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“IGOR SIKORSKY KYIV POLYTECHNIC INSTITUTE”
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Modeling of the inner structural band of the aortic valve bio prosthesis

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RELEVANCE

- Aortic valve diseases (insufficiency or stenosis) leads to it's severe dysfunction causing backflow on the valve or increased it's resistance. The consequence of this pathology is severe heart failure, reduced duration and quality of life.
- The only treatment is surgical replacement of the valve with an artificial prosthesis or aortic valve plastic. Replacing of a sick aortic valve with an artificial prosthesis is an effective method of preventing heart failure, increasing duration and improving quality of life.
- As with any implantable device, issues related to biocompatibility, longevity, and function of replacement are important. Artificial mechanical heart valves have been clinically available for over 50 years.
- Bio-prosthetic valves are composed of natural valves from a pig, which has a cardiovascular system most similar to humans. *(Artificial Organs, Gerald E. Miller, www.morganclaypool.com, ISBN: 1-598290-48-7 paper, ISBN: 1-598290-49-5 e-book, DOI: 10.2200/S00023ED1V01Y200604BME004, A Publication in the Morgan & Claypool Publishers' series, SYNTHESIS LECTURES ON BIOMEDICAL ENGINEERING, Copyright © 2006 by Morgan & Claypool, p.4-7)*
- Modern research is aimed at improving the design of bioprostheses. to bring them as close as possible to the natural human valves. (*https://www.sciencedaily.com/releases/2021/01/210126082709.htm6; https://www.frontiersin.org/articles/10.3389/fcvm.2019.00047/full)*

PURPOSE AND TASK

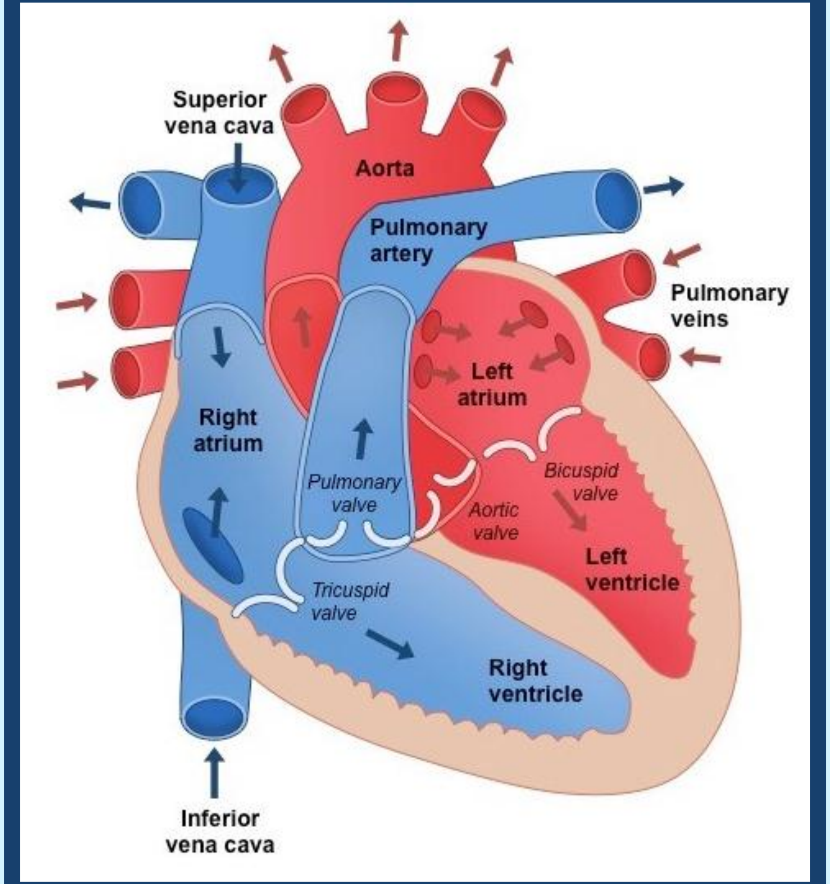
The aim of the work: design of the artificial heart valve frame that meets the requirements of biocompatibility, reliability and manufacturability.

Tasks:

1) Based on a review of the anatomy and pathology of the heart valve to formulate requirements for the design of an artificial valve.
2) Carry out a comparative analysis of existing prototypes of artificial heart valves.
3) Analyze the material options for the manufacture of the valve frame.
4) To offer models of designs of frameworks of the artificial valve of heart.

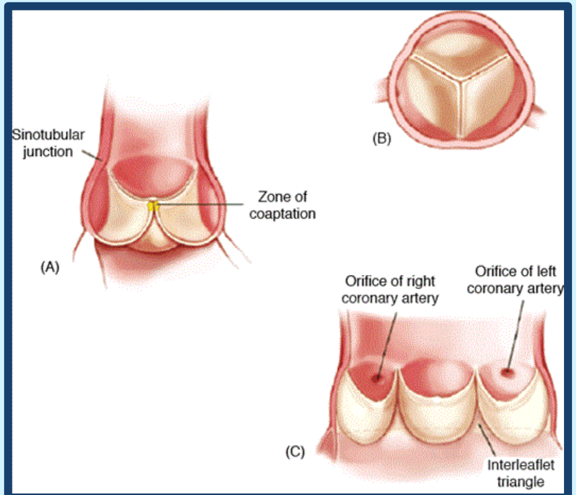
Object of research: the frame of the artificial heart valve

Subject of research: design and material of the artificial heart valve frame and technological features of its manufacture

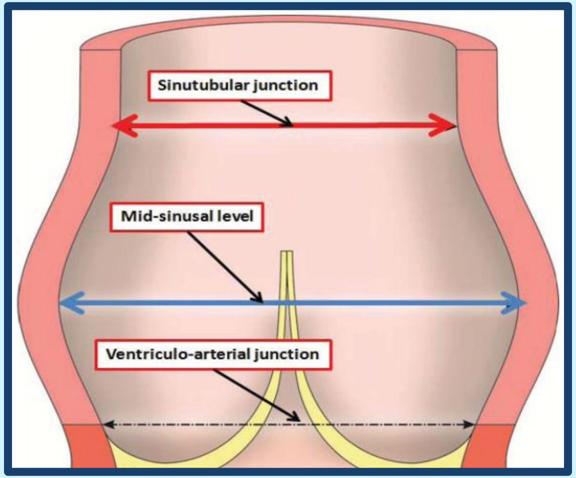


INTRODUCTION

The human heart consists of four chambers: the left and right atria, and the left and right ventricles. Between the chambers of the heart are valves, through which the blood moves in one direction and doesn't flow back. The left ventricle supplies blood to all parts of the body through a large artery called the aorta. Between left ventricle and the aorta is a valve that allows blood to move without returning to the ventricle.



https://www.google.com/url?sa=i&url=https%3A%2F%2Fthoracickey.com%2Faortic-valve-disease-4%2F&psig=AOvVaw1vscg1AhKACzovg1HYS7sR&ust=1621238738562000&source=images&cd=vfe&ved=0CAIQjRxqFwoTCOD_pN_gzfACFQAAAAAdAAAAABAd



https://www.mdpi.com/2308-3425/1/3/177/htm

ANATOMY

The aortic valve is one of the valves of the heart, located between left ventricle and aorta, preventing the return flow of blood from aorta to the left ventricle in diastole.

The aortic valve of the heart is experiencing the greatest hydrodynamic loud.

The figures represent the geometry of aortic valve structures.

AORTIC VALVE INSUFFICIENCY

Type of acquired heart defect with impaired hemodynamics, characterized by the return flow of blood from the aorta to the left ventricle in diastole due to a defect in the aortic valve or increases its resistance. The consequence of this pathology is severe heart failure, reduced duration and quality of life. On Figure 1 is a types of aortic valve pathologies, on Figure 2 – is scheme of lines which have to be reinforced to be opened by surgical treatment.

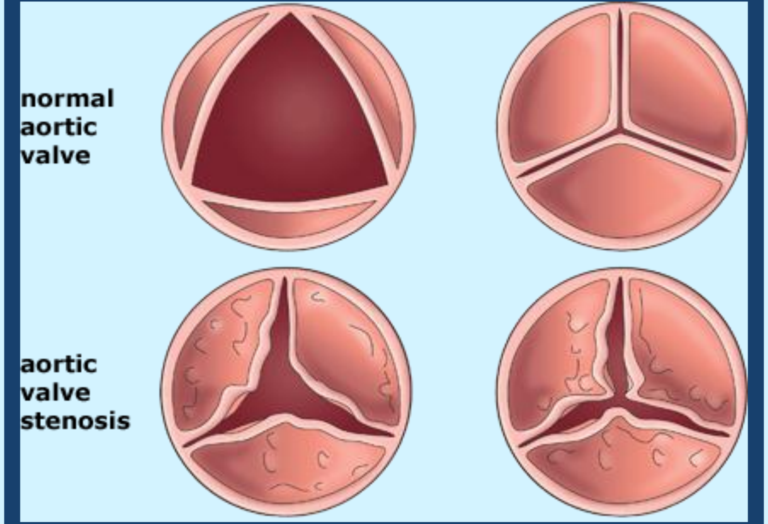


Figure: 1

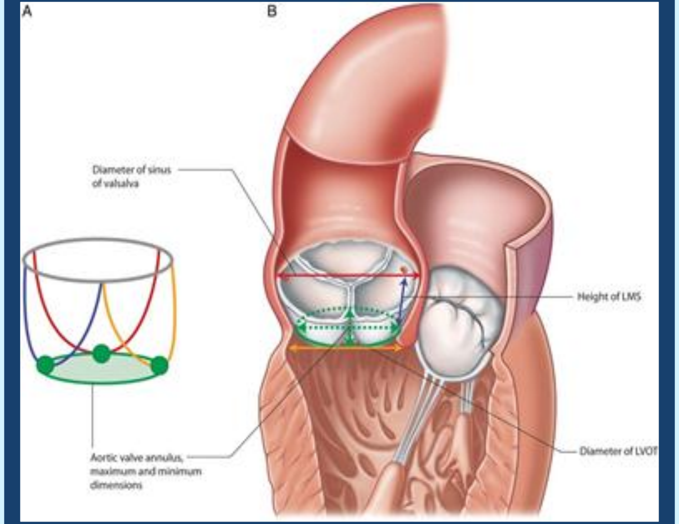
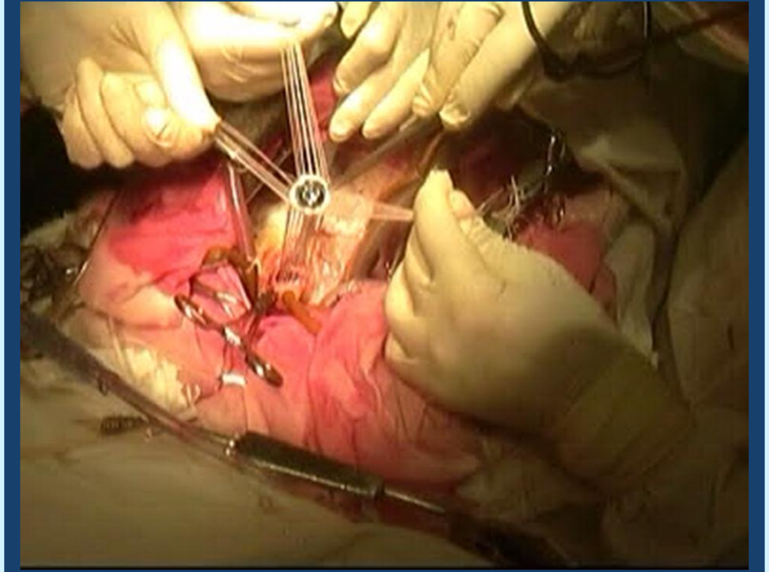


Figure: 2 https://www.mdpi.com/2308-3425/1/3/177/htm

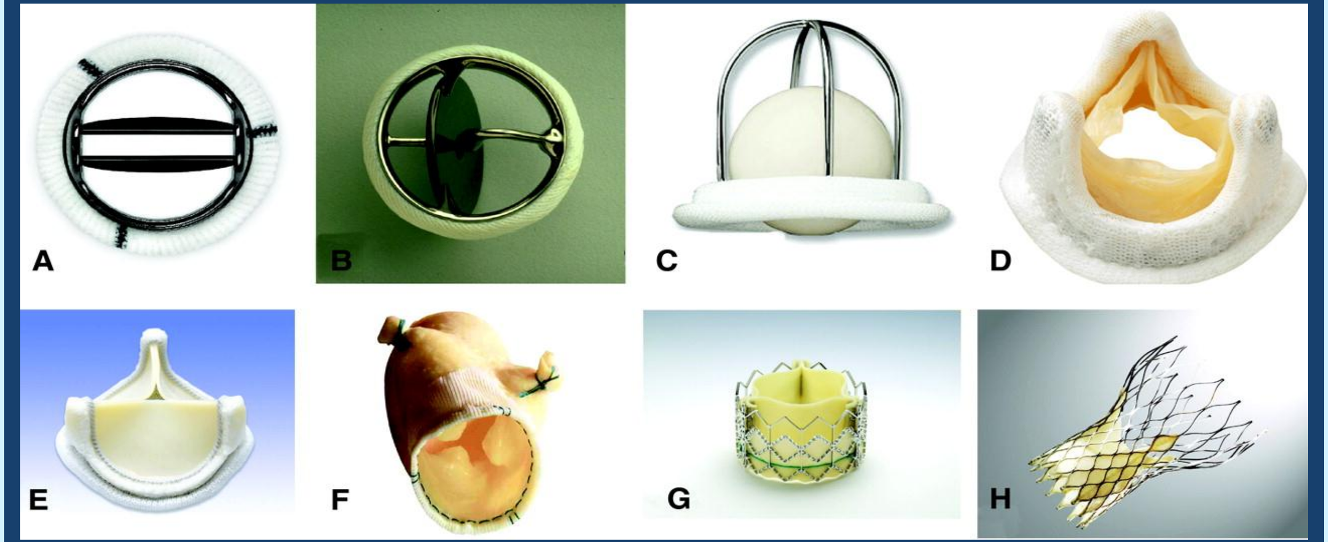
TREATMENT

Prosthetic aortic valve



Surgery to repair

TYPES OF VALVES



Mechanical valves

- Caged ball valves
- Tilting-disc valves
- Bileaflet valves

Biological tissue valve

- Porcine (pig) tissue
- Bovine (cow) tissue

Modern research is aimed at improving the design of bio-prostheses to bring them as close as possible to the natural human valves. (https://www.sciencedaily.com/releases/2021/01/210126082709.htm6; https://www.frontiersin.org/articles/10.3389/fcvm.2019.00047/full)

ULTIMATE DEMANDS TO ARTIFICIAL HEART VALVE PROSTHESIS ARE

1. Biocompatibility
2. Minimal resistance to blood flow
3. **Antithrombotic properties**
4. Mechanical resistance

THE CURRENT STATE OF ENGINEERING AND SCIENTIFIC PROBLEMS

The performance of artificial heart valves is closely governed by the fluid mechanics within these valves, which, in turn, is strongly related to the geometry, material and mechanism of the valve design. The obvious engineering challenge is to design an optimal heart valve. Such a challenge is currently being pursued in three main directions:

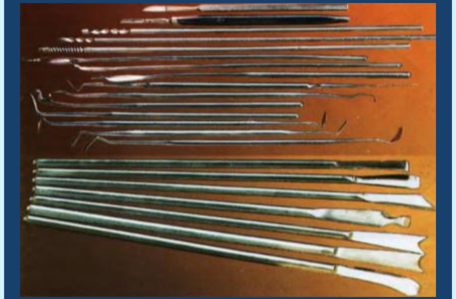
1- Researchers have taken a step back from the concept of artificial devices and have taken the route of engineering a living tissue valve with as many characteristics of the native heart valve as possible.

2- Engineers are developing advanced computational fluid dynamics (CFD) tools to accurately predict the fluid mechanics in the vicinity of heart valves down to the resolution of individual blood cells.

3- Research is being conducted to pinpoint the exact coagulation mechanisms triggered by hemodynamics in heart valves using ex vivo and in vitro experiments, thus opening avenues to improve on existing designs based on direct coagulation measures.

MATERIALS OVERVIEW

(a)



(b)

Figure 1 - The use of titanium nickelide: (a) semi-finished products: rods, plates, wire, tubes; (b) - surgical instruments with a variable geometry of the working part.

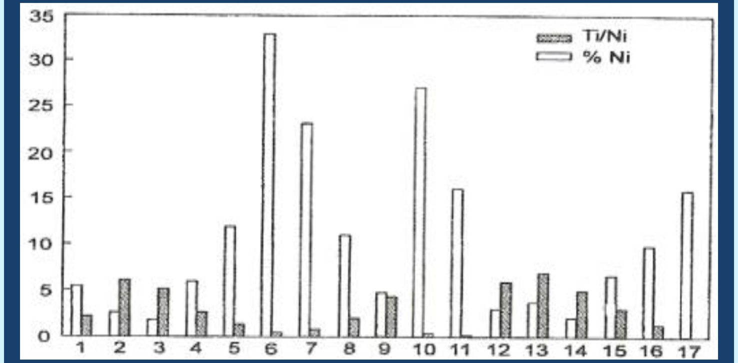
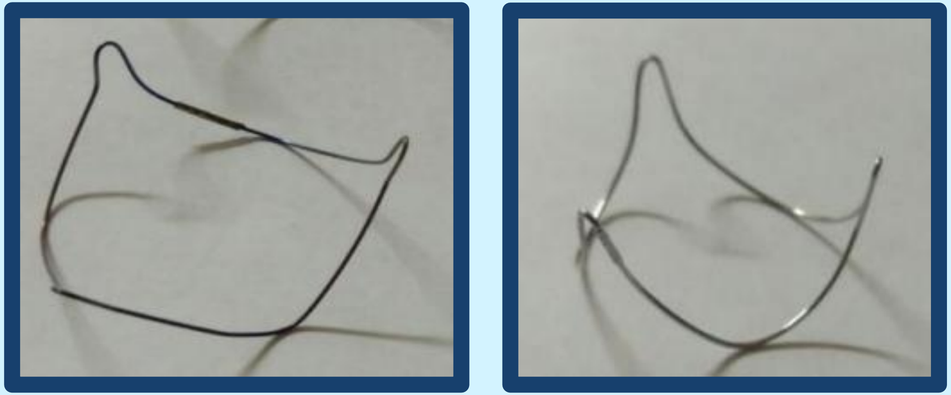


Figure 2 - The ratio of Ti / Ni in the surface layers of the alloy Ti / Ni after: 1 - mechanical polishing (MehP); 2- MehP and chemical etching in HF / HNO3 solution; 3-5 - steam treatment in an autoclave (PA) for 30, 60 and 120 min in accordance; 6- boiling in water for 30 minutes; 7-9 - treatment in water autoclave (VA) for 30, 99 and 180 minutes in accordance; 10- immersion in 30% hydrogen peroxide solution for 22 hours; 11- electrolytic polishing (EP); 12- EP + PA; 13- EP + heating in air; 14- EP + processing in ethylene oxide; 15 - EP + disinfection with CH3CO3H acid; 16- EP + processing in hydrogen peroxide; 17-EP + treatment in CH3CO3H acid.

In the course of the work the main materials are analyzed used for medical use. It is established that nitinol is one of the most promising materials in this area and is increasingly used in medical practice. Implementation of materials with new characteristics and properties will improve construction, just as the selection and application of new materials for valve prosthesis inner structural band design.

STRUCTURE OF FRAME IN PROTOTYPES



(a) (b)

Figure 3.1 – (a) Prototype of the framework of the aortic biological prosthesis of the heart valve, made of nitinol (b) and a sample "Valve 1"

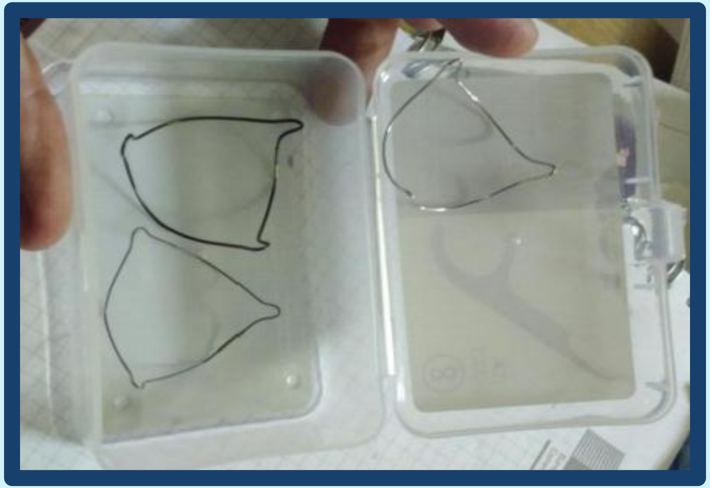


Figure 3.2 - Deformation of the skeleton of the aortic biological prosthesis of the heart valve at low temperatures

Figure 3.2 - Details of the valve frame 1

X-RAY SPECTRUM ANALYSES OF MATERIALS

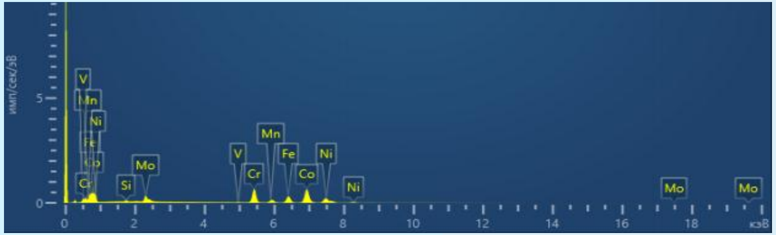


Figure 4.1 - Energy dispersion X-ray spectrum at local analysis of the outer surface of the lamellar frame element valve 1

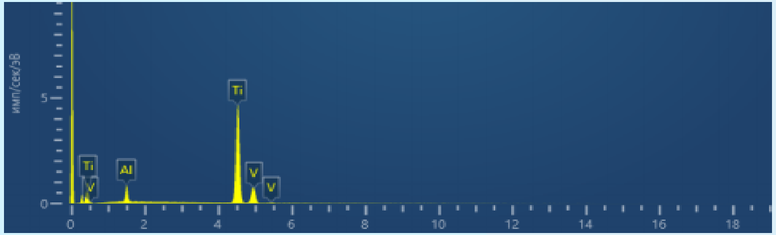


Figure 4.2 - Energy Dispersive X-ray spectrum in the local analysis of the plate frame element of the valve 2

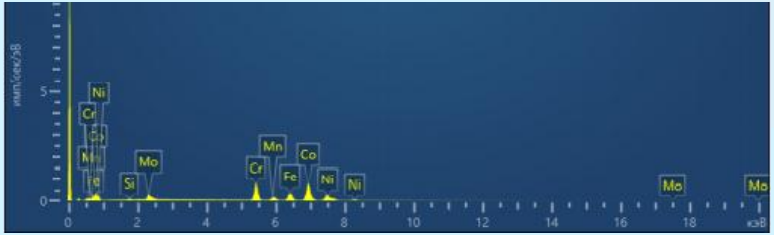


Figure 4.3 - Energy dispersion X-ray spectrum in the local analysis of the end surface of the plate frame element of the valve 3

Table 1.1 - Chemical composition of the outer surface of the frame valve element 1

Spectrum 1				
Element	Line type	Weight. %	Sigma weights%	Atom. %
Cr	K-series	19.75	0.20	22.18
Co	K-series	38.26	0.30	37.90
Fe	K-series	14.13	0.20	14.77
Ni	K-series	14.95	0.25	14.87
Mo	L-series	9.51	0.26	5.78
Mn	K-series	2.16	0.13	2.29
Si	K-series	0.86	0.07	1.78
V	K-series	0.37	0.07	0.42
Total		100.00		100.00

Table 1.2 - Chemical composition of the plate frame element of the valve 2

Spectrum 5				
Element	Line type	Weight. %	Sigma weights%	Atom. %
Al	K-series	7.47	0.18	12.56
Ti	K-series	88.60	0.30	83.93
V	K-series	3.94	0.26	3.51
Total		100.00		100.00

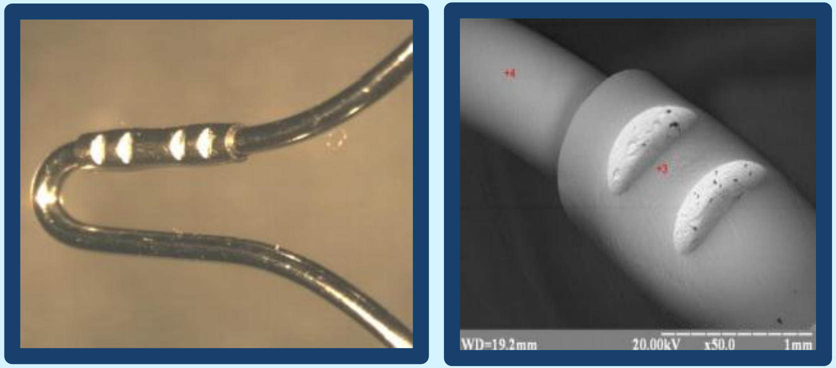
Table 1.3 - Chemical composition of the plate frame element of the valve 3

Spectrum 10				
Element	Line type	Weight. %	Sigma weights%	Atom. %
Co	K-series	40.06	0.45	39.42
Cr	K-series	20.88	0.30	23.28
Fe	K-series	15.00	0.31	15.57
Ni	K-series	14.78	0.38	14.60
Mo	L-series	6.83	0.35	4.13
Mn	K-series	2.03	0.19	2.15
Si	K-series	0.42	0.09	0.86
Total		100.00		100.00

TECHNOLOGY OF FRAME CONNECTION

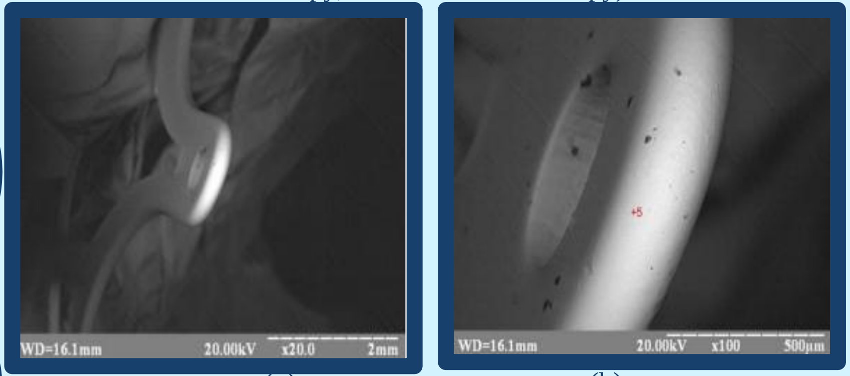
(a) (b)

Figure 5.1 - Plate spot connection frame element of valve 1 (a – light microscopy; b - electron microscopy)



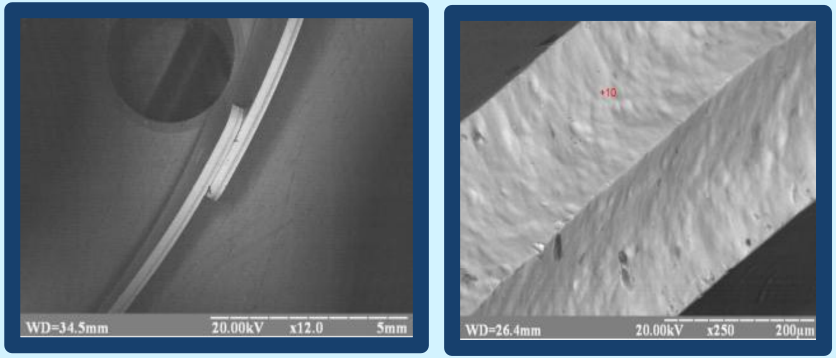
(a) (b)

Figure 5.2 - Connection of the wire frame element of the valve 1. a - light microscopy (x7.5); b - electron microscopy (x50)



(a) (b)

Figure 5.3 - Geometry of the protrusion on the plate frame element of the valve 2. a - electron microscopy (x20); b - electron microscopy (x100)



(a) (b)

Figure 5.4 - Spot welding (a - electron microscopy) and the geometry of the side (edge) of the plate frame element (b - electron microscopy) of the valve 3

CONCLUSIONS ABOUT PROTOTYPES

1. Plate frame elements of valve made by different technologies:
    - the manufacture of blanks from rolled sheet material using methods of chemical or electrolytic etching, followed by connection by spot welding
    - coupling mechanical connection with its subsequent pressing;
2. The materials of the frame elements correspond to two types of chemical composition:
    - the cobalt alloy ASTM F105891 includes up to 0.5% vanadium and inflated to 1% molybdenum;
    - the Ti-6Al-4V ELI (ASTM F136-84, F620-87) or Ti-6Al-4V (ASTM F1108-88).

DESIGN OF INNER FRAME OF AORTIC VALVE BIO PROSTHESIS (MATERIAL)

(a) (b) (c)

Figure 6 – (a) Samples of biological nitinol (b) dental dental plate made of nitinol (c) and nitinol wire used for experiments in the home

Table 2 - Chemical composition of biological nitinol

Elements	Share, wt.%	Error, %
Ti	33,38	0,193
Ni	59,371	0,191
Fe	1,371	0,040
Cr	0,764	0,048
Mo	0,156	0,009

DESIGN OF INNER FRAME OF AORTIC VALVE BIO PROSTHESIS (PROPERTIES)

Table 3 - Mechanical properties of nitinol

Symbol	Physical characteristics	Value	Unit of measurement
EA	Austenite elasticity	63000	Mpa
vA	Austenite Poisson’s ratio	0.33	-
EM	Martensite elasticity	30000	MPa
vM	Martensite Poisson’s ratio	0.33	-
εL	Transformation strain	0.042	-
(δσ δT)L	Stress-Temperature rate during loading	6	MPa/°C
σL S	Start of transformation loading	495	MPa
σL E	End of transformation loading	540	MPa
T0	Reference test temperature	22	°C
(δσ δT)U	Stress-Temperature rate during unloading	6	MPa/°C
σU S	Start of transformation unloading	285	MPa
σE S	End of transformation unloading	229	MPa
σCL S	Start of transformation stress during loading in compression	742	MPa
εV L	Volumetric transformation strain	0	-

Figure 7 - Prototype of the framework of the aortic biological prosthesis of the heart valve, made of nitinol.

DESIGN OF INNER FRAME OF AORTIC VALVE BIO PROSTHESIS

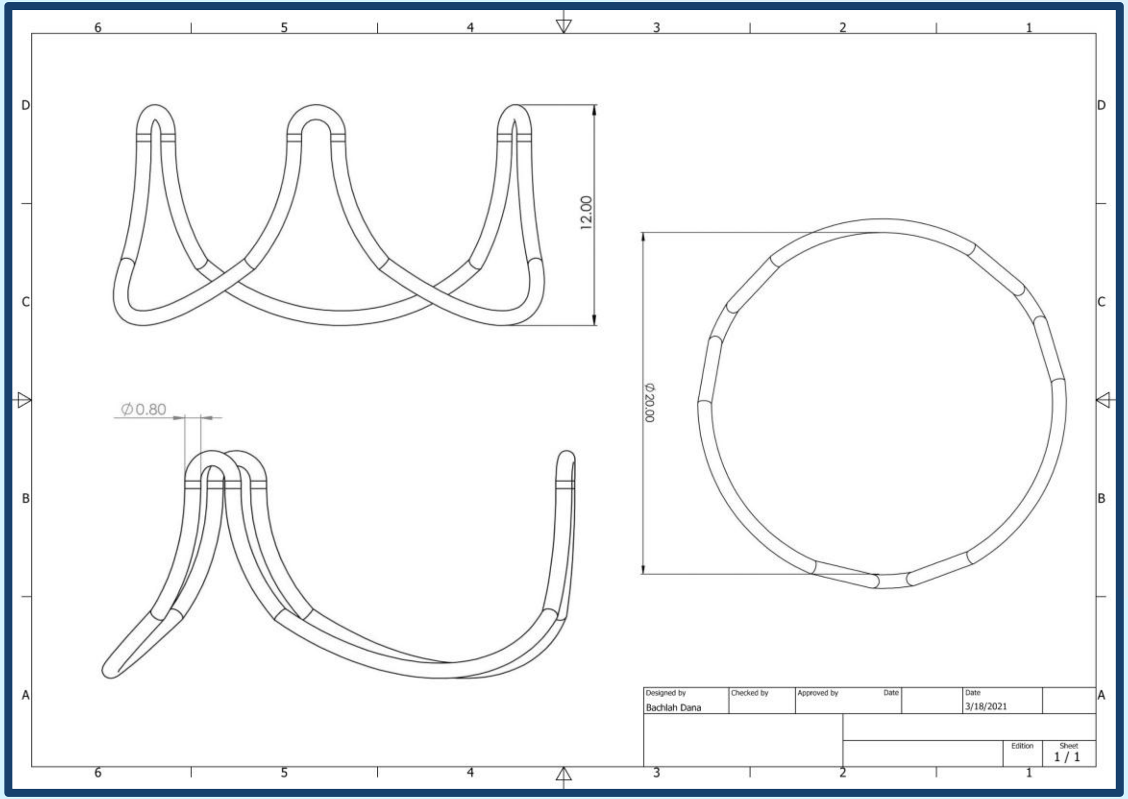


Table 4 - Appendices with drawings for models

Diameter of the aortic ring of the heart valve, mm	Possible model error, mm	Heart valve frame material	Diameter of a rod for a framework of the valve, mm	Figure
20	0,1	Ti-Ni	0.8	4.2
22	0,1	Ti-Ni	0,8	2.3
24	0,1	Ti-Ni	0,8	4.4
26	0,1	Ti-Ni	0,8	4.5
28	0,1	Ti-Ni	0,8	4.6

CONCLUSION

- The study of the aortic valve confirmed that its anatomical structure and function can be reproduced in the design of a mechanical prosthesis repeating the size of the ring.
- Comparative analysis of existing aortic heart valve prostheses confirms the high efficiency of mechanical and biological prostheses, while biological prostheses create more prospects for the development of modern implantation technologies, do not require lifelong use of anticoagulants and are the best choice for elderly patients. Therefore, we have chosen a bio prosthesis as a prototype for farther evaluation and design.
- Evaluation of materials and design of the artificial heart valve frame that meets the requirements confirmed that most acceptable are: the cobalt alloy ASTM F105891; Ti-6Al-4V ELI (ASTM F136-84, F620-87) or Ti-6Al-4V (ASTM F1108-88) which are close to "biological Nitinol" (Ti-Ni), which are taken into account in the developed models of heart valve frames.
- Models of frameworks of artificial heart valves based on titanium nickelide (Ti-Ni) have been developed for several sizes of ring diameters: 20 mm, 22 mm, 24 mm, 26 mm, 28 mm. Allowed us to answer the question of choosing the optimal design of artificial heart valve prostheses frames.
- The selection and application of new materials for valve prosthesis inner structural band design let us to obtain frame construction improvement.

THANK YOU FOR ATTENTION!