Innovative Structure and Modified Geometric Form of Woven Bifurcated Vascular Prostheses

Viktoriya Kancevicha[1], Andreys Lukyanchikovs[2], [1-2] *Riga Technical University*

Abstract. **Woven vascular prostheses with the innovative wall structure and with improved geometric form have been manufactured within the framework of the research project. Several prototypes of linear and bifurcated prostheses have been fabricated from polyester and polyurethane yarns. The main biomechanical properties, including deformation of wall of woven tubular implant in radial direction have been improved. In this case, the elastic deformation of a new synthetic prosthesis is close to a natural blood vessel. However, the geometric shape of the segment of the bifurcation has been improved. Such geometric shape of the cross-section of bifurcation improves the prosthesis incorporation into living tissues. This innovation also normalizes the blood flow and as a result normal long-term hemodynamic process in the vascular system after prosthesis implantation.**

Keywords: vascular implant, woven prosthesis, bifurcated implant, implant of aorta, polyester yarn, polyurethane yarn.

I. Introduction

Now a surgical method is used in approximately 25% of cases of treating pathology of a vascular system. In other cases, the method of invasive stenting is applied. Stenting is a very good method, but it cannot be applied to all cases of practical cardiology. In some cases, stent may cause the excessive growth of endothelial cells, and, as a result, the lumen of the stent may be closed over time. Metal internal frame of stent may also gradually grow in the living tissues of a natural blood vessel. Such a risk is not desirable for the patient. Platelets are able to actively accumulate this metal structure on the elements. This factor is also the disadvantage of long-term exploitation of metallic stent.

All modern commercial vascular prostheses have a higher rate of hardness indicator than natural blood vessels. These implants also have a lower rate of modulus of elasticity in comparison with natural blood vessels. Consequently, the commercial prosthesis has less stretchy properties. For this reason, the pressure of pulse wave increases in the anastomosis after implantation. In this case, the gap can be formed at the junction of the blood vessel and prosthesis. Arterial aneurysm may also occur as a result of this problem. In some cases, pathologic hyperplasia of artery intima appears, as a reaction to surgery and implantation.

Traditional geometrical form is typical of the commercial bifurcated prostheses and recent scientific inventions. In this case, the sum of diameters of the two branches is equal to the diameter of the main tube. In some cases, the sum of diameters of the two branches is even less than the diameter of the main tube. The e geometrical form designing and calculation of dimensions of cross-sections of the main tube and branches have become popular in recent years [1, 2].

In recent years, scientists have been trying to develop alternative geometrical parameters of three-dimensional prostheses.

This paper proposes innovative solutions to improve the structure of the wall of prosthesis and to improve the geometric form of woven prosthesis.

II. Manufacturing of Linear Vascular Prostheses

The samples of innovative vascular prostheses have been designed and proposed within the framework of the present research. These new implants have a special structure and unique form [3-5].

The wall of the prosthesis has been made from polyester and polyurethane yarns. Polyester yarns have very good mechanical properties, including high resilience to cyclic deformations. These yarns have a high rate of breaking elongation and tensile strength.

Polyester yarns are not toxic to living organisms, and these yarns are inert to acids and alkalis. Polyurethane yarns have very good elastic properties. This is the main advantage of polyurethane in this case. Polyurethane has another positive indicator. This material does not contribute to clots in contact with blood.

Many scientists have also researched the possibility of polyester and polyurethane composition for the manufacturing of the implant with improved biomechanical properties [6-14]. In our case, a unique ratio of yarns and special weave has been proposed.

The samples of innovative vascular prostheses have been made by weaving technology. Polyester warp yarns and polyurethane warp yarns have been used in the ratio 2:1, but in the weft system only polyurethane yarns have been used. Some of these structural innovations of woven vascular implants have been presented at various international scientific conferences [15-18]. The samples of different vascular linear implants based on this technology are shown in the photos (see Fig.1).

In recent times, the designing of innovative structure of elastic implant, which will have the biomechanical properties close to bio-mechanical properties of human blood vessels, is the priority in science. In real hemodynamics, these implants should be able to simulate the pulsating effect of blood flow under pressure.

Such high elastic parameters are required for both types: linear prostheses and bifurcated prostheses.

Not only structure of the wall affects the quality of the prosthesis. The dimensional shape of implant, length of implant, cross-sectional diameter and other geometrical parameters of implant are very influential factors to ensure the normal process of hemodynamics. The ratio of these parameters is particularly important for high physiological quality of bifurcated prosthesis.

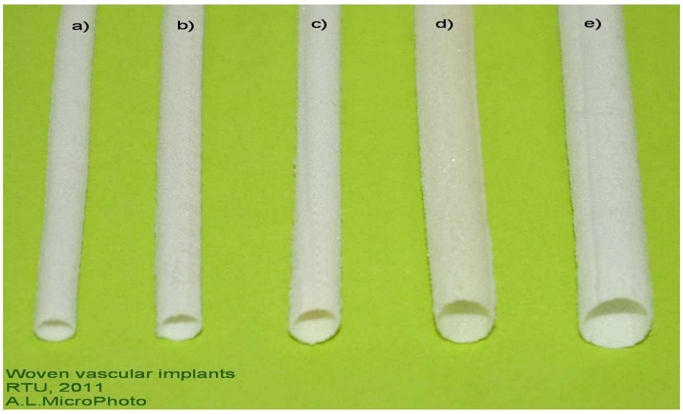

Fig. 1. Woven linear vascular implants:
a) 6 mm; b) 7 mm; c) 8 mm; d) 9 mm; e) 12 mm

For this reason, the study of bifurcated woven implants has initiated the second phase of the project.

III. Manufacturing of Bifurcated Prostheses with Innovative Form

At present, the development of a completely new geometric type of bifurcated implant is a very important scientific direction in modern science, because it is one of major problems in the design and functional characteristics of bifurcated prostheses. The swirls of blood flow occur in the process of separation in the bifurcation. Then, the main parameters of blood flow (velocity, pressure) are changed in the separation zone of the implant. Therefore, blood viscosity parameter is also changed. Under such circumstances, organic sediment will actively adhere to the walls of blood vessels in the separation zone.

The idea of exclusion of the possibility of formation of turbulent eddies has been focused on the design and development of the innovative form of the bifurcated implant. As a result of theoretical research and practical work, we offer the patented method of manufacturing of the woven bifurcated implant with a completely new geometric form [19].

The diameter of the main tube increases by 20%, i.e. exceeding three centimetres, which can be split into two branches. Respectively, such change in the geometric form of the main section of prosthesis allows increasing the size of diameter of the two branches.

This design eliminates the possibility of blood flow turbulences in the divided segments of the bifurcated implant. The scheme of the innovative shape implant is illustrated in Fig. 2.

Vascular bifurcated prostheses have been made by analogy with linear prostheses as five different diameters of the main tube: 6 mm, 7 mm, 8 mm, 9 mm and 12 mm. The diameter of the main tube has gradually been increased close to the zone of separation, leading to the changes in three centimetres from the zone of separation. As a result, the separation zone and the diameter of the branches have been increased by 15-20% in comparison with the diameter of the main tube.

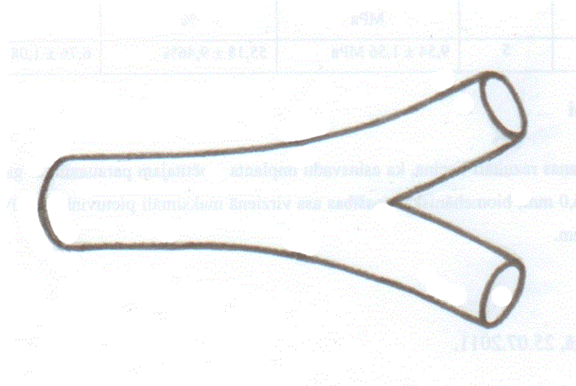

Fig.2. Scheme of an improved geometric form of bifurcated vascular implant

The woven bifurcated prosthesis has been manufactured by weaving technology (See Fig. 3). Polyester warp yarns and polyurethane warp yarns have been used in the ratio 2:1, but in the weft system only polyurethane yarns have been used. The bifurcated prosthesis has been made by analogy with the linear prosthesis.

The impregnation of wall structures with the biological and synthetic solution is the next step after manufacturing and sterilization of the implant. After impregnation, the next step is thermo-fixation.

Then thirty impregnated samples of implants have ben tested for water permeability based on ISO 7198 standard. As a result, the test has shown zero water permeability of the wall of woven implants (0 ml/min/cm^2).

Fig.3. Woven bifurcated vascular implant

After conducting the water permeability test, the main biomechanical properties of implants have also been studied based on the standard “Cardiovascular implants – Tubular vascular prostheses”.

A special stand has been used for testing. Test stand consists of a mechanical device, device to change the pressure, computer system, sensors, and video recording device. In the process of testing, various properties have been identified: internal pressure, stress, deformation of the walls in longitudinal and radial directions. The computer has recorded all changes of the geometric shape of specimen of prostheses.

IV. Biomechanical Properties of Woven Vascular Implants

In the course of practical experiment, main properties of prostheses have been defined (see Fig. 4). The samples of woven vascular implants have been tested under pressure from 0 mm Hg to 240 mm Hg.

Step change in pressure has been 20 mm Hg. The length of each sample of implants has not been changed in each trial.

Internal pressure, Mm Hg	Stress, kPa	Deformation, %
0	0	0
20	20.09	4.00
40	41,85	6.20
60	64,95	8.00
80	89,84	10.03
100	115,75	11.71
120	142,53	13.10
140	168,62	13.95
160	194,61	14.51
180	221,10	15.00
200	247,65	15.50
220	274,62	16.00
240	303,45	16.75

Fig.4. Main indicators of biomechanical properties

The overall result of test has shown that the walls of a woven synthetic implant have a non-linear dependence of pressure and deformation (see Fig. 5).

The maximum deformation is 16.75 %, if critical internal pressure is 240 mm Hg. Modulus of elasticity in this case is 5.4 mPa. This is similar to the biomechanical properties of human vascular vessels.

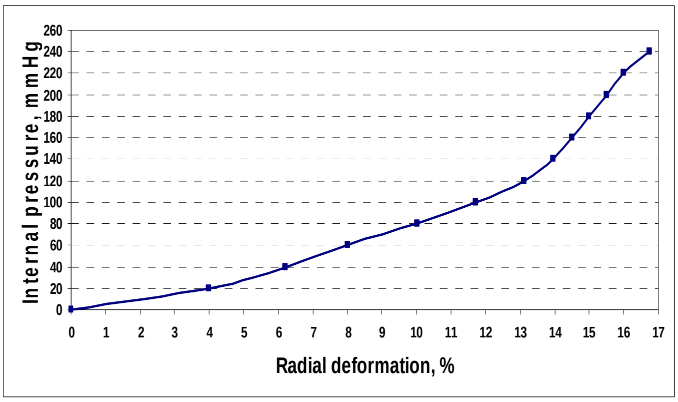

Fig.5. Dependence of internal pressure on radial deformation

In the course of the scientific project, a completely new form of woven bifurcated prosthesis has been developed and proposed. The new elastic structure of the wall of implant has also been developed and tested. The results of research confirm that the innovative structure of walls of implants and improved geometric form provide very good biomechanical properties, and these properties are similar to the properties of human vascular vessels.

V. Histological Studies

The histological studies have been conducted after removing vascular implants from the body (which happened after six months). The results of the study have shown that the prosthesis is covered by connective tissue throughout its length. Connective tissue also grows in space between synthetic fibres. Neointima has formed on the inside walls of the prosthesis. Lumen of prosthesis is not closed; it is clean (see Fig. 5).

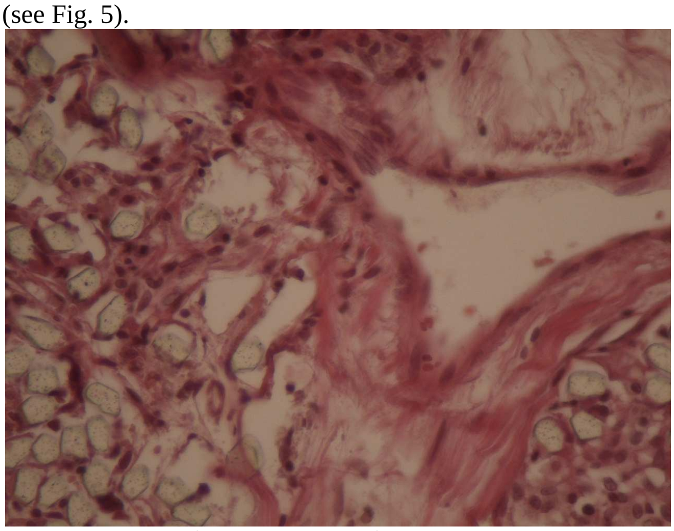

Fig.5. Micro-picture of histological study of prosthesis (100x, sample painted by *hematoksilin-eozin*)

VI. Conclusions

The innovative woven wall structure and unique geometric form allow improving the basic biomechanical properties of an implant. The deformation properties of tubular implant have been improved in the axial and radial directions. In this case, the rate of elastic deformation of new synthetic prostheses is close to a natural blood vessel. The modified geometric form and improved woven structure enable the bifurcated prosthesis to better incorporate into living tissues. This extended shape eliminates the swirls of blood flow. This innovation also normalizes the long-term process of hemodynamics in the vascular system after prosthesis implantation.

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Viktoriya Kancevicha
Chief Researcher
Riga Technical University
Scientific degree: Dr.habil.sc.ing. (1994, H-11, RTU)
Research direction: Manufacturing of vascular implants and study of their properties
E-mail: Viktorija.Kancevica@rtu.lv

Andreys Lukyanchikovs
Chief Researcher
Riga Technical University
Scientific degree: Dr.sc.ing. (1998, H-11, RTU)
Research direction: Manufacturing of vascular implants and study of their properties
E-mail: Andrejs.Lukjancikovs@rtu.lv

Viktorija Kanceviča, Andrejs Lukjančikovs. Inovatīvas struktūras un modificētas formas austas bifurkācijas asinsvadu protēzes
Šī zinātniskā pētījuma galvenais praktiskais uzdevums bija izstrādāt austas bifurkācijas asinsvadu protēzes ar galvenā stobra modificētu ģeometrisku formu. Šāds konstruktīvs risinājums izslēdz asins plūsmas virpuļošanos pirms protēzes sazarojuma. Darba realizācijas gaitā tika izstrādāta arī inovatīva asinsvada sieniņu struktūra, kas nodrošina protēzei labas hemodinamiskas īpašības. Protēzes sieniņu inovatīvā struktūra tika veidota no smalkiem poliestera un poliuretāna pavedieniem ar sarežģītu pinuma rakstu. Pirmajā darba etapā izstrādājām lineārās protēzes, bet otrajā etapā – bifurkācijas implantus, izmantojot patentētu metodi. Pēdējā paredz bifurkācijas protēzē galvenā stobra diametru palielināt par 15 līdz 20% pirms tā sazarojuma, kas ļauj izveidot arī atzarus ar palielinātu diametru. Salīdzinājumā ar komerciālām bifurkācijas protēzēm, modificētās ģeometriskās formas protēze izslēdz asins plūsmas turbulenci pirms sazarojuma. Inovatīvas struktūras asinsvadu protēzes paraugus testējām laboratorijas apstākļos, izvērtējot galvenos biomehāniskos raksturlielumus un pie maksimāli augsta iekšējā spiediena to sieniņu ūdens caurlaidību. Izpētes rezultāti ļauj secināt, ka apdares procesā izveidotās elastīgās membrānas protēzes porās spēj nodrošināt sieniņu ūdens necaurlaidību, vienlaicīgi saglabājot protēzei teicamas elastības īpašības ass un aploces virzienā. Piedāvātās struktūras un ģeometriskās formas asinsvadu protēžu deformatīvās īpašības ir maksimāli pietuvinātas cilvēka asinsavadu īpašībām, kas spēs ilgtermiņā nodrošināt normālu hemodinamiku.

Виктория Канцевича, Андрей Лукьянчиков. Инновационная структура и модифицированная геометрическая форма тканых бифуркационных протезов кровеносных сосудов
Главной практической задачей данного научного исследования является производство образцов тканых бифуркационных протезов кровеносных сосудов с модифицированной геометрической формой поперечного сечения главного ствола и двух его ответвлений. Данные конструкционные новшества являлись необходимым условием для улучшения процесса гемодинамики в реконструированной кровеносной системе. В процессе реализации данной научной работы была также предложена инновационная структура стенки тканых протезов кровеносных сосудов. Предложенная структура позволяет достигать очень хорошие биомеханические показатели для васкулярных протезов в условиях естественной гемодинамической пульсации, в том числе - высокие показатели продольной и радиальной упругой деформации. Образцы тканых протезов были изготовлены при помощи сложного переплетения. В качестве нитей основы и утка в данном случае применялись полиэфирные и полиуретановые нити малой линейной плотности. На первом этапе научно-практической работы были изготовлены линейные трубчатые протезы, а на втором – бифуркационные. В процессе производства бифуркационных протезов был использован ранее запатентованный метод, который предусматривает увеличение диаметра главного ствола импланта на 15-20% за 2-3 см до начала его разделения. Такое увеличение диаметра главного ствола обеспечивает и соответственное увеличение диаметров двух его бифуркационных ответвлений. Данная инновация, структуры стенки и геометрической формы протеза, была предложена для нормализации процесса гемодинамики и исключения возможных турбулентных завихрений кровяного потока в зоне бифуркации, характерных при практическом применении традиционных коммерческих протезов. Изготовленные образцы были протестированы в лабораторных условиях, где изучались водопроницаемость стенки протеза и основные параметры биомеханических свойств. Результаты экспериментов показали, что мембраны, образовавшиеся в порах изделия, надежно обеспечивают нулевую водопроницаемость, а сами протезы обладают высокой продольной и поперечной деформацией, показатели которой близки оптимальным показателям эластичных свойств кровеносных сосудов человека.