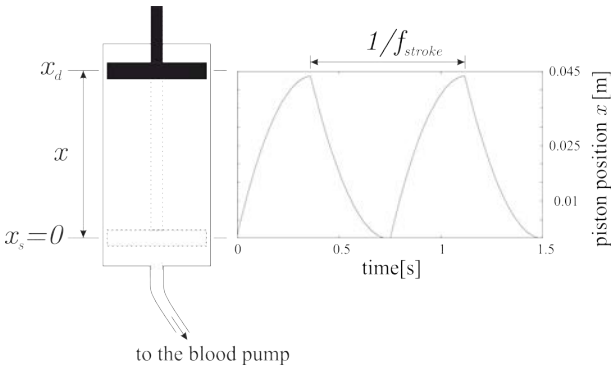

Fig. 6. Schematic of the piston movement to achieve cyclic pumping

depletion of the pump can be achieved. The process is time variant since parameters like friction, flow resistances or the patient itself change in wide range over the time. Due to this, the movement between the diastolic reversal point x_d and the systolic reversal point x_s is controlled with a fixed trajectory shape. The chosen trajectory is shown in Fig. 6. An offline model based optimization lead to a cubic shape for best control results. The optimization loss function was defined under technical and medical constraints. The loss function contains:

- energy consumption
- mechanical wear
- cavitation in the blood
- shear strain in the blood

As shown in Fig. 6 the piston movement is defined by the trajectory shape, the amplitude and the time scale. The systolic reversal point x_s is fixed to zero. Thus the amplitude of the piston movement is defined by the value of the diastolic reversal point x_d. The time scale is defined by the parameterized pump frequency $1/f_{stroke}$. f_{stroke} is determined by a cardiologist offline.
The control of the pump process by the piston movement is reduced to one process variable. Instead of controlling the whole trajectory dynamically, only the diastolic reversal point must be controlled. This scales the trajectory and the piston movement can be adapted to the pump process.
In section 4.1 the estimation equation to determine the achieved filling state $V_d(k)$ and depletion state $V_s(k)$ was introduced. These values are calculated once within a pump cycle. So the control of the piston movement is also done once within a cycle. At the beginning of each diastole the diastolic reversal point is controlled by

$$\begin{aligned} x_d(k+1) = & x_d(k) + K_{stroke} \cdot ((V_d(k) - V_{dref}) \\ & + (V_s(k) - V_{sref})). \end{aligned} \quad (16)$$

The controller parameter K_{stroke} is pump size specific and determined by simulation tests. The reference values V_{sref} and V_{dref} are defined by the physical properties of the used artificial pump. As a result the piston position trajectory is generated once a cycle after the control of the diastolic reversal point.

Because the available control signal is a motor torque and not the piston position, an underlying piston position

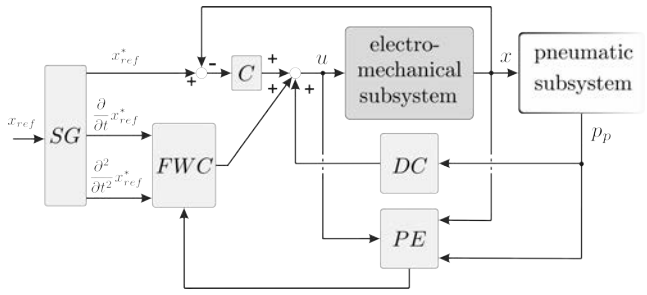

Fig. 7. Schematic of the piston position controller

controller was developed. Its task is to control the piston position as exactly as possible to realize the calculated trajectory. This part of the process was described in section 3 by equations 1 and 2. Fig. 7 gives an overview over the structure of the developed controller. It consist of a non-linear feed-forward controller FWC, a linear feedback controller C, a disturbance compensation DC, a signal generator SG and a parameter estimator PE. The disturbance compensation DC uses the available measurement of the piston drive pressure p_p to compensate the moment caused by the pressure on the piston. A feed-forward controller FWC controls the friction and the acceleration of the piston based on the given reference trajectory and its gradients. This references are generated by the signal generator SG. The used friction function is adapted by the parameter estimation PE by the equation

$$M_f(v) = -\frac{2 \cdot \pi \cdot J}{\mu} \cdot \dot{v} + M_m - M_p(p_p). \tag{17}$$

So the corresponding friction moment $M_f(v)$ to the actual piston velocity v can be calculated online from the measurements. The piston is accelerated cyclical up to the maximum necessary piston velocity. So a complete nonlinear friction function can be determined during the term of operation. To avoid problems of the dynamic coupling of the adapted open-loop control and the closed-loop controller a filter and validation step is integrated into the parameter estimation. Results of the introduced piston position controller are given in section 5.1.

4.4 The Air Mass Controller

The air mass controller has to compensate pneumatic leakages during the pump process. Furthermore the enclosed air mass must be synchronized with the piston movement. This synchronization leads to an equal filling and depletion state for the actual piston stroke. The control of the air mass follows heuristic motivated rules. For example, if after a pump cycle the artificial pump was filled completely but the depletion was incomplete, the air mass in the pneumatic system was too low. The other way round a too high air mass leads to a incomplete filling and a full depletion. The resulting control equation is given by

$$\begin{aligned} m_c(k+1) =& K_{air} \cdot ((V_d(k) - V_{dref}) \\ & - (V_s(k) - V_{sref})) \end{aligned} \tag{18}$$

where K_{air} is determined by simulation tests.

As a reminder the existing manipulating variable beside the motor torque is a balancing valve. This valve can be opened or closed by the control system. Thus the controller output $m_c(k+1)$ can not be directly applicated to the balancing valve. Furthermore the compensation of air mass can only be done passively against the environmental pressure p_e. If the controller output $m_c(k+1)$ is negative a defined amount of air mass must be released to the environmental air. That is only possible during the systolic phase because the piston drive pressure p_p exceeds the environmental pressure. An opening of the valve in the diastolic phase is performed if additional air mass in the pneumatic system is required. The valve is kept opened until an estimated air mass compensation m_e is equal to the controller output $m_c(k+1)$. The estimation of the achieved compensated air mass is done by

$$m_e = \int_{t(open)}^{t(close)} \sqrt{\frac{p_p - p_e}{R_{valve}}}\, \mathrm{d}t. \tag{19}$$

Experiments were performed to determine the parameter R_{valve}.

5. RESULTS

The results of the developed control system are presented in this section. At first the quality of the piston position controller is shown. Finally the control output of the pump depletion state is presented.

5.1 Control Results Of The Piston Movement

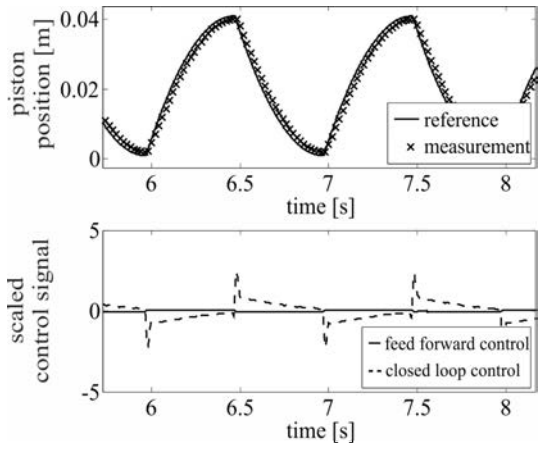

Fig. 8. Piston position control results immediate after power on

The control approach is based on a cyclic piston movement with a given trajectory. Therefore a good control performance must be achieved for the piston position. An adaptive control approach was implemented. Fig. 8 shows the control performance immediate after the power on of the system. The upper plot shows a moderate control quality because a middle-rate starting value for the friction estimation was chosen. A look to the control signal in the lower plot illustrates that the open loop control is not well adapted to the process. After 130 seconds (Fig. 9) the open loop control is considerably better adjusted. That leads to a very high control accuracy. So a good control

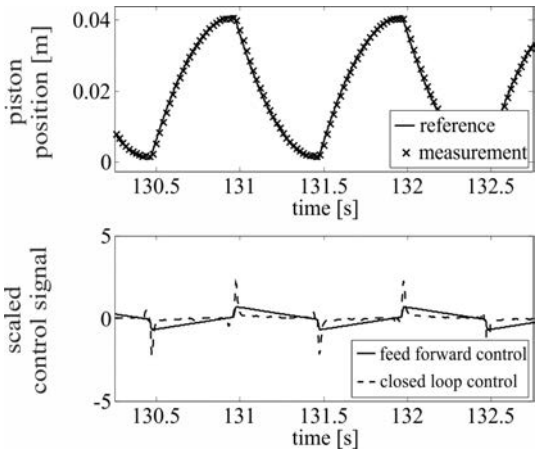

Fig. 9. Piston position control results 130 seconds after power on

performance can be achieved during the complete lifetime of the heart assist device.

5.2 Control Results Of Pump Output

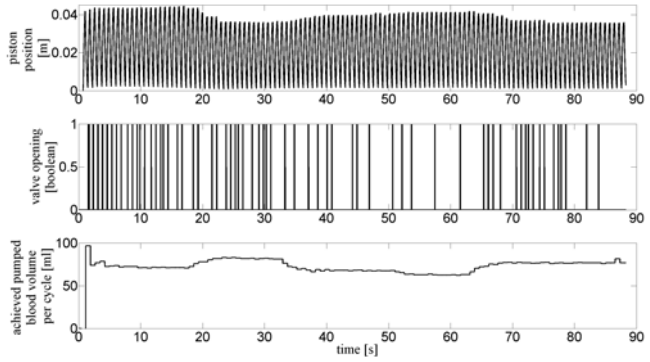

Fig. 10. Pump output during changing pump conditions

The task of a heart assist device is the maintenance of a sufficient pump supply to the patient. Therefor an adaption to the patient needs is required. Fig. 10 shows the achieved pump output per cycle for different operating conditions. The achieved pumped blood volume per cycle is determined by external sensor equipment. Additionally the control signal of the balancing valve and the controlled piston position is plotted. Up to the twentieth second the pump drive operates against a very high arterial counter pressure of the patient. For test conditions a real patient is replaced by a mock simulation. For a very high counter pressure the control of the heart assist device operates with control signal limitation. The maximum stroke of the piston drive is limited to 0.045 m due to design aspects. That is the reason for a decreased output of 70 ml per cycle in the first phase. The nominal output of the applied blood pump is 80 ml. After the twentieth second the arterial counter pressure is decreased in the test scenario to an expectable value of a nominal patient. The control system decreases the piston stroke and a full output of 80 ml is achieved. A further variation of the arterial counter pressure is performed at about second 35 and 65. As shown the developed control system is able to compensate variations of the human circulatory system within a few pump cycles. A sufficient pump supply to the patient is achieved.

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