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Real World Experience with an Optimized Control Scheme for a Ventricular Assist Device

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Abstract: A closed-loop control software for the new mobile Berlin Heart EXCOR® driving unit was optimized to balance usability, durability, pump wash out, blood stress and power consumption. The piston of the electro-pneumatic cylinder is moved on a pump-cannula-specific trajectory. A friction and a valve model are adapted online. Verification and real world data show constant flow, low power consumption and the adherence of all limits.

Keywords: ventricular assist device, pulsatile, pediatric, closed-loop control, algorithm, paracorporeal, EXCOR

1 Introduction

Heart failure affects 26 million people worldwide. When the heart becomes too weak, ventricular assist devices (VADs) are used to partially or fully generate the necessary blood flow until a donor heart is available. The Berlin Heart EXCOR® system is a paracorporeal ventricular assist device for pediatric and adult patients requiring single-ventricular or bi-ventricular support. The outcomes of small children have improved significantly since 2013 [4]. Long-term results for pediatric patients in Japan show a survival rate of 100 % [5]. A new small EXCOR® Active driving unit[1] was developed to allow for more mobility of the patients. Control loop development of the new driving unit aimed at achieving the partially conflicting targets of usability, durability, pump wash out, low blood stress and low power consumption. [1] presented a model of the electronic, pneumatic and hydraulic sub-systems as a basis for the control design. Later, a control scheme on the basis of the partially verified model was proposed [2]. This control scheme focused on a high degree of automation but could not achieve acceptable reliability, performance and usability. Therefore, alternative methods and improvements were proposed in [6]. This contribution presents the final choice of a control design, the verification method and target and meaningful test results, especially first real world data.

1 The use of EXCOR® VAD for adults, RVAD-support, Excor mobile and EXCOR® Active is not FDA-approved.

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2 Methods

2.1 Simulation Model

The simulation model contains the software, the electronics and the mechanical components of the driving unit, the pneumatics and the fluid dynamics within the blood pump, the cannulas and the patient. Similar to Benkmann et al. [2] the core is the chain from desired motor current to actual current to piston movement to pressure generation to diaphragm movement to blood flow generation. Another important component is the influence of a switching valve on the air mass within the system. However, additional experiments resulted in changes in structure and parameter values. For the current context, three differences to the model in Benkmann et al. [2] shall be pointed out: 1) The friction model is based on experiments with different pump sizes and settings and the changes during the lifetime of the driving unit, see section 2.3.2. 2) Electronics were modeled in detail to allow for a good compensation, see section 2.3.2. 3) The valve model was replaced, by

$$\Delta p = \frac{t_O \cdot \sqrt{|p_R|}}{k \cdot V} \quad . \tag{1}$$

Δp is the pressure change that results from an opening duration t_0 at relative pressure p_R and volume V. k was determined experimentally.

2.2 Mock Circulation Model

The overall goal for the control is a reproducible deflection of the pump's membrane with minimal wear and current consumption. In order to develop a control that fulfills these goals, experiments were performed by connecting the driving system to a blood pump which was then connected to a mock circulation model. These tests started in the early development phase with the initial task of finding appropriate control variables for the air mass. Experiments were then executed throughout the entire development process, from control optimization 2.3 to final verification 2.4.

The driving system supports a range of possible patient blood pressures [3] through various pump sizes and different combinations of cannula sizes at the pump inlet and outlet. The result is a highly variable control plant that is dependent on these parameters. The mock circulation model must therefore be configurable in this parameter space.

The mock circulation model consists of two cylinders partially filled with a test fluid that has a viscosity similar to blood. Via connectors, the inlet cannula of the chosen pump is connected to the first cylinder and the outlet cannula to the second cylinder. The first cylinder is vented to atmospheric pressure whereas the second cylinder is sealed such that an increase in fluid height produces a higher pressure at the outlet cannula. Additionally, a proportional valve connects the two cylinders and is controlled by a closed loop controller. When pumping is started, fluid flows from the outlet cannula into the second cylinder while the closed loop controller adjusts the flow from the second cylinder into the first such that the desired pressure at the outlet cannula is achieved. The pressure at the end of the inlet cannula is always much lower and can be set by the fluid level in the first cylinder.

2.3 Control Optimization

Optimizing the control scheme involved defining quality criteria in addition to a set of system parameters that can be changed to bring all quality criteria into an admissible range. Quality criteria were: a) Equivalence of fluid dynamics to the established Ikus driving unit (for good pump washout and low blood stress). b) Blood flow ranges for all Berlin Heart EXCOR® pumps and cannulas. c) Constant and low power consumption (mobility). d) Keeping the speed below a threshold (durability). e) Ratings of user interface prototypes (usability). The following subsections describes the system parameters and the reasons for their final value. An overview of the resulting controller is shown in Figure 1.

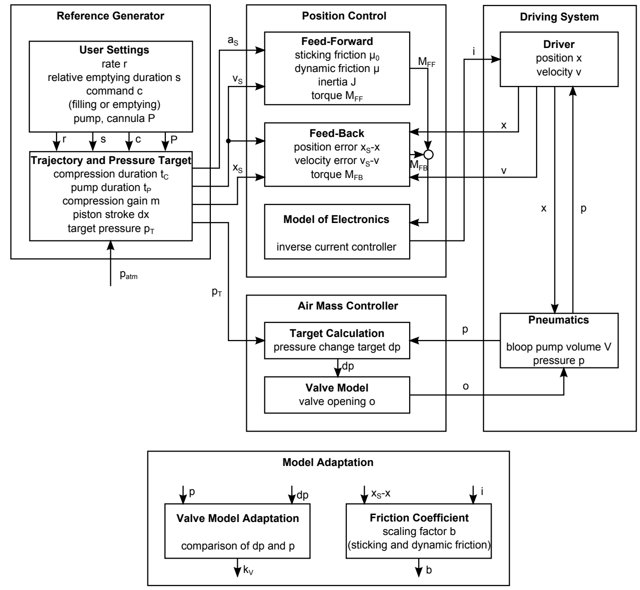

Fig. 1: Architecture of the implemented controllers. i: current, p: relative pressure, a_S: reference acceleration, v_S: reference speed, x_S: reference position.

2.3.1 Piston Movement

The piston movement controller needs to reject disturbances and generate a high blood flow while taking hardware and pressure limits into account. Therefore, it was decided to control piston position and not current or pressure. The desired trajectory must have enough parameters to fullfill current and pressure targets. Figure 2 illustrates the limits and the final trajectory parameters that are tuned for each pump-cannula-combination. A linearly decreasing acceleration in the beginning allows for a shift of power towards the beginning of a pump cycle and a fast pressure change. A constant velocity in the next phase moves the membrane without load peaks. Finally, a constant deceleration supports the overall target of a jerk free movement. Additionally, a high priority pressure controller reduces the current, when pressure limits are exceeded.

2.3.2 Feed-forward compensation

It is necessary to minimize the piston position control error because it directly affects the driving pressure curve. The pressure curve must be similar in each stroke to ensure a reproducible membrane deflection. Large variability of stroke pressure curves would lead to large variability of stroke mean pressure values and thus, an undesired coupling between the piston position and the air mass controller.

Therefore, the reference tracking result of the closed loop controller is improved by a feed-forward control. The mathematical plant model must be carefully identified, since the quality of the feed-forward control directly depends on how well the real plant is approximated by the mathematical model. For the plant model, the equilibrium of torques is used:

$$\tau_J = \sum_i \tau_i = \tau_p + \tau_m + \tau_\mu, \tag{2}$$

with the motor torque, τ_m, the torque caused by the inertial mass, τ_J, the friction torque, τ_μ, and the torque generated due to the piston pressure, τ_p. Since the pressure is directly mea-

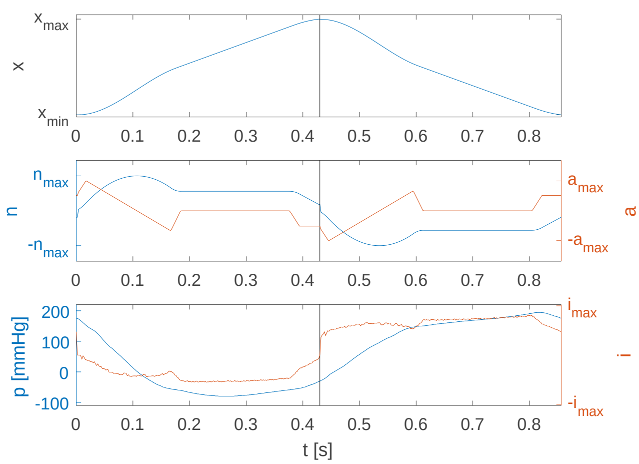

Fig. 2: Optimized trajectory for the piston movement: position x (top), speed v and acceleration a (center), relative air pressure p and motor current i (bottom)

sured and the inertial mass is known, these two torques can be precisely calculated. The motor torque is proportional to the motor current which is adjusted by the motor current controller to the current requested by the control. There are sometimes major deviations between this set point and the actual current which are dependent on the speed and the voltage supply of the motor. These nonlinear effects are compensated for by lookup tables that were generated from detailed motor model simulations.

The remaining term is the friction torque. Here, all different sources of friction, like bearing friction and friction form the piston sealing are combined. There is no clear physical description because the friction depends on many influential parameters. 455 experiments were executed with different driving units, pumps, and settings for the purpose of determining a friction model that estimates the friction torque well enough in all cases. The free parameters of the friction models were calculated by minimizing a quadratic cost function of the friction torque estimation error. The following combination of sticking friction and dynamic friction was used:

$$|\tau_\mu| = \mu(|\dot{x}| + \beta) \tag{3}$$

It was found out that there is a relationship between the sticking friction and the velocity proportional friction. There exists one constant β for all experiments such that the cost function value with adapting only μ in each experiment is similar to the case that the two parameters μ and β are adapted in each experiment.

The experimental data shows that the calculated friction value varies i. a. due to manufacturing tolerances. Therefore, the friction value is adapted on-line as the last free parameter of the feed-forward model equation. This adaptation is done by minimizing the quadratic position control error averaged over each piston stroke.

2.3.3 Air Mass Regulation

Different control targets for the pneumatic valve where compared in experiments with a closed valve and various air masses and loads. The goal was good disturbance rejection in addition to a sensitivity to air mass changes that was configuration independent. The most robust control target is the mean relative pressure over a stroke, which is therefore used in steady operation. Because the user is currently accustomed to independently tuning the filling and emptying of the pump, it was decided to automatically translate desired filling and emptying changes to changes in mean pressure and piston stroke. Prototypes with different algorithms were built and rated by users. The selected algorithm changes the stroke directly and temporarily changes the air mass control target to filling or emptying pressure. An adapting valve model is used to keep the pressure change per stroke in a fixed range.

2.4 Verification

Verification was done using state-of-the-art tests: Mock loop in vitro tests, endurance tests and a visualization of the fluid dynamics with particle image velocimetry (PIV). Real world data was obtained from the log files of the driving unit, including data from the driver's flow sensor. The main target is to fully support the wide range of Berlin Heart pump-cannula-combinations and settings (including flow targets) with a battery run-time of at least 4 hours.

3 Results

In vitro tests show that the control software meets its functional requirements. Furthermore, all Berlin Heart EXCOR® pumps and cannulas can be operated. Figure 3 shows that the entire flow range for pediatric and adult patients can be supported. Battery in-vitro tests and the first real world experience show that a battery run-time up to 7 hours is possible.

Endurance tests prove: A maintenance interval of 34 million pump cycles can be supported.

Log file data of a bi-ventricular assist device (BVAD) and a left ventricular assist device (LVAD) patient show that the control scheme generates a stable flow with hardly any user interaction. In the 21 evaluated days of the BVAD case the flow deviated no more than the displayed accuracy of 0.1 lpm

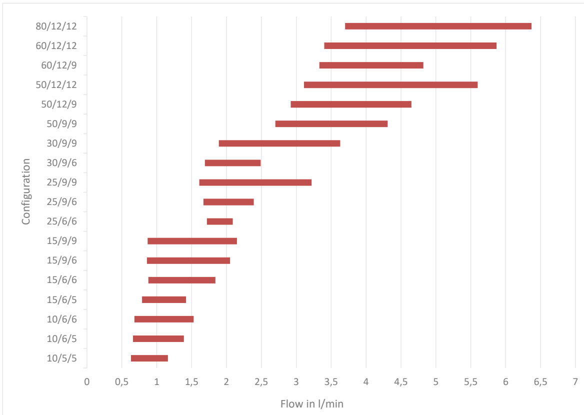

Fig. 3: Blood flow ranges for all pump cannula combinations

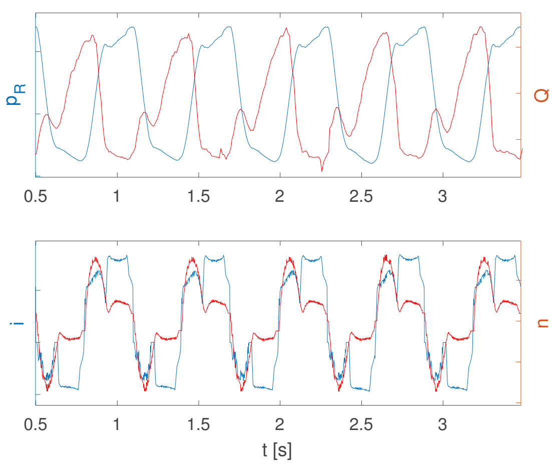

Fig. 4: Logging data for the left 30-ml-pump of a bi-ventricular support patient at a rate of 100 bpm. Drive-line pressure (p_R), blood flow (Q), motor current (i) and piston speed (n)

for both pumps as long as user settings where unchanged. An evaluation of the first 3 days of the LVAD case reveals a maximal deviation that was a bit higher: 0.2 lpm. Exceptions are a few alarmed short-term flow drops. These drops were caused by events like kinked cannulae. Figure 4 shows recorded signals from the left pump of the BVAD patient for a short representative period. It can be seen that the high speed at the beginning of each filling and emptying phase leads to a fast pressure change. The velocity profile also leads to a long pumping phase with an acceptable peak pressure and a steady current over each half pump cycle.

PIV measurements show that the fluid dynamics in the blood pump with the EXCOR® Active driving unit is equivalent to the fluid dynamics with the Ikus driving unit for all pump sizes. Figure 5 contains exemplary comparison of the fluid dynamics for the 10-ml-pump.

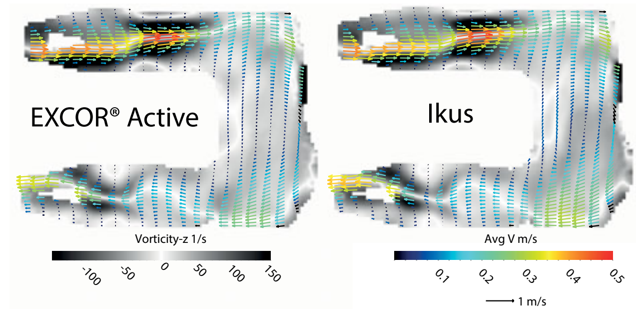

Fig. 5: PIV results for the new EXCOR® Active and the established Ikus driving unit. Vorticity and velocity are averaged over the pump cycle.

4 Conclusion

The new control scheme supports all Berlin Heart EXCOR® pumps and cannulas with a set of optimized piston trajectories. Robust control targets for air mass regulation ensure usability and constant blood flow in clinical practice.

Author Statement

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