

The concept of preparation of oesophageal prosthesis based on long-fibre composite material

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Materials

ABSTRACT

Purpose: In the work, there was investigated the possibility of an application of long-fibrous composite material as a based material for prototype of oesophageal prosthesis (tubular element) with the use of so called arms, using coiling, plaiting and winding techniques.

Design/methodology/approach: Coiling, plaiting and winding techniques were used. As a reinforcement, aramid fibres bound with different types of so called silicone rubbers. Selection of winding parameters has been made in order to fabrication of prosthesis with appropriate mechanical parameters.

Findings: Technological tests have given promising results. In the summary, comments and technological remarks are described. For prototype of prosthesis manufacturing, components, which in the form of composite materials are characterized by biocompatibility, have been used, that is medical silicone and aramid fibres.

Research limitations/implications: The pilot investigation of fabricated prototypes of internal oesophageal prosthesis show that it is necessary to change the fabrication technology onto dry winding followed by closing obtained reinforcement in a mould and saturation with silicone. The idea is to get better silicone content and connected with it better elasticity and tightness of the prosthesis.

Originality/value: Accepted method of winding is the most effective due to fabrication of prototypes of internal oesophageal prosthesis in laboratory. In industry, probably the better method will be plaiting, e.g.: as in the case of high-pressure hose of applied hydraulics.

Keywords: Composites; Engineering polymers; Aramid fibres; Silicone; Biomaterials; Coiling; Plaiting and winding techniques

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1. Introduction

Basic indications for application of prosthesis of upper human gastrointestinal tract are its contractions, injuries, or cancers. The most popular cancer of gastrointestinal tract is adenoma, much more rarely occurring are sarcomas, lymphomas and secondary tumours (metastasis of breast cancer or melanoma). Oesophageal cancer is a type of cancer with exceptionally high dynamic of growth. Usually, people with diagnosed cancer are referred to surgical treatment consisting in removal of the pathologically changed segment of oesophagus with the closest lymph nodes. First-aid in restoration of the functionality of oesophagus and, thus whole gastrointestinal tract of the patient, is extremely important in order to protect him against starvation death or the discomfort of usage gastrostomy. In some cases, it is possible to pull up to the chest cavity and interposed other segments of digestive tract like stomach or part of the Colon or jejunum. however, there is many cases that requires implantation of internal oesophageal prosthesis to enable the "normal" patient life [1-5].

It is estimated that the frequency of occurrence of oesophagus cancer is 5-6 cases per 100 000 persons, although, in some regions of the world (southern Russia, northern China, India, Iran) morbidity index exceeds 100 cases per 100000. According to the researches made in the year 2005, in Poland there were 5.6 men and 1.4 women suffered from this disease [22-26]. The oesophagus cancer develops between age of 50 and 60, though it is more frequently diagnosed in young people slightly older than 30 years old. In consequence of difficulties in swallowing, general debility, loss of weight as well as devastation in human body takes place. In the early stage disorders are imperceptible. The swallowing disorder that can be as bad as eating is impossible occurs later on. Additionally, the loss of weight, the unpleasant breath, the hoarse, the nausea, the vomiting and the reflux occurs when the acidic contents of the stomach squeeze or 'slosh' back through the sphincter and enter the lower oesophagus, causing symptoms such as heartburn appear. Hardly diagnosed and so hardly curable oesophagus cancer attacks more and more often. A lot of patients are already incurable ill when the cancer is recognized. It is the reason for the importance of temporary assistance in overcoming disorders connected with complications or discomfort and immobilization of the patient [23-31].

The aim of this work is attempt of fabrication of prototype of internal oesophageal prosthesis (tubular element) with the use of so called arms, using coiling, plaiting and winding techniques. Selection of winding parameters has been made in order to fabrication of prosthesis with appropriate mechanical parameters. For prototype of prosthesis manufacturing, components, which in the form of composite materials are characterized by biocompatibility, have been used, that is medical silicone and aramid fibres.

2. Construction of internal oesophageal prosthesis

The starting point for study on internal oesophageal prosthesis are detailed literature and experimental research regarding human oesophagus, strictly speaking its structure, localization and function

in human body. Oesophagus is very important part of digestive tract connecting pharynx with stomach. From topographic point of view, there can be distinguished its cervical, pectoral and abdominal parts. The oesophageal wall is built from following layers: mucosa, submucosa, muscularis externa, adventitia.

From the mechanical point of view, human oesophagus seems to be a kind of muscular tube through which food travels from the mouth to the stomach. Unfortunately, it is impossible to reconstruct the peristalsis in artificial oesophagus. Therefore it should be emphasized the structure and internal surface of prosthesis, that facilitate free movement of food in the stomach direction by gravitation forces. A type of junction between the prosthesis and the stump of oesophagus as well as the surgical technique – the place and the way of implantation in human body are another elements that must be taken into the consideration.

On the ground of literature data and consultations in Department of Digestive Tract Surgery of Silesian Medical University in Katowice, there have been selected a few geometrical models of internal prosthesis of oesophagus, that have been analysed according chosen criteria. The analysis is described in details in literature position no [3].

In connection with this analysis, there have been chosen one geometrical model of internal oesophageal prosthesis, that was the best in the ranking, and for this model further optimization of its constructional features was done. Preliminary evaluated constructional model of oesophageal prosthesis with winding stages is presented in Figure 1.

Necessity of multistage winding process is forced by pointed out multi-layered construction of the prosthesis. In the first stage, the layer of fibre saturated with silicone and with properly matched architecture will be wound up. This layer will be put on previously prepared core coated with medical silicone. In the next stage silicone ring enabling stable junction between the prosthesis and the stump of oesophagus without damage to internal layer of the prosthesis will be put on. In the last third stage, second stabilizing layer of fibre saturated with silicone will be wound up. This layer will protect silicone rings against displacements and it will stiffen the whole construction.

3. Material

Due to specific functional properties of internal oesophageal prosthesis, it has been decided to evaluate the composite material which is characterized by biocompatibility and high purity as well as specified mechanical properties. Taking into consideration the length of the prosthesis and high probability of occurrence of internal tissues injures resulting from prosthesis presence it has been specially emphasized the adequate elasticity and biocompatibility of the material to avoid such type of medical complications. After initial verification, following components of composite material have been chosen:

- Aramid fibre Kevlar 49 type 2200 1610 manufactured by DuPont (Fig. 2), characterized by following properties:
 - Density 1.44 g/cm³;
 - Young's modulus 105 GPa;
 - Tensile strength 3053 MPa;
 - Ultimatum at rapture 2.70 %;
 - Decomposition temperature 490 °C;

- Contraction in hot air (15 min at the temperature of 190 °C) => 0.1 %;
- Thermal resistance (48 h at the temperature of 200 °C) => 90 %;
- Medical silicone provided by DOW CORNING, with following physical properties (data come from the tab product support):
 - Boiling temperature/ranges > 82 °C;
 - Flash-point 13.3 °C (Pensky-Martens closed crucible);
 - Specific gravity 0.865 g/cm³;
 - Viscosity 132 cSt (at the temperature of 25 °C).

The aramid fibre has been chosen due to promising results of degree of its biocompatibility studies, which were carried out in Department of Experimental Surgery and Biomaterials Research of Wrocław Medical University. In the first stage, investigations included: determination of physical properties, haemolytic

properties, degree of cytotoxicity, intradermal reactivity of water extracts, and in the second stage: evaluation of tissue reaction after implantation in early and late period of time, evaluation of systemic and local stimulation of immunological cytokines IL-1 and IL-6 induction after implantation and corrosion resistance of fibres. The results turned to be very successful. It was stated that aramid fibres cause minimal tissue reaction which is comparable to the one appeared around polyester fibre. Moreover, aramid fibres do not cause local or systemic stimulation of immunological cytokines IL-1 and IL-6. In comparison to widely used polyester fibres with well known and accepted biological interactions, aramid fibres show significantly higher dynamic and static mechanical strength, do not undergo biocorrosion and can be useful in increasing mechanical strength of medical materials or as self-contained biomaterial that sustains high mechanical loads [4-6].

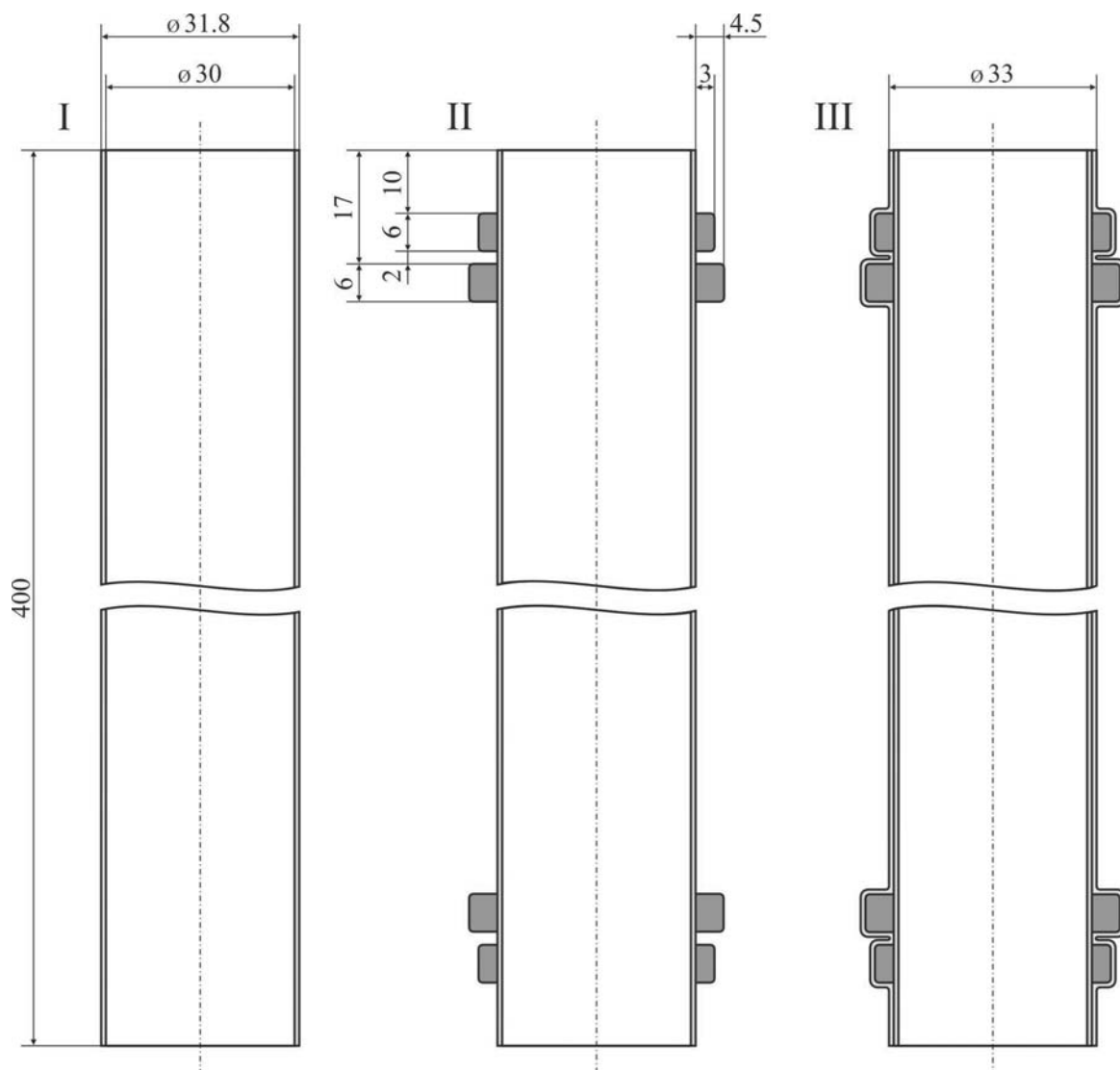


Fig. 1. Constructional model of oesophageas prosthesis

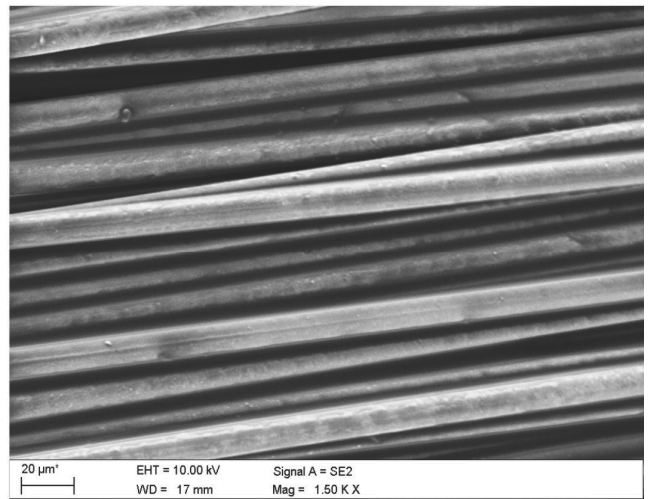
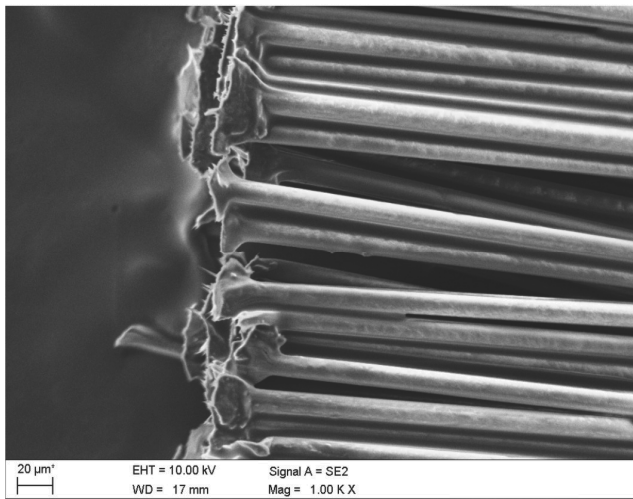


Fig. 2. Structure of 2200 1610 aramid fibres; Scanning Electron Microscope (Zeiss, USA)

Saturant – medical silicone, has been chosen because of its low viscosity (only 139 cSt), which positively influence on manufacturing process of composite – it facilitates operation of fibre saturation, eliminating additional processes of dilution by this feature. Important factor is also production of this type of silicone in conditions of very high chemical purity, that guarantee lack of substances undergoing in biochemical reactions resulting in inflammatory conditions, irritations, allergies, and even cell mutation after long-period contact.

Taking into considerations components described above, it might be assumed, that those materials mixed together can create composite material, which is bio medically inert [2, 4-5].

4. Investigations

Initially, the series of samples were prepared by the hand operated saturation of aramid fabric method in order to preliminary study of composite material and to determine hardening parameters. The results of the studies were satisfied therefore, it was decided to create mechanized prosthesis of oesophagus production work stand. There exist many methods of tubular elements fabrication from fibrous composite materials. The Most often used methods of fabrication such elements are the ones based on semi-finished products like strips, fabrics, or sleeves and the most popular methods of winding and plaiting of the fibre onto previously prepared core. Due to the numerous difficulties with chucking, tension and connection of particular elements of prosthesis occurring in the early stage of investigations, it was given up from possibility of usage the semi-finished products mentioned above. For this reason, authors paid special attention on other two methods, that is winding and plaiting. Plaiting method requires very big material input (several dozen spool of winded fibre used in one operation), and accessibility of machine allowing to fabricate the prototype with

specified diameter equal to 30 mm have appeared to be limited. The plaiting machine placed in Institute of Electrical Engineering Pilot Plant III in Międzyzlesie has enabled to fabricate the tubular element with diameter equal to 26 mm. The second accessible machine is placed in The Institute of Lightweight Engineering and Polymer Technology Technische Universität Dresden. Nevertheless, it is designated to the production of elements with much higher overall dimensions [7-11].

In the light of the aforementioned prerequisites, it have been decided to fabricate the internal oesophageal prosthesis using winding method. For this purpose, wind-up reel placed in laboratory of Institute of Materials Science and Applied Mechanics, Wrocław University of Technology has been used.

Classic version of winding the tubular element consists in winding the bundle of fibres onto rotating core, which is removed after resin hardens and reused after cleaning in production of further elements. In the Figure 3 there is presented scheme of winding the tubular element onto core [9].

In the case of prototype tubular elements fabrication designated for mentioned oesophageal prosthesis aramid fibre Kevlar 49 type 2200 1610 manufactured by DuPont has been used. Spool with fibre has been placed in rewinder with controlled tension. The tension has been adjusted to 5 N. The fibre has been saturated with the use of specially designed drum saturation unit. It has been winded with fibre speed equal to 0.2 m/s at the angle of $\pm 45^\circ$. The proper arrangement of fibre requires synchronize rotation of winder and motion of fibre feeder (reciprocating, parallel to the axle of winded element). Used winder is equipped with electronic control system with APCI-8001 card (ADDI-DATA company). Additionally, algorithm of control system bases on table method and Windows 2000/XP operating system. Applied table method in program algorithm enables to generate winded structures in methodological manner [13-15], resulting in the best choice of fibre beam. The main idea is to ensure proper elasticity of finished prosthesis with satisfying strength properties.

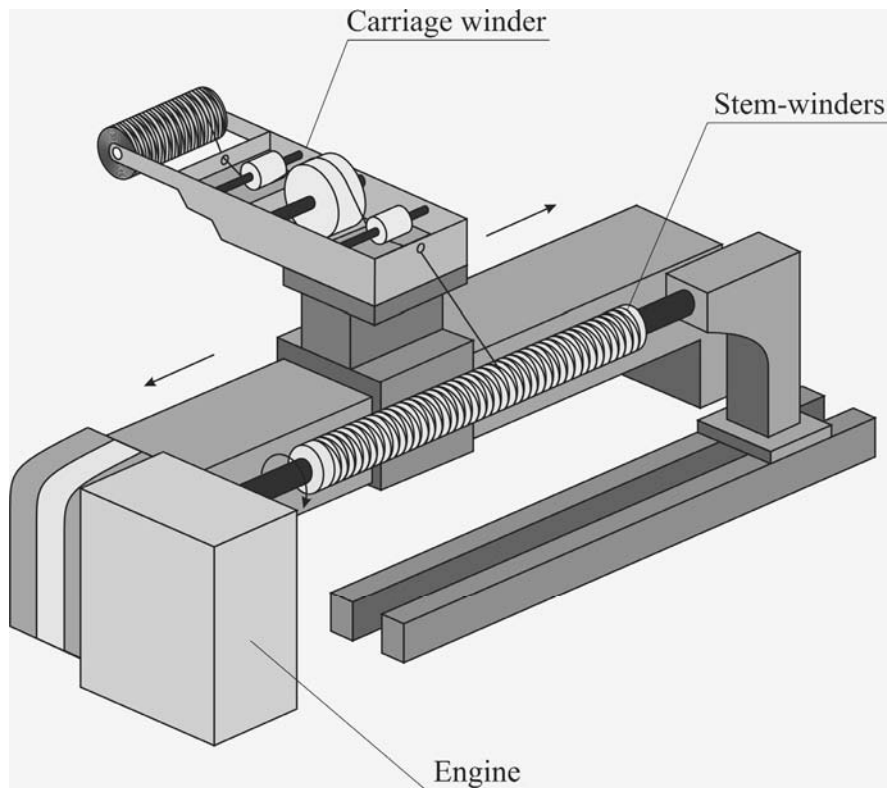


Fig. 3. The winding of tubular element on mandrel [9]

5. The structure of winding choice

The measurement of aramid fibre bundle width has been done in first place while choosing the structure of winding and it equals approximately $e = 2.6$ mm (pictorial diagrammatic drawing is presented in Fig. 4). Because it has been wound at the angle $\alpha = 45^\circ$, the fibre width at right section of core (internal diameter of prosthesis) equals to $e_x = 3.7$.

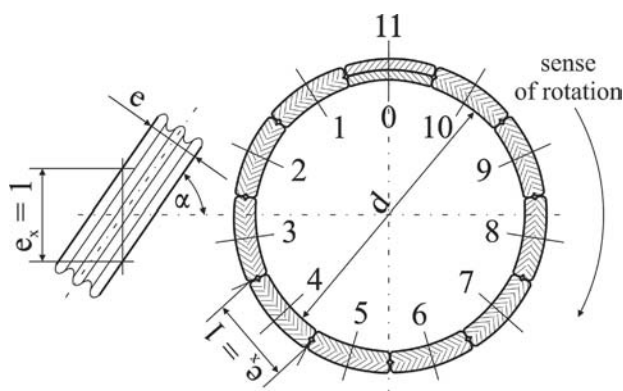


Fig. 4. Pictorial diagrammatic drawing of cross section of cylindrical part of the mandrel with No. 1 winding structure, e – fibre bundle width, $e_x = e / \cos \alpha$

It has been found, that the fibre bundle spacing should be equal to 0.5 mm. Spacing is necessary to obtain adequate elasticity of the structure. It will be fulfilled with silicone material, which will ensure elasticity between bundles. The fibre bundles will be able to move slightly between each other. Similar phenomenon occurs in elastic hose of applied hydraulics. Finally, it has been accepted that fibre width at right section of the core (the value e_x in the Fig. 4.) is equal to 4.2 mm. After dividing this value by perimeter of the core $\pi \cdot d \rightarrow \pi \cdot 30 = 94.2$ mm, the number 22 is obtained. According to the table method [3-5] beam from the group 22 should be chosen. Unfortunately, number 22 is not the prime one and because of that the group of generated types of beam is incomplete. It is the reason for choosing beams from the group 19 and 23 for further studies, as well as so called double beams from group 43. For these structures spacing between bundles are respectively, 1.3 mm for 19, 0.4 mm for 23 and 0.7 mm for 43. To check the elasticity and influence on strength, it has been possibility of testing tubes with different bundle spacing during fabrication of samples from all mentioned groups. The next subject is choice of winding structure for investigations. As a choice criterion, the structure in which radial spacing between fibre bundles is the highest and is the most uniform has been chosen. This condition are best fulfilled by structures No. 2, that is the structures with the highest number and the uniform distribution of interleaves. This type of structures is the closest to the plaited ones. In order to achieve comparable effect as in structures No. 2, structure No. 4 has had to be selected while

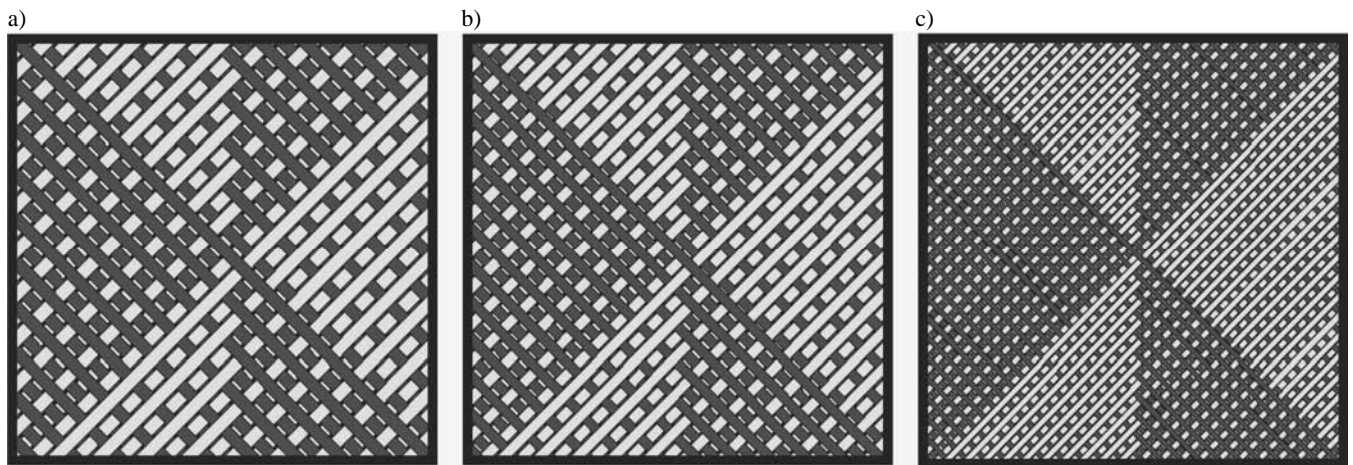


Fig. 5. Selected structure of prototypic prostheses: a) 19/2, b) 23/2, c) 43/2

winding prosthesis with the structures from group 43. In this case, the winding process has gone in following way: winding of the first layer up to bundle 22, putting silicone rings on and further continuation of the winding up to the last bundle – number 43. Thus two structures similar to 22/1 have been obtained.

To sum up the foregoing, according to table method, structures of winding 19/2, 23/2 and 43/2 have been selected to make prototypic prostheses of oesophagus. Those structures are presented in Fig. 5.

6. Conclusions

Accepted method of winding is the most effective due to fabrication of prototypes of internal oesophageal prosthesis in laboratory. In industry, probably the better method will be plaiting, e.g.: as in the case of high-pressure hose of applied hydraulics.

Obtained samples have been investigated in pressure tests. Applied original method of investigation shows useful operational feature, that is work of single fibre bundles in matrix which undergo a deformation (but do not disturb the continuity of matrix) at the moment of local load and return to its original shape after load is removed.

The pilot investigation of fabricated prototypes of internal oesophageal prosthesis show that it is necessary to change the fabrication technology onto dry winding followed by closing obtained reinforcement in a mould and saturation with silicone. The idea is to get better silicone content and connected with it better elasticity and tightness of the prosthesis.

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