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PLANIKS DISK VALVE PROSTHESES

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The design of new types of mechanical disk valve prostheses on the basis of domestic biocompatible materials is described. The hydrodynamics of PLANIKS artificial valves was investigated on an original pulse duplicator that imitated the function of the left parts of the heart. The results confirm high qualitative hydrodynamic characteristics of domestic prostheses and allow the prediction of their successful clinical application.

The occurrence of acquired heart failure (AHF) with damage to the valvular apparatus in the population comes to 0.62-0.72%. With natural progress of the disease, 50% of the patients perish in the first five years from the time of the appearance of initial clinical signs [1-6].

Surgical treatment of the pathology of a valvular apparatus is a method selected for correcting hemodynamically significant heart failures. After valve prosthetics, the survival rate five years after operation exceeds 80–90% [7-14].

The number of AHF patients in Belarus is considerably greater than in developed countries [15]. Basically these are middle-age patients with injuries to the valvular apparatus due to a rheumatic process, which in majority of cases does not allow one to use bioprostheses or employ plastic procedures. One should also take into account the constantly increasing number of patients with multiple injuries to heart valves. This makes it possible to determine the need of rheumatic patients in artificial cardiac valves (ACV) for up to 1700–1900 prostheses a year. At the level of the costs of prostheses on the world market, additional expenses for the Republic amount to $3.7 million in U.S. dollars every year.

Thus, the timeliness of creating modern cheaper domestically produced artificial cardiac valves not inferior to world analogs is evident.

With the current state in anesthesiology, extracorporal blood circulation, and revivification, the most essential factor that influences the results of treatment and the quality of life for patients is the design of ACV [16-24].

Long-term application of ACV made it possible to formulate requirements for the prostheses developed [25-31]: good hemodynamic characteristics, durability, simple implantation, tolerance by a patient, and absence of hemolysis, as well as a minimum number of thromboembolic complications.

Experience gained by cardiosurgeons has proved the advantages of mechanical disk prostheses over other types of ACV by the majority of the parameters indicated. In view of this, the aim of this investigation was the development of a new construction of a disk prosthesis with the use of domestic biocompatible materials, as well as the creation of a rig for testing ACV and thus for estimating the hydrodynamic characteristics of a prosthesis.

Beginning in 1991, the Belarusian Scientific-Research Institute of Cardiology together with the Planar Scientific Industrial Association began the development of PLANIKS mechanical disc prostheses. At the present time bench tests and experimental certification were carried out with two types of prostheses: single-cuspid (PLANIKS-M) and bicuspid (PLANIKS-D) valves. The former is being used successfully at the clinic of the Republican Center of Cardiovascular Surgery; more than 500 prostheses have been implanted in AHF patients.

The PLANIKS-M ACV consists of three main parts: a casing, a disk locking element, and a sewn cuff.

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The casing is made of type VT-16 (OST1-9001381) titanium and has no places of soldering or welding. There are two hinges in the casing with limiting panels into which a locking element is inserted, as well as four disk limiters made in the form of small lips protruding out of the casing.

Along the circumference of the inner surface of the casing a ledge is made on which the disk rests in a closed position of the valve. In contrast to other similar constructions of ACVs, this element of the PLANIKS-M prosthesis has the minimum height in the region of hinges that gradually increases to the side of free poles of the casing. Such a configuration makes it possible to increase the throughput of the valve, decrease pressure gradient, and decrease the volume of return flow.

The disk limiters have the most minimal (of all the known ACVs of this type) dimensions, with two of them being made in the form of longitudinal lips on the panels of the hinges; they are located in the direction of the blood flow and do not create stagnant zones. The casing of the PLANIKS-M has a low profile (the maximum height with the limiting panels of the hinges is 7.4–9.1 mm) and thin walls for improving the inner diameter/cuff diameter ratio.

The overall design of the casing ensures minimum flow turbulence, good washing of the hinges, and reduction of stagnant zones. The eccentricity of the axis of the hinge mechanism makes it possible to more uniformly distribute the flow over the large and small straight-through holes.

The locking element is made of USB-2 (ETO 035209 TU) carbon-sital in the form of a convexo-concave disk. Such a form of the disk favors the creation of a laminar flow and decreases its stress states, facilitates the processes of complete and fast opening and closing of ACV, and ensures stability of the disk in an open position.

The locking element does not have points of constant contact with the casing; it freely floats in the hinges and stably rotates in the casing (the speed of rotation is 0.4–5 deg/cycle).

The sewn cuff is made of polyether fabric (POVM-13M, TS 17-09-122-82 polyethylenetetraphthalate). Mitral and aortal prostheses have cuffs of different shapes: the cuff of an aortal valve is thinner and higher and that of a mitral valve is thick and broad. The overall construction of the cuff ensures adaptation of ACV to the uneven fabric bed.

The PLANIKS-D ACV also consists of free basic parts: a casing, a locking disk element in the form of two flaps, and a sewn cuff.

The casing of the prosthesis is made of a single piece of USB-15 (TS 48-4807-261-91)-type carbon-sital. The hinge mechanism on the side of the inner surface of the casing has recesses as portions of torus surfaces that are located on the rotation axes of the locking element flaps. The recesses and the torus surface are separated in the direction of the blood flow by radius ledges. The height of the casing along the entire circumference is equal to 4.5–7.7 mm depending on the size of the prosthesis.

The overall design of the casing ensures the minimum turbulence of flow, good washing of hinges and decrease in stagnant zones. The symmetric nature of the axis of the hinge mechanism allows one to more uniformly distribute the flow over straight-through holes.

The locking element is made in the form of two flaps also made of carbon-sitall. From the side of effluence the flaps have guiding lips whose centers are located on the rotation axes of the flaps. In closed position the flaps are at an angle of 20° to the plane of the casing; this decreases the time of complete opening of the valve. The maximum angle of opening is 75°.

The rotation of the flaps at the time of the opening of ACV is determined by the shape of the torus recesses in the casing and by the guiding lips of the locking element. In the closed position the rotation of the flaps is limited by the surfaces of the recesses in the casing. In this position both halves of the locking element adjoin each other by chamfered surfaces providing sufficient tightness of valve closing.

Guarding against falling out of the flaps from the casing in the process of valve operation is ensured by the ledges of the flaps placed in the recesses of the casing and by the torus surfaces of variable radius.

The design of hinges with an open exit to the general canal of the valve forsees free irrigation by blood flow of the zones of contact of the flaps with the valve casing; this makes it possible to decrease hemolysis and thrombogenesis.

TABLE 1. Technical Characteristics of the PLANIKS-M/D Prostheses

Type of a valve	Size of a valve	Setting diameter, mm	Flow-through diameter, mm		Area of flow-through hole, cm^2		Height of a closed valve, mm	
Aortal	A–19	19	14.0	14.4	1.5	1.6	7.4	4.5
	A–21	21	16.0	16.4	2.0	2.1	7.6	4.9
	A–23	23	18.0		2.5		7.9	5.5
	A–25	25	20.0		3.1		8.1	6.0
	A–27	27	22.0		3.8		8.3	6.5
Mitral	M–23	23	18.0		2.5		8.5	5.5
	M–25	25	20.0		3.1		8.7	6.0
	M–27	27	22.0		3.8		8.9	6.5
	M–29	29	24.0		4.5		9.1	7.0
	M–31	31	24.0	26.0	4.5	5.3	9.1	7.7

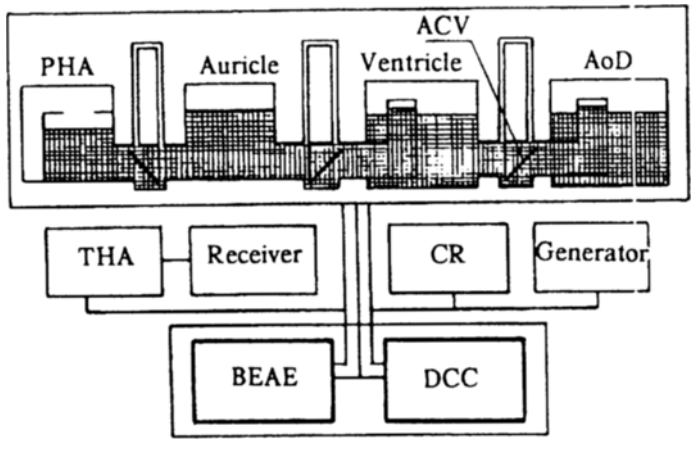


Fig. 1. A rig for evaluating the physiological parameters of an ACV.

At the same time the rotation mechanism in the form of torus recesses with extended surfaces and ledges on the flaps with the surface corresponding to the surfaces of the recesses makes it possible to reduce the specific pressure as well as friction in the hinges and to decrease the wear of the elements of the valve, since friction between the casing and the flaps is distributed over the developed torus surfaces and radius surfaces of the ledges in the casing.

The sewn cuff is made of polyether knitted fabric based on carbon. Mitral and aortal prostheses have cuffs of the same height, but of different shape, fitted to the prosthesis casing with a banding device of unique design providing for free rotation of the casing relative to the cuff.

The PLANIKS prostheses are made of 10 standard sizes intended for implantation into mitral and aortal positions. The main technical data on ACV are presented in Table 1.

The tightening of requirements for reliability and durability of ACV resulted in the creation of a pulse duplicator that allows one with a high degree of validity to determine the main hydrodynamic characteristics of prostheses and, consequently, to predict their function in vivo. For this purpose the following problems were solved: a rig for testing was developed that most completely imitates the function of the left parts of the heart, and a mathematical model is developed for control and automated evaluation of the hydrodynamic characteristics of ACV with the use of modern computing means. The rig (Fig. 1) includes:

TABLE 2. Time-Amplitude Regime of Pressures in Checking the Function of the Locking Element of ACV, Its Flow-Through Ability and Reverse Flow for the Aortal (A) and Mitral (M) Positions

Names of parameters	A and M			
	Function of the locking element		P_{sys}, V_{cl}, $\dot{V}_{leak}$	
	A	M	A	M
Constant excess pressure at the inlet of an ACV (GPa)	2.7	2.7	27	13
Amplitude of variable pressure at the exit of an ACV (GPa)	200	270	130	160
Time characteristics of the pressure pulse curve at the exit of an ACV (sec):				
a) duration of leading front	0.1	0.1	0.1	0.1
b) duration of constant value (T_{pf})	0.1	0.1	0.45	0.15
c) duration of trailing front	0.1	0.1	0.1	0.1
d) duration of pressure pulse (T_{sys})	0.3	0.3	0.65	0.35
Frequency of cycles (Hz)	1.7	1.7	1.2	1.2
Error of setting a constant excess pressure at the inlet of an ACV, GPa	+0.7	+0.7	+2.7	+2.7
Error of setting the amplitude of variable pressure at the exit of an ACV (%)	10	10	10	10
Error of setting time characteristics of the pressure pulse curve at the exit of an ACV, sec	+0.5	+0.5	+0.5	+0.5
Error of setting the frequency, %	10	10	10	10

a) a facility for testing including a testing block, a thermostat-heater and a thermostat-storage (THS), a receiver, control relays (CR), and a Sinus-AH 3 pulse pumping oscillator;

b) a unit for control and automatic documentation consisting of a dialog-computational complex (DCC) based on a personal computer and a block of electroautomatic equipment (BEAE).

The basic diagram of the testing block consists of the following chambers: "auricle," "ventricle," aortic damper (AoD), and a pneumohydroaccumulator (PHA).

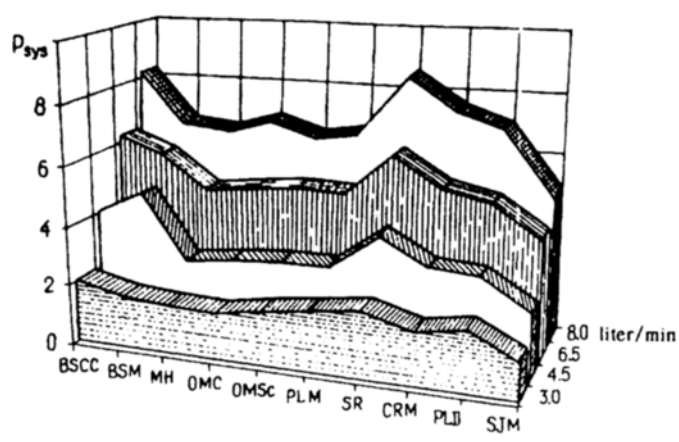
The control of the testing block and calculation of the hydrodynamic parameters of ACV is carried out with the help of a special program on an IBM AT in the real time regime.

An obligatory condition for checking ACV for jamming is operation for not less than 600 cycles. Automatic documentation of data for the certificates of the PLANIKS valves is forseen. Moreover, visual control of all the hydrodynamic characteristics is possible.

In the process of the tests of ACV for transmissive capacity the angle of disk opening, jamming and resource, as well as the mean pressure gradient (P_{sys}), reverse flow at the time of valve closing (V_{cl}), and the volume of leakage of a closed valve (V_{leak}), the control unit assigns hydrodynamic parameters that are close to physiological ones: constant excess pressure at the ACV inlet is from 2.7 to 27 GPa, at the ACV exit from 130 to 270 GPa; the overall duration of the pressure pulse is 0.3–0.65 sec, and the frequency of pulses is 1.2–1.7 Hz. The error of the measurement of all the parameters does not exceed 10% of the prescribed one.

The time-amplitude regime of pressures created by the rig is presented in Table 2.

Thus, the possibilities of the rig make it possible not only to carry out standard tests that guarantee the normal functioning of each prosthesis in vivo (the angle of opening of the disk, absence of jamming), but also more complex investigations that open up the prospect of determining the general "qualitative coefficient" of ACV.



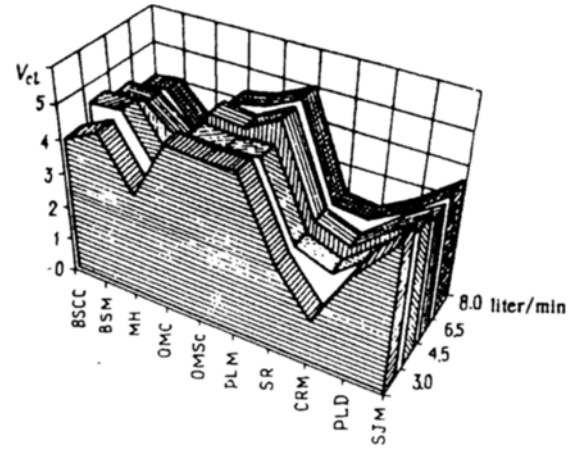


Fig. 2. Systolic pressure gradient.

Fig. 3. Reverse flow during closure of an ACV.

One of the most important advantages of disk prosthesis over other types of ACVs is their durability. The estimation of the wear resistance of the PLANIKS prostheses is performed during their resource tests on the pulse duplicator with the operation of not less than 400 mln cycles, which is equivalent to a 10-year period of ACV functioning in the organism.

Such a constructive solution as free floating in hinges and stable rotation in the casing of the locking element of the PLANIKS-M ACV makes it possible to decrease the wear of the disk to 1–2 μm/yr with its uniform distribution over the entire surface of the locking element.

The design of the rotational mechanism of the PLANIKS-D ACV also allows one to reduce the specific pressure and friction in hinges and still further decrease the wear (to 0.5–1.5 μm/yr), conducive to which is the much smaller mass of the locking elements.

This leads one to conclude that the theoretical time of the normal function of the PLANIKS prostheses in the organism approaches 200 years.

To determine the general "qualitative coefficient" of domestically produced prostheses and their place among the world-famous designs of ACV, we investigated the hydrodynamic characteristics of the PLANIKS prostheses and of 8 different foreign models of artificial cardiac valves.

Calculations of hydrodynamic parameters are based on reproducible tests recommended by the FDA (Food and Drug Administration, U.S.). Investigation was carried out with valves 27 mm in diameter in the aortal position at a fixed frequency of 70 beats per minute (beats/min) with the heart ejection of 3.0–8.0 liter/min. In this case the systole duration was 300 msec, the mean aortal pressure was 100 mm Hg, and the mean precordial pressure was equal to 10 mm Hg.

We determined the following characteristics: P_{sys}, V_{cl}, V_{leak}, general regurgitation ($V_{cl} + V_{leak}$) for each ACV. The mean value of each parameter was calculated on an IBM AT on the basis of the following formulas:

$$P_{sys} = \frac{1}{T_{sys}} \int_{T_{sys}} (p_{iv} - p_a)\, dt\,, \quad V_{cl} = \int_{T_{cl}} V_{AO}\, dt\,, \quad V_{leak} = \int_{T_{leak}} V_{AO}\, dt\,.$$

We present the results (Figs. 2, 3, 4, 5) of the tests of the following ACVs: Bjork–Shiley convexo-concave (BSCC), Bjork–Shiley Monostrut (BSM), Medtonic–Holl (MH), Omnicarbon (OMC), Omnisciens (OMSc); Planiks-M (PLM) single-cuspid valves and Carbomedics (CRM), Planiks-D (PLD), St. Jude Medical (SJM) bicuspid valves.

Systolic Pressure Gradient (P_{sys}). According to the results of the tests, the SJM bicuspid ACVs had the smallest mean systolic pressure gradient (4.7 mm Hg at the heart ejection of 8.0 liter/min). Thin flaps and a large (85°) angle of opening determine the minimum stenotic effect of this ACV.

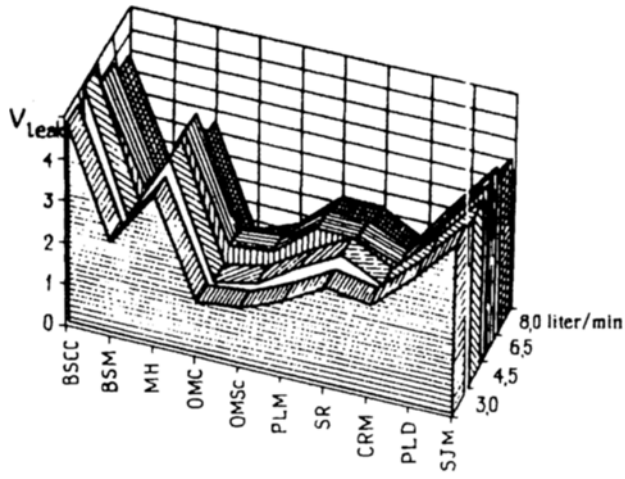


Fig. 4. Volume of leakage of a closed valve.

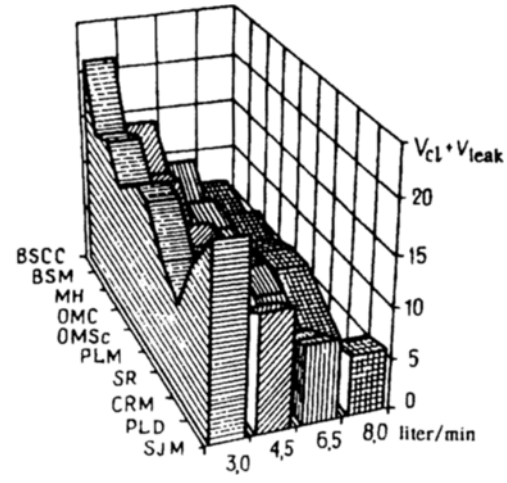


Fig. 5. General regurgitation, % of stroke volume.

At the same time, the Bjork-Shiley convexo-concave and Sorin single-cuspid prostheses with the disk opening angle of 60^0 have the maximum pressure gradient (8.2–8.6 mm Hg).

By this characteristic (6.6 mm Hg) the PLANIKS-M ACV, just as the majority of other single-cuspid prostheses (6.3–6.8 mm Hg) occupy the middle position. A PLANIKS-D creates a less expressed stenotic effect (P_{sys} – 7.1 mm Hg) than a CRM (7.5 mm Hg at virtually the same opening angle). In our opinion, this is due to the more perfect design and light flaps of the PLANIKS-D prosthesis.

Reverse Flow at the Time of Valve Closure (V_{cl}). The Sorin prosthesis (2.3 ml/beat) with a small opening angle displays the smallest losses at the time of the ACV closure. An increase in the opening angle of the valve leads to lengthening of the time of ACV closure and correspondingly to the growth of reverse flow. In this connection, such ACV as OMSC, OMC, and SJM have enlarged reverse flow volumes (3.7–4.6 ml/beats).

Moreover, this characteristic is influenced by the geometric form, inertial mass of the flaps and the general design of the prosthesis. The latter explains such different values of the indicated parameter for the Carbomedics (2.2 ml/beats), PLANIKS-M (5.0 ml/beats) and PLANIKS-D (2.8 ml/beats) ACVs.

Volume of leakage of a closed valve (V_{leak}) depends on the difference of pressures on both sides of the ACV, diastole length, size of potential slits between the casing and locking element, as well as on the viscosity of the liquid used. Omnisciens, Omnicarbon, Carbomedics, and PLANIKS-M ACVs have a circular ledge on the inner surface of the casing that creates additional hermetic sealing at the place of contact of the disk with the ACV casing. This explains the smallest (from 0.5 to 1.8 ml/beats) volumes of leakage.

Larger volumes of irrigation characteristic for St. Jude Medical bicuspid ACVs (3.6–4.0 ml/beats), on the one hand, are conducive to the prophylaxis of thrombogenesis in the stagnant zone and, on the other hand, potentially increase the possibility of hemolysis due to the strengthening of the so-called "shearing" effect.

In contrast to the St. Jude Medical prostheses, the design of the locking elements of the PLANIKS-D prevents discharge through the slit between the flaps, decreasing the leakage volume (2.4 ml/beats) and correspondingly the "shearing" effect.

The General Regurgitation (V_{cl} + V_{leak}). The minimum general regurgitation equal to 2–9% of the stroke volume (SV) is characteristic for the Carbomedics ACV, while the maximum one is typical of the St. Jude Medical (6–19% SV) and Bjork–Shiley convexo-concave (6–21% SV) ACVs. Due to their design specific features, the PLANIKS prostheses have mean values of this hydrodynamic parameter (5–15% SV) despite a relatively appreciable volume of regurgitation at the time of ACV closure.

The results of our rig tests of various models of mechanical ACVs have shown that there is no prosthesis that would possess ideal characteristics of all the parameters investigated. The gain in the reduction of pressure gradient and, consequently, in the decrease of potential losses of energy at the valve attained by an increase in the

ACV opening angle is levelled off by an increase in the general regurgitation and correspondingly by an increase in energy expenditures for displacing additional volumes of liquid.

Investigation of the hydrodynamic characteristics of the PLANIKS-M ACV at different heart ejection volumes has shown that judging from each parameter (mean pressure gradient, reverse flow at the time of ACV closure, leakage volume of a closed valve) the home-made prostheses occupy a mean position in a row of the well-known disk ACVs, while for each parameter the PLANIKS-D ACV approaches the leaders in the group of the prostheses investigated.

This proves that the PLANIKS prostheses have an excellent design, allowing us to look forward to good results when using them in clinical practice. Moreover, the selection of materials for a PLANIKS ACV, namely, carbon-sital, titanium, polyether fabric on the basis of carbon, on the one hand ensure durability and biocompatibility and on the other hand are very adaptable to commercial production. The latter determines a much lower cost of a prosthesis and its high competitiveness.

However, despite the fact that rig tests allow one to compare different ACV models under identical conditions, some caution is required in the application of the results and their prediction in vivo. In an organism the geometric relationships between an ACV and inner structures of the heart and aorta substantially alter the character of blood flow, creating stagnant and turbulent zones and causing the processes of hemolysis and thrombogenesis.

The hemolysis caused by the "shearing" effect is most characteristic for a high-velocity blood flow. Such conditions of hemodynamics arise when blood passes through an ACV (pressure gradient) and during reverse flow through the prosthesis (leakage volume of a closed valve). In this case the velocity of blood passage through the slits of a closed ACV is 3–5 times larger than at the height of the systole. On the other hand, an increased volume of irrigation prevents thrombogenesis in stagnant zones formed by an ACV.

Moreover, it is known that the blood viscosity is 3.7 times higher than that of the working fluid (distilled water) used in the rig. This fact potentially alters the relationship between many of the parameters investigated during the operation of an ACV in vivo. The most probable in this case are a 7% decrease in energy losses due to the reduction of regurgitation and a 7% increase in energy expenditures due to the increase in the pressure gradient [26, 28, 29].

Thus, the results of rig tests of home-made PLANIKS ACVs make it possible to predict satisfactory results of their clinic application. However, the final evaluation of the physiological adaptability of prostheses is possible only after their long application in the clinic taking into account the entire spectrum of the possible reactions of the organism.

CONCLUSIONS

1. The construction of the rotational mechanisms and locking elements of home-made disk PLANIKS-M and PLANIKS-D ACVs makes it possible to create optimum hydrodynamic conditions on a prosthesis.

2. The use of biocompatible and wear-resistant materials (titanium, carbon-sital) ensures high durability and reliability of the construction, as well as making it possible to predict good results of the clinical application of prostheses.

3. An automated rig for evaluating the hydrodynamic characteristics of ACVs allows one to carry out a standard checking of an ACV before its implantation in a patient, as well as to evaluate the quality of the prosthesis design.

NOTATION

P_{sys}, mean pressure gradient, mm Hg; V_{cl}, reverse flow at the time of valve closure, ml/beats; V_{leak}, volume of leakage of a closed valve, ml/beats; $V_{cl} + V_{leak}$, general regurgitation (% of stroke volume); T_{sys}, systole duration (sec); T_{cl}, duration of valve closure (sec); T_{leak}, duration of leakage of a closed valve, sec; p_{iv}, pressure in the

"ventricle" chamber, mm Hg; p_a, pressure in the "auricle" chamber, mm Hg; V_{A_0}, volumetric flow velocity in an aorte, liter/min.

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