Control Strategies for Mechanical Heart Assist systems

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Abstract—Mechanical Heart Assist Systems are one option to treat cardiovascular disease being the main cause of death worldwide. Since the reliability of these devices has increased and patients on mechanical heart assist systems are even able to leave the hospital, the need for enhanced control algorithms that automatically adapt the output of the devices to the patients need is growing. This review paper aims to give an overview on control strategies proposed for Mechanical Heart Assist Systems. Typical aspects of designing control algorithms are introduced and issues regarding the control of biomedical applications are discussed. Different approaches to control Mechanical Heart Assist Systems are presented and research topics that need further development are identified.

I. INTRODUCTION

In the member countries of Eurotransplant at the end of 2011 1222 patients were on the waiting list for a heart transplantation. This is more than the double amount of patients who received a heart transplantation, namely 553 [1]. In 2010 27.5% of the patients awaiting a donor heart were on the waiting list more than 24 months [2]. These numbers show the need for enhanced therapy with Mechanical Heart Assist Systems, which can not only save the patients life for a limited period of time but also improve their quality of life or even become the final destination for therapy.

Mechanical Heart Assist Systems are used to treat patients suffering from severe heart failure who do not adequately respond to pharmacological or surgical therapy any more. Here, three kinds of mechanical heart assist systems are discussed:

- Intra-Aortic Ballon Pump (IABP),
- Ventricular Assist Devices (VAD),
- Total Artificial Hearts (TAH)

Available systems on the market can be categorized regarding their operating principle and control challenges, see fig. 1

An IABP is a balloon that is usually inserted through the femoral artery via a catheter and is placed in the thoracic aorta. This balloon is inflated during diastole and deflated during systole. Thus, the IABP improves the perfusion of the coronaries and reduces the afterload of the left ventricle by volume displacement. Due to this volume displacement an IABP can increase the energy balance of the heart up to 15% (see [3]) and the cardiac output up to 20% (see [4]). However, the volume displacement results in a pressure relief but is not able to decrease the volume loading of the heart. According to [3] typical indications for the implantation of an IABP are cardiogenic shock after an acute myocardial infarction, a perioperative low cardiac output syndrome and an unstable angina pectoris. For mechanical heart assist the IABP is the first choice. Out of the three discussed Mechanical Heart Assist Systems the IABP is the least invasive one.

VADs are mechanical pumps that are typically connected to the apex of the ventricle or the atrium. Right ventricular assist devices (RVADs) eject into the arteria pulmonalis, whereas left ventricular assist devices (LVADs) eject into the aorta. With regard to their historical development VADs can be divided into three generations. Most VADs of the first generation are positive displacement pumps and show therefore a pulsatile pumping behaviour. VADs of the second generation are rotary pumps, i.e. either centrifugal pumps or axial flow pumps. The third generation VADs are also rotary pumps with a magnetic bearing of the rotor. This reduces the complications and additionally, these systems need little maintenance. VADs are either implanted as bridge to transplant, destination therapy, bridge to recovery or bridge to bridge, [5].

TAHs replace the ventricles of the patient completely. Therefore, they are connected to the auries and eject into the arteria pulmonalis and the aorta. The indication for a TAH is e.g. a heart tumor or the rejection of a donor heart or cases where an LVAD or biventricular support with VADs is not possible anymore. With regard to the insufficient supply of donor organs it would be desirable that TAH could be used as permanent solution. At present only two TAHs for implantation are available: the AbioCor TAH and the SynCardia temporary TAH. The AbioCor TAH is a destination therapy device that is only indicated for patients who are no candidates for a cardiac transplant (see [6]). The Syncardia temporary TAH is indicated as a bridge to transplant ([7]). So far only pulsatile TAHs have reached product maturity, however first concepts of continuous flow TAHs have been tried as well [8].

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II. CONTROL IN BIOMEDICAL APPLICATIONS

The design of control systems in medical devices is a challenge in respect to the inherent risk of harming a patient connected to the medical device. Typically, the defense mechanisms of organisms are bypassed (e.g. reflexes) or breached on purpose (e.g. skin barrier) so there is a direct interaction between the technical and biological system. In most cases this direct interaction is the intended use in order to influence physiological quantities in a therapeutic way. On the other hand, the grade of invasiveness and interaction defines the risks involved and the necessary safety measures which have to be employed. In terms of control systems the interactivity of medical device and physiological system can be categorized into (I) device-internal control loops, (II) patient oriented control loops and (III) physiological compensatory control loops.

Category (I) of device-internal control loops is characterized by the fact, that all control variables and sensor signals are device internal and that there is no or negligible backward interaction from the patient (load independence), see Fig. 2. As a result, these control loops are solely technical. The desired value is well defined, output- and state-quantities are mostly well measurable and typically a process model is parametrizable with relatively good accuracy. The safety system can typically be limited to supervision of boundary values of the output quantities.

![Fig. 2. Class I device control loop.](image)

In the category (II) of patient oriented control loops, all control variables and sensor signals are still available inside the medical device, but a reverse interaction between device and physiological system is present, e.g. changing load for the device (Fig. 3), which can be described by a disturbance model. Typically the control loop compensates this disturbance, however, the effect may destabilize the control significantly or can lead to the failure of meeting predefined control-targets or -precision. In some cases adaption or adjustment to different patient categories is implemented to increase system performance. The safety system is typically similar to category (I) loops, however more considerations regarding limits and gradients might be necessary and a formal proof of overall stability might not be possible.

![Fig. 3. Patient oriented class II control loop.](image)

Category (III) physiological compensatory control loops encompasses control loops, where the patient is part of the control process (Fig. 4). The control variables are typically physiological parameters. This adds uncertainty into the control design process, as the process model will include non-linearities, time varying parameters and large inter-individual spread. This category can further be subdivided into two subcategories of (IIIa) "measurable signals, quantifiable therapeutic goal" and (IIIb) "not (yet) measurable signals, mainly qualitative therapeutic goal". Whereas in the first case typically analytical control laws will be employed, the latter is often similar to therapeutic decisions a physician might take and therefore realized by either implicit or explicit knowledge based controllers. The safety system requires both supervising device output quantities as well as control variables. However, it might be very difficult to obtain redundant (and thus reliable) sensor measurements for physiological quantities. Additionally in category IIIb systems safety margins are often similarly fuzzy as the control goals.

![Fig. 4. Class III physiological compensatory control loop.](image)

III. BIOLOGICAL CARdiovascular CONTROL

The main purpose of the human circulatory system is the transport of blood between lung and organs, so that these are supplied with oxygen and nutrients and waste products are removed. Interconnected with blood vessels the blood flows from the left heart through the systemic high pressure vessels which bifurcate in several generations from arteries to arterioles to capillaries in the inner organs. From there blood is collected in the systemic venous vessels and finally reaches the right heart. This generates the driving pressure for the blood to flow through the pulmonary circulation through the lung to the left heart again.

Hydraulically we can view the circulatory system as a system of hydraulic resistances where two interconnected pumps create a driving hydraulic pressure difference in each sub-circle, see fig.5. The arterial vessels, especially the Aorta exhibit a significant elasticity, so these act as a pressure storage, represented as a capacity in the schematic. The veins are even more distensible, but as these are on the low pressure side of the circulation act as a volume storage.

Physiological control of circulation is realized by two major mechanisms. On organ level, blood flow is regulated demand driven. Depending on organ type this means, that for example in muscles or brain, blood flow is regulated such, that oxygen and de-carboxylation requirements are met. Other organs like the kidneys require a internal blood pressure regulation to function properly, the skin is an actuator in the bodies temperature regulation system and uses bloodflow for cooling. In every case blood flow into
the organ is influenced in actively changing the hydraulic resistance by increasing or decreasing the diameter of the afferent (feeding) small arterioles. This leads to a varying load for the heart. In order to conserve energy and prevent the heart from unnecessarily pumping always for full load, a second physiological control loop exists for controlling arterial blood pressure: the baroceptor control. Here blood pressure is sensed as a distention of blood vessels walls (most prominent in the carotid sinuses and aortic arch) processed in the brain stem which controls changes in heart rate and heart contractility.

In pathological conditions, pump efficiency of the heart is reduced by muscle failure (e.g. after myocardial infarction or infection of the muscle) or mechanical failure (e.g. heart valves). In this situation the heart pumps at maximum power even when the body is at rest and can not handle additional demand caused by physical exercise. Heart assist devices are used to augment the pump efficiency of the heart muscle. In fig. 5, the application of a left ventricular assist device (LVAD) is shown, which is connected in parallel to the pumping chamber of the left heart. A intracoronary balloon pump (IABP) can be seen as a modulator for the aortic compliance (not shown). In case of a total artificial heart (TAH), left and right heart would be replaced by the technical pump system.

IV. CONTROL OF HEART ASSIST DEVICES

The control algorithms of an intracoronary balloon pump (IABP) determine mainly three operating variables: operating pressure and the timing of inflation and deflation of the balloon. The control of the pneumatic driving pressure is a typical Class (I) control problem and handled inside the machine. There is very little backward interaction from the physiological system and all of the control variables are technical.

Critical parameters for the performance of an IABP are the timing consideration of inflation and deflation in relation to the hearts pumping cycle [10]. Typically these are triggered events and trigger points are extracted from the ECG (middle of the T wave for inflation and QRS complex for deflation) or the arterial pressure curve (just prior to the closure of the aortic valve for inflation). However, this triggering is a purely open loop algorithm and needs adjustment to heart physiology or heart rate changes. Zelano [11] introduces a scheme to estimate the systolic time interval by detecting the "second heart sound" $S_2$ from the aortic pressure curve. This improves the alignment of timing intervals to the heart cycle and even can adapt immediately to arrhythmias.

Barnea [12] introduced a control concept based on the observation that changes in cardiac oxygen balance correlate with the timing settings of the IABP. While the IABP itself can not reduce oxygen consumption, if timing is set improperly oxygen consumption increases significantly. This is a typical class (IIIa) control problem as at least the minimization of a physiological parameter is a specific control goal. However the continuous measurement of cardiac oxygen consumption online is both difficult and potentially dangerous. Thus he derived a performance index from aortic pressure measurements, where he could prove, that mean diastolic pressure and peak systolic pressure are appropriate substitutes for this measurement (they are closely correlated to cardiac perfusion). Implementing an control scheme for iteratively optimising this performance index could prove the optimal adjustment of the timing parameters.

The control problem of VADs depends on their respective pumping mechanism. In [13] Farra et al. summarizes three operating modes for pneumatic driven (pulsatile pumping) VADs:

1) Full-to-Empty Asynchronous
2) Fixed Rate Asynchronous and
3) R-wave Synchronization.

In the first case the VAD pumps when filled appropriately with a fixed stroke volume but at a variable rate. In fixed rate asynchronous mode the VAD is driven with a fixed rate that does not depend on the heart rate. The last mentioned mode uses the ECG of the patient and stops the ejection phase of the VAD with the R-wave. This mode is also called "counterpulsation" mode. However, the constraint for pulsatile pumping VADs is to avoid stagnation of blood flow in the VAD since this may lead to thrombus formation.

Common for all of the operating modes is the necessary control of the driving pressure of the pumping chamber. Whereas simpler constructions would only control the pressure source in the console (category (I) control loop), advanced control targets the pressure of the driving chamber itself. This pressure is influenced both by the losses in the driveline as well as systolic and diastolic blood pressure. This control can now be categorized in (II). For example Sievert [14] introduces a control scheme, where a model based control of the chamber pressure is implemented.

Driving consoles for commercially available continuously pumping VADs (rotary VADs) typically feature internal control strategies for controlling pump speed. E.g. the authors presented a controller approach for a catheter
based LVAD [15]. Depending on the backward interference sensitivity of the pump characteristic, these controllers fall into category (I) or (II). This inner cascade might as well be extended by a mass flow controller, which controls pump flow independent of afterload. This would have the advantage, that reverse flow through the VAD could inherently be prevented. An additional feature is the integration of a pressure sensor in order to detect suction of the atrial wall, in case pump flow exceeds venous return. Some groups managed to detect suction based only on motor speed and current measurements e.g. [16].

For the control for continuously pumping VADs (rotary VADs) Boston et al. [17], [18] introduce a hierarchical control scheme. This hierarchical control structure has two cascades. The first cascade focuses on technical control which keeps the speed of the pump at reference value. In [17], [18] it is called the “Motor Speed Control”, see fig.6. The second cascade includes three controllers and a supervisor. The supervisor selects one of the controllers depending on the available information. The controller on the lowest level of the second cascade is a default controller. Since this controller does not include any interaction between the device and the patient but generates a constant pump speed it is also considered to belong to category (I). The pump speed in this case is adjusted to deliver an adequate flow and it should still avoid suction. The second controller in the second cascade is called a “heuristic algorithm”. This controller uses various indices, which are based on pump parameters influenced by the patients state. Therefore, this controller allows the device to deliver the maximum flow that does not induce suction in the ventricle but it does not deliver the optimal flow regarding patients needs. As the control targets implicitly are cardiac output, arterial pressure and pump speed this control structure would be categorized in (IIIa).

The objective of the third controller is to adapt the output of the device to the patients needs. This “Optimal Performance” controller uses a model of the systemic circulation load of the individual patient and of the VAD. In addition, this controller should fulfil three constraints with respect to the cardiac output, the systolic arterial pressure and the left atrial pressure. This optimal performance controller belongs to a controller of category (IIIa), as control goals are still quantifiable and sensor signals available.

An alternative approach has been introduced by Giridharan [19], [20]. The basic idea is to maintain an average differential pressure $\Delta P_r$ between the left ventricle and the aorta as depicted in fig. 7. Giridharan et al. argument that, keeping this pressure difference at a constant value embeds indirectly the cardiovascular regulation into the control algorithm of the VAD. This is due to the fact that the natural regulation achieves its required flow of blood mainly by adjusting the vascular resistance. In [20] the control concept was tested for an axila and a centrifugal flow VAD using a software simulation of the circulatory system. For both pumps a PI-controller (with different parameters) was implemented. The parameters of the PI-controller were calculated by minimization of a quadratic objective function that incorporates the deviation of $\Delta P$ as well as the rate of change of the rotational speed of the pump. In a publication by Giridharan in 2006 [21] an extension of the $\Delta P$-controller is given to overcome the use of pressure sensors. Here, intrinsic pump parameters are used to estimate the differential pressure. This control concept was already adopted by others e.g. [22] and according to [20] it can also be used to control a TAH by keeping the average $\Delta P$ between the pulmonary vein and the aorta constant. Again we categorize this as a class (IIIa) controller. However a continuous reliable pressure measurement is not yet available and the presented substitutes are prone to inaccuracies in case of device deviation from nominal or changing hydrodynamic properties of blood.

Ferreira et al. [23] et al. proposed a two-staged control concept for a rotary VAD. The objective of their control concept is to adjust the VADs outflow to the patient’s activity level. The first stage of their concept contains a suction detection systems using the pump flow as input (category II). The pump flow signal is used to calculate several indices which are used in a discriminant analysis model to generate discriminant scores. Experimental data from an animal trial were used to train the system. The second stage of the concept is a fuzzy-logic controller which adjusts the pump speed based on the discriminant scores. The control concept was tested in software simulations. For this a lumped parameter model of the cardiovascular system and the LVAD was used. To simulate various states of the patient (hypertension, exercise, sick heart etc.) the contractility, the
heart rate as well as the systemic vascular resistance were varied. Similar to the control concept proposed by Boston et al. [17], [18] this one is classified as a controller of category IIIa.

A physiological controller which was even tested in clinical trials was introduced by Vollkron et al. [24]. The control is based on two goals, whereas the first focuses on security aspects as to find maximum possible values for pump flow dependent on cardiac venous return to prevent suction of the cannulae. The second module is responsible for adjusting pump flow in order to reach sufficient perfusion. The control consists of four interacting units, fig.8:

- Closed loop controller for controlling pump speed
- Suction clearance controller for preventing suction of the ventricle (expert system)
- Speed variation controller I: In a given operating point periodic speed variations are imposed as to identify behaviour. If an ineffective operating point is detected, pump speed is adjusted
- Speed variation controller II: Determination of venous return and subsequently adjusting desired values of P2P flow

The inner closed loop controller is a typical category II control problem. The outer loop is less attributable. Part of the controllers target pump parameters directly (e.g. suction prevention scheme) and are thus of category II, others target measurable physiological parameters as P2P Flow pulsatility as a physiological target and are thus category IIIa.

V. CONCLUSIONS

The progress in the technical development of heart assist devices enables increasing application times and widespread use. Originally purely mechanical systems, modern devices developed into mechatronic systems with integrated control and steering mechanisms. So far these focus mainly on device operation and the simple but extremely difficult question on what device parameter to set on the console remains for the user.

Several examples for control strategies have been presented and demonstrate how the complex goal of physiological device control while maintaining a desired level of heart support might be reasonably approached.

However, so far none of the control algorithms available address category (IIib) physiological targets like "sufficient blood supply for the organs", "unloading/support of the ventricle by XX%", "cardiac support by XX Watt" or "peripheral gas concentration". Device parameters to reach these control targets remain to be set and adjusted by the specialized physician in charge. While this is manageable on a shorter time scale, no patient is supervised that closely 24/7 around the clock. This leads to the situation, that treatment parameters are not constantly adapted to patient and therapeutic needs. The situation escalates when patients are mobilized and even leave the clinic.

So there is a large potential for further development of "truly" physiological controllers with a large impact on independence, mobility and thus life quality of VAD dependent patients.

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REFERENCES


