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Constructional model of internal oesophageal prosthesis

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ABSTRACT

Purpose: The aim of this work is to study of constructional model of internal prosthesis of oesophagus with determined functional features; the prosthesis will replace the upper part of the digestive system – the oesophagus.

Design/methodology/approach: Constructional model of internal prosthesis of oesophagus was worked out in the basis of physiological build of oesophagus considering surgical techniques.

Findings: Development of optimal constructional model of internal prosthesis of oesophagus considering functional features and surgical techniques.

Research limitations/implications: Developed constructional model of modern, internal prosthesis of the human oesophagus will be used to design the manufacturing technology and to manufacture given prosthesis.

Originality/value: Worked out construction is the part of the research project realized by authors, that will result in cognitive, constructional and technological effects, but first of all, it will enable the real help very sick people.

Keywords: Oesophagus prostheses; Oesophagus cancer; Composites; Engineering polymers; Biomaterials; Aramid; Silicone; Application

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MATERIALS

1. Introduction

Basic indications for the application of the prostheses of the upper part of digestive system are contractions, injures or tumours. The oesophageal cancer is the most frequently observed. Sarcomas, lymphomas and metastatic tumours (the cancer spreading to someone chest, melanoma) occurs with lower frequency. The dynamics of development of the cancer of oesophagus is especially high and quick. It is spread through circulatory and lymphatic systems. Very highly developed and well-off lymphatic system in oesophagus and the lack of the serous membrane are propitious conditions for very quick propagation of tumour along the oesophagus as well as deep inside its wall. The tumour quickly spreads to lymphatic system and relatively quickly attacks structures of the mediastinum [1-6,8,12].

The well-off net of lymphatic system is the reason of spreading the tumour, regardless of the place of occurrence of the lesion, not only to the nearest glands but also to the glands being apart from the primary lesion.

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 bed 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 [13-23,32-38].

Among commonly used methods of oesophagus cancer treatment, surgery, radiotherapy and chemotherapy should be named. Each of these methods is justified and takes place in medicine. The most important is the degree of disease progress when the particular way of treatment is chosen. Determination of the degree of disease progress and detailed histopathological diagnosis must be taken into consideration necessarily together with the patient's general condition as well as its circulatory and respiratory capacity. The surgical treatment, which consists in excision of pathologically changed part of oesophagus, seems to be the most efficient. The temporary assistance in restoration of functionality of oesophagus and, thus the whole patient's digestive system is unusually important, in order to save one from starvation in that way. In some cases, there is possibility of joining the part of oesophagus remaining after the surgery with stomach and, in other ones, of insertion of part of intestine instead of oesophagus. However, there are a lot of cases, when implantation of prosthesis of oesophagus is necessary so as to enable the "normal" functioning of patient [7,18-25].

The aim of this work is to study of constructional model of internal prosthesis of oesophagus with determined functional features. Moreover, the realization of whole research program will result in cognitive, constructional and technological effects, but first of all, it will enable the real help very sick people.

2. Review of solutions used for oesophagus prostheses

From the mechanical point of view, the oesophagus is kind of tubing, which transports food into the stomach using peristaltic motion. The direction of the food motion is controlled by constrictors that prevent withdrawal of food. In case of injury or dysfunction of oesophagus caused by disease (oesophagus cancer), there is necessity of replacing it with prosthesis.

Currently known oesophagus prostheses can be simply divided into natural and artificial. This basic division can be additionally extended with stents, which temporary widen inside diameter of oesophagus limited by tumour but without the excision of part of oesophagus [19-21,34]. Examples of oesophageal stents shapes are presented in Figure 1.

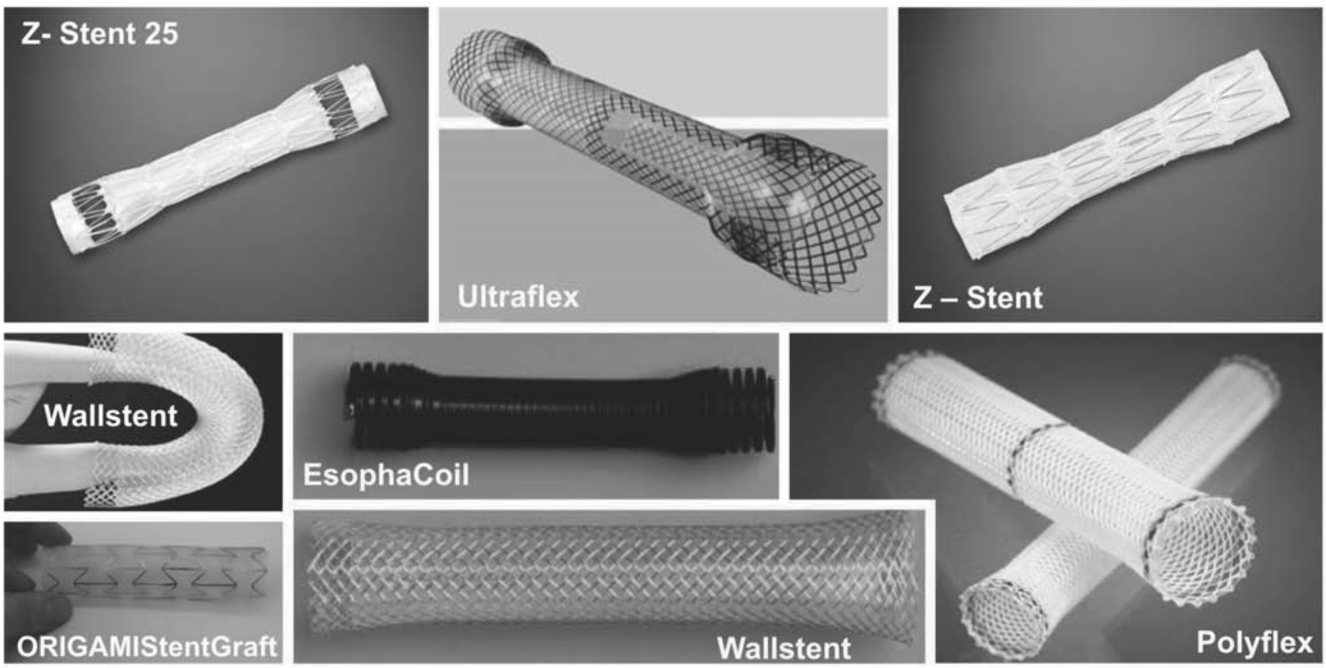

Fig. 1. Examples of commonly used shapes of oesophageal stents [29]

The best materials used in reconstruction of removed oesophagus are vital tissues of human digestive system. Such reconstruction consists in stretching remaining part of digestive system, e.g. the stomach, in place of removed pathologically changed oesophagus, and, in some cases, when the stomach is also removed, stretching of the duodenum or the small intestine in place of loss (Fig. 2) [28-35].

In cases of impossible or dangerous for life use of solutions mentioned above, more radical ones, using false oesophagus prostheses made of natural and artificial based materials.

For years, there were several attempts of solving this problem. First attempts recorded in history, were made in the year 1845, when pipes made from bones after decalcification were used for internal replacing of oesophagus. 1n 1914 Guisez introduce oesophagus drain similar to Pezzer’s catheter in construction. In 1924 Gouttar presented 100 patients suffered from cancer treated with internal replacing of pathologically changes with rubber pipe. Results of using endoprostheses were also described by Cayas (1954), Maynard (1955), Mousseau, Barbin (1956) and Celestin (1959). In 1947 Grindlay proposed pipes made of polyethylene foil as prostheses of gall-passages, trachea and large intestine. In 1952 Berman used, among the synthetic materials useful in surgery, methacrylic and polyethylene pipes for experimental prostheses of oesophagus [24,32-38]. Chalnot and co-workers were among the ones, who were using polyvinyl pipes as prosthesis of chest part of the oesophagus. They were removing 2-4 cm of oesophagus and replacing it with much longer pipes with very good results. Whereas Roth and co-workers were using pipes made of methacryl and PVC as prosthesis of the chest part of the oesophagus. However, they determined prosthesis displacement and perforation of stomach (PVC one) and leak of anastomosis. Similar observations were made by Razemon and co-workers.

Shackelford and Sparkhul described patient, who have lived with oesophagus prosthesis made of plastic after palliative resection of oesophagus cancer for 183 days. More and co-workers published publicized the results of investigations carried out on 36 rabbits since 1949. They were using, just like Berman, plastic pipes as oesophagus prostheses, but the results appeared to be unsatisfactory. The main reason of animals’ death was pus infection in the area of the chest. Disadvantages of used prostheses were standard sizes and lack of the possibility of making anastomosis of stomach and prosthesis with the help of standard methods, it means by stitches [28,31-36].

In 1972 Stoner and co-workers did not have good results of transplantation of intestine on neck with the use of microsurgical vascular technique. Bad results were obtained in the case of 7 dogs, when exposed horse vessel was used as the prosthesis. As prosthesis of oesophagus, especially its upper part, also skin in the form of coiled layer of skin joined with digestive system during multi-step, time consuming operations. Removed part of oesophagus was replaced by prepared skin-intestine tube. Extension of surgical intervention and medical complications were the reasons of condemnation, in 1932 in Madrid on International Congress of Surgeons, of using such widespread, carrying highly increased risk operations of patients with oesophageal cancer [31-38].

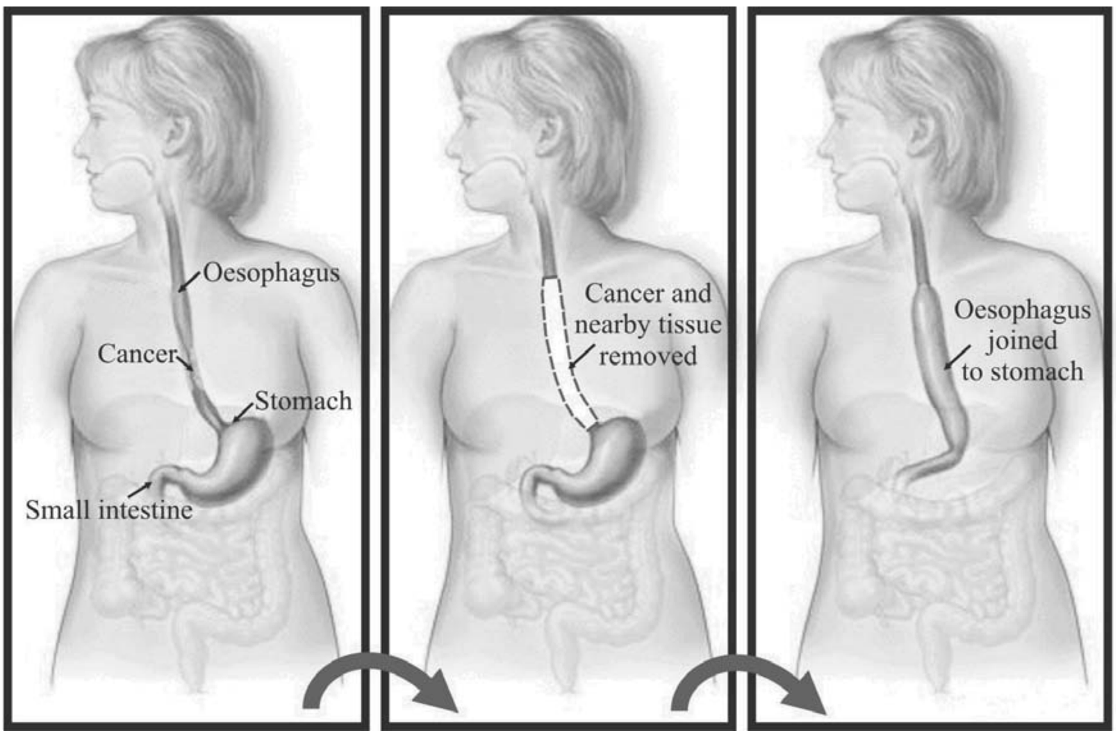

Fig. 2. Reconstruction of oesophagus with the help of vital tissues of digestive system [33]

The methods proposed later, consisted in application of coiled skin or skin-muscular flakes, can not be taken into account especially in palliative treatment .of oesophageal cancer. Fredrikson an co-authors were comparing patients treated by replacement of the stomach up to the neck with the group of patients that were reconstructed continuity of digestive system by skin-muscular layer. Time of patient's stay in hospital after the stomach replacement amounts to 12 days, whereas after surgery of reconstruction of oesophagus with the use of skin-muscular layers amounts to 90 days. Klop used in his investigations skin layers together with prosthesis made of polyethylene foil. In the group of animals, where apart from the foil skin was also used, there were reduced complications by half. Edgerton proposed prosthesis made of skin stretched on tantalum gauze as prosthesis of cervical oesophagus and trachea. He recognized temporary results of four operated patients as satisfactory [28,31-38].

Foster and Campo as prosthesis of oesophagus a free layer of skin protected for three weeks with plastic tube, which was removed after some time. During investigation it was discovered intubationing pipe choking. In clinic , they were using this method in order to avoid infiltration in pectoral oesophagus. Cornar and co-authors were using autogenic layer of skin as prosthesis in case of fourteen dogs. They observed shrinkage of skin graft more visible along its length rather then its circumference. The fistulas were not observed accept one perforation of of oesophagus caused by foreign object. Covering of the graft by epithelium was noticed.

In 5 dogs, internal intubation with the use of plastic tube was used and no influence on prevention against shrinkage was found out. Free slices of skin were also used by Cenna in his investigation and similar results were obtained [31-38].

Surgeons working on restoration surgery had early draw their attention to the fascia. Hohmeier and Neuhoff closed the remaining of trachea with the help of fascia. Next step of Neuhoff was its application for the oesophagoplasty. Rob and Beteman used fascia lata supported by tantalum gauze as prosthesis of upper oesophagus inside three patients and as prosthesis of trachea inside one patient. The patients' condition immediately after the surgery was good, but it was observed isolation of slough and separation of tantalum gauze after the lapse of some period. Baranofsky (1951) used tantalum netting surrounded with fascia lata in both sides in order to do the prosthesis in place of removed upper oesophagus and pharynx. One month later, the patient excreted tantalum netting with a stool. She died e a few months later, probably because of tumour progress. Dumn and co-authors (1955) coverd polyethylene tubes with fascia lata and such constructed prostheses were implanted inside eighteen dogs. Perioperative deaths were estimated on the level of 50 percent. Among nine dogs, that died in the perioperative period, seven had fistulas of anastomosis resulted from slough of fascia. Among the group of nine longer lived dogs, in six cases malnutrition, resulted from difficulties in food intake occurred, and in four cases mechanical choking was noticed. In implanted section shrinkage was observed. It was recognized that fascia badly tolerated contact with digestive track [30-35,38].

In 1956 it was made an attempt to construct the internal oesophageal prosthesis using slices of pleura and .pericardium. Slices of pleura were used in case of sixteen dogs, and ones of pericardium in case of thirty dogs. There were received 62.5 % and 63.4 % of survives correspondingly. In 1963 Kawamura and co-authors constructed and applied prostheses, in the investigations carried out on dogs, made of collagen-silicone polymer, amorphous collagen polymerized with silicone. The prosthesis were investigated after impamentation into the intestine or oesophagus. In spite of noticed leaks in anastomosis and shrinkages in place of prosthesis implementation, the results seemed to be encouraging to make similar attempts.

Nowadays, when it is known that only surgical intervention is effective, temporary assistance in restoration of functionality of oesophagus and, thus the whole patient's digestive system, appears to be extremely important in order to save one from starvation. There exist a lot of cases that required implantation of oesophagus for restoration of digestive system defects reaching up to 40 cm, in order to enable function of patient as normal as possible [15-25]. At present, the most commonly used are external systems (polymeric tube temporarily connected with the organism through the area of neck in one side and through the abdominal area in another). Previously, natural prosthesis were frequently used (fragment of ox digestive system), which were very good alternative for external systems. Unfortunately in last years, application of such prosthesis is completely abandoned in Poland, because of detection of several cases of BSE, although they fulfilled expected functions very well [1-2].

3. The functional model of human oesophagus (constructional assumptions)

The starting point for determination of internal prosthesis of oesophagus is the functional and constructional model of human oesophagus. Human oesophagus is very important part of digestive system connecting pharynx with stomach (Fig. 3) with the topographic point of view, it can be divided its cervical, pectoral and abdominal parts. The oesophagus wall is made of several layers: mucosa, submucosa, muscularis externa, adventitia. The junction between the oesophagus and the pharynx contains upper sphincter. At rest, it is stayed closed, what prevents air-flowing to the oesophagus during breathing in. In the early stage of swallowing this sphincter is released, and after food is squeezed lower it contracts again. Two sphincters prevent acidic contents of the stomach flowing back into the lower oesophagus: internal and external. The internal sphincter corresponds to abdominal part of oesophagus. As external sphincter are determined bundle of muscles of medial branch of lumbar part of diaphragm. Man does not control the work of digestive system in any way; it is done without human will.

Simplifying, it can be assumed that from the mechanical point of view human oesophagus is kind of muscular tube through which food travels from the mouth to the stomach. Because of impossibility of reconstruction of peristalsis in artificial oesophagus, it should be emphasized the structure and internal surface of prosthesis, which facilitate free movement of food in the stomach direction by gravitation forces.

Additional elements that must be taken into the consideration are 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.

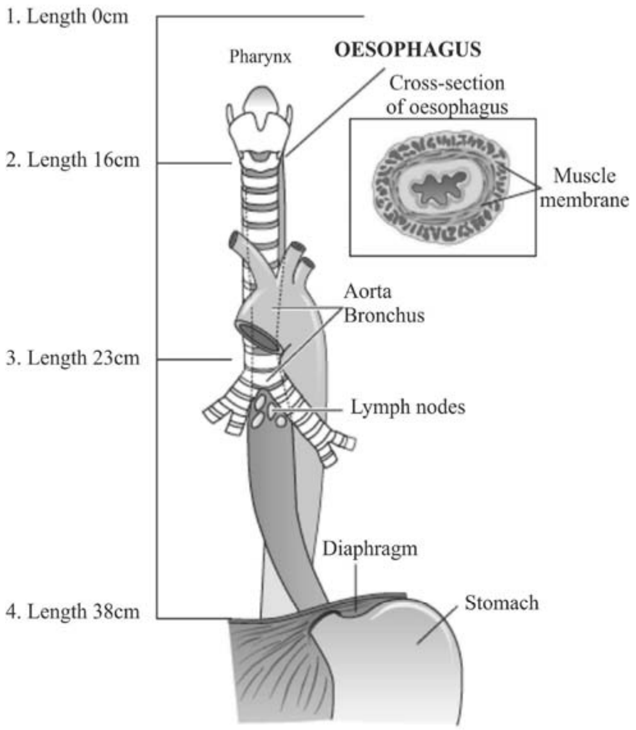

Fig. 3. Oesophagus [34]

4. Experimental constructio-nal model of internal prosthesis of oesophagus

Experimental constructional model of internal prosthesis of oesophagus originates in Institute of Engineering Materials and biomaterials, Silesian University of Technology. In the early stage, there were chosen and preliminary investigated components for composite material for manufacturing prototype of internal prosthesis of oesophagus. It was assumed that the prosthesis is from biocompatible aramido-silikone composite material [15-17].

The following materials were chosen for the production of elastic aramid silicone laminate: aramid fabric CCC120, of various basic weights, manufactured by Havel Composites PL. SP. Z O. O.; medical silicone MDX4-4159 manufactured by DOW CORNING.

Aramid fabrics was applied because of its specific properties like strength, heat resistance, chemical resistance, high elastic modulus, low flammability and high strength to density ratio. Furthermore, recently there have been performed interesting researches on degree of biocompatibility aramid fabrics with living tissue that have been reported in [13-22].

The silicone is an amine functional polymer with incorporated reactive methoxy groups and has structure presented on the Figure 4. The main reason for choosing the medical silicone MDX4-4159, among the others available on the market, was its low adhesiveness – an important factor in the production of composite (it simplified soaking procedure and eliminated additional dilution of resin). Moreover, an important role biocompatibility of the discussed substance played that made obtaining biologically neutral composite possible. Dow Corning MDX4-4159 silicone with 50% Medical Grade Dispersion consists of silicone – 50% dissolved in co-solvent system of 70% Stoddar Solvent (mineral alcohols) and 30% isopropanol (iPA).

On the ground of literature research and medical consultations in Medical University of Silesia in Katowice it was possible to select several geometrical forms of internal prosthesis of oesophagus, which were preliminary analyzed. Following criteria were considered:

- Criterion (K1), complexity of prosthesis manufactures; it is characterized by the problem if it is simple technology or it requires additional operations and /or specialist equipment;
- Criterion (K2), adaptability of the prosthesis, describing the problem of adjusting the proposed geometrical form of prosthesis to the body environment;
- Criterion (K3), stability of the prosthesis determining if the prosthesis' position is constant in time;
- Criterion (K4), unit price of the prosthesis, describing the influence of the prosthesis' manufacture costs on the validity of its use;
- Criterion (K5), expected deformability during compression, pointing whether the proposed geometrical form of prosthesis will increase the chance of stresses exceeding Re;
- Criterion (K6), maintenance of breathing patency, describing elimination of influence of implemented prosthesis on respiratory ability of patient.

In the connection of this analysis, one, the best in ranking geometrical form of internal oesophageal prosthesis was chosen with respect to which later optimization of constructional features of prosthesis were done. Preliminary determined constructional model of oesophageal prosthesis is shown in Figs. 4 and 5.

The main stages of prosthesis manufacture are presented in order to illustrate the process of moddeling its shape.

Stage I consists of preparation of internal layer of prosthesis – plait of matrix with aramide fibres saturated with medical silicone. Stage II is applying of four silicone rings that facilitate anastomosis between the prosthesis and the stump of oesophagus, without damage of internal layer of the prosthesis. Stage III is preparation of external layer of the prosthesis, - plait that reinforces and stiffens the construction. It is also anticipated eventual additional reinforcement of the prosthesis in the form of spring-actuated skeleton that will be placed between the layers.

However, authors are currently putting off applying such kind of solution to avoid unnecessary over-stiffening of the construction, which leads to perceptible patient's discomfort and, what is worse, to appearance of bedsores inside the body and connected complications. The decision about usage of additional reinforcement will be made after preliminary analyses of deformations and tensions using Finite Elements Method as well as after the prototype will be prepared.

Presented geometrical form of oesophageal prosthesis was undergone the simulation test using Finite Element Method in the next step. The results of tests will be published in the following articles of authors.

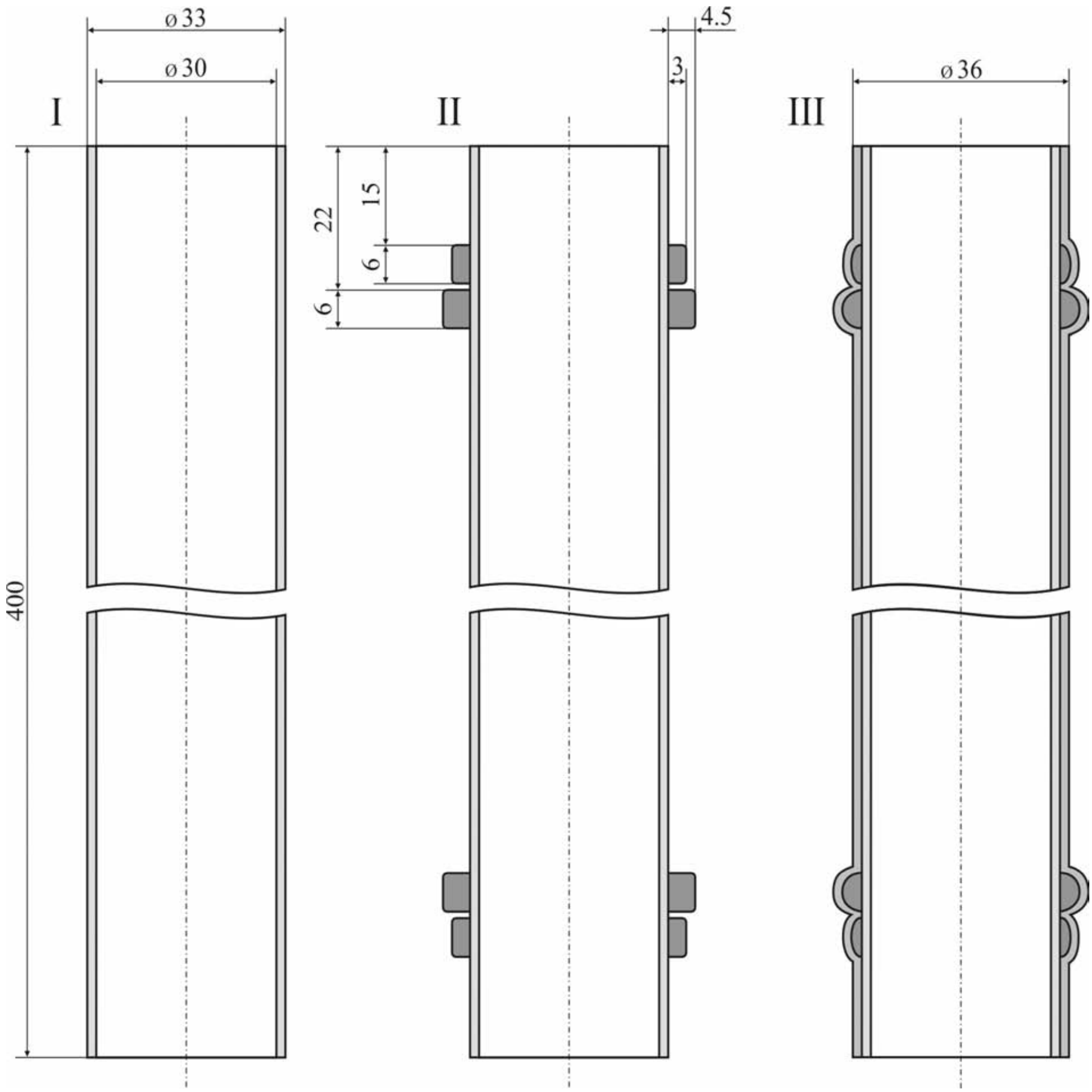

Fig. 4. Constructional model of internal prosthesis of oesophagus with manufacturing steps

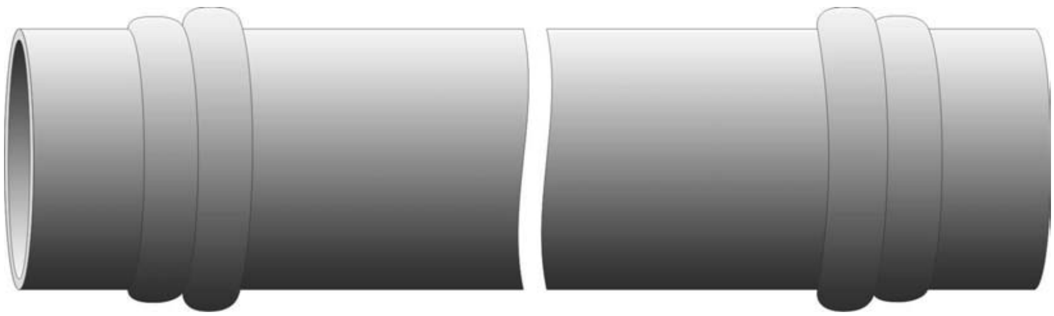

Fig. 5. Model of internal prosthesis of oesophagus

5. Conclusions

Prepared constructional model of internal prosthesis of oesophagus is the solution of the constructional model connected with reconstruction of upper part of digestive system influencing its continuity. Presented solution is the ground for simulation tests using Finite Element Method that enable biomechanical analysis of internal prosthesis of oesophagus. Additionally, prepared by the authors model will be used for preparation of 3-dimensional model of prosthesis and remaining digestive system, with the help of which it will be possible to analyze the relations between those two objects during their work taking into account the shape of the prosthesis and its material features. It seems to be very important because of the lack of the opportunity for determining the interactions of those two elements *in vivo*.

Prepared model is first of all, the basis for preparation of advanced prototype of internal oesophageal prosthesis, which will be undergone clinical tests in Medical University of Silesia in Katowice. Moreover, finished prosthesis will result in cognitive, constructional and technological effects, but first of all, it will enable the increase of comfort of life of the very sick people after resection of pathologically changed oesophagus.

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