PARTIALLY RESORBABLE HERNIA MESHES

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1. Introduction

Hernias are a very serious social problem, statistically appearing in 2% of the human population. They can be healed by surgical methods, and special surgical meshes are used in the so-called non-tension method applied in 50%-70% of hernia cases. These meshes are mostly manufactured of non-resorbable synthetic fibres [1, 2]. An essential disadvantage of surgical methods, which use non-resorbable implants, is the patients' discomfort which appears after longer time-periods from the implantation, connected with the stiffening of the implant; this latter is caused by streaking the implant with fibrous tissue. This phenomenon can even lead to problems with an inadequate blood supply to the organs lying in the implant's surroundings, as well as to complications of the stoma or adhesion type in the case of an implant's direct contact with inner organs [3, 4]. Applying surgical meshes, which would be partially resorbable, would allow us to eliminate the majority of the disadvantages caused by meshes manufactured of non-resorbable polymers [5].

The following advantages result from applying surgical meshes manufactured with a content of partially resorbable components:

- a decreasing intensity of the infectious chronic reaction, thanks to introducing a smaller amount of non-resorbable synthetic material into the human body, as in the case of totally non-resorbable meshes,
- the patient's health improves, especially over long post-operation periods,
- the aesthetic effect, and
- a shortening of the hospitalisation time.

Some enterprises already manufacture meshes which are partially or totally resorbable. The VYPRO®I, VYPRO®II, and Proceed meshes manufactured by ETHICON, and the PARIETEX® meshes from SOFRADIM [6] are examples of partially resorbable meshes. The meshes from the VYPRO® type are manufactured of resorbable polyglactine 910

(a copolymer of glycol and lactic acid) and nonresorbable polypropylene threads (VYPRO®I includes a PP multifilament, whereas VYPRO®II uses a PP monofilament). In contrast, the PARIETEX® mesh is produced from polypropylene yarn with a deposited layer of cross-linked beef-originated collagen.

Up to the present day, no partially re-sorbable surgical meshes have been manufactured in Poland. TRICOMED S.A., which is the only producer of this type of medical product, manufactures only the following non-resorbable surgical meshes: DALLP® R-11, DALLP® R-13, DALLP®PP TMS, DALLP® PP TMD, DALLP® PP JS, OPTOMESH™ Macropore, and OPTOMESH™ Thinlight; all of these are manufactured with the use of polyester or polypropylene multifilament or monofilament threads [7].

2. Aim of the investigation

The aim of the research work presented in this paper was to develop a method for manufacturing modern, partially resorbable surgical meshes or partially resorbable surgical implants dedicated to protecting hernias. The investigations were conducted within the two following variants:

- Variant I consisted in the use of a knitting technique. Two kinds of yarns were used: a resorbable multifilament chitosan thread and a non-resorbable biocompatible monofilament polypropylene thread.
- Variant II consisted in the use of a complex technique. The surface of the non-resorbable OPTOMESH™ Macropore surgical mesh was covered by a microporous resorbable chitosan coating [8]. Functional chitosan forms developed in the Institute of Biopolymers and Chemical Fibres (IBWCh) were used.

The modified surgical meshes were tested, after sterilisation by ethylene oxide (EO), in order to determine their physico-mechanical features and their chemical & biological purity. A future part of our work will be devoted to testing the susceptibility to enzymatic degradation of the selected variant of the surgical implants, as well as carrying out biomedical investigations into estimating the cytotoxity, the irritating and allergic effects, and implantation tests with experimental animals. The results of all these investigations will be presented in a subsequent publication. The whole research project is being carried out in co-operation with the TRICOMED S.A., Łódź enterprise.

3. Materials

Chitosan yarn: multifilament manufactured in IBWCh
Linear density: 572 ± 5 dtex
Breaking force in conditioned state: 881 ± 5 cN
Elongation at break in conditioned state: 4.2 ± 0.0%

Polypropylene yarn: monofilament
Linear density 185 dtex

Surgical mesh: OPTOMESH™ Macropore produced by TRICOMED S.A.
Woven from PP monofilament yarn
Area mass: 80 g/m^2

Chitosan products: microcrystalline chitosan, modified microcrystalline chitosan and chitosan fibrids, all manufactured in IBWCh.

Chitosan from the LaNiCo enterprise, Vietnam of M_V = 450 kD, and deacetylation degree of DD = 87.9% was used in order to obtain the chitosan yarn.
Chitosan from the Vanson HaloSource enterprise, USA, batch 03-CISB-0278 of M_V = 340 kD, and deacetylation degree of DD = 87.9% was used in order to obtain the functional chitosan forms.

4. Investigation results and discussion

4.1. Manufacturing chitosan fibres dedicated to resorbable yarns, and estimating their properties

The chitosan fibres devoted for the partially resorbable meshes were manufactured in IBWCh with the use of a spinning installation for wet spinning, according to a method elaborated in IBWCh. Chitosan from LaNiCo, Vietnam was used, and special attention was paid to optimising the fibres' finishing conditions and selecting an appropriate finish which ensured suitable processing properties of the chitosan filament fibre parties to be selected for further processing. The chitosan fibres were manufactured with the use of a 300-hole spinneret. The fibres obtained were characterised by the following basic parameters, which were in general similar for all the parties obtained: linear density of circa 2.4 dtex, tenacity of circa 15.4 cN/tex, elongation at break of up to 8.5%, and loop tenacity of 3.4 cN/tex.

4.2. Developing a method of introducing resorbable yarn into the surgical meshes

Tests were carried out to estimate the processing capabilities of chitosan yarns being worked into the basic stitch manufactured from the polypropylene monofilament with a linear density of 185 dtex, with the use of a warp-knitting machine. The tests were carried out in the Department of Knitting Technology and Structure of Knitted Products at the Technical University of Łódź with the use of an RL 5 NF laboratory warp-knitting machine. Four knitted fabric variants of a-jour stitches were differentiated by the density of chitosan threads threaded (samples 1, 2, 5, and 6 in Table 1), and two further variants were differentiated by the report of the stitch formed by chitosan yarn. The chitosan yarn was worked in during knitting without major disturbances. Yarn breakages were not observed, and small levels of fuzz were indicated, which was the result of elementary fibre breaks while the yarn was being conducted through the holes of the needle bars; this did not significantly disrupt the technological process. Knitted fabrics of different chitosan yarn content (from 12% wt to 50% wt), and with various area masses of 58 g/m^2 to 104 g/m^2 were obtained, and are presented in Table 1.

4.3. Developing the method and conditions for depositing the chitosan coating on the knitted fabric

Polypropylene monofilament OPTOMESF™ surgical meshes and various chitosan forms, such as gels, salts, fibrids, and microcrystalline chitosan, were used for our research. All the forms mentioned above were manufactured from the initial chitosan made by Vanson HaloSource. The chitosan suspensions or gels were one-side deposited on the meshes by the knife method. Glycerine was used as the plasticiser in all coating blends. We changed the concentration of coating blends, the degree of deposition and the drying conditions. The meshes modified were dried either by liophilisation, or conventionally in a drier with forced air flow.

Table 1. *Parameters of the chitosan/polypropylene knitted fabrics; * knitted fabrics with different stitch report of the chitosan yarn.*

Test number.	Area mass. g/m^2	Chitosan yarn content. %	Thickness. mm
0	52	0	0.7
1	58	12	0.8
2	64	22	0.8
3*	76	35	0.9
4*	76	35	0.9
5	82	41	1.0
6	104	50	1.0

The durability of joining chitosan with the mesh, the coating layer elasticity and its resistance to physiological salt solutions were tested. We established that the most porous, but also the least durable, were the lyophilised coatings produced with the use of microcrystalline chitosan and chitosan fibrids. The meshes covered by chitosan gels or microcrystalline chitosan, with decreased pH, and dried in a drier with air flow (Figure 1) and by sublimation (Figure 2), were characterised by more advantageous properties, principally durability and elasticity.

4.4 Developing the method of finishing the flat-knitted products

During the first stage of our investigations, the composite meshes were processed by a finish procedure which consisted of thermal stabilisation and processing in an autoclave or irradiation by an UV lamp under the following conditions:

1. The mesh in the form of knitted fabrics with the addition of chitosan yarn (variant I) were stabilised at a temperature of 154 °C for 2.5 min, and next processed in an autoclave at the temperature of 121 °C for 1 hour.
2. The mesh with deposited chitosan coating (variant II) were irradiated by an UV lamp, in the clean zone of the laboratory for 30 min in order to clean the product from microbiological contamination.

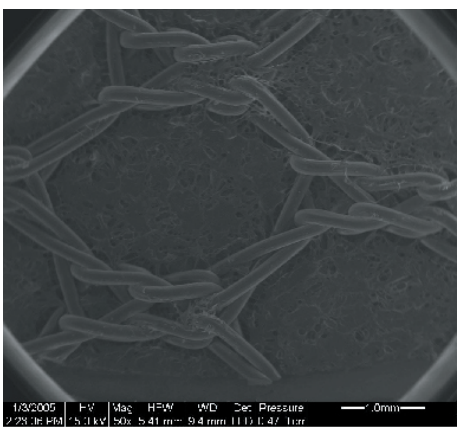

Figure 1. *Microscopic photo of a modified mesh dried in an air flow drier.*

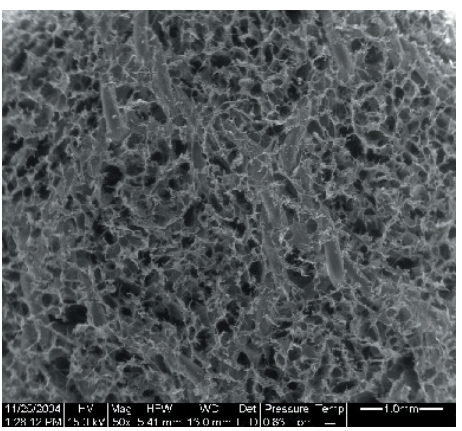

Figure 2. *Microscopic photo of a modified mesh dried by liophilisation.*

We additionally established that the meshes will be packed in a double foil/paper wrapping produced by OPM, Poland, and sterilised by ethylene oxide. The choice of the method of sterilisation was caused by the necessity to ensure the optimum strength parameters of the modified surgical meshes. Estimation of the meshes' mechanical properties was carried out on the basis of assessing the maximum tensile strength and the relative elongation, the piercing force (by the cone-method), and the bending rigidity. Independently, the porosity after OE-sterilisation was also determined.

Table 2. *Selected mechanical parameters of surgical meshes which we manufactured.*

Parameter	Raw mesh	Modified mesh
Piercing force, kN	3.24	3.54
Piercing displacement, mm	19.5	22.8
Length of bending in longitudinal direction, cm	3.85	5.45
Length of bending in transversal direction, cm	3.88	6.18
General unit bending rigidity	0.051	0.201

The surgical meshes with chitosan coatings were characterised by slightly higher tensile strength and bending rigidity in comparison with the OPTOMESH^{TM} Macropore raw meshes.

4.5. Evaluating the modified surgical meshes

Evaluating the chemical purity of the modified surgical meshes was conducted on the basis of aqueous extractions (aqueous extraction at the temperature of 121 °C, for 1 hour) according to appropriate standards for medical products. The pH of the aqueous extractions of the surgical meshes whose surface was modified by chitosan (variant II) decreased, compared with the pH of the aqueous extraction of the half-product, whereas that of the meshes with chitosan fibres (variant I) was higher. In both cases, the pH of the aqueous extractions was within the acceptable range of ±1.0 of a pH unit. The presence of ammonia ions was stated only in the aqueous extraction of variant II, for which we observed an insignificant excess of the acceptable level of 0.01 mg NH_4^+/g. The ion content of heavy metals, chlorides, and sulphates was below the acceptable level for implanted medical products.

After thermal stabilisation, the area mass of the composite with deposited chitosan coating was 100.7 ± 2.0 g/m^2 which, considering the average area mass of the half-product of 80.3 g/m^2, means that the average area mass of the chitosan coating was 20.4 g/m^2.

The average area mass and the thickness of the mesh manufactured from both kinds of threads in reality increased after thermal stabilisation, the area mass to as much as 140 g/m^2, and was significantly higher than the area mass of meshes from variant II. The thickness of the composite mesh of variant I was 1.32 mm, whereas that of variant II was only 0.74 mm.

The evaluation of the microbiological contamination, carried out by the methods of direct inoculation and membrane filtration, indicated that the modified meshes after sterilisation were characterised by an average of 3 cfu/100 cm^3 for bacteria, and 0 cfu/100 cm^3 for fungi. The presence of pathogenic micro-organisms of the Enterobacteriaceae and Staphylococcus

aureus families, as well as those of Pseudomonas aeruginosa were not stated, whereas the content of bacterial endotoxins, determined by the LAL half-quantity method, was lower than 20 EU per product.

5. Summary

On the basis of estimating the physico-mechanical properties, and evaluating the chemical properties, as well as the chemical and biological purity, we stated that the implants of variant II with an area mass of about 100 g/m^2 are potentially optimal products for further modification, considering their better strength parameters. The meshes of variant I manufactured with the use of chitosan yarns, characterised by high porosity, were accepted as being least advantageous, taking into consideration the possibility of infection.

6. References

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Editorial notes

- *The surgical meshes modified by chitosan developed within the scope of the project we have carried out were granted the Silver Medal at the EUREKA'2006 fair in Brussels.*
- *The paper presented herewith is an abridged version of the article entitled 'zxzxzxzxz' which has been published in Fibres & Textiles in Eastern European, vol 15, No. 3(62), 2007.*