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Nanostructured Polyester Yarn Integration in Woven Vascular Implants

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Abstract − **Woven synthetic vascular prosthesis consisting of polyester yarn, nanostructured particles of colloidal silver and polyurethane yarns and natural silk surgical thread were offered in the process of this scientific and practical activity. Previous scientific and practical experience of manufacturing various types of vascular prostheses was used in designing a new prosthesis. Advanced biomechanical and other properties used in the development of yarns were examined. The innovative structure of woven walls of prosthesis has normal biomechanical properties. Expressed antimicrobial activity of nanostructured wall of the prosthesis is an important indicator for the successful incorporation of synthetic implant in a living organism. These prostheses are capable of providing long-term normal physiologic hemodynamics in the recycled circulatory system.**

Keywords − **Silver nanostructured yarn, synthetic vascular implant, woven synthetic vascular prosthesis.**

I. Introduction

The heart is the most significant organ of the vascular circulatory system of the body. Cardiovascular diseases are often associated with abnormal blood flow in the coronary arteries. As a result, the heart muscle does not get enough oxygen and nutrients. All of these problems lead to bad consequences when physiological and biological functionality of principal organs deteriorate.

In conservative cardiovascular surgery pathologically bad vessels or vessels with atherosclerosis are replaced with implants. For these important purposes there is a need for synthetic high-quality implant made of modern composite-structural textile material. These materials should have properties which could successfully solve the problems of vascular implantation and other surgery tasks, for example, treatment and restoring the overall full functionality of the body. In some cases, the situation requires replacing the sections of blood vessels damaged by atherosclerosis or the natural blood vessel damaged by thrombosis.

Integrated in a living organism an implant should passively pulsate under internal pressure immediately after the operation. It should simulate a rhythmic blood flow wave with the help of synthetic woven walls.

During the constant popping process of pulsation of blood the diameter of lumen of natural vascular blood vessel is extended by 10 percent to 12 percent, but the diameter of synthetic vascular implant used in the clinical practical surgery is extended only by 3 percent to 5 percent (1). In this case, this data means that the biomechanical properties of such types of synthetic implants cannot fully ensure the blood wave move at a constant speed and pressure in the human vascular system. This extremely negative factor usually creates strong tension in the circular connection points (anastomosis) and it can easily break the surgically stitched points of the artificial prosthesis with natural blood vessel. This external factor of intense exposure really may be caused by an extensive hyperplasia of intima layer of vascular wall, and in this case the aneurysm also may evolve. All of these processes always have negative impact on overall vascular system.

Currently, surgeons use other vascular implants that are not able to function similarly to nonlinear elastic natural blood vessel woven walls. Commercial implants are not always completely effective. Often such prostheses are not capable to adequately pulsate under the conditions of real hemodynamics.

Another serious problem typically exists in the surgical implantation. Antimicrobial activity is very important at the stage of postoperative healing. However, it is necessary to achieve high strength and deformation quality of an implant.

In modern surgery autogenous implants (small and medium diameters, d = 6 mm – 8 mm) are also used, but there exist a number of limitations for such type of implantation.

After full final diagnosis the doctor checks and determines the best method of next treatment of the patient. This decision depends on the patient’s condition and external circumstances. Often the doctor makes a radical decision to do surgical operation if other therapeutic methods are not so effective.

Synthetic prosthesis implantation is a complex tool to aid the person who needs help. The initial healing period and adaptation after surgery is the most dangerous stage. An implant must grow into the living tissue without inflammation. Therefore, the problem of antimicrobial activity in the process of integration of synthetic prosthesis into the body is very relevant.

II. Previous Research Experience

The morphological cellular basis and structural basis of inner smooth layer of the wall of blood vessel is unique. This layer is very elastic. It consists of collagen cell and its structure is similar to the elastic organic frame (skeleton). Such frame provides elastic properties of blood vessel channel. The thin outer shell of this skeleton provides other functions. It helps the process of living cells growing into the synthetic fibers and micro capillaries. It also promotes the normal long-term formation of proximal sites and distal sites, as well as evenly dampens the permanent and periodical waves pounding of blood pulsation in the body.

The middle layer consists of muscle cells. This muscular layer supports the desired tone of the blood vessels. It also regulates the internal blood pressure.

Currently, as mentioned in this article, surgeons use synthetic elastic implants that are not always able to function ideally. These commercial prostheses do not work as nonlinear natural blood vessels in the body.

Manufacturers of different synthetic vascular implants often make prostheses of various types and configurations and these implants are often made as tubular hollow products (for example, woven medical product, knitted medical product, braided medical product etc.). Then they make a wavy (goffered) wall for these medical products. Specialists make this technological procedure during subsequent process of thermal stabilization and finishing. Handlers usually use additional equipment for these purposes.

Goffered walls are usually made after the weaving process of the tubular implant. Corrugated surfaces provide good elastic and other properties in the longitudinal direction. But the radial elastic deformation is not always consistent with the desired criteria. Previous experience shows that such wavy implants are not always able to adequately pulsate under the necessary conditions of real permanent hemodynamics.

Usually goffered synthetic vascular prostheses can provide blood flow turbulence in the segment of lumen, especially in the places where these prostheses have been implanted. Presumably this wavy or goffered structure of the implant strongly changes the median longitudinal speed of the blood flow and this structure of prosthesis also changes blood pressure on the walls of the implants and also on the walls of natural vessels. Thus, these unwanted dynamic turbulent processes of blood flow necessarily contribute to the formation of small organic deposits on the walls of the prosthesis and therefore these negative processes consequently lead to the formation of blood clots in the vascular channel.

It should be emphasized that the deformation elastic properties of the prosthesis are getting worse over time because goffers are stretched in the body.

Synthetic implants offered on the contemporary medical market are not fully compatible with natural blood vessels in some aspects.

Typically, these prostheses do not possess the necessary biochemical properties. In addition, the structure of the wall does not always facilitate perfect functioning of the prosthesis in a living organism. Man-made prosthesis with such inadequate structure almost always suffers from full thrombosis. Early thrombosis occurs in 25 % of cases. In some cases, this statistics was even worse.

Some specialists use different polytetrafluoroethylene-PTFE woven implants with additionally inserted liners. This special liner should always be inserted into a tubular woven skeleton. It is thin nonwoven impermeable polymer product.

The main deformation properties and other properties of double-layer implants with tubular polymer liner do not comply with the deformation, biomechanical and other criteria of human blood vessels. Such practical tests have been carried out many times.

Now, the important practical task is to develop and to produce new vascular prostheses which could provide and guarantee normal long term hemodynamics in the partially reconstructed human cardio-vascular system.

Some popular and well known scientists of economically high developed countries diligently continue to research activity in this scientific direction (structural improvement of implants). All practical researchers actively begin to use various very specific polymer materials in man-made implants.

The main and very important problem of modern cardio-vascular surgery is the lack of synthetic vascular implants with ideal biomechanical properties. These properties of implants unfortunately are not fully similar to properties of natural human blood vessels, but the similarity or dissimilarity of properties is most important in the process of implantation and rehabilitation.

The next important task is the successful integration of man-made prosthesis into the damaged living tissue without inflammation.

In our case, the authors of this research are continuing the development of new prosthetic devices. These new products are closest to the properties of human blood vessels. The authors are developing also new models of implants with successful biological adaptation. During the process of recent scientific and practical work the authors have suggested innovative models of woven synthetic grafts.

Practical testing of the new prosthesis uniquely confirmed a good option of modulus of elasticity. The new prosthesis must unconditionally ensure excellent elastic-deformation properties in both directions: longitudinal and radial. All of these elastic and other properties are very important for the correct implantation and integration. This is also important because the new man-made implants will function under internal pressure of blood pulsation. This is also very important to ensure normal blood hemodynamics after operation.

Many models of innovative implants have been tested on animals.

These previous theoretical studies and empirical works give many beneficial results in the field of design, manufacture and use of synthetic implants.

III. Raw Materials and the Structure of the Implant

This scientific-practical research was successfully based on previously long conducted research in this science area. The authors of the research took into account the data of the influential international scientific expertise and basic scientific and practical work experience. The authors also took into account the numerous publications in the field of the development of various modifications of the man-made vascular implants.

Previous experience confirms that it is very important to develop a new implant with excellent long-term strength, strain and bactericidal properties.

This new developed innovative wall structure shall provide all of these very important properties, as well as help fiber partial and easy degradation in vivo. It should be noted that such partial and fragmentary degradation of natural fibers will contribute to a much better biological incorporation of cells of living tissue in the synthetic woven wall after surgical operation.

The geometric dimensions, shape and volume of the tubular hollow prosthesis and innovative structure of wall of prosthesis radically influence its biomechanical functionality. It is well known that a positive practical implementation of the requirements of the modern implants always depends also from the various properties of raw material. For example, the biomechanical properties of synthetic raw materials significantly influence the desired properties of vascular tubular prostheses. Other properties of the raw materials also strongly influence the properties of the medical product.

Every developer has to take into account that any man-made material that is used for tubular synthetic vascular prostheses should guarantee the following properties (1): 1) biocompatibility and not-immunogenicity of synthetic fibers; 2) long-term bio, chemical and mechanical stability of used materils; 3) processability during the manufacturing of the prosthesis; 4) elastic and deformation properties of medical synthetic product should be similar to natural blood vessels of the body; 5) geometrically adequate micro-pore size and its normal distribution; 6) ability to prevent synthetic implant leakage which can lead to seroma formation and unwanted blood loss in living organs; 7) modern implant should be resistant to abrasion; 8) the implant should provide the attachment of living and synthetic cells, but the new fiber material should provide good angiogenesis; 9) it should guarantee low level of biological and chemical toxicity (locally, systemically and from process of products bio-degradation); 10) a new synthetic material can be absorbable or not-absorbable (individual approach depending on the specific situation); 11) the material should possess such property as ability to release special bio-active substances and compounds; 12) the implant must have smooth internal surface of lumen.

The main standardized requirements and options for hollow tubular implants (vascular prostheses) are indicated in many international standards (one of them is the approved and recognized international document "Cardiovascular Implants – Tubular Vascular Prostheses", ISO 7198:1998). Similar standards are also approved in other international and national papers. For example: bio-compability, bio-stability, thrombo-resistence, no-problematic incorporation of tissue, full sterility, and some other.

Polyester (PE) fibers, polyurethane (PU) fibers and natural surgical silk fibers are always considered to be as biologically non-toxic and mechanically compatible synthetic implantable materials. These materials can be used in the production of implants.

Natural silk surgery sutures have good and even exclusive properties. These sutures are relatively strong and elastic (maximum elongation to break approximately till 20 %). Natural silk yarn structures also have good thermo resistant properties. It is usually destroyed at the temperature of approximately 175 °C. Natural silk fibers completely dissolve in the body within two-three years. It has been tested during previous scientific studies. The complex mechanism of bio-degradation of silk fibers depends on several factors: physical, chemical and biological, but the activity of various biological enzymes in the body has the main role in the process of productive bio-degradation. The human body constantly activates various groups of enzymes, and these enzymes actively accelerate the process of destruction of micro elements of natural silk (2).

Some famous international scientists confirm full suitability of using of natural silk yarns and fiber materials in surgery medicine. They consider this theory and practical experience as absolutely reliable (3) – (16).

It is well known, that natural silk fibers and these surgical sutures are able to resist negative effects of different sort of micro-organisms, bacteria, toxins and officinalis antibiotics. It is also well known, that natural silk materials are a bio-resistant for a living organism. It should be reiterated, that these fibers and yarns fully dissolve (process of internal bio-destruction) within two to three years. This slow biological process occurs without negative adverse effects for health. The authors of this study have performed many tests for biomechanical characteristics of thin yarns made of natural silk fibers. These studies were carried out in the bio-mechanical laboratory on a special stand and such practical testing studies were very necessary in order to properly use these yarns in the innovative structure of the wall of the new woven bio-composite vascular implant.

The results of multiple system experiments confirm that natural silk surgical suture has very good biomechanical and other properties. For example, average data of maximum strain of the samples (ε max) = 21.75 %. Thus, researchers can make definite conclusion that this bio-textile natural material absolutely rightly can be used in the structure of woven composite vascular implants.

It has to be especially noted that the process of bio-absorption of these fibers and yarns contributes to normal hemodynamics of blood in the reconstructed cardio-vascular system of a natural body. The fibers of the implant partially dissolve (the process of biological degradation), and the new living cells, tissues, and small blood vessels grow in these areas. As a result of the process of substitution the woven synthetic prosthesis will gradually be more similar to the natural blood vessel.

Standard surgical silk sutures have been successfully used for many years especially when sewing together the different types of synthetic implants with natural blood vessels. For example, natural silk threads are usually successfully used in facial plastic and other plastic surgery, in different types of cardial surgery, in different areas of traumatic surgery and other surgical operations.

It has been repeatedly scientifically proven that these proposed natural silk threads are able to effectively provide the anti-thrombotic properties for the inner surface of lumen of the installed implant; the overall structure of the threads is able to effectively provide the normal speed and pressure of blood flow after operation in forced reconstructed cardio-vascular system. Vascular prostheses made of natural silk guarantee normal options of physiological hemodynamics and positive anti-thrombotic indicators. Previous studies show that these important indicators of natural silk implants are better than similar indicators of other man-made vascular prostheses (made of PTFE fibers, etc.) (17).

It is well known that silver has strongly pronounced anti-bacterial properties (*inhibere*), and silver ions on the surface of polyester filaments contribute to regeneration of the damaged cells and tissues. The silver ions also help to reduce inflammation. Particles of colloidal silver can eliminate or hinder the development of about 650 kinds of pathological bacteria, viruses and fungi. At the same time useful micro-organisms do not suffer from silver. The silver content in the fibers from 10^{-3} up to 10^{-4} is safe (18)–(22).

Colloidal silver not only hampers the development of microorganisms but also has immune modulating effect.

Modified yarns were obtained by physical adsorption of colloidal silver composition in the form of hydrosol with the concentration of Ag 0.015 % and gelatin 0.05 %.

Textile polyester fiber material was structured by the spherical nanoparticles of 50 nm.

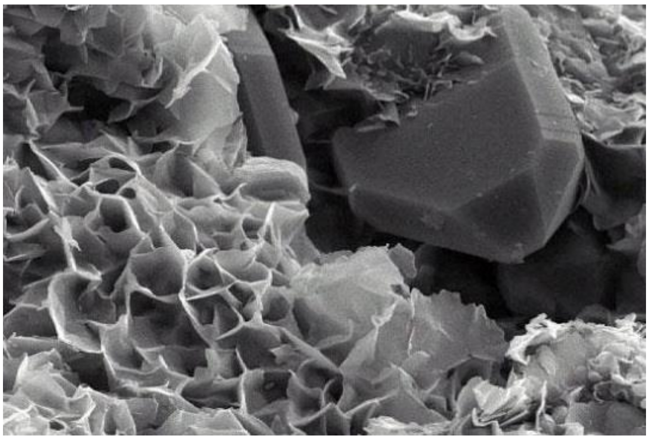

Fig. 1. Nanostructure of silver.

In this research the authors offer a new model of prosthesis produced by weaving technology using the combination of natural silk, polyurethane and nanostructured polyester yarns.

This combined structure of walls of woven implant partly biologically degrades (natural silk) within two years allowing the living tissues to grow into the walls of the implant.

Polyester yarns structured with colloidal silver form the permanent frame of the prosthesis.

The outer surface of the walls of the prosthesis is fleecy (loops). This also contributes to rapid growth of the living tissue into the implant.

Warp and weft polyurethane yarns provide a longitudinal and radial deformation of the wall of the implant.

IV. Woven Tubular Prostheses

The implants were made using the automatic loom (Jakob Muller AG Frick) with a computerized setting of technological parameters. Hollow interlocking was used in the process of weaving (basic 2/2 twill weave). Samples of woven vascular implants can be seen in Fig. 2.

This prosthesis has excellent strain properties and is able to integrate successfully into the body. The man-made implant should be able to pulsate under the dynamic blood pressure. It is very important mechanical and physiological condition for its normal long-term functioning in the body. This means that the high-quality prosthesis must be able to be cyclically radially deformed under blood flow internal pressure from 10.00 % − 15.00 % (data in the radial direction). The implant is able to provide normal hemodynamics in a living organism.

Fig. 2. Innovative woven vascular implant.

Arrangement of warp yarns.

The first tuft consists of three yarns together: one polyester yarn nanostructured by silver and two polyurethane yarns. This tuft passes through the one eye of the heddle frame.

The next tuft consists of one surgical natural silk yarn and two polyurethane yarns. This tuft passes through the next eye of the heddle frame.

All warp threads are systematized in such sequence in the heddle frame.

Warp yarns were refueled in the reeds (Nr. 200). Tuft of eight warp yarns was inserted into one tooth of reeds of loom. Then three empty teeth of reeds followed. Then tuft of eight warp yarns was once more inserted into one tooth after three empty teeth. All warp tufts were systematized in such sequence in the reeds.

Woven weft system consists only of polyurethane yarns. Linear density of polyurethane weft yarn is 0.5 of linear density of polyurethane warp yarn.

The most important indicator of biomechanical properties and therefore the most important evaluation criterion is the tangent modulus of elasticity of the implant. In this particular case this parameter was repeatedly studied during the practical testing of the prototype of woven implant. Modulus of elasticity of the synthetic composite implant should be similar to the modulus of elasticity of natural blood vessel of the human body (23)–(24).

Indicators of module of elasticity in longitudinal direction for tested samples of vascular implants can be seen in Fig. 3.

All other properties of innovative woven product will be tested in the course of further research, including mandatory preclinical testing. These studies are planned in the near future.

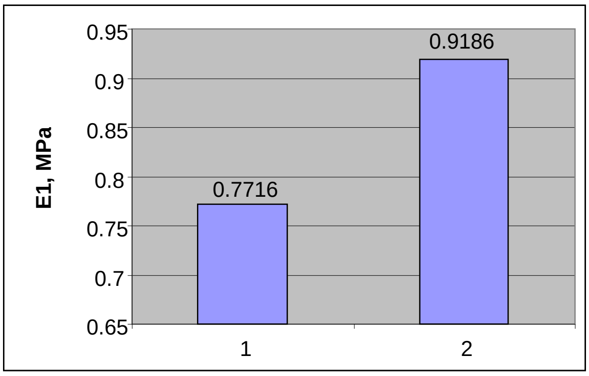

Fig. 3. Indicators of module of elasticity in longitudinal direction for tested samples of vascular implants.

1. Modulus of elasticity of implant with polyester yarn nanostructured by silver integrated into woven structure.

2. Modulus of elasticity of implant with polyester textile yarn integrated into woven structure.

V. Additional Processing of Woven Prostheses

The structure of the composite walls of synthetic woven prosthesis was thermally stabilized after weaving. Then the walls of prosthesis were impregnated with bio active solution in a vacuum. Thus, elastic membranes were formed in the pores of the prosthesis. Finally, the finished woven prostheses were sterilized in gas sterilizer and packed in sterile packaging.

VI. Conclusion

In the process of this scientific and practical research authors have offered pulsating blood vessel implants with anti-microbial properties close to human biochemical properties. These implants may be suitable for implantation and lasting actions in living tissue. These woven prostheses also will be able to ensure better integration into the body.

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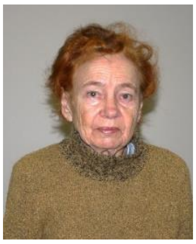

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Viktorija Kanceviča, Andrejs Lukjančikovs. Nanostrukturētu poliestera pavedienu integrācija austā asinsvadu implantā
Tiek piedāvāta austa sintētiska asinsvadu protēze, kuras karkasā integrēti nanostrukturēti poliestera pavedieni ar sudraba koloīda daļiņām starp poliuretāna un dabiskiem ķirurģiskiem zīda pavedieniem. Projektējot inovatīvu asinsvada implanta sieniņas struktūru tika ņemta vērā pasaules zinātniskā un praktiskā pieredze dažādu asinsvadu protēžu izstrādāšanā. Tika veikta arī jaunās struktūras protēžu biomehānisko īpašību izpēte. Nanostrukturētais implants ir ar izteikti antimikrobām īpašībām, kas ļauj tam veiksmīgi inkorporēties dzīvā organismā. Šāda asinsvadu protēze nodrošinās normālu hemodinamiku rekonstruētā asinsvadu sistēmā.

Виктория Канцевича, Андрей Лукьянчиков. Интеграция наноструктурированных полиэфирных нитей в тканый васкулярный имплант
В процессе реализации данной научно-практической работы был предложен тканый синтетический васкулярный протез, состоящий из полиэфирных нитей, наноструктурированных частицами коллоидного серебра, полиуретановых нитей и натуральных шелковых хирургических нитей. При проектировании нового протеза был использован предыдущий научный и практический опыт в области изготовления различных типов имплантов кровеносных сосудов, а также изучались биомеханические свойства разработанных имплантов. Предложенная иновационная структура стенки протеза обладает нормальными биомеханическими свойствами. Выраженная антимикробная активность наноструктурированной стенки протеза является важным показателем для успешной инкорпорации синтетического импланта в живой организм. Такие протезы способны обеспечивать нормальную гемодинамику в условиях реконструированной кровеносной системы.