THE DEVELOPMENT AND MANUFACTURE OF POLYMERIC ENDOPROSTHETIC MESHES FOR THE SURGERY OF SOFT TISSUES

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Abstract

'Esfil' endoprosthetic meshes made of polypropylene monofilaments, 'Eslan'made of lavsan multifilaments and 'Ftorex' made of lavsan multifilaments with waterproofing fluoropolymer coating have been developed and manufactured for the plasty of soft supporting tissues after tumour resection and herniotomies, by damage to the abdominal wall and the diaphragm and in other surgical procedures.
'Esfil' polypropylene endoprostheses are biologically inert and resist the action of tissue fluids. The hydrophoby and solidity of the threads prevent the meshes from becoming infected. Prompt spreading of the fibroblasts along the filaments promotes the reparation of soft tissues. The 'Eslan' meshes are substantially softer and can be used when so-called 'gentle' implants are required. However, the capillarity of lavsan filaments may cause wound infections. The 'Ftorex' prostheses do not suffer from this disadvantage, due to impregnation of the pores between multifilaments with fluoropolymer. At the same time, the manipulation properties of the prostheses remain stable and their biocompatibility and bioresistance increase. Physico-mechanical, medical, biological and clinical tests allowed us to determine the optimal knitting structures of the endoprostheses we developed.

Key words: Endoprosthesis, polypropylene monofilaments, lavsan filament, fluoropolymer coating

Introduction

Defects in soft tissues are the direct result of radical resections of cancerous tumours, infected and necrotising tissues, and large hernias, as well as of post-traumatic and incisional wounds. Operations on hernias of different localisation are carried out on 180,000 patients every year in Russia, 500,000 in the USA, and 230,000 in Germany [1,2].

The initial closure of large defects by violent constriction of tissues usually causes necrosis of these tissues and suppurative complications [3].

Today, nonconstringent operations with the use of endoprosthetic meshes are widely used. The implanted mesh holds the soft tissues in a fixed position, and strengthens them during and after healing [1, 4].

There are around 10 types of endoprostheses on the world market which are designed to correct defects in supporting soft tissues during reconstructive operations. The most widely used are meshes made of polypropylene (PP), such as the Prolene meshes manufactured by Ethicon (Great Britain), the Surgipro meshes made by USSC (USA), the Polypropylene meshes from Resorba, and the Premilene meshes from B. Braun (both of German origin), as well as endoprostheses made of polyethylene terephthalate (PET) filaments (the Mersilene meshes from Ethicon, USA), and dacron (the Meadox meshes made by Medicals Inc., USA).

In some countries meshes are used as implants in more than 60% of all herniotomies [2]. Up to one million meshes are implanted world-wide every year [5].

Meshes made of polypropylene monofilaments are remarkable for their high biocompatibility and resistance to the action of the tissue environment for a very long period. Endoprostheses made of polyethylene therephthalate are to some extent inferior in biocompatibility and bioresistance. However, they are substantially softer when manufactured from multifilaments, but in this case their significant capillarity increases the risk of infection [2].

Most of the endoprostheses mentioned above vary in structure, and therefore in strength, rigidity, size and shape of pores, convenience in use, and other properties. The analysis of publications shows that every type exhibits certain disadvantages to a greater or lesser degree.

The aim of investigation

The Main Institute of Scientific Research of the Textile and Apparel Industries in Russia developed the POSM-4 lavsan mesh over 30 years ago. This mesh, though made of high tensile strength fibres, has low overall strength. At present this product is not being manufactured.

In view of the absence of high-quality domestically produced endoprostheses, and the relatively high prices (in the conditions of the economical transformations in Russia) for endoprostheses manufactured abroad, a strong demand arose to develop, and further to manufacture, endoprostheses of sufficient high quality (if possible even better than those manufactured in other countries) which would have an acceptable price. To perform this task, the research team of the Saint-Petersburg State University of Technology & Design, in co-operation with the Vishnevsky Institute of Surgery of the Russian Academy of Medical Sciences and the 'Lintex' JV Company, Saint Petersburg, has developed some variants of warp knitted materials made of polypropylene monofilaments of different thicknesses under the trade-name 'Esfil', of lavsan filaments under the trade-name 'Eslan', and of lavsan filaments with waterproof fluoropolymer coating, under the trade-name 'Ftorex'.

Determination of the mesh properties

Test conditions and methods

For the choice of an endoprosthetic mesh which would be adequate in different surgical situations, it was necessary to study the physical and mechanical properties of the successive manufactured variants. They were evaluated mainly by methods intended for knitted fabrics (e.g. State Standards No. 8844-75 – 8847-75), considering that endoprostheses are numbered among the knitted fabrics regarding their manufacturing technology. Non-standard methods that characterise the special medical and technical properties of endoprostheses were used for some cases. The following properties were defined:

- linear density of the filaments L, in tex,
- diameter of the filaments D, in mm,
- surface density of the mesh Ss, in g/m^2,
- thickness of the mesh T, in mm, and
- bursting strength of the mesh defined by pushing a ball of 20 mm diameter through the specimen Pb, in N.

The last property and the test applied reproduces most precisely the real loading in operation conditions.

As non-standard methods, we selected the defining of the mesh porosity and the estimation of the tensile strength of the endoprostheses' structures under the action of surgical sutures (fibres).

The porosity was measured by cutting microphotographs and weighing the porous area (Wp) and the remaining part (Wf). The relative porosity (effective cross-section) was defined as:

Rp = [Wp/(Wp = Wf)] 100%

The important feature which characterises the unloosening of the mesh structure and the reliability of fixation of the edges by surgical sutures or staple is the tensile strength, which is measured by a fibre passing through a pore of approximately 6.5 mm (which is the minimal interval recommended for fastening the endoprostheses) from the edge to the wale (Sw, in N) or course (Sc, in N).

Moreover, when characterising the meshes it is of interest to evaluate the packing factor (Fp) of the mesh, which was defined as the ratio of the mesh cubic density and the fibre density (for polypropylene the fibre density is 0.91 g/mm, for lavsan 1.38 g/cm. The cubic density of the mesh was calculated as the ratio of the mesh surface density to its thickness.

For comparison we carried out simultaneous tests on endoprostheses manufactured abroad. We tested the Prolene, Surgipro and Prelimine meshes which are most widely used in hernioplasty.

The experimental and calculated data are presented in Table 1.

Selection of mono- and multifilaments

As raw material for manufacturing the Esfil mesh fabrics, we used surgical PP monofilaments with a diameter of 0.10 ±0.01 mm and 0.15 ±0.01 mm. The monofilaments were mass-dyed with a blue phtalocyanine pigment aimed at contrasting with the wound background, whereas similar foreign endoprostheses were made of undyed PP monofilaments with a diameter of 0.17 mm.

Eslan 7 was knitted of lavsan multifilament with the line density of 7.5 tex and the other types of the filament of 9.5 tex. For producing Ftorex endoprostheses, the same filaments impregnated with fluoropolymer were used.

When choosing the endoprosthesis, above all it is essential to consider its biological, physical and mechanical properties. Biocompatibility and bioresistance are mostly determined by the chemical constitution and structure of the fibres used.

As stated above, PP-monofilaments are remarkable for the high biological inertness and resistance to the action of tissue fluids. Polymer hydrophoby and its solidity predetermine the full absence of capillarity, and therefore secure the monofilaments against infection. Fibroblasts fasten easily to the PP-fibres and spread quickly, which promotes the reparation of the abdominal wall. At the same time, PP-endoprostheses are notable for the increased rigidity and traumatic effect of their sharp edges on surrounding tissues.

The meshes made of multifilaments are much softer and can be used in situations that require 'gentle' implants. However, it is known [6] that multifilaments have pores between filaments with sizes of up to 10 μm, where microorganisms from the environmental tissues (with sizes of around 1 μm) freely penetrate. Inside the fibres, they find refuge from macrophages and neutrophilic granulacytes, the size of which exceeds 10 μm, as well as the nutrient medium and favourable temperature. This often leads to paraendoprosthetic wound infections after the implantation of such materials.

Taking this into account, Ftorex endoprostheses made of lavsan multifilaments were developed their pores were closed by means of impregnation by waterproof fluoropolymer, . They are remarkable for the total absence of capillarity, together with their maintenance of the manipulation properties of Eslan endoprosthesis. At the same time, the biocompatibility and bioresistance of lavsan fibers is increased.

Selection of knitted structures

The physical and mechanical properties of endoprostheses are determined by the properties of the fibres as well as by the structure of knitted fabrics. All meshes are warp-knitted because such interweaving has a fixed structure that neither loosens or peels off during cutting in any direction. Moreover, knitting as a way of manufacturing allows wide ranges of thickness, porosity, material capacity of endoprostheses and their strength properties to be varied.

Table1. Structure and strength properties od endoprosthetic meshes

Mesh indication	D, mm	L, tex	T, mm	S_s, g/m^2	R_p, %	F_p, %		P_b, N	P_b/S_s, N/g/m^2	S_w, N	S_c, N
						fiber	pores				
Polypropylene											
Esfil 1 (010)	0.10	10.4	0.50	60.5	43.9	13.3	86.7	280	4.6	19.7	19.0
Esfil 2 (010)	0.10	10.4	0.47	53.0	44.8	12.4	87.6	250	4.7	14.0	16.7
Esfil 2 (015)	0.15	18.75	0.66	83.3	46.9	13.9	86.1	420	5.0	30.5	25.2
Esfil 4 (010)	0.10	10.4	0.46	37.5	55.5	9.0	91.0	170	4.5	11.9	8.9
Esfil 4 (015)	0.15	18.75	0.57	62.1	45.2	12.0	88.0	298	4.8	16.1	19.4
Esfil 13 (010)	0.10	10.4	0.42	45.5	52.7	11.9	88.1	234	5.14	14.1	17.4
Prolene	0.17	21.2	0.65	95.9	49.8	16.2	83.8	544	5.6	72.8	52.9
Surgipro	0.17	21.2	0.57	84.0	44.9	16.2	83.8	414	4.9	41.9	56.8
Premilene	0.17	21.2	0.48	80.1	48.0	15.2	84.8	400	5.0	41.4	36.5
Lavsan											
Eslan 5	0.045	9.5	0.38	79.5	57.1	15.2	84.8	216	2.7	11.3	13.3
Eslan 6	0.045	9.5	0.35	68.6	61.0	14.2	85.8	110	1.6	7.8	11.1
Eslan 7	0.04	7.5	0.30	46.0	63.3	11.1	88.9	102	2.2	9.3	13.7
Eslan 8	0.045	9.5	0.30	60.3	58.0	14.6	85.4	232	3.8	8.9	11.2
Eslan 14	0.045	9.5	0.45	78.5	60.1	12.6	87.4	208	2.7	17.8	19.3
Lavsan with fluoropolymer coating											
Ftorex 9 (5)	0.047	9.5	0.45	88.0	57.1	14.2	85.8	219	2.5	12.1	11.0
Ftorex 10 (6)	0.047	9.5	0.38	74.0	61.0	14.1	85.9	120	1.6	8.2	9.4
Ftorex 11 (8)	0.047	9.5	0.33	64.5	58.2	14.2	85.8	229	3.6	7.3	10.9
Ftorex 12 (7)	0.042	7.5	0.30	47.6	63.1	11.5	88.5	100	2.1	7.5	10.9
Ftorex 15 (14)	0.047	9.5	0.47	85.0	60.2	13.1	86.9	200	2.35	13.2	14.4

Test results

It is quite natural that the decrease of endoprosthesis thickness results in a more close contact of surrounding tissues and promotes quicker growth of conjunctive tissue through the implant without complications. Of all the polypropylene endoprostheses, Prolene and Esfil 2 (015) are the thickest; the thickness of the others varies from 0.42 mm to 0.57 mm. The thickness of Eslan endoprostheses fluctuates between 0.30 mm and 0.45 mm, while that of Ftorex endoprostheses varies between 0.30 mm and 0.47 mm.

As can be seen from the table data, the heaviest polypropylene endoprostheses are the foreign ones (made of monofilaments with the diameter of 0.17 mm) and Esfil 2 (015). Depending on monofilament diameter and mesh fabric structure, the surface density of all the other Esfil endoprostheses varies from 37.5 to 62.1 g/mm^2, that of Eslan –from 46.0 to 79.5 g/mm^2, and Ftorex from 47.6 to 88.0 g/mm^2.

In contrast to the magnitudes of thickness and surface density, the mesh porosity is much harder to define. Taking into account requirements for stability of size and limited endoprosthesis stretching to all directions, in mesh fabrics the pores of complex geometric shape with longitudinal, transversal and diagonal thread feed are formed. That is why the pore size can be evaluated quite relatively.

There is an opinion that for optimal ingrowth of the conjunctional tissue the pores with the average size of no less than 100 μm are required [2]. All the endoprostheses comply with this requirement. The capacity of fabrics for the ingrowth of tissue can be reflected more fairly by their surface porosity - effective cross-section and bulk porosity.

The highest surface porosity of all the polypropylene endoprostheses is obtained by Esfil 4 (010) and by Esfil 13 (010); for others this magnitude varies from 43.9% to 49.8%. The bulk porosity of Esfil 4 (010) and Esfil 13 (010) is also higher, and the ranking of the foreign endoprostheses is maintained. Eslan and Ftorex meshes have almost the same high magnitudes of surface and bulk porosities.

It is obvious that surgeons will try to use implantation meshes with minimal intensity of use and with satisfactory strength properties. The maximum bursting strength is obtained by Prolene meshes, the bursting strength of Esfil 2 (015), Surgipro and Premilene is approximately 20% lower, and this figure for all the other polypropylene meshes is even lower.

It is advisable to introduce an index that connects porosity and intensity of use for endoprostheses - the ratio of the bursting strength by the ball to their surface density. The relative bursting strength is the highest for Prolene, Esfil 13 (010) and Esfil 2 (015) and slightly lower (maximum for 17%) for the other endoprostheses.

The bursting strength of Eslan endoprosthesis is about 200 N for Eslan 5, 8 and 14 and about 100 N for Eslan 6 and 7. The relative bursting strength has almost the same distribution.

The magnitude of absolute and relative bursting strength of Ftorex endoprostheses are close to their Eslan analogues.

It is notable that the lowest bursting strength of the Ftorex 12 (7) endoprosthesis - 100 N (1.6 kg/cm^2) – is far higher than the highest possible intra-abdominal pressure - 260 mm Hg (millimetres of mercury) (0.354 kg/cm^2).

A proper comparison of relative bursting strengths is possible only for the group of endoprostheses made of fibres of the same type, because the specific density of the fibres varies greatly (PP - 0.91 g/cm^j, lavsan - 1.38 g/cm^j), and therefore their intensity of use is different.

It may be assumed that the organism's response to a foreign substance is predetermined for the most part not by its mass but by its volume, on which depends the area as well as the structure of the endoprosthesis' contact with the surrounding tissues. The packing factor of PP-monofilament of foreign endoprostheses is 1.3-1.8 times more than of the Russian ones and reaches 16.2%. Eslan and Ftorex have F_p higher than Esfil does, but mainly this does not exceed 14.5%.

The tensile strength of polypropylene endoprostheses by the stitch is the highest for Prolene (72.8 N along the wale and 52.9 N along the course), slightly lower for Surgipro (41.9 N and 56.8 N) and for Premilene (41.4 N and 36.5 N), much lower for Esfil (on average from 15.0 N to 30.0 N). For Eslan and Ftorex it fluctuates between 10.0 N and 19.0 N (on average). As surgical practice demonstrated, such a structure strength was entirely satisfactory. It is notable that the Mresylene mesh made of polyester has a tensile strength in all directions of about 15 N.

Conclusions

- It can be concluded from the tests carried out that meshes made from polypropylene monofilaments are biologically the most inert and most resistant.
- One characteristic of foreign endoprostheses is that they do not have well-matched properties; for example their strength exceeds the physiological necessity by many times, and in a large amount of implanted fabrics the mesh rigidity causes (as many authors and developers have noted [4]) such complications as seromas, uncomfortable feelings and decrease in the front abdominal wall mobility of more than half of the patients. Moreover, the Surgipro and Prolene meshes have too few pores, which impedes the free ingrowth of the tissues.
- The properties of the Esfil endoprostheses we have developed vary to a sufficiently wide-ranging degree, and it is possible to choose the adequate mesh (light or harder) depending on the given surgical situation.
- The Eslan and Ftorex meshes are also diverse in their properties and are applicable in soft tissue plasty, as well as in other surgical procedures.
- As can be seen from the discussion above, the aim of our investigation was achieved: a range of high quality meshes, which are even sometimes better than the meshes manufactured in Western countries, has been developed and manufactured by the ‘Lintex’ JV Company.

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