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Physico-mechanical characteristics of biomaterial patches for numerical modeling problems

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A full-scale study of the physical and mechanical properties of a number of samples of commercial biomaterials-patches was carried out. It is shown that all materials have a pronounced non-linearity of behavior, manifested in the presence of an initial gentle stress section with a subsequent increase in stiffness, however, there are quantitative differences in the length of these sections and, accordingly, in the final characteristics: tensile strength, elongation at break, elasticity. The results of numerical verification of the obtained coefficients of hyperelastic materials models showed high convergence with the results of field tests. Keywords: numerical modeling, physical and mechanical tests, hyperelastic material model, polynomial approximation..

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Introduction

Numerical modeling, as a tool that actively accompanies the life cycle of medical devices for the treatment of cardiovascular diseases, demonstrates its effectiveness starting from the early stages of development [1–3]. The application of this approach simplifies the design stage by studying a significant variety of shapes without the need for a large number of prototypes. In addition, numerical simulation simplifies a number of complicated, complex studies, for example, the evaluation of life time — long and costly experiment [2], which is inappropriate for a wide range of product designs. At the same time, life time, as the ability of long-term operation without a critical risk for the recipient, is a key characteristic for cardiovascular surgery products, which must be evaluated and predicted as early as possible when designing [4].

The most common algorithm for numerical simulation is the finite element method, which is based on the approximation of complex three-dimensional models by a set of „simple" objects from the point of view of mathematics, i. e. tetrahedra, hexahedra, etc., calculating the mechanics and the behavior of which, simultaneously the work of the initially studied object is evaluated [5]. For this approach the key aspects of success are obtaining the exact geometry of the object under study and a detailed description of the properties of the materials used in this object. If the first issue is studied in a significant number of papers with methods (3D laser scanning, computed microtomography) [6,7], software products (Amira Software, Mimics, SolidWorks) [8], approaches to obtaining models [9–11], then the properties of the materials most commonly used in medical devices are given limited attention, and are represented often by simplified models [12,13]. Nevertheless, there are a number of works that provide a complete description of the material properties, which can be adapted or directly used in the problems of numerical simulation of medical devices. First of all, this concerns titanium nickelide (Nitinol) [14], medical steels [15], some biomaterials: self-processed xenopericardial patches [16–18] and ePTFE [19]. In turn, we represent the expansion of such knowledge based on our own developments in the field of study and simulation of materials used as components for medical devices for cardiovascular surgery. Namely, detailed results of physical and mechanical studies of the material properties, their transformation for use in distributed engineering analysis package, as well as the results of these models verification.

1. Material and methods

The objects of the study were samples of commercial strips used in reconstructive interventions on the heart and blood vessels, available on the territory of the Russian Federation (Table 1). Additionally, the study included the samples of native xenopericardium of great cattle taken from adult animals and not subjected to subsequent stabilization with preservative solutions.

Three key blocks should be distinguished in studies and present study results representation:

1) Obtaining the physical and mechanical properties of materials *in vitro* under the conditions of uniaxial tensile test. For each studied strip 10 samples were prepared in the form of a double-sided blade according to GOST ISO 37-2020, type 4 [20] by cutting with a standard knife

Table 1. Generalized characteristics of the studied materials used for reconstructive interventions in the cardiovascular system

№	Animal	Treatment	Name	Manufacturer	Application
1	GC	GA	„Cardioplant“	LLC „Cardioplant“ (NPP „MedInzh“), Penza	Xenopericardial strip for intracardiac repair
2	GC	GA	„BioLAB“	A.N. Bakulev NMITs SSKh, Moscow	
3	GC	DEE	„KemPeriplas-Neo“	CJSC „NeoKor“, Kemerovo	
4	Pig	GA	„Vascutek“	„Terumo“, USA	
5	ePTFE	none	„Gore-Tex“	„Gore“, USA	Cardiovascular patch
6	GC	none	Xenopericardium native	–	Native xenopericardialum w/o treatment

Note. GC — great cattle, GA — glutaraldehyde, DEE — diglycidyl ether of ethyleneglycol.

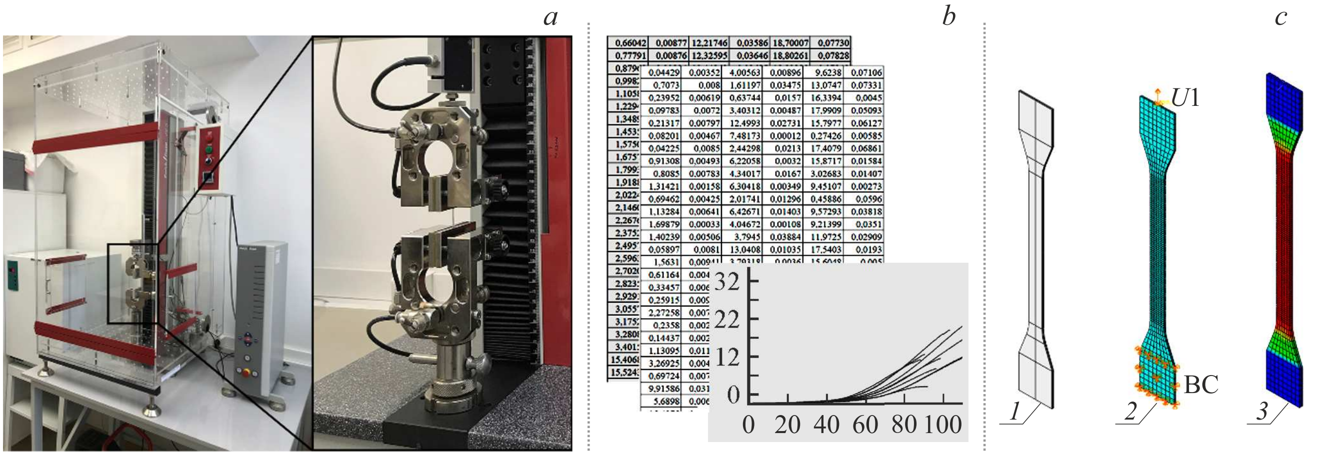

Figure 1. Material and methods of this study: *a* — universal testing machine 2.5Z (Zwick/Roell, Germany) with enlarged clamps for uniaxial testing of strip samples; *b* — conditional visualization of obtained tabular data when testing physical and mechanical characteristics; *c* — setting up numerical simulation of strip properties, sequence of calculation steps: *1* — initial 3D model of the sample for simulation, *2* — 3D model with visualized finite elements mesh, *3* — deformed model with visualization of uniaxial tensile stress distribution.

on a cutting press. The samples thickness was measured using a thickness gauge — (TR, Russia) with limit of allowable error ± 0.01 mm (pressing force maximum 1.5 N). The specimens were stretched on 2.5Z universal testing machine (Zwick/Roell, Germany) using a transmitter with a nominal load of 50 N at an ambient temperature of 37°C maintained by a thermal chamber (Fig. 1). The study was carried out in air without immersing the material into liquid media or buffer solution. Stretching speed — 10 mm/min. Taking into account the anisotropy of material properties described in the literature [21], due to the orientation of the collagen fibers of the connective tissue, for some models this direction was visually determined, and two sets of stretching experiments were performed — along and perpendicular to the fibers passage.

In the course of the study, „stress–strain“ curves were obtained for each sample of each of the materials, after which approximations of these curves were built in the Excel program, „averaging“ the results obtained to one characteristic curve — polynomial III or IV degree depending on the complexity of the material, type

$$\sigma = x_1 \times \delta + x_2 \times \delta^2 + x_3 \times \delta^3 + x_4 \times \delta^4,$$

where x_1–x_4 — coefficients of averaged equations for each material that describe the physical and mechanical behavior, δ — deformation.

The coefficient of determination (R^2) was used as a characteristic of the approximation quality. The obtained results were supplemented with a quantitative description of the materials in the form of a Table containing thickness, relative elongation at break, tensile strength [20], averaged over all ten specimens studied.

2) Obtaining coefficients of material models. The characteristic („averaged“) curves for each material were imported into the „Abaqus/CAE“ environment as „stress–strain“ pairs and, by this built-in calculator use the coefficients were obtained for this complex of engineering analysis in the form of polynomial models.

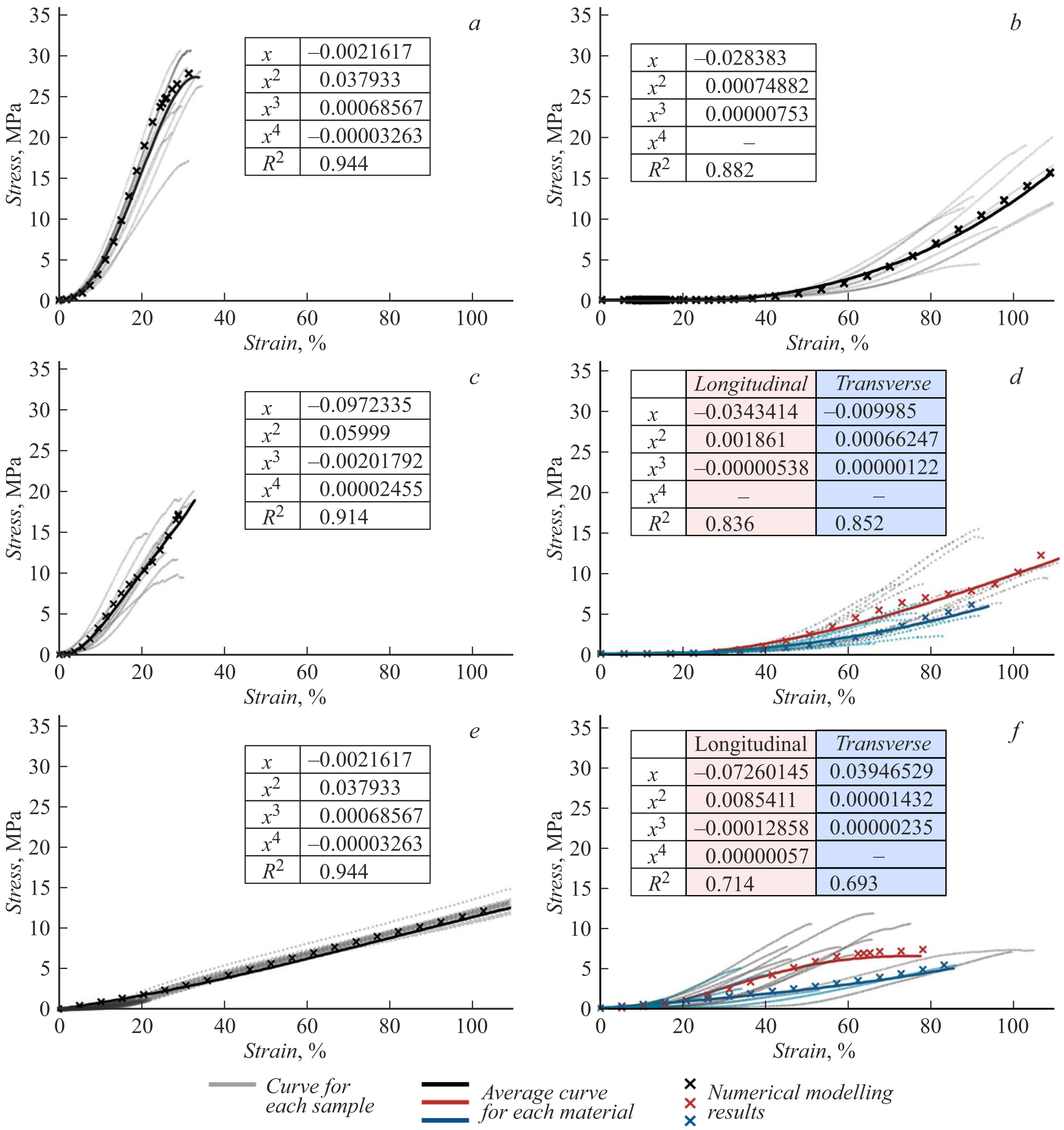

Figure 2. Curves „stress−strain“ for all studied commercial strip materials used in the reconstruction of heart structures: *a* — for material „Cardioplant“; *b* — for material „BioLAB“; *c* — „Vascutek“, *d* — „KemPeriplus-Neo“; *e* — „Gore-Tex“; *f* — native xeno-pericardium. Additionally, the approximations of the curves by polynomials of various degrees and the coefficient of determination are presented in the form of Tables.

3) Verification. To assess how the model coefficients obtained reflect the mechanical behavior demonstrated by the materials at the first stage, a numerical experiment of uniaxial stretching was executed using the three-dimensional geometry of a double-sided blade according to GOST ISO 37-2020, type 4. The blade model was presented in the form of a solid volumetric finite element mesh of C3D8H type (hybrid). The boundary conditions corresponded to the full-scale experiment: the lower platform of the blade is completely fixed against movement, the upper platform — moves vertically, thus simulating the stretching of the central part. The used solver — Abaqus Standard, taking into account the nonlinearity (Ngeom = on) and automatic stabilization by the energy dissipation level 0.0002.

Table 2. Integral characteristics of materials obtained during field tests

№	Name	Thickness, mm $M \pm \sigma$ [95% CI]	Direction fibers	Tensile strength, MPa $M \pm \sigma$ [95% CI]	Elongation at break, % $M \pm \sigma$ [95% CI]
1	„Cardioplant“	0.26 ± 0.04 [0.23; 0.28]	–	25.5 ± 4.3 [22.4; 28.6]	31.1 ± 2.4 [29.4; 32.8]
2	„BioLAB“	0.49 ± 0.08 [0.43; 0.55]	–	13.4 ± 4.9 [9.8; 16.9]	102.6 ± 10.9 [94.8; 110.4]
3	„KemPeriplus-Neo“	0.86 ± 0.09 [0.79; 0.92]	Longitudinal	9.8 ± 3.1 [7.5; 11.9]	93.7 ± 10.8 [86.0; 101.5]
			Transverse	3.4 ± 1.6 [2.2; 4.5]	75.3 ± 7.9 [69.7; 80.9]
4	„Vascutek“	0.12 ± 0.02 [0.1; 0.13]	–	14.9 ± 3.5 [12.4; 17.4]	27.9 ± 3.6 [25.3; 30.5]
5	„Gore-Tex“	0.58 ± 0.01 [0.56; 0.58]	–	29.9 ± 0.9 [28.9; 30.8]	275.9 ± 9.0 [270.5; 287.8]
6	Xenopericardium native	0.56 ± 0.12 [0.47; 0.66]	Longitudinal	7.5 ± 1.9 [6.9; 9.6]	64.3 ± 19.7 [52.6; 80.7]
			Transverse	4.1 ± 1.4 [2.0; 5.5]	48.4 ± 20.7 [25.3; 76.7]

Note. All quantitative data are presented as mean (M) and one standard deviation, as well as 95% confidence interval (CI).

2. Results

2.1. Study of physical and mechanical properties of materials *in vitro*

In general all materials demonstrated during the tests a pronounced non-linear behavior, and also significantly differed quantitatively and qualitatively in their physical and mechanical characteristics (Fig. 2).

Some materials shown different behavior depending on the fibers orientation. Thus, the properties of the xeno-pericardial strip „KemPeriplas-Neo“ and the native xeno-pericardium are presented as two different curves and, accordingly, two sets of approximation coefficients.

From the resulting graphs — values of the coefficient of determination (R^2) and the tabular data below — it can be seen that in most cases commercial materials show little variability of properties between individual specimens. However, the native xeno-pericardium, on the other hand, turned out to be less homogeneous“: the standard deviation through thickness, tensile strength, and relative elongation at break covers a large portion compared to the amplitude of the average values (Table 2).

2.2. Determination of coefficients of material models

The coefficients for polynomial models are tabulated below. Note that different degrees of curves were used for the best approximation (see column „model type“, Table 3).

2.3. Verification

The verification of the obtained models under the conditions of numerical simulation of uniaxial stretching demonstrated high convergence with the results of full-scale tests — „of the averaged“ curves for each material (Fig. 2). All experiments proved to be stable and made it possible to obtain data in all studied deformation ranges.

3. Discussion

In general, in this paper we demonstrate input data for applied use in the problems of numerical simulation of the behavior of various materials used in reconstructive surgery of the heart and blood vessels, especially with a focus on commercial samples of the Russian Federation. The key focus of papers that study cardiovascular repair using computer simulation is the task of predicting the outcomes of reconstructive interventions as part of pre-surgery planning. In such studies, it is worth assuming the use of the properties of commercial materials —xeno-pericardial or synthetic strips, so the results of this study can be combined and used in such studies. So, for example, the work of the Russian team headed by Yu.N. Zakharov [22,23] or a number of foreign studies [12,13] that consider reconstructions of carotid arteries and myocardium using various strips, can be supplemented with materials from our study, considering the properties of materials available in the market. It is worth mentioning that the list of commercial strips we studied is certainly not completely exhaustive, but it represents a sufficient range

Table 3. Coefficients of material models for use in Abaqus/CAE

№	Name	Direction	Model Type	C10	C20	Ca30	C40	C50
1	„Cardioplant“	–	Reduced Polynomial (Order 3)	0.8093	107.087	−195.973	–	–
2	„BioLAB“	–	Reduced Polynomial (Order 4)	0.02497	−0.1774	0.6976	−0.125	–
3	„KemPeriplus-Neo“	Longitudinal	Reduced Polynomial (Order 5)	0.02163	−0.2394	2.1590	−1.320	0.2468
		Transverse	Reduced Polynomial (Order 3)	0.00791	0.2111	0.1712	–	–
4	„Vascutek“	–	Reduced Polynomial (Order 5)	0.00335	159.3169	−1279.34	4786.83	−6470.28
5	„Gore-Tex“	–	Reduced Polynomial (Order 4)	1.3373	1.1812	−0.3881	0.0547	–
6	Xenopericardium native	Longitudinal	Reduced Polynomial (Order 4)	0.0890	3.57105	−2.0728	0.3853	–
		Transverse	Reduced Polynomial (Order 4)	0.6959	0.4754	−0.1908	0.0564	–

Note. For applied use the presented coefficients must be imported into the „Material“ module as a model type „Hyperelastic“ with the selection of the appropriate „Strain energy potential“ and order. For all models, the D1 coefficients were set equal to 0.01; the coefficients D2, D3, D4 are equal to zero.

of strips most commonly used in the Russian Federation, and in most cases it should satisfy the needs of numerical simulation specialists. Besides, this paper as a whole can be a structured sequential method (almost a practical guidance) for groups of researchers who have their own u nits for obtaining the physical and mechanical properties of biomaterials, and solving the problems of their use in numerical simulation.

Despite the fact that the initial task of this paper was to present the applied tool — detailed models of materials applicable in reconstructive interventions on the heart and blood vessels, it is worth focusing on the features, i. e. the physical and mechanical behavior of these objects. The results of the study demonstrate two conclusions: firstly, all xeno-pericardial plates have a pronounced nonlinear dependence „stress−strain“, and secondly, it is possible to distinguish two groups of materials that qualitatively differ in properties.

The first of the aspects (nonlinearity) was repeatedly discussed in the literature with a sufficiently detailed justification for the reason for this behavior: gradual straightening and subsequent non-simultaneous rupture of complex tortuous collagen molecules — the basis of the connective tissue [24,25]. It is noteworthy that despite such knowledge a number of researchers use the linear models of materials based on the elastic modulus. The biomechanics of materials, as can be seen from the graphs, is more complicated than straight line — there is an initial section, which is characterized by large deformations at low tensile forces with a gradual accelerating increase in stiffness in the form of increased slope of the curve. This behavior can quantitatively differ: for some materials, the plateau is more extended (Fig. 2, *b, d, f*), for others — less extended (Fig. 2, *a, c*), but always present. However, note that the use of linear models in many problems is justified. Literature data on simulation the behavior of objects of the cardiovascular system demonstrate that most of the loads that such biological materials undergo under normal conditions are concentrated in the region of low stresses (up to 0.5 MPa [12,26–28]), which in most cases corresponds to the initial plateau of the mechanical behavior curve. Following this logic, researchers rationally choose linear models that provide better convergence and speed of computer calculations, while focusing on detailing other aspects of their studies. On the other hand, the strategy of using nonlinear models in the analysis of the work of blood vessels or the heart is also actively presented, despite similar obtained stress amplitudes [29–35]. Some authors, trending towards the position of complicating material models, argue this by the possibility of obtaining more accurate results [36], however, of course, the final choice between linear and non-linear description in their studies is shared with the scientific teams themselves. On our part, by offering detailed non-linear models for computer simulation, we supplement the existing list of properties of biomaterials for such a choice.

The second conclusion that needs to be discussed is — the difference in physical and mechanical properties between commercial grades. Thus, it is clearly shown that two xeno-pericardial strips („Cardioplant" and „Vascutek"), despite on their different origin (GC and pig, respectively), and the difference in manufacturers demonstrate a qualitatively similar pattern of behavior. Both materials have a short initial plateau and quickly increase stiffness, thus having a low elongation at break (31.1 ± 2.373 and $427.914 \pm 3.649\%$, respectively). The strips „BioLAB", „ChemPeriplas-Neo" and native xeno-pericardium, on the other hand, contain a longer initial section and, accordingly, are able to demonstrate greater elongation. Such a difference in mechanical behavior is due to the microstructure of the xeno-pericardium — the presence of tortuous collagen fibers, which were mentioned above, and the specifics of these strips manufacturing, which affects this microstructure. Taking into account that the plateau of the non-linear mechanical behavior of materials is provided by the straightening of the collagen fibers [24,25], it is worth assuming that for strips „Cardioplant" and „Vascutek" during production process this straightening was already partially carried out and fixed with a preservative solution (glutaraldehyde). Just this picture of the plateau shortening and the stiffness increasing due to pre-stretching was demonstrated in the literature [37,38]. Other presented strips — „BioLAB", „KemPeriplas-Neo" and native xeno-pericardium, apparently, do not include the technological stage of the collagen fibers straightening, and retain tortuosity during operation. Differences in the mechanical properties of these two groups allow the surgeon to choose, depending on the situation or purpose, one or another strip — more rigid or more stretched, which, of course, expands the range of tools for reconstructive interventions.

As expected, the materials differ in properties from different animals also — thinner pig pericardium („Vascutek") turns out to be less durable in terms of deformation than bovine pericardial strips. In this case, the mechanical properties are largely affected by the described specific preservation process with the fixation of the preloaded state of collagen. Differences in thickness are precisely due to the type of animal, which is also confirmed by literature data [39]. The presence of a thinner strip among commercial models allows the use of xenogenic materials in minimally invasive devices — first of all, transcatheter heart valve prostheses, for which minimization of cusp thickness is a key condition for ensuring minimal invasive access.

Finally, the results of comparing the strips treated with preservative solutions with native xeno-pericardium are also consistent with the literature data — as a result of preservation the stiffness and strength of the material increase [39,40]. Such effect is expected and is due to the idea of processing biomaterials as such: in addition to the main motivation for the use of preservative solutions — reduction of immunogenicity due to cross-linking of antigens — the use of chemical fixers is aimed at the mechanical properties of materials improvement [37].

Conclusion

The paper demonstrates its own results of study of the physical and mechanical properties of strips popular in the Russian Federation for reconstructive surgery of the heart and blood vessels. It is shown that all xeno-pericardial models have a pronounced nonlinearity of „stress–strain" pairs and distinguishing integral quantitative characteristics: tensile strength and relative elongation at break. The coefficients of the models of the studied materials are obtained and verified for application in numerical calculations by the finite element method.

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Conflict of interest

The authors declare that they have no conflict of interest.

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