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STRUCTURAL EVOLUTION OF MECHANICAL HEART VALVES (REVIEW)

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Prosthetic heart valves are widely used biomedical devices. The need for these prostheses is increasing due to the increasing life expectancy of the general population and the consequent incidence of age-related degenerative valvular defects. However, even though mechanical prosthetic valves have been significantly modernized over the last decades, they are still associated with several life-threatening complications, the main one being thrombosis. Addressing this problem is challenging and requires collaboration between bioengineering and cardiothoracic surgery. Thus, the problem of creating the most adapted model of prosthetic heart valve (PHV) turns out to be at the confluence of sciences – medicine, biology, applied mechanics, mathematical modeling, etc. Today, it seems clear that the engineering ideas for hemodynamic adaptation of PHV models have been fully developed. However, research in the field of materials science, as well as a search for surface modification methods, remain a pressing bioengineering challenge.

Keywords: heart valves, mechanical valves, acquired heart diseases.

The prevalence of mitral and/or aortic heart disease is above 10% among patients aged >75 years and it continues to increase every year [1–3]. Prosthetic heart valve replacement remains an effective and often the only possible way to treat heart valve diseases. This procedure eliminates pathologically altered structures, improves intracardiac hemodynamics and patient's quality of life [4, 5]. Since the first aortic valve replacement surgery was performed in March 1960 by Dwight Harken at Boston City Hospital, hundreds of thousands of such interventions have been carried out [6, 7]. However, despite the obvious progress in the development of PHV models and improvement of surgical implantation technique, the postoperative period is associated by a high risk of several complications [8–10]. According to surgical registries, between 250,000 and 280,000 prosthetic heart valves are implanted worldwide each year: the approximate ratio is 50/50 between mechanical and biological ones [5, 11].

Despite the availability of many modern anticoagulants and antiplatelet agents, the use of even the latest PHV models is associated with thromboembolic events in 0.7–6.4% of patients [12]. According to Dangas et al., thromboembolic syndrome occurs in 0.1–5.7% of cases [13]. Studies by Pibarot et al. showed that about 10% of patients with implanted mechanical PHV have one episode of thromboembolism per year [14]. At the same time, the incidence of PHV dysfunction ranges from 0.4% to 6.0% per year of the total number of prosthetic operations performed. According to many authors, this figure is significantly underestimated because routine screening aimed at detecting prosthetic valve dysfunction in the postoperative period is not performed in most cases if there are no clinical symptoms that would lead to suspicion of dysfunction [15–18]. Implantation of mechanical PHVs requires lifelong use of anticoagulants, which is also associated with a risk of complications. Patients taking oral anticoagulants to prevent thromboembolism are prone to hemorrhage, especially retroperitoneal, gastrointestinal, and intracranial hemorrhage. Bleeding complications occur in approximately 4% of patients annually, with 5–10% of these events resulting in death [16]. In addition to anticoagulants, patients at high risk of thromboembolism take platelet inhibitors, which are associated with a 55% increased risk of bleeding [17].

The development of reliable design and the search for inert/hypothrombogenic materials have been the subject of many years of scientific and engineering research. Since the first mechanical PHV models were introduced, they have been continuously improved. However, creating a PHV model that fully matches the characteristics of native human heart valves remains a dream for designers, cardiac surgeons, and patients.

The main function of any PHV is to provide unidirectional blood flow. An ideal prosthesis should meet the following requirements: it should have a reliable and fairly simple design that pressures long-term continuous functioning for decades; it should have good hemodynamic characteristics, i.e. it should provide laminar blood

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flow that is as close as possible to physiological characteristics, and should not create excessive pressure gradient between the heart chambers that it shares; it should be biologically inert, be hemocompatible/hypothrombogenic, be easy to implant, have good radiographic visibility, and have low noise characteristics [18].

The invention of balloon-expandable prosthetic valves undoubtedly provided a tremendous boost to surgical treatment of heart valve diseases. Since the introduction of the Starr–Edwards PHV model in 1960 through 1998, over 175,000 such valves have been implanted in mitral, aortic, or tricuspid positions [19]. However, the large weight, height (profile), and inertia of the locking element limited the use of balloon models in many cases: in patients with severe mitral stenosis, in patients with a small left ventricular cavity, etc. (Fig. 1).

The Starr–Edwards model underwent 8 modifications between 1960 and 1965 based on surgeon feedback, analysis of postoperative complications, and patient outcomes. The last improved model was then used unchanged until 2004 [20]. The use of ball-locking prosthetic models was often associated with turbulent flow, episodes of thromboembolism, and lack of effective orifice area.

According to Best et al., during the first year after implantation of the Starr–Edwards model, mortality was

Fig. 1. Starr–Edwards mechanical heart valve model

Fig. 2. Björk–Shiley mechanical heart valve model

21%; over the next 7 years, this rate decreased to an average of 3% per year [21]. However, 10-year freedom from prosthetic valve thrombosis, thromboembolism, and prosthetic valve endocarditis for the Starr–Edwards model was 91, 91, and 97, respectively [22–24].

The results described were primarily associated with imperfections in the design of the prosthesis itself. However, in fact, a significant decrease in the incidence of thromboembolic complications after implantation of this PHV model over time was down to the evolution of anticoagulant therapy protocols. By 1997, freedom from this type of complication ranged from 74% to 87% at 10 years after implantation [25, 26]. Nevertheless, in November 2015, Albert Starr documented cases of the longest functioning of the Starr–Edwards balloon model after primary implantation – 51.7 years and 44.4 years in aortic and mitral positions, respectively [20].

The next fundamentally new PHV models were rotary disc valves, where the closing element was a disc that rotates around an eccentric axis, thus opening and closing the flow orifice (Fig. 2).

The hemodynamic characteristics of this model were significantly better than ball valves. The dimensions of the valve allowed safe implantation in cases where the annulus fibrosus was small and avoided the development of low cardiac output syndrome in patients with a "small" left ventricle. The first implantation of the most successful model of disc prosthesis, the Björk–Shiley valve, was performed in Sweden in 1969 [27]. Structurally, this valve was a freely moving disc occluder enclosed in a Teflon-treated stellite cage. The opening angle of the valve was 60 ± 2° [28], nevertheless, this angle was quite sufficient to prevent excessive hemolysis.

So in a study by Falk et al. [29], the serum lactate dehydrogenase (LDH) level was elevated in all patients who had the Starr–Edwards valve implanted in the aortic position, but was elevated only in one third of patients after implantation of the Björk–Shiley model. The size of the prosthesis was of particular importance, as smaller balloon valves especially in the aortic position caused more significant hemolysis than larger prosthetic valves. However, the degree of hemolysis in the case of the Björk–Shiley model is so small that the size of the prosthesis had little or no effect. According to Björk, in a group of 1657 patients carrying Björk–Shiley valve models, the 15-year actuarial survival rate was 54%, and thromboembolic complications were observed in the long-term period in 5.4% of cases [30].

A study by Gunn et al. conducted at Turku University Hospital (Finland) involved 279 patients. Mean actuarial survival after implantation of the Björk–Shiley model in the aortic position was 19.8 years, the mean follow-up period was 19.2 years (maximum 34 years). Freedom from reoperation was 91.3% at 30 years. There were three cases of outlet strut fracture, two of which were fatal [31–34].

In 1977, a third-generation mechanical prosthesis was developed; St. Jude Medical Inc. (USA) produced a bicuspid carbon fiber prosthesis (Fig. 3) [35].

Fig. 3. St. Jude Medical mechanical heart valve model

The St. Jude Medical valve body and flaps were made of pyrolytic carbon, which has exceptional strength and low thrombogenicity. The flaps had an 85° opening angle to minimize flow turbulence. The low profile of this valve model and the rotation mechanism of the locking elements allowed for comfortable positioning of the prosthesis and minimized contact with subvalvular structures. With more than 84% of the valve area in the orifice, the average transprosthetic pressure gradient did not exceed 10 mmHg (in the aortic position), which was the lowest of all PHV models available at that time. However, the hinge units in this model were placed in the center of the prosthesis, which created three blood flows through the valve (Fig. 4) [14, 36, 37].

Based on an analysis of 25 years of experience with the St. Jude Medical valve, operative mortality was 4% and 9% when implanted in the aortic and mitral positions, respectively. Patient survival at 10 years after prosthesis

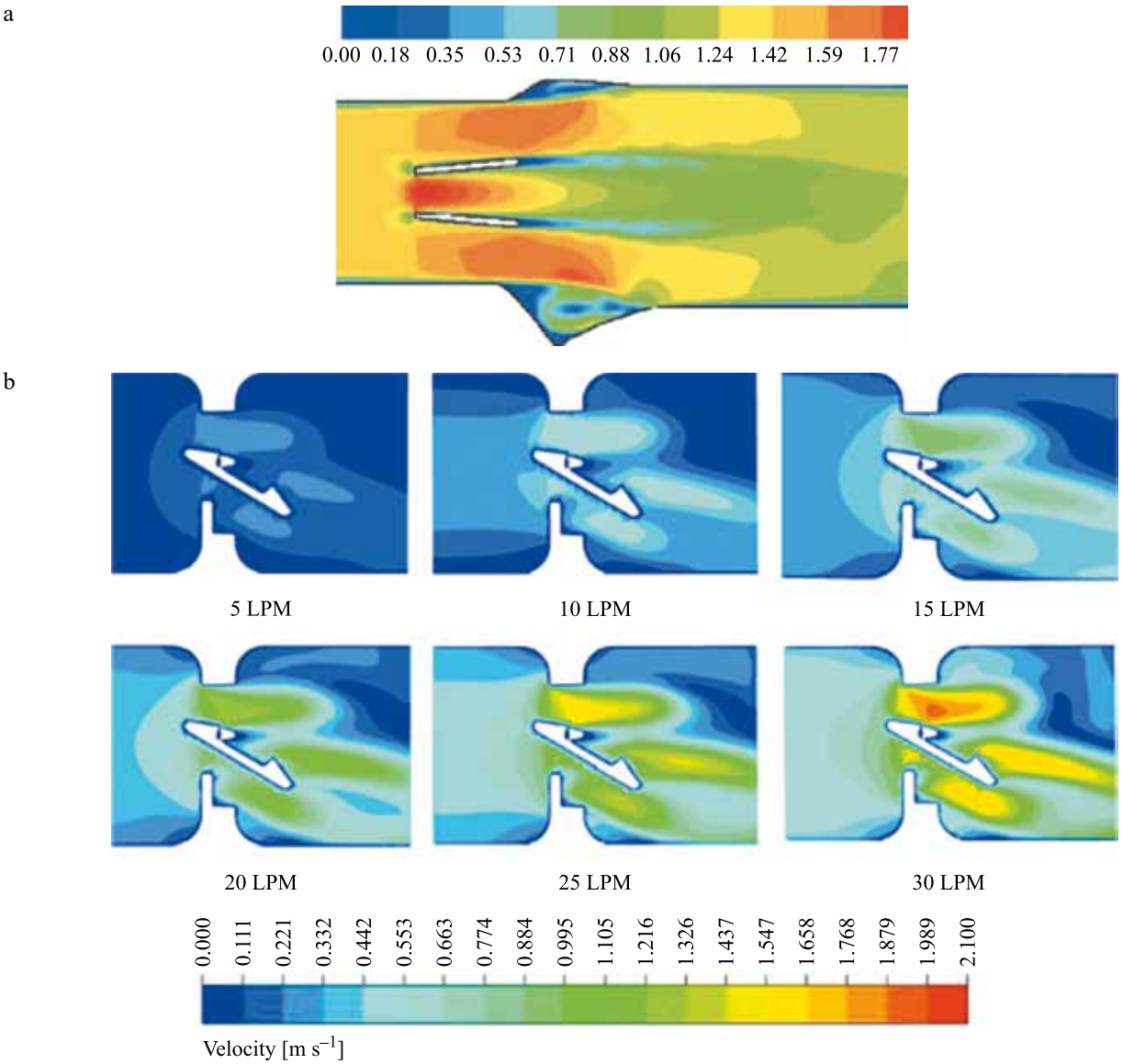

Fig. 4. Numerical modeling showing the distribution of flow velocity through a bicuspid valve model (a) and Björk–Shiley disc prosthesis (b) at a cardiac output of 5 L/min [14, 38]

was 57 ± 3% and 60 ± 2%, respectively [39]. According to Johnson et al. [40] the late actuarial survival of patients undergoing aortic valve replacement with St. Jude prosthesis was 62 ± 2%, 32 ± 2%, and 14 ± 3% after 10, 20, and 30 years, respectively. Thirty-year freedom from reoperation, thromboembolism, prosthetic valve thrombosis, bleeding, and endocarditis were 92 ± 2%, 79 ± 3%, 96 ± 1%, 56 ± 5%, and 92 ± 2%, respectively. A study by Rodrigues et al. [41] reported that valve-related mortality with the St. Jude prosthesis in the aortic valve replacement group was 11.3%, of which bleeding and thromboembolism accounted for 78%. In the mitral valve replacement group, 14% of deaths were valve-related, of which bleeding and thromboembolism accounted for 89%.

However, the St. Jude Medical valve model was also subjected to numerous modifications, resulting in the PHV On-X, a bicuspid mechanical heart valve prosthesis, the main feature of which was the presence of protrusions at the locking point of the flaps. In the open position, each leaf was deflected, forming an angle of 90° relative to the plane of the support ring. This property largely determined the laminar nature of flow through the valve.

The best results of On-X valve implantation among all known models of mechanical PHVs allowed us to explore the possibility of optimizing the safe international normalized ratio (INR) value in order to reduce the risk of complications associated with anticoagulant therapy [42]. The PROACT study investigated the safety of using different anticoagulant and antiplatelet therapy regimens after PHV On-X aortic valve replacement in low- and high-risk patients. Dual antiaggregant therapy in low-risk patients has been shown to result in a significantly higher incidence of neurological complications. This necessitated early termination of the study in this group [42, 43]. In the high-risk group (reduced left ventricular ejection fraction, increased left atrial volume, presence of atrial fibrillation), a reduced INR proved to be safe: no difference in survival and major cardiac events after 5 years [43].

Results of a study of survival after aortic valve replacement with different mechanical heart valve models are presented in Table.

The bicuspid aortic valve prosthesis design is used in prosthetic heart valves like ATS Medical Prosthesis, Sulzer CarboMedics, Sorin, MedInj, and others. Since the development of the bicuspid aortic valve, over 2.1 million implantations have been performed worldwide [36, 40]. However, the development of prostheses with the largest possible effective orifice to provide a hemodynamics that is close to that of the native valve remains a priority in PHV development. In our country, the improved PHV model is the domestic full-flow bicuspid valve MedEng-ST (Fig. 5) [5, 54].

The main advantage of the MedEng-ST valve is its design: the leaflets are fixed on hinge fasteners located on opposite sides of the ring, which helps to eliminate stagnant zones around the fasteners and reduces the likelihood of thromboembolic complications. A distinctive feature is the obturative element made in the form of two cylindrical segments, covering blood flow through the valve from the outside and providing blood flow centralization, minimal traumatization of formed elements, increasing the effective area of the valve orifice and reducing transprosthetic pressure gradient [5, 54].

Fig. 5. MedEng-ST mechanical heart valve model

Table

Actuarial survival after aortic valve replacement with different mechanical heart valve models

Literature	Valve model	Mean age, years, M ± SD	Survival (%)				
			1 year	5 years	10 years	15 years	25 years
Khan et al., 2001 [44]	St. Jude Medical	64.5 ± 12.9	91–95	71–87	39–73	17–61	N/A
Emery et al., 2005 [39]	St. Jude Medical	64 ± 13	N/A	N/A	N/A	N/A	<25
Toole et al., 2010 [45]	St. Jude Medical	56 ± 14	N/A	81	59	41	17
Tatsuishi W., 2015 [46]	St. Jude Medical	58.3 ± 11.7	N/A	96.2	92.7	88.8	N/A
Tossios et al., 2007 [47]	On-X	62.7	N/A	N/A	67.9	N/A	N/A
Carrier et al., 2006 [48]	CarboMedics	57 ± 12	N/A	83	70	62	N/A
Butchart et al., 2001 [49]	Medtronic-Hall	60 ± 11	N/A	N/A	64	45	N/A
Svennevig et al., 2007 [50]	Medtronic-Hall	54.3 ± 13.6	N/A	78.6	61.9	46.7	24.9
Ahn et al., 2007 [51]	Björk–Shiley Monostrut	34.5	96.8	N/A	91.1	86.5	N/A
Dietrich et al., 1989 [52]	Björk–Shiley Monostrut	60.5	N/A	98	N/A	N/A	N/A
Kallewaard et al., 2000 [36, 53]	Björk–Shiley convexo-concave	53.5 ± 13.9	92.1	83.7	68.7	55.0	N/A

Analysis of velocity distribution fields by finite element method using COMSOL Multiphysics program (Stockholm, Sweden) made it possible to clearly assess the degree of adaptation of PHV models and the ability to maintain laminar blood flow (Fig. 4 and 6). Unlike predecessor models (St. Jude Medical, Björk–Shiley), the MedEng-ST full-flow valve demonstrates excellent hemodynamic characteristics and flow laminarity of the profile.

Hemodynamic factors of thrombosis include the local hemodynamics features of the PHV, as well as individual parameters of patient hemodynamics [56]. Blood flow laminarity and the washability of all PHV components are among the main conditions for the effectiveness and safety of the PHV model. Reduced shear stress leads to stasis and increased blood coagulation [57], just as reduced cardiac output is a predictor of postoperative prosthetic valve thrombosis [58, 59]. Because of this, prosthetic valve thrombosis is almost 20 times more common in tricuspid valve replacement than mitral valve replacement. Similarly, PHV thrombosis in the mitral position is 2–3 times more common than prosthetic aortic valve thrombosis [60].

The flow characteristics of a prosthetic heart valve is considered the most important factor on which the safety and durability of a PHV model depend. However, an equally important condition determining the risk of thromboembolic complications is the surface properties of the materials from which the PHV components are made [61, 62]. Today, the main material used for manufacturing PHV locking elements is pyrocarbon. Widespread clinical use of pyrolytic carbon components for heart valve replacement began in October 1968, when Dr. Michael DeBakey implanted an aortic valve with a pyrolytic hollow-centered occlusion balloon with carbon ball [63]. After the first experience with the pyrolytic carbon component of PHVs, several million prosthetic mechanical valves made of this material have been implanted. The use of pyrolytic carbon in the fabrication of mechanical prosthetic heart valves was heralded as an "exceptional event" because the excellent durability, stability, and biocompatibility of pyrolytic carbon allowed the valves to be used for the lifetime of the patients [64]. Despite the modern pyrolytic carbon coating of prostheses, patients with implanted mechanical heart valves require lifelong anticoagulant therapy with vitamin K antagonists to prevent thromboembolic complications [65].

In contrast to healthy endothelium, which actively resists thrombosis, artificial surfaces promote clotting through a complex series of interrelated processes, including protein adsorption, platelet, leukocyte, and erythrocyte adhesion, thrombin generation, and complement activation. Rapid adsorption of plasma proteins onto artificial surfaces is thought to be the initiating event in thrombus formation because the protein layer modulates subsequent reactions of the coagulation cascade [66]. In turn, the dynamics of this process are related to the

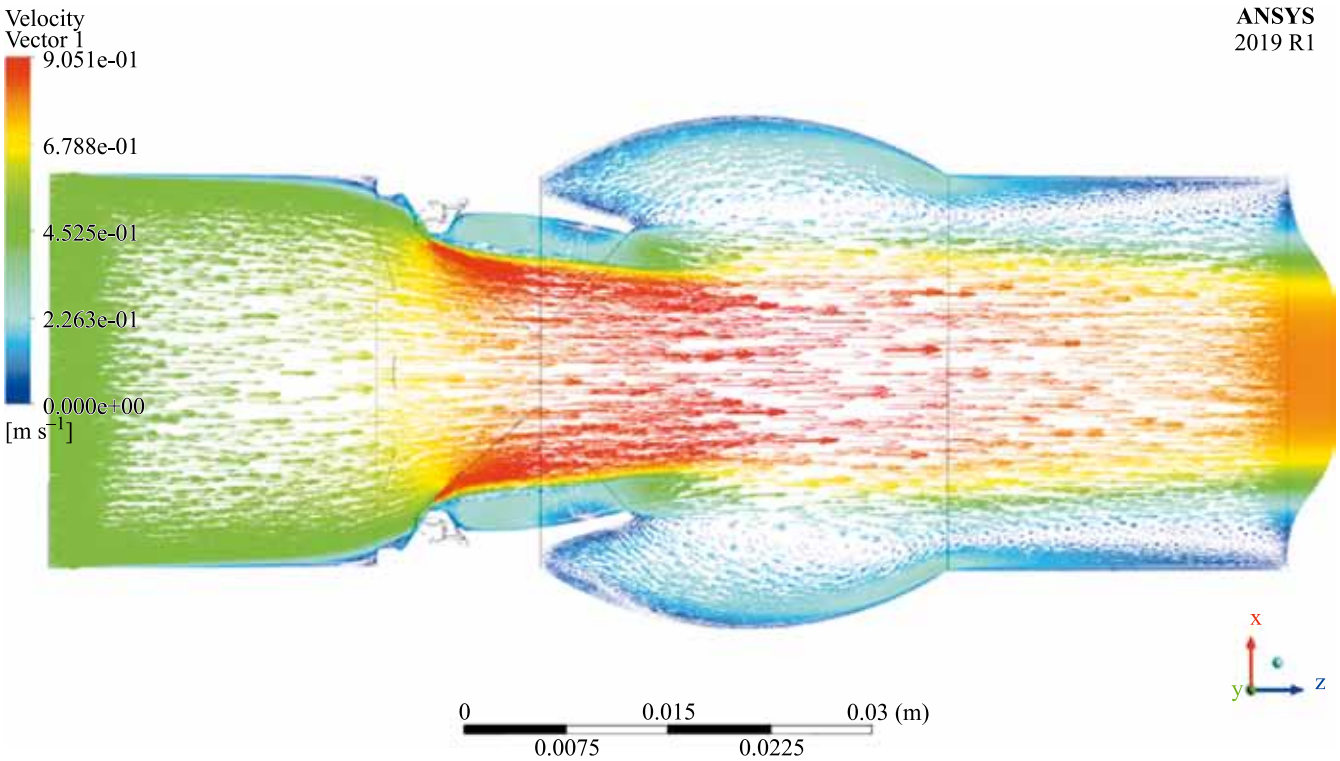

Fig. 6. Numerical modeling showing the distribution of flow velocity through the MedEng-ST model at a cardiac output of 5 L/min [55]

chemical and physical properties of the blood-contacting surface. Adsorbed proteins can form a monolayer surface with a 2–10 nm thickness, and their concentration on the surface can be 1000 times higher than in plasma [16, 67]. This process is particularly active on negatively charged surfaces [3] and appears to be flux independent [68]. At the same time, hydrophilicity is a key factor determining protein adsorption [67, 69]. The activation cascade is largely initiated by fibrinogen. Fibrinogen is one of the first plasma components to be adsorbed onto artificial surfaces. Other adhesive proteins, including Willebrand factor, also co-mediate platelet adhesion together with fibrinogen. Adsorbed fibrinogen is soon replaced by components of the contact system, including factor XII, high-molecular-weight kininogen, prekallikrein, and factor XI [70]. Activation of factor XII not only triggers thrombin generation through the intrinsic coagulation pathway, but also activates the complement system, which enhances thrombin generation [71–73]. Platelets adhered to the artificial surface of PHV are activated and they release thromboxane A2, ADP and other agonists of the hemostasis system. Leukocytes, especially neutrophils, also stimulate fibrinogen adsorption via CD11b/CD18 [74, 75]. In contrast to receptor-mediated adhesion of platelets and leukocytes to the protein monolayer, erythrocyte adhesion occurs passively [76]. Cross mechanisms between the complement and coagulation systems lead to formation of a platelet-fibrin network on the surface of prostheses [66].

Several studies have shown that platelet activation at the blood-material interface is dependent on a high albumin/fibrinogen (A/F) adsorption ratio (>1.00). That is, the higher the A/F ratio, the lower the number of adhered platelets [77]. Although pyrolytic carbon adsorbs albumin, concentration of fibrinogen on its surface is much higher and comparable to that in contact with silicone rubber [77]. However, in addition to protein absorption, the interaction energy and, consequently, the possibility of conformational changes in the protein layer are important in the development of subsequent thrombogenic reactions. Nyilas E. et. al, in the course of studying the interaction of blood plasma with foreign surfaces by measuring the heat of absorptions using the microcalorimetric method, found that this parameter for fibrinogen was significantly lower on pyrolytic carbon surfaces than on the known thrombogenic control (glass) surface up to completion of the formation of the first monolayer coating [78]. Furthermore, the measured net heats of adsorption of gamma globulin on pyrolytic carbon were about 15 times smaller than those on glass. As a result, the authors concluded that the low heat of adsorption on the foreign surface implies small interaction forces without conformational changes in the proteins that could activate the coagulation cascade. Thus, the protective protein layer formed after the first contact with blood ensures continuous exchange of protein molecules in an unchanged state, masking the pyrolytic carbon surface as a non-native one [79]. Approximately 3 months after implantation, the fibrin coating is replaced by a neointimal layer consisting of smooth muscle cells, elastin fibers, and endothelial cells. Over time, the neointimal layer matures and becomes more fibrous [80].

Chemical and physical surface properties of materials, such as hydrophobicity, hydrophilicity and surface energetics, determine biological reactions at the interface [81]. In addition, the topography of the biomaterial surface plays an essential role in determining bioinertness – it is this parameter that largely influences cell behavior (cell adhesion, proliferation, differentiation, and apoptosis). However, although this fact has long been known, the mechanisms underlying this process remain unexplored. It is known that cells can sense and respond to the nano-relief of a material using the so-called “contact guidance” [82, 83]. Superhydrophobic surfaces may provide an alternative approach to minimizing the thrombotic risk associated with blood-material interactions [84, 85]. These surfaces are fabricated by combining materials with low surface energy (typically <15 mN $\cdot$ m^{-1}) and texture [86]. It is known that these materials can reach contact angles as high as 120°. Microscopic air pockets existing in textured surfaces result in a composite liquid-air-solid interface and thus minimize the solid-liquid interface [86]. In addition to minimizing blood contact, material surface responses based on the Cassie-Baxter state can alter local hemodynamics through fluid slippage, potentially reducing the risk of hemolysis and platelet activation caused by increased shear stress [87].

The search for new synthetic materials that most closely mimic the properties of native endothelium has led to the emergence of a number of technologies for surface hypothrombogenic modification of implants. The machining and grinding operations of PHV parts do not exclude the appearance of cracks or surface defects, which can subsequently affect the service life of the product. Precise control of the surface modification process provided the possibility of applying a coating layer with the thickness necessary to eliminate surface defects caused by mechanical grinding, the main method of processing pyrolytic carbon [88, 89].

Surface modification of PHVs with coatings of various compositions can be used to improve selective properties (thromboresistance, anti-inflammatory effect) without changing their volumetric properties [90]. Over the past decade, diamond-like carbon (DLC) coating has been actively investigated for its possible use to improve the biocompatibility of synthetic materials, including PHVs [91–93]. In 1993, Dion et al. reported pronounced hypothrombogenic properties of DLC coatings during a study of the hemocompatibility of DLC-treated prosthetic heart valves made of titanium alloy T16A14B (SFERO-FII, St. Just Malmont, Frances) [94].

Since the early 2000s, DLC films have been shown to be bioinert, resistant to mechanical stress and corrosion, and non-cytotoxic to monocytes/macrophages, fibroblasts, and osteoblasts [95]. They have quite good hemocompatibility due to the optimal ratio of sp^3- and sp^2-hybridized carbon atoms [96]. In the last 5 years, due to some dissatisfaction with the results of biomedical testing of DLC coatings, publications on their physicochemical modification (in particular, with silicon and its oxides) improving the consumer properties of a-C:H:SiOx surface on medical materials and products have been accumulating [95]. Over the past few years, the study of cytotoxicity of a-C:H:SiOx coatings in relation to blood leukocytes, platelet adhesion, proinflammatory cytokine/chemokine production, as well as mechanical, anticorrosion and tribological properties has delivered impressive results. However, the safety and efficacy of such surface modification remains a subject of debate [91, 92, 97–99].

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