Scientific Journal of Riga Technical University
Material Science. Textile and Clothing Technology
2011
Volume 6

Structure of Elastic Woven Vascular Implants

Viktoriya Kancevicha[1], Andreys Lukyanchikovs[2], [1-2]*Riga Technical University*, Alberts Auzans[3], [3]*Latvian Agricultural University*

Abstract **Vascular implants are used to replace the abnormal segments of the cardiovascular system. Such operations are necessary to restore a normal blood flow. Scientists propose the arterial prosthesis and the aortic prosthesis of various innovative structures and designs. The implants have been manufactured by weaving and then impregnated with a solution of biologically active agents. Polyester yarns and polyurethane yarns have been used for the manufacturing of implants. These implants have very good deformation properties in the longitudinal and radial directions. Zero water permeability is achieved by means of a special impregnation. The structure of the wall of the prosthesis can be incorporated into a living organism without complications. These prostheses provide normal hemodynamics for a long time.**

Keywords **– woven implant, vascular prosthesis, implant of aorta**

I. Introduction

Scientific advances in recent years indicate that the main basis of atherosclerosis of blood vessels is the violation of lipid metabolism (dyslipidemia). This negative process leads to deposition of lipids on the blood vessel walls. On the inner walls of blood vessels clumps of connective tissue develop reactively. Inner diameter of the lumen becomes smaller. Under these conditions, the wall structure changes, the mechanical and elastic properties of the wall also change. Wall of the pathologically altered blood vessel is not able to extinguish the pulse wave oscillations of blood. As a result, the heart muscle and overall cardiovascular system begin to function at high loads. All these pathological changes in blood vessels disturb normal hemodynamics. Organs and tissues receive less oxygen and nutrients.

In the field of implantology, the results of surgical cardiovascular operations can be drastically improved with a gradual improvement in the production of synthetic implant technology and application of new composite polymer materials.

II. Background and Trends in the Production of Vascular Prostheses

At present, different countries offer different technologies and different designs of vascular prostheses, but no one can offer a universal solution to this problem. These important criteria should be as the development of a new type of vascular prostheses:

- The structure of the implant provides a normal hemodynamics and prevents the formation of blood clots in the lumen;
- The wall of synthetic implant provides ingrowth of living tissue for normal incorporation and the formation of a layer of endothelial;
- Some elements of the implant bio-degrade over time; this process facilitates the exchange of synthetic implant elements on the cellular structure of living tissues;
- The implant is impregnated with a solution of biologically active substances; such treatment promotes better ingrowth into the wall, eliminates bleeding through the wall, and prevents inflammation in anastomosis.

Surgeons devote a particular attention to the design of implants with the innovative structure of a wall. Such structures allow simulating the biomechanical properties of human blood vessel and restoring a normal hemodynamics after incorporation of the implant into the overall cardiovascular system. The wall of implants must to be elastic, porous, water-resistant, mechanically stable, biocompatible, anti-thrombogenic, resistant to infection, anti-carcinogenic, non-toxic and non-allergic.

It is known that any implantable material is not completely inert to a living tissue. The implant can be considered a bio-compatible product, if it is able to normally function without the inflammation of a living tissue.

Most implants used today are much stiffer than natural human blood vessels. These synthetic implants have a higher modulus of elasticity.

Diameter of natural blood vessel can be expanded under the pressure in the process of pulsation of heart, but the diameter of the stiff synthetic implant is not extended so well. As a result, the surgical connections (anastamosis) of natural blood vessel with implant can break.

It is well known, the diameter of a natural blood vessel can be expanded by approximately 10%, but the diameter of the synthetic implant extends only to 1-3%.

Biomechanical properties of the synthetic implants are mainly dependent on raw materials, technological characteristics, porosity, physical parameters, etc.

This confirms the need to create an innovative implant structure that can deform elastically and provide normal hemodynamics.

III. Types of Synthetic Materials and Yarns Used for Woven Implant Manufacturing

Synthetic Yarns

Currently, specialists use such synthetic yarns for woven prostheses:

- Polyethelene terephtalate, $(C_{10}H_8O_4)n$ /Polyester, PET/ - Dacron®, Terylene®, Trevira®, Tergal® etc.;
- Polytetrafluorethylene, CnF2n+2 /PTFE/ - Teflon®;
- Polypropylene, $(C_3H_6)n$ /PP/.

Polyethelene terephtalate yarns have good mechanical and hygroscopic properties, as well as resistance to high cyclic strains. This material is inert to acids and alkalis.

Polytetrafluorethylene yarns are bio-stable in vivo, and these yarns are anti-thrombogenic. This material has also good physical and mechanical properties. It is resistant to heavy loads. Typically, the surface of PTFE implants can be coated with biological substances (albumin, collagen, etc.) or a solution of synthetic polymers such as silicone.

Polypropylene yarns have a relatively low density and high hardness. Under cyclic loading, the material greatly reduces the physical and mechanical properties.

After analyzing the dependence of the stress apmlitude (MPa) and number of cycles on the failure (number) of three synthetic materials it can be concluded (see Fig.1): three types of yarns (PET, PTFE and PP) are sufficiently resistant to a physical fatigue cycle. The scientific community traditionally considers that polyester is the most suitable material for the manufacturing of woven implants. This material has good mechanical, physical and biological properties.

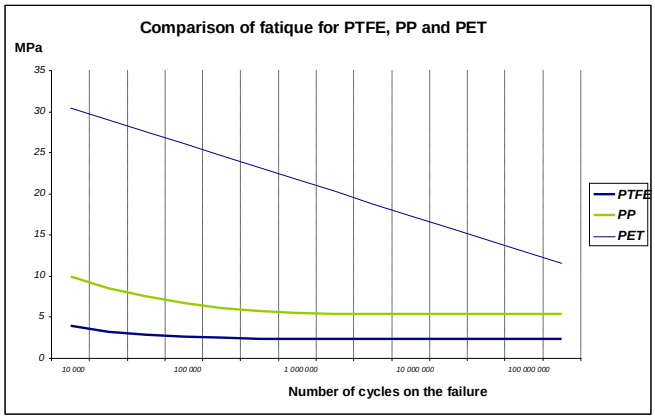

Fig.1. Comparison of fatigue curves for PTFE, PP and PET

In recent years, polyamide (PA, Nylon®, Perlon® etc.) and polyethylene (PE) filaments are not used for the production of woven vascular prostheses. These synthetic materials are not promising for these purposes.

During the implementation of the theoretical and practical scientific problems, other types of yarns and filaments can be used. In modern science some designers begin to study the possibility of using of polyurethane for the production of vascular implants. Combination of polyester and polyurethane is especially good in order to get excellent elastic properties.

At the same time, other materials are promising for the manufacturing of implants, for example, non-toxic synthetic biodegradable materials based on polymers of organic acids. Thus, the biodegradable material polilaktat (PLA) is made from organic polilaktat lactic acid, and poliglikolid (PGA) made of glycolic acid. This material completely degrades during 60-90 days.

At the moment, a new synthetic material Biomer Biopolyester (PHB) is known. It has biodegradable properties over a long period, but this material can not be used for the production of implants, because biomer is not completely cleared of contaminants and chemical impurities.

Special Coating

Currently, producers are interested in modern technologies of finishing of implants.

For example, to get the prostheses with anti-thrombogenic properties, lumen is coated with a thin elastic layer of synthetic material (silicone) and then with colloidal silica solution – a highly dispersed system, which consists of tiny particles at the dispersed phase (Cab-O-Sil, 1 - 1000 nm). These components are cross-linked and form a matrix of lumen. This structure facilitates the ingrowth of natural tissue through the wall of the implant and the formation of neointima. Such coverage also repels negatively charged platelets, preventing formation of blood clots from undissolved fibrin.

If the lumen of vascular prostheses is covered with synthetic materials using an ion-plasma method, then it is possible to form nano-level of bio-compatible coating (α–C:H, DLC) on the walls of the implant. This coating improves the surface structure of the walls of the implant, made of polytetrafluorethylene and polyethelene terephtalate yarns. In this case, this treatment improves the biocompatibility of synthetic materials with natural tissue and blood cells, and reduces the surface roughness [1-8].

IV. Woven Vascular Implants

We offer practical solutions to ensure the normal physiological properties of the reconstructed vascular system:

1. Elastic goffered vascular implants have been made of polyester and polyurethane yarns using a special hollow weave. The implant is made using plain weave as the base. Two weft yarns (one polyester and one polyurethane) are laid with the help of one rapier of loom. As a result, the wall of the implant is formed as rep weave. Thus, in every shed just four weft yarns are laid. In the area of the rapier mechanism weft yarns are stretched by 50%. At the exit from the working area of weaving machine stretched polyurethane yarn is compressed and returned to the previous condition, but the long overlap of inelastic polyester weft yarns form a corrugated wall of the implant. Such prosthesis can deform in the tangential direction at 25-35% ensuring the stability of the configuration (see Fig. 2) [9].

Fig. 2. Sample of goffered vascular implant

2. Another elastic implant with the looped surface structure has been designed and manufactured. Samples of these implants have been manufactured by weaving hollow elastic and flexible tubes using a special weave. The wall of the implant has a specific structure. This woven structure consists of a composition of polyester and polyurethane yarns. On the outer wall of implant the loop formed as double velours, and the inner lumen surface is smooth (see Fig. 3) [10].

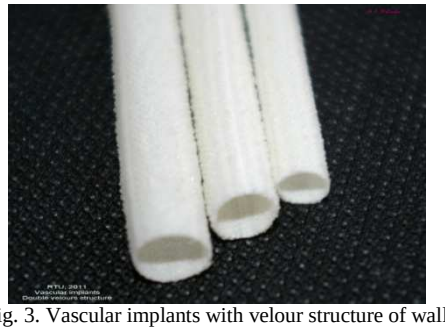

Fig. 3. Vascular implants with velour structure of wall

3. Implant for reconstruction of the aorta has been designed and manufactured by the method of weaving. For woven samples manufacturing, polyester and polyurethane yarns have been used. Implants of aorta with main hollow tube and tubular hollow branches have been produced. This implant has been made using a twill 3/1 weave (see Fig. 4) [11].

Fig. 4. Bifurcated implant of aorta

V. The Elastic Structure of the Wall of the Implant

These implants have been manufactured by weaving hollow elastic and flexible tubes using a special weave. The wall of the implant has a specific structure. This woven structure consists of a composition of polyester and polyurethane yarns. The structure of the wall of the implant (see Fig. 5) is as follows: 1 - polyester warp yarns; 2 - polyurethane warp yarns; 3 - polyester weft yarns; 4 - polyurethane weft yarns.

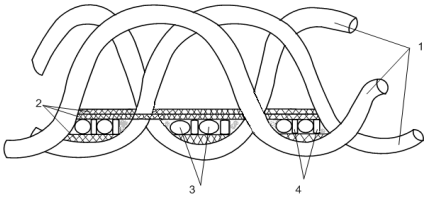

Fig. 5. Cross-section of the wall of the implant

After weaving these implants were thermo stabilized and sterilized. Then the implants have been impregnated with a solution of bioactive agents in a vacuum chamber. As a result, elastic membrane has been formed on the wall of the prosthesis. It provides zero permeability of wall of implant. Impregnation is also necessary for better incorporation of implant into body without inflammation. Impregnated segment of the wall of the implant – the image at the magnification of 50x (see Fig. 6).

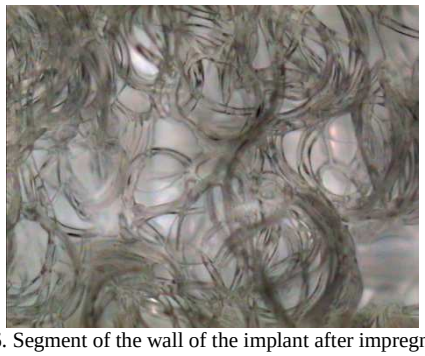

Fig. 6. Segment of the wall of the implant after impregnation

VI. Study the Properties of Implants

Three different designs of implants have been developed: goffered, velour, smooth. All these types have been made as the linear and bifurcated ones. Linear and bifurcated implants with velour structure of a wall have been investigated thoroughly.

Biomechanical Test Results

Samples of these blood vessel implants have been tested using the test machine Zwick/Roell BDO–FBO 5ST. In the course of the study the following biomechanical parameters have been obtained:

The maximum tensile strength in the longitudinal direction:
$\sigma_{max1} = 7{,}30 \pm 1{,}58$ MPa;

The maximum tensile strength in the radial direction:
$\sigma_{max2} = 5{,}94 \pm 0{,}82$ MPa;

The maximum strain in the longitudinal direction:
$\varepsilon_{max1} = 64{,}91 \pm 6{,}09$ %;

The maximum deformation in the radial direction:
$\varepsilon_{max2} = 163{,}11 \pm 20{,}75$ %;

Modulus of elasticity in the longitudinal direction:
$\bar{E}_1 = 4{,}27 \pm 0{,}58$ MPa;

Modulus of elasticity in the radial direction:
$\bar{E}_2 = 3{,}61 \pm 0{,}62$ MPa.

Preclinical Studies

Currently preparatory work is being implemented for the tests on animals. Veterinarians perform a permanent monitoring of the animals, and they carry out special tests.

VII. CONCLUSIONS

In the process of this scientific project, the specimens of innovative pulsating implants have designed and manufactured. The elastic structures of the wall have been made by weaving the used polyester and polyurethane yarns. Three different designs of implants have been developed. Thus, the biomechanical properties of bifurcated and linear velour implants have been tested. These prostheses have also been tested on animals. Various studies show that such structures of prosthesis provide long-term normal hemodynamics in a vascular system of the organism.

ACKNOWLEDGEMENT

This work has been supported by the European Social Fund within the project “Establishment of interdisciplinary research groups for a new functional properties of smart textiles development and integrating in innovative products", Nro.2009/0198/1DP/1.1.1.2.0./09/APIA/VIAA/148.

REFERENCES

[1] De Scheerder, I. et al. Stents with a diamond like coating. US Patent 6,572,651 B1. 2003.
[2] Kill, I. R., Franks, J. Medical implant comrising a biological substrate and a diamond-like carbon coating. Patent WO/2006/061598. 2006.
[3] Kill, I. R., Franks, J. Medical implant comrising a biological substrate and a diamond-like carbon coating. US Patent 2009/0299467 A1. 2009.
[4] Jelinek, M. et al. 4th European Conference of the International Federation for Medical and Biological Engineering. IFMBE Proceedings, 2009, Volume 22, Part 17, 2173-2174, DOI:10.107/ 978-3-540-89208-3-519.
[5] Podlaha, J. et al. Experimental Assessment of a New Type of Carbon-Coated ARTECOR Vascular Prosthesis in Sheep. ACTA VET.BRNO 2009, 78:115-120; DOI: 10.2754/avb200978010115
[6] Ремеева, Е. А. Влияние наноструктурирования поверхности медицинских полимерных материалов на их физико-химические и биологические свойства. Автореферат диссертации на соискание ученой степени кандидата физико-математических наук, М.-2007.
[7] Eliezer, M., Alcantara et al. Mechanics of biomaterials: vascular graft prostheses. University of Puerto Rico, Mechanics of Biomaterials (Prostheses in Human Body), VolumeI: Word documents, Puerto Rico, 2005.
[8] Rosenberg, N et al. A circumferentially elastic arterial prosthesis: Three-year studies of a dacron-spandex graft in the dog. Journal of Surgical Research, Volume 34, January 1983, Pages 7-16, Section of Vascular Surgery, University of Medicine and Dentistry of New Jersey, Rutgers Medical School, Piscataway, New Jersey 08854, USA.
[9] Kanceviča, V. et al. Gofrēta asinsvadu protēze. Patents LV 10836 B. 1996.
[10] Kanceviča, V. et al. Artēriju protēze. Patents LV 12702 B. 2001.
[11] Kanceviča, V. et al. Aortas implanta veidošanas metode. Patents LV 13861 B. 2009.

Viktoriya Kancevicha. Chief Researcher of Riga Technical University.
Scientific degree: Dr. Habil. Sc. Ing. (1994, H-11, RTU).
Research direction: Vascular implant manufacturing and research on their properties.
E-mail: Viktorija.Kancevica@rtu.lv

Andreys Lukyanchikovs. Chief Researcher of Riga Technical University.
Scientific degree: Dr. Sc. Ing. (1998, H-11, RTU).
Research direction: Vascular implant manufacturing and research on their properties.
E-mail: Andrejs.Lukjancikovs@rtu.lv

Alberts Auzans. Asoc. Professor of Latvia University of Agriculture.
Scientific degree: Dr. Vet. Med. (1993, H-5, LAU).
Research direction: radiology in veterinary medicine.
E-mail: vmf@llu.lv

Viktorija Kanceviča, Andrejs Lukjančikovs, Alberts Auzāns. Elastīgu, austu asinsvadu protēžu struktūra
Mūsdienās kardioloģijā tiek plaši izmantoti sintētiski asinsvadu implanti, lai aizvietotu sklerotiski skartos un patoloģiski izmainītos asinsvadu posmus. Šādu ķirurģisku operāciju mērķis normalizēt izmainītu hemodinamiku, uzlabojot arteriālo un venozo asinsriti. Modernā zinātne piedāvā dažādus praktiskus risinājumus sintētisko asinsvadu protēžu izgatavošanai. Realizējot šo pētnieciski - zinātnisko darbu, izmantojām aušanas tehnoloģiju un izstrādājām inovatīvas struktūras artēriju un aortas implantu paraugus ar labām biomehāniskām īpašībām ass un aploces virzienā. Protēžu sieniņu elastība tika apstiprināta eksperimentāli. Implantu paraugu izstrādāšanai izmantojām poliestera un poliuretāna pavedienus ar zemu lineāro blīvumu. Apdares procesā implantus piesūcinājām ar biosaderīgu, bioloģiski inertu preparātu šķīdumu, kas izžūstot veido elastīgas membrānas un izpilda barjeras lomu pret aktīviem reaģentiem. Pēc implanta pieslēgšanas kopējai asins sistēmai inovatīvā sieniņu struktūra un elastīgās membrānas spēj modelēt fizioloģisko hemodinamiku rekonstruētā gultnē. Piedāvātā asinsvadu protēzes konstrukcija izslēdz tās sieniņu caurlaidību un nodrošina labu implanta inkorporēšanos organismā.

Виктория Канцевича, Андрей Лукьянчиков, Албертс Аузанс. Структура эластичных тканых протезов кровеносных сосудов
В настоящее время синтетические васкулярные импланты активно применяются в современной медицине для лечения поврежденных и патологически измененных участков натуральных кровеносных сосудов. Такие операции производятся с целью нормализации процесса гемодинамики и улучшения венозного и артериального кровотока. Современная наука предлагает различные практические решения в области разработки и изготовления синтетических протезов кровеносных сосудов. В процессе реализации данной научно-исследовательской работы были разработаны и изготовлены образцы тканых имплантов артерии и аорты, обладающие хорошими деформационными свойствами в продольном и поперечном направлениях. Высокие показатели эластичности стенки протеза были подтверждены экспериментально. Для изготовления трубчатых протезов были использованы полиэфирные и полиуретановые нити малой линейной плотности. В дальнейшем образцы протезов были обработаны специальным раствором, включающим в себя различные компоненты, биологически - активные вещества и добавки. Дополнительная обработка обеспечила нулевую гидропроницаемость стенки протеза, что было экспериментально подтверждено в лабораторных условиях. Низкий уровень гидропроницаемости является необходимым условием для хорошей имплантации протеза в ходе операции. Такие сосудистые импланты обеспечивают нормальную гемодинамику. Предложенная инновационная структура стенки протеза способствует успешной инкорпорации импланта в живые ткани организма без дополнительных компликаций.