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COMPARATIVE IN VITRO RESEARCH OF THE HUMAN AORTIC BIOPROSTHESIS

ABSTRACT

Evaluate of the usefulness and reliability of structures based on the analysis of recorded parameters determining the flow through the Human Aortic Bioprosthesis (HAB) have been dealt with. By flow parameters changes determining the performance environment of prosthesis analyzed change of the motion dynamics of the valve leaflets as a function of pressure, thereby determining the degree of alignment of the prosthesis to the performance conditions. Based on the gathered measurement data a comparative analysis of flow rate valve prostheses for different frequency values of the piston pump imitating the heart, different ejection capacity and pressure conditioning work environment prosthesis were studied. Interpretation of the recorded image gave the basis for determining the Effective Orifice Area (EOC).

Key words: *human aortic bioprosthesis, aortic valve prosthesis, fatigue tests, heart valves*

INTRODUCTION

Aortic valve is exposes to the highest load pressure [1] therefore is the most common surgically replaced in case of damage and the consequences of its dysfunction. Distinguished by biological and mechanical heart valve prostheses. The structure of the biological prosthesis is similar to the natural and the mechanical valve made of alloys and synthetic materials [2]. Bioprosthesis are characterized by a good hemodynamic parameters [3,4,5,6] but their stability is not sufficient [7] so there is a need to construct a functional bioprosthesis resistant to phenomenon called calcification and degeneration of the leaflets. Each bioprosthesis model must be tested for its biocompatibility, functionality and durability - strength and fatigue resistance [8]. Verification of the expectations posed prosthesis model is performed using multiple research trials. The study presents the results of a pilot research of Human Aortic Bioprosthesis. Based on the collected measurement data comparative analysis of the dynamics and efficiency of the prosthesis HAB with two prosthetic reference was conducted . The study was conducted at the Ship Design and Research Centre in Gdansk under the direction of M.D.,D.Sc. Piotr Siondalski. The study was carried out to observe performance of HAB prosthesis for a period corresponding to 200,000 cycles and to record the measured parameters: flow rate and pressure values.

MATERIALS AND METHODS

An innovative HAB prosthesis is of autologous - made from the patient's own tissues so that the risk of rejection by the organism is remote and the assessment of aortic root size (diameter and height of the ring of the aortic root) allows to perform individual prosthesis for each patient. The height of the aortic valve prosthesis is equal to the length of the segment joining the ring plane of the natural valve of the artery cross-sectional plane at the height of the sinotubular junction joining and its value provides sufficient surface contact closing leaflets. Characteristic of the HAB prosthesis is the way form a "T"- shaped tabs which, thanks to their design significantly reduces the stresses induced in the aortic wall during operation of the prosthesis. The performance of the HAB prosthesis placed in the measuring area of the station was observed by 53 hours which is equivalent to about 200,000 cycles. Recording measurements were made every ten hours of operation at six different values of the piston pump frequency (from 500 to 1000 ms), and two working capacity (90 and 100 ml). The operating range contains images of acting HAB prosthesis recorded by high-speed camera allowing for quantitative assessment of variation in the time course of relationship of the hydraulic cross-sectional to the cross-sectional of the aorta at the site of sewing leaflet. Interpretation of the obtained results makes possibility to assess the adaptation of the prosthesis to the full physiological range of flow parameters and to assess its effectiveness and functionality of the structure. The main purpose of in vitro HAB valve comparative studies is to determine usefulness and reliability of its construction based on the parameters analysis defining the flow through the prosthesis. Based on changes in the flow parameters determining the working environment of prosthesis analyze the change of dynamics of the valve leaflets as a function of pressure was conducted thereby defining the degree of alignment of the prosthesis to the conditions of it performance. Based on the measurement data gathered a comparative analysis of flow rate valve prostheses were studied for different frequency values of the pump piston imitating heart function, different ejection volume and pressures conditioning work environment prosthesis. Interpretation of registered image gave the basis for determining the Effective Orifice Area.

RESULTS

Analysis of HAB prosthetic operation in varying conditions of pressure

To evaluate the efficiency of the prosthesis under varying conditions the valve was subjected to a fatigue test in the environment of variable pressure which have been obtained by adjusting parameters such as stroke volume of the piston pump and the frequency of movement of the piston thus affecting the number of cycles in a given time. The operation of the human aortic bioprosthesis placed in test section of the flow stand was observed for 53 hours which is about 200 thousand duty cycles. On average every ten hours of recording measurements were made at six different values of the period of the piston pump (from 500 to 1000 ms) and two working capacity (90 and 100 ml). The figure 1 and 3 show a comparison of the change pressure measured ahead and behind HAB and reference prosthesis (Reference_1 and Reference_2) for two values of the period of the piston: 500 and 900ms. Variations of pressure over time function for all three tested prosthesis (for the piston frequency 900ms which are equivalent to 54 heartbeats per minute) is comparable indicating

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properly matched geometry of the prosthesis. While valve HAB is fully open (contraction of the left ventricle) the maximum aortic root pressure measured behind prosthesis come up to 150 mmHg which is a characteristic value for hypertension but its high value may be related to too low elasticity of the arterial system. At the closure of the prosthesis pressure falls to 70 mmHg and the mean maximum differential pressure (figure 2) amount 90 mmHg. Comparing the characteristic values for a specific phase of the cycle to the pressure values available in the PN-EN ISO 5840 performance of the valve HAB in the environment defined by the above-mentioned parameters can be considered appropriate for a healthy heart valve action [8]. For high piston frequency (the period of 500 ms or 120 beats/min) the exact values of the measured pressure ahead the prosthesis has not been registered because of too narrow measuring range of the used sensors and hence the differential pressure (figure 4) of the HAB prosthesis in time corresponding to the ventricular systole is equal to zero.

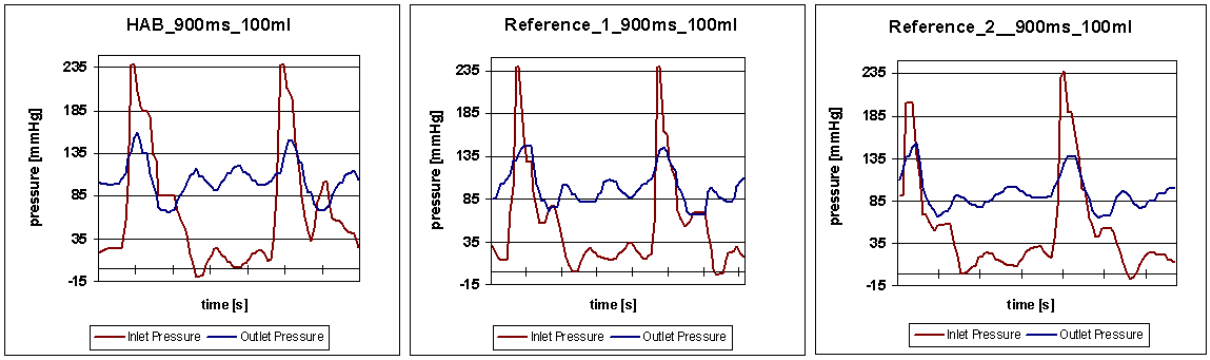

Fig. 1. Comparison of pressure values run during the two cycles of studied valves for 900 ms piston frequency and 100 ml working volume pump

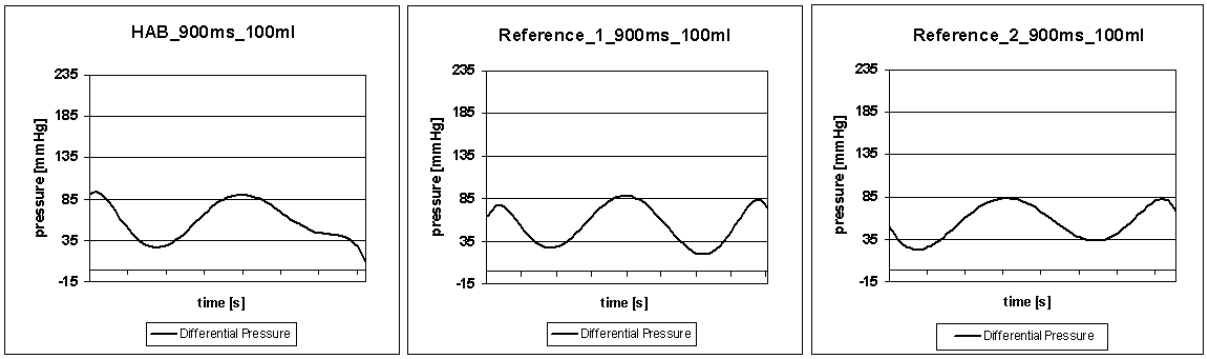

Fig. 2. Changes in valvular pressure difference of the three tested prostheses for 900 ms piston frequency and 100 ml working volume pump

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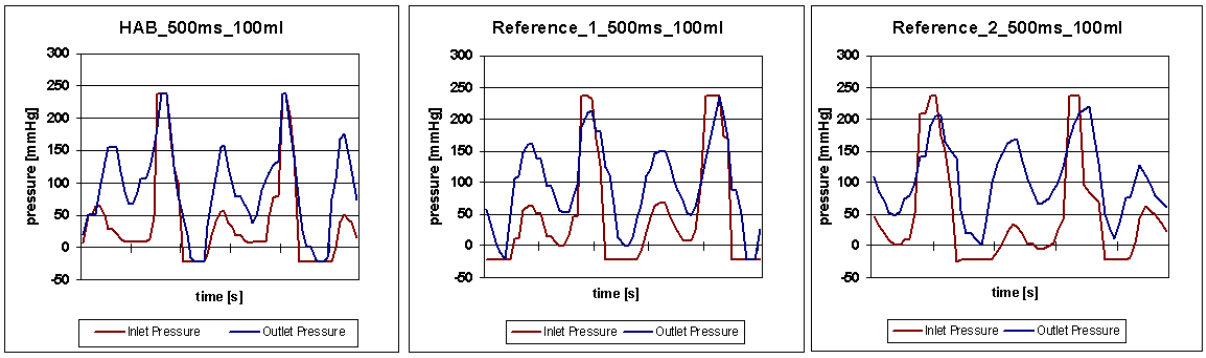

Fig. 3. Comparison of pressure values run during the two cycles of studied valves for 500 ms piston frequency and 100 ml working volume pump

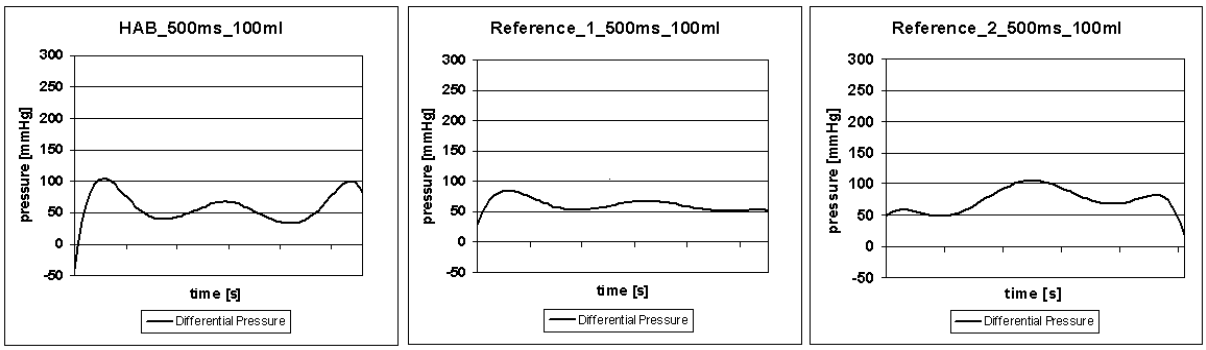

Fig. 4. Changes in valvular pressure difference of the three tested prostheses for 500 ms piston frequency and 100 ml working volume pump

The analysis of the pressure function for HAB prosthesis (period 500 ms and piston 100 ml) allowed the classification of the prostheses with a wide range category. Although specific to the advanced stage of hypertension conditions prosthesis HAB fulfills its purpose, its operation is stable and the pressure difference in during the full closure is equal to about 100 mmHg what gives a strong argument demonstrating the absence of reverse flow. No registration measurements operating prosthesis for reduced pressure conditions (the lower frequency of the piston) does not allow to set the lower limit of the effective operating of the HAB prosthesis. Still based on the analysis of the pressure function in the working environment referred to specified parameters may be confirm the functionality of the valve structure, and the possibility of to adapt to the physiological range of flow parameters.

Analysis of flow rate under varying conditions

Through the valve of healthy person being standstill passes about 5 liters of blood in the course of one minute. The measure of effective work prosthetic valve is flow rate, which depends on the geometry and the possibility of adapting the operating mode of the valve to the specific conditions of pressure. Flow rate through the HAB valve is similar to the flow rate of the reference prostheses which confirms its functionality (Figure 5). Figure 6 presents the images (captured by the high-speed camera) of full open prosthesis for equal frequency of the piston and the working capacity what fully argue obtained volume flow measurement. Low flow rate of the Reference_1 valve prosthesis result from irregularities in the retaining of

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the angular commissure position (120 °) whereby one of the cusps during the full opening of the valve instead of being pressed to the wall of the aorta forms a secant passing by two other commissures of the prosthesis thus inhibiting the flow.

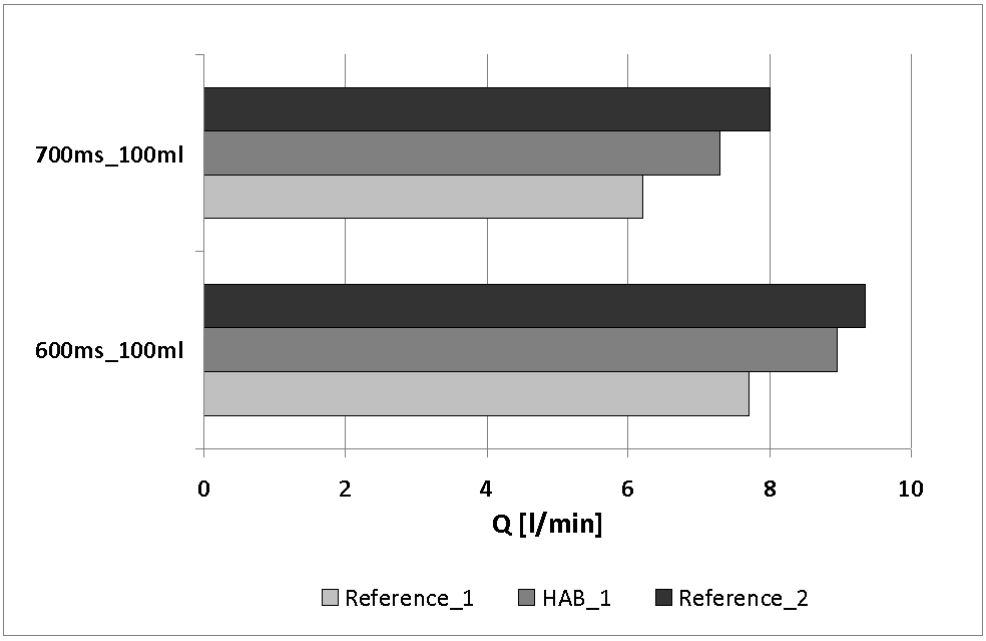

Fig. 5. Comparison of the flow rate through the test valve prostheses for different frequencies of the pump piston

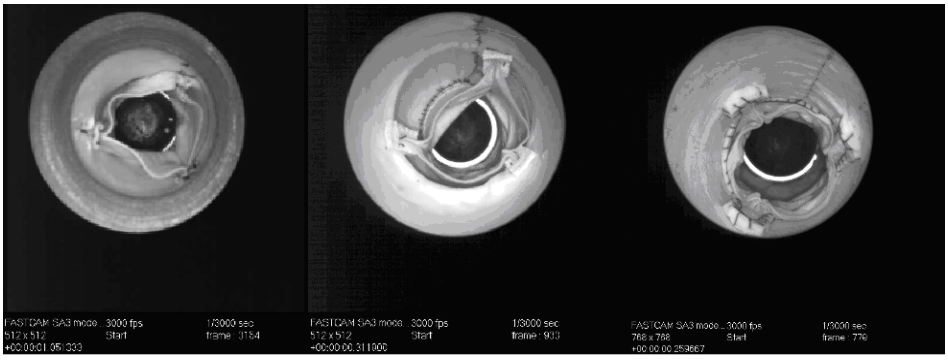

Fig. 6. Image captured by the high-speed camera showing the full opening of the implants treated with the same parameters of the flow. On the left: HAB_1, Reference_1, Reference_2.

Digital image analysis of aortic valve prosthesis

Recording of prosthetic performance has enabled to determinate the ratio of the Effective Orifice Area to cross-sectional area of the prosthesis in place of sewn allowing an objective assessment of the effectiveness of the HAB prosthesis. Using knowledge of the hydraulic cross-sectional to aorta cross-sectional ratio (Figure 7) for variable flow conditions it is possible to determinate the effective performance point of the prosthesis which largely depends on the geometry of the valve.

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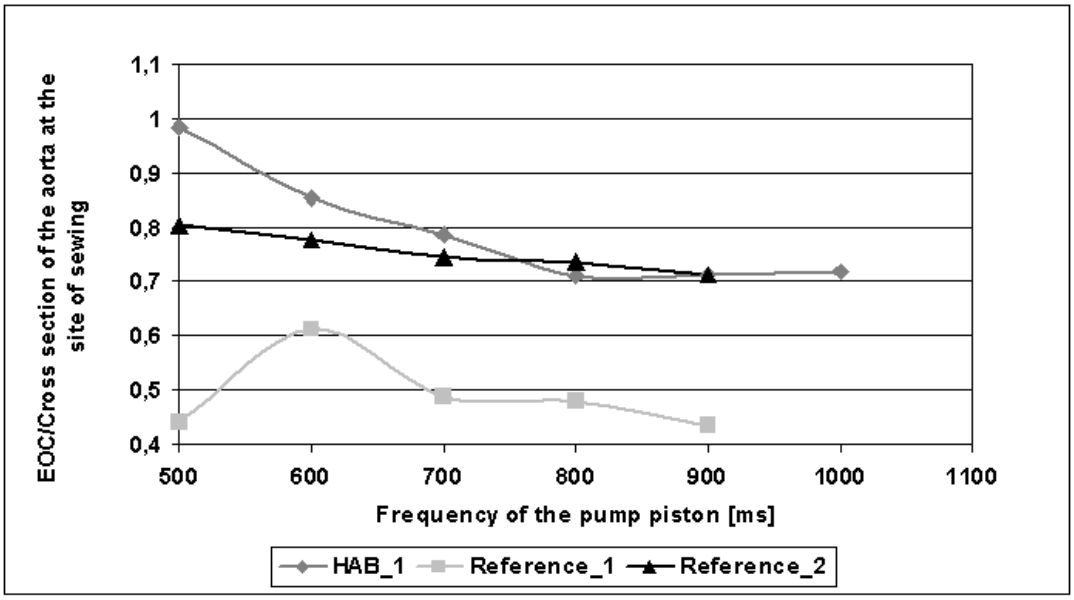

Fig. 7. Changing the Effective Orifice Area for a different frequency of the pump piston and working volume of 100 ml

Based on the results of the research test HAB prosthesis can be considered as the most functional of investigated as it allows for the flow of the working medium through the largest hydraulic cross-section for flow conditions characterizing the blood flow of a healthy person. Increased efficiency of the HAB prosthesis towards greater frequency of the pump piston results from the large diameter of the valve prosthesis. Extending the duration of one duty cycle of the prosthesis by reducing the frequency of the pump creates a low pressure environment for which the prosthesis having a diameter of 49 mm is less susceptible. To improve the performance of the prosthesis (at low frequency) diameter of the prosthesis should be reduced providing greater susceptibility and sufficient flow rate or provide a greater pressure difference which is subjected to.

DISCUSSION

Pilot fatigue tests of HAB prosthesis prove the possibility of adapting it to the full, physiological range of flow parameters and the results of the research test become a strong argument qualify HAB prosthesis for long-term fatigue tests performed in accordance with ISO 5840. In order to standardize the research trial should be made synchronize the high-speed camera's output signals with pressure sensors which will become the basis for analysis of the change of Effective Orifice Area in function of differential pressure. Registration pressure using sensors with a wider range of measurement is essential for a reliable analysis of the prosthesis performance and the observation of change flow rate in function of time will allow the determination of the relation between flow rate and pressure gradient as well as confirmation of the hypothesis of the absence of reverse flow.

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CONCLUSIONS

The analysis of the pressure function running and flow values for different flow conditions through the HAB confirm the accuracy of the geometry of the prosthesis, and the ratio of Effective Orifice Area to cross-sectional area of the aorta at the site of sewing testify about high effectiveness of performance. HAB prosthesis fully fulfills its function and created on the basis of long-term fatigue tests made in accordance with ISO documentation becomes a strong argument to start in vitro testing and clinical trials. Conducted pilot study allowed to assess the performance of the HAB prosthesis in terms of its dynamics and efficiency but also to define the requirements bench are the basis for the implementation of long-term fatigue tests. Define on the basis of strength tests and microscopic analysis of material requirements will create a biocompatible, long-term aortic valve prosthetic which does not require the use of anticoagulation therapy and is created individually for each patient.

REFERENCES

1. Li J, Luo XY, Kuang ZB., A nonlinear anisotropic model for porcine aortic heart valves. Journal of Biomechanics 34 (2001), 1279–1289.

2. Dasi LP, Simon HA, Sucosky P, Yoganathan AP., Fluid Mechanics of Artificial Heart Valves. Clin Exp Pharmacol Physiol 36(2) (2009), 225–237.

3. Bartuś K, Sadowski J, Kapelak B, Myć J, Bartuś S, Oleś K, Filip G., Evaluation of the aortic valve gradient in the patients with stentless 3F bioprothesis made of equine pericardium – one year follow-up [in Polish]. Kardiochirurgia i Torakochirurgia Polska, 8 (3) (2011), 328–331.

4. Maselli D, Pizio R, Bruno LP, Di Bella I, De Gasperis C., Left Ventricular Mass Reduction After Aortic Valve Replacement: Homografts, Stentless and Stented Valves. Ann Thorac Surg. 67 (1999), 966 –971.

5. Kunadian B, Vijayalakshmi K, Thornley AR, de Belder MA, Hunter S, Kendall S, Graham R, Stewart M, Thambyrajah J, Dunning J., Meta-Analysis of Valve Hemodynamics and Left Ventricular Mass Regression for Stentless Versus Stented Aortic Valves. Ann. Thorac. Surg. 84 (2007) 73–79.

6. Rocha Farias F, Diniz Affonso da Costa F, Mendel Balbi Filho E, de Fátima Fornazari D, Collatusso C, Dumsch de Aragon Ferreira A, Veiga Lopes S, Fernandes TA., Aortic valve replacement with the cardioprotese premium bovine pericardium bioprosthesis: four-year clinical results. Interactive Cardio Vascular and Thoracic Surgery 15 (2012), 229–234.

7. Niclauss L, von Segesser LK, Ferrari E., Aortic biological valve prosthesis in patients younger than 65 years of age: transition to a flexible age limit? Interactive CardioVascular and Thoracic Surgery, 16 (2013), 501–508.

8. Polish Standard PN-EN ISO 5840:2009, Cardiovascular implants-implants heart valves

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