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Characteristics of a self-expanding anatomically shaped valve for prosthetic replacement of the right ventricular outflow tract

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Abstract

Background. *Patients following radical corrections of conotruncal congenital heart defects often develop right ventricular outflow tract dysfunctions as the child grows. It is well known that repeat surgical interventions, in addition to technical challenges, are associated with high risks and mortality. With advancements in endovascular surgery, transcatheter prosthetic right ventricular outflow portion (RVOP) replacement has become a viable alternative to thoracotomy surgery for a specific patient group. However, the choice of the "ideal" valve for transcatheter interventions remains a subject of debate.*

Objective. *The aim of this study was to develop a valve for transcatheter implantation into the pulmonary artery position, considering anatomical*

variations of the RVOP, and to evaluate the hydrodynamic properties of the valve in vitro using bench testing.

Material and methods. *Based on the data obtained from a retrospective analysis of patients after radical correction of conotruncal congenital heart defects, a team of researchers from the Bioprosthetics Laboratory at the Center for New Surgical Technologies of National Medical Research Center n.a. Academician E.N. Meshalkin developed a prototype of a self-expanding nitinol frame for transcatheter pulmonary artery replacement.*

Conclusions. *The prototype of the first domestically produced self-expanding pulmonary bioprosthesis for transcatheter implantation with an anatomically shaped nitinol frame demonstrated optimal hydrodynamic properties during the initial stages of preclinical testing. The anatomical design of the frame allows for valve implantation into the native right ventricular outflow tract without prior stenting.*

Keywords: congenital heart defects, pulmonary artery stenosis, valve dysfunction, tetralogy of Fallot, valve endoprosthetics

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CHD, congenital heart defect
CRF, rebounding force
DSC, differential scanning calorimetry
PA, pulmonary artery
RcF, recoil force
RF, radial force
RRF radial resistance force
RV, right ventricle
RVOP, right ventricular outflow portion

Introduction

The prevalence of congenital heart defects (CHD) among newborns is approximately 9% [1]. Of these, 20% of cases involve abnormalities of the pulmonary artery (PA) valve or right ventricular outflow portion (RVOP) [2] with defects such as tetralogy of Fallot, common arterial trunk, or pulmonary atresia. In patients in this group, the surgical treatment during the first month of life improves the prognosis [3]. However, after definitive treatment of such anomalies, as the child grows, the right ventricular (RV) outflow tract dysfunctions occur, as a rule, requiring further interventions. It is known that repeated surgeries are not only technically challenging but also associated with increased risks, including high mortality. With the development of endovascular surgical technologies, transcatheter prosthetic replacement of the RV outflow tract has become a worthy alternative to thoracotomy operations in a certain group of patients. P. Bonhoeffer et al. [4] performed the first transcatheter pulmonary valve implantation in 2000, which marked the beginning of a significant improvement in valve systems, and today there is an active search for “ideal” prostheses [5] for transcatheter treatment of this cohort of patients. Today, two main groups of valve systems are used for implantation in the PA valve position. The first group is balloon-expandable valves, in which the prosthesis is manually mounted on a balloon catheter. The disadvantage of such systems is the anatomical discrepancy of the placement zone in many patients. In such clinical cases, there is a need for preliminary stenting of the RV outflow tract, which in turn increases the volume and risks, as well as the cost of the intervention. The second group of valve systems are self-expanding prostheses, which do not require preliminary stenting of the RV outflow tract. Although a pulmonary valve replacement is a life-saving procedure

for children and adolescents with severe RV outflow tract insufficiency, a critical issue for all types of valve systems is the diverse anatomical variations of the pulmonary outlet tract and trunk in patients after definitive treatment of conotruncal congenital cardiac defects. We have developed frame configuration for the transcatheter pulmonary valve replacement which does not require prior stenting of the native outlet of the right ventricle or a valve-containing conduit and significantly reduces the time of intervention, the cost of the operation, and the development of perioperative and long-term complications leading to valve dysfunction.

The objective of our study was to develop a valve for transcatheter implantation in the position of the pulmonary artery, taking into account the anatomical variants of the outflow tract from the right ventricle, and to evaluate the hydrodynamic properties of the valve in vitro using bench testing.

Material and methods

Frame design

The first stage was a retrospective data analysis of 250 pediatric patients (aged 7 to 18 years) who underwent a procedure to form the outflow tract from RV to PA performed at the National Medical Research Center n.a. Academician E.N. Meshalkin from November 2011 to April 2022. Three-D reconstructions of the RV outflow tracts in this group of patients were analyzed and morphological anatomical variants were identified. Forming the RV-PA outflow tract was performed using different methods. These include pulmonary homografting (OOO Cardiostar, St. Petersburg, Russia), transannular grafting, transannular grafting with a bovine jugular vein monocusp (Contegra pulmonary valved conduit; Medtronic, Minneapolis, MN, USA). A valve-containing xenopericardial conduit (BioLAB KK/B, A.N. Bakulev National Medical

Research Center of Cardiovascular Surgery, Ministry of Health of the Russian Federation, Moscow, Russia), xenopericardial conduit containing a porcine aortic valve (AB-Composite, NeoCor, Kemerovo, Russia), xenopericardial valve-containing conduit (Pilon, NeoCor, Kemerovo, Russia). The choice of the implanted xenoconduit depended on the preferences of the operating surgeon. Based on the obtained morphological forms of the RV outflow tract, a team of employees of the bioprosthetics laboratory of the Center for New Surgical Technologies of the National Medical Research Center n.a. Academician E.N. Meshalkin developed a prototype of a self-expanding nitinol frame for transcatheter pulmonary valve replacement using laser cutting. Laser cutting was performed from a titanium nickelide tube (4.5 mm in diameter and 0.3 mm in wall thickness) corresponding to the ASTM 2633–13 standard (Standard Specification for Wrought Seamless Nickel-Titanium Shape Memory Alloy Tube for Medical Devices and Surgical Implants) according to the layout developed at the computer modeling stage. The stent was machined using a JWM 200 (LK-Laser, China), a specialized precision tube cutting laser system. The laser-cut prosthesis frame blank was gradually stretched to the required shape in several stages using thermoforming technology. The thermoforming process was performed in a P 310 programmable muffle vacuum furnace (Programat, Austria), followed by water quenching. Zero-stress conditions were imposed on the stent to eliminate load history. During the post-processing stage, which included microabrasive surface cleaning and electropolishing, the prosthesis frame was thoroughly cleaned of the oxide film. This process is important for removing unwanted oxide deposits that may form on the material surface as a result of previous processing steps. Additionally, post-processing included smoothing sharp edges, which improves the graft safety. Particular attention was also paid to imparting a shine and

smoothness to the frame surface. This not only improves the aesthetics of the product but also reduces the friction between the prosthesis and surrounding tissue, which in turn contributes to improved durability and reliability.

Mechanical properties of the frame

Radial and axial compression tests were conducted in a radial force machine on two identical frames at 37°C. A compression head, consisting of 12 movable wedges arranged around a rotational axis, compressed the frames from their nominal diameter to 15 mm, then to a diameter corresponding to 18 Fr (6 mm). The frame was compressed at a rate of 1 mm/s. The head displacement was later reversed, allowing the nitinol frame to expand on its own. Radial forces, axial compression forces, and diameter were recorded.

Mechanical properties of the valve system

The valve leaflet system was prepared from xenopericardium. The pericardium was laser-cut to design the valve leaflet shape. They were manually mounted on the frame using surgical techniques, suture material, and instruments. The internal biological lining of the frame body was also made of xenopericardium. The xenogeneic biomaterial was anticalcium treated with a 2–5% epoxy solution in combination with diphosphonate. The introduction of diphosphonate as an anticalcium agent significantly increases the resistance of the epoxy-treated biomaterial to calcification. Diphosphonate acts by reducing calcium binding activity, which, in turn, improves the overall effectiveness of the anticalcium treatment. Stabilization of the biomaterial with epoxy compounds contributes to the formation of a strong and biocompatible structure, making it more reliable for use in medical settings. These epoxy

compounds, thanks to their chemical properties, provide protection against calcification by creating a barrier that prevents an interaction with calcium, which is especially important for increasing the service life of implants and reducing the risk of complications.

Hydrodynamic testing of the valve system

The resulting heart valve prototype underwent hydrodynamic testing at the MedIntell facility (MedIntell, Russia) to verify the prosthetic heart valve's hydrodynamic characteristics. The facility is designed to test the functioning of the prosthetic heart valve's closure elements, valve flow capacity, and backflow through the valve in accordance with State Standard (GOST 26997-2002). Testing was performed using the following parameters (Table 1).

Table 1. Test parameters

Parameters	Data
Pressure impulse duration	200 ms
Pause duration	633 ms
Frequency	1.2 Hz
Number of cycles	300
Input duration	180 ms
Output duration	610 ms
Test environment	Sterile isotonic sodium chloride solution, 37°C

During testing, the valve leaflet closure and opening were monitored visually and using a high-speed camera. The prosthesis's throughput and backflow volumes per cycle were measured according to the methodology outlined in the test rig's Manual.

The obtained heart valve prototypes underwent hydrodynamic testing in a rig for accelerated cyclic loading of a ViVitro HI-Cycle heart valve prosthesis (ViVitro Labs Inc., Canada). The rig is designed for

testing heart valve prostheses (from 1 to 6 at a time) for destruction under accelerated cyclic loading conditions (up to 27.5 Hz).

Three prototypes of the valve prosthesis (frame with a leaflet system) were used for testing. They were initially tested in the MedIntell hydrodynamic testing rig (MedIntell, Russia) and then installed in the ViVitro durability testing rig (ViVitro Labs, Canada). Full opening and closing of the valves and their integrity were assessed and monitored visually during accelerated testing, using a stroboscope set up to the test frequency, and with the rig turned off during the replacement of the test medium. After successfully completing the durability test, the valves were retested on a hydrodynamic testing rig (MedIntell). The test methods and parameters are presented in Table 2.

Table 2. Test methods and parameters

Parameters	Data
Cyclic load frequency	20 Hz
Differential pressure amplitude	75 mmHg
Number of cycles	280 million
Duration of the test	3880 h
Test medium replacement interval	Weekly
Test environment	Buffer solution, 37°C
Refusal criteria	Formation of cracks, holes, potholes in the material, separation of elements into two or more parts, excessive wear of the material and connections, assemblies, reduction in throughput capacity by more than 20%, increase in backflow by more than 20%

Differential scanning calorimetry

Stent frames made of a shape-memory alloy (titanium nickelide) were prototyped and their characteristics were verified using thermal analysis that is the differential scanning calorimetry (DSC). The alloy

phase transition temperatures were studied: martensitic transformation onset temperature (Ms), martensitic transformation end temperature (Mf), austenitic transformation onset temperature (As), and martensitic transformation end temperature (Af). For the study, random elements were mechanically removed from the frames and placed in standard aluminum crucibles for DSC. The sample weight ranged from 10 to 20 mg. An empty crucible was placed in the support channel. The measurements were performed on a DSC-200F3 calorimeter (NETZSCH-Geratebau, Germany). Measurements began at room temperature (20°C), and then the sample was cooled to -40°C and then heated to +60°C. The cooling and heating rates were 10 K/min.

Results

Frame design

The valve being developed is a self-expanding framework designed based on the morphological shapes of the right ventricular outflow tract, made of superelastic nitinol with a leaflet system and porcine pericardium lining. The valve shape optimally matches the anatomical variations of the right ventricular outflow tract in patients undergoing definitive treatment of conotruncal congenital heart defect. The prototype framework for the prosthetic system consists of three zones: an outflow zone, a central zone, and an inflow zone. The outflow zone of the framework, the "crown" of the framework, consists of four plates interconnected at the apex, forming an atraumatic structure. This zone of the valve is positioned at the bifurcation of the pulmonary artery, thereby performing the additional function of fixing and retaining the valve prosthesis within its trunk. The central zone of the framework is a cylinder with a mesh structure formed by radially closed rows of cellules, each of which is bounded by ribs connected by dumbbell-shaped bridges.

Each row contains 10–12 cellules. The inflow zone of the frame has a similar cellular structure and a smoothly expanding shape. The inflow portion of the frame corresponds to the RV outlet and, when implanted, adheres to ensure the fixation of the valve graft. The valve design allows for both transjugular and (preferably) transfemoral implantation access using an 18-Fr delivery system. The prosthetic system is loaded into the delivery device with preliminary compression in water at a temperature of 0–4 °C. Upon the release, the valve returns to its original shape, fitting tightly against the annulus and the RV outlet.

Mechanical properties of the frame

The results showed that the radial resistance force (RRF) and chronic rebounding force (CRF) of the pulmonary valve stent were within the limits indicated in the technical specifications for pulmonary valve products (25 mmHg ≤ recoil force (RcF) ≤ 500 mmHg; radial force (RF) ≥ 100 mmHg), confirming that the product meets the stated requirements of the design and manufacturing process for this pulmonary valve. The typical compression hysteresis curves of nitinol can be observed. According to the test results, the stiffness of the first iteration of the frame designs was found to be insufficient; after the adjustment, the second iteration frames had higher stiffness (Fig. 1). It should be noted that the RF considerably increased when the frame was further compressed to a size equivalent to 18F (6 mm). This characteristic is consistent with the experimental results of radial crimping according to Isayama and Hirdes [6, 7]. The source of this sudden increase in force is self-contact within the struts. It is precisely because of this increase in self-contact force that the maximum crimping force is not a good indicator of the stent's RF. Furthermore, contact with the artery occurs well below this peak value.

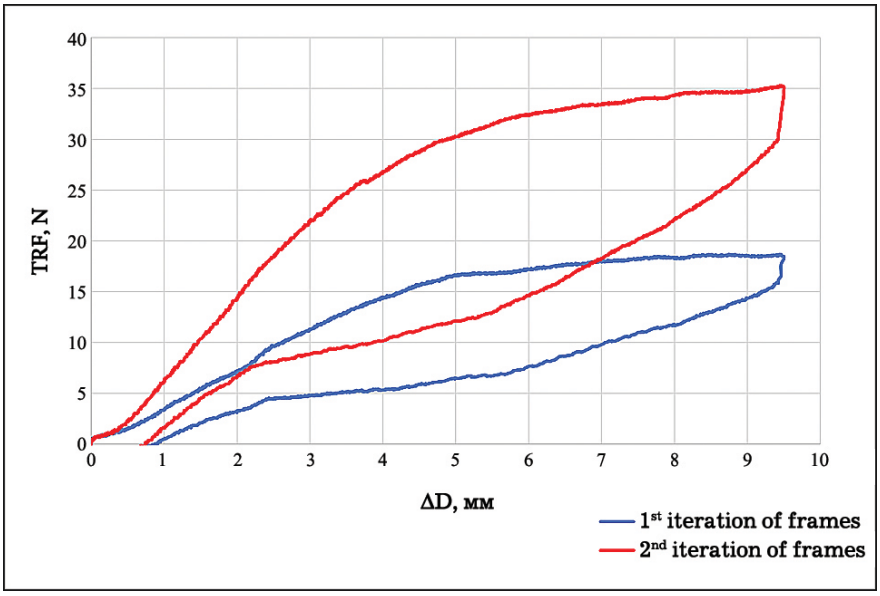

Fig. 1. The load curves from the radial tests of the studied frames

Mechanical properties of the valve system

The valve biomaterial and the suture points were undamaged after compression. The compression time was 1 hour. The valve biomaterial and suture technology met product specifications. The valve's special anticalcium treatment, a combination of epoxy treatment and diphosphonate, represents an effective approach to improving the properties of xenogeneic biomaterial, enhancing its reliability and functionality in various medical applications.

Hydrodynamics and wear of the valve system

The test results showed that the valve demonstrated good hydrodynamic properties. The time-amplitude characteristics of the tested valve and the volumetric characteristics are shown in Fig. 2 and Table 3, respectively.

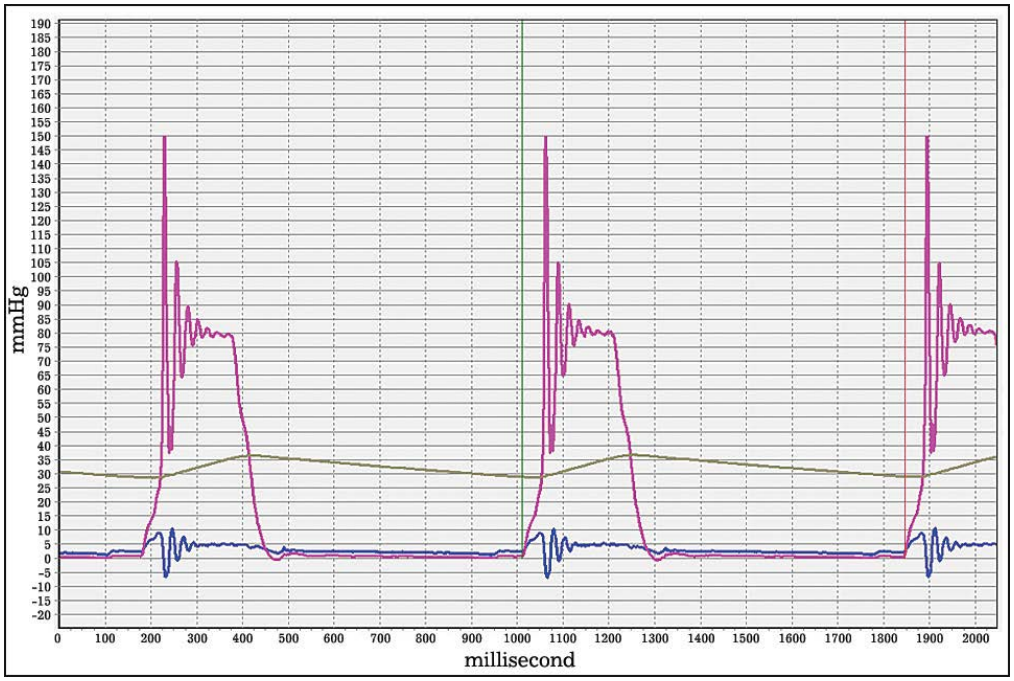

Fig. 2. Time-amplitude diagram of a heart valve prosthesis test. Red is the valve outlet pressure, blue is the valve inlet pressure

Table 3. The results of testing the cuspid system of the heart valve prosthesis prototype

Parameters	Data
Constant excess pressure at the valve inlet	5 mmHg
The amplitude of the variable pressure at the valve outlet	150 mmHg
Throughput per cycle, no less than	60 cm^3
Reverse flow per cycle, no more than	8 cm^3
Number of cycles	300

Differential scanning calorimetry analysis

Based on the results of the DSC study, the samples were found to have phase transition temperatures that corresponded to those required for the proper functioning of the frames (Fig. 3):

- The temperature at which the alloy becomes plastic and soft for ease of placement in the delivery system is 8.71°C (the required range is from 0 to 10°C).

• The temperature for restoring the frame’s original shape and superelastic properties is 20.18°C (required range from 10°C to 36°C).

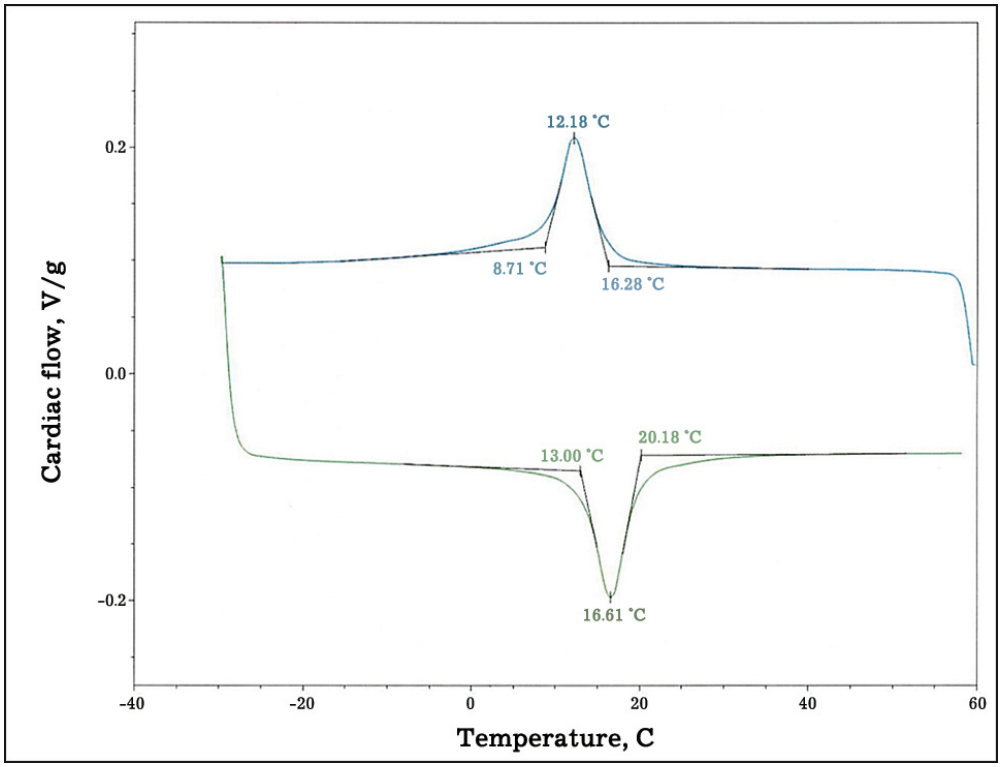

Fig. 3. Differential scanning calorimetry curve of the studied sample

Discussion

Patients with conotruncal CHD often experience progressive pulmonary valve dysfunction after definitive treatment [8]. This dysfunction can manifest itself as a severe pulmonary valve insufficiency, leading to PA overload, which is often observed in patients who have undergone RV outflow tract plastic surgery.

In contrast, patients with a conduit between the RV and PA are more likely to develop progressive stenosis of RVOP in the long term, which in turn causes increased RV pressure. In some cases, mixed forms of the dysfunction occur, when both the pulmonary insufficiency and PA stenosis are observed simultaneously. This leads to a progressive dilation

and/or hypertrophy of the RV with the development of its insufficiency [8]. The treatment of RVOP dysfunctions with progressive RV insufficiency has long required surgical intervention with the placement of a new conduit or bioprosthetic valve, which have a limited service life. This results in the need for repeated surgery to replace the conduit or valve, which is associated with the development of serious peri- and postoperative complications. Therefore, the development of transcatheter methods for the treatment of RV outflow tract dysfunction is a key aspect in the management of such patients. Despite advances in transcatheter valve technologies, many patients undergoing definitive treatment of conotruncal congenital heart defect by using RVOP plastic surgery face a number of limitations in the use of such prosthetic systems. Selecting inappropriate transcatheter valves can lead to complications such as valve prosthesis dislocation, PA wall rupture, stent fracture, and paraprosthetic fistulas [9, 10].

The National Medical Research Center n.a. Academician E.N. Meshalkin developed a prototype transcatheter valve. Its configuration, unlike existing analogues, allows this system to be used in patients with various anatomical forms of the right ventricle, without prior stenting. The prototype framework was developed based on an analysis of computed tomography data from 350 patients undergoing right ventricle reconstruction.

The stiffness of the nitinol frame was selected based on the physical and mechanical properties of the conduits and native tissue [11]. It is well known that rigid nitinol frames are well-fixed and fracture-resistant; however, the high rigidity of the material poses challenges in the delivery of such valves. Conversely, overly soft nitinol structures can be easily positioned through the delivery system; however, during implantation, poor adhesion of the frame to the pulmonary artery wall can

lead to a valve dislocation and endoleaks between the valve and the pulmonary artery wall. Therefore, selecting the optimal rigidity of the frame structure is a key step in the development of prosthetic systems.

The main advantages of our transcatheter valve are the following: first, the anatomical shape of the design, which allows implantation of such a system in the native RVOP without preliminary stenting. Second, the "crown" of the frame, which prevents valve migration, prevents damage to the pulmonary artery wall and serves as an additional "anchor" for the valve fixation. In an experiment on large laboratory animals, the damage to the radial arches of the "crown" was noted in 25% of cases. However, the problem was solved by increasing the number of radial arches from 4 to 6, which more evenly distributes the pressure on them and reduces the risk of fractures [12]. As a locking element of the transcatheter valve, unlike international analogues [13, 14], we used xenopericardium with an anti-calcium treatment with a solution of epoxy compounds and diphosphonate. N. R. Nichay et al. demonstrated in their study that epoxy compounds and diphosphonate have higher efficacy compared to that of glutaraldehyde in anticalcium protection of xenomaterial [15]. The study noted the absence of a significant pressure gradient on the transcatheter valve, and neither calcification of the leaflets nor signs of valve insufficiency were detected during the 6-month follow-up period [12].

Another advantage of this valve is its wide range of sizes, which allows the prostheses to be used in both pediatric cardiac surgery and in adult patients.

Conclusion

A prototype of the first homeland self-expanding bioprosthesis for transcatheter implantation with an anatomically configured nitinol frame

demonstrated optimal hydrodynamic properties in the initial stages of preclinical testing. The radial resistance force and chronic rebounding force of the pulmonary valve stent were within the limits indicated in the technical specifications for pulmonary valve products (25 mmHg ≤ recoil force ≤ 500 mmHg; radial force ≥ 100 mmHg). The phase transition temperature samples meet the required standards (the temperature at which the alloy becomes plastic and soft for ease of placement in the delivery system is 8.71°C and the temperature at which the frame recovers its original shape and superelastic properties is 20.18°C). The anatomical shape of the design allows for implantation of such a valve in the native outflow tract of the right ventricle without preliminary stenting.

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