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Influence of the inlet and outlet compliance on the effectiveness and work safety of a pneumatically-driven paracorporeal prosthetic ventricle

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The paper deals with the problems connected with mechanical assistance to cardiovascular system by means of the pneumatically driven artificial ventricle POLVAD-MEV and, more precisely, the influence of the pump elements' compliance being placed directly in the front of the inflow valve (inlet compliance) and behind the outflow valve (outlet compliance) on the effectiveness and safety of this assistance. The authors concentrated mainly on the changes in the output flow of the artificial ventricle and inertia phenomena (water-hammer effect) occurring together with different values of the compliance. All experiments were carried out in the Biocybernetics Laboratory of the Institute of Heart Prostheses in Cardiac Surgery Development Foundation in Zabrze by means of a mock circulation and a physical model of the inlet and outlet compliance.

Key words: compliance, Windkessel, artificial ventricle, VAD, hydrodynamic measurements, water hammer effect

1. Introduction

Ventricular Assist Devices (in short VADs) are the blood pumps connected in parallel to the patient's cardiovascular system by means of elastic tubes called

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cannulae. Such devices are usually used in the case of ischemic heart disease, postcardiotomy ventricular failure and cardiomyopathy (peripartum, idiopathic, viral). They ensure a right perfusion of organs in hemodynamic insufficiency of one (LVA, RVA) or both heart ventricles (BVA). Artificial ventricles are also more and more frequently being used as a final therapy during sometimes long period of waiting for heart transplantation. At present different kinds of such pumps are available: electrohydraulic (intracorporeal), electromechanic (intracorporeal) and pneumatic (intracorporeal/paracorporeal) [1], [2]. The last ones are the most popular because of the easiness of their insertion, effectiveness of the assist, low failure frequency and simple structure. In Poland, pneumatic paracorporeal cardiac assist pumps are designed at the Heart Prostheses Institute in Cardiac Surgery Development Foundation and Artificial Heart Laboratory of Medical Academy of Silesia in Zabrze. Since 1996, POLVAD-MEV pumps were applied 156 times at six Cardiac Surgery Departments in Poland and once in Argentina. The patients were between 15 and 76 years old. An average assist time was 94 days [3].

A lot of medical and technical aspects of pulsatile blood pumps are the source of the success of this mechanical circulatory assistance. The way of steering the pump and its structure are considered to be main technical problems in the pump design. These problems are as follows:

- an appropriate choice of the driving curve shape (by means of changing the diastolic drive pressure (DDP), systolic drive pressure (SDP), systolic duration (% SYS), asynchronous rate mode (AHR)) proceded by test on a mock circulation [4],
- optimization of the geometry of artificial ventricle elements, which come into contact with blood, in order to ensure a good wash and elimination of dead space areas (areas of low flow and stagnation) which cause dangerous thrombus [5],
- the choice of appropriate mechanical or biological valves, their orientation inside the blood chamber and the way of fixing in artificial ventricle [4], [5],
- selection of biomaterials for constructional elements of a ventricular assist device with such characteristic features as thromboresistance and biotolerance as well as appropriate mechanical properties [6]–[8], including the compliance whose importance is underlined by us.

The compliance (ability to change the volume at increasing or decreasing pressure) of the constructional elements of ventricular assist device plays a specific role in the process of blood pumping. First of all this concerns the connectors and cannulae which are situated directly between the inflow valve of the VAD and cardiovascular system (inlet compliance) and between the outflow valve and cardiovascular system (outlet compliance). Due to their elasticity they eliminate a lot of side effects which have a negative influence on the work safety of the artificial ventricle. They can also assure a better blood supply to the chamber, increasing the effectiveness of the pump, and, to a certain degree, make the inflow independent of the compliance of venous vessels and the condition of the atrium walls. The possibility of decreasing *afterload*

being connected so far with a total peripheral vascular resistance is also very important. The process is as follows: the elements of the ventricular assist device situated directly behind the outflow valve can accumulate a huge amount of potential energy of elastic deformation and behave like an air-chamber during the systolic phase of the cardiac assist pump's work. This enables generating an additional pressure of blood in the periods between systoles. The hydraulic air-chamber theory – Windkessel [9] announced by Stephen Hales in 1773 – describes the phenomenon in detail.

2. Materials and methods

It is impossible to establish *in vivo* the influence of the inlet and outlet compliance on the effectiveness and safety of the mechanical heart assistance by means of a pulsatile artificial ventricle. Therefore we constructed a universal device which together with a mock circulation (Heart Prostheses Institute, Cardiac Surgery Development Foundation, Zabrze, Poland) ensured the effectiveness of the research. During the experiment the Polish cardiac assist pumps POLVAD-MEV equipped with mechanical tilting discs' valves Sorin Allcarbon (Sorin Biomedica Cardio, Sallugia, Italy) of 27 mm in diameter were used. A detailed description of the device can be found in the monograph [10].

2.1. Mock circulation

Hydrodynamic model of the circulatory system designed in the Institute of Heart Prostheses, Cardiac Surgery Development Foundation in Zabrze (figure 1), is a double-ventricle system composed of a number of transparent reservoirs and hydraulic resistances which are connected by means of stiff ducts. The left side of the mock circulation usually enables the pulmonary circulation modelling (low-pressure). It consists of the artificial ventricle POLVAD-MEV which is driven pneumatically by means of driving unit JSN-301. The inflow tube (left) is connected to an atrial reservoir. The fluid level in atrial reservoir guarantees an appropriate atrial pressure. Outflow tube (right) is connected to the pulmonary arterial compliance reservoir. Behind the pulmonary arterial compliance reservoir there is a capillary resistor (Starling resistor) which contains 1316 steel capillaries (0.9 mm in diameter) closed in a metal housing. The number of tracks of open capillaries are controlled by a special diaphragm. Due to that mechanism it is possible to copy exactly the pulmonary vascular resistance. In the next part of the hydraulic simulator, there is an equalizing reservoir. The right side of the mock circulation enables the systemic circulation modelling (high-pressure). It consists of the second POLVAD-MEV ventricle driven pneumatically by the same driving and monitoring unit. The inflow tube (left) is connected to the next atrial reservoir which models the pressure in the left atrium. Above the atrial reservoir there is a systemic compliance reservoir. The outflow tube of the ventricle (right) is connected to the

analogue to the peripheral vascular resistance which consists of 178 steel capillaries.

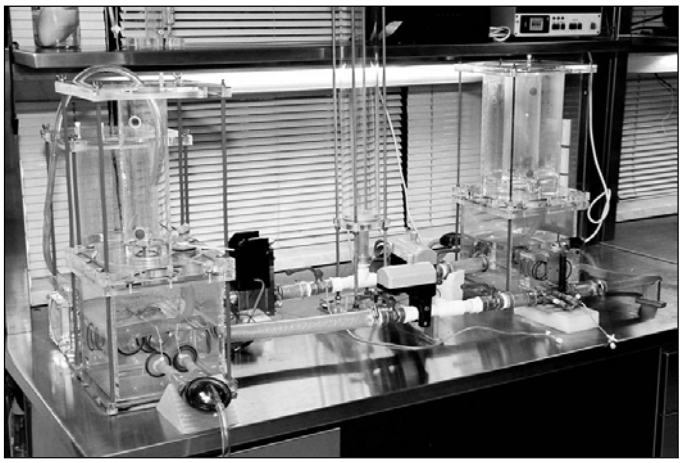


Fig. 1. Mock circulation with Ventricular Assist Devices POLVAD-MEV designed by Z. Nawrat at the Institute of Heart Prostheses in Cardiac Surgery Development Foundation in Zabrze

In the next part, there are hydraulic valves controlled both manually an electrically. All the hydraulic elements, compliance and inertia (vascular inertia resistance) are supervised by a special computer and an appropriate software.

2.2. Physical model of inlet and outlet compliance

The device consists of three main parts, i.e. the system which steers the membranes and a pair of two-chamber reservoirs (figure 2). The driving unit of the steering system is an engine run by variable current and resistance potentiometer which enables smooth turn control. The engine is attached to a stiff mounting plate and connected to aluminum wheels by means of a driving belt which drives the piston rods placed in both reservoirs (a rotary motion is changed into to-and-fro motion). The sheave and the wheels used to attaching the connecting rod turn on a common shaft. The steering system has been specially constructed to enable independent control of the maximum change in the position of both steel piston rod pins. This regulation is possible thanks to the holes in eccentric wheels and a specific shape of eccentrics themselves. The frequency of movement of piston rods is always the same (the frequency depends on the engine gear) but in opposite phase and regulates the volume of test fluid in the cylinder. A model of the active inlet and outlet compliance constructed in this way has been situated directly in the front and behind the cardiac assist pump. The structure of transparent, polyurethane reservoirs is quite specific and universal. The bottom cylinders of every reservoir have holes in their bases which enable attaching a pair of steel connectors

adapted to the connectors of the VAD pumps. The bottom cylinders are covered with rubber membranes whose tips have been screwed on to the steel pins. The upper cylinder enables introduction of a particular volume of compressed air inside the device (pneumatic volume). Such a system after reducing the membrane and the pin works like a hydraulic air-chamber and is a physical analogue to the passive inlet and outlet compliance. Additionally, next to the hydraulic valves there are two steel jibs used to adjust the maximum change of the position of pins in the case of measurement without steering system. This device has been constructed based on Windkessel's theory.

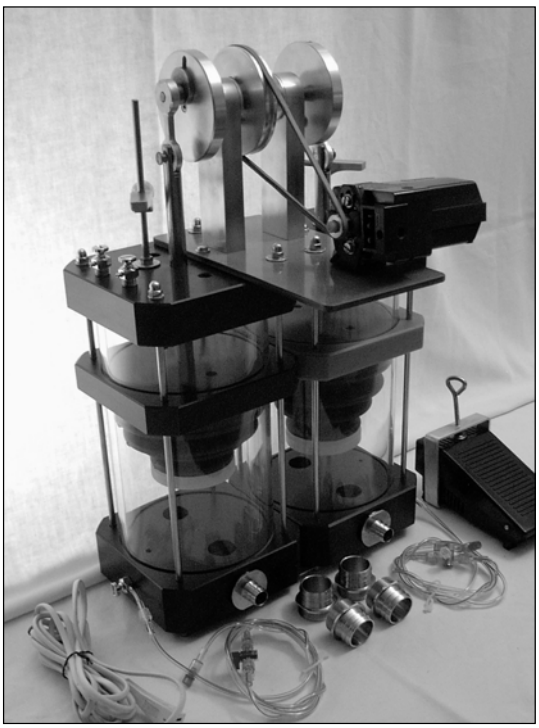


Fig. 2. Physical model of inlet and outlet compliance designed and made by M. Paszkowski based on Windkessel's theory

A physical model of the inlet and outlet compliance was connected between the POLVAD-MEV cardiac assist pump and a mock circulation by means of four stiff tubes. While doing research only the left part of the mock circulation was used (the right part was cut off) simulating the right ventricular assist (RVA) and the conditions of the pulmonary circulation (low-pressure), i.e. 2 kPa *afterload* (mean blood pressure in the low-pressure system is *in vivo* 1.2–2.5 kPa [9]) and the atrial pressure of 0.6 kPa (mean blood pressure in the right atrium is *in vivo* 0.1–0.7 kPa [9]). On every tube there is a special pressure transducer DPT-6009 (Smiths Medical Deutschland GmbH,

Germany) of the measuring range from –50 mm Hg to 300 mm Hg to measure the fluid pressure. The transducer sensitivity is 5 μV/V/mm Hg (± 3% accuracy). It was situated between the physical model of the outlet compliance and the reservoir in the mock circulation and indicated the fluid pressure in the pulmonary circulation. Similar transducers measured the fluid pressure inside the cylinders of the physical model of inlet and outlet compliance. In front of inflow valve and behind outflow valve, the flow probes have been placed (Transonic Systems, Ithaca, New York, USA) which were connected to the two-channel ultrasonic flowmeter T206 (Transonic Systems, Ithaca, New York, USA) with the measuring range from 10 cm^3/min to 20 dm^3/min (the accuracy of ±7%). All the transducer data was recorded in real time by a special computer unit with the software for collecting biomedical signals (BioSig-Aquis version 1.7, the Institute of Heart Prostheses, Cardiac Surgery Development Foundation, Zabrze, Poland). During the experiment a distilled water was used as a test fluid. Different values of compliance were achieved by the authors in two stages: by regulating the membrane deflection and the selection of appropriate pneumatic volumes. Reading the changing pressure value inside the bottom cylinders (left and right) after application a precise volume of fluid (up to 60 cm^3), the values of simulated compliances were calculated (0.09 cm^3/kPa, 0.63 cm^3/kPa, 2.08 cm^3/kPa, 6.45 cm^3/kPa, 13.04 cm^3/kPa and 81.67 cm^3/kPa). The calibration was conducted in static conditions.

3. Results

In the first stage of the research, the influence of the simulated compliance on the pumping effectiveness of test fluid at different artificial ventricle steering parameters was estimated. The analysis proved that the influence of inlet and outlet compliance on the output flow of the pump is most noticeable in a short time of filling it up (high pump rate) (figures 3, 4).

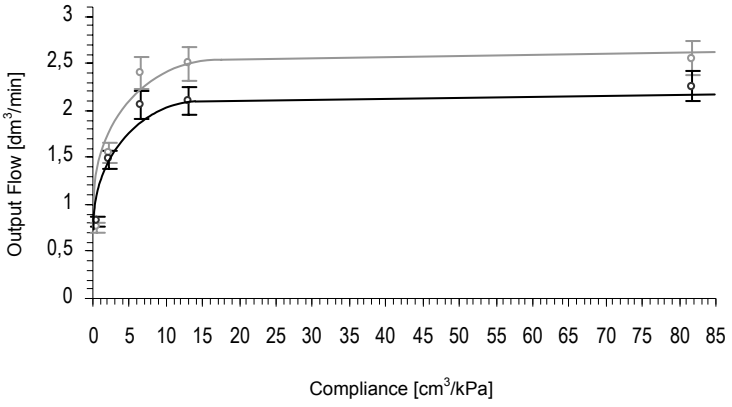


Fig. 3. The relationship between output flow and simulated inlet and outlet compliance at the following steering parameters: diastolic drive pressure p^- (DDP) of –4 kPa, systolic drive pressure p^+ (SDP) of 15 kPa, systolic duration (%SYS) of 40, pump rate (AHR) of 120 beats/min
—— Changing the output flow during simulation of five inlet compliance values and zero outlet compliance (0.63 cm^3/kPa – 81.67 cm^3/kPa)
—— Changing the output flow during simulation of five outlet compliance values and zero inlet compliance (0.63 cm^3/kPa – 81.67 cm^3/kPa)

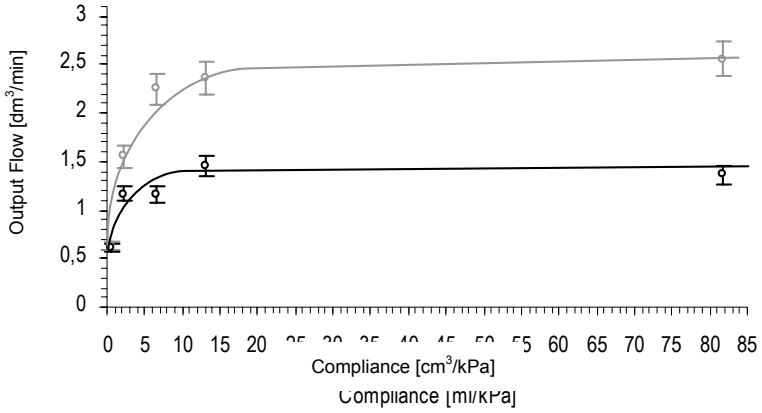


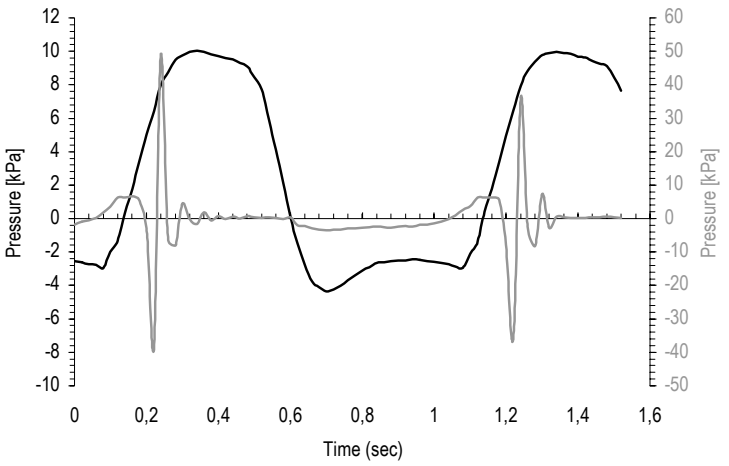
Fig. 4. The relationship between output flow and simulated inlet and outlet compliance at the following steering parameters: diastolic drive pressure p^- (DDP) of –2 kPa, systolic drive pressure p^+ (SDP) of 15 kPa, systolic duration (%SYS) of 40, pump rate (AHR) of 120 beats/min
—— Changing the output flow during simulation of five inlet compliance values and zero outlet compliance (0.63 cm^3/kPa – 81.67 cm^3/kPa)
—— Changing the output flow during simulation of five outlet compliance values and zero inlet compliance (0.63 cm^3/kPa – 81.67 cm^3/kPa)

The diagrams show that the inlet compliance plays the main role in fluid pumping which is visible at the diastolic drive pressure of –2 kPa. The difference in the output flow at the simulated compliance of 81.67 cm^3/kPa in the front of inflow valve and behind the outflow valve at diastolic drive pressure of –4 kPa (figure 3) was 0.3 dm^3/min. At a diastolic drive pressure of –2 kPa (figure 4) the difference increased up to 1.19 dm^3/min. It is interesting that the compliance ranges from 20 cm^3/kPa to about 80 cm^3/kPa in the upper *plateau*, where the changes of output flow are almost imperceptible.

During the experiment a special attention was focused on the water-hammer effect in the front of inflow valve in the systolic phase concomitant with the simulation of extreme inlet and outlet compliance values. It was caused by the big fluctuations in fluid pressure which was connected with rapid changes in the flow velocity [11]. The rate of pressure increasing *dP/dt* depends on the velocity of the wave of increased pressure, rheological properties of liquid, inertial effects and the inlet compliance. During the flow the highest pressure appears in the front of the closed inflow valve as a result of the additional volume of fluid inflow. The pressure being increased *in vivo* as a result of gradual stopping the fluid spreads along the inflow draining cannula at

a very high velocity (the velocity of the shock-wave propagation). As a results an elastic tube widens and its volume increases depending on the compliance. During a final stage of this process the liquid pressure in the front of the valve drops and the return shock wave appears. Due to the pressure difference between the left atrium and a closer end of the inflow draining cannula a renewed change of the flow direction appears. The process is repeated many times at a very high speed and in a relatively short time as long as the flow energy is dissipated. The charts (figure 5) show the simulation results of the influence of the extreme inlet and outlet compliance values on the levelling of the water-hammer effect in the front of the inflow valve.

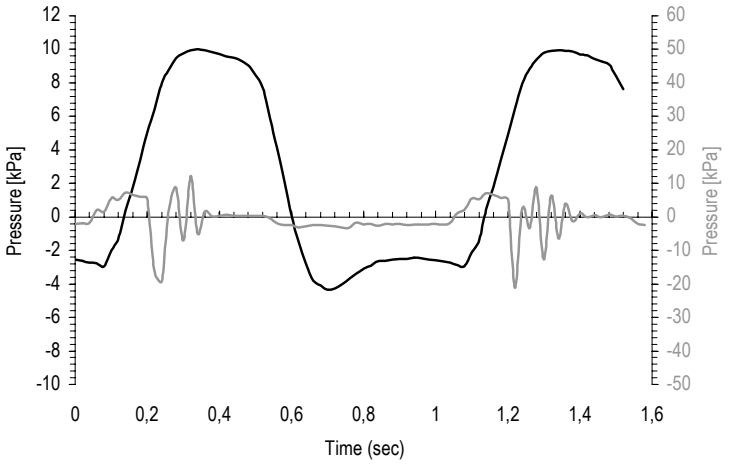
a)



—— The driving curve

—— The pressure in front of the inflow valve after simulation of the inlet and outlet compliance of 0.09 cm^3/kPa

b)



—— The driving curve
—— The pressure in front of the inflow valve after simulation of inlet and outlet compliance of 81.67 cm^3/kPa

Fig. 5. The driving curves and the water-hammer effect appearing in the front of inflow valve of cardiac assist pump in two time cycles after the simulation of two extreme compliance values: a) 0.09 cm^3/kPa and b) 81.67 cm^3/kPa. The experiment was done with the *afterload* of 2 kPa and the following steering parameters: diastolic drive pressure p^- (DDP) of –6 kPa, systolic drive pressure p^+ (SDP) of 15 kPa, systolic duration (%SYS) of 40, pump rate (AHR) of 60 beats/min

The similar experiments demonstrating the influence of the inlet and outlet compliance on the water-hammer effect have been also presented by OGINO and others [16] but the values of the simulated compliance are 0.0428 cm^3/kPa, 0.0714 cm^3/kPa, 0.0968 cm^3/kPa so it is not possible to compare the results.

During the measurements at a very high systolic drive pressure p^+ (SDP), i.e. 40 kPa, some interesting inertial phenomena in the front of the inflow valve and behind the outflow valve were observed. Single peaks of pressure occurred periodically. Their amplitude went beyond 50 kPa (figure 6). It appears that the outlet compliance has a great influence on eliminating the inertial phenomena on the inflow side of the ventricle. The inlet compliance leads to the same result on the outflow side. The above-mentioned study is original. Very often the single peaks of pressure of such a high amplitude are accompanied by cavitation phenomena and the local increase in the shearing stress. The cavitation phenomena are due to reducing the pressure in system to the level lower than the vaporizing pressure of the flowing liquid. This process is accompanied by the phase change (liquid phase changes into gaseous phase), formation of vapour bubbles (micro-jets) (their diameters range from 10 to 100 μm, and the speed exceeds 200 m/s) and local rise in temperature. The cavitational bubbles can join to form bigger structures (they lose their stability). In this way, the additional pressure impulses caused by the implosion of cavitational bubbles appear on the surface of the body. This process is accompanied by cavitational erosion. Uncontrolled cavitation causes the damage to tissue [12] and structural elements of cardiac assist pump (mainly heart valves [13]–[15]). The charts (figures 6, 7) show a distinct fall in the maximum amplitude of pressure to 45.33 kPa (±1.36 kPa) and 34.82 kPa (±1.04 kPa) with an increase in the inlet and outlet compliance to 13.04 cm^3/kPa.

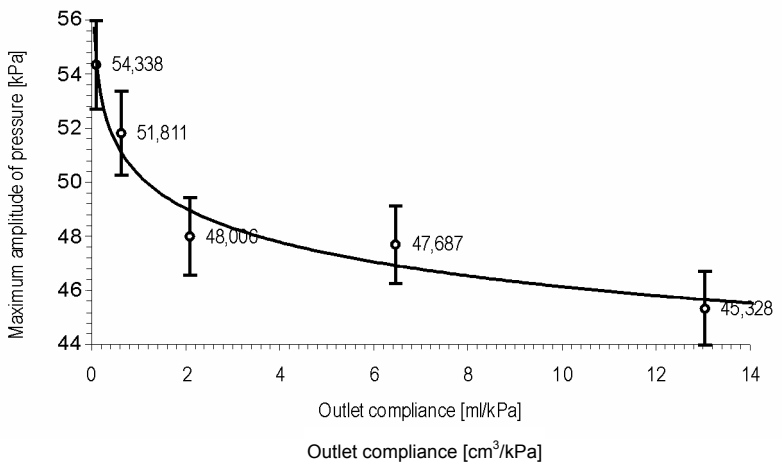


Fig. 6. The relationship between the maximum amplitude of pressure in the front of the inflow valve and the simulated outlet compliance
—— The maximum amplitude of pressure in front of the inflow valve

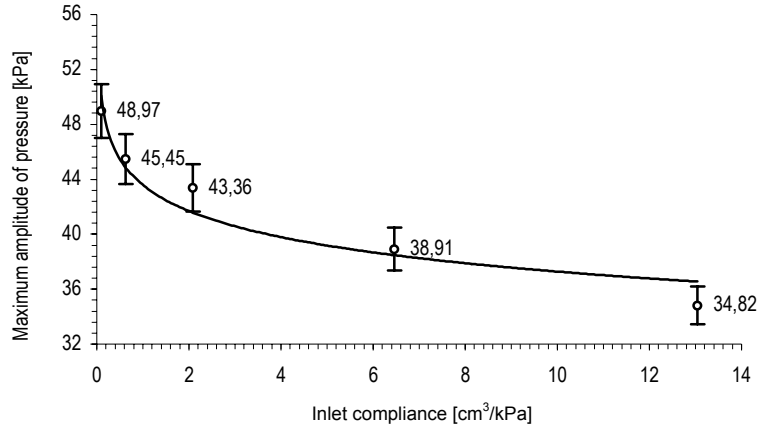


Fig. 7. The relationship between the maximum amplitude of pressure behind the outflow valve and the simulated inlet compliance
—— The maximum amplitude of pressure behind the outflow valve

In the experiments, the inlet and outlet values of compliance without electric system steering the membrane movement inside the cylinders were simulated. This was connected with the lack of synchronization of the pistons' position and the pressure generated by an artificial heart-driving unit. The authors are going to use the electronic detectors of the pistons' position.

4. Conclusion

1. The inlet and outlet compliance plays the most important role at short time of filling up the blood chamber of artificial verticle (high pump rate).

2. The effectiveness of the mechanical heart assistance is the highest at the high inlet compliance values.

3. The compliance has a great influence on the work safety of the artificial ventricle. Low inlet and outlet compliance enhances the probability of dangerous inertial phenomena (water-hammer effect) responsible for the damage to heart valves and red blood cells. In the study of heart valve cavitation phenomena, a special observation equipment, i.e. fast video camera (about 1000 frames/min), is needed.

The next study based on the method developed is planned. Physical model of the inlet and outlet compliance can be used for the simulation of fast atrial rhythms (tachycardia) with variable frequency and evaluation of their influence on the effectiveness of a mechanical heart assistance. We proved in this paper that changing the compliance we were able to affect the pump's work processes being critical to its safety. Generally, in the case of paracorporeal VAD it is possible to change the compliance of cannulae: geometry and biomechanical properties of material.

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